Background information

Coroners Prevention Unit

Methadone takeaway dosing for opioid replacement therapy: managing the risk of diversion

Prepared by Jeremy Dwyer

5 June 2013

Table of Contents

Purpose and scope of report

Coroner Jacinta Heffey is investigating the death of Helen Stagoll, who was 16 years old when in 2010 she suffered fatal respiratory arrest caused by the effects of methadone and alprazolam. I understand the material before the coroner suggests the methadone that contributed to Helen Stagoll's death was not prescribed to her, but rather was diverted to her from another person to whom it was dispensed as a takeaway dose for opioid replacement therapy.

Coroner Heffey requested that I prepare a report for purposes of background information addressing methadone provision for opioid replacement therapy in Victoria, the risks (including diversion) associated with takeaway versus supervised methadone dosing, and how (if at all) these risks could be better managed. The report is structured as follows:

- Section 1 introduces methadone for opioid replacement therapy, and briefly describes the 2006 Victorian policy that guided provision of opioid replacement therapy at the time Helen Stagoll died, as well as the revised Victorian policy that took effect in January 2013.
- Section 2 comprises a review of published research on the risks and benefits of takeaway versus supervised methadone dosing for opioid replacement therapy.
- Section 3 sets out the Court data on annual frequency of methadone deaths in Victoria 2000-2012, and a pilot study of evidence for takeaway methadone diversion in Victorian methadone deaths during the years 2010-2011.
- Section 4 summarises previous Victorian coroners' recommendations regarding methadone, takeaway dosing and dose diversion, as well as relevant responses made under the *Coroners Act 2008* (Vic).
- Section 5 presents my suggestions regarding opportunities for managing the risks of methadone takeaway dose diversion in Victoria.

Statement of expertise

I am a case investigator in the Coroners Prevention Unit, Coroners Court of Victoria. I have an expert knowledge of Victorian coronial data on deaths involving acute drug toxicity. I developed this expertise through designing, building and populating the Court's acute drug deaths database.

I do not have any expertise in opioid replacement therapy. The information in this report regarding (1) the Victorian system for opioid replacement therapy, (2) the Australian and international literature on risks and benefits of takeaway versus supervised methadone dosing, (3) the interpretation of coronial data in the context of the Victorian opioid replacement therapy system, and (4) opportunities for further interventions to prevent takeaway methadone dose diversion in Victoria, should be regarded as informed analysis rather than expert opinion.

1. Methadone for opioid replacement therapy in Victoria

In this section I provide a basic introduction to methadone for opioid replacement therapy and how it is delivered in Victoria, including the role of takeaway dosing.

1.1 Opioid replacement therapy

An opioid dependent person is at risk of a range of poor social and health outcomes. Opioid replacement therapy (also known as opioid substitution therapy, opioid maintenance treatment, and maintenance pharmacotherapy for opioid dependence) is an evidence-based substitution therapy to reduce these risks. The World Health Organization defines substitution therapy as follows:

> [...] the administration under medical supervision of a prescribed psychoactive substance, pharmacologically related to the one producing dependence, to people with substance dependence, for achieving defined treatment aims.[1]

In a sense, opioid replacement therapy can be regarded as a process of shifting the person's dependence from one opioid to another. However, the substitute opioid invariably has a safer risk profile than the abused opioid(s), and the regular provision of controlled doses under clinical supervision is usually safer for the person's health than uncontrolled opioid self-administration, while creating opportunities to pursue broader treatment goals. As explained by Amato and others:

> Once on a stable dose, experiences of intoxication or withdrawal are infrequent. Although still physically dependent on the maintenance medication, there will be less need to spend time on drug-related activities, and when ready, they may withdraw from the maintenance treatment in an attempt to lead an opiate-free life.[2]

1.2 Methadone for opioid replacement therapy

The Therapeutic Goods Administration (TGA) has approved methadone for opioid replacement therapy to treat opioid dependence. It is suited to this purpose for a number of reasons including the following:

- Methadone is a synthetic opioid that binds to the same opioid receptors as morphine (the main active metabolite of heroin) and other commonly abused opioids, thereby reducing physiological opioid cravings and the symptoms associated with opioid withdrawal syndrome.
- Methadone is a long-acting opioid, so it can be administered less frequently than commonly abused opioids and provides longer-lasting relief from cravings and symptoms of opioid withdrawal.
- Methadone does not produce the same level of euphoric effects associated with commonly abused opioids such as morphine.
- Methadone is effective when administered orally, so health risks associated with opioid injection (including overdose and disease transmission) are reduced.

Numerous large-scale studies conducted in countries around the world have shown that opioid replacement therapy using methadone is an effective treatment for

---

1 World Health Organization, "Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper", 2004, p.12.

2 Amato L, et al, "An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research", *Journal of Substance Abuse Treatment*, vol 28, no 4, June 2005, pp.322.

heroin dependence as it decreases heroin use and assists to retain clients in drug treatment programs.[3] There is additionally evidence that it might reduce a range of harms associated with opioid dependence, including risk of HIV infection from drug injection, and heroin use-related criminal activity.[4]

1.3 Regulation

Like all opioids, methadone can be addictive and, when consumed in large enough quantities, its depressive effects on the central nervous system can cause death. For these reasons methadone is listed as a Schedule 8 controlled drug under the *Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons* (the SUSMP), which came into effect on 1 September 2010. Previously it was a Schedule 8 controlled drug under the *Commonwealth Standard for the Uniform Scheduling of Drugs and Poisons*. Schedule 8 controlled drugs are defined identically in both Standards as:

> [...] substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

While drugs are classified into schedules in the SUSMP, which is a Commonwealth legislative instrument, the actual implementation of the scheduling (as regards controls over manufacture, supply, distribution, possession and use) occurs through state and territory legislation. In Victoria the relevant legislation is the *Drugs Poisons and Controlled Substances Act 1981* (Vic) and *Drugs Poisons and Controlled Substances Regulations* 2006 (Vic). Drugs and Poisons Regulation (DPR) at the Victorian Department of Health is responsible for administering this legislation,[5] and is therefore responsible for regulating methadone in Victoria including its use for opioid replacement therapy.

Under Section 34 of the *Drugs Poisons and Controlled Substances Act 1981* (Vic), a Victorian medical practitioner who wishes to prescribe methadone to a person for opioid replacement therapy must apply for a Schedule 8 permit to do so. The DPR administers the permit system and, as a condition of issuing permits, ordinarily requires the prescriber to undertake training in pharmacotherapy and drug

---

3 See for example Mattick RP, et al, "Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence", *Cochrane Database of Systematic Reviews*, Issue 3, 2009; Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.7; World Health Organization, "Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper", 2004, pp.12-13.

4 See for example Amato L, et al, "An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research", *Journal of Substance Abuse Treatment*, vol 28, no 4, June 2005, pp.325-326; Peterson JA, et al, "Why don't out-of-treatment individuals enter methadone treatment programmes?", *International Journal of Drug Policy*, vol 21, no 1, January 2010, p.36; Harris M, Rhodes T, "Methadone diversion as a protective strategy: the harm reduction potential of 'generous constraints'", *International Journal of Drug Policy*, in press, 2012, <http://dx.doi.org/10.1016/j.drugpo.2012.10.003>, accessed 28 May 2013, p.1.

5 Originally the legislation was administered by the Drugs and Poisons Regulation Group at the Victorian Department of Human Services. After the Victorian Department of Health was created in 2009, the Drugs and Poisons Regulation Group was transferred here and maintained its responsibility for Schedule 8 drugs. Recently the word "Group" was dropped from its name, so at present Drugs and Poisons Regulation is the name of the Victorian Department of Health entity responsible for regulating Schedule 8 drugs including methadone for opioid replacement therapy.

addiction. A separate application must be submitted to the DPR for each patient before treatment is commenced.

Similarly, the *Drugs Poisons and Controlled Substances Act 1981* (Vic) requires that a pharmacist who wishes to dispense methadone for opioid replacement therapy must apply for approval to do so. The DPR assesses applications and requires that training be completed in advance of approving an application. An approved pharmacist must supply methadone consistently with the Act and its associated Regulations, meeting relevant storage, record-keeping, administration and other requirements. An opioid replacement therapy client is registered to a particular approved pharmacy for dispensing of the methadone, and the pharmacy is recorded by the DPR.

1.4 Policy in Victoria

The DPR produces policies to guide Victorian prescribers and dispensers engaged in the provision of opioid replacement therapy. At the time of Helen Stagoll's death, the key policy for this purpose was the *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, which was published in 2006 when the DPR was part of the Department of Human Services (referred to from here as "the 2006 policy"). The DPR, under the auspices of the Department of Health, published a revised *Policy for Maintenance Pharmacotherapy for Opioid Dependence* in January 2013 (referred to from here as "the 2013 policy").

1.5 The 2006 policy

1.5.1 Supervised and takeaway dosing

Under the 2006 policy, a Victorian client being treated with methadone for opioid replacement therapy can have the methadone dispensed in one of two ways:

- Through supervised dosing, where the client attends at an authorised dosing point and consumes the methadone at that point.
- Through takeaway dosing, where the client is dispensed a quantity of methadone that is taken away from the dispensing pharmacy for consumption.

The 2006 policy states that "pharmacotherapy in Victoria is based on the principle of supervised dosing",[6] however that takeaway doses can be made available to clients who are assessed to be suitable. The medical practitioner determines whether the client is suitable for takeaway dosing; the decision should be made in accordance with principles and practices outlined in the 2006 policy.

1.5.2 Considerations in evaluating suitability for takeaway dosing

One important principle that underpins the delivery of opioid replacement therapy in the 2006 policy, is that it should be integrated into the community, to remove negative connotations and inconvenience the client as little as possible. Reflecting this important consideration, primary health care professionals including general practitioners and community pharmacists are centrally involved in providing opioid replacement therapy.

The 2006 policy lists a number of ways that takeaway dosing might promote community integration. For example:

- The prospect of accessing takeaway doses can provide incentive for the client to maintain engagement in treatment, thereby achieving sustained social and health benefits.

---

6 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.22.

- Being relieved of the need to attend the dosing point every day, means the client can meet work and family commitments with less disruption.
- Takeaway dosing enables clients to attend holidays, conference and so on away from the dosing point.[7]

A second important principle in opioid replacement therapy is risk mitigation. Drugs involved in opioid replacement therapy bring benefits to the community, but they also carry inherent risks. Methadone is a particularly toxic drug when misused, and the 2006 policy notes takeaway dosing can create opportunities for misuse including:

- The provision of takeaway doses can facilitate methadone hording and consumption outside the recommended dosing schedule.
- Clients can inject methadone when it is provided for unsupervised consumption away from a dosing point.
- Takeaway doses can be diverted (shared with or sold to other people).
- Takeaway doses can be accessed by people who live with or visit the client.
- Clients can consume takeaway doses in a risky manner when unsupervised, for example in combination with alcohol and/or other central nervous system depressants.[8]

1.5.3 Balancing benefits and risks

The guidance on methadone dosing in the 2006 policy reflects the need to strike a balance between the principle of community integration and the principle of risk mitigation. As stated in the policy:

> Arrangements for take-away doses should balance the need to minimise the risk to the community with the stable patient's need to normalise their lives.[9]

Under the policy, a client is not automatically entitled to access takeaway doses of methadone, but must first meet a number of criteria that include:

- The client should have participated in the pharmacotherapy program on a supervised dosing basis for at least two months.
- The client should be stable in treatment, meaning inter alia that he or she has adhered to the planned dispensing regime, attended for scheduled clinical reviews, demonstrated an improvement in overall psychosocial functioning, reduced or ceased heroin use, and is not experiencing significant withdrawal symptoms or cravings.
- The client should be living in stable accommodation and must be able to access a locked or secure cupboard for storing medication.
- The client should not be suffering any acute or unstable illnesses (including psychiatric illnesses) that would make takeaway doses inadvisable.
- The client should not be abusing other drugs or medications (particularly sedatives) that might contribute to increased overdose risk in pharmacotherapy.

---

7 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.22.

8 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.22.

9 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.23.

- The client should not have a recent history of misusing or diverting prescribed takeaway doses of methadone.

The prescriber should consult with other people involved in treatment (including the dispenser) to assess whether the client meets these criteria and therefore is suitable for takeaway dosing. The DPR plays no role in the decision (which is left to the prescriber's clinical judgment), however the 2006 policy includes a ready reckoner tool to assist the evaluation process.[10]

If the client is assessed to be suitable for takeaway methadone dosing, a number of safety measures are put in place, including the following:

- The policy mandates the supply of takeaway doses in containers with child-resistant closures, to mitigate the risk that an unsupervised child may access and consume the methadone.
- Containers must be appropriately labelled with warnings as required under the SUSMP. These warnings indicate clearly that the substance must be handled and stored very carefully, and is dangerous if not taken as directed by the person to whom it was dispensed.
- The methadone must be diluted with water to deter injection.
- The quantity of takeaway doses permitted and level of accompanying supervision is contingent on the risk the client presents.
- Decisions on continued eligibility for takeaway dosing should be supported using tools such as random urine drug screens.

The 2006 policy describes three levels of supervision that a methadone client can be subject to, and the level of takeaway dosing associated with each:

- **High intensity supervision**, where the client must attend for daily dosing and cannot receive takeaway doses.
- **Medium intensity supervision**, where the client has demonstrated stability in treatment and has participated continuously for at least two months. A client on this level of supervision can receive between one and two takeaway doses per week.
- **Low intensity supervision**, where the client has demonstrated stability in treatment and has participated continuously for at least six months. A client on this level of supervision can receive up to five takeaway doses per week, but with no single supply exceeding three doses.[11]

The intention behind the assessment process and safety measures is to ensure as far as possible that any opioid replacement therapy clients given takeaway doses will not engage in risky behaviours such as dose diversion, taking extra doses, and so on. This answers the principle of risk mitigation. The benefit of takeaway doses is that they can contribute to normalising clients' lives, allowing them to function like anybody else within the community and demonstrate socially reasonable behaviours. This answers the principle of community integration.

---

10 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, pp.25-26.

11 Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006, p.24.

1.6 Changes to takeaway dosing guidance in the 2013 policy

The revised 2013 policy includes several changes to takeaway dosing regulation. The following is a basic overview of the major changes.

1.6.1 Buprenorphine is treated differently to methadone

The 2006 policy did not differentiate in any meaningful way between use of methadone and use of buprenorphine for opioid replacement therapy. In contrast, the 2013 policy explicitly recognises that buprenorphine has a different risk profile and therefore is regulated differently to methadone.

Like methadone, buprenorphine is a synthetic opioid approved in Australia (and in many other countries) for opioid replacement therapy. Clinical research demonstrates that buprenorphine has similar efficacy to methadone in treating opioid dependence, though some studies suggest that in certain circumstances it might not achieve the same level of patient retention and suppress heroin use to the same extent as methadone.[12] Identified advantages of buprenorphine over methadone include that it is safer in overdose, it has a longer duration of action, and withdrawal symptoms are less severe. In combination preparations with the opioid antagonist naloxone, buprenorphine is even safer in overdose and also might be less likely to be diverted or used illicitly (such as via injection).[13]

With respect to buprenorphine/naloxone, the 2013 policy differs from the 2006 policy in the following two important ways.

- **Training**. The 2006 policy required any medical practitioner to undergo training and assessment to become an approved opioid replacement therapy provider. The 2013 policy retains this requirement for methadone, however a medical practitioner may prescribe buprenorphine/naloxone for up to five patients without the requirement to undergo training or assessment in opioid replacement therapy. The prescriber is still required to obtain a Schedule 8 permit before prescribing to the patient.[14]
- **Takeaway dosing**. The 2006 policy set out three levels of supervised dosing and the maximum number of takeaway doses available at each level: (1) high intensity, no takeaway doses permitted; (2) medium intensity, up to two takeaway doses weekly permitted; and (3) low intensity, up to five takeaway doses per week permitted. The 2013 policy retains these three levels for takeaway methadone dosing, but adds another level for patients taking

---

12 See for example Kahan M, et al., "Buprenorphine: New treatment of opioid addiction in primary care", *Canadian Family Physician*, vol 57, no 3, March 2011, p.282; Mattick R P, et al, *Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence*, The Cochrane Collaboration, The Cochrane Library, Issue 3, 2008, pp.9-10; Pinto H, et al, "The SUMMIT Trial: A field comparison of buprenorphine versus methadone maintenance treatment", *Journal of Substance Abuse Treatment*, vol 39, no 4, December 2010, pp.340-341.

13 Lintzeris N, et al, *National clinical guidelines and procedures for the use of buprenorphine in the maintenance treatment of opioid dependence*, October 2006, pp.3-4; Milne M, et al, "Buprenorphine for Opioid Dependence", *Journal of Pain and Palliative Care Pharmacotherapy*, vol 23, no 2, 2009, pp.153-154; Bell J, et al, "Comparing overdose mortality associated with methadone and buprenorphine treatment", *Drug and Alcohol Dependence*, vol 104, no 1-2, 1 September 2009, pp.74-77; Ling W, et al, "Selective review and commentary on emerging pharmacotherapies for opioid addiction", *Substance Abuse and Rehabilitation*, vol 2, no 1, 2011, pp.184-185.

14 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, p.14.

buprenorphine/naloxone: (4) very low intensity, up to six takeaway doses per week permitted.[15]

- **Length of stability in treatment.** The 2006 policy required the patient to be stable in treatment for at least two months before being eligible for medium intensity supervision, and for at least six months before being eligible for low intensity supervision. The 2013 policy states that for buprenorphine/naloxone clients the continuous stability requirements are two weeks (medium), then two months (low), then six months (very low).[16]

1.6.2 Methadone takeaway dosing requirements

The takeaway methadone dosing requirements in the 2013 policy are largely identical to the requirements in the 2006 policy:

- **Level of supervised dosing.** Both policies set out three levels of supervised dosing and the maximum number of takeaway doses available at each level: (1) high intensity, no takeaway doses permitted; (2) medium intensity, up to two takeaway doses weekly permitted; and (3) low intensity, up to five takeaway doses per week permitted. The only difference is that under the 2006 policy a client would need to be stable on methadone for two months before being eligible for medium intensity supervision, whereas in the 2013 policy this has been decreased to one month of stability.[17]
- **Consultation with pharmacist.** Both policies direct the prescriber to consult with the pharmacist when assessing patient stability on methadone. In the 2013 policy increased attention is drawn to this requirement, with a statement that pharmacist consultation is "essential" when considering whether to introduce or change the number of takeaway doses.[18]
- **Eligibility for takeaway dosing.** Together with the stability requirements, both policies set out identical additional considerations for assessing takeaway dosing eligibility: attendance at medical reviews, missed dosing, provision of urine drug screens, and so on.[19]

1.7 Future policy directions

In January 2013 the Department of Health released its *Enhancing the Victorian Community Based Pharmacotherapy System: Directions Paper*. The paper identified limitations of the current system delivering opioid replacement therapy in Victoria, including:

- Not enough prescribers and dispensers involved in the delivery of opioid replacement therapy.
- Problems with referral and support pathways between primary care providers and specialist services, including limited access to the specialist system.

---

15 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, pp.21-24.

16 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, p.24.

17 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, p.23.

18 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, p.23.

19 Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013, p.25.

- Varied quality of care between providers.
- Limited development, mentoring and support opportunities for providers. [20]

A number of solutions were proposed for addressing these limitations, including the development of area-based pharmacotherapy networks around the state to provide support across local prescribers, dispensers and specialist services:

> The pharmacotherapy networks will constitute a platform for formalised partnership arrangements between pharmacotherapy providers. They will aim to enhance access to pharmacotherapy, improve service coordination including referral pathways to specialist services and build capacity of the associated workforce.[21]

The paper does not discuss takeaway dosing directly, and I am uncertain how if at all takeaway dosing assessment and delivery might change in response to the proposed solutions.

1.8 Discussion

Takeaway dosing is a key component of the Victorian opioid replacement therapy system overseen by the DPR. The DPR has consulted widely with clinical and other experts to compile guidelines for prescribers and dispensers with the intention to ensure, to the greatest degree possible, that takeaway doses are not misused or diverted.

The opioid replacement therapy system in Victoria is presently undergoing changes as outlined in the revised 2013 policy and Directions Paper. The implications of these changes for delivery and regulation of takeaway methadone dosing are not clear at present.

---

20 Victorian Department of Health, *Enhancing the Victorian Community Based Pharmacotherapy System: Directions Paper*, January 2013, p.5.

21 Victorian Department of Health, *Enhancing the Victorian Community Based Pharmacotherapy System: Directions Paper*, January 2013, p.6.

2. Literature review

In this section I review recently published research that addresses the benefits and risks of takeaway dosing versus supervised dosing for opioid replacement therapy. I focus particularly on studies that compare outcomes between takeaway and supervised dosing. The purpose of the review is to inform the coroner regarding the current state of the empirical evidence in this area, in case the coroner wishes to consider at her discretion Victorian opioid replacement therapy policy in the light of Ritter and di Natale's observation that:

> The development of take-away policies should be based upon evidence: evidence of risks and evidence of benefits.[22]

Acknowledging my lack of expertise in opioid replacement therapy, I do not present this review as an authoritative account of the empirical evidence. Rather, it should be regarded as an outline summary of major themes and findings I identified in the literature. Expert input could be sought regarding the completeness and accuracy of the information presented herein.

2.1 Client preference

Between 2007 and 2009 three key Australian studies were published that reported on the perspectives of a diverse range of people involved in methadone for opioid replacement therapy, including clients and providers.[23] A clear finding across these three studies was that clients prefer takeaway dosing over supervised dosing for the following reasons:

- Clients believe that takeaway dosing better enables them to obtain employment or continue existing employment. Particular benefits identified were that takeaway dosing reduced the need to (1) obtain permission for time off from work or altered hours to accommodate dosage point attendance; (2) travel to a dosing point that might be far from the workplace; and (3) disclose to an employer that the client is on a methadone program.
- Clients believe that takeaway methadone has a positive effect on family functioning. Takeaway dosing means parents do not have to take their children to dosing points and expose them to an aspect of life that is undesirable for children. Further to this, dosing point attendance can be expensive and difficult to manage if children are required to travel with the parent, or if care needs to be organised for children at home while the parent attends.
- Clients value the confidentiality and privacy attendant in takeaway dosing. The National Centre in HIV Social Research (NCHSR) study in particular showed that the majority of methadone clients want to keep their methadone taking as discreet as possible, and having to go to a dosing point every day makes this much harder to do. Allowing for takeaway doses gives clients a much better chance of keeping their privacy intact.

---

22 Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, p.347.

23 Treloar C, Fraser S, Valentine K, "Valuing methadone takeaway doses: The contribution of service-user perspectives to policy and practice", *Drugs: Education, Prevention and Policy*, vol 14, no 1, February 2007, pp.61-74; Fraser S, Valentine K, Treloar C, MacMillan K, "Methadone maintenance treatment in New South Wales and Victoria: Takeaways, diversion and other key issues", National Centre in HIV Social Research, 2007; Ritter A, Chalmers J, "Polygon: The many sides to the Australian opioid pharmacotherapy maintenance system", Australian National Council on Drugs Research Paper 18, 2009, p.35.

- Clients report that maintaining positive self-esteem is a major factor in them continuing in the methadone program and staying illicit drug free, and that due to takeaway dosing they are able to maintain relationships easier with others and be less embarrassed and ashamed by taking part in the methadone program. A methadone client who is required to receive doses daily at a dosing point has a greater chance of identification at the dosing point by people who are unaware as to them being a client of the methadone program and are not aware of their history of illicit drug use. The potential uncovering of this personal information could damage relationships significantly, to the detriment of the clients and their potential participation and advancement in the program.
- Clients believe that takeaway dosing reduces potentially negative interactions at dosing points. Usually only two methadone clients are allowed inside a dosing point at one time, while the rest must queue outside and wait, and this can pose a number of risks for the clients. Regular contact between clients can lead to the illicit selling of methadone, buying methadone from current clients, or attempting to sell illicit drugs as heroin to clients who are most often in a vulnerable state. The NCHSC research in particular found that queuing at a dosing point was a major area of concern expressed by methadone clients. Clients indicated that it is hard being on the program, and placing added pressures on them such as contact with other clients and possibly illicit drug users can cause them to relapse in their treatment, sometimes with fatal consequences.
- Clients report more trust in opioid replacement therapy when they are provided access to takeaway dosing; they feel as though they are making progress and the program is leading to improvements in their lives.

2.2 Treatment outcomes

Some studies were identified that compared treatment outcomes (construed broadly to include retention in treatment, drug use, employment, social integration and other measures of relevance) between opioid replacement therapy client receiving methadone on a takeaway versus supervised dosing basis:

- In a 1998 US study, methadone clients were randomly assigned to one of two treatment groups: five attendances versus two attendances per week at a clinic for supervised dosing, with takeaway doses provided for the remaining days. A greater proportion of clients on the two supervised dose per week schedule were retained in treatment over a 24-week study period. No significant difference was observed between the two groups in supplemental use of illicit and illegal drugs, or in risk of contracting HIV.[24]
- A 2000 meta-analysis of data from previous studies concluded that provision of takeaway doses as an incentive to clients who return negative urine screens, was more effective than supervised dosing at reducing illicit drug use among opioid replacement therapy clients.[25]
- In a 2006 US study, stable methadone patients were randomly assigned to one of three treatment groups: two groups received a month's supply of takeaway methadone at a time, and the third group received a week's supply at a time. Drug use and retention outcomes were similar across all groups, but the groups

---

24 Rhoades HM, et al, "Retention, HIV risk, and illicit drug use during treatment: methadone dose and visit frequency", *American Journal of Public Health*, vol 88, no 1, 1998, pp.37-38.

25 Griffith JD, et al, "Contingency management in outpatient methadone treatment: a meta-analysis", *Drug and Alcohol Dependence*, vol 58, no 1, 2000, p.63.

receiving a month of methadone at a time reported "initiating new vocational or social activities" to a greater extent than the weekly dispensing group.[26]

- A 2011 Italian study measured various treatment outcomes between clients at three clinics that had different methadone dispensing practices: supervised dosing at clinic only, contingent takeaway dosing, and non-contingent takeaway dosing.[27] There was better client retention and adherence to treatment among the contingent group compared to the non-contingent group, as well as less engagement in crime and less self-reported methadone diversion. There were no significant differences between the contingent and dosing point clients on any of these measures.[28]

Of tangential relevance, some published studies examined program outcomes before and after methadone dosing practices were changed. For example:

- A 1996 Australian study found that clients were retained in treatment longer after two sets of takeaway dosing streams were added to its supervised dosing stream (though interpretation of this result is complicated by a concomitant finding that takeaway clients also received higher methadone doses, which other studies have shown assists in treatment retention).[29]
- A 1996 Italian study found that a cohort of methadone clients forewarned about a change in regulation that would ban takeaway dosing, discontinued treatment at a higher rate than a retrospective matched comparison group from before the regulatory change was announced; this was interpreted as showing that "the loss of take-home dosages is an obstacle to retention in treatment".[30]

2.3 Diversion

Drug diversion encompasses a range of behaviours:

> Diversion is usually defined as diversion of medication to the illicit market, but importantly also includes diversion of supervised medication for

---

26 King VL, et al, "A 12-month controlled trial of methadone medical maintenance integrated into an adaptive treatment model", *Journal of Substance Abuse Treatment*, vol 31, no 6, 2006, p.390.

27 Takeaway methadone can be provided on either a contingent or non-contingent basis. Contingent takeaway dosing describes arrangements where the client must comply with certain requirements (which may range across drug use, attendance, stability in treatment, and so on) to be eligible; the takeaway doses are in a sense an incentive to engage in treatment, and a reward for engagement. Takeaway dosing arrangements in Victoria are a good example of a contingent system. Non-contingent dosing entails provision in the absence of any requirements or conditions the client must meet.

28 Gerra G, et al, "Supervised daily consumption, contingent take-home incentive and non-contingent take-home in methadone maintenance", *Progress in Neuro-Psychopharmacology and Biological Psychiatry*, vol 35, no 2, 2011, pp.486-487.

29 White JM, Ryan CF, Ali RL, "Improvements in retention rates and changes in client group with methadone maintenance streaming", *Drug and Alcohol Review*, vol 15, no 1, 1996, p.86. On the effect of methadone dose on treatment retention see for example Amato L, et al, "An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research", *Journal of Substance Abuse Treatment*, vol 28, no 4, June 2005, p.326.

30 Pani PP, et al, "Prohibition of take-home dosages: negative consequences on methadone maintenance treatment", *Drug and Alcohol Dependence*, vol 41, no 1, May 1996, p.84.

personal use outside the supervised treatment site and may be for the purposes of injecting.[31]

Most researchers appear to accept implicitly that takeaway dosing, by its very nature, presents greater opportunities for methadone diversion than supervised dosing. This concern is supported by some research linking takeaway dosing with greater prevalence of methadone diversion:

- A 2005 Australian study examined the incidence of methadone injection between states that had different methadone dosing policies. The general finding was that states with more restrictive takeaway methadone policies had lower rates of methadone injection. However there were findings that contradicted this trend, indicating that methadone injection might be influenced by other factors such as dose dilution and general availability of heroin in the community; the authors concluded that "the relationship between methadone take-away doses and methadone injection is unlikely to be as straightforward as is sometimes suggested".[32]
- A 2008 UK study examined measures of medication non-adherence (including missed doses, split doses, dose diversion and injection) among methadone clients in a community treatment setting. Non-adherence was greater among clients who received takeaway doses than those who received supervised doses, and was greatest among those who had more frequent takeaway doses.[33]
- The 2011 Italian study discussed earlier found less self-reported methadone diversion among clients provided contingent takeaway doses as compared to non-contingent takeaway doses; there was no significant difference in reported methadone diversion between clients receiving contingent takeaway doses and clients receiving methadone under supervised dosing arrangements.[34]

Additionally, studies have clearly indicated that supervised dosing might deter diversion, but does not entirely prevent it.[35]

The literature documents numerous harms associated with the diversion of methadone, including overdose death, injection-related harms (such as vein damage) and instability in treatment. However some researchers have argued that methadone diversion may additionally serve protective functions. For example, a 2013 study reported on interviews with current injecting drug users in London and found inter alia that:

---

31 Winstock AR, et al, "Prevalence of diversion and injection of methadone and buprenorphine among clients receiving opioid treatment at community pharmacies in New South Wales, Australia", *International Journal of Drug Policy*, vol 19, no 6, December 2008, p.450.

32 Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, p.350.

33 Haskew M, et al, "Patterns of adherence to oral methadone: implications for prescribers", *Journal of Substance Abuse Treatment*, vol 35, no 2, 2008, p.113.

34 Gerra G, et al, "Supervised daily consumption, contingent take-home incentive and non-contingent take-home in methadone maintenance", *Progress in Neuro-Psychopharmacology and Biological Psychiatry*, vol 35, no 2, 2011, pp.486-487.

35 See for example Haskew M, et al, "Patterns of adherence to oral methadone: implications for prescribers", *Journal of Substance Abuse Treatment*, vol 35, no 2, 2008, p.113; Varenbut M, et al, " Tampering by office-based methadone maintenance patients with methadone take home privileges: a pilot study", *Harm Reduction Journal*, vol 4, no 15, published online 30 October 2007, DOI 10.1186/1477-7517-4-15, p.2.

- Takeaway methadone enables clients to self-regulate their dosing rather than (as occurs under a supervised arrangement) being forced to take the whole dose at once. This means they can trial alternate regimens such as reducing their daily dose and 'splitting' the dose (taking it in stages over 24 hours rather than all at once), thus taking control of their treatment and adapting it to suit their current needs and goals.
- Clients can stockpile methadone provided as takeaway doses by consuming less than they have been dispensed. The stockpiled methadone acts as a "safeguard" for unanticipated situations such as if they missed a regular dose or a script was cancelled, so they would not need to resort to street drugs.
- Where takeaway methadone was diverted to another person, interviewees reported they were often motivated by empathy, in that they provided it (either without charge or for a token fee) to other opioid dependent people who had missed their dose or were suffering withdrawal or so on. Methadone was also diverted as part of reciprocal social arrangements that benefited all parties and reduced risky drug-taking behaviours.[36]

The authors concluded their findings illustrated that:

> [...] the generous constraints of unsupervised consumption can act with individuals to have harm reducing as well as harm producing potentials, and conversely, how the rigid constraints of supervised consumption can produce as well as reduce harm.[37]

This conclusion was consistent with earlier findings by some other researchers, who identified methadone diversion practices that were associated with harm reduction rather than (for example) seeking euphoric effects.[38]

2.4 Deaths

Several researchers and commentators have attributed observed declines in methadone-related deaths to declines in takeaway methadone dispensed and the introduction of supervised dosing regimes.[39] The strongest evidence for these claims comes from a 2010 UK retrospective population-level study published in the *British Medical Journal*. According to the study's authors, unsupervised methadone dosing was linked with significant harms including deaths in the United Kingdom during the 1980s and 1990s. Consequently:

> Methadone prescribing practice in the UK was changed in the mid-late 1990s, with the aim of reducing deaths related to overdose of methadone;

---

36 Harris M, Rhodes T, "Methadone diversion as a protective strategy: the harm reduction potential of 'generous constraints'", *International Journal of Drug Policy*, in press, 2012, <http://dx.doi.org/10.1016/j.drugpo.2012.10.003>, accessed 28 May 2013.

37 Harris M, Rhodes T, "Methadone diversion as a protective strategy: the harm reduction potential of 'generous constraints'", *International Journal of Drug Policy*, in press, 2012, <http://dx.doi.org/10.1016/j.drugpo.2012.10.003>, accessed 28 May 2013, p.7.

38 For a brief summary of the research see Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, p.348. More recently see Duffy P, Baldwin H, "The nature of methadone diversion in England: a Merseyside case study", *Harm Reduction Journal*, vol 9, no 3, 2012, DOI 10.1186/1477-7517-9-3, p.4.

39 See for example Swensen G, "Opioid drug deaths in Western Australia: 1974-1984", *Australian Drug and Alcohol Review*, vol 7, no 2, 1988, p.184; Zador D, et al, "Commentary: decline in methadone-related deaths probably relates to increased supervision in UK", *International Journal of Epidemiology*, vol 35, no 6, 2006, p.1586.

daily dispensing and supervision of methadone dosing were introduced or increased to reduce diversion.[40]

The study examined trends in methadone overdose deaths in Scotland and England between 1993 and 2008, to evaluate the impact of increased supervision. The central finding was that over this period the number of UK deaths involving methadone per million prescribed annual defined daily doses of methadone[41] decreased more than fourfold. The authors concluded:

> Our findings show a remarkable improvement in the safety of methadone prescribing in both Scotland and England, particularly over the period 1995-2004. [...] We found that the timing of these changes was precise and was related to a specific change in clinical practice that occurred at different times in the two countries - namely, the widespread supervision of methadone dosing during the early months of treatment.[42]

They additionally noted that the reduction in deaths occurred despite a steady increase in methadone supply for opioid replacement therapy to treat opioid dependence during the study period.

The logical corollary here is that if access to takeaway methadone is liberalised, there should be an increase in frequency of methadone deaths. Researchers have observed that a rising frequency of methadone deaths might be linked to increased availability of takeaway methadone,[43] however I was unable to identify any study that specifically examined the purported link as had been done in the *British Medical Journal* study discussed above.

2.5 Discussion

The published literature describes a complex relationship between the benefits and harms of takeaway methadone dosing in opioid replacement therapy. For example, studies have found that takeaway dosing is associated with better social and employment outcomes but poorer adherence to medication regimes; that reducing access to takeaway doses reduces methadone-related deaths, but also contributes to loss of clients from treatment; that takeaway dose diversion and misuse can have both harmful and beneficial effects.

Furthermore, the literature suggests the benefits and harms of takeaway and supervised methadone dosing are influenced by broader contextual factors including the way in which the takeaway doses are provided (on a contingent or non-

---

40 Strang J, et al, "Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland", *British Medical Journal*, published online 16 September 2010, DOI 10.1136/bmj.c4851, p.1.

41 The defined daily dose is a standardised unit of measurement used by the World Health Organization and defined as: "[...] the assumed average maintenance dose per day for a drug used for its main indication in adults". See World Health Organization, "Defined daily dose: definition and general considerations", 17 December 2009, <http://www.whocc.no/ddd/definition_and_general_considera/>, accessed 31 May 2013.

42 Strang J, et al, "Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland", *British Medical Journal*, published online 16 September 2010, DOI 10.1136/bmj.c4851, p.4.

43 See for example Heinemann A, et al, "Methadone-related fatalities in Hamburg 1990–1999: implications for quality standards in maintenance treatment?", *Forensic Science International*, vol 113, no 1-3, 2000, p.455; Bell J, "The Global Diversion of Pharmaceutical Drugs", *Addiction*, vol 105, no 9, 2010, pp.1532-1533.

contingent basis), the strength of the dispensed daily dose, and the use (or not) of random urine screening to support decisions around access to takeaway dosing. Ritter and di Natale noted this complexity in their observation that:

> [...] a number of variables drive methadone diversion, and indeed take-away policy may not be a primary driver. The variables, all of which are broad systems variables, include drug preference, drug availability, treatment availability and degree of treatment penetration.[44]

A weakness of the existing literature is that each study only examines a subset of the interrelated benefits and harms attached to opioid replacement therapy. For example, the *British Medical Journal* study linking an increase in supervised dosing to a decrease in methadone-related deaths, only considered deaths as an outcome of interest. The authors did not consider how reducing access to takeaway methadone impacted on heroin deaths, on HIV and hepatitis C transmission, on client retention in treatment, or so on. Similar comments apply to the Australian study establishing a general inverse relationship between takeaway dosing policy restrictiveness and prevalence of methadone injection.

Another weakness is that as delivery of opioid replacement therapy varies from jurisdiction to jurisdiction, and so too does the broader context in which the delivery takes place, the findings from a study in one jurisdiction are not necessarily applicable in other jurisdictions. Taking again the *British Medical Journal* study as an example, the main change to UK opioid replacement therapy delivery during the study period was increased dose supervision during induction rather than increased dose supervision across all clients.[45] Therefore, it is problematic to speculate as to what the research might tell us about introducing stricter takeaway dose controls in Victoria, where supervised dosing for induction already exists.

Finally, in my review of the literature I could not find any studies that directly address the crucial question of whether takeaway methadone dosing reduces the risk of heroin-related deaths more effectively than supervised methadone dosing. Similarly, I could not find any literature on how - if at all - the feared negative impact of supervised methadone dosing on social integration, employment, and related areas, translated into increased risk of death.

In summary, the published literature offers some guidance regarding the risks and benefits of takeaway methadone dosing versus supervised methadone for opioid replacement therapy, but the overall complexity of the interactions between these risks and benefits, and the number of contextual factors that might have a bearing on outcomes, means that the literature offers limited direction on how opioid replacement therapy with methadone should be delivered in a way that maximises benefits and minimises risks.

---

44 Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, p.351.

45 See Strang J, et al, "Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland", *British Medical Journal*, published online 16 September 2010, DOI 10.1136/bmj.c4851, p.2.

3. Takeaway dose diversion in Victorian deaths

The CPU maintains a database of deaths involving acute drug toxicity that were reported to the Coroners Court of Victoria between 2000 and 2012.[46] To assist the coroner's investigation, I extracted the subset of deaths where methadone was found to have been a contributing drug (referred to for convenience as 'methadone deaths') and undertook the following:

- A general analysis of deaths by annual frequency and co-contributing drugs, to provide background context on the contribution of methadone in Victorian deaths reported to the coroner between 2000 and 2012.
- A pilot analysis to establish what proportion of the deaths might have been associated with diversion of a takeaway methadone dose provided for opioid replacement therapy.

In this section I present the preliminary findings, as well as a discussion of how the data could potentially be interpreted.

3.1 Victorian methadone deaths, 2000-2012

I identified 537 Victorian deaths from acute drug toxicity including methadone ('methadone deaths') between 2000 and 2012. Figure 1 shows that the annual frequency of methadone deaths rose steadily over this period, particularly from 2007 onwards, peaking at 74 deaths in 2012.

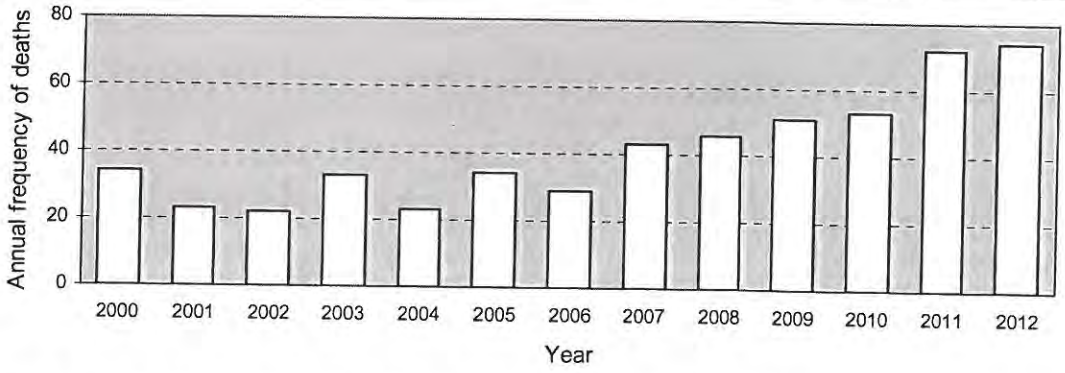

Figure 1: Annual frequency of methadone deaths, Victoria 2000-2012.

Table 1 shows that most deaths involved methadone in combination with other drugs (n = 457, 85.1%) rather than methadone alone (n = 80, 14.9%).

Table 1: Co-contributing drug involvement in methadone deaths, Victoria 2000-2012.

Drug involvement	n	%
Methadone alone	80	14.9%
Multiple drugs including methadone	457	85.1%
All methadone deaths	*537*	*100.0%*

Medications were the main co-contributors, playing a role in combination with methadone in 75.7% of deaths (see Table 2). Illegal drugs played a co-contributory role in 33.9% of deaths.

46 The database composition and case inclusion criteria are described in Attachment A.

Table 2: Co-contributing drug types in methadone deaths, Victoria 2000-2012.

Drug type	n	%
Medications	412	76.7%
Illegal drugs	182	33.9%
Alcohol	76	14.2%
Methadone alone	*80*	*14.9%*

Table 3 shows that the benzodiazepine diazepam was the most frequent co-contributor to Victorian methadone deaths, following by the illegal drug heroin and the pharmaceutical opioid analgesic codeine.

Table 3: Most frequent individual co-contributing drugs to methadone deaths, Victoria 2000-2012.

Individual contributing drugs	n	%
Diazepam	270	50.3%
Heroin	140	26.1%
Codeine	94	17.5%
Alcohol	76	14.2%
Alprazolam	72	13.4%
Oxazepam	62	11.5%
Methamphetamine	54	10.1%
Temazepam	46	8.6%
Olanzapine	39	7.3%
Mirtazapine	38	7.1%
Amitriptyline	37	6.9%
Nitrazepam	36	6.7%
Quetiapine	36	6.7%
Paracetamol	32	6.0%

3.2 Takeaway dose diversion in deaths

I restricted the pilot study of methadone sources to 2010-2011 because full case files (including Victoria Police inquest brief, toxicology and pathology reports) were readily available for most deaths in these two years.

3.2.1 Method

I reviewed available case file material for each of the 124 methadone deaths reported to the Coroners Court of Victoria and investigated by Victorian coroners in the period 2010-2011. The purpose was to identify any evidence regarding the source of the fatal methadone dose. To this end, I coded the following variables for each death where there was positive evidence on which to base the coding:

- The reason why the methadone was prescribed (for analgesia or for opioid replacement therapy).
- The basis upon which the methadone was dispensed (for consumption at a dosing point, or for consumption away from dosing point).
- The person to whom the methadone was dispensed (the deceased or another person).

3.2.2 Results

Figure 2 is a flowchart of my findings regarding the source of the fatal methadone dose in methadone deaths, Victorian 2010-2011. I was able to positively identify the methadone source in 68 (54.8%) of the 124 deaths.

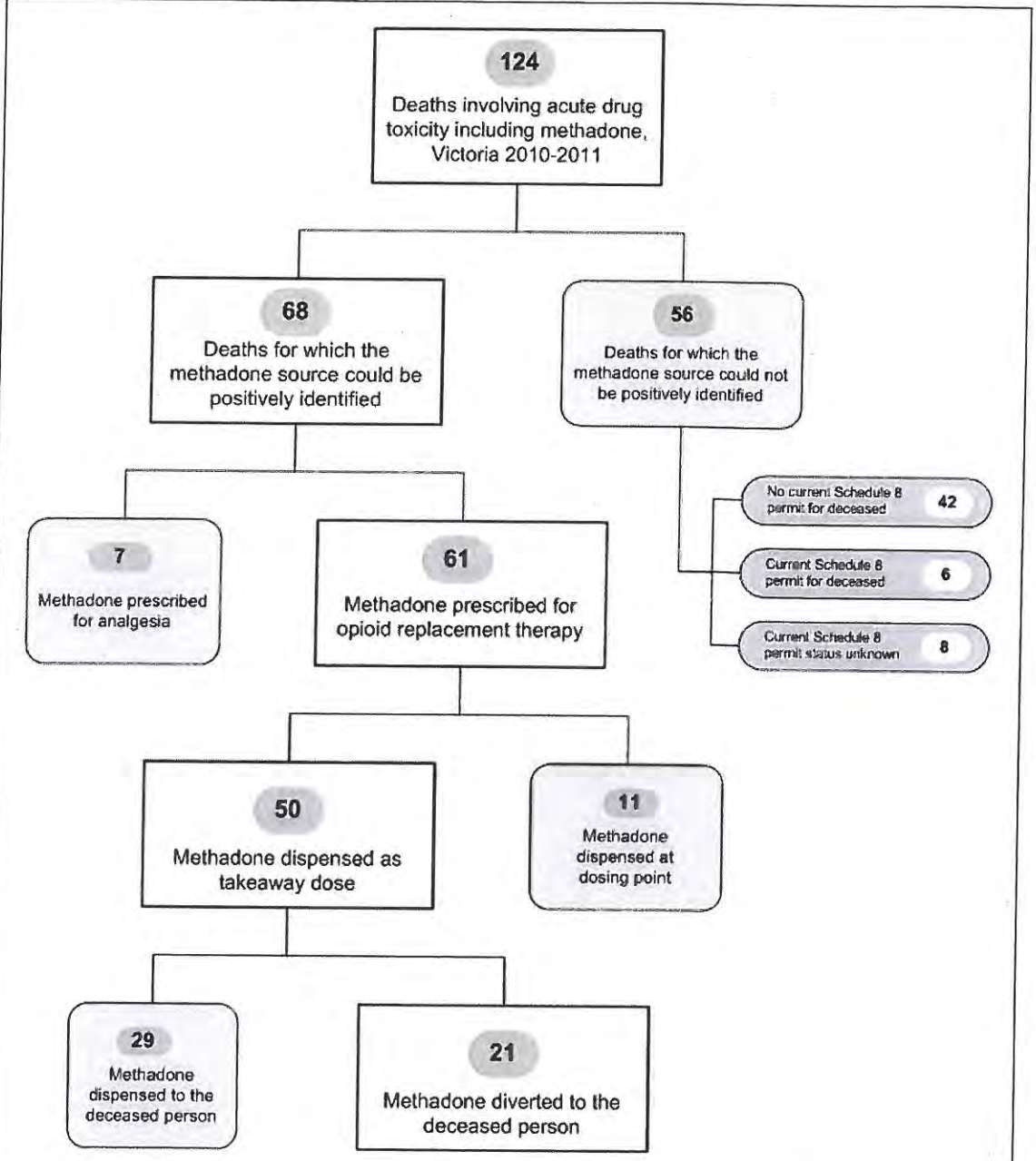

Figure 2: Source of fatal methadone dose in methadone deaths, Victoria 2010-2011.

The main findings were:

- Among the 68 deaths where the methadone source was identified, in 61 deaths the methadone had been dispensed for opioid replacement therapy, and in the remaining seven deaths the methadone had been dispensed to treat pain.
- Among the 61 opioid replacement therapy deaths, 11 involved methadone dispensed at a dosing point and 50 involved takeaway methadone doses consumed at another location. These included 29 takeaway doses dispensed to the deceased, and 21 to somebody other than the deceased.

3.3 Discussion

Between 2000 and 2012, I identified 537 Victorian deaths involving acute drug toxicity where forensic scientific experts identified methadone as contributory to death ('methadone deaths'). The annual frequency of methadone deaths fluctuated between 22 and 34 during the period 2000-2006, before commencing a steady rise from 2007 onwards, peaking at 74 deaths in 2012.

Through a pilot review of available case file material, I established the source of the fatal methadone dose in 68 of the 124 Victorian methadone deaths that occurred in 2010-2011. In 61 deaths the source was positively confirmed to be methadone prescribed for opioid replacement therapy; these included 21 deaths where the methadone was dispensed as a takeaway dose to another person and diverted to the deceased.

The full extent of diverted methadone involvement is likely to be greater than could be confirmed. This is suggested in particular by the finding that of the 56 deaths where I could not positively identify the methadone source, in 42 deaths no practitioner held a current Schedule 8 permit to prescribe methadone to the deceased. This is consistent with diversion,[47] although there are reasons why a person might be prescribed methadone in Victoria (either for analgesia or for opioid replacement therapy) without a current valid Schedule 8 permit.

The findings suggest some preliminary hypotheses regarding methadone-related deaths in Victoria that could be explored further.

3.3.1 Methadone death frequency and methadone client numbers

For 61 of the 68 Victorian methadone deaths in 2010-2011 where I positively identified the methadone source, it was prescribed for opioid replacement therapy. The large minority of deaths (45.2%) for which the methadone source was unknown renders problematic any attempt to generalise this finding. However it is consistent with a recent study showing that for most people who died with methadone in their system between 2001 and 2005 in Victoria, the methadone had been prescribed for opioid replacement therapy.[48]

This suggests a preliminary hypothesis: that if opioid replacement therapy is the main source of contributing methadone in Victorian methadone deaths, there might be a relationship between frequency of methadone deaths and frequency of Victorian opioid replacement therapy clients receiving methadone. To explore this, I plotted the annual number of Victorian clients receiving methadone[49] against the annual frequency of Victorian methadone deaths (Figure 3).

On visual inspection there appeared to be a positive association between the two sets of data; that is, the number of Victorian methadone deaths increased as the number of Victorian methadone clients increased. However, when the two sets of data were combined to calculate the annual rate of Victorian methadone deaths per

---

47 See for example Pilgrim J, McDonough M, Drummer O, "A review of methadone deaths between 2001 and 2005 in Victoria, Australia", *Forensic Science International*, no 226, vol 1-3, 2013, p.217.

48 Pilgrim J, McDonough M, Drummer O, "A review of methadone deaths between 2001 and 2005 in Victoria, Australia", *Forensic Science International*, no 226, vol 1-3, 2013, p.219.

49 The annual number of opioid replacement therapy clients in Victoria receiving methadone was taken from Victorian Department of Health, "Pharmacotherapy Newsletter", April 2013, p.2.

10,000 Victorian methadone opioid replacement therapy clients (Figure 4), this showed that the annual frequency of deaths rose between 2000-2012 at a greater pace than the annual number of methadone clients.

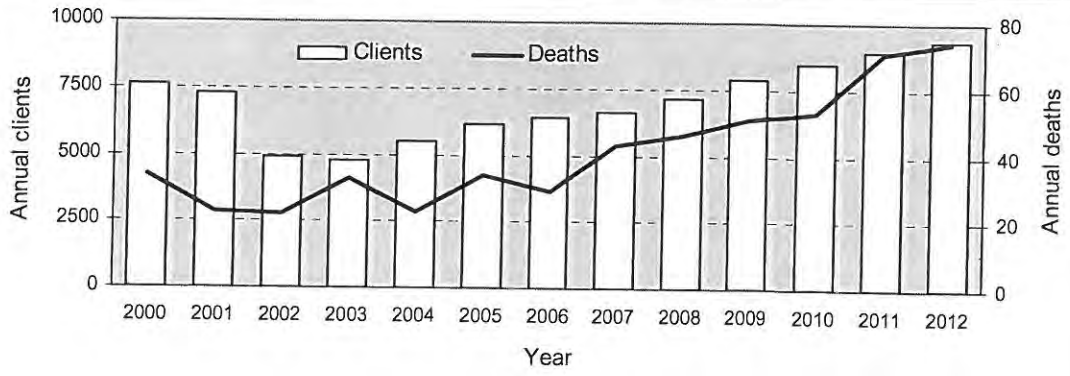

Figure 3: Annual frequency of methadone deaths (black line, right axis) plotted against annual number of opioid pharmacotherapy clients receiving methadone (white bars, left axis), Victoria 2000-2012.

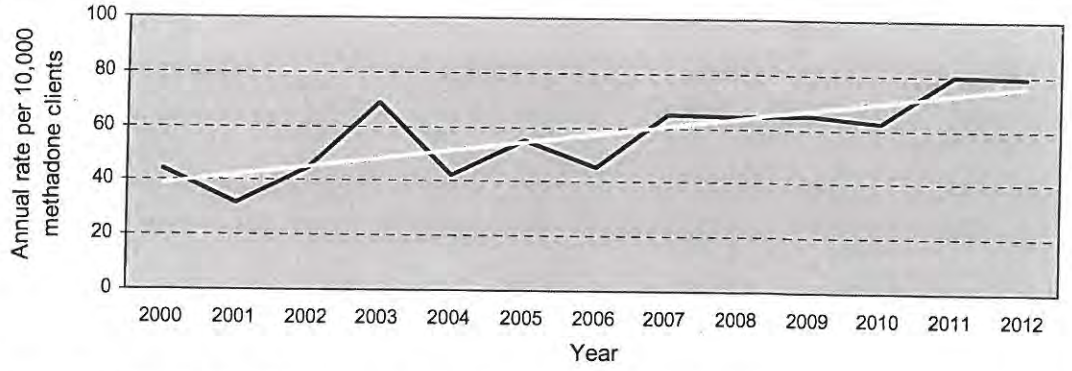

Figure 4: Annual rate of Victorian methadone deaths per 10,000 methadone clients, Victoria 2000-2012. (The white line is the linear line of best fit.)

I interpreted this finding as indicating that the annual frequency of Victorian methadone deaths might not be merely a function of the annual number of Victorian methadone clients.

3.3.2 Methadone death frequency and analgesic scripts

An alternative hypothesis is that changes in the annual frequency of Victorian methadone deaths might be driven by changes in the number of methadone scripts dispensed in Victoria on the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) for methadone to treat severe pain.[50] To explore this hypothesis, I plotted the two sets of data against one another (see Figure 5).

Again, on visual inspection there appeared to be a positive association between the two sets of data, with the frequency of Victorian methadone deaths increasing over time together with the annual number of scripts. However, when the two sets of

---

50 The PBS items for methadone to treat severe pain are 1606M, 1609Q, 5399E and 5400F. The CPU extracted the data cubes for these four PBS items by state and calendar year for 2000-2012 at Commonwealth Department of Human Services, "Pharmaceutical Benefits Schedule Item Reports", 24 May 2013, <https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml>, accessed 28 May 2013.

data were combined to calculate the annual rate of Victorian methadone deaths per 10,000 methadone scripts dispensed in Victoria on the PBS/RPBS for severe pain (Figure 6), this showed that the annual frequency of deaths rose between 2000-2012 at a greater pace than the annual number of scripts.

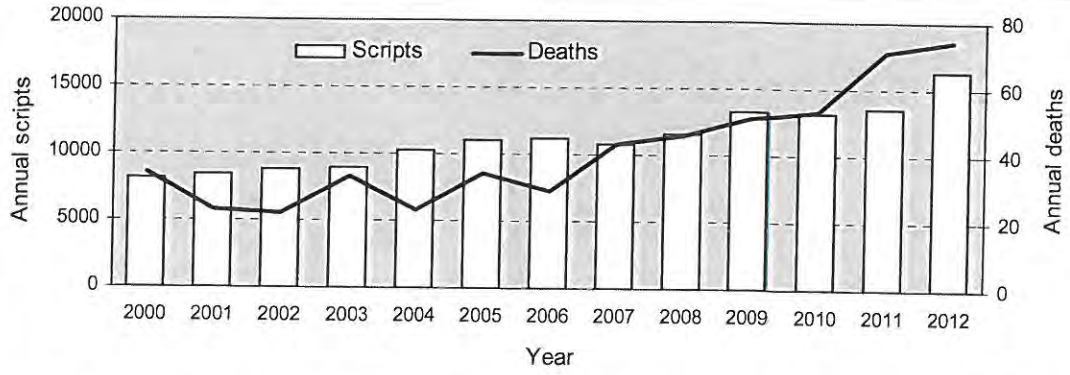

Figure 5: Annual frequency of methadone deaths (black line, right axis) plotted against annual number of scripts dispensed on the PBS/RPBS for methadone to treat severe pain (white bars, left axis), Victoria 2000-2012.

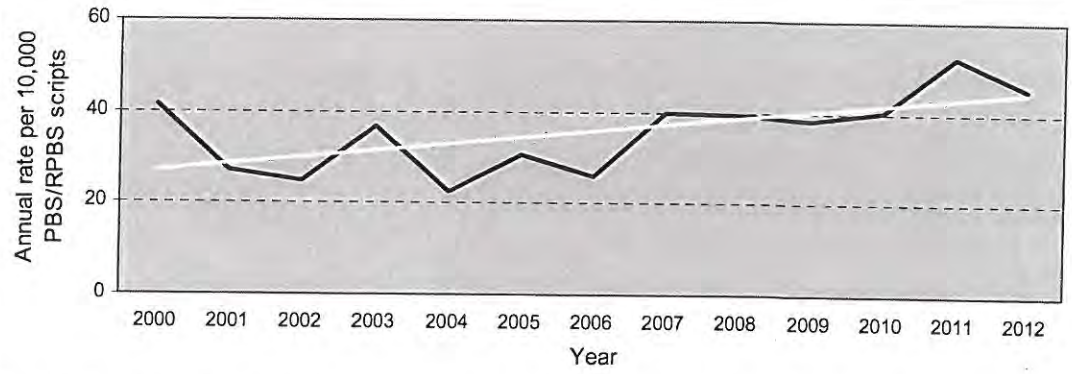

Figure 6: Annual frequency of methadone deaths (black line, right axis) plotted against annual number of PBS/RPBS methadone scripts dispensed to treat severe pain (white bars, left axis), Victoria 2000-2012.

I interpreted this finding as indicating that the annual frequency of Victorian methadone deaths might not be merely a function of the annual number of methadone scripts dispensed in Victoria.

3.3.3 Methadone death frequency and policy change

A third hypothesis I proposed was that policy change might be a driver for changes in the frequency of Victorian methadone deaths. This hypothesis was suggested by the finding that the annual frequency of methadone deaths fluctuated within relatively stable parameters in the period 2000-2006, then exhibited steady year-on-year increases from 2007, the year after the Victorian Department of Human Services introduced a new policy for opioid replacement therapy.

A possible explanation is that the 2006 policy heralded a significant shift in the availability of takeaway methadone doses for Victorian opioid replacement therapy clients. The policy prior to 2006 was as follows:

- No takeaway doses for the first two months after commencing treatment.
- One takeaway dose per week thereafter.

- In exceptional circumstances, three takeaway doses on consecutive days, but only for one week per month.[51]

As outlined in Section 1, the quantity of takeaway methadone doses a client could access under the 2006 policy was far greater than this: up to five per week depending on assessment of client stability and length of time in treatment. Greater population exposure to the risks presented by takeaway methadone in the community (including the risks of diversion and misuse) could potentially have contributed to the post-2006 rise in annual Victorian methadone deaths. There is some empirical evidence in support of this hypothesis:

- In the recently published study of Victorian deaths that occurred in the presence of methadone in 2001-2005, the researchers reported that 42 of 206 relevant deaths (20.4%) involved takeaway doses of methadone syrup.[52]
- In the above pilot study of Victorian methadone deaths for 2010-2011, in 50 of the 68 deaths where I could positively confirm the methadone source (73.5%), the source was a takeaway dose dispensed for opioid replacement therapy.

I note the two studies used different inclusion criteria for Victorian methadone deaths, and different methods of identifying methadone sources. Additionally, and as already discussed, I was unable to confirm the methadone source in a large minority (45%) of deaths examined for the pilot. However, accepting these limitations, the data at the very least suggests there might have been an increase between 2001-2005 and 2010-2011 in the frequency and proportion of annual Victorian methadone deaths for which the fatal methadone dose was dispensed as a takeaway dose for opioid replacement therapy.

3.3.4 Other explanations

There are undoubtedly other plausible explanations for the findings reported from this pilot study; opinion could be sought from a relevant expert.

3.3.5 The need for further research

Further research and data would be needed to better understand the possible reasons for the recent increase in the annual frequency of Victorian methadone deaths. For example:

- Data is needed on the annual frequency of methadone doses dispensed on a supervised versus takeaway basis in Victoria from 2000 through to the present. This would enable researchers to establish whether the 2006 policy led to an increase in the frequency and proportion of methadone doses dispensed annually in Victoria on a takeaway basis, and test hypotheses regarding the link between takeaway dosing and deaths in Victoria.
- The Court could expand and improve its analysis of methadone sources in Victorian methadone deaths, to produce data on the frequency and proportion of deaths involving various methadone soruces for the entire period 2000-2012, and also to reduce the number of deaths where the methadone source is unknown.

---

51 This information is drawn from Fraser S, Valentine K, Treloar C, MacMillan K, "Methadone maintenance treatment in New South Wales and Victoria: Takeaways, diversion and other key issues", National Centre in HIV Social Research, 2007, p.29.

52 Pilgrim J, McDonough M, Drummer O, "A review of methadone deaths between 2001 and 2005 in Victoria, Australia", *Forensic Science International*, no 226, vol 1-3, 2013, p.218.

- Further to this last point, data linkage with the Victorian Department of Health could enhance the Court's capacity to identify likely methadone sources in Victorian methadone deaths. The Victorian Department of Health would presumably be able to use the information to fine-tune the risk-reducing measures in its policy.

4. Coroners' recommendations on takeaway methadone

The CPU maintains a database of recommendations that Victorian coroners have made in findings for deaths investigated from 1 January 2000 to present. The CPU searched this database using the terms "methadone", "takeaway", "take-away" and "pharmacotherapy", to identify relevant findings in which coroners made recommendations that address methadone takeaway dosing for opioid replacement therapy.

4.1 Overview of recommendations

The CPU identified eight relevant recommendations in four findings; the following is an overview of recommendations in chronological order, together with responses from statutory authorities and entities where the recommendations were made under the provisions of the *Coroners Act 2008* (Vic). Where a recommendation has been made under the *Coroners Act 2008* (Vic), both the finding and any recommendation responses are publicly available on the Coroners Court of Victoria's website.[53]

4.1.1 Tabitha Curnow 20044506

Coroner Audrey Jamieson investigated the death of Tabitha Curnow and found that she died from toxicity to methadone in circumstances where the methadone was a diverted takeaway dose prescribed and dispensed to another person for opioid replacement therapy. The evidence was not clear as to whether Tabitha Curnow was provided to dose, or whether she took it without the person's knowledge. In the finding dated 15 November 2005, Coroner Jamieson recommended:

> I **recommend** that the Department of Human Services review Section 4.5 of the Methadone Guidelines which deals with take-away doses. In particular, I recommend that the qualifying requirements for take-away dose entitlement be restricted to "special circumstance" patients and that this requirement be more clearly defined for the prescriber.

This recommendation was made pursuant to the *Coroners Act 1985* (Vic) and therefore no response was submitted.

4.1.2 Melissa Irwin 20095712

Coroner Kim Parkinson investigated the death of Melissa Irwin and found that she died from methadone toxicity in circumstances where the methadone was a diverted takeaway dose prescribed and dispensed to another person for opioid replacement therapy. Coroner Parkinson concluded that Melissa Irwin was able to access the methadone because it was not safely stored. In her finding delivered 16 December 2010 she commented:

> An issue arises in this case as to the appropriateness of the storage of the methadone at the premises and the supervision by any authority of the safety of that storage. The ready availability of the methadone in this case has contributed to [Melissa Irwin's] death.
>
> [...] The guidelines do not specifically identify who is responsible for the oversight of matters such as safe storage or what steps are required to be taken to ensure safety prior to take away doses being allowed. To leave the decision making and storage arrangements solely in the hands of the addicted person seems to be an approach which is fraught with risk, given

53 Access via: <http://www.coronerscourt.vic.gov.au/home/coroners+written+findings/>.

the unreliability often associated with persons suffering with substance addiction.

Coroner Parkinson directed two recommendations to the Victorian Department of Health in its capacity as the responsible regulatory authority for opioid replacement therapy. The recommendations were made pursuant to the *Coroners Act 2008* (Vic) and responses were received.

The first recommendation was:

> **Recommendation 1**. That regulatory authorities establish a clear mechanism of supervision of the safety arrangements for storage of take away dosage of methadone.

The (undated) Victorian Department of Health response to this recommendation, signed by Secretary Fran Thorn, indicated the following:

> The *Drugs, Poisons and Controlled Substances Act 1981* (the Act) and its associated regulations empower the department to mandate storage conditions for drugs and poisons to the point of dispensing or supply to the intended consumer. That is to say that neither the Act nor the regulations mandate storage conditions for drugs and poisons in individual places of residence.
>
> It is not practically possible for the department to oversee the safe storage of take-away doses by pharmacotherapy clients in their private residences. The presence of a safe storage facility, such as a lockable cupboard, in no way guarantees that a client will store take-away doses within that lockable facility at all times. This proposed regulatory role for the department is therefore not possible to enforce.

The second recommendation was:

> **Recommendation 2**. That there be a prohibition upon take away methadone dosage unless a responsible regulatory authority is satisfied that safe storage arrangements are in place in the premises in which the drug is to be stored.

In its response to the second recommendation, the Victorian Department of Health indicated that its *Policy for Maintenance Pharmacotherapy for Opioid Dependence* contained "numerous safeguards to ensure the safe storage of methadone take-away doses". These safeguards including a requirement for the prescriber to be satisfied that the client was in stable accommodation and had a "locked or secure cupboard" for storing medication, as well as a requirement for the pharmacist to advise the client regarding safe storage. The Victorian Department of Health further indicated:

> Any legislative amendments to implement the recommendations would need to be compatible with the Charter of Human Rights and Responsibilities 2006 (the Charter). The Charter provides that any limitations on a person's rights, such as the right to privacy, have to be demonstrably justified and take into account such matters as the nature of the right and any less restrictive means reasonably available to achieve the purpose. It is difficult to envisage that the proposed measures would be the least restrictive means available.

4.1.3 Michael Gledhill 20085241

Coroner Kim Parkinson investigated the death of Michael Gledhill and found that he died from combined drug toxicity including methadone in circumstances where he was dispensed a large quantity (28 doses) of takeaway methadone that was not safely stored. In her finding delivered 17 February 2011 she made four

recommendations pursuant to the *Coroners Act 2008* (Vic); responses were received to these recommendations.

The first two recommendations effectively reiterated the recommendations in Coroner Parkinson's finding for the death of Melissa Irwin:

> **Recommendation 1**. That the responsible regulatory authorities, The Department of Human Services (Victoria) and the Department of Health (Victoria), establish a clear mechanism of supervision of the safety arrangements for take away dosage of methadone.
>
> **Recommendation 2**. That there be a prohibition upon take away methadone dosage unless responsible regulatory authorities, the Department of Human Services (Victoria) and the Department of Health (Victoria), are satisfied that safe storage arrangements are in place in the premises in which the drug is to be stored.

The Victorian Department of Health response to these two recommendations, which was signed by Secretary Fran Thorn and received by the Court on 19 May 2011, was identical in content to the responses in the death of Melissa Irwin.

Coroner Parkinson's third recommendation was:

> **Recommendation 3**. That the responsible Minister/s give consideration to legislative amendment if necessary to enable the implementation of appropriate levels of supervision and safety arrangements.

The Victorian Department of Health responded to this recommendation on behalf of the Minister,[54] indicating inter alia:

> As discussed in the response to the first recommendation, neither the Act nor the regulations include provisions regulating the storage of drugs and poisons in individual places of residence.
>
> A legislative proposal for the department to regulate the safe storage of takeaway doses by pharmacotherapy clients in their private residences is unworkable as it would not be possible to enforce. Further, any legislative amendments to implement the proposed measures would need to be compatible with the Charter of Human Rights and Responsibilities 2006 (the Charter).

Coroner Parkinson's fourth recommendation was informed by evidence that Michael Gledhill had proximal to his death been arrested for heroin possession and taken to hospital for a suspected overdose. Coroner Parkinson noted that neither his methadone prescriber nor dispenser knew about these events, which would have been highly relevant to any assessment of suitability for takeaway dosing. She recommended:

> **Recommendation 4**. That the responsible Minister/s give consideration to legislative amendment if necessary to enable the provision of health information, such as overdose events or drug related arrests, to the General Practitioner supervising a patient's pharmacotherapy program such as the methadone maintenance program.

The Victorian Department of Health again responded on behalf of the Minister, indicating inter alia:

---

54 The Hon Mary Wooldridge MP, Minister for Mental Health, wrote a letter to the Court dated 12 May 2011 indicating that she had received the finding and had delegated her formal response to the Victorian Department of Health.

> Without a client disclosing that he or she is receiving pharmacotherapy treatment, police would not have knowledge of a client's pharmacotherapy treatment details. Regardless, it is unlikely that an individual would give consent to allow Victoria Police to disclose information on drug-related offences to a medical practitioner.
>
> A legislative amendment to enable this provision of information regarding drug-related arrests by the police to a medical practitioner would be unworkable. This is because the police would not know which offenders are pharmacotherapy clients and would therefore be potentially obliged to contact the department for any alleged drug-related offence to determine whether the individual is being treated with pharmacotherapy. Further, any such legislative amendment would potentially engage the right to privacy under the Charter and would be difficult to justify on the grounds that there is no less restrictive means available.

The Victorian Department of Health also noted in its response that health practitioners in hospitals could contact the Department and check whether a person is currently receiving pharmacotherapy.

The Court's Principal Registrar Gayle Chirgwin subsequent wrote to the Victorian Department of Health on 15 June 2011, seeking clarification on the Charter claims made in the Department's responses to Coroner Parkinson's recommendations in the deaths of Melissa Irwin and Michael Gledhill. The Victorian Department of Health, by reply dated 11 July 2011 and signed by Secretary Fran Thorn, indicated that:

> Legislative reform of takeaway doses of methadone would potentially engage rights under the Charter. Firstly, any proposal for the Department to legislate for the safe storage of takeaway doses for use by pharmacotherapy patients in their private residence would engage the right to privacy under Section 13 of the Charter. For such a proposal to be effective, authorised officers of the Department would require powers of entry into people's homes to monitor and enforce compliance with the requirement. Section 13 provides that a person has the right not to have his or her privacy, family, home or correspondence unlawfully or arbitrarily interfered with.
>
> [...] Similarly, the legislative proposal to enable the provision of health information, such as overdose events or drug related arrests, to the General Practitioner supervising a patient's pharmacotherapy program also engages the right to privacy under section 13 of the Charter. The interference with this right would also have to be considered in the development of the legislative proposal and an analysis undertaken to show that it is reasonable and demonstrably justified in accordance with section 7.

4.1.4 Damien Perceval 20092063

Coroner Kim Parkinson investigated the death of Damien Perceval and found that he died from combined methadone and alcohol toxicity in circumstances where the methadone was diverted from another person who had been prescribed it for opioid replacement therapy. In her finding delivered 28 September 2012, Coroner Parkinson made one recommendation pursuant to the *Coroners Act 2008* (Vic):

> **Recommendation 1**. That the Minister for Health take steps to prohibit the supply of 'take-away' doses of the Schedule 8 drug Methadone by drug addicted persons and require that methadone therapy be delivered and administered at a pharmacy premises under the supervision of a registered pharmacist.

The Victorian Department of Health response, signed by Secretary Dr Pradeep Philip and received by the Court on 24 December 2012, indicated:

> The overall long-term success of maintenance therapy and patient retention in treatment is contingent on providing patients the opportunity to normalise their lives through the provision of takeaway doses. Takeaway doses facilitate a patient's reintegration into the community and enable stable patients to meet work and family commitments with minimal disruption.

The Victorian Department of Health indicated that it maintained the position put forward in previous responses to recommendations in the deaths of Melissa Irwin and Michael Gledhill.

4.2 Discussion

Of the eight relevant coroners' recommendations regarding takeaway methadone for opioid replacement therapy, seven were made under the *Coroners Act 2008* (Vic) and directed to the Victorian Department of Health. The Victorian Department of Health did not indicate that it accepted any of the recommendations.

5. Managing methadone diversion risks

Helen Stagoll died from the combined toxic effects of methadone and alprazolam in circumstances where the methadone was a diverted dose originally dispensed to another person for purposes of opioid replacement therapy. Her death occurred in a broader context of increasing annual frequency of methadone deaths in Victoria, and was one of (at least) 21 Victorian acute drug toxicity deaths in 2010-2011 where diverted methadone dispensed for opioid replacement therapy was found to contribute. This suggests that Helen Stagoll's death was the tragic outcome not only of the unique circumstances in which it occurred, but also of systemic issues with managing the risk of takeaway methadone dose diversion in Victoria.

I have not been directed by the coroner to examine the unique circumstances of Helen Stagoll's death. Therefore, in this concluding section I consider only potential systemic opportunities to prevent further Victorian deaths associated with methadone dose diversion in opioid replacement therapy.

5.1 The need for expert input

In Section 2 of this report, I concluded that the current available empirical evidence indicates that takeaway methadone dosing and supervised methadone dosing for opioid replacement therapy both carry benefits and risks relative to one another, which range across overdose and death, engagement in treatment, engagement in criminal activities, social integration, methadone injection, diversion, and use of illegal drugs, among other areas. The benefits and risks are influenced by factors such as dosing frequency, dose strength, and use of urine testing to support treatment aims; and are also influenced by broader factors such as changing heroin availability in the community.

Additionally, I identified several gaps in the extant research regarding relative risks and benefits of takeaway dosing. I believe that Ritter and di Natale's 2005 observation on this point remains relevant today:

> Ultimately, the aim of any regulation regarding methadone take-away dosing is to strike the right balance between effective methadone treatment and minimizing the risks. There has been a surprisingly small amount of research in the area of methadone take-away policy, so there is considerable debate over where this correct balance lies.[55]

Therefore any discussion regarding how to reduce the risk that methadone dispensed as a takeaway dose for opioid replacement therapy in Victoria will be diverted, must involve expert input. In particular, expert input is needed to evaluate potential opportunities with respect to what likely benefits and harms might flow from implementing them.

5.2 Potential opportunities

The following are some potential systemic opportunities to prevent further Victorian deaths associated with methadone dose diversion in opioid replacement therapy. As already explained, they should be scrutinised through expert input.

---

55 Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, p.348. For other experts who make similar observations on the difficulty of striking this balance, see Bell J, "The Global Diversion of Pharmaceutical Drugs", *Addiction*, vol 105, no 9, 2010, p.1534; Varenbut M, et al, " Tampering by office-based methadone maintenance patients with methadone take home privileges: a pilot study", *Harm Reduction Journal*, vol 4, no 15, published online 30 October 2007, DOI 10.1186/1477-7517-4-15, p.2.

5.2.1 Strengthening policy oversight

The Victorian *Policy for Maintenance Pharmacotherapy for Opioid Dependence* describes in detail the potential risks of takeaway dosing, and provides thorough guidance on what prescribers and dispensers should consider in evaluating a client's suitability for takeaway methadone.

The weakness of the policy is that, while it is thorough and detailed in its guidance on risk assessment, prescribers and dispensers must effectively rely on client self-report to implement it in full. For example:

- The client should be in stable accommodation and store takeaway doses in a secure place. As the Victorian Department of Health explained in its response to Coroner Kim Parkinson's recommendations in the deaths of Melissa Irwin and Michael Gledhill, there is no way for the prescriber to establish that these requirements are met short of client self-report.
- The client should not be diverting takeaway doses. Again, short of a client admission against self-interest, the prescriber would have no way of establishing that takeaway diversion is occurring.

Additionally, there are some assessment criteria for which (excepting client self-report) there are barriers to applying objective measures. For example:

- The requirement that the client should not be abusing other drugs or medications (particularly sedatives) that might contribute to increased overdose risk in pharmacotherapy, could be checked through random urine testing. However the client ordinarily bears the cost of urine testing, so financially disadvantaged clients could be disadvantaged in treatment and other clients could claim financial disadvantage.
- The requirement that the client should have reduced or ceased heroin use, could also be checked through random urine testing; the financial barriers as described above again apply.
- Evidence of recent injecting sites could presumably be checked through asking the client to submit to a physical examination. However this may encourage injecting in locations that are more easily concealed from doctors but are also more dangerous (such as the groin).

This effectively creates a situation in Victoria where the policy is intended to ensure only appropriate clients receive takeaway methadone dosing, but in practice general practitioners cannot execute the policy to ensure that its goals are met. I note this is not a situation unique to Victoria; see for example the following commentary on opioid replacement therapy in New South Wales:

> Although current NSW guidelines support the selection of clients considered appropriately stable to receive takeaway doses [...], this is not enforceable and in many cases takeaways are provided to clients who do not comply with the prescribers' key expectation that the medication will be taken as directed by the person to whom it was prescribed.[56]

There may be opportunities to improve this situation by supporting and encouraging prescribers to use independently measurable risk indicators effectively. One possibility is that there could be subsidised random urine tests for clients so cost is not a barrier

---

[56] Winstock AR, Lea T, Sheridan J, "Prevalence of diversion and injection of methadone and buprenorphine among clients receiving opioid treatment at community pharmacies in New South Wales, Australia", *International Journal of Drug Policy*, vol 19, no 6, December 2008, p.451.

to using them. Input from an expert on this and other potential initiatives in this area could be sought.

5.2.2 Improving the evidence base for policy

The existing evidence regarding the risks and benefits of takeaway methadone dosing is equivocal, and there are significant lacunae in our understanding of the area. In section 3, I identified a range of data that would assist the Court in better understanding fatal harms associated with different methadone dosing regimes, including data on annual frequency of methadone doses dispensed on a supervised versus takeaway basis to opioid replacement therapy clients in Victoria. Experts will undoubtedly have other relevant suggestions for research and data that could improve the evidence base for reducing deaths.

5.2.3 Encouraging buprenorphine/naloxone uptake

Under the revised 2013 policy any treating practitioner can commence a patient on buprenorphine/naloxone for opioid replacement therapy if there is an immediate need without mandatory training. This has been the case in France for over a decade, where it has been credited with significantly reducing drug-related deaths.[57] Potential benefits include:

- As any doctor can now consider taking on some clients without undergoing the training and assessment process, there is an increase in the number of potential opioid replacement therapy providers.
- In turn, the increased number of potential opioid replacement therapy providers could reduce waiting lists for opioid replacement therapy and thus undermine the market for diverted pharmaceutical opioids.
- The combination of easier to access buprenorphine/naloxone and incentives (ie increased takeaway dosing access) for requesting it, will hopefully translate into clients selecting buprenorphine over the more dangerous methadone, thus reducing community exposure to takeaway methadone.
- The ultimate outcome of the above is hoped to be a reduction in diversion, harms and deaths associated with opioid replacement therapy.

To support these outcomes, use of buprenorphine/naloxone over methadone could be encouraged further by making methadone less attractive to clients. For example:

- All new Victorian opioid replacement therapy clients could be required to commence on buprenorphine/naloxone unless there is a compelling clinical reason for using methadone.
- The maximum number of allowable weekly takeaway methadone doses could be reduced without making any change to buprenorphine/naloxone takeaways.

Expert input in this area would be required, not least because buprenorphine, while possibly safer than methadone, is certainly still not a safe drug: it is still subject to diversion, abuse, and fatal and non-fatal overdose.

5.2.4 Methadone and the *National Health Act 1953* (Cwth)

In recent years, public health researchers and government officials have increasingly discussed the question as to whether opioid replacement therapy is best delivered under Section 100 of the *National Health Act 1953* (Cwth) ('the NHA'), or whether it should be moved to Section 85 of the NHA.

---

57 Carrieri MP, et al., "Buprenorphine Use: The International Experience", *Clinical Infectious Diseases*, vol 43 (Supplement 4), 2006, pp.S199-S201.

By way of background to this issue, the purpose of the Pharmaceutical Benefits Scheme (PBS) is to ensure affordable access to necessary medicines. Under the PBS, certain medications are approved for certain uses, are listed in the Schedule of Pharmaceutical Benefits, and are subsidised by the Australian Government.

The normal subsidy arrangements for listed PBS medications are described in Section 85 of the NHA. Under this section, the patient attending a community pharmacy with a prescription pays up to a certain amount (currently $35.40 for general patients, and $5.80 if the patient is eligible for a concession rate) for a dispensed medication, and the PBS pays the remainder (this payment is called the PBS co-contribution). The dispensed price comprises a number of components including the wholesale cost of the medication to the pharmacist, the retail mark-up, a dispensing fee (currently $6.42 for a ready-prepared medication, or $8.46 if the pharmacist needs to do any preparation at the time) and any other applicable fees.[58]

Patients who receive medications under these 'normal' Section 85 arrangements are also usually eligible for the PBS safety net:

- When a general patient reaches the safety net threshold of expenditure on PBS medications within a calendar year (currently $1363.30), all further PBS medications for that year are supplied at the concessional rate.
- When a concessional patient reaches the safety net threshold of expenditure on PBS medications within a calendar year (currently $348.00), all further PBS medications for that year are supplied free of charge except for any extraordinary charges such as a brand premium attached to a medication.

The purpose of the PBS safety net is to assist patients who might require frequent medication dispensing for a chronic medical condition or otherwise; it protects them from massive out-of-pocket expenses.

In addition to normal arrangements, Section 100 of the NHA allows for certain drugs to be made available under special arrangements, where these are considered appropriate. Drugs used for opioid replacement therapy (currently methadone, buprenorphine and buprenorphine/naloxone) are currently dispensed under such a special arrangement, which works as follows:

> A pharmaceutical wholesaler or manufacturer supplies the medicines under the ODT [Opioid Dependence Treatment] Program to a community pharmacy at no cost and then seeks reimbursement from the Australian Government. The remuneration to community pharmacies for the supply of medicines available under the ODT Program is different to the remuneration for the supply of medicines declared under Section 85 of the NHA. Specifically, pharmacies do not receive the dispensing fee nor do they receive the dangerous drug fee for supplying drugs of dependence. Participating pharmacies do however charge clients a fee which varies, but on average is around $5.00 per day. The value of the fee charged may depend on which medicine the client receives and on how many takeaway doses they obtain.[59]

---

58 For example, the patient might (depending on the medication) also need to pay a premium for a particular brand of a medication, a special contribution if the drug is not supplied at a benchmark price set by the PBS, a fee for dispensing of a controlled or dangerous drug, or so on. For a full discussion of PBS fees see Medicare Australia, "Explanation of PBS Pricing", June 2011, pp.3-13.

59 Australian Healthcare Associates, *Final Report: Review of the Existing Supply and Remuneration Arrangements for Drugs Listed under Section 100 of the National Health Act 1953*, February 2010, p.78.

Other special arrangements attached to dispensing for opioid replacement therapy include that the pharmacy must dispense in line with State or Territory regulations for opioid replacement therapy; in Victoria the relevant legislation is the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) administered by the Department of Health.

A 2010 Australian Government-funded review identified several problems with dispensing methadone for opioid replacement therapy under Section 100 Special Arrangements, including the following:

- Pharmacists must stock and supply Section 85 medications.[60] Methadone for opioid replacement therapy falls under Section 100, and therefore pharmacies do not have to stock and supply it; the requirement is rather that the pharmacy must be approved by the Department of Health for this task. Consequently, there is an uneven geographical distribution of approved pharmacies for opioid replacement therapy, and clients may have to travel long distances,[61] which in turn promotes provision of takeaway doses to reduce the travel burden on the clients.
- The pharmacist is not reimbursed through the PBS for dispensing methadone for opioid replacement therapy under Section 100, and therefore must charge a dispensing fee. In some situations, given the extra training and resourcing required to dispense methadone for this purpose, the dispensing will cost the pharmacist more than is charged. Additionally, if the client cannot or will not pay the fee, the pharmacist is put in a very difficult situation, as treatment refusal is not clinically desirable.[62]
- For clients, the dispensing fee charged by the pharmacist is not counted towards the PBS safety net and is often charged per dose rather than per dispensing event. Therefore, a client can incur considerable expense when participating in opioid replacement therapy, which can serve to push the client into non-compliance or encourage the client to re-sell takeaway doses illicitly to fund participation in the program.[63]

Shifting methadone dispensing for opioid replacement therapy to Section 85 could have the following benefits as regards diversion:

- Clients could be dispensed their methadone from any pharmacy, which would obviate the need for takeaway dosing in contexts where the rationale is mitigating client travel requirements.

---

60 Under Section 24 of the Fifth Community Pharmacy Agreement signed between the Pharmacy Guild of Australia and the Australian Government, "The parties agree that Approved Pharmacists will keep adequate medicine stocks for the supply of pharmaceutical benefits to ensure reasonable and timely access to those medicines by consumers".

61 Australian Healthcare Associates, *Final Report: Review of the Existing Supply and Remuneration Arrangements for Drugs Listed under Section 100 of the National Health Act 1953*, February 2010, pp.79-80.

62 Australian Healthcare Associates, *Final Report: Review of the Existing Supply and Remuneration Arrangements for Drugs Listed under Section 100 of the National Health Act 1953*, February 2010, pp.90-91.

63 Australian Healthcare Associates, *Final Report: Review of the Existing Supply and Remuneration Arrangements for Drugs Listed under Section 100 of the National Health Act 1953*, February 2010, pp.87-94; see also Royal Australian College of Physicians, "Submission to the Review of the Existing Supply and Remuneration Arrangements for Drugs Listed Under Section 100 of the National Health Act 1953", 2010, pp.17-18.

- Pharmacists would receive PBS dispensing fees for methadone, which should render provision more profitable and thereby encourage pharmacist participation in opioid replacement therapy.
- Client financial incentives to divert (re-sell illicitly) takeaway methadone doses would be reduced.

However several other issues would need to be worked through, such as providing adequate training to pharmacists who are recruited into opioid replacement therapy as a result of the shift. An alternative option would be to keep methadone under Section 100, but move buprenorphine/naloxone into Section 85, which would further encourage doctors and clients to select it over methadone for opioid replacement therapy.

Works cited

Amato L, Davoli M, Perucci CA, Ferri M, Faggiano F, Mattick RP, "An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research", *Journal of Substance Abuse Treatment*, vol 28, no 4, June 2005, pp.321-329.

Australian Bureau of Statistics, "Drug-induced deaths: a guide to ABS causes of death data", 8 August 2002.

Australian Healthcare Associates, *Final Report: Review of the Existing Supply and Remuneration Arrangements for Drugs Listed under Section 100 of the National Health Act 1953*, February 2010.

Bell J, Butler B, Lawrance A, Baret R, Salmalainen P, "Comparing overdose mortality associated with methadone and buprenorphine treatment", *Drug and Alcohol Dependence*, vol 104, no 1-2, 1 September 2009, pp.73-77.

Carrieri MP, Amass L, Lucas GM, Vlahov D, Wodak A, Woody G, "Buprenorphine Use: The International Experience", *Clinical Infectious Diseases*, vol 43 (Supplement 4), 2006, pp.S197-S215.

Drugs and Poisons Regulation Group, Victorian Department of Human Services, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2006.

Drugs and Poisons Regulation, Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence*, 2013.

Duffy P, Baldwin H, "The nature of methadone diversion in England: a Merseyside case study", *Harm Reduction Journal*, vol 9, no 3, 2012, DOI 10.1186/1477-7517-9-3.

Fraser S, Valentine K, Treloar C, MacMillan K, "Methadone maintenance treatment in New South Wales and Victoria: Takeaways, diversion and other key issues", National Centre in HIV Social Research, 2007.

Gerra G, Saenz R, Busse A, Maremmani I, Ciccocioppo R, Zaimovic A, Gerra ML, Amore M, Manfredini M, Donnini C, Somaini L, "Supervised daily consumption, contingent take-home incentive and non-contingent take-home in methadone maintenance", *Progress in Neuro-Psychopharmacology and Biological Psychiatry*, vol 35, no 2, 2011, pp.483-489.

Griffith JD, Rowan-Szal GA, Roark RR, Simpson DD, "Contingency management in outpatient methadone treatment: a meta-analysis", *Drug and Alcohol Dependence*, vol 58, no 1, 2000, pp.55-66.

Harris M, Rhodes T, "Methadone diversion as a protective strategy: the harm reduction potential of 'generous constraints'", *International Journal of Drug Policy*, in press, 2012, <http://dx.doi.org/10.1016/j.drugpo.2012.10.003>, accessed 28 May 2013.

Haskew M, Wolff K, Dunn J, Bearn J, "Patterns of adherence to oral methadone: implications for prescribers", Journal of Substance Abuse Treatment, vol 35, no 2, 2008, pp.109-115.

Heinemann A, Iwersen-Bergmann S, Stein S, Schmoldt A, Puschel K, "Methadone-related fatalities in Hamburg 1990–1999: implications for quality standards in maintenance treatment?", *Forensic Science International*, vol 113, no 1-3, 2000, pp. 449-455.

Kahan M, Srivastava A, Ordean AI, Cirone S, "Buprenorphine: New treatment of opioid addiction in primary care", *Canadian Family Physician*, vol 57, no 3, March 2011, pp.281-289.

King VL, Kidorf MS, Stoller KB, Schwartz R, Kolodner K, Brooner RK, "A 12-month controlled trial of methadone medical maintenance integrated into an adaptive treatment model", *Journal of Substance Abuse Treatment*, vol 31, no 6, 2006, pp.385-393.

Ling W, Mooney L, Zhao M, Nielsen S, Torrington M, Miotto K,, "Selective review and commentary on emerging pharmacotherapies for opioid addiction", *Substance Abuse and Rehabilitation*, vol 2, no 1, 2011, pp.181-188.

Lintzeris N, Clark N, Winstock A, Dunlop A, Muhleisen P, Gowing L, Ali R, Ritter A, Bell J, Quigley A, Mattick RP, Monheit B, White J, *National clinical guidelines and procedures for the use of buprenorphine in the maintenance treatment of opioid dependence*, October 2006.

Mattick RP, Kimber J, Breen C, Davoli M, "Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence", *Cochrane Database of Systematic Reviews*, Issue 3, 2008.

Mattick RP, Breen C, Kimber J, Davoli M, "Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence", *Cochrane Database of Systematic Reviews*, Issue 3, 2009.

Milne M, Crouch BI, Caravati EM, "Buprenorphine for Opioid Dependence", *Journal of Pain and Palliative Care Pharmacotherapy*, vol 23, no 2, 2009, pp.153-155.

Pani PP, Pirastu R, Ricci A, Gessa GL, "Prohibition of take-home dosages: negative consequences on methadone maintenance treatment", *Drug and Alcohol Dependence*, vol 41, no 1, May 1996, pp.81-84.

Peterson JA, Schwartz RP, Mitchell SG, Reisinger HS, Kelly SM, O'Grady KE, Brown BS, Agar MH, "Why don't out-of-treatment individuals enter methadone treatment programmes?", *International Journal of Drug Policy*, vol 21, no 1, January 2010, pp.36-42.

Pilgrim J, McDonough M, Drummer O, "A review of methadone deaths between 2001 and 2005 in Victoria, Australia", *Forensic Science International*, no 226, vol 1-3, 2013, pp.216-222.

Pinto H, Maskrey V, Swift L, Rumball D, Wagle A, Holland R, "The SUMMIT Trial: A field comparison of buprenorphine versus methadone maintenance treatment", *Journal of Substance Abuse Treatment*, vol 39, no 4, December 2010, pp.340-352.

Ritter A, Chalmers J, "Polygon: The many sides to the Australian opioid pharmacotherapy maintenance system", Australian National Council on Drugs Research Paper 18, 2009, p.35.

Ritter A, Di Natale R, "The relationship between take-away methadone policies and methadone diversion", *Drug and Alcohol Review*, vol 24, no 4, July 2005, pp.347-352.

Rhoades HM, Creson D, Elk R, Schmitz J, Grabowski J, "Retention, HIV risk, and illicit drug use during treatment: methadone dose and visit frequency", *American Journal of Public Health*, vol 88, no 1, 1998, pp.34-39.

Royal Australian College of Physicians, "Submission to the Review of the Existing Supply and Remuneration Arrangements for Drugs Listed Under Section 100 of the National Health Act 1953", 2010.

Strang J, Hall W, Hickman M, Bird SM, "Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland", *British Medical Journal*, published online 16 September 2010, DOI 10.1136/bmj.c4851.

Swensen G, "Opioid drug deaths in Western Australia: 1974-1984", *Australian Drug and Alcohol Review*, vol 7, no 2, 1988, pp.181-185.

Treloar C, Fraser S, Valentine K, "Valuing methadone takeaway doses: The contribution of service-user perspectives to policy and practice", *Drugs: Education, Prevention and Policy*, vol 14, no 1, February 2007, pp.61-74.

Varenbut M, Teplin D, Daiter J, Raz B, Worster A, Emadi-Konjin P, Frank N, Konyer A, Greenwald I, Snider-Adler M, "Tampering by office-based methadone maintenance patients with methadone take home privileges: a pilot study", *Harm Reduction Journal*, vol 4, no 15, published online 30 October 2007, DOI 10.1186/1477-7517-4-15.

Victorian Department of Health, "Pharmacotherapy Newsletter", April 2013.

White JM, Ryan CF, Ali RL, "Improvements in retention rates and changes in client group with methadone maintenance streaming", *Drug and Alcohol Review*, vol 15, no 1, 1996, pp.83-88.

Winstock AR, Lea T, Sheridan J, "Prevalence of diversion and injection of methadone and buprenorphine among clients receiving opioid treatment at community pharmacies in New South Wales, Australia", *International Journal of Drug Policy*, vol 19, no 6, December 2008, pp.450-458.

World Health Organization, "Defined daily dose: definition and general considerations", 17 December 2009, <http://www.whocc.no/ddd/definition_and_general_considera/>, accessed 31 May 2013.

World Health Organization, "Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper", 2004.

Zador D, Mayet S, Strang J, "Commentary: decline in methadone-related deaths probably relates to increased supervision in UK", *International Journal of Epidemiology*, vol 35, no 6, 2006, p.1586-1587.

Attachment A

The following is a basic description of the CPU's database of deaths involving acute drug toxicity, and the cases and data it contains.

A.1 Definitions

Where a death is currently under investigation by a coroner, it is described as an 'open case'; likewise, where a coroner has completed his or her investigation into a death it is described as a 'closed case'.

The CPU definition of the term 'drug' is largely consistent with the Australian Bureau of Statistics (ABS) definition, encompassing substances that "may be used for medicinal or therapeutic purposes, or to produce a psychoactive effect".[64] Like the ABS, the CPU excludes tobacco and volatile solvents such as petrol and toluene from its definition of a drug. However, the CPU considers alcohol to be a drug, whereas it is excluded under the ABS definition.

A death involving acute drug toxicity is a death for which the acute toxic effects of one or more drugs played a causal or contributory role.

A.2 Inclusion and exclusion criteria

To be coded as a death involving acute drug toxicity, the death must meet one of the following two criteria:

- the coroner's death investigation was complete and the coroner found that acute drug toxicity played a causal or contributory role in the death; or
- the coroner's death investigation was still under way and the forensic pathologist determined that acute drug toxicity played a causal or contributory role in the medical cause of death.

Deaths from causes other than acute drug toxicity where consumption of drugs by the deceased or another person may have contributed to the death (such as motor vehicle crashes and drownings) are excluded.

A.3 Case identification

The CPU identifies potentially relevant deaths through searches (including keyword searches and coded field searches) of the CPU surveillance database, the National Coroners Information System (NCIS), and other data repositories. All deaths identified are uploaded into the database, and relevant case file material is reviewed to determine whether they meet the inclusion criteria.

A.4 Data collection

For each death meeting the inclusion criteria, the CPU records the following information: the deceased's age and sex; cause of death; and the suburb and local government area where the fatal drug consumption occurred. Additionally the CPU records every drug that the expert death investigator (coroner or forensic pathologist) found to have made an acute toxic contribution to the cause of death. The coding rules for contributing drugs are:

- If the finding or pathology report explicitly nominates the specific contributing drugs (for example "1(a) combined toxic effects of morphine and diazepam"), each nominated drug is coded as contributory.

---

64 Australian Bureau of Statistics, "Drug-induced deaths: a guide to ABS causes of death data", 8 August 2002, p.2.

- If the finding or pathology report does not explicitly nominate the specific contributing drugs (for example "1(a) combined drug toxicity"), the forensic toxicologist's report is reviewed for any advice on drug contribution. If no such advice can be found, all drugs present in post-mortem toxicology are coded as contributory, excepting any drugs for which there is evidence of administration for treatment following the fatal toxic event.

These coding rules are consistent with the Drug Abuse Warning Network (DAWN) approach to identifying drug-related deaths.

A.5 Limitations

The database only contains confirmed deaths involving acute drug toxicity reported to the Court. Where (for example) a cause of death is not ascertained, or the contribution of acute drug toxicity is not clearly indicated, or contributing drugs cannot be established, the death is not included in the database, which may lead to an under-estimation of Victorian deaths involving acute drug toxicity.