ADDENDUM 3

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Attention: Acting Principal In-House Solicitor Jodie Burns
Coroners Court of Victoria
Level 12
222 Exhibition Street
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PRIVATE & CONFIDENTIAL
Expert opinion on behalf of the Coroner:
Inquest of HELEN STAGOLL

Writer qualifications

I am a registered medical practitioner, obtaining my MBBS degree from the University of Melbourne in 1986, and I am an addiction specialist with Fellowship of the Australasian Chapter of Addiction Medicine, under the Adult Medicine Division of the Royal Australasian College of Physicians, conferred in 2004.

My current substantive employment is as Clinical Director, Turning Point Alcohol and Drug Centre, Eastern Health. I also work sessionally as an addiction specialist at Caulfield Pain Management and Research Centre, Alfred Health. I am currently President of the Australasian Chapter of Addiction Medicine and hold an honorary lecturer position with Monash University School of Psychology and Psychiatry.

In my role as part of the executive committee of the Chapter of Addiction Medicine and as a senior medical specialist within the Victorian public alcohol and drug health sector, I have been extensively involved in opioid maintenance pharmacotherapy. Over the last decade, I have contributed to the content and delivery of prescriber training programs and to the development of opioid pharmacotherapy policy, including being a member of the expert advisory group for the updated (2013), current Victorian opioid pharmacotherapy policy, the *Policy for Maintenance Pharmacotherapy for Opioid Dependence.*

I have read and fully understand the Coroners Court's Code of Conduct for Expert Witnesses.

The opinion below represents my views as a qualified addiction specialist, not those of my employers or professional organisations to which I belong. I have in the past been granted honorarium payments from Reckitt-Benckiser (who manufacture the medications buprenorphine-naloxone and buprenorphine used for the treatment of opioid addiction). As stated above, I was involved in an advisory group auspiced by the Victorian Department of Health's Mental Health and Drugs and Regions Division that developed the current updated 2013 policy on opioid maintenance pharmacotherapy that is referred to in the opinion below. I do not believe that these or any other of my past or current professional activities would constitute a conflict of interest in the provision of this opinion.

Background

In formulating this opinion I have been supplied with a document written by CPU case investigator Mr Jeremy Dwyer dated 5 June 2013: "Methadone takeaway dosing for opioid replacement therapy: managing the risk of diversion". I have been asked to comment on issues raised in Mr Dwyer's report. Although the report arises from the case of the death of Helen Stagoll, I have no detail about that matter other than that provided in Mr Dwyer's report and will not comment on specifics of that case.

Issues raised in Mr Dwyer's report

Mr Dwyer's report was supplied to me as a 43 page document divided into sections that cover a range of issues, with a focus on the risks of methadone take away (unsupervised) dosing. The document is referenced from peer reviewed journal articles and policy documents and it is outside the scope of this opinion to review the literature, summarise and respond to all the issues raised in Mr Dwyer's report. However, aspects of this report are of particular relevance and interest to my field of expertise as a specialist medical practitioner, as outlined below.

Based on an analysis of some of the available data on methadone deaths in Victoria, Mr Dwyer observes that:

- Multiple drugs are usually implicated in these deaths, such as benzodiazepines
- In 124 cases of methadone deaths between 2010-2011, where the source of methadone could be identified, it was prescribed for opioid maintenance therapy (OMT)
- Between 2000-2012, the increased rate of Victorian methadone cannot be directly ascribed to an increase in patients on OMT or on methadone prescribed for other indications
- There is some limited evidence that the increase in deaths may be related to a change in Victoria's "take away" methadone policy in 2006
- There are gaps in data about unsupervised methadone doses in patients on OMT in Victoria

Mr Dwyer's report refers to well accepted evidence of better outcomes, including treatment retention, where there is access to unsupervised OMT doses such as contingency-based take aways. However, there is also Australian and overseas

evidence of increased diversion and injection of methadone where take away policies are more liberal. This risk versus benefit balance is fundamental to the discussion of methadone take away policy. Limited evidence is available to guide policy, and the issue is further complicated by the variation in jurisdictional conditions for OMT provision.

Previous Victorian Coroner's recommendations have focused on the need for reducing risks inherent in methadone take away provision, such as:

- Developing systems that would ensure that safe storage of methadone is verified
- Firming up criteria for unsupervised dosing
- Ceasing take away dosing altogether
- Enabling communication between emergency services such as police, and prescribing GPs

In addressing these recommendations, it is clear that solutions are likely to be a complex mixture of regulatory, legal, ethical, public health, clinical and practical implications.

Current OMT policy context

Changes to the Victorian alcohol and drug service system are likely to affect OMT service delivery by GPs and, by extension, risk related to methadone prescribing and dosing. As noted by Mr Dwyer, exactly what the implications of the overarching reconfiguration and re commissioning canvassed by the Department, such as in the Mental Health, Drugs and Regions' recent Discussion Paper and Call for Submissions, are unclear. However, the updated 2013 Victorian Policy document, *Policy for Maintenance Pharmacotherapy for Opioid Dependence* provides clear guidelines for changes to take away dosing of buprenorphine-naloxone and the relaxing of the need for training for medical practitioners to prescribe buprenorphine-naloxone for up to five patients. These policy recommendations clarify the distinction between the relatively high risk inherent in diversion and toxicity of the opioid agonist drug methadone compared to the partial agonist combination preparation buprenorphine-naloxone (Suboxone ®).

Opinion

I will respond to some of the issues raised by Mr Dwyer below.

The current policy and limitations of self-report

Mr Dwyer states that the weakness of the Victorian 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".

Addiction is characterized by behavioural disturbance of varying severity, and the addiction treatment is a field of clinical medicine where self-report is often unreliable, particularly when open disclosure of drug use may lead to consequences that a patient perceives as negative. This is a challenge for GPs working in a doctor patient relationship model whose strength is the engagement of patients through trust and honesty.

While self-report is an imperfect tool in addiction treatment, there are objective measures of substance use that are useful where a patient's report is inconsistent with his or her behaviour. The current Victorian Policy includes reference to clinical assessment of stability when determining eligibility for unsupervised doses. Patient history is only one component of this assessment, which should also involve the more objective indicators of substance use, such as signs of intoxication, physical examination of injection sites and urine drug screening.

Concern has been raised by Mr Dwyer about the cost of urine drug screening. Currently, Medicare assigns a benefit for urine drug testing, that in many cases pathologists will "bulk-bill". Most laboratories will test for common substances of misuse that may influence take away dosing provision such as psychostimulants, opiates and benzodiazepines. Additional "GCMS" testing is often provided for no extra fee. Urine testing is in my view greatly underutilized by Victorian pharmacotherapy prescribers for a range of reasons, including a mistaken belief that it has no benefit in risk reduction.

Inspection of injection sites is often overlooked in review of pharmacotherapy patients. In my opinion, the risk that routine examination of arm injection sites will lead to patients injecting in feet or femoral veins is greatly overstated, very rare and not a reason to reject a valuable objective indicator of drug injection.

In my opinion, OMT prescribing should place an increased emphasis on medical signs of substance use, ie physical and biochemical indictors, in assessment of risk.

Changes in 2013 Policy

Mr Dwyer has reiterated the fact that buprenorphine-naloxone has a lower risk of toxicity than methadone and has raised the possibility of buprenorphine-naloxone as first line treatment "unless there is a compelling clinical reason" for using methadone. In my opinion it is unlikely that changing the indication for methadone would substantially reduce risk related to methadone take aways. The cornerstone of Victorian (and Australian) OMT programs is access to methadone and buprenorphine treatment from primary care providers, rather than centralising methadone treatment in large specialist clinics. However, I agree that the policy changes that make buprenorphine-naloxone available to untrained prescribers is an ideal way to improve access to treatment and to encourage use of a lower risk medication.

As Mr Dwyer points out, buprenorphine-naloxone is subject to diversion and injection (for example in prison populations), although toxicity risk of buprenorphine preparations taken by opioid naïve individuals is much lower than methadone. Nevertheless, the recent policy changes should be an opportunity to educate GPs about opioids and addiction rather than allow unregulated access to poor quality treatment.

Pharmaceutical medication and risk
Given the strong association between medications such as benzodiazepines and methadone deaths, it would be remiss in my opinion not to reiterate my support for a prescription monitoring system which is likely to reduce risk of overdose from prescription drug combinations.

PBS pricing of methadone therapy
A full discussion of the problem of OMT dispensing fees within the current S100 system has been canvassed in a range of reports and forums over the years and is beyond the scope of this expert opinion document. Dispensing fees are a significant barrier to methadone treatment. One of the advantages of methadone programs are the inherent structured supervised dosing regimens. This structure is often indicated in patients with addiction to opioid analgesics prescribed for pain. The cost to the consumer of methadone treatment can be up to 30 times that of the relatively affordable PBS funded prescription pain killers. This is a huge disincentive for treatment engagement. A more equitable system for service users has a number of advantages including in relation to risk reduction as outlined by Mr Dwyer.

Area based networks and data gaps
I have alluded to the reconfiguration of the Victorian pharmacotherapy system through Area Based Networks and given it is in a relatively early stage and I will not comment extensively on it. I agree with Mr Dwyer, that it is unclear whether these changes will significantly affect unsupervised methadone dosing.

Coordinated systems of area-based service delivery with population health planning may provide opportunity for addressing the data collection gaps identified by Mr Dwyer. These data gaps include current lack of knowledge of numbers of patients receiving take away doses, dose ranges of methadone prescribed, treatment drop outs, data on patients prescribed methadone and other drugs of dependence such as benzodiazepines and links with utilization of emergency and acute services (police, ambulance, hospitals etc.).

A key component of area based systems is specialist support which would be expected to improve access to specialist assessment and treatment planning to reduce risk (such as of unsupervised dosing) for complex/high risk patients.

Another goal of an improved pharmacotherapy system is an increase in GP prescribers, reducing pressure on the small cohort of doctors (and pharmacists) who currently carry 80% of Victoria's OMT patients. The ability for OMT patients to be carefully and regularly reviewed by a GP who is managing their general health needs, is more likely to allow better decisions about eligibility and safety of unsupervised dosing.

Unsupervised dosing
Take away dosing of methadone is a key component of treatment programs designed to enable recovery from opioid addiction. Removal of unsupervised dosing provisions for methadone would effectively lead to collapse of a treatment system that has huge benefits to individuals and the community.

However, some work needs to be done through enhancing prescriber capacity, allowing easier access to specialist assessment and improving systems, through new initiatives such as the opportunities in area-based restructuring and through building on current strengths in the system, to mitigate risk from methadone take away doses. A balance that allows stable patients access to treatment that does not interfere with recovery and integration is warranted and achievable for Victoria.

Signed

Matthew Frei