Coroners Act, 1996
[Section 26(1)]

Western Australia

RECORD OF INVESTIGATION INTO DEATH

Ref No: 9/15

I, Evelyn Felicia Vicker, Deputy State Coroner, having investigated the death of ***Shayne Andrew BERRY****, with an Inquest held at Perth Coroners Court, CLC Building, 501 Hay Street, Perth, on 12-13 & 17-20 March 2015 find the identity of the deceased was* ***Shayne Andrew BERRY*** *and that death occurred on 24 November 2012 at 179b Richardson Way, Bulgarra, Karratha, as a result of Combined Drug Effect in the following circumstances:*

Counsel Appearing:

Ms K Ellson assisted the Deputy State Coroner
Ms J Hook (State Solicitors Office) appeared on behalf of the WA Department of Health
Mr M Williams (instructed by DLA Piper) appeared for Drs Wilkinson and Myburgh
Mr D Bourke (instructed by MDA National) and with him Ms A de Villiers appeared for Dr Drummond
Mr A Oswald (Oswald Legal) appeared for Dr Kumar

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INTRODUCTION

Shayne Andrew Berry (the deceased) died on 24 November 2012 after he had taken a mixture of oxycodone (OxyNorm and OxyContin) medications and Valium (benzodiazepine) and antibiotics he had been prescribed by different doctors, at different practices, the previous day for back pain and 'flu' like symptoms.

He was 44 years of age.

Oxycodone is a Schedule 8 opioid of the Western Australian *Poisons Act 1964,* which incorporates the standard for the uniform scheduling of medicines and poisons (SUSMP) utilised by the Commonwealth Therapeutic Goods Administration (TGA) to promote standardised scheduling, packaging and labelling for a variety of medicines available across Australia. Oxycodone comes in a slow release form, OxyContin, and a regular release form, OxyNorm.

Valium (diazepam) is a benzodiazepine listed in Schedule 4 of the Western Australian *Poisons Act 1964,* which incorporates SUSMP utilised by the TGA to promote standardised scheduling, packaging and labelling for a variety of medications available across Australia.

SUSMP Schedule 8

Schedule 8 medicines are often referred to as controlled drugs[1] which are defined as *"substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use as to reduce abuse, misuse and physical and psychological dependence."*

Opioid drugs such as morphine, fentanyl and oxycodone are Schedule 8 medicines often used as pain killers (analgesics). Opioid drugs such as buprenorphine, naloxone, and methadone are Schedule 8 medicines often also used as substitution for the illicit use of opioids with a view to decreasing dependency. They are also pain killers in their own right.

There are restrictions imposed by legislation[2] and regulation on the prescription of Schedule 8 medicines:-

1. Where a medical practitioner wishes to prescribe a Schedule 8 medicine for more than 60 days in any 12 month period, that medical practitioner must apply for authorisation from the Chief Executive Officer of the Western Australian Department of Health (CEOWAH).[3]

2. If the person to whom a medical practitioner wishes to prescribe a Schedule 8 medicine is a *"notified or registered drug addict"* under the *Drugs of Addiction Notification Regulations 1980* (WA) then the medical practitioner must apply for an authorisation from the CEOWAH.

3. Where a medical practitioner believes or suspects a person is addicted to drugs they are required to notify the Executive Director, Public Health within 48 hours.

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[1] Schedule 8 drugs are referred to by a number of names, controlled medicine, drugs of addiction, S8 poisons, controlled drug, narcotic substance, drug of dependence, s8 substance.
[2] WA *Poisons Act 1964* shortly to be replaced by WA *Medicines and Poisons Act* (assented to 2 July 2014, not yet proclaimed.)
[3] Ex 10, tab 13, p3

A register is kept of all notifications in the WA Department of Health.[4]

4. Where a medical practitioner wishes to treat a person with pharmacotherapy (usually methadone or buprenorphine) for an opiate addiction the medical practitioner must be an authorised prescriber.[5]

5. In Western Australia treatment is available through the Community Program for Opioid Pharmacotherapy (CPOP) and a CPOP prescriber must be trained and approved by the WA Department of Health.[6]

6. A pharmacy must also be authorised to dispense pharmacotherapy.[7]

7. A person listed as a registered drug addict is required to disclose that fact to any medical practitioner from whom they seek to obtain relevant drugs (Schedule 8 opioid medicines and the benzodiazepines, alprazolam and flunitrazepam.).

The deceased was listed as a registered drug addict on 9 December 2010 for participation in CPOP. This was due to expire on 9 December 2012, however, the deceased had stopped following the program sometime in 2011 when there was difficulty in locating an appropriately authorised prescriber due to the absence of his usual prescriber for Suboxone (buprenorphine and naloxone). The deceased signed an acknowledgement he understood he was a registered drug addict on 8 December 2010.[8]

Despite regulation of the prescribing of Schedule 8 medicines, those wishing to abuse Schedule 8 medicines appear to have little difficulty in obtaining sufficient quantities to allow such abuse due to the tension for prescribers in distinguishing those patients with a real need

[4] Ex 8, tab 1, p2
[5] Ex 8, tab 1, p3
[6] Ex 11, tab A1
[7] Ex 8, tab 1, p2
[8] Ex 1, tab 4, p6

for the drugs, and those who have developed an addiction to the effects of the drugs.

Both the Commonwealth Department of Health and the WA Department of Health have developed strategies aimed at assisting prescribers with their decision making when considering the prescription of a Schedule 8 medicine or alternative. However, both systems require the prescriber to have a level of suspicion about the patient, and actively seek information which is highly confidential, and often impossible to access at the time needed for good decision making around prescribing.

The Commonwealth system is a *"real time"* information service but is restricted to Pharmaceutical Benefits Scheme (PBS) medications and does not provide information for drugs prescribed off-PBS (privately).[9] It is a 24 hour service but will only provide specific information on prescriptions where there is a recent, defined history of multiple prescribers.

The WA system cannot provide information in real time, because it relies on collation (partly manual) from pharmacies before it becomes available. It only operates in regular business hours and only provides information on enquiry as to a drug addict registration. It covers both PBS and off-PBS Schedule 8 medicines. If a patient is not a registered drug addict it does not provide an enquiring doctor with any information.

SUSMP Schedule 4

SUSMP also lists drugs under a Schedule 4. These include *"substances, the use or supply of which should be by, or on the order of, persons permitted to prescribe and available from a pharmacist on a prescription".* Schedule 4 drugs include benzodiazepines (diazepam, temazepam, oxazepam) often used to treat anxiety and insomnia. From February 2014 the benzodiazepine, alprazolam, was removed from Schedule 4 and listed in Schedule 8.

[9] It is restricted in the information it can share with enquiring doctors.

Schedule 4 drugs are therefore prescription only but, now excluding alprazolam and flunitrazepam, do not need specific training for prescription long term, and do not attract registration for drug addiction. They are widely used for the treatment of anxiety and used as a sedative/calmative in the elderly and those with chronic ill health.

They are often co-prescribed with Schedule 8 medicines for their calming effect, and are sought after by those with a drug habit to ameliorate a disruption of supply. They are therefore very commercial.

The "Doctor Shopping" Inquests

Both Schedule 4 and Schedule 8 drugs can be prescribed using Pharmaceutical Benefits Scheme (PBS) prescriptions or non-PBS (private) prescriptions (no PBS benefit). Only PBS prescriptions are monitored by the Commonwealth via Medicare. WA Health collates information on both PBS and off PBS medication[10] but is very delayed (sometimes months) in its ability to track prescriptions.

This means a person can still be a registered drug addict (or whatever name is used in that state or territory) but attend a number of prescribers seeking Schedule 8 drugs in a short period of time. These will probably be provided if the registered drug addict does not inform the prescriber they are a registered drug addict and the prescriber has no reason to believe, or is not in a position to make the necessary inquiry, there may be a reason not to prescribe.

Obviously this is a technique which can also be used by non-registered drug addicts and others with drug seeking behaviours.

The death of the deceased was examined at inquest, along with two others,[11] where registered drug addicts obtained drugs which contributed to their deaths, despite the controls imposed by legislation. The three cases are quite

[10] Ex 1, tab 1
[11] Adrian Marcus WESTLUND & Daniel James HALL

different, but all demonstrate the difficulties facing prescribers in attempting to treat patients sympathetically, without the ability to verify information in real time, and still maintain a relationship with their patient which allows them to prescribe in the patient's best interest.

In all three cases the Commonwealth Prescription Shopping Information and Alert Service advice line (doctor shopping hotline) would not have assisted an enquiring medical practitioner despite it being a *"real time"* monitoring tool due to the fact none of the deceased fulfilled the criteria for "doctor shopping" status, although clearly demonstrating drug seeking behaviour.

The State drug addict register would have provided information to an enquiring medical practitioner about that registration in two of the cases, but in both of those the deceased had advised the currently prescribing doctors of a prior problem with drug addiction. An enquiry may have alerted the doctors to a credibility/reliability issue, but in both cases the drug seeking behaviour leading to death appeared to be a one off request for pain relief and did not arouse the practitioner's suspicion of the need to make further enquiry.

The third case related to issues around prescribing for a CPOP registration and enquiry of either the Commonwealth or State would not have taken the matter further for the prescriber than did his discussion with the Next Step doctor over the application for registration. In that case the issue was more to do with benzodiazepine (Schedule 4) prescribing than Schedule 8 medicines.

The oral evidence in each case was fairly specific with respect to drugs and dosages out of necessity for the facts of each case. I have intentionally avoided reproducing all the specifics in the written findings, with knowledge these are public documents and accessible via the internet. Those interested in misusing prescription medications are generally well informed and I have no desire to add to their knowledge with specific amounts and combinations of drug levels at which these deceased died in defined

circumstances. It is enough that they died as a direct result of the misuse of prescription medication.

The drugs in question were Schedule 8 (opioids) and Schedule 4 (benzodiazepines) and the issue of tolerance in individuals is always a relevant factor.

BACKGROUND[12]

The Deceased

The deceased was born on 13 May 1968 in Canberra, Australian Capital Territory. He lived in New Zealand and Queensland before moving to Western Australia in 2008, where his family was located in Karratha.[13] He had a history of bipolar affective disorder and anxiety for which he was medicated.

During his time in Queensland he had lived on the Gold Coast in a long term relationship which produced two boys. The deceased missed his sons following his separation from their mother.

The deceased had considerable difficulties with drug abuse and the police while in Queensland. His involvement in the drug scene involved him in numerous charges relating to a drug abuse lifestyle. He self-reported as a heroin addict since 24 years of age.

After the deceased's relationship with the mother of his boys ended he met Sally Habets in 2003 in Queensland and they had their own son in 2005. Both the deceased and Ms Habets abused drugs and used heroin. Both participated in a methadone program while in Queensland.

The deceased's family were in Karratha in 2008 and he moved to Karratha in an attempt to find work and break his

[12] I need to acknowledge the submissions of counsel assisting Ms K Ellson, as the basis of the summary of fact, in conjunction with my understanding of the evidence led at inquest, any mistakes will be mine.
[13] t 12.03.15, p210

drug addiction. Ms Habets and their son followed some months later.

The deceased was most frequently out of work and this caused some volatility in their relationship. At the time of his death the deceased had not worked for approximately two years. While the couple had abused prescription medication extensively they did not appear to be as exposed to a drug lifestyle while living in Karratha, and the deceased made some genuine attempts to break his drug seeking behaviours. He appeared to be comparatively drug free for some months prior to his death. This is likely to have decreased his tolerance to opioid drugs.

Registration as a Drug Addict in 2010

While in Karratha the deceased used the Karratha Medical Centre for some of his medical problems. His prescription history with that practice appears to have started in August 2008. He also attended Gemini Medical Centre (now Kinetic Health) in Karratha, a separate practice, with no interaction between the doctors at either practice.

On Tuesday 7 December 2010 the deceased attended at the Karratha Medical Centre and was seen by Dr Cornelius Myburgh.[14] Dr Myburgh in evidence recalled the attendance of the deceased and described him as *"very honest"*.

> *"It's very rare that you see a patient come in and freely admit they are an intravenous drug addict and wanted to do something about it. He was extremely honest about it and it's not very often in my notes that I will document something like 'very honest'."*[15]

Dr Myburgh was not an authorised CPOP prescriber and referred him to another doctor at Karratha Medical Centre he believed was appropriately authorised. This was Dr Martin Kumar. There was also a Dr Germaine Wilkinson at that practice in 2010 who was an authorised CPOP

[14] Ex 7, tab 4C
[15] t 13.03.15, p304

prescriber, but Dr Myburgh did not understand her to be similarly authorised and referred the deceased to Dr Kumar.

Dr Kumar applied for authorisation to provide CPOP to the deceased at his consult on Thursday 9 December 2010. The deceased told Dr Kumar he had been using methadone and the quantities he had been using. He also reported using diazepam and temazepam on a daily basis.[16] This use or quantity is not reflected in the deceased's PBS records[17] and would therefore not have been checkable using the Commonwealth Prescription Shopping Information and Alert Service (doctor shopping hotline).

Dr Kumar made an application for CPOP for the deceased for Suboxone (buprenorphine and naloxone) as the preferred method of treatment as the deceased did not wish to return to using methadone. The CPOP authorisation was done under the stamp of Dr Wilkinson due to a difficulty with Dr Kumar's authorisation at that time, which had expired. Dr Wilkinson is adamant she was unaware of the application using her stamp and I accept her evidence that she would not have allowed her stamp to be used without herself reviewing the relevant patient.[18]

I also accept Dr Kumar used Dr Wilkinson's stamp with the best intentions with respect to the deceased, in that he believed the deceased needed help urgently and he, Dr Kumar, was merely at a lapse in his authorisation which would soon be rectified.[19] The result was the deceased was registered with Dr Wilkinson as his authorised prescriber although she had no knowledge of that authorisation. Dr Kumar's evidence was his authorisation was reinstituted within the week but he continued as the deceased's authorised prescriber, under the incorrect name.

The intention was to stabilise the deceased at a dose of Suboxone equivalent to the methadone level he reported, with the aim it be reduced over time.[20] The authorised

[16] t 12.03.15, p231-232
[17] Ex 6, tab 18
[18] t 12.03.15, p264
[19] t 12.03.15, p235, 237
[20] t 12.03.15, p234/5

pharmacy was the Pharmacy 777 in Karratha. This commenced on 9 December 2010 and recorded three *"takeaways"* only. The deceased appeared to comply with that arrangement but lapsed in March 2011 to the extent he needed to be re-inducted.

Dr Kumar was absent from Karratha in March 2011 and there was no alternative authorised prescriber in Karratha. The deceased was directed to Port Hedland to see Dr Afolabi as an alternative authorised prescriber in Dr Kumar's absence.[21]

This was unsuccessful and the deceased contacted Next Step directly for assistance on 4 April 2011. This is considerable effort for a known drug seeker and indicated the deceased was seriously attempting to overcome his drug addiction problems.[22]

There is no record of the deceased attending any other doctors for help with his CPOP and his last recorded dose of Suboxone from Pharmacy 777 Karratha was 18 February 2011.[23] None of the deceased's Suboxone prescriptions appear on his PBS record.[24]

In summary, the deceased was registered as a CPOP registered drug addict on 9 December 2010 and appears to have been treated with Suboxone until 18 February 2011, off PBS. His participation in CPOP lapsed due to his inability to find an appropriate alternative prescriber in Karratha. His registration did not expire until 9 December 2012.

Ms Habets' evidence was that while the deceased was very positive about being a registered drug addict and attempting to reduce his addiction by use of CPOP, the bureaucracy associated with being on an opiate reduction program was prohibitive and he didn't continue with the program.[25] As

[21] Ex 6, tab 29B
[22] Ex 6, tab 29A
[23] Ex 6, tab 20A
[24] Ex 6, tab 18
[25] t 12.03.15, p211

far as she understood he was not using opioid drugs following the lapse of his CPOP.

Ms Habets confirmed the deceased used benzodiazepines, in the form of diazepam, heavily, and was prescribed quetiapine while in Karratha.[26]

In 2009 the deceased started to see doctors at another practice in Karratha (Gemini Medical Centre now Kinetic Health). [27] Initially, he saw Dr Mark Lawry, but on Friday 24 August 2012 he was seen by Dr Craig Drummond for the second time.[28] The deceased explained to Dr Drummond he was an ex-heroin user but had not used illicit drugs for two years. Dr Drummond continued the deceased's prescription for Valium (diazepam). The deceased continued consults with Dr Drummond through August 2012, following his difficulties with maintaining the CPOP program through Karratha Medical Centre in mid-2011.

The deceased continued to see Dr Drummond for his general medical needs including an infected gallbladder and anxiety. The deceased visited Perth with respect to gastric problems and was expecting an operation for his gallbladder.[29]

On 15 November 2012 the deceased saw Dr Drummond at Kinetic Health and described to him lower back pain. His description of lower back pain was very persuasive and Dr Drummond saw no need to question his need for OxyContin tablets.[30] It was the first time the deceased had received any oxycodone preparation from Dr Drummond.[31]

There was a letter on the Kinetic file dated 23 March 2011, addressed to Dr Singh at Gemini Medical Services from Neil Keen, the WA Chief Pharmacist (Kinetic and Gemini are the same practice).[32] In that letter Mr Keen advised Dr Singh the deceased was a registered drug addict authorised to

[26] t 12.03.15, p211
[27] Ex 7, tab 1
[28] Ex 7, tab 1A, t 13.03.15, p323
[29] t 13.03.15, p324/5
[30] t 13.03.15, p327
[31] Ex 7, tab1A-K
[32] t 12.03.15, p262

participate in CPOP under the care of Dr Wilkinson. The letter advised Dr Singh a doctor may not supply a schedule 8 medicine for a person who is a notified drug addict without authorisation from the CEO WA Health. Dr Singh was no longer with Kinetic.[33] There was a suggestion the file be suitably annotated to prevent other doctors at that practice from prescribing schedule 8 medicine. This letter was copied to Dr Wilkinson who had been a doctor at Karratha Medical Centre.

Dr Wilkinson had left Karratha and was no longer a registered CPOP provider in 2011.[34]

Dr Drummond was unaware of the 2011 letter advising Dr Singh the deceased was a notified drug addict and could not be prescribed Schedule 8 medicines by an unauthorised prescriber. Dr Drummond provided a script for five days OxyContin at 20mg/tablet. Dr Drummond was unaware of any difficulty with this prescription.

Ms Habets advised that on Friday 23 November 2012 the deceased rang Dr Drummond at Kinetic Health seeking an appointment but was unable to get an appointment that day. Consequently, he rang Dr Myburgh at the Karratha Medical Centre and obtained an appointment with Dr Myburgh.[35]

The deceased attended at the Karratha Medical Centre and was seen by Dr Myburgh who, on the deceased's description of his back pain, provided him with a prescription for a low dosage of oxycodone tablets. Dr Myburgh was not an authorised CPOP prescriber but was able to prescribe short term opioids for pain relief, provided the patient was not an authorised drug user.

Dr Myburgh described the deceased as walking in a very *"stiff and what I would term an antalgic gait. It's a gait with pain and - yes. I can – he looked like he was in pain."*[36]

[33] t 13.03.15, p322
[34] t 12.03.15, p264
[35] t 12.03.15, p213
[36] t 13.03.15, p308

Dr Myburgh believed the deceased was genuine in his complaint of pain, hence his prescription for low dose OxyNorm. Dr Myburgh did not understand the deceased's issues with drug abuse from December 2010 were still an issue in November 2012, nor that he was a registered drug addict.

The deceased obtained his prescription for OxyNorm from the Pharmacy 777 Karratha, his authorised pharmacy for the CPOP program while registered with Karratha Medical Centre.

The records for the Pharmacy 777 Karratha indicate the deceased had been provided with Suboxone in December 2010 – 18 February 2011 which confirms his registered drug user status at that time. However, there was nothing about the prescription of OxyNorm on 23 November 2012 to alert a pharmacist enquiries needed to be made concerning the prescription of Schedule 8 medicines. The Suboxone history was long enough prior to November 2012 for it not to be observed easily on a check of the pharmacy records, which would not usually occur in these circumstances.[37]

Ms Habets indicated on his return home both she and the deceased were surprised he had been able to obtain a prescription for opioid medication while still a registered drug user.

On his return home the deceased received a telephone call from Kinetic Health advising Dr Drummond had a cancellation and would be prepared to see the deceased that afternoon. The deceased attended at Kinetic Health where he saw Dr Drummond and again described severe lower back pain. Dr Drummond prescribed the deceased another script for OxyContin, slow release oxycodone, and an antibiotic. Dr Drummond had prescribed OxyContin for the deceased on 15 November 2012 without any apparent ill effect for the deceased, and the prescriptions were far enough apart for Dr Drummond not to query a drug seeking motive.

[37] t 12.03.15, p284

Consequently, being unaware of his status as a registered drug addict Dr Drummond saw no difficulty in supplying the deceased with another script for OxyContin on 23 November 2012 because there was no indication there had been any misuse of the medication.

The deceased filled his prescription from Dr Drummond at Help Pharmacy.[38]

Help Pharmacy records reflect the prescription for the deceased for 20mg OxyContin on both 15 & 23 November 2012 from Dr Drummond. Carly Doyle, Pharmacy Manager at Help Pharmacy advised the court that in those circumstances a pharmacist may question the presenter of the scripts, but there was nothing about the scripts, with sufficient answer, to raise any concern to query Dr Drummond.[39]

Help Pharmacy would not have had records of the deceased's prior CPOP Suboxone scripts, and the WA Drug Addict Register is not available to pharmacists. There was no ability for Help Pharmacy to know of the deceased's drug addict status without his informing them of that fact.

On his return home Ms Habets said both she and the deceased were *"blown away"* that the deceased had managed to obtain two scripts for oxycodone on the same day, while being a registered drug addict. She did not believe it would be harmful for the deceased because he had been clean and drug free for such a long time.[40]

Due to the fact the deceased appeared to be drug free and genuine in his need for pain relief, neither doctor queried his need for oxycodone medication and, because it was not easily accessible on the deceased's file, had no way of knowing the deceased was still at risk and likely to drug seek due to his registration.

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[38] Ex 6, tab 19A, p7
[39] t 12.03.15, p293
[40] t 12.03.15, p215

FOLLOWING THE DECEASED OBTAINING OXYCODONE ON 23 NOVEMBER 2012

Ms Habets did not believe the deceased had injected any oxycodone preparation for approximately three years.[41] On that afternoon the deceased was very happy and excited to have the opportunity to use the drugs for recreational purposes.

The deceased had been to the needle exchange on the way home from the pharmacy so he and Ms Habets could inject the medication. Ms Habets told the court they used some of the OxyContin (stronger) tablets.[42]

Ms Habets described them both as feeling very good and she went out to dinner returning home at approximately 8pm to watch television. Ms Habets did not know if the deceased had used more tablets while she was out. After his death the OxyNorm (weaker) tablets were missing so in hindsight she believed he may have used those as well in her absence. They were both in a good mood and Ms Habets fell asleep and did not wake until 7am the following morning, 24 November 2012.

The deceased was in the kitchen making breakfast and advised Ms Habets he had been up all night with a bad headache despite which he was in a very good mood. She told him to go back to bed, which he did, and she watched over him for the next few hours while he was asleep.[43]

At approximately 11am on 24 November 2012 Ms Habets attempted to wake the deceased to assist in taking their son swimming. The deceased would not wake up, but Ms Habets believed this was because he simply did not wish to go swimming.[44]

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[41] Ex 6, tab 8, para 42
[42] t 12.03.15, p216
[43] Ex 6, tab 8
[44] t 12.03.15, p221

Although Ms Habets believed the deceased was refusing to wake up for various reasons including the approach of Christmas, which depressed him, she was still concerned he may have taken more tablets without her knowledge. As a result Ms Habets wrote him a note asking him to be careful about taking any more of his prescription oxycodone.

Ms Habets took their son swimming and returned home at approximately 3:30pm. When she went to check on the deceased he wasn't snoring or breathing and she was unable to wake him. She called emergency services.

The ambulance officers arrived at the address at 4:05pm and spent 20 minutes trying to revive the deceased.[45] They were unable to resuscitate the deceased and he was certified as dead at 4:30pm on 24 November 2012.

The police attended at the home and commenced an investigation into the circumstances of the deceased's death.

POST MORTEM EXAMINATION

The post mortem examination of the deceased was undertaken by Dr Clive Cooke, Chief Forensic Pathologist at the PathWest QE2 Medical Centre Laboratory, on 30 November 2012.

Dr Cooke formed the view the deceased's death was as the result of combined drug effect.[46]

Toxicology revealed a blood concentration of oxycodone generally considered toxic, as well as therapeutic levels of several different benzodiazepines.

The deceased's lungs showed changes raising the possibility of terminal aspiration of vomit, early atherosclerotic hardening of the arteries and apparent early cirrhosis of the liver, with a gall stone.

[45] Ex 6, tab 16, tab 9 & tab 8
[46] Ex 6, tab 20, 21 & 22

Dr Cooke considered the levels of prescription type medication including the level of oxycodone, to have a combined sedating and intoxicating effect, which when combined in high levels can result in impairment of consciousness, coma and death.

It was the impaired consciousness which leads to the possibility of terminally aspirating regurgitated vomit.

PBS PRESCRIPTIONS BEFORE DEATH

Examination of the deceased's Medicare and PBS scripts in the three months before his death, that is from 24 August 2012 – 24 November 2012 as the relevant timeframe for any enquiry to the Commonwealth Prescription Shopping Information and Alert Service, would not have revealed a concern with the deceased's drug seeking behaviours. He did not fit the criteria.[47] He had only received scripts from Dr Drummond, Dr Sterrett and Dr Myburgh. He had been dispensed diazepam three times, including 23 November 2012, and oxycodone hydrochloride three times.

The only scripts of concern being those of 23 November 2012 from different Karratha doctors and pharmacies. This information would not have triggered doctor shopping status.

The only productive enquiry with a government agency would have been one to the State Drug Addict Register Advice Line which would have advised both Dr Drummond and Dr Myburgh the deceased was a registered drug addict, but would have provided no other information because they were not his authorised prescriber for CPOP medication. Neither doctor had any reason to query the deceased's drug addict status in November 2012. They believed any drug dependency issues to be a thing of the past and that short term pain relief oxycodone was appropriate.[48]

[47] t 12.03.15, p266
[48] t 18.03.15, p561

EXPERT EVIDENCE

Professor David Joyce[49]

Professor Joyce is a Professor of Clinical Pharmacology and Toxicology at the University of Western Australia and also has a clinical practice at Sir Charles Gairdner Hospital. He provided the court with expert evidence to assist with the analysis of the post mortem toxicology and the contribution of those drugs to the death of the deceased.

Professor Joyce reviewed the available medical information with respect to the deceased. He noted the deceased's history of bipolar affective disorder and anxiety. In addition the deceased was reported to suffer hepatitis C, but a liver function test did not indicate any chronic liver disease in October 2012, although post mortem examination did indicate some fatty changes and appearances of early cirrhosis. Professor Joyce also noted resection of testicular cancer in 2011, hypertension being treated, possible sleep apnoea, obesity, chronic lumber back pain and heroin, cannabis and benzodiazepine drug abuse. The evidence was the deceased had used cannabis heavily when younger but had not used in the month preceding death.

Professor Joyce examined the deceased's opioid exposure preceding death and noted that despite his heroin addiction of approximately 20 years, which had been treated with methadone in Queensland and Suboxone in Western Australia up to approximately 18 February 2011, the deceased did not appear to have had any opiate substitution or opiate antagonistic (such as Narltrexone) treatment since March 2011.

The PBS records indicated intermittent use of oxycodone medicines over the preceding three years which had drawn the attention of the Health Department when they advised Kinetic the deceased was a registered drug addict in response to one of the prescriptions written in 2010/2011.

[49] Ex 6, tab 27, t 19.03.15, p602-611

Overall, the available history would indicate the deceased was not in any state of:-

> *"….exposure induced tolerance for opiate/opioid drugs in November 2012."*[50]

While Dr Drummond had prescribed oxycodone to the deceased on 15 November 2012 there was no apparent adverse effect from that prescription and Dr Drummond believed the deceased's self-proclaimed abuse history was no longer a problem, as evidenced by letters from two consultants who had reason to be concerned with the deceased's drug use in relation to some of his other illnesses which were being treated.

Professor Joyce noted the deceased had a heavy benzodiazepine history which on the whole was consistent with a prescribed rate of two tablets daily interspersed with periods of quite high usage. Ms Habets confirmed the deceased's continued heavy use of benzodiazepines due to his bipolar affective disorder and anxiety. The deceased's medical conditions also provided him with the medications amitriptyline, quetiapine and valproate which Professor Joyce noted as being taken in conventional therapeutic amounts.

An analysis of the deceased's post mortem toxicology results indicated a blood (femoral preserved) level of 0.22mg/L of oxycodone, along with some of his other prescribed medications. Of the drugs found at post mortem Professor Joyce indicated both amitriptyline and nortriptyline were sedating and at safe concentrations, without the addition of other drugs which can add to the toxic potential of drugs that kill by sedation and respiratory suppression. Quetiapine is used to manage psychotic illnesses and disorders exhibiting excessive anxiety and arousal. Again the levels seen would not be expected to be a risk to life in the absence of other drugs.

[50] Ex 6, tab 27

Diazepam (benzodiazepine) is a sedating drug, as are its metabolites. The levels found in the deceased's blood at post mortem do not reflect his high prescription and are at a rate lower than would threaten life in the absence of other drugs.

It was the oxycodone level of 0.22mg/L which Professor Joyce believed to be the most significant factor in the death of the deceased despite its relatively low concentration for a fatal outcome.

Professor Joyce described oxycodone as a potent pain killer with a high abuse potential. The level at post mortem in the deceased was around 5 ½ times higher than the average maximum serum concentration after the administration of a therapeutic dose of 20mg of immediate release (OxyNorm) oxycodone. It was substantially higher than concentrations used in chronic therapy with conventional doses, but was near the bottom end of the range found in oxycodone deaths, and those mainly occurred in opioid naïve patients.

The fact the deceased had used heroin many years earlier would not have provided tolerance to opioid drugs years after that abuse. Effectively, the deceased had been relatively opioid free for approximately 21 months and would not have had a high tolerance to oxycodone.

The fact the deceased took the oxycodone intravenously, also affected its impact on his functions by supplying a large, and potentially toxic, dose immediately. Professor Joyce does not believe the amount the deceased took became toxic as a result of any of his hepatitis C difficulties, but was directly attributable to the amount of drug he injected when no longer protected by a level of tolerance.

In Professor Joyce's view the most important drug in the combination taken by the deceased, contributing to his death, was the oxycodone. He no longer had tolerance to opioid medication and the concentration post mortem would confer serious toxicity and was potentially lethal, even without the addition of the other sedating drugs in his system at the time.

The levels of amitriptyline, nortriptyline, quetiapine and diazepam were all safe, but in combination with the level of oxycodone, induced the potential for a fatal outcome due to sedation and suppression of respiratory drive. Benzodiazepines increase the lethality of opioid drugs because they are muscle relaxants. This affects the relaxation of the upper airway muscles and causes obstruction, in addition to reducing the respiratory drive from the brain.

Professor Joyce believed the level of oxycodone was just borderline for lethal outcomes, but the addition of the benzodiazepines enhanced the toxic effect to make a borderline oxycodone level, lethal. Professor Joyce believed the evidence, post mortem, for vomiting was a classic opiate overdose situation and would indicate the opiate toxicity led directly to death by way of the inability of the sedated person to protect themselves.

> *"The most obvious one is the evidence for vomiting, because that commonly occurs in opiate overdoses and, because the person is so deeply unconscious from the opiate overdose, they're not able to arouse and clear their airways, and so the death is a combination of asphyxiation and the respiratory depression. The second thing that looks like it might be important here is (the deceased) body size and habitus. At a body weight of 142 kilograms there would be a fairly good chance of obstructive sleep apnoea which also increases the risks from opiates."*[51]

While the oxycodone concentration post mortem on its own may have been survivable, the presence of other drugs which would exacerbate the effects of the oxycodone was the reason for the lethal outcome in the case of the deceased.

[51] t 19.03.15, p604/605

Professor Stephen Schug[52]

The inquest also heard evidence from Professor Schug, an anesthesiologist who has specialised in pain management, and is currently director of pain management with the WA Department of Health at RPH, and establishing a pain clinic at Fiona Stanley Hospital (FSH). The approach to pain management currently is to use techniques other than ongoing medication.

Professor Schug was strongly against use of opioids for anything other than very short term strong pain relief, outside the treatment of terminally ill cancer patients.[53]

Professor Schug pointed out the incidence of prescribing opioids for chronic pain which is not cancer related, is fairly recent. It arose due to the success of pain management for cancer sufferers with opioids, and was extended to non-cancer pain without there being appropriate scientifically based evidence for its efficacy. Professor Schug stated the little evidence that is available indicates most chronic non-cancer pain does not respond very well to opioids, especially long term treatment.[54] While opioids reduce the level of pain, they do not improve a patient's functionality or quality of life. Patients develop tolerance and may even become increasingly sensitive to pain. Professor Schug indicated the increased prescribing of opioids has led to an increase in its availability for illicit use. They are highly commercial.

Professor Schug agreed the deceased died as the consequence of an overdose of oxycodone in combination with benzodiazepine use, complicated by risk factors of obesity and most likely obstructive sleep apnoea.[55] Although the deceased was a notified drug addict on the WA Department of Health register, with a long history of opioid abuse, the fact he had not been exposed to Suboxone for some 21 months indicated he would no longer have a high

[52] Ex 9
[53] t 20.03.15, p702-705
[54] t 23.03.15, p702
[55] Ex 9, tab 1

degree of tolerance to oxycodone, and the amount of oxycodone needed for a lethal outcome, in combination with the other drugs, would be very much lower than had he still had opioid exposure.

Professor Schug believed all three deceased in these cases died from opioid-induced ventilatory impairment (OIVI) as a consequence of a combined use of benzodiazepines and opioids. He described OIVI as a more correct description of the consequences of opioids on ventilation in humans, where both the depression of the respiratory centre in the brain and the impairment of maintenance of airways was affected by the use of opioids. He described the addition of benzodiazepines to opioids as resulting in an additional effect on the respiratory centre, but more importantly in muscle relaxation and the consequence of loss of airway maintenance. In these situations further risk factors such as obesity seen in the deceased and obstructive sleep apnoea or vomiting can contribute to the potential outcome.[56]

In evidence, Professor Schug clarified he did not have any difficulty with the level of prescription of OxyContin to the deceased on 15 November 2012 by Dr Drummond, other than the fact as a registered drug addict application should have been made for the dispensation of opioids for a back problem. The fact the deceased had been on a replacement program would have affected his tolerance to oxycodone medication, not recalled by Dr Drummond on that date. In Professor Schug's view, for acute back pain, 20mgs of OxyContin was a moderate dose.

Professor Schug was more concerned at the same script being written on 23 November 2012 by Dr Drummond because it would be before the prior prescription had been completed.[57] However, on understanding there was a weekend involved, and concern the deceased would not be able to obtain an appropriate appointment in time Professor Schug understood Dr Drummond's prescription.[58] The fact

[56] Ex 9
[57] (not clear this is correct – script on 15.11.2012 was for five days)
[58] t 20.03.15, p719/20

the deceased had a track record of appropriate drug use would encourage Dr Drummond to prescribe in the same way again.

Similarly with the script on the morning of 23 November 2012 from Dr Myburgh, Professor Schug agreed the prescribing of 5mg OxyNorm was a common response to a presentation of acute back pain such as described by the deceased. Again, without knowledge the deceased was a registered drug addict and therefore permission was required from Next Step, the prescription was perfectly in order. Professor Schug agreed the prescription of 5mg OxyNorm was a very moderate dose and would not necessarily encourage a doctor to make enquiries of the State drug addict register. Professor Schug indicated OxyNorm 5mgs, even to a *"non-opioid tolerant patient",* would not be a problem.

Similarly Professor Schug would not expect the 20mgs of OxyContin to be a problem for a normal adult irrespective of their opioid experience. It would be sedating, but not fatal.[59]

Professor Schug agreed with Professor Joyce that if the deceased had taken both the OxyNorm and OxyContin as prescribed it is unlikely there would have been a lethal outcome. The difficulty was the deceased taking the medication intravenously in excessive amounts and in combination with other sedating drugs, the benzodiazepines.

Professor Peter Winterton

Professor Winterton is a Clinical Associate Professor in Paediatrics and Community Practice. He is on the board of the Royal Australasian College of GPs to advise in areas affecting general practice.

He was asked to comment upon the GP care of the deceased.

[59] t 20.03.15, p721

Other than the fact Professor Winterton was extremely sceptical about providing strong opioid pain killers for unknown patients presenting with back problems, he did not consider the prescriptions to the deceased by either Dr Drummond or Dr Myburgh to be extreme. Professor Winterton would not prescribe OxyNorm (rapid release) as a first time script for back pain.

It was Professor Winterton's preference presentations for acute back pain in general practice be treated by other means. He agreed the problem with the scripting for the deceased was he had taken both scripts, not in accordance with the prescription, and used an excessive amount.[60]

Professor Winterton agreed that without knowledge the deceased was a registered drug addict, neither Dr Myburgh nor Dr Drummond (who he believed should have the knowledge) would have reason to ring the State drug register information line. There was also nothing in the prescribing of the medications which would have triggered a response from the Commonwealth "doctor shopping hotline". It was more the fact both doctors could have had knowledge of his past drug abuse which made Professor Winterton wary of the prescription of oxycodone medication for a back issue.

Overall, all three experts called with respect to the prescriptions for the deceased believed, that for short term strong pain relief, there was not a difficulty with the individual prescriptions. It was rather the lack of knowledge/recall of his prior dependency, which may induce him to misuse any opioid prescription; and the fact the deceased did misuse the prescriptions, in conjunction with his heavy benzodiazepine dependency, which caused his death on 24 November 2012.

The deceased no longer had opioid tolerance, having been relatively opiate free and no longer on opiate substitution medication. He used an intravenous dose of oxycodone in

[60] t 18.03.15, p553

excess of any prescription, in conjunction with other sedating (benzodiazepine) medication.

Professor Joyce described it this way:-

> *"….the reason for that is that the oxycodone concentration here is just on the borderline of lethal concentrations. We sometimes see oxycodone levels around this amount in people who are picked up for badly impaired driving, so very tolerant people can actually survive and even get behind the wheel with this level of oxycodone. I suspect that, even in a person without tolerance to opiates, the .22mg/L might be survivable. So it suggests that there are other contributors. The one – the pharmacological contributor that presents itself would be the diazepam and desmethyldiazepam, perfectly survivable on their own but can enhance the toxicity of oxycodone. There's also a couple of things which have occurred in this death which are probably influential. The most obvious one is the evidence for vomiting, because that commonly occurs in opiate overdoses and, because the person is so deeply unconscious from the opiate overdose, they're not able to arouse and clear their airways, and so the death is a combination of asphyxiation and the respiratory depression. The second thing that looks like it might be important here is (the deceased's) body size and habitus. At a body weight of 142 kilograms there would be a fairly good chance of obstructive sleep apnoea – also increases the risk from opiates…because it, too, tends to obstruct the upper airways…so the amitriptyline, diazepam, desmethyldiazepam and the quetiapine and, of course, the oxycodone have sedating effects."*[61]

[61] t 19.03.15, p604/5

CONCLUSION AS TO THE DEATH OF THE DECEASED

I am satisfied the deceased was a 44 year old male who had a past history of heroin addiction. He had attempted opiate substitution programs in Queensland (methadone) and WA (Suboxone).

The substitution program in WA using Suboxone saw him registered as a drug addict with the WA Department of Health in December 2010, due to expire in December 2012. The deceased attempted to continue with his Suboxone program (CPOP) but due to the absence of appropriate prescribers in Karratha in early 2011, his compliance with the program lapsed.

His partner, Ms Habets, indicated that while the deceased's compliance with the Suboxone program failed, he did not return to using heroin or opioid medication in the way he had in the past. However, he compensated due to his other illnesses, with heavy diazepam use.

It is also clear the deceased did obtain oxycodone prescription medication on occasions despite registration as a drug addict, but does not appear to have misused the prescriptions in a way which drew attention to his drug use from prescribing doctors, until letters were sent from the WA Chief Pharmacist in 2011. Unfortunately, by the time this information reached the deceased's file at the relevant practice, the relevant doctors were no longer with the practice. The information seems to have been lost in the depths of the deceased's file and was not readily accessible to doctors who later became his medical practitioners.

Ms Habets advised in evidence the deceased missed his two older sons greatly and Christmas was always a difficult time for him. In November 2012 she felt he was feeling depressed about the coming of Christmas and his separation from his two older children. His bipolar and anxiety disorders provided him with medication upon which he was dependant for his mood and stability.

It is not clear Ms Habets knew of the deceased's prescription for OxyContin from Dr Drummond on 15 November 2012, but it would seem the ability to obtain that prescription may have encouraged the deceased to seek oxycodone medication again on 23 November 2012 for recreational purposes.

I accept it was entirely opportunistic the deceased was given the opportunity to obtain two lots of oxycodone medication on 23 November 2012, due to the difficultly of obtaining an earlier appointment with Dr Drummond.

The deceased was known at both practices, to both doctors, and his past issues not considered or remembered to be of concern. His presentation seemed authentic and both doctors wished to alleviate his pain.

The deceased first obtained a script from Dr Myburgh which he filled at one pharmacy. He was then provided with an appointment to see Dr Drummond at another practice and obtained another prescription which he filled at a different pharmacy.

In addition to obtaining two unauthorised scripts while still a registered drug addict, the deceased also misused those scripts, firstly by taking more than the scripted amounts and secondly by the method of use. Ms Habets did not believe the deceased had a sore back. He certainly had problems with his gallbladder, but she believed the deceased was being misleading when he sought oxycodone medication from the two doctors involved.[62]

As Ms Habets said of her own involvement *"I have been an intravenous drug user for 20 years, and when supplied with drugs, I use them."* Up until that time Ms Habets had not misused drugs in Karratha, but presented with the opportunity she took it.[63]

I am satisfied the deceased on his way home from the Help Pharmacy stopped at the needle exchange in Karratha to

[62] t 12.03.15, p221
[63] t 12.03.15, p221

obtain clean needles with the anticipation he would use the oxycodone medications intravenously.

He returned home and he and Ms Habets injected ground up soluble oxycodone on the afternoon of 23 November 2012. Ms Habets then went out for the evening.

On her return Ms Habets noted the deceased was in a very good mood. After watching television Ms Habets fell asleep and did not wake up until the following morning. The deceased was awake and happy although he said he had a very bad night.

Ms Habets suggested the deceased go to bed and get some sleep to try and work the drugs out of his system. He complied and went to sleep and fell asleep very heavily. It would appear likely from the lack of medication remaining after death the deceased took more oxycodone tablets at some point.

Ms Habets attempted to wake the deceased at approximately 11am on 24 November 2012 but was unsuccessful. He was still asleep and she assumed he was sleeping off the effect of the drugs.

It is clear the deceased had taken an excessive amount of the prescription oxycodone. In conjunction with his other sedating medication he fell into a state of deep sedation which prevented him from protecting his airways. At some time in her absence the deceased vomited and aspirated.

He died.

On her return home Ms Habets was unable to revive the deceased.

Ms Habets called emergency services but it was not possible for the deceased to be resuscitated and he was declared deceased. There is no indication the deceased wished to die.

I find death arose by way of Misadventure.

PUBLIC HEALTH ISSUES IDENTIFIED AS A RESULT OF THE DEATH OF THE DECEASED

In this case the deceased was not an extreme drug seeker, but opportunistic. His need for medication for his bipolar and anxiety disorders allowed him to legitimately, and apparently safely, compensate for a lack of illicit opioids by heavy benzodiazepine use. The fact he attempted to continue with his CPOP program in the absence of an authorised prescriber, and when unable to continue did not return to illicit opioid abuse, was commendable. He was clearly trying to desist from his original lifestyle.

The deceased's difficulty in finding an authorised CPOP prescriber reflects the preference many doctors have not to be involved in community programs for the replacement prescribing for opiate dependency. Many doctors throughout the course of the inquests described the difficulty in dealing effectively with patient drug seeking behaviour. It is because of the vulnerability of doctor prescribers to being misled into prescribing for drug seekers that relevant tools need to be implemented to assist doctors in acting in a patient's best interest. Regulation will assist by ensuring drug seekers understand prescribers' discretion may be limited by the type of drug being sought.

Those dependent on drugs may understand the harm they are doing themselves but the desired effects of misuse of prescription medication can be difficult to overcome. As Ms Habets stated of her own use, if the opportunity arose she would use whatever came her way. I accept it is likely the deceased was not suffering from as bad a back problem as he demonstrated. Presumably he had suffered an appropriately bad back in the past and was provided with oxycodone medication, giving him a template for symptoms which would elicit oxycodone medication, when it was more commonly prescribed than it perhaps is in 2015, with alternative pain management strategies being emphasised.

I also accept that on occasion the deceased would use short term pain medication recreationally, but it does not appear

to have been habitual. His tolerance to opioid medication was not as high as it would have been when he was an habitual user, and on the 23rd to 24th November 2012 the deceased seriously miscalculated his ability to tolerate unprescribed levels of oxycodone medication in conjunction with heavy benzodiazepine use. Both medications affect respiratory drive and opiate toxicity induces vomiting.

The deceased's death demonstrates how easily prescribers can unwittingly provide lethal prescriptions for known patients they have treated for a long time without apparent problem. Neither Dr Myburgh nor Dr Drummond considered they were dealing with an unknown "walk-in" seeking strong analgesics. They had both dealt with the deceased before and did not recall his past dependency problems in the face of seemingly appropriate short term prescriptions for strong back pain. They did not suspect he would misuse their prescriptions, by both the amount and method of ingestion.

The troubling truth is that doctors cannot rely on people with drug habits/dependencies to be truthful. The controls around prescribing these drugs seek to protect those with dependencies from themselves, but do not provide those treating them with reliable tools by which to assess need as opposed to desire. Most doctors do not want to be continually suspicious about their patients, where there does not appear to be a need to be wary.

The deceased had largely controlled his recreational use of opioids, but apparently not his desire. When the opportunity arose he misused prescribed oxycodone without realising his reduced tolerance left him susceptible to toxicity. Had either doctor had easy and direct access to a system which alerted them to the deceased's past opioid dependency and that he was still a registered drug addict, they would have been alerted to the fact their prescription for Schedule 8 medication to the deceased was unauthorised. They needed to provide alternative pain relief.

Communication of his drug addict registration on 23 November 2012 in real time would have provided four separate points at which his death could have been prevented, twice through doctors and twice through pharmacies, despite his failure to disclose his registration.

Had Dr Drummond had easy and direct access to a real time dispensing information system it is unlikely the deceased would have obtained two scripts on the same day, following the dispensing of the first prescription from Dr Myburgh from Pharmacy 777 Karratha.

In the event he had, it is unlikely a second script for the day would have been dispensed when presented to the Help Pharmacy if pharmacists also had access to a real time dispensing information system.

The points at which the deceased's drug difficulties could have been communicated were:–

On the 15 November 2012:-

- when Dr Drummond prescribed oxycodone he would have understood the deceased was still a registered drug addict and the prescription was unauthorised;
- The pharmacy dispensing the prescription on the 15 November from Dr Drummond would also have understood the deceased was a registered drug addict and the prescription was unauthorised;

On the 23 November 2012:-

- Dr Myburgh would have understood his prescription was unauthorised for a registered drug addict;
- The Pharmacy 777 Karratha would have understood the deceased was a registered drug addict and authorisation would be needed for the prescription;
- Dr Drummond would have understood, had he not already been alerted on the 15 November the deceased was a registered drug addict, that he required authorisation for a script. Dr Drummond would also

have understood the deceased had already been dispensed oxycodone medication that day;
- The Help Pharmacy would have understood the deceased was a registered drug addict and that the prescription was unauthorised and the deceased had already received an oxycodone prescription that day

If at any of those points the deceased had been confronted with his unauthorised use of oxycodone medication and the prescription not supplied his death could have been prevented.

Current Prescribing

The drugs sought by those with a prescription medication dependency are those prescribed as an analgesic (Schedule 8 opioids) as in this case or for their calming/sedative effect (Schedule 4 benzodiazepines). They are medications used to aid those with an illicit drug dependency overcome that dependency and assist with withdrawal effects by providing the patient with an alternative, but less intense, effect. Prescription anti-depressants and anti-psychotics are also often misused.

Opioids as an analgesic are legitimately prescribed for acute pain, but the benefits of prescription long term (chronic pain) for non-cancer patients is currently being reassessed. As short term pain relief they are effective.[64] Doctors need to treat pain and so will use opioids for appropriate patients. Inevitably there will be some overlap between appropriate and inappropriate, especially with changing medical practice. It is because of the seriousness of the outcomes of over medicating opioids, their prescription has become controlled by use of legislation. While accepted as necessary, it adds a layer of difficulty for medical practitioners without good information as to the reality of prescription use and dispensing of the drugs prescribed.

[64] It should be noted that OxyContin and other slow release forms of oxycodone are not currently PBS listed for use in acute pain. Australian Government PBS website. TGA Product Information for OxyContin.

Benzodiazepines as sedatives are very effective in treating a number of difficulties in the elderly and chronically unwell. Some, such as alprazolam and flunitrazepam, are so potent they have been rescheduled into Schedule 8 medicines in an attempt to control their prescription. The rest remain in Schedule 4 where they need prescription, but are not as strictly controlled as the Schedule 8 medicines. This does not alter the fact that misuse of benzodiazepines is equally as concerning as the misuse of opioids, and can cause toxicity and death due to their effect on suppression of respiratory effort.

Both opioids and benzodiazepines induce individual tolerance which brings with it a misguided perception of a patient's ability to tolerate high levels, and addiction.

Recognition of these problems has led to the introduction of both the Commonwealth Prescription Shopping Information and Alert Service telephone advice line (doctor shopping hotline) and the State Drug Addict Register Information Line. Both systems have serious shortcomings in reality despite being of benefit where a practitioner has reason to believe there may be an issue and has the ability to act upon it in a timely manner.

The WA Drug Addict Register

There is a State register of authorised drug addicts for those recorded as addicted to Schedule 8 medicines. To be treated once recorded as a registered drug addict a patient has to agree to only seek Schedule 8 medicines from a specific doctor and pharmacy.

The system can be abused in the short term because by the time evidence emerges the patient has obtained Schedule 8 medicines from another doctor or pharmacy there may already have been an oversupply. This oversupply can be misused, used as a bank or sold on the black market.

Community Program for Opioid Pharmacotherapy (CPOP)

The WA Community Program for Opioid Pharmacotherapy (CPOP) and its ability to monitor registered opioid dispensing can only provide information on opioid prescriptions (PBS and Off PBS) because it relies on information collected from pharmacies on a monthly basis which needs to be collated. The fact a person is a registered drug addict can be obtained by an enquiring medical practitioner, but with no details of any current medication plan.

The inquests heard evidence from Dr Alan Quigley, Director of Clinical Services Branch (Next Step) of the WA Drug and Alcohol Drug Office. Next Step provides treatment services to people with drug and alcohol problems with a focus on prevention and education. It developed CPOP, introduced in 1997, to support GP's and community pharmacists in their provision of pharmacotherapy, largely methadone or buprenorphine treatment, to opioid dependent patients.[65]

Medical practitioners need to be accredited, following training, to prescribe pharmacotherapy, patients need to be registered, and there is the availability of advice and assistance from Next Step practitioners for any treatment regime. Although it focuses on opioids, the prescribing of benzodiazepines and co-prescribing of those classes of medicines is, of necessity emphasised. This is for outpatient treatment. There are also available various inpatient treatment facilities in the private sector.[66]

As seen in the current case the deceased was registered on 9 December 2010 by Dr Kumar (in the name of Dr Wilkinson) but other doctors providing him with prescriptions for opioids as short term analgesics were not notified of their breaches of his registration, of which they were not aware, until receipt of the relevant letters, some months after the event. By that time the deceased was no

[65] t 23.03.15, p730
[66] t 23.03.15, p732

longer being provided with pharmacotherapy due to the inability to find doctors prepared to be involved in community treatment programs with those with drug dependencies. This left the deceased in an extremely vulnerable position, and doctors unaware of the fact he was a registered drug addict at times where it would have been possible to avoid prescription.

Advising practitioners of a breach in regulation for their prescription months after the prescription has occurred helps no-one. Where the patient is still a patient it may reassure the prescribing doctor their patient no longer has a problem, although it may alert them to a reliability issue.

Once a patient is registered, any medical practitioner asked for Schedule 8 drugs can ring the relevant advice line for information about the fact of registration, but to do so is an indication of a lack of trust, and many doctors will not ring an advice line if they are not suspicious about the patient with whom they are dealing. In the case of the deceased the doctors with whom he dealt regularly were aware of his past dependency. They did not believe there was a necessity to ring either of the controlled drug information lines to check on him as there did not appear to be a continuing problem with drug seeking behaviours. It certainly was no longer habitual.

Currently, a pharmacist in WA is not in a position to access drug addict registration information.[67] This is despite the fact a pharmacist may be in a better position than a general practitioner to suspect the prescription they are asked to dispense may be used inappropriately. Currently a pharmacist, if concerned about a prescription, may ring the prescribing doctor or if really concerned can refuse to dispense, but is not in a position to access the drug addict register themselves. If more of a Schedule 8 medicine is dispensed than the patient uses, it provides an immediate oversupply for the black market or for the use of that patient.

[67] t 19.03.15, p640-641

Thus while there is a WA community program to assist patients with their wish to reduce their drug dependency via an authorised prescriber, it is reasonably easy to circumvent without real time information to the prescriber or dispenser as to the patient's actual access to prescription medication.

Commonwealth Prescription Shopping Information and Alert Service advice line ("doctor shopping" hotline)

The "doctor shopping" hotline provides up to date information to medical practitioners on PBS only prescriptions for people identified as a prescription shopper.[68] The criteria for a prescription shopper are set by legislation, regulation 20(a), of the *Human Services (Medicare) Regulations 1975*, and not all patients who are potentially drug seeking are captured.

The PBS data for the deceased in this case would not have identified him as a prescription shopper despite the fact he was seeking analgesic and benzodiazepine medications, apparently for his pain and bipolar condition. Even under the Commonwealth system there can be a significant delay before the fact of the prescription shopper has been established to the extent the shopper and the prescribers are notified.[69] This is despite the fact the collation of PBS data is in real time from the online pharmacy dispensing data. It captures all PBS dispensing of controlled drugs, but not private dispensing.

The doctor shopping hotline is available to pharmacists 24/7 but does not provide information off PBS, and if the person about whom an inquiry is made does not fit the criteria, as in this case, then no information is available.

None of the deceased in these three cases would have fit the prescription shopper criteria.

They all died as a result of the misuse of prescription medication.

[68] Ex 10, tab 1 and t 17.03.15, p495
[69] t 17.03.15, p498

ELECTRONIC RECORDING AND REPORTING OF CONTROLLED DRUGS (ERRCD)

Following a Tasmanian initiative (DORA) the Commonwealth Government has developed a system for the real time monitoring of dispensed prescriptions for Schedule 8 medicines based on the on-line dispensing data from pharmacies Australia wide. It is a software system which will enable State/Territory regulators and medical practitioners to have real time access to that data for their State/Territory.[70] That is all dispensed events relating to controlled drugs and any other drugs of interest for which information can be collected according to relevant State and Territory legislation.[71] This is ERRCD.

The evidence at the inquest from the Commonwealth is that this data is available and operational on a server host and will be provided to all States and Territories once each individual State or Territory has finalised a licensing agreement for the exchange of the information.[72] Currently Western Australia has finalised a sub-licensed agreement with the Commonwealth which allows access to the database and is examining the ways in which that system will need to be modified to work at the State level.[73]

Each state or territory interface with the Commonwealth system will differ in line with the individual State legislation and regulation. This means dispensing data will still not be available Australia wide, unless there is an agreement and modification to achieve consent to the sharing of information across jurisdictions.

The WA Health Department, as the State regulator, collects all pharmacy data on all dispensed Schedule 8 medicines[74]. Once WA has implemented its interface with the Commonwealth System, it will be possible for WA

[70] t 23.03.15, p678
[71] Ex 10, tab 2, Fact Sheet 8 May 2013
[72] t 23.03.15, p677
[73] t 19.03.15, p640
[74] t 19.03.15, p638

pharmacies to provide all their medicine dispensing data into a secure WA system. It would then be possible to construct an access point for WA prescribers to access WA information in real time, using pharmacy data for both on and off PBS medicines.

While WA has recently passed legislation (*Medicines and Poisons Act 2014*) to achieve that outcome, the regulations have not yet been finalised as to how that outcome will occur.[75] One of the desirable outcomes would be pharmacy access to that information sharing system, especially that which relates to the drug addict register, as an additional aid in the control of the dispensing of controlled medicines. Similarly, because it is based on pharmacy records, and the legislation requires a record to be kept of prescribing and dispensing of drugs of addiction it could be extended to benzodiazepines, not just Schedule 8 medicines, as drugs of addiction. The State legislation has also reworded the terms used around, "dependency" and "addiction" which will make the sharing of relevant information less prejudicial.

The State data will need to be compatible with the commercial software used in the majority of medical practices so that information received from pharmacies can be accessed via the State held database in real time. Because the State holds the equivalent of the drug addict (user, dependent etc) register, it would be possible for software to be implemented which would provide alerts from the database to the prescriber, when the name of a person on the register is entered. The intention would be to prevent the writing of a prohibited script at the source.[76] That information, available in pharmacies as well as medical practices, would ensure pharmacists would not dispense unauthorised prescriptions to users from an unrecognised prescriber.

A prescriber would still need to log into the system but it would be open to commercial software providers to develop automatic links to State drug registers and real time dispensing data. In the current case that would have

[75] t 19.03.15, p641 & 648
[76] t 19.03.15, p643

prevented all Schedule 8 prescriptions, following the deceased's 9 December 2010 drug addict registration, from being written for the deceased. It has the potential to stop it at the prescription level for electronically produced prescriptions for registered drug addicts, and at the pharmacy level for dispensing wherever handwritten prescriptions are still in use.

There is also the potential for a decision to be made as to what other drugs/medicines are being used inappropriately and should be considered for stricter control. These could include medicines of concern, benzodiazepines and some antipsychotics (Schedule 4).

Prescribers logging onto the system would be able to view a real time dispensing history for that patient before making a decision as to the appropriateness of a prescription before them at that moment.[77]

Should benzodiazepines be controlled like Schedule 8 medicines

This is a vexed issue. A surprising number of doctors heard at inquest believed benzodiazepines should be controlled in the same way as Schedule 8 medicines despite the additional paperwork this would involve.[78] Others were very concerned this would lead to a number of elderly patients being labelled as "drug addicts" and great reluctance by doctors to then be involved in prescribing benzodiazepines to elderly or needy patients. There is no doubt in the minds of those treating patients the term, "drug addict" can be prejudicial.[79]

Labelling is not a major concern because different terms can be used such as, "authorised drug user" but the additional paperwork may be a difficulty for busy clinicians who have a large practice of those needing benzodiazepines (nursing homes) but choose not to be authorised for Schedule 8

[77] t 19.03.15, p665
[78] t 12.03.15, p269 (Wilkinson)
[79] t 18.03.15, p540-541 (Winston)

pharmacotherapy programs (CPOP) and can refer those to suitably accredited clinicians.

Interestingly, the doctors who believe benzodiazepines should be controlled in the same way as Schedule 8 medicines tended to be those who were authorised pharmacotherapy prescribers, or had been, due to the extent of misuse they see of those drugs surrounding opioid dependency. The doctors who did not believe benzodiazepines should be controlled like Schedule 8 medicines were those who did not wish to be involved in CPOP prescribing, and referred those of their patients requiring it to other practitioners.

Professor Joyce believed there were some arguments for further control of benzodiazepines. He reminded the court many of the falls seen in the elderly, in nursing homes, which often led directly to death could be avoided if those patients were more alert, and not as sedated with benzodiazepines.[80]

Professor Schug was of the view long term prescribing of benzodiazepines was undesirable, even in the elderly.[81]

Challenges for prescribers

The intention for the regulation of Schedule 8 medicines is to provide adequate medications to those who are in need of it, but to try and prevent its misuse by controlling prescriptions for medication which is not necessary. Medical practitioners desire to treat patients with a medical problem in the most effective way possible without doing harm. Lack of knowledge of a patient's real need for medication puts a prescribing medical practitioner at a great disadvantage when trying to determine the potential harm of a prescription. As one medical practitioner said:-

> *"There's all these people that have died because – as a GP in those situations, you try – none of us are malicious. We try and do our best, we try and judge the*

[80] t 19.03.15, p590
[81] t 23.03.15, p710-11

situation. But people who are addicts and who really want the drugs are cleaver, and unfortunately, sometimes can be quite aggressive and quite persuasive."[82]

The capacity of opioids, and to some extent benzodiazepines, to induce tolerance in a patient, which similarly can diminish quite quickly adds another layer of complication for a prescriber. Both groups of drugs can cause respiratory depression which has its own challenges, and if prescribed together can cause additional issues. The black market also relies on overprescribing to some extent. This can occur where a patient no longer requires a high level of medication, but does not inform their prescriber or exchanges one drug for others.

Aside from tolerance to Schedule 8 medicines there is also the aspect of addiction to opioids which elevates a desire for the psychological outcome. Addiction to a drug can cause many undesirable outcomes, not the least of which is an addict's propensity to lie to obtain the drug, and indulge in drug seeking behaviour (violence or intimidation) where access to the drug of choice is restricted.

Throughout the inquest doctors related very frightening and threatening interchanges they had experienced with patients seeking drugs which the doctor had questioned. This was quite separate from the issue of continually being concerned a patient may not be reliable in their medication history:-

"One of the oppressive parts of medical practice is dealing with patients whose relationship with you is entirely based on deceit and manipulation and to have those better controlled in practice will improve the medical practitioners capacity to enjoy the quality of professional life."[83]

None of the deceased in the three inquests chosen for these "doctor shopping" matters were in the intimidating or

[82] t 12.03.15, p267
[83] t 19.03.15, p591

threatening category. They all appeared to the prescribing doctors to be genuine in their need for pain relief medication or their desire to overcome a dependency by use of controlled prescribing. The doctors concerned consistently took them to be credible and reliable as to their medication history when dealing with them.

In the current case Dr Myburgh had referred the deceased to Dr Kumar for pharmacotherapy. Almost two years later when he prescribed short term oxycodone for specific back pain problem for the deceased he did not recall the deceased's past problem as a current problem. Similarly Dr Drummond was aware of the deceased's past heroin dependency but believed it was just that, a thing of the past, and that there was no longer a problem with him providing the deceased with oxycodone medication for short term pain relief. Neither of those doctors understood that presented with the opportunity to misuse prescription medication the deceased would do so.

Although I accept the deceased's misuse was opportunistic rather than habitual, he:-

1. did not disclose his current drug addict status to either doctor, not surprising as he had tried to continue with CPOP;
2. was able to obtain both prescriptions at pharmacies where he was not recognised as a still registered drug addict; and
3. did not comply with either prescription and took more oxycodone medication than he was able to tolerate.

He died.

His medical practitioners did harm where they had only ever wanted to treat him for his medical difficulties. This is simply not fair on doctors where there is available a method which could minimise the ability for those seeking drugs for recreational use to obtain drugs by misrepresenting themselves to prescribers. Had either Dr Myburgh's or Dr Drummond's software provided an alert the deceased

was a registered drug addict, it would not have been necessary to hear that information from the deceased.

Neither doctor would have supplied the deceased with oxycodone medication without referring to his authorised prescriber, non-existent as a prescriber was at that time. Further, neither pharmacy, if they had access to the drug addict register, would have provided the deceased with medication from an unauthorised prescriber. Had Dr Drummond's software informed him the deceased had already been dispensed a prescription for oxycodone medication that day he would have been in a position to confront the deceased about his intentions around additional medication. If any of those things had happened the deceased's death could have been prevented, despite himself.

Every practitioner appearing in the course of the three inquests was strongly in favour of the implementation of an electronic information system which would provide them with real time dispensing information for Schedule 8 drugs.[84] The majority of them would also appreciate up to date information on the dispensing of benzodiazepines as an information system as opposed to a regulation system. The Schedule 8 opioids and Schedule 4 benzodiazepines, are often used in conjunction in areas of drug dependency and because they both operate as respiratory depressants information or access to their dispensing history would be appropriate.

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[84] t 10.03.15, p71 Bradford
t 10.03.15, p96 Wilson
t 10.03.15, p118 Wolman
t 11.03.15, p153 Rodoreda
t 11.03.15, p183 Mahon
t 12.03.15, p245 Kumar
t 12.03.15, p267 Wilkinson
t 13.03.15, p310 Myburgh
t 13.03.15, p334 Drummond
t 16.03.15, p370 Foley
t 16.03.15, p445 Buntine
t 16.03.15, p483 Davies
t 18.03.15, p528 Winterton
t 19.03.15, p590 Joyce
t 20.03.15, p710 Schug
t 20.03.15, p748 Quigley

Dr Quigley, on behalf of Next Step, was of the view dispensing information was the most important fact in attempting to assist those with a dependency. Access to dispensing information would also provide information about the last prescription which would enable the receiving doctor to make enquiries of the previously prescribing doctor. In his view dispensing information was predominately the useful information.

Similarly, Professor Schug was of the view the usefulness of the dispensing information outweighed prescription information.

It is dispensing information which is available from ERRCD. One of the significant similarities of two of the three matters is the fact that none of the prescriptions issued would have been fatal had the recipient used the drugs as prescribed. Even in this matter the expert view was the deceased could have taken both prescriptions obtained on the same day without a fatal outcome had he taken both as prescribed. He did not, he used multiples of the prescription intravenously, serious abuse, which caused toxicity, sedation, aspiration and death.

It is because drug abusers misuse prescription medicines legislative restrictions have been put in place in an attempt to save them from themselves. Blaming prescribers when drug abusers circumvent those restrictions is destined to reduce the number of doctors willing to expose themselves to the risk of attempting to assist those with dependencies. It is more constructive to provide prescribers with a tool which will better enable them to treat patients effectively, than chastise them for providing apparently competent medical prescriptions because they have the potential to be misused.

Recent research by the Victorian Coroners Court Prevention Unit on the outcomes of the use of the real time prescription monitoring system developed in Tasmania suggests that the frequency of overdose deaths in Tasmania has not decreased overall, but there has been a notable decrease in overdose deaths involving the prescription medications that

are monitored by the system. A particularly pronounced decrease was observed following the Tasmanian implementation, in the frequency of Tasmanian overdose deaths involving pharmaceutical opioids. It was emphasised it was important to ensure those prescribing or supplying relevant medication used the system.[85]

Recommendations

I wish to acknowledge the assistance of the Chief Pharmacist and Next Step in commenting on the proposed recommendations. Where I have deviated from that input it was as a result of my intended deviation.

Secure Database

1. WA prioritise the real time collection of dispensing data from all pharmacies for all Schedule 8 and reportable Schedule 4 poisons.[86]

2. All WA real time dispensed medicine data be held in a secure regulated database held by the WA government regulator.

3. WA regulate to ensure the supply or dispensation of all Schedule 8 and reportable Schedule 4 poisons are recorded in the secure regulated database held by the WA Government regulator.

4. WA regulate to provide both prescribers, registered pharmacists[87] and authorised suppliers access to that secure data via secure software links to facilitate real time decision making around both prescribing, supplying and dispensing of Schedule 8 and reportable Schedule 4 poisons.

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[85] Presentation: Tasmanian overdose deaths before and after the DAPIS implementation: Dr Jeremy Dwyer (et al), Coroners Court of Victoria: Asia Pacific Coroners Society Conference 12 November 2015, Hobart, Tasmania.
[86] The phrase 'reportable Schedule 4 poisons' is adapted from definitions contained in Part 6, *Medicines and Poisons Act* 2014 (WA), assented to on 2 July 2014, not yet proclaimed.
[87] Those pharmacists registered under the *Health Practitioners Regulation National Law (WA)* in the pharmacy profession.

5. The current Schedule 8 (controlled drug) dependency register be part of that secure database and provide that information along with real time information about medicines dispensed on enquiry by a prescriber, registered pharmacist or authorised supplier.

6. The information from any register regulated (e.g. reportable Schedule 4 poisons) as part of the secure database, be similarly available on enquiry for dispensed medicines.

7. Once real time WA dispensing data is available for use there be a regulated time period to allow commercial practice case management software to be developed to facilitate real time access. Once that period is over it be regulated that prescribers access the available data prior to completing any prescription or supply for Schedule 8 or reportable Schedule 4 poisons. The intention is to ensure those with drug seeking behaviour understand prescribers must comply with regulation to enable a prescription to be written.

Benzodiazepines

8. All benzodiazepines be included as reportable Schedule 4 poisons.

9. There be a method implemented to assist prescribers and dispensers with decision making around benzodiazepine dependency, and restrictions imposed on recognised unsafe prescribing or supply. How that is achieved is up to the regulator. Again the concern is not with policing but providing prescribers with a mechanism with which to decline to prescribe in the face of undue pressure from drug seekers.

CPOP

10. CPOP prescribers be given information about a patient's prior CPOP programs and prescribers when seeking authorisation to commence a new program.

11. CPOP prescribers to provide advice when seeking authorisation as to other medications to be prescribed in conjunction with the authorised program medicine. This is to include reportable Schedule 4 poisons and amounts with intended reduction regime, if that is applicable.

Australia Wide Dispensing Information

12. The ultimate aim for the secure regulated database held by the WA Government regulator be for all prescription medicines to be captured. If medication warrants a prescription, it warrants monitoring.

13. The ultimate aim for real time ERCCD data should be for Australia wide access to dispensing data for medical practitioners, registered pharmacists and authorised suppliers.

E F Vicker
Deputy State Coroner
10 February 2016