IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2009 4088

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the ***Coroners Act 2008***

I, HEATHER SPOONER, Coroner having investigated the death of DANIEL ANDERSON

without holding an inquest:
find that the identity of the deceased was DANIEL MALCOLM JOHN ANDERSON
born on 5 November 1975
and the death occurred on 20 August 2009
at 17 Wilton Close, Wyndham Vale 3024
from:

1 (a) TOXIC EFFECTS OF OXYCODONE

Pursuant to section 67(2) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances**:

1. Mr Daniel Anderson was aged 33 when he died. He was a security guard and lived at 17 Wilton Close, Wyndham Vale. Mr Anderson had a past medical history that included anxiety, depression, migraine and chronic alcohol abuse.

Brief summary of events leading to death

2. A police investigation was conducted into the circumstances surrounding the death. It was apparent that Mr Anderson resided alone at Wyndham Vale, though he was in a relationship with Ms Joanne Philo and they would often spend time at one another's homes. On Wednesday, 19 August 2009, Mr Anderson attended an appointment in Hoppers Crossing with psychologist Tim Murphy then ate dinner with Ms Philo at her Hoppers Crossing home. He left at approximately 9.30 pm and attended his usual treating general practitioner, Dr Anthony Farnbach, who prescribed 60 capsules of 10mg oxycodone (brand name OxyNorm) to him. Mr Anderson then went to his Wyndham Vale home; he told Ms Philo that he needed to organise flights to Bali and installation of new carpet.

3. Throughout the course of Thursday, 20 August 2009, Mr Anderson's father Malcolm Anderson tried to call him several times on his home and mobile telephone numbers without success. At approximately 5.15 pm that day, Mr Malcolm Anderson went around to his son's home and found him deceased. Victoria Police Senior Constable Katie Shores, who subsequently attended the property, noted that in the immediate vicinity of the deceased were alcohol swabs, a used syringe, empty and full OxyNorm blister packs, and white powder residue. The circumstances were suggestive of crushing and injecting OxyNorm tablets.

Post mortem examination

4. An autopsy was performed by Associate Professor David Ranson at the Victorian Institute of Forensic Medicine. He formulated the cause of death and commented in part:

> *The post mortem toxicology reveals an Oxycodone level of approximately 0.5 mg/L, Venlafaxine and Diazepam with its metabolite was also identified. The level of Oxycodone was that could explain this individual's death.*
>
> *The post mortem CT scan showed nothing of note with respect to the potential cause of death and the principal factors contributing to determination of the cause of death was the results of the toxicology as well as the circumstantial information available regarding the scene of death.*

Family Concerns

5. Letters of concern were received from both Mr Anderson's father and Ms Philo regarding Dr Farnbach's management and treatment of Mr Anderson, given the risks associated with such a strong opioid as oxycodone.

CPU review

6. I directed the coroners prevention unit CPU[1] to review the appropriateness of the prescribing of the oxycodone to Mr Anderson. The CPU reviewed the available medical material in an effort to understand when and why Dr Farnbach prescribed oxycodone.

7. It was apparent that Dr Farnbach treated Mr Anderson for migraines from May 2006 at Werribee Primary Health Care and before that at Werribee Group Health Centre. The

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[1] The Coroners Prevention Unit is a specialist service for coroners created to strengthen their prevention role and provide them with professional assistance on issues pertaining to public heath and safety.

treatments included the opioid analgesics codeine, morphine and pethidine and from July 2008 entailed daily doses of oxycodone.

Oxycodone prescribing

8. According to Dr Farnbach in his statement dated 28 June 2011 he prescribed oxycodone to treat Daniel Anderson's migraines:

> *He had seen neurologists for the migraines and had a full host of investigations and trials of prophylactic medications, such as Inderal,[2] etc. When I moved to the clinic in the plaza in 2005, I discontinued pethidine, as it is no longer a recommended treatment for migraines. His migraines were intermittent. He would go for months with none, then may have a cluster over 3-4 weeks. He did not display drug seeking behaviour at any stage. In the end, as far as I knew, he responded well to oral OxyNorm which he would hold, and use when needed.*

9. Dr Farnbach further explained in this statement that he was not concerned about prescribing oxycodone because Daniel Anderson never exhibited any of the behaviours that are usually associated with drug dependence. In particular, Daniel Anderson never presented claiming lost or stolen scripts, never presented early for scripts, and:

> *Some of the other clues of drug dependency were also missing, the main one being the infrequent presentations with acute migraines. He would go for many months with nothing, then he would present. The usual pattern with drug dependent people is a more regular predictable presentation, as the clinic need is dictated by pharmacological factors rather than underlying pathology.*

10. Finally, Dr Farnbach stated that:

> *He gave me the impression that he was using it [oxycodone] as directed and it was doing the job quite well. In retrospect, he had misled me (and others) into believing that he was not misusing his medications.*

11. I directed the CPU to contact Drugs and Poisons Regulation at the Victorian Department of Health to find out if there was a valid Schedule 8 permit to prescribe oxycodone to Daniel Anderson. Justin Lam, the Manager of Treatment Approvals and Projects there, confirmed the following:

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[2] Inderil is a brand name of the beta blocker propranolol.

- Dr Farnbach was granted a permit to prescribe 5mg daily oxycodone to Daniel Anderson on 4 July 2008.
- On 24 September 2008 a revised permit was issued, for Dr Farnbach to prescribe 10mg daily oxycodone to Daniel Anderson.
- On 30 January 2009 a revised permit was issued, for Dr Farnbach to prescribe 30mg daily oxycodone to Daniel Anderson.

12. The CPU further contacted Drugs and Poisons Regulation to find out what reason Dr Farnbach gave as the clinical justification for the oxycodone prescribing. Justin Lam replied via email that:

> The clinical diagnosis stated on Dr Farnbach's first two applications was 'intermittent migraines'. The third application was 'migraines'.

13. I directed the CPU to request a PBS Patient Summary to establish the dates Dr Farnbach prescribed oxycodone, and in what quantities, in the lead-up to Daniel Anderson's death. The PBS Patient Summary contained only two instances (from April and May 2008) of oxycodone prescribing.

14. The CPU then reviewed the medical records provided by Werribee Primary Health Care, which listed additional oxycodone prescriptions to Daniel Anderson. It was apparent that Daniel Anderson must have been prescribed and dispensed these prescriptions on a private script. It was not clear why private scripts would have been provided, as the PBS Patient Summary showed that Daniel Anderson was eligible for the concessional rate on prescribed medications.

15. Table A1 in Attachment A shows each recorded oxycodone prescription from Dr Farnbach to Daniel Anderson at Werribee Primary Health Care between 3 May 2006 and his death in August 2009. The first recorded prescription was on 5 May 2006, and appeared to be to treat back pain. Subsequent entries are consistent with Dr Farnbach's 28 June 2011 statement to the Court; they indicate that the reason for prescribing was to treat pain associated with migraine.

16. Dr Farnbach prescribed oxycodone to Daniel Anderson only intermittently in 2006 and 2007 (a total of four occasions). In April 2008 he commenced prescribing more regularly; between April 2008 and Daniel Anderson's death in August 2009, Dr Farnbach prescribed him oxycodone in total 22 times. Additionally the quantity of prescribed oxycodone

increased, from 20 tablets per prescription in mid-2008 to between 60 and (on one occasion) 120 tablets in mid 2009. This increase appears to mirror the increase in oxycodone permitted to be supplied under the Drugs and Poisons Regulation permits.

Other opioid prescribing

17. Dr Farnbach prescribed Daniel Anderson several opioids in addition to oxycodone during the period between 3 May 2006 and 20 August 2009. Table B1 in Attachment B shows each relevant recorded opioid prescription or administration mentioned in the electronic patient medical history. The prescribed opioids included pethidine, morphine, dextropropoxyphene, codeine and tramadol; the usual reason Dr Farnbach recorded for providing these prescriptions was to treat Daniel Anderson's migraines.

Treatment provided by other doctors

18. There were also a number of other clinicians, including importantly Dr Abdalla, and practices other than Werribee Primary Health Care who were involved in Mr Anderson's care in the period leading up to his death. A significant feature of the treatment provided by other practitioners, is that with the exception of Dr Matkovic and psychologist Tim Murphy, they all provided opioid analgesics to Mr Anderson at one stage or another. If these analgesics are considered together with the opiods provided by Dr Farnbach, it becomes even more apparent that Mr Anderson had probably developed opioid dependence long before his death.

Comments and conclusions

19. Dr Anthony Farnbach's clinical notes show that from at least early 2006 he regularly prescribed strong opioids - including at various times detropropoxyphene, codeine, oxycodone, injectable morphine, injectable pethidine and tramadol - to treat Daniel Anderson's migraines.

20. In mid-2006 Dr Farnbach applied to Drugs and Poisons Regulation, Victorian Department of Health[3] for a permit to treat Daniel Anderson's migraines with injections of the Schedule 8 opioid pethidine. The permit was rejected for the following reason set out in a letter to Dr Farnbach dated 7 July 2006:

[3] Which at the time was known as the Drugs and Poisons Regulation Unit, and was located within the Department of Human Services; the shift into the Department of Health occurred after the Department of Health was created in 2009.

As you will see from the accompanying information sheet about pethidine, professional organisations and guidelines about pain management indicate that this drug, particularly in the injectable form, is not suitable for the treatment of migraine.

21. I note that the clinical issues regarding injectable pethidine for migraine treatment include the risk of developing opioid tolerance and addiction, and the risk of exacerbating migraine symptoms.[4]

22. Subsequently Dr Farnbach applied to Drugs and Poisons Regulation for a permit to treat Daniel Anderson's migraines with the Schedule 8 opioid oxycodone. The Manager of Treatment Approvals at Drugs and Poisons Regulation, confirmed the following permits were granted:

    - Dr Farnbach was granted a permit to prescribe 5mg daily oxycodone to Daniel Anderson on 4 July 2008. The clinical diagnosis nominated on the permit application was "intermittent migraines".
    - On 24 September 2008 a new permit was granted for Dr Farnbach to prescribe 10mg daily oxycodone to Daniel Anderson. Again, the clinical diagnosis was "intermittent migraines".
    - On 30 January 2009 a new permit was granted for Dr Farnbach to prescribe 30mg daily oxycodone to Daniel Anderson. The clinical diagnosis nominated on the permit application was "migraines".

23. Clinical notes indicate that Dr Farnbach prescribed oxycodone to Daniel Anderson in quantities consistent with these permits; Pharmaceutical Benefits Scheme (PBS) data shows that Daniel Anderson presented the scripts and was dispensed the oxycodone. In addition, Dr Farnbach continued to supply other opioids (particularly codeine, and to a lesser extent pethidine injections) to Daniel Anderson while treating him with an escalating daily dose of oxycodone.

24. From the outset of my investigation, I held concerns regarding Dr Farnbach's practice of prescribing oxycodone to treat Daniel Anderson's migraines. If pethidine was regarded as a clinically inappropriate treatment for migraine, I could not identify any reason why oxycodone - another powerful opioid analgesic with significant potential for dependence

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[4] Somogyi AA, "Pethidine is inappropriate for migraine", *Australian Prescriber*, vol 20, 1997, p.71.

and abuse - should be deemed appropriate. I was further concerned because the oxycodone was prescribed on a daily basis, whereas the clinical diagnosis nominated in the first two permits was "intermittent migraine". A logical conclusion to draw from this was that the oxycodone must have been prescribed not only to treat episodes of acute migraine, but for ongoing migraine prophylaxis (prevention of migraine onset).

25. To assist this aspect of my investigation, the CPU reviewed a range of clinical guidelines for using drugs to treat migraine. The CPU identified two Australian guidelines[5] and four international guidelines[6] published since 2000 that address the use of drugs (1) to treat acute migraine symptoms, and (2) for migraine prophylaxis/prevention. In summary:

- Two guidelines recommended that opioids should never be used to treat acute migraine symptoms.
- Two guidelines recommended that opioids must be avoided to treat acute migraine symptoms.
- Two guidelines recommended that opioids should only be used to treat acute migraine symptoms where other treatments have failed and/or where appropriate controls are in place to manage the significant risk of dependence, abuse and over-sedation.
- No guidelines recommended opioids for migraine prophylaxis.

26. The apparent lack of a clinical rationale for prescribing daily oxycodone to treat intermittent migraine, in turn led me to question why Drugs and Poisons Regulation would grant the permits that enabled the prescribing. I directed the Coroners Court of Victoria Principal Registrar to make inquiries of Drugs and Poisons Regulation in a letter dated 2 March 2013. The Court received a response from the Chief Officer, Drugs and Poisons Regulation by letter dated 8 May 2013.

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[5] Best J, et al, "Headache and Migraine", *National Prescribing Service Newsletter*, vol 38, January 2005; Therapeutic Guidelines, "Migraine", *eTG Complete*, revised June 2011.

[6] Silberstein SD, "Practice parameter: Evidence-based guidelines for migraine headache (an evidence-based review)", *Neurology*, vol 55, no 6, September 2000; Evers S, et al, "European Federation of Neurological Societies guideline on the drug treatment of migraine – revised report of an EFNS task force", *European Journal of Neurology*, vol 16, 2009, pp.968-981; MacGregor EA, et al, " Guidelines for All Healthcare Professionals in the Diagnosis and Management of Migraine, Tension-Type, Cluster and Medication-Overuse Headache", British Association for the Study of Headache, third edition (first revision), 2010; National Institute for Health and Clinical Excellence, "Headaches: Diagnosis and management of headaches in young people and adults," NICE Clinical Guideline 150, September 2012.

27. I have attached to this finding the Court letter and the Chief Officer's response, so I do not intend to recount their contents here in detail. Rather, I draw particular attention to certain significant exchanges. In response to a question about why the oxycodone permit was granted in circumstances where pethidine was not considered suitable, the Chief Officer indicated:

> *A permit for oxycodone was granted because it is a Schedule 8 drug approved for us in Australia and is indicated for the clinical diagnosis provided by Dr Farnbach. Unlike pethidine, the department has not been provided with recommendations from professional organisations advising that the risks with using oxycodone for migraine pain significantly outweigh its therapeutic benefit.*

28. I hold some reservations regarding this response. Specifically, the claim that oxycodone was "indicated for the clinical diagnosis provided by Dr Farnbach" does not appear to be supported by extant clinical guidelines. There are differences between guidelines on the question of whether opioids are appropriate to treat acute migraine symptoms, but to my knowledge no guideline supports long-term daily opioid administration for intermittent migraine.

29. I am surprised by the Chief Officer's response to a question regarding the Department's current position on prescribing daily oxycodone to treat migraine for an extended period:

> *Such considerations are matters of clinical judgment for the practitioner to assess in each particular case.*

30. This suggests that Drugs and Poisons may be continuing to issue permits for doctors to treat migraine with Schedule 8 opioids on a daily basis, thus supporting and propagating a practice that (even if properly managed) may not be clinically efficacious and which may result in opioid dependence while potentially exacerbating migraine symptoms.

31. I acknowledge the Drugs and Poisons Regulation indication that it "has not been provided with recommendations from professional organisations" regarding long-term daily prescribing of oxycodone to treat migraine, though I note that there are several addiction medicine specialists within the Victorian Department of Health who might provide this clinical guidance. I also acknowledge that the migraine treatment guideline analysis was undertaken by CPU staff who are not clinical experts in either migraine management or addiction medicine. For these reasons, I am not in a position to make any recommendation directly addressing the clinical appropriateness of issuing Schedule 8 permits to treat

migraine. Rather, my recommendations address the pressing need for Drugs and Poisons Regulation to inform itself regarding use of opioids to treat migraine, and thus to prevent harms and deaths associated with clinically inappropriate opioid prescribing.

Finding

I find that Mr Daniel Anderson unfortunately died from oxycodone toxicity in the circumstances set out herein.

RECOMMENDATIONS

Pursuant to section 72(2) of the **Coroners Act 2008**, I make the following recommendation(s) connected with the death:

1. That the Victorian Department of Health consult with relevant peak medical bodies such as the Australian and New Zealand College of Anaesthetists' Faculty of Pain Medicine and the Royal Australasian College of Physicians' Australasian Chapter of Addiction Medicine to obtain expert advice on the clinical appropriateness of (1) short-term opioid prescribing to treat migraine, and (2) long-term (greater than eight weeks) continuous opioid prescribing to treat migraine.

2. That, having obtained expert advice on use of opioids to treat migraine, Drugs and Poisons Regulation review its procedures to ensure any application nominating migraine (intermittent as otherwise) as the clinical diagnosis for prescribing a Schedule 8 opioid, is evaluated consistently with the expert advice.

3. That, having obtained expert advice on use of opioids to treat migraine, Drugs and Poisons Regulation review all current valid permits nominating migraine (intermittent as otherwise) as the clinical diagnosis for prescribing a Schedule 8 opioid, and assess whether each permit was issued consistently with the expert advice. Drugs and Poisons Regulation should take appropriate steps to notify prescribers and if necessary cancel permits that were not issued for appropriate clinical diagnoses.

Pursuant to rule 64(3) of the Coroners Court Rules 2009, I order that the following be published on the internet:

The circumstances, finding and recommendations.

I direct that a copy of this finding be provided to the following:

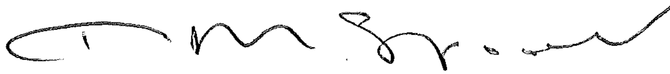
The Family of Mr Daniel Anderson

Mr Malcolm Anderson

Ms Joanne Philo

Interested parties

Signature:



HEATHER SPOONER
CORONER
Date: 13. 2. 2014

Attachment A

Table A1: Oxycodone prescribing to Daniel Anderson by Dr Anthony Farnbach at Werribee Primary Health Care, 3 May 2006 to 20 August 2009.

Date	Brand	Qty	Dose	Reason for prescribing
5 May 2006	OxyNorm 10mg	20	Not specified	"Still has a sore back. No radiation down the legs. Stiff. No relief with the Paradex. Muscle tenderness in para sacral region. Protected gait. Physiotherapy. OxyNorm 10mg (20)."
9 May 2006	Proladone	U/K	Not specified	"Ongoing back pain. [...] Morphine 30mg intramuscular injection with Stemetil. Advised that can't just dish this out on a virtually daily basis. Try Proladone."
16 Feb 2007	OxyNorm 10mg	20	Not specified	"Looking for something to have as he has a migraine at 2 in the morning ... discussed trial of OxyNorm."
30 Mar 2007	OxyNorm 10mg	20	PRN	"Has had continuing migraine / stress / depression. Has a migraine yesterday ... two different doctors."
15 Apr 2008	Endone 5mg	20	Not specified	"In for some treatment for his chronic intermittent migraine. He is looking for an oral alternative ... pethidine, prescribed at the other clinic is no longer available ... discussed. [...] Trial of Endone ... he has had this before and it worked OK."
13 May 2008	Endone 5mg	20	1 tablet QID / PRN	"Has had a good run with his headaches ... needs a backup script for the next bout. OK now."
29 May 2008	Endone 5mg	20	1 tablet QID / PRN	"Script for early migraine control. Endone... only uses three or four boxes a year."
2 Jul 2008	Endone 5mg	20	1 tablet QID / PRN	"Has had an excellent response to the Endone. Has not had a shot since he started. Endone ... taking about five a wekk (in non daily doses. Mersyndol Forte. Permit sent off to Drugs and Poisons."
15 Jul 2008	Endone 5mg	20	Not specified	"Permit has arrived from the Health Department."
7 Aug 2008	Endone 5mg	20	1 tablet QID / PRN	"Going to Bali in a week. Needs scripts / needs a note for the airport."
29 Aug 2008	Endone 5mg	20	1 tablet QID / PRN	"Scripts for the migraines."
11 Sep 2008	Endone 5mg	20	1 tablet QID / PRN	Nothing in notes.

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Table A1 continued.

Date	Brand	Qty	Dose	Reason for prescribing
23 Sep 2008	OxyNorm 10mg	20	Not specified	"In for acute migraine. He is concerned about the use of too much Endone... using two tablets a time. Going through a packet of 20 in four weeks, then three weeks, then two weeks. [...] Increase the oxycodone to 10mg (fast release). Permit sent off ... one box every three weeks."
15 Oct 2008	OxyNorm 10mg	20	1 capsule PRN	Nothing in notes.
16 Oct 2008	OxyNorm 10mg	40	Not specified	"Tells me that he left the OxyNorm and Duofilm on the car roof last night... came to look for it today... not there. Made a report to the police. As he does not have a record of losing or overusing scripts, then I will replace it... police report scanned."
28 Oct 2008	OxyNorm 10mg	40	Not specified	Nothing in notes.
29 Nov 2008	OxyNorm 10mg	60	Not specified	Nothing in notes.
31 Dec 2008	OxyNorm 10mg	60	1 capsule PRN	"Migraines have been stable."
22 Jan 2009	OxyNorm 10mg	60	Not specified	"Still having migraines. Using on average 2-3 OxyNorm capsules. Permit is only for one ... need to increase the dose on the permit. New script written ... permit application sent off."
4 Feb 2009	OxyNorm 10mg	20	Not specified	"Migraine... script"
5 Feb 2009	OxyNorm 10mg	60	Not specified	"Full OxyNorm Script... auth."
3 Mar 2009	OxyNorm 10mg	60	1 capsule TID	Nothing in notes.
25 Mar 2009	OxyNorm 10mg	60	Not specified	"Repeat script for OxyNorm... using two / day... permit is for three / day."
21 Apr 2009	OxyNorm 10mg	120	1 capsule TID	Nothing in notes.
14 Jul 2009	OxyNorm 10mg	60	Not specified	Nothing in notes.
19 Aug 2009	OxyNorm 10mg	60	1 capsule TID	"Using an average two OxyNorm / day to control migraine... working well".

Attachment B

Table B1: Opioids other than oxycodone prescribed to Daniel Anderson by Dr Anthony Farnbach at Werribee Primary Health Care, 3 May 2006 to 20 August 2009. (*AIC means the opioid was administered in clinic rather than prescribed.)

Date	Opioid	Brand	Qty	Reason for prescribing
3 May 2006	Dextropropoxyphene Codeine	Paradex Mersyndol Forte	60 40	"Patient is well known to me from other clinic. Has a sore lower back with some discopathy symptoms. Using Indocid and Mersyndol Forte. Has a history of chronic migraines. Will occasionally require IM narcotic analgesia ... genuine patient, not a drug seeker."
7 May 2006	Morphine	(injection)	*AIC	"Partial response to the OxyNorm. Walking with an extreme protected gain. Spasm / reduced range of movement. Morphine 30mg IMI with Maxolon 10mg."
9 May 2006	Morphine	(injection)	*AIC	"Ongoing back pain. [...] Walking with an extreme protected gait. Morphine 30mg IMI with Stemetil. Advised that can't just dish this out on a virtually daily basis. Try Proladone. If he needs more narcotic pain relief ... may have to refer him to hospital for further treatment."
11 May 2006	Morphine Codeine Pethidine	(injection) Mersyndol Forte (injection)	*AIC 40 5	"Back is significantly better. [...] Still has some back pain, though able to function okay. Unable to tolerate morphine due to nausea. Good response to Proladone. Requesting a care plan for his migraines. [...] Care plan for migraine done. Will have to give him a script for pethidine next time he presents with an acute migraine ... he will keep them here."
5 Jul 2006	Pethidine	(injection)	5	Nothing in notes.
7 Jul 2006	Codeine	Mersyndol Forte	20	"Migraine today. Has been under a lot of stress with his mother dying. Not coping. Pethidine / Maxolon. No more tomorrow as three days in a row would be too much."
11 Jul 2006	Codeine	Mersyndol Forte	40	"Should be expecting an improvement in his migraines / anxiety over the week or so. Still having migraines / headaches. Permit for pethidine has bee knocked back. Mersyndol Forte. [...] Discussed non-pethidine alternatives for the migraines."
3 Aug 2006	Codeine	Mersyndol Forte	40	"Has come in for a repeat script. Has been doing well."
22 Aug 2006	Pethidine	(injection)	*AIC	"Acute migraine today. Has been working five days in a row. Woke up this morning at 6am with an acute migraine. No photophobia. [...] In obvious pain. Pethidine 100mg with Maxolon."

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Table B1 continued

Date	Opioid	Brand	Qty	Reason for prescribing
22 Aug 2006	Morphine	(injection)	*AIC	"Has returned with his migraine. Didn't go with the [pethidine shot I gave approximately five hours ago. Doubled over in pain. Morphine 15mg given IV with partial effect only."
24 Aug 2006	Codeine	Mersyndol Forte	60	"Feeling much better than his last visit. Concerned about the headaches. Would like to make sure that there is nothing sinister. Well / alert / in no apparent pain. [...] Repeat script for Mersyndol Forte."
6 Oct 2006	Codeine	Mersyndol Forte	60	Nothing in notes.
11 Jan 2007	Codeine	Mersyndol Forte	60	"Recurrent headaches. Has had a good run lately."
30 Jan 2007	Codeine	Mersyndol Forte	60	"In for a repeat script. Has been in good health."
16 Feb 2007	Codeine	Mersyndol Forte	60	"Wants some Mersyndol Forte. Also looking for something to have as he has a migraine at 2 in the morning."
2 Mar 2007	Morphine Codeine	MS Contin Mersyndol Forte	20 20	"Has had a migraine for the last week. Related to some stressors with his wife, who is wanting to split up. Taking oxycodone etc with no effect on the headache. Some effect with Nurofen Plus. As a one off ... MS Contin."
30 Mar 2007	Codeine	Mersyndol Forte	60	"Has had continuing migraine / stress / depression. Has a migraine yesterday ... two different doctors. Migraine not so bad today, but the anxiety and depression are still a problem. Wanting something that he can take at home in case he is unable to get to a doctor."
29 May 2007	Codeine	Mersyndol Forte	60	Nothing in notes.
14 Aug 2007	Codeine	Mersyndol Forte	60	Nothing in notes.
30 Aug 2007	Codeine	Mersyndol Forte	120	"Going to Bali in a week. Needs some scripts and a letter for customs."
14 Nov 2007	Codeine	Mersyndol Forte	120	"Give some Mersyndol as a back up for his migraine ... discussed."
15 Dec 2007	Morphine	(injection)	*AIC	"Of note ... developed an acute migraine while here in the clinic. Given morphine 15mg with Maxolon 10mg IMI."
24 Feb 2008	Codeine	Mersyndol Forte	60	"Needs some Mersyndol for the headaches."
11 Mar 2008	Codeine	Mersyndol Forte	120	"Has been well."

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Table B1 continued

Date	Opioid	Brand	Qty	Reason for prescribing
13 May 2008	Codeine	Mersyndol Forte	60	"Has had a good run with his headaches ... needs a backup script for the next bout."
27 May 2008	Codeine	Panadeine Forte	60	"Had a migraine this morning. [...] Taking PRN Mersyndol Forte ... wants a script ... given Panadeine Forte and Restavit (as requested) to save money."
2 Jul 2008	Codeine	Mersyndol Forte	60	"Mersyndol Forte."
7 Aug 2008	Codeine	Mersyndol Forte	60	"Going to Bali in a week. Needs scripts / needs a note for the airport."
29 Aug 2008	Codeine	Mersyndol Forte	60	"Has not been to Bali yet. [...] Scripts for the migraines."
2 Sep 2008	Codeine	Panadeine Forte	20	"Tenderness over the frontal sinus."
23 Sep 2008	Codeine	Mersyndol Forte	60	"In for acute migraine."
15 Oct 2008	Codeine	Mersyndol Forte	60	Nothing in notes.
29 Nov 2008	Codeine	Mersyndol Forte	60	"Some insomnia, is having some building / construction outside his house."
31 Dec 2008	Codeine	Mersyndol Forte	60	"Migraines have been stable. [...] Referral to Dr Matkovic for an MRI (has not had one yet)."
1 Jan 2009	Pethidine	(injection)	*AIC	"Acute migraine since 11pm last night (not related to booze ... being New Year's Eve. Clearly in pain. Photophobia and sonophobia noted. Pethidine 100mg / Maxolon."
3 Mar 2009	Codeine	Mersyndol Forte	60	"In for scripts. Has been doing well."
21 Apr 2009	Codeine Tramadol	Mersyndol Forte Tramal	60 20	Nothing in notes.
14 Jul 2009	Codeine	Mersyndol Forte	60	Nothing in notes.
16 Jul 2009	Pethidine	(injection)	*AIC	"Has a migraine today. Oxycodone and Mersyndol are not controlling it. Pethidine 100mg with Maxolon 10mg given IMI."

Coroners Court of Victoria

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2 March 2013

Matthew McCrone
Chief Officer
Drugs and Poisons Regulation
Mental Health, Drugs and Regions
Department of Health
50 Lonsdale Street
Melbourne VIC 3000

Dear Mr McCrone

Coroner Heather Spooner is investigating the death of Daniel Anderson (reference number 4088 of 2009), who was found deceased on 20 August 2009 from the toxic effects of prescribed oxycodone. Coroner Spooner directed me to seek your advice on certain issues relating to the Schedule 8 permits that the Department of Health issued for Dr Anthony Farnbach to prescribe oxycodone to Daniel Anderson.

Attachment A to this letter sets out the specific questions that Coroner Spooner would like you to address regarding the permits. A response by 29 March 2013 would be most appreciated.

If you require any further information or clarification, or you are unable to meet the requested timeline, please do not hesitate to contact Jeremy Dwyer (the Coroners Prevention Unit case investigator who is directly assisting the coroner) on (03) 8688 0746 or via email: <Jeremy.Dwyer@coronerscourt.vic.gov.au>.

Yours sincerely

Margaret Craddock
Principal Registrar
Coroners Court of Victoria

Attachment A

<u>Background: Permits issued to prescribe oxycodone to Daniel Anderson</u>

On 3 January 2012 the Court contacted Drugs of Dependence to request the history of permits issued to prescribe Schedule 8 poisons to Daniel Anderson. Justin Lam, the Manager of Treatment Approvals and Projects, replied on 10 January 2012 to confirm that three permits had been granted:

- On 4 July 2008 Dr Anthony Farnbach was granted a permit to prescribe 5mg daily oxycodone to Daniel Anderson.
- On 24 September 2008 a revised permit was granted for Dr Farnbach to prescribe 10mg daily oxycodone to Daniel Anderson.
- On 30 January 2009 a revised permit was granted for Dr Farnbach to prescribe 30mg daily oxycodone to Daniel Anderson.

The Court further contacted Justin Lam on 13 December 2012 to find out what Dr Farnbach listed as the clinical diagnosis to support the oxycodone prescribing. Justin Lam responded on 18 December 2012 that:

> The clinical diagnosis stated on Dr Farnbach's first two applications was 'intermittent migraines'. The third application was 'migraines'.

The Court obtained the Pharmaceutical Benefits Scheme (PBS) Patient Summary for Daniel Anderson as well as Dr Farnbach's clinical notes, and confirmed that oxycodone had been prescribed and dispensed to Daniel Anderson consistently with permit quantities across the period from July 2008 to his death in August 2009.

The Court notes that in addition to the three permits listed above, Dr Farnbach applied to Drugs and Poisons Regulation in 2006 for a permit to treat Daniel Anderson's migraines with pethidine. This application was rejected by Drugs and Poisons Regulation on 7 July 2006 for the following reason:

> As you will see from the accompanying information sheet about pethidine, professional organisations and guidelines about pain management indicate that this drug, particularly in the injectable form, is not suitable for the treatment of migraine.

<u>Questions regarding permit policy between July 2008 and January 2009</u>

According to the August 2009 Drugs and Poisons Regulation Group "Policy for the issue of permits to prescribe Schedule 8 poisons", the following was the normal practice at the time of Daniel Anderson's death for assessing the clinical merits of an application:

> Normally the clinical judgement of the practitioner will be accepted when assessing applications. Where an application is received and:-
>
> i. the drug is indicated for the specified diagnosis for that patient, and

ii. is within the normal therapeutic dose range, and

iii. there is no history of previous permits or notifications

the permit will generally be issued with no further contact with the applicant.

However the Court does not have the earlier policy that would have been in force between July 2008 and January 2009 when the Drugs and Poisons Regulation Group originally granted the permits to Dr Farnbach.

1. Between July 2008 and January 2009, when Drugs and Poisons Regulation Group staff considered whether or not to grant an application to treat a patient with a Schedule 8 drug, what consideration was given to the clinical diagnosis listed in the application?
2. Between July 2008 and January 2009, did the Drugs and Poisons Regulation Group have a position on the suitability of prescribing Schedule 8 opioids on a daily basis for an extended period (greater than eight weeks) to treat acute migraine and/or for migraine prophylaxis?
3. Between July 2008 and January 2009, did the Drugs and Poisons Regulation Group believe that daily oxycodone was indicated for migraine treatment, and that 30mg daily would be within the normal therapeutic dose range for treating migraine?
4. The Drugs and Poisons Regulation Group rejected Dr Farnbach's application for a permit to treat Daniel Anderson's migraines with pethidine, but granted Dr Farnbach's subsequent applications for permits to treat Daniel Anderson's migraines with daily oxycodone. Why was the oxycodone permit granted in circumstances where pethidine was not considered suitable?
5. The daily dose of oxycodone approved for prescribing and dispensing to Daniel Anderson, rose from 5mg daily to 10mg daily then 30mg daily in the space of six months. Between July 2008 and January 2009 would this have been regarded as repeated dose escalation? If so, would Drugs and Poisons Regulation have expected Dr Farnbach to seek specialist advice to support the prescribing?

<u>Questions regarding current policy and practice</u>

The May 2011 Drugs and Poisons Regulation "Policy for the issue of permits to prescribe Schedule 8 poisons", contains identical text to the August 2009 Policy as regards consideration given to assessing clinical appropriateness:

> Normally the clinical judgement of the practitioner will be accepted when assessing applications. Where an application is received and:-
>
> i. the drug is indicated for the specified diagnosis for that patient, and
>
> ii. is within the normal therapeutic dose range, and
>
> iii. there is no history of previous permits or notifications

the permit will generally be issued with no further contact with the applicant.

This May 2011 Policy appears to be the most recent such policy issued by Drugs and Poisons Regulation, and is therefore regarded as current.

6. Presently, when Drugs and Poisons Regulation considers whether or not to grant an application to treat a patient with a Schedule 8 drug, what consideration is given to the clinical diagnosis listed in the application? In particular, are there any considerations beyond those set out in the May 2011 Policy?

7. Does Drugs and Poisons Regulation currently have a position on the suitability of prescribing oxycodone on a daily basis for an extended period (greater than eight weeks) to treat acute migraine and/or for migraine prophylaxis? If so, what is the position?

8. Does Drugs and Poisons Regulation currently believe that daily oxycodone is indicated for migraine treatment, and that 30mg daily would be within the normal therapeutic dose range for treating migraine, in line with the May 2011 policy?

9. If Drugs and Poisons Regulation received today an application for a permit to prescribe 30mg daily oxycodone for an extended period (greater than eight weeks), and the clinical diagnosis on the application was "migraines" or "intermittent migraines", under what circumstances would the permit be granted?

<u>Other issues</u>

10. If there is any further information or comment you wish the coroner to consider in her investigation, this would be welcomed.

Department of Health

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Our Ref: e3067103

Your Ref: 4088/2009

8 May 2013

Margaret Craddock
Principal Registrar
Coroners Court of Victoria
Level 11, 222 Exhibition Street
MELBOURNE 3000

Dear Ms Craddock

Coroners Court reference: 4088/2009 Daniel Anderson

Thank you for your letter dated 2 March 2013 requesting a response in relation to questions raised by Coroner Spooner, as part of the Coroner's investigation into the death of Daniel Anderson.

I provide the following information in response to Coroner Spooner's queries:

1. *Between July 2008 and January 2009, when Drugs and Poisons Regulation Group staff considered whether or not to grant an application to treat a patient with a Schedule 8 drug, what consideration was given to the clinical diagnosis listed in the application?*

Although there was no published policy at that time, the standard procedures for departmental officers in assessing an application included considering whether the Schedule 8 drug was approved for use in Australia and/or indicated for the clinical diagnosis provided.

2. *Between July 2008 and January 2009, did the Drugs and Poisons Regulation Group have a position on the suitability of prescribing Schedule 8 opioids on a daily basis for an extended period (greater than eight weeks) to treat acute migraine and/or for migraine prophylaxis?*

None of the applications from Dr Anthony Farnbach mentioned the use of opioids for migraine prophylaxis. The department does not have a position on the suitability of prescribing Schedule 8 opioids on a daily basis for an extended period to treat acute migraine and/or for migraine prophylaxis. Such prescribing considerations are matters of clinical judgment for the practitioner to assess in each particular case.

3. *Between July 2008 and January 2009, did the Drugs and Poisons Regulation Group believe that daily oxycodone was indicated for migraine treatment, and that 30mg daily would be within the normal therapeutic dose range for treating migraine?*

Medical practitioners are required to take all reasonable steps to ensure a therapeutic need exists when prescribing any prescription drug. An oxycodone dose of 30mg daily is within the normal therapeutic dose range for use as an analgesic. The department relies on the clinical judgment of the practitioner to assess the appropriateness of prescribing a Schedule 8 drug and the severity of the condition to require the use of a Schedule 8 drug in each particular case.

4. *The Drugs and Poisons Regulation Group rejected Dr Farnbach's application for a permit to treat Daniel Anderson's migraines with pethidine, but granted Dr Farnbach's subsequent applications for permits to treat Daniel Anderson's migraines with daily oxycodone. Why was the oxycodone permit granted in circumstances where pethidine was not considered suitable?*

The department's procedures at the time were to not issue permits for pethidine for migraine, unless specialist support had been obtained for its use. The refusal to issue a permit for pethidine was consistent with recommendations from professional organisations with regard to the established risks of pethidine use. In refusing to issue a permit, the department had provided an information leaflet prepared by a departmental medical advisor in April 2003 outlining the risks of use of pethidine for migraine to Dr Farnbach. A copy of the pethidine information leaflet is enclosed for your reference (Attachment A).

A permit for oxycodone was granted because it is a Schedule 8 drug approved for use in Australia and is indicated for the clinical diagnosis provided by Dr Farnbach. Unlike pethidine, the department has not been provided with recommendations from professional organisations advising that the risks with using oxycodone for migraine pain significantly outweigh its therapeutic benefit.

5. *The daily dose of oxycodone approved for prescribing and dispensing to Daniel Anderson, rose from 5mg daily to 10mg daily then 30mg daily in the space of six months. Between July 2008 and January 2009 would this have been regarded as repeated dose escalation? If so, would Drugs and Poisons Regulation have expected Dr Farnbach to seek specialist advice to support the prescribing?*

In circumstances where repeated dose escalations occur unsanctioned by the medical practitioner, the department would expect medical practitioners to seek specialist advice to support the prescribing, as this may be an indicator of drug dependency or aberrant drug-related behaviours being exhibited by the patient. The department was not informed that dose increases of oxycodone being prescribed by Dr Farnbach were as a result of unsanctioned dose escalation. That is to say, the increased doses are a matter for Dr Farnbach's clinical judgment.

6. *Presently, when Drugs and Poisons Regulation considers whether or not to grant an application to treat a patient with a Schedule 8 drug, what consideration is given to the clinical diagnosis listed in the application? In particular, are there any considerations beyond those set out in the May 2011 Policy?*

The matters that are considered are outlined in the *Policy for the issue of permits to prescribe Schedule 8 poisons* (the Policy), and include whether the Schedule 8 drug was indicated for the clinical diagnosis provided.

7. *Does Drugs and Poisons Regulation currently have a position on the suitability of prescribing oxycodone on a daily basis for an extended period (greater than eight weeks) to treat acute migraine and/or for migraine prophylaxis? If so, what is the position?*

Such considerations are matters of clinical judgment for the practitioner to assess in each particular case.

8. *Does Drugs and Poisons Regulation currently believe that daily oxycodone is indicated for migraine treatment, and that 30mg daily would be within the normal therapeutic dose range for treating migraine, in line with the May 2011 policy?*

Medical practitioners are required to take all reasonable steps to ensure a therapeutic need exists when prescribing any prescription drug. The Policy refers to guidelines which advise practitioners that the maximum dose of oxycodone should not exceed 80mg daily without specialist advice.

9. *If Drugs and Poisons Regulation received today an application for a permit to prescribe 30mg daily oxycodone for an extended period (greater than eight weeks), and the clinical diagnosis on the application was "migraines" or "intermittent migraines", under what circumstances would the permit be granted?*

The department relies on the clinical judgment of the practitioner to assess the appropriateness of prescribing a Schedule 8 drug and the severity of the condition to require the use of a Schedule 8 drug in each particular case. The department also expects practitioners to have formulated a pain management plan when deciding to prescribe opioids. In the absence of a reported history of drug dependency or aberrant drug-related behaviour, a permit to treat a patient with oxycodone 30mg daily that the practitioner has deemed appropriate to prescribe would likely be issued.

I trust this information addresses your questions sufficiently. Should you need further information please contact me on (03) 9096 5066.

Yours sincerely

Matthew McCrone
Chief Officer
Drugs and Poisons Regulation

ATTACHMENT A

Pethidine injections: not for migraine.

In the past decade there has been a dramatic improvement in the management of migraine, including the introduction of a new class of drugs (triptans) to treat acute migraine.

At the same time there is increased recognition that pethidine causes more adverse outcomes than other opioids. Since pethidine has no clinical advantage, it is a poor choice if multiple doses are required.

Professional organisations now recommend that pethidine be avoided, particularly for the treatment of migraine (see box below).

As a result, pethidine use in Victoria has decreased by 44% since 1994. Despite this, Victoria has the second highest per capita use of pethidine in Australia.

PROFESSIONAL RECOMMENDATIONS ABOUT MIGRAINE AND PETHIDINE

Australian Association of Neurologists' ad hoc committee on the use of opioids in the management of migraine.
"Pethidine should not be used for migraine treatment unless the patient is unresponsive to all other measures or during pregnancy when the use of ergotamine tartrate preparations, triptans and dihydroergotamine is contraindicated."
"Frequency of use should be monitored as administration of short-acting opioids may reinforce drug-seeking behaviours and physiological dependence. Recognition of an apparent increase in dose or frequency of pethidine in this context should prompt specialist referral." (cited in NH&MRC Acute Pain Management: Scientific Evidence document below).

Australian Medicines Handbook, 2002.
"Inappropriate for treatment of migraine, has a short duration of effect, and is associated with drug-seeking behaviour." (p39).

Molloy A. Does pethidine still have a place in therapy? Aust Prescriber 2002;25:12-13.
"Pethidine is not recommended for conditions such as migraine."
Comments for Consumers: "Sometimes pethidine has been used to treat the severe headaches of migraine. This is no longer the correct treatment."

Murtagh J. Drugs for the doctor's bag. Aust Prescriber 1996;19:89-91.
"Dependence is an issue, so pethidine should be avoided for frequently recurring conditions such as migraine."

National Prescribing Service. Prescribing pointers: pethidine has no place in primary care, 2002.
"Pethidine is widely considered to be associated with drug-seeking behaviour, especially for recurring conditions such as migraine." "Pethidine has no role in the management of migraine, low back pain, or chronic pain."

NH&MRC Acute pain management: Information for general practitioners, CP59, Canberra, 1999.
"The use of short-acting opioids in young migraine patients may contribute to long-term pain management problems. Management of severe recurrent migraine requires detailed evaluation, especially if long-term use of opioids has arisen."

NH&MRC Acute pain management: scientific evidence, CP57, Canberra, 1999.
"Randomised, controlled trials have shown that pethidine is no more effective than dihydroergotamine, chlorpromazine or NSAIDS..." in the treatment of migraine.
There are very few situations in which pethidine is useful in acute migraine........

Somogyi AA. Pethidine is inappropriate for migraine. Aust Prescriber 1997;20:71.
"In the treatment of migraine, pethidine is less efficacious than dihydroergotamine plus metoclopramide: it can aggravate nausea, there is a risk of dependence and it has a short duration of effect necessitating additional medication. Its use cannot therefore be substantiated."

Therapeutic Guidelines Limited: Analgesic Guidelines 2002.
"Opioid analgesics should be used with great reluctance in the treatment of headache and only after all other measures have been tried and failed."
"If an opioid is required for the relief of a migraine attack, pethidine *should not* be used, as it is the opioid with the greatest potential for dependency and abuse."

Prepared by Drugs and Poisons Regulation Group, Department of Human Services, April 2003.
For references or more information, telephone: 1300 364 545

Victoria

RISKS OF PETHIDINE INJECTION FOR MIGRAINE.

Drug dependence and drug-seeking for pethidine
Any use of opioids is associated with a risk of dependence. The rapid onset of a euphorigenic effect from pethidine injections is particularly reinforcing of drug dependence. Pethidine is the drug most frequently abused by health professionals, and is commonly sought by patients seeking opioids. One in five PBS prescriptions for pethidine injections is obtained by individuals identified as 'doctor shoppers' attending 15 or more different general practitioners a year.

Analgesic-induced (rebound) headache.
Analgesics can promote headache. Analgesic-induced headache may result from chronic use of analgesics more frequently than on 2-3 days per week. The headache may be indistinguishable from the original headache, and lead to escalating drug use.

Norpethidine toxicity.
The pethidine metabolite norpethidine has a long half-life, and it accumulates with high or repeated dosing. Norpethidine is neurotoxic, causing CNS excitation, and risk is higher in the elderly and those with renal or hepatic impairment. Symptoms include tremor, agitation, confusion, muscle twitching and seizure. Pethidine lowers the seizure threshold in epileptics, and should be avoided.

Serotonin syndrome.
This syndrome results from an excessive dose of a drug or a combination of drugs that enhance CNS serotonin activity. Symptoms include: shivering, fever, sweating, tremor, incoordination, mental state changes, hyperreflexia, myoclonus, agitation, and diarrhoea. Drugs involved include pethidine, tramadol, and antidepressants.

Fibrous myopathy.
This is a deforming, fibrous infiltration of muscle tissue used for frequent and repeated injection. Muscle in the thighs and buttocks is replaced with dense, acellular fibrous tissue, clinically evident as woody induration. Affected tissue is prone to chronic abscess formation.

Pethidine is unsuitable for the treatment of migraine.

- It has a shorter duration than morphine, with no additional analgesic benefit
- It has just as many side-effects as morphine, including bronchospasm and increased biliary pressure
- It is metabolised to norpethidine, a neurotoxic metabolite with a long half-life, that accumulates with chronic use, especially in the elderly and patients with renal dysfunction
- It is associated with potentially serious interactions with other drugs, causing the serotonin syndrome
- Chronic injection creates a risk of serious fibrous myopathy and chronic abscess formation at the sites of injection
- It is the drug most commonly requested by patients seeking opioids for misuse
- It is the drug most commonly abused by health professionals.

MIGRAINE PRESCRIBING GUIDELINES

The ***New South Wales Therapeutic Assessment Group*** migraine treatment guidelines are accessible on the Internet at: http://www.clininfo.health.nsw.gov.au/nswtag/publications/index.html

Therapeutic Guidelines: Analgesic provides advice about migraine management. Copies can be obtained from:
Therapeutic Guidelines Limited
Level 2, 55 Flemington Road, North Melbourne, Vic 3051
Telephone (03) 9329 1566, email: sales@tg.com.au website: www.tg.com.au

The ***Australian Medicines Handbook 2002*** includes information about pethidine, and recommendations about the management of migraine. It can be obtained from:
Australian Medicines Handbook
PO Box 240, Rundle Mall, Adelaide SA 5000
Telephone (08) 8222 5861 email: amh@amh.adelaide.edu.au website: www.amh.net.au

PATIENT INFORMATION

The ***New South Wales Therapeutic Assessment Group*** patient leaflet about migraine describes the reasons that pethidine should not be used to treat it.
Website: http://www.clininfo.health.nsw.gov.au/nswtag/publications/guidelines/migraine_patient.pdf

The ***Australian Prescriber*** also provides a brief patient information leaflet accompanying an article "Does pethidine still have a place in therapy?" It states: "Sometimes pethidine has been used to treat the severe headaches of migraine. This is no longer the correct treatment."
Website: http://www.australianprescriber.com/index.php?content=/magazines/vol25no2/pethidine.htm