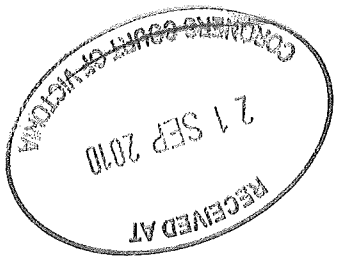
victorian pharmacy authority



20 September 2010

Ms Ainsley Marston
Coroner's Registrar
Coroners Court of Victoria
Level 1, 436 Lonsdale Street, MELBOURNE VIC 3000

Dear Ms Marston

Re: Court Ref:1816/07 Joeanne Brady

The Coroner, Mr John Olle inquired into the death of Mrs Joeanne Maree Brady (Court Ref No. 1816/07) who died from mixed drug toxicity (methadone, oxycodone, hydromorphone, mitrazapine, diazepam and promethazine).

Mr Olle made the following recommendation:
"That the Pharmacy Board of Victoria direct pharmacists to place warnings on narcotic medication, highlighting the fatal risks associated with combining narcotic medication".

The Board believed that the recommendation as it stands is inappropriate as many patients are, properly, taking two opioids, one being the base drug - usually an extended release product - and another being for breakthrough pain. The dose and frequency of administration of each drug as well as its particular pharmacokinetic properties must all be taken into account. To refer to "fatal risks" on the label is likely to discourage people in severe pain from taking analgesics.

Such risks should be advised by pharmacists when counselling clients for whom they are supplying narcotic medications, particularly when methadone represents a peculiar problem because of its unpredictable pharmacokinetics.

Such information has been routinely communicated to pharmacists in Circulars published by the Pharmacy Board of Victoria. The Board earlier this year funded a research project titled "Opioid replacement therapy in Victoria: the attitudes, understanding and suggestions of pharmacists" undertaken by researchers at the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University.

The Board resolved that an alternative to the Coroner's recommendation would be to publish the attached article (Attachment A) on the website.

The Board also believes that the article (Attachment B) published earlier this year by the Wyoming State Board of Pharmacy may be of assistance to the Coroners.

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For your information, the Pharmacy Board of Victoria has been decommissioned and its successor in law is the Victorian Pharmacy Authority with responsibility for the licensing of pharmacy owners and the registration of pharmacy premises. All matters pertaining to the registration and investigation of notifications regarding pharmacists is the responsibility of the Pharmacy Board of Australia following commencement of the National Registration and Accreditation Scheme on 1 July 2010.

If I can be of further assistance please do not hesitate to contact me on tel. 9356 8407.

Yours sincerely

Stephen Marty
Registrar

Methadone - unpredictable pharmacokinetics may lead to problems

Methadone's original role was as a synthetic substitute for morphine for the relief of pain and also for intractable cough. Since the pioneering work of Dole and Nyswander in the mid-1960s[1], its use has almost totally centred on its role in opioid dependency and many readers may not have used it for its original purposes. In recent years, there has been a return to its primary and important role as an analgesic, especially in chronic pain.

Methadone has a long terminal half-life which may cause problems with accumulation and toxicity. The time taken to reach steady-state concentrations following a change in dosing may be up to 12 days. Dose conversion ratios from other opioids are not static, but are a function of previous opioid exposure.[2] Although methadone is 1-2 times the potency of morphine in single dose studies, it has about 10 times the potency in individuals on long-term morphine. Its half-life on continuous dosing schedules is highly variable and may be up to about 100 hours, the increase being non-predictable. The potency and the half-life are patient dependent.[3] Accordingly, the current practice is to add a small dose to other opioids rather than a total conversion and switching; then it may be possible to reduce the dose of the background opioid.[4]

A recent coronial hearing that inquired into the death of a 39-year old woman with chronic non-malignant pain highlights the potential dangers of methadone. The patient had been taking oxycodone 30mg twice daily and hydromorphone parenterally 2mg two to three times per week; other drugs were mirtazapine, diazepam and promethazine. The physician decided to replace the oxycodone with methadone 20mg twice daily. The patient misunderstood the need to replace the oxycodone with methadone and took both drugs. The patient became "very lethargic" soon after taking the methadone and died several days later in her sleep.[5] It is not known how much methadone she took in total or whether more than one dose was taken.

With the increased use of opioids in general and methadone in particular, pharmacists need to ensure that the patient or the carer has a thorough understanding of the doses to be used and that the major adverse effect is respiratory depression which is manifested as sedation. As well as sharing this property with other opioids, large doses of methadone can produce QT prolongation and torsade de pointes.[6] Close attention to the patient's medication records at the time of dispensing is essential having regard to the doses and pharmacokinetics of other drugs (especially opioids) that the patient may be taking concomitantly.

References

1. Dole VP, Nyswander, ME. A medical treatment for diacetylmorphine (heroin) addiction, *JAMA* 193:646-650, 1965.
2. Palliative Care Expert Group. *Therapeutic Guidelines Palliative Care* Version 2, 2005, pp 101-102, 191.
3. Eap CB et al. Interindividual variability of the clinical pharmacokinetics of methadone: implications for the treatment of opioid dependence. *Clin Pharmacokinet* 2002; 41:1153-1193.
4. Casanova J. Opioid equivalence (part 2). *RGH Pharmacy E-Bulletin* 2010; 37(7).
5. Coroners Court of Victoria. Court reference 1816/07 www.coronerscourt.vic.gov.au accessed on 22 March 2010.
6. Andrews CM et al. Methadone-induced mortality in the treatment of chronic pain: role of QT prolongation. *Cardiol J* 2009; 16(3): 210-217

March 2010

Wyoming State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
http://pharmacyboard.state.wy.us

Inspections in 2009

By Richard Burton, RPh, Inspector/Compliance Officer

Each year the Wyoming State Board of Pharmacy requires the inspectors to ' esults of their yearly inspections. The results from these inspections wi y from year to year but a number of the discrepancies or findings reappear each year. There seems to be a correlation between the reappearance in some of these findings and the changing of the pharmacist-in-charge (PIC) at the pharmacies. The PIC does carry more responsibility, but the main responsibility is supervision of the pharmacy staff and making sure they do their job. When you read the listing below of inspector findings for 2009, you will find that each infraction is covered by rules in the Wyoming Pharmacy Practice Act or Wyoming Controlled Substance Act. These rules apply not just to the PIC but to each pharmacist and technician. Each pharmacy staff member has a responsibility to comply with the rules that govern the practice of pharmacy.

Major Findings for the 2009 Inspections

- Failure to sign and date controlled substance invoices when order received
- Failure of reconciliation of Schedule II perpetual inventory
- Technicians working with no license posted in the pharmacy
- Failure to separate controlled substance invoices from non-controlled substance invoices
- Expired drugs on active drug shelf
- (ily log book not current or signed
- dule II prescriptions not signed or dated when filled
- Technicians working without name tags
- Product ID on prescription with incomplete identification
- Pharmacists not displaying pharmacy license in the pharmacy
- Failure to complete Drug Enforcement Administration (DEA) Form 222 when order received

Methadone Deaths on the Rise

By Amanda Thompson, PharmD Candidate

Methadone, an opioid analgesic traditionally used as an agent for management of opioid, heroin, and morphine addiction, is now increasingly being prescribed for pain relief. According to the Centers for Disease Control and Prevention (CDC), "methadone has become one of the most widely prescribed opioid pain relievers, with 4 million prescriptions written for pain relief in 2006 alone." The CDC also states that deaths from opioid use have tripled since 1999 with 4,000 deaths in 1999 and 13,800 deaths in 2006, and methadone deaths, specifically, have increased from 790 to 5,420 respectively. Methadone's increasing use for pain management has made the medication more available for therapeutic and non-prescribed use. Its increased availability, lack of knowledge amongst providers and patients about methadone's potential hazardous effects, and lack of adequate monitoring all contribute to the rise in methadone related deaths.

The shift to methadone use from other opioids, such as OxyContin®, is partly due to the increased concern of OxyContin's abuse potential and high price. Methadone, a cheaper long-acting opioid analgesic, presents with various life threatening effects if not correctly monitored and dosed. Potentially fatal respiratory depression, cardiac effects, and varied range of elimination and drug interactions all add to methadone's risks. When used for management of opioid addiction, methadone is regulated by methadone-specific state and federal laws and closely monitored through the program. Only physicians enrolled in such programs are allowed to prescribe methadone for this use. When prescribed for pain, methadone is regulated by state and federal laws generally applied to all other controlled substances, and any physician is able to prescribe for its use. In this case, methadone could be prescribed by physicians who may not be fully aware of methadone's risks, monitoring needs, and dose individualization.

Most patients are also unaware of the potential risks of methadone. Methadone's pain alleviation lasts from around four to eight hours, and patients seeking adequate pain relief may take more medication than prescribed to them. The potential danger associated with this is that even though methadone's pain alleviation is relatively short, it can remain in the body for up to 59 hours. By continually adding extra doses, patients may find themselves unknowingly overdosing on methadone. Patients may also concomitantly take medications or substances such as benzodiazepines and alcohol that show to be dangerous and possibly fatal when taken with methadone. Patients taking non-prescribed methadone also fall into these risks. Data from DEA shows that nationwide methadone drug loss and theft has more than doubled, from 176 incidences in 2000, to 393 in 2007.

Efforts are being made to increase methadone's safety through physician and patient education, newly revised labels including more safety information for methadone tablets, and prescription drug monitoring program utilization. The state of Wyoming currently does not have any opioid treatment centers. Therefore, methadone prescriptions from physicians in the state will most likely be for pain and could possibly be less strictly monitored than when used for management of opioid addiction. Recorded deaths in Wyoming from methadone use remain extremely low; however, the use, overdose, and abuse of methadone are concerningly on the rise within the United States. Physicans, pharmacists, other health care providers, and patients can all play a role in methadone awareness and overdose and death prevention.

Major Focus of Board Inspectors During the 2010 Inspections

1. PIC responsibilities
2. Format to use for clear reconciliation of Schedule II perpetual inventory

continued on page 4

Court Reference: 1816 / 07

FORM 1

Rule 21

REGISTERED POST – SENDER TO KEEP
563507571010

AFFIDAVIT OF SERVICE

Section 55(2)(a) of the ***Coroners Act 2008***

In the matter of the investigation/inquest into the death of Joeanne Brady

I, Ainsley Nola Marston of Level 1, 436 Lonsdale Street, Melbourne in the State of Victoria make oath and say that—

1. At 4.30pm ON 10th June 2010 at Level 1, 436 Lonsdale Street, Melbourne, I served Mr Stephen Marty, Registrar, Pharmacy Board of Victoria with the following document(s):
   a) The Findings in relation to the death of Ms Joeanne Brady with Recommendations.

2. The method of service was by Registered Post

3. True copies of the documents served are attached.

SWORN/DECLARED by the deponent

At Melbourne
On 10th June 2010

Before me:

LIDIA LO GIUSTO
REGISTRAR
CORONERS COURT OF VICTORIA