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Royal Australian College of General Practitioners

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11 November 2022

Nicole D'Rozario
Coroner's Registrar
Coroners Support Services
65 Kavanagh Street
Southbank VIC 3006

cpuresponses@coronerscourt.vic.gov.au

Dear Coroner's Registrar D'Rozario

Re: Court ref: COR 2017 002579 – Investigation into the death of Jessica Higgins

The Royal Australian College of General Practitioners (RACGP) thanks the Coroners Court of Victoria for the letter dated 26 August 2022 regarding the investigation into the death of Jessica Higgins.

Requested responses to the following recommendations:

> *170. I therefore make the following recommendation (1):*
>
> *I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of considering buprenorphine in chronic pain management in appropriate cases.*
>
> *171. Furthermore, it is important that practitioners remain conscious of the need to consider the risks associated with concurrent medication prescribing in vulnerable patients, and that frequent reviews are undertaken in a face-to-face setting, to assess patients for signs of sedation or other adverse symptoms.*
>
> *172. I therefore make the following recommendation (2):*
>
> *I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate the risks associated with patients who are prescribed multiple and concurrent medications with sedative properties, and that frequent reviews of patients ought be undertaken in a face-to-face setting to assess for adverse signs and symptoms.*
>
> *173. Finally, as noted above, Ms Higgins' death prevents an opportunity to revisit the importance of ensuring that all interactions between providers and their patients are comprehensively documented in the patient's medical records, and that clear communication, including written records, is conducted in patients with multiple treating providers.*
>
> *174. Furthermore, providers should always confirm, in writing, clear instructions for patients regarding their medication usage and doses to avoid any ambiguity or possible adverse outcomes.*
>
> *175. I therefore make the following recommendation (3):*
>
> *I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of practitioners ensuring that all interactions with their patients, especially those with multiple providers, are documented in clear, written form in the patient's medical record, and that all patients are instructed in clear, written terms regarding their medication usage and doses to avoid potential adverse outcomes.*

RACGP Responses pursuant to section 72(2) of the Act:

170. I therefore make the following recommendation (1):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of considering buprenorphine in chronic pain management in appropriate cases.

Importance of buprenorphine in chronic pain management

Buprenorphine is a synthetic opioid derived from thebaine (1). Its long half-life (mean half-life 35 hours (2)) underpins its suitability for opioid agonist therapy. Its role in opioid agonist therapy was validated by a Cochrane review (3) which found that, "Buprenorphine is an effective medication in the maintenance treatment of heroin dependence, retaining people in treatment at any dose above 2 mg, and suppressing illicit opioid use (at doses 16 mg or greater) based on placebo-controlled trials."

Buprenorphine is available in Australia in the following formulations:

- **Temgesic sublingual tablets**: 200 mcg
- **Temgesic solution for injection**: 300 mcg / ml
- **Subutex sublingual pills**: 400 mcg / 2 mg / 8 mg
- **Suboxone sublingual film (co-formulated with naloxone 4:1 ratio)**: 2 mg (2/0.5mg) / 8 mg (8mg/2mg)
- **Transdermal patch:** 5 / 10 / 15 / 20 / 25 / 30 / 40 mg
- **Long-acting injectable buprenorphine (LAIB)**
- **Buvidal**: 8 / 16 / 24 / 32 / 64 / 96 / 128 / 160 mg
- **Sublocade:** 100 mg / 300 mg

Only Subutex, Suboxone, Buvidal and Sublocade are licensed in Australia for the purposes of opioid agonist therapy.

Dynamics of buprenorphine

Buprenorphine has antagonist activity at κ- and δ-opioid receptors. It is identified as a partial agonist at the mu receptor; however, it should be noted that whilst it is a partial agonist at mu in terms of the risk of respiratory depression, it is not a partial analgesic. In the context of pain management, the doses that are commonly used do not demonstrate an analgesic ceiling effect (4). Its unique properties as a full μ-opioid receptor agonist for analgesia, partial μ-opioid receptor agonist for respiratory depression, and κ-opioid receptor antagonist make this drug appealing as an analgesic, especially with regard to its adverse effects.

Partial agonist ceiling effects

Dahan et al. (4) demonstrated the ceiling effect of buprenorphine and stated that "We believe that [there] is sufficient proof to state that buprenorphine displays ceiling in respiratory depression over a dose range (0.05–0.6 mg) without causing any ceiling in analgesic effect".

This is confirmed by statements made in "Acute Pain Management: Scientific evidence" (5). *In clinically relevant doses, there is a ceiling effect for respiratory depression with buprenorphine but not for analgesia.*

Khanna et al. (6) also reports that buprenorphine has a ceiling effect with regard to ventilatory impairment. However, the further point is made in "Acute Pain Management: Scientific evidence": *Buprenorphine alone can cause fatal respiratory depression* (7)*, although in most cases (90%) other medications, in particular benzodiazepines and other sedatives, were found.*

172. I therefore make the following recommendation (2):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate the risks associated with patients who are prescribed multiple and concurrent medications with sedative properties, and that frequent reviews of patients ought be undertaken in a face-to-face setting to assess for adverse signs and symptoms

Risks associated with multiple and concurrent sedatives

Australia's annual overdose report 2022 (8), published by the Pennington Institute confirms once again that firstly polysubstance hypnosedative overdose remains the commonest cause of unintentional overdose related death in Australia, and secondly that opioids and benzodiazepines continue to make the greatest contribution to this risk. SafeScript, Victoria's real time prescription monitoring service identities the risk of overdose associated with high doses of opioids, and the use of combinations of methadone and fentanyl with any dose of any benzodiazepine. This position is supported by evidence that firstly high dose opioids (OMED in excess of 100 mg) are associated with an elevation in the risk of death by up to a factor of eleven (9), and secondly that combinations of benzodiazepines and opioids elevate the risk of death by up to a factor of ten (10).

Face to face reviews for assessment of adverse signs and symptoms

In the context of the prescribing of benzodiazepines (11), the importance of face to face reviews has been explicitly stated: "No repeat prescriptions will be made without face-to-face contact".

In other guidance (12) regarding the appropriate prescribing of opioids recommendations for a practice prescribing policy include the following:

- *All requests for repeat scripts for drugs of dependence will go to your usual doctor*
- *Requests may require a clinical review by your doctor*

In light of the coroner's findings the RACGP supports the strengthening of this advice and explicitly recommends that all patients in receipt of all SafeScript Monitored Medications be reviewed face to face prior to the issuance of a prescription unless exceptional circumstances preclude such a face-to-face review.

175. I therefore make the following recommendation (3):

I recommend that the Royal Australian College of General Practitioners and the Faculty of Pain Medicine reiterate to their members the importance of practitioners ensuring that all interactions with their patients, especially those with multiple providers, are documented in clear, written form in the patient's medical record, and that all patients are instructed in clear, written terms regarding their medication usage and doses to avoid potential adverse outcomes.

The RACGP reiterates and supports AHPRA's guidance in "Good Medical Practice" (13) wherein is stated the following regarding record keeping:

Maintaining clear and accurate medical records is essential for the continuing good care of patients. Good medical practice involves:

10.5.1 Keeping accurate, up to date and legible records that report relevant details of clinical history, clinical findings, investigations, diagnosis, information given to patients, medication, referral and other management in a form that can be understood by other health practitioners.

10.5.4. Ensuring that the records are sufficient to facilitate continuity of patient care.

The RACGP therefore supports and will enact the following coronial recommendation: "that the Royal Australian College of General Practitioners…reiterate to their members the importance of practitioners ensuring that all interactions with their patients, especially those with multiple providers, are documented in clear, written form in the patient's medical record, and that all patients are instructed in clear, written terms regarding their medication usage and doses to avoid potential adverse outcomes".

We hope that this information is useful. If you have any further questions about the above, please contact RACGP Victoria State Manager Kon Kakris via kon.kakris@racgp.org.au.

Yours sincerely

Dr Anita Muñoz
Chair, Victoria Faculty

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