ARTICLE

Opioid prescribing pitfalls: medicolegal and regulatory issues

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SUMMARY

Inappropriate opioid prescribing can lead to patient harm as well as a medicolegal risk to prescribers.

Prescribers need to be familiar with the indications, contraindications and harms associated with opioids.

When prescribing opioids, doctors must be aware of their clinical, ethical and legal responsibilities, particularly the legislative requirements in their state. Failure to comply with these can result in disciplinary action.

To avoid potential conflict with differing state regulations on opioid prescribing, doctors should advise patients to get their prescription dispensed in the same state in which it was written.

Introduction

In June 2014, a New South Wales deputy state coroner handed down findings into the deaths of three young patients in Sydney.[1] The coroner found that prescription drugs, some of which were opioids, caused or contributed to these unintentional deaths. The inquest highlighted examples of the difficulties in dealing with doctor-shopping behaviour, and involved hearing evidence from numerous practitioners who were often concurrently involved in the care of these patients.

More recently in December 2014, a Victorian coroner delivered findings into the death of a 38-year-old man with a long history of mental illness.[2] The man died of pneumonia in the setting of methadone and benzodiazepine use. The coroner found that the deceased received care and prescriptions from two GPs who had never met or spoken to each other about him. This reveals the difficulties and challenges of sharing prescribing information between doctors and practices.[2]

In their published findings, both of these coroners, along with others around the country, have recommended reforms to the way opioids are regulated, monitored and prescribed.

Opioid use in Australia

The use of opioids in acute pain and malignant disease is rarely in dispute. In contrast, their use for chronic non-malignant pain is controversial and there is limited evidence to justify the long-term use of opioids for this indication. This is partly due to the difficulty of conducting trials in patients with such heterogeneous conditions.[3,4] The evidence is often based on highly selected patients with minimal comorbidities, and placebo is used as the comparator rather than other pain control measures.[3,4] Population studies are not supportive of a good outcome for patients, but are often criticised because they are unable to show a causative link between opioids and overall health outcomes.

The prescription and consumption of opioids have markedly increased in Australia.[5] In the 20 years to 2012, there was a 15-fold increase in the number of opioid prescriptions dispensed.[6] In 2013 in Australia, there were 12 different opioids available in 241 formulations. Opioid use in Australia is high, particularly oxycodone and morphine,[6] but it is nowhere near the epidemic proportions seen in the USA.[7,8]

An editorial examining some of the reasons for the explosive increase in the use of opioids in the USA describes a paradigm shift in the treatment of pain.[7] The author states that 'In contemporary medical culture, self-reports of pain are above question, and the treatment of pain is held up as the holy grail of compassionate medical care.'

Not all opioid prescribing is for chronic pain. An Australian analysis of 4666 GP encounters found that 3.5% of opioids were prescribed for malignant neoplasm, 43.9% for chronic pain, and the remainder for non-chronic pain and other causes.[5,9] Nevertheless, there has been increasing concern surrounding the volume of opioids used for chronic non-malignant pain and associated harms. The need for vigilance has been highlighted.[3,9] Illicit diversion of opioids, which mirrors the increase in their prescription, is also of concern.[8]

The Pain and Opioids IN Treatment study[10] supports concern that opioids may impede patients getting

back to work, or do not help.[11] The study found that approximately two-thirds of patients treated with opioids are unemployed or receiving government benefits. This has prompted calls for practitioners to re-examine the goals of opioid therapy in patients.[11]

Harm from opioids

Adverse events associated with opioid use have been well documented.[3,12] Hospitalisations and deaths in which opioids have been a contributing factor are increasing.[6] As highlighted by the Coroners Court of Victoria, 82.8% of drug-related deaths in Victoria were due to prescription drugs.[13] The top contributing medicines were opioids and benzodiazepines.

The importance of regulation

The regulation of opioids is a public health issue.[14] The National Poisons Standard[15] sets out the scheduling of all poisons in accordance with the degree of individual risk, and the risk to public health and safety.[14] Each state and territory in Australia has the power to impose statutory control over the supply, access, record keeping, administration and disposal of all medicines and poisons.[14] Each state also has a system of monitoring the dispensing of opioids. However, they vary in their capability and scope of monitoring. Only Tasmania has a real-time dispensing monitoring system, referred to as Electronic Recording and Reporting of Controlled Drugs (ERRCD).

In writing a prescription for an opioid, doctors have a clinical, ethical and legal responsibility. The importance of abiding by the laws and regulations that govern prescribing cannot be understated. Doctors who disregard their responsibility risk being the subject of civil, disciplinary or coronial proceedings.

A review of 32 Victorian and NSW disciplinary decisions involving opioid prescribing between 2010 and 2014 has been reported. It found the practitioners were all GPs who were guilty of inappropriate prescribing of Schedule 8 or Schedule 4 drugs. The decisions all involved failure to keep adequate records and mostly involved inappropriate prescribing to multiple patients. However, three GPs had each prescribed to only one patient.[16] All of the doctors had conditions placed on their practice, and some were suspended or de-registered. Sanctions ranged from a caution through to a reprimand.[16]

Responsible and lawful prescribing

Treating patients with chronic non-malignant pain is always challenging. In addition to medicolegal considerations, all prescribers should consider and balance what is in the best interests of their patient (see Fig.). Opioids, which may have a role to play in some patients' management, should be prescribed in accordance with established guidelines and good clinical practice. In order to prescribe opioids safely, effectively, responsibly and lawfully, we recommend that GPs address a number of sequential questions.

Are opioids an appropriate choice?

To address this question, it is necessary to consider patient-specific factors that contribute to a doctor's clinical decision making including:[3,12,17,18]

- Should opioids be prescribed at all?
- Have all non-pharmacological options of management been considered?
- Is there a plan of management in place?
- Have the goals of treatment been defined?
- Have all of the pyschosocial factors been considered?
- Is the patient at risk of dependence?
- Are there potential drug interactions?
- Have the maximum dose and exit strategy been defined?

Before and after commencing an initial trial period of opioids, a comprehensive assessment should be performed.[19]

Are the clinical indication, dose, frequency, repeats and management plan clearly documented?

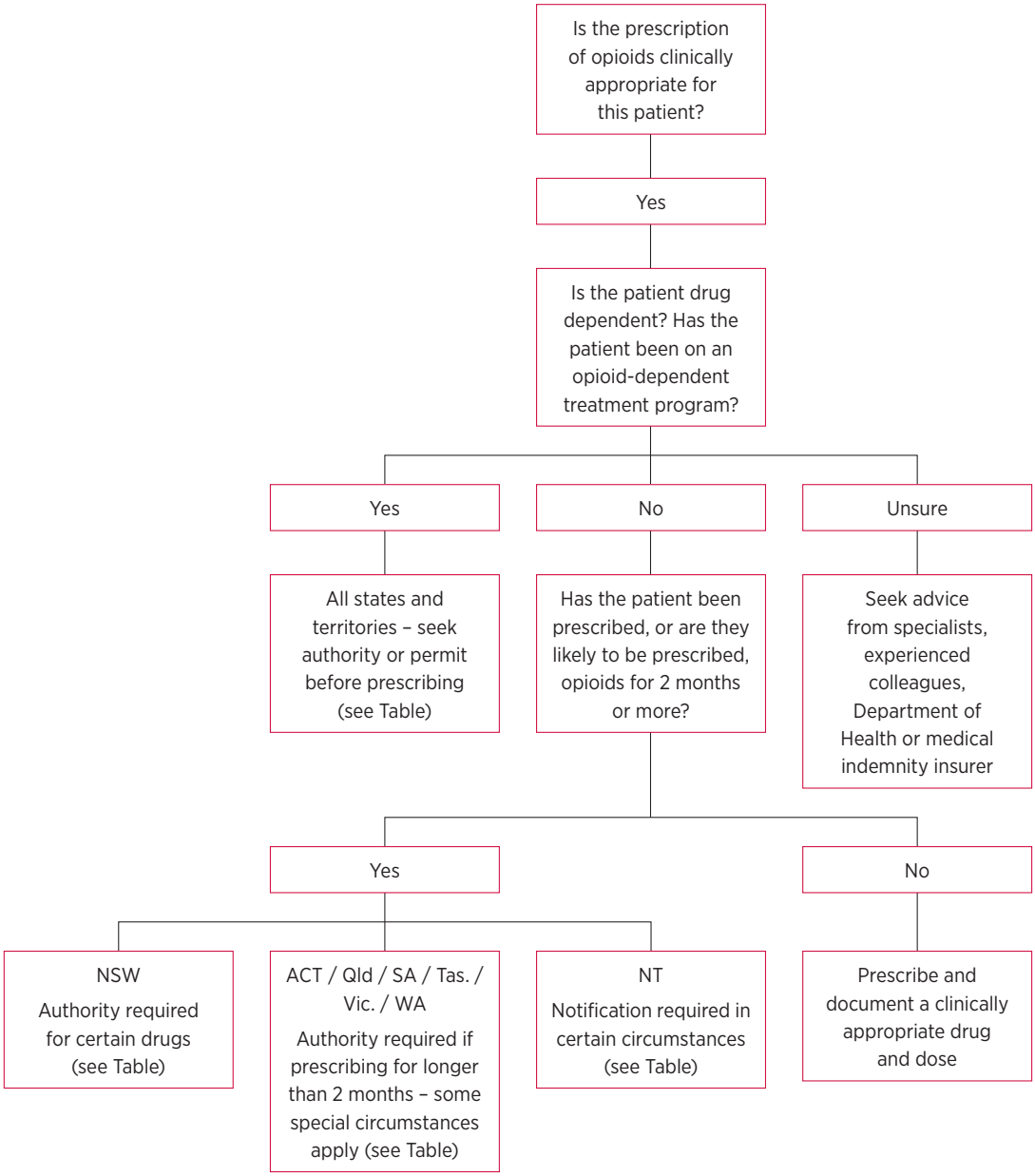
Clear, complete and adequate medical records are good clinical practice and reduce medicolegal risk. In some states, such as NSW, they are a statutory requirement.[20] Medical records are also a requirement of the Medical Board of Australia's Code of Conduct.[21]

Is an authority from the state-based pharmaceutical services unit required in addition to any PBS authority?

Many prescribers are not aware that an authority from the Pharmaceutical Benefits Scheme (PBS) is not the same as seeking an authority, or a permit, from the state-based pharmaceutical services unit or equivalent.

A sound understanding of the legislative definition of drug dependence is crucial. A prescriber must use clinical judgment to determine whether the patient is drug dependent in accordance with the legislative definition. The definition varies between states (see Table), but usually relates to the patient's behaviour (drug seeking or otherwise) rather than the medical definition of drug dependence which traditionally refers to physical dependence.[14] In many patients, this is not a simple task. Various coroners have noted that prescribers are often limited in their ability to identify such behaviour by systemic issues such as the absence of real-time prescription monitoring.

Fig. **Guide to the steps required to lawfully prescribe opioids**



It is crucial that all prescribers are aware of and comply with the legislative requirements (see Table). Although these differ from state to state, GPs should be aware of the following:

- If a GP knows (or ought to know) that a patient is drug dependent, an authority or permit must be sought (Table). This applies equally in circumstances where a patient who is on opioids starts to exhibit behaviour that would reasonably lead the GP to conclude that the patient is drug dependent. Furthermore, special consideration needs to be given to patients who are (or have been) on opioid treatment programs, as some states consider these patients as drug dependent.
- If the patient is not drug dependent, in most states (except NSW) the prescriber must notify or apply for a permit or authority if the patient has been treated with opioids (by any doctor) for longer than two months (see Table).
- In NSW, all injectable opioids, and some oral opioids (such as buprenorphine, methadone and hydromorphone), require an authority to be prescribed for longer than two months. The other opioids do not require an authority.
- In some states (such as Qld), rules for notification or permits apply for some Schedule 4 drugs of dependence, such as benzodiazepines.

- Advice on whether an authority or permit is required can be sought from the relevant state-based authority.

Failure to apply for a permit or authority is the most common allegation brought against GPs who find themselves the subject of disciplinary proceedings.

Interstate prescriptions

The movement of patients (and GPs) across state borders is not uncommon. It is therefore important to be aware of legislative restrictions that apply in the state where the prescription is dispensed (see Table next page). Generally, the prescribing doctor must act in accordance with the regulations that apply in that state. These regulations differ in each state, and are not the same as the regulations of the PBS. This is a particular issue for doctors working in towns close to state borders. To avoid any potential conflict with state regulations, doctors should advise the patient that prescriptions should be dispensed in the state in which the prescription is written.

Conclusion

Due to the consistent and substantial increase in opioid prescription and associated harm to patients, the regulation of Schedule 8 drugs is of increasing relevance and importance.

The gaps in knowledge and awareness of state legislation and regulation of opioids result in medicolegal risk. Furthermore, inconsistencies across states relating to the definition of drug dependency, authorities required for prescribing, and the rules of interstate prescribing, create additional complexity for practitioners. Awareness of such intricacies is essential to reduce medicolegal risk and helps ensure the safe and effective prescription of opioids to patients. ≺

Conflict of interest: none declared

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Table **Opioid prescribing in Australia: definitions of drug dependence, state and territory authority requirements* and prescription rules**

State	Statutory definition of drug dependent †	Local authority required to prescribe opioids		Interstate prescription rules	Useful websites
		For drug-dependent patients	For non-drug-dependent patients		
ACT	A person who, due to the administration of the drug/substance, shows impaired control, or drug-seeking behaviour suggesting impaired control; and, due to the cessation of the drug/substance, is likely to experience symptoms of mental/physical distress or disorder.	Approval is required for all Schedule 8 drugs, and will only be provided if prescribing is in accordance with opioid treatment guidelines.	Approval is required if prescribing for longer than 2 months.	Interstate prescriptions are allowed as long as the relevant approvals are fulfilled.	ACT Health: www.health.act.gov.au/public-information/businesses/pharmaceutical-services/controlled-medicines
NSW	A person who has acquired an overpowering desire for the continued administration of a drug of addiction or a prohibited drug listed in Schedule 1 of *Drug Misuse and Trafficking Act 1985* (NSW).	Authority is required for all Schedule 8 drugs.	Authority is required when prescribing the following drugs for more than 2 months: • any injectable form of any Schedule 8 drug • alprazolam • buprenorphine • flunitrazepam • hydromorphone • methadone.	Interstate prescriptions require prior authorisation.	NSW Ministry of Health: www.health.nsw.gov.au/pharmaceutical/doctors/Pages/Prescribe-S8-opioid.aspx
NT	Addiction to a regulated substance means a state of physiological or psychological dependence on, or increased tolerance to, the habitual and excessive use of the substance, and includes pain and other symptomatic indications arising specifically from withdrawal of the substance.	Authority is required.	Authorisation is required when prescribing an unrestricted Schedule 8 drug for more than 15 patients. Notification is required when prescribing for more than 8 weeks or in a specific example such as the replacement of lost or stolen prescriptions. Refer to the Code of Practice Schedule 8 Substances[22] for further examples.	No interstate prescriptions are allowed unless the subject of an authorised exemption.	Northern Territory Department of Health: www.health.nt.gov.au/Environmental_Health/Medicines_and_Poisons_Control/Medical_Practitioners/index.aspx
Qld	A person who, as a result of repeated administration of dangerous drugs, demonstrates impaired control, or exhibits drug-seeking behaviour that suggests impaired control, over the continued use of dangerous drugs; and who, when the administration of those drugs ceases, suffers or is likely to suffer mental/physical distress or disorder.	Approval is required to prescribe Schedule 8 and Schedule 4D drugs.	Notification and treatment report are required if prescribed for longer than 2 months.	Interstate prescriptions are allowed as long as the relevant requirements are fulfilled. No interstate prescriptions for methadone or buprenorphine will be allowed for patients on opioid treatment programs.	Queensland Health: www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/drugs-of-dependence/regulation/default.asp#treatment

Table **Opioid prescribing in Australia: definitions of drug dependence, state and territory authority requirements* and prescription rules (continued)**

State	Statutory definition of drug dependent †	Local authority required to prescribe opioids		Interstate prescription rules	Useful websites
		For drug-dependent patients	For non-drug-dependent patients		
SA	A person who, due to repeated administration of prescription drugs or controlled drugs, has an overpowering desire for the administration of any such drug and is likely to suffer mental/physical distress or disorder upon cessation of administration of that drug; or has a history of consuming or using prescribed drugs in a manner that presents a risk to that person's health or which is contrary to a medical practitioner's instructions.	Authority is required to prescribe all Schedule 8 drugs.	Authority is required if prescribing for more than 2 months.	Interstate prescriptions are allowed as long as the relevant notifications and permit requirements are fulfilled.	SA Health: www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/drugs+of+dependence
Tas.	A person who seeks to obtain a drug of dependence to sell or supply to another person, or for non-medical purposes, or as a result of administration exhibits impaired ability to manage properly the use of any such drug, or behaviour which suggests impaired ability. Failure to obtain drugs of dependence for a non-medical purpose, and consequent mental/physical distress or disorder, is also a sign.	Authority is required immediately to prescribe Schedule 8 drugs. Notification of drug-seeking or other aberrant behaviour is also required.	Authority is required to prescribe for more than 2 months. If alprazolam is concurrently prescribed, authority is required after 1 month.	Interstate prescriptions of Schedule 8 or Schedule 4 drugs cannot be dispensed in Tas.	Tasmanian Department of Health and Human Services: www.dhhs.tas.gov.au/psbtas/guidelines
Vic.	Not defined in the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).	A permit is required to prescribe Schedule 8 drugs.	A permit is required to prescribe continuously for more than 8 weeks.	Interstate prescriptions are allowed as long as the relevant requirements are fulfilled.	Victorian Department of Health and Human Services: www.health.vic.gov.au/dpcs/reqhealth.htm
WA	A person who, under a state of any periodic or chronic intoxication produced by a drug of addiction or any substitute, or is under a desire/craving to take that substance/any substitute until the desire or craving is satisfied, or is under a psychic‡/physical dependence to take a drug of addiction or any substitute; or is listed in the register for information kept under the Drugs of Addiction Notification Regulations 1980.	Authority is required to prescribe Schedule 8 drugs.	Authority is required when prescribing for longer than 60 days (or for more than 60 days in any 12-month period).	Interstate prescriptions can be dispensed in WA if they comply with the Regulations. Further restrictions on some Schedule 8 drugs apply.	Western Australian Department of Health: www.public.health.wa.gov.au/2/1292/2/drugs_of_dependence_schedule__medicines.pm

* This does not refer to Pharmaceutical Benefits Scheme requirements.
† In Tasmania, the Act defines drug-seeking behaviour rather than drug dependent.
‡ Psychic is used to legally define a drug-addicted patient in the WA Regulations.