Consent to treatment

Communicating medication risks in long-term prescribing

NAOMI LEWIS BA; **USHMA NARSAI** MB BCh, FRACGP

This series highlights common medicolegal issues in general practice. Written by a team from medical defence organisation Avant, the scenarios are based on a range of previous cases with details changed for privacy and some issues summarised for discussion. This scenario of a woman who is prescribed lithium for bipolar disorder and becomes pregnant two years later illustrates the importance of informed consent as a patient-centred process and the need for a structured approach to monitoring long-term use of medications.

Australian law and professional codes of practice recognise the right of patients to make informed decisions about the medical treatment they receive. It is essential that sufficient information about the potential benefits and risks of treatment is disclosed, to ensure patients consent only to the risks that are acceptable to them. This is especially important for long-term medications, particularly those that may potentially impact on a patient's fertility or a pregnancy.

MedicineToday 2019; 20(3): 49-51

Ms Lewis is Assistant Claims Manager, Avant Mutual Group, Sydney.
Dr Narsai is Senior Medical Adviser, Avant Mutual Group, Sydney; and a GP Research Physician in Sydney, NSW.

Case scenario

Patient history

Mary, then aged 21 years, first attended Dr White in 2014 for contraceptive advice and was prescribed a combined oral contraceptive. Dr White developed a good rapport with Mary and became her regular GP; she continued to prescribe the oral contraceptive. Dr White observed that Mary was displaying symptoms of bipolar disorder, such as mood alternating between elevated and depressed states, and disinhibited behaviour. In 2015, at Dr White's recommendation, Mary consulted Dr Jones, a psychiatrist, who diagnosed bipolar disorder and prescribed lithium. Mary responded well to treatment and her mood stabilised. Dr Jones referred her back to Dr White for long-term management, with six-monthly reviews by Dr Jones.

Dr White continued to prescribe lithium. Her usual practice was to discuss medication risks at the time of prescribing, but she did not make a particular point of this with Mary, believing Dr Jones had done so. When Mary attended consultations, it was Dr White's usual practice to ask Mary if she had any concerns, but not to ask about specific side effects.

In late 2017, Mary presented with an unplanned pregnancy at seven weeks' gestation. Mary told Dr White that she wished to continue with the pregnancy, and Dr White referred Mary for urgent psychiatric review by Dr Jones.

At a subsequent consultation, Dr White provided Mary with a fact sheet on prenatal screening tests. Mary said she did not wish to undergo prenatal screening. Dr White referred Mary to an antenatal clinic for ongoing management of her pregnancy. During the consultation, Mary told Dr White that she had not attended her appointment with Dr Jones. Dr White arranged for an appointment within the week with Dr Jones.

Mary returned at 18 weeks' gestation with a viral respiratory tract infection. Dr White enquired as to her progress and appointment with Dr Jones. Mary told Dr White she had not had time to attend the antenatal clinic and had forgotten about the

RESOURCES SUPPORTING PRESCRIBING PRACTICES

Therapeutic Goods Administration (TGA)
Safety information for medical professionals: www.tga.gov.au/safety-information-health-professionals

Safety alerts: www.tga.gov.au/alerts

Product Information (PI): www.tga.gov.au/product-information-0

Consumer Medicines Information (CMI): www.tga.gov.au/consumer-medicines-information-cmi

National Prescribing Service (NPS)
Medicinewise: https://nps.org.au/

Therapeutic Guidelines
https://tgldcdp.tg.org.au/index

Royal Hospital for Women, NSW
Mothersafe: www.seslhd.health.nsw.gov.au/royal-hospital-for-women/services-clinics/directory/mothersafe

appointment with Dr Jones. Dr White subsequently contacted Dr Jones, who advised that Mary should continue taking lithium because she was now 18 weeks' gestation and in his clinical judgement the benefits outweighed the possible risks. Dr White also arranged an urgent appointment with a high-risk antenatal clinic.

Mary's son was born in May 2018 at 38 weeks' gestation. In July 2018, he was diagnosed with a congenital heart defect and underwent corrective surgery.

Mary commenced civil proceedings against Dr White. Mary alleged that Dr White had breached her duty of care to her by inappropriately prescribing lithium during her pregnancy, and by failing to warn that lithium carried an increased risk of congenital heart defects. Mary alleged that if she had been properly warned of the risk of cardiac defects then she would have ceased taking lithium or terminated the pregnancy.

Legal issues

For a court to determine whether Dr White breached her duty of care to Mary, it needs to consider the following:

- whether the prescription of lithium was appropriate professional practice, both at the time it was first prescribed and as Mary's circumstances changed. In determining the relevant standard of care, the court would be guided by expert opinion and by any relevant guidelines or protocols that provide evidence of accepted professional practice.
- whether Dr White appropriately warned Mary of the risks of harm so that Mary could make an informed decision about her treatment.

Discussion

Informed consent is not a checklist, but a conversation guided by the individual patient's needs, concerns and priorities. Obtaining informed consent is a key part of shared decision-making.

Medical practitioners are not required to warn patients of every conceivable potential risk and side effect. In Australian law, doctors' duty of care to patients requires them to inform patients of 'material risks' – that is, those risks to which:

- a reasonable person in the patient's position would be likely to attach significance, or
- the practitioner is or should be aware that the particular patient would be likely to attach significance.

In the context of treatment with medication, communication of known risks would generally include:

- common side effects
- significant adverse effects, even when the occurrence is rare
- specific risks associated with interactions with other medications
- risks of inappropriate self-medication, including sudden withdrawal or overdose (where applicable).

In addition, doctors are required to make an assessment of what is important to the patient in choosing treatment outcomes and what they may be particularly worried about. A useful approach is to ask open-ended questions, such as:

- What is your understanding of your condition?
- What result are you looking for from treatment?
- What is the most important outcome for you?
- What do you understand the risks to be?

When prescribing medication commenced by a specialist, a GP needs to ensure that the patient has understood the specialist's explanation by asking questions such as:

- What you do understand the purpose of this medication to be?
- What side effects are you aware of?
- What symptoms should you let me know about?
- What do you need to do if you experience particular side effects?

Providing printed information sheets can reinforce the information discussed. Product Information and Consumer Medicine Information sheets are useful references when prescribing medication. However, medical practitioners should not rely on these as a substitute for a discussion.

In some circumstances, too much information may overwhelm the patient. The consent process for patients with poor health literacy, complex medical needs or a history of noncompliance may need more time. It may be necessary to schedule a second appointment and, if appropriate, to suggest the patient bring a support person. For patients with complex needs, referral for a second opinion may also be appropriate.

Documenting consent

Medical practitioners need to ensure that they document their discussion in the patient's clinical record as evidence that the relevant risks have been disclosed. The record should include:

- the patient's history and presentation
- an outline of the clinical decision-making process
- the nature of the treatment and proposed approach
- the risks discussed (with specific details, rather than 'risks discussed')

- any printed material provided to the patient.

It is important to be aware that it is not enough to rely on a consent form. Any provision of a consent form should be done in conjunction with a conversation that is then recorded in the notes, as outlined above.

Long-term prescribing

A management plan should be put in place for patients who are prescribed medication long term. It is important to schedule periodic reviews of the medication dosage, monitor for any side effects and ensure medication levels and other medication specific parameters are regularly assessed. The renewal of a prescription is a useful trigger to schedule a review.

Patients should be informed of the effects of prolonged use of a medication, including any potential effects on fertility or risks arising with pregnancy, including the risk of relapse, as appropriate. It is crucial that the medical practitioner review medication risk when becoming aware of any change in the patient's circumstances, such as commencing a new relationship, when the patient's wishes around contraception may change.

In monitoring side effects, clinicians should not rely on the patient to raise concerns, but should use targeted questioning to discuss common side effects and elicit information about any clinical changes. Any unexpected side effects should be reported to the TGA.

It is important to document the review in the patient's clinical notes, including any questions or concerns raised by the patient. It is essential to document any nonadherence to or variation from treatment recommendations, such as patient-initiated changes to dosage.

Adherence to guidelines and protocols, such as those issued by colleges or hospitals, are persuasive evidence that a doctor is practising in accordance with widely held peer professional opinion. If it is a doctor's clinical judgement that departing from clinical guidelines is appropriate, it is important to document the circumstances in the clinical record as evidence of this clinical decision-making.

Patients should be informed of the effects of prolonged use of a medication, including any potential effects on fertility or risks arising with pregnancy, including the risk of relapse, as appropriate.

Emerging risks

A key challenge in the practice of medicine is keeping up-to-date with emerging risks and ensuring that a patient is appropriately warned of these.

To keep up-to-date with emerging risks, including the long-term impacts of medication, resources that support evidence-based practice should be utilised, such as evidence-based guidelines on a range of clinical issues. Useful online resources are listed in the Box.

When planning continuing professional education, doctors can seek courses that cover the full range of their practice areas. A course in evidence-based medicine to enhance critical appraisal skills could be considered.

Outcome

Dr White obtained a supportive expert opinion from a GP, who opined that Dr White had followed the relevant guidelines for prescribing lithium and that it was reasonable for Dr White to rely on the advice provided by Dr Jones. However, the expert was critical of Dr White for failing to advise Mary of the risks associated with taking lithium during pregnancy. Dr White's recollection was that she had warned Mary during a discussion about contraception that it could be dangerous for the baby if she fell pregnant while taking lithium. However, there was no record of this in the clinical notes.

In relation to causation, it was noted that Mary had declined to attend specialist psychiatric review and the antenatal clinic, and declined to undergo antenatal screening. It was arguable that as Mary had accepted the risk of congenital defects generally, she would not have made a different decision if warned of the risk of cardiac defects associated with the medication.

Given both parties were exposed, the matter settled at mediation.

Conclusion

Informed consent is a not an event, but a patient-centred process that enables patients to make informed choices about their healthcare options. Using open-ended questioning and a structured approach to monitoring long-term prescriptions increases the likelihood that patients will be informed of any risks that are of significance to them. MT

Further reading

1. Boyce P, Buist A. Management of bipolar disorder over the perinatal period. Aust Fam Physician 2016; 45: 890-893.
2. Avant Mutual. Podcast: issues of patient consent. February 2019. Sydney: Avant Mutual; 2019. Available online at: www.avant.org.au/Resources/Public/Podcast--Issues-of-patient-consent--A-conversation-with-Georgie-Haysom-and-Ian-Incoll/ (accessed March 2019).
3. Haysom G, Narsai U. Informed consent and communicating information. Medical Observer March 2019; 41-47.
4. Avant Mutual. Medical records: the essentials. 2016. Sydney: Avant Mutual; 2016. Available online at: www.avant.org.au/Resources/Public/20150910-medical-records-the-essentials/ (accessed March 2019).
5. Jammal W. Ten tips for good, patient-centred record keeping. Sydney: Avant Mutual; 2018. Available online at: www.avant.org.au/news/10-keys-to-good-patient-centred-record-keeping/ (accessed March 2019).

COMPETING INTERESTS: None.

Don't miss

Managing bipolar disorder: key clinical recommendations on p27