Sara Bird, MBBS, MFM (Clin), FRACGP, is Medicolegal Adviser, MDA National.

Case histories are based on actual medical negligence claims, however, certain facts have been omitted or changed by the author to ensure the anonymity of the parties involved. Medication errors are a common cause of medical negligence claims involving general practitioners. One of the medications frequently involved in these claims is warfarin. This article examines some of the medicolegal issues surrounding the initiation and monitoring of warfarin in general practice.



Case history

Mr Jackson, an 81 year old retired bus driver, attended his general practitioner for an annual driver's licence medical assessment. The GP, Dr Sparke, noted Mr Jackson was remarkably well. He generally only saw him once a year for the medical examination regarding his fitness to drive. Physical examination revealed an irregular pulse and an ECG confirmed the presence of atrial fibrillation. On closer questioning, the patient said he had noticed occasional palpitations but denied any dizziness or syncope. The GP decided to refer the patient to a local cardiologist for review before completing the certificate for an unconditional driver's licence.

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A few weeks later, on a busy Friday afternoon, the patient re-attended Dr Sparke. The local cardiologist had written to the GP stating the patient was fit to drive from a cardiovascular point of view. However, in view of the apparently recent onset of atrial fibrillation, the cardiologist recommended that the patient should commence warfarin. Dr Sparke discussed the cardiologist's recommendations with the patient, who agreed to commence the new medication. The GP briefly discussed the action of warfarin and the potential side effects and complications. He stressed the need for regular monitoring, including blood tests. Dr Sparke advised the patient to commence warfarin one tablet once per day for three days and then have a blood test. Because Dr Sparke was going to be on annual leave for the next two weeks, he asked Mr Jackson to ring the practice nurse for the result of his international normalised ratio (INR) test on the Monday and obtain her advice regarding the appropriate dose of warfarin. He told Mr Jackson that if he had any problems he should see his practice partner in his absence, otherwise he would see him in two weeks when he returned to the practice. Dr Sparke gave the patient a prescription for warfarin 5 mg x 60 tablets and a pathology request form for the INR test to be performed on the following Monday.

As he was rushing out of the surgery later that evening, Dr Sparke mentioned to his practice partner that he had just commenced Mr Jackson on warfarin and that she or the practice nurse may contact him if there were any problems with adjusting the dose of warfarin.

Two weeks later, on his first day back at work, Dr Sparke received a phone call from the local police station. The police officer said that Mr Jackson's daughter had found him dead at home that morning. He wanted to know if Dr Sparke was able to complete a death certificate.

Medicolegal issues

Dr Sparke advised the police officer that he was unable to complete a death certificate because he was uncertain as to the cause of Mr Jackson's death. He said he would discuss the matter with practice staff and get back to him later that morning. The GP asked his practice partner if she had seen Mr Jackson in his absence. She said she hadn't heard from him. On review of Mr Jackson's medical records, Dr Sparke noted that an INR result of 2.5 had been received by the practice on the first Monday that he was away. The practice nurse had filed the test result in his absence. There was no record of any subsequent INR results. Later that morning, Dr Sparke spoke to the practice nurse who said she had not contacted the patient because the INR result was in the normal range. The practice nurse said she had been 'incredibly busy' on the Monday and had not had a chance to review the patient's medical records. In view of the normal INR result, she had assumed everything would be okay. Dr Sparke also reviewed the practice's appointment book. Mr Jackson had rung the practice on the Monday afternoon to speak with Dr Sparke. According to the receptionist, when she informed Mr Jackson that the GP was on leave for two

weeks, he had told her it wasn't urgent and made an appointment to see Dr Sparke on the Tuesday after his return to work.

Mr Jackson's death was reported to the coroner. An autopsy revealed a massive retroperitoneal haemorrhage. The INR was >10. A bottle of warfarin tablets was found on Mr Jackson's bedside table. Only 43 tablets remained in the bottle. It appeared likely that Mr Jackson had continued to take warfarin 5 mg per day and his death was the result of a haemorrhage caused by the warfarin therapy and excessive anticoagulation.

Discussion

It has been estimated that up to 25% of medical negligence claims involving GPs are the result of errors in prescribing, monitoring and administering medicine. The medications commonly involved in these claims include:

- anticoagulants
- nonsteroidal anti-inflammatory drugs
- opiates
- · antibiotics, and
- intramuscular iron injections.

The Australian Incident Monitoring Study² found the most common types of pharmacological incidents were:

- inappropriate drug
- prescribing error
- · administering error, and
- inappropriate drug dosage.

Clinical indications for the use of warfarin have increased over the past few years with a number of complex issues surrounding its prescription and monitoring:

- warfarin dosage varies widely among patients. Even for an individual patient, the dose is subject to adjustment because of interactions with other medications, diet and intercurrent illnesses
- there are at least three strengths of warfarin tablets and two brands that are not interchangeable
- warfarin has a narrow therapeutic range of effectiveness and safety. Poor management may lead to bleeding or thromboembolic problems, and
- the use of warfarin requires frequent

and ongoing blood test monitoring. Therefore, the prescription of warfarin requires patients who are well instructed, able to communicate clearly, cognitively intact, cooperative and compliant.

Risk management strategies

The Australasian consensus guidelines for warfarin therapy³ provide valuable guidance regarding its indications, commencement and maintenance. Bleeding is most likely to occur during the first three months of therapy and often follows trauma or unmasks a previously unsuspected comorbidity. According to the guidelines, the risk of bleeding is 'minimised by regular monitoring to avoid an excessive INR and by educating patients about how warfarin works, why their dose requirements may change, and the likely settings and symptoms of bleeding complications. Successful warfarin therapy requires a partnership with patients, who should be encouraged to have their INR checked after any change in their normal routine'.3

Risk factors for major haemorrhage secondary to warfarin include old age, serious illness (cerebral, cardiac, kidney or liver disease), cerebrovascular or peripheral vascular disease, and an unstable anticoagulant effect. Forgetfulness, nonsteroidal anti-inflammatory drugs and alcohol abuse also contribute.

The Royal Australian College of General Practitioners 'Standards for General Practices'4 recommend that general practices have a system for reviewing, acting upon and incorporating in the medical record all pathology results, diagnostic imaging reports and clinical correspondence received. The intention of this recommendation is to ensure that all results and correspondence relating to a patient's clinical care are reviewed by a doctor and acted upon. The guidelines state: 'While practices are not expected to contact patients with the results of every test or investigation undertaken (it is the patient's responsibility to seek such results), there may be significant patient risk in not following up abnormal results. An abnormal result must be reviewed by a doctor to determine its significance to the ongoing care of the patient'.4

General practitioners should ensure that their practice has a system to track INR results to determine whether:

- the test ordered was performed
- the results have been received
- the results have been seen by you, eg. signed and dated
- the results have been reported to the patient
- the results have been acted upon, and
- the report has been filed in the patient's medical records.

With respect to warfarin dosing instructions and adjustments, GPs should give clear verbal and written instructions and review the instructions before the patient leaves the surgery. If changing the warfarin dose by telephone, ask the patient to write down the instructions and repeat the instructions back to you.

SUMMARY OF IMPORTANT POINTS

- When commencing or adjusting the dose of warfarin, GPs need to give clear verbal and written instructions to their patients.
- General practices should have a test result tracking system in place to ensure INR results are reviewed, acted upon and incorporated in the medical records in a timely manner.

Conflict of interest: none declared.

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