QUEENSLAND COURTS

OFFICE OF THE STATE CORONER

FINDINGS OF INVESTIGATION

CITATION:	**Non-inquest findings into the death of Mr B**
TITLE OF COURT:	Coroner's Court
JURISDICTION:	Brisbane
DATE:	29 February 2016
FILE NO(s):	2015/1036
FINDINGS OF:	Ainslie Kirkegaard, Coronial Registrar
CATCHWORDS:	CORONERS: Investigation, DVT, new oral anticoagulants, rivaroxaban, management of associated bleeding risk, Jehovah's Witness, National Inpatient Medication Chart

Mr B was an 84 year old man who died at a tertiary hospital on 16 March 2015. Mr B was a practicing Jehovah's Witness.

Mr B's death was reported to the coroner because he was considered to have died from complications of prescribed anticoagulation therapy, the symptoms of which were potentially masked by the concurrent use of a naturopathic compound.

Review of Mr B's medical records shows he had a complicated medical history including ischaemic heart disease with ischaemic cardiomyopathy, congestive cardiac failure (ejection fraction 30%), type 2 diabetes mellitus, peripheral vascular disease, hypertension, hyperuricaemia and gout and chronic kidney disease (stage IIIb).

Mr B presented to his general practitioner on 11 February 2015 with a history of having twisted his right foot the previous morning when he slipped off a chair. On examination, the foot was very hot and swollen. He was diagnosed with gout and prescribed colchicine. He was to return for further review on 13 February.

Mr B presented to regional hospital on 12 February 2015 with a swollen right foot. A Doppler scan revealed deep vein thrombosis (DVT). He was initially treated with enoxaparin (anticoagulant medication) which was changed to rivaroxaban (an oral anticoagulant) when discharged home on 19 February. Mr B's admission was complicated by acute renal impairment and possible cellulitis secondary to DVT, which was successfully treated with antibiotics.

At this time Mr B had been taking an off-the-shelf naturopathic product marketed by Nature's Goodness as Joint Formula Cherry Juice Concentrate with Anthocyanin Complex. Information provided by his family indicates he was taking this product to help alleviate pain associated with his gout. He had been passing dark/black bowel motions for approximately two weeks which he attributed to the cherry compound.

Mr B presented to his general practitioner for scheduled review on 11 March 2015 complaining of feeling 'washed out'. Blood test results showed a haemoglobin of 83 (which had dropped from 132 in February 2015).

Mr B represented to the regional hospital on 14 March 2015 with a history of dizziness, reduced exercise tolerance and a two week history of dark bowel motions. Blood tests revealed a haemoglobin of 70g/dL and a troponin leak of 0.53. ECG revealed a left bundle branch block which had not been present in a previous ECG from 2009. Tests repeated 12 hours later revealed a further drop in his haemoglobin and a troponin in leak of 0.86 leading to a diagnosis of a likely cardiac event in the context of severe anaemia secondary to upper gastrointestinal bleeding.

Mr B refused treatment with blood products and was instead treated with an iron infusion, injection with erythropoietin (a hormone to induce blood cell production), vitamins K, B12 and folate, tranexamic acid to stem bleeding and infusion with proton pump inhibitor for a suspected gastric ulcer. His rivaroxaban was ceased (unable to be reversed).

On 15 March 2015, Mr B's haemoglobin decreased further to 59 g/dL. An urgent upper gastrointestinal endoscopy revealed a bleeding submucosal lesion. The bleeding

ulcer was directly injected with adrenaline. Mr B was advised that his prognosis was guarded without the administration of blood products and he was also at increased risk of blood clot with the treatment of tranexamic acid and vitamin K.

Given the limitations on what treatment could be offered and in the context of his faith-based refusal to accept blood products, Mr B was then transferred to a tertiary hospital for further management and intervention should his condition deteriorate acutely. He arrived at the tertiary hospital at 10:06pm that evening and was transferred to the ward on a protein pump inhibitor infusion.

Mr B's condition deteriorated the next morning with hypotension which did not respond to intravenous fluids. While being reviewed by the intensive care team, he experienced a sudden onset of crushing chest pain and became unresponsive at 12:50pm. Unfortunately, despite prolonged emergency resuscitation efforts, Mr B's condition was irreversible. After discussion with the family, active treatment was withdrawn, he was extubated and comfort cares instituted. He died at 1:40pm.

Preliminary independent clinical review

Preliminary review of Mr B's medical records by an independent doctor from the Department of Health Clinical Forensic Medicine Unit identified concerns that Mr B was taking naturopathic treatment as well as the rivaroxaban, the latter being anticoagulation medication that is unable to be monitored or reversed. The reviewing doctor questioned the appropriateness of the decision to prescribe a drug that cannot be reversed urgently in a person whose faith forbids transfusion. The reviewing doctor was also concerned that Mr B's presentation to his general practitioner on 11 March 2015 may have been a missed opportunity to have acted earlier on the acute haemoglobin drop, particularly when he was known to be taking rivaroxaban at that time.

After further investigation of the Nature's Goodness cherry formula, the reviewing doctor was satisfied that it had not directly affected the therapeutic efficacy or increased the risk of bleeding with rivaroxaban use.

Family concerns

Mr B's family expressed concerns about the clinical decision to prescribe rivaroxaban to a person with faith-based issues relating to blood transfusions.

Autopsy findings

An external examination and medical records review were performed at Forensic and Scientific Services on 25 March 2015. Having considered the available clinical information, the pathologist considered that Mr B died from an acute myocardial infarction precipitated by loss of blood caused by on-going blood loss from a gastric ulcer (upper gastrointestinal haemorrhage) which was exacerbated by rivaroxaban therapy.

Response from Mr B's general practitioner

I provided the GP with an opportunity to respond to concerns about his management of Mr B's presentation on 11 March 2015.

The GP confirmed having received a copy of Mr B's discharge summary from the

regional hospital pharmacy department on 20 February 2015, listing the medications which he had been prescribed while in hospital and the medications on which he was to continue. The summary advised that Mr B was commenced on Xarelto (rivaroxaban) at 15mg, initially twice a day, and then 20mg daily for 10 weeks with advice to monitor his renal function. The GP advised that he updated the practice records to reflect this. He did not receive a clinical discharge summary from the hospital.

The GP reviewed Mr B on six occasions after being discharged home from hospital on 19 February and before being readmitted on 14 March 2015:

- 25 February - Mr B presented with pressure ulcers between the third and fourth toes of his right foot. This was as a consequence of the swelling he had suffered with his gout, cellulitis and DVT reported to have developed in his right calf. He reported having seen an after-hours doctor who prescribed antibiotics. He also had a fresh skin tear on the left calf, which was dressed. He was asked to return for further review the next day;

- 27 February – Mr B returned with ongoing pain between his third and fourth right toes. The clinic nurse redressed the pressure ulcers. The GP noted that Mr B was due to have his rivaroxaban dose increased to 20mg daily on Monday 9 February (it should have been a reference to 9 March) as instructed by the hospital pharmacy discharge summary;

- 2 March – Mr B was noted to be looking much better, despite ongoing pain in his foot that morning. The redness and swelling was noted to have lessened. He was asked to return on 4 March and 6 March for further redressing and review;

- 4 March – The GP noted that the ulceration between the right toes had virtually healed and the swelling had reduced considerably, though Mr B was still complaining of pain in the right forefoot which was attributed to his gout. He was prescribed another course of colchicine for the gout and his wound was redressed by the clinic nurse;

- 6 March – Mr B returned for review as requested. His right toes were noted to have healed completely, the swelling had reduced significantly and he was tolerating colchicine tablets at the twice daily dose. As this medication can cause diarrhoea, the GP asked specifically whether Mr B was experiencing any ‘tummy problems or diarrhoea’. Mr B advised that he was not. He was still experiencing a deep ache and throbbing pain in the right forefoot. His leg wounds were redressed and he was asked to return for further review on 11 March

- 11 March – Mr B’s toe and leg wounds were noted to be healing well. He complained of feeling ‘washed out’. The GP says he was concerned about Mr B’s renal function given the recent medication changes, so he referred Mr B for specialist review and blood tests (with a copy of the blood test results to be sent to the specialist also). Mr B advised he had a specialist appointment in the very near future (possibly 16 March).

The GP received the blood test results on 12 March. He advises that they indicated moderate renal impairment but this was an improvement from testing done in December 2014. The GP also noted a drop in haemoglobin to 83. He made an annotation to discuss this with Mr B when he next returned for review scheduled on 20 March. The GP explained that he did not phone Mr B about the results at this time as he had already referred him for specialist review and the blood test results were to be sent to the specialist also. Mr B did not phone in to the practice to follow up his blood test results.

The GP advised that:

he was not aware that Mr B was taking the cherry compound and had not prescribed it to him

- he was not involved in the hospital treating team's decision to prescribe rivaroxaban and having not received a clinical discharge summary, was not aware of the reason for this medication having been prescribed to Mr B

- the focus of his consultations with Mr B from February 2015 onwards was to review and redress the wounds on his lower limbs. There was nothing in these presentations to indicate that Mr B was suffering from gastrointestinal bleeding. He did not ever describe melena or other abdominal symptoms, even when asked whether he was experiencing any tummy problems

- as soon as being told Mr B was feeling 'washed out', he immediately referred Mr B for specialist review and ordered blood tests to be sent directly to the specialist

- while Mr B's haemoglobin level 'certainly warranted further investigation', he did not consider it to be critically low. He commented that the peripheral film was a macrolytic one and not at all the picture of an acute or chronic bleeding problem

- he considered the haemoglobin level, while 'concerning', was a level that would be investigated in the very near future either by him when Mr B returned for his scheduled review on 20 March (depending on what action and investigations had been arranged by the specialists), or by the specialists at the clinic.

- he considered that his management of Mr B was reasonable and he responded appropriately to the reported symptoms and blood test results.

Having considered the GP's response, the reviewing doctor acknowledged that the GP was reviewing Mr B in the context of foot ulcers and wound dressings. However, in context of Mr B feeling 'washed out' and being on rivaroxaban which could not be monitored or reversed, the reviewing doctor remained of the view that while the GP had appropriately ordered blood tests and referred Mr B for specialist review, he was still apprised of clinical information (a haemoglobin level of 83 that represented a 40% drop from the previously reported level) prior to Mr B's presentation to hospital on 14 March that warranted further action such as a phone call asking Mr B to return for

earlier review or to inquire further as to his symptoms. The reviewing doctor did not consider it appropriate for the GP to leave this for the future specialist review as there was no known confirmed appointment timeframe.

The regional hospital clinical incident review outcomes

I provided the regional hospital with an opportunity to respond to the concern about the decision to prescribe rivaroxaban to Mr B, given his status as a practicing Jehovah's Witness.

I received a response from the relevant hospital and health service on 28 October 2015 and a further update on 12 November 2015. Mr B's clinical management was reviewed initially by the treating consultant and the Deputy Director Medical Services and subsequently by the Medical Morbidity and Mortality Committee. These reviews identified the following clinical management issues:

- Mr B's religious beliefs or blood transfusion acceptance were not known to the admitting doctor, Principal House Office Dr S, or discussed at the time of admission on 12 February 2015

- Mr B was started on Clexane for treatment of suspected (and subsequently diagnosed) DVT

- investigations were ordered to assess Mr B's acute kidney injury

- Dr Sk reviewed Mr B on 13 February during the post-intake ward rounds with the plan to commence him on Warfarin, not rivaroxaban, because of the acute kidney injury

- the treatment was changed on 16 February when Dr S commenced Mr B on rivaroxaban instead of warfarin – there is no record in the patient chart as to why this change occurred though Dr Sk recalled that Mr B was anxious to return home as soon as possible to care for his frail wife, so it may have been to avoid a prolonged initiation process with warfarin. However, the rivaroxaban was commenced without discussion with a senior member of the treating team as might be expected in a normal handover after a weekend

- Mr B was discharged home on rivaroxaban on 19 February. The medical record indicates that bleeding risk was discussed with him upon discharge

- The medical record contained a note in the surgical ward discharge instructions for the general practitioner to review Mr B in a week's time and to monitor him for bleeding because of the rivaroxaban.

The relevant hospital & health service reviews led to the making of a number of recommendations to help prevent a recurrence of these issues:

- ensuring clinician discussion with any patient who is started on anticoagulation therapy about the treatment risks, lack of a reversal agent for the new oral anticoagulants (like rivaroxaban) and the patient's position on accepting blood transfusions, for any reason, not limited to religious beliefs

- ensure the hospital pharmacy department is involved in the patient education process about the risks of anticoagulants – it is understood this already happens in practice but is not documented in the patient chart

- require documentation in the patient chart of the commencement of therapy and the reasons for the decision

- better documentation of those discussions to confirm patient understanding and acceptance of the treatment

- better documentation of patient requests regarding their treatment and discharge preferences

- better communication within treating teams

- advocating for changes to the patient education box on the national medication form to include reference to warfarin and other anticoagulants (it currently only refers to warfarin).

The relevant hospital & health service has confirmed its acceptance of these recommendations.

Having considered the hospital & health service response, the reviewing doctor was reassured that the clinical management and medical record keeping practices had been reviewed and there was formal acknowledgement that the medication choice could have been better.

Conclusion

Mr B died from recognised complications of oral anticoagulant therapy (rivaroxaban) prescribed to treat deep vein thrombosis. The clinical decision to commence rivaroxaban rather than warfarin (which could be monitored and reversed) in a patient who had faith-based reasons not to accept blood products increased Mr B's risk of experiencing these complications. The apparent failure to provide a clinical discharge summary to Mr B's general practitioner represented a missed opportunity to clearly flag the need for ongoing clinical monitoring of the rivaroxaban-associated bleeding risk. I am satisfied that the Hospital and Health Service has carefully reviewed the care provided to Mr B during his admission in February 2015 and identified appropriate changes to clinical decision making and medical record keeping to address the clinical management issues identified by my investigation.

There was also a missed opportunity for the upper gastrointestinal bleeding to have been identified sooner by more urgent referral by the general practitioner after the blood test results from 11 March 2015 became available to him. I accept the independent clinical opinion that the GP should have taken more proactive steps to escalate Mr B for medical review once he became aware of the haemoglobin results, rather than leaving it for a forthcoming specialist appointment or when Mr B was scheduled to return for review on 20 March 2015. However, given Mr B's faith-based refusal to accept blood products, I am unable to say with certainty whether medical intervention prior to his presentation to hospital on 14 March 2015 would have

prevented his death.

Findings required by s. 45

Identity of the deceased – Mr B

Place of death – A tertiary hospital

Date of death– 16 March 2015

Cause of death –

1(a)	Acute Myocardial infarction
1(b)	Ischaemic heart disease
2	Upper gastrointestinal haemorrhage in context of rivaroxaban therapy for deep vein thrombosis

I have provided a copy of my findings to the Office of the Health Ombudsman and the Department of Health Medications Regulation & Quality for their consideration.

Ainslie Kirkegaard
Coronial Registrar
29 February 2016

Queensland
Government

Department of Health

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Ms A Kirkegaard
Registrar
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Dear Ms Kirkegaard

Thank you for your letter dated 29 February 2016 requesting that Medicines Regulation and Quality consider the issues arising from a coronial investigation into the death of and possible opportunities to enhance clinical awareness via prompts on the medication chart of the importance of documenting patient education about the risks of new oral anticoagulants.

The National Inpatient Medication Chart is governed by the Australian Commission on Safety and Quality in Health Care's Health Services Medication Expert Advisory Group to which Queensland has jurisdictional representation. The suggestion to amend the warfarin patient education section to include reference to other anticoagulants will be tabled for consideration by this group at the next available opportunity.

In relation to the management of Mr B anticoagulation therapy in hospital, the coronial investigation raised significant concerns regarding:

- the appropriateness of prescribing rivaroxaban, an anticoagulant with no current reversal agent, in a patient where blood transfusions are not an available therapeutic option
- the lack of clinician awareness of a patient's self-medication using over-the-counter complementary medicines
- patient education of anticoagulant medicines commenced in hospital
- communication between treating teams.

Medicines Regulation and Quality will issue a statewide Patient Safety Notification drawing attention to the concerns raised above and providing recommendations to reduce the risk of harm from similar incidents.

Issues associated with the use of new oral anticoagulants are receiving increasing attention at both the state and national levels. We will continue to monitor our response in relation to this emerging issue. Thank you for bringing this to our attention.

Yours sincerely

Dr Sue Ballantyne
Director
Medicines Regulation and Quality Unit
7/3/16

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