Senior Medical Officer, Dr C
Lakes District Health Board

A Report by the
Health and Disability Commissioner

(Case 17HDC00191)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. Mrs A (aged 75 years) presented to the Emergency Department of a public hospital in 2016 feeling generally unwell with a headache, shortness of breath (SOB), a tight chest, nausea, and lethargy, and was admitted to the Medical Assessment & Planning Unit.

2. Mrs A was under the care of a senior medical officer, Dr C. On the morning of Day 2,[1] Dr C started Mrs A on antibiotics for a urinary tract infection, and clopidogrel[2] and aspirin for a transient ischaemic attack (TIA).[3] The SOB was thought to be secondary to a pulmonary embolism (PE),[4] or an exacerbation of her chronic obstructive pulmonary disease (COPD).[5] Mrs A had a history of a PE in 2006. Later that day, Mrs A was started on enoxaparin (Clexane) in case she had a PE, and her clopidogrel treatment was stopped. She was transferred to the Medical Unit.

3. On Day 4, following a delay owing to equipment failure, Mrs A had a CT scan of her chest, which confirmed bilateral PE. Dr C then started Mrs A on a further blood-thinning medication, dabigatran, in addition to enoxaparin. Either medicine can be used to treat PE, but they should not be administered together.

4. Initially, Mrs A appeared to be recovering, but on Day 7, she had a severe headache and elevated blood pressure. On Day 8, Dr C ordered a CT scan of the head, which showed a new subdural haemorrhage in the posterior fossa. Dr C planned to reverse the dabigatran with Praxbind.[6] Dr C consulted with the on-call haematologist at another district health board (DHB2), and learned that co-administration of dabigatran and Clexane is not recommended. Anticoagulation with dabigatran and Clexane was stopped, and Mrs A was transferred to the intensive care unit, where her condition deteriorated.

5. On Day 9, Dr C disclosed to Mrs A's family that a potential medication error may have contributed to Mrs A's deterioration. Dr C apologised for the error. Mrs A was transferred home, and she died a short time later.

Findings

6. Services were not provided to Mrs A with reasonable care and skill. Issues regarding education, guidelines, and policy implementation at Lakes DHB were identified, including the prescribing of contraindicated drugs, the SBARR[7] implementation failure, inadequate content and communication of the open disclosure policy, inadequate anticoagulation guidelines, inadequate pharmacy review, and a systemic knowledge deficit regarding the

[1] Relevant dates are referred to as Days 1–12 to protect privacy.
[2] Clopidogrel is an anti-platelet medication used to prevent blood clots.
[3] A brief episode of cerebral ischaemia that is often characterised by temporary blurring of vision, slurring of speech, numbness, paralysis, or syncope (fainting), and may be predictive of a serious stroke.
[4] Obstruction of a pulmonary artery or one of its branches, usually produced by a blood clot that has originated in a vein of the leg or pelvis and travelled to the lungs.
[5] Long-standing, typically irreversible airway obstruction that results in a slowed rate of exhalation.
[6] Praxbind is the brand name for idarucizumab, which is a reversal agent specific for the blood-thinning medication dabigatran. Praxbind is used to trap dabigatran rapidly in order to inactivate its effect.
[7] Communication tool (Situation, Background, Assessment, Recommendation, Response).

correct use of dabigatran. Accordingly, the Commissioner found that Lakes DHB breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[8]

7. The Commissioner was critical that Dr C prescribed dabigatran and Clexane together when this was contraindicated, and considered that the manner in which the error was disclosed was not ideal.

Recommendations

8. The Commissioner recommended that Lakes DHB (a) provide an update on its implementation of the recommendations in the Lakes DHB Root Cause Analysis Report; (b) provide evidence of nursing staff orientation and training on the Early Warning Score; (c) consider implementing a policy for the monitoring of haemostasis in patients on anticoagulation medications; (d) provide evidence of a prescriber alert system for anticoagulants; (e) audit 50 sets of clinical records; (f) take steps to improve its documentation and decision-making around the appropriate prescribing of anticoagulants; (g) update its anticoagulant guidelines; and (h) provide a written apology to Mrs A's family.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided by Lakes District Health Board (DHB) and Dr C to Mrs B's mother, Mrs A. The following issues were identified for investigation:

- *Whether Lakes DHB provided Mrs A with an appropriate standard of care between Days 1 and 9.*
- *Whether Dr C provided Mrs A with an appropriate standard of care between Days 1 and 9.*

10. The parties directly involved in the investigation were:

Mrs B	Complainant/consumer's daughter
Dr C	Senior Medical Officer/provider
Lakes DHB	Provider

Also mentioned in this report

RN D	Registered nurse
Dr E	House officer
Dr F	Haematologist

[8] Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill.

11. Independent expert advice was obtained from Dr John Fink, a consultant neurologist, and is included as Appendix A.

Information gathered during investigation

Background

12. Mrs A, aged 75 years, presented to the Emergency Department (ED) of Lakes DHB. This report concerns the co-administration of enoxaparin (Clexane)[9] with dabigatran[10] to Mrs A to treat a pulmonary embolism (PE).

13. Either medicine can be used to treat PE, but they should not be administered together. A Lakes DHB root cause analysis found that there was a systemic knowledge deficit amongst its clinicians regarding the correct process for switching to dabigatran.

Day 1

14. On Day 1, Mrs A was taken to the ED by family. She had been feeling generally unwell during the previous three days, and had a blocked nose, a dull headache, shortness of breath (SOB), a tight chest, nausea, and lethargy. When she had awoken at 8 o'clock that morning, she had also felt weakness in both legs. Mrs A had slurred speech and a facial droop, and appeared confused.

15. Mrs A was triaged in ED at 12.16pm. She was examined by ED staff, and at 1.45pm a computed tomography (CT) scan of the head was performed, the results of which were reported as normal.

16. It is documented at 3.07pm that the initial impression was of a cerebrovascular accident (CVA)[11] and SOB, which was assumed to be her chronic obstructive pulmonary disease (COPD), although a PE was also considered. The stroke team did attend, but it was considered too late to treat for CVA, as it was over 4.5 hours from the onset of symptoms.

17. At 3.20pm, Mrs A was transferred to the Medical Assessment & Planning Unit (MAPU). At 3.35pm, she was given paracetamol. During her stay in ED and transfer to MAPU, Mrs A was under the care of the on-call Senior Medical Officer (SMO).

Day 2

18. On the morning of Day 2, Mrs A felt dizzy, nauseous, clammy and sweaty, and had SOB on exertion.

[9] Clexane is a brand name for enoxaparin. It is used to treat blood clots.
[10] Dabigatran is an anticoagulant drug that inhibits the action of thrombin (an enzyme in blood plasma that causes the clotting of blood). It is used to reduce the risk of stroke, and to treat or prevent deep vein thrombosis and pulmonary embolism.
[11] A stroke.

19. A medicines reconciliation found several discrepancies between the admission and charted medicines. The pharmacist added missed medicines to the chart, and provided a salbutamol inhaler, as Mrs A was experiencing more SOB than usual.

20. At 10.10am, Mrs A was reviewed by the on-call SMO, Dr C, and a urinary tract infection (UTI) was diagnosed. It was thought that the UTI symptoms could be mimicking stroke-like symptoms, but the possibility of a transient ischaemic attack (TIA) was also considered. Mrs A's SOB was thought to be either a PE or an exacerbation of her COPD. Mrs A had had a PE in 2006, which had been treated with warfarin for six months. Mrs A was started on antibiotics for the UTI, and treated with clopidogrel and aspirin for the possible TIA. Mrs A was placed under the care of Dr C.

21. At 11.00am, an Early Warning Score (EWS) was calculated incorrectly, and it was noted that Mrs A's next observations were to be undertaken three hours later, rather than escalated to half-hourly with the doctor being notified. However, Mrs A had been reviewed by Dr C at 10.10am and a clear plan put in place, and when Mrs A's observations were taken three hours later, her oxygen saturations had recovered, and at this time the EWS was calculated correctly.

22. At 11.30am, a CT scan of the chest was ordered. However, when Mrs A went for the scan at 3.15pm, it could not be completed, as the scanner had broken down.

23. At 5.20pm, Mrs A was started on enoxaparin (Clexane) 70mg BD injections in case of a PE. Clopidogrel treatment was stopped at this time.

24. At 6.30pm, Mrs A was transferred to the Medical Unit.

Day 3

25. On Day 3, the scanner was still not working. At 1.30pm, the plan was to discuss a potential transfer to DHB2 for a scan, and to continue Clexane and trimethoprim.[12] At 1.45pm, Dr C's request to transfer Mrs A to DHB2 was refused by the medical consultant on call, as he felt that it could wait until the following day. Later that evening, Mrs A was booked for a CT scan of the chest at 8.00am the next day.

26. On Days 2–4 Mrs A complained of feeling dizzy, light-headed, and nauseous, and had bouts of vomiting.

Day 4

27. The CT scan of Mrs A's chest was undertaken on the morning of Day 4, and confirmed bilateral pulmonary emboli.

28. At 1.00pm, Dr C commenced Mrs A on a further blood-thinning medication, dabigatran 150mg BD.[13]

[12] An antibiotic used to treat acute UTI.
[13] BD means "twice daily".

29. Dr C stated:

> "[M]y plan was to cover dabigatran with treatment dose Clexane for 5 days, with dual therapy over the 5 days. After this time, the plan was to continue dabigatran alone for treatment for pulmonary embolus."

30. A pharmacy note at 2.00pm states: "[P]lease review dabigatran dose and consider decreasing dose to 110mg BD due to patient's age if considered low thromboembolic risk and high bleeding risk."

31. Dr C did review the dose of dabigatran after the pharmacy note suggested decreasing from 150mg to 110mg BD. However, as Mrs A was not a low thromboembolic risk, and in light of the extensive nature of her PE, the dose was continued at 150mg BD.

32. Dr C stated that she did not consult with anyone regarding this decision. Her decision was based on a Grand Round presentation on venous thromboembolism given by a haematologist at Lakes DHB. Dr C recalls the presenter discussing bridging[14] dabigatran treatment with Clexane, and she interpreted this to mean that co-administration of dabigatran and Clexane was required for five days, and then Clexane therapy would stop and dabigatran therapy alone should continue.

33. The haematologist who presented at the Grand Round indicated that he may have used the word "bridging" in the conversation about perioperative management of patients on regular dabigatran. He said that the intended interpretation was to take a high-risk patient off his or her regular anticoagulant, ready for a surgical procedure, and use an alternative such as Clexane until it was safe to switch back to the regular anticoagulant.

34. However, Lakes DHB identified differences in the interpretation that different professions give to the term "bridging". Dr C's interpretation was to use an additional anticoagulant as dual therapy until a slower acting anticoagulant reached therapeutic levels.[15]

Day 5

35. By Day 5, Mrs A was still feeling nauseous and unwell due to vertigo, and was unsteady on her feet, although she was no longer feeling hot and sweaty. During the afternoon ward round, the finding of pulmonary emboli and the need for lifelong anticoagulants were discussed with Mrs A.

[14] Bridging anticoagulation refers to giving a short-acting blood thinner, such as Clexane (enoxaparin), around the time that therapeutic anticoagulation is interrupted. Bridging anticoagulation aims to reduce a patient's risk of thromboembolism.

[15] Dabigatran acts as a direct thrombin inhibitor and does not require transitioning/co-administering with Clexane (unlike warfarin). While the clinical rationale for dabigatran use is similar to that of warfarin, dabigatran targets a different part of the clotting cascade, and does not require transitioning with other anticoagulants, as it is fast acting.

Day 6

36. By Day 6, Mrs A appeared to be recovering. At 2.00pm, the nursing notes state: "[P]atient has bleeding from the injection site,[16] pressure plaster in situ." In the evening, the nursing notes state: "[V]ertigo symptoms appear to have decreased, patient states vertigo ↓."

Day 7

37. On Day 7, Mrs A complained of a severe headache all day, and her blood pressure was elevated. She was given paracetamol with good effect in the morning when her family visited.

38. At 7.00pm, RN D gave Mrs A paracetamol and codeine for a headache that Mrs A had reported as 8/10 pain. At the time, RN D was an NETP[17] nurse. The notes record that the on-call house officer, Dr E, was notified. At 9.30pm, Mrs A vomited and her blood pressure was raised. Dr E was notified again, and he considered that her raised blood pressure was a result of the nausea and pain. Dr E did not review Mrs A physically on either occasion — all advice was given over the telephone. Mrs A had another vomiting episode at 11.00pm.

39. The telephone discussions between RN D and Dr E were not documented on an SBARR form. However, RN D stated that she did use the SBARR format in her verbal communication. Dr E could not recall whether the SBARR format was used, or the level of concern expressed by RN D.

40. Dr E did not write a review note on Mrs A's file.

41. The Duty Nurse Manager's report for the evening shift notes that it was a "[v]ery busy shift for [the] ED". Dr E had up to five patients waiting to be admitted.

Day 8

42. On Day 8, Mrs A continued to feel unwell. She did not eat breakfast or lunch, vomited when moved, and was incontinent of urine.

43. At 9.15am Dr C reviewed Mrs A and noted her ongoing nausea and vomiting, severe headache the previous day, and nystagmus[18] on right and vertical upward gaze.

44. Dr C's plan was for a repeat CT scan of the head, two further doses of Clexane for bridging, and to continue dabigatran 150mg BD for six months, and then 110mg BD thereafter for life.

45. The scan was performed at 11.55am, and the team was informed of the preliminary findings at 12.15pm. The scan showed a new subdural haemorrhage in the posterior fossa.

[16] Where Clexane had been injected.
[17] Nurse Entry to Practice — a year-long programme for a nurse in his or her first year in the workforce following graduation.
[18] Rapid involuntary movements of the eyes.

46. A plan was made to reverse the dabigatran with Praxbind. The guidelines on prescribing Praxbind, set by the tertiary centre and adopted by Lakes DHB, state that Praxbind may be approved only by an ED physician (SMO) or a haematologist.

47. Dr C discussed the reversal of dabigatran with the on-call haematologist at DHB2, Dr F. During the discussion, Dr F mentioned that co-administration of dabigatran and Clexane is not recommended.

48. Dr F suggested checking the coagulation factors and ensuring that the thrombin clotting time was prolonged before administering Praxbind. This was in line with the DHB2 guidelines at the time. He also suggested stopping all anticoagulants, transferring Mrs A to ICU for closer monitoring and treatment, and ordering an ultrasound to check for DVT.[19]

49. Anticoagulation with dabigatran and Clexane was stopped. The last dose of dabigatran had been given at 8.30am that day, and the last dose of Clexane had been administered at 8.30pm the previous night.

50. Dr C consulted with the neurosurgeon at DHB2. He reviewed images and advised that in light of the recent pulmonary emboli, any procedure or intervention would have a high surgical risk. The possibility of Mrs A transferring to DHB2 for on-going monitoring and treatment was discussed.

51. These new developments were discussed with Mrs A's family.

52. Mrs A was transferred to the intensive care unit (ICU), and at 3.30pm the ICU house officer carried out a neurological examination. Mrs A had unequal pupils and had deteriorated clinically. Her Glasgow Coma Scale score had reduced from 15 to 3. The thrombin clotting time results were still pending.

53. At 3.50pm, the ICU consultant informed the family that Mrs A's condition had deteriorated since the morning, and she was no longer responsive to voices. The family decided to avoid invasive treatment, and opted for comfort cares. Mrs A's thrombin clotting time results were discussed, but in light of her clinical situation, comfort care was considered appropriate.

54. At 4.00pm, Mrs A was moved to a single room. At 5.00pm, Dr C reviewed Mrs A and spoke to her family.

Days 9–11

55. At 8.50am on Day 9, Dr C and her team visited the family and offered their condolences for Mrs A's condition. They also disclosed that a potential medication error made in the course of treatment may have contributed to her deterioration, and Dr C apologised for the error. The information was disclosed to the family, including younger family members, while they were awaiting transfer of Mrs A.

[19] Deep vein thrombosis — the formation of a clot within a deep vein (eg, in the leg or pelvis). Dislodgment of part or all of the clot can result in a potentially life-threatening pulmonary embolism.

56. At 10.00am, the Chief Medical Officer (CMO) spoke to the family and discussed the medication error. It was explained that any such incident is serious, and that an investigation would be undertaken.

57. At 10.15am, the house surgeon had a discussion with the family to explain the clinical situation and to offer an opportunity for the family to ask questions. The timing and method of disclosure by Dr C were raised as having not been ideal, and as having added to the family's distress. Support from the hospital risk management team was offered and provided.

58. Mrs A was transferred home by ambulance at 1.00pm, and she died at home.

Additional information

Dr C

59. Dr C has made changes to her medical practice. She does not co-administer Clexane and dabigatran, and advises patients that the medications should not be taken together. She told HDC that she keeps fully up to date with anticoagulation best practice, and seeks specialist advice if in any doubt.

60. Dr C said that she now considers requesting repeat imaging and other investigations and assessments earlier during admission if a patient is not improving as expected.

61. On reflection, Dr C identified ways in which she could have improved her communication with Mrs A's family. Dr C said that she could have asked the family to step out of the ICU room for a private discussion away from younger family members. Dr C regrets that she may have rushed through events and failed to provide an adequate and appropriate explanation to the family.

62. Dr C could not recall receiving specific training on the Lakes DHB's open disclosure policy. The root cause analysis by Lakes DHB (detailed further below) highlighted that the policy was not well understood by clinicians, and did not provide practical guidance to staff.

Pharmacy review

63. Lakes DHB conducted a review of the medications prescribed and dispensed for Mrs A.

64. Enoxaparin (Clexane) was first prescribed on Day 2, and dabigatran on Day 4. On Day 4, a clinical pharmacist wrote a note in Mrs A's file and raised concerns with the medical registrar about the dose of dabigatran. The co-prescribing was also raised with the registrar after the charts were re-checked.

65. After writing the note, it was drawn to the clinical pharmacist's attention by a pharmacist in the dispensary that two anticoagulants (enoxaparin and dabigatran) had been co-prescribed. The clinical pharmacist re-checked the original chart and then raised the concern with the medical registrar. The medical registrar responded that the patient was a high thromboembolic risk, and was adamant that this was what Dr C wanted.

66. Dr C did review the dose of dabigatran after the pharmacy note suggested decreasing the dose. As Mrs A was not a low thromboembolic risk, and in light of the extensive nature of her pulmonary emboli, the dose remained unchanged. Dr C felt confident that she was doing the right thing based on up-to-date knowledge, and reassured her junior team members of this when they questioned it.

67. Pharmacy staff remained concerned, so it was agreed with the medical registrar that only two doses of dabigatran would be dispensed, and the decision revisited by the medical team on Day 5.

68. Over the weekend of Days 6–7, nursing staff continued to obtain a supply of dabigatran from another ward's imprest stock,[20] and therefore the pharmacy was unaware that the dual therapy had continued over the weekend.

69. On Day 8, the pharmacy received a further order for dabigatran 150mg BD. Upon seeing the continued dual anticoagulation therapy, the Pharmacy Manager sent a clinical pharmacist to the ward to discuss whether this was intended. Dr C had already stopped the anticoagulants by this time.

Root Cause Analysis Review by Lakes DHB — July 2017

70. Lakes DHB conducted a root cause analysis of Mrs A's case. A summary of the findings of the review is set out below.

71. Mrs A had a PE in 2006, after which she was treated with warfarin for six months. This was appropriate treatment at the time.

72. The expert neurology opinion suggests that, in hindsight, Mrs A had an embolic stroke without changes on acute CT scan, but that eventually it evolved over the next few days. Whilst there is a difference in the retrospective diagnosis, it is not considered that the treatment would have been any different, only the monitoring.

73. It is considered appropriate that Mrs A was admitted to the Medical Unit rather than the Acute Stroke Unit, based on her unresolved shortness of breath.

74. The scanner failure and delay in obtaining a CT scan of the chest was not considered causal in Mrs A's adverse event, as treatment was underway. However, the distraction may have contributed to reduced situational awareness.

75. It is thought that the major risk of bleeding was created by the dual anticoagulant therapy of Clexane and dabigatran for four days. A misunderstanding in regard to bridging dabigatran with Clexane led to an over-anticoagulation.

76. A presentation by a haematologist at a Grand Round was attended by Dr C. The investigation identified differences in the interpretation that different professions give to the term "bridging".

[20] Medication stock on a ward.

77. Two other incidences of co-prescribing enoxaparin and dabigatran were identified within the organisation within a few weeks of Mrs A's case. Both incidents involved separate clinicians who were not involved in Mrs A's case. This would indicate a systemic knowledge deficit amongst some clinicians around the correct process for switching to dabigatran.

78. Discussion with the Health Quality & Safety Commission (HQSC) Medication Safety Team revealed that this knowledge deficit had also been identified by another DHB through audit, and was presumed to be widespread around New Zealand.

79. There was no requirement to monitor haemostasis[21] in patients on the specific individual anticoagulation and antiplatelet medications administered, owing to "predictable" responses. Evidence suggests that in certain situations it may be useful to carry out some laboratory testing of haemostasis. The use of tests to detect over-anticoagulation has been referred to the New Zealand Chapter of the Haematology Society of Australia and New Zealand.

80. Lakes DHB has a communication tool called SBARR, which supports staff to document "situation, background, assessment, recommendation and response". In practical terms, the SBARR framework has had a failed implementation at the DHB. Lakes DHB noted that if the SBARR prompts had been used, it is likely that the investigations carried out on the morning of Day 8 would have been initiated on the evening of Day 7, approximately 12 hours earlier. There is a possibility that this may have led to earlier identification of the intracerebral bleed.

81. Mrs A's clinical presentation made the likelihood of a haemorrhage due to over-anticoagulation so likely that the idarucizumab (Praxbind) should have been given immediately. An expert opinion was obtained from a clinical haematologist outside the region, who also agreed that it would have been clinically appropriate to give the idarucizumab. There is no way of determining whether treatment would have been successful.

82. The Early Warning Score (EWS) was calculated incorrectly on Day 2. This meant that Mrs A's next observations were taken three hours later, rather than half an hour later. However, this would have made little difference, if any, to the course of treatment, as Mrs A's oxygen saturations had recovered by the next recording. There is a national programme addressing EWS charts and nurse education.

83. On Day 8, the pharmacy received an order for further dabigatran. Upon seeing the continued dual anticoagulation therapy, the Pharmacy Manager sent a clinical pharmacist to query and confirm that this was intentional. Nurses had obtained dabigatran from another ward's imprest stock over the weekend, and therefore the pharmacy was unaware that the dual therapy had continued over the weekend.

84. Open disclosure of this event to the patient's family was suboptimal, and was not done in a safe way for the patient's family or the staff involved.

[21] Stopping of bleeding.

85. Lakes DHB sent out an urgent communication to all clinical staff outlining the dangers of co-administration of anticoagulation medicines. Unfortunately, a relative of Mrs A works for the DHB and received the email without any support or warning.

86. The open disclosure policy is not well understood by clinicians, nor does it provide practical guidance for staff. Lakes DHB undertook to review the policy and include procedural steps for clinicians to follow, and to consider a process for alerting families prior to emailing alerts to staff.

Actions taken

87. Lakes DHB advised HDC that the following actions have been taken since Mrs A's case:

- Dabigatran dispensings and Clexane imprest items are labelled with warnings not to co-administer the anticoagulants. Access to dabigatran has been tightened.
- The learnings were published in the Health Quality & Safety Commission's Open Book Alert, which was sent to all DHBs, and a poster presentation of Mrs A's story was presented at the International Forum on Quality and Safety in Healthcare Melbourne in September 2018. Learnings have been acknowledged by Pharmacy Now.
- Lakes DHB issued an internal alert to all prescribers and Clinical Nurse Managers in late November 2016.
- This event was discussed at the national CMO group meeting in August 2017.
- The authorisation for use of idarucizumab has been referred to the Lakes DHB pharmaceutical advisory committee for discussion, and there is agreement to review the current process to allow provision for situations when waiting for laboratory results could be detrimental.
- Concerns were raised with the HQSC Medication Safety Expert Advisory Group (MSEAG) around:
    - the co-prescribing of direct acting oral anticoagulants (dabigatran) and low molecular weight heparin (Clexane) anticoagulants
    - the need to update the National Medication Chart and the e-Learning tool.
- Lakes DHB has updated its "Open Disclosure Policy and Procedure", undertaken training with the Cognitive Institute, and is looking at a user friendly e-learning tool for staff.
- Lakes DHB has introduced alert stickers related to anticoagulant prescribing and administration, and is trialling a medication sheet to be used only for anticoagulants.

Responses to provisional opinion

88. Mrs B was given an opportunity to comment on the "information gathered" section of the provisional report, and Lakes DHB and Dr C were given an opportunity to comment on the relevant parts of the report. Their comments have been incorporated where appropriate.

89. Mrs B, Dr C, and Lakes DHB acknowledged the provisional findings. Lakes DHB has undertaken steps to meet the provisional recommendations, as detailed in the recommendations section of the report. Lakes DHB also stated:

> "Lakes DHB has taken this incident very seriously and has used it as a real opportunity to not only improve our own processes, procedures and guidelines but also to influence better understanding of this 'thinking error' nationally and internationally."

90. Dr C told HDC that she has worked on her practice relating to open disclosure. She stated that she has taken on board my expert advisor's comments about open disclosure, and has changed her practice accordingly. She stated:

> "I am familiar with the professional guidelines provided by the Medical Council and will ensure that in future I carefully follow [Lakes] DHB's policy on open disclosure should the occasion arise."

Opinion: Dr C

Co-administration of dabigatran and Clexane — adverse comment

91. On Day 4, a CT scan of Mrs A's chest showed evidence of pulmonary emboli (PE). The treatment response was to continue the Clexane injections and start treatment with dabigatran.

92. Dr C's plan was to cover dabigatran with treatment dose Clexane for five days, with dual therapy over the five days. After this time, the plan was to continue dabigatran alone for treatment of the PE.

93. The Medical Council of New Zealand (MCNZ) outlines the standards expected of doctors when prescribing, and states that to ensure that prescribing is appropriate and responsible, doctors should "be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that [they] prescribe".

94. Regarding the co-administration of dabigatran and Clexane in Mrs A's case, I note the comments of my independent expert advisor, Dr John Fink:

> "[D]abigatran has immediate activity … so this type of overlap of enoxaparin with the long-term anticoagulation is both unnecessary and dangerous. This use would be viewed as a very serious error by my peers, who are specialist stroke neurologists. However, the fact that others have made similar errors indicates a more widespread deficit in knowledge in the generalist community beyond just the responsible SMO in this case."

95. I note that when Dr C became aware of the error, she appropriately consulted with a neurosurgeon and a haematologist. She stopped the anticoagulation with dabigatran and Clexane, and planned to reverse the dabigatran with Praxbind.

96. I also note a more general confusion with the term "bridging", and that Dr C was not alone in her interpretation that "bridging" meant that Clexane and dabigatran therapy should be co-administered for five days.

97. Regarding the pharmacy review, whereby Dr C's prescription of dabigatran was queried, I note Dr Fink's comments:

> "Pharmacy review appropriately drew some attention to [the prescribing] and limited the dispensing, but additional supplies were obtained from CCU/ICU over the weekend. It is doubtful that any change to this process would have made a substantial difference to the outcome, as the prescription was a considered one, not accidental, the instructions to medical staff were clear and the misunderstanding regarding 'bridging' and dabigatran was not unique to [Dr C]."

98. The prescribing of dabigatran and Clexane together was contraindicated, and I am concerned that Dr C prescribed these medications together for Mrs A. I note that there was some general confusion about "bridging" anticoagulants, and note Dr Fink's comment that the fact that others have made similar errors indicates a more widespread deficit in knowledge in the generalist community.

99. Dr C's decision to co-administer dabigatran and Clexane was based on her interpretation of a Grand Round presentation by a haematologist. Dr C was confident that she was doing the right thing based on up-to-date knowledge. I agree with Dr Fink's comment:

> "As dabigatran was a relatively 'new' agent, the need for a greater education component could have been recognised in the preparation of the guideline (Lakes DHB Dabigatran — Perioperative Guideline)."

100. I note the response by Lakes DHB to address the wider knowledge deficit, and note that learnings from this case were published in the Health Quality & Safety Commission's Open Book Alert, which was sent to all DHBs in New Zealand. In addition, a poster presentation of Mrs A's story was presented at an International Forum, and learnings have been acknowledged by Pharmacy Now.

101. Nonetheless, prescribers are responsible for ensuring that they have an understanding of the medications they are prescribing, and of how these interact with any other drugs the patient is taking. In this case, that did not occur.

Revision of diagnosis — no breach

102. Mrs A's initial diagnosis was TIA/stroke, and treatment included aspirin and clopidogrel.

103. On Day 2, the diagnosis of TIA/stroke was revised to peripheral vertigo with a high clinical suspicion of PE. Treatment with Clexane was started, and clopidogrel treatment stopped to lessen the risk of bleeding.

104. Regarding the revised diagnosis in Mrs A's case, I note Dr Fink's comments:

> "The neurological diagnosis of TIA/stroke versus peripheral cause for vertigo was difficult. I think the overall standard of care in this regard was reasonable … The only way a diagnosis of stroke might have been confirmed would have been with an MRI brain scan. However, in the context of a medically unwell patient requiring more urgent diagnosis and management of PE, and who already had a clear indication for anticoagulation, it is reasonable to conclude that an MRI scan was unnecessary as life-long anticoagulation was needed regardless."

105. I accept Dr Fink's advice, and consider that the care provided by Dr C in respect of Mrs A's diagnoses was reasonable.

Open disclosure — adverse comment

106. After recognising the potential medication error on Day 8, Dr C disclosed this to Mrs A's family at the first available opportunity — the morning ward round on Day 9.

107. The MCNZ guideline "Disclosure of Harmful and Adverse Events" (December 2010) states that when a patient is harmed while receiving medical treatment, MCNZ expects that the senior doctor responsible for the patient's care will advise the patient (or, where appropriate, the patient's family) of the facts of the harm in the interests of an open, honest and accountable professional relationship.

108. Regarding the open disclosure of information related to medication error, I note Dr Fink's comment that "the key principles of Open Disclosure were followed including honesty and involvement of senior clinicians".

109. I accept Dr Fink's advice, and consider that Dr C did openly disclose the medication error. I recognise that the disclosure was done in a timely manner in line with the MCNZ guideline. However, the manner of the disclosure could have been better, as Dr C has acknowledged. Asking the family to step out of the ICU room for a private discussion, away from younger family members, would have been less distressing for Mrs A's family. In this regard, I note Dr Fink's advice that communication of bad news and news of error is inherently difficult, and even senior clinicians need to continue to develop their skills in this area.

110. I note that Lakes DHB's Root Cause Analysis Report recommended that the DHB review the open disclosure policy and include procedural steps for clinicians to follow where open disclosure is required. A clear policy that is easy to follow will support the communication of a disclosure in a safe way for the patient's family and the staff involved.

Opinion: Lakes District Health Board

System issues at Lakes DHB — breach

111. A number of issues have come to light regarding education, guidelines, and policy and implementation failures at Lakes DHB.

SBARR failed implementation

112. Lakes DHB has a communication tool, SBARR, which supports staff to document a "situation, background, assessment, recommendation and response".

113. On the evening of Day 7, RN D notified the on-call house officer, Dr E, twice regarding Mrs A's condition. The discussions were conducted over the telephone, and the SBARR form was not used to document the communication. It cannot be determined exactly what level of information was communicated by RN D to Dr E.

114. RN D stated that she did use the SBARR format in her verbal communication. Dr E did not review Mrs A physically on either occasion — all advice was given over the telephone. Dr E could not recall whether the SBARR framework was used, or the level of concern expressed by RN D.

115. In its Root Cause Analysis Report, Lakes DHB noted that if the SBARR prompts had been used, it is likely that escalation of care would have occurred sooner, and the investigations carried out on the morning of Day 8 would have been initiated on the evening of Day 7, approximately 12 hours earlier.

116. Both staff involved were junior, and Lakes DHB identified a failed implementation of the SBARR framework.

117. I note that Lakes DHB has undertaken to re-launch the SBARR tool as a priority.

Inadequate content and communication of the open disclosure policy

118. In its Root Cause Analysis Report, Lakes DHB acknowledged that open disclosure of this event to Mrs A's family was suboptimal, and was not done in a safe way for the family or the staff involved. Dr C could not recall receiving specific training on Lakes DHB's open disclosure policy.

119. Lakes DHB acknowledged that the open disclosure policy was not well understood by clinicians, and did not provide practical guidance for staff as to whom they should contact for support and guidance through the process prior to approaching a patient or the patient's family.

120. I note that Lakes DHB has undertaken to review and communicate the open disclosure policy.

Inadequate anticoagulation guidelines

121. Dr Fink reviewed the guidelines current in 2015/16, and commented that interpretation of the Dabigatran — Perioperative Management Guideline was "open to some error in the understanding of the intersection between enoxaparin use and dabigatran". The guidelines lacked clarity regarding the way enoxaparin should be managed in the setting of dabigatran initiation. As dabigatran was a relatively new agent at the time, the need for a greater education component could have been recognised. In addition, idarucizumab (Praxbind) had recently become available as a reversal agent for dabigatran, and the guideline needed to be updated.

122. My independent expert advisor, Dr Fink, has identified a number of areas where review and revision of the current guidelines should be made. The guidelines are for perioperative management, and the sections relevant to Mrs A's case are "less obvious than ideal". Dr Fink advised that the three perioperative guidelines overlap and contradict in parts, and should be rationalised.

123. Guidance on emergency procedures should be easier to find. Dr Fink has suggested that a specific guideline for management of bleeding in patients who are on anticoagulation therapy, ideally available electronically, would enable clinicians to locate guidance rapidly in an emergency situation.

Inadequate pharmacy review

124. The clinical pharmacist wrote a note in Mrs A's file raising concerns about the dose of dabigatran, and this advice was considered by Dr C. However, concerns about the co-administration of dabigatran and Clexane were raised only later with the medical registrar, who responded that the patient was a high thromboembolic risk, and was adamant that this was what Dr C wanted.

125. Pharmacy staff remained concerned, so it was agreed with the medical registrar that only two doses of dabigatran would be dispensed, and the decision revisited by the medical team. Despite this, over the weekend, nursing staff obtained a supply of dabigatran from another ward's imprest stock, and continued to administer the drug to Mrs A.

126. The pharmacy should have been clearer in enforcing that dabigatran and Clexane should not be co-administered. The pharmacy review is an important safety-net to check, and sometimes challenge, prescribing.

Systemic knowledge deficit

127. Dr C co-administered Clexane and dabigatran in light of her interpretation of the term "bridging". However, as discussed, dabigatran acts as a direct thrombin inhibitor, and (unlike warfarin) does not require transitioning/co-administration with Clexane. While the clinical rationale for dabigatran use is similar to that of warfarin, dabigatran targets a different part of the clotting cascade, and does not require transitioning with other anticoagulants, as it is fast-acting.

128. Within a few weeks of Mrs A's case, Lakes DHB identified two other incidences of co-administration of Clexane and dabigatran within the organisation. Both incidents involved separate clinicians who were not involved in Mrs A's case. This would indicate a systemic knowledge deficit amongst some clinicians around the correct process for switching to dabigatran.

129. In addition to Lakes DHB, the Health Quality & Safety Commission Medication Safety Team was aware of the same knowledge deficit at another DHB, and issued an Open Book Alert in June 2017. I note Dr Fink's comment:

> "This raises … the imperative for adequate education to be incorporated with the launch of new drugs that have both the potential for significant hazard and the potential for very widespread use by non-specialists."

Conclusion

130. I consider that the prescribing of contraindicated drugs, the SBARR implementation failure, the inadequate content and communication of the open disclosure policy, the inadequate anticoagulation guidelines, the inadequate pharmacy review, and the systemic knowledge deficit amounted to suboptimal care. Accordingly, Lakes DHB failed to provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights.

Other comment — delay in prescribing Praxbind

131. The guidelines on prescribing Praxbind, set by the tertiary centre and adopted by Lakes DHB, stated that Praxbind may be approved only by an ED physician (SMO) or a haematologist. Dr C appropriately contacted the on-call haematologist, Dr F (at DHB2) as per the guidelines. She was advised by Dr F to check the thrombin clotting time before administering Praxbind. This was in line with the guidelines at the time.

132. Regarding the delay this caused in prescribing Praxbind in Mrs A's case, I note Dr Fink's comments:

> "[T]he advice from the haematologist to delay a decision to reverse the dabigatran until a specialised clotting test was obtained was inappropriate in the circumstances of a life-threatening bleed and in the context of unequivocal administration of therapeutic doses of dabigatran: when dabigatran is not only prescribed but clearly demonstrated to have been taken as in an inpatient situation one can be certain that the clotting test would show an abnormal result, rendering the delay to obtain it unnecessary."

133. However, Dr Fink also commented:

> "Praxbind was an extremely new agent at the time this patient was admitted and experience with its use in an emergency setting in these centres will have been very limited indeed at that time."

134. I accept Dr Fink's advice, and note that all parties followed the guidelines on the use of Praxbind. I agree that there was a lack of clinical judgement override in the process at the time, and acknowledge that Praxbind was an extremely new drug. This matter has been referred to the Lakes DHB Pharmaceutical Advisory Committee for discussion. There is agreement to review the current process for prescribing Praxbind, which is appropriate.

Recommendations

135. I recommend that Lakes DHB provide Mrs A's family with a written apology. The apology is to be sent to HDC within three weeks of the date of issue of this report, for forwarding to Mrs A's family.

136. In the provisional opinion, I recommended that Lakes DHB:

a) Provide an update on the recommendations outlined on pages 13 to 15 in the Lakes DHB Root Cause Analysis Report dated June 2017.

   Lakes DHB agreed to this recommendation.

b) Implement the Early Warning Score (EWS) national programme, and provide HDC with evidence of nursing staff orientation and training on the use of the tool.

   Lakes DHB advised it has been proactive in working with the HQSC around the EWS and has already updated its plans. Lakes DHB is also involved in a Deteriorating Patient Programme, and is working to ensure that the new EWS continues to evolve.

   I recommend that Lakes DHB provide HDC with evidence of nursing staff orientation and training on the use of the tool and provide HDC with a report on implementation progress.

c) Implement a policy for monitoring of haemostasis in patients on the specific individual anticoagulation and antiplatelet medications administered.

   Lakes DHB advised that it has asked a specialist haematologist to provide content to inform a policy and a procedure for monitoring of haemostasis in patients on anticoagulation therapy.

   I recommend that Lakes DHB provide HDC with a copy of the new policy and procedure.

d) Update the current Lakes DHB Anticoagulant Guidelines to reflect the comments from Dr Fink, and provide HDC with a copy of the updated policies.

   Lakes DHB advised that currently it is updating its peri-operative anticoagulant guidelines, including the management procedures, as well as addressing the use of direct acting oral anticoagulant reversal agents, e.g., Praxbind.

   I recommend that Lakes DHB provide HDC with a copy of the updated policies.

e) Report back to HDC on the above recommendations within three months of the date of this report being issued.

137. Lakes DHB has advised that it is developing a regional electronic prescribing system. I recommend that Lakes DHB include an alert in this system to highlight the interaction between dabigatran and Clexane.

138. I recommend that Lakes DHB audit 50 sets of clinical records, in relation to weekend entries, to ascertain the compliance with Medical Council of New Zealand standards. If standards are not being met, Lakes DHB is to provide HDC with details of the planned actions to achieve this, within six months of the date of this report.

139. I recommend that Lakes DHB take steps to improve its documentation and decision-making around the appropriate prescribing of anticoagulants, and provide HDC with details of the planned actions to achieve this, within three months of the date of this report.

140. I also recommend that PHARMAC, Medsafe, and the Health Quality & Safety Commission incorporate adequate education to the sector with the launch of new drugs that have both the potential for significant hazard and the potential for very widespread use by non-specialists.

Follow-up actions

141. A copy of this report with details identifying the parties removed, except the expert who advised on this case and Lakes DHB, will be sent to DHB2, the Health Quality & Safety Commission, the New Zealand Pharmacovigilance Centre, the Stroke Foundation New Zealand, the National Chief Medical Officer's Group, the New Zealand Chapter of the Haematology Society of Australia and New Zealand, the Royal Australasian College of Physicians, Medsafe, and PHARMAC, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from consultant neurologist Dr John Fink:

> "Thank you for requesting file review and expert advice regarding this complaint. My background is a Consultant Neurologist at Christchurch Hospital since 2001 and clinical director of the Department of Neurology at Christchurch Hospital since 2011. I am Co-director of the acute stroke service at Christchurch Hospital, current chair of the South Island Stroke Workstream and former chair of the New Zealand National Stroke Network. I am medical adviser to the Stroke Foundation of New Zealand. I was Editor of the New Zealand Stroke Guideline, 2010. I am a member of the PHARMAC therapeutics advisory committee neurological subcommittee.
>
> I have reviewed all of the documents provided by HDC including the letter of complaint, Lakes DHB response, Root Cause Analysis report, [the] family meeting notes and Lakes DHB clinical records.
>
> Having reviewed these documents, my conclusion is that the findings and recommendations of the Root Cause Analysis report prepared by Lakes DHB are both thorough and appropriate. I find that I have little of great substance to add to that report.
>
> The neurological diagnosis of TIA/stroke versus peripheral cause for vertigo was difficult. I think the overall standard of care in this regard was reasonable. The patient was treated empirically initially for TIA as appropriate with aspirin plus clopidogrel, even though the diagnosis was not confirmed on initial CT head. The diagnosis was revised to 'vertigo: likely peripheral cause' on Day 3. Concern re-focussed on the likely diagnosis of PE. Clexane was appropriately commenced based on this clinical high suspicion, even when CTPA was unavailable. Clopidogrel was appropriately stopped to lessen bleeding risk when Clexane was started and with the diagnosis of TIA/stroke considered less likely. Given the revision of the diagnosis from TIA/stroke to peripheral vertigo on Day 3 discussions about the monitoring protocols for TIA are not necessarily relevant to the case beyond that point as the patient would have been removed from any such protocol. The only way a diagnosis of stroke might have been confirmed would have been with an MRI brain scan. However, in the context of a medically unwell patient requiring more urgent diagnosis and management of PE, and who already had a clear indication for anticoagulation, it is reasonable to conclude that an MRI scan was unnecessary as life-long anticoagulation was needed regardless.
>
> The most important departure from accepted care is the co-administration of enoxaparin with dabigatran. I would consider myself an expert user of these agents, so, for me, the issue is very obvious: dabigatran has immediate activity, unlike warfarin which takes several days to take effect, and so this type of overlap of enoxaparin with the long-term anticoagulation is both unnecessary and dangerous. This use would be viewed as a very serious error by my peers, who are specialist stroke neurologists. However, the fact that others have made similar errors indicates a

more widespread deficit in knowledge in the generalist community beyond just the responsible SMO in this case. The issues regarding confusing use of the term 'bridging' has been discussed appropriately in the RCA report. The open book alert is an appropriate measure to begin to address this educational deficit, however I am left uncertain as to whether this is sufficient. How do we know if this potentially hazardous misunderstanding is still commonly present? As DHBs move increasingly to electronic prescribing a mechanism for alerting to this hazard is presented, but is it known whether DHBs actually include this interaction as a routine alert?

I reviewed the nursing clinical notes from Day 7. It is easy to see how the severe headache and vomiting were treated symptomatically over this period as there was no change to EWS and observations noted to be 'stable'. Although a potential opportunity for earlier detection of intracranial bleeding might have been missed, I don't think this represents a major departure from accepted practice.

The need for repeat CT scan was recognised the next morning, but the patient's neurological status was still relatively stable at that point. The CT scan was performed at 1155, and the team notified of findings at 1215. The patient has been noted to have deteriorated before the nursing entry at 1300 and an SMO update is provided at 1315 following discussions with other relevant specialists at the tertiary centre. The situation is indeed very difficult as described in the case notes with a serious thrombotic disorder (PE) and now a critically serious bleeding disorder. As discussed in the RCA report, the advice from the haematologist to delay a decision to reverse the dabigatran until a specialised clotting test was obtained was inappropriate in the circumstances of a life-threatening bleed and in the context of unequivocal administration of therapeutic doses of dabigatran: when dabigatran is not only prescribed but clearly demonstrated to have been taken as in an inpatient situation one can be certain that the clotting test would show an abnormal result, rendering the delay to obtain it unnecessary. It is also worth noting, however that Praxbind was an extremely new agent at the time this patient was admitted and experience with its use in an emergency setting in these centres will have been very limited indeed at that time. […]

I agree with the recommendations for improvement in the RCA report. I would additionally suggest an audit of DHB electronic prescribing alert systems to ensure this alert is routinely included.

Please do not hesitate to contact me if you require any further clarification or addition to this advice.

Yours sincerely

John Fink
Neurologist"

Further expert advice

"Thank you for requesting further expert advice regarding the care provided to [Mrs A] by Lakes DHB and [Dr C] [in] 2016. I have previously provided advice on this case in my report from 20 September, 2017 and presented my credentials in that report. To provide this advice I have reviewed all of the documents provided by HDC, including copies of the original hospital case file.

There are some new documents provided in addition those available when I prepared my report in September 2017.

There are a number of errors or potential errors identified that may have contributed to the outcome, which I will briefly summarise

1. Misdiagnosis of stroke as peripheral vertigo [Days 1–3]
2. Concurrent prescription of dabigatran and Clexane [Days 4–8]
3. Possible delay in diagnosis of neurological deterioration overnight [Day 7]
4. Delay in obtaining approval to use Praxbind reversal agent for dabigatran [Day 8]

1. Misdiagnosis of stroke as peripheral vertigo. There is no new information which adds to this issue as assessed in my previous report. As I discussed previously, the neurological diagnosis of TIA/stroke versus peripheral cause for vertigo was difficult and the overall standard of care in this regard was reasonable, particularly given the complexity of the presentation with evolving pulmonary embolism.

2. Concurrent prescription of dabigatran and Clexane. There is no new information which adds substantially to the previous assessment. This was a deliberate prescription by [Dr C] based on a misunderstanding around 'bridging' of anticoagulants. Pharmacy review appropriately drew some attention to this and limited the dispensing, but additional supplies were obtained from CCU/ICU over the weekend. It is doubtful that any change to this process would have made a substantial difference to the outcome, as the prescription was a considered one, not accidental, the instructions to medical staff were clear and the misunderstanding regarding 'bridging' and dabigatran was not unique to [Dr C].

3. Possible delay in diagnosis of neurological deterioration overnight [Day 7]. There is some new information pertinent to the events that evening.

    a. I note the response from [RN D] (13/9/2018) who was the nurse caring for [Mrs A] on the evening shift [Day 7]. She indicates that she was well aware of and followed the SBARR reporting format in her communication with the on-call house officer (OCHO), as per Lakes DHB policy. I note other discussions regarding difficulties with consistent implementation of the SBARR policy at Lakes DHB, however it does not appear to have been an important factor in this case.

    b. [RN D] indicates that the OCHO 'did not write notes after reviewing this patient twice within that shift.' The response from [Dr E] (3/10/18), now orthopaedic

registrar, who was the OCHO that night, indicates he has no recollection of the case.

It is very poor practice for a doctor to review a patient and not make any documentation of this in the notes. This would fall short of expected standards. In this case, it would have significantly compromised the ability of any night house-officer who might have been called to attend [Mrs A] the next shift to make an accurate assessment. As it happened, no call to the night house officer was made, and the lack of documentation in the notes is unlikely to have made a material difference to the outcome. The quality of the OCHO assessment cannot be determined but the RN entry in the notes at 2130 indicates that verbal feedback from the OCHO was received. The fact that the OCHO was called twice to the same patient in one shift is evidence that there was clinical concern at nursing level. It is also noted that she was visited by the family and ate well during that shift, however. As I described in my previous report, it is easy to see how the severe headache and vomiting were treated symptomatically over this period as there was no change to EWS and observations noted to be 'stable'. The background reported in any SBARR format advice would have included the diagnosis of peripheral vertigo and pulmonary embolism and would not have raised stroke as an issue. It is likely that the OCHO would have recognised pulmonary embolism as the more clinically threatening problem and have been reassured that she was stable from that perspective. The RCA report notes the Duty Manager described the evening as a 'very busy shift for [the] ED'. The next medical assessment was at the consultant ward round by [Dr C] at 0915. A repeat CT scan was requested, but the plan to continue anticoagulants was not changed immediately, once again suggesting that the clinical level of neurological concern was not very high and suggesting that the OCHO assessment to manage symptomatically without requesting repeat CT scan the previous evening was understandable under the circumstances.

4. Delay in obtaining approval to use Praxbind reversal agent for dabigatran [Day 8]. There is no new information adding to my previous assessment of this issue.

As well as the above issues related to the clinical care of [Mrs A], an issue is raised about the open disclosure of information related to medical error that was communicated to [Mrs A's] family. [Dr C] indicates in her response (10/9/18) that she identified some ways that she might have improved the way she communicated with [Mrs A's] family, and that she did not recall receiving specific training on the Lakes DHB's open disclosure policy. However the key principles of Open Disclosure were followed including honesty and involvement of senior clinicians. It is evident from the clinical records that [the] Clinical Director of Quality Innovation, was involved early and discussed the findings with [Mrs A's] husband at 1550 on [Day 8] and the CMO was involved the following morning.

In answer to your specific questions:

1. Whether the care provided by Lakes DHB to [Mrs A] was reasonable.

Overall — yes, apart from the medication prescription error resulting in concurrent use of dabigatran and Clexane. I have previously provided advice on that issue, which is not changed by the new information provided.

2. Whether the information provided changes your previous advice in any way, with regard to Lakes DHB.

The failure of the OCHO to document his assessments in the notes is important to note, even though it is unlikely to have materially influenced the outcome in this case. This is a departure from accepted practice, of moderate significance. My peers would view this as an indication of poor performance in an RMO. Even though we recognise the often very demanding nature of their work, documentation remains a very high priority. Recommendations for improvement include some review, survey or audit to determine how common an issue this might be then review of RMO orientation information and if identified as a common problem consideration for publicity/education to effect a change in culture/practice.

3. If it does, please explain the change and reasons for the change.

The issue of house-officer orientation/documentation policy has not been identified previously.

4. Whether the care provided by [Dr C] to [Mrs A] was reasonable.

Care provided by [Dr C] was reasonable apart from the error related to concurrent prescription of dabigatran and Clexane.

5. Whether the information provided changes your previous advice in any way with regard to [Dr C]

No change to previous advice.

6. n/a

7. The adequacy of the policies and systems in place at the time of events with regard to stroke thrombolysis procedure, organised stroke service protocols, early warning system observation chart system, open disclosure policy (2016–2018) and the Guidelines at 6(n) to 6(q).

The stroke thrombolysis and organised stroke service protocols and systems appear adequate. As per my previous advice, the revision of the diagnosis from TIA/Stroke to peripheral vertigo on [Day 3] means that those protocols and systems no longer applied to [Mrs A] from that point. There is nothing about this case that causes me to question the EWS observation chart system: a minor error in EWS calculation occurred related to her respiratory status which had no impact on clinical management or outcome. [Mrs A's] EWS did not change during the night of [Day 7], however this did not prevent the nurse from requesting OCHO attention appropriately on two occasions. I am satisfied that the principles of the Open Disclosure Policy were followed in good faith. Communication of bad news and news of error is inherently difficult and even senior clinicians need to continue to develop their skills in this area.

I do not know what 'Guidelines at 6(n) to 6(q)' refers to.

Yours sincerely,

John Fink
Neurologist"

Further expert advice (Addendum on updated guidelines)

Addendum re: Lakes DHB Anticoagulant Guidelines

"This is an addendum to my report dated 18/12/2018 and specifically reviews the adequacy of the policies and systems at Lakes DHB described in Appendix 14 of the HDC documentation. Appendix 14 includes the following Lakes DHB documents:

- Oral Anticoagulants Perioperative Management Guideline
- Perioperative Anticoagulant & Antiplatelet Guideline
- Warfarin — Perioperative Management Guideline

In order to formulate this advice, I have reviewed all of the documents above. Although the content of the guidelines is very largely reliable and appropriate, I have identified a number of areas where further review and consideration of revision of these guidelines should be made.

1. 'Perioperative' guidelines.

   a. My first comment is to note that as these guidelines are for 'perioperative' management, the sections that are relevant for the clinical situation of [Mrs A] are less obvious than ideal. [Mrs A] had intracranial bleeding, a potentially life-threatening condition, as a complication of anticoagulant treatment for pulmonary embolism, but she had not had an operation. The perioperative guideline primarily addresses the prevention of thromboembolic and bleeding events in a perioperative setting. There is a section entitled 'Guidelines for Management of Bleeding Associated with DOAC' which is directly relevant to [Mrs A]. However, this appears as the third of three subsections of 'Appendix 1' of the 'Oral Anticoagulants Perioperative Management Guideline.' I could not initially find any guidance on management of bleeding associated with Warfarin, but finally located the advice in Step 4 of section 4 'Procedure/Management' of the 'Perioperative Anticoagulant & Antiplatelet Guideline' where it is stated 'Guidance on emergency reversal of warfarin is on page 5 and NZ Blood Reversing Warfarin smart phone app'. All of these emergency procedures need to be easier to find.

      My suggestion is that Lakes DHB consider a specific guideline for management of 'Bleeding on Anticoagulation', and that, ideally, this guideline should be available in electronic form for clinicians to be able to locate rapidly in an emergency situation. I note that my own DHB, CDHB, has exactly such a guideline available on its 'Hospital Health Pathways' web-based guideline platform. I'm not sure if a 'smart phone app' similar to that mentioned for warfarin reversal is available.

b. The three perioperative guidelines provided are overlapping, in part redundant, and contradictory. The names of the first two guidelines are similar. Warfarin management is described in both the second and third guideline. It is not obvious which guideline (or more than one) should be referred to for which patient. These guidelines should be rationalised and contradictions removed. I have pointed out some obvious contradictions below, there may be others.

2. 'Oral Anticoagulants Perioperative Management Guideline.'

   a. The name of this guideline is potentially misleading. It refers only to 'Direct' oral anticoagulants and does not apply to warfarin. Although this is clear in the stated purpose of the guideline it would make sense to change the title to 'Direct Oral Anticoagulants Perioperative Management Guideline' also.

   b. Section 4.1 Outline, Dabigatran

      i. I am pleased to note that the guideline states prominently and appropriately that dabigatran '… has a fast onset of action which means, unlike warfarin, full anticoagulant effect is achieved after ONE therapeutic dose. There is no need to have any cross over of therapy.' The need for clear understanding of this point is one of the findings of the review of [Mrs A's] case. However, the implications for rivaroxaban are not mentioned (see below).

      ii. The advice for use of idarucizumab (Praxbind), the reversal agent for dabigatran, is in need of some revision as the guideline can be interpreted that it is only indicated if there are 'completed coagulation studies compatible with dabigatran-induced anticoagulation.' In [Mrs A's] case, administration of idarucizumab was unnecessarily delayed due to insistence on results of anticoagulant testing before approval of use of the agent by the haematologist, even though she clearly had a potentially life-threatening intracranial bleed and was known to have taken a therapeutic dose of dabigatran in hospital. Although it is reasonable to expect completed coagulation studies in most situations, it is important to recognise that there can be exceptions.

   c. Section 4.1 Outline, Rivaroxaban. The speed of onset of rivaroxaban action and the need or otherwise for cross-over/bridging therapy is not mentioned specifically. This should be addressed specifically to avoid any confusion.

   d. Section 4.3 Management. Rivaroxaban management is not explicitly described, only dabigatran, and needs to be addressed.

   e. Appendix 1, Guidelines for management of bleeding associated with DOAC.

      i. Life Threatening Bleeding. Reversal with Praxbind is mentioned with the additional instruction '(see above)'. This instruction is less than completely clear and it would be better to have greater clarity for guidance in the setting of life threatening bleeding.

3. Perioperative Anticoagulant & Antiplatelet Guideline.

   a. I am pleased to note that an appropriate caution is given against co-administration of LMWH and either dabigatran or rivaroxaban: '**Warfarin** is the **only oral anticoagulant** where patients may be **on both warfarin and LMWH.** If on dabigatran or Rivaroxaban, there should be **no** overlap required.' As previously, the need for clear understanding of this point is one of the findings of the review of [Mrs A's] case.

   b. Tables D1 and D2, stopping dabigatran preop and restarting dabigatran post op and tables R1 and R2 regarding rivaroxaban (pages 6–7/11 original guideline; pages 17–18 .pdf). These tables reproduce and in some places contradict some similar advice provided in the preceding (and somewhat similarly named) guideline 'Oral Anticoagulants Perioperative Management Guideline', Appendix 1, Table 2 'Summary for perioperative management of direct oral anticoagulants.' (page 10/10 original guideline; p11 .pdf)

   c. Table N Management of oral anticoagulation in patient undergoing neuraxial procedure.

      i. This table (p19 .pdf) also overlaps with and contradicts tables 1 and 2 in the appendix of the preceding guideline (p11 .pdf), where neuraxial anaesthesia and neurosurgery are considered 'High bleeding risk' but similar to other surgeries including thoracic, cardiac, abdominal cancer, major orthopaedic surgery.

      ii. The terms 'LMWH' and 'Enoxaparin' appear to be used interchangeably but haphazardly. It would be better to just stick with one term.

   d. Figure 2 Suggested management for patients receiving DOACs undergoing urgent surgery.

      i. I do not find any guideline for patients receiving LMWH who are undergoing urgent surgery.

4. Warfarin — perioperative management guideline.

   a. 4. Procedure/Management, Outline, bullet point 2: 'Chronically anticoagulated patients are most at risk of thromboembolic events when the INR is sub-therapeutic (<20).' This is a typographic error and should be corrected to '<2.0'

   b. Table: 'Perioperative Management of Anticoagulant Drugs Arterial and Venous Thromboembolism (TE) Risk Stratification'

      This table unnecessarily appears twice on successive pages (page 9 of 10 and page 10 of 10 of the paper document, or pages 31 and 32 of the .pdf file."

Further expert advice (Addendum on guidelines current in 2015/16)

Addendum re: Lakes DHB Anticoagulant Guidelines 2015/2016

"This is a further addendum to my reports dated 20/9/2017 and 18/12/2018 and specifically reviews the adequacy of the anticoagulation guidelines in use at Lakes DHB in 2015/2016.

I have reviewed the following documents supplied:

- 769154 Dabigatran Peri-operative Management Guideline
- 1113280 Warfarin Perioperative Management Guideline
- 425338 Warfarin Pre Flow Chart
- 425335 Perioperative Management of Anticoagulant Drugs Arterial and Venous Thromboembolism (TE) Risk Stratification Table Post Flowchart
- 86130 IV Heparin Infusion for anticoagulation (Adult)

I was asked in particular to comment on:

1. The adequacy of the Dabigatran — Perioperative Management Guideline, particularly as Lakes DHB advises they did not have specific guidelines relating to the management of DVT or PE.
2. The use of the term 'bridging' in the dabigatran guideline eg. section 4.3, fourth bullet point on page 3.
3. The adequacy of these guidelines in supporting a general physician such as [Dr C's] decision making in the use of dabigatran for a patient with PE.

1. Dabigatran — Perioperative Guideline.

   a. The guideline (4.1 Outline) specifically states 'There is no specific treatment available to immediately reverse the effect of Dabigatran.' This was inaccurate at the time, as iduracizumab (Praxbind) had recently become available. An update might conceivably have assisted this aspect of the management of [Mrs A] when dabigatran reversal was required. The issue of timeliness of update of guidelines in the event of new treatments becoming available is one that all health providers face, and it may be unreasonable to have expected Lakes DHB to have completed this update for the dabigatran guideline at this time-point. I think it is relatively unlikely that an update of this guideline to include Praxbind would have had any impact on this case, however, as [Dr C] was clearly aware of the role of this agent and the delay in provision of Praxbind for [Mrs A] was due to adherence to standard Haematology guidelines, when an exception should have been made due to the circumstances, as has been discussed previously. This demonstrates that guidelines cannot cover every eventuality or replace clinical judgement and clinical experience.

   b. The section on 'Restarting Dabigatran after surgery' is less than optimal in that it does not explicitly make clear that enoxaparin and dabigatran should **not** be co-

prescribed or overlapped (ie 'bridging' is not required). The relevant advice provided is:

> 'If parenteral anticoagulants are used post surgery, e.g. Enoxaparin, Dabigatran should be given 0–2 hours prior to the time that the next parenteral dose would be due.'

It is not explicitly clear that enoxaparin should be stopped and that the 'next' dose should not be given. Although the guideline is 'perioperative', this section on 'restarting' dabigatran is relevant to use in other settings such as DVT and PE as it refers to the initiation of dabigatran. Interpretation of this guideline is open to some error in the understanding of the intersection between enoxaparin use and dabigatran. As dabigatran was a relatively 'new' agent, the need for a greater education component could have been recognised in the preparation of the guideline.

c. The perioperative guideline does not otherwise have direct relevance to [Mrs A's] care as she was not 'perioperative'. I do not have a strong opinion regarding the importance of having a specific guideline for dabigatran use in PE or DVT, as, in general, initiation of anticoagulation is a relatively standard process in the absence of other factors which influence bleeding risk, such as surgery. The main issue with use of dabigatran for PE or DVT is usually not initiation of treatment, as it has an immediate onset of action, but what to do if a bleeding complication occurs, the advice regarding which needed updating, as above.

2. Use of the term 'bridging' in the dabigatran guideline (4.3)

The use of the term 'bridging' is entirely in keeping with standard conventions in this guideline. It refers to use of an alternative, parenteral, short-acting anticoagulant (usually Clexane) to maintain anticoagulant activity preoperatively for patients at high thromboembolic risk when a longer-acting oral anticoagulant, warfarin, is either being withdrawn or initiated during a period when the warfarin is expected to be subtherapeutic. In this case, only pre-operative withdrawal of warfarin is covered.

3. The adequacy of these guidelines in supporting a general physician such as [Dr C's] decision making in the use of dabigatran for a patient with PE.

a. The IV Heparin guideline (86130) contains a specific reference to initiation of dabigatran: page 4, 'Changing between IV heparin and treatment doses of other anticoagulants.'

i. I note that the term 'bridging' is **not** used in this setting.

ii. Instructions for initiation of dabigatran follow directly after instructions for initiation of warfarin and the contrast is clear:

> 'Heparin to warfarin — consider that it might take several days for the warfarin to take effect and the INR to be therapeutic.'

> 'Dabigatran … Once the dabigatran has been started, the heparin can be discontinued (there does not need to be overlap).'

The scope of this guideline is for initiation of IV heparin in any clinical setting, not just 'perioperative' and would apply directly to the setting of PE and DVT. Use of enoxaparin (Clexane) is featured with relationship to heparin use. The guideline is appropriate. Although the specific issue of co-administration of enoxaparin (Clexane) and dabigatran is not mentioned, familiarity with the contents of this guideline would be expected to enable clinicians to avoid the mistake of co-prescription of these two agents as it is clearly stated that there does not need to be overlap with heparin, and enoxaparin is used as a substitute for heparin.

b. 425335 Perioperative Management of Anticoagulant Drugs Arterial and Venous Thromboembolism (TE) Risk Stratification Table and Warfarin Therapy Post-Op Management Flowchart.

   i. The flowchart does not have direct relevance to anticoagulation in other non-surgical settings.

   ii. Only warfarin is covered, new direct oral anticoagulants are not mentioned.

   iii. The term 'bridge' is used, and while not explicitly defined, it is clearly used according to the same convention as described above (in my answer to item #2).

c. 425338 Perioperative management of anticoagulant drugs. Warfarin therapy — Pre-op Management Flowchart.

   i. The flowchart does not have direct relevance to anticoagulation in other non-surgical settings.

   ii. Only warfarin is covered, new direct oral anticoagulants are not mentioned.

   iii. The term 'bridging' is used, and while not explicitly defined, it is very clear from its use that the other adjacent parts of the flowchart are, in fact, the guideline and thus definition of what 'bridging' treatment should be used, and when. The use of the term is according to the same convention as described above.

   iv. Only warfarin is covered, new direct oral anticoagulants are not mentioned.

d. 1113280 Warfarin — Perioperative Management Guideline.

   i. A comprehensive guideline for pre and post-operative anticoagulation with warfarin and LMWH (when appropriate) is included

   ii. New oral anticoagulants such as dabigatran are excluded

   iii. The term 'bridge' is used (5.1.8, 5.2.6, 5.3.4) and is used according to convention (as described previously) in the setting of re-initiation of warfarin postoperatively, with the explicit instruction '… until INR within therapeutic range.'

iv. 'bridging' is used 5.3.2, appropriately ('… no bridging with LMWH required.' in the setting of low thromboembolic risk.

v. Instructions for reversal of warfarin are included

In summary, while the use of the term 'bridge' or 'bridging' appears to be consistent and clear in these guidelines, the major deficiency is the complete lack of any information at all about dabigatran or other new direct oral anticoagulants in many of them. Lack of any explicit mention of these agents and generic titles referring to 'anticoagulant drugs' might have contributed to the risk of error in assuming that new oral anticoagulants should be managed the same way as warfarin. In contrast to the detailed and clearly presented information provided in the warfarin guideline, which had the benefit of many years of use and no doubt many revisions and improvements over that time, the dabigatran guideline is lacking in clarity regarding restarting of dabigatran and the way enoxaparin should be managed in the setting of dabigatran initiation.

It needs to be emphasised that the new oral anticoagulants were still genuinely somewhat 'new' in 2015/16 and this is reflected in the lack of good knowledge about their onset of action by [Dr C] and some of her colleagues, the lack of experience with use of the reversal agent, Praxbind, even by the specialist Haematologist involved, and the deficiencies in the guidelines identified above.

Finally, I have one additional general observation to make with respect to introduction of dabigatran and new oral anticoagulants to widespread medical use in NZ. The HDC will be very aware of a considerable number of cases of prescriber error and subsequent adverse patient outcome with introduction of dabigatran in NZ including other cases where bleeding complications resulted from inappropriate overlap of dabigatran with other anticoagulants. This raises to me the imperative for adequate education to be incorporated with the launch of new drugs that have both the potential for significant hazard and the potential for very widespread use by non-specialists. Perhaps PHARMAC should have a greater role in this setting."