Wairarapa District Health Board

A Report by the

Health and Disability Commissioner

(Case 11HDC01434)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A, aged 82 years, had a stroke at home at about 9pm on a Friday in late 2011. At Hospital 1, an emergency department (ED) house surgeon, Dr D, fast-tracked Mr A onto the thrombolysis pathway.[1]

2. Dr D discussed Mr A with the ED senior medical officer, Dr E, who advised Dr D that as Mr A's symptoms had been present for less than an hour, it would be reasonable to observe him past the one-hour mark to establish the trajectory of his condition.

3. Mr A had a CT head scan, which showed no intracerebral bleeding[2] and no visible acute ischaemic changes.[3] A medical consultant, Dr F, advised Dr D to start thrombolysis, given that Mr A was very well prior to this episode and that his dysphasia[4] was a major symptom.

4. The Stroke Thrombolysis Protocol (the protocol), which was the protocol used at Hospital 1 at the time, advised to administer t-PA. This protocol had been provided by another hospital/DHB (Hospital 2). Dr D was unsure what medication this referred to. Dr D was advised by an ED nurse that the only t-PA available in the ED was tenecteplase. Dr D was uncertain whether or not this was the correct drug, as there was inconsistency in the dosing.

5. Dr D decided to seek specialist and senior advice from Hospital 2, to clarify the correct drug to use. He telephoned Hospital 2 at about 10.45pm, and asked to speak to the on-call stroke registrar. He was put through to registrar Dr G.

6. Dr D told Dr G that they had only tenecteplase in stock at Hospital 1 and asked her if that was the t-PA referred to in the protocol.

7. Dr G replied that she was not able to answer this question, but would consult her seniors and call Dr D back. Dr G called Dr D back 10 minutes later and told him that tenecteplase was the medication they used at Hospital 2.

8. Dr D prescribed tenecteplase. At 8am, Mr A's neurological status deteriorated. A CT head scan showed that Mr A had had an intracranial haemorrhage.

9. Mr A should have been given the t-PA drug alteplase, which was available at Hospital 1. Tenecteplase should not be used for the treatment of stroke, and is used only for treatment of myocardial infarction.[5]

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[1] Thrombolysis is the breakdown of blood clots using drug therapy, commonly a tissue plasminogen activator (t-PA) drug.
[2] Intracerebral bleeds (within the brain) are the second most common cause of stroke, accounting for 30–60% of hospital admissions for stroke.
[3] Brain ischaemia, also known as cerebral ischaemia, is a condition in which there is insufficient blood flow to the brain. This leads to poor oxygen supply or cerebral hypoxia, and thus to the death of brain tissue or cerebral infarction/ischaemic stroke.
[4] Difficulty putting words together.
[5] Myocardial infarction is the medical term for a heart attack.

Findings

10. Mistakes were made by staff at both Wairarapa DHB and DHB 2. It was inappropriate for Wairarapa DHB to adopt and implement the protocol without first reviewing the protocol to ascertain its applicability at Wairarapa DHB and amending it to reflect the DHB's own processes. The protocol provided no guidance to Wairarapa DHB staff on which drug should be used, how to access that drug within the DHB, and who to contact with questions or queries about the protocol.

11. The protocol referred to t-PA, which Dr D correctly interpreted as referring to "tissue plasminogen activators" — which include tenecteplase, used for cardiac patients, and alteplase, used for acute ischemic stroke. Dr D was uncertain which of these drugs was appropriate for his patient and the protocol did not assist him.

12. This uncertainty then resulted in a series of actions — all 'small holes' in the provision of care — which lined up with disastrous results. Dr D was informed that tenecteplase was the only drug available in the ED. Concerned that the packaging indicated that the dosage in the protocol was higher than the manufacturer's instructions, Dr D sought advice. He called Hospital 2, because it was a Hospital 2 protocol. He did not consult the Hospital 1 consultant as he was expected to do.

13. When speaking to Dr G at Hospital 2 the question 'should I give tenecteplase to thrombolyse a stroke patient?' was incorrectly conveyed to or heard by the consultant as 'is tenecteplase what we use for thrombolysis?', and the question was assumed to relate to a cardiac patient. The answer conveyed to Dr D was 'yes'.

14. No further checks were made — either by reference to MIMS or Medsafe data, or the Wairarapa DHB on-call consultant. Concerns held were allayed, warning bells had, it was thought, been heeded, and the drug was administered.

15. Had the protocol clearly identified the relevant drug, had the Wairarapa DHB consultant been called, had the manufacturer's guidelines been complied with, had the question been correctly asked and answered in Hospital 2, a different outcome may have resulted. Nonetheless there was a series of missed opportunities through Wairarapa DHB's systems and staff to catch what would become a fatal error.

16. Wairarapa DHB failed to provide services with reasonable care and skill and so breached Right 4(1)[6] of the Code of Health and Disability Services Consumers' Rights (the Code).

17. Comment was made about Drs D, G, and I.

[6] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

18. The Commissioner received a complaint from Mr C about the services provided to his father, Mr A, by Wairarapa District Health Board. The following issue was identified for investigation:

- *Whether Wairarapa District Health Board provided an appropriate standard of care to Mr A in 2011.*

19. The parties directly involved in the investigation were:

Mr A (dec)	Consumer
Mr C	Consumer's son/complainant
Wairarapa DHB/Hospital 1	Provider

20. Information was reviewed from:

Dr D	House surgeon
Dr E	Senior medical officer
Dr F	Medical consultant
Dr G	Medical registrar
RN H	Registered nurse (High Dependency Unit)
Dr I	ED consultant
New Zealand Police	

Also mentioned in this report:

Mrs A	Mr A's wife
RN J	Registered nurse
Hospital 2/DHB 2	Another hospital/DHB

21. Independent expert advice was obtained from general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

22. Mr A, aged 82 years, had a stroke at home at about 9pm on a Friday in late 2011. He had had a stroke in April 2002, but was normally fit and well. He was taking anti-platelet agents, aspirin and dipyridamole.[7]

23. Mr A arrived at the public hospital's Emergency Department (ED) at 9.20pm. He was examined by an ED house surgeon, Dr D.

[7] Anti-platelet agents are medications that block the formation of blood clots by preventing the clumping of platelets. Dipyridamole is sometimes used with aspirin to lessen the chance of stroke.

24. Dr D had difficulty obtaining a clinical history from Mr A because of his expressive dysphasia, but his wife, Mrs A, who had accompanied Mr A to the hospital, was able to tell Dr D what had happened to Mr A that evening.

25. Mrs A told Dr D that Mr A had been in the kitchen doing the dishes, when she saw him freeze, and then lean to the right. He was unable to speak fluently, replying to questions with one word answers, and speaking hesitantly. When the ambulance staff arrived at the house, they noted that Mr A had obvious speech difficulties and marked weakness in his right arm.

26. Dr D noted that this episode had occurred at about 9pm and, as he had assessed Mr A within five minutes of his arrival in ED, he was well within the four-hour thrombolysis window for treatment. Thrombolysis treatment should be administered to eligible patients up to 4.5 hours after onset of the stroke.

27. Dr D stated that Mr A was "fast-tracked onto the thrombolysis pathway using the pre-printed [Hospital 2] stroke thrombolysis guidelines (issued on 10 May 2011) kept in the ED office".

28. The Thrombolysis Checklist section of the protocol notes: "Stroke Consultant Decision — You MUST contact the on call Stroke Consultant for final thrombolysis approval (contact through the DHB Operator)."

29. Dr D completed his physical examination of Mr A, took blood for laboratory analysis, and arranged for him to be transferred to the radiology department for an urgent CT head scan.

30. While Mr A was having the CT scan, Dr D filled out the Hospital 2 stroke thrombolysis pathway form. Dr D stated:

> "After going through the exclusion criteria, it became quickly apparent that [Mr A] might be a good candidate for thrombolysis. In my mind however, there were several 'relative' contraindications which could possibly preclude treatment. These were:
>
> 1. Age >80 years. This is not stated as a contraindication in the Hospital 2 guidelines; however it is a relative contraindication in overseas guidelines.
> 2. I wondered if the symptoms were rapidly improving and therefore might not warrant thrombolysis.
> 3. I wondered if the symptoms were considered to be too 'minor' to thrombolyse (dysphasia and mild right arm weakness)."

31. Dr D discussed his thoughts with the ED senior medical officer, Dr E. Dr E advised Dr D that as Mr A's symptoms had been present for less than an hour, it would be reasonable to observe him past the one-hour mark to establish the trajectory of his condition. Dr E said that either Mr A's symptoms would improve, in which case the episode would be classified as a transient ischaemic attack (TIA or minor stroke),

which would not necessitate thrombolysis, or the symptoms would worsen or remain static, in which case thrombolysis might be warranted.

32. When Mr A arrived back in the ED from radiology, it was well past the one-hour mark. Dr D reviewed Mr A and established that his symptoms were static and had not improved. Mr A still had marked dysphasia and mild, but clinically detectable, right arm weakness. Dr D reviewed the CT head scan, which showed no intracerebral bleeding and no visible acute ischaemic changes. However, Mr A's blood test results were not available at that time.

33. Dr D spoke to Mr and Mrs A and their daughter about the possibility of thrombolysis, and explained that there was a risk of intracranial bleeding with this treatment. Dr D said that he was waiting to see the results of Mr A's formal CT radiology report, and the INR[8]/platelets test, which could determine whether to thrombolyse Mr A. Dr D advised Mr A and the family members that if these results were normal, he would discuss Mr A's case with the on-call medical consultant, Dr F. The clinical notes do not indicate that the increased risk of adverse outcome from thrombolysis because of Mr A's age and anti-platelet therapy was discussed.

34. Twenty minutes after this discussion, the radiologist telephoned Dr D and confirmed that the CT head scan did not show any intracerebral bleeding. The blood test results also became available and showed an INR and platelets within normal parameters. Dr D examined Mr A again and found no change in his symptoms. Dr D telephoned Dr F and explained the situation, including his concerns about the relative contraindications of Mr A's case. Dr F advised Dr D to start thrombolysis, given that Mr A was very well prior to this episode and that his dysphasia was deemed a major symptom.

35. Dr F supported Dr D's recollection of their discussion. He said that the "t-PA pathway" was the correct one, and he advised Dr D to begin the process using the thrombolytic protocol from Hospital 2.

36. Dr D explained to Mr A and his family the discussion he had had with Dr F, and reiterated the risk of bleeding. Dr D said, "The family was in agreement to start treatment."

37. Dr D stated:

> "I adhered closely to the Hospital 2 stroke-thrombolysis guidelines (page 4) which states:
>
> **t-PA**
>
> Total Dose = (0.9mg/kg with max dose 90mg)
> - 10% of total dose. IV bolus over 1 minute
> - remaining 90% infused over 60 minutes

[8] International normalised ratio — a system established for reporting the results of blood coagulation (clotting) tests.

> In my mind, and throughout my clinical training, the term t-PA has always referred to a family of drugs called 'tissue plasminogen activators' of which there are three different types in clinical use:
>
> 1. Alteplase
> 2. Reteplase
> 3. Tenecteplase
>
> Given my lack of experience at thrombolysing strokes, I was unsure which of the above three medications the term 't-PA' was referring to."

38. Dr D was advised by one of the ED nursing staff that the only t-PA available in the ED was tenecteplase. Dr D was uncertain whether or not this was the correct drug, as there was inconsistency in the dosing. The protocol specified a total dose of 90mg. However, the maximum dose for tenecteplase was stated on the pack as 50mg.

39. Dr D said that, because he was using the Hospital 2 protocol, he decided to seek specialist and senior advice from Hospital 2 to clarify the correct drug to use.

40. Dr D stated that he could not explain why he did not consider calling Dr F for advice in the first instance. He stated:

> "The decision to call [Hospital 2] was an automatic, subconscious response; as an emergency house officer, I consult various sub-specialties in [Hospital 2] on a daily basis when I have questions in relation to the clinical management of specialist conditions. In this case it seemed logical to consult [Hospital 2] given that
>
> 1. We were using the [*Hospital 2]* stroke-thrombolysis protocol AND
> 2. Specialist advice could be sought directly from the stroke specialists who use this protocol frequently."

41. Dr D telephoned Hospital 2 at about 10.45pm, and asked to speak to the on-call stroke registrar. He was put through to Dr G, a medical registrar working in the Hospital 2 ED. Dr G has provided a statement of events to the New Zealand Police and to DHB 2 (see below).

42. Dr D recalls telling Dr G that he had an 84-year-old patient (sic) with a stroke, whom he wanted to thrombolyse. He said that he was using the Hospital 2 protocol, but was unsure what was meant by t-PA. Dr D told Dr G that they had only tenecteplase in stock at Hospital 1 and asked her if that was the t-PA alluded to in the guidelines.

43. Dr D stated that Dr G replied that she was not able to answer his question, but would consult her seniors and call Dr D back on his mobile phone. Dr G called Dr D back 10 minutes later and told him that tenecteplase was the medication they used at Hospital 2.

44. Dr D said, "With this information I prescribed tenecteplase using the calculated dose … with the understanding that t-PA meant tenecteplase in this instance."

45. Registered nurse (RN) RN H stated that she checked with Dr D that he would call to confirm the correct drug to be given to Mr A, while she and RN J settled Mr A into the High Dependency Unit. RN H stated:

> "[Dr D] then attended and stated that he had checked the medication with a senior doctor and, although the dose was high for the particular drug, it was correct."

46. RN H recalls asking Dr D if he was sure that Mr A's stroke was caused by a clot and not a haemorrhage. Dr D told RN H that he was sure that it was a clot.

47. RN H said she checked the drug with RN J, when Mr A was about two and a half hours post the initial onset of this stroke. Dr D was present when the drug was checked. RN H then administered the tenecteplase, as per Dr D's prescription. She said that about an hour and a half after Mr A was given the tenecteplase, some of the symptoms he was admitted with were no longer present, and he was able to communicate in three- or four-word sentences.

48. Dr D stated that although his shift ended at 10.30pm, he stayed in the hospital to watch over Mr A's treatment. He said that he was "elated", at 2.20am, when an HDU nurse told him that Mr A's symptoms had markedly improved. Dr D called into the HDU to see Mr A and found that he was able to speak in fluent phrases and, although his right arm remained weak, Dr D felt that Mr A was "on the right trajectory".

49. When Dr D arrived at work the next day, Saturday, he was distressed to hear that Mr A's neurological status had deteriorated at around 8am that morning. A CT head scan performed that morning showed that Mr A had suffered an intracranial haemorrhage. Sadly, Mr A died on Monday.

Dr G

50. Dr G advised the New Zealand Police that she recalls that on the Friday night she took a call from a doctor who asked what drug was used for stroke thrombolysis. Dr G stated that she asked whether the Stroke Thrombolysis Protocol had been followed. She said that the enquiring doctor said that the name of the drug was not on the protocol, and asked if the drug was tenecteplase.

51. Dr G stated that as she was unsure of the drug to use, she asked the on-call ED consultant, Dr I, "Which thrombolytic drug is used for stroke thrombolysis, is it Tenecteplase?" He replied, "Yes it is".

Dr I

52. Dr I told DHB 2 that he recalls that he was speaking on the telephone about another matter when Dr G asked him for advice about what drug was used in the emergency department for thrombolysis. In response to the provisional opinion he stated that he had no clinical responsibility for Dr G. Dr I said he was not given any information about the patient, and he did not prescribe or recommend any drug. He said he responded to the question Dr G asked about the drug that is used in ED for thrombolysis, to which he replied, "Tenecteplase".

53. Dr I stated to the New Zealand Police that when he finished his telephone conversation, he followed up with Dr G, to confirm that tenecteplase was the drug used in ED for thrombolysis. In response to the provisional opinion Dr I stated that he first thought the question related to drug availability for a patient under Dr G's care. Dr I said that at no stage was he aware that the question related to a stroke, but believed that her question referred to a cardiac thrombolysis, in which case tenecteplase would be the correct drug.

54. In response to the provisional opinion, Dr I stated that at Hospital 2 none of the ED senior medical officers thrombolyse stroke patients, because such patients would be thrombolysed by the Stroke Team, although the ED team can receive myocardial infarction patients. As tenecteplase had recently replaced reteplase for the treatment of myocardial infarction, he thought the question "might relate to that issue". He stated that he has never advised any staff on patient care, other than those working in emergency medicine, and he would not advise a medical registrar in another hospital on the care of an internal medicine patient.

Actions taken

Dr F

55. Dr F stated that when he reviewed Mr A's clinical records on the day he died, he noted that Mr A had been given the t-PA drug tenecteplase instead of alteplase. He said that tenecteplase should not be used for the treatment of stroke, and is used only for treatment of myocardial infarction. Dr F advised the family and the Coroner that, as a result of being given the incorrect medication, Mr A had died from a cerebral haemorrhage.

56. On Thursday, Dr F contacted the Coroner again to advise him that the wrong t-PA agent had been given to Mr A. Dr F commented that Dr D had correctly followed the protocol in checking that a t-PA should be given, but he checked this with Hospital 2 staff instead of speaking to him. Dr F commented in his police statement that the usual protocol is that junior doctors should always check with the responsible clinician if they are uncertain about patients.

57. Dr F stated that tenecteplase is available in the Hospital 1 ED, but alteplase is also stocked at Hospital 1. It is available 24 hours a day and can be uplifted on request from the hospital pharmacy, by a nursing supervisor.

Family meeting

58. On Thursday, senior staff from Wairarapa DHB had an initial meeting with members of Mr A's family to explain the medication error and its circumstances. A further meeting was held the following month.

Wairarapa DHB

59. Wairarapa DHB conducted a Serious Event Review into the circumstances of Mr A mistakenly being given tenecteplase instead of alteplase, and the dose being based on the alteplase recommended dose.

60. The key findings of the Review were that the root cause of this medication error was the ambiguity of the stroke protocol used, ie, the term "t-PA" was used in the protocol but it did not specify the medication intended.

61. The report noted that the term "t-PA" is widely used to refer to three tissue plasminogen activators, alteplase, reteplase and tenecteplase, and that the staff involved in Mr A's treatment went to "some lengths to check what medication was intended". The report stated:

> "In the process of checking, it was determined (incorrectly based on a number of contributing factors…) that in the protocol the term, 't-PA' was referring to Tenecteplase. … The review team consider that had the protocol been worded to specify the medication 'Alteplase' the adverse event was very unlikely to have occurred."

62. The contributing factors identified by the Review were:

- Adoption of a tertiary hospital's protocol by another DHB without the protocol being reviewed and amended to reflect the adopting DHB's processes.
- Ambiguity in the protocol regarding from whom protocol/treatment advice should be sought.
- Misunderstanding about the availability of medication stocked by the DHB.
- Miscommunication between clinicians, with advice being provided on the basis that the issue related to cardiac thrombolysis rather than stroke thrombolysis.

63. Wairarapa DHB immediately made the following changes to its Stroke Protocol:

- The name "alteplase" is used in every instance where the term "t-PA" had been used.
- Junior doctors are to obtain advice from the treating DHB consultant before consulting with a tertiary DHB.
- The treating DHB consultant is to be directly involved in the supervision of any stroke thrombolysis and, before initiating or changing a treatment plan, the junior doctor must involve the consultant.

64. DHB 2's Stroke Protocol was amended to state "alteplase" in every instance where the term "t-PA" had been used.

65. The key recommendations from the Review were that, in addition to the above:

- The amended Wairarapa DHB Stroke Protocol and the findings of the Review would be circulated to other DHBs, and attention drawn to the risks of the general adoption of documents developed by other DHBs.
- Learning from this incident would be used in staff education related to stroke thrombolysis at Wairarapa and DHB 2, and shared with other DHBs.
- Wairarapa DHB would seek assurance from senior physicians that it can and should continue to offer stroke thrombolysis, and the decision reported back to the Reportable Event Group and the Clinical Board.

- If Wairarapa DHB elects to continue to offer stroke thrombolysis, clear locally appropriate protocols and algorithms would be developed, in line with the New Zealand Clinical Guidelines for Stroke Management 2010, implementation plan, November 2011, section 2, to ensure safe implementation.
- Wairarapa DHB and DHB 2 would jointly notify all New Zealand DHBs, the Health Quality and Safety Commission, the New Zealand Stroke Foundation Thrombolysis Working Group, and the National Stroke Clinical Networks Leadership Group of the findings of this review to ensure that other documents regarding the use of t-PA are clarified to improve future patient safety ("the Learning Report").

Further actions

66. On 7 August 2012, Wairarapa DHB advised HDC that DHB 2's ED Fast Track Stroke Protocol was amended in December 2011, in line with the Serious Event Review report, and updated on 23 March 2012. The new, locally appropriate stroke thrombolysis protocols and algorithms are now in place and are readily available in the ED and on the intranet.

67. Wairarapa DHB also circulated a memo to staff on 2 December 2011, noting that consultations outside the hospital are to be "consultant to consultant" to reduce the risk of mistakes and/or misunderstandings.

68. On 4 May 2012, a Stroke Management Education Day was held for Central Region DHBs, and a DHB 2 Stroke Clinical Nurse Specialist is taking ongoing teaching sessions for DHB 2 ED staff.

69. On 9 May 2012, the Wairarapa DHB and DHB 2 circulated the Learning Report to New Zealand DHBs, the Health Quality and Safety Commission, the New Zealand Stroke Foundation Thrombolysis Working Group, and the National Stroke Clinical Networks Leadership Group.

70. Wairarapa DHB senior physicians have met to consider the appropriateness of continuing to offer t-PA as part of the stroke pathway at Hospital 1. The chair of the group advised the Reportable Event Group and the Clinical Board that the senior physicians agreed that Wairarapa DHB should continue to offer this service.

Police

71. In December 2012, the New Zealand Police reported to the Coroner the findings of their investigation into the circumstances of Mr A's death. The Police advised the Coroner that there was insufficient evidence to pursue criminal charges against either the hospital staff or the DHBs involved.

Reponses to provisional opinion

72. The following responses to the provisional opinion were provided in addition to those incorporated into the facts gathered section.

Mr C

73. In response to the "information gathered" section of my provisional report, Mr C stated that the family have no issue with Dr D and think he did all that he could.

Wairarapa District Health Board

74. Wairarapa District Health Board stated that they have no material comment on the provisional findings.

Dr D

75. Dr D stated that he agrees with the provisional findings and the comments made with regard to his care.

Dr G

76. Dr G submitted that she and Dr I are equally responsible for their miscommunication.

DHB 2

77. DHB 2 stated that it wished to further extend its condolences to Mr A's family and that "this has been a tragic event from which both Wairarapa DHB and DHB 2 have learned and implemented valuable lessons and shared those nationwide as a result".

Opinion: Breach — Wairarapa District Health Board

78. Mr A's sudden and unexpected death was very distressing for his family. It is evident that the care provided to Mr A fell well short of the expected standard. I consider that mistakes were made by several staff at both Wairarapa DHB and DHB 2. However, those errors occurred in the context of deficiencies in the systems operating at Wairarapa DHB and, accordingly, I consider that Wairarapa DHB bears ultimate responsibility for failing to provide an appropriate standard of care to Mr A.

79. The New Zealand Clinical Guidelines for Stroke Management 2010 state that a standardised assessment tool should be used to improve reliability of assessment, and several stroke-specific scales have been developed. I note that a recognised stroke disability scoring system was not used at Wairarapa DHB as part of the decision-making process, despite such a tool being recommended in the guidelines.

80. In my view, it was inappropriate for Wairarapa DHB to adopt and implement the Hospital 2 Stoke Thrombolysis Protocol without first reviewing the protocol to ascertain its applicability at Wairarapa DHB and amending it to reflect the DHB's own processes. The protocol provided no guidance to Wairarapa DHB staff on which drug should be used, how to access that drug within the DHB, and who to contact with questions or queries about the protocol. This was inadequate.

81. The protocol referred to t-PA, which Dr D correctly interpreted as referring to "tissue plasminogen activators" — which include tenecteplase, used for cardiac patients, and

alteplase, used for acute ischemic stroke. Dr D was uncertain which of these drugs was appropriate for his patient and the protocol did not assist him.

82. This uncertainty then resulted in a series of actions — all 'small holes' in the provision of care — which lined up with disastrous results. Dr D was informed that tenecteplase was the only drug available in the ED. Concerned that the packaging indicated that the dosage in the protocol was higher than the manufacturer's instructions Dr D sought advice. He called Hospital 2, because it was a Hospital 2 protocol. He did not consult the Hospital 1 consultant as he was expected to do.

83. When speaking to Dr G at Hospital 2 the question 'should I give tenecteplase to thrombolyse a stroke patient?' was incorrectly conveyed to or heard by Dr I as 'is tenecteplase what we use for thrombolysis?', and the question was assumed to relate to a cardiac patient. The answer conveyed to Dr D was 'yes'.

84. No further checks were made — either by reference to MIMS or Medsafe data, or the Wairarapa on-call consultant. Concerns held were allayed, warning bells had, it was thought, been heeded, and the drug was administered.

85. Had the protocol clearly identified the relevant drug, had the Wairarapa DHB consultant been called, had the manufacturer's guidelines been complied with, had the question been correctly asked and answered in Hospital 2, a different outcome may have resulted. Nonetheless there was a series of missed opportunities through Wairarapa DHB's systems and staff to catch what would become a fatal error.

86. In these circumstances, I find that Wairarapa DHB failed to provide services to Mr A of an appropriate standard and with reasonable care and skill, and so breached Right 4(1) of the Code.

87. Whilst it does not diminish the identified deficiencies in Wairarapa DHB's systems, I note that the DHB has acted appropriately in acknowledging its shortcomings, taking responsibility, and putting measures in place to ensure that such an event does not recur. Wairarapa DHB has amended its Stroke Protocol to provide greater clarity on the management of thrombolysis in stroke cases, including the expectation that the treating DHB consultant be directly involved before any such treatment is given. In my view, those measures are appropriate.

Staff concerns

88. It is evident that some staff were concerned about the administration of the medication to Mr A. RN H checked with Dr D that he would call to confirm the correct drug to be given to Mr A, and was told that he had checked the medication with a senior doctor and that, although the dose was high for the particular drug, it was correct. RN H also asked Dr D if he was sure that Mr A's stroke was caused by a clot and not a haemorrhage. Dr D told RN H that he was sure that it was a clot.

89. RN H then checked the drug with RN J, about two and a half hours after the initial onset of Mr A's stroke.

90. It was reasonable in these circumstances for RN H to have been reassured by Dr D's response. I have been provided with no evidence that she remained concerned about the administration of the drug to Mr A.

Other comment

Dr D

91. Mr A was administered the incorrect medication in a dose outside the manufacturer's recommendations. A number of factors contributed to this medication error. These included Dr D's failure to identify alteplase as the drug to be used in the thrombolysis protocol, and his failure to confirm with his senior consultant the thrombolytic therapy he was about to undertake. In addition, Dr D failed to sufficiently consider the product information (or to consult MIMS or obtain Medsafe data) when using a drug with which he was not familiar. However, I note that he noticed the dose discrepancy, and said that this was one of the factors that caused him to contact Hospital 2.

92. RN H queried whether tenecteplase was the correct drug for Mr A, but Dr D reassured her that he had checked and ascertained that it was. Given the advice given by the Hospital 2 clinician, this was not an unreasonable response. Dr Maplesden advised that Mr A "was administered the incorrect medication in a dose outside the manufacturers recommendations. This must be regarded as a severe departure from expected standards, and had a tragic outcome for [Mr A] and his family. However, there were multiple factors, predominantly systemic, contributing to the error and I do not think [Dr D] can be singled out for criticism, although it was obviously a significant error of judgement…"

93. I accept that there were systemic factors that contributed to the error, as set out above, and I note that Dr D did attempt to clarify the drug to be used, and followed what he thought were the protocol recommendations for administration of tenecteplase.

94. As stated, I consider that Wairarapa DHB bears ultimate responsibility in this case. However, Dr D should reflect on his actions and their contribution to the tragic outcome.

Dr G and Dr I

95. Dr D telephoned Hospital 2 and spoke to Dr G, a medical registrar working in the Hospital 2 ED.

96. Dr D recalls telling Dr G that he had an 84-year-old patient (sic) with a stroke, whom he wanted to thrombolyse. Dr D said that he was using the Hospital 2 protocol, but was unsure what was meant by "t-PA". He told Dr G that they had only tenecteplase in stock at Hospital 1, and asked her if that was the t-PA alluded to in the protocol.

97. Dr G said that she would consult her seniors and call Dr D back. Dr G called Dr D back and told him that tenecteplase was the medication they used at Hospital 2.

98. Dr G stated that, as she was unsure of the correct drug, she asked the on-call ED consultant, Dr I, "Which thrombolytic drug is used for stroke thrombolysis, is it Tenecteplase?" He replied, "Yes it is".

99. Dr I recalls that he was speaking on the telephone about another matter when Dr G asked him for advice about which drug was used for thrombolysis. Dr I said that he was not given any information about the patient, and he did not prescribe or recommend any drug. He said that he responded to the question asked by Dr G, for whom he had no clinical responsibility, about the drug that is used in ED for thrombolysis, and he replied, "Tenecteplase." In response to my provisional opinion, he said that he first thought the question related to drug availability for a patient under Dr G's care.

100. Dr I said that at no stage was he aware that the question related to a stroke, but believed that Dr G's question referred to a cardiac thrombolysis, in which case tenecteplase would be the correct drug. In response to my provisional opinion Dr I stated that at Hospital 2 none of the ED senior medical officers thrombolyse stroke patients, because they would be thrombolysed by the Stroke Team, whereas the ED team can receive myocardial infarction patients. In addition, as tenecteplase had recently replaced reteplase for the treatment of myocardial infarction, he thought the question "might relate to that issue". He stated that he has never advised any staff outside emergency medicine on patient care.

101. I am unable to make a finding on whether Dr G mentioned stroke to Dr I or asked specifically about tenecteplase.

102. In my view, it was unwise for Dr G to obtain advice in such an informal manner when Dr I was otherwise occupied on a telephone call. She should have provided Dr I with more of the information that Dr D had given her, for example, "I have a question from a house surgeon at [Hospital 1] who has an 82-year old patient with a stroke, whom he wants to thrombolyse".

103. Similarly, I remain of the view that Dr I should have specifically ascertained whether he was being asked about a stroke patient or a cardiac patient before responding to the question.

Further comment

104. This case provides a salutary reminder to all DHBs that care needs to be taken when implementing new policies and procedures, to ensure that they are appropriate to the particular operating environment at that DHB. In that respect, I note that Wairarapa DHB has circulated its Learning Report to all DHBs in New Zealand, and the case has been brought to the attention of the Health Quality and Safety Commission, the New Zealand Stroke Foundation Thrombolysis Working Group, and the National Stroke Clinical Networks Leadership Group to ensure that the important lessons from this

case are widely shared. This case has also been used widely in staff education at Wairarapa DHB and DHB 2.

Recommendations

105. Dr D has sent an apology to be forwarded to the family for his contribution to the suboptimal care provided to Mr A.

106. Wairarapa DHB has sent an apology to be forwarded to the family for its failings when providing care to Mr A.

107. I recommend that Wairarapa DHB:

- audit its compliance with the amended Stroke Thrombolysis Protocol since its amendment in December 2011, and provide HDC with the outcome of that audit within three months of the date of issue of the final opinion;

- review the orientation and training of junior and new staff to ensure they know how to access all medications within the DHB, and who to contact with questions or queries; and supply a copy of the training and induction material for junior and new staff within three months of the date of issue of the final opinion.

Follow-up actions

108. - A copy of this report will be sent to DHB 2 and the Coroner.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case and Wairarapa District Health Board, will be sent to the Health Quality and Safety Commission.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case and Wairarapa District Health Board will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Clinical advice to the Commissioner

The following expert advice was obtained from vocationally registered general practitioner Dr David Maplesden:

"My name is David Maplesden. I am a vocationally registered general practitioner practicing in Hamilton, New Zealand. My qualifications are MB ChB (Auckland University 1983), Dip Obst (1984), FRNZCGP (2003).

1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mr C] about the care provided to his late father, [Mr A], by Wairarapa DHB. To my knowledge, I have no personal or professional conflicts of interest. I have examined the available documentation: complaint from [Mr C]; response from WDHB; documentation provided to the Coroner including results of a Sentinel Event internal investigation and revised Stroke Thrombolysis protocol; [Hospital 1] clinical notes. The complaint relates to treatment [Mr A] received at [Hospital 1] on [Friday] following his presentation there with symptoms of a stroke. He was deemed a candidate for thrombolytic therapy but was given the wrong medication and an inappropriate dose of the medication. This led to a cerebral bleed to which he succumbed on [Monday] 2011.

2. The clinical details of the incident in question have been clearly described in the DHB reports to the Coroner, including the Sentinel Event Report (SER) and will not be reiterated here. The accounts are consistent with the contemporaneous clinical notes although there appears to be an error in the transcribing of [Mr A's] regular medications into the initial Coronial report (pg 3) in that amino-salicylic acid (mesalamine) is listed as a regular medication when this should be the anti-platelet agent acetyl-salicylic acid (aspirin). I note [Mr A] was taking an additional platelet modifying agent, dipyridamole. The fact that a medication error occurred has been acknowledged by the DHB and openly discussed with [Mr A's] family. The specific error was twofold — administration of a drug not indicated in this country for the condition in question (tenecteplase was administered in place of alteplase), and administration of an inappropriate dose of that drug (90mg when the maximum recommended dose is 50mg). The medication error has been acknowledged as causing the cerebral haemorrhage that led to [Mr A's] death.

3. The Medsafe data sheet for tenecteplase[9] includes the following comments:

(i) *Tenecteplase is indicated for the thrombolytic treatment of the acute phase of myocardial infarction (AMI). Treatment should be initiated as soon as possible after symptom onset. Treatment can be initiated within 12 hours of symptom onset.* Thrombolytic treatment of ischaemic stroke is not listed as an indication for use of tenecteplase in New Zealand.

(ii) *Tenecteplase should be administered on the basis of body weight, with a maximum dose of 10,000 units (50 mg tenecteplase).* A dose of 90mg was administered in [Mr A's] case — this dose was appropriate for alteplase.

[9] Available at: http://www.medsafe.govt.nz/profs/datasheet/m/Metalyseinj.pdf.

(iii) Contraindications listed include *ischaemic stroke or transient ischaemic attack (TIA) in the preceding 6 months* although I note the drug has been used successfully on a trial basis for stroke thrombolysis, but in doses lower than that administered to [Mr A].

(iv) Precautions (carefully weighing risks and benefits) include *advanced age, i.e. over 75 years* ([Mr A] was 82 years old).

(v) *Medicinal products that affect coagulation or those that alter platelet function may increase the risk of bleeding prior to, during or after tenecteplase therapy*. [Mr A] was taking dipyridamole and aspirin, both of which affect platelet function.

4. One of the benchmark studies on medical error in hospitals was undertaken in Australia with results published in 1995[10]. A review of the medical records of over 14,000 admissions to 28 hospitals in New South Wales and South Australia revealed that 16.6% of these admissions were associated with an "adverse event", which resulted in disability or a longer hospital stay for the patient and was caused by health care management; 51% of the adverse events were considered preventable. In 77.1% the disability had resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died.

5. A 2000 literature review on medical error[11] commented on the contribution adverse drug events made to the total error rate. Using a computerised model to detect adverse drug events among patients at a hospital in Salt Lake City, Utah, one study found that adverse drug events occurred in 1.7% of admissions. In comparison, using both chart review and prompted self reports from clinicians, another American study found that adverse drug events occurred among 6.5% of patients and potential adverse drug events occurred among 5.5% of patients admitted to two teaching hospitals in Boston. Of the adverse drug events 28% were due to errors, making the rate of serious medication errors (that is, preventable adverse drug events plus potential adverse drug events) 7.3%.

6. A more recent study[12] notes that adverse drug reactions (ADRs) constitute a major problem for the individual as well as for the community. In previous studies, the prevalence of hospital admissions due to ADRs ranged from 2.4% to 12.0%. The incidence of fatal ADRs (FADRs) in patients admitted to hospital has been reported ranging from 0.05% to 0.44% while the incidence of FADRs in patients experiencing ADRs during hospital stays ranges from 0.05% to 0.19%. In a Finnish, single hospital study, 5.0% of all deaths during 1 year were considered to be drug-related. A large meta-analysis of hospitalized patients in the US estimated that ADRs accounted for 4.6% of all fatalities. The investigators of the referenced paper also concluded that haemorrhages amount to almost two-thirds

[10] Wilson, RM et al, "The Quality in Australian Health Care Study", *Med J Aust*, 163(9):4586 (6 Nov 1995).
[11] Weingart, S et al, "Epidemiology of medical error", *BMJ*, 320(7237): 774–777 (18 March 2000).
[12] Wester, K et al, "Incidence of fatal adverse drug reactions: a population based study", *Br J Clin Pharmacol*, 65(4): 573–579 (April 2008).

of the fatal adverse drug reactions and antithrombotic agents are implicated in more than half of the suspected fatal adverse drug reactions.

7. A 2009 Cochrane review[13] on thrombolytic treatment for stroke was summarised as: *thrombolytic therapy is one of the most promising treatments for acute ischaemic stroke. The majority of strokes are due to blockage of an artery in the brain by a blood clot. Prompt treatment with clot dissolving (thrombolytic) drugs can restore blood flow before major brain damage has occurred. Successful treatment could mean the patient is more likely to make a good recovery from their stroke. Thrombolytic drugs can also, however, cause serious bleeding in the brain, which can be fatal. Thrombolytic therapy has now been evaluated in several randomised trials in acute ischaemic stroke. The thrombolytic drug alteplase (rt-PA) has been licensed for use within three hours of stroke in the USA, Canada, and most European countries but only few patients receive the treatment. This review of 26 trials involving 7152 patients confirmed that thrombolytic treatment can reduce the risk of disability, despite the bleeding risks. However, there was not enough evidence to answer several questions. How big is the overall benefit? What is the latest time window in which the treatment is still beneficial? Which grades of stroke severity and which types of stroke, as judged clinically and on brain imaging, are more likely to respond favourably to treatment? Should patients aged over 80 years receive thrombolysis? Which types of patients are most likely to be harmed by, and which to benefit from, treatment (e.g. with or without other major medical conditions like cardiac arrhythmias, diabetes, hypertension, or other disorders and concomitant medication)? To answer these questions reliably, and in particular to be able to tailor treatment to the individual patient, more data are needed from new randomised controlled trials.*

8. The New Zealand Guidelines for Stroke Management 2010 include the following relevant recommendations regarding thrombolytic therapy (described as *intravenous tPA*) for stroke:

(i) *All patients with suspected stroke should have an urgent brain CT or MRI ("urgent" is immediately where available, but within 24 hours). Patients who are candidates for thrombolysis should undergo brain imaging immediately.* Although there were some delays in gaining optimum views, imaging took place reasonably promptly in [Mr A's] case.

(ii) *Thrombolytic therapy appears most beneficial if provided in experienced centres in highly selected patients. Widespread use of thrombolytic therapy in routine clinical practice in non-organised stroke care is not recommended.*

(iii) *Intravenous tPA in acute ischaemic stroke should only be undertaken in patients satisfying specific inclusion and exclusion criteria.* In his response, [Dr D] has outlined his clinical rationale for considering thrombolysis in [Mr A] including consideration of his age and degree of functional impairment. Following

[13] Wardlaw, JM et al, "Thrombolysis for acute ischaemic stroke", *Cochrane Database of Systematic Reviews*, Issue 4, Art. No.: CD000213 (2009). DOI: 10.1002/14651858.CD000213.pub2.

blood tests and brain imaging, it appears there were no specific contraindications to thrombolysis, although there were the risk factors of advanced age and concomitant use of a platelet modifying agent.

(iv) *Intravenous tPA should be given as early as possible in carefully selected patients with acute ischaemic stroke as the effect size of thrombolysis is time-dependent. Where possible, intervention should commence in the first few hours but may be used up to 4.5 hours after stroke onset.* In [Mr A's] case, therapy was commenced at 2320hrs, two hours and 20 minutes following onset of his symptoms.

(v) *Intravenous tPA should be given under the authority of a physician trained and experienced in acute stroke management.* [Dr D] sought the advice of his ED senior, the local on-call physician, and the medical registrar at [Hospital 2]. It is unclear whether any of these providers had specialist expertise in acute stroke management, although the on-call physician is likely to have been the most experienced in this field. [Dr D] admits he had limited experience in use of thrombolytic therapy for stroke, hence his desire to clarify which thrombolytic agent was referred to in the protocol being used.

(vi) *Thrombolysis should only be undertaken in a hospital setting with appropriate infrastructure, facilities and network support. This includes: an interdisciplinary acute care team with expert knowledge of stroke management who are trained in delivery and monitoring of patients treated with thrombolysis; pathways and protocols used to guide medical, nursing and allied health acute phase management. Pathways or protocols must include guidance in acute blood pressure management; immediate access to imaging facilities and staff trained to interpret the images.* The DHB is best placed to comment on whether they have the recommended staffing infrastructure in place. Other recommendations appear to have been met at the time of the incident.

(vii) *The commencement of aspirin for patients who have received thrombolysis should be delayed for 24 hours (usually after a follow-up scan to exclude significant bleeding).*

9. Comments:

(i) It seems that consideration of stroke thrombolysis for [Mr A] was reasonable from a clinical perspective, and that the guideline recommendations were largely followed. A recognized stroke disability scoring system was not used as part of the decision making process — such a tool is recommended in the New Zealand stroke guidelines and has been incorporated into the revised stroke management protocol in use by the DHB. There was some mention made in the SER of the relatively infrequent use of the thrombolysis protocol in [Hospital 1] and whether acute stroke management with thrombolysis should continue there. Given the travel time between [Hospital 1] and [Hospital 2], it seems likely that restricting use of the protocol to [Hospital 2] might disadvantage those stroke patients presenting to [Hospital 1] with even a moderate delay, particularly with the tight

time frames required for successful administration of the treatment and need for preliminary investigations to be undertaken. It is not entirely clear from the clinical notes and responses whether the increase in risk of adverse outcome from thrombolysis associated with [Mr A's] advanced age and concomitant anti-platelet therapy were fully discussed as part of the consenting process, although neither of these factors are contraindications to treatment.

(ii) The SER has identified a number of factors contributing to the error that occurred. These included: inadequate identification of alteplase as the drug to be used in the thrombolysis protocol; erroneous advice that ED did not stock alteplase; communication error surrounding advice obtained by [Dr D] from [Hospital 2] regarding use of tenecteplase; failure by [Dr D] to confirm with his senior consultant the thrombolytic therapy he was about to undertake. Additional factors that I feel may have contributed to the error were the relative inexperience in stroke thrombolysis of both medical registrars involved ([Hospital 1] and [Hospital 2]), and the failure by [Dr D] to consider the product information (or to consult MIMS or obtain Medsafe data) when using a drug with which he was not familiar, or to override product recommendations if he did obtain them. He [Mr A] may have been at increased risk of an adverse outcome whichever thrombolytic agent was used because of concomitant drug therapy and his age, but he was also at increased risk of an adverse outcome from his stroke, if untreated, because of his age.

(iii) The actions undertaken by the DHB have been appropriate. There appears to have been open communication with [Mr A's] family. Appropriate lines of communication when consulting between DHBs have been defined and are clarified as part of the house surgeon orientation programme. The thrombolysis protocol has been reviewed and is now explicit with respect to drugs to be used and involvement of senior physicians. The risks associated with existing protocols (use of tPA (in line with the originally published recommendations internationally) rather than naming the drug) have been conveyed to other DHBs and appropriate national bodies. The outcome of the investigation should be a significant reduction in risk of an incident such as this being repeated, both in [Hospital 1] and throughout the country.

(iv) Sections 4–6 were included to emphasise that, unfortunately, medical errors, including medication errors, are common in primary and secondary care. Adverse drug reactions, including fatal reactions, are also recorded with significant frequency, with medication errors contributing 28% of such adverse reactions in one study. The fact that such errors are relatively common does not make this an acceptable situation, but provides relevant context when considering appropriate reaction to the case in question. In [Mr A's] case, he was administered the incorrect medication in a dose outside the manufacturers recommendations. This must be regarded as a severe departure from expected standards, and had a tragic outcome for [Mr A] and his family. However, there were multiple factors, predominantly systemic, contributing to the error and I do not think [Dr D] can be singled out for criticism, although it was obviously a significant error of judgment for him to ignore the manufacturer's recommendations with respect to dose of the drug. However, he had sought to clarify the drug to be used and followed what he

thought were the protocol recommendations for administration of tenecteplase. While of little comfort to the bereaved family, it is important to note that appropriate actions have been undertaken by the DHB and these should enhance the safety of those patients throughout the country who might be candidates for post-stroke thrombolysis in the future."