House Officer, Dr B

General Physician, Dr C

Nelson Marlborough District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC01676)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

Background

1. In late 2013, at about 9.30pm (Day 1[1]), Mr A, aged 77 years, suffered the onset of an ischaemic stroke, and was taken to the Emergency Department (ED) at a public hospital (the hospital) via ambulance. At about midnight he was assessed by house officer Dr B who, in consultation with the consultant on call, Dr C, determined that he was an appropriate candidate for thrombolysis.

2. Thrombolysis, also known as clot-busting, is the breakdown of blood clots using types of drugs called tissue plasminogen activator (tPA) drugs. Thrombolysis can be used for patients who have suffered an ischaemic stroke or a heart attack (myocardial infarction), provided the patient satisfies specific criteria and the treatment is given within the appropriate timeframe. There are a number of risks associated with thrombolysis, including intracerebral haemorrhage (bleeding in the brain).

3. Although it was usual practice for stroke thrombolysis to be administered in the Intensive Care Unit (ICU), Dr B decided to treat Mr A in the ED rather than the ICU.

4. In addition, Dr B prescribed Mr A tenecteplase rather than the expected alteplase. Both are tPA drugs, but in New Zealand tenecteplase is used for treatment of myocardial infarction (heart attack) rather than ischaemic stroke. The Nelson Marlborough District Health Board (NMDHB) Stroke Thrombolysis Pathway refers in parts to the generic term "tPA", but in other parts (including on the attached dose calculation sheet, which Dr B filled out for Mr A) states "tPA (Alteplase)".

5. Dr B prescribed Mr A tenecteplase because she understood from nursing staff that there was no alteplase available at the hospital. In addition, she was aware of studies that support the use of tenecteplase in stroke. However, she followed the New Zealand Formulary (NZF) guidelines for the use of tenecteplase in myocardial infarction. In doing so, she prescribed Mr A at least twice the dose of tenecteplase recommended for treatment of ischaemic stroke. In addition, she prescribed tenecteplase to be administered as a 10% bolus with the remainder to be administered as an infusion over one hour (the correct mode of administration for alteplase), whereas tenecteplase should be given as a single bolus (ie, all at once).

6. Dr B did not discuss with Dr C her decision to give Mr A treatment in the ED or prescribe tenecteplase at the dose and mode of administration that she did.

7. Partway through the administration of tenecteplase, Dr B was informed that alteplase was available at the hospital in the ICU. She telephoned Dr C for advice about whether or not to continue the infusion. Dr C advised that the infusion should continue.

[1] Relevant dates are referred to as Day 1-14 to protect privacy.

8. Following the infusion Mr A initially showed signs of improvement, but a computed tomography scan at 8.30am showed that he had suffered an intracerebral haemorrhage. He died a few days later.

Findings

9. The Commissioner found that Dr B made significant errors of judgement in failing to transfer Mr A to the ICU, in deciding to prescribe tenecteplase to Mr A at the dose and via the mode of administration that she did, and in failing to consult Dr C about the use of tenecteplase. Overall, the Commissioner considered that Dr B failed to provide care to Mr A with reasonable care and skill and, in doing so, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

10. As the senior doctor responsible for Mr A's care, it was Dr C's responsibility to ensure that open disclosure regarding the use of tenecteplase and its potential consequences occurred promptly and in a manner consistent with professional standards. The Commissioner was critical of the steps Dr C took to openly disclose to Mr and Mrs A what had happened.

11. There were inadequacies in NMDHB's Stroke Thrombolysis Pathway. In addition, there was evident confusion amongst nursing staff about the correct process for administering thrombolysis, and Dr B had not been orientated to the Stroke Thrombolysis Pathway adequately. NMDHB had a responsibility to ensure that its staff had the right tools, including adequate policies and training, to provide this service safely. The Commissioner found that NMDHB failed in this regard and, accordingly, did not provide services of an appropriate standard to Mr A, in breach of Right 4(1) of the Code.

Complaint and investigation

12. The Commissioner received a complaint from Mrs A about the services provided to her late husband, Mr A, at the hospital. The following issues were identified for investigation:

- *Whether Dr B provided Mr A with an appropriate standard of care in 2013.*
- *Whether Dr C provided Mr A with an appropriate standard of care in 2013.*
- *Whether Nelson Marlborough District Health Board provided Mr A with an appropriate standard of care in 2013.*

13. The parties directly involved in the investigation were:

Mrs A — Complainant

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

Dr B	House officer/Provider
Dr C	General physician/Provider
Nelson Marlborough District Health Board	Provider

14. Also mentioned in this report:

RN D	Registered nurse
SN E	Senior Nurse
RN F	Registered nurse

15. Information was also reviewed from ACC and the Coroner.

16. Independent expert advice was obtained from internal medicine specialist Dr David Spriggs (**Appendix A**).

Information gathered during investigation

Background

17. At 11.21pm on Day 1, in late 2013, Mr A, aged 77 years, arrived via ambulance at the Emergency Department (ED) having suffered an ischaemic stroke.[3] This report concerns the thrombolysis treatment provided to Mr A at the hospital.

18. Thrombolysis, also known as clot-busting, is the breakdown of blood clots by using types of drugs called tissue plasminogen activator (tPA) drugs. Thrombolysis can be used for patients who have suffered an ischaemic stroke or a heart attack (myocardial infarction), provided the patient satisfies specific criteria and the treatment is given within the appropriate timeframe. There are a number of risks associated with thrombolysis, including intracerebral haemorrhage (bleeding in the brain).[4]

Assessment for thrombolysis

19. At approximately 9.30pm in the evening of Day 1, Mr A's wife, Mrs A, noticed that her husband was acting strangely. He said that he had a headache, but when she tried to give him painkillers, his spatial awareness was "off", and he could not see her standing at his left side. Mrs A called an ambulance, concerned that her husband was having a stroke.[5]

20. Mr A was admitted to the hospital at 11.25pm. At midnight, house officer Dr B[6] assessed Mr A. Dr B recorded in the Emergency Department Discharge Summary

[3] Occurs when an artery to the brain is blocked, preventing blood flow to the brain.
[4] There is ongoing controversy about the use of thrombolysis, and significant ongoing discussion between emergency physicians and neurologists about whether this treatment should be used at all.
[5] As recorded in the ambulance service's Patient Report Form and the hospital's Discharge Summary.
[6] At the time, Dr B was employed as a house officer. She had worked at the hospital for two periods totalling 18 months before these events. She had worked for three months at a time in different departments at the hospital.

that, on examination, Mr A was alert and responding appropriately to questions, with normal observations. However, Dr B also recorded that Mr A's head was turned to the right throughout the examination, and she noted left-sided neglect[7] with complete homonymous hemianopia.[8] Dr B recorded that there was no facial asymmetry, but noted that Mr A had reduced strength in his left arm and leg. She diagnosed Mr A with having suffered a stroke.

21. Dr B told HDC that her clinical impression was that Mr A had suffered a severe stroke and that, based on NMDHB's Stroke Thrombolysis Pathway (the Stroke Pathway), she determined that, pending a computed tomography (CT) scan of his head, Mr A was an appropriate candidate for thrombolysis. Dr B told HDC that previously she had never given this treatment to a patient.

22. Dr B recorded that Mr A was within the treatment time for thrombolysis,[9] and that none of the exclusion criteria applied. She noted on the Discharge Summary that she discussed Mr A's presentation by telephone with the on-call medical consultant, general physician Dr C.[10]

23. Dr C told HDC that she was woken by Dr B's call. Dr C stated:

> "[Dr B] communicated with me that [Mr A] had a very significant neurological defect, with a left hemiparesis[11] and left homonymous hemianopia. This meant that the risk of him dying from this stroke without further treatment was very high, and if death did not occur he would be left with a very significant disability and probably require long term hospital level care. I therefore felt that the risk of giving thrombolysis justified its use."

24. At around 12.47am on Day 2 Mr A underwent a CT scan. No contraindications to thrombolysis were identified.

25. Dr C told the Police that Dr B called her again after Mr A had had the CT scan, and told her that there was nothing found in terms of the Stroke Pathway to exclude Mr A from having thrombolysis treatment. They agreed that Mr A was an appropriate candidate for thrombolysis. Dr C told the Police that she instructed Dr B to give thrombolysis using the Stroke Thrombolysis Guideline. Dr C said that she had a lot of confidence in Dr B.

[7] A perceptual disorder that frequently occurs when someone has a stroke in the right side of their brain. Left-hand neglect is inattention of the body, things or people on the left side.
[8] Hemianopia is visual field loss on the left or right side of the vertical midline. It can affect one eye but usually affects both eyes. Homonymous hemianopia is a visual field loss on the same side of both eyes.
[9] The Stroke Pathway stated that initial assessment of the patient needed to occur within three hours of the onset of stroke symptoms, and that thrombolysis needed to commence no more than four and a half hours after the onset of stroke symptoms.
[10] Dr C is a general physician and endocrinologist.
[11] Hemiparesis is weakness of the entire left or right side of the body.

Thrombolysis given in ED

26. Mr A's treatment was commenced in the ED. NMDHB told HDC that Mr A's stroke thrombolysis treatment should have occurred in the intensive care unit (ICU) under the guidance of a consultant physician, rather than in the ED. It acknowledged that, at the time of these events, the Stroke Pathway did not specifically state that treatment should be given in the ICU, but stated that this is part of NMDHB's orientation documentation. The Stroke Pathway provides that if a patient is for thrombolysis on the basis of the initial exclusion criteria, the next step is to "call on call physician", and the section "Nursing Guidelines for Thrombolysis" states: "Patient to stay in ICCU for 24 hours following tPA infusion."

27. NMDHB provided HDC with a document titled "Emergency Department Orientation", which includes a "Stroke" section that states:

> "We aim to rapidly identify patients for whom the physicians may wish to offer thrombolysis. In essence this is done by rapidly gaining a CT scan and following the Stroke Pathway. We DO NOT thrombolise stroke patients in [the] ED — patients must be transferred to ICU under the care of a physician. Our FACEM [Fellow of Australasian College of Emergency Medicine] group is well versed in the stroke thrombolysis literature and at this time we do not believe there is sufficient evidence for this treatment to be offered in ED; however, we will identify potential lysis patients for our colleagues in a timely manner. It is then up to the physicians to screen the patients more thoroughly, consent them and to administer the lysis as they feel appropriate."

28. When asked whether that document was current at the time these events occurred, NMDHB advised that it was unable to identify whether any changes had been made to the document since 2013. It stated that the ED Head of Department at the time of these events considered that the document "had probably been 'tweaked' very slightly but mostly in relation to [another section]".

29. RN D told HDC that after Dr B said that Mr A was for thrombolysis, she (RN D) "suggested [they] call the emergency department consultant on call back into the department for this procedure", but Dr B replied that "this was not needed and she would talk with the on call physician, [Dr C]".

30. When asked whether she considered sending Mr A to ICU, Dr B told HDC:

> "At the time of seeing [Mr A] I was aware that there was only one other doctor, who was less senior than me, in [the hospital] and I believed that [Mr A] would have greater supervision in the Emergency Department. I was also very conscious that the time window for efficacy of thrombolysis treatment was closing and I did not want to delay the time for him to receive thrombolysis."

31. In response to the provisional opinion, Dr B stated that "moving [Mr A] from the ED to the ICU was not considered by her prior to the administration of tenecteplase".

32. Dr B further stated:

> "I now understand that the standard protocol at [the hospital] was that this [treatment] was to be given in ICU and not in the Emergency Department … I did not at any point tell any staff not to move [Mr A] from ED to ICU … I did not overrule any other suggestion that he be transferred as this was not suggested to me by anyone."

33. Dr C said that she did not tell Dr B to transfer Mr A from ED to ICU. Dr C stated:

> "[During my conversations with Dr B] I assumed that [Mr A] would be moved to ICU and have thrombolysis there, as it was my understanding that all thrombolysis (stroke and myocardial thrombolysis) had previously occurred in ICU. I did not realise that thrombolysis for acute myocardial infarction had recently started being given in the Emergency Department on some occasions."

34. In her statement to the Police, Dr C said:

> "At [the hospital] there had been relatively recent changes where the ED Nurses had been training in administering thrombolysis for heart attacks using Tenecteplase, but not for strokes using Alteplase, as it was assumed that this would be administered in the ICU. The Nurses were familiar with Tenecteplase medications, its availability in ED and what to do."

Consent

35. Following an extensive list of exclusion criteria to determine whether a patient is an appropriate candidate for thrombolysis, the Stroke Pathway states the following:

> "Complete consent form
>
> Administration of tPA (see attached dose calculation sheet)
>
> Medical management following thrombolysis … [list of instructions]"

36. The consent form is titled "Consent for acute stroke treatment with tPA (Alteplase[12])". The consent form describes the treatment and includes a place for the patient or next-of-kin and the doctor to sign; a place to write the date; and tick boxes that state:

> "Verbal consent only: from: _____reason:
>
> Treatment without formal consent reason_____"

37. None of these were filled out on Mr A's consent form, and the consent form was not signed. NMDHB stated:

[12] There are different types of tPA drugs. Alteplase is a tPA drug, given directly into a vein, that is used to treat conditions caused by arterial blood clots, including heart attacks, strokes, chest pain at rest (unstable angina), blood clots in the lungs (pulmonary thrombosis or embolus), and other less common conditions involving blood clots. Alteplase is an enzyme that occurs naturally in humans and causes blood clots to dissolve.

> "The consent to treatment form for [Mr A] was not signed, this is often not signed by the patient who is impaired after a stroke. It is our understanding that … treatment risks were discussed with [Mrs A] over the telephone."[13]

38. NMDHB stated that it agreed that not filling in the consent form was an oversight by Dr B. Dr B told HDC that she had not used the "Consent for acute stroke treatment with tPA (Alteplase)" form previously, and was not familiar with "this part of the protocol".[14] Dr B said that Mr A was physically unable to sign the consent form, and she took verbal consent from him. Dr B documented Mr A's consent in his electronic discharge document but not on the hard copy paper protocol. Mr A's electronic discharge summary states: "Discussed [thrombolysis] with patient — explained risks vs benefits — consent given for thrombolysis."

39. With regard to obtaining Mr A's consent to the treatment, Dr B said that she explained to Mr A that he had had a severe stroke, and that there was a small chance that it could be treated by giving thrombolysis. She also said that she "[tried] hard to explain fully the risks of thrombolysis and consent Mr A to treatment at the time". She said that she also did her best to explain the proposed treatment and its associated risks to Mrs A by telephone, and that "both [Mr A] and his wife indicated to [Dr B] that [Mr A] wanted to be treated if possible".

40. Mrs A said that an ED doctor rang her and said they were going to give her husband something, and asked what his weight was. Mrs A said that she replied that she did not know, and asked why the doctor did not ask Mr A himself, as when she had last seen him he was able to talk and he would have known his weight. Mrs A said that "the doctor was quite rude and [she] was quite annoyed". Mrs A stated that she definitely was not told anything about risks and benefits, but that she would have agreed to the treatment if asked.

41. Dr C told HDC that during her telephone conversation with Dr B, Dr B advised that she had fully explained to Mr and Mrs A the risks associated with thrombolysis, including intracerebral haemorrhage and death, and had obtained verbal consent to treatment.

42. Dr B documented in the Discharge Summary that she discussed Mr A with Dr C, but neither Dr B nor Dr C documented the content of their conversation.

Dose calculation sheet

43. The dose calculation sheet attached to the Stroke Pathway is titled "Alteplase Dose Determination". It states that the total dose of alteplase should be 0.9mg/kg, administered as a 10% bolus[15] and a 90% infusion.[16] It includes a table that calculates

[13] Mrs A told HDC that initially she did not accompany her husband to the hospital because she was unwell, but that after she received the telephone call from the doctor, she decided to go to the hospital, and arrived at about midnight.

[14] Other parts of the Stroke Pathway, including a tick-box list of exclusion criteria and an NIHSS (National Institute of Health Stroke Scale), have been completed for [Mr A].

[15] A dose given intravenously or by injection for the purpose of rapidly achieving the needed therapeutic concentration in the bloodstream.

[16] The intravenous administration of a solution (which is a slower form of administration than a bolus).

the total dose and bolus and infusion doses according to the patient's weight. Mr A's weight was 90kg which, according to the table, required a total alteplase dose of 81.0mg, administered as an 8.1ml bolus dose and a 72.9ml infusion dose over one hour.

44. On Mr A's dose calculation sheet, the word "Alteplase" in the title "Alteplase Dose Determination" is crossed out (there is no record of who crossed it out). However, below, it states:

> "IV Alteplase (tPA) bolus given Time 01:17
> IV Alteplase (tPA) infusion commenced Time 01:20"

Prescription and administration

Drug and dose

45. On Mr A's prescription chart, it states that Dr B prescribed 50mg of tenecteplase (as opposed to 81mg alteplase according to the dose calculation sheet), to be administered intravenously, and that RN D had administered it. Dr B recorded in the clinical notes that she calculated the dose based on the New Zealand Formulary (NZF) guidelines.[17]

46. Tenecteplase is another type of tPA drug, and is also used to dissolve blood clots. However, in New Zealand it is used for treatment of myocardial infarction (heart attack) rather than ischaemic stroke. The NZF guidelines referred to by Dr B, as well as the Medsafe datasheet for tenecteplase,[18] list the sole clinical indication for tenecteplase as acute myocardial infarction. Some research has reported success in treating stroke patients with tenecteplase using a lower dose of the drug than for treatment of myocardial infarction. However, the Medsafe datasheet states that the drug is contraindicated in a number of circumstances, including the patient having had a haemorrhagic stroke[19] or a stroke of unknown origin at any time, and having had an ischaemic stroke[20] or transient ischaemic attack (TIA) in the preceding six months. The Medsafe datasheet states that patients over 90kg should be given 50mg tenecteplase (the maximum dose).

47. Dr B provided HDC with her statement to the Police, which, regarding her decision to prescribe tenecteplase, stated:

> "I was informed by ED nursing staff [RN D] that [alteplase] was not available. Treatment efficacy for thrombolysis of stroke is time dependent. It must be commenced within [a] maximum of 4.5 hours and ideally 3 hours. [Mr A's] care had passed the 3 hour mark at 0030.
>
> I was advised that Tenecteplase was available. Although not yet licensed for treatment of stroke in New Zealand there is evidence that Tenecteplase can be used for stroke. Tenecteplase is in the same class of drug as Alteplase and works

[17] http://nzf.org.nz/nzf_1574.html.
[18] http://www.medsafe.govt.nz/profs/Datasheet/m/Metalyseinj.pdf.
[19] Haemorrhagic strokes result from the rupture of a blood vessel or an abnormal vascular structure.
[20] In an ischemic stroke, blood supply to part of the brain is decreased, leading to dysfunction of the brain tissue in that area.

> in the same way. I decided to proceed with thrombolysis at 0117. My intention at all times as the Emergency Department doctor was to achieve the best possible clinical outcome for [Mr A] within the critical time constraints for thrombolysis."

48. Dr B did not contact Dr C again to discuss her decision to use tenecteplase instead of alteplase. Dr B said: "I completely acknowledge and accept that I should have contacted [Dr C] to confirm the next plan of action as soon as I was advised that alteplase was not available."

49. Dr B said that she discussed with Mr A that the drug of first choice (alteplase) was not available in the hospital, but that it did have a drug of the same class (tenecteplase) that might give him the best chance for treatment in the circumstances, although it was not licensed for this specific indication.[21] Dr B stated that she explained that there were bleeding risks associated with the drug, and said it was her impression that Mr A understood this information.

50. Regarding the availability of alteplase, RN D stated that she told Dr B that "[ED] did not have alteplase in the cupboard but [it] did have tenecteplase". RN D said:

> "I rang ICU and spoke with SN [Senior Nurse] [SN E]. I asked her if tenecteplase was the same as alteplase. She confirmed they are the same as each other … As I was left with the impression … that tenecteplase and alteplase were the same, I did not ask [SN E] if alteplase was available in ICU."

51. Regarding whether she had any other conversations with ICU staff, RN D told HDC:

> "I may have called ICU earlier in the evening to book a bed for [Mr A] although my memory isn't clear on this point."

52. In contrast, SN E told HDC:

> "I got a phone call from ED at approx. 01.30 informing me of an admission to ICU. … A second phone call asking if alteplase is the same as actilyse [brand name for alteplase] and I confirmed that, thinking that the house surgeon was charting the drug. At that stage I asked for the patient's weight and with that information I prepared the actilyse to be given. Time lapsed and still no patient. Next thing we realised that the patient was being thrombolysed in ED with TNK [tenecteplase]. We told them that is the wrong drug."

53. In response to the provisional opinion, Dr B stated that initially she was not aware that alteplase was available in ICU, or that ICU staff had drawn up the drug in anticipation of Mr A's transfer from ED to ICU.

54. Regarding the dose of tenecteplase prescribed, Dr B told HDC:

[21] As stated above, tenecteplase is approved by Medsafe only to be used in the treatment of myocardial infarction.

> "I did look online to find literature to support [my] decision [to prescribe tenecteplase] and although I did find some evidence that tenecteplase has been used effectively to treat stroke, I did not find a suggested dose. I have always found the NZF to be a trusted reference and in the absence of other New Zealand based dosing suggestions I thought it the safest option. Although I knew that selecting tenecteplase was a compromise from the medication I thought was unavailable in Nelson (Alteplase), I mistakenly thought it would be safer to adhere to the dose described in the NZF for tenecteplase … I now realise this was a grave misjudgement."

Mode of administration

55. According to the NZF guidelines referred to by Dr B (which, as stated above, concern the use of tenecteplase in the treatment of myocardial infarction), when administering tenecteplase, the whole dose should be given to the patient as a bolus over 10 seconds. However, Dr B prescribed 50mg of tenecteplase as an 8ml bolus followed by an infusion of the remainder of the dose over one hour. Accordingly, Mr A was administered tenecteplase over a 58 minute period. The administration was commenced at 1.17am and completed at 2.15am.

Discussion with Dr C

56. Partway through the administration of tenecteplase, an ICU nurse, RN F, telephoned ED to ask where Dr B was, because ICU was expecting him. RN F told HDC:

> "The [ED] RN told me they were giving the first part of the drug treatment in ED, I then went to the Emergency Department (next door to ICU) to check. I noticed the TNK [tenecteplase] was being given instead of the actilyse [alteplase] but the TNK was being given at the dose one would give actilyse at … I told [RN D] and the ED Reg [Dr B] they were giving the incorrect dose and that they should call the consultant … and report the error."

57. RN D stated that RN F "arrived in the ED with alteplase on a drip pole ready to go". RN D said that she halted the administration of the tenecteplase immediately and advised Dr B of the error.

58. In her statement to the Police, Dr B said that, about 10–20 minutes into the tenecteplase infusion, she was informed by an ICU staff member that alteplase was available at the hospital. She stated that, at that time, she telephoned Dr C, who made the decision to continue the tenecteplase infusion. Dr B told HDC that she believes she quoted the NZF guidelines she had relied on, and that, accordingly, they discussed the dose of tenecteplase and the mode of administration. She said she believes she queried whether she should continue the tenecteplase.

59. Dr C told HDC:

> "My recollection … was that [Dr B] phoned me and told me that they had been unable to find alteplase, as per the stroke thrombolysis guideline at that time, and they had therefore administered tenecteplase as per the myocardial infarction thrombolysis guideline, and that they were half way through administering it,

> when it was brought to her attention that alteplase was available in [the hospital]. …
>
> My instructions were to continue the tenecteplase as she was half way through giving it. My understanding was that tenecteplase could be used for stroke thrombolysis instead of alteplase. My thoughts at the time were that if we stopped the tenecteplase we wouldn't know how much alteplase to give, to give the equivalent of a full dose, and also did not know if there were any potential problems with mixing the two drugs. I did not make any enquiries as to the dose or mode of administration of tenecteplase as, at the time, I was not aware that the dose or mode of administration of tenecteplase used in stroke thrombolysis is different to that used for myocardial thrombolysis. I have subsequently learned that the recommended dose of tenecteplase used in stroke thrombolysis is less than that used for myocardial infarctions thrombolysis."

60. Dr C further stated to HDC that she does not remember whether she and Dr B discussed the dose of tenecteplase being administered, but said: "I do recall that I instructed [Dr B] to continue with the tenecteplase using the method she was currently using, which I now know she had accessed from a myocardial infarction dosing schedule."

61. Dr C also told the Police: "It was my decision to continue with the Tenecteplase. Reasons for this include that it is a general principle that one drug shouldn't be stopped and exchanged for a similar drug mid-treatment. Furthermore, I was aware of studies that have found Tenecteplase to be beneficial to stroke patients." However, she said that she was not aware that Mr A had been given tenecteplase according to the guidelines for heart attack patients, or that the recommended dose of tenecteplase for strokes is different from the dose for heart attack treatment.

62. Dr B said that after she had the conversation with Dr C, she advised Mr A that the first choice of drug had been located, but that it was thought better to continue with the treatment that had already been commenced.

63. Regarding the use of tenecteplase, Dr B recorded in Mr A's Discharge Summary:

> "NOTE — Confusion over availability of Alteplase — patient started on Tenecteplase.
>
> Phoned [Dr C] to discuss whether to change to Alteplase — advised can continue on Tenecteplase.
>
> Dose as per NZ formulary guidelines
>
> On review at 1hr — [patient] states he feels 'fine', observed using left arm, although gaze still fixed to right."

64. Nursing notes at 1.40am record: "Tenecteplase used for thrombolysis — [Dr C] advised of this & happy with this treatment."

Subsequent events

Deterioration

65. At around 2.40am Mr A was transferred to ICU and, initially, he showed some improvement. The clinical notes record that, at 5am, he reported having a headache. By 7am Mr A showed progressive confusion,[22] and his headache continued. The clinical notes record that he was reviewed by Dr C at 8.10am. Dr C documented her suspicion that Mr A was suffering a post-thrombolysis bleed, which was likely to be a terminal event. Dr C ordered a CT scan, which was performed at 8.30am and showed haemorrhaging. Mr A deteriorated over the following three days and, sadly, he died from intracerebral haemorrhage.

Disclosure of error

66. Dr C told HDC that she does not recall having a conversation with Mr A about the error. She stated: "From memory he was too obtunded to have any meaningful conversations about such issues. I did tell [Mr A] that he had had a stroke and where he was ie in [the hospital]."

67. There is no record in the clinical notes that either Mr A or his wife were told about the medication error although, in a letter of Day 14 to Mr A's general practitioner Dr C advised that Mr A had been given tenecteplase instead of alteplase, and stated: "Today I had a conversation with [Mrs A] and went over everything that had happened including that an error had been made with the drug given. I don't believe there was any change in the outcome because of this drug."

68. Dr C told HDC that she had many conversations with Mrs A during Mr A's admission and following his death.[23] Dr C stated that, on the morning of Day 2, she explained to Mrs A "about the inadvertent use of tenecteplase rather than alteplase", and that full and open disclosure occurred. Dr C said she told Mrs A that the drugs could be used interchangeably, and that the inadvertent use of tenecteplase "was of no consequence to the events that happened".

69. Dr C also told HDC that following Mr A's death she "attempted to arrange a family meeting with [Mrs A] and other family members to go over all the details again, but … [Mrs A] did not want to travel [to the hospital], so instead [they] arranged a telephone meeting". However, there is no record of such conversations having occurred. Dr C acknowledged to HDC that her discussions were not documented adequately, and apologised for this.

70. In contrast, Mrs A told HDC that her husband's funeral was held about five or six days after his death. The following day, someone from the hospital rang and asked her to go in to see them, but she refused because she did not want to return to the hospital. She said that Dr C then rang her and told her what had happened. Mrs A said she was shocked by what she was told, but she was not provided with any information about her right to complain to HDC until the hospital sent her a standard letter asking her to rate the standard of care provided by the hospital. The letter included a reference to

[22] Nursing notes state that, at 4pm, Mr A was still orientated to year/month/time of day/place.
[23] Mrs A is the executor of her husband's estate.

HDC. Mrs A said that there was no acknowledgment or apology for what had happened to Mr A, and that she thought it was "unbelievable" in the circumstances that the hospital would ask her to rate the care provided to her husband.

71. Following Mr A's death, medical and/or administrative staff at NMDHB did not immediately report Mr A's death to the Coroner, or initiate an ACC claim on Mrs A's behalf. Dr C told HDC that she accepts that she should have reported Mr A's death to the Coroner and offered to initiate an ACC claim. She stated:

> "My thinking at the time was that [Mr A] had died as a direct result of having a stroke [rather than being given tenecteplase] and that intracerebral haemorrhage was a known recognised complication of thrombolysis, for which full consent had been obtained, and therefore a report to the Coroner [or the initiation of an ACC claim] was not necessary."

NMDHB's response

72. In February 2014 NMDHB undertook an internal review of the care provided to Mr A. NMDHB identified the following care delivery problems:

- Thrombolysis was commenced in the ED rather than the ICU.
- The incorrect drug (tenecteplase) was used for treatment.
- Once the error was recognised, the infusion was continued.
- Following the error the Coronial, ACC and serious event management processes were not activated correctly.

73. Regarding the care provided to Mr A, NMDHB's review identified a number of contributory factors to the care delivery problems, which are summarised as follows.

- There was time pressure to investigate and commence thrombolysis.
- Use of stroke thrombolysis is a relatively new practice, which had been used 22 times over three years within NMDHB.
- Dr B was not orientated to the Stroke Pathway adequately.
- The Stroke Pathway is used relatively infrequently.
- The Stroke Pathway was not explicit about stroke thrombolysis being given in ICU where the staff have more specific training. In addition, it was ambiguous in that it referred to alteplase in some parts but, in others, referred to tPA, the generic group of thrombolytic medications (which includes tenecteplase).
- The labelling on tenecteplase does not "overtly" exclude its use in stroke.
- There are "scientific reports highlighting the efficacy of tenecteplase for use in stroke".
- The significance of the difference in dosing between alteplase and tenecteplase is not appreciated.
- Each thrombolytic medication has three names (a generic name, a trade name and a three letter acronym) and the names are similar for the different medications, creating opportunities for confusion.
- Expert support from the physician on call or the ED consultant within the hospital was not provided or sought at key points.

- Communication between ED and ICU nursing staff did not support the use of the correct medication and added to the confusion.
- There were no medical registrars (who would have had more experience) on duty in the hospital, and the Stroke Pathway did not require the on-call physician to come into the hospital personally to lead the process.

74. NMDHB also listed a number of changes that have occurred, or are occurring, to reduce the risk of similar errors in the future, including but not limited to the following:

- The Stroke Pathway has been updated; it now states that stroke thrombolysis is to be given in ICU, under the direct supervision of a senior medical officer, and refers only to alteplase (rather than including reference to the more generic term tPA).
- NMDHB is undertaking continued audits of compliance with the Stroke Pathway.
- The errors made in this case were discussed by staff at a monthly physician education, peer review and audit meeting.
- ED orientation for house officers has been reviewed and now includes specific orientation with regard to high risk care pathways and processes, particularly clarifying the need to consult with senior medical staff in relation to any deviation from care pathways.
- NMDHB now employs medical registrars.

75. Regarding the failure to initiate Coronial, ACC and serious event management processes appropriately, NMDHB's review identified a lack of clarity and co-ordination among staff about appropriate post-death processes. It also stated that its serious event management systems were in transition at the time, and required review and development.

76. NMDHB has now developed an "After the Death of a Patient Checklist" to reduce the risk of omissions such as a failure to notify the Coroner or lodge ACC claims after a death. It also advised that it had reviewed and formalised its serious event management system, and that it is updating its electronic reportable event system.

Further information

77. Dr B told HDC:

> "… [N]ot discussing the administration and dose of tenecteplase with [Dr C] remains the most sincere and profound regret of my life. I have been affected deeply by this case. It has permanently affected my practice and I will remember it for the rest of my life. I am truly sorry and extend my condolences to the family of [Mr A]."

78. Dr B also stated:

> "[On the night of these events] I was under extreme pressure. From 0100 hours … I was the most senior doctor on site and the only doctor in the Emergency

> Department. Only one other House Officer was rostered to cover the rest of [the hospital] … There were no registrars rostered to provide assistance to the House Officers on the night shift. I was simultaneously trying to see patients and maintain oversight over the busy Emergency Department by myself, answer clinical management questions from nursing staff, speak to family members in the department, field phone calls and maintain documentation of patient notes as best I could."

79. Dr C told HDC: "Our sincerest condolences go to [the family] …"

Responses to the provisional opinion

Mrs A

80. Mrs A commented that she was told that the doctor had made a mistake with a drug but was given no precise detail about the error. She stated that she was pleased that NMDHB had made changes in response to the events.

NMDHB

81. NMDHB made no comment in response to the provisional opinion.

Dr C

82. Dr C stated that "it is [her] own personal view that a number of systemic issues led to the error", including a lack of senior medical staff on site, a recent change in process with heart attack thrombolysis being given in ED rather than ICU, and the time pressure to administer the drug within the accepted timeframe.

83. Dr C reiterated that she believed full consent was obtained from Mr A, and submitted that there was "certainly full and **open disclosure** regarding the drug error to the family" [emphasis in original]. She stated that this occurred at the earliest appropriate time, but she did not document the conversations in the medical notes.

84. Dr C accepted that she should have discussed the case with the Coroner and made a referral to ACC, and that her documentation was inadequate. She stated: "I apologise for my lack of documentation of the conversations that I had with [Mrs A] and family members, around this very sad time."

85. Dr C stated that she has made a number of changes to her practice, including giving more attention to documentation of conversations with patients and families, and consideration when deciding whether or not to make a referral to the Coroner and/or ACC.

Dr B

86. Dr B stated that she accepted the finding that she made "significant errors of judgment in failing to transfer [Mr A] from ED to ICU, in deciding to prescribe tenecteplase to Mr A at the dose and via the mode of administration that she did, and in failing to telephone the Consultant on call about the use of tenecteplase".

87. Dr B also stated that "her regret and sorrow for what happened and the tragic consequences are genuine and heartfelt".

Opinion: Dr B

Decision to commence thrombolysis treatment — No breach

88. Mr A suffered a stroke and was transported by ambulance to the ED. At around midnight, Mr A was assessed by Dr B. At the time of these events Dr B was a house officer. She had worked at the hospital for two periods totalling 18 months before these events. Dr B diagnosed that Mr A had suffered a stroke, and said that, based on NMDHB's Stroke Pathway, she determined that, subject to the results of a CT scan, Mr A was an appropriate candidate for thrombolysis.

89. Dr B telephoned Dr C and discussed the possibility of Mr A receiving thrombolysis. Dr C considered the risk of giving thrombolysis was justified in the circumstances. At around 12.47am Mr A underwent a CT scan, which showed no contraindication to thrombolysis. Following a further conversation between Drs B and C, Mr A was commenced on thrombolysis.

90. Regarding the use of thrombolysis in Mr A's case, I note the comment of my independent expert, general physician Dr David Spriggs:

> "Thrombolysis and stroke is very contentious. The overall risks and benefits are closely matched and about the time of this incident there was active debate about the appropriate use of thrombolysis … That debate continues. The stroke community however is unanimous in their support for thrombolysis in the appropriate clinical context. [Mr A] fulfilled these criteria."

91. I accept Dr Spriggs' advice, and consider that Dr B's decision to commence thrombolysis treatment for Mr A was reasonable.

92. Dr B said that she discussed with Mr A that the drug of first choice (alteplase) was not available in the hospital, and she "explained that [the hospital] did have a drug of the same class (Tenecteplase) that might give him the best chance for treatment in the circumstances although it was not licensed for this specific indication". Dr B said that Mr A consented to the administration of tenecteplase on that basis.

Treatment provided — Breach

Treatment in ED

93. NMDHB's expectation was that stroke thrombolysis would be given only in the ICU. The Stroke Pathway did not explicitly require this, although it did state under the section "Nursing Guidelines for Thrombolysis": "Patient to stay in ICCU for 24 hours following tPa infusion."[24] In response to the provisional opinion, Dr B stated that she did not consider moving Mr A to ICU prior to administering the tenecteplase. She also told HDC that she decided not to move Mr A to ICU because she believed he would have greater supervision in ED, and because she was the most senior doctor in the

[24] NMDHB told HDC that its ED orientation information stated that stroke thrombolysis should be given in ICU, but could not advise whether or not the relevant document, as provided to HDC, was in place at the time of these events. As such, I have not included reference to it in my consideration below.

hospital that night. (Dr B told HDC that she was the only doctor on site in the ED, and that there was another house officer responsible for the rest of the hospital.) She also said that she was concerned about the time window for efficacy of thrombolysis, and did not want to delay Mr A receiving the treatment.

94. Dr C did not tell Dr B to transfer Mr A to ICU because she assumed he would be thrombolysed in ICU. Dr C told HDC that she was not aware that, due to a recent change at the hospital, thrombolysis for the treatment of myocardial infarction had, on some occasions, been given in ED. In other words, she was not aware that there existed an opportunity for confusion about the appropriate place to give thrombolysis treatment to patients. I acknowledge that the Stroke Pathway was not clear that stroke thrombolysis should be given in ICU; nonetheless, I am concerned that Dr B proceeded to provide thrombolysis treatment to Mr A in ED for the reasons that she did. Furthermore, I do not accept that Mr A would have had a higher level of supervision in ED than in ICU, as was submitted by Dr B.

Use of tenecteplase

95. At some stage before thrombolysis commenced, RN D rang ICU and spoke to SN E. RN D told HDC that she asked whether tenecteplase was the same as alteplase, and was told that they are. In contrast, SN E said she was asked whether alteplase is the same as Actilyse (a brand name for alteplase), and she confirmed that they are.

96. Given the conflicting accounts between RN D and SN E, I am unable to make a finding as to the details of their conversation. In any event, I accept Dr Spriggs' advice that Dr B must take responsibility for prescribing tenecteplase instead of alteplase. Dr Spriggs stated that Dr B "should have been aware that the risk:benefit ratio for thrombolysis in stroke is narrow and the protocol has to be followed accurately". Dr Spriggs considered that, while the Stroke Pathway referred in parts to tPA rather than alteplase, Dr B knew enough to question the use of tenecteplase, and should have talked to Dr C about it.

97. RN D told Dr B that they did not have alteplase in the ED, but they did have tenecteplase. Dr B said that she was aware that tenecteplase was not licensed for treatment of stroke in New Zealand, but she knew there was some evidence that tenecteplase could be used for ischaemic stroke.

98. I note that, despite the Stroke Pathway not being explicit in stating that alteplase should be used, the dose calculation sheet referred to alteplase, and the word "alteplase" was crossed out (although the record does not indicate by whom this was crossed out). Dr B told HDC that she was aware that the use of tenecteplase was a "compromise". I note in this regard that the NZF guidelines Dr B relied on, and the Medsafe datasheet for tenecteplase, both list the sole clinical indication for its use as myocardial infarction.

99. Professional standards require doctors to prescribe medication according to best practice guidelines and, if prescribing outside of accepted norms in special

circumstances, to discuss the proposed treatment with a senior colleague.[25] Dr B prescribed tenecteplase to Mr A, and did not discuss this decision with Dr C. Dr B acknowledged and accepted that she should have contacted Dr C to confirm the next steps as soon as she was advised that alteplase was not available. I agree with Dr B's assessment.

Dose and mode of administration

100. Dr B prescribed tenecteplase at a dose of 50mg to be given as a 10% bolus, with the remainder given as an infusion over a period of one hour. Dr B stated that she prescribed the dose based on the NZF guidelines for tenecteplase for the treatment of myocardial infarction. Dr Spriggs advised that if tenecteplase were to be used in the treatment of a stroke patient, it would be given as a bolus (ie, all at once) at a dose of 0.25mg/kg with a maximum of 25mg. He noted that as Mr A weighed 90kg, the dose prescribed by Dr B (which would have been the correct dose for a patient being treated for myocardial infarction) was at least double the recommended dose for treatment of ischaemic stroke.

Conclusion

101. I acknowledge that Dr B was faced with time pressure, that she had never given thrombolysis treatment previously, that she was not orientated to the Stroke Pathway sufficiently, and that she was the only doctor working on site in the ED that night (and one of two doctors on site at the hospital). However, advice from a senior colleague (Dr C) was available to Dr B over the telephone, and yet she made decisions to deviate from standard practice without seeking that person's advice.

102. In my view, Dr B made significant errors of judgement in failing to transfer Mr A to ICU, in deciding to prescribe tenecteplase to Mr A at the dose and via the mode of administration that she did, and in failing to consult Dr C about the use of tenecteplase. Overall, I consider that Dr B failed to provide care to Mr A with reasonable care and skill and, in doing so, breached Right 4(1) of the Code.

103. I note that, when she became aware that alteplase was available at the hospital, Dr B appropriately contacted Dr C about how to proceed.

Opinion: Dr C

104. On the evening of Day 1 Dr C was contacted by house officer Dr B and told that Mr A had suffered a severe stroke. Dr C and Dr B discussed Mr A's suitability for thrombolysis and, following a CT scan, they spoke over the telephone again and agreed that he was an appropriate candidate.

[25] Medical Council of New Zealand, *Good Prescribing Practice* (April 2010).

Supervision of Dr B — No breach

105. Dr C stated to HDC that she did not tell Dr B to transfer Mr A to ICU, because she assumed that this would happen. Dr C noted that she had a lot of confidence in Dr B, and she was not aware that thrombolysis for heart attack patients had recently been given in the ED. While I consider that it would have been prudent for Dr C to advise Dr B specifically that Mr A should be moved to ICU, I accept that, given that the usual practice at NMDHB was to conduct stroke thrombolysis in ICU, it was not unreasonable for her to have assumed that Dr B would be aware of NMDHB's expectation in that regard, and that accordingly Mr A would be moved to ICU.

106. Dr B did not consult Dr C about her decision to prescribe Mr A tenecteplase. However, partway through its administration, Dr B again spoke to Dr C, who advised that the tenecteplase infusion should continue.

107. Regarding that conversation, Dr B told HDC that she believes she quoted the NZF guidelines she had relied on, and that, accordingly, they discussed the dose of tenecteplase and the mode of administration. Dr C remembers being told that Dr B had given the wrong drug, but does not remember whether they specifically discussed the dose or mode of administration. Dr C instructed Dr B to continue the tenecteplase. She told the Police that she was not aware at that time that Mr A had been given tenecteplase according to the guidelines for heart attack patients, or that the recommended dose of tenecteplase for stroke is different from the dose for heart attack treatment.

108. My expert advisor, Dr Spriggs, considered that if Dr C was aware that the incorrect dose of tenecteplase was being administered, it would have been appropriate for her to discontinue the infusion. However, he noted that he would not expect a general physician to be aware of the dosing of tenecteplase for stroke patients, and that, in the event Dr C was not aware that the dose was incorrect, her advice to continue the infusion was reasonable.

109. In the circumstances, I do not consider there to be sufficient information for me to make a finding about whether the dose of tenecteplase being administered to Mr A was discussed between Dr B and Dr C. In any event, I am satisfied that Dr C was not aware of the correct recommended dose of tenecteplase for stroke patients. I accept Dr Spriggs' advice that most general physicians would not be aware of this, and that, accordingly, Dr C's advice to continue the infusion was reasonable in the circumstances.

Open disclosure — Adverse comment

110. At around 2.40am on Day 3 Mr A was transferred to ICU and, initially, he showed some improvement. The clinical notes record that, at 5am, he reported having a headache. By 7am, Mr A showed progressive confusion, and his headache continued. The clinical notes record that he was reviewed by Dr C at 8.10am.

111. Right 6(1) of the Code provides that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to

receive. In my view, a reasonable consumer in Mr A's circumstances would expect to have the medication error that happened in this case openly disclosed to them.

112. The Medical Council of New Zealand (MCNZ) Guideline "Disclosure of Harmful and Adverse Events" (December 2010) (the MCNZ Disclosure Guideline) 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.[26]

113. The MCNZ Disclosure Guideline states that the disclosure should be made in a timely manner, and that it is appropriate to make the initial disclosure as soon as practical, with a more detailed discussion with the patient to follow once the team has had the opportunity to meet and discuss the circumstances that led to the patient being harmed. This will give time for the patient to think about the situation and provide an opportunity to ask for more information.

114. The MCNZ Disclosure Guideline also states that the doctor should document in the patient's clinical notes details of the nature of harm, and any subsequent action, including disclosure to the patient. MCNZ recommends that the patient's clinical notes include who was present during the disclosure, what was discussed, the patient's reaction, and any issues regarding continuity of care.

115. There is no record in the clinical notes that Dr C disclosed to Mr A that a medication error had occurred. Dr C does not recall having a conversation with Mr A about the medication error. She stated: "From memory he was too obtunded to have any meaningful conversations about such issues. I did tell [Mr A] that he had had a stroke and where he was ie in [the hospital]."

116. However, Dr C told HDC that she had many conversations with Mrs A during Mr A's admission and following his death, and that full and open disclosure occurred "that [Mr A] had inadvertently received tenecteplase instead of alteplase for thrombolysis". Dr C said she told Mrs A that the drugs were interchangeable, and that the fact that he received a different drug from that intended "was of no consequence to the events that happened". Mrs A said she was told that the doctor had made a mistake with a drug, but was given no precise detail about the error. There is no record of any such conversations between Dr C and Mrs A. The only documented disclosure of the error is in Dr C's letter to Mr A's general practitioner dated Day 14, which states that Dr C had a conversation with Mrs A that day (Day 14) and told her about the error.

117. Mrs A said that it was not until the day following her husband's funeral, five or six days after his death, that someone from the hospital rang and asked her to go to the hospital. She told HDC that she refused to do so, and that Dr C then rang her and told her what had happened.

[26] I note that the clinical notes do not include any assessment of competence, and that nursing notes state that at 4pm on Day 2 Mr A was still orientated to time and place.

118. The importance of the medical record is well established. It is often stated by medical defense lawyers that "if it isn't documented, it didn't happen". Indeed, this Office has often observed that providers whose evidence is based solely on their subsequent recollections (in the absence of written records) may find their evidence discounted.[27]

119. In the absence of any such record, I remain concerned that Dr C does not appear to have provided either Mr A or Mrs A with a timely and clear explanation of what had occurred. I note Dr C's statement that, at the time, she thought Mr A's intracerebral haemorrhage was a direct result of having a stroke and subsequent thrombolysis, rather than being given tenecteplase, and that when she reviewed Mr A on the morning of Day 3 he was "too obtunded to have any meaningful conversations about such issues". Nonetheless, she accepted that a medication error had occurred and, accordingly, open disclosure about the error and its potential consequences needed to occur, either to Mr A if he was competent, or to another appropriate person, in this case, Mrs A.

Other comment

120. I note Dr Spriggs' view that Dr C should have reported Mr A's death to the Coroner and initiated an ACC claim on Mrs A's behalf. Dr C told HDC that she accepts that she should have reported Mr A's death to the Coroner and offered to initiate an ACC claim. She stated that, at the time, she thought Mr A had died as a direct result of having a stroke, rather than being given tenecteplase, and therefore a report to the Coroner (or the initiation of an ACC claim) was not necessary. Dr C has reflected on her actions in this regard, and advised that she would act differently in the future.

Opinion: Nelson Marlborough District Health Board — Breach

121. The care provided to Mr A occurred in the context of a relatively junior doctor being the only doctor on site in the ED at the hospital. However, as stated above, Dr B had access to advice from a senior colleague over the telephone. Nonetheless, as identified in NMDHB's internal investigation, a lack of clarity in the relevant policy in place, the Stroke Pathway, appears to have contributed to Dr B's error.

Inadequate policies — Breach

122. While the Stroke Pathway referred to alteplase in some places, it did not explicitly specify alteplase as the tPA to be used in the case of stroke thrombolysis and, in some places, used the more generic term tPA. I note Dr Spriggs' advice that this was common in other DHBs in New Zealand at that time. I am concerned that it did not provide sufficient clarity to support staff using the Stroke Pathway correctly and providing safe care to consumers.

[27] See, for example, Opinion 12HDC00779 (18 June 2015) and Opinion 04HDC03530 (14 February 2006), available at www.hdc.org.nz.

123. Dr Spriggs also advised that the Stroke Pathway was inadequate in not stating that alteplase should be given only in ICU. Had the Stroke Pathway clearly identified the relevant drug, and that it was to be administered only in ICU, Dr B would have been better supported in prescribing this treatment, and the error might have been avoided. I agree with Dr Spriggs that the Stroke Pathway was inadequate. In addition, I note that, according to NMDHB's internal investigation, Dr B was not orientated to the Stroke Pathway sufficiently.

124. In addition, in my view, the communication between ED and ICU nursing staff in this case also demonstrates that there was confusion amongst NMDHB staff about the correct process to follow for stroke thrombolysis patients.

125. NMDHB had a responsibility to ensure that its staff had the right tools, including adequate policies and training, to provide thrombolysis safely. I consider that this case demonstrates that NMDHB failed in this regard and, accordingly, did not provide services of an appropriate standard to Mr A, in breach of Right 4(1) of the Code.

126. This is not the first time I have considered a case involving confusion between the use of alteplase and tenecteplase for thrombolysis of stroke patients.[28] In the previous case, I stated:

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

127. I am thoughtful that a similar error occurred in this case, in circumstances where the relevant DHB's protocol did not clearly identify the relevant drug, and the consultant was not called for advice when she should have been. It is essential that these cases are used as learning opportunities, to prevent similar errors from occurring in other DHBs. Accordingly, I will recommend to the National DHB CMO Group that it take steps to ensure that all DHBs' policies/guidelines in relation to stroke thrombolysis are clear and consistent. I will also send a copy of this report to the Health Quality and Safety Commission.

Further comment

128. I agree with Dr Spriggs' comments that the delay in instituting a sentinel event investigation by NMDHB in this case is regrettable. However, I note that Dr Spriggs advised that the subsequent investigation and recommendations in action plans were to be commended, and I note that NMDHB has made appropriate changes to its Stroke Pathway.

[28] Opinion 11HDC01434 (20 November 2013).

Recommendations

129. I recommend that Dr B apologise to Mr A's family for her breach of the Code. The apology is to be sent to HDC, for forwarding to Mr A's family, within three weeks of the date of this report.

130. I recommend that Dr C apologise to Mr A's family. The apology is to be sent to HDC, for forwarding to Mr A's family, within three weeks of the date of this report.

131. I recommend that NMDHB apologise to Mr A's family for its breach of the Code. The apology is to be sent to HDC, for forwarding to Mr A's family, within three weeks of the date of this report.

132. I also recommend that, within three months of the date of this report, NMDHB:

a) provide HDC with the outcome of its audit regarding compliance with the updated Stroke Pathway;
b) review the orientation 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; and
c) update HDC regarding the changes it has made to its electronic reportable events system.

133. I will recommend to the National DHB CMO Group that it take steps to ensure that all DHBs' policies/guidelines in relation to stroke thrombolysis are clear and consistent, including in relation to the appropriate medication, dose and mode of administration to use, and the level of supervision required, and report back to HDC within six months of the date of this report.

Follow-up actions

134.
- A copy of this report will be sent to the Coroner.
- A copy of this report, with details identifying the parties removed, except the expert who advised on this case and Nelson Marlborough District Health Board, will be sent to the Medical Council of New Zealand, and Dr B and Dr C will be named in the accompanying correspondence.
- A copy of this report, with details identifying the parties removed, except the expert who advised on this case and Nelson Marlborough District Health Board, will be sent to the Health Quality and Safety Commission, the New Zealand Pharmacovigilance Centre, and the Stroke Foundation New Zealand.
- A copy of this report, with details identifying the parties removed, except the expert who advised on this case and Nelson Marlborough District Health Board, will be 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 general physician Dr David Spriggs:

"I have been asked to advise the Commissioner on the care of [Mr A] during his [stay in the hospital].

I practise as a General Physician and Geriatrician at Auckland District Health Board and am vocationally registered for Internal Medicine. I have been a Fellow of the Royal Australasian College of Physicians since 1993. I have no conflict of interest in regard to this case and have read and understand the Commissioner's guidelines for independent assessors.

My instructions from the Commissioner are to review the documentation and advise whether I consider the care provided to [Mr A] at [the hospital] was reasonable in the circumstances and why. In particular (and without limiting the scope of this request), I have been asked to comment on:

1. the reasonableness of [Dr B's] actions/clinical rationale, including but not limited to her decision to treat [Mr A] in the ED and her decision to prescribe tenecteplase;
2. the reasonableness of [Dr C's] actions/clinical rationale, including but not limited to her instructions to continue administering tenecteplase part-way through the infusion;
3. whether [Dr B], as [a house officer], was under sufficient supervision;
4. the adequacy of the relevant policies and procedures in place at NMDHB at the time of the events complained of; and
5. the adequacy of the relevant policies and procedures currently in place at NMDHB, including any further changes that you consider may be appropriate.

I have also been asked to comment on any other aspects of the care provided by NMDHB that I consider warrant such comment.

I have been provided with the following documents:

1. Summary of facts.
2. Complaint dated […].
3. [Mr A's] clinical records from NMDHB, [Days 1- 5].
4. Letter from NMDHB to HDC dated 5 February 2014.
5. Letter from NMDHB to HDC dated 1 April 2014.
6. Letter from NMDHB to HDC dated 5 May 2014.
7. Letter from NMDHB to HDC dated 23 July 2014, including enclosures.
8. HDC's Guidelines for Independent Advisors.

BACKGROUND:

[On Day 1] at 22.10hrs an ambulance was dispatched to the home of [Mr A] as his wife had noticed he was 'acting weird' and he had a headache. [Mr A] was unable to take a glass of water. On arrival at the home the ambulance staff noticed dribbling of the left side of the face. [Mr A's] speech was difficult and slurry, he was weak in the left hand and there was paralysis of the left leg. The ambulance staff delivered him to [the hospital] at 23.11hrs. He was triaged in [the Emergency Department] at 23.24hrs. I note the triage sheet states his Glasgow Coma Score was 0/15 (this is probably an error as his GCS was much greater both before and after this assessment). At midnight he was assessed by the nursing staff and at some time he was assessed by the attending [House Officer], [Dr B]. No contemporaneous notes are available to me from that assessment. However there is an Emergency Department Discharge Summary which was written at 0220hrs on [Day 2] which, I believe, refers to the initial assessment when [Mr A] was responding appropriately to questions but his head was turned to the right. [Dr B] noticed left sided neglect with complete homonymous hemianopia. She did not notice any facial asymmetry but there was reduced strength on the left arm and leg. A diagnosis of stroke was made.

[Mr A] was previously living at home. He had a history of a permanent pacemaker due to a cardiomyopathy, the cause of which is not clear in the information that I have available.

[Mr A] went forward for an urgent CT head which was performed at 00.47hrs on [Day 2]. The CT excluded a haemorrhage. [Dr B] decided that thrombolysis ('clot busting treatment') was appropriate and discussed this over the phone with her supervising consultant [Dr C]. It is not documented when this discussion took place. [Dr C] agreed that thrombolysis was appropriate and in her report to the New Zealand Police on the 19/02/14 she states that she understood 'that the risks and benefits of thrombolysis including intracerebral haemorrhage, were explained by [Dr B] to [Mr A] and his wife. I understand they both gave consent to start thrombolysis'. There is no contemporaneous note recording the consent process and the 'Consent for acute stroke treatment with tPA (Alteplase)' form was not filled in. I note that [Dr B] in her ED Discharge Summary states 'discussed with patient — explained risks vs benefits — consent given for thrombolysis'. I believe that by this time [Mrs A] had left [the hospital]. In her statement of 17th June 2014, [Dr B] states that in regard to the failure to complete the 'Consent for Acute Stroke Treatment with tPA (Alteplase)' form, she had not used this form before and was not familiar with that part of the protocol. She goes on to state that [Mr A] was unable to physically sign consent. However the clinical notes, such as they are, suggest that he was 'responding appropriately to questions' and the power on the right side was normal. There is no statement as to whether he was right or left handed.

The drug used for thrombolysis is 'Alteplase' and the Alteplase Dose Determination sheet for [Mr A] is filled in correctly. It was planned that the first bolus dose of Alteplase be given at 01:17hrs followed by an infusion. The

standard protocol at [the hospital] was that this drug be given in ICU and not in the Emergency Department. However there had been a recent change in the management of myocardial infarction such that Tenecteplase, a different drug with a similar action and different pharmaco-kinetics/dynamics (it works in a similar way to Alteplase but needs different dosing), could be given by the nursing staff in the Emergency Department. [Mr A] at this stage was in the Emergency Department. Alteplase was not available in this department. There was a discussion between the Emergency Department Nurse [RN D] and her ICU colleague [SN E]. [RN D's] account is that she asked [SN E] 'if Tenecteplase was the same as Alteplase. She confirmed they are the same as each other'. [SN E] recalls the conversation asking if Alteplase was the same as Actilyse. [SN E] does not recall any conversation at that stage about Tenecteplase. Alteplase was available in the ICU and the staff there drew up the drug at the appropriate dose. However Tenecteplase was prescribed at a dose of 50 mg intravenously by [Dr B]. This was to be given over a period of an hour. [Dr B] states that this dose is 'as per NZ formulary guidelines'. She does not recognise that this guideline is for the treatment of myocardial infarction not stroke. In fact, if Tenecteplase was to be used in stroke, it would be given as a bolus at a dose of 0.25mg/kg with a maximum of 25mg as it had been in the studies using the drug in this condition (Parsons et al. NEJM 2012). [Mr A] weighed 90kgs. The dose prescribed was therefore at least double the recommended dose.

In [Dr B's] statement of 17th June, she said that she wanted to give the thrombolysis in the emergency department rather than ICU as she was more senior than the doctor in ICU and '[Mr A] would have greater supervision in the Emergency Department'. The Tenecteplase infusion was started at 01.17hrs. About half an hour later an ICU nurse, [RN F], went to the Emergency Department as they were expecting [Mr A] to be transferred to their care in ICU. [RN F] found that [Mr A] was receiving Tenecteplase and stated that this was the incorrect drug. He also made the staff aware that Alteplase was available in ICU. [Dr B] was informed of this and she phoned [Dr C] to ask if they should stop the Tenecteplase and replace it with Alteplase. [Dr C's] advice was that they should complete the Tenecteplase infusion knowing that Tenecteplase had a very similar action to Alteplase. [Dr C] was also aware that Tenecteplase had been used in trials for the management of stroke but she 'was not aware that the dose or mode of administration of tenecteplase used in stroke thrombolysis is different to that used for myocardial infarction thrombolysis'.

Following the infusion, [Mr A] was transferred to ICU where he was clerked by [the Night House Officer] at 0240 hours. This is the first contemporaneous clinical note by a doctor. At that stage the homonymous hemianopia persisted, there was a mild left facial weakness and mild weakness of the left side of the body. There was significant visual neglect and sensory loss down the left side. It was felt that he had started to improve following the thrombolysis. At 07.10hrs [the Night House Officer] was asked for a review as [Mr A] had started to deteriorate. This was discussed with [Dr C] and it was felt that a post thrombolytic bleed was likely. [The Night House Officer] records that this was discussed over the phone

with Mrs A at that time. An urgent repeat CT was requested and performed at 11.07hrs. This confirmed a post thrombolytic bleed with two haematomata (blood clots) on the right side. The clinical team considered that this was a terminal event and [Mr A] was placed on the Liverpool Care Pathway (this is a care pathway for those with a very short life expectancy to enable appropriate End of Life Cares). It is recorded that [Mrs A] was 'spoken to by H/S'. The timing of this conversation is not clear. There are medical notes confirming that [Dr C] reviewed [Mr A] daily over the weekend until [his death]. The nursing reports confirm that the family visited frequently, indeed Mrs A stayed overnight on [Day 4]. There is no record in the notes of conversations between medical staff and the family prior to death with the exception of a reference to the consent at the start of the admission and the two telephone calls to Mrs A early on [Day 2]. I note, however, that in [Dr C's] statement to the police on 19/2/14 she states that 'I had a number of conversations with [Mrs A] and fully explained what had occurred including the use of Tenecteplase in his treatment'.

Following [Mr A's] death the Death Certificate was [signed by a doctor] giving cause of death as

1 a — intracerebral haemorrhage,

b — thrombolysis for ischaemic stroke.

[The doctor] also signed the cremation form.

On [Day 14] [Dr C] wrote a letter to [Mr A's] GP acknowledging that 'there was confusion' and 'Tenecteplase was given instead of Alteplase. The Tenecteplase was given as per heart attack thrombolysis guideline instead of stroke thrombolysis guideline'. [Dr C] mentions in the letter that she had a conversation with [Mrs A] on the [Day 14] and 'went over everything that had happened including that an error had been made with the drug given'. No referral to the Coroner was made. In her statement to the police, [Dr C] explained that she did not feel the death of [Mr A] was 'an unexpected outcome' and no 'foul play' was considered. [Dr C] 'considered [Mr A's] death a possible outcome of the thrombolysis treatment he received and indeed of the stroke that he had had. This outcome was not therefore unexpected and had been explained to the family as a possibility'. For these reasons [Dr C] felt that Coronial referral was not appropriate. In her note to [the] (Clinical Governance Support Officer) from 18th June, she states that 'With hindsight, I can see that the possibility of the thrombolysis being a factor in [Mr A's] death makes the assessment under the Coroner's act more complex. Should a similar situation occur in the future I would consider contacting the Coroner for advice on whether or not reporting was required'. Once the DHB started to look into the death of [Mr A], the DHB spoke to the Coroner and completed a late referral. It is not clear when this occurred but the Coroner was certainly notified before 5th February 2014.

In [Dr C's] letter of [Day 14] she confirms that 'this error has been cited as a sentinel event in our hospital and will be investigated'. This review was initiated

but was not completed straight away. The review happened [in February 2014]. There was also a review, the date which was not clear [by a] Physician working at [the hospital], who has a particular interest in stroke. The outcome of the February review is clearly described in Appendix 1 and they identified four major issues.

1. Treatment was commenced in the Emergency Department
2. The wrong drug was used
3. Once the error was recognised the infusion was continued
4. The failure to report to the Coroner, ACC and to initiate a serious event management process were not correctly activated.

The DHB made several recommendations which include:

> clarification of the stroke protocol such that Alteplase is specifically mentioned rather than the more generic phrase 'tPA'
>
> the need for more senior medical staff on site and all stroke patients entering the thrombolytic pathway should be personally assessed by a senior medical officer/physician
>
> the development of an 'after the death of a patient checklist' to ensure that appropriate coronial and other referrals are made.

OPINION:

I have no doubt that the prescription of Tenecteplase at an excessive dose given over a period of about an hour is very likely to have contributed directly to the intracerebral bleed that [Mr A] suffered and to his subsequent demise. I agree with [Mrs A] that this was a Major Medical Error. Although intracerebral bleeding is a recognised complication of thrombolysis with Alteplase, it is likely that the high dose of Tenecteplase increased this risk significantly. I note the Commissioner reported on a similar case in his decision number 11HDC01434 where again Tenecteplase was administered inappropriately and the patient suffered a subsequent intracranial haemorrhage. It is therefore clear that the error that led to [Mr A's] death is not a 'one off' and is likely, at least in part, to be a systemic risk in New Zealand. I acknowledge the devastating effect that this error has had on [the family].

1. The reasonableness of [Dr B's] actions/clinical rationale.

   [Dr B] was a [relatively experienced house officer]. She had previously worked [at the hospital for two periods totalling18 months] until this event.

   She should have been aware of most significant clinical protocols and she was certainly aware of some of the thrombolytic protocol, most of which she followed appropriately. She must take responsibility for prescribing Tenecteplase instead of Alteplase. She should not have relied on the nurses to give her information about the suitability of Tenecteplase in stroke or its equivalence to Alteplase. She should have been aware that the risk:benefit ratio for thrombolysis in stroke is narrow and the protocol has to be followed

accurately. While I acknowledge that at the time the DHB's protocol referred to tPA rather than Alteplase specifically, [Dr B] knew enough to question the use of Tenecteplase. She should have either looked up the indications for the drug or talked specifically to her senior physician. Not only did she use the wrong drug, she also administered at an inappropriate dose over an inappropriate duration. In addition to using the incorrect drug she also chose to give the drug in the Emergency Department believing that she was more senior than other medical staff in [the hospital]. This led directly to the incorrect impression that Alteplase was not available. It is very likely that had the patient been transferred to ICU the nursing staff in that unit would have ensured that the protocol was followed appropriately.

I recognise the contributing factors identified by the DHB. In particular there is an intense time pressure when considering thrombolysis in stroke. I understand that this is a relatively novel therapy and it is possible that [Dr B] had never done this herself before. The stroke pathway was not explicit in using Alteplase and the physician on-call was off site. However [Dr B] had the opportunity to discuss the use of the Tenecteplase with [Dr C] and chose not to do so until most of the drug had been given.

2. The reasonableness of [Dr C's] action/clinical rationale when continuing to administer Tenecteplase.

   [Dr C] acknowledges that she was aware of studies showing that Tenecteplase can be used in stroke but did not know the dosing or administration guidelines. By the time [Dr C] was contacted at least half the Tenecteplase had been given and her rationale for continuing this until the end of the infusion is reasonable. There is no reason to believe that [Dr C] was aware that an incorrect dose was being given. I do not think that most general physicians would know the dose or administration method for this drug in stroke and [Dr C's] decision to continue the Tenecteplase is probably in keeping with the actions of most of her colleagues.

3. Supervision of [Dr B].

   [Dr B] was [a House Officer] with significant experience at the DHB. At that stage the DHB did not have registrars on site overnight. As advised in the protocol [Dr B] phoned [Dr C] to ensure that thrombolysis was appropriate, but she did not contact [Dr C] when she deviated from the protocol and chose to give a different drug in a different location. While the supervision of [Dr B] was not ideal, I believe her decision not to call her supervising consultant but to authorise Tenecteplase in ED was her decision and cannot be the responsibility of [Dr C]. The DHB's response to this event is appropriate.

4. The adequacy of relevant policies and procedures.

   At the time of this event the stroke thrombolysis pathway did not specify Alteplase but used the more generic term tPA. This was common in other DHBs in New Zealand. The pathway in use at the time does not state that the tPA should only be given in ICU. It states that 'advance warning to ICU' be given. This pathway was inadequate.

5. The adequacy of current relevant policies and procedures.

   I commend NMDHB for the changes made to the stroke thrombolysis pathway which now specifies Alteplase and there is a clear statement that Alteplase is 'only to be given in ICU under the direction of a physician'. I note that the DHB recommends that the on call senior medical officer/physician should be required to come into [the hospital] to personally supervise care along the thrombolysis pathway and they propose to employ medical registrars on site 24 hours a day. I recognise that the internal investigation made a series of other recommendations and actions, all of which are appropriate.

   The failure to keep contemporaneous notes in the Emergency Department is not addressed. While it may be usual practice for low-intensity care in ED to be recorded only in the discharge note, when patients have major illness requiring complex interventions, including consent for major procedures, it would be reasonable to expect the Emergency Department staff to keep contemporaneous notes. I am uncertain if the failure to do so was in keeping with normal practice in the emergency department or that of [Dr B].

I note that the New Zealand National Thrombolysis Working Group has put together a protocol for the use of Alteplase in acute ischaemic stroke and I hope that this protocol will be widely circulated throughout the DHBs in New Zealand.

ADDITIONAL MATTERS:

1. Consent.

   There is an obligation on all health providers to gain appropriate consent from patients before initiating any intervention. Consenting acute stroke is difficult as there is enormous time pressure that does not allow for considered reflection by the patient or their family. The patient has suffered an acute brain injury and their ability to handle complex decisions will inevitably be impaired. Sometimes there are specific language problems. The family are likely to be distressed. It is therefore recognised that the quality of consent in acute stroke is inevitably compromised. However, in the case of [Mr A] there is no contemporaneous record of an attempt to gain consent from [Mr A] or his wife. The local pathway has a well worded consent form, [Dr B] was unaware of its existence and although she states after the event that she received consent from [Mr A] and his wife this is not adequately recorded. [Dr C] believes that appropriate consent was obtained but I am unsure as to the grounds for that belief.

Thrombolysis and stroke is very contentious. The overall risks and benefits are closely matched and about the time of this incident there was active debate about the appropriate use of thrombolysis as evidenced by the BMJ paper published 29th August 2013 entitled 'Do risks outweigh benefits in thrombolysis for stroke?'. That debate continues. The stroke community however is unanimous in their support for thrombolysis in the appropriate clinical context. [Mr A] fulfilled these criteria.

2. Failure to refer to the Coroner and ACC.

At the time of [Mr A's] death [Dr C] was aware that he had died of a complication of the Tenecteplase that was given inappropriately. Whilst she might consider that a similar complication could have arisen had Alteplase been used, in her letter of the [Day 14], she recognises the connection between the thrombolysis and the intracerebral bleed. I have no doubt that most physicians would consider that the Tenecteplase given to [Mr A] was a major contributing factor to his death.

[Dr C] should have known that any patient dying of a complication of treatment given in error must be discussed with the Coroner. As a senior physician practising in New Zealand she has an obligation to be aware of the rules about coronial referrals. In her note of 18th June, [Dr C] states that she 'would consider contacting the Coroner for advice on whether or not reporting was required' if a similar situation should occur. This suggests that she continues to believe that Coronial referral is discretionary. Such referral is obligatory. Likewise any patient suffering the ill effects of treatment is entitled to an ACC referral and [Dr C] should have known this.

3. Communication with the family.

The consent issues are discussed above. After the development of the intracranial bleed, there is no documented meeting between [Dr C] and the family. The family were visiting regularly and there was plenty of opportunity to sit down with [Mrs A] and other family members to discuss what went wrong and to acknowledge the error. [Dr C] stated to the police that she had such conversations but they are certainly not documented. It would be very unusual for an open disclosure conversation with the relatives in this circumstance not to be recorded. Most physicians would formally convene such a meeting and invite the relatives to bring a support person. Formal notes would be taken, action points recorded and copied to relatives if they wished.

There was a conversation [six days after Mr A's death], but I am uncertain whether this was face to face or over the phone.

Open disclosure about medical errors is an important part of our professionalism. It seems that this did not happen at least until after [Mr A] had died.

4. Delay in instituting a sentinel event investigation.

I am uncertain as to why it took at least two months to begin an investigation into this event. I recognise that over Christmas and New Year it can be difficult to pursue such an enquiry; however the greater the time-lag between the event and the enquiry the greater the risk of important information being mislaid.

5. Death certification.

The Death Certificate was signed by the House Officer; this is usual practice. However given the preceding events it would be usual practice for the consultant to at least supervise the signing of the Death Certificate. In the case of [Mr A] there was plenty of opportunity before death to discuss the death certification and referral to Coroner and ACC. It seems this did not occur.

SUMMARY:

[Dr B] must bear responsibility for prescribing an inappropriate drug at an inappropriate dose. She also decided unilaterally to give this drug in ED rather than in ICU. [Dr B] made no contemporaneous notes; indeed the first medical entry in the clinical notes is at 0240 on [Day 2], long after the thrombolysis had been given. I believe that her colleagues would consider that there had been a **SEVERE DEPARTURE FROM USUAL STANDARDS OF CARE.**

[Dr C] was not informed of the use of Tenecteplase after most of the drug had been given, [and] at that stage she decided to continue the drug. I believe that in this regard [Dr C's] colleagues would consider her decision justified. Her failure to a) supervise appropriate death certification, b) report to the Coroner and refer to ACC, c) be clear about her obligations with regard to Coronial referrals in the future and d) to communicate openly with the family prior to [Mr A's] death and subsequently or, at least, to record such disclosure is a **SEVERE DEPARTURE FROM EXPECTED STANDARDS OF CARE**.

The delay of instituting a sentinel event investigation by Nelson Marlborough District Health Board is regrettable. However I acknowledge that their subsequent investigation into this event and their recommendations and action plans should be commended. The quality and timing of Emergency Department note keeping should be reviewed.

Should you wish for any further advice please do not hesitate to contact me.

Yours sincerely

David Spriggs, MBChB, FRCP(Lond), FRACP, MD
General Physician and Geriatrician
General Medicine
Auckland District Health Board"

Further expert advice

"I have been asked by the Commissioner to advise whether, having reviewed the new information below, I wish to amend the original advice in my report of 9th January 2015, and to consider specifically:

1. NMDHB's comments about documentation in the Emergency Department context.
2. Whether, if the Commissioner were to find that [Dr B] and [Dr C] discussed the dose and mode of administration of Tenecteplase partway through the infusion, your advice regarding the reasonableness of [Dr C's] decision to continue the infusion would change.
3. Any other issues you consider warrant comment.

I have been provided with the following documents:

1. A copy of my advice dated 9 January 2015.
2. [Dr B's] letter to HDC dated 8 April 2015 (excluding all enclosures except [the physician's] report dated 4 March 2014).
3. [Dr C's] letter to HDC dated 10 April 2015.
4. NMDHB's letter to HDC dated 16 April 2015 (including two Emergency Department policy documents also enclosed with the letter but not listed as enclosures on the letter).
5. [Dr C's] letter to HDC dated 19 May 2015 (excluding enclosures).
6. HDC's Guidelines for Independent Advisors.

OPINION:

1. I have read the response from Nelson Marlborough District Health Board from 16/04/15, in particular the response from the Emergency Department. They acknowledge that the failure to complete the appropriate Consent Form is 'an oversight on the SHO's behalf'. They feel that my criticism about the absence of contemporaneous notes is unfounded. The 'Discharge Summary' was begun at 1.48 am on [Day 2]. This is a little over 2 hours following [Mr A's] presentation at the Emergency Department and after the Tenecteplase had been started. I note that this 'electronic medical note is the only (their emphasis) consultation record that is generated'. I understand the rationale behind developing the electronic medical record. However, I believe that a 'Discharge Summary' is not usually considered to constitute a contemporaneous clinical record. As stated in my original opinion of 09/01/15, it may be reasonable for care that is not complex to be recorded only in the discharge note; however for patients requiring complex interventions in the Emergency Room including resuscitation I wonder whether the inability to record any other clinical notes is adequate. In particular, if there is no way to record the timing of any intervention, then the notes will lack significant detail. In the case of [Mr A], it is not possible to determine when any particular examination, conversation or treatment was offered. It may be that

the Commissioner feels it appropriate to seek the advice of an Emergency Physician on this matter. I do acknowledge that [Dr B] was following the usual protocol in the Emergency Department and I feel, therefore, that my initial criticism of her was not warranted and her note keeping was acceptable, at least to the Emergency Department. If her notes were written as part of a physician's assessment, they would remain inadequate.

2. I have reviewed the response from [Dr C]. As said in my report of 09/01/15 I believe that [Dr B] spoke to [Dr C] on the phone informing her that the Tenecteplase had been prescribed instead of Alteplase. If [Dr C] had been informed that the dosing was incorrect it would have been appropriate for [Dr C] to discontinue this infusion. If [Dr C] was not informed of this, I would not expect a General Physician to be aware of the dosing of Tenecteplase in acute stroke and therefore her decision to continue this infusion would be reasonable.

ADDITIONAL MATTERS:

1. Failure to refer to Coroner.
   I acknowledge [Dr C's] comments that 'should an equivalent event occur I would of course refer it to the Coroner'. I also acknowledge that I may have misinterpreted her comments on this matter.
2. The role of [Dr B].
   I am struck by the report from the Emergency Department from the 16/04/15 stating '[the] ED and General Medicine agree to disagree on the role of lysis in stroke. For some years now [the] ED has declined to allow the administration of lytics for stroke in the ED'. [Dr B] was working under both the supervision of the Emergency Department and the General Physicians. It is clear that she was getting mixed messages from her various supervisors. This may have added to her uncertainty. As said in my original report there is considerable debate about the use of thrombolysis in acute stroke. This is one of the reasons why careful consent in this circumstance is important. This however does not excuse [Dr B] of her responsibility for the prescription of the wrong drug at the wrong dose.
3. Communication with [Mr A's] Family:
   [Dr C], in her letter of 10/04/15, states that '[Mrs A] and myself had many conversations both during [Mr A's] admission to hospital and following his death'. She 'explained to [Mrs A] about the inadvertent use of Tenecteplase rather that Alteplase'. She also arranged a telephone meeting after [Mr A's] death with [Mrs A] and her family. The only clinical note that I can find reflecting such conversations is on [Day 3] when [Dr C] 'Explained to family L-sided neglect'. This is the only record of conversations between [Dr C] and the family while [Mr A] was in hospital. [Dr C] also states in a letter to [Mr A's] GP after his death that on [Day 14] she 'went over everything that had happened including that an error had been made with the drug given'.

[Dr C], in her letter of 10/04/15, continues to 'believe that [it] is impossible to know that the likelihood of the intracerebral haemorrhage occurring with Tenecteplase was necessarily greater than if the correct drug Alteplase had been given'. While I accept that Alteplase carries with it a significant risk of causing intracerebral haemorrhage the risk from a much larger equivalent dose of Tenecteplase given by infusion is very likely to be significantly greater than that of Alteplase given correctly. If [Dr C] had openly disclosed to [Mr A's] family that it was likely that the intracerebral bleed was a direct consequence of the incorrect drug being given in an incorrect manner at the wrong dose, then this should have been recorded in the notes. Indeed it would have been appropriate to travel to [Mrs A's home] with a patient advocate to explain this to [Mrs A] and her family should they have requested it. [Dr C] acknowledges that 'my various discussions were not adequately documented and I apologise for this'. If [Dr C] continues to believe that intracerebral bleed was not a direct consequence of the Tenecteplase then it is likely she did not disclose fully the probable sequence of events.

[Dr C] states that she did oversee the writing of the Death Certificate. The House officer was instructed to complete the form. At the time [Dr C] did not feel Coronial referral was needed.

4. I acknowledge the thoroughness of the investigation by Nelson-Marlborough District Health Board and the improvements to the systems as described in the letter [on] 16/04/15.

ADDITIONAL COMMENT:

Sadly I think it is likely that the current debate about the appropriate use of thrombolysis in acute ischaemic stroke will continue. This has polarised the medical community dealing with acute stroke, as it has done in [the hospital]. It seems very unlikely that those dealing with acute stroke will consider performing an appropriate trial to answer questions about the suitability of this treatment both in New Zealand and elsewhere. This question can only be reasonably answered by such a pragmatic, randomised trial which could be conducted in New Zealand if the parties concerned agreed. The current level of uncertainty will inevitably mean that doctors on the frontline receive conflicting messages and it will be impossible for patients, their families and the public at large to come to informed decisions about the best course of action. The currently used consent forms would not be considered appropriate by those who believe the data do not support such treatment.

SUMMARY:

I believe the notes made by [Dr B] were in keeping with the expectations of the Emergency Department but not the expectations of the Medical unit. In her role on the night of [Day1/2], she was working for both those departments concurrently. I would consider that her note-keeping was therefore acceptable. I would, however, question the appropriateness of the electronic discharge summary being the only clinical record kept in the Emergency Department.

[Dr B] must however continue to bear responsibility for prescribing an inappropriate drug at an inappropriate dose by an inappropriate route and doing so in the Emergency Department rather than ICU as was expected in the policy. This is a **SEVERE** departure from usual standards of care.

If [Dr C] was not informed of the use of Tenecteplase until almost all the drug had been given and she was not informed of the incorrect dosage, I believe it was reasonable for her to recommend continuing this drug.

If she had openly disclosed the prescribing error and the consequent effects in terms of the intracerebral haemorrhage causing the death of [Mr A] to the family, then she must take responsibility for her failure to record any of these discussions. This would be a **MODERATELY SEVERE** departure from expected standards of care. If, however, she had failed to openly disclose to [Mr A's] family the error and its consequences then this is a **SEVERE** departure from expected standards. In addition, as stated in my initial report, her failure to be clear about her obligations with regard to referral to the Coroner is a **SEVERE** departure from expected standards**.**

I acknowledge the changes that [Dr B], [Dr C] and Nelson-Marlborough District Health Board have made.

Should you wish for any further information please do not hesitate to contact me.

Yours sincerely,

David Spriggs, MBChB, FRCP(Lond), FRACP, MD
General Physician and Geriatrician
General Medicine
Auckland District Health Board"