HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Death of patient following endovascular surgery

Introduction

1. This office received a referral from the Coroner regarding the care provided to the late Ms A, aged 51 years at the time of events. Sadly, Ms A passed away after an endovascular[1] procedure at her local public hospital (Health New Zealand | Te Whatu Ora (Health NZ)), which resulted in a complication. The complaint was supported by Ms A's partner, Ms B, who was also concerned about the manner in which the surgery was carried out by Dr C.

2. I offer my sincere condolences to Ms B and Ms A's family and commend Ms B for her support of this investigation and her reason of not wanting anyone else to go through Ms A's experience.

Background

3. When the matter was referred from the Coroner in May 2023, the Health and Disability Commissioner (HDC) was provided with substantive documentation.[2] This is referred to throughout this decision, together with further information obtained by HDC during the investigation.

4. In 2012, having been unwell from congenital cardiac issues, Ms A received an aortic and mitral valve[3] replacement.

5. On 5 May 2019, Ms A was admitted to her local public hospital after complaining of 'loose stools, vomiting and fevers' with '[p]ossible speech disturbance/visual inattention and delirium'. A computed tomography (CT) head scan showed a small brain bleed in the right parieto-occipital[4] region.

6. On 6 May 2019, due to concerns about cardiac failure, Ms A was transferred to the High Dependency Bay and treated for gastroenteritis, possible stroke, and infective endocarditis.[5]

7. On 7 May 2019, Ms A's breathing continued to deteriorate, and an acute kidney injury was diagnosed. Health NZ's medical team had a discussion with Ms A in which she confirmed

[1] Performed inside blood vessels.
[2] A copy of Health NZ's correspondence and clinical notes, including a statement from Dr D (a consultant neurosurgeon), a Systems Analysis Review (SAR) with a chronology of events between 5 and 22 May 2019, and a statement from Dr C dated 30 July 2019 and attachments (including clinical records).
[3] Two of the four heart valves.
[4] An area of the brain involved in functions such as language, visuo-spatial recognition, writing, reading, symbol processing, calculation, self-processing, working memory, musical memory, and face and object recognition.
[5] Inflammation of the lining of the heart and its valves.

that she did not want to receive cardiopulmonary resuscitation[6] (CPR) or intubation[7] in the event of a cardiac arrest.

8. On 8 May 2019, Ms A was transferred to the Intensive Care Unit (ICU) with suspected endocarditis, left lower lobe pneumonia, and an acute kidney injury. She remained in ICU until 13 May 2019, when she was considered 'unwell but stable' enough to be transferred to a ward.

9. On 20 May 2019, a CT scan and CT angiogram[8] of Ms A's head was done. The CT scans showed that whilst the small brain clot had resolved, she had a likely infective 4mm mycotic aneurysm[9] (MA) in the right posterior parietal region of the brain, and possibly another aneurysm in the right occipital lobe. Ms A was diagnosed with intracerebral haemorrhage[10] (IH) secondary to MA and endocarditis.

10. As a result of the diagnosis, Ms A required urgent[11] cardiac surgery to replace the heart valves, although the risks of this were considered high.[12] This risk had reportedly been explained to Ms A by the cardiothoracic surgery team in the days leading up to the diagnosis and is referred to by Dr C in the angiogram clinical record for 21 May 2019. Health NZ stated that without this surgery, Ms A would almost certainly have died. Health NZ said that discovery of the brain bleed and MA added to the risk that cardiac surgery would not be successful, and the cardiothoracic surgeon decided that the MA needed to be treated before the cardiac surgery could be done. It was considered that for Ms A to have a reasonable chance of survival, the cardiac surgery needed to be done by 22 May 2019 at the latest.

11. Ms A was referred to Dr D (the on-call neurosurgical consultant at the time) for 'advice and management of the MA'. Dr D discussed this with Dr E, a cardiothoracic surgeon, and Dr C, a diagnostic and interventional neuroradiologist (INR), and it was decided that the safest way to treat the MA was through endovascular embolisation.[13]

12. On 21 May 2019, Ms A was first on the surgical list for the endovascular embolisation. In his statement to the Coroner, Dr C said that prior to the surgery, he discussed with Ms A the different treatment options and potential complications such as risks of stroke[14] and 'intra-procedural rupture', and consent was obtained. This is recorded by Dr C in the angiogram clinical record and in his handwritten clinical notes.

13. Ms A was taken to the procedure room for embolisation of her MA at 8.45am. Dr C was the first operating surgeon, and Dr F was the second. A cerebral (brain) angiogram was

[6] An emergency lifesaving procedure of manually pumping blood around a person's body when the heart stops beating.
[7] Insertion of a tube through the mouth or nose into the airway (trachea) to hold it open.
[8] A medical imaging technique that uses X-rays to view blood vessels and organs.
[9] Infection of an aneurysm (an abnormal swelling in the wall of a blood vessel).
[10] Bleeding into the brain tissues.
[11] Within 24–48 hours.
[12] A mortality risk of 30–40% was mentioned under the Technical Details of the Angiogram clinical record subsequently prepared by Dr C.
[13] A procedure to treat abnormal blood vessels in the brain and other parts of the body. It is an alternative to open surgery. The procedure cuts off the blood supply to a certain part of the body.
[14] He noted: '[Q]uoted risk: stroke 10–15% & other 5%.'

performed whilst Ms A was under general anaesthetic. Ms A's case and images from the angiogram were discussed in a neurosurgery multi-disciplinary meeting (MDM) review whilst Dr C and Dr F waited with Ms A, who remained under general anaesthetic. After viewing the images, the consensus from those present (three neurosurgeons and two neurointerventional radiologists) was that the safest way to treat the MA was through the endovascular route. This was conveyed to Dr C.

14. Dr C and Dr F proceeded with surgery. Dr F told HDC that their own involvement in the angiographic procedure was 'very passive', as Dr C was 'very used to work[ing] by himself'. Dr G, a third INR, was present in the angiography suite console room as an observer.

15. The anaesthetic registrar, Dr H, described becoming aware of potential procedural difficulties when Dr G 'entered the angiography room to offer a second opinion about the intervention, asking "Are you sure you want to do it like that?"'. Dr H said that Dr G appeared concerned about the procedural decisions being made by Dr C.

16. Dr G told HDC that in his opinion, when Dr C was removing a microcatheter that had become temporarily stuck, the 'distal access catheter was not adequately controlled and surged forwards, injuring a more proximal vessel (causing a dissecting pseudo-aneurysm) and causing extravasation of contrast (intracranial bleeding)'. Dr G stated that he believes Dr C 'thought that the vessel injury was caused by injection of contrast', but Dr G did not agree with this.

17. Dr G noted that Dr F mentioned to Dr C that the microcatheter had been in for a while following the injection of the embolic agent[15] and asked Dr C what he was going to do about the 'pseudo-aneurysm', and Dr C replied: '[W]hat pseudo-aneurysm.'

18. In Dr C's subsequent clinical written report of the surgery signed on 22 May 2019, he stated that '[u]nfortunately the injection resulted in a small intimal [MA] M3-segment branch dissection with pseudo-aneurysm' and he noted the three treatment options available to deal with this.[16] I note from information provided by Health NZ that a fourth option explained by Health NZ's independent experts would have been to 'pause, monitor and take more images to see if the injury bled'. Dr C did not discuss options with his colleagues present and made the decision that conservative treatment, with Ms A kept on a heparin infusion for both her heart and the dissection, was the best option.

19. In a statement provided to the Coroner, Dr D confirmed that, in a telephone call, Dr C had made him aware of a 'small iatrogenic dissection of a major parent vessel without any bleeding'. Dr D said that he agreed that this should be treated 'without vessel occlusion[17] (which would cause a major ischaemic stroke) and keeping [Ms A] on heparin anticoagulation'.

[15] This increased the likelihood of it getting stuck.
[16] '[C]onservative with no action apart from heparin anticoagulation, stenting; however, this would have required the use of antiplatelet medication, which would have prevented the planned surgery from going ahead and thirdly vessel occlusion, which in turn would have resulted in a large hemispheric stroke.'
[17] Blockage of blood vessels.

20. Dr H told HDC that, after the surgery, he expressed concern to the ICU senior registrar that according to [Dr G], 'there may have been an iatrogenic [18] injury that may make anticoagulation[19] for [cardiopulmonary bypass[20]] unsafe' and that Dr C 'had not declared any procedural complications' to theatre staff at the conclusion of the procedure even though he had overheard a comment made by Dr C to Dr F 'about a bleed'. Dr G also raised his concerns with the cardiothoracic registrar.

21. Dr F told HDC:

> 'Although scrubbed theoretically as an assisting INR I was not involved in catheter manipulation, dynamic discussion or decision making as [Dr C] was very used to work[ing] by himself. The complication of pseudo-aneurysm with high bleeding risk created by distal catheterization of a risky friable vessel was not recognized/ appreciated/acted upon on time. The additional runs to demonstrate/exclude it were not performed. Overall the final decision of conservative management was incorrect.'

22. Ms A was transferred back to the ICU at around 1.30pm, as noted on the Intensive Care Admission report (ICAr). In contrast to the information provided by Dr H, Dr C told the Coroner and HDC that he 'formally handed the patient over to the ICU personnel with a full description of the procedure, complicated by a vessel dissection, and the rationale behind continuation of the heparin[21] infusion'. The ICAr notes that Ms A had been admitted 'following interventional radiology procedure for coiling for mycotic aneurysm'.

23. Whilst the endovascular treatment of the MA was successful, the ICAr noted that there had been an 'iatrogenic proximal pseudoaneurysm[22] subsequent to [the] procedure'. Due to the complication of the dissection of the arterial vessel wall, this resulted in an intracranial bleed six hours after surgery, and Ms A's condition began to deteriorate at 8.00pm that evening.

24. Sadly, Ms A passed away. Her cause of death was stated to be 'extensive intra-cerebral haemorrhage most likely incurred during the treatment of cerebral complications of bacterial endocarditis'. Health NZ's records noted 'haemorrhage with no possible surgical intervention'.

25. On 28 May 2019, a further MDM was held by Health NZ in which the 'initial decision to proceed with treatment was therefore deemed sound', as the risk of rupture was still regarded as very high, irrespective of the aneurysm having ruptured or not. However, as highlighted in Dr D's statement to the Coroner dated 7 August 2019, it was noted by the INR's that some very subtle extravasation of contrast at the dissection site during the early phase of the angiogram was not recognised by the three INR's present at the procedure, and the 'iatrogenic dissection did actually bleed, which later caused the large right intra-parenchymal bleed and subsequent death' of Ms A.

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[18] Induced unintentionally.
[19] The process of hindering the clotting of blood.
[20] A procedure that diverts blood circulation away from the heart and lungs.
[21] A blood-thinner medication.
[22] A pooling of blood caused by injury to a blood vessel.

26. The MDM concluded that the second support catheter that had advanced distally during the withdrawal of the primary embolisation catheter (which had its tip stuck in the embolic material — a common occurrence during any embolisation) was the most likely cause of the vessel wall dissection (with subsequent later fatal haemorrhage). The MDM noted that this was an unfortunate but known complication of this type of procedure and that, overall, 'the recommendation would still have been in favour of endovascular treatment'.

Health NZ's Systems Analysis Review

27. Health NZ carried out a Systems Analysis Review (SAR) to help to understand what had happened, why it had happened, and what could be done to prevent a similar event in the future. Concerns had also been raised with the Radiology management relating to the manner or technique in which the embolisation procedure was carried out, as well as Dr C's reporting of the dissection injury size and stability of the injury upon Ms A's return to the ICU.

28. Health NZ's SAR made the following findings and recommendations:

1. 'Loose leaf structured medical notes, with documented pre and post procedure information were provided to the Review Team by [Dr C]. A copy of these notes was not available in the medical record and were held in the office of [Dr C].' This was against Health NZ's 'Medical Record' policy at the time, as a key principle stated that medical records should be 'reliable, accurate, complete and timely' and therefore would have required any loose-leaf medical files to be included in the patient's medical record.

   Recommendation
   'All loose-leaf medical files in interventional radiology are collected and put into medical records.'

2. 'Staff interviewed expressed that they did not always feel able to speak up directly to other staff within the department when they were concerned about a safety issue. Staff described a culture of a lack of trust and confidence that they would be heard, or their concerns acted upon.' Health NZ told HDC that the INR was described as operating independently with decision-making, and that staff felt unable to speak up to Dr C.

   Recommendations
   'All interventional radiology staff attend/be booked to attend the Speaking Up For Safety training' and that 'Communication/team building sessions be conducted with all members of the interventional team'.

3. 'There [was] no evidence that all treatment options were considered and discussed with the team, when the injury occurred.'

   Recommendation
   'A process be developed for when complications arise during angiography, that when followed ensures that all treatment options will be discussed with the team and agreed upon.'

4. ‘The micro-catheter was thought to be placed distally within the aneurysm, and was left too long in the filling agent, which increased the likelihood of the micro-catheter sticking.’[23]

   Recommendation
   ‘A checking process be formalised regarding the placement of the micro-catheter and the length of time it is placed near the filling agent.’

5. There were multiple failures in relation to communication around there being no post-procedure briefing, which meant that the injury and increased risk of bleeding was not discussed further, and the way the injury was described in documentation[24] at the initial handover and in the ICU Admission Report and medical entry also would not have alerted the wider ICU team to the increased risk of bleeding from the injury. Health NZ confirmed that there was no structured ‘team handover’, which is usual practice in ICU.

   Recommendations
   Pre- and post-debriefings are to be conducted and documented for every patient, and learnings and care planning are to be discussed at debriefing meetings by modifying its ‘Safe Surgery Checklist’ and using it in Interventional Radiology, for every patient. An iatrogenic injury must be described in the medical record so that the receiving team can fully understand the risks, and the existing handover between Interventional Radiology and ICU should be refined so that all risk factors can be explained by all parties.

6. For ICU Nursing Assessment and Monitoring, Health NZ noted that, for frequency of neuro-observations there were three sources of information to rely on,[25] but in the ‘handover to ICU the frequency of observations was assumed, not discussed’, and there was no reference to two out of the three source documents, the day and night nurses did not check the neuro-observations together during the ICU shift handover against standard practice, and there were no neurological observations documented three hours leading up to the time that Ms A’s pupil was noted to be unreactive.

   The SAR also found that neither of the two documents that provided post-angiography monitoring instructions were available for clinical staff to read, and whilst printed copies were in Ms A’s medical record, they were not referred to during handover. Because of this, the standard practice source of information was used, in which the neuro-observations were less frequent (hourly).

   Recommendations

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[23] Health NZ explained in the SAR that ‘[w]hen using a filling agent in angiography, there is an informal process to monitor time. The M[edical] I[maging] T[echnician] calls a [two] minute “warning”, so that the INRs are aware of how much time has passed since the filling agent was injected. This helps reduce the chances of the filling agent hardening around the micro-catheter.’ Health NZ noted that ‘[f]inal solidification occurs within five minutes for all product formulations’.

[24] ‘[S]mall dissecting aneurysm more proximal — stable.’

[25] ‘1. Standard practice ICU[:] Hourly Neuro-observations post-procedures 2. Post-procedure care — Angiogram nursing intervention document[:] Half-hourly Neuro-observations for the first 2 hours, then hourly. 3. Interventional Radiology & Cardiology Services Nursing guidelines post procedure[:] Half-hourly Neuro-observations for the first 2 hours, then hourly.’

'For one "post-angiography monitoring" document to be agreed, which is socialised within ICU and Interventional Radiology, referred to during handover, and be readily available (in full) for staff to access' in their database system, […]. A referral is to be made to the Chief Nurse for a quality improvement focus on ICU nursing assessment, management and handover of patients post neuro-interventional radiology procedures.

Health NZ's External Independent Review (EIR) of Dr C's clinical practice

29. Given the concerns raised about Dr C, including that he was 'operating independently with decision-making and staff felt unable to speak up', Health NZ arranged for an EIR of Dr C's clinical practice by two INR peers from a different hospital (the reviewers). HDC was provided with the EIR report relating to Dr C's care of Ms A (dated August 2020). I have outlined specific findings of the EIR in relation to Ms A's care below.

30. The EIR highlighted a 'number of concerns' about Dr C's care of Ms A, although it acknowledged that her case would have been difficult and the treatment attempted was reasonable given the risks discussed above. However, the reviewers' findings outlined the following:

a) Dr C spent considerable time, and had quite some difficulty, in accessing the site that he wished to reach, and it is likely that in doing this he caused the injury to the vessel that was not recognised at the time.

b) Dr C unnecessarily complicated the procedure. The reviewers noted that biplane[26] angiography would have avoided this.[27]

c) Pre-emptive counter-traction was required during surgery when significant force was required to move the microcatheter. It is noted that insufficient or no counter-traction was placed, which should have been anticipated.

d) Images acquired suggested to the reviewers that a severe injury to the vessel had not been appreciated by Dr C.

e) Dr C should have sought help, given that he had not encountered this situation previously, and it was noted that other INRs were present, including Dr F, and in that situation, any INR should be seeking assistance.

f) It would have been advisable for Dr C to have completed an on-table or post-procedural CT to ensure that there was no active bleeding. The reviewers considered that there was insufficient monitoring of the injury.

g) When asked by a colleague[28] about his plan for the dissection,[29] Dr C is stated to have replied, '[W]hat dissection?' In response to the provisional decision, Dr C told HDC that this was made sarcastically in reference to the brain-bleeding because it was so obvious that an injury had occurred. The reviewers considered that given the complication and

[26] A medical imaging device that uses two X-ray sources and detectors to capture high-resolution, three-dimensional images of blood vessels from different angles simultaneously.
[27] Dr C had a good lateral view of the anatomy and aneurysm at 11.09am during the procedure and then changed the projection to a different view.
[28] Known to be Dr G.
[29] Dr G told HDC that he specifically asked Dr C what he was going to do about the 'pseudo-aneurysm'.

risk, this was not appropriate. No contrasting information was provided about what was discussed between the colleague and Dr C, with the reviewers suggesting that no further discussion occurred, as claimed by Dr C.

h) Dr C's clinical notes to the ICU team recorded the injury as a 'small' dissection, which the reviewers considered significantly underplayed the significance of the injury. The reviewers also considered it likely that Dr C also underplayed the significance to the INRs. It was noted that Dr C 'had a duty to inform all other relevant treating professionals of what had occurred given the impending cardiac surgery which would involve heparinisation.[30]

i) There was also concern about Dr C continuing the heparinisation of Ms A when they considered it 'ma[de] no sense at all'.[31]

j) Dr C did not understand the distinction between arterial dissection and traumatic false aneurysm.

k) Dr C was reluctant to take advice from other INR colleagues when offered. The EIR found that this was justified.

31. The EIR also recognised that, for a significant time,[32] Dr C was in the 'unenviable, and unsustainable position' of being the only INR working at that local district Health NZ, and his workload was stated to be 'unacceptable'.

Recommendations from EIR

32. The main recommendation was that Dr C should not be permitted to be the sole nor primary operator for neuro-interventional procedures, unless in a well-supported environment with at least two experienced colleagues.

33. The EIR also recommended that, as a matter of urgency, if Health NZ in that local district is to continue to provide an INR service, a biplane angiography machine should be installed.

34. In addition, the EIR recommended a prompt for better training of INRs commencing practice for Health NZ.

Royal Australasian College of Surgeons Code of Conduct

35. The Royal Australasian College of Surgeons (RACS) Code of Conduct (the Code of Conduct) defines the professional behaviour expected of all surgeons. Amongst medical knowledge and technical expertise, the Code of Conduct outlines that collaboration with colleagues and others engaged in healthcare delivery is required. In particular, Section 3 of the Code of Conduct relating to 'Working with other Health Care Professionals' states that a surgeon will 'seek the involvement of other health care professionals or more experienced colleagues if this will benefit the patient'.

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[30] The administration of heparin to prevent blood clotting.

[31] The reviewers considered that 'the risk of the iatrogenic injury bleeding was at least equivalent, but probably more likely to bleed than the original aneurysm'.

[32] Dr C told the Coroner that he was the sole INR from approximately the beginning of September 2018 until the beginning of April 2019, when two newly recruited INRs began to assist by doing minor diagnostic procedures.

Other information

36. In its response to HDC, Health NZ expressed 'how very sorry [it is] that this event occurred and for the ongoing distress it will have caused [Ms A's] family'.

37. Health NZ acknowledged that Dr C's workload was significant at the time of the event. However, Health NZ stood by the findings of the reviewers in the EIR.[33]

38. Health NZ confirmed that at the time of the event and surgery for Ms A, 'the dynamic of the team was such that no staff member felt empowered to speak up to [Dr C]'. Health NZ explained that Dr C had a 'history of persevering despite recommendations from other INRs on previous cases, and a culture had developed where staff were not empowered to speak up'.

39. Health NZ acknowledged and agreed that the monoplane angiography machine was sub-standard. However, it referred to a statement by the reviewers that the 'inadequate equipment does not justify nor excuse the complications that have occurred'. In Health NZ's view, Dr C undertook the procedure knowing that the equipment was suboptimal, and this should have been factored into his decision to attempt certain high-risk procedures.

40. In his response to HDC, Dr C again stated that he wished to pass on his condolences to the family and friends of Ms A. Dr C also said that the impact of this case has been felt by him personally, and it has had a huge impact on his work and his career, and on his family.

41. Dr C highlighted that, at that local district Health NZ Endovascular INR unit, it performed an average of 150 cases per year, and it experienced a year-on-year growth in the number of procedures performed. The Angiography suite was shared with Vascular Surgery and General Interventional Radiology with intense competition for theatre time, and, despite these challenges, 'morbidity and mortality statistics of the Unit were on par with similar units in Australasia and the rest of the world'.

42. Dr C told HDC that the 'angiography suite complex was grossly understaffed as far as nurses and M[edical] R[adiation] T[echnologists] are concerned'.

43. Dr C was surprised that the new INRs had found him difficult to work with. Dr C's lawyers further responded to HDC stating: 'We are talking here about qualified senior doctors, professionals, not very junior House Officers where some reticence may have been at least understandable.' Dr C's lawyers also considered that this came across as 'self-justifying' and a failure by Dr F and Dr G to take 'at least some responsibility'.

44. However, Dr C reflected that he may have had an unconscious bias against his colleagues due to their relative lack of experience. Dr C told HDC that, at the time of Ms A's surgery, he had worked together with Dr G and Dr F for only a short period of time,[34] and, in his view, they were 'still relatively unknown quantities regard[ing] their abilities and this, together

[33] That this situation was contributed to by Dr C's conduct with other INRs.

[34] Four months with Dr G and three months with Dr F.

with [his] concerns about complications arising, played a definite role in his willingness to take advice from them'.

45. Dr C has recognised that mistakes were made during what he described as an 'extremely complex case', namely:

a) 'Riding up of the supporting distal access catheter which caused a vessel dissection was not recognised.'

b) 'There was a failure to note haemorrhage from the dissecting aneurysm.'[35]

c) 'With the benefit of hindsight, he should have consulted with Dr I [a former neuro-interventionist colleague].'[36]

d) 'A post-procedural CT would have helped to identify active haemorrhage.'

e) He 'should have informed not only neurosurgeon Dr D of the whole picture,[37] but other involved clinicians should also have been informed more fully without relying on Neurosurgery to do this'.

f) 'A contributing factor was that the M[edical] [Radiation] T[echnologist] failed to do the two-minute notification before the filling agent hardened.'[38]

g) In relation to the concerns raised by the anaesthetist, Dr H, Dr C believed there was a 'communication breakdown' in that he made a general statement to the whole room and Dr H had received second-hand information from Dr G instead of speaking to him. However, Dr C told HDC that the handover to the ICU team could have been handled better, and his thought processes around the situation, as conveyed to the Neurosurgery team, could have been expressed more clearly.

46. Dr C confirmed that he has not participated in endovascular neuro-interventional radiology procedures since May 2019.

Responses to provisional decision

47. Ms B was given an opportunity to respond to the provisional decision and was thankful for the in-depth investigation into Ms A's care. Ms B told HDC that the impact of what happened has had a devastating effect on her, and she hopes that this decision will prevent a similar situation from happening to anyone else.

48. Health NZ was given an opportunity to respond to the provisional decision and told HDC that it accepts the findings and has commenced work on the actions required. Health NZ also stated:

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[35] Dr C stated that it was documented in the subsequent MDM on 28 May 2019 that none of the three INRs present had noted that active haemorrhage had occurred.

[36] Even though Dr I was at that time managing the Neurosurgery MDM and was no longer doing INR work.

[37] Dr C said that he conveyed to Dr D that the embolised aneurysm was secure but that a more proximal vessel dissection (resulting in a pseudo-aneurysm) had occurred immediately after his handover to ICU.

[38] Dr C subsequently reported to Health NZ that this was done by a 'stopwatch'-type timer that appears in digital form on the bottom left of the second angio monitor hanging over the patient bed in front of the INRs. It was noted that when Dr C was alerted, he acted accordingly.

> 'We welcome the decision and hope that the outcome of this process may offer some measure of closure and reassurance to [Ms A]'s whānau. We remain deeply sorry that this event occurred and for the distress it has caused.'

49. Dr C was also given an opportunity to respond to the provisional decision. Dr C stated that he accepted the findings, recommendations, and follow-up actions and again wishes to extend his sincere condolences to Ms B and Ms A's extended family.

Decision

Introduction

50. First, it is important for me to outline that my decision has been reached based on the substantive information provided by the parties, including the clinical records, backed up by the findings in the SAR and EIR. I have used the SAR and comprehensive EIR commissioned by Health NZ as part of my decision-making in relation to the levels of departure from the Code of Health and Disability Services Consumers' Rights (the Code) by Health NZ and Dr C. My reasoning for these exceptional circumstances also took into consideration that the EIR was independent insofar as the reviewers worked at a different hospital and region to Dr C, and the limited number of INRs in New Zealand,[39] which created an increased risk of a conflict of interest and an inability to engage an independent expert advisor in a timely way to meet the justice needs of the parties, with the provider having circumstances that compel a timely assessment, and to bring closure for Ms A's partner and family.

51. I note that Ms A was very unwell, and the endovascular surgery was a very high-risk procedure, and the potential complications had been explained to her, such as the risks of stroke and intra-procedural rupture, as noted by Dr C in the clinical records. However, I note that there were multiple failings in the system and in decisions made on the day of Ms A's surgery, and it is tragic for Ms B and Ms A's extended family that they occurred at all.

Health NZ — breach

52. I acknowledge that several changes and improvements to address the 'multiple system failures' highlighted by the SAR and the EIR were instigated by Health NZ (see the 'changes made' section below). I also note with approval that a bi-plane angiography machine has since been installed at this local hospital.

53. However, having reviewed all the available information in this case, I consider that Health NZ breached Right 4(1) of the Code. I have outlined the reasons for my decision below.

54. Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill. I note that there were multiple serious systemic issues at Health NZ in relation to Ms A's care, as follows:

a) There were no clear guidelines in place for the actions to take when complications arose during angiography.

[39] In his response to HDC dated 30 July 2019, Dr C outlined that there were only 14 INRs in New Zealand in May 2019.

b) There was no formalised process for checking the placement of the micro-catheter and the length of time it had been placed in the filling agent.

c) There was no post-procedure debriefing or structured team handover, which is usual practice in ICU.

d) While there were three documents providing post-angiography instructions, two of those were not available for staff to read, which meant that nursing staff relied on standard practice information, and the neuro-observations were less frequent than they should have been.

e) Nurses did not check Ms A's neuro-observations together during the ICU shift handover, against standard practice.

55. These factors contributed to Ms A not receiving the required care and checks before her passing. Accordingly, I find that Health NZ failed to ensure that services were provided to Ms A with reasonable care and skill, and that Health NZ breached Right 4(1) of the Code.

Health NZ — adverse comment

56. In my view, it is important for staff to work in an environment in which they can speak up, especially where this concerns a patient's safety. Health NZ confirmed that staff had felt unable to do this because of a culture that had developed through Dr C's practice of persevering despite recommendations from other INRs. Dr C acknowledged that he may have had an unconscious bias against colleagues due to their lack of experience and because they were 'unknown quantities'. In particular, he noted that this played a part in his unwillingness to take advice from Dr G and Dr F.

57. I note that Health NZ acknowledged that Dr C's workload was significant at the time of the event, and he described being 'burnt out', having been the only INR at the hospital up until early 2019. In my view, Health NZ had an organisational responsibility to staff its service safely.

58. I recognise that 'Speaking up for Safety' training was provided to staff as a result of the SAR recommendations. However, at the time of this event, multiple INR clinicians felt unable to raise their concerns. I am critical that the environment was such that clinicians felt unable to speak up to senior management at this hospital to enable this to happen. I also consider that, had this been done prior to this incident, Dr C could have been made aware of the consequences of his conduct and been provided with appropriate training or support for this to improve, which Dr C later stated he was willing to undertake.

Dr C — breach

59. I note that HDC's usual process is to obtain independent advice on the care provided by an individual provider. I refer to my reasoning in paragraph 47 above and emphasise that having considered all the evidence obtained from the parties, I have used the SAR and comprehensive EIR commissioned by Health NZ as part of my decision-making in relation to the level of departure from the Code by Dr C.

60. I note that Dr C's vocational registration now excludes endovascular INR practice, and that he has limited his practice to diagnostic and general interventional radiology with a

requirement by the Medical Council of New Zealand for him to participate in an approved recertification programme relevant to the vocational scope in this regard. I also note that he has since completed training to improve his communication skills. In addition, the EIR reviewers acknowledged that Ms A's case would have been difficult, and the treatment attempted was reasonable given the risks discussed.

61. However, Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill, and I consider that this was not the case when Dr C provided services to Ms A on 20 May 2019.

62. Dr C was the senior INR and primary operating surgeon for Ms A's surgery. During the surgery, the microcatheter was left too long in the filling agent, increasing the likelihood of it sticking. The reviewers noted that Dr C failed to place sufficient or any counter-traction when using force to remove the microcatheter, and it is likely that he caused the injury to Ms A's vessel.

63. As part of Health NZ's EIR, Dr C acknowledged to the reviewers that he had not encountered such difficulties and complications previously, yet, in his response to HDC, he outlined his reasoning why he was reluctant to seek help, advice, or assistance from the other INRs present when the injury occurred. Dr C further acknowledged that he may have had an unconscious bias with colleagues and was reluctant to take advice from those present on the day of Ms A's surgery due to their lack of experience, having worked with them for only a short period of time, and being unsure of their abilities. I consider that Dr C should have sought, and been amenable to, help, advice or assistance from his fellow INRs when the injury occurred, and, whilst I acknowledge his lawyer's comments in his response about the other INRs taking some responsibility, Dr C was the primary INR. It is also evident that Dr G attempted to query Dr C's actions regarding the dissection, and in the evidence Dr F commented that, because Dr C was used to working by himself, Dr F had not been involved in the decision-making. This is consistent with the information provided by Health NZ in its response to HDC about the culture that had developed where no staff member felt empowered to speak up to Dr C, and with the findings of the SAR and subsequent EIR. This is also contrary to RAC's Code of Conduct regarding seeking the involvement of other healthcare professionals or more experienced colleagues if it will benefit the patient, and I am critical that Dr C failed to do this.

64. I am also concerned about Dr C's response to Dr G when asked about his plan regarding the dissection during the surgery. To state, '[W]hat dissection?' with sarcasm was inappropriate in the circumstances, given the risks to Ms A at that time, and I am extremely critical of this.

65. I note that Dr C failed to comply with Health NZ's Medical Record policy by retaining loose-leaf structured medical notes with pre- and post-procedure information on Ms A in his own office rather than with her medical records. I also note that Dr C described the injury as a 'small dissection' in Ms A's clinical notes, and that this 'significantly underplayed the significance of the injury', as noted by the reviewers of the EIR. I consider this to be wholly inappropriate because it meant that other clinicians/staff were relying on incomplete medical records and misleading information regarding the significance of Ms A's injury when treating and monitoring her subsequently post-surgery.

66. Dr C recognised that the handover to ICU staff could have been handled better and that his thought processes could have been expressed to other clinicians and staff more clearly. I consider that Dr C should have carried out a structured handover in line with Health NZ's practices and alerted the wider team to the severity of the injury and the increased risk of bleeding faced by Ms A. It concerns me that due to the lack of information and uncertainty around Ms A's injury, and the lack of clear direction from Dr C around the post-angiography monitoring needed by the ICU nursing staff, this resulted in less-frequent neuro-observations than should have occurred, as staff relied on standard practice information. In my view, this did not make for a safe environment for staff working with Dr C and/or his patients.

67. My views align with the conclusions of Health NZ's SAR and the EIR carried out by experts, which, as Health NZ stated in its response, found 'significant concerns' in relation to Dr C's competence.

68. Dr C had a responsibility to provide Ms A with services with reasonable care and skill. I find that, by his actions in failing to notice the microcatheter being left too long, and not placing sufficient or any counter-traction when using force to remove it, which likely caused Ms A's vessel injury; failing to seek help, advice, or assistance from other INRs at the point of injury; failing to record the significance of the injury to Ms A accurately in her clinical notes, to alert the ICU staff and other colleagues as to the severity of her injury and increased risk of bleeding; and failing to provide complete clinical records to ICU staff at handover, Dr C breached Right 4(1) of the Code.

69. Right 4(2) of the Code states that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

70. As the senior INR, Dr C was in a position of authority for Ms A's surgery. Whilst I recognise that Dr C had been used to working alone, there is a balance to be maintained of being responsible for making important procedural decisions, and of involving less senior INRs to ensure that they receive appropriate learning, and of being amenable to feedback and discussions with them. Given the concerns raised by staff and outlined in Health NZ's response to HDC, and in the SAR and EIR, it is clear that INR clinicians did not feel comfortable in raising concerns with Dr C about any procedural difficulties/complications due to his conduct. Dr C acknowledged his reluctance to accept views of other colleagues, and I am critical that he chose not to seek advice, help, or assistance at a crucial time in Ms A's surgery when the injury occurred, especially given the high risks involved. This also goes against the RACS Code of Conduct in relation to the requirement that a surgeon will seek the involvement of other healthcare professionals or more experienced colleagues if this will benefit the patient, especially given that he had not encountered these difficulties previously. Accordingly, I also find Dr C in breach of Right 4(2) of the Code, for failing to comply with professional standards.

71. In conclusion, I commend the staff, particularly the anaesthetist, Dr H, and Dr G, for voicing their concerns to senior staff, the EIR reviewers, and Health NZ.

Changes made

Health NZ

72. Following the recommendations from the SAR, Health NZ provided HDC with a list of the actions taken, which are attached as Appendix A.

73. Following the recommendations from the EIR, Health NZ confirmed the following:

a) Prior to the review, Dr C was stood down from INR and has not been reinstated.

b) A bi-plane angiography machine was installed at that local hospital in July 2022.

c) Health NZ contracted an experienced INR from another district to mentor and work with remaining INR at that local district Health NZ. It also commenced a long period of supervision for new INRs, with a gradual transition to independent practice over the course of the first six months. INRs are also supported to attend annual ReMind[40] and NeuroExchange[41] meetings.

74. Health NZ also confirmed that a service review of the INR and Cardiology service was undertaken in 2021, which resulted in additional service improvements that included the appointment of a Service Manager of the INR and Cardiology Unit.

Dr C

75. Dr C confirmed that following the EIR he was 'ready, able, and very willing' to undertake some retraining in line with the areas identified by the reviewers, including consideration of working six months or more at another approved INR unit. However, no opportunity was provided by Health NZ for this.

76. Dr C also confirmed that he was willing to go on team-building courses in order to work better with his INR colleagues and was committed to undertaking any additional courses, training, or reviews that were deemed necessary. In this regard, in January 2021, he completed a Communications Skills training course (Workplace Interpersonal Skills Training Course) run by Connect Communications in Auckland.

77. In February 2021, Dr C voluntarily undertook not to carry out any reporting in interventional radiology and to limit his practice to diagnostic and general interventional radiology.

78. On 9 April 2021, Dr C confirmed that he was no longer seeking to continue INR work, having not participated in INR procedures since May 2019.

Recommendations

79. I am conscious that a substantive number of recommendations came out of the positive action taken by Health NZ following Ms A's passing, which I commend. With this in mind, I recommend that Health NZ:

[40] An annual meeting of New Zealand INRs with an opportunity to share and review complex and challenging cases in a peer review environment.

[41] An annual Australian and New Zealand morbidity and mortality meeting with similar aims as those of ReMind.

a) Provide a written apology to Ms A's partner, Ms B, and Ms A's extended family for the failures identified in this report. The apology is to be provided to HDC within three weeks of the date of this report.

b) Report back to HDC on its review of how the INR team debriefs when an acute complication has taken place is working. This information is to be provided to HDC within three weeks of the date of this report.

c) Provide HDC with a copy of the Surgical Safety Compliance and Checklist that was due to be scheduled for completion in December 2024, within three weeks of the date of this report.

d) Use an anonymised version of this report as a case study for training INR clinicians. Evidence of the training is to be provided to HDC within six months of the date of this report.

Dr C

80. I recommend that Dr C provide a written apology to Ms A's partner, Ms B, and Ms A's extended family for the deficiencies in care outlined in this report. The apology is to be provided to HDC within three weeks of the date of this report.

81. I also recommend that at a point when Dr C returns to practice, he undertake further education by way of the RACS Training in Professional Skills (TIPS) course, which covers the benefits and challenges associated with effective teamwork, collegial communication in surgical practice, identifying personal strengths and areas for improvement with respect to skills in surgical practice, and achieving appropriate professional behaviours. Evidence of attendance and a written reflection on the learnings and how these will be applied in practice are to be provided to HDC within six months of returning to practice.

82. Should Dr C decide to return to endovascular INR practice, and if this were to be supported by the Medical Council of New Zealand, he should undertake refresher training in this field of surgery, including arranging for regular mentoring from a peer in endovascular INR practice for a period of six months. Should that happen, the mentor is to provide evidence to HDC that the mentoring has occurred and that Dr C is maintaining appropriate standards of professional conduct, within three months of Dr C returning to endovascular INR practice.

Follow-up actions

83. A copy of this report will be sent to the Coroner.

84. A copy of the sections of this report that relate to Dr C will be sent to the Medical Council of New Zealand.

85. A copy of this report with details identifying the parties removed, except Health NZ, will be sent to Health NZ National Office and the Medical Council of New Zealand and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner

Appendix A: List of actions taken by Health NZ arising from the recommendations in the SAR

[redacted] Action list outcomes

Appendix 5

Recommendations (these must relate to the main issues identified)	Accountable person and review date	Outcome measure	Actions taken/outcomes	Status
1. All loose-leaf medical files in Interventional Radiology be collected and put into medical records.	Clinical Leader of Radiology 3 months	No loose-leaf medical files held in the department.	Loose leaf medical files retrieved and returned to Medical Records for filing.	Closed
2. All Interventional Radiology staff attend/be booked to attend the Speaking Up For Safety training.	Clinical Leader of Radiology 3 months	100% attendance/ booked onto SUFS training.	SUFS is now part of the mandatory orientation that all staff to attend SUFS training when on boarding into organisation.	Closed
3. Communication/team building sessions be conducted with all members of the interventional team.	Clinical Leader of Radiology 3 months	Agenda/Minutes	Due to the high turnover of staff since this event and the change in culture of the service with the changes implemented as part of this review. A formal team building session was not indicated. Rather, a cultural shift has been developed in which, a team debrief is expected practice after an acute complication. These debriefs are not minuted to provide a safe space for all team members and allow for open communication between team members about what occurred.	Closed
4. A process be developed for when complications arise during angiography, that when followed ensures that all treatment options will be discussed with the team and agreed upon.	Clinical Leader of Radiology 3 months	When a case is reviewed, this criteria is audited. Team Meeting minutes.	The outcome of the external review confirmed that a specific individual was not reporting complications rather than this being a system issue. Since the event there is often opportunity for dual operators to perform Interventional neuro cases. These cases are performed with shared decision making and collaboration. Team member feedback is encouraged as SUFS. The IR service as a whole is collaborative with other services and INR and IR's share an office space allowing	Closed

			more collaborative approach to case management and discussions.	
5. A checking process be formalised regarding the placement of the micro-catheter and the length of time it is placed near the filling agent.	Clinical Leader of Radiology 3 months	Process is developed and completed	Due to change in practice, this product is no longer routinely used and as such, the recommendation is no longer relevant to current practice.	Closed
6. The safe surgery checklist is to be modified and used in interventional radiology, for every patient.	Clinical Leader of Radiology, Vascular Surgery 3 months	Documentation of formal pre and post-debriefs for every procedure should be evident in medical records. Monthly auditing of an agreed number of patients. Team Meeting minutes.	The surgical safety checklist has been modified for use in Interventional Radiology and the posters are displayed in all the procedure rooms. For Neuro-interventional lists the INR's conduct a pre list briefing and handover in person to PACU/ICU post procedure. Audit conducted in 2021 led to a reset of surgical safety compliance. This was led by [redacted]	Closed
7. An iatrogenic injury must be described in the medical record so that the receiving team can fully understand the risks.	Clinical Leader Radiology 3 months	When a case is reviewed, this criteria is audited.	At the end of Interventional Neuro-Radiology procedure, responsible INR documents procedure details, aftercare and any complications that occurred using: [redacted] Operation Record To ensure visibility to relevant staff caring for the patient, this document is scanned into the Radiology Information System (RIS) and filed into the patient notes which remain with the patient during their admission.	Closed

Recommendations (these must relate to the main issues identified)	Accountable person and review date	Outcome measure	Actions taken/outcomes	Status
			Spot sampling audit November 2022 and November 2023 demonstrated good compliance with this process.	
8. Refine the existing handover between Interventional Radiology and ICU, where all risk factors can be explained by all parties.	CNM IRCL, CNM ICU 3 months	Handover tool is developed and completed.	Handover process has been reviewed. Regular ICU, Radiology and IRCL staff meetings resulted in an update to the verbal handover process. As above, INR's transfer to ICU with patients post procedure for a direct doctor to doctor handover. (Alongside the nursing handover). This aligns with the organisational Clinical Handover policy which was updated, standardising the handover process across the region.	Closed
9. For one 'post-angiography monitoring' document to be agreed, which is socialised within ICU and Interventional Radiology, referred to during handover, and be readily available (in full) for staff to access in	Clinical Leader of Radiology; CNM IRCL 3 months	One guideline on [redacted]	Consideration was given to a specific handover tool. However due to the diverse range of procedures carried out in the Angio suite a single tool was deemed too complex. Standard documents/tools are used for specific procedures: – District [redacted] Arterial sheath removal & wound care following femoral approach angiography (NB The wound care protocol from this guideline is also printed in the Interventional Radiology procedure record Doc [redacted]) – District [redacted] Neurological Observations. This document covers the neurological observations required for various neurological conditions including coiling, cerebral embolisation etc. – District [redacted] Stroke fast track protocol This includes post care following cerebral clot retrieval [redacted]	Closed

			In addition to this the [redacted] nursing staff include pre-printed written post procedure instructions in the patient notes based on these guidelines above Socialisation of these procedure specific documents, the use of the post procedure 'operation note' and the change to the medical handover post procedure of what is included in the verbal handover from [redacted] > PACU/ICU has resulted in a decision not to proceed with a sing e dor ment.

a) The policy(ies) covering the requirements recommended following the CINU review dated 31 October 2018.

No specific formal policy was written, however the recommendations were implemented and continue to be undertaken in the following ways:

Recommendation 1

Most vascular cases and all complex cases should be discussed in a forum of neurosurgical and radiological specialists

- Weekly Neuro-Vascular meeting are held where elective cases are discussed between Neurosurgeons and Interventional Neuro-Radiologist's (INR's).
- Acute cases are discussed between Neurosurgeon and INR. Usually at least one other opinion (third) is sought (Neurosurgeon or INR).

Recommendation 2

Following diagnostic angiography at the beginning of the treatment event, the decision to proceed to endovascular treatment should be re-evaluated and discussed in the neurovascular forum considering all inherent risks.

- Endovascular cases are frequently carried out by dual operators. INR and Neurosurgeon (NS) will review the CTA and hold a discussion before an angiography procedure. Resultant of this discussion, if the INR feels they can safely treat they will continue with the procedure. If there is an equivocal decision to be made, the case will be discussed again, with additional opinions sought.

Recommendation 3

Wherever possible, two endovascular operators should be involved in the treatment of neurovascular pathology and cases. It is reasonable to have this team consist of a radiologist and a neurosurgeon (scrubbed or unscrubbed in the suite).

- Two endovascular operators are present for the majority of INR cases. Resource constraints prohibit this for every case.

Recommendation 4

Additional opinions should be sought from independent operators if local experience cannot come to a calculated definitive treatment plan.

- We have developed relationships with national colleagues who we seek opinions and reviews of cases as above.

b) Medical Record policy

Please refer to Appendix 1.

c) Handover policy i.e. Between interventional radiology to ICU.

Please refer to Appendix 2.

d) Speaking Up For Safety training material

Please refer to Appendix 3.

e) The process for when complications arise during angiography.

There are no formal policies for management of complications as operators are expected to recognise and manage these as part of their experience and training. In practice, when complications are recognised, operators will treat as appropriate and call for collegial support as appropriate.

In this event, the operator did not recognise the complication at the time of the procedure.

f) Standard practice of shift handover between day and night nurses to check the neuro-observations together (particularly the pupils) in ICU and how this is documented and the organisational Clinical Handover policy

Please refer to Appendix 4. ICU Handover Guide.

g) Post-procedure care – Angiogram nursing intervention document.

Please refer to Appendix 5.

h) Interventional Radiology & Cardiology Services post procedure nursing guidelines.

Please refer to Appendices 6 and 7.

i) The standard documents listed in the recommendations relating to the 'post angiography monitoring ' e.g. District Docs 1.8134

Please refer to Appendices 8, 9 and 10.

j) Surgical safety compliance.

This has not yet been completed, this has been scheduled for December 2024.