Pacific Radiology Group Limited
Radiologist, Dr B

A Report by the
Health and Disability Commissioner

(Case 19HDC00062)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report primarily concerns the advice given to a man (who had a history of mechanical heart valve replacement) to stop taking blood-thinning medication prior to a radiological procedure. The Commissioner highlights that deficient administrative protocols and procedures can create a risk of harm to consumers.

2. The man stopped taking his blood-thinning medication (warfarin) five days prior to the procedure at Pacific Radiology, after being told to do so by an administrative team member. The man did not take any other blood-thinning medication (ie, Clexane) during this time. On the morning of the procedure, the man had issues with his speech, and his INR (a measurement of how long blood takes to clot) was 1.0, which is within the normal range for someone not taking blood-thinning medication.

3. When the man presented to Pacific Radiology, two staff members were concerned about his presentation. The radiologist (Dr B) undertook a brief assessment and decided to proceed with the procedure. Afterwards, the radiologist recommended that the man attend his GP so that he could be given Clexane. Later that day, the man's GP assessed him as having likely had a stroke, and she sent him to hospital, where the diagnosis was confirmed.

Findings

Pacific Radiology

4. The Commissioner considered that the individual errors that led to the man being advised to stop his warfarin without clinical input were the result of inadequate procedures in place at Pacific Radiology. In the Commissioner's view, these deficiencies amounted to a failure to provide services to the man with reasonable care and skill. Accordingly, Pacific Radiology was found to have breached Right 4(1) of the Code.

Radiologist Dr B

5. The Commissioner considered that the weight of evidence was that the man was suffering speech issues at the time of his assessment with the radiologist. The Commissioner found that the radiologist's failure to pick up and/or fully appreciate the extent and significance of the man's speech difficulties, and his failure to appreciate the significance of the information provided to him about the symptoms the man was exhibiting, amounted to a failure to provide services with reasonable care and skill. Accordingly, the radiologist was found to have breached Right 4(1) of the Code.

Sports physician Dr C

6. The Commissioner considered that it would have been safer practice for the physician who originally referred the man for the procedure to have included the man's history of a mechanical heart valve in his referral.

Recommendations

7. The Commissioner recommended that Pacific Radiology undertake an audit of patients booked for CT-guided procedures to ensure compliance with its updated booking protocol;

report back to HDC on whether its new process for additional vetting of referrals has been implemented at Pacific Radiology and progress made on reviewing its anticoagulation policy; and provide a written apology to the man.

8. The Commissioner recommended that Dr B undertake further training on neurological assessment, and provide a written apology to the man. The Commissioner also recommended that the Medical Council of New Zealand consider undertaking a competence review of the radiologist, should he reapply to practise in New Zealand.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her husband, Mr A, by Pacific Radiology Group Limited. The following issues were identified for investigation:

- *Whether Pacific Radiology Group Limited provided Mr A with an appropriate standard of care in September and October 2018.*
- *Whether Dr B provided Mr A with an appropriate standard of care on 4 October 2018.*

10. The parties directly involved in the investigation were:

Mr A	Consumer
Mrs A	Complainant
Pacific Radiology Group Limited	Group provider
Dr B	Radiologist

11. Further information was received from:

Dr C	Sports physician
Sports medicine clinic	
Medical centre	
District Health Board	

12. Also mentioned in this report:

Ms D	Medical receptionist
Ms E	Medical radiation technologist
Ms F	Medical radiation technologist
Dr G	General practitioner

13. Independent expert advice was obtained from a radiologist, Dr John Gunn (Appendix A).

Information gathered during investigation

Introduction

14. This report relates to advice provided to Mr A, aged 60 years at the time of events, by Pacific Radiology Group Limited (Pacific Radiology) to stop taking his blood-thinning medication (warfarin) five days prior to having a radiologically assisted (computed tomography (CT)[1] guided) steroid (cortisone[2]) injection. After stopping his warfarin, Mr A suffered a stroke.[3]

Background

15. Mr A had a history of a mechanical aortic valve[4] replacement in 2014. He also had a rapid, erratic heartbeat (paroxysmal atrial fibrillation).

16. Patients who have a mechanical heart valve are prescribed anticoagulants (blood thinners) to prevent the blood from clotting, and Mr A's regular medications included warfarin.

Referral for MRI

17. In March 2018, Mr A had been referred to a sports medicine clinic by a general practitioner (GP) for review of an acute back injury.

18. On 25 June 2018, Mr A was seen by a registrar at the sports medicine clinic. The registrar referred Mr A for a Magnetic Resonance Imaging (MRI)[5] scan at Pacific Radiology with a plan to review him again after the MRI had been completed.

19. The MRI referral form recorded that Mr A had a lower back strain, and clinically had a disc lesion. It was noted that an X-ray had been performed previously but the report was not available. No other medical information is recorded on the referral.

20. On 23 July 2018, the Pacific Radiology booking system recorded: "[P]atient has aortic valve replacement — checked by [MRI technician] on 23/07/2018 and patient is safe to scan." No other clinical information was recorded, including any reference to warfarin. Pacific Radiology told HDC that this note was added into the system when Mr A was being booked for the MRI, as he told Pacific Radiology about his aortic valve replacement. Pacific Radiology also said that an MRI safety questionnaire was completed and checked by one of its MRI technicians. In response to the provisional opinion, Mrs A told HDC that before this MRI was carried out, she had to contact the hospital overseas where Mr A's aortic valve replacement was performed to obtain information before the MRI could proceed.

21. On 13 August 2018, the MRI scan was performed. The MRI was reported as showing some abnormalities in the lumbar spine.

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[1] A method of producing a three-dimensional image of an internal body structure by computerised combination of two-dimensional cross-sectional X-ray images.
[2] A steroid used to reduce inflammation.
[3] Damage to the brain caused by reduced blood flow.
[4] A valve between the left ventricle of the heart and the aorta.
[5] An imaging technique.

Referral for CT-guided injection

22. On 27 September 2018, Mr A was reviewed by sports medicine physician Dr C[6] at the sports medicine clinic. Dr C noted the MRI results and referred Mr A for a CT-guided cortisone injection.

23. The referral to Pacific Radiology, written on a standard Pacific Radiology referral form, requested a "CT guided [right] L4/5 and L5/S1 facet [joint] cortisone [injection] please". Under "Clinical Information", Dr C documented: "facet [joint] arthropathy" (a type of arthritis that develops between the joints of the spine in the lower back). No other clinical information was recorded on the referral form, or attached with the referral.

24. In a statement to HDC, Dr C commented on the information provided with his referral. He stated:

> "It is important to note that although the referral for the procedure was brief, this should not be taken in isolation. [Mr A] had previously been referred to the same practitioner with regard to his back for diagnostic procedure of a MRI scan of his lumbar spine. I believe that the information provided with regard to a patient's history and examination findings is more important in the setting of a diagnostic procedure rather than an interventional procedure and as this interventional procedure was being performed by the same practitioner this information had already been provided."

25. However, Dr C also acknowledged that Mr A's history with respect to his aortic valve replacement and anticoagulation medication had not been provided to Pacific Radiology prior to sending the 27 September 2018 referral.

Pacific Radiology procedures

26. Pacific Radiology told HDC that administrative staff are responsible for scheduling all patient appointments.

27. Pacific Radiology explained that the protocol — "CT Booking Table" — for booking patients for CT procedures is embedded in its Reception Manual. The CT Booking Table protocol in place at the time of this incident stated under "booking patient in":

> "If patient is on Anticoagulation, find out why patient is on it and talk to Radiologist as some conditions you can't stop it e.g. Mechanical heart valve, risk recurrent [pulmonary embolism]/[deep vein thrombosis]/? …
>
> **If Warfarin —** Stop for 5 Days, need to do INR on morning of ap[pointmen]t, procedure day 6 afternoon." (Emphasis in original.)

28. INR refers to the International Normalised Ratio, which is a measure of how long blood takes to clot (coagulate). People with a mechanical heart valve, such as Mr A, will take

[6] Dr C is vocationally registered in Sports and Exercise Medicine.

anticoagulation to achieve a specific target (ie, ideal) INR, often between 2.5 and 3.5.[7] At the time, Mr A's target INR was 2.0–3.0.

Booking — advice to stop warfarin

29. On 28 September 2018, an administrative staff member, Ms D,[8] telephoned Mr A to schedule his appointment.

30. Mrs A told HDC that she took the call from Ms D because Mr A was driving. Mrs A said that during the call she was asked whether Mr A was taking any blood-thinning medication, and she confirmed to Ms D that he was on warfarin. Mrs A said that she was told by Ms D that Mr A should stop taking the warfarin ahead of the procedure. Ms D did not ask why Mr A was taking warfarin.

31. Ms D booked Mr A for an appointment on 4 October 2018. He ceased taking his warfarin five days prior to his appointment, as advised.

32. In a "Corrective Action Form" incident report dated 26 October 2018, Ms D wrote:

> "With the booking instructions we have that [Dr B] made, I made the appointment for 4/10/18 and advised he needs to stop warfarin for 5 days prior. And would need INR done on the morning of his appointment. He was booked on [Dr B's] list. [Dr B] was not around to talk to about this [as] it was a Friday. This was my mistake. I did get his INR [on 4 October 2018] and put this in the visit [record]."

33. In a second Corrective Action Form completed by another staff member, it is documented:

> "Admin instructions are to check why patient is on anticoagulation and talk to [radiologist]. [Dr B] advised me that admin staff have been told that if a patient taking medication for 'atrial fibrillation' okay to stop 5 days prior to injection (?verbally told, not in manual). There is a clear note in the comrad[9] saying patient has aortic valve replacement."

34. Pacific Radiology told HDC that it appears that Ms D misinterpreted the guidance and followed the advice specifically for warfarin (stop for five days), and overlooked the general advice not to stop anticoagulation for patients with mechanical heart valves. Pacific Radiology further stated that the radiologist booked to do the procedure, Dr B,[10] was not consulted in relation to Ms D's advice to Mr A to stop taking his warfarin.

35. In relation to the adequacy of the information contained on the referral form from Dr C, Pacific Radiology stated that when insufficient information is contained on the referral, its

[7] Health Navigator New Zealand "Warfarin and INR" (February 2020): https://www.healthnavigator.org.nz/medicines/w/warfarin-and-inr/ Accessed April 2021.
[8] Pacific Radiology advised that Ms D is a "capable and experienced Medical Receptionist and was aware of the CT related procedures".
[9] Comrad is the clinical records system.
[10] Dr B was awarded the Diagnostic & Interventional Radiology vocational scope of practice in 2013.

policy is for it to be returned to the referring doctor for additional information. However, Pacific Radiology also stated:

> "[T]he clinical details provided for the CT guided facet joint injection — 'facet joint arthropathy' — was, and still is, considered appropriate clinical information for the procedure requested."

36. Pacific Radiology added that although it is strongly preferred if referrals include information about patients' medications such as warfarin, it is extremely common for referrers to leave off this information from the referral forms.

INR

37. At 8.18am on 4 October 2018, Mr A presented to a medical laboratory for a blood test to measure his INR. Mr A attended the appointment by himself.

38. In her complaint, Mrs A said that after the appointment, when he had returned to work, Mr A told her that he had "had increased difficulty with word finding and was unable to explain his scheduled appointment" (that is, he did not remember why he was there).

39. The medical laboratory advised that the phlebotomist who took Mr A's blood no longer works there, and it was unable to provide comment on Mr A's presentation on the day.

40. The test showed that Mr A's INR was 1.0, which is within the normal range for someone not taking blood-thinning medication. The result was faxed through to Pacific Radiology at 12.58pm.

CT-guided injection

41. Mr A's CT-guided cortisone injection was scheduled for 2.15pm.

42. Mrs A said that she drove Mr A to his appointment at Pacific Radiology because he did not feel well enough to drive. She said that on arrival she completed the "CT questionnaire" on behalf of Mr A because he was experiencing "[i]ncreased difficulty with word finding, [e]xcessive skin clamminess, and [was] [f]eeling acutely unwell".

43. Pacific Radiology told HDC that two medical radiation technologists (MRTs), Ms E and Ms F, were involved in Mr A's care prior to the CT injection being carried out.

44. The Corrective Action Form completed by Ms E dated 10 October 2018 states:

> "I called [Mr A] from the waiting room where he was sitting with his wife. [H]e was wearing a hooded sweatshirt with the hood up and looked very overheated. I took him through to the area by the CT cubicles and noticed he was very unsteady on his feet so I got him to sit down outside the cubicles and had a chat to him.
>
> I was concerned about his health and asked some questions such as is this normal for you to feel unsteady on your feet?

> [Mr A] was unable to communicate very clearly and seemed a bit confused, I also suggested that he took his sweatshirt and hood [off] to see if that made him feel better and offered him a cold drink of water.
>
> At this stage I also asked [Ms F] to get [Dr B] as I was concerned about whether the procedure should go ahead."

45. The Corrective Action Form completed by Ms F dated 10 October 2018 stated:

> "Upon arrival [Mr A] was feeling unwell and unsteady on his feet. [Ms E] called him through to be scanned and noticed these symptoms and called me to get [Dr B] to speak to patient to see if the examination would still go ahead. We learned he had been on Warfarin which was stopped 5 days prior to the booked injection."

46. Mrs A said that while her husband was speaking to staff, his words were so slurred that she had to answer on his behalf.

47. After being told by Ms F that there was some concern about Mr A's clinical condition, Dr B spoke with Mr and Mrs A. This was Dr B's first involvement in Mr A's care.

48. Dr B told HDC that he asked Mrs A about her concerns, and she told him that Mr A was not feeling well, was having difficulty finding words, and had driven dangerously early that morning. Dr B said that Mr A looked tired but was responding appropriately to his verbal questions. In addition, in contrast to the statements from Ms E and Mrs A, Dr B told HDC that Mr A was not slurring his speech and did not have any difficulty finding words. However, Mrs A is adamant that Mr A had word-finding difficulties when he was speaking to Dr B.

49. Dr B further stated:

> "While I was speaking to [Mr A], I noted the sound of a mechanical heart valve … I questioned [Mr A] about whether he was still taking anticoagulation medication. He informed me that he had been advised by the clerical staff to stop his Warfarin a few days prior to the planned procedure. On learning this, and knowing that he had had an INR test that day, I asked the clerical staff to obtain the INR result. It was 1.0."

50. Dr B said that, when asked, Mr A told him that he had not received any interim blood-thinner medication (Clexane) while he had stopped his warfarin. Dr B said that he was aware that Mr A's risk of a stroke was higher, so he suggested that Mr A attend his GP to commence Clexane and to receive a thorough neurological assessment. In response to the provisional opinion, Dr B explained that his rationale for sending Mr A to his GP was that the GP would have the benefit of knowing whether Mr A's medical history (including any medications he was taking) could have influenced his condition.

51. Dr B said that he then rang Mr A's GP practice to speak to Mr A's GP, Dr G, but was unable to reach anyone. He therefore asked Mr A to move into the CT room to be assessed for stroke symptoms. In response to the provisional opinion, Dr B told HDC that while

administrative staff continued to try to reach Dr G, he considered that it would be productive and in Mr A's best interests to gather as much information as possible through a more detailed assessment, so as to best inform his conversation with the GP. Dr B said that he asked Mr A to walk in a straight line and heel-to-toe, and Dr B did not observe any unsteadiness.

52. Dr B initially[11] told HDC that his assessment of Mr A was "primarily observation during conversation". He subsequently[12] told HDC that although he did not undertake a comprehensive neurological assessment, he did a number of tests in the CT room over five to ten minutes. Specifically, Dr B said that he asked Mr A to smile, blow his cheeks, stick out his tongue and move it left and right, repeat back the words "La la la" and "No ifs, ands or buts", touch his own nose and then Dr B's index finger, look for Dr B's fingers in his peripheral vision, follow Dr B's moving finger with his eyes, push against Dr B's palms by turning his head left and right, shrug his shoulders against Dr B's palms, abduct his shoulders and arms, push Dr B's palms away with his shins, squeeze Dr B's fingers, and push his thighs up against Dr B's hands. However, Dr B did not document that he performed these tests.

53. Dr B said that he did not observe any facial droop or asymmetrical facial movement, weakness or numbness, or obvious loss of motor function. He stated that he felt satisfied that Mr A did not have any obvious signs of neurological deficit. Dr B added that if he had found significant neurological deficit, he would have cancelled the procedure and sent Mr A to the public hospital for immediate treatment.

54. Mrs A told HDC that she can recall Dr B asking Mr A to walk in a straight line heel-to-toe, and that Mr A was able to do so. However, she was not present in the CT room. Mr A told HDC that Dr B may have said something to him about his face, to which Mr A responded: "It's my back I'm here for." Mr A does not recall Dr B asking him to blow out his cheeks, stick out his tongue, smile, or say "La la la". He also does not remember whether Dr B performed the other tests to assess his motor function.

55. Dr B said that he then tried to ring Dr G, but again could not reach her. He stated:

> "I informed [Mr A] and his wife that I did not detect any convincing neurological defect and that I felt I could proceed with the facet joint injection, with an aim to alleviate his pain, if he wished. I also explained to them that my chief concern was that he had stopped his Warfarin. … [Mr A] indicated that his back was painful and he agreed to go ahead and have the procedure."

56. The procedure took 10–15 minutes, and Dr B said that he continued to communicate with Mr A during the procedure.[13] After the procedure, Dr B successfully contacted Dr G, who

[11] On 28 June 2019.
[12] On 4 February 2021.
[13] Dr B stated that Mr A followed his instructions with respect to positioning, and Mr A described the nature of the pain he was experiencing and indicated that he felt an immediate effect on the pain after the procedure.

agreed with his suggestion that Mr and Mrs A go directly to be seen by her. Dr B stated that after speaking with Dr G, he felt reassured that his decision to refer Mr A to his GP in the first instance was appropriate. Dr B said that had he not been able to contact Dr G, he would have referred Mr A to the public hospital for further investigation.

57. On the procedure record, electronically signed by Dr B that day, he documented:

> "Of note the patient was told to stop his warfarin 5 days prior. I note patient has a St Jude heart valve. INR today is 1.
>
> I asked if the patient had symptoms of power weakness or decreased sensation and he denied any. I advised the patient to return to GP for immediate therapeutic Clexane[14] injection and contacted the GP myself.
>
> I was later informed by GP surgery that he might have symptoms of slurring of speech and was sent to hospital for further assessment."

58. Mr and Mrs A told HDC that they both recall Dr B telling them that he could not get hold of Mr A's GP, but deny that he advised them of the need for an urgent Clexane injection.

Assessment by GP

59. Immediately following the completion of the injection procedure, Mrs A drove Mr A to the medical centre. Mr A was assessed by Dr G. On examination, Mr A was noted to have slurred speech and word-finding difficulty. All other neurological assessments were normal. Dr G's assessment was "likely stroke", and she referred him to the Emergency Department at the public hospital. In the referral, Dr G documented:

> "Referred by [Dr C] from [the sports medicine clinic] to have steroid injection to his back. Was told by radiology to stop warfarin but didn't have clexane cover, was going to have steroid injection to his back. Radiologist rang … to say INR is 1 and needs him covered with clexane today.
>
> Reviewed [Mr A] urgently, unable to speak properly today since this morning, no weakness or numbness. No headache."

60. A nurse practitioner at the medical centre documented calling Dr B that day to advise him that Mr A had had a stroke. She noted that Dr B "claim[ed] that [Mr A] was speaking absolutely fine when he was in the clinic, in full sentences". The nurse practitioner also noted, however, that Mrs A had said that Mr A "woke up sounding 'odd' couldn't speak properly. Losing words and unable to say what he wants to say."

Assessment at public hospital

61. Mr A was transported to the ED by ambulance and arrived at 4.37pm. In both the ambulance care summary and ED notes, Mr A was noted to have slurred speech and word-finding difficulties. The initial impression at the public hospital was that Mr A had had a

[14] A fast-acting anticoagulant/blood-thinning medication.

stroke, and subsequently this was confirmed by CT scan.[15] Mr A was admitted to the Stroke Unit and restarted on warfarin.

62. Mr A was discharged on 8 October 2018. At the time of discharge he had minor slurring of speech. His motor strength was normal, and he was fully independent with activities of daily living.

63. Mr and Mrs A told HDC that Mr A has ongoing speech difficulties and weakness.

Further information

Comment from Mrs A

64. Mrs A said that she believes that had Pacific Radiology accurately taken Mr A's medical history into account, this incident would not have occurred.

Pacific Radiology

65. Pacific Radiology stated:

> "With a mechanical heart valve, [Mr A] should not have had his Warfarin stopped without specialist advice and informed consent from a haematologist or similarly qualified medical specialist. The protocol used at Pacific Radiology … explicitly states that Warfarin should not be stopped for certain conditions including a mechanical heart valve. Pacific Radiology would like to apologise to [Mr A] and his family for this error. We would reassure you that the bookings process has been modified to prevent this scenario happening again."

66. In the incident form documented by Ms D, under "What might prevent a reoccurrence of the situation?", Ms D stated:

> "More staff?? So many referrals coming in, for months now I've felt under a lot of pressure. [Dr B] was leaving and we were booking as much as we could with him. I don't think reception staff should be booking these patients. An MRT could do it?"

Responses to provisional opinion

67. Mr and Mrs A, Pacific Radiology, Dr B, and Dr C were all given the opportunity to comment on the relevant sections of the provisional opinion. Where appropriate, their comments have been incorporated into this report.

68. In addition, Mrs A reiterated her view that Dr B should not have performed the CT-guided injection without first speaking to Mr A's GP, Dr G, especially because Mr A's INR was 1.0 that morning. Mrs A also told HDC that, in May 2021, they found out that Mr A had been declined spinal surgery because he was "not fit for surgery".

69. Pacific Radiology told HDC that it accepted most of the findings in the report. It added that, with respect to referrals being sent to it: "The lack of provision of relevant

[15] The CT scan showed a left middle cerebral artery territory infarction, which is a blockage of an artery that innovates the brain.

information [in referrals] initially is typically only made apparent by subsequent events which make it relevant. We cannot ask for information we are not aware of." Pacific Radiology also commented that it relies on the expertise of referring clinicians, who are best placed to consider the risk–benefit analysis of any proposed intervention. It noted that this does not abdicate a radiologist's responsibility, "but if a clinician who has thoroughly examined the patient … deems the procedure warranted that is very influential".

70. Pacific Radiology added:

> "[Mr A's] use of Warfarin was identified by the bookings process. Its significance (anticoagulation for a prosthetic heart valve); human and systems errors (which have now been addressed) contributed to the unfortunate events of 4 October 2018, rather than insufficient clinical information."

71. Dr B reiterated that he does not recall detecting any obvious impairment to Mr A's speech during his conversations and assessments of Mr A, and notes that Ms F also did not note this in her Corrective Action Form. Dr B also stated that his assessment and the recollections of those present differ on the point of Mr A's steadiness on his feet. He noted that although Ms E observed that Mr A was unsteady on his feet upon arrival at Pacific Radiology, he (Dr B) did not observe any unsteadiness when he asked Mr A to walk in a straight line during his assessment. Mrs A confirmed this, and the GP assessment also did not detect an issue with gait. Dr B commented that with the benefit of hindsight, these discrepancies may reflect fluctuating neurological deficit, which can present in the early stages of stroke.

72. Dr B also told HDC that in his current places of work (predominantly at hospital sites), typically the patients he sees have already been assessed by other frontline specialists. He therefore considers that it would be very unlikely that he would have to undertake a physical assessment of a patient. Nonetheless, since these events, he has undertaken reading and research into stroke presentations.

73. Dr C told HDC that he accepts that it is appropriate to include relevant past medical history in radiology requests. However, he submitted that informing Pacific Radiology of Mr A's artificial heart valve and anticoagulation medication was not relevant information in this case. Dr C explained:

> "The main reason I believe this is that stopping anticoagulation for any reason for this procedure is not appropriate. It is irrelevant whether he was anticoagulated for an artificial heart valve, a previous DVT or any other reason as stopping anticoagulation for this procedure is contraindicated. I do not think that it is appropriate to expect me to provide a list of contraindications for guided injections to the providers of this injection."

74. Dr C provided several journal article references[16] in support of his view that stopping anticoagulation prior to a radiological procedure is not appropriate. He added that, had he been asked by Pacific Radiology whether it was appropriate to stop Mr A's anticoagulation medication prior to the injection, he would have said that that this was not correct clinical practice.

Opinion: Pacific Radiology — breach

Procedure for booking

75. It is accepted by Pacific Radiology that Mr A was advised by its bookings team member, Ms D, to stop taking his warfarin five days before his appointment. This was contrary to the CT Booking Table protocol, which indicated that "anticoagulation" cannot be stopped for certain conditions — for example, a mechanical heart valve. Ms D did not enquire about the reason Mr A was taking warfarin, nor did she speak to the radiologist, Dr B, prior to advising Mr A that he should stop his warfarin.

76. Pacific Radiology told HDC that it appears that Ms D misinterpreted the CT Booking Table protocol and followed the specific advice for warfarin, while overlooking the general advice about patients who take anticoagulation.

77. The CT Booking Table protocol in place at the time of this incident stated under "booking patient in":

> "If patient is on Anticoagulation, find out why patient is on it and talk to Radiologist as some conditions you can't stop it e.g. Mechanical heart valve, risk recurrent PE/DVT/? …
>
> **If Warfarin** — Stop for 5 Days, need to do INR on morning of apt, procedure day 6 afternoon." (Emphasis in original.)

78. My expert advisor, radiologist Dr John Gunn, advised:

> "The accepted practice at the time for a radiological spinal injection procedure on a patient on Warfarin with an artificial heart valve is to obtain advice from a Radiologist (or Cardiologist or Haematologist) prior to cessation of Warfarin and to delay booking the procedure until such advice has been obtained."

79. Dr Gunn advised that the failure of staff to seek clinical input before advising a patient who had a mechanical aortic valve replacement to stop warfarin was a serious departure from the standard of care. I accept Dr Gunn's advice. It appears that Ms D incorrectly followed

[16] https://academic.oup.com/painmedicine/article/19/3/438/4055846; https://publishing.rcseng.ac.uk/doi/full/10.1308/rcsann.2015.0044; and https://www.practicalpainmanagement.com/treatments/interventional/injections/examining-safety-joint-injections-patients-warfarin.

the advice specific to warfarin — that a patient on warfarin should be advised to stop taking it five days prior to the procedure. Given that Mr A had a mechanical heart valve, this should never have occurred without consultation with a specialist. I also note that Pacific Radiology has acknowledged that Mr A should not have been advised to stop taking his warfarin without specialist input.

80. In considering why this error occurred, I have assessed Pacific Radiology's Booking Table Protocol, which in my view lacks clarity and is open to interpretation. It is also my view that, as a non-clinical staff member, Ms D could not be expected to know or assess whether warfarin was an anticoagulation medicine to which the first part of the policy applied. That is, Pacific Radiology's booking protocol tasked non-clinical staff, who may have been unfamiliar with different anticoagulation medications, with booking these procedures and giving clinical advice. I consider that Pacific Radiology is therefore responsible for the inappropriate and unsafe advice given to Mr A to stop his warfarin.

81. I note that subsequently Pacific Radiology changed its policy to make it clear that if a patient is on anticoagulant medication, advice must be sought from the radiologist. I consider that this provides much clearer guidance to booking staff, although it presumes that the patient understands that their medication is for anticoagulation, and/or that the non-clinical booking staff recognise certain medications as anticoagulants. In this respect, I note Dr Gunn's view that when booking a patient for an invasive imaging-guided procedure, such as Mr A was having, "the discussion should be between the Radiologist and the patient or, when necessary, their referring doctor NOT the clerical non-clinical staff. Alternatively a Radiology Practice Nurse[17] involved in these procedures may be perfectly suited to this responsibility." I suggest that Pacific Radiology consider this advice.

Conclusion

82. In my opinion, where a patient is being advised to stop any type of medication, there needs to be a clear and robust process in place to ensure that the advice is appropriate for the patient's clinical circumstances. While clearly there were individual errors that led to Mr A being advised to stop his warfarin without clinical input, it is my view that these were the result of inadequate procedures in place at Pacific Radiology. In particular:

- The booking protocol lacked clarity and was open to interpretation.
- The booking protocol placed the responsibility on non-clinical booking staff to extract and interpret clinical information.

83. I consider that the above deficiencies amount to a failure to provide services to Mr A with reasonable care and skill. Accordingly, I find that Pacific Radiology breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

84. In my view, had Pacific Radiology had a robust booking system, Mr A would not have been advised to stop his warfarin without adequate clinical input. As a result of the deficient process, Mr A was unnecessarily exposed to the risk of harm in the form of an increased

[17] Emphasis in original.

likelihood of stroke. Ultimately, and unfortunately, this risk was realised. In my opinion, this case highlights that deficient administrative protocols and procedures can create a very real risk of harm to consumers.

Adequacy of referral — adverse comment

85. While acknowledging the submissions of Pacific Radiology, I remain of the view that a further contributing factor to what occurred in this case may have been the adequacy of the referral sent by Dr C. Dr C's role in this is discussed below.

86. The referral recorded the procedure for which Mr A was being referred, and the reason, but did not include Mr A's relevant past medical history. In particular, it did not record that Mr A had an artificial heart valve or that he was taking warfarin, nor did it contain sufficient clinical details to justify the clinician's choice of treatment (clinical symptoms and examination findings).

87. Dr Gunn stated:

> "It is notable that the referral form for [Mr A's] spinal injection procedure contained no clinical information and therefore no mention of the patient's artificial heart valve and/or anticoagulation treatment. This type of referral requires appropriate relevant clinical information and if such information is not present on the referral it is mandatory that it be obtained prior to booking the appointment. This then allows a 'risk benefit assessment' prior to decisions regarding cessation of Warfarin and appointment scheduling."

88. Pacific Radiology said that where a referral contains inadequate information it would be sent back, but in this case, it considered that the referral included appropriate clinical information for the procedure requested. However, Pacific Radiology also commented that it is "strongly preferred" if referrers routinely include information such as a consumer's medication and other relevant medical history on referral forms.

89. Dr Gunn disagrees that the clinical information contained in the referral was sufficient, and noted that the information was "simply a request for a procedure". Dr Gunn advised:

> "[The referral] contained no description of the patient's clinical symptoms and/or examination findings and no mention of his artificial heart valve or anticoagulation drug therapy. This is not safe or acceptable clinical practice and the receiving Radiology practice would be strongly advised to request an appropriately relevant new referral from the referring Doctor or to at least contact the referrer by telephone for the additional information prior to contacting the patient for an appointment booking."

90. While I note that Mr A's relevant clinical history of an aortic heart valve replacement was available to Pacific Radiology staff, having been recorded at the time he was booked for an MRI prior to these events (and as a result of Mr A volunteering that information), I accept Dr Gunn's advice that the referral in this case was lacking important clinical information. The referral was extremely brief, and simply requested the procedure for facet joint

arthropathy. In my view, Pacific Radiology should have contacted the referring clinician, Dr C, to ascertain more information about Mr A's clinical symptoms and/or Dr C's examination findings.

91. It is clear that Pacific Radiology relies on the expertise of referring clinicians when proposing an intervention, although it acknowledges that radiologists nevertheless carry their own professional responsibilities. In light of my conclusions in this respect (supported by the expert evidence), I suggest that Pacific Radiology give consideration to the minimum standards it should reasonably expect from such referrals in the future.

Opinion: Dr B — breach

92. Dr B was the radiologist who undertook Mr A's CT-guided corticosteroid injection on 4 October 2018. Dr B's first involvement with Mr A was immediately prior to the procedure. There are differing accounts about Mr A's presentation at that time.

93. Mrs A told HDC that Mr A had difficulty with word finding and slurred speech, clammy skin, and was feeling acutely unwell. Similarly, according to accounts documented in the Corrective Action Forms by MRTs Ms E and Ms F, Mr A was unwell and unsteady on his feet (Ms F's account), as well as overheated, unable to communicate clearly, and a little confused (Ms E' account). The MRTs' accounts were written six days after the events.[18]

94. Dr B agreed that he was asked to review Mr A because of concerns about his clinical condition. Dr B said that Mrs A told him that she was concerned because Mr A was not feeling well, was having difficulty finding words, and had driven dangerously early that morning. Dr B said that on becoming aware that Mr A had stopped taking warfarin and was not taking Clexane in the interim, and that Mr A's INR was 1.0, he was alert to the possibility of a potential stroke. Dr B stated that although he did not perform a comprehensive neurological assessment, he undertook a number of tests.[19]

95. In contrast to the accounts from Mrs A and Ms E, Dr B stated that he did not notice Mr A slurring his speech or having any difficulty finding words when asking him questions. Dr B also said that he did not observe any facial droop or asymmetrical facial movement, weakness or numbness, or obvious loss of motor function. Dr B concluded that Mr A did not have any obvious signs of neurological deficit and, with Mr A's agreement, carried out the injection.

[18] On 10 October 2018.

[19] More specifically, Dr B said that he asked Mr A to smile, blow his cheeks, stick out his tongue and move it left and right, repeat back the words "La la la" and "No ifs, ands or buts", touch his own nose and then Dr B's index finger, see Dr B's fingers in his peripheral vision, follow Dr B's moving finger with his eyes, push against Dr B's palms by turning his head left and right, shrug his shoulders against Dr B's palms, abduct his shoulders and arms, push Dr B's palms away with his shins, squeeze Dr B's fingers, and push his thighs up against Dr B's hands.

96. Dr B did not document any of the tests he said he undertook, although he did record that Mr A denied symptoms of power weakness or decreased sensation. Mr A does not recall whether Dr B performed the tests described, but stated that he may have been asked something about his face. Mrs A recalled Mr A being asked to walk in a straight line, which he was able to do.

97. Dr B said that after carrying out the procedure, he spoke with Mr A's GP and advised Mr A to go to his GP for an urgent Clexane injection. Dr B said that he would have sent Mr A to hospital had he not been able to contact Mr A's GP.

98. Prior to receiving Dr B's detailed statement in response to my investigation, Dr Gunn's advice was that if Mr A was presenting in the way described by Ms E and Ms F, "without delay accepted practice would be to cancel the procedure and directly transfer the patient to [hospital] for assessment and treatment (not via his GP)". Dr Gunn advised that the failure to do so in these circumstances would be a serious departure from accepted practice.

99. Dr Gunn later reviewed Dr B's detailed response and advised, assuming that Dr B's account was factually accurate, that "it was reasonable in the circumstances that Dr B described for him to proceed with the spinal facet joint injection". Dr Gunn also noted that in either scenario, the decision to proceed with the procedure was unlikely to have had a significant impact on Mr A's outcome.

100. There are differing accounts about Mr A's presentation at his appointment on 4 October 2018. I accept that Dr B undertook some tests to assess Mr A's neurological status, noting that Mr and Mrs A recall some aspects of that testing, which are consistent with what Dr B has stated. On the information before me I am unable to make a finding about the extent of the tests undertaken. Given the acknowledged risk of stroke and the seriousness of the implications of that risk, I am critical that Dr B did not document that testing.

101. There is a conflict in the evidence regarding Mr A's speech. It is difficult to reconcile Dr B's account with those of Ms E (that Mr A was unable to communicate very clearly and seemed a bit confused) and of Mrs A (that Mr A had had difficulty finding words all morning and was having the same difficulty at Pacific Radiology, as well as slurred speech). I acknowledge that Ms F did not note any speech issues in her account. However, Mrs A is adamant that Mr A was having speech difficulties during his conversation with Dr B. I note further that a short time after the injection, Mr A was assessed by his GP as having slurred speech such that a stroke was suspected, and he was referred by ambulance to hospital. The dominant symptom noted in the ambulance summary and at the public hospital was an inability to formulate and find words, and slurred speech.

102. Dr B submitted that the discrepancies in the parties' recollections may reflect that Mr A's neurological deficit was fluctuating, which can happen in the early stages of stroke. He further advised that he thought that Mr A's GP would have the benefit of information that he did not — and hence his rationale for sending Mr A there.

103. Dr Gunn advised that, assuming that Dr B's account was factually accurate, it was reasonable in the circumstances described by Dr B to proceed with the procedure. However, I do not accept that the account was factually accurate, to the extent that I have little difficulty concluding on the evidence (the statements and documentation) that Mr A was suffering speech difficulties (slurred speech and word finding difficulties) when he was at Pacific Radiology. Mrs A's evidence is compelling, consistent, and corroborated by Ms E. It is also consistent with the subsequent observations of Mr A's GP, and ambulance and the public hospital staff. As such, it is my view that Dr B failed to pick up and/or fully appreciate the extent and significance of Mr A's speech difficulties at the time of his involvement with Mr A.

104. I allow the possibility that the speech difficulties were subtle. It is also possible that Dr B was reassured by the negative findings of his assessment (relating to power, gait, and sensation — which were also normal when Mr A was examined by his GP shortly afterwards). I also acknowledge Dr B's more recent submission of the possibility that Mr A's neurological deficit was fluctuating, as sometimes occurs in the early stages of a stroke.

105. However, I do not consider that these factors materially mitigate Dr B's actions. Dr B knew that Mr A's anticoagulation medication had been stopped, and that his INR was 1. He was therefore on notice that Mr A was at increased risk of stroke (which he accepts he was aware of). Dr B also obtained a history of concerning symptoms from Mrs A regarding Mr A's recent abnormal speech and driving. She was an appropriate person to give this clinical history, being the person who knew Mr A the best. Dr B was further alerted to immediate concerns about Mr A's well-being by clinical staff (Ms F and Ms E). Knowing that symptoms can fluctuate should also have informed his decision-making. With all this knowledge, it is my view that Dr B's decision to proceed with the procedure at that time was not appropriate.

106. In my opinion, Dr B's failure to pick up and/or fully appreciate the extent and significance of Mr A's speech difficulties, and/or his failure to adequately consider the significant clinical history (as reported by Mrs A and clinical staff), in the clinical situation of Mr A having had his anticoagulation medicine stopped, amounts to a failure to provide services with reasonable care and skill. Accordingly, I find that Dr B breached Right 4(1) of the Code. As stated above in paragraph 100, I am also critical that Dr B did not document the neurological testing he says he undertook.

107. As a result of Dr B's failure, there was a delay in Mr A receiving the appropriate assessment and treatment for his stroke. Dr Gunn pointed out that the delay is unlikely to have had a significant impact on Mr A's outcome. Nonetheless, in my view it was an unnecessary delay that put Mr A's well-being at risk, with time generally being of the essence when it comes to diagnosing and treating stroke.[20]

[20] Best practice: "Time is brain: emergency treatment of stroke." https://bpac.org.nz/BPJ/2010/March/docs/bpj26_stroke1_pages32-37.pdf.

Opinion: Dr C — adverse comment

108. This section discusses the completeness of the information Dr C included in his referral of Mr A for a CT-guided cortisone injection on 27 September 2018.

109. The Medical Council of New Zealand publication *Good Medical Practice* (2016) states that a doctor "must provide [their] colleagues with the information they need to ensure that the patient receives appropriate care without delay". Further to this, in relation to referring a patient, it states: "When you refer a patient, you should provide all relevant information about the patient's history and present condition."

110. Dr C completed a standard Pacific Radiology referral form, noting that Mr A had a "facet [joint] arthropathy". Dr C did not provide any additional clinical information with the referral. In particular, Dr C did not document, or make reference to, Mr A having an artificial valve and that he was taking warfarin.

111. Three months earlier, in June 2018, Mr A had been referred to Pacific Radiology by a registrar in Dr C's office for an MRI relating to the same injury. After receiving this referral, on 23 July 2018, it was recorded in the Pacific Radiology patient database: "[P]atient has aortic valve replacement." This was information volunteered to Pacific Radiology by Mr A earlier and was not obtained from that referral.

112. Dr C acknowledged that the September referral was brief. However, he stated that it should not be viewed in isolation, noting the previous MRI referral from the sports medicine clinic to Pacific Radiology. In his response to the provisional opinion, Dr C also agreed that it is appropriate to include relevant past medical history in radiology requests. However, he disputed that Mr A's artificial heart valve and anticoagulation treatment was relevant information to include on the referral.

113. In relation to the latter submission, Dr C advised that in his view, stopping anticoagulation for any reason for this procedure is not appropriate (indeed contraindicated). In support of his view, Dr C attached three journal articles from publications based in the UK and in the United States showing that stopping anticoagulant therapy for any injections (except epidurals) leads to more harm than benefit. He told HDC that he does not consider it his role to list contraindications for guided injections.

114. However, I note that the three journal articles referred to by Dr C acknowledge that there is limited data on this topic and differing views and guidelines about the circumstances in which anticoagulation therapy should be stopped for interventional procedures in radiology.

115. In my view, this highlights a difference of clinical view as to the importance and relevance of the information to inform appropriate clinical decision-making by the radiologist undertaking the procedure.

116. I note Dr Gunn's advice:

> "The referral for the spinal injection on [Mr A] contained no description of the patient's clinical symptoms and/or examination findings and no mention of his artificial heart valve or anticoagulation drug therapy. This is not safe or acceptable clinical practice …"

117. Dr Gunn also said:

> "I believe that the referral clinical information of 'facet joint arthropathy' is insufficient for the request for 'CT guided facet joint cortisone injection'. It is simply a request for a procedure.[21] Information provided on the referral should include sufficient clinical details to confirm that the clinician's choice of the CT guided imaging procedure is appropriate and fully justified."

118. While Dr Gunn's advice that a new referral should have been requested or the referring practitioner contacted for more clinical information relates to Pacific Radiology, it is my opinion that Dr C holds some of the responsibility for ensuring the completeness of the clinical information provided to Pacific Radiology. In this case, it is my view that Dr C's referral should ideally have included the important medical information that Mr A had a mechanical aortic valve and that he was taking warfarin. I suggest that Dr C reflect on his process for writing radiological referrals and ensuring that they include relevant medical history.

Changes made

119. Since this incident, Pacific Radiology has changed its booking protocol, which now states:

> "If patient is on Anticoagulation, find out the name of the medication and why they are taking it. **Discuss with radiologist** who will advise how to proceed.
>
> Only Radiologist can make the decision to cease Anticoagulation medication.
>
> If the patient is on Warfarin you will need to obtain the most recent INR blood test results, show to MRT and scan into COMRAD."

120. In addition, in response to the provisional opinion, Pacific Radiology told HDC:

- A process is being rolled out to all Pacific Radiology subsidiaries, in which after bookings are completed by specialist administrative staff, referrals have another layer of vetting through review by CT Medical Imaging Technologists.

[21] Emphasis in original.

- Pacific Radiology is also establishing a working party under the guidance of Pacific Radiology's Clinical Advisory Group, with the brief of ensuring that the anticoagulation policy is based on best available evidence, and with clear pathways dealing with different scenarios.

121. Dr B told HDC that in the future, in a similar clinical scenario, regardless of any initial views on assessment, the preferred approach would be to direct the patient as soon as possible to the nearest hospital.

Recommendations

122. Bearing in mind the changes made by Pacific Radiology since these events (as set out above), I recommend that Pacific Radiology:

a) Undertake an audit of patients booked by Pacific Radiology for CT-guided spinal interventions over a six-month period to ensure compliance with the updated booking protocol — in particular, whether input was sought from a radiologist in cases of patients on anticoagulation medication. Pacific Radiology is to provide to HDC evidence of the audit, and a report on additional changes taken to address any issues that were identified, within six months of the date of this report.

b) Report back to HDC, within six months of the date of this report, as to:

i. Whether the process for additional vetting of referrals (referred to in paragraph 120 above) has been implemented at Pacific Radiology; and

ii. The progress that has been made by the working party (referred to in paragraph 120 above) on reviewing the anticoagulation policy.

c) Provide a written letter of apology to Mr A for its breach of the Code. The apology should be provided to this Office within three weeks of the date of this report, for forwarding.

123. I recommend that Dr B:

a) Undertake further training on neurological assessment. Dr B should report back to HDC within three months of the date of this report, with details of any training he has either undertaken or is enrolled in.

b) Provide a written letter of apology to Mr A for the breach of the Code identified in this report. The apology should be provided to this Office within three weeks of the date of this report, for forwarding.

124. I recommend that the Medical Council of New Zealand consider undertaking a competence review of Dr B, should he reapply to practise in New Zealand, and/or consider any further appropriate action based on the information contained in this report.

Follow-up actions

125. A copy of this report with details identifying the parties removed, except the name of Pacific Radiology and the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name, for the purpose of considering whether a review of his competence is warranted.

126. A copy of this report with details identifying the parties removed, except the name of Pacific Radiology and the expert who advised on this case, will be sent to the Royal Australian and New Zealand College of Radiologists, and it will be advised of Dr B's name.

127. A copy of this report with details identifying the parties removed, except the name of Pacific Radiology and the expert who advised on this case, will be sent to the Health Quality & Safety Commission, the Royal Australian and New Zealand College of Radiologists, and the Australasian College of Sport and Exercise Physicians, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from radiologist Dr John Gunn:

"I have been asked to provide an opinion to the Health and Disability Commissioner (the Commissioner) on Case Number C19HDC00062.

I have read the 'HDC Guidelines for Independent Advisors' and agree to follow them.

My qualifications:

- M.B. Ch.B. (Bachelor of Medicine and Surgery; 1968)
- F. F. Rad (D.) (Fellow of Faculty of Radiology; South Africa; 1977)
- M. Med (Rad. D) (Master of Medicine in Radiology; University of Cape Town; 1977)
- FRANZCR (Fellow of the Royal Australasian College of Radiology)

My training:

- Radiology Registrar (Groote Schuur Hospital; Cape Town; 1974–1977)
- The training included extensive procedural radiology

My experience:

- 41 years of Diagnostic and Interventional procedural radiology as a Consultant Specialist in Australia (1978–1996) and New Zealand (1996 to currently in practice).
- This experience includes performing extensive procedures requiring placement of needles and other devices using imaging guidance, including spinal needle placements.
- My experience includes time as Clinical Director of Radiology at:
  - Freemantle Hospital, Perth Western Australia; 1985–1996
  - Auckland DHB; 1996–1999
  - Waitematā DHB; 2005–2008

I have reviewed all the sources of information sent to me by the Commissioner on 10 December 2019 including:

1. Letter of Complaint
2. Response from Pacific Radiology
3. Clinical records from Pacific Radiology
4. Clinical notes from [the sports medicine clinic]
5. Clinical notes from [the public hospital's] Older Persons and Rehabilitation Department

Expert advice requested

1. The processes in place at Pacific Radiology at the time of the incident.

   a. Standard of care/accepted practice?

The accepted practice at the time for a radiological spinal injection procedure on a patient on Warfarin with an artificial heart valve is to obtain advice from a Radiologist

(or Cardiologist or Haematologist) prior to cessation of Warfarin and to delay booking the procedure until such advice has been obtained.

The Pacific Radiology guidelines in place at the time advises booking staff are required to find out why the patient is on anticoagulation and talk to a Radiologist as some conditions you can't stop it.

b. Departure from accepted practice

On this occasion the booking staff member did not follow the above instructions. This departure from accepted practice is in my opinion a significant serious departure.

c. Recommendations for improvement

A revised Reception Manual CT booking protocol dated 20 February 2019 from Pacific Radiology advised that 'only a Radiologist can make the decision to cease anticoagulation medication'. This above revision adds appropriate emphasis to their required protocol.

2. [Mr A's] management by Pacific Radiology staff.

a. Standard of care/accepted practice?

The Pacific Radiology booking protocol was not followed as I have described under 'processes in place' in 1.a. above. It is notable that the referral form for [Mr A's] spinal injection procedure contained no clinical information and therefore no mention of the patient's artificial heart valve and/or anticoagulation treatment. This type of referral requires appropriate relevant clinical information and if such information is not present on the referral it is mandatory that it be obtained prior to booking the appointment. This then allows a 'risk benefit assessment' prior to decisions regarding cessation of Warfarin and appointment scheduling.

b. Actions taken by Pacific Radiology staff on [Mr A's] presentation

CT staff noted [Mr A] looked overheated, appeared unsteady on his feet, had communication difficulties and appeared confused. CT staff called the Radiologist and also got [Mrs A] to join the conversation. The Radiologist assessed [Mr A] prior to the procedure. His CT Lumbar Spine injection report 4 October 2018 states he asked the patient if he had any symptoms of power weakness or decreased sensation which the patient denied. His report described the procedure as 'uneventful'. The Radiologist noted the patient's INR was 1. (INR stands for International Normalised Ratio and is an indicator of the patient's coagulation therapy status. An INR of 1. is equivalent to a zero effective anticoagulation. It is the expected result for anybody NOT on anticoagulants.)

In a letter from the Radiologist to [Pacific Radiology] dated 28 June 2019 regarding his assessment of [Mr A] prior to the procedure in which he describes finding no evidence of facial or limb muscle weakness, no slurring of speech, he stated [Mr A] could understand his questions. The Radiologist contacted [Mr A's] GP and advised the

patient to proceed directly to his GP for a Clexane injection (anticoagulation) and for further assessment.

Concluding comments

1. There are differing accounts of [Mr A's] clinical status prior to the procedure.

There is notable variation between (a.) the CT staff reporting [Mr A] 'appeared overheated, unsteady, unable to communicate and confused', as opposed to (b.) the Radiologist not finding similar clinical concerns allowing him to discuss the risks and benefits of the procedure with [Mr A].

If scenario (a.) the CT staff description of [Mr A's] clinical state of confusion was an accurate assessment, then without delay accepted practice would be to cancel the procedure and directly transfer the patient to [hospital] for assessment and treatment (not via his GP).

If scenario (b.) was correct, then continuing on to perform the procedure as scheduled was appropriate as was referral to his GP for routine post procedural Clexane injection (effectively recommencing anticoagulation).

2. The referral for the spinal injection on [Mr A] contained no description of the patient's clinical symptoms and/or examination findings and no mention of his artificial heart valve or anticoagulation drug therapy. This is not safe or acceptable clinical practice and the receiving Radiology practice would be strongly advised to request an appropriately relevant new referral from the referring Doctor or to at least contact the referrer by telephone for the additional information prior to contacting the patient for an appointment booking.

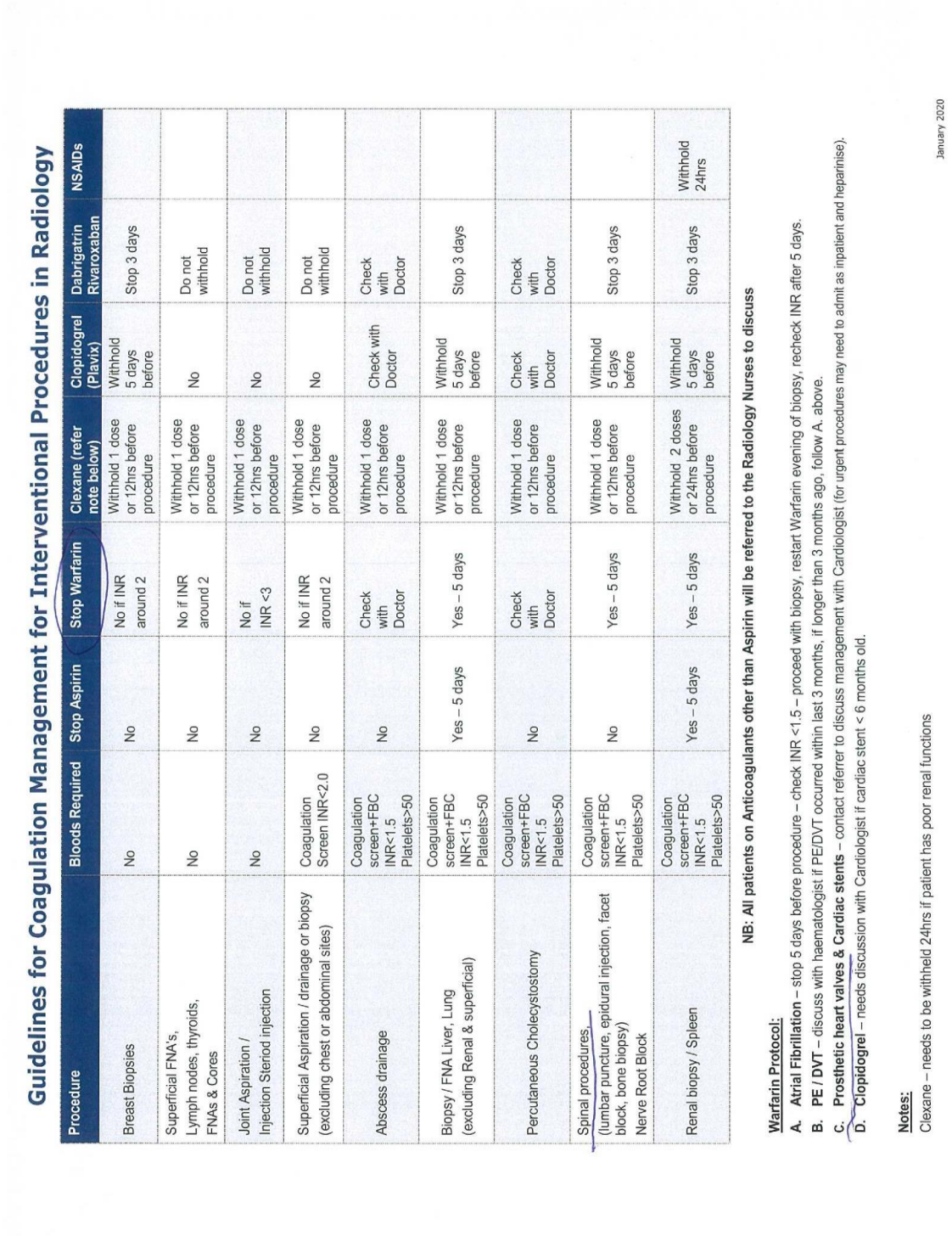
I have discussed this complaint (anonymously) with Specialist Radiologists and Nursing colleagues who are currently involved in the practice of these procedures and care of similar patients at major public Auckland hospitals regarding their protocols for these procedures. Their practice and advice is similar to that contained in my letter and their replies were made without hesitation or uncertainty.

Please find enclosed 'Guidelines for Coagulation Management for Interventional Procedures in Radiology' from the Waitematā DHB Radiology manual (the protocol for patients on Warfarin with artificial heart valves has not effectively changed in the last two decades).

Yours sincerely

Dr John Gunn
Consultant Radiologist
Waitematā DHB

Enc Guidelines for Coagulation Management for Interventional Procedures in Radiology"



Guidelines for Coagulation Management for Interventional Procedures in Radiology

Procedure	Bloods Required	Stop Aspirin	Stop Warfarin	Clexane (refer note below)	Clopidogrel (Plavix)	Dabrigatrin Rivaroxaban	NSAIDs
Breast Biopsies	No	No	No if INR around 2	Withhold 1 dose or 12hrs before procedure	Withhold 5 days before	Stop 3 days	
Superficial FNA's, Lymph nodes, thyroids, FNAs & Cores	No	No	No if INR around 2	Withhold 1 dose or 12hrs before procedure	No	Do not withhold	
Joint Aspiration / Injection Steriod injection	No	No	No if INR <3	Withhold 1 dose or 12hrs before procedure	No	Do not withhold	
Superficial Aspiration / drainage or biopsy (excluding chest or abdominal sites)	Coagulation Screen INR<2.0	No	No if INR around 2	Withhold 1 dose or 12hrs before procedure	No	Do not withhold	
Abscess drainage	Coagulation screen+FBC INR<1.5 Platelets>50	No	Check with Doctor	Withhold 1 dose or 12hrs before procedure	Check with Doctor	Check with Doctor	
Biopsy / FNA Liver, Lung (excluding Renal & superficial)	Coagulation screen+FBC INR<1.5 Platelets>50	Yes – 5 days	Yes – 5 days	Withhold 1 dose or 12hrs before procedure	Withhold 5 days before	Stop 3 days	
Percutaneous Cholecystostomy	Coagulation screen+FBC INR<1.5 Platelets>50	No	Check with Doctor	Withhold 1 dose or 12hrs before procedure	Check with Doctor	Check with Doctor	
Spinal procedures (lumbar puncture, epidural injection, facet block, bone biopsy) Nerve Root Block	Coagulation screen+FBC INR<1.5 Platelets>50	No	Yes – 5 days	Withhold 1 dose or 12hrs before procedure	Withhold 5 days before	Stop 3 days	
Renal biopsy / Spleen	Coagulation screen+FBC INR<1.5 Platelets>50	Yes – 5 days	Yes – 5 days	Withhold 2 doses or 24hrs before procedure	Withhold 5 days before	Stop 3 days	Withhold 24hrs

NB: All patients on Anticoagulants other than Aspirin will be referred to the Radiology Nurses to discuss

Warfarin Protocol:

A. **Atrial Fibrillation** – stop 5 days before procedure – check INR <1.5 – proceed with biopsy, restart Warfarin evening of biopsy, recheck INR after 5 days.
B. **PE / DVT** – discuss with haematologist if PE/DVT occurred within last 3 months, if longer than 3 months ago, follow A. above.
C. **Prosthetic heart valves & Cardiac stents** – contact referrer to discuss management with Cardiologist (for urgent procedures may need to admit as inpatient and heparinise).
D. **Clopidogrel** – needs discussion with Cardiologist if cardiac stent < 6 months old.

Notes:
Clexane – needs to be withheld 24hrs if patient has poor renal functions

January 2020

The following further advice was obtained from Dr Gunn:

> "I have reviewed the 81 pages of new documentation dated 23 June 2020 and find no reason to amend my advice of 30 January 2020 but to add the following addendum.
>
> **As requested to comment on:**
>
> **The robustness of the policy of non-clinical staff giving information to consumers regarding anticoagulation therapy management.**

In the CORRECTIVE ACTION FORM the Receptionist involved, [Ms D], states (under the heading of 'What might prevent a recurrence of the situation?') 'I don't think Reception staff should be booking these patients. An MRT could do it'. This is clearly indicative of reluctance to accept this responsibility. It is important to note [Ms D] is described as a capable and experienced Medical Receptionist employed by Pacific Radiology since 2013.

It is very possible that a patient/consumer may simply reply 'to make my blood thinner' if asked why they are on anticoagulants. They may not be aware of the precise indication(s) for their need for anticoagulation. There are many cardiovascular indications for anticoagulation and there would be more than one indication in some patients. My advice is that if a referral is for a CT guided injection (or similar invasive imaging guided procedure) the discussion should be between the Radiologist and the patient or, when necessary, their referring doctor NOT the clerical non-clinical staff. Alternatively a Radiology Practice Nurse involved in these procedures may be perfectly suited to this responsibility.

If the referral contained the appropriate information that the patient is on anticoagulants (and the reason(s), it should be passed directly on to the Procedural Radiologist (or Practice Nurse) to manage the booking.

Any other issues that you identify

With respect to [Pacific Radiology's] comments, my advice was 'to request a new referral or contact the referring doctor for additional information' NOT 'referrals not containing sufficient information should be returned to the referring doctor for additional information'.

I believe that the referral clinical information of 'facet joint arthropathy' is insufficient for the request for 'CT guided facet joint cortisone injection'. It is simply a request for a procedure. Information provided on the referral should include sufficient clinical details to confirm that the clinician's choice of the CT guided imaging procedure is appropriate and fully justified.

Procedural Radiologists are often only privy to the clinical information imparted on the referral form with which they have to achieve appropriate 'informed consent' for the procedure.

I note that there is, as yet, no supplied response from [Dr B] with respect to my concluding comments on the very notable variations between the CT MRT Staff reporting [Mr A's] condition and [Dr B] not finding similar clinical concerns. Thus allowing him to discuss the risks and benefits of the procedure with [Mr A] and proceeding to perform the procedure.

Yours sincerely

Dr John Gunn
Consultant Radiologist, Waitematā DHB"

The following further advice was obtained from Dr Gunn:

> "IF the CT staff description of the patient's condition was accurate I would personally not have remotely considered continuing to perform the procedure. As such I would consider the decision to continue to perform the procedure as a serious departure from sensible safe practice. However, it would quite possibly not have had any impact on the outcome as I suspect the cerebral event had already occurred due to the cessation of anticoagulation.
>
> Again, I reiterate Radiology referrals need relevant Clinical information and that initial glaring absence was the prime cause of the patient's negative outcome, not the final procedural event."

The following further advice was obtained from Dr Gunn:

> "Having read the very detailed reply by the Radiologist [Dr B], I am of the opinion it was reasonable in the circumstances that [Dr B] described for him to proceed with the spinal facet joint injection.
>
> Yours sincerely
>
> Dr John Gunn
> **Consultant Radiologist**
> **Waitematā DHB**"