General Practitioner, Dr D

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 13HDC01237)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A was a patient of general practitioner Dr D at Medical Centre 1 for a number of years, before transferring to Medical Centre 2 in 2008. On 18 Month1 2013, Mr A transferred his care back to Medical Centre 1.

2. On 19 Month1 2013[1], Medical Centre 2 transferred an electronic and a paper copy of Mr A's medical records to Medical Centre 1. On 20 Month1, Dr D reviewed the electronic records. Dr D told HDC that it was not apparent from the electronic records that Mr A had had a mitral valve replacement, and it was not clear that he was taking warfarin. Dr D said that the electronic notes he received from Medical Centre 2 lacked clear identification of the long-term conditions and medications. Dr D's practice nurse, Ms F, received the paper copy, reviewed the transfer summary, and noted that there had been no changes to Mr A's medication since 2003.

3. On 26 Month1, Mr A attended a consultation with Dr D. A trainee intern was with Dr D on that day, and he instructed the intern to review Mr A's notes and assess him as a new patient. Dr D said that he briefed the intern to conduct a comprehensive medical history and thorough clinical examination. However, the intern did not elicit from Mr A that he had had cardiac surgery, and Mr A did not advise him that he was taking warfarin. During the physical examination, the intern did not detect a metallic "click", which is associated with a mechanical mitral valve, or record that Mr A had a sternotomy scar. Dr D told HDC that the intern was competent, and that his findings were consistent with the aspects of Mr A's medical history with which Dr D was already familiar. As such, Dr D saw no reason to repeat the clinical examination.

4. On 27 Month1, Mr A attended a consultation with Dr D. At this appointment, Dr D was made aware by Mr A that he was taking warfarin. When Dr D asked Mr A why he was taking it, he said that Mr A gave a vague reply about it being for his heart. Dr D told HDC that he assumed Mr A was taking warfarin for a rhythm disturbance. Dr D did not investigate further, and advised Mr A to stop taking warfarin.

5. On 25 Month2, Mr A consulted Dr D with complaints of palpitations. Mr A advised Dr D that he had taken four warfarin tablets, which had made him feel better. Dr D was concerned that Mr A was self-medicating with warfarin, and again advised him to stop taking it.

6. On 6 Month3, Mr A died in hospital after suffering several strokes.

Findings

7. By failing to review Mr A's medical records adequately, and by failing to investigate the reason why Mr A had been prescribed warfarin before advising him to stop taking it, Dr D did not provide services to Mr A with reasonable care and skill and breached

[1] Relevant dates are referred to as Month1 – Month3 to protect privacy.

Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

8. Dr D breached Right 6(1)[3] of the Code for failing to provide Mr A with information about the risks and benefits of discontinuing warfarin therapy, which was information that a reasonable consumer would expect to receive in Mr A's circumstances. Mr A did not receive sufficient information about the risks and benefits of stopping warfarin, and so was not in a position to make an informed choice and give informed consent to the discontinuation of that treatment. Accordingly, Dr D also breached Right 7(1)[4] of the Code.

9. Adverse comment is made about Medical Centre 2 for providing suboptimal electronic notes, and Medical Centre 1 for not ensuring that its staff were clear about whose responsibility it was to review which aspects of a new patient's medical record. Ms F is also criticised for recording incorrect information in a consultation note.

Complaint and investigation

10. The Commissioner received a complaint from Mr B and Mr C about the services provided by general practitioner (GP) Dr D[5] and Medical Centre 1 to their father, Mr A (deceased). The following issues were identified for investigation:

- *The appropriateness of the care provided by Dr D to Mr A between 26 Month1 and 3 Month3 2013.*
- *The appropriateness of the care provided by Medical Centre 1 to Mr A between 26 Month1 and 3 Month3 2013.*

11. The parties directly involved in the investigation were:

Mr A (deceased)	Consumer
Mr B	Complainant — consumer's son
Mr C	Complainant — consumer's son
Dr D	Provider — general practitioner
Medical Centre 1	Provider — general practice owner/operator

12. Information from Dr E, a GP at Medical Centre 2; Ms F, a practice nurse at Medical Centre 1; the District Health Board; and the Medical Council of New Zealand was also reviewed.

[2] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."
[3] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"
[4] Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."
[5] Dr D is a vocationally registered GP.

13. Independent expert advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Background

Medical Centre 1

14. Medical Centre 1 has completed two cycles of the CORNERSTONE Accreditation Programme.[6] It is officially recognised as a teaching practice, and hosts approximately 15 medical students a year.

Mr A

15. Mr A was a patient of Dr D at Medical Centre 1 from 5 April 2000 to 14 February 2008 (apart from a brief period in 2006). Between 14 February 2008 and 19 Month1 2013, Mr A attended another practice, Medical Centre 2.

Transfer back to Medical Centre 1

16. Mr A's son, Mr B, told HDC that his father had spent most of his life going backwards and forwards between Medical Centre 1 and Medical Centre 2, depending on how he felt at the time. Mr B explained that at the beginning of 2013, Dr E from Medical Centre 2 told his father that he was no longer able to drive. Mr B said that his father was upset by this decision, so he decided to transfer back to Dr D at Medical Centre 1. Mr A remained a patient at Medical Centre 1 from 18 Month1 2013 until his death.

Medical conditions prior to transfer to Medical Centre 2

17. Dr D had been Mr A's GP in the past, and told HDC that he was aware of Mr A's complex medical history, which included poorly controlled high blood pressure, ischaemic heart disease,[7] severe mitral valve prolapse[8] and, in 2005, a stroke. Dr D was also aware that Mr A had had compliance issues with medication.

18. Dr D said that at the time of Mr A's transfer to Medical Centre 2 in 2008, he had been referred for coronary bypass grafting and a mitral valve replacement.[9] Dr D told HDC

[6] CORNERSTONE is an accreditation programme specifically designed by the Royal New Zealand College of General Practitioners for general practices in New Zealand. Accreditation is a self-assessment and external peer review process used by healthcare organisations to assess their level of performance accurately in relation to established standards, and to implement ways to continuously improve the healthcare system. Once accredited, practices move into an annual maintenance programme. The annual programme is based on a four-year cycle.

[7] Ischaemic heart disease occurs when the coronary arteries, which deliver oxygen to the heart muscle, become narrowed or blocked as a result of the build-up of fat and/or cholesterol within the artery wall.

[8] The mitral valve is the valve between the heart's left upper chamber (left atrium) and the left lower chamber (left ventricle). Mitral valve prolapse occurs when the mitral valve does not close properly.

[9] Coronary bypass grafting is a surgical procedure in which one or more blocked coronary arteries are bypassed by a blood vessel graft to restore normal blood flow to the heart. Mitral valve replacement is a cardiac surgical procedure in which a patient's diseased mitral valve is replaced by either a mechanical or a bioprosthetic valve.

that he was unaware that these procedures had been performed by the time Mr A transferred back to his care in Month1.

Receiving and reviewing patient records

19. On 20 Month1 2013, Dr D requested Mr A's medical records from Medical Centre 2. Dr D stated that Medical Centre 1 reviews medical records for new patients as follows:

a) First, the electronic records are reviewed by the provider, who receives them in his or her electronic inbox, and the long-term and currently relevant classifications, alerts, allergies, and long-term medications are added to the patient's medical record on the Practice Management Software (PMS).

b) Secondly, when the paper copies are received, the practice nurse or doctor reviews them and adds relevant information (as described in (a)) to the patient's medical record on the PMS.

c) Thirdly, when the patient is first seen, a detailed history is obtained and followed by a relevant examination. Amendments or additions are made to the electronic record at this stage and/or when further information is received.

20. Dr D, on behalf of himself and Medical Centre 1, stated:

> "The purpose of the review by the Practice Nurse is to highlight any obvious medical history issues including, in particular, changes to medications. My Practice Nurse had been employed by me for approximately three years and is competent and well experienced."

21. HDC was provided with a copy of the practice nurse's job description, which contains a detailed list of the tasks and responsibilities expected of a practice nurse. Reviewing the paper notes for a new patient is not listed as one of the responsibilities.

22. Dr D reviewed Mr A's medical records electronically. Dr D told HDC that it was not apparent from the electronic records that Mr A had had a mitral valve replacement. Dr D said that the electronic notes he received from Medical Centre 2 lacked clear identification of Mr A's long-term conditions and medications. Dr D was aware from the notes that Mr A was on warfarin therapy,[10] but said that the reason for this therapy was not readily apparent.

23. Dr D's practice nurse, Ms F, told HDC that she does not recall seeing Mr A's medical record. She explained her usual practice in relation to new patients:

[10] Anticoagulant therapy. Warfarin is the most widely used anticoagulant in New Zealand, having a key role in preventing thrombosis. International normalised ratio (INR) testing is used to maintain warfarin response within a therapeutic window, as maintaining the INR within the target range is vital in minimising the risk of bleeding while providing anticoagulation benefits. People who have had a mitral valve replacement will need to take an anticoagulant medicine such as warfarin for the rest of their life. This is because a mechanical valve is made of artificial material, which increases the risk of a blood clot developing on the valve's surface.

> "When receiving new patients to the surgery, [Medical Centre 1] would receive electronic notes, paper notes and a transfer summary that was usually enclosed on the top of the paper notes. My responsibility was to view the transfer summary which would include past medical history, any allergies, medications, immunisations, smears (if appropriate) and recalls. I would look at relevant areas in the electronic notes to ensure that any alerts for immunisations, allergies and recalls arising from the transfer summary were set up. If there was anything else that needed to be attended to, arising from the transfer summary, I would document this as a 'consult note'. For [Mr A] I documented as a consultation note that his medications had not been updated since 2003. It was not my practice to go through the patient's paper notes, as this was completed by the Doctor on the patient's first visit."

24. In response to my provisional opinion, Ms F stated that the electronic notes and electronic summary would be sent directly to the patient's doctor, whose role it was to ensure that current medications appearing in the electronic records were placed on Medical Centre 1's own electronic system. In relation to medications, Ms F said that it was her role to ensure that the patient's medications that were already on the electronic system were consistent with the medications listed on the paper transfer summary. Ms F cannot recall whether Mr A's medications already appeared on the electronic system at the time she viewed the paper transfer summary. She told HDC that she was performing an administrative role and not a clinical review, and it was not her responsibility to establish Mr A's past medical history.

25. The consultation note written by Ms F on 20 Month1 records: "[P]aper notes seen, no update of medications since 2003." This is incorrect as, since 2003, Mr A's medications had been updated to include, amongst other medication, Marevan (a brand name for warfarin) and aspirin. The transfer summary that was included with Mr A's paper notes, and reviewed by Ms F, lists Marevan (warfarin) as one of his long-term medications. On the second page, under "Long term classifications", it was noted that Mr A had undergone a mitral valve replacement.

26. In response to my provisional opinion, Ms F accepts that if she viewed the transfer summary, then the consultation note that she made was incorrect. However, Ms F stated that this was "a communication to the doctor of this relatively unusual situation and a signal that a full review of their medications should be undertaken at their first appointment". Ms F now questions whether she saw an old transfer summary for Mr A rather than the 2013 summary. Ms F said further that it is unlikely that she misread 2013 for 2003, as:

- it would be relatively unusual for a patient not to have had a review of his or her medication in over 10 years; and
- she made the note in Month1, and the medications had been reviewed in January 2013, so there would have been no need to place such an alert in the system.

27. Ms F said that it is possible that she was distracted at the time, as she is the only nurse working at the practice. She also noted the possibility that she saw an old patient transfer summary for Mr A.

28. Dr D stated that there were several errors in the way Medical Centre 2 provided Mr A's medical notes to his practice. Dr D stated:

> "[T]here was no 'hand-over' note;
>
> there was no 'current problem list' easily found in the notes received — either electronic or paper notes;
>
> the paper notes were in no particular order and voluminous; …"

29. Dr D told HDC that it appeared that when Mr A transferred back to Medical Centre 1 there was some complacency regarding the review of his medical notes, because he had been a patient at Medical Centre 1 previously. Dr D stated: "It was recognised that what occurred deviated from both our own expected standard and what should be the usual professional standard."

Medical Centre 2

30. Dr E stated that on 19 Month1, Mr A's computer notes were sent to Medical Centre 1 electronically (by electronic data interchange (EDI))[11] and the physical notes were sent by courier. The notes were not photocopied because of the size of the file, so Dr E sent the originals.

31. Dr E told HDC that he was disturbed to find that the notes sent electronically did not include the classification list, nor the medication list. It included only the consultation notes and any prescriptions given. However, Dr E noted that the couriered physical file contained all the relevant clinical information.

32. Dr E stated that Medical Centre 2 has changed the way in which it transfers clinical notes, and now uses GP2GP,[12] which allows clinical notes to be integrated into the new record. Dr E told HDC that this system is a big improvement from transferring notes by EDI.

33. Dr E told HDC that Mr A was aware of the reason he was being prescribed warfarin, and said he believed that Mr A was compliant with taking the prescribed amount.

First consultation, 26 Month1

34. On 26 Month1, Mr A attended a consultation with Dr D, presenting with acute toe pain consistent with gout, a skin rash, and a request to have his driver's licence restored. At this time, Dr D had an intern with him on a placement at Medical Centre 1.[13] Dr D told HDC that Mr A's case was a suitable opportunity for utilising the

[11] Electronic data interchange (EDI) is an electronic communication system that provides standards for exchanging data via any electronic means.
[12] Updated software that enables patients' electronic health records to be transferred directly and securely between GP practices.
[13] The Medical Council of New Zealand's publication *Education and Supervision of Interns* states: "Appropriate supervision will vary depending on the intern's competence in the procedure or skill. The intern will be working as part of a team and practising the skills with a level of support and responsibility that should be stimulating but safe for both patient and doctor."

services of the intern. Dr D stated that he explained to the intern that he should review Mr A's notes and assess him as a new patient. Dr D said that he briefed the intern to conduct a comprehensive medical history and a thorough clinical examination. The intern presented his clinical findings to Dr D.

35. In terms of Mr A's medical history, the intern did not elicit from Mr A that he had had cardiac surgery, and Mr A did not advise the intern that he was taking warfarin.

36. During the physical examination, the intern detected a mitral regurgitation murmur,[14] but did not detect a metallic "click", which is associated with a mechanical mitral valve. The intern did not record that Mr A had a sternotomy scar.[15] Dr D told HDC that the intern's findings were consistent with those aspects of Mr A's medical history with which he was already familiar. As such, Dr D said that he had no reason to doubt the intern's competence, and did not repeat the clinical examination. Dr D provided treatment that included a change in diuretic medication, and he declined Mr A's request regarding his driver's licence.

37. Dr D has accepted responsibility for the failure to establish Mr A's medical history correctly during the consultation on 26 Month1. Dr D advised HDC:

> "I must be clear that I do not … attribute this oversight to the trainee intern who reported the clinical history and his own assessment/findings to me. I accept I was responsible for [Mr A's] care and I am truly devastated by what happened."

Consultation, 27 Month1

38. On 27 Month1, Mr A returned to Medical Centre 1 for a review, as he had "flaked out" (felt faint) after taking his medications that morning. Dr D said that Mr A's blood pressure was significantly lower than the previous day, and he felt that this was the basis for Mr A's symptoms.

39. Dr D told HDC that at the end of the consultation Mr A asked him: "What must I do about the [w]arfarin?" Dr D initially told HDC that he had not been aware that Mr A was taking warfarin. Dr D later told HDC that he was aware from the electronic notes that Mr A was taking warfarin, but the reason was not readily apparent. Dr D said that he asked Mr A why he was taking warfarin, and that Mr A gave a vague reply about it being for his heart. Dr D told HDC that he assumed Mr A was taking warfarin for a cardiac rhythm disturbance. However, such a rhythm disturbance was not noted by the intern as a finding from the physical examination, nor was there any mention of it in Mr A's medical notes.

40. Dr D asked Mr A to describe what his warfarin tablets looked like, so that he could determine the current dose. Dr D stated:

> "[Mr A] was advised (and he agreed) that the [w]arfarin should be stopped as an interim measure until we had adequately controlled his current presenting

[14] See footnote 8 above. Mitral regurgitation is where blood leaks back through the mitral valve in the heart, as the valve does not close properly. When this occurs, a doctor is often able to hear a distinctive heart murmur on auscultation.
[15] A vertical scar along the sternum, which usually indicates previous cardiac surgery.

complaints and made arrangements for suitable monitoring of his INR[16] and his [w]arfarin dose. He was to remain on [a]spirin."

41. Dr D accepts that his advice to Mr A to discontinue warfarin did not meet appropriate standards.

Consultation, 12 Month2

42. On 12 Month2, Mr A presented to Medical Centre 1. Dr D recorded that Mr A's blood pressure had improved and was stable, and his gout symptoms had improved. Mr A had persistent peripheral oedema,[17] so Dr D increased the diuretic he had prescribed on 26 Month1. Dr D gave Mr A a medication card[18] and ordered blood tests (which were conducted). The blood tests did not include an INR. Dr D explained that this was because he believed Mr A had stopped taking warfarin.

43. Ambulatory blood pressure monitoring[19] was also performed, and the results, which were received on 18 Month2, showed an improved control with some low readings.

Consultation, 25 Month2

44. On 25 Month2, Dr D saw Mr A, who had presented with complaints of frequent urination during the night and heart palpitations. Mr A advised Dr D that he had consumed a large volume of Gatorade[20] before bed, and that he had taken four warfarin tablets, which had made him feel better. Dr D's notes record: "MUST DISPOSE OF WARFARIN AND NOT SELF-MEDICATE" (emphasis in original). Dr D told HDC: "I was extremely concerned by his self-medicating with warfarin. He admitted to doing this in the past as well when he had experienced palpitations."

45. Dr D recorded that Mr A's heart failure, gout and blood pressure had all improved. Dr D arranged for Mr A's medication regimen to be reviewed the following week, but did not arrange for Mr A's INR to be tested.

Hospital admission

46. On 2 Month3, Mr A's sons, Mr B and Mr C, were contacted by Medicare and advised that their father's medical alarm had been activated. Mr B went to check on his father and found him in a dazed and confused state. Mr B called an ambulance, and Mr A was taken to hospital and admitted into the intensive care unit.

47. Dr D advised HDC that on 3 Month3 he received an X-ray report from the intensive care unit at hospital. The X-ray showed sternal wires and a metallic mitral valve prosthesis. Dr D stated that he immediately undertook a review of Mr A's paper records and found a cardiothoracic discharge summary reporting his cardiac surgery. Dr D recorded in his notes: "X-ray report for ICU shows valve replacement! Not clearly documented in notes. **If had MVR** [mitral valve replacement] **then should have stayed on Warfarin!!!! Why was this not alerted?**" (emphasis in original).

[16] International normalised ratio. The INR is a test of blood clotting, which is primarily used to monitor warfarin therapy, where the aim is to maintain an elevated INR in a certain range, eg, 2.0 to 3.0.
[17] The swelling of tissues due to the accumulation of fluids.
[18] A card detailing Mr A's medications, the reason for taking them, and his allergies.
[19] A unit that takes blood pressure and heart rate measurements for a 24-hour period.
[20] A sports drink made up of a combination of water, carbohydrates, and electrolytes.

48. Dr D stated: "I was very distressed to read this report as had I been aware of it I would never have stopped his [w]arfarin — certainly not without consultation. Shortly thereafter I received a telephone call from the house surgeon in ICU and expressed the same response."

49. During his hospital admission, Mr A suffered several strokes, and died.

Changes made

50. Medical Centre 1 and Dr D advised HDC of the following changes made as a result of this complaint:

a) Clinical notes are now received by a new model, GP2GP format.

b) New patients are requested to bring their medications, including packages, with them to their first consultation. Dr D told HDC that this has improved documentation of current medications and allowed for closer questioning regarding the indications for the treatments.

c) New patients are now seen (where possible) with the paper notes to hand, so that these can be referred to during the consultation.

51. Dr D advised that he has a heightened awareness from this case, and will take extra caution to ensure that this is not repeated.

Medical Council competence review

52. The Medical Council of New Zealand (MCNZ) undertook a competence review of Dr D. Following that assessment, MCNZ ordered that Dr D undertake a 12-month educational programme.

Apology

53. Dr D told HDC: "I offer my sincerest condolences to the family of [Mr A] and understand their grief. I apologise unreservedly on behalf of myself and the Practice for any distress we may have caused."

Response to provisional opinion

54. Dr D, Medical Centre 1 and Mr A's family advised HDC that they have no further comments to make.

55. Medical Centre 2 stated:

> "I agree with your provisional opinion, and with Dr Maplesden that the electronic transfer was suboptimal. As stated previously, I was disturbed to find the classification list and medication list were not included in the electronic transfer. We should have verified for inclusion, despite any technical errors."

56. Medical Centre 2 also advised that it now codes warfarin in the 'Medical Warnings and Classification' section of the transfer summary.

57. Ms F's response to my provisional opinion has been incorporated below and into the 'information gathered' section where appropriate. Ms F's legal representative stated:

> "[I]f she has made an error, she sincerely apologises for this. She states that it is her usual practice that any records that she makes are accurate and is particularly concerned if in this instance she has misread the [patient transfer summary] and made an incorrect recording."

58. Ms F advised HDC that she will, with the assistance of the New Zealand Nurses Organisation, seek to establish more clarity with her employers regarding her role and the expectations of her within the practice.

Opinion: Dr D — Breach

Introduction

59. I note that my role does not extend to determining the cause of Mr A's death. I am primarily concerned with the standard of care provided by Dr D to Mr A, and whether that care accorded with accepted standards. Mr A was entitled to an appropriate standard of care, which included Dr D familiarising himself with Mr A's medical history and making appropriate treatment decisions. This opinion highlights the importance of getting the basics right to ensure that a good standard of clinical care is provided. This includes adequately assessing the patient's condition, taking account of the patient's history and his or her views, reading the patient's notes, and examining the patient as appropriate.[21]

60. Dr D was aware that Mr A had a complex medical history and had been treated in the past for cardiac issues. After Mr A transferred back to Medical Centre 1, Dr D had a duty to be vigilant when reviewing Mr A. Dr D missed several opportunities to investigate the reason Mr A was taking warfarin, including failing to review Mr A's medical record adequately, and failing to contact Mr A's previous GP for information. I find the pattern of suboptimal performance in relation to Mr A concerning.

Failure to provide services of an appropriate standard

Inadequate medical record review

61. When Mr A transferred back to Medical Centre 1 in Month1, as his GP, Dr D had a responsibility to review Mr A's medical records thoroughly to refamiliarise himself with his patient and to identify any changes to Mr A's medical history and medications. Medical Centre 2 transferred Mr A's notes both electronically and in paper form.

62. Dr D and Medical Centre 1 advised that it was their expectation that the practice nurse would review the paper notes and highlight any obvious medical history. However, that requirement was not included in the practice nurse job description. Dr D's practice nurse, Ms F, advised that she understood that her responsibility was to review the transfer summary but not to read or go through the paper notes, as this was carried out by the doctor. Ms F told HDC that her only involvement with Mr A was

[21] Medical Council of New Zealand, *Good Medical Practice*, Wellington, 2013.

reviewing his transfer summary and documenting a consultation note in his medical record. On 20 Month1, Ms F wrote in Mr A's medical record: "[P]aper notes seen, no update of medications since 2003." This was incorrect. Since 2003, Mr A's medications had been updated to include, amongst other medication, Marevan (a brand name for warfarin) and aspirin.

63. Dr D reviewed Mr A's medical records electronically on 20 Month1. Dr D told HDC that it was not apparent from the electronic records that Mr A had had a mitral valve replacement. Dr D said that the electronic notes he received from Medical Centre 2 lacked clear identification of the long-term conditions and medications. However, in the body of the computerised notes provided, there was reference to Mr A having had a valve replacement, being prescribed warfarin, and having INR monitoring. My expert clinical advisor, Dr Maplesden, advised that those references were not particularly obvious, especially if only a cursory review of the old notes was undertaken.

64. Dr D did not review the paper records at that time. He advised HDC that at Mr A's consultation on 26 Month1, he instructed a trainee intern to "review the notes and assess Mr A for discussion and consideration in conjunction with myself".

65. I acknowledge that the electronic copy of Mr A's medical notes provided by Medical Centre 2 was incomplete and had important documents missing. However, a complete set of paper notes was transferred to Medical Centre 1. I am concerned that the paper notes were reviewed by the intern, and that important information was not identified.

66. Dr Maplesden noted that with a brief perusal of the notes (less than three minutes), in the order provided, he was able to establish Mr A's history of valve surgery and his current medications, including warfarin. Dr Maplesden stated that it is not uncommon to receive clinical notes that are disorganised and require some work to determine whether there is reference to important clinical issues. In my view, it is clear that an adequate review of the notes did not occur in Mr A's case. Had Dr D reviewed Mr A's medical notes in any detail, he would have been alerted to important aspects of Mr A's medical history, including his mitral valve replacement, and the fact that he had been prescribed warfarin and was undergoing INR monitoring.

67. Dr D advised HDC that there appeared to be some complacency at Medical Centre 1 when reviewing Mr A's notes, as he had been a previous patient of the practice and there were already extensive records within the PMS. Dr D stated that "what occurred deviated from both our own expected standard and what should be the usual professional standard".

68. Dr D has accepted responsibility for the trainee intern's failure to establish Mr A's medical history correctly during the consultation on 26 Month1. Dr D advised HDC:

> "I must be clear that I do not … attribute this oversight to the trainee intern who reported the clinical history and his own assessment/findings to me. I accept I was responsible for [Mr A's] care and I am truly devastated by what happened."

69. In my view, Dr D had overall responsibility to ensure that an adequate review of Mr A's medical record was carried out. I consider that Dr D was responsible for the medical record review undertaken by the intern, and that his oversight of the intern was unsatisfactory. Furthermore, it was not acceptable in those circumstances for Dr D to rely on Ms F to review the records and identify important medical information.

Failure to investigate reasons for taking warfarin

70. On 27 Month1, Mr A attended a consultation with Dr D. At the end of his consultation he asked Dr D about the warfarin he was taking. In Dr D's initial response to HDC he said that he had not been aware that Mr A was taking warfarin. In a subsequent response, he said that he was aware from the electronic notes that Mr A was taking warfarin but the reason was not readily apparent.

71. Dr D said that when he asked Mr A the reason he was taking warfarin, Mr A answered with a vague reply and said it was for his heart. Dr D assumed Mr A was taking warfarin for a cardiac rhythm disturbance. Dr D asked Mr A to describe what his tablets looked like so that he could determine the current dose. Dr D stated:

> "[Mr A] was advised (and he agreed) that the [w]arfarin should be stopped as an interim measure until we had adequately controlled his current presenting complaints and made arrangements for suitable monitoring of his INR and his [w]arfarin dose. He was to remain on [a]spirin."

72. There is no record of any arrangements being made to monitor Mr A's INR.

73. As Mr A was unable to provide Dr D with clear reasons why he was taking warfarin, Dr D should have gone back and reviewed Mr A's clinical notes further. At the very least, Dr D should have contacted Dr E for further information. Dr Maplesden stated:

> "Once [Dr D] established [Mr A] was taking warfarin on 27 [Month1] (and was also on aspirin) it was important he established beyond doubt the clinical indications for this therapy in the patient in order to satisfy himself (and the patient) of the risks versus benefits of stopping the medication."

74. I agree. In my view, it was unacceptable for Dr D to have made an assumption about the reason Mr A was taking warfarin, and to have advised him to stop taking it.

75. On 12 Month2, Mr A presented to Dr D again. Dr D ordered blood tests but did not include an INR. Dr D explained that this was because he believed Mr A had stopped taking warfarin. In my view, this was a further missed opportunity where Dr D could have taken appropriate steps to clarify the reason why Mr A was taking warfarin.

76. On 25 Month2, Mr A was seen by Dr D with complaints of palpitations. Mr A advised Dr D that he had taken four warfarin tablets, which had made him feel better. Dr D's notes record: "MUST DISPOSE OF WARFARIN AND NOT SELF-MEDICATE" (emphasis in original). Dr D told HDC: "I was extremely concerned by his self-medicating with warfarin. He admitted to doing this in the past as well when he had experienced palpitations." This presented Dr D with yet another opportunity to take the necessary steps to establish the reason why Mr A had been prescribed warfarin.

77. Dr Maplesden stated that the accepted practice for a patient on maximal anticoagulant therapy (ie, warfarin and aspirin) is for all reasonable steps to be taken to "accurately confirm the clinical indications for such therapy … before any decision [is] made to advise permanent cessation of the therapy". Dr D told HDC that he accepts that he did not meet appropriate standards when he advised Mr A to discontinue warfarin.

78. In my view, there were a number of missed opportunities where Dr D should have investigated further the reason why Mr A had been prescribed warfarin. At no point did Dr D clarify the reason why Mr A was taking warfarin before advising him to stop taking it. That information was readily available by perusing the medical records. However, Dr D did not conduct a further and more thorough review of Mr A's medical records when faced with this uncertainty, nor did he contact Mr A's previous GP to question him about the warfarin. It is also surprising given that Dr D actually referred Mr A for coronary bypass grafting and a mitral valve replacement in 2008. I consider that there were missed opportunities to clarify the situation, which highlight an alarming pattern of suboptimal conduct.

Conclusion

79. Dr D did not take reasonable care and skill when he failed to review Mr A's medical records adequately, and when he failed to investigate adequately the reason why Mr A had been prescribed warfarin, before advising him to stop taking it. For these reasons, I consider that Dr D breached Right 4(1) of the Code.

Information

80. On 27 Month1, Dr D was informed by Mr A that he was taking warfarin. As noted above, Dr D advised Mr A to stop taking the warfarin. Dr D again advised Mr A to stop taking warfarin on 25 Month2. Dr D told HDC that had he been aware of Mr A's mitral valve replacement, he would never have stopped Mr A's warfarin, and "certainly not without consultation".

81. Dr Maplesden advised:

> "I would expect an awareness that a patient such as [Mr A] had several factors increasing his risk of stroke (even if his valve replacement surgery was unrecognised) and any decision regarding cessation of anticoagulant therapy therefore needed to be undertaken with careful consideration of risks and benefits and discussion of risks and benefits with the patient and possibly with a neurologist or cardiologist before any decision was made."

82. Mr A had a right to be informed about any risks and benefits of discontinuing warfarin before a decision to stop taking it permanently was made. Dr D did not provide that information to Mr A either on 27 Month1 or on 25 Month2 when discontinuing warfarin was discussed. In Mr A's circumstances, this was information that was crucial to him. Right 6(1) of the Code provides that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. In my view, a reasonable consumer in Mr A's circumstances would expect to receive information about the risks and benefits of discontinuing warfarin therapy. I find that by not providing that information, Dr D breached Right 6(1) of the Code.

Informed consent

83. As set out above, I do not consider that Mr A received sufficient information about the risks and benefits of stopping warfarin, and so was not in a position to make an informed choice and give informed consent to the discontinuation of that treatment. Accordingly, I find that Dr D also breached Right 7(1) of the Code.

Opinion: Medical Centre 1 — Adverse comment

84. I am concerned that there was lack of clarity among staff about whose responsibility it was to review which aspects of a new patient's medical record. Dr D and Medical Centre 1 expected the practice nurse to carry out a review of patients' paper records. However, Ms F's job description did not list this as being one of her responsibilities, nor did Ms F understand this to be her responsibility. Instead, Ms F advised that her role was to check the transfer summary.

85. Dr Maplesden advised:

> "I would expect a practice to have a formal process for handling of old notes received, and for this process to be familiar to all staff … Best practice would be for this process to be recorded in a written document and to be part of the orientation of all new staff (administration, nurses and doctors)."

86. While not having a formal written policy, Medical Centre 1 advised HDC of the process it had in place. However, staff were not clear about that process. If the review of some aspects of new patients' records is to be carried out by the nurses at Medical Centre 1, I consider it essential that this be made very clear to the nurses (for example, by recording this task in the job description) and appropriate training should be provided. Ensuring that a patient's medical record is handled and reviewed carefully is fundamental to providing good clinical care. It also ensures that patients can have an efficient and safe transition between two practices and receive continuity of care.

Opinion: Ms F — Adverse comment

87. I accept that it was not Ms F's responsibility to review new patients' medical records thoroughly. However, Ms F understood that it was her responsibility to review the patient's transfer summary and ensure that any alerts for immunisations, allergies and recalls arising from the transfer summary were set up.

88. In response to my provisional opinion, Ms F stated that it was her role to ensure that the patient's medications that were already on the electronic system were consistent with the medications listed on the paper transfer summary. Ms F cannot recall whether Mr A's medications already appeared on the electronic system at the time she viewed the paper transfer summary.

89. Ms F accepts that if she viewed the transfer summary, then the consultation note that she made was incorrect. Ms F said that it is possible that she was distracted at the time as she is the only nurse working at the practice. She also noted the possibility that she saw an old patient transfer summary for Mr A.

90. Ms F reviewed Mr A's transfer summary and recorded in a consultation note that Mr A's medications had not been updated since 2003. Irrespective of whether Ms F reviewed the wrong transfer summary or was distracted at the time, the consultation note was incorrect, and I remind Ms F of the importance of accurate record-keeping.

Opinion: Medical Centre 2 — Adverse comment

Medical record transfer

91. Dr E acknowledged that the electronic copy of Mr A's medical notes that was emailed to Medical Centre 1 was missing a number of important documents, including a long-term classification list and a long-term medication list. I agree with Dr Maplesden that the electronic notes provided to Medical Centre 1 were suboptimal. I consider that it would have been prudent for Medical Centre 2 to have provided the medical records to Medical Centre 1 in such a way as to ensure that the key documents could be easily identified. I am pleased that Medical Centre 2 has updated its procedure for transferring electronic copies of clinical notes.

Recommendations

92. In response to the proposed recommendations in my provisional opinion, Dr D provided a written apology for forwarding to Mr A's family.

93. I note that Dr D has undergone a Medical Council of New Zealand competence review and that, following the assessment, MCNZ ordered that Dr D undertake a 12-month educational programme. I recommend that, on completion of the educational programme, MCNZ consider whether a further review of Dr D's competence is warranted.

94. I recommend that Dr D review the relevant aspects of his practice in light of this report, and provide evidence to this Office of this review and the subsequent changes he has made, within one month of the date of this report.

95. I recommend that Medical Centre 1 arrange an independent audit of patients who returned or transferred to the practice over a 12-month period, to ensure that on transfer all the medical records were reviewed adequately. The results of the audit are to be provided to HDC within six months of the date of this report.

96. I recommend that Medical Centre 1 provide to HDC evidence of further training provided to its staff about transferring and reviewing medical records, within one month of the date of this report.

Follow-up actions

97.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, the Royal New Zealand College of General Practitioners, and the District Health Board, and they will be advised of Dr D's name.

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

Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden, on 27 November 2013, with an addendum dated 20 January 2014:

"1. Thank you for providing this file for advice. I have reviewed the available information: complaint from [Mr B] and [Mr C], sons of [Mr A] (dec); response from [Dr D]; limited GP notes ([Medical Centre 1]); [Hospital] clinical notes. I understand further GP notes are being obtained from either [Dr D] or [Mr A's] previous provider. I require notes from the time of [Mr A's] cardiac surgery (some time in 2008). [Mr A's] sons' complaint [is] that [Dr D] stopped their father's warfarin medication in [Month2] without being aware of his past medical history (mechanical mitral valve replacement and previous stroke) which placed him at high risk of stroke without the medication. Sadly, [Mr A] suffered a stroke about two weeks after the warfarin was stopped and succumbed to the effects of the stroke a few days later.

2. [Dr D] has provided a comprehensive response which includes the following points:

(i) [Mr A] had been a patient at [Medical Centre 1] from April 2000 to February 2008 apart from a brief period in 2006. Between February 2008 and [Month1 2013] he was attending another practice prior to transferring back to [Medical Centre 1]. Old notes were requested and 'hard copy' notes were reviewed by a practice nurse on 20 [Month1]. On reviewing the notes, it was not readily apparent that [Mr A] had had cardiac surgery including valve replacement in 2008 and this information was not captured following the notes review. It is not clear whether there was also a transfer of electronic notes — this will become apparent when the additional notes I have requested are reviewed.

(ii) From his previous contact with [Mr A], [Dr D] was aware he had a history of poorly controlled hypertension, ischaemic heart disease with previous MI and severe mitral valve prolapse, and stroke in 2005 from which [Mr A] had made a good recovery. At the time of his transfer away from the practice in 2005, [Mr A] had been referred for coronary artery bypass grafting (CABG) and mitral valve repair. [Dr D] was also aware that [Mr A] had had compliance issues with medication in the past.

(iii) [Mr A] was seen at [Medical Centre 1] on 26 [Month1] — the first consultation since his transfer back to the practice. He was reviewed initially by a trainee intern being supervised by [Dr D], with the instruction being to treat [Mr A] as a 'new patient' implying past medical history should be reviewed as well as the presenting symptoms. There was no history of cardiac surgery obtained, and the regular medications [Mr A] was asked to present did not include warfarin. The presenting symptoms were acute toe pain consistent with gout, a skin rash, and a request to have his driving license restored. [Mr A's] symptoms and clinical findings were presented by the intern to [Dr D], and [Dr D] had no reason to doubt the competency of the intern. The intern had detected a murmur of mitral regurgitation but had not detected the metallic 'click' associated with a

mechanical mitral valve, and he did not mention the presence of a sternotomy scar. However, his findings were consistent with those aspects of [Mr A's] medical history [Dr D] was already familiar with, and he saw no reason to repeat the clinical examination. Treatment was provided including a change in diuretic medication and [Dr D] declined the request regarding the drivers license until clinical follow-up had taken place.

(iv) On 27 [Month1] [Mr A] returned for review following an apparent syncopal episode after taking his medications that morning. His blood pressure was significantly lower than previously (although now well controlled) and it was felt this was the basis for his symptoms. At the end of the consultation [Mr A] asked *what must I do about the warfarin.* [Dr D] had not been aware [Mr A] was taking this medication, and when asked the reason for it [Mr A] gave *the vague reply it was for his heart*. [Dr D] assumed [Mr A] was taking warfarin for a rhythm disturbance. He determined the current dose from [Mr A's] description of his tablets ([Mr A] did not know the milligram dosage). *He was advised (and he agreed) that the warfarin should be stopped as an interim measure until we had adequately controlled his current presenting complaints and made arrangements for suitable monitoring of his INR and his warfarin dose. He was to remain on Aspirin.*

(v) [Dr D] describes the process used at his practice for monitoring of INR in patients taking warfarin.

(vi) [Mr A] presented next on 12 [Month2] with a medication query. His blood pressure was improved and stable and his gout symptoms had improved. Diuretic was increased in view of persistent peripheral oedema. A medication card was completed. Blood tests were taken but did not include an INR as [Dr D] believed [Mr A] had stopped the warfarin as previously instructed. Ambulatory blood pressure monitoring was performed with result (18 [Month2]) showing improved control with some low readings.

(vii) On 25 [Month2] [Mr A] was seen with complaints of nocturia. He reported he had had an episode of palpitations *and that he had taken an additional 4 warfarin tablets and had felt better.* [Dr D] was concerned at [Mr A's] self-adjustment of warfarin dose which he had apparently done on previous occasions. Although not stated, it is implied the recommendation to stop the warfarin was repeated at this point. [Mr A's] heart failure, gout and blood pressure had all improved. Review was arranged for a week's time for review of his medication regime.

(viii) On 3 [Month3] [Dr D] received an X-ray report from [the] ICU which showed sternal wires (indicating previous sternotomy) and a metallic mitral valve prosthesis. [Dr D] reviewed [Mr A's] old notes and found a cardiothoracic discharge summary reporting his cardiac surgery. *I was very distressed to read this report as had I been aware of it I would never have stopped his warfarin — certainly not without consultation.*

(ix) [Dr D] describes the results of a literature search on risk of thrombosis associated with mitral valve replacement, and risk of bleeding on warfarin. He notes there is significant reduction in risk of thrombosis and risk of major bleeding using aspirin alone, but the reduction in risk of thrombosis is significantly higher using warfarin (as is the risk of bleeding). This has been discussed in some detail later in this report. [Dr D] quite accurately states there is a risk of thrombosis even when the patient is taking aspirin and warfarin.

3. Current ([Dr D]) clinical notes review (and see Addendum)

(i) There is a nurse entry in the [Medical Centre 1] notes dated 20 [Month1]: *paper notes seen, no update of medications since 2003.*

(ii) Clinical notes for the consultation of 26 [Month1] are consistent with the response. The intern notes are of reasonable quality and, when combined with [Dr D's] notes, give a good summary of [Mr A's] presentation, clinical findings and management plan. There is no mention of sternotomy scar or metallic heart sounds. Blood tests were ordered and review arranged in a week. Some medical history has been coded (presumably by the intern): congestive heart failure, gout, hypothyroidism and gastro-esophageal reflux. [Dr D] has included *Known IHD, previous MI with severe MR, in CHF…* there is no mention of warfarin.

(iii) Clinical notes for the consultation of 27 [Month1] are of a good standard and are consistent with the response. They include the comment *Apparently on warfarin as well — notes unclear re testing. Apparently on 6mg daily. Stop — at least for time being as risk of significant interactions is present — gout Rx* ([Mr A] had been prescribed a short course of naproxen), *Spironolactone, Aspirin etc.*

(iv) Notes for 12 [Month2] begin *Came to find out what medications are for. Friend is on bisoprolol … discussed CHF and management goals. Hand written drug card provided …* repeat bloods were taken [no blood results on notes currently provided]. On 13 [Month2] [Dr D] has recorded *will need to be on Allopurinol — urate 0.71. Discuss at review.* Results of ambulatory blood pressure recordings are summarised in an entry on 18 [Month2].

(v) Notes for 25 [Month2] refer to [Mr A's] nocturia and palpitations — *took 4 warfarin and felt better!!!!! ... P72 SR BP: 135/85mmHg … Discussed. Advised re Rx. Will need to be on Allopurinol … MUST DISPOSE OF WARFARIN AND NOT SELF-MEDICATE.*

(vi) On 3 [Month3] [Dr D] has recorded *X-ray report for ICU shows valve replacement! Not clearly documented in notes.* ***If had MVR*** [mitral valve replacement] ***then should have stayed on warfarin!!! Why was this not alerted?*** *Searched through paper notes — had CABGx3 + MVR 02/09/2008. Letter to ICU.*

(vii) [Hospital] notes indicate [Mr A] was admitted on 1 [Month3] with a history of headache and confusion after being found at home by family who had been unable to contact him. ED MO notes refer to a medical history of CABG only, and heart sounds are recorded as normal with no reference to prosthetic sounds.

Admitting MO notes *very little history from patient* but chest X-ray had by this stage shown the presence of a mechanical mitral valve prosthesis. Admitting MO assessment findings include reference to metallic heart sounds and systolic murmur. Comments include *No recent drug changes apart from discontinuation of the warfarin by the GP despite MVR …* Brain CT showed right temporal lobe changes thought to be due to infarction or encephalitis but later evolving to be consistent with infarction. [Mr A] developed signs of aspiration pneumonia. Following a period in ICU, and after confirmation of a large cerebral infarction with poor prognosis for recovery, it was decided in consultation with family members to provide [Mr A] with comfort cares only. He was extubated [and died a short time later].

(viii) On 3 [Month3] a [Hospital] MO has recorded a conversation with [Dr D] regarding the rationale behind cessation of [Mr A's] warfarin including … *[Mr A] expressed no reason when asked why he was on warfarin but did admit to erratic self-dosing at other points. Overall [Mr A] was described as a poor historian with poor memory and at that time without knowledge of MVR, felt risks of bleeding was much greater than continuing warfarin → changed to aspirin* [in fact [Mr A] was already taking aspirin when he transferred to [Medical Centre 1]].

4. What follows is very much a retrospective discussion as [Dr D] was unable to accurately weigh up risks of bleeding versus thrombosis in [Mr A] at the time he advised cessation of warfarin because he was not aware of all of [Mr A's] relevant risk factors (in particular the mechanical mitral valve replacement). However, it may give some context to the overall clinical rationale adopted by [Dr D] when he recommended [Mr A] stop his warfarin.

(i) A large meta-analysis referred to in a 2008 review article[1] looked at the risks of thromboembolism in patients with mechanical heart valves. *This study included 13,088 patients studied for 53,647 patient-years. The incidence of valve thrombosis was 1.7% per year (in the absence of anticoagulation) and the incidence of major embolism (death, residual neurological deficit or peripheral ischaemia requiring surgery) was 4% per year. These risks are influenced by the position and type of mechanical valves. Mitral valves have a fivefold increase in the risk of valve thrombosis and 1.5-fold increase in the risk of major embolism when compared with aortic valves. Ball and cage valves (e.g. Starr-Edwards©) have approximately twice the risk of embolism as compared to bileaflet valves (e.g. CarboMedics©).*

(ii) *Aspirin reduces the risk of valve thrombosis from 1.7% to 1.0%. Anticoagulation reduces it further to 0.2%. Use of aspirin reduces the risk of major embolism from 4% to 2.2% per year, while warfarin reduces it to 1% per year. In one case-series of 1,608 anticoagulated patients followed during 6,475 patient-years in The Netherlands, the overall frequency of thromboembolic events was 0.5% per year with mechanical aortic valves, 0.9% per year with mechanical mitral valves, and 1.2% per year with both mitral and aortic valves. The overall*

[1] McKenzie D et al. The Management of Patients With Mechanical Heart Valves and Intracerebral Haemorrhage. Br J Cardiol. 2008;15(3):145–148.

frequency of thromboemboli was 0.5% per year with bileaflet valves, 0.7% per year with tilting disk valves (e.g. Medtronic Hall©) and 2.5% per year with caged ball and caged disk valves.

(iii) Another literature review article on prosthetic heart valves stated[2]: *Systemic embolization (predominantly cerebrovascular events) occurs at a frequency of approximately 0.7 to 1.0 percent per patient per year in patients with mechanical valves who are treated with warfarin. In comparison, the risk is 2.2 percent per patient per year with aspirin and 4.0 percent with no anticoagulation. Within this group, those with mitral valve prostheses are at approximately* ***twice*** *the risk compared to those with aortic valve prostheses ... most cases of valve thrombosis (70 percent in one series) occur during periods of inadequate anticoagulation.*

(iv) *Recommendations for warfarin and aspirin (or other antiplatelet agent) in patients with mechanical heart valves have been published by three major societies: the American College of Cardiology/American Heart Association (ACC/AHA) in 2006, the Ninth American College of Chest Physicians (ACCP) guidelines on antithrombotic therapy in 2012, and the European Society of Cardiology (ESC) in 2012. The three guidelines recommended that all patients with mechanical prosthetic valves be treated with warfarin. Although there were some differences in detail, all recommended that the intensity of warfarin therapy varies with the thrombogenicity of the valve, the presence or absence of other risk factors for thrombus formation (eg, atrial fibrillation, low left ventricular ejection fraction, prior thromboembolism), and/or the site of valve placement (aortic or mitral). Higher values of INR are associated with an increased risk of bleeding*.

(v) With respect to interruption of anticoagulation for surgery in patients with prosthetic heart valves: *In an individual patient, the thromboembolic risk must be balanced against the bleeding risk, which largely depends upon the nature and urgency of the surgery. Most patients tolerate short-term interruption of anticoagulation without valve thrombosis or thromboembolism. This was illustrated in a report of 159 patients who underwent a total of 180 noncardiac operations with mitral or combined mechanical valves. Oral anticoagulants were discontinued one to three days preoperatively and for one to seven days after surgery. There were no perioperative thromboembolic events.*

(vi) A validated tool can be used to assess risk of major bleeding on anticoagulation therapy (the HAS-BLED score[3]) although it is used primarily for assessment of risk versus benefit of anticoagulation in patients with atrial fibrillation. Nevertheless, noting [Mr A's] risk factors of impaired renal function, hypertension history, age ≥ 65 years and [Dr D's] impression that [Mr A's] intermittent and self-determined use of warfarin (and concurrent use of aspirin) may predispose to bleeding, a score of 4 is obtained which is interpreted as a bleeding risk of 8.9% in one validation study and 8.70 bleeds per 100 patient-

[2] Aurigemma G et al. Antithrombotic therapy in patients with prosthetic heart valves. Uptodate. Last updated September 2013. www.uptodate.com
[3] See: http://www.mdcalc.com/has-bled-score-for-major-bleeding-risk/

years in another validation study. The risk of major bleeding includes, but does not equate to, risk of a haemorrhagic stroke.

5. Comments

(i) The process used by [Medical Centre 1] to transfer relevant medical history and data from old 'hard copy' notes to their electronic system is apparently suboptimal and should be reviewed by the practice. The process undertaken did not detect [Mr A's] relevant past history of CABG and valve replacement, or that he was taking warfarin. While it may well be there was sub-optimal documentation by [Mr A's] previous provider in this regard (and this is yet to be determined), [Dr D] was able to confirm the history on later perusal of the notes. I have noted marked variation in the standard of medical history coding and even recording of regular medications as such in clinical notes I have examined as part of my HDC work. The problem is even more apparent in the few 'paper' notes I have reviewed. I do not think it reasonable to rely solely on a list of patient codes or medication list when transcribing 'old notes' for a new patient. A combination of thorough review of the notes combined with direct questioning of the patient regarding medical history is an acceptable process but was deficient in this case.

(ii) [Mr A] was reviewed by a trainee-intern (TI) on 26 [Month1]. This was a reasonable proposition and I have no reason to believe the supervision provided by [Dr D] was inadequate. The diagnostic formulation and associated management plan were clinically sound (acknowledging neither the TI nor [Dr D] was aware [Mr A] was taking warfarin). The TI detected a cardiac murmur but did not detect metallic heart sounds. However, the ED MO at [the hospital] did not detect metallic heart sounds (or obtain a history of valve replacement) — the abnormal heart sounds becoming evident only after the valve replacement history was established. I must assume therefore that it was not immediately obvious [Mr A] had had a valve replacement. The presence of a sternotomy scar would normally be noted at the time of heart auscultation but is not pathognomonic for valvular surgery — it is most commonly undertaken for CABG ([Mr A] had both processes performed). What is unclear is whether the TI asked [Mr A] what was undertaken at the time of sternotomy, or whether he assumed [Mr A] had had only a CABG (or was told this). Either way, the relevant history of cardiac surgery was not recorded which was a departure from expected practice for management of a 'new patient' as the TI had been instructed to regard [Mr A].

(iii) The failure by the TI, and the nurse reviewing [Mr A's] old notes, to establish [Mr A's] history of previous cardiac and valve surgery was a significant factor influencing [Dr D's] later management decisions. A further relevant factor was [Mr A's] apparent vagueness and/or lack of understanding regarding his previous surgery and the rationale for his taking warfarin (and the importance of notifying any health provider that he was taking this drug). This could reflect ongoing impairment in [Mr A's] cognitive function or suboptimal education at the time of surgery and following commencement of warfarin. If there was some doubt regarding [Mr A's] understanding of his surgery and medication (and perhaps as best practice in any case), it might have been appropriate for his providers at the

time to equip him with a Medic-alert bracelet recording both his warfarin usage (which would generally be life-long) and his prosthetic valve.

(iv) Additional comments will be provided once additional relevant notes are received including: [Dr D's] failure to adequately assess [Mr A's] stroke risk or question why he was on maximal anticoagulation therapy (aspirin + warfarin) normally reserved for very-high risk (of stroke) situations; realistic assessment of risk of bleeding; ability for [Mr A] to make an informed choice regarding cessation of his medication; warfarin monitoring; importance of determining precise stroke risk in the presence of a vague historian; retrospective comment regarding bleeding versus thrombosis risk.

Addendum 20 January 2014

6. On 9 December 2013 [Dr D] corresponded with HDC emphasising that he had received a disorganised medical file from [Dr E] in which there was no easily accessible 'current problem' list, nor was any formal handover letter provided. He emphasised also that [Mr A] was an unreliable historian.

7. [Dr E] responded to HDC confirming he had sent computerised notes (transferred electronically via EDI) and a hard copy of old clinical notes was couriered to [Dr D] on 19 [Month1]. On reviewing the notes sent electronically he has since discovered the classification and medication list (both of which were up to date and included reference to [Mr A's] warfarin therapy and valve replacement) were not included in the electronically transferred notes due to an administrative error. The practice has since changed the method by which notes are transferred electronically (GP2GP) to reduce the risk of such an omission in the future. However, originals of all outpatient and hospital discharge notes were included in the couriered parcel of notes, as was [Mr A's] warfarin monitoring documentation. [Dr E] states [Mr A] was aware of the reason he was taking warfarin and had been largely compliant with dosage instructions since commencing the medication in 2008 with a majority of his INR recordings being within the therapeutic range. [Dr E] uses a manual register for recording INR doses and instructions and this was part of the 'hard-copy' notes couriered to [Dr D]. [Dr E] stated [Mr A] did not have a Medicalert bracelet as far as he knew.

8. I have reviewed the computerised consultation notes provided by [Dr E]. These confirm reference to valve replacement in the Long Term Classifications (2 September 2008) and listing of warfarin (as Marevan) in the Long Term Medication list. However I note the information in this form was not available to [Dr D]. On reviewing the computerised notes sent to [Dr D] (last clinical entry 13 [Month1]) I agree with [Dr D] that it is not readily apparent from these records, in the absence of a list of long-term medications and conditions, that [Mr A] was taking warfarin or that he had a previous valve replacement. The first reference to a prescription for warfarin is 11 December 2012 as a 'stand alone' entry, the drug not present when [Mr A] has received repeats of his other 'usual' medications. However, there are frequent references to requests for Prothrombin Ratio which would generally indicate warfarin monitoring, and there are multiple INR results on file, the most recent being 16 January 2013 (2.3). The computerised notes refer

predominantly to [Mr A's] ongoing problems of congestive heart failure and gout. On 2 September 2008 is an entry *Dx: Un-classified Problem — MITRAL VALVE REPLACEMENT* and in consultation notes through 2008 there is reference to [Mr A] being investigated for, and awaiting, valve replacement surgery. In the file are various referral request letters from [Dr E] after 2008 which include a list of long-term conditions, one of these being *MITRAL VALVE REPLACEMENT*. There is also a 'History' list which records only minor conditions, and an 'Alert' list which does not refer to [Mr A's] warfarin therapy.

Comment: I conclude that the computerised notes provided to [Dr D] were suboptimal in that a Long Term Classification list and Long Term Medication list were not included in the electronic transfer, even though the lists had been completed. This omission was confirmed by [Dr E] and his procedure for electronic transfer of notes has been changed. There was reference, in the body of the computerised notes provided, to [Mr A] having had a valve replacement and to him being prescribed warfarin and undertaking INR monitoring. However, these references were not particularly obvious particularly if only a cursory review of old notes was undertaken. [Dr E] has since improved the electronic notes transfer process. If he continues with a manual method for recording warfarin therapy, I think it is important he consider documenting in a prominent place on the computer record (under 'Patient Alert' or 'Long Term Conditions') that the patient is receiving such therapy.

9. I have reviewed the 'hard copy' notes provided to [Dr D], evidently in the format (order) received by him. Initially there are copies of [Mr A's] old computerised notes relating to his care under [Dr D] from 2000–2008. There is then a copy of [Mr A's] current electronic 'front page' which does include his long-term medications (including warfarin), classifications (including mitral valve replacement) and allergies. This page should ideally have been at the front of the notes supplied. There are then some miscellaneous pages in no particular order, including an INR monitoring sheet from 5 February 2010 to 5 May 2011. The current warfarin monitoring sheet (showing relatively stable INR although towards the low end of the desired range) is out of order about half way though the pile of notes. Preceding this are multiple hospital clinic and discharge letters many of which refer to [Mr A's] cardiac surgery and warfarin therapy (along with his other regular medications). However, a letter from the Cardiology Clinical Nurse Specialist dated 17 December 2010 did not include warfarin in the listed current medications prior to 2000.

Comment: I agree with [Dr D] that the 'hard copy' notes provided were somewhat disorganised and a formidable appearing pile. However, with a brief perusal of notes in the order provided (less than three minutes) I was able to establish [Mr A's] history of valve surgery and his current medications, including warfarin. As [Dr D] has noted, it is not uncommon to receive clinical notes (particularly hard copy notes) which are disorganised and require some work to determine whether there is reference to important clinical issues. Practices have various methods to ensure no important clinical data is overlooked. Using GP2GP, there is usually reasonable automatic integration of clinical notes provided by the previous GP,

although this has been a relatively recent development. However, because the quality of clinical documentation can vary significantly between providers (and GP2GP is PMS dependent) it is also vital that the patient is questioned regarding relevant clinical history (although it is not uncommon for patients to be somewhat vague about various aspects of their clinical care) and that any additional historical notes provided, particularly those relating to hospital admissions or specialist assessments, are reviewed in a timely fashion. This latter step is important to ensure any history gained from the patient is accurate and complete, and to ensure any notes transferred electronically and integrated into the PMS are also complete. While the failure by [Mr A] to mention he was on warfarin or had had cardiac surgery is somewhat surprising given [Dr E's] comments, it might be regarded as a mitigating factor, together with the quality of information received by [Dr D] from [Dr E], when considering this case. However, I think it is clear there was inadequate review of the clinical information available to [Dr D] by him, either as a routine practice on receiving old notes but certainly once it was established there was a lack of clarity over the reason for [Mr A] being anti-coagulated, even if that information required a modest amount of time to extract. Once [Dr D] established [Mr A] was taking warfarin on 27 [Month1] (and was also on aspirin) it was important he established beyond doubt the clinical indications for this therapy in the patient in order to satisfy himself (and the patient) of the risks versus benefits of stopping the medication. This would have taken a three minute perusal of the old notes or a phone call to [Dr E]. A phone call to [Dr E] or the laboratory, or a review of the INR results provided electronically, would have given an indication of [Mr A's] historical compliance with his warfarin (on the basis of INR recordings). There were no symptoms or signs recorded on 27 [Month1] to suggest hypercoaguability secondary to warfarin overdose, and no INR was performed to determine current INR/warfarin compliance and to aid in the decision making process regarding risk versus benefit of continuing warfarin. There is nothing to suggest from the clinical notes that the risks versus benefits of stopping warfarin were discussed with [Mr A] on 27 [Month1] or 12 [Month2], and an adequate discussion was precluded by the failure to accurately establish [Mr A's] cardiac history — that history being pivotal to this decision making.

10. I conclude that [Dr D] advised [Mr A] to stop taking warfarin on 16 [Month1] and again on 25 [Month2] without ensuring he had adequate information on which to base such a decision. This precluded him from having an adequate discussion with [Mr A] regarding risks and benefits of ceasing the medication and therefore for him to make an informed choice. While [Mr A's] vagueness and the suboptimal state of the clinical notes received were mitigating factors, in some ways this heightened the need for [Dr D] to seek the information required before advising [Mr A], and such information was available in the notes on file — while not immediately evident the information was not unduly difficult to acquire. The consultation notes dated 27 [Month1] did not indicate there was an urgent need to stop warfarin permanently. There was certainly adequate time following this consultation for [Dr D] to perhaps advise temporary cessation of warfarin while INR was ordered and previous clinical notes reviewed, and for this information to direct further management of [Mr A's] warfarin therapy. Instead, the order to stop

warfarin was given on 27 [Month1] on the basis of vague information from [Mr A] (which was not consistent with the observation he had been on maximal anticoagulant treatment of aspirin and warfarin) and the advice reiterated on 12 [Month2] without any further attempts to clarify [Mr A's] clinical situation. I think this represents a moderate departure from expected practice despite the mitigating factors discussed above — the expected practice being that in a patient on maximal anticoagulant therapy all reasonable steps should have been taken to accurately confirm the clinical indications for such therapy (so benefits and risks of permanent cessation of therapy could be accurately assessed) before any decision was made to advise permanent cessation of the therapy, and that the benefits and risk of cessation were discussed with the patient before a decision was made to permanently stop therapy. The degree to which the decision to stop warfarin contributed to [Mr A's] subsequent demise is difficult to quantify — while there was a temporal relationship between medication cessation and the stroke, as discussed in section 4 while anticoagulant therapy reduces the risk of stroke it does not remove it completely."

Further expert advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden, on 26 May 2014:

"1. Thank you for the request that I provide further clinical advice in relation to this case. I have reviewed the response from [Dr D] (dated 13 March 2014) to my original advice. I have reviewed Medical Council of New Zealand (MCNZ) documentation including correspondence between MCNZ and [the] CMO [of the] DHB, and between [the CMO] and [Dr D]. I have reviewed relevant practice policies from [Medical Centre 1].

2. The practice policies are robust and consistent with expected standards. The changes in process related to handling of medical notes for new patients are appropriate and should very much reduce the risk of an incident similar to that in question being repeated. All providers should be aiming to keep significant medical history and long-term medication lists updated and prominent in the clinical file.

3. The MCNZ correspondence does not [add] any additional factual information to that already obtained during the HDC review.

4. In his response, [Dr D] discusses the lack of evidence for clinical benefit from the combination of aspirin and warfarin. He states: *I can find no indication for the combination as a consequence of severity of underlying conditions. In truth the combination bears little relevance to this matter but may be an interesting academic discussion.* An updated review article on the use of combination anticoagulant therapy for patients with mechanical valve replacement[4] includes: *Support for the addition of antiplatelet therapy to anticoagulant (VKA) therapy rather than anticoagulation alone in patients with mechanical valves comes from randomized trials. These results were summarized by two meta-analyses that each*

[4] Aurigemma G et al. Antithrombotic therapy in patients with prosthetic heart valves. Uptodate. Last updated December 2013. www.uptodate.com

found that combined antiplatelet and anticoagulant therapy reduced the risk of mortality as well as the risk of thromboembolism as compared to anticoagulant therapy alone[5,6,7]*. The latter of these found moderate-quality evidence that combined therapy versus anticoagulation alone significantly reduced the mortality rate (OR 0.57, 95% CI 0.42-0.78). In addition, the analysis found high-quality evidence of significantly reduced thromboembolism (OR 0.43, 95% CI 0.32–0.59) and moderate-quality evidence of increased risk of major hemorrhage (OR 1.58, 95% CI 1.14–2.18) with combined therapy versus anticoagulant only therapy.* I think [Dr D] is right that there is little evidence for benefit of combination therapy in situations other than mechanical valve replacement, but I believe the very fact [Mr A] was taking both medications should have alerted [Dr D] to the possibility of a specific condition in which such a combination was recommended (that being valve replacement) and it is therefore of more than academic relevance to this case.

5. [Dr D] assumed [Mr A] was taking warfarin for a rhythm disturbance, presumably atrial fibrillation, yet this diagnosis was not included in the medical notes nor was it noted on [Mr A's] physical examination. However, even if [Mr A] had been taking warfarin because of atrial fibrillation, he also had a personal history of previous thromboembolic stroke, heart failure and hypertension which placed him at increased risk of thromboembolic stroke compared with isolated atrial fibrillation — this increased risk confirmed on objective scoring using a validated tool (CHA_2DS_2-VASc Score for Atrial Fibrillation Stroke Risk[8]). While I would not expect a GP to routinely use the CHA_2DS_2-VASc or HAS-BLED (see section 4(vi) of my original advice) scoring tools, I would expect an awareness that a patient such as [Mr A] had several factors increasing his risk of stroke (even if his valve replacement surgery was unrecognised) and any decision regarding cessation of anticoagulant therapy therefore needed to be undertaken with careful consideration of risks and benefits and discussion of risks and benefits with the patient and possibly with a neurologist or cardiologist before any decision was made. I would not regard this as 'benefit of hindsight' comment. As discussed in detail in my original advice, there was no apparent urgency to make a decision regarding cessation of therapy, and [Dr D] did not take appropriate steps (review of INR history and current INR) to confirm his suspicion or risks of [Mr A's] suboptimal compliance with his anticoagulant treatment. As also previously discussed, [Dr D] did not take adequate steps to confirm the clinical indications for [Mr A's] anticoagulant therapy before advising its cessation. I remain of the view that [Dr D's] management of [Mr A] represents a moderate departure from expected practice and there is nothing presented in the additional information provided that alters this opinion."

[5] Whitlock RP, Sun JC, Fremes SE, et al. Antithrombotic and thrombolytic therapy for valvular disease: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141:e576S.
[6] Massel DR, Little SH. Antiplatelet and anticoagulation for patients with prosthetic heart valves. Cochrane Database Syst Rev 2013; 7:CD003464.
[7] Little SH, Massel DR. Antiplatelet and anticoagulation for patients with prosthetic heart valves. Cochrane Database Syst Rev 2003; CD003464.
[8] http://www.mdcalc.com/cha2ds2-vasc-score-for-atrial-fibrillation-stroke-risk/

Further expert advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden, on 6 November 2014:

> "1) On 26 [Month1] the medical student intern conducted a physical assessment of [Mr A] and reported back to [Dr D]. With regards to the physical assessment, what level of supervision would you expect [Dr D] to have provided?
>
> This depends somewhat on the clinical context. If the patient was unwell and the trainee intern detected abnormal findings, or if the trainee intern's findings appeared to be inconsistent with the clinical presentation (either presence or absence of specific clinical signs), I would expect the supervising doctor to 'recheck' relevant aspects of the examination. In other cases the supervising doctor might be aware the patient has an abnormal sign (eg longstanding heart murmur) and would review this sign with the trainee intern if it was not detected by the intern during the examination. In the case in question, this was essentially a 'routine' check for a driver's license together with a review of localised symptoms (toe pain and rash) and I do not think review of the patient's cardiovascular examination by [Dr D] was indicated given the absence of any symptoms referable to this system at the time, and the absence of any significantly abnormal findings by the trainee intern.
>
> 2) Was a further physical assessment of [Mr A] on 27 [Month1] and/or 12 [Month2] and/or 25 [Month2] clinically indicated?
>
> I do not believe so. [Mr A] was observed to have low blood pressure on 27 [Month1] which provided an explanation for his syncopal episode. He did not complain of any other symptoms particularly suggestive of a neurological cause for the syncope. He had improved subjectively and clinically at the consultations of 12 and 25 [Month2], and was noted to have a normal heart rate and regular rhythm at the latter consultation meaning an ECG was unlikely to demonstrate significant arrhythmia to account for his complaint of palpitations.
>
> 3) [Dr D] stated that it was the nurse's responsibility to review the medical notes of a patient that had transferred and highlight any obvious medical history. It was not in the nurse's job description nor did the nurse understand this to be her responsibility. Would you expect a GP practice to have a policy about reviewing medical notes?
>
> I would expect a practice to have a formal process for handling of old notes received, and for this process to be familiar to all staff. The process may be different for notes received electronically via GP2GP when there is a certain amount of automatic integration into the PMS compared with notes received in paper form. Best practice would be for this process to be recorded in a written document and to be part of the orientation of all new staff (administration, nurses and doctors). The actual process is likely to vary from practice to practice, with some using nursing resource for old notes review and transfer of relevant data and others requiring the GP to formally review notes and enter relevant data. In my own practice it is the responsibility of the nurses to ensure relevant immunisation and screening data is transferred, while the GP is responsible for transferring other

clinical data including relevant medical history, long-term medications and patient alerts.

4) Can you confirm that the attached document is a transfer summary?

5) What is the difference (if any) between a handover note, a transfer summary and an electronic front page?

I am not aware of any specific definition of what constitutes a transfer summary versus handover note or electronic front page. The attached document could be regarded as any of these although in Medtech there is a dedicated electronic 'front page' which contains much the same information as that provided in the attached document but in slightly different format. The attached document does illustrate the basic elements required for efficient transfer of clinical information: patient demographic details, long-term conditions, regular medications and medication alerts. Some doctors will include general comment regarding the patient's health status as part of the transfer documentation particularly if there are outstanding issues to be addressed by the new GP. However, it is not uncommon for notes to be transferred without any specific or dedicated 'handover' letter."