General Practitioner, Dr D

A Report by the

Health and Disability Commissioner

(Case 09HDC01765)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. As a result of an aortic valve replacement in 2006 at the age of 22, Mr A needed to be on an ongoing anticoagulant regime. Mr A was prescribed a daily dose of the anticoagulant warfarin and needed regular blood testing to ensure the warfarin was working. The standard test for this is INR testing.

2. The target INR level for Mr A was between 2.5 and 3. Depending on the result of the blood test, his warfarin would be adjusted.

3. The clinical record indicates that Mr A attended for blood tests and his INR results were noted. Sometimes the blood tests were weekly, sometimes fortnightly, and other times less frequently. For example, between May 2007 and February 2008, Mr A had an INR blood test only three times.

4. Mr A's INR results fluctuated (as shown in Appendix C) and the medication needed to be adjusted frequently. Sometimes Mr A would tell the clinic staff that he had missed his medication, and the clinical records show that practice staff warned him of the need to take the medication regularly. Staff also spoke to him outside of the clinic to remind him about being tested, and arranged appointments for him at the same time as a family member to make it more likely he would attend.

5. Sadly, Mr A collapsed and died playing social sport in early 2009, aged 25. His mother and partner both complained to HDC that he had not been adequately monitored and managed. This report considers the standard and appropriateness of care provided to Mr A by Dr D.

6. Expert advice from GP Dr David Maplesden is that the management of Mr A's anticoagulant regime was of a reasonable standard. It is apparent that staff at the practice went to considerable effort to ensure that Mr A attended for INR testing and the medication was adjusted as required.

7. As his GP, Dr D had overall responsibility for the anticoagulant regime. Beyond this, he was also responsible for Mr A's overall care. In the normal course of events, this would mean that Dr D would be aware of his medical history, test results, and correspondence from other providers such as the hospital. Any assessments should be appropriately documented, with the basic observations such as pulse and blood pressure recorded for future reference.

8. I consider that Dr D's approach to management of Mr A's care was casual. His documentation of the assessments that he says he undertook is scant. The most basic information, such as blood pressure and pulse, are not routinely recorded.

9. Although Dr D says that some documentation has been lost or was not recorded because of difficulties with the computer system, this would have been obvious to him if he had reviewed the clinical records for the purpose of assessing Mr A. The fact that he was not aware of the shortcomings in the documentation until this complaint was made is evidence that he failed to review what limited records were available before assessing Mr A.

10. Dr D was found in breach of Right 4(2)[1] of the Code of Health and Disability Services Consumers' Rights (the Code).

Investigation Process

11. On 18 and 25 September 2009 the Commissioner received complaints from Ms C and Mrs B respectively, about the care provided to Mr A by Dr D.

12. After preliminary assessment, an investigation was commenced on 30 November 2009. Relevant information was sought and received from:

Mrs B	Mr A's mother, complainant
Ms C	Mr A's partner, complainant
Dr D	General practitioner
Ms E	Barrister
Hospital 1/the DHB	Dr D's employer
Medical centre	Rural medical practice
Ms F	Practice nurse
Ms G	Practice nurse

Also mentioned in this report:

Hospital 2	Public hospital in another main centre
Dr H	Cardiologist
Dr I	House officer
Dr J	Locum consultant physician
Dr K	ED Accident and medical doctor
Dr L	Locum general practitioner
Dr M	General practitioner

13. The scope of the investigation was:

> *Whether Dr D provided Mr A with medical care and services of an appropriate standard from January 2006 until his death in early 2009, particularly in relation to the monitoring and management of Mr A's INR levels and anticoagulation medication regime.*

[1] Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

14. Independent clinical advice was obtained from the Commissioner's in-house clinical advisor, vocationally registered GP Dr David Maplesden (attached as Appendix A). Dr Maplesden provided advice during the preliminary assessment of the complaint, which was then updated and revised (attached as Appendix B) once a decision was made that HDC would formally investigate the complaint and further information was received.

Information gathered during investigation

Background

15. Dr D is a sole practitioner in a large, isolated, rural practice located approximately 30 minutes' drive from the nearest town. He is the only general practitioner in the 140kms between two townships. Dr D is vocationally registered. He works with four part-time practice nurses and two part-time rural health nurses, who all make key contributions to the management of patients cared for by the centre. The practice is owned and managed by the district health board (the DHB), which employs the nurses. Dr D has a contract with the DHB and receives a salary.

16. Mr A's partner, complainant Ms C, worked at the medical centre as a casual receptionist at the time of the events complained of.

17. Mr A was a long-standing patient of the medical centre. In January 2006 Mr A, aged 22, had an urgent aortic valve replacement (using a St Jude regent prosthesis) at a large public hospital in another region (Hospital 2). He was discharged from Hospital 2 on 18 January 2006.

18. Following surgery, the medications prescribed included the anticoagulant warfarin at 2mgs daily. Mr A needed to take the warfarin long term and to have the medication monitored by way of regular INR testing.

19. Warfarin is the most widely used anticoagulant in New Zealand, having a key role in preventing thrombosis. However, its use has serious risks. INR testing[2] 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. Regular testing of INR levels is essential for people on warfarin. In most cases, once INR is stable the rate of testing can be extended to two-

[2] INR — International Normalised Ratio: An international system established to assist the reporting of blood coagulation (clotting) tests. All results are standardised using an international sensitivity index (ISI) for reagents and instruments used to perform the test. For example, a patient taking the anticoagulant warfarin might optimally maintain an INR of 2 to 3. Regardless of which laboratory checks the prothrombin, the result should be the same. This international standardisation permits a patient on warfarin to travel and still obtain comparable test results.

weekly and then four- to six-weekly. People at higher risk may need more frequent testing.[3]

Discharge

20. The discharge summary from Hospital 2, copied to Dr D and Dr H, cardiologist, outlined Mr A's various medications and stated in the "remarks" section:

> "cardiology follow-up 6/52 [6 weeks]
> continue warfarin + aspirin + accupril (warf 2mg until INR check)
> GP follow up re warfarin [and] check potassium."

21. The discharge summary form from Hospital 2 did not specify a target INR level or range. Mr A's outpatient follow-up was ticked and listed as being with Dr H at Hospital 1.

22. The medical centre's clinical records show that Dr I of Hospital 2 telephoned the medical centre on 18 January 2006, and spoke to clinic nurse Ms F advising that Mr A's INR had been sitting at 2.3 and that his target INR was 2.5. However, the cardiothoracic surgical operation note was not dictated until almost five months later, on 8 May 2006, and sent to Mr A (with copies to Dr D and Dr H) on 9 May 2006. The operation note stated "warfarin as per INR (aim 2.5–3.5)". It was noted in relation to follow-up:

> "The patient will be reviewed by his GP re monitoring of his bloods and will be reviewed by [Dr H], visiting cardiologist, [Hospital 1], in 4–6 weeks time."

INR monitoring — 2006–2008

23. In general, a process was adopted by medical centre staff that at each blood withdrawal the results (including previous doses, and the results of the latest and previous INR) would be discussed with Dr D to determine the warfarin dosage for the week, to keep Mr A within the therapeutic INR range. Mr A would then be contacted to inform him of the results and dosage needed.

24. Between 2006 and 2008 Mr A's INR levels fluctuated. He had periods of stability when it remained within the desired therapeutic range, and at other times the levels varied, which the staff associated with non-compliance taking the medication (see **Appendix C**). In this period there was, at times, some difficulty contacting Mr A, and his relatives would pass on messages from medical centre nurses.

Consultations with Dr D

25. The medical centre uses the patient management system (PMS) MedTech 32 to document consultations. The first postoperative review recorded in the notes as being completed by Dr D was performed on 24 January 2006. There is no record of any observations such as pulse or blood pressure or chest auscultation. Dr D noted "to

[3] Best Practice Advocacy Centre New Zealand (BPAC) Ltd. Better Medicine. *INR Testing*, pp 4–5. October 2006. See http://www.bpac.org.nz/resources/campaign/inr/bpac_inr_poem_2006_pf.pdf

contact [Hospital 2] to find target INR for [Mr A]". It is unclear why this was noted in view of Dr I's call six days earlier.

26. The next full review by Dr D took place on 2 March 2006. Mr A is noted to be "keeping well" and his INR stable on 4mg warfarin. There is no record of any physical examination. On 10 March Mr A had an echocardiogram at Hospital 1.

27. On 14 March 2006 Dr J, Locum Consultant Physician, reviewed Mr A at Hospital 1. In his summary letter to Dr D regarding the consultation, Dr J felt that the INR was a little on the low side (at 1.9–2.4) and the warfarin dose was increased to 6mg. Dr J advised that "his ideal INR would be around 3". Future follow-up with Dr H was mentioned, and Dr J noted that he had advised Mr A to have a medic alert bracelet as "he doesn't seem to know a lot about his artificial valve". A nurse from the medical centre (Ms F) rang Dr J on 16 March 2006 and, according to her entry in the records, he wanted the INR to be "between 2.5 and 3.0".

28. On 27 March 2006 Mr A saw Dr D in relation to Work and Income paperwork. On 5 April 2006 he sought help from Dr D to apply to have his phone reconnected. He supplied his new number to the clinic on 19 April 2006.

2007

29. There is no record that Mr A was seen by Dr D in 2007 although his blood pressure was taken by clinic nurse Ms F on one occasion that year (16 March 2007). Throughout 2007 Mr A failed to attend seven appointments for INR monitoring — nurses subsequently contacted him by telephone or left an answerphone message for him on three of those occasions.

2008

30. Mr A did not attend an appointment on 25 January 2008. He was seen by Dr D for review on 4 February 2008, but there is no record that any physical examination was undertaken. Dr D recorded: "[Mr A] is currently well and asymptomatic. No pain. INR is stable [1.9] on warfarin 4mg daily. Work and Income medical certificate completed. For repeat INR."

31. On 6 March 2008 a locum GP, Dr L, reviewed Mr A and noted:

> "Has been well, he is unable to do heavy work … he has been very poor at having his INR testing done and at communication about warfarin dose adjustment … He has a plastic aortic valve, INR [1.8] should be in the 3–4 range … compliance with medications is good."

32. Dr L also noted the absence of oedema, a regular pulse of 76, normal blood pressure and mechanical heart sounds with a grade 1 systolic murmur.

33. There is no record of subsequent cardiovascular review of Mr A in 2008. The 4 February 2008 entry in the record is the only one made by Dr D in the period between 2007 and Mr A's death in early 2009. Dr D outlined that it is "always his practice to write something when [he] see[s] a patient, even if a nurse is also making a record". He said he either writes in hand on the INR result or on the system. He expects in all

usual circumstances to have a computer entry whenever a consultation occurs. Dr D acknowledges that the hard copy INR results for early 2009, 14 November 2008, and 29 September 2008 are missing from the file and have been unable to be located.

34. Dr D advised HDC, "I recall examining [Mr A] and would expect that I would do so every six months." He said he knew with certainty that he carried out a comprehensive examination of Mr A on 14 August 2008. He said he sat down at the nurses' computer to type up the notes and that he recalls it as it coincided with the spike in INR. He said he remembered documenting the details of the bruising and Mr A's cardiovascular status. He had difficulty changing the system to record the notes in his name. He is certain he would have typed in the full examination findings, but acknowledged that nothing he entered appears in the computer record.

35. Dr D responded to HDC that his clinical notes did not accurately reflect reviews of Mr A that he had actually undertaken. He advised that the circumstances influencing this included: the many appointments that were missed by Mr A (especially from mid-2007); the high percentage of opportunistic appointments attended and thus occasional entries ending up being made on nurses' computers; problems with the clinic's Patient Management System apparently not accepting some data; and some instances of his writing by hand on INR result sheets.

36. As part of a statement to HDC, clinic nurse Ms F recalled asking Dr D to review Mr A on 14 August 2008. She remembered Dr D taking a thorough physical, advising Mr A to stop his warfarin until they knew the result of his INR, and giving advice on emergency treatment. Dr D documented this in front of her on her PC, but for some reason Dr D's record of this consultation does not appear on the PMS. She indicated that the medical centre had experienced IT problems including lost documents which the IT department of the DHB had not resolved.

37. Dr D said that following the complaint he had looked into this issue. On checking the appointment record, he ascertained that Mr A consulted him at the clinic on 29 May, 25 August, and 28 August 2008 and that this was borne out by an audit log in the PMS software. Dr D did not provide the appointment record or audit log. His consultation notes did not appear on the system. Dr D concluded that the problem arose when two practitioners tried to record consultations at the same time. He indicated that he now always checks that his notes, especially those not recorded on his own PC, are on the system.

38. However, in contrast, in his response to HDC on 27 October 2009, Dr D claimed that the notes had been made but were missing because "the file has gone back and forward to the DHB and has been looked at by a number of people, so tracing where the missing parts may have gone to is problematic".

Other health issues

39. On 18 April 2006 Dr H wrote to Dr D after reviewing Mr A's echocardiogram from 6 March 2006. Dr H observed a left ventricular dysfunction, which he suspected was chronic. He did not have Mr A's old records to confirm this and requested that Dr D

check whether Mr A was on betablocker[4] medication. If not, he encouraged a dosage so that the baseline heart rate was about 60 beats per minute.

40. On 27 April 2006 a practice nurse saw Mr A at the medical centre. His blood pressure was recorded as 120/74. His heart rate was not recorded by the nursing staff, but Dr D advised HDC that he was confident the nurses would have discussed any concerns with him if the heart had been tachycardic. In relation to whether Dr H's recommendation was noted and/or actioned, Dr D responded to HDC that he would have probably received Dr H's letter by this date (despite postal service delays at that time) and that if he had been told of a raised heart rate on questioning, he would have prescribed a betablocker. A heart rate was not recorded during Mr A's visits in May and June 2006.

41. On 20 July 2006, at a scheduled appointment, a clinic nurse recorded Mr A's blood pressure as 140/88 and his heart rate as 60. There is no record of Dr D having reviewed Mr A at this visit but he advised HDC that as the heart rate was at Dr H's desired baseline, he did not feel a betablocker should be prescribed.

42. On 27 July 2006 Mr A's heart rate was very low (bradychardic) at 38 beats per minute and was described as strong but irregular. No other symptoms were apparent. Mr A's blood pressure was 142/79. The clinic nurse discussed this with Dr D, and Mr A's blood was tested for cardiac enzymes. Dr D advised HDC that at this low heart rate, the introduction of a betablocker at this time would have been contraindicated and dangerous. Later that day at 4.50pm, the laboratory telephoned to advise that the Troponin I result was elevated at 0.64 µg/L (normal range being 0–0.15)[5]. Dr D decided to refer Mr A to the Emergency Department (ED) at Hospital 1 for assessment.

43. Mr A was examined at Hospital 1 ED by Dr K at 7pm that evening. His heart rate was 83 and his blood pressure was 140/90. Dr K noted a Troponin I level of 0.88 (and that it had been historically elevated — 0.66 in November 2005). Mr A was diagnosed with a chronic elevated Troponin I level. Dr K discussed this with Dr J. No treatment was considered necessary. Dr K advised the GP practice to repeat the Troponin I test in 1–2 weeks, and said that the result was most likely to be elevated constantly at 0.60–0.80 owing to Mr A's enlarged heart.

44. Mr A's baseline heart rate remained in the desired range of close to 60 beats per minute (66 on 3 August 2006 and 62 on 17 August 2006). The addition of a

[4] By blocking the action of the sympathetic nervous system on the heart, betablockers relieve stress on the heart; they slow the heartbeat, lessen the force with which the heart muscle contracts, and reduce blood vessel contraction in the heart, brain, and throughout the body. Betablockers may be used to treat abnormal heart rhythms and prevent abnormally fast heart rates (tachycardias) or irregular heart rhythms such as premature ventricular beats.

[5] Troponin I and T are myocardium specific proteins. They are released into the bloodstream when myocardium is even minimally damaged. The troponin test is used to help diagnose a heart attack, to detect and evaluate mild to severe heart injury, and to distinguish chest pain that may be due to other causes.

betablocker was not recommended at either of Mr A's subsequent specialist reviews (in July 2006 and March 2007) following Dr H's suggestion of 18 April 2006.

45. On 13 March 2007 a consultant physician reviewed Mr A. He included in his summary letter to Dr D that:

> "[Mr A] has not been having the INR monitored regularly and I have cautioned him in this regard … the aim is to keep the INR between 2.5–3.5."

14 August 2008 INR result

46. On 20 March 2008 Mr A asked medical centre staff to have his regular INR testing done through the laboratory in the nearest town to avoid waiting in the clinic. The necessary forms were supplied to his partner, Ms C, and the laboratory was contacted. Mr A telephoned and repeated this request on 2 May 2008.

47. On 12 May 2008 Mr A presented to the clinic for his INR result, which was 1.5. A clinic nurse discussed "at length" with Mr A the need for his INR to be in the 2.5 to 3.5 range and for him to have regular surveillance. An agreement was made that Mr A and his grandmother would visit the clinic together fortnightly, in order for them both to have their INR testing. After the nurse discussed the result with Dr D, the warfarin dosage was increased to 8mgs.

48. On Thursday 14 August 2008 Mr A (who was on 8 mgs warfarin at this point) presented to a nurse at the medical centre for his INR test and was noted to have "spontaneous bruising back of thighs to top of calf on both legs" after standing all day at work. Mrs B informed HDC that this was the time she became most concerned for her son.

49. Mr A was seen by Dr D, who advised him to stop the warfarin until his INR results were known. He also advised him to do no more of that type of work at that time. The INR result was 5.67. The nurse discussed the result with Dr D, who advised that Mr A should stop the warfarin until a further INR test was carried out on Monday 18 August 2008. The nurse recorded that she gave Mr A advice about what to do in an emergency, which included that he should present to the ED if bleeding occurred.

Re-warfarinisation

50. Dr D considers that the likely explanation for Mr A's sharp INR increase was that he had not been taking his warfarin regularly and, when the dose was increased to 8mgs and he started to take it, this resulted in the potentially very serious INR level of 5.7.

51. Mr A next attended for an INR test on 21 August 2008. He was feeling well and had no bleeding. The result was 1.0. In his response to HDC, Dr D explained his subsequent clinical action and reasoning as follows:

> "This presented me with a management dilemma. In an ideal situation, I would have re-warfarinised [Mr A] by giving him a loading dose regime after this incident. However, given his erratic taking of warfarin, this would have been extremely dangerous. If the loading regime was not taken exactly as directed, it would have posed an unacceptably high risk of a fatal haemorrhage. I took advice

> from my peers at the time and I have subsequently reflected in depth on this decision. I believe it was right to cautiously re-warfarinise in these circumstances and colleagues who have studied this case are in agreement."

52. In a later response to this Office Dr D indicated that at the time he was making decisions about the issue, he discussed Mr A's low INR results in depth with his practice team, rather than his peers.

53. Mr A was recommenced on 2mgs daily, and was to return in a week. On 28 August 2008 his INR was still 1.0. Mr A told clinic staff that he had not forgotten to take any tablets. Dr D was advised of this by the nurse, and he decided that Mr A should remain on 2mgs, with repeat testing in a week. On 3 September 2008 bloods for INR were taken. The result was 1.0 and Dr D advised the nurse to increase the dose to 3mgs and to repeat the test in five days.

54. On 10 September 2008 Mr A's blood was tested again. The notes show that he was "[o]n Warfarin 1mg". The clinic RN recorded that he had been "labile" over August, but that he "feels well, still working, no untoward symptoms". The INR result was recorded the following day as 1.1. This was discussed with Dr D, who advised to increase the dose to 4mg and repeat the testing in a week. On 19 September 2008, the INR result for bloods taken the previous day was recorded as 1.4. Mr A advised clinic nurses that he had not forgotten any tablets. He was told (by phone) to remain on 4mgs and repeat the testing in a week.

55. In Dr D's responses to HDC he described unpredictability as the most dangerous factor in warfarin management. He stated that when Mr A took his medication, his INR went up. An INR of 1.0 demonstrates that a patient is not taking any warfarin. Therefore, the issue with Mr A was to improve his compliance and not just to increase his dose of warfarin. Dr D summarised this period by stating:

> "[Mr A's] INR did not respond to the increased dose of warfarin and remained in the range of 1.0 to 1.5. I did not believe that this was possible if [Mr A] was regularly taking his prescribed dose of 4 or 5mgs of warfarin, especially considering his extreme reaction when he took 8mg of warfarin."

56. Dr D told HDC that he discussed this with Mr A, who admitted to episodes when he did not take his medication. Dr D said that he reinforced the seriousness of this to Mr A and explained the risks this posed. He also cautioned Mr A against high-risk activities such as contact sports. However, although the records indicate that the nurses emphasised the importance of taking the medication, the advice given by Dr D is not recorded.

57. On 29 September 2008 (a Monday) Mr A presented for his blood test. The INR result was 1.2. The entry in the records for that day show that he told the clinic nurse that he had missed taking his warfarin on Saturday night as he had been drinking alcohol. Although there is only one recorded reference in the notes to this, Dr D recalls nurses reporting Mr A making this concession to them on other occasions.

58. Ms C is of the view that her partner seldom drank alcohol and, when he did, it was never to excess. Mr A's mother informed HDC that at times her son did drink alcohol.

59. Mr A had a further echocardiogram on 30 October 2008.

2009

60. Early in 2009 Mr A's blood was tested. He indicated to nursing staff that he was taking 4mgs warfarin at that time; however, the INR result recorded was 1.0. He did not attend an appointment scheduled for nine days later but did have his blood tested the following day. The notes indicate that he was then taking 5mgs warfarin. A handwritten note on the lab report (INR result was 1.2) says "takes 5mg, last INR 1.0 on [9 days ago], ↑ from 4 to 5mgs, Hx Aortic valve repair, 6mg, message left plus passed message onto [Ms C]".

61. A short time later, Mr A collapsed on a hot day while playing sport. Sadly, he was unable to be resuscitated by those attending the scene. The death certificate was signed by Dr D with the cause of death recorded as "*cerebrovascular accident 15 minutes*" with antecedent causes listed as "*mitral valve regurgitation 5 years, rheumatic fever 20 years*". No post mortem was conducted.

Collegial advice

62. Dr D responded to HDC that he had reflected at considerable length on his decision not to use a loading dose for the re-warfarinisation following Mr A's dangerously high INR level on 14 August 2008. He had discussed his care with his immediate practice team at the time and, following Mr A's death, he had discussed it with senior colleagues at the Royal New Zealand College of General Practitioners (RNZCGP), who supported his management. He had also discussed his care with a haematologist.

63. Dr D also obtained an opinion from an independent peer. He was happy with the cautious approach to re-warfarinisation taken by Dr D, and agreed that, in the circumstances of this patient, if a loading regime had been prescribed, but not taken as advised, this could have led to an overdose situation with potentially lethal consequences.

Issues relating to compliance

64. Dr D described Mr A as having a casual and laid-back approach to life and to his medical treatment, and said he found it consistently hard to make Mr A realise the seriousness of his condition. In his initial response to the complaint Dr D said:

> "I spent a considerable amount of time with [Mr A], explaining the importance of the regular INR blood tests to monitor his anticoagulation status and the importance of adjusting his warfarin dosage accordingly."

65. Mr A often travelled to obtain casual work, and this made a fixed testing routine difficult. Dr D said that the practice team had worked hard to persuade Mr A to take his anticoagulant therapy seriously, and fully discussed the implications of this with him.

66. Ms C agreed that her partner had a laid-back approach to life. However, when it came to his health, she felt he took his medical treatment seriously and that he took his medication as prescribed. She acknowledged, however, that he seldom talked about his ill health and did not want to burden anybody, but said that he did talk to her about how he was feeling most of the time.

67. Mrs B considers that her son had a good relationship with the medical centre nurses and said he had never expressed concerns about his care. She recalled that he did not like waiting for results and considered it "a bit *hōhā*" (tiresome). She enquired about his check-ups, but he would often say he was waiting for results and tended not to share much information with her. She felt that he probably covered up the extent of how sick he felt for the sake of his family.

68. In his response to HDC, based on the practice's appointments diary, Dr D outlined that in the period 1 January 2007 to the time of Mr A's death in 2009 there were 66 entries relating to Mr A, who attended nine booked appointments. Twenty-three booked appointments were not attended, 33 appointments were opportunistic, and one was cancelled. Of the 42 times he attended the surgery, the majority of the consultations (79%) were opportunistic. As a result, those consultations did not occur in Dr D's room but in the nurses' room after Mr A's bloods were done. Dr D would be asked to go to Mr A, rather than sending him into the waiting room after seeing the nurses because if he became impatient with waiting and left, the opportunity might be lost. However, the notes recorded by the nurses refer on almost all occasions to the INR being "D/W" (discussed with) Dr D and the nurse conveying to Mr A the dosage of warfarin he should take.

69. At times, medical centre staff had difficulty contacting Mr A when INR results were received. This was of concern if the results were outside the desired range. He was often contacted through messages and advice being left on his answer phone or passed on to his partner, Ms C, and other family members. Mr A's mother confirmed that he had no landline phone at one point, and that he needed some financial help to obtain one, although he did have a mobile phone. His financial concerns also meant that he sometimes could not afford prescriptions.

70. Ms C informed HDC that, in her view, the reason Mr A attended opportunistic appointments was because she would call him to let him know when a nurse had an available slot, otherwise he could wait up to two hours for his blood test. As they lived only one kilometre from the clinic, and this was no problem for him or the clinic staff, it was a practice frequently utilised with Mr A (and other patients) owing to waiting times. Ms C was of the view that she and other staff members, rather than Dr D, were mostly responsible for chasing up Mr A.

71. Dr D outlined that the nature of the rural practice means that clinic staff often use informal means to encourage patients to attend required appointments and take steps to make it easier for them to comply with treatment. For example, the local pharmacy delivers medications to the general store so that patients do not always have to travel to town, and supplies of some medications (including warfarin) are kept on hand at the clinic.

72. In Mr A's case, when nurses fortuitously saw him in the township, he was prompted to go straight to the clinic or encouraged to attend later that day. Mr A's attendance at the clinic was seldom self-motivated, and usually the result of this type of successful intervention or "capture" in the community by the practice team. While acknowledging that perhaps this should have been spelt out in the notes, Dr D considers that their approach was a reflection on what was being achieved rather than what was not.

73. The clinic staff developed innovative ways to encourage Mr A's attendance, such as arranging for him to transport his grandmother, with whom he was very close. His grandmother had similar monitoring requirements at the clinic, so they would attend together. This was successful for a time, but did not continue if Mr A found work or was unavailable.

74. Staff also avoided keeping Mr A waiting at the clinic in case he left, and advised him of the risks to his health if he did not take his medication or attend for regular INR testing. Mr A was followed up by Ms C and clinic staff if he did not pick up his warfarin prescriptions. Dr D considers that better attendance at the clinic was achieved in the last three months of Mr A's life.

75. Dr D advised HDC that Ms C's role at the clinic resulted in greater circumspection in the medical notes, particularly those made by nursing staff, when he compared them to his recollection of the exasperation reported to him verbally by the nurses.

76. However, Ms C, in response to this point, stated to HDC:

> "I find [Dr D] was using my position at the practice as an excuse as to excuse his lack of file notes. Why were the notes not recorded? This has happened a number of times apparently! I only had limited access rights. I could not look up the consultation notes, which the doctor had been recording. I find this to be inexcusable for a professional of his standing."

77. In contrast, in a further response on 14 January 2010, Dr D claimed that he did document his consultations, but the consultation notes were not in the system, because:

> "There have been issues about the system. Recently I have come to the conclusion that the problems seem to mainly arise when two practitioners try to record consultations at the same time. Because of what I have discovered in this case, I am now going back to notes, especially those not recorded on my own computer, to check that they are on the system."

Action taken and changes to practice

78. As a result of the issues raised by the complaint and in response to the initial clinical advice given to the Commissioner by Dr Maplesden, Dr D outlined additional actions he had taken, and changes made to his practice.

79. Dr D informed HDC that he is aware of, and expects to follow, best practice to regularly examine patients with cardiac conditions (including pulse, blood pressure,

auscultation findings, and the presence or absence of peripheral oedema), and to document these examinations. Dr D stated: "I am horrified that the notes do not reflect that this was done and are not up to the standard I set for myself."

80. Dr D undertook a two pass (three months apart) self-audit of his documentation — the RNZCGP record audit *The Content of Medical Records*, showing an apparent improvement between the two audits.

81. Dr D reviewed the Best Practice Advocacy Centre (BPAC) New Zealand Ltd *Better Medicine* recommendations regarding INR testing and has gone over them thoroughly with all his practice staff.

82. Dr D informed HDC that a senior rural colleague, Dr M, with a similar practice structure, spent a week reviewing his practice in late 2009. This involved sitting in on consultations, discussing cases, undertaking case reviews, discussing chronic disease management and practice systems, and reviewing INR monitoring and warfarin treatment. Dr D indicated he was preparing a joint statement to submit to the RNZCGP as part of his professional development.

83. Dr M informed HDC that his visit to Dr D's clinic was arranged by the Medical Protection Society and that its purpose was a supportive one — providing mentorship, guidance and advice together with some review of Dr D's consultation style, his practice, and its systems.

84. The medical centre was assessed and awarded RNZCGP Cornerstone Practice Accreditation in January 2009, which involved practice-wide audits. Changes made to the practice as a result include continuing audit of medical records.

85. Dr D undertook a monthly audit of all patients on anticoagulant treatment in the practice to record if patient INR readings were within the therapeutic range. Results for the latter half of 2009 were reported on and provided with Dr D's response. He intends to continue this audit indefinitely.

86. The medical centre started a new protocol to assist with patients' anticoagulant treatment. A point-of-contact testing system is being used that allows an INR measurement from a sample of blood from a finger prick, providing an instant result. This is coupled with an online service that provides a personalised graph for patients, charting their INR readings and providing recommended dose adjustments according to best practice. This encourages patient engagement, adherence, and interest in their treatment.

87. In concluding his response, Dr D outlined that this matter has also been extremely distressing for him. He had reflected on it at length and agonised over his decision to cautiously re-warfarinise Mr A. He expressed his very sincere and heartfelt sympathy to Ms C, Mrs B and to all Mr A's family for this tragic loss.

Opinion: Breach — Dr D

Introduction

88. During the course of this investigation I have carefully considered the appropriateness of Dr D's standard of care and clinical decision-making. At the outset, it is important to stress that my consideration of the patient compliance issue is a necessary part of an investigation into the GP's management of the long-term anticoagulation therapy, and should in no way be interpreted as blaming the patient. My focus is whether Dr D provided services of an appropriate standard. However, provision of effective long-term patient care, such as warfarin use, requires effective communication and an interactive "two-way" doctor–patient relationship.

Compliance

89. Mr A was a young man who, no doubt, became frustrated and bored by the ongoing need to take medication and undergo regular blood tests. His mother said he found the process "a bit *hōhā*" (tiresome). It appears likely that he did not always take his prescribed medication.

90. I consider that staff at the medical centre made every effort in the circumstances to inform and educate Mr A of the importance of compliance with his medication regime (as evidenced in the medical centre records and of other clinicians), to facilitate his INR testing, and to discuss the implications of not doing so. This included: use of informal and impromptu means to encourage his attendance at appointments when he happened to be seen in the township by staff; Dr D sometimes seeing him in the nurses' rooms after his blood tests to reduce the chance of his leaving the clinic; arranging for him to transport his grandmother to the clinic so they attended together; arranging for him to attend the laboratory for blood tests to avoid clinic waiting times; providing reminders when prescriptions were not picked up; and verbal agreements for him to contact the clinic if he had not heard about INR results on the day of the tests.

91. I sought advice from my in-house clinical advisor, Dr David Maplesden, who commented:

> "It is apparent that the practice made genuine and persistent efforts to engage [Mr A] in a partnership model of care. It is unfortunate that this model of care was ultimately ineffective for [Mr A] …"

INR management

92. Initial clarification of Mr A's appropriate therapeutic INR range following his surgery in early 2006 was not aided by the information from the secondary providers. Notably, one of the potential risks involved in transfer of care across the primary–secondary interface is highlighted in Best Practice Advocacy Centre (BPAC) New Zealand's recommendations regarding INR testing. It states that:

> "… poor communication on discharge may leave the primary care clinician with inadequate information to make safe testing and dose adjustment decisions".[6]

93. Formal documentation from Hospital 2's cardiothoracic surgical team containing reference to the target INR range ("2.5–3.5") was not dictated, typed and sent to Dr D until early May 2006 (almost five months later). In addition, a target INR range was not included in the basic discharge summary faxed to Dr D from the hospital on the day of discharge, although a warfarin dosage of 2mg was noted "until INR check". The effect appears to have been minor but could have been more significant if it had not been for a timely phone call to the medical centre from Dr I at Hospital 2 verbally informing a clinic nurse that the "target is 2.5" shortly after Mr A's discharge on 18 January 2006. This was recorded in the patient's running records, but there appears to have still been some initial uncertainty in the first few weeks post-surgery. This was probably not helped by the above omission, together with physician's review correspondence in March 2006 indicating that 1.9–2.4 was "a bit on the low side" and the ideal INR was "around 3", later described over the phone to a clinic RN as "2.5–3.0".

94. From 2006 to mid-2007 Mr A's attendance at the medical centre (and later at the laboratory on occasions) for regular blood testing was generally good, and his INR results were largely within the therapeutic range recommended (with one exception in early July 2006) while usually taking between 4–6 mgs of warfarin daily. However, from mid-2007 onwards it is clear that his attendance became less structured and more opportunistic, the number of "did not attends" for appointments increased, and variable compliance with his warfarin medication occurred. His records indicate that sometimes tablets were missed, and on occasions it appears that he may have altered the dose himself.

95. Dr Maplesden was of the view that:

> "Prior to August 2008, INR recording was undertaken at less than recommended intervals given the results. However, on reviewing the additional information supplied [to HDC] it is apparent that the major factor in [Mr A's] failure to maintain a therapeutic INR from the time of his operation was his lack of compliance with recommendations of medical staff, and I cannot see that much more could have been done to improve his situation."

96. A brief period of INR result stability occurred in mid-2008 while Mr A was on 8mg warfarin daily, until the dosage was temporarily stopped on 14 August 2008 owing to the 5.7 INR result. Dr Maplesden (drawing on BPAC guidelines for managing over-anticoagulation and alterations in INR)[7] initially advised that the INR management from 14 August 2008 onwards was overly cautious, while acknowledging that Dr D's concerns regarding compliance contributed to the cautious strategy he undertook. Mr A was taking 8mg warfarin (although occasionally missing doses) at the time the elevated INR (5.7) was noted. Dr Maplesden advised that the medication was

[6] Best Practice Advocacy Centre New Zealand (BPAC) Ltd. Better Medicine. *INR Testing*, pp 4–5. October 2006. See http://www.bpac.org.nz/resources/campaign/inr/bpac_inr_poem_2006_pf.pdf
[7] Ibid, pp 15–16.

appropriately stopped at this point — ideally the INR would have been taken two to three days later and, once back in the target range or at least <5, warfarin recommenced at a reduced dose of approximately 20% less than the previous dose. Dr Maplesden revised his clinical advice based on the further information gathered by HDC reinforcing Mr A's variable compliance.

97. With respect to the more cautious re-warfarinisation strategy Dr D adopted, Dr Maplesden advised that:

> "… it was appropriate for [Dr D] to stop the medication temporarily and monitor as discussed [in the initial advice]. It is unlikely, as noted in [Dr D's] response (1(iv) [of Dr Maplesden's more recent advice]), that [Mr A] was taking any warfarin or taking it very intermittently, during the period 21 August to 21 October 2008. On reflection, I am of the opinion that it was therefore quite reasonable for the approach to be one of encouraging compliance with currently prescribed doses of warfarin, and therefore to gain an accurate idea of therapeutic response, rather than just recommending higher doses which may have been somewhat unsafe in the face of variable compliance."

98. In my opinion, by mid-2008 Dr D was aware of Mr A's compliance issues, which meant that a regime of higher doses of warfarin after 14 August 2008 carried with it a potential to harm Mr A, given his history of variable adherence to prescribed warfarin medication. While a cautious strategy also appears to have had a degree of risk attached, I am satisfied, based on Dr Maplesden's advice, that the rationale behind the decision to adopt a more cautious re-warfarinisation strategy was reasonable. I consider that Dr D and the clinic staff were acting in the best interests of Mr A when this decision is coupled with their patient-centred and individually tailored efforts to encourage his compliance with prescribed doses. These were reasonable actions in the circumstances.

99. From then until early 2009, Mr A did not achieve an INR approaching his target range. Dr Maplesden noted that an INR result of 1.0 (no warfarin being taken) in early 2009 indicated that Mr A's compliance had lapsed and efforts were being made to regain a therapeutic INR when, sadly, Mr A died.

100. While the overall INR management process in the practice appeared less than ideal, it was, based on Dr Maplesden's experience, consistent with current practice. He also commented:

> "… as noted in my original advice, I have experienced similar and even less structured approaches to INR monitoring in other practices I have worked in, but have also seen far more robust processes as well."

101. In relation to the timeliness of Mr A's INR results being received and acted upon, Dr Maplesden advised:

> "On review of the notes, it is apparent that a majority of INR results have been received and acted upon within 24 hours of the test and this would be consistent with expected standards in a rural area."

Betablocker medication issue

102. I do not consider that Dr D gave full consideration at first to Dr H's suggestion in April 2006 of a betablocker to keep a baseline heart rate of 60, as neither the suggestion nor any pulse monitoring reference was recorded in his clinical records, and subsequent nursing reviews of heart rate were relatively irregular (60 on 20 July 2006, 66 on 3 August, 62 on 17 August). In any event, the records do not show any periods of a raised heart rate that would have warranted serious concern, and when Mr A actually presented with a slowed irregular heart rate (38) on 27 July 2006 (leading to Dr D organising cardiac enzyme tests and a referral to Hospital 1 ED) a betablocker would have been contraindicated. Dr Maplesden advised with regard to this issue as follows:

> "I note that beta-blocker use was not advocated or recommended by the two specialists [Mr A] saw following [Dr H's] advice, even though a copy of this advice was in the hospital notes. While I am not confident that [Dr D] did note [Dr H's] recommendation, as evidenced by the lack of reference to the advice in his clinical notes, or any arrangement made for regular review of his pulse rate, the circumstances are such that the failure by [Dr D] to commence [Mr A] on a beta-blocker, as recommended by [Dr H], is probably not a significant departure from expected practice."

103. In relation to whether Dr D should have instigated any further action in response to Mr A returning an, albeit expected, high repeat Troponin I result of 0.93 on 4 August 2006 following the review undertaken and the advice given at ED two weeks earlier, Dr Maplesden advised that:

> "[i]n this clinical context, I do not think there was any strong indication to repeat the test as [Mr A] was asymptomatic, had known impairment of cardiac function and an enlarged heart, and there was an expectation the level would remain elevated. I am not aware that taking serial troponin levels is a valid means of monitoring left ventricular dysfunction. The increased level might have raised the issue of beta-blocker therapy to reduce strain on the heart, but had this been deemed appropriate I would have expected such advice to have come from the physician attending [Mr A] on 27 July 2006. Given [Mr A's] presentation with bradycardia, such therapy may not have been appropriate.

104. Overall I do not consider that the management of the INR levels or beta blocker use amount to a breach of the Code.

105. *Medical assessments and documentation*

I am less satisfied with Dr D's management of Mr A's clinical reviews and Dr D's documentation. Given Mr A's surgical history, cardiac dysfunction, and medication list, Dr Maplesden advised that it would be accepted practice for Mr A to be reviewed by a GP at least six-monthly (in addition to the reviews by the practice nurses) and that the GP reviews should include heart rate and blood pressure checks, a check for oedema, and auscultation of heart sounds and lung fields. Dr D was not able to say that he carried out a comprehensive assessment of Mr A every six months, only that he would "expect that he would do so".

106. The records indicate that Dr D saw Mr A five times in 2006; however, there is no recorded consultation in 2007, and in 2008 there is only one recorded consultation prior to 14 August 2008 when Mr A presented with bruising.

107. The records of the consultations that exist indicate that Dr D generally established that Mr A was "well". However, the notes do not record any physical examination, in particular the heart rate and blood pressure checks, check for oedema, and auscultation of heart sounds and lung fields. This is in contrast to the structured GP review of Mr A performed and recorded by locum Dr L on 6 March 2008.

108. Dr D responded to HDC that his clinical notes did not accurately reflect the reviews of Mr A that he had actually undertaken. He advised that the circumstances influencing this included: the many appointments that were missed by Mr A (especially from mid-2007); the high percentage of opportunistic appointments attended and thus occasional entries ending up being made on nurses' computers; problems with the clinic's Patient Management System apparently not accepting some data; and some instances of Dr D writing by hand on INR result sheets.

109. I do not accept that Mr A having missed appointments and others being made in an opportunistic manner (for example, by his partner contacting him and telling him to come to the clinic) excuse the failure to keep records. In this regard, I note that the nurses and locum were able to ensure that the Patient Management System worked effectively. Furthermore, if records were made on the nurses' computer when Dr D saw Mr A in the nurses' room, this made it less likely that another user was making entries at the same time.

110. The conflicting explanations given by Dr D have impeded this investigation. He has variously stated that he did not make detailed records because Mr A's partner worked in the clinic, he did make records but they were lost in the system and he did make records but they were lost because "the file has gone back and forward to the DHB and has been looked at by a number of people, so tracing where the missing parts may have gone to is problematic".

111. Dr Maplesden advised that:

> "[t]here have been some extenuating circumstances described in [Dr D's] response, including PMS difficulties and the effect [Mr A's] opportunistic presentations had on the ability to satisfactorily record observations. Nevertheless, I remain of the opinion that the standard of clinical documentation in this case, a young man with a prosthetic heart valve and significantly impaired cardiac function, departed from expected standards to a mild degree. [Dr D] has acknowledged that the content of the notes was not up to his usual standard, and subsequent audits have shown a reasonable and improving standard of documentation."

112. I accept that a mixture of handwritten and computerised notes may be appropriate in some situations, if they are appropriately integrated. I note that the vast majority of general practices operate fully computerised notes systems. However, in this case the mixture of having an electronic record but also making handwritten notes on some

INR result sheets was unfortunate. Some of these records have been lost (see paragraph 33). There was no consistent practice to enable continuity of care. Other practitioners, such as locums, should be able to be confident that all relevant information is present.

113. I consider that many of the documentation shortcomings were within Dr D's control, and should have been avoided by adopting a more structured and consistent approach to the recording of the assessments performed, INR results obtained, and advice given, particularly for a patient with Mr A's clinical history.

114. Regardless of the various explanations supplied for the omissions in the record, there was a clear onus on Dr D to ensure that the record was complete, especially given the prolonged time frame involved. I note here that Dr D's records would have also informed the locum GP's consultations with Mr A and ensured continuity of care.

115. In my view, the failure to ensure that there were clear and up-to-date records of physical examinations for a young man with a prosthetic heart valve and significantly impaired cardiac function is concerning. I am particularly concerned that Dr D did not record Mr A's heart rate, blood pressure, whether he had oedema, and the results of auscultation of his heart sounds and lung fields. In such circumstances, I find Dr D's explanations unconvincing in relation to his clinical findings and assessments not appearing in the clinical record over such an extended period of time.

116. In considering this case, I am also mindful of the following comments made by this Office in relation to documentation:[8]

> "In her response to the provisional opinion, Ms A accepted that the record was 'not always completed accurately', but that 'it cannot be assumed that, because a medication is not recorded as having been given, it was not actually given'. However, Baragwanath J stated in his decision in *Patient A v Nelson–Marlborough District Health Board*[9] that it is through the medical record that health care providers have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk by a doctor). In my view this applies to all health professionals who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted."

117. I note that the Medical Council of New Zealand publication *The Maintenance and Retention of Patient Records*[10] states: "Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation". It requires a doctor to keep clear and accurate patient records.

[8] Opinion 08HDC10236, 28 November 2008, page 11.
[9] *Patient A v Nelson–Marlborough DHB* (HC BLE CIV–2003–204–14, 15 March 2005).
[10] August 2008.

118. Dr D failed to adequately comply with professional standards relating to documentation and therefore breached Right 4(2) of the Code.

Review of notes when examining patient

119. Dr D maintains that he spent a "considerable amount of time" with Mr A and says that his practice is to write something every time he sees a patient. He says he did not realise until during the course of my investigation that his records were not up to standard and many of the notes he said he made were absent in the period between 2006 and 2009. This infers that he did not read or review the notes properly when seeing his patient as, if he had attempted to read them, he would have realised prior to Mr A's death that records were missing.

120. Even if Dr D knew Mr A was well, it was still necessary to contrast his current condition with that existing at previous reviews, in order to assess any trends in Mr A's presentation. This required him to refer to Mr A's records at each of the regular reviews. He advised HDC "I recall examining him and would expect that I would do so every six months."

121. The Medical Council of New Zealand publication "Good Medical Practice: A Guide for Doctors"[11] states that good clinical care includes adequately assessing a patient's condition, taking account of the patient's history and his or her views and examining the patient as appropriate. Dr D's apparent ignorance of the state of the clinical record indicates that he failed to adequately review the record for the purpose of examining Mr A.

Summary

122. From 2006 to 2009 the staff at the medical centre took appropriate action to inform and communicate to Mr A the importance of compliance with his prescribed warfarin dosage, regular INR testing, and the risks involved if this did not occur. When it became apparent that Mr A's attendance for testing was irregular and compliance with prescribed warfarin dosage was not always occurring — culminating in mid-2008 in the potentially harmful high INR result outside the desired range — Dr D decided to cautiously re-warfarinise Mr A. I accept that this was a clinical course of action reasonable in the circumstances.

123. However, Dr D failed, over a prolonged period, to appropriately attend to a fundamental aspect of good medical practice when providing care to Mr A. He did not ensure that the clinical record was complete and adequately reviewed for each consultation. Accordingly, Dr D breached Right 4(2) of the Code.

Changes to practice

124. In response to the complaint and to Dr Maplesden's initial advice, Dr D advised the Office that he has thoroughly reflected on Mr A's care and instigated changes and improvements to his practice, which included: an audit of his documentation; a review of the BPAC recommendations regarding INR testing involving all his practice staff; a practice review involving a senior rural colleague; gaining RNZCGP Cornerstone Practice Accreditation involving practice-wide audits; ongoing audit of medical

[11] June 2008

records and practice patients' anticoagulation treatment; and adoption of a new point-of-contact INR testing and monitoring system.

125. Dr Maplesden reviewed results of the audits to date, which he considered appeared very satisfactory. The two pass medical records audit results also appear satisfactory with constructive reflective comments and apparent improvement in standards between the two passes. Overall, Dr Maplesden concluded that Dr D had made "significant changes to his practice that should somewhat reduce the risk of a similar situation occurring".

126. Summarising the improvements made to the clinic's INR management systems, Dr Maplesden advised:

> "The steps taken by [Dr D] to improve INR management appear appropriate and should benefit all patients at the medical centre. The new system, including the regular audit, is probably robust enough to provide a model of excellence for other rural practices. I do not see the need for any additional remedial measures."

Recommendations

127. I recommend, in light of this report, that Dr D provide by **30 July 2011**:

a) the results of any further medical documentation audits he has conducted;

b) the results of the ongoing audits of all patients on anticoagulant treatment in the medical centre practice;

c) a copy of the joint statement submitted to the RNZCGP as part of his professional development following the review of his practice; and

d) progress information about the adoption of the point-of-contact INR testing system.

e) a separate apology to both Ms C and Mrs B. The apologies are to be sent to this Office to be forwarded to Ms C and Mrs B.

Follow-up actions

- A copy of this report will be sent to the DHB and the Medical Council of New Zealand.

- A copy of this report, with details identifying the parties removed except the name of my expert, will be sent to the Royal New Zealand College of General Practitioners, and it will be advised of Dr D's name.

- A copy of this report, with details identifying the parties removed except the name of my expert, will be sent to Hospital 2 and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to the Commissioner — GP

The following clinical advice was obtained from Dr David Maplesden, Clinical Advisor:

> "Thank you for the request that I provide clinical advice in relation to the complaint from [Ms C] (partner of [Mr A]) and [Mrs B] (mother of [Mr A]) about the care provided to [Mr A] (dec) by [Dr D]. To my knowledge I have no personal or professional conflicts of interest although I have had collegial contact with [Dr D] in the past.
>
> **1.** [Documents reviewed by Dr Maplesden listed here]
>
> **2. Complaint**
>
> 2.1 The complaints note that [Mr A] had had a heart valve replacement in January 2006 and was required to be on warfarin and aspirin after this. The medication was to be monitored with regular INR testing. However the levels were low for quite some time before [Mr A's] death at the age of 25 years.
>
> 2.2 The complainants are concerned that [Mr A] did not get the care and monitoring which he needed and deserved and that this contributed to his death. They want the doctor to be held accountable for this situation and an apology made to the family.
>
> **3. Provider(s) response**
>
> 3.1 [Dr D] begins by noting that [Mr A's] partner, [Ms C], is a staff member (receptionist) at his clinic and he would welcome any opportunity to speak with her or any other family member over the incident, or to attend mediation. He feels that [the DHB] has been preventing him from offering [Ms C] his condolences or supporting her in her bereavement. He describes his isolated rural practice which is supported by part-time practice and rural nurses. He discusses the nature of his practice which involves long hours, patients often presenting to him at home after hours, and the requirement for telephone consultations because of long travel distances involved. He indicates that the practice, which is owned by [the DHB], is chronically under-resourced. He notes that [Ms C's] role in reception may, on occasions, have led to the medical notes on her partner being somewhat more circumspect than would ordinarily be the case, particularly around the frustrations experienced by staff in trying to optimise his compliance with medication.
>
> 3.2 [Dr D] notes that [Mr A] was a longstanding patient of the practice and that 'he had a casual and laid-back approach to life and to his medical treatment and it was consistently difficult to make him appreciate the seriousness of his condition'. He had a somewhat itinerant lifestyle — 'he travelled away from home to obtain casual work … it was difficult to get him into a routine and comply with his treatment'. [Dr D] describes further the challenge of getting [Mr A] to attend regularly for review and blood tests and the use of innovative measures to encourage such review — these included opportunistic

encouragement whenever a staff member saw [Mr A]; organising [Mr A] to provide transport for another family member that required monitoring; avoiding keeping [Mr A] waiting when he did attend for review. [Dr D] states 'we set out in strong terms the risk to him of non-compliance but were careful not to turn every attendance into a time of being lectured as this would have driven him away'. These discussions included education around the importance of warfarin testing and precise compliance, and the consequences of not doing so.

3.3 [Dr D] and his team also 'energetically chased up [Mr A] when he did not pick up his prescriptions of warfarin'. To help facilitate compliance with prescriptions, medications were delivered from the nearest pharmacy to the local store and the practice kept considerable supplies on hand for immediate use. There were problems contacting [Mr A] with his INR result when he did have tests done, and [Dr D] is of the opinion that [Mr A] was largely non-compliant with his medication regime as evidenced by persistently low INR results in the face of a significant dose of warfarin being prescribed, with episodic binge drinking acknowledged by [Mr A] on occasions also to be interfering with his compliance.

3.4 [Mr A] had a St Jude aortic valve replacement and a target INR of 2.5–3.5. By mid-2008 this target had been achieved and results indicated INR levels within the target range in June and July of that year, the level being 3.5 on 31 July 2008 and 3.4 on 7 August 2008. However, the test on 14 August 2008 was 5.7 and was associated with spontaneous bruising. There had been no preceding change in warfarin dosage and [Dr D] felt this result was most likely the result of improved compliance with the usual dose of medication. The warfarin was stopped because of the elevated result and INR had dropped to 1.0 by 21 August 2008. [Dr D] was reluctant to anticoagulate [Mr A] with a loading dose of warfarin at this point because of his previous compliance issues and desire to avoid the risk of overdose and haemorrhage. After consultation with colleagues, he elected to cautiously re-warfarinise [Mr A] with 2mg warfarin daily (he had been on 8mg regularly at the time of the elevated INR test). However even at 4–5mg daily [Mr A's] INR remained in the range of 1–1.5 which [Dr D] felt indicated that [Mr A] was not compliant with the medication. This was discussed with [Mr A] who admitted forgetting his medication and not taking it at weekends when he went out drinking, or if he was using non-prescription drugs. The seriousness of this situation was emphasised to [Mr A] by [Dr D] and his nurses. [Mr A] had also been cautioned against playing contact sports but was in the midst of a [sports] game when he collapsed and died.

3.5 [Dr D] is 'presently arranging for an experienced rural colleague to attend the practice and assist me in reviewing systems and my manner of practice'. He notes that the practice has recently received RNZCGP Cornerstone accreditation and that practice-wide audits are a part of the accreditation process. Management of patients on anticoagulant treatment has been reviewed and the practice has 'developed a new protocol for following up and documenting INR test results and the action taken as a result of the test' including purpose specific software. A

recent INR audit has shown that '100% of our patients on Warfarin had their INR level within their desired range'.

3.6 [Dr D] concludes by noting that some results are missing from the file. These include hard copy results with hand written advisory notes on them for dates [early] 2009, 29 September 2008 and 14 November 2008. He would like to express his 'very sincere and heartfelt sympathy to [Ms C] and to all of [Mr A's] family for this tragic loss'.

4. Review of clinical records

4.1 The GP notes are recorded on a Medtech practice management system. The 'front page' details note that [Mr A] died [in early] 2009. Regular medications are listed as warfarin, Cartia and accupril with the most recent prescription being 17 October 2008. Warfarin monitoring and a history of aortic valve replacement are included under history and long term classifications.

4.2 Notes from 18 January 2006 record a message from a [Hospital 2] doctor saying [Mr A] has had an aortic valve replacement and has had five days of warfarin 2mg daily. INRs have been around 2.3 'Target for INR 2.5'. There is a record of a call from [Mr A] the next day asking how much warfarin to take that night and when to come in for a blood test. First post-operative review by [Dr D] is 24 January 2006. There is no record of any observations such as pulse or blood pressure or chest auscultation. [Dr D] notes 'to contact [Hospital 2] to find target INR for [Mr A]'. On 3 February 2006 the INR is 1.9 (on warfarin 3mg) — the dose is increased to 4mg although there is difficulty contacting [Mr A] to pass on the instructions. Further review by [Dr D] takes place on 2 March 2006. [Mr A] is noted to be 'keeping well' and the INR is stable on 4mg warfarin. There is no record of any physical examination. On 16 March 2006 warfarin dose is increased to 6mg ([Dr J, Hospital 1]) who 'now wants [Mr A's] INR between 2.5 and 3.0'. On 7 April 2006 the dose is reduced from 6mg to 5mg following an INR of 3.3. Until the end of August 2006 it is evident that [Mr A] is having approximately weekly INR tests. These are predominantly within the therapeutic range on 5mg warfarin daily, and the result with advice re dosage changes is consistently recorded in the electronic notes. On Friday 7 July 2006 the INR is 4.8 — warfarin is stopped with the intention of a blood test the following Monday. However the test is not done for a week and [Mr A] does not take any warfarin over that time. Warfarin is recommenced at 5mg daily on 13 July 2006. On 4 August 2006 the INR is 3.2 and [Dr D] reduces warfarin to 4mg. The dose is increased to 4/5mg alternate days on 8 September 2006. On 27 October 2006 the dose is recorded as 5mg daily and INR then 2.7. There is no record of an INR being performed from then until 11 January 2007 and no comment in the notes regarding this although two prescription requests are actioned over this time.

4.3 There are only nine recorded INR tests in 2007 although a majority of these are within the therapeutic range. The result from 26 January 2007 is 1.9 with instructions to increase the warfarin dose to 6mg daily and repeat the test in a week. The next result (14 March 2007) is 3.8 — advice is recorded as 'Increase warfarin to 6mg daily and repeat blood in 2/7. [Mr A] informed via phone'

although the next day advice is recorded as 'Advised [Mr A] on [Dr L's] instructions to reduce warfarin to 4mg daily'. On 18 April 2007 INR is 3.3 and notes record 'd/w [Dr D] — 3.3 — same dose, same interval. [Mr A] doesn't really have a set interval so suggested 2/52.' Tests are taken monthly in April, May and June 2007 with another in August and one in November. There is no record that [Mr A] was seen by [Dr D] in 2007 although blood pressure was taken by a provider (MT) on one occasion that year (16 March).

4.4 [Mr A] is seen by [Dr D] for review on 4 February 2008. There is no record that any physical examination was undertaken. '[Mr A] is currently well and asymptomatic'. On 6 March 2008 [another provider] reviews [Mr A] and notes 'Has been well, he is unable to do heavy work … he has been very poor at having his INR testing done and at communication about warfarin dose adjustment … He has a plastic aortic valve, INR should be in the 3–4 range … compliance with medications is good.' [The provider] notes the absence of oedema, regular pulse of 76, normal blood pressure and mechanical heart sounds with a grade 1 systolic murmur. See section 4.7 for INR results and comments through 2008. On 20 March 2008 [Mr A] requests to get his testing done through the laboratory in [the main town] on a regular basis 'to avoid clinic wait here'. Appropriate forms are supplied and requested again on 2 May 2008 with no recorded results during that period, although [Mr A's] dose as 'currently taking warfarin 6mg daily'. On Thursday 14 August 2008 [Mr A] presents for an INR and is noted to have 'spontaneous bruising back of thighs to top of calf on both legs' after standing all day pruning grapes. [Dr D] advises cessation of warfarin until INR results are known (result is 5.7) then to remain off warfarin until further INR in three days (Monday 18 August 2008), and 'emergency advice re bleeding given & to present to ED if this happens'. Point of care testing is discussed (provider […]) on 10 September 2008 and [Mr A] 'feels well, still working, no untoward symptoms'. On 22 October 2008 the comments is made '[Mr A] contacted to see why he hadn't picked up his script. He has picked it up now. He couldn't afford to pick it up initially.' There is no record of a cardiovascular review of [Mr A] by [Dr D] in 2008 although the review by [Dr L] in March of that year was comprehensive. There is a note for [early] 2009 which states 'Deceased [early] 2009' but I have no information regarding the likely cause of death.

4.5 Hospital records show that [Mr A] underwent urgent aortic valve replacement on 13 January 2006 after an investigation for shortness of breath showed that he had severe aortic regurgitation with global dilatation of the left ventricle. Target INR is given as 2.5–3.5 with follow-up arrangements being review by GP re monitoring of bloods and review by visiting cardiologist at [Hospital 1] in 4–6 weeks. Locum physician notes for 14 March 2006 note 'in general he is doing just fine although his INR is a bit on the low side usually between 1.9 and 2.4 so I have increased his warfarin today to 6mg and told him his ideal INR would be around 3'. Cardiologist notes for 18 April 2006 advise the GP to check that [Mr A] is on beta-blockers and 'increase the dose so that his baseline heart rate is about 60 beats per minute'. There is an ED presentation at [Hospital 1] on 27 July 2006 after [Mr A] was noted to have an elevated troponin (performed because he had an irregular pulse) — this elevation was thought to be chronic. Locum

physician notes for 13 March 2007 do not record any beta-blocker medication and note 'he has not been having the INR monitored regularly and I have cautioned him in this regard'. Follow-up echocardiography in October 2008 showed the left ventricle to be severely dilated and global function moderately to severely impaired.

4.7 INR results and provider comments for 2008:

Date	INR	Comment *(H=handwritten Dr comment on result sheet, otherwise electronic in notes)*
4/2/08	1.4	(*last recorded INR 1.4 on 16 November 2007 on 4mg warfarin*)
6/3/08	1.8	Increase to 5mgs per Dr L. To rtn 1/52
8/5/08	1.5	target 2.5 to 3.5 for plastic heart valve replacements. [Mr A] aware…re regular surveillance for health. Discussed @ length, agreed to come fortnightly with [grandmother] for regular INRs.
15 /5/08	2.2	Currently on warfarin 8mg…r/v with DW — remain @8mgs, same interval. Seems more interested in self care
29/5/08	1.5	Currently taking warfarin 8mgs. Missed taking tablet last night.
5 /6/08	2.7	
12/6/08	3.4	Another INR to be taken today to assess whether this is an upward trend
16/6/08	3.1	Currently taking warfarin 8mg daily. Has forgotten to take tabs 2 days this week
16/7/08	2.9	Remain on same dose of warfarin & rpt INR 1/52
24 /7/08	2.6	Has not taken tabs for last 2/7, as ran out & not been to pick script up
31/7/08	3.5	No meds missed this time
7/8/08	3.4	Has not missed any tablets
14/8/08	5.7	Stop warfarin until result of INR is known
21/8/08	1.0	To recommence on 2mg warfarin daily and recheck in 1/52
28/8/08	1.0	Remain on warfarin 2mg daily and repeat INR 1/52 (not forgotten any tabs)
3/9/08	1.0	Increase warfarin to 3mg daily and rpt INR on Wednesday (one week)
10/9/08	1.1	Increase warfarin to 4mg daily and rpt INR 1/52
18/9/08	1.4	Has not forgotten any tablets. Remain on warfarin 4mg & repeat INR 1/52
29/9/08	1.2	Did not take warfarin on Saturday night, as had been drinking alcohol.
17/10/08	1.0	Not taking his warfarin regularly. Must have regular INRs and take tabs regularly.

		Hx aortic valve repair — must take 4mg daily. Recheck 1 wk. (H)
21/10/08	Re above	Discussed with [Dr D]. Had not forgotten any tablets. Increase warfarin to 5mg daily and repeat INR 1/52
14/11/08	1.5	Currently taking warfarin 4mgs daily. Has not forgotten any tablets
1 /12/08	1.6	Increase dose to 4mg. [Mr A] contacted — must have weekly bloods+understand risk if he does not take tabs (H)
[…] 09	1.0	1.0–4mgs warfarin
[…] 09	1.2	Takes 5mg. Last INR 1.0 on 5/1/09 ↑ from 4 to 5mgs. Hx aortic valve repair. 6mg. Message left plus passes message onto [Ms C] (H)

5. Comments

5.1 Any adverse comments regarding [Mr A's] management in the following discussion should not be perceived as having contributed to his death as there is no confirmation in the medical record as to cause of death and certainly no indication from the medical record that he was significantly unwell prior to his death. The first issue to be addressed is [Mr A's] overall management, particularly medical reviews. Anticoagulant management will be dealt with specifically in section 5.2. I am somewhat surprised that [Mr A] was not seen for regular GP review given his past history of aortic valve replacement and known persisting left ventricular dysfunction. The only formal GP review of [Mr A's] cardiovascular status was that undertaken by [Dr L] (presumably a locum) in March 2008 (4.4). I note that [Mr A] was seen by [Dr D] on other occasions and the comments at these consultations usually indicate that he was 'well' but there was no recorded contact with [Dr D] in 2007, and at other contacts there are no recorded findings to suggest that a physical examination ever took place. There were occasional checks of blood pressure recorded by the practice nurse, and annual cardiologist review was undertaken. Comments made by the cardiologist in April 2006 (4.5) regarding beta-blocker use do not appear to have been actioned by [Dr D], although the issue was not raised at subsequent specialist visits. I suggest that it would be common and accepted practice for a patient with [Mr A's] medical history and medication list to be reviewed by a GP at least six monthly (with practice nurse review alternating) and for a GP review to include blood pressure and pulse recording, auscultation of the heart sounds and lung fields and check for oedema. While there were obviously issues of patient compliance from mid 2007, throughout 2006 [Mr A] was attending every week for his blood test and at least monthly until mid to late 2007. The failure to undertake and record a structured review of [Mr A's] cardiovascular status at least six-monthly following his surgery probably represents a mild departure from expected standards, although I note that [Dr D] at least established that [Mr A] was 'well' on the occasions that he saw him, and there was contribution from the practice nurses to monitoring of some of his clinical parameters, although not in an obviously structured way. I suggest that [Dr D] reflect on the content of the

consultations he undertook with [Mr A], particularly as they relate to documentation and appropriate clinical assessment. [Dr D], through his work and senior office with the RNZCGP, is no doubt aware of the recommendations of the College regarding content of the medical record and it would be reasonable for him to consider undertaking a self-audit of his documentation.

5.2 [Mr A] was required to keep his INR between 2.5 and 3.5 — this was clearly stated in his hospital discharge summary yet there appears to have been ongoing confusion regarding the target from the time [Mr A] was first seen by [Dr D] following his surgery (4.2), not helped by recorded telephone advice from [Hospital 1] that the target was 'around 2.5', and further conflicting advice from [Dr J] in March 2006 that the target should be 3. However, had the discharge letter been read, expected practice would be that the target then be documented in the notes to prevent further confusion. This confusion led to [Dr D] adopting perhaps an overly cautious approach to [Mr A's] INR management with dose reductions being made in April and August 2006 when the INR was actually within the target range (3.3 and 3.2 respectively). I am mildly critical of the overall INR management documentation with some episodes of dose changes not recorded, and advice sometimes handwritten on lab result sheets and other times documented in the notes. It is difficult to establish how much [Mr A's] compliance contributed to some episodes of apparent poor documentation (was he changing the dose himself and then notifying staff?). I feel that the management of [Mr A's] INR from the time of his potentially dangerous result of 5.7 on 14 August 2008 was suboptimal, but that concern regarding [Mr A's] compliance contributed significantly to the strategy undertaken. [Mr A] was thought to be taking 8mg warfarin with occasional missed doses when the elevated INR was noted. Appropriately the medication was stopped at this point — ideally the INR would have been taken two to three days later and, once back in the target range or at least < 5, warfarin recommenced at a reduced dose of approximately 20% less than the previous dose[12]. The strategy undertaken by [Dr D] was overly cautious and [Mr A] did not achieve an INR approaching his target range from 21 August 2008 until the time of his death in [early] 2009. Over this time his level of compliance was recorded by nursing staff and appeared reasonable with an occasional missed tablet and acknowledgement of intermittent alcohol intake, although review of the comments made over that period is somewhat confusing (see 4.7). This confusion also relates to the doses that were being advised and taken. It was important for [Mr A] to achieve his target INR given his medical history and high risk of a thromboembolic event and [Dr D's] strategy of small dose adjustments with at least a week recommended between tests despite the INR being low was not satisfactory. I acknowledge the difficulties faced by [Dr D] in terms of [Mr A's] less than ideal compliance although given his apparently stable INR from June until mid-August 2008, and good attendance for his blood tests over this same period, I wonder if the compliance issue might have been somewhat overstated. In summary, [Dr D's] clinical management of [Mr A's] anticoagulation, at least from mid-August 2008, did in my opinion, depart from expected standards to a mild to moderate degree

[12] BPAC New Zealand. *INR Testing.* October 2006

even taking into account [Mr A's] compliance issues. The overall INR management process in the practice, while somewhat less than ideal, was probably consistent with current practice — I base this comment on my experience working at a variety of practices over the past five years, some of which have had superior processes but others whose processes have been inferior to those of [Dr D's] practice. I note also that improvements have been made to INR management processes in the practice recently and that an audit has shown these changes to be effective (3.5). I commend the practice on the efforts made to assist [Mr A] with his compliance (3.2) and note that a variety of providers had impressed on him the importance of maintaining his INR levels within the target range. Finally, I suggest that all clinical staff based in [the township], including [Dr D], review the bpac[nz] recommendations regarding INR testing.

6. Opinion

6.1 On the basis of the records available to me, and referring to comments in section 5, I am of the opinion that the overall management of [Mr A] by [Dr D] departed from expected standards to a mild degree with respect to clinical documentation and assessment, and to a mild to moderate degree with respect to the management of [Mr A's] anticoagulation therapy, at least from mid-August 2008 until the time of his death in [early] 2009. I cannot comment as to whether these omissions contributed in any way to [Mr A's] death.

Dr David Maplesden
Clinical Advisor
Health and Disability Commissioner"

Appendix B: Further clinical advice to the Commissioner — GP

Dr Maplesden then provided further clinical advice once additional information had been received by HDC.

> "Thank you for providing additional information regarding [Mr A] (dec) and [Dr D]. I have summarised this information together with relevant comments.
>
> **1. Response from [Dr D] to my original advice**
>
> (i) [Dr D] has undertaken a clinical notes audit (results viewed).
>
> (ii) [Dr D] recalls undertaking at least six-monthly reviews of [Mr A] but acknowledges that his clinical notes do not accurately reflect this. This was due in part to the difficulty 'capturing' [Mr A] for review (there was a long history of missed appointments — appointment log has been viewed and confirms this), and a majority of the reviews were done opportunistically in the nurse consultation room when [Mr A] presented for blood tests. He may have entered notes using the nurse computer but failed to change provider details so the nurse was recorded as provider.
>
> (iii) [Dr D] has established that the PMS may not have recorded notes he made for consultations of 29 May, 25 August and 28 August 2008 as the audit log records that consultations took place on these dates and [Dr D] recalls entering data into the system, yet no notes are evident in the computer record.
>
> (iv) [Dr D] reinforces the difficulty gaining compliance from [Mr A] with respect to both his attendance at the clinic and appropriate dosing of warfarin. He notes that some of the blood tests from 2008 clearly indicate [Mr A] was not taking any warfarin, and the aim was to improve compliance rather than prescribe increasing amounts of the drug. This approach was supported in an independent peer review. All staff at the medical centre are now familiar with the BPAC recommendations regarding warfarin therapy.
>
> (v) [Dr D] has had a comprehensive review of his practice undertaken by a senior and well-respected rural colleague ([Dr M]). Practice systems, in particular INR monitoring, were discussed in detail amongst a variety of other topics. The practice has been awarded RNZCGP Cornerstone accreditation as of 22 January 2009. Practice audits undertaken and changes made to practice as a result of these are listed. [Dr D] is continuing a monthly audit of all patients in the practice on warfarin therapy to ensure all are achieving therapeutic INR levels. Results of the audits to date have been reviewed and appear very satisfactory.
>
> (vi) The practice has adopted point-of-contact testing of INRs coupled with a computerised monitoring system that enhances patient engagement. This system lends itself well to the practice and community environment although there were some initial problems with discrepancies between the community laboratory and point-of-contact results which have since been resolved.

(vii) [Dr D] has maintained all the requirements for MOPS recertification.

(viii) [Dr D] would prefer a mediation approach to resolving any outstanding issues as this would be the most culturally appropriate response under the circumstances.

(ix) Content of Medical Records two pass audit results have been reviewed and appear satisfactory with constructive reflective comments and apparent improvement in standards between the two passes. However, I remain of the opinion that the standard of clinical documentation completed for [Mr A] was suboptimal although there may have been extenuating circumstances as discussed above.

2. Statement from [Ms F] (practice nurse [the] Medical Centre)

(i) [Ms F] reiterates the difficulties all staff at the medical centre encountered with [Mr A's] poor compliance with appointments and medication, complicated by his admissions of alcohol and marijuana use during which time he would stop his medication. He was very difficult to contact and staff would spend considerable time attempting to track him down through his partner and relatives to convey his blood results and medication adjustments.

(ii) [Ms F] was present on several occasions when [Dr D] discussed with [Mr A] the importance of medication compliance. [Mr A] appeared quite satisfied with the care he was receiving.

(iii) [Ms F] recalls [Dr D] undertaking a comprehensive examination of [Mr A] on 14 August 2008 which he undertook in her presence, and which was documented on her computer. It is unclear why the notes did not appear on the computer later although this has been an intermittent but persistent problem with the PMS.

(iv) [Ms F] is confident in the clinical abilities of [Dr D].

3. Statement from [Ms G] (practice nurse [the] Medical Centre)

(i) [Ms G] notes her role in [Mr A's] care which was made difficult by his poor compliance with appointments for blood tests and being very difficult to contact with results and treatment advice. [Mr A's] partner worked at the medical centre and she was also involved by nursing staff in an attempt to improve his compliance with testing and treatment.

(ii) Staff went to extraordinary measures to try and ensure [Mr A's] compliance with his regime. This included attempts to coincide his blood testing with that of his grandmother so the two could support each other with respect to transport and appointment keeping, and approaching [Mr A] at every opportunity out of the medical centre setting to encourage compliance.

4. Response from [Ms E] Barrister

(i) The response relates to my comments regarding [Dr D's] apparent failure to consider the advice of specialist [Dr H] (18 April 2006) regarding the use of beta-blockers for [Mr A]. [Dr D] is unsure when [Dr H's] advice was received but he was aware of the advice when [Mr A] presented with a slow pulse rate in July 2006 and beta-blockers would have been contraindicated.

(ii) [Dr D] is disturbed to note that [Mr A's] pulse rate was not recorded by the practice nurse when his blood pressure was taken on several occasions in 2006. However, he is confident that the nurses would have discussed with him any concerns if the heart rate had been raised on these occasions.

(iii) [Dr D] notes that [Mr A] was seen by specialists on 27 July 2006 and in March 2007 and that no problems with [Mr A's] pulse rate, or comment regarding beta blocker use, was made.

(iv) I have reviewed the clinical notes and cannot find any episode or marked tachycardia with pulse rates generally between 66 and 76. The reason for [Dr H] advising commencement of a beta-blocker was his observation of [Mr A's] chronic left ventricular dysfunction on his echocardiogram. It is quite possible that, had [Dr D] commenced the medication as recommended, it would have been stopped in July 2006 when [Mr A] presented with significant bradycardia. I note that beta-blocker use was not advocated or recommended by the two specialists [Mr A] saw following [Dr H's] advice, even though a copy of this advice was in the hospital notes. While I am not confident that [Dr D] did note [Dr H's] recommendation, as evidenced by the lack of reference to the advice in his clinical notes or any arrangement made for regular review of his pulse rate, the circumstances are such that the failure by [Dr D] to commence [Mr A] on a beta-blocker, as recommended by [Dr H], is probably not a significant departure from expected practice.

5. [Ms C's] response to [Dr D]

(i) [Ms C] notes that [Mr A's] opportunistic presentations to [the] Medical Centre were a result of him having to wait up to two hours at a time for blood tests on some occasions.

(ii) [Ms C] disputes [Dr D's] assertion that he was 'energetically' involved in chasing up [Mr A] regarding his treatment, although she and other staff members did so.

(iii) [Ms C] notes some discrepancies in [Dr D's] explanations of his warfarin prescribing. She also maintains that [Mr A] took his medication as prescribed.

6. Further discussion:

You have asked for a response to specific questions. These responses are to be read in conjunction with my original advice, and the comments made above.

1. *Please comment generally on the overall standard and appropriateness of care provided to [Mr A] by [Dr D].+*

i) **Management of INR:** From August 2008 until the time of [Mr A's] death (see 4.7 and 5.2 in original advice), it is clear that [Mr A] was variably complaint with his medication. Comments on 31 July 2008 (INR 3.5) and 7 August 2008 (INR 3.4) indicate that compliance was apparently satisfactory with 8mg warfarin daily so the sudden rise of INR to 5.7 was somewhat unexplained. Nevertheless, it was appropriate for [Dr D] to stop the medication temporarily and monitor as discussed previously. It is unlikely, as noted in [Dr D's] response (1(iv) above), that [Mr A] was taking any warfarin, or taking it very intermittently, during the period 21 August to 21 October 2008. On reflection, I am of the opinion that it was therefore quite reasonable for the approach to be one of encouraging compliance with currently prescribed doses of warfarin, and therefore to gain an accurate idea of therapeutic response, rather than just recommending higher doses which may have been somewhat unsafe in the face of variable compliance. Affidavits from the practice nurses support [Dr D's] assertion that very considerable efforts were made to facilitate [Mr A's] compliance. From 14 November 2008 (INR 1.5), nurse comments indicate that [Mr A] was taking his tablets regularly, and there are conflicting notes regarding recommended doses (see table 4.7 in original advice). An INR result of 1.0 [in early] 2009 does indicate that [Mr A's] compliance had lapsed and efforts were being made to regain a therapeutic INR when [Mr A] unfortunately died. Prior to August 2008, INR recording was undertaken at less than recommended intervals given the results. However, on reviewing the additional information supplied above, it is apparent that the major factor in [Mr A's] failure to maintain a therapeutic INR from the time of his operation was his lack of compliance with recommendations of medical staff, and I cannot see that much more could have been done to improve his situation. There was a mild departure from expected standards with respect to the structure of INR monitoring, particularly the absence of a consistent approach to recording of results and advice given (a mixture of handwritten and computerised) which made overall monitoring somewhat difficult. However, as noted in my original advice, I have experienced similar and even less structured approaches to INR monitoring in other practices I have worked in, but have also seen far more robust processes as well. On review of the notes, it is apparent that a majority of INR results have been received and acted upon within 24 hours of the test and this would be consistent with expected standards in a rural area. The steps taken by [Dr D] to improve INR management appear appropriate and should benefit all patients at the medical centre. The new system, including the regular audit, is probably robust enough to provide a model of excellence for other rural practices. I do not see the need for any additional remedial measures.

(ii) **Clinical documentation:** There have been some extenuating circumstances described in [Dr D's] response, including PMS difficulties and the effect [Mr

A's] opportunistic presentations had on the ability to satisfactorily record observations. Nevertheless, I remain of the opinion that the standard of clinical documentation in this case, a young man with a prosthetic heart valve and significantly impaired cardiac function, departed from expected standards to a mild degree. [Dr D] has acknowledged that the content of the notes was not up to his usual standard, and subsequent audits have shown a reasonable and improving standard of documentation. I do not see the need for any additional remedial measures.

(iii) Prescribing of beta-blockers: this is discussed in 4(iv) above.

2.*When [Mr A] returned a repeat Troponin I result of 0.93 on 4 August 2006, should [Dr D] have taken any further action in response to this result?*

[Mr A] was noted to have an irregular pulse on 27 July 2006. There was no chest pain or shortness of breath, Troponin was elevated at 0.64 ug/L (normal 0–0.15). [Mr A] was referred ED at [Hospital 1] for review. Here it was noted that the troponin was 0.88 and had been 0.66 in November 2005. There were no ischaemic changes on ECG and [Mr A] remained asymptomatic. The comment on the discharge summary is *Elevated Trop I (chronic).* [specialist] — *no treatment needed. GP practice can repeat Trop I in 1–2 weeks to see if it changes (most likely to be elevated constantly @ 0.60–0.80 due to enlarged heart).* This advice is noted in the GP notes for 28 July 2006. On 3 August 2006 [Mr A] was reviewed (provider listed as […]) — Blood pressure was a little elevated but pulse rate satisfactory and he was well. Repeat troponin was taken as advised and returned as 0.93. In this clinical context, I do not think there was any strong indication to repeat the test as [Mr A] was asymptomatic, had known impairment of cardiac function and an enlarged heart, and there was an expectation the level would remain elevated. I am not aware that taking serial troponin levels is a valid means of monitoring left ventricular dysfunction. The increased level might have raised the issue of beta-blocker therapy to reduce strain on the heart, but had this been deemed appropriate I would have expected such advice to have come from the physician attending [Mr A] on 27 July 2006. Given [Mr A's] presentation with bradycardia, such therapy may not have been appropriate.

3. *Which professional standards and guidelines are most applicable in relation to [Dr D's] care of [Mr A].*

(i) Clinical documentation: RNZCGP *Content of Medical Records* Cornerstone audit module, available at www.rnzcgp.org.nz/.../Cornerstone-Content-of-Medical-Records-2009.pdf

(ii) INR management: BPAC publication *INR Testing* October 2006, available at http://www.bpac.org.nz/resources/campaign/inr/bpac_inr_poem_2006_pf.pdf

4. *Are there any aspects of the care provided by [Dr D] that you consider warrant additional comment? Please outline any further recommendations you may have to address concerns raised by this complaint.*

(i) **Certification of death:** The death certificate has been signed by [Dr D] and is dated [the day of Mr A's death]. Cause of death is recorded as *cerebrovascular accident 15 minutes* with antecedent causes listed as *mitral valve regurgitation 5 years, rheumatic fever 20 years*. [Dr D] states on the certificate that he last saw [Mr A] on [the day before his death]. The medical notes do not record a specific consultation on this date but I note that [Mr A] did attend for a blood test on this date and therefore may have been seen by [Dr D]. The last recorded formal consultation with [Dr D] was 14 August 2008 even though no examination results were recorded at this time apart from a practice nurse note that he had reviewed [Mr A's] bruising (but see discussions above). There had been a comprehensive review by of [Mr A] by locum [Dr L] on 6 March 2008, and blood pressure and pulse recordings by provider [Ms F] (presumably a practice nurse) most recently on 14 November 2008. [Mr A] had had a follow-up echocardiogram by [a consultant physician] on 30 October 2009 (showing good functioning of the aortic valve replacement but moderately severely impaired left ventricular function) and he was evidently overdue for specialist review. The Burial and Cremation Act 1964, Subsection (2) of section 46B (Doctor's certificate in relation to illness) states *A doctor who attended the person during the illness must, if (and only if) satisfied that the person's death was a natural consequence of the illness, give a doctor's certificate for the death immediately after the doctor learns of the death.* The Coroners Act 2006, Subsection 1(a) of section 13 (Deaths that must be reported) includes *every death that appears to have been without known cause, or suicide, or unnatural or violent.* It could be argued that the sudden death of a 25-year-old man while active in the community, even with a known aortic valve replacement and impaired cardiac function, would warrant a Coroner referral particularly as [Mr A] was apparently well until the time of sudden death, and was actually playing [sport] at the time. It is also relevant that [Mr A] had not had a documented GP assessment for over six months prior to his death. It is unclear on what clinical basis [Dr D] made the diagnosis of cerebrovascular accident as cause of death. However, I understand that cultural issues are very relevant in this situation and referral for autopsy may not have been culturally acceptable when [Dr D] felt confident in the most likely cause of death. It may be of interest to seek the opinion of a coroner on what would be the most appropriate course of action in these circumstances.

(ii) **DHB information:** On reviewing the notes it is apparent that the operation note for [Mr A], which was the only formal documentation from [Hospital 2] to include the target INR range, was not typed and sent to [Dr D] until almost four months after the surgery. This observation, and the fact that the target INR range was not included in the basic (but more timely) discharge summary sent to [Dr D], are mild departures from standards expected of DHB documentation (see 5.2 of original advice for context). The departure would be more severe if there had not been telephone contact from [Hospital 2] verbally stating the target INR range shortly after [Mr A's] discharge.

(iii) **Further recommendations:** It is my opinion that [Dr D] [this section has been redacted as it is not relevant to the clinical advice] had made significant changes to his practice that should somewhat reduce the risk of a similar situation

occurring. It is apparent that the practice made genuine and persistent efforts to engage [Mr A] in a partnership model of care. It is unfortunate that this model of care was ultimately ineffective for [Mr A] but he was within his rights to take his medication as he wished, and was aware of the potential consequences of his actions. [This section has been redacted as it is not relevant to the clinical advice].

Dr David Maplesden MB ChB Dip Obst FRNZCGP
Clinical Advisor
Health and Disability Commissioner"

Appendix C: INR/Warfarin table

Date	Warfarin taken	INR result	Warfarin amount to be taken
Day after discharge			2mg
3 February 2006	3mg	1.9	4mg
9 February to 24 February 2006	4mg	weekly tests – mid 2.0s	4mg
2 March 2006	4mg	stable	4mg
6 March 2006	4mg	1.7	5mg
10 March 2006	5mg	2.6	5mg
14 March 2006	5mg	1.9-2.4	6mg
Rest of March 2006	6mg	weekly tests – 2.2-2.8	6mg
7 April 2006	6mg	3.3	5mg
Until end of August 2006	5mg	weekly tests	5mg
27 April 2006	5mg	2.7	5mg
May and June 2006	5mg	2.2-3.4	5mg
7 July 2006	5mg	4.8	stopped
13 July 2006	nil	1.1	5mg
21 July 2006	5mg	2.1	5mg
4 August 2006	5mg	3.2	4mg
14 August 2006	4mg	1.9	4mg
18 August 2006	4mg	2.0	4mg
8 September 2006	4mg	1.5	4/5mg alternate days
27 October 2006	5mg	2.6	5mg
26 January 2007	5mg	1.9	6mg
14 March 2007	6mg	3.8	6mg (?error)
15 March 2007			4mg
23 March 2007	4mg	3.5	4mg
18 April 2007	4mg	3.3	4mg
April and May 2007	4mg	2.4	4mg
June 2007		2.8	5mg
November 2007		1.4	4mg
4 February 2008	4mg	1.9	4mg
6 March 2008	4mg	1.8	4mg
10 March 2008	4mg		5mg
12 May 2008	5mg	1.5	8mg
15 May to 7 August 2008	8mg	2.2-3.5	8mg
31 July 2008	8mg	3.5	8mg
7 August 2008	8mg	3.4	8mg
14 August 2008	8mg	5.7	stopped
21 August 2008	stopped	1.0	2mg
28 August 2008	2mg	1.0	2mg
3 September 2008	2mg	1.0	3mg
10 September 2008	1mg	1.1	4mg
19 September 2008	4mg	1.4	4mg
29 September 2008	4mg	1.2	4mg
17 October 2008	4mg	1.0	4mg
21 October 2008	4mg	-	5mg
14 November 2008	4mg	1.5	5mg
1 December 2008	4mg	1.6	4mg?
[…] 2009	4mg	1.0	5mg
[…] 2009	5mg	1.2	6mg
Died […] 2009			