Auckland District Health Board

Waikato District Health Board

Bay of Plenty District Health Board

A Report by the

Health and Disability Commissioner

(Case 14HDC00885)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In early 2010, Mrs A (then aged 62 years) developed a nephrotic syndrome (a non-specific kidney disorder). By late 2010, the cause of Mrs A's nephrotic syndrome was diagnosed as AA amyloidosis, a rare disease caused by an abnormal accumulation of proteins in the tissues of the body.[1] Generally, amyloidosis is associated with some form of chronic inflammation. The underlying cause of Mrs A's inflammation was unknown.

2. In February 2011, Mrs A underwent a trial of prednisone[2] to reduce the chance of further organ involvement by amyloidosis. In April 2011, Mrs A commenced peritoneal dialysis.[3]

3. Mrs A's general practitioner (GP), Dr D, was located at a medical centre in her home town, and her domicile district health board was Bay of Plenty (BOPDHB). BOPDHB does not have its own renal service, and renal services for residents of the Bay of Plenty region are therefore delivered by Waikato District Health Board (WDHB) as part of the Midland Regional Renal Service.

4. This investigation focuses on the evaluation of Mrs A as a recipient for kidney transplantation, including the evaluation of her daughter, Ms C, as a living donor.

Recipient evaluation

5. There was an agreed process in place for WDHB to communicate with Auckland Regional Transplant Group (ARTG) about recipient and donor evaluations. This involved presenting WDHB cases to ARTG at outreach clinics or ARTG transplant recipient and donor selection meetings when the WDHB renal team considered that the case had met the ARTG requirements. However, there were several points in Mrs A's transplant evaluation where delays occurred because errors were made or the proper process was not followed by WDHB.

6. On 16 August 2012, renal physician Dr K's referral to Tauranga Hospital Cardiology Department was erroneously sent to Waikato Hospital's Cardiology Department. The error was not identified and corrected until 7 September 2012.

7. On 17 December 2012, Mrs A had a normal perfusion scan. Two and a half weeks later, on 4 January 2013, WDHB emailed ADHB to check whether, given the normal scan and noting that the cardiologists "did not want to do MRI due to gadolinium", this was "okay as far as cardiac assessment goes". WDHB told HDC that the implication of this email was that "a positive response would constitute a conclusion

[1] The initial diagnosis was made by Waikato District Health Board haematologist Dr E in September 2010. A subsequent kidney biopsy on 18 November 2010 confirmed the presence of serum amyloid A (SAA).
[2] A synthetic corticosteroid, used as an anti-inflammatory and immunosuppressant.
[3] A dialysis technique in which a catheter is placed into the peritoneum (abdominal lining) to filter waste products from the blood with the assistance of dialysate (a cleansing fluid). The technique can be controlled by the individual at home.

of [Mrs A's] transplant evaluation and listing for presentation to ARTG at the monthly meeting". The email was not responded to.

8. Mrs A's case was not presented at the WDHB renal physician meeting in January or February 2013, nor was she listed for an ARTG transplant recipient meeting during these months.

9. When Mrs A was presented to the WDHB renal physician meeting in March 2013, the decision recorded was "? present to ARTG — Yes, finish evaluation". There was no detail recorded about what was required to finish the evaluation, and Mrs A was not listed for presentation at the ARTG. No renal physician meeting took place in April because of Easter, and therefore Mrs A's case was not presented until the next meeting on 6 May 2013.

Donor evaluation

10. On 4 July 2013, three weeks after Mrs A was accepted onto the deceased donor waiting list, Ms C completed an initial evaluation to become a donor for her mother. As Mrs A's daughter, the first screening test was to crossmatch samples of Mrs A's and Ms C's blood. This test was requested on 9 July 2013, and it was completed on 23 July 2013. There is no record of any further tests until 4 September 2013, when Ms C's ambulatory blood pressure test was performed and reported to be normal.

11. Ms C was presented to an ARTG clinic on 11 November 2013, where she was provided education about the transplant procedure and what she could expect throughout the donation process. She also had a psycho-social assessment completed, and was assessed by ADHB transplant surgeon Dr L. On 27 November 2013, Ms C was seen by ARTG transplant nephrologist Dr N.

12. Ms C was accepted to proceed as a living kidney donor, which allowed for the next and final stages of evaluation to be completed (referral to a psychiatrist or clinical psychologist, and a CT renal angiogram).

13. Ms C's donor evaluation was protracted and of an unreasonable duration in the circumstances. Ms C was young and healthy, and her assessment began following Mrs A's acceptance for transplant. Ms C's ambulatory blood pressure report was completed on 4 September 2013, but she was not presented to the ARTG until November 2013. These meetings are held monthly, and Ms C should have been presented to the ARTG before November 2013.

14. Unfortunately, around August 2013 key staff at WDHB went on unplanned extended leave and the remaining staff had to take over the additional workload without any handover. This resulted in the remaining staff having a large workload and being unable to check proactively on the status of all their consumers.

Findings

15. WDHB breached Right 4(5)[4] of the Code. The continuity of Mrs A's care was compromised owing to the fact that there were several points in the evaluative process where there was delay because of error, failure to follow agreed process in communicating with ARTG, resource allocation, or lack of clarity regarding roles.

16. Adverse comment is also made about ADHB for not providing greater clarity regarding what cardiac investigations were necessary, the delay by ADHB in communicating to WDHB its initial acceptance for recipient evaluation of Mrs A, and ADHB not responding to WDHB's enquiry regarding the adequacy of the cardiac evaluation.

17. Adverse comment is also made about neither ADHB nor WDHB taking the lead in resolving whether Mrs A should have a cardiac MRI and progressing her case. The advice that a cardiac MRI was not practical in Mrs A's case was given clearly in October 2012, and again in November 2012. And yet the concern was still being raised in May 2013.

Recommendations

18. It is recommended that WDHB, ADHB, and BOPDHB collaborate in reviewing their system for sharing information regarding renal transplants.

    a) A policy should be agreed upon that includes:

        i. A clear method for seeking and providing advice.

        ii. The form in which information is shared.

        iii. The responsibility of each party — this may include establishing a responsible renal physician at WDHB and/or ADHB for each consumer, or one renal physician at WDHB responsible for all transplantation evaluations.

        iv. Timeframes wherever appropriate.

    b) Where appropriate, template letters or documents should be created or amended to align with the policy.

    c) A system should be developed for providing regular education/training to all relevant staff to ensure that the communication pathways are understood and that the practices do not deviate from the policy over time.

19. It is recommended that WDHB:

    a) Update HDC on the changes it has put in place. In particular:

        i. Development of an IT platform.

[4] Under Right 4(5) of the Code, "[e]very consumer has the right to co-operation among providers to ensure quality and continuity of services".

ii. Details of the service improvements that have occurred as a result of the monthly meetings organised by the lead transplant physician.

b) With the assistance of other district health boards, establish clear guidelines for the evaluation of living donors. The guidelines should include:

i. What circumstances are required for evaluations to begin prior to a recipient being accepted onto the deceased donor list.

ii. Which tests will be completed prior to recipient acceptance.

iii. Guidelines around timeframes for completion of tests.

c) Review staffing ratios to ensure that the needs of consumers can be met safely.

d) Provide a written apology to Mrs A's family for its breach of the Code.

20. It is recommended that ADHB establish a system for providing clear and specific instructions at the outset as to what is necessary for recipient evaluation in circumstances that deviate from the norm (such as dealing with complex and rare diseases), including where certain evaluations may not be required.

Complaint and investigation

21. The Commissioner received a complaint from Ms B about the services provided to her sister, the late Mrs A.

22. The following issues were identified for investigation:

- *The appropriateness of the care provided to Mrs A by Waikato District Health Board between 2012 and 2014.*
- *The appropriateness of the care provided to Mrs A by Bay of Plenty District Health Board between 2012 and 2014.*
- *The appropriateness of the care provided to Mrs A by Auckland District Health Board between 2012 and 2014.*

23. An investigation was commenced on 2 September 2015.

24. The parties directly involved in the investigation were:

Ms B	Complainant/consumer's sister
Ms C	Consumer's daughter/executor of estate
Auckland District Health Board	Provider
Bay of Plenty District Health Board	Provider
Waikato District Health Board	Provider

25. Information was reviewed from:

Dr D	Provider/general practitioner
Medical centre	Provider
Dr E	Provider/haematologist (WDHB)
Dr F	Provider/Clinical Director, Midland Regional Renal Services (WDHB)

Also mentioned in this report:

Dr K	Renal physician
Dr L	Transplant surgeon
Dr M	Rheumatologist
Dr N	Transplant nephrologist
Dr O	Renal physician
Dr P	Cardiologist
Dr Q	Cardiologist
Dr S	Nephrologist

26. Independent expert advice was obtained from a renal physician, Dr Grant Pidgeon (**Appendix B**).

Information gathered during investigation

Background

27. In early 2010, Mrs A (then aged 62 years) developed a nephrotic syndrome (a non-specific kidney disorder). By late 2010, the cause of Mrs A's nephrotic syndrome was diagnosed as AA amyloidosis, a rare disease caused by an abnormal accumulation of proteins in the tissues of the body. Generally, amyloidosis is associated with some form of chronic inflammation. The underlying cause of Mrs A's inflammation was unknown.

28. In February 2011, Mrs A underwent a trial of prednisone to reduce the chance of further organ involvement by amyloidosis. In April 2011 Mrs A commenced peritoneal dialysis.

29. Mrs A's general practitioner (GP), Dr D, was located at the medical centre in her home town, and her domicile district health board was Bay of Plenty (BOPDHB). BOPDHB does not have its own renal service, and renal services for residents of the Bay of Plenty region are therefore delivered by Waikato District Health Board as part of the Midland Regional Renal Service (see below).

30. This investigation focuses on the evaluation of Mrs A as a recipient for kidney transplantation, including the evaluation of her daughter, Ms C, as a living donor. The referral for transplant evaluation followed unsuccessful attempts by haematologist Dr

E and rheumatologist Dr M to obtain special authority from PHARMAC[5] for a medication named anakinra[6] in the hope of slowing the progression of Mrs A's renal disease.

31. Mrs A died in 2014.

Kidney transplantation services in New Zealand

32. In New Zealand, both at the time of these events and currently, kidney transplantation services are not provided at a national level and, at the time of these events, there were no national guidelines for recipient and donor assessment.

33. With respect to provision of transplantation services, within New Zealand there are three types of district health board:[7]

1) **Transplanting district health boards.** These district health boards provide kidney transplantation services for their local population and several other district health boards. They also have comprehensive dialysis services. There are three of these, including Auckland District Health Board (ADHB).
2) **Referring district health boards with "comprehensive" dialysis services.** These district health boards provide their own dialysis services without any involvement from other district health boards. There are eight of these, including WDHB.
3) **District health boards without comprehensive dialysis services.** These district health boards are dependent on referring or transplanting district health boards for at least part of their dialysis service. There are nine of these, including BOPDHB.

34. Assessments and diagnostic testing for potential recipients and donors may be provided at non-transplanting district health boards. Depending on where people live, there is variability on who provides the assessment, which elements of assessment are provided, in which order, and by which district health board.

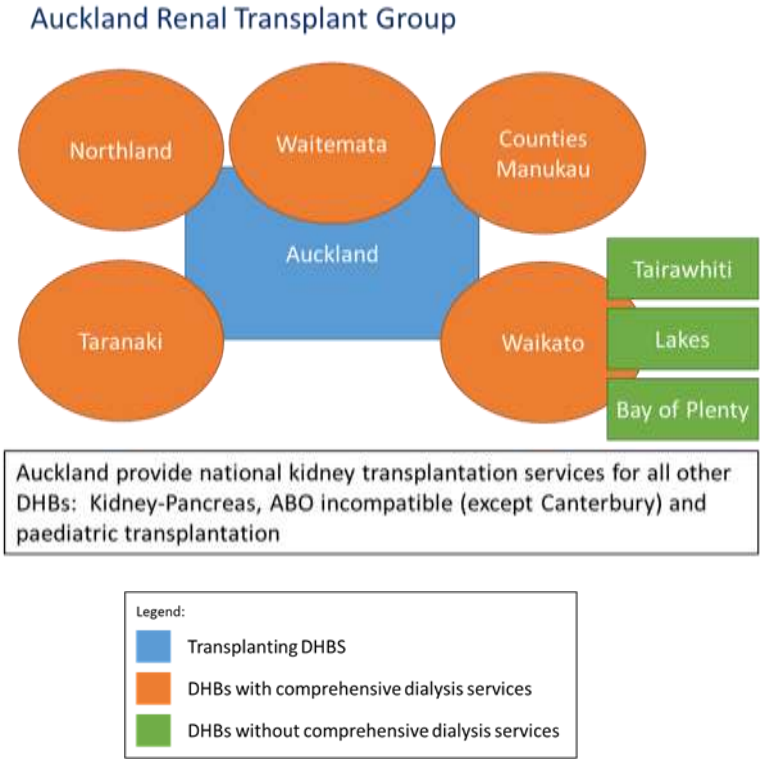
35. Mrs A fell within the catchment of the Auckland Renal Transplant Group (ARTG), which provides a supra-regional kidney transplant service for patients referred from district health boards in the northern half of the North Island.

Auckland Renal Transplant Group

36. The ARTG is one part of a wider ADHB group, the Intra-abdominal Transplant Service (IATS). The IATS provides solid organ transplant services for individuals

[5] PHARMAC is the New Zealand government agency that decides which pharmaceuticals to fund publicly in New Zealand.
[6] Anakinra is a recombinant, non-glycosylated form of the human Interleukin-1 receptor antagonist primarily used to treat rheumatoid arthritis. Currently, anakinra is funded by PHARMAC via the Special Authority process, where funding is assessed and granted for a particular individual.
[7] "Kidney Transplant Activity New Zealand — 2014 Calendar Year", National Renal Transplant Service, 1 May 2015, at 2. Available at http://www.health.govt.nz/system/files/documents/pages/nrts-kidney-transplant-activity-nz-2014.pdf.

requiring liver, pancreatic (both national services), and kidney transplantation. The arrangement of the ARTG is described in the figure below.[8]



37. ADHB told HDC:

> "Whilst there are clear guidelines about avoiding any discrimination between parties from within, compared to without the service DHB, there are importantly, no guidelines about the time frame for evaluating either recipients or potential living donors."

ADHB Guideline — Renal Transplant Adult Recipient: Patient Selection[9]

38. The "Renal Transplant Adult Recipient: Patient Selection" guideline describes the selection pathway for potential recipients. This guideline arose from a review of ARTG's 2006 "Renal Transplant Protocol" and was in practice in September 2012 (approximately three months after Mrs A's evaluation began).

39. The document advises:

> "Following referral to the ARTG the transplant coordinator[10] should ensure that all necessary investigations and assessments have been completed. They should

[8] "Kidney Transplant Activity New Zealand — 2014 Calendar Year", National Renal Transplant Service, 1 May 2015, at 3. Available at http://www.health.govt.nz/system/files/documents/pages/nrts-kidney-transplant-activity-nz-2014.pdf.
[9] Published December 2012.
[10] The transplant coordinator's role is discussed in more detail at paragraph 50.

> arrange for an assessment by a renal transplant surgeon, nephrologist and coordinator in preparation for presentation to the ARTG selection meeting.
>
> Patients, particularly those with an identified live donor, should be considered for transplantation prior to the institution of dialysis. For this to occur, the need for dialysis must be imminent and/or the nature of the underlying disease process sufficiently well-defined to ensure the continued deterioration of renal function will ensue …"[11]

40. Cardiac studies are included in the tests the transplant coordinator ensures are completed. These are performed in order to assess the likelihood of cardiovascular complications during or following transplantation. Following electrocardiogram (ECG)[12] and cardiac history assessment, patients are divided into two risk groups: "low risk" (not applicable to Mrs A) and "intermediate and high risk". Patients in the intermediate and high risk categories are to be referred for echocardiogram[13] and a provocative cardiac stress test.[14] Subsequent management would depend on the outcome of these studies.

41. The guideline includes the following disclaimer:

> "No guideline can cover all variations required for specific circumstances. It is the responsibility of the health care practitioners using this ADHB guideline to adapt it for safe use within their own institution, recognise the need for specialist help, and call for it without delay, when an individual patient falls outside of the boundaries of this guideline."

Midland Regional Renal Service

42. The Midland Regional Renal Service, based at Waikato Hospital (WDHB), is responsible for providing tertiary renal care in the Midland area (including Waikato, Lakes, Tairāwhiti, and Bay of Plenty district health boards). Within the umbrella of the Midland Regional Renal Service, each district health board remains responsible for the care that its staff provides.

43. BOPDHB told HDC that it is responsible for the collation of referrals to the WDHB renal service for Bay of Plenty residents. The patients are then graded by WDHB and cared for by WDHB renal physicians at outpatient clinic rooms at BOPDHB.

[11] These paragraphs are also contained in the 2006 Protocol.
[12] A graphic tracing of the variations in electrical activity of the heart.
[13] An echocardiogram (or cardiac echo) is a sonogram of the heart, in which ultrasound images of the heart are created.
[14] Cardiac stress tests measure the amount of stress the heart can manage before developing either an abnormal rhythm or evidence of ischaemia (inadequate blood flow to the heart).

44. WDHB has no renal information technology (IT) platform, and the renal transplant coordinators work from Excel spreadsheets and hardcopy patient folders to monitor patients manually regarding their evaluations to assess suitability for transplant.[15]

Relationship between ADHB and WDHB

45. ADHB told HDC that, at the time of Mrs A's evaluation, ARTG conducted outreach clinics in referring district health boards (including WDHB), to undertake the evaluation of potential kidney transplant recipients and live donors. A transplant surgeon, nephrologist,[16] and renal transplant coordinator (transplant coordinator) would travel to the outreach clinic to see the patients who were scheduled by that district health board.

46. ADHB said that selection conferences are held twice a month within the ARTG, and the WDHB nephrologists present their patients for consideration even though the patients also will have been seen by ARTG staff at one of the outreach clinics.

47. ADHB said that there is no protocol regarding the interactions between the WDHB renal service and ARTG. Communication is primarily through the transplant coordinators, although the nephrologists at WDHB also communicate with the nephrologists and transplant coordinators at ARTG. ADHB said that there is a "general expectation that all patient visits are recorded by means of a clinic letter and all decisions made at the selection conference meeting are documented, again by means of a letter".

48. WDHB told HDC:

> "Any relevant tests and correspondence regarding potential transplant recipients and donors are filed in patient dedicated folders and scanned by the Waikato transplant co-ordinators to the relevant Auckland based clinician (co-ordinator, physician or surgeon). Material sent to Auckland is identified as 'scanned ARTG' with a date."

49. WDHB told HDC that the Midland Regional Renal Service's role in the relationship with ARTG includes:

a) Midland clinical staff identify potential kidney transplant recipients.

b) WDHB transplant coordinators organise an education session for transplant recipients.

c) If the potential recipient is suitable, WDHB transplant coordinators coordinate evaluation following the standardised evaluation protocol developed by the ARTG.

[15] There was a recommendation made in "Regional Service Plan for the Midland Region: Part Two Recommendations — Options and Opportunities" (December 2004) to develop a business case to support the development of a database that would allow analysis of patient flow and the services. This information management system was to centre on an integrated regional end-stage renal failure prevention programme across the Midland region.

[16] A nephrologist (or renal physician) is a medical specialist who deals with diseases of the kidneys.

d) When WDHB clinical staff feel that the potential recipient or donor has met ARTG requirements, they are referred to the visiting ARTG team, who review at a monthly Waikato-based ARTG clinic.

e) If the ARTG considers further tests are needed, a letter will be sent from the visiting transplant physician requesting these.

f) Once WDHB clinical staff feel that they have met additional ARTG requirements satisfactorily, WDHB lists the patient for presentation at a monthly ARTG transplant recipient and donor selection meeting (these are done via conference call between WDHB and ARTG).

Role of renal transplant coordinators

50. In New Zealand, transplant coordinators are registered nurses with a current practising certificate who have specialist experience in renal services and work with a multidisciplinary team to coordinate care relating to kidney transplantations.

51. During the relevant period, WDHB's renal transplant service lacked a sufficient number of transplant coordinators. Transplant coordinators, in partnership with ARTG, is responsible for the assessment and education of all potential kidney and pancreas/kidney transplant recipients and live donors in the Midland region. One aspect of this role is to select recipients and donors suitable for the monthly ARTG review meetings.

52. The ARTG transplant coordinators' role was to liaise with the WDHB's transplant coordinators, and when a patient is ready to be presented at the recipient review meeting the WDHB transplant coordinators ask the ARTG transplant coordinators to add the patient's name to the agenda.

53. BOPDHB does not employ any transplant coordinators.

Timeline of transplant recipient evaluation of Mrs A

54. On 22 May 2012, Dr E referred Mrs A via email to a renal physician at ARTG, to assess her suitability for a kidney transplant. Dr E copied WDHB renal physician Dr O into this letter, along with Mrs A's GP. A transplant coordinator was not included in this correspondence.

55. Dr E noted in the referral that he had made it directly to ARTG, rather than the renal physicians at WDHB, because they were in the process of changing personnel in the region. Dr E's clinical experience included three years overseas at a centre where he saw all patients with amyloidosis in the region, and offered advice regarding amyloidosis to many colleagues.

56. On 1 June 2012, Mrs A was booked into the next available ARTG clinic at Waikato Hospital, scheduled for 18 June 2012. At the ARTG clinic, renal transplantation and live donation with Mrs A and her daughter, Ms C was discussed. Mrs A was also seen by ADHB transplant surgeon Dr L and ADHB transplant nephrologist Dr N.

57. ADHB told HDC that Dr N discussed with Mrs A that a careful review of the literature would be needed to help guide decisions about transplantation, and that it was not a decision that would be made independently by Dr N, but required a discussion with the wider transplant group. ADHB said that a review of literature was undertaken and presented to ARTG for discussion. The issues that arose in respect of Mrs A included older age, increased risk of infection and, in particular, increased risk of cardiac complications in the post-transplant period.

58. Dr N's clinic letter to Dr F, a renal physician at WDHB, was typed approximately six weeks later, on 30 July 2012. The letter states:

> "… The literature is a little mixed with regard to renal transplantation in those with systemic AA amyloid. The outcomes may not be as good as those with other causes of end-stage renal disease but this is not necessarily a contraindication to proceeding with her transplant evaluation. It has been noted that older age and recurrent disease are associated with an increased risk of death and there does appear to be an increased risk of cardiac and infectious complications in the post-transplant period in some series."

59. The letter went on to state that Dr N had discussed Mrs A's case with his colleagues and they had decided that it was not unreasonable for her to be assessed for transplantation on her own merits, but she would need to have a careful cardiac evaluation. Dr N questioned whether Mrs A should have cardiac magnetic resonance imaging (MRI) to ensure that she did not have any specific disease that had not been noted on echocardiography. WDHB told HDC that it did not receive Dr N's clinic letter until 13 August 2012, and provided HDC with two copies of this letter. The first copy, which WDHB said was Dr E's copy, includes the handwritten notes, "HG → file" and "Received 13/8/12". In addition, the date of clinic (18 June 2012) and the date of typing (30 July 2012) are circled with "!!!" alongside it. The second copy has a handwritten note, "ARTG letter" but does not have any date received recorded.

60. On 22 June 2012, a renal social worker assessed Mrs A's social situation and advised that there were no barriers to progressing with transplantation.

61. On 16 August 2012, WDHB renal physician Dr K referred Mrs A to the Cardiology Department at Tauranga Hospital for a dobutamine stress echocardiogram.[17] Dr K also requested a written report on whether or not Mrs A would require a cardiac MRI to ensure that she did not have any specific disease that had not been identified on echocardiography. Although addressed to Tauranga Hospital, Dr K's letter was sent to the Cardiology Department at Waikato Hospital in error. The following day, WDHB wrote to Mrs A to advise her of the referral, and explained that the waiting time might be up to six months.

62. On 6 September 2012, the cardiology service manager at Waikato Hospital wrote to Dr K advising that the referral had been declined because the service was available at

[17] A dobutamine stress echocardiogram assesses the heart muscles under stress. The medication dobutamine stimulates the heart in a way that is similar to exercising.

Tauranga Hospital. The cardiology service manager recommended that Dr K refer Mrs A to Tauranga Hospital, and copied the letter to Mrs A's GP and to the Elective Services Manager at Tauranga Hospital. BOPDHB told HDC that it received the original referral on 7 September 2012 (22 days later) and, once received, the referral was graded as "three" (semi-urgent) and an appointment was made for 27 September 2012.

63. On 27 September 2012, BOPDHB cardiologist Dr Q performed an ECG, which he reported was normal. Dr Q's clinic letter, dated 27 September 2012 and sent to Mrs A's GP, a WDHB renal physician, Dr E, Dr O, Dr K, and Dr P (WDHB cardiologist), noted that Mrs A's previous echocardiogram in August 2011 supported the argument that she had no significant cardiac involvement with amyloid, but that this could not be excluded. Dr Q advised that Mrs A's echocardiogram images were not adequate for her to undergo a dobutamine stress echocardiogram. Dr Q booked Mrs A for an exercise tolerance test (ETT),[18] and suggested that if this was non-diagnostic, Mrs A should be referred back to Waikato Hospital for a myocardial perfusion scan (perfusion scan).[19]

64. Dr Q's letter also states that he would defer to Dr P to consider whether a cardiac MRI could be done safely, as there is a higher incidence of gadolinium[20] related toxicity in people with renal disease. Dr Q told HDC that BOPDHB does not have cardiac MRI or perfusion scanning services, so these tests are routinely referred back to WDHB. The letter notes that it is to be copied to Dr E; however, Dr E told HDC that he has no recollection of receiving it. Dr Q wrote to Dr P requesting his opinion regarding the risk of gadolinium toxicity in undertaking a cardiac MRI compared with the importance for the transplant work-up process to discover whether Mrs A had amyloid involvement in her heart. Dr Q asked that Dr P list Mrs A for a cardiac MRI if he thought it was reasonable.

65. On 16 October 2012, Mrs A underwent the ETT. Dr Q reported:

> "Conclusion: Poor functional capacity as evidenced by inability to complete equivalent stage 2 standard Bruce protocol.[21] No evidence of inducible ischaemia[22] at maximal heart rate. Hypertension."[23]

66. On 26 October 2012,[24] Dr Q wrote to WDHB renal physicians providing the ETT report and advising that he had discussed the issue of the cardiac MRI with Dr P, and

[18] An exercise tolerance test is a method used to measure the severity of coronary heart disease. Essentially, it assesses how the heart handles work as the treadmill speed and incline are increased.
[19] A myocardial perfusion scan uses a small amount of a radioactive chemical to create images that illustrate the function of the heart.
[20] A chemical element used as a contrast in MRIs.
[21] The Bruce protocol is an exercise stress test in which the treadmill speed and incline are increased every three minutes. It ranges from stage 1 (lowest) to stage 7 (highest). Stage 2 refers to a 12% grade and 4km per hour.
[22] Inducible ischaemia refers to an inadequate supply of oxygen to the heart occurring with physical stress.
[23] High blood pressure.
[24] The letter was dictated by Dr Q on 24 October and typed on 26 October 2012.

had also received an email from Dr O. From this correspondence, Dr Q advised that there was significant risk (minimum 1%) of nephrogenic systemic fibrosis[25] if gadolinium were to be administered, and that Dr P advised that the MRI would not be helpful if gadolinium could not be used. In this letter, Dr Q stated: "If cardiac amyloid involvement was considered a critical issue for [the] purposes of transplant consideration, the other alternative would be to ask the transplant cardiologists in Auckland to perform an echo guided biopsy of the interventricular septum."[26] This information was scanned and emailed to ARTG on 1 November 2012. The email included no other details or requests.

67. On 5 November 2012, Mrs A's case was discussed at a WDHB renal physician meeting. It was decided at this meeting that Dr O would refer Mrs A for a perfusion scan. On 7 November 2012, a letter informing of this decision was shared with Dr D, the transplant coordinators, Dr Q, and the Continuous Ambulatory Peritoneal Dialysis (CAPD) Unit at Tauranga Hospital. On 14 November 2012, WDHB wrote to Mrs A advising her that she could expect to undergo a perfusion scan at Waikato Hospital within the next few months.

68. Mrs A underwent a perfusion scan at Waikato Hospital Radiology Department on 17 December 2012. The scan results were normal.

69. On 4 January 2013, an email attaching a copy of the perfusion scan report was sent from WDHB. The email asked whether this report was "okay as far as cardiac evaluation goes", and stated: "[T]he cardiologists did not want to do an MRI due to gadolinium." WDHB told HDC:

> "The email asked the [ARTG] to confirm that [Mrs A] had satisfactorily completed her cardiac evaluation (with the implication being that a positive response would constitute a conclusion of [Mrs A's] transplant evaluation and listing for presentation to ARTG at the monthly meeting)."

70. The staff member who sent the email to ADHB then went on annual leave for two weeks, shortly after her return her colleague resigned and was not replaced.

71. ADHB told HDC that the perfusion scan results were received and signed into the ARTG records on 10 January 2013, and were reviewed by Dr N on 13 January 2013. There is no evidence of ARTG providing any response to WDHB following Dr N's review. ADHB told HDC:

> "[T]he ARTG would not respond directly to the myocardial perfusion scan result as this would be coordinated by the Waikato DHB and when they felt that a

[25] Nephrogenic systemic fibrosis is a disease of fibrosis (thickening and scarring) of the skin and internal organs. It is often disabling and can be fatal. According to the Royal Australian and New Zealand College of Radiologists' 2013 Guideline on the use of gadolinium-containing MRI contrast agents in patients with renal impairment, "[r]eported cases have occurred almost exclusively in patients with severe renal disease, and almost all have been associated with prior use of gadolinium-containing MRI contrast agents".

[26] The wall separating the lower chambers (ventricles) of the heart from one another.

patient was suitable for discussion for renal transplantation would place on the meeting agenda."

72. Mrs A's transplant evaluation was next considered at a WDHB renal physician meeting on 4 March 2013 (more than 11 weeks after she had the perfusion scan). The minutes of the meeting on 4 March 2013 state:

> "[Perfusion scan satisfactory], cardiac MRI due to gadolinium ?present to ARTG — Yes, finish evaluation."

73. There is no detail about what was required to finish the evaluation. WDHB told HDC that its staff were to check that Mrs A's evaluation was complete, and then to add Mrs A to the list for presentation to ARTG. There was a lack of clarity about whether anything else was required after Mrs A's file had been collated and this was to be clarified at the next WDHB renal physician meeting.

74. There is no record of any further consideration of Mrs A's transplant evaluation until a BOPDHB renal nurse emailed WDHB on 15 April 2013 requesting an update for Mrs A. The renal nurse was advised that Mrs A's case would be discussed at the next renal physician meeting at the beginning of May, to find out whether there was anything else Mrs A required. However, no renal physician meeting was held in April because the date fell over Easter.

75. The renal physician meeting took place on 6 May 2013. The outcome of the meeting was that Mrs A's case would be presented to ARTG at the transplant waitlist patient review the following week, on 14 May 2013.

76. WDHB provided HDC with two handwritten records from the ARTG review. Both versions note that the results from the 16 October 2012 ETT showed poor functional capacity, and the 17 December 2012 perfusion scan results showed normal LV systolic function. Only one of the documents states the outcome of the meeting, which is recorded as "ARTG requested further cardiac review". Both documents reference Mrs A's survival score,[27] with one of the documents stating: "Score 67.6 if 14/5/2013 is date of [referral] when discussed by ARTG. 77.2 if 25/5/12 — date [referred] to transplant co-ord[inator]. 81.8 if one month post dialysis start date."[28]

77. Also on 14 May 2013,[29] WDHB nephrologist Dr S wrote to a WDHB cardiologist and asked whether he thought that "an echo without obvious amyloid cardiac involvement would be good evidence for them to consider [Mrs A] free of cardiac amyloid and therefore consider her suitable for a transplant from that point of view".

78. On 15 May 2013, an ADHB nephrologist dictated a letter to Dr S (typed on 20 May 2013) on behalf of the transplant recipient review team. The nephrologist

[27] In line with TSANZ recommendations, New Zealand requires that people being listed for deceased donor kidney transplantation must have an estimated five-year survival of greater than 80%.
[28] The other document does not include the survival score at 14 May 2013. Both these documents appear to have been written by the same person.
[29] Typed 15 May 2013.

acknowledged that Mrs A's perfusion scan was satisfactory but noted that there had been a letter from Cardiology suggesting that Mrs A should have a cardiac MRI. The nephrologist requested that Mrs A be re-presented for renal transplant recipient review at ARTG with a cardiac MRI result. ADHB said that it is not clear whether Dr Q's letter of 26 October 2012 was available for review or presented for discussion with regard to the issue of cardiac MRI.

79. On 17 May 2013, Dr E emailed Dr S. Dr E's email stated:

> "I've had an email from the patient of mine whom I know well with AA amyloidosis. She is pretty annoyed about the length of time it is taking to address the transplant assessment issues. I must say I can see her point given that I referred her for this exactly 12 months ago. I understand it is difficult when dealing with 3DHBs and frequent changes of SMO personnel in your department and I see that you've written to the cardiologists about the case this week. I would add, though, that the chances of having significant involvement of the heart in AA amyloidosis are virtually nil (2/224 in an expert centre) — see attached.[30]
>
> I'm really just letting you know that the patient, justifiably I think, feels it has taken far too long so far."

80. On 21 May 2013, Dr S emailed Dr N requesting that approval be expedited based on current evidence and Dr E's advice. The following day, Dr N replied that he agreed that it therefore seemed unlikely that Mrs A had any possible cardiac involvement. However, he asked Dr S to obtain confirmation from the cardiologists by email or telephone about whether or not a cardiac MRI was needed.

81. Dr S requested this information from Dr Q by email on 4 June 2013. Dr Q replied by email the same day, and advised that an echocardiogram is not able to exclude amyloid or any other cardiac tissue infiltration. Dr Q said that an MRI is considered a better imaging modality to look for cardiac infiltration but is also not a definitive diagnostic test, and could not be performed on Mrs A because radiologists will not use gadolinium contrast on people with severe renal impairment. Dr Q said: "[Dr E] is the expert in this field and I think his comments are probably the most helpful to feed back to the transplant committee."

82. On 5 June 2013, Dr S forwarded Dr Q's email to Dr N. Following this, Mrs A was re-presented to the ARTG recipient review committee on 11 June 2013, and accepted onto the deceased donor list that day.

[30] Dr E attached: Lachmann et al (2007) Natural History and Outcome in Systemic AA Amyloidosis *The New England Journal of Medicine* 356, 2361–2371.

Evaluation of Ms C's suitability as a living donor

83. ADHB guidelines[31] provide the pathway to be followed for evaluating suitability as a live donor (**Appendix A** — ADHB's "Directed Live Donor Pathway" is a flowchart of this process).

84. ADHB told HDC that, in accordance with the living kidney donor protocol, a crossmatch is the first test completed in the situation where a biologically related child to mother is a potential donor. In other circumstances, it would not usually be one of the screening tests completed. ADHB said that the standard period of time to obtain the formal crossmatch result is four to six weeks.

Timeline of transplant donor evaluation of Ms C

85. An ARTG renal transplant coordinator completed an initial evaluation form with Ms C over the telephone on 4 July 2013, and then referred her to the WDHB transplant coordinators for further evaluation. On 9 July 2013, WDHB emailed New Zealand Blood Service requesting a crossmatch for Mrs A and Ms C to determine the compatibility of their blood types.

86. On 23 July 2013, a negative crossmatch result was received. This was copied to an ADHB renal physician. A negative crossmatch demonstrates that the blood types did not react, meaning that Ms C could be a suitable donor.[32]

87. Unfortunately, around this time, key staff at WDHB went on unplanned extended leave and the remaining staff had to take over the additional workload without any handover. This resulted in the remaining staff having a large workload and being unable to check proactively on the status of all their consumers."

88. On 4 September 2013, a report of Ms C's 24-hour ambulatory blood pressure (BP) test[33] was completed. The results were normal.

89. On 11 November 2013, Ms C was presented to an ARTG clinic. This included education about the transplant procedure and what she could expect throughout the donation process, a psycho-social assessment, which found her to be "an excellent candidate for donation", and an assessment by transplant surgeon Dr L.

90. On 27 November 2013, Dr N examined Ms C and reported that her screening investigations were satisfactory and that she should proceed with evaluation. His report commented that Ms C had been considering donating for the last "two–three" years.

[31] Renal Transplant Adult Live Donor: Work up, Surgery and Care and ARTG living kidney donor protocol (February 2013).
[32] Mrs A also had a further echocardiogram performed on 12 August 2013, which showed good biventricular systolic function and no significant valvular stenosis or regurgitation. The results of the repeated echocardiogram were emailed to ARTG on 16 August 2013.
[33] The monitoring of an individual's blood pressure over a 24-hour period as the person carries out his or her daily activities.

91. ADHB told HDC that the results of all Ms C's tests were presented to the November ARTG transplant assessment clinic. ADHB said that Ms C was accepted to proceed as a living kidney donor at the allocation meeting, and this acceptance allowed for the next and final stages of evaluation to be completed (referral to a psychiatrist or clinical psychologist, and a computed tomography (CT) renal angiogram[34]).

Subsequent events and further comments

Mrs A

92. On 12 December 2013, WDHB sent a request to ADHB (received the following day) to suspend Mrs A from the waitlist as she had been admitted to Tauranga Hospital. At this stage, Ms C still required a CT renal angiogram and a radiology review to complete the donor evaluation.

93. Due to ill health, Mrs A was declared "no longer suitable" to receive a transplant.

94. Mrs A died in 2014.

Waikato District Health Board

95. It was identified that one of the biggest challenges staff faced was accessing appointment times and results from different district health boards.

96. At the time of Mrs A's evaluation, staff were overworked because there was not enough staff to manage the volume of work. WDHB told HDC that there were two main reasons for this:

    1. There was an organisational restructuring, which included a review of every vacant position. This resulted in increased delays to normal recruitment processes.

    2. The principal cause was unexpected long-term leave in a small team.

97. WDHB said that the service attempted to mitigate the difficult staffing situation by increasing hours. It also said that it continued to review the situation, and additional staff were employed once it became clear that it was not a sustainable situation. WDHB told HDC that the service is now fully staffed, and it is hopeful that such a situation will not be repeated in future.

98. WDHB has endeavoured to streamline the evaluation process by having a named referring physician, to whom all queries about the evaluation are addressed. In addition, "[WDHB has] a lead physician for transplant and meet monthly to discuss and implement strategies to improve the service".

99. WDHB told HDC that it is in the process of developing an IT platform that will assist with the management of renal patients.

[34] An imaging test that looks at the blood vessels in the kidneys, and is able to identify narrowing or blockages of the blood vessels.

Auckland District Health Board

100. ADHB told HDC that ARTG is part of the NRTS, and committed to its initiatives (detailed below), but it is also aware that processes could be improved at a local level in the interim.

Literature around AA amyloidosis and cardiac involvement

101. There is limited literature regarding cardiac involvement with AA amyloidosis. ADHB told HDC:

> "The most recent and up to date paper Kofman et al (2011)[35] showed a worse than current standard prognosis in these patients with a 5 year survival of 82%. Currently the New Zealand and Australian 5 year patient survival for primary deceased donor renal allografts[36] is 90% and for primary live donor renal allografts is 95% (ANZDATA Report 2014) … This lower survival rate is due to patient mortality with a high rate of acute cardiac events (25%) and cardiac mortality (43%) of the overall mortality rate."

102. This article does not describe what cardiac assessments, if any, were performed prior to transplantation.

National Renal Transplant Service

103. The NRTS was established in September 2014, following endorsement from the National Health Board and the Ministry of Health.[37]

104. NRTS, told HDC that addressing inconsistencies in access to kidney transplantation across New Zealand is an important reason for the existence of the National Renal Transplant Leadership Team, set up under the NRTS to enable collaboration between clinical teams and DHB management between transplanting and non-transplanting district health boards.

105. The NRTS is in the process of implementing initiatives aimed at improving the assessment pathway for recipients and donors. The initiatives include:

1. Definition of nationally agreed pathways for flow of recipient and donors between primary and hospital-based care, both within and between district health boards.

2. Development of a publicly accessible website for publication of these pathways.

3. Quality improvement metrics designed to highlight key potential bottlenecks in the process, including metrics to measure the length of time taken for complete workups, and developing guidelines around appropriate durations.

[35] Kofman, T et al. "Renal Transplantation in Patients with AA Amyloidosis Nephropathy: Results from a French Multicenter Study" 2011 *American Journal of Transplantation* 11: 2423–2431.
[36] A tissue graft from a donor of the same species.
[37] Its establishment came after a Scoping Paper by the National Renal Advisory Board in 2006 highlighted the need for a national strategic plan for renal services based in part on the existence of unequal provision of renal services across New Zealand.

4. Eligibility for the deceased donor waiting list. This involves reviewing the TSANZ guidelines and establishing a process for appeals for patients declined access to the waiting list, to improve national consistency in decision-making.

106. NRTS told HDC that, in addition, the Ministry of Health has provided funding for the establishment of donor liaison coordinators, who primarily will assist living donors to traverse the workup pathway, but may also assist potential recipients of transplants from living donors.

The Transplantation Society of Australia and New Zealand

107. The Transplantation Society of Australia and New Zealand (TSANZ) represents clinicians and scientists in the field of organ transplantation. Its 2011 document "Organ Transplantation from Deceased Donors: Consensus Statement on Eligibility Criteria and Allocation Protocols"[38] is referenced by the ARTG as a guiding document for eligibility of kidney transplantations. Inclusion criteria for kidney transplantation in the consensus statement are: "end-stage kidney failure requiring dialysis; anticipated low perioperative mortality; and a reasonable postoperative life expectancy, defined as an 80% likelihood of surviving for at least 5 years after transplantation". Exclusion criteria include cardiovascular disease, infection, and other comorbid medical conditions.

108. The consensus statement records:

> "Referrals for renal transplantation (from renal/dialysis units) should be assessed initially at the level of the transplanting hospital. This review and a decision regarding acceptance for listing should involve a transplant physician and surgeon.
>
> The transplant unit should have a system to allow borderline candidates to be assessed by a broader group of transplant specialists …"

Response to provisional decision

Ms B

109. Ms B was provided with an opportunity to comment on the "information gathered" section of the provisional decision.

Waikato DHB

110. Waikato DHB was provided with an opportunity to comment on the provisional decision. It advised that it accepted my findings and that the report included useful recommendations.

Auckland DHB

111. Auckland DHB was provided with an opportunity to comment on the provisional decision. It advised that it accepted my recommendations.

[38] Version 1.1 — 23 June 2011. A background review was completed in December 2014 as a reference document to revising the 2011 consensus statement.

Bay of Plenty DHB

112. Bay of Plenty DHB was provided with an opportunity to comment on the provisional decision. It advised that it had no further comment to make.

Opinion: Introduction

113. I have carefully considered the standard of care provided to Mrs A by BOPDHB, WDHB, and ADHB. It took approximately one year to assess Mrs A's suitability to receive a kidney transplant, and then a further six months to assess her daughter's suitability as a living donor (at which stage the majority of the assessments had been completed).

114. I am mindful that kidney transplantation services are not run at a national level, and New Zealand does not have clear standards around the length of time that recipient and donor evaluations should take. I am also mindful of the varied conditions and health status of the recipients and donors being assessed. As my expert advisor, renal physician Dr Grant Pidgeon, advised:

> "There is no doubt that recipient evaluation is a complex process, even more so when there are multiple services and DHBs involved in the assessment. This illustrates the importance of clarity of process, as well as appropriate communication of when patients have progressed through the various stages of the evaluation process."

115. I am critical of some aspects of the coordination of Mrs A's transplantation evaluation, which, in my view, caused unnecessary delay in her particular circumstances. However, this should not be interpreted to mean that these lengths of time are always too long. There may be circumstances where it is appropriate for an evaluation to exceed these periods.

116. In addition, it is not my role to make findings as to the cause of death. Accordingly, the findings in this report should not be interpreted as having any implication as to the cause of Mrs A's death.

Opinion: Waikato District Health Board — breach

Waikato District Health Board's role

117. As the referring district health board in charge of the Midland Regional Renal Service, WDHB had the overall responsibility for coordinating Mrs A's evaluation. WDHB's role included identifying Mrs A as a potential kidney transplant recipient, arranging the appropriate tests to be carried out in accordance with the standardised evaluation protocol developed by ARTG, and presenting Mrs A at a monthly ARTG

transplant recipient and donor selection meeting (via conference call between WDHB and ARTG). An ARTG team also conducts monthly reviews at Waikato Hospital, and WDHB's role is to allocate patients to be reviewed at these clinics as it sees fit.

Mrs A's assessment

Initiation of transplant evaluation

118. Mrs A was diagnosed with systemic AA amyloidosis in late 2010. In April 2011 Mrs A commenced peritoneal dialysis. In the hope of slowing the progression of Mrs A's renal disease, Dr E and Dr M requested special authority from PHARMAC for the medication anakinra, but this was declined in March 2012.

119. Dr Pidgeon advised:

> "[I]t is generally agreed that renal transplantation is the preferred method of renal replacement therapy for all patients well enough to receive a transplant. Ideally assessment should occur prior to the requirement for dialysis, aiming for pre-emptive transplantation wherever possible. This was not possible for [Mrs A] as it was initially considered necessary to diagnose her underlying inflammatory state and then control this, prior to transplantation being considered. Thus she was not referred to the ARTG until June 2012 following the definitive determination of Pharmac regarding the potential use of anakinra. I do not consider this delay unreasonable given the advice received by [Dr E], the treating haematologist."

120. I accept Dr Pidgeon's advice. I am satisfied that it was reasonable that Mrs A's transplant evaluation did not occur until after she was receiving dialysis.

Recipient evaluation

121. There was an agreed process in place for WDHB to communicate with ARTG about recipient and donor evaluations. This involved presenting WDHB cases to ARTG at outreach clinics or ARTG transplant recipient and donor selection meetings when the WDHB renal team considered that the case had met the ARTG requirements. However, there were several points in Mrs A's transplant evaluation where delays occurred because errors were made or the proper process was not followed by WDHB.

122. On 16 August 2012, Dr K's referral to Tauranga Hospital Cardiology Department was erroneously sent to Waikato Hospital's Cardiology Department. The error was not identified and corrected until 7 September 2012. I am critical of the error in sending the initial cardiology referral to Waikato Hospital's Cardiology Department, and of the delay in identifying and remedying this error.

123. On 17 December 2012, Mrs A had a normal perfusion scan. Two and a half weeks later, on 4 January 2013, an email was sent from WDHB to ADHB checking whether, given the normal scan and noting that the cardiologists "did not want to do MRI due to gadolinium", this was "okay as far as cardiac assessment goes". WDHB told HDC that the implication of this email was that "a positive response would constitute a conclusion of Mrs A's transplant evaluation and listing for presentation to ARTG at the monthly meeting". The email was not responded to. Although I

understand that WDHB attempted to communicate with ARTG via email to seek confirmation about whether the normal perfusion scan and cardiologist advice was sufficient, this was not the agreed process, and instead Mrs A's case should have been presented to ARTG's transplant recipient meeting.

124. Mrs A's case was not presented at the WDHB renal physician meeting in January or February 2013, nor was she listed for an ARTG transplant recipient meeting during these months.

125. When Mrs A was presented to the WDHB renal physician meeting in March 2013, the decision recorded was "? present to ARTG — Yes, finish evaluation". There was no detail recorded about what was required to finish the evaluation, and Mrs A was not listed for presentation at the ARTG. WDHB told HDC that its staff were to check that Mrs A's evaluation was complete, and then to add Mrs A to the list for presentation to ARTG. There was a lack of clarity about whether anything else was required after Mrs A's file had been collated and this was to be clarified at the next WDHB renal physician meeting. However, no renal physician meeting took place in April because of Easter, and therefore Mrs A's case was not presented until the next meeting on 6 May 2013.

126. In Dr Pidgeon's opinion, the nearly six-month period from the time that the normal perfusion scan was reported in December 2012, to the time that it was responded to by the ARTG in May 2013 was unacceptable. He noted that "there were several opportunities between January and May 2013 for WDHB to minimise this delay".

127. I agree. WDHB may have considered that the email to ARTG on 4 January 2013 implied a referral to ARTG to consider whether Mrs A had completed all that was required for transplant evaluation. However, as noted above, WDHB did not follow the agreed process for communication, and this is a failing on its part. In addition to this mis-communication, there were a number of missed opportunities for WDHB to progress Mrs A's case, through presentation to WDHB renal physician meetings in January and February, and following her initial presentation to the meeting in March. I am critical that the WDHB team failed to utilise these opportunities and progress Mrs A's case in a timely fashion, resulting in a delay of nearly six months.

128. I also agree with Dr Pidgeon's statement that "there is some lack of clarity regarding the responsibilities of the various units, specifically relating to the formal procedure of submission of information, and exactly where a patient lies on the evaluation pathway".

Donor evaluation

129. On 4 July 2013, three weeks after Mrs A was accepted onto the deceased donor waiting list, Ms C completed an initial evaluation to become a donor for her mother. As Mrs A's daughter, the first screening test was to crossmatch samples of Mrs A's and Ms C's blood. This test was requested on 9 July 2013, and it was completed on 23 July 2013. There is no record of any further tests until 4 September 2013, when Ms C's ambulatory blood pressure test was performed and reported to be normal.

130. Ms C was presented to an ARTG clinic on 11 November 2013, where she was provided education about the transplant procedure and what she could expect throughout the donation process. She also had a psycho-social assessment completed, and was assessed by transplant surgeon Dr L. On 27 November 2013, Ms C was seen by ARTG transplant nephrologist Dr N.

131. Ms C was accepted to proceed as a living kidney donor, which allowed for the next and final stages of evaluation to be completed (referral to a psychiatrist or clinical psychologist, and a CT renal angiogram).

132. Dr Pidgeon advised HDC:

> "There are few standards relating to donor assessment. The British Transplantation Society issued guidelines for living kidney transplantation 3rd edition May 2011, from a joint working party of the British Transplantation Society and the Renal Association. These indicate a time period of 11 weeks from commencement of assessment to readiness for transplantation is reasonable.
>
> In young healthy donor candidates it should therefore be possible to progress full assessment over a 3 month period. This assumes that all assessments are normal, and there is no need to proceed to more specialist assessments."

133. In relation to Ms C's evaluation, Dr Pidgeon further advised:

> "[Ms C] was a young, healthy donor and the information provided indicates no issues with any of her tests that would have precluded her from further evaluation, or required anything more than the standard assessment. Despite this, the initial component of her assessment required five months from July 2013 to a point where she was deemed acceptable in December 2013, but still required further assessments including psychological review and the CTA. I would expect these further assessments would take another one to two months, leading to a total workup time of roughly six to seven months.
>
> For a young, healthy donor with no complexities I consider this too long …"

134. Ms C's donor evaluation was protracted and of an unreasonable duration in the circumstances. As stated, Ms C was young and healthy, and her assessment began following Mrs A's acceptance for transplant. Ms C's ambulatory blood pressure report was completed on 4 September 2013, but she was not presented to the ARTG until November 2013. These meetings are held monthly, and Ms C should have been presented to the ARTG before November 2013.

135. Unfortunately, around August 2013 key staff at WDHB went on unplanned extended leave and the remaining staff had to take over the additional workload without any handover. This resulted in the remaining staff having a large workload and being unable to check proactively on the status off all their consumers.

136. WDHB agreed that there were staffing issues at this time, due to both organisational restructuring and leave of a key member of a small team. WDHB noted that while initially this was anticipated as being short term, it became long term. WDHB stated that it attempted to mitigate the difficult staffing situation.

137. I do not consider the delays in Ms C's evaluation to be the failing of any individual. My concern is that WDHB did not have sufficient resources allocated to continue Ms C's evaluation when faced with an unexpected staff departure. In my opinion, there needed to be greater management control to ensure that Ms C's case progressed in a reasonable timeframe. I am critical of WDHB for failing to ensure continuity of services for Ms C and Mrs A.

Conclusion

138. Under Right 4(5) of the Code, "[e]very consumer has the right to co-operation among providers to ensure quality and continuity of services".

139. As the district health board that held overall responsibility for Mrs A's transplant evaluation, including the recipient evaluation process and the evaluation of Ms C as a living donor, it was WDHB's role to facilitate seamless service provision between itself, BOPDHB, and ADHB, and ensure that the process progressed in a timely manner.

140. In my view, the continuity of Mrs A's care was compromised owing to the fact that there were several points in the evaluative process where there was delay because of error, failure to follow agreed process in communicating with ARTG, resource allocation, or lack of clarity regarding roles.

141. WDHB erroneously sent a cardiology referral to Waikato Hospital Cardiology Department on 16 August 2012, and the error was not identified and corrected until 6 September 2012. Mrs A then had a normal perfusion scan in December 2012, but her case was not presented at the next monthly ARTG meeting via the usual process because more informal channels were used. Mrs A's case was not presented to the WDHB renal physician meeting in January or February 2013 for no apparent reason, and when it was presented in March 2013 there was a lack of clarity as to what was required to facilitate presentation to the ARTG at that time.

142. There was a period of almost six months from the normal perfusion scan until presentation at the ARTG, and multiple missed opportunities for WDHB to minimise this delay.

143. Ms C's evaluation as a living donor was also unreasonably protracted. Ms C presented for the initial evaluation in July 2013, following Mrs A's acceptance onto the deceased donor waiting list. There is no record of further follow-up until August 2013. Ms C's ambulatory blood pressure report was completed on 4 September 2013, but she was not presented to the ARTG until November 2013. While there were staffing issues at WDHB that impacted on the progress of this evaluation, where a young, healthy donor is being assessed for transplant, the timeline from initial

evaluation to presentation at the ARTG was too long, impacting on the coordination and progression of Mrs A's care.

144. In light of the above, I find that WDHB breached Right 4(5) of the Code.

Opinion: Auckland District Health Board — adverse comment

Auckland District Health Board's role

145. ADHB, through the Auckland Renal Transplant Group (ARTG), provides renal transplants for consumers in the Midland region, in addition to those in the Auckland, Northland, and Taranaki regions. As Dr Pidgeon advised, ARTG's role "is to ultimately determine the suitability of patients for transplantation. In this regard they provide guidelines for assessment, but are not responsible for undertaking such assessment".

146. In Mrs A's case, ADHB's role was to determine whether Mrs A was suitable to commence assessment for kidney transplant, and to provide the guidelines for her assessment. ADHB was also responsible for providing guidance to the WDHB renal team when Mrs A was presented to ARTG clinics and the transplant selection committee.

Mrs A's assessment

Initial communication from Dr N

147. Mrs A was seen by transplant surgeon Dr N at ARTG on 18 June 2012. His clinic letter was typed approximately six weeks later, on 30 July 2012. According to ADHB, this delay was because Dr N undertook a review of the literature around amyloidosis and renal transplantation, and presented this to ARTG for discussion. The letter recorded that Dr N had discussed Mrs A's case with his colleagues, but made no other reference to the reasons for the delay.

148. WDHB told HDC that it did not receive Dr N's clinic letter until 13 August 2012. The copy filed in Dr E's records includes the handwritten note, "Received 13/8/12". However, WDHB provided another copy of the letter that does not have any date received recorded.

149. While I accept ADHB's account that the six-week period between Dr N's clinic and the typing of the letter was due to ARTG's consideration of the literature around amyloidosis and renal transplantation, I am critical that there is no documentation about the research undertaken and the ARTG's consideration of this.

Clarity of information provided re cardiac investigations

150. When ARTG accepted Mrs A for transplant recipient evaluation, it noted that there appeared to be an increased risk of cardiac and infectious complications in the post-transplant period in those of older age with recurrent disease. In his letter of 30 July 2012, Dr N advised WDHB that while it was not unreasonable for Mrs A to be

assessed for transplantation on her own merits, she would need to undergo a "careful cardiac evaluation". Dr N queried "whether [Mrs A] should have a cardiac MRI to ensure that she [did] not have any specific disease that [was] not noted on echocardiography".

151. Following receipt of this information, Mrs A was referred for a dobutamine stress echocardiogram in August 2012, with a request for a report on whether a cardiac MRI was required. A series of referrals between services occurred, as detailed above, and in September 2012 an echocardiogram was performed. This was followed by an exercise tolerance test, and a referral back to WDHB. There was ongoing uncertainty as to the need for a cardiac MRI from August until November 2012, when Mrs A was referred for a myocardial perfusion scan.

152. Dr Pidgeon advised:

> "[T]here was a lack of clarity regarding which cardiac investigations were necessary and whose opinion should have been sought to provide this information. This led to confusion within the renal and cardiology teams as to exactly what was necessary and contributed to the delays in assessment. It would have been preferable for very clear instructions right from the outset as to what was necessary to allow her acceptance onto the waiting list."

153. Dr Pidgeon said that a more categorical delineation of the cardiac tests deemed necessary could have been provided at one of the ARTG meetings in 2012 when Mrs A was discussed. I accept Dr Pidgeon's advice. ADHB's "Renal Transplant Adult Recipient: Patient Selection" guideline provides standardised guidelines for the evaluation pathway; however, it would have been beneficial for ADHB to have provided more detailed advice at the outset, or shortly into the evaluation, regarding what cardiac investigations were necessary.

Communication regarding myocardial perfusion scan

154. Mrs A had a perfusion scan at Waikato Hospital on 17 December 2012, the results of which were normal. On 4 January 2013, an email attaching a copy of the perfusion scan was sent from WDHB to ADHB checking whether this was "okay as far as cardiac evaluation goes", and advised that "the cardiologists did not want to do an MRI due to gadolinium".

155. ADHB told HDC that the perfusion scan results were signed into the ARTG record on 10 January 2013 and reviewed by Dr N on 13 January 2013. There is no evidence of ARTG providing any response to WDHB following Dr N's review. ADHB told HDC:

> "[T]he ARTG would not respond directly to the myocardial perfusion scan result as this would be coordinated by the Waikato DHB and when they felt that a patient was suitable for discussion for renal transplantation would place on the meeting agenda."

156. As WDHB told HDC, there was an agreed process in place for communicating with ARTG about recipient and donor evaluations, which involved presenting their cases to

the ARTG at outreach clinics or ARTG transplant recipient and donor selection meetings when the WDHB renal team considered that it had met the ARTG requirements.

157. I acknowledge that WDHB did not follow this process regarding the perfusion scan result. However, I am concerned that ARTG did not respond to the email regarding the perfusion scan result and cardiologist view regarding MRI, even if simply to advise that Mrs A could be presented to an ARTG meeting.

Conclusion

158. In my view, the continuity of care in respect of Mrs A's transplant evaluation was compromised. I am critical of ADHB for not providing greater clarity regarding what cardiac investigations were necessary, and of the delays by ADHB in communicating to WDHB its initial acceptance for recipient evaluation of Mrs A. I am also concerned that ADHB did not respond to the email regarding the adequacy of the cardiac evaluation. ADHB's role was one of guidance in this case, and there were a number of missed opportunities for it to provide greater leadership and clarity.

Opinion: Bay of Plenty District Health Board — no breach

Bay of Plenty District Health Board's role

159. BOPDHB's role is to provide the support services necessary for the delivery of care to the consumers within its catchment who are under the Midland Regional Renal Service. Dr Pidgeon advised that "[t]his would include clinic facilitation and access to investigations and specialty opinion as required. For instance access to timely cardiological opinion and investigation is necessary for the assessment of patients for transplantation."

Mrs A's assessment

160. Once Mrs A's initial cardiology referral was received by Tauranga Hospital, on 7 September 2012, this was graded and an appointment provided with cardiologist Dr Q within three weeks, on 27 September 2012. Dr Q performed an ECG on Mrs A, which was normal. He also reported that her previous echocardiogram in August 2011 supported the argument that she had no significant cardiac involvement with amyloid but that this could not be excluded. Dr Q advised that Mrs A's echocardiogram images were not adequate for her to undergo a dobutamine stress echocardiogram. He booked her for an ETT and suggested that, if this was non-diagnostic, Mrs A be referred to Waikato Hospital for a perfusion scan. Dr Q noted that there was a higher incidence of gadolinium-related toxicity in people with renal disease, and sought the advice of WDHB cardiologist Dr P about whether a cardiac MRI could therefore be done safely. Dr P advised that the MRI would not be helpful if gadolinium could not be used.

161. On 16 October 2012, Dr Q performed the ETT on Mrs A. The results were not diagnostic. Dr Q provided WDHB with the results and the information from Dr P and Dr O, which outlined the significant risk of nephrogenic system fibrosis involved with a cardiac MRI if gadolinium were administered, along with the advice that a cardiac MRI without gadolinium would not be a useful diagnostic test. As an alternative if cardiac amyloid involvement was considered critical for transplant consideration, Dr Q recommended that the transplant cardiologists at ADHB could consider performing an echo-guided biopsy of the intraventricular septum.

162. At a WDHB renal physician meeting on 5 November 2012, it was decided that Mrs A would have the perfusion scan. As BOPDHB does not provide this service, it had no further involvement in Mrs A's transplant evaluation.

163. Dr Pidgeon advised:

> "The Cardiology service at BOPDHB appeared to provide an exemplary service to the referral for cardiac assessment and there would be few DHBs across the country who would match this level of service. Similarly the advice regarding the suitability of the various modalities of cardiac assessment seemed very appropriate."

164. I accept Dr Pidgeon's advice. BOPDHB's role was to perform the tests on Mrs A that WDHB referred to it. I am satisfied that BOPDHB provided these within acceptable timeframes, and the advice provided to WDHB was appropriate. Accordingly, I consider that BOPDHB did not breach the Code.

Opinion: Waikato District Health Board and Auckland District Health Board — adverse comment

Cardiac care

Cardiac MRI

165. Mrs A was considered for a cardiac MRI on several occasions during her transplantation evaluation, to assess for cardiac amyloidosis (the presence of which would increase her risk for transplantation).

166. Concerns about the impact of cardiac-related features on Mrs A's suitability for transplant were raised throughout the period from June 2012 to May 2013. In his letter to WDHB dated 30 July 2012, Dr N raised the need for careful cardiac evaluation, and queried whether Mrs A should have a cardiac MRI.

167. This request was then passed on to the BOPDHB Cardiology Department in WDHB renal physician Dr K's referral dated 16 August 2012. Following discussion with WDHB renal physician Dr O and WDHB cardiologist Dr P, BOPDHB cardiologist Dr Q advised against a cardiac MRI. Dr Q's letter was sent to WDHB on 26 October 2012, and was copied to ARTG on 1 November 2012. The cardiologist's view was

reiterated in the email to ARTG dated 4 January 2013, which accompanied the results of the myocardial perfusion scan.

168. On 15 May 2013, an ADHB nephrologist requested that Mrs A be re-presented to ARTG for renal transplant recipient review with a cardiac MRI result and, on 22 May 2013, Dr N asked WDHB renal physician Dr S to obtain confirmation from the cardiologists about whether a cardiac MRI was needed.

169. Dr Pidgeon was concerned by the repeated reconsideration of a cardiac MRI, as he advised that "it is widely recognised that gadolinium enhanced MRI is contraindicated in dialysis patients due to a risk of nephrogenic systemic fibrosis,[39] and therefore cardiac MRI to prove or disprove the presence of amyloid was not practical for this patient". Dr Pidgeon noted that, "[a]s late as May 2013 the need for MRI was still being raised as a barrier, and this delayed her acceptance by a further month".

170. I share Dr Pidgeon's concern that cardiac MRI was still being considered as late as May 2013, particularly given that Dr Q had provided advice about the significant risk of systemic nephrogenic fibrosis associated with gadolinium in his letter of 26 October 2012.

171. I note that Dr Pidgeon has advised that the cardiac services provided by BOPDHB were exemplary.

172. However, I am critical that neither ADHB nor WDHB took the lead in resolving this issue and progressing Mrs A's case. The advice that cardiac MRI was not practical in Mrs A's case was given clearly on October 2012, and again in November 2012. And yet the concern was still being raised in May 2013.

173. This is yet another example of a delay in progression of Mrs A's case that could have been overcome through improved communication and coordination.

Communication with Dr E

174. In light of the issues raised above, I wish to comment briefly on the involvement of Dr E in Mrs A's ongoing care.

175. In May 2012, Dr E referred Mrs A for consideration of transplant. Dr E has considerable clinical experience in the treatment of amyloidosis, including spending three years at an amyloidosis centre overseas. As he stated in Mrs A's referral, he offers advice regarding amyloidosis to many colleagues nationally. Dr E was copied into several of the communications regarding Mrs A's transplant evaluation, but his opinion regarding cardiac involvement was not sought.

176. Regarding this matter, Dr Pidgeon advised:

> "The renal teams at both Waikato and Auckland sought advice from the local cardiology service, which generally is appropriate. In a complex and rare case

[39] See paragraph 67.

> such as this a consideration of further expert advice would have been helpful, although I recognise this is said with the benefit of hindsight. I would not consider this a significant departure from accepted standard of care, which would be to seek advice from the local cardiologists."

177. Noting Dr Pidgeon's advice, I am mildly critical of WDHB and ADHB for not specifically seeking Dr E's advice about the cardiac involvement of amyloidosis at an early stage. While I acknowledge that it was accepted practice to seek such advice from cardiologists in the first instance, I note that ADHB told HDC that Dr E's advice was helpful in resolving the issue regarding cardiology clearance for Mrs A, and acknowledged that his earlier input would have been beneficial.

Clarity and communication

178. In his advice, Dr Pidgeon observed:

> "It seems clear from the information provided by both ADHB and WDHB that there is some lack of clarity regarding the responsibilities of the various units, specifically relating to the formal procedure for submission of information, and exactly where a patient lies on the evaluation pathway. There is no doubt that recipient evaluation is a complex process, even more so when there are multiple services and DHBs involved in the assessment. This illustrates the importance of clarity of process, as well as appropriate communication of when patients have progressed through the various stages of the evaluation process."

179. While there were other complicating factors in Mrs A's case, the findings of this investigation demonstrate the impact that this lack of clarity and associated communication issues have on service delivery. There are opportunities for improvement in these areas.

Recommendations

180. Mrs A's experience highlights the difficulty in coordinating renal transplant services across multiple district health boards, and the need to clarify the responsibility of each clinical team. With this in mind, I make the following recommendations and ask that evidence of the action taken is provided to HDC within six months of the date of this report.

181. I recommend that WDHB, ADHB, and BOPDHB collaborate in reviewing their system for sharing information regarding renal transplants.

a) A policy should be agreed upon that includes:

   i. A clear method for seeking and providing advice.

   ii. The form in which information is shared.

iii. The responsibility of each party — this may include establishing a responsible renal physician at WDHB and/or ADHB for each consumer, or one renal physician at WDHB responsible for all transplantation evaluations.

iv. Timeframes wherever appropriate.

b) Where appropriate, template letters or documents should be created or amended to align with the policy.

c) A system should be developed for providing regular education/training to all relevant staff to ensure that the communication pathways are understood and that the practices do not deviate from the policy over time.

182. I recommend that Waikato District Health Board:

a) Update HDC on the changes it has put in place. In particular:

i. Development of an IT platform.

ii. Details of the service improvements that have occurred as a result of the monthly meetings organised by the lead transplant physician.

b) With the assistance of other district health boards, establish clear guidelines for the evaluation of living donors. The guidelines should include:

i. What circumstances are required for evaluations to begin prior to a recipient being accepted onto the deceased donor list.

ii. Which tests will be completed prior to recipient acceptance.

iii. Guidelines around timeframes for completion of tests.

c) Review staffing ratios to ensure that the needs of consumers can be met safely.

d) Provide a written apology to Mrs A's family for its breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

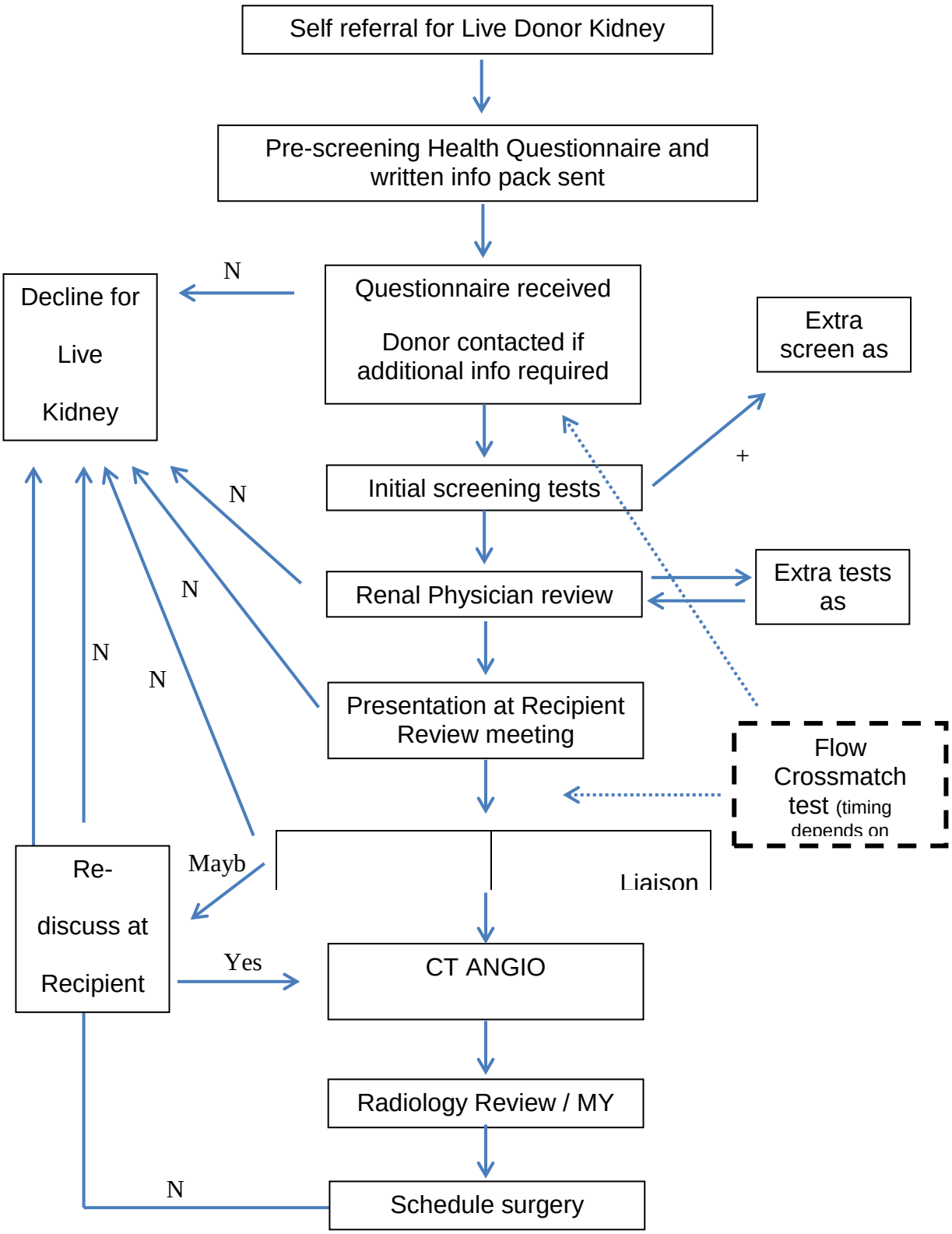
183. I recommend that Auckland District Health Board establish a system for providing clear and specific instructions at the outset as to what is necessary for recipient evaluation in circumstances that deviate from the norm (such as dealing with complex and rare diseases), including where certain evaluations may not be required.

Follow-up actions

184. A copy of this report with details identifying the parties removed, except Waikato District Health Board, Auckland District Health Board, Bay of Plenty District Health Board, and the expert who advised on this case, will be sent to HealthCERT and the National Renal Transplant Service, for educational purposes.

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

Appendix A: Directed Live Donor Pathway



Names have been removed (except Waikato DHB, Auckland DHB, Bay of Plenty DHB and the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from renal physician Dr Grant Pidgeon:

"I have been asked to provide expert advice to the HDC regarding the care provided by Bay of Plenty District Health Board (BPDHB), Waikato District Health Board (WDHB) and Auckland District Health Board (ADHB) to Mrs A, regarding her assessment for kidney transplantation between 2012 and [2014].

I have read the Commissioner's guidelines for independent advisors and agree to follow these guidelines. I have no conflicts of interest in providing this advice. My qualifications are MBChB (1986) University of Otago, and Fellow of the Royal Australasian College of Physicians 1995. I am vocationally registered as a Renal Physician and have practised as a general and transplant renal physician at Wellington Hospital since 1996.

Background

The complaint involves the coordination of care between the three District Health Boards in assessing [Mrs A's] suitability for kidney transplantation. [Mrs A] was first referred to the renal transplant service in Auckland on 21 May 2012 and was finally accepted for transplantation on 11 June 2013. The delay is attributed to assessing for cardiac involvement by her systemic amyloidosis.

[Mrs A] had family members willing to be live kidney donors. Assessment of her daughter [Ms C], as a live donor, commenced on 4 July 2013 and appears from the records to be ongoing on 27 November 2013, despite a note on 11 November 2013 that [Ms C] was an excellent candidate for donation.

Issues

1. **Assessment of [Mrs A's] suitability for transplant took approximately one year.**
   a) Please comment on the appropriateness of this length of time and the management of the assessment overall.
   b) In an email to [Dr S] (WDHB) on 17 May 2013 [Dr E] states 'the patient, justifiably I think, feels that it has taken far too long so far regarding 12 months to assess suitability for transplant'. [Dr E] also provides his opinion that significant involvement of the heart in AA amyloidosis is virtually nil (2 out of 224 in an expert centre) see attached. It appears that reliance was placed on [Dr E's] advice. Should [Dr E's] advice have been sought at an earlier stage? If yes please detail at what date this might have been appropriate.

2. **Assessment of [Ms C] for transplantation suitability took approximately 5 months.**
   a) Please comment on the appropriateness of this length of time
   b) Assessment of [Ms C] did not occur until after [Mrs A] had been accepted onto the deceased donor list. Is this appropriate and accepted practice?

c) In respect of 2a does the fact that the recipient of the transplant had been accepted onto the deceased donor list hasten the expected wait?

3. We are currently uncertain who held responsibility for the coordination of both [Mrs A] and [Ms C's] assessment for transplantation suitability. BPDHB advises that the responsibility lay with WDHB. Are you able to provide advice as to which individual and group providers would be expected to hold responsibility in such circumstances?

4. Any other relevant comments you wish to make.

Background

[Mrs A] was a 61 year old woman who presented to her general practitioner in March 2010 complaining of abdominal pain and was found to have heavy proteinuria and deteriorating renal function. She was then referred to [a] Gastroenterologist who had seen her in the past and had previously diagnosed eosinophilic colitis. The proteinuria was documented at 3.17 grams per day.

She was then referred to the WDHB Renal Service who saw her at Tauranga Hospital on 23 June 2010. The suspicion was of lupus nephritis and she underwent renal biopsy in July 2010. This surprisingly showed renal amyloidosis leading to a referral to [Dr E] in the haematology service in Waikato DHB.

[Dr E] undertook various investigations over the next few months, which confirmed the diagnosis of AA Amyloidosis. The underlying inflammatory cause was never proven, despite numerous investigations, particular of her gastrointestinal system.

She was then reviewed again by the renal service in Tauranga Hospital in January 2011, where it was noted that her serum creatinine was further raised at 223 micromoles per litre and it was estimated that she would likely require dialysis within the next 6 months. At this time both [Dr E] and [Dr M], Rheumatologist at WDHB applied to Pharmac, under exceptional circumstances, to use anakinra an Il-1 antibody, as a means of reducing her chronic inflammation and treating her systemic amyloidosis.

At this stage she was also trialled on high dose prednisone as a general anti-inflammatory agent, but she proved poorly tolerant to this. She was seen in the renal service in March 2011, where it was thought that she was developing uraemia and would need to commence dialysis shortly. There was discussion at that time about commencing transplant evaluation in the near future.

A Tenckhoff catheter was inserted in late April 2011 and she commenced peritoneal dialysis training in March 2011, transferring rapidly to automated peritoneal dialysis.

In June 2011 she was again seen in the Haematology department by [Dr E], who thought it was necessary to reduce her inflammation before she could be

considered for transplantation, and to this end a further application to Pharmac was made for anakinra. At this time a decision was made to stop the prednisone which had proved ineffective. Later that month she underwent an echocardiogram which was reported as showing satisfactory left ventricular function, with mild changes only. Throughout 2011 she had a number of reviews by the renal physicians from WDHB, stating that she was doing well on dialysis, but these reviews did not mention transplant status. A further haematology review in November 2011 mentioned a fluctuating course with predominately bowel symptoms and nausea. Again the issue of anakinra was raised as a means of making her suitable for renal transplantation.

In February 2012 a renal review stated that they were awaiting clearance from [Dr E] regarding treatment of the amyloid prior to initiating transplant workup. Eventually in March 2012 Pharmac made a definitive decision to decline the application for anakinra, on the basis that this would make no difference to her prognosis while she was on dialysis. However if she were transplanted then this could be revisited, as a means of prolonging survival with a renal transplant.

On this basis [Dr E] referred [Mrs A] to the Auckland Renal Transplant Group (ARTG), requesting consideration of transplantation, and stating that his opinion was that it was not necessary to suppress the inflammation prior to this consideration. She was quickly reviewed by the ARTG surgeon who thought she was suitable for transplant, but that 'first of all we have to discuss about her original disease and prognosis as well'. On the same day she was seen by an ARTG renal physician who thought it not unreasonable to assess for transplantation, but that she required careful cardiac evaluation, possibly magnetic resonance imaging (MRI).

In August 2012 a referral letter was sent by [Dr K], WDHB renal physician, to the BPDHB Cardiology Service requesting a dobutamine stress echo and also asking for a written response to the question of the need for cardiac MRI. She was quickly seen in the cardiac service at Tauranga Hospital, where it was noted an earlier ECHO in 2011 was satisfactory showing reasonable LV function with normal wall thickness. Advice was sought from [Dr P], Cardiologist at WDHB, who subsequently replied that an MRI would not be useful given the contraindication of using gadolinium in patients on dialysis. He gave consideration to possibly undertaking myocardial biopsy, but thought that even this would be of low sensitivity. In October 2012 [Mrs A] underwent an exercise stress test which showed no evidence of induced ischaemia but she could only reach stage 2 of the Bruce protocol. This was determined to be sub-optimal and she then underwent a myocardial scan in December 2012, which was reported as showing normal LV function with no evidence of cardiac ischemia.

In May 2013 a letter from the ARTG noted the satisfactory perfusion scan, that her 5 year predicted survival was 77.2%, but again raised the question of the need for cardiac MRI. A series of emails between the renal physicians of WDHB, [Dr Q] Cardiologist, and [Dr E] led to the advice that the risk of cardiac disease with AA amyloidosis was very low, that MRI is not useful in renal patients, and that a

determination that a lack of significant cardiac involvement could be made without further investigations. This culminated in an email from [Dr Q] saying that he could not give categorical assurance on the echo images that she did not have cardiac amyloid, but he agreed in principle with [Dr E's] comments that this was unlikely. On this basis the ARTG renal physician, [Dr N], accepted this opinion and sought to table her assessment at the next meeting of the ARTG. Subsequently on 11 June 2013 [Mrs A] was accepted onto the deceased donor list without the need for further investigations.

With regard to [Mrs A's] daughter [Ms C], the notes are unclear as to when she first sought to be assessed as a living kidney donor for her mother. There is reference to a negative cross match on 22 July 2013, and then a letter from the ARTG on 27 November 2013 stating that she seemed acceptable for living donation workup, and that screening tests including a 24 hour ambulatory blood pressure monitor was satisfactory. It was determined that she could proceed with further evaluation, but no further details of these assessments are included. Unfortunately due to [ill health] [Mrs A] was subsequently suspended from the deceased donor waiting list and was never well enough to be reconsidered. She failed to improve with marked deterioration in her health over the next few months, to the point where active treatments were withdrawn and she died [in 2014].

Issue 1a

Assessment of [Mrs A's] suitability for transplant took approximately one year. Please comment on the appropriateness of this length of time and the management of the assessment overall.

The process of evaluating a dialysis patient for possible renal transplantation is often convoluted and frustrating for the potential recipient. Though on paper a suitable evaluation protocol can be agreed, and completed rapidly for a very healthy recipient, those with significant comorbidities can prove more challenging, leading to the assessment being more prolonged. There are no agreed standards regarding the timing of transplant assessment, nor indeed when this should be initiated. However it is generally agreed that renal transplantation is the preferred method of renal replacement therapy for all patients well enough to receive a transplant. Ideally assessment should occur prior to the requirement for dialysis, aiming for pre-emptive transplantation wherever possible. This was not possible for [Mrs A] as it was initially considered necessary to diagnose her underlying inflammatory state and then control this, prior to transplantation being considered. Thus she was not referred to the ARTG until June 2012 following the definitive determination of Pharmac regarding the potential use of anakinra. I do not consider this delay unreasonable given the advice received by [Dr E], the treating haematologist.

In an ideal scenario it should be possible to assess most recipients regarding their suitability for transplantation within a 3 month period. Many patients require a careful cardiac assessment to ensure satisfactory survival in the post-transplant period. This generally involves an echocardiogram and some form of cardiac

stress test, either exercise or pharmacologically induced. This is often the rate-limiting step for assessment as many cardiology departments do not have the resources to speedily assess asymptomatic renal patients. The complication for [Mrs A] was the perception that her amyloidosis may have involved her heart and that this required more careful assessment to determine her likely prognosis post-transplantation.

The referral letter from the renal service to the cardiology department at BPDHB was not sent until 16 August 2012, two months following advice from the ARTG to proceed with assessment. However it is not clear when the letter from ARTG was received by the WDHB renal team, as there are often delays between dictation and the sending of correspondence. Following this referral she was quickly seen in the cardiology service at Tauranga Hospital and underwent an exercise stress test and repeat echocardiogram. These are reasonable first assessments for cardiac ischaemia and function, although experience indicates that many dialysis patients are not able to exercise sufficiently to provide a definitive assessment, as was the case for [Mrs A]. She subsequently required a dobutamine stress echocardiogram, which could not be completed until December 2012. This showed normal LV function with no evidence of cardiac ischaemia in keeping with previous echo findings. Therefore from the time of acceptance of transplant evaluation by the ARTG, baseline cardiac investigations took a further 6 months. Although this is not uncommon, due to delays in gaining access to cardiac investigations, I think this delay is unacceptable and a moderate departure from accepted standards. The delay was compounded by the 2 month delay in referring to the cardiology service.

The myocardial perfusion scan was completed in December 2012 but it is not clear at which stage that result was forwarded to the ARTG. There was a further renal outpatient assessment in February 2013, but progress regarding the transplant workup was not mentioned. It was not until May 2013 that ARTG responded to the perfusion scan report indicating that this was satisfactory. They also mentioned that [Mrs A] had a 5 year predicted survival of 77.2%, which was marginal but acceptable.

Unfortunately again at this stage a request for consideration of MRI was made. This was unusual on two counts. Firstly it is widely recognised that gadolinium enhanced MRI is contraindicated in dialysis patients due to a risk of systemic nephrogenic fibrosis, and therefore cardiac MRI to prove or disprove the presence of amyloid was not practical for this patient. Secondly the opinion of the cardiologists the previous year had been that MRI would not be useful, and that if a definitive diagnosis of cardiac amyloidosis was necessary then this would require a myocardial biopsy. Even then it was noted that this would not be very sensitive due to the possible focal nature of cardiac amyloidosis.

There is scant literature regarding cardiac involvement with AA amyloidosis and it appears that the renal and cardiology teams were extrapolating their experience with the far more common AL amyloidosis. What literature there is suggests that significant cardiac involvement is very rare and an infrequent cause of death for

these patients. A study in 1996 showed echo evidence of cardiac amyloidosis in only 2 of 44 patients (4.5%) and no patient died of cardiac causes (Dubrey et al). A more recent paper in 2011 describes outcomes of renal transplantation in 59 patients with AA amyloidosis. Although the prognosis was worse in these patients the 5 year patient survival was still a very reasonable 82%. Unfortunately this paper does not describe what if any cardiac assessments were performed prior to transplantation (Kofman et al).

The further delay of 6 months from the time of the normal perfusion scan to this being responded to by the ARTG is unacceptable, and a moderate departure from accepted standards.

Throughout the assessment of [Mrs A] for consideration of transplantation there appears to be a lack of coordination. It has been noted in the original complaint that she was seen by four different renal physicians and I recognise that this is often necessary for outreach clinics, such as those held at Tauranga Hospital. However the lack of a consistent renal physician did mean that during some visits her transplantation status was not discussed or reassessed, and I suspect this led to further delays in her presentation to the ARTG. In such circumstances it might have proved useful if there was a recipient donor coordinator based at WDHB Renal Service to follow up important investigations and ensure that the process continues appropriately. It is not clear from the clinical notes whether there was any involvement from a transplant coordinator.

Issue 1b

Regarding the opinion from [Dr E], it would certainly have been useful to have sought this earlier. It appears that his email following assessment in May 2013 expressing concern at the delay in the transplant assessment then led to reconsideration by the ARTG. It would appear that [Dr E] was seen as the local, if not national, expert on amyloidosis and his input was instrumental in the diagnosis of AA amyloidosis for [Mrs A]. However his opinion regarding likely cardiac involvement was not sought. The renal teams at both Waikato and Auckland sought advice from the local cardiology service, which generally is appropriate. In a complex and rare case such as this a consideration of further expert advice would have been helpful, although I recognise this is said with the benefit of hindsight. I would not consider this a significant departure from accepted standard of care, which would be to seek advice from the local cardiologists.

Issue 2a

Regarding the assessment of [Ms C] for transplantation, this appeared to commence in July 2013 once [Mrs A] was deemed accepted onto the deceased donor waiting list. I did not receive notes regarding the various assessments undertaken for [Ms C]. There is, however, documentation of a suitable cross match in July 2013 and then consideration by the ARTG in November 2013. At that time it was thought that the screening tests were satisfactory including 24 hour blood pressure monitoring, and that proceeding with the evaluation was acceptable. Thus it took 4 months from the cross-match and 5 months from [Mrs

A's] acceptance onto the deceased donor waiting list for [Ms C] to reach the point of 'proceeding' with evaluation, and I would consider this prolonged and indicative of a poorly coordinated process.

There are few standards relating to donor assessment. The British Transplantation Society issued guidelines for living kidney transplantation 3rd edition May 2011, from a joint working party of the British Transplantation Society and the Renal Association. These indicate a time period of 11 weeks from commencement of assessment to readiness for transplantation is reasonable.

In young healthy donor candidates it should therefore be possible to progress full assessment over a 3 month period. This assumes that all assessments are normal, and there is no need to proceed to more specialist assessments. All too frequently, however, the assessment of seemingly normal candidates throws up unexpected findings which require further tests. This is particularly true with imaging of the renal tract, requiring more intensive tests such as MRI or targeted ultrasounds. I could find no records to indicate that there were any complications in [Ms C's] assessment that might have led to significant delays. Neither could I determine what screening tests were lacking at the time of the ARTG assessment in November 2013. I would consider the timing of her assessment to be a moderate departure from accepted clinical practice.

2b

[Ms C's] assessment did not occur until [Mrs A] had been accepted onto the deceased donor waiting list. It is difficult to assess the appropriateness of this. There is no doubt that donor assessment is a costly and time consuming process. Whether to proceed with donor assessment prior to the recipient being deemed suitable for transplantation depends very much on the likelihood of recipient acceptance. In [Mrs A's] case it was not deemed appropriate to consider her for transplantation during the first year of her time on dialysis as it was thought necessary to reduce the state of inflammation, possibly using anakinra if this could be sought through the exceptional circumstances policy.

It would have been reasonable to undertake some basic screening tests as soon as [Ms C] approached the renal service as a potential donor. This could have included baseline blood and urine tests, blood group and possibly a cross-match. This would have given an early indication as to whether she was likely to be a suitable donor. Once [Mrs A] was accepted onto the transplant waiting list the remaining tests such as CT arteriogram and ambulatory blood pressure monitoring could have been performed more speedily. I accept, however, that different units will have different approaches in this regard and I do not consider this a significant departure from the accepted standard of care.

2c

Once a recipient has been accepted onto a transplant waiting list this should make no difference to the timing of donor assessment. As mentioned above, if all tests prove normal it should be possible to progress assessment within a 3 month period

and it would not be easy to shorten this just because a recipient had been accepted onto the transplant waiting list.

3

With regard to who held the responsibility for the coordination of both [Mrs A] and [Ms C's] assessment, this clearly is the responsibility of the renal service responsible for [Mrs A's] care. The WDHB holds the renal contract for patients in the Bay of Plenty area, and is responsible for the management of patients on dialysis and requiring transplantation. The responsibility of the Bay of Plenty DHB is to provide the support services necessary for the delivery of care to the patients under the renal service. This would include clinic facilitation and access to investigations and specialty opinion as required. For instance access to timely cardiological opinion and investigation is necessary for the assessment of patients for transplantation. In [Mrs A's] case the initial cardiac assessment was very timely, but unfortunately was inadequate in that the exercise stress test was not definitive. There was then some delay in proceeding to the dobutamine stress echocardiogram, but most DHBs have limited capacity for such investigations.

The role of the ARTG is to ultimately determine the suitability of patients for transplantation. In this regard they provide guidelines for assessment, but are not responsible for undertaking such assessment. In the case of [Mrs A] there was a lack of clarity regarding which cardiac investigations were necessary and whose opinion should have been sought to provide this information. This led to confusion within the renal and cardiology teams as to exactly what was necessary and contributed to the delays in assessment. It would have been preferable for very clear instructions right from the outset as to what was necessary to allow her acceptance onto the waiting list.

References

Dubrey S, Cha K, Simms R et al. Electrocardiography and Doppler echocardiography in secondary (AA) amyloidosis. Am J Card 1996; 77: 313–315

Kofman T, Grimbert P, Canoui-Poitrine F et al. Renal transplantation in patients with AA amyloidosis nephropathy: results from a French multicentre study. Am J Transplant 2011; 11: 2423–2431

United Kingdom Guidelines for Living Donor Kidney Transplantation (Compiled by a Joint Working Party of The British Transplantation Society and The Renal Association), Third Edition, May 2011"

The following further advice was obtained from renal physician Dr Grant Pidgeon:

"**Supplementary Expert Advice to Health and Disability Commissioner regarding:**

[Mrs A]
DOD [2014]
HDC Reference C14HDC00885

I previously provided expert advice on this case to the legal investigator of the Health and Disability Commissioner in July 2015. Following the completion of that report responses have been received from the Bay of Plenty District Health Board (BOPDHB), Waikato District Health Board (WDHB) and Auckland District Health Board (ADHB) with further information related to the case, and in regard to the guidelines and protocols used for renal transplant and recipient and donor evaluations. On the basis of these responses I have been asked to review my former advice and to comment on the documents supplied to the HDC.

The conclusions of my previous report essentially focussed on two major issues. The first being the prolonged time for the assessment of [Mrs A] for acceptance onto the deceased donor waiting list. In particular there were extended delays in the cardiac assessment, due in part to the complexity of the case relating to the potential for the AA amyloidosis to cause cardiac dysfunction. The second major issue referred to was the length of time taken for the donor assessment of [Mrs A's] daughter, [Ms C], which was never completed, but took at least five months from first assessment.

Recipient Assessment of [Mrs A]

In regard to the first issue related to the cardiac assessment of [Mrs A], both the Auckland and Waikato DHBs have provided greater detail relating to the assessment process. [Mrs A] was first seen by the Auckland Renal Transplant Group (ARTG) in clinic on 18 June 2012 when letters were dictated by [Dr L] (Transplant Surgeon ADHB) and [Dr N] (Transplant Nephrologist ADHB). The letter from [Dr N] was not typed until 30 July 2012, and advised the need for detailed cardiac assessment, possibly including cardiac MRI. Unfortunately [Mrs A] was then referred to the WDHB Cardiology service for cardiac assessment, instead of the BOPDHB Cardiology service, and therefore did not receive assessment until 27 September 2012, some three months from the ARTG review.

As noted previously, she then speedily underwent exercise stress testing and echocardiography, which unfortunately was not satisfactory to exclude significant cardiac disease. [Dr Q] (Cardiologist BOPDHB) had already indicated that a dobutamine stress echo would not be a suitable investigation, and that she would require myocardial perfusion scanning, which could only be performed at WDHB. Of note he also mentioned the relative contraindication to MRI because [Mrs A] was dialysis-dependent, and instead suggested that an endomyocardial biopsy may be more appropriate, although even then would still likely not provide diagnostic information.

The myocardial perfusion scan was completed in December 2012 and reported as satisfactory. This result was emailed to ARTG on 4 January 2013 with the following email *'Hi Can you talk to [Dr N] about [Mrs A], is this okay as far as cardiac evaluation goes, the cardiologists did not want to do MRI due to gadolinium.'* The response to HDC from WDHB (7 August 2015) suggests that the implication of this email was that the cardiac assessment was completed and that [Mrs A] should be presented to the ARTG monthly meeting. This is not

however clear from the email and indeed there was no subsequent response from ARTG to this email.

[Mrs A] was next assessed by WDHB renal service on 13 February 2013 by [Dr S] but her transplant status was not addressed. On 4 March 2013 her status was again raised at the WDHB renal physician meeting querying whether to present to ARTG with the conclusion being to finish the evaluation. This would seem to indicate that according to WDHB the evaluation was not complete and that she had not yet been formally presented to ARTG for evaluation. This did not then occur until the ARTG meeting of 14 May 2013. At that stage a further cardiac assessment was requested by ARTG as there was *'a letter from cardiology suggesting that she should probably have a cardiac MRI to look for amyloid involvement of the heart'*. In fact the BOPDHB cardiologist had indicated that this was contraindicated and inappropriate and the suggestion that an MRI was needed had previously come from ARTG itself.

[Dr E] then contacted the WDHB on 17 May 2013 expressing concern at the delay and indicating that cardiac involvement was unlikely. On receipt of this information the ARTG accepted this advice and cleared [Mrs A] for transplantation on 11 June 2013.

Therefore from the receipt of the normal myocardial perfusion scan it took a further five months until 11 June 2013 for [Mrs A] to be accepted onto the deceased donor transplant waiting list. The ARTG make it clear in their response, that the responsibility to place patients on the agenda of the monthly transplant assessment meetings is that of the home DHB, ie WDHB. From reading the various job descriptions this would appear to be the responsibility of the Transplant Coordinator at WDHB. Although WDHB consider that this referral was implied through the email correspondence on 4 January 2013 this was clearly not sufficient. This appears to have been recognised by the WDHB transplant coordinator through the discussion at the renal physicians meeting on 4 March 2013, and yet [Mrs A] was still not submitted to the ARTG meeting until May 2013. [Dr F's] response to HDC of 7 August 2015 states *'This delay was outside the control of WDHB. The ARTG may be better placed to explain this delay'*. I consider this statement inaccurate and that there were several opportunities between January and May 2013 for WDHB to minimise this delay.

It seems clear from the information provided by both ADHB and WDHB that there is some lack of clarity regarding the responsibilities of the various units, specifically relating to the formal procedure of submission of information, and exactly where a patient lies on the evaluation pathway. There is no doubt that recipient evaluation is a complex process, even more so when there are multiple services and DHBs involved in the assessment. This illustrates the importance of clarity of process, as well as appropriate communication of when patients have progressed through the various stages of the evaluation process.

The other issue related to the cardiac assessment, which undoubtedly complicated matters and further delayed [Mrs A's] acceptance for transplantation, was the implied requirement for her to undergo MRI to assess for cardiac amyloidosis. It is surprising to me that the only physician to mention the relative contraindication to MRI due to her dialysis-dependence, was [Dr Q] the cardiologist in BOPDHB, and that this was not raised by any of the renal physicians. As late as May 2013 the need for MRI was still being raised as a barrier, and this delayed her acceptance by a further month. It would have been preferable at the outset for there to have been more categorical delineation of the cardiac tests deemed necessary, and this could have been done at one of the ARTG meetings in 2012 when [Mrs A] was discussed.

With regard to my previous conclusion, that the delays in cardiac assessment were unacceptable and a moderate departure from accepted standards, I hold to this conclusion despite the further information provided to the HDC.

Donor Assessment of [Ms C]

The second major issue is that of the length of time taken for the donor assessment of [Mrs A's] daughter [Ms C]. I had indicated previously that I thought a three month period should be sufficient for donor workup where there are no complexities. [Ms C] was a young, healthy donor and the information provided indicates no issues with any of her tests that would have precluded her from further evaluation, or required anything more than the standard assessment. Despite this, the initial component of her assessment required five months from July 2013 to a point where she was deemed acceptable in December 2013, but still required further assessments including psychological review and the CTA. I would expect these further assessments would take another one to two months, leading to a total workup time of roughly six to seven months.

For a young, healthy donor with no complexities I consider this too long and a moderate departure from accepted standards. I would note, however that the phrase 'accepted standards' is a difficult concept, in that within the New Zealand framework there are no accepted standards. These are being developed at present by the National Renal Transplant Leadership Team (NRTLT). It is possible that they will conclude that three months is not sufficient time for complete assessment of the average donor, however I would be disappointed if they concluded that six or seven months was acceptable.

You have also asked me to respond to a number of new questions:

1. The framework for transplant evaluation under ARTG

The documents for both recipient and donor evaluation under ARTG are consistent with accepted practice across New Zealand. There are some minor differences with the equivalent protocols used in the Christchurch and Wellington transplant units, but these are minor and would not impact significantly on the timeliness of evaluation.

2. The apparent conflict between ADHB and WDHB regarding the responsibility for developing the agenda of the ARTG renal transplant allocation meetings

This has been addressed in my response above.

a) Who in your expert opinion would you expect to follow up on the outcome of the myocardial perfusion scan

I would expect the result of this scan to be reviewed initially by the WDHB Renal Team, and then presented to the ARTG as part of the completed workup. It appears that initially the WDHB renal team had thought that they had done this, through the email from the Renal Transplant Coordinator. There was, however, no response to this email from the ARTG which then led to a period of inactivity. There were a number of subsequent opportunities for WDHB to correct this and more officially seek to present [Mrs A] to ARTG but this did not happen until May 2013.

3. The reference to the British Transplantation Society Guidelines for Living Kidney Transplant indicating workup time of 11 weeks being inconsistent with discussions locally

It is stated that this three month period is not consistent with the tenor of discussions taking place in the NRTLT currently. I have not seen any outcome of these discussions, and as mentioned above it would not surprise me if the conclusion was that a time period of three months is not achievable. I would, however, be disappointed if the accepted timeframe was set at six to seven months for an uncomplicated donor.

4. BOPDHB's assertion that it has no direct involvement in the coordination of transplant evaluation apart from providing support services

I would concur with this and indeed my previous advice was in this regard. The Cardiology service at BOPDHB appeared to provide an exemplary service to the referral for cardiac assessment and there would be few DHBs across the country who would match this level of service. Similarly the advice regarding the suitability of the various modalities of cardiac assessment seemed very appropriate.

5. Other Guidelines for Transplantation Assessment Timing

I am not aware of other guidelines other than the British Transplantation Society Guidelines. The Amsterdam Forum gives information regarding appropriate assessment, but gives no guidance with regard to acceptable timeframes for either recipient or donor assessment. The ARTG response includes on page five a statement from a representative of the New Zealand National Renal Transplant Service. His statement indicates that an important work stream of the NRTLT will be the development of quality improvement metrics, and that this will include metrics to measure the length of time taken for complete workup, including guidelines around appropriate duration. This piece of work, however, has not been concluded and I am not aware of any draft recommendations from the NRTLT.

6. Transplantation Evaluation at CCDHB

Transplantation evaluations undertaken at Capital and Coast DHB (CCDHB) are very similar to those of the ARTG, although these are probably less well-documented. There are some minor differences, particularly for straightforward uncomplicated donors. For instance at the present time CCDHB does not require psychological evaluation of all donors, particularly related donors. Similarly the use of ambulatory blood pressure monitoring is only used in circumstances where patients have raised blood pressure in clinic, possibly due to white coat hypertension. The cardiac assessment of recipients is very similar to that suggested by ARTG, in that recipients are screened according to high or low risk, and the same cardiac investigations are undertaken.

7. Final Comments

This case highlights the difficulty of coordinating services across multiple DHBs and services. ARTG has undertaken considerable work to provide outreach services to the renal services that it provides transplantation services to, particularly Northland and Waikato. Their protocols and guidelines are very thorough and detailed. Despite this, in this particular case, there remained little clarity regarding where [Mrs A] sat on that recipient evaluation pathway, and considerable inactivity for many months. There appears to have been considerable confusion between the WDHB Renal Service and ARTG, as to what was required for definitive cardiac assessment, and when [Mrs A] could be considered as having undertaken full assessment for the allocation meeting. It would be useful to clarify the particular responsibilities of the different teams in this regard, and in such complex situations provide very clear detail with regard to the expected investigations required."