Orthopaedic Surgeon, Dr B

Te Whatu Ora | Health New Zealand South Canterbury (formerly South Canterbury District Health Board)

A Report by the

Deputy Health and Disability Commissioner

(Case 20HDC00067)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a man who had metal-on-metal hip replacement surgery in 2006 and 2012. In 2013, a clinical nurse specialist in the Orthopaedic Outpatient Clinic at Te Whatu Ora South Canterbury (formerly South Canterbury District Health Board (SCDHB) undertook follow-up review of the man's joint replacement, which included blood tests for cobalt and chromium levels. The tests were recorded as having been requested by an orthopaedic surgeon.

2. The cobalt and chromium test results significantly exceeded the normal reference levels. However, despite this, no action was taken on the results. At the time, SCDHB had no electronic sign-off process, and it appears that the paper results were not sighted or actioned by the orthopaedic surgeon or any other clinician, and the man was not scheduled for follow-up orthopaedic review of his hip replacements.

3. From 2013 to 2019, the man presented to SCDHB for various health issues, including heart failure. There is no documented evidence that the man received further orthopaedic review of his hip replacements during this period, and his cobalt and chromium levels were not tested again until Month2.

4. The man was admitted to SCDHB on 14 Month2 following an increase in his heart rate, shortness of breath, and swelling. The man's cobalt and chromium test results, received on 26 Month2, showed significantly elevated and toxic levels. It was at this point that the man was advised of the missed results from 2013. The results led clinicians to believe that the elevated levels could explain the man's refractory heart failure.

5. The man was administered calcium disodium edetate (EDTA) as an antidote to treat the toxicity. EDTA is rarely used in New Zealand, and the only stock that could be obtained had passed its expiry date. A safety assessment was undertaken, and, because of the urgency of the situation, SCDHB clinicians treated the man with the expired stock.

6. Sadly, the man passed away.

Findings

7. The Deputy Commissioner considered that SCDHB did not provide the man with the timely, competent, and appropriate services he needed based on his significantly abnormal chromium and cobalt test results. The failure to action the man's 2013 test results meant that the heavy cobalt toxicity remained undiagnosed, and this contributed to the man's eventual heart failure.

8. The Deputy Commissioner considered that SCDHB's system for receiving and communicating laboratory test results to clinicians was inadequate and prone to human error, and SCDHB did not have safety-netting steps in place to mitigate this. The Deputy Commissioner noted that proactive steps were not taken to ensure that the man was reviewed in accordance with SCDHB's relevant policies and guidelines, which resulted in the

Names have been removed (except SCDHB/Te Whatu Ora South Canterbury 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.

man receiving no further postoperative follow-up between 2013 and 2019. The Deputy Commissioner considered that human error also occurred in the orthopaedic administrative process in relation to booking the man's follow-up appointment.

9. The Deputy Commissioner agreed with SCDHB's Serious Adverse Event Review findings that the man's follow-up did not meet the recommendations for patients with metal-on-metal hip replacements, and that the circumstances were "wholly preventable".

10. The Deputy Commissioner found SCDHB in breach of Right 4(1) of the Code.

11. The Deputy Commissioner considered that the use of the expired EDTA was reasonable in the circumstances, but was concerned about aspects of the informed consent process.

12. The Deputy Commissioner considered that the orthopaedic surgeon was not culpable in missing the man's test results due to the human errors in the paper-based system, which did not alert him to the abnormal findings. Accordingly, the Deputy Commissioner did not find the orthopaedic surgeon in breach of the Code.

Recommendations

13. SCDHB advised HDC of a number of changes made following its review of the care provided to the man. The Deputy Commissioner recommended that in addition, Te Whatu Ora provide HDC with a summary of a recent audit of the existing register of patients with metal-on-metal hip replacements, and steps taken to address any issues identified; provide an update regarding the implementation and effectiveness of the existing current protocol for the long-term management of total hip replacement and a summary of changes implemented to ensure that diagnostic testing and investigations ordered for orthopaedic patients have been received and actioned; and provide the man's family with a written apology.

14. The Deputy Commissioner received information from the National Poisons Centre on its project for hospital pharmacies to establish a central store of antidotes and rarely used medicines. The Deputy Commissioner will ask Te Whatu Ora|Health New Zealand to consider a national strategy on this matter.

Complaint and investigation

15. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her late husband, Mr A, by South Canterbury District Health Board

(SCDHB), now Te Whatu Ora South Canterbury.[1] The following issues were identified for investigation:

- *Whether South Canterbury District Health Board provided Mr A with an appropriate standard of care in respect of blood test results reported on 19 February 2013, and in respect of the post-operative review of the hip replacement surgery between February 2013 and 2019.*
- *Whether Dr B provided Mr A with an appropriate standard of care in respect of blood test results reported on 19 February 2013.*

16. This report is the opinion of Dr Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

17. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer's wife
SCDHB	Provider/DHB
Dr B	Orthopaedic surgeon

18. Further information was received from:

Dr C	General practitioner (GP)
Dr D	Clinical Director of Orthopaedics/SCDHB
Dr E	Cardiology consultant

19. Independent pharmaceutical advice was obtained from Associate Professor Matthew Doogue (Appendix D).

Information gathered during investigation

Introduction

20. Mr A, aged in his fifties in 2019, was a patient who had received hip replacement surgery in 2006 and 2012. At the time of these surgeries, he was reported to be a fairly fit and well man (an ex-smoker) with an elevated BMI and obstructive sleep apnoea. By September 2015, it was reported that Mr A had ongoing serious heart issues,[2] which continued the

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references to SCDHB and related entities now refer to Te Whatu Ora South Canterbury.

[2] Mr A was transferred to another DHB in 2015 for investigation of his tachycardia (rapid heartbeat), elevated troponin (a protein found in heart muscles that becomes elevated when the muscles are damaged) and heart failure symptoms.

deterioration of his overall health before his death from cardiomyopathy (heart failure)[3] in 2019. Although Mr A received care by various providers over an extensive period, the purpose of this opinion is to consider the issues brought to HDC's attention by his wife, Mrs A. The issues Mrs A wished to be considered included:

a) Whether it was reasonable that the laboratory test results ordered in February 2013 were not viewed or acknowledged by Dr B or by SCDHB. The test results showed that Mr A had significantly abnormal levels of cobalt and chromium in his body after the metal-on-metal hip replacement surgery performed in April 2012.

b) Whether the cobalt and chromium poisoning caused and/or contributed to Mr A's ongoing heart failure.

c) Whether the approval and use of the expired medication calcium disodium edetate (EDTA)[4] on 28 Month2[5] 2019 was reasonable.

21. I am unable to determine the extent to which the abnormal cobalt and chromium levels contributed to Mr A's subsequent heart failure and death, and I note that conclusions regarding cause of death are for the Coroner to determine, not this Office. I am, however, able to assess the standard of care provided to Mr A by the various providers identified. I do acknowledge that SCDHB has accepted that the missed cobalt and chromium level test results contributed to Mr A's heart failure.

Background

Right hip replacement — May 2006

22. On 4 May 2006, Mr A underwent a right hip replacement[6] performed by an orthopedic surgeon at another DHB. The surgery was undertaken because it had been assessed that Mr A had a "grossly degenerate right hip" that was suggestive of a degenerative hip condition.[7]

23. According to Dr D, the Clinical Director of Orthopaedics at SCDHB (who reviewed Mr A in Month2), Mr A had an "uneventful post-operative recovery". No further notes are available for any of his follow-up after the surgery in 2006. This was confirmed in SCDHB's Serious Adverse Event Report (SAE Report),[8] which stated:

[3] Mr A passed away from refractory congestive heart failure (CHF). The preliminary post-mortem result provided by the New Zealand Coronial Services advised HDC that Mr A's death was due to "end-stage cardiomyopathy from heavy metal toxicity".

[4] Also known as sodium calcium EDTA. Primarily this medication is used to treat heavy metal poisoning. The drug chelates or binds to the metals in the body to remove them.

[5] Relevant months are referred to as Months 1-2 to protect privacy.

[6] A Birmingham resurfacing hip replacement, which replaces the two surfaces of the hip joint. The procedure is bone conserving, as the head of the femur is retained. The socket is replaced with a metal implant, which is wedged directly into the bone.

[7] Clinical notes indicate appearances suggestive of an old slipped capital femoral epiphysis (SCFE) — a hip disorder where the head of the femur slips down and backward off the neck of the bone.

[8] The SCDHB SAE Report was completed on 23 July 2020. It provides a review of Mr A's death from congestive heart failure secondary to toxic heavy metal poisoning. A Root Cause Analysis (RCA) approach was applied to understand the causal factors that led to the missed diagnosis.

> "[Mr B] attended an Outpatient Appointment in [a main centre] on the 13 June 2006 where no issues were identified. The clinic letter indicated that Mr B should be seen in one [year's] time in Orthopaedic Clinic for a repeat AP Pelvis and for clinical assessment. There is no evidence on [electronic medical records] that a follow-up appointment took place."

Orthopaedic assessment of left hip — September and December 2011

24. On 27 September 2011, Mr A's family doctor, Dr C, referred Mr A to the Orthopaedic Outpatients Department for assessment of ongoing pain in his left hip. The referral letter states that Mr A's left hip was "increasingly painful". The referral letter also states: "[Mr A] doesn't have any follow up arranged for his right Birmingham hip replacement."

25. The Orthopaedic Outpatients Department triaged this referral as category 2 (to be seen within three months), and Mr A was referred for an orthopaedic physiotherapy appointment.

26. On 21 December 2011, an orthopaedic physiotherapist at SCDHB noted that Mr A had not received any follow-up in five years. SCDHB stated that the orthopaedic physiotherapist completed Mr A's five-year postoperative check of the right hip at this assessment. A note attached to the clinical documentation indicated that Mr A needed to be put in the system for further review by 2016.

27. The orthopaedic physiotherapist noted that Mr A was experiencing worsening left hip pain, and that it was more painful than the right hip, with a "constant burning sensation". Although the pain was being managed with heat packs and pain relief,[9] this reduced only the severity of the pain,[10] and Mr A's hip continued to feel stiff, weak, and unstable.

28. X-rays were performed on both of Mr A's hips, and the results were assessed by an orthopaedic surgeon that day. The orthopaedic surgeon considered that the right hip replacement was in a good position with no signs of infection, loosening, or lysis (damage to the cell membrane). However, the X-ray of the left hip showed signs of bone collapse,[11] and Mr A was placed on the waiting list for a left hip replacement, with the intention that the surgery be performed within six months. This information was communicated to Mr A's GP by the orthopaedic physiotherapist.

Left hip replacement — April 2012

29. On 27 April 2012, Mr A presented to SCDHB for his left hip replacement,[12] which was performed by orthopaedic surgeon Dr B. The surgery was uneventful, and Mr A was discharged on 29 April 2012.

[9] Codeine phosphate, paracetamol, and ibuprofen.
[10] Mr A reported the pain as 5–7 out of 10.
[11] This was assessed as "severe osteoarthritic changes with femoral head collapse".
[12] Left Birmingham hip resurfacing.

30. The postoperative instructions in Dr B's operation note refer to a follow-up appointment in six weeks' time, prior to removal of the clips. Following this appointment, Dr B wrote to Dr C on 19 June 2012 stating that Mr A's left hip wound was healing well and that he was mobilising without major problems. Specifically, the letter stated: "We will see him at the one year stage in the nurse led clinic for routine follow up of both hips with x-rays on arrival."

Follow-up review with blood tests for cobalt and chromium — 12 February 2013

31. On 12 February 2013, Mr A presented to the Orthopaedic Outpatient Clinic at SCDHB for his routine joint replacement review, which was undertaken by a clinical nurse specialist. X-rays were taken of both Mr A's right and left hips, and the findings were reviewed by a radiologist. The SAE Report stated that during this consultation, the clinical nurse specialist also provided Mr A with an explanation regarding metal-on-metal hip replacement and blood level monitoring, and discussed a letter that had been received relating to "impact recall/cessation". The clinical notes document:

> "There has been no interval change in position or alignment of the bilateral hip resurfacing when compared to previous. Right-sided femoral stem again is noted close to anterior femoral cortex but unchanged."

32. As part of routine follow-up tests, blood for cobalt and chromium levels[13] was taken and sent to the medical laboratory (part of SCDHB) for review on the same day. The test was recorded as having been requested by Dr B.

33. The cobalt and chromium test request was received by the medical laboratory on 13 February 2013, and a final report was issued on 19 February 2013. The report stated that the cobalt level was 1981.0 nmol/L and the chromium level was 1374.0 nmol/L. Both levels of cobalt and chromium significantly exceeded the normal reference levels.[14]

34. According to the SAE Report, the results were stamped "COPY" with the date "12 March 2013/Visiting Consultant" but with no signature on the results. In particular, the Report stated:

> "The Serious Adverse Event Review Team found that there was a lack of clear evidence that the Laboratory Results had been reviewed by the Consultant and there was no documentation to support any action being taken if the results had been viewed."

35. The SCDHB Clinical Tests: Signing of Results Protocol (see Appendix A) in 2013 stated:

[13] Recent literature reviews note that metal-on-metal hip implants have been linked with several health issues, including cobalt and chromium poisoning. This occurs when corroded cobalt or chromium enters the patient's bloodstream. There is evidence that both cobalt and chromium poisoning have been associated with neurological, cardiac (arrhythmias and cardiomyopathy), and endocrine symptoms.
[14] The normal level of cobalt is <12.0 nmol/L. The normal level of chromium is between 1–8 nmol/L.

> "The Medical Officer ordering a test is responsible for follow-up of results. For legal purposes and good clinical practice the Medical Officer who ordered the tests must verify that test results have been reviewed."

36. However, SCDHB told HDC that the normal process in place in 2013 was that the clinical nurse specialist for orthopaedics (who saw Mr A on 12 February 2013) could request the laboratory tests on behalf of the orthopaedic surgeon (in this case Dr B), and that the hard-copy results would then go to the orthopaedic surgeon for review. The results would not go back to the clinical nurse who requested them. SCDHB explained:

> "At the time paper copies of result were sent to the laboratory, who then forwarded it on to the orthopaedic secretary who would then assign it to either the specified consultant requesting the test or the consultant on call. If the test was normal, the paper copy was sent to CNS [Clinical Nurse Specialist] who would contact the patient. If the result was abnormal it would trigger further investigations and a review appointment."

37. In this case, while the tests were shown to have been requested by Dr B, the tests were actually requested by the clinical nurse specialist. This was in accordance with SCDHB's usual practice at the time.

38. A note in Mr A's GP medical records shows that the test request for cobalt and chromium levels was sent to the medical laboratory. However, there is no evidence that a request was made for Dr C (Mr A's GP) to be copied into the results. Therefore, Dr C did not receive the results.

39. Dr B told HDC that the copy of the chromium and cobalt test results was not signed off or seen by himself or by any other clinician. He said that the normal practice and process in SCDHB was for patients with metal-on-metal hip replacement to be followed up annually in the nurse-led clinic, with a set of tests[15] undertaken. After the clinic, the nurse would meet with the orthopedic surgeon to discuss the clinical findings and to review the X-rays. The blood samples would be sent to another DHB, and the results would come back as hard copies, one to two weeks later.

40. Dr B explained that at the time, there was no electronic sign-off process for laboratory results in SCDHB. Instead, the paper results were placed in consultants' mail inboxes to be reviewed and physically signed and annotated, with any actions to be filed in the case-notes by the medical records team. Dr B stated:

> "It was well known that the paper-based processing of lab results was very error prone, and eventually an electronic sign-off process was introduced (a project that I led in my later role as Clinical Lead for IT in SCDHB). I think from memory that the introduction of electronic sign off happened in approximately 2015 or 2016 …

[15] These tests included a clinical examination, X-rays, and blood tests of metal ion levels.

> I think it would seem that unfortunately [Mr A's] lab results were filed in his notes without ever having been seen or signed by myself or by my surgical colleagues."

41. Although SCDHB is unsure whether the error was a systemic or human error, Dr B considers that it was due to an "unfortunate system error which was related to the unreliable paper-based processes in place at the time rather than to a clinical error of judgement". He said that as a consequence of this, "no action was taken despite [Mr A's] tests being significantly abnormal, and he was subsequently lost to follow up". Dr B stated that the standard practice for patients with elevated serum metal ion levels would be further investigation with CT and/or MRI of their hips, with further clinical review by one of the orthopaedic surgeons.

42. It eventuated that no further cobalt and chromium tests were taken until 2019, when Mr A was being assessed for the further hip surgery (as part of that preoperative screening).

Care received between 2013 and 2019

43. Between 2013 and Month2, Mr A presented to SCDHB for various health issues. A brief summary of the relevant presentations is set out below to provide additional context about Mr A's health during this period. However, the care that Mr A received during this time is not the focus of this report.

44. The SAE Report noted that there was a note in the clinical file from the orthopaedic nurse, stamp dated as received on 13 February 2013, for the orthopaedic secretary to book Mr A into a Clinical Nurse Specialist Holding Clinic in 2016 so that he was not lost in the DHB system. Although this was signed and dated as having been completed by the orthopaedic secretary on 13 February 2013, the SAE review team found that the follow-up appointment was not scheduled or sent to Mr A. The review team found that it was "most probably human error that this appointment was not made".

45. In September 2015, Mr A presented to SCDHB for an urgent assessment of a presumed viral illness with a rapid onset of swelling[16] in his lower limbs and shortness of breath. Mr A was transferred to the Cardiology Ward at a main centre hospital with a suspected infection of the heart.[17] Subsequently, Mr A was discharged home for follow-up[18] in the community. Although Mr A's condition improved, he underwent further investigations[19] during this period.

46. A cardiac MRI was requested in May 2016 (due to mildly elevated troponin levels) and was performed in September 2016. This showed evidence of increased scar tissue[20] in Mr A's heart. Despite some concerns, it was noted that the Cardiology consultants did not "feel

[16] Oedema — swelling in the ankles, feet, or legs caused by a build-up of fluid.
[17] The impression at this stage was of viral myocarditis causing biventricular failure.
[18] With the cardiac rehabilitation service and his GP, and by the visiting cardiologists.
[19] Including sleep apnoea assessments, angiograms, an electrocardiogram (ECG) and a transthoracic echo cardiogram.
[20] The cardiac MRI indicated delayed enhancement involving the basal to mid left ventricular inferior and inferolateral segments on the short axis and four chamber images.

that there was sufficient evidence to pursue a cardiac biopsy at that stage". Mr A continued to be observed in 2017, and his troponin levels remained persistently elevated.

47. In May 2018, Mr A was reviewed again, and an echocardiogram[21] showed severe left ventricular (LV) impairment[22] and mild right ventricular (RV) dysfunction. The possibility of a heart transplant was suggested but not actioned. By November 2018, a repeat cardiac MRI showed further deterioration[23] of Mr A's heart. As a result, plans were made for Mr A to receive an ICD[24] to assist with his cardiac function. This was performed in 2019 and Mr A was discharged with no significant problems.

48. Despite the ICD, Mr A continued to experience heart failure,[25] with episodes of increased heart rate (tachycardia). It is documented that a few days after the ICD, Mrs A rang the GP practice to discuss the development of pain around Mr A's ICD site. Mr A was reviewed by Dr C that day.

Presentation to SCDHB for heart failure — 14 Month2

49. On 29 Month1, Mr A presented to Dr C for a further review. It is documented that Mr A was sore around the upper abdomen, and had no appetite or energy, but his breathing was "ok". It is noted that Mr A was to see a cardiology nurse, and potentially to co-ordinate with a cardiologist.

50. On 11 Month2, an orthopaedics referral was submitted alongside a request for routine blood tests, which included assessment of cobalt and chromium levels. The test results were sent to Dr C's inbox on 12 Month2, and indicated that Mr A's cobalt levels were high. Dr D, the Clinical Director of Orthopaedics at SCDHB, confirmed to HDC that the cobalt and chromium tests were ordered by him.

51. On 12 Month2, Mr A was reviewed at the Orthopaedic Department at SCDHB by the same clinical nurse specialist who had reviewed Mr A in February 2013 prior to his left hip replacement. The nurse noted that the previous right and left hip replacements had been performed in 2006 and 2012 respectively. The X-rays undertaken for this consultation were reviewed by Dr D, who explained that the metal-ion debris had caused some of Mr A's bone to be eaten away, and that "the bone ha[d] now cracked through on the left and [was] likely

[21] A procedure in which views of the heart are obtained by moving a small instrument (a transducer) to different locations on the chest or abdominal wall.
[22] LV diastolic dysfunction is the condition in which the relaxation process of the heart is disturbed as the left ventricle has become stiffer than normal.
[23] The repeat cardiac MRI showed extensive diffuse mild myocardial delayed enhancement predominantly affecting the lateral LV wall with extension to the anterior and inferior walls with relative septal sparring.
[24] An Implantable Cardioverter Defibrillator (ICD) — a device to prevent risk of malignant ventricular arrhythmias (irregular heart rhythms). An ICD is used to monitor the heart continuously and help regulate the heart's rhythms by promoting a normal heartbeat (a shock can be delivered) and by recording and storing information about the patient's heart rhythm.
[25] This was also indicated as heart decompensation (decompensated heart failure).

to progress to the same issue on the right-hand side", thereby causing the ongoing pain for Mr A.[26] A plan was made for Mr A to see Dr D in a week's time for further assessment.

52. Dr D said that the cobalt and chromium tests taken on 12 Month2 showed significantly high and toxic levels.[27] However, he said that he received these results only about two weeks later, and they were not communicated to Mr A at the time. This is confirmed by the laboratory test result report for the cobalt and chromium levels, which was produced on 26 Month2.

Admission to SCDHB — 14 Month2

53. Subsequent to the orthopaedic review, Mr A presented to SCDHB as an emergency on 14 Month2 for increased heart rate (tachycardia), swelling (oedema), and shortness of breath. The Emergency Department referral documented "worsening CHF [congestive heart failure]", and that Mr A was due for urgent hip surgery.

54. During Mr A's admission to SCDHB, primarily he was seen by consultant cardiologist Dr E, as part of the cardiology intervention team. Dr E documented that Mr A's heart failure and ongoing swollen feet[28] was presumed secondary to a "predominantly right greater than left sided cardiac decompensation". Although initially it appeared that Mr A was responding favourably to the treatment plan and medication,[29] over the next few days it was observed that his response to the treatment had deteriorated, and he was experiencing increasing pain in his left hip.

55. Dr D was due to review Mr A on 19 Month2 prior to the planned hip surgery, but because Mr A's condition had deteriorated, the surgery was postponed until Mr A was "stable from a cardiac perspective". Dr D advised Dr C of this by letter on the same day. Over the course of the week, Mr A continued to experience ongoing discomfort, including pain in his right shoulder and left hip.

Use of expired EDTA to treat heavy metal toxicity — 28 Month2 onwards

56. Once Dr D received Mr A's significantly elevated cobalt and chromium level results (reported on 26 Month2), he notified Dr E that the results indicated heavy metal toxicity. Dr E stated that these results, together with subsequent research, and advice from Dr D, led them to understand that the "elevated Cobalt levels could potentially explain the ongoing problems and refractory heart failure in [Mr A]".

57. According to the SAE Report, as per SCDHB's open disclosure policy, Mr A and his family were advised of both the missed cobalt and chromium level test results from February 2013, and the recent test results. The nursing progress notes document that the cobalt and

[26] Dr D noted extensive lysis around both Mr A's hip resurfacings, which had developed into a neck-of-femur fracture on the left-hand side and showed typical features of ARMD (adverse reaction to metal debris).
[27] Cobalt level of 5244 nmol/L and chromium level of 3071 nmol/L. Significant increase in plasma cobalt and chromium levels is consistent with failure of hip replacement and potential systemic cobalt toxicity.
[28] Bilateral pedal oedema.
[29] Mr A was commenced on IV furosemide to treat his fluid retention and reduce the swelling caused by his congestive heart failure.

chromium toxicity was explained to Mr A on the morning of 28 Month2. The notes document the following interactions:

> "Explained cobalt toxicity 2° to hip prosthetic + associated potential cardiomyopathy. Explained surgical removal difficult given condition. Explained potential use of binding agents."

58. Both Dr D and Dr E proceeded to discuss the cobalt and chromium results with their colleagues and with the New Zealand National Poisons Centre, and sought help and advice regarding the treatment and management of the presumed cobalt toxicity. Dr E was advised to start Mr A on EDTA and to continue for five days. A pharmacist was asked to obtain the EDTA, including further stock from a main centre hospital[30] (as there was insufficient quantity at SCDHB).

59. Before the EDTA was given to Mr A, it was noted that the available EDTA had expired almost one month previously.[31] SCDHB contacted other hospitals to try to obtain stock, but because the EDTA antidote was rarely used in New Zealand, it was difficult to obtain. Given the time it would take for new stock to arrive, SCDHB decided to proceed with the treatment, and Mr A was commenced on EDTA on 28 Month2. In rationalising the safety aspect of the drug, SCDHB stated:

> "Expired antidotes are not discarded, while waiting for new stock, because they are regarded as reasonably 'safe' to use depending on how long ago they expired. An expiry of one month previous is considered minimal."

60. SCDHB explained that in this case, with consideration of the safety of the use of the EDTA,[32] given that the alternative was that no chelation (bonding treatment) would have been available, "there was only benefit from using the expired calcium disodium edetate and no extra risk from it being out of date". SCDHB's lead pharmacist concurred with this assessment, and stated:

> "I strongly advised [the pharmacist who obtained the EDTA] (and [Dr E]) to use the antidote, as with my expertise in Chemistry (PhD) the fact it had expired by less than one month, was not going to make any difference in the treatment … Additionally, as there are no national antidote guidelines or minimum stock levels in New Zealand (and

[30] The EDTA stock from the main centre hospital had also expired.

[31] SCDHB stated that the EDTA stocks were held in SCDHB and the main centre hospital. Both stocks (50mg/m: batch […]) had expired on 30 Month1. The stock was exactly 28 days out of date. The SCDHB SAE report initially incorrectly stated that the EDTA had expired only two days prior to Mr A's commencement (28 Month2). However, it was later confirmed that the medication had expired on 30 Month1.

[32] SCDHB stated that 28 days out of date for EDTA is a relatively short period of time compared to the chemical stability, because generally it requires high temperatures (>100°C) in acidic or basic conditions to undergo oxidative and reductive processes to degrade into other chemical compounds. As the EDTA was packaged in a sterile, sealed glass ampoule and protected from light, this would have minimised any degradation.

obtaining antidotes in non-urgent situations is reasonably difficult due to their rare use), in urgent situations it is only possible to source from within New Zealand."

61. The SAE Report also noted that the EDTA used to chelate the heavy metal cobalt is rarely used in New Zealand, and that it would have taken a very long time to chelate all the cobalt, and it was "impossible to determine how long this would have taken, or what quantity of the medication was required". The report concluded that the use of out-of-date EDTA did not have an impact on Mr A's death.

Consent to use of expired EDTA

62. Mrs A raised concern to HDC that she did not understand why the expired EDTA was used and whether it was safe to use.

63. Although there is no documented confirmation of Mr A's consent to the use of the expired EDTA, SCDHB told HDC that Dr E recalls having had several discussions with Mr and Mrs A around the use of the EDTA and the fact that only expired stock existed in the country. SCDHB stated that verbal consent was obtained at the time.

Subsequent events

64. After the commencement of the EDTA, it was reported that initially Mr A appeared to tolerate the treatment reasonably well, although the pain in his left hip remained difficult to control. Over the next three days, Mr A's health continued to deteriorate, and nursing notes record that his health remained poor.

65. Sadly, Mr A passed away.

66. The SAE Report noted the following:

- The missed finding of the raised cobalt and chromium levels contributed to the delayed diagnosis. If the results had been identified by an orthopaedic consultant, the options of revision surgery and/or management with reversal treatment would have been available to Mr A.
- The routine follow-up appointment (for patients with metal-on-metal implants) was missed. If the appointment had been made, Mr A could have been reviewed in 2014. The follow-up did not meet the recommendations for patients with metal-on-metal hip replacements.
- "The actual test results [2013] were not copied to the GP, and the tests were requested by a hospital orthopaedic surgeon. There was thus no impetus, at the time, on the basis of this information, for action on the part of the GP."
- "The analysis of the events makes Mr [A's] death wholly preventable, had the system dealing with abnormal test results triggered a response to his grossly elevated metal ion levels. And, absent any action on the initial notification, a failure or backup notification should have been activated."

67. No post-mortem examination was performed on Mr A by the Coronial service, which stated:

> "[A] post-mortem examination would not reveal anything as to the cause and circumstances of death. She [the forensic pathologist] considered that 'it is a reasonable assumption, and on the balance of probabilities, looking at the timing of hip replacement surgeries and cobalt and chromium levels taken over time it fits with toxicity poisoning'."

Further information

Mrs A

68. Mrs A told HDC that Mr A had no follow-up for both of his hips. She questions the effectiveness of the furosemide (fluid retention) medication prescribed, which did not appear to help. She also raises concern why the Coroner refused to perform an autopsy for a piece of Mr A's heart for further research.

SCDHB

69. SCDHB told HDC that it apologises to Mrs A that no action was taken when the cobalt and chromium toxicity levels were identified in 2013. SCDHB said that it has continued to review its processes for identifying patients with metal-on-metal implants to ensure that such an event does not happen again. The SAE conducted by SCDHB acknowledged that the introduction of the electronic sign-off process in 2016 would have resulted in Mr A's cobalt and chromium plasma laboratory results being escalated to another orthopaedic surgeon or the Clinical Director of Orthopaedics when the report had not been viewed or signed off.

70. SCDHB also explained that during 2012/2013, the clinical nurse specialist for orthopaedics identified that new patients moving into the SCDHB area with a preexisting metal-on-metal joint replacement were not being reviewed annually to identify any issues.

71. The SCDHB Total Hip Replacement Procedure/Protocol (the THRP) (February 2012, see Appendix C) stated that patients who have had hip replacement surgery are expected to be reviewed postoperatively at 1, 3, 5, and 10 years, and every 5 years thereafter. The investigations to be performed included X-rays of the standing AP pelvis and lateral hip, and blood tests for cobalt and chromium levels for patients with metal-to-metal articulating surfaces. The management section of the policy stipulated that the responsible clinicians were to remind patients of their ability to contact the orthopaedic secretary or outpatient appointment office to initiate review by a consultant if they had any concerns regarding their joint replacement. The THRP also required ultrasound scans for patients who showed elevated levels of metal ions.[33]

72. The updated version of the THRP (which applied from February 2015, see Appendix B) removed the management section requiring the responsible clinicians to remind patients to contact the orthopaedic staff to initiate a review, and the requirement for review three years after the surgery.

[33] Cobalt > 250nmol/L and chromium > 400nmol/L.

73. In response to Mrs A's concern about the use of furosemide, SCDHB explained in the SAE Report that the medication was intended to treat the fluid overload but not to reverse the heart failure. SCDHB stated: "[T]he reason Furosemide was not effective enough, was due to the severity of the heart failure."

Dr D

74. Dr D told HDC that orthopaedic surgeons have been fully aware of the risk of raised metal-ion levels with the metal-on-metal bearing hip replacements that were extremely popular worldwide from early to mid-2000s until about 2013/2014. Dr D provided anecdotal evidence of high complication rates due to the adverse reaction to metal-ion levels.

75. Dr D stated that although guidelines from 2014–2015 suggested yearly follow-ups of any patient with a metal-on-metal bearing hip replacement, the orthopaedic community were unsure of what the "strict guidelines" were in terms of when to operate. Dr D said that the "NICE" guidelines[34] recommended that for "any cobalt level greater than 120 nmols per litre and chromium above 100 nmols per litre, patients had to be followed-up carefully and if these levels rose, to look at doing revision surgery of the component".

Surveillance of metal-on-metal implants

76. The SAE Report discussed that in 2011/12 the New Zealand Ministry of Health became aware of issues with metal-on-metal hip replacements, and that patients with elevated cobalt and chromium levels had been identified internationally. Accordingly, in October 2012 Medsafe issued an alert to surgeons[35] that patients who had had a Birmingham hip modular head implant should be "followed up more frequently by their doctor".

77. The SAE Report identified that in 2012/2013, the SCDHB Orthopaedics Department made contact with the NZ Joint Registry to obtain a list of all patients who had had metal-on-metal implants in SCDHB (with the implant invoice records double checked). A record of the left and right hip replacements performed for Mr A was registered with the National Joint Register. The Orthopaedics Clinical Nurse Specialist identified at the time that there was a gap in the check for any person who had moved into the SCDHB area with a pre-existing metal-on-metal joint replacement.

78. Although the SAE Report disclosed that there were no specific metal-on-metal policies, procedures, or guidelines in place at SCDHB, the staff followed the Medsafe and the New Zealand Orthopaedic Association (NZOA) advice to healthcare professionals issued by the UK Medicines and Health Products Regulatory Agency (MHRA) at the time, which was in place until 2015.

[34] The National Institute for Health and Care Excellence (NICE) recommendations on how healthcare and other professionals should care for people with specific conditions.

[35] The Medical Device Alert required action by medical directors, orthopaedic departments, orthopaedic surgeons, and staff involved in the management of patients with joint replacement implants.

National Poisons Centre

79. In the context of receiving expert advice from Associate Professor Doogue, HDC received information from the New Zealand National Poisons Centre. The National Poisons Centre told HDC that currently it has an active project with an aim to develop a national antidote stocking guideline for hospital pharmacies. The guideline is intended to be a "living guideline" that is reviewed and updated regularly.

Responses to provisional opinion

Mrs A

80. Mrs A was given an opportunity to comment on the "information gathered" section of the provisional opinion. Mrs A requested clarification in relation to certain facts, and, where relevant, additions have been made to the "information gathered" section to provide this clarification.

81. Mrs A stated that every time her husband went to a clinic appointment or was in hospital, his blood test results were sitting in his file. She queried why they were not "red flagged" so they were seen.

82. Mrs A told HDC that it was not an excuse that there was a gap identified in 2012/2013 in checks for any person who moved into the SCDHB region with a pre-existing metal-on-metal joint replacement. She noted that SCDHB was aware of Mr A's right hip replacement by 2011.

SCDHB

83. SCDHB was given an opportunity to comment on the provisional opinion. SCDHB confirmed that it had no further comments to make.

Dr B

84. Dr B was given an opportunity to comment on the provisional opinion. Dr B confirmed that he had no further comments to make.

Opinion: SCDHB (now Te Whatu Ora South Canterbury)

85. First, I would like to express my condolences to Mrs A for the passing of her husband. What follows is an examination of the care provided to Mr A by SCDHB.

Management of significantly abnormal cobalt and chromium test results — breach

86. Mr A received left hip replacement surgery from SCDHB on 27 April 2012. The surgery was unremarkable, and a routine follow-up review was undertaken by a clinical nurse specialist on 12 February 2013. As part of the follow-up review, a test for cobalt and chromium levels was ordered and sent to the medical laboratory. The results were reported on 19 February

2013 and indicated that both Mr A's cobalt and chromium levels were significantly high (exceeding the normal reference range), indicating heavy metal toxicity.

87. Despite the results being stamped "COPY", it was found by SCDHB's SAE review team that the results were not reviewed or verified by a consultant, and were not communicated to any other provider (for example, Mr A's GP), or to Mr A. This resulted in the diagnosis being missed, and Mr A was lost to follow-up. SCDHB acknowledged that this error made Mr A's death "wholly preventable".

88. The New Zealand Health and Disability CORE standards[36] outline the responsibility of healthcare providers to ensure that "consumers receive timely, competent, and appropriate services in order to meet their assessed needs and desired outcome/goals". In Mr A's case, it was SCDHB's responsibility to communicate the significant cobalt and chromium levels in a timely manner to both the correct clinician and Mr A, before providing Mr A with the appropriate services to treat this condition. However, this did not happen. Having assessed the information carefully, I am critical of SCDHB's management of Mr A's test results. My reasoning is set out below.

89. The "Signing of Results Protocol" (the Protocol) sets out that the medical officer who orders a test is responsible for the follow-up of the results, and for verifying that the results have been reviewed. The Protocol also imposes further duties on the requesting medical officer (see Appendix A). The referral form for the cobalt and chromium levels test shows Dr B to have requested the tests.

90. SCDHB told HDC that the normal process in 2013 was that the clinical nurse specialist could also request laboratory tests on behalf of the orthopaedic surgeon (Dr B in this instance), and the hard copy of the result would then be sent to the orthopaedic secretary to give to the surgeon. Abnormal results would trigger further investigation for the patient and a review appointment. However, this did not happen for Mr A despite his significantly abnormal cobalt and chromium test results, and there is no evidence to suggest that the results were reviewed before the report was filed in Mr A's medical notes.

91. I am not concerned about the tests having been ordered by the clinical nurse specialist, as this was common practice, as acknowledged by both the orthopaedic surgeon and SCDHB. However, in my view, ideally SCDHB's Protocol should have reflected SCDHB's usual practice. I expect SCDHB to have updated the policy since 2012, and suggest that SCDHB reflect on whether its current policy reflects its current practice.

92. Dr B explained that at the time of events, the laboratory results came back as paper hard copies and were filed via a paper process system, as no electronic sign-off process was

[36] The New Zealand Standard Health and Disability (CORE) Standards (NZS 8134:2008). NZS8134.3 outlines the expectations for continuum of service delivery. NZS8134.1.3.3 states: "Consumers receive timely, competent, and appropriate services in order to meet their assessed needs and desired outcome/goals." NZS81341.1.3.10 further states: "Consumers experience a planned and coordinated transition, exit, discharge, or transfer from services."

available. The paper results were placed in consultants' mail inboxes to be reviewed, signed, and annotated with any actions, before being filed in the case notes by the medical records team.

93. Although the results were stamped with "COPY", there was no signature of a consultant having viewed the results. In my view, it is likely that once the results were sent to the orthopaedic secretary for forwarding, they were filed into Mr A's notes without Dr B or another orthopaedic surgeon having been alerted to them.

94. Upon conducting the internal investigation into this case, the SAE Report also pointed towards a separate incident where a follow-up appointment was signed and dated by the clinical secretary on 13 February 2012 as having been completed, but the follow-up appointment was neither scheduled nor communicated to Mr A. In my view, this is further evidence of human error within the Orthopaedic Department's administrative processes that contributed to Mr A not receiving the appropriate follow-up.

95. The SAE Report also acknowledged that the electronic sign-off process introduced in 2016 would likely have escalated Mr A's results to another orthopaedic surgeon or the Clinical Director of Orthopaedics if they had not been viewed or signed off. However, the absence of this process in 2013 indicated a deficiency in safety-netting.

96. Previous HDC decisions[37] have emphasised the responsibility of district health boards to have in place clear, effective, and formalised systems for the reporting and following up of test results, to enable their staff to action the results appropriately. In this instance, the orthopaedic service identified that there was no formalised process in place to ensure that diagnostics, including metal ions and X-rays that had been ordered for orthopaedic patients, had been received or actioned by the consultant clinician.

97. In my view, SCDHB's paper tracking system appears to have failed in the circumstances, as there was no other system to alert clinicians to Mr A's abnormal results. I consider that SCDHB's procedures were not sufficiently robust to ensure that it could identify when results had been missed. The manual process appears to have been reliant on human accuracy, with no safety-netting in place.

98. Whilst human errors can occur in any referral process, it was acknowledged by Dr B that the paper test result system at the time was "well known" to be "error prone". I am very concerned by this comment, and consider that proactive steps could have been taken by SCDHB at the time to include safety nets in the paper-based process to ensure that important results were not overlooked.

99. In particular, I would have expected SCDHB to have had in place a process for requesting that a copy of the results be copied by the laboratory to the GP. This would have reduced the likelihood of the abnormal results being overlooked completely, and would have provided an additional opportunity for the abnormal results to be followed up in the event

[37] See cases 16HDC01980 and 15HDC01204, available at www.hdc.org.nz.

of SCDHB's omission. I am critical that the lack of any such process placed even more dependency on SCDHB's paper tracking system.

Postoperative follow-up after hip replacement surgery according to SCDHB's policy

100. In addition to my criticisms above in relation to the management of Mr A's significantly abnormal cobalt and chromium test results, I have also identified that SCDHB failed to follow its own Total Hip Replacement Procedure/Protocol (THRP) that applied at the time. This resulted in Mr A not receiving the appropriate orthopaedic follow-up and blood tests.

101. The left hip replacement surgery was performed by Dr B on 27 April 2012. After Mr A attended a follow-up appointment to remove the clips, on 19 June 2012 Dr B wrote to Dr C stating that Mr A's left hip was healing well and that Mr A would be seen "at the one year stage in the nurse clinic routine follow up for both hips with X-rays on arrival". This is consistent with the THRP that applied at the time of events (Appendix C), as patients who underwent hip replacement surgery were expected to be reviewed one year following their surgery.

102. On 12 February 2013, Mr A presented to the Orthopaedic Clinic at SCDHB for the expected hip replacement review undertaken by a clinical nurse specialist. X-rays were taken of both Mr A's right and left hips, and blood was taken to test his cobalt and chromium levels, in accordance with the THRP.

103. The SAE Report noted that during the consultation, the clinical nurse specialist provided Mr A with an explanation regarding metal-on-metal hip replacement and blood level monitoring, and discussed a letter the DHB had received about impact recall/cessation. It is assumed that the letter relates to the alert SCDHB received from Medsafe in October 2012. However, there is no documentation on when the next planned hip replacement review was to take place, or whether Mr A was informed that it was expected that he would receive further review.

104. Between 2013 and Month2, there is no documented evidence that Mr A received further orthopaedic review of either his left or right hip replacements. SCDHB's SAE Report documented that Mr A received follow-up for treatment of heart failure, but not that he received any routine orthopaedic review.

105. I am concerned that the THRP that applied following Mr A's surgery in April 2012 (see Appendix C) stated that patients were expected to be "reviewed post operatively at 1, 3, 5, 10 years and every 5 years thereafter". Given that the surgery was performed in 2012, the next orthopaedic review (following the one that occurred in February 2013) expected for Mr A would have been in 2015, and thereafter in 2018. There is no evidence that the second postoperative review in 2015 was arranged or took place, nor the third postoperative review in 2018. I note that the SAE Report identified a note in the clinical file for the orthopaedic secretary to book Mr A for a clinical nurse review in 2016. However, the SAE review team found that this follow-up appointment was not scheduled.

106. The "management" section of the THRP stipulated that the responsible clinician was to remind patients of their ability to contact the orthopaedic secretary or outpatient appointment office to initiate a review with the consultant if they had any concerns regarding their joint replacement. Absent any clear evidence of this being documented in the clinical review by the clinical nurse specialist in February 2013, it does not appear that Mr A was informed about his ability to contact orthopaedic staff.

107. I note that the THRP was updated in February 2015 (version 4, see Appendix B), which removed the expectation of a postoperative review three years after the surgery. Irrespective of which THRP policy applied at this stage, the fact remains that following the February 2013 review, Mr A did not receive any further orthopaedic review until his condition deteriorated in 2019 — a period of more than six years.

108. I am concerned that in addition to the mismanagement of Mr A's cobalt and chromium test results, SCDHB failed to follow its own THRP policy. Had Mr A been reviewed according to the THRP policy, further blood tests may have been performed at an earlier stage, and his heavy metal toxicity identified and appropriate treatment initiated. In addition, had the 2013 test results been followed up, SCDHB would have been alerted to undertake ultrasound scanning of Mr A in accordance with the THRP, as Mr A's levels were well in excess of those outlined in the policy. Unfortunately, these further investigations did not occur.

109. In my view, SCDHB did not have in place adequate safety-netting to ensure that patients who underwent hip replacement surgery received the monitoring and care required in light of the known risks of the surgery.

Conclusion

110. It is the responsibility of healthcare organisations to ensure that there are robust systems in place to minimise the risk of such errors occurring. I find that SCDHB was responsible for the following failings in Mr A's care:

- The system for receiving and communicating laboratory test results to clinicians was inadequate and prone to human error. There is evidence that human error occurred in the orthopaedic administrative process in relation to booking Mr A's follow-up appointment.
- SCDHB did not have in place safety-netting steps to mitigate the error-prone paper-based laboratory result review system, for example by ensuring that laboratory results were copied to a patient's GP.
- SCDHB failed to follow its own THRP policy, which resulted in Mr A receiving no further postoperative follow-up between 2013 and 2019. This was a missed opportunity for Mr A to receive further blood tests for chromium and cobalt levels, and for ultrasound scans to be undertaken in response to the 2013 results.

111. Overall, SCDHB failed to comply with the New Zealand Health and Disability CORE standards by failing to provide Mr A with the timely, competent, and appropriate services he needed based on the significantly abnormal chromium and cobalt test results. The failure to action Mr A's test results meant that the heavy cobalt toxicity remained undiagnosed, and this contributed to Mr A's eventual heart failure. This has been acknowledged by SCDHB's internal SAE Report, and I agree with SCDHB that these circumstances were "wholly preventable". Accordingly, I find that SCDHB breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[38]

Surveillance of metal-on-metal implants — adverse comment

112. Both the SAE Report and comments made by Dr D identified that around the time of Mr A's 2012 surgery, there was evidence of patients having adverse reactions to metal-on-metal hip replacement surgery. The SAE Report stated that in 2011/2012, the New Zealand Ministry of Health became aware of issues with metal-on-metal hip replacements and international cases of patients with elevated cobalt and chromium levels. In October 2012, Medsafe issued an alert to surgeons that patients who had had Birmingham hip modular head implant surgery should be "followed up more frequently by their doctor".

113. Further, in 2012/2013, orthopaedic staff from SCDHB made contact with the NZ Joint Registry to obtain a list of all patients who had had metal-on-metal implants in SCDHB. A record of the left and right hip replacements performed for Mr A was registered with the National Joint Register. However, the Orthopaedics clinical nurse specialist identified that there was a gap in a check for any person who moved into the SCDHB area with a pre-existing metal-on-metal joint replacement.

114. SCDHB stated that it did not have any specific metal-on-metal policies or guidelines, but staff followed the Medsafe and the New Zealand Orthopaedic Association (NZOA) advice to healthcare professionals issued by the UK Medicines and Health Products Regulatory Agency (MHRA) at the time, which was in place until 2015.

115. I accept that during the one-year postoperative review in February 2013, the clinical nurse specialist discussed an impact/recall letter with Mr A. This appears consistent with the advice that was issued by Medsafe, and in accordance with the MHRA recommendations. However, I am concerned that despite the clinical staff at the time knowing that Mr A was specifically a high-risk patient under this recall, it appears that no other proactive steps were taken by SCDHB to ensure that (i) Mr A would be reviewed regularly; (ii) his family doctor was aware of the issue; and (iii) Mr A would be informed about the high complication rates.

116. I acknowledge that SCDHB has accepted in its SAE Report that the follow-up of Mr A's Birmingham hip modular head implant devices "did not meet the recommendations for patients with metal-on-metal hip replacements". Accordingly, I am concerned that SCDHB failed to survey Mr A's metal-on-metal implants in accordance with the policies and guidelines as set out above.

[38] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Use of expired EDTA from 28 Month2

117. During Mr A's stay at SCDHB in Month2, his missed abnormal cobalt and chromium test results were discovered by the treating consultants, primarily Dr D and Dr E, and new results showed greater elevated levels of the metals. Dr E consulted with his colleagues and with the New Zealand National Poisons Centre, and was advised to commence Mr A on EDTA. Unfortunately, the only EDTA available in New Zealand had expired around a month previously, and it could not be obtained quickly from overseas. As a result, the expired EDTA was used on the presumption that it was still safe (the alternative being no chelating treatment). The treatment commenced on 28 Month2. Subsequently, Mr A passed away.

118. Based on the information provided during this investigation, and the complaint raised by Mrs A, my two main concerns were whether it was reasonable in the circumstances for the expired EDTA to be used, and whether informed consent for use of the expired medication was obtained at the time.

Reasonableness of using expired EDTA — other comment

119. When the clinicians became aware of Mr A's high cobalt and chromium levels, they immediately sought a treatment plan for Mr A. The plan was explained to Mr A, as documented by Dr E and in the nursing notes.

120. Although the EDTA had expired a month previously, I accept SCDHB's explanation that the relatively safe use of the medication outweighed the risk, given that Mr A's health was deteriorating. I am reassured by the comment of SCDHB's lead pharmacist that the fact that the EDTA had expired by less than one month would not have made any difference to the treatment. The alternative was that no other medication or chelating agent was available to Mr A.

121. I obtained expert advice on this issue from a clinical pharmacologist and consultant physician, Associate Professor Matt Doogue (see Appendix D).

122. Associate Professor Doogue told HDC:

> "I have no concerns about the use of [the] expired medicine in these circumstances. It would be equally effective one month after it as one month before the 'expiry date'. Having the medicine administered promptly to [Mr A] after it was decided to use it was in [Mr A's] best interest."

123. On the basis of Associate Professor Doogue's advice, I accept that the use of the EDTA was reasonable in the circumstances.

124. I acknowledge Mrs A's concern that the expired medication may have contributed to or accelerated Mr A's deterioration. Although this is a query I am unable to determine, I am reassured by the conclusion in the SAE Report that the use of the out-of-date EDTA did not have an impact on Mr A's death.

125. Associate Professor Doogue commented that this case raises a wider matter of availability of rarely used medicines that may be needed urgently for use in New Zealand. He suggested to HDC that a single national strategy is preferred to individual DHB[39] stock-holding decisions. I provide a follow-up action below in relation to this point.

Consent to use of expired EDTA — adverse comment

126. In Mrs A's complaint to HDC, she queried why the expired medication was used. The SAE Report and nursing notes document that the chromium and cobalt toxicity, along with the potential use of "binding agents", was explained to Mr A in the early morning of 28 Month2.

127. SCDHB told HDC that Dr E recalls having had several discussions with Mr and Mrs A around the use of the EDTA, and that only expired stock existed in the country. It has been stated that verbal consent was obtained, although there is no written documentation of this.

128. If Mrs A had received an explanation from Dr E or nursing staff, I would not have expected her to raise this query if she had felt fully informed. It is difficult to make a finding as to whether verbal consent was obtained, but I would have expected these discussions to have been documented, given that use of an expired medication is something that a reasonable consumer may have been concerned about. Without written documentation on the extent of the discussion about the use of expired EDTA, I am concerned that the informed consent process and disclosure of the reasons for its use may have been lacking.

129. I encourage Te Whatu Ora to consider the circumstances of this case, and reflect on the importance of documenting the informed consent process undertaken and the information shared, particularly for any emergency medications used.

Opinion: Dr B — no breach

130. Dr B performed the left hip replacement for Mr A on 27 April 2012. Almost a year later, on 12 February 2013, Mr A presented to the clinical nurse specialist for routine follow-up of the surgery. As explained above, the cobalt and chromium level tests were ordered by the clinical nurse specialist on behalf of Dr B. The significantly abnormal results were issued on 19 February 2013, but were not reviewed, and Mr A was lost to follow-up.

131. Under SCDHB's Clinical Tests: Signing of Results Protocol, Dr B was the medical officer responsible for following up and verifying Mr A's test results. However, he was not the clinician who ordered the tests. I accept SCDHB's explanation that the normal practice at SCDHB was for tests to be requested by the clinical nurse specialist on behalf of the surgeon,

[39] The report from Associate Professor Doogue regarding each individual DHB holding antidotes and medication was provided before the enactment of the Pae Ora (Healthy Futures) Act 2022 on 1 July 2022, which disestablished DHBs.

and for a hard copy of the results to be sent to the orthopaedic secretary for physical forwarding to the surgeon.

132. Both the SAE Report and Dr B stated that Mr A's cobalt and chromium levels were not viewed or signed off by Dr B or any other clinician. Dr B told HDC that this omission was an "unfortunate system error which was related to the unreliable paper-based processes in place at the time rather than to a clinical error of judgement".

133. I agree with Dr B's assessment. In my opinion, Dr B was not culpable in missing Mr A's test results. Dr B was not alerted to the abnormal results, due to human errors within the paper-based system. As discussed above, the tracking system appears to have failed in the circumstances, and no other system was in place to alert Dr B that Mr A's abnormal results were available. Further, SCDHB did not have in place an effective process to allow for a copy of the results to be forwarded to Mr A's GP, meaning that an additional opportunity for medical review was missed. The SAE Report undertaken by SCDHB identified that if an electronic sign-off process had been in place at the time (this was introduced in 2016), it is likely that Mr A's results would have been escalated to another clinician to review and sign off.

134. Accordingly, I do not find Dr B to have failed to provide services to Mr A with reasonable care and skill in relation to the cobalt and chromium test results having been overlooked and filed without medical review. I acknowledge that this was an unfortunate circumstance that went beyond Dr B's control and purview, and that currently he is addressing this in his present line of work (see below).

Changes made since complaint

135. Following Mrs A's complaint, and the subsequent review undertaken by SCDHB, the DHB advised HDC of the following changes made:

- Development of a form in 2014 to record when metal ion levels, X-rays, and CT scans were requested and signed off as viewed.
- Introduction of specific consultant folders for storing these results until they are signed off.
- Introduction of a register for patients who have received a metal-on-metal hip implant within Southern Canterbury (including at the private hospital) from 6 September to 14 September 2012. An audit of patients on this register occurs every three years and examines a variety of factors.[40] The information from the audits is disseminated through

[40] The register consists of 157 patients, and identifies the patient's GP, the dates of joint replacement revision, last blood tests including cobalt and chromium levels, last X-rays taken, and next planned orthopaedic appointment.

a grand round teaching forum, which is attended by both hospital and community practitioners across South Canterbury.

- Active education for health professionals on the issue of metal toxicity.
- Implementation of its current protocol [41] (last updated in May 2020), "Total Hip Replacement, Long Term Management" (see Appendix B).
- Development of a letter template issued to patients and their GP to notify SCDHB that a patient is moving to another region.

136. Dr B told HDC that he no longer works as an orthopaedic surgeon, but instead works in clinical informatics. He is leading the implementation of electronic systems, many of which are aimed at addressing areas of clinical risk such as that highlighted by Mr A's case.

Recommendations

137. In light of the changes already made by SCDHB, I recommend that Te Whatu Ora South Canterbury:

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

b) Provide HDC with a summary of the recent audit of the existing register of patients with metal-on-metal hip replacements, and report back on any issues identified through the audit and steps taken to address these.

c) Report back to HDC regarding the implementation and effectiveness of the existing current protocol for "Total Hip Replacement — Long Term Management", and advise this Office if further changes are required based on the findings of this report.

d) Provide HDC with a summary of the changes implemented to ensure that diagnostic testing and investigations ordered for orthopaedic patients have been received/ actioned.

e) Report back to HDC on the progress of recommendations b) to d), within three months of the date of this report.

[41] Review was due in May 2022.

Follow-up actions

138. I will be writing to Te Whatu Ora|Health New Zealand to request that consideration is given to establishing a national strategy, in addition to the National Poisons Centre's project for hospital pharmacies (see paragraph 79), to establish the central storage of antidotes and rarely used medicines. At present, this is the responsibility of each locality-based hospital and, as in this case, has the potential to put clinicians in the difficult and unnecessary position of making decisions regarding the potential harm of a recently expired but urgently needed life-saving medicine.

139. A copy of this report with details identifying the parties removed, except SCDHB/Te Whatu Ora South Canterbury, will be sent to the Health Quality & Safety Commission, the Royal Australasian College of Surgeons, and the Ministry of Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: SCDHB Clinical Tests: Signing of Results Protocol (2012)

"**Objective**

The Medical Officer ordering a test is responsible for follow-up of results. For legal purposes and good clinical practice the Medical Officer who ordered the tests must verify that test results have been reviewed.

Responsibility

Medical Staff

Procedure

- Laboratory and test results forms are to be sighted, dated and signed legibly by Medical Officer on a regular basis, preferably daily.
- When the Medical Officer becomes aware of an adverse test result, the Medical Officer is responsible for ensuring that the patient is made aware of this information.
- Any significant abnormal test results and associated action should be noted in the patient's clinical record.
- No test result forms are to be filed until they are signed by a Medical Officer.
- It is the responsibility of the Resident Medical Officer assigned to each consultant to check the test results of inpatients and notify the Senior Medical Officer of significant results.
- If the Medical Officer is on leave, it is the responsibility of the Medical Officer to arrange for a colleague to sight and sign and action their test results while they are on leave.

The Senior Medical Officer assigned to the care of the patient is ultimately responsible for the actioning of a test result.

Reference

SCDHB Clinical Records Documentation Standards 2005"

Appendix B: SCDHB Total Hip Replacement — Long Term Management — Outpatient Department Procedure/Protocol (February 2015)

"**Objective**

To provide consistency and best practice in management of patients following hip replacement surgery and to detect early any complications.

Responsibility:

- Orthopaedic consultants
- Registered nurse trained in orthopaedics and working under the direction of the consultant.

Frequency:

Routine patients for review are expected to be reviewed post operatively at 1, 5, 10 years and every 5 years thereafter.

Contraindications:

Patients requiring closer supervision following complications.

Investigations:

X-ray: Standing AP pelvis and lateral of replaced L) &/or R) hip.

Blood levels of cobalt and chromium for patients with metal/metal articulating surfaces.

Management:

- Patient completes a questionnaire on mobility and activity of daily living.
- Patient education: hip precautions re dislocation, infections.
- Complete Harris Hip Score and Womac Index.
- Review x-ray films with consultant and arrange for next review.
- Update data base.
- Ultrasound Scan for patients with elevated metal ions (cobalt > 250 nmol/L, chromium > 400 nmol/L)

References

- British orthopaedic association — Total hip replacement: A guide to best practice (August 2006)"

Appendix C: SCDHB Total Hip Replacement — Long Term Management — Outpatient Department Procedure/Protocol (February 2012)

"**Objective**

To provide consistency and best practice in management of patients following hip replacement surgery and to detect early any complications.

Responsibility:

- Orthopaedic consultants
- Registered nurse trained in orthopaedics and working under the direction of the consultant.

Frequency:

Routine patients for review are expected to be reviewed post operatively at 1, 3, 5, 10 years and every 5 years thereafter.

Contraindications:

Patients requiring closer supervision following complications.

Investigations:

X-ray: Standing AP pelvis and lateral of replaced L) &/or R) hip.

Blood levels of cobalt and chromium for patients with metal/metal articulating surfaces.

Management:

- Patient completes a questionnaire on mobility and activity of daily living.
- Patient education: hip precautions re dislocation, infections.
- Remind patients of ability to contact orthopaedic secretary or outpatient appointment office to initiate review by consultant if they have any concerns re their joint replacement.
- Complete Harris Hip Score and Womac Index.
- Review x-ray films with consultant and arrange for next review.
- Update data base.
- Ultrasound Scan for patients with elevated metal ions (cobalt > 250 nmol/L, chromium > 400 nmol/L)

References

- British orthopaedic association — Total hip replacement: A guide to best practice (August 2006)"

Appendix D: Independent advice to Deputy Commissioner

The following independent pharmaceutical advice was obtained from Associate Professor Matthew Doogue:

> "I have been asked to comment on a complaint regarding the care of [Mr A]. Specifically I've been asked to comment on the use of an 'expired' medicine in his treatment and whether that had any bearing on the outcome of his care.
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> I have been provided with a copy of the following: Extracts from the medical notes and medication chart. A letter from the pharmacy manager (which includes the product details). The Serious Adverse Event Review Report from South Canterbury DHB. [Dr E's] report to the coroner. I have not reviewed the complete file (but could do if needed).
>
> **Declaration**
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> I am a qualified medical practitioner with vocational registration in the specialties of Clinical Pharmacology and Endocrinology (NZMC Registration No. 22733). My qualifications include MBChB and FRACP. I am employed by the University of Otago — Christchurch as Associate Professor of Medicine and by the Canterbury District Health Board as a Senior Medical Officer, working in Clinical Pharmacology and General Medicine.
>
> I was not involved in this case. I have no potential conflicts of interest to declare.
>
> My comments are in the context of my expertise as a physician specialist in clinical pharmacology. I have a particular interest in quality use of medicines and have several roles in medication safety including chairing the National Medication Safety Expert Advisory Group. I am clinical director of the department of Clinical Pharmacology at CDHB, the medicines information service in our department frequently answers questions related to product stability and appropriate use.
>
> **Discussion**
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> I have not summarized the case as my advice pertains to the product used to manage the patient rather than decisions about the management of the patient.
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> The medicine is calcium disodium edetate, which is an 'antidote' for heavy metal poisoning. The product has a 3 year expiry date from the date of manufacture and in this case was 28 days expired at the time it was administered to the patient.
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> There are two risks to manage. Firstly the quality of the medicine, that it is as listed on the label a specified amount of the active ingredient and has not degraded. Secondly that there has not been contamination with bacteria, other infectious agents, or other harmful substances. There is no suggestion that this product was not sterile.

With respect to stability the 'expiry date' has a particular meaning and using that information correctly for clinical decisions is important. The expiry date on medicines refers to the date the manufacturer certifies the medicine is as it says on the label. This date is based on stability studies of the medicine which are a requirement for approval by regulators.

The studies can determine 'expiry date' in two different ways. Firstly if a product is inherently unstable in storage the time before one can no longer rely on it. This is similar to a perishable food product. One might use it under some circumstances, but care is needed. Secondly if a product is inherently stable, the expiry date reflects the duration of the stability studies. That is the case here, we know it is stable for 3 years and as far as I know it has not been tested longer. In this circumstance the main issue is not the 'expiry date' but whether the product has been appropriately stored and handled.

The 'expiry dates' provided are conservative and I am sometimes asked about using expired medicines and often about other 'unapproved' (outside manufacturer's guidelines) medicines use. Using medicines within the manufacturer's guidelines is sensible if this is possible. Where it is not possible, it is often in the best interest of the patient (and good practice) to use the medicine for the benefit of the patient. In such cases expert input is needed and in clinical guidelines it is common to advise 'unapproved' use of medicines, e.g. much paediatric medicines use is 'unapproved'. In this case the pharmacy manager has the requisite expertise and applied her expertise appropriately for the best interest of the patient.

Opinion

I have no concerns about the use of this expired medicine in these circumstances. It would be equally effective one month after it as one month before the 'expiry date'. Having the medicine administered promptly to [Mr A] after it was decided to use it was in [Mr A's] best interest.

Additional Comment

This raises a wider matter of availability of rarely used medicines that may be needed urgently for use in New Zealand. This is an example, there are other 'antidotes' and other rarely used medicines. This is something that could and should be addressed with a single national strategy rather than by individual DHB stock holding decisions.

Associate Professor Matt Doogue"