Capital and Coast District Health Board

A Report by the
Health and Disability Commissioner

(Case 19HDC01210)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided by Capital and Coast District Health Board (CCDHB) to a woman between August 2018 and April 2019 for lymphoma (cancer of the white blood cells). The woman had a history of hepatitis B infection and required treatment with an antiretroviral medication (lamivudine) to prevent the hepatitis B reactivating, as the cancer treatments suppressed her immune system.

2. The intention was that the woman would continue taking lamivudine for one year following chemotherapy, but owing to a number of systemic issues at CCDHB, the medication was inadvertently stopped and the woman suffered a reactivation of hepatitis B and required a liver transplant, which was complicated by a small bowel infarction[1] and kidney injury.

3. The report highlights the importance of clarifying roles and responsibilities to enable continuity of care for a complex clinical picture, ensuring that protocols are up to date and formalised, and ensuring that systems have checks and balances in place, such as clear plans, medicine alerts, and adequate information provided to the patient and GP.

Findings

4. The Commissioner found CCDHB in breach of Right 4(1) of the Code. The Commissioner was critical that the system at CCDHB lacked clarity about roles and responsibilities, there was no formal protocol for the prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy, and there was no clear plan to ensure that the woman stayed on lamivudine following chemotherapy. Medicine prescribing was paper based, and there was no provision for alerts. The information provided to the woman regarding the need to continue her lamivudine medication was inadequate, being only verbal in nature, with no reinforcement via patient information pamphlets, clinic letters copied to her, or medication labelling on the lamivudine. The toxicity review was deferred, and no "end of treatment" summary was provided to the woman or her GP. As a consequence, the woman's prescription for lamivudine was stopped too early and this went un-noticed, resulting in the woman's hepatitis B being reactivated.

5. The Commissioner also found CCDHB in breach of Right 4(5) of the Code. The Commissioner was critical that the system failed to ensure quality and continuity of services between teams at CCDHB and with the woman's GP.

6. The Commissioner was also critical that the on-call liver transplant clinician did not explore the woman's lymphoma prognosis in enough detail to determine her suitability for a liver transplant on 19 April 2019.

Recommendations

7. The Commissioner recommended that CCDHB provide an update on the changes it has made as a result of this event, use an anonymised version of this report as a case study during education sessions at CCDHB, and provide a written apology to the woman.

[1] Tissue death caused by inadequate blood supply.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided by Capital and Coast District Health Board (CCDHB) to Ms A. The following issue was identified for investigation:

- *Whether Capital and Coast District Health Board provided Ms A with an appropriate standard of care between August 2018 and April 2019 (inclusive).*

9. The parties directly involved in the investigation were:

Ms A	Consumer
Ms B	Complainant
CCDHB	Provider

10. Further information was received from:

Dr C	Medical oncology senior medical officer (SMO)
Medical centre	General practice
District Health Board 2	
ACC	

11. Also mentioned in this report:

Dr D	Transplant clinician

Information gathered during investigation

Background

12. This report concerns the care provided to Ms A by the CCDHB Oncology service for cancer of the white blood cells (lymphoma).[2] Ms A had a history of hepatitis B infection,[3] which was monitored with six-monthly blood tests.[4]

13. Before commencing chemotherapy[5] on 28 August 2018, Ms A started taking a medication called lamivudine[6] to prevent the hepatitis B reactivating. The intention was that she would continue taking lamivudine for one year following chemotherapy. Ms A's lymphoma responded well to chemotherapy, and radiotherapy[7] was completed by 30 January 2019. However, Ms A did not continue on lamivudine after chemotherapy, and she suffered a

[2] Diffuse large B-cell lymphoma (DLBCL).
[3] A liver infection caused by the hepatitis B virus.
[4] Blood tests were organised through the Hepatitis Foundation and copied to Ms A's GP.
[5] Treatment with powerful chemicals to kill fast-growing cells.
[6] An antiretroviral medication.
[7] A treatment that uses high doses of radiation to kill cancer cells and shrink tumours.

reactivation of hepatitis B and required a liver transplant, which was complicated by a small bowel infarction[8] and kidney injury.

14. This opinion looks at the reasons why lamivudine was stopped inadvertently.

Diagnosis

15. On 9 August 2018, Ms A, aged in her forties, was referred by a medical centre GP to the Women's Acute Assessment Service at CCDHB with a suspected labial abscess.[9] She was seen the next day (10 August 2018) and examined under anaesthetic, and biopsies were taken.

16. On 16 August 2018, at the Gynaecology Oncology Multidisciplinary Meeting, a diagnosis of lymphoma was confirmed, and Ms A was referred to the Medical Oncology service. On 21 August 2018, CT scans were performed to assess the stage of the tumour.[10] Ms A was informed of the diagnosis and her referral to Medical Oncology, and told that a cure was considered achievable with chemotherapy.

Medical Oncology — chemotherapy treatment

17. Ms A was under the care of Medical Oncology SMO Dr C, and was seen by her in clinic on 22 August 2018. Dr C's clinic letter, sent to a CCDHB gynaecologist and copied to the medical centre, referred to hepatitis B reactivation prevention in the management plan and in the "problem list" at the top of the letter:

> "**Problem List:**
>
> 1. Diffuse large B cell lymphoma …
> 2. Chronic Hepatitis B … to commence [l]amivudine August 2018 and to continue during chemotherapy and for one year following.
>
> …
>
> **Management/Plan:**
>
> … I have given her a prescription for lamivudine and asked [her] to start taking this immediately to reduce the risk of reactivation of Hepatitis B during and after chemotherapy and rituximab.[11]"

18. Dr C told HDC that she included the potential for hepatitis B reactivation in the problem list because of its importance and the "potential severity of this" for Ms A. The problem list is repeated on every subsequent Medical Oncology clinic letter.

19. As part of the discussion on risks with Ms A, Dr C said that she discussed the risk of hepatitis B reactivation and the need for prevention (prophylaxis) with lamivudine, and the need for

[8] Tissue death caused by inadequate blood supply.
[9] Also known as a Bartholin's abscess (a lump on the outer lips of the vagina).
[10] Investigations showed extensive disease localised to the vulva and perineal regions.
[11] A medicine used to treat B-cell lymphoma.

this to be taken both during and after completion of chemotherapy and rituximab.[12] Dr C prescribed a three-month supply of lamivudine. However, a lot of information was covered at the appointment, and Ms A received only verbal information about hepatitis B prophylaxis, and the clinic letter was not provided to her.

20. On 23 August 2018, Ms A presented to the Emergency Department (ED) with vaginal bleeding and discharge. She started taking lamivudine as an inpatient that day.

21. Ms A commenced chemotherapy as an inpatient on 28 August 2018. No hepatitis B viral load[13] was detected at that time.

22. Ms A was discharged on 31 August 2018 and given a new prescription for lamivudine. The discharge letter to the medical centre records Ms A's co-morbidity of hepatitis B, and the medication list includes lamivudine.[14] However, there is no reference to a specific management plan for preventing the reactivation of the hepatitis B, and no duration of lamivudine therapy or the reason for the lamivudine prescription.

23. On 27 September 2018, Ms A telephoned CCDHB to request a repeat prescription. A three-month prescription for lamivudine (and other regular medications) was provided.

24. On 31 October 2018, a further CT scan showed a significant reduction in size[15] of the tumour.

25. Ms A then attended Chemotherapy Oncology clinics on 11 and 20 September, 11 October, 1 and 22 November 2018, and 13 December 2018. Ms A recalls being told at the last appointment that she did not need to take any more pills, and she was not given a prescription at this clinic. However, the clinic letter does state that lamivudine is "to continue during chemotherapy and for one year following". Ms A was seen by a registrar under the supervision of Dr C. The registrar cannot recall whether lamivudine was discussed at this appointment.

26. The clinic letter from 13 December 2018 recorded that blood test results were acceptable and that the plan was to "proceed with Cycle 6 of the R/CHOP chemotherapy". The letter also stated: "We will catch up with [Ms A] in six weeks' time for a toxicity review and review of the results."

27. Ms A had the sixth cycle of chemotherapy on 13 December 2018, and a haematology doctor provided a prescription for three weeks' supply of lamivudine. The haematology doctor told CCDHB that she cannot recall the circumstances for prescribing this, but would have prescribed it in line with previous prescriptions.

[12] An antibody therapy used to treat cancer.
[13] The amount of hepatitis B virus in the bloodstream.
[14] A one-month supply was given on discharge.
[15] Regression.

28. Dr C told HDC:

> "I had believed that [Ms A] was continuing to take lamivudine, as per the documented treatment plan. I certainly did not give any instructions for her to stop taking this medication."

29. Dr C had planned to see Ms A on 24 January 2019 for a toxicity review, but Ms A requested that her Medical Oncology follow-up appointment be cancelled, to avoid duplication of follow-up during this phase of care. This was communicated by the radiation oncologist to Dr C, who agreed to defer Ms A's follow-up Medical Oncology appointment for three months.

Liver function tests

30. Protocols [16] recommend monthly monitoring of liver function tests (LFTs). During chemotherapy, Ms A's LFTs were monitored three-weekly and remained normal (the last check on 12 December 2018 was within normal range).

Medical centre

31. Medical centre staff contacted Ms A on 6 September 2018, after her discharge from hospital, to check on her progress. Her clinical notes record: "[N]il concerns with [discharge] meds when asked."

32. On 24 September and 29 October 2018, Ms A attended the medical centre for a goserelin[17] injection (as prescribed by the oncologist). The medical centre told HDC that in October 2018, the practice was advised by the Medical Oncology team that Ms A had been started on lamivudine in August 2018 and was to continue on it during chemotherapy and for one year following. The GP never prescribed lamivudine,[18] but documented it as a long-term medication. The letters from the radiation oncologist to the medical centre continued to note that Ms A was "on lamivudine".

Radiation Oncology

33. Ms A attended her first Radiation Oncology clinic on 11 September 2018 to discuss radiotherapy. The clinic letter to the medical oncologist, and copied to the medical centre, again states under the "Problem List": "Lamivudine commenced August 2018 to continue during chemotherapy for one year post."

34. At the completion of chemotherapy, Ms A moved on to the radiation therapy component of her care. On 18 December 2018, she attended a Radiation Oncology clinic. The problem list in the clinic letter states: "Hepatitis B carrier, on [l]amivudine"; however, there is no reference to lamivudine needing to be continued for one year after chemotherapy.

[16] CCDHB's "Prevention of Hepatitis B reactivation in patients undergoing immunosuppressive therapy: Discussion document" (refer to Appendix).
[17] Brand name Zoladex, used to reduce the levels of the female hormone oestrogen.
[18] There was no formal handover of prescribing to the GP, as Ms A remained under the care of the Oncology service.

35. From 7 to 30 January 2019, Ms A had 17 daily radiotherapy treatments. Medical reviews focused on radiation-related issues, and notes are almost exclusively recorded in a system[19] available only to Radiation Oncology staff. Radiation Oncology practitioners do not usually prescribe antiviral medications such as lamivudine, as this is not within their area of expertise. They would prescribe for patients already on a medication, but only if requested by the patient.

36. The clinic letter for the appointment on 19 March 2019 states that Ms A "had a favourable MRI scan, with no residual disease demonstrable". The "problem list" in the letter states: "hepatitis B, on lamivudine". However, Ms A last took lamivudine on 3 January 2019.

Lamivudine prescriptions

37. On 3 January 2019, Ms A came to the end of her prescription for lamivudine. No further prescription for lamivudine was given, and it was Ms A's understanding that she was on lamivudine only whilst on chemotherapy. Accordingly, lamivudine was stopped, and the planned one-year course after chemotherapy was not completed. A table of lamivudine prescriptions and dispensing for Ms A can be found in Appendix B.

Admission to hospital

38. On 16 April 2019, Ms A contacted the medical centre complaining of being unwell with nausea and dark urine, and was advised to seek urgent medical attention. She presented to the ED with vomiting and jaundice and was admitted to Medical Oncology at CCDHB with deteriorating liver function secondary to hepatitis B reactivation.[20]

39. Dr C saw Ms A on the ward on 17 April 2019 and the diagnosis was discussed. Ms A was reviewed by the Gastroenterology team and was given medication[21] to treat hepatitis B. Ms A's inpatient care was led by a consultant medical oncologist, and later another consultant medical oncologist. Ms A was monitored closely over the following days. The on-call liver transplant clinician in DHB2, Dr D, was consulted on 19 April 2019, at which time Ms A was assessed as not eligible for a liver transplant.

40. DHB2 told HDC that Dr D's understanding was that although Ms A had severe liver inflammation,[22] she had not, at that point, developed liver failure.[23] He further commented that in his view, liver transplantation would be contraindicated because of Ms A's very recent malignancy, for which she had only just completed treatment. This was on the basis that any cancer that had spread[24] to other parts of the body would progress more rapidly on the immunosuppressive[25] medication used in all liver transplant recipients. DHB2 told HDC that Ms A had not met the criteria for transplant listing at that point.

[19] Called Aria.
[20] Confirmed on 24 April 2019 from a viral DNA test done on 17 April 2019.
[21] Tenofovir.
[22] Hepatitis.
[23] So was not a candidate for a liver transplant at that point.
[24] Untreated micro-metastatic disease.
[25] Partially or completely suppressing the immune response of an individual.

41. The risks of liver failure and death were discussed with Ms A on 21 April 2019, and with Ms A and her partner on 23 April 2019. Ms A failed to respond to intensive antiretroviral therapy, and on 23 April 2019 was diagnosed with liver failure with impaired clotting of the blood.[26] CCDHB stated that based on information provided by Dr D, staff informed Ms A's whānau that if the liver did not repair itself, Ms A's prognosis would be poor, and she was not a candidate for a liver transplant because of her lymphoma diagnosis. It was hoped that she would improve on antiretroviral therapy.

42. On 28 April 2019, Ms A's condition deteriorated, and she was transferred to the Intensive Care Unit (ICU). There was a further discussion of the risk of death with Ms A's partner and daughter, and the opinion of DHB2 that she was not a candidate for a liver transplant was explained. However, on 29 April 2019, Ms A was accepted for a transplant, following further discussions between CCDHB staff and the DHB2 transplant unit.[27] A meeting with Ms A's whānau took place in ICU to explain this.

43. DHB2 told HDC that Ms A's lymphoma was in fact very local in nature and had been treated aggressively with a combination of chemotherapy and radiotherapy. On learning that Ms A's prognosis in this specific scenario was excellent, DHB2 advised that a liver transplant was not contraindicated. Dr D acknowledged that "in retrospect, … [he] should have sought more information about [Ms A's] prognosis from the lymphoma" during the initial telephone call with CCDHB.

44. Ms A was transferred to DHB2 on 29 April 2019 and underwent a successful liver transplant on 2 May 2019. Her recovery was complicated by a small bowel infarction requiring resection, and acute kidney injury[28] secondary to multiple surgeries.

45. Ms A told HDC that a few weeks after the operation, while she was still in DHB2, she received a telephone call from CCDHB to remind her about an appointment with Oncology. Ms A had to explain that she was in another hospital having undergone major surgery, and was not in a position to attend the appointment. This left Ms A feeling "upset" and "disenfranchised in a system that was demonstrating, yet again, how little it cared about her".

Further information

Ms A

46. Ms A told CCDHB that she did not receive any clinic letters, and would have liked to have received these. She also queried why there was no follow-up to ensure that she was still taking lamivudine.

47. Ms A identifies as Cook Island Māori. Ms B, on behalf of Ms A, commented that institutional racism is embedded in the system, and the treatment injury sustained by Ms A aligns with the poorer outcomes experienced by Pacific peoples in New Zealand's health system. Ms B stated that hepatitis B is a problem that disproportionately affects Māori and Pasifika. She

[26] Coagulopathy.

[27] DHB2 said that Ms A's liver disease had progressed to the point of meeting the King's College criteria for acute liver failure evaluation, providing her prognosis was 100% five-year disease-free survival.

[28] A sudden decrease in kidney function.

said that therefore, the lack of clarity about roles and responsibilities for managing the prevention of hepatitis B reactivation for patients undergoing immunosuppressant therapy and that no action had been taken by the DHB for six years (once it had identified the issue), likely impacted Māori and Pasifika disproportionately, and would be evidence of institutional racism.

48. Ms B also stated that as information about hepatitis B reactivation was communicated to Ms A only verbally, this was evidence of institutional racism. Ms B told HDC that "Pasifika patients such as [Ms A], who have limited education and for whom English is a second language, may suffer more adverse outcomes as a result of not having information communicated to them in an appropriate way".

49. Ms B commented that Ms A experienced interpersonal racism when she presented at hospital suffering significant liver failure. Ms B stated:

> "[T]he response of medical staff was to assume that [Ms A] had not completed the course of medication prescribed for her, resulting in the liver failure, and consequently implying [Ms A] was to blame for the poor health outcome she was experiencing. This was completely inaccurate and demonstrates at the very least, unconscious bias on the part of the staff concerned."

50. Ms B told HDC that she believes that without the support and intervention of educated, articulate members of Ms A's whānau, Ms A's case would not have been reviewed, and it is likely that Ms A would not have received the liver transplant. Ms B considers that while those involved in Ms A's treatment may not have been consciously racist, Ms A was not supported by the health professionals to overcome the barriers to her receiving the treatment she should have received if she had been more articulate and educated. Ms B said: "[Ms A] did not know her rights or the questions to ask and the health professionals did not bridge the gap to ensure an equitable outcome for [Ms A]."

CCDHB

51. CCDHB acknowledged that it may not have communicated the risk of stopping lamivudine in a way that Ms A could understand and remember, noting the challenges in communication and care of a patient undergoing toxic and demanding chemotherapy and radiotherapy treatment, which adds to the patient's vulnerability. The findings of CCDHB's Systems Analysis Review are included as Appendix C.

52. CCDHB told HDC:

> "[CCDHB] does not consider the individuals involved in [Ms A's] care as having caused an error in [Ms A's] management. A complex interplay of circumstances between hospital services, community pharmacy and primary care led to the inadvertent cessation of [lamivudine]. The systems review described how clinicians could use more effective communication and therapeutic monitoring to minimise risk, particularly when multiple clinicians and services are involved in care."

53. The DHB also acknowledged Ms B's comments concerning institutional racism. It told HDC:

> "The DHB recognises it has an obligation to do better for Māori and Pacific patients who unquestionably do experience inequitable health outcomes."

54. Dr C commented: "I would like to express my deepest and sincere regret that this has occurred while [Ms A] was in our care."

Responses to provisional opinion

55. Ms B was given an opportunity to respond to the "information gathered" section of the provisional opinion. She told HDC:

> "I can't even begin to describe the catastrophic impact this has had on [Ms A's] life and on the lives of her husband and children. We only hope that no-one else will need to suffer in the same way again."

56. Where appropriate, some changes have been made to the "information gathered" section in response to Ms B's comments.

57. CCDHB was given an opportunity to respond to the provisional opinion, and it accepted the proposed recommendations. CCDHB stated: "The care provided to [Ms A] by CCDHB from August 2018 was not to the standard we want for any member of our community to receive." CCDHB confirmed that it is working on "means of more explicitly allocating responsibility for prescribing ongoing medications for patients whose care is shared between specialties and with primary care".

58. Dr D was given an opportunity to respond to the relevant sections of the provisional opinion, and he accepted the findings. He sincerely apologised for the distress to Ms A's family that resulted from his initial incorrect advice regarding the management of her case. He added that if a similar situation occurs again, he will ensure that he seeks all appropriate information and discusses the case with his colleagues.

Opinion: Capital and Coast District Health Board — breach

Introduction

59. CCDHB had an organisational duty to provide services to Ms A with reasonable care and skill. Ms A was treated successfully at CCDHB for lymphoma, and her outcome was excellent. However, Ms A had hepatitis B and required treatment with lamivudine to stop it reactivating, as cancer treatments suppressed Ms A's immune system. Treatment with lamivudine was to continue for one year following chemotherapy. Unfortunately, the treatment did not continue after her chemotherapy and she suffered a reactivation of hepatitis B, which required a liver transplant. She subsequently had a complicated recovery.

60. A number of system failings at CCDHB contributed to Ms A not continuing to take lamivudine. I do not find any individual staff to be at fault. Rather, the system was disjointed and did not provide sufficient checks and balances to enable continuity of care for a complex clinical picture. These system failings are described in CCDHB's Systems Analysis Review (SAR) in Appendix C, which I will refer to in my opinion.

Lack of clarity about roles and responsibilities

61. Ms A's care involved clinicians from Gastroenterology, Infectious Diseases, Medical Oncology, and Radiation Oncology. None of the clinicians saw it as their primary responsibility to manage the prevention of hepatitis B reactivation once Ms A had finished chemotherapy. There was no plan to ensure the continuation of lamivudine for one year after chemotherapy, only a stated intention during her treatment with the Medical Oncology team.

62. CCDHB highlighted in the SAR that there was no formal protocol for the prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy at CCDHB. This lack of protocol to guide staff contributed to a lack of clarity about roles and responsibilities across the different teams that provided care for Ms A. A draft document and protocol had been circulated in 2013, and was being followed informally, but this did not specify responsibilities for managing viral hepatitis prophylaxis. I am critical of the lack of protocol at CCDHB to direct staff on their responsibility for preventing hepatitis B reactivation in patients undergoing immunosuppressive therapy.

Paper-based medicine prescribing system

63. Medication prescribing in Medical Oncology is paper based, and copies of previous prescriptions are stored in a patient's oncology paper file. This limits the accessibility and visibility of medication prescribing, which can introduce risk, especially when there are changes to the frequency of monitoring and/or where different specialty teams become involved in patient care.

64. It was at the point of change-over from chemotherapy to radiotherapy that Ms A's prescription for lamivudine was missed inadvertently. In addition, the paper-based system does not contain prompts for when a patient will require a new prescription for a medication.

65. There are clear areas of risk in this paper-based system, in particular for a patient like Ms A who had multiple teams providing care in a complex health situation, and I am critical that the system did not provide for alerts or other forms of safety-netting to support safe and appropriate prescribing.

Patient information about hepatitis B reactivation

66. Insufficient information was provided to Ms A regarding the risk of hepatitis B reactivation. The information provided was verbal only, and no patient information leaflets were available to reinforce the message. In addition, Ms A did not receive copies of her clinic letters, which state that the treatment plan was to take lamivudine during chemotherapy

and for one year afterwards. Also, the medication label printed on the lamivudine did not have the instruction to continue on the medication for one year following chemotherapy.

67. I am critical that Ms A was not provided with appropriate information in a form that supported and reinforced an understanding that she needed to continue on lamivudine for one year after chemotherapy. This could have enabled Ms A to advocate for herself when the medication was stopped. This is not intended to reduce the clinical responsibility to provide the appropriate prescription, but would have provided an important safety-net to empower Ms A to be an active participant in her health and well-being.

Medical Oncology toxicity review

68. The potential toxicity of treatment was significant for Ms A and, after chemotherapy treatment ended, a Medical Oncology follow-up appointment was scheduled for 24 January 2019 to review toxicity and to discuss survivorship issues, including disease monitoring and ongoing treatment plans. Ms A was undergoing radiotherapy at that time, and she requested that the appointment be cancelled. Radiation Oncology communicated this request to Medical Oncology, who verbally agreed to avoid duplication of follow-up and deferred the appointment for three months. By this time, Ms A had been admitted to hospital with deteriorating liver function secondary to hepatitis B reactivation.

69. The appointment deferral was at Ms A's request and was intended to avoid duplication, but I am very concerned that this left Ms A without a toxicity review at a crucial time when her lamivudine had been stopped. I note that CCDHB's SAR recommended that Medical Oncology provide patients and their GP with an "end of treatment" summary so that survivorship issues can be highlighted for ongoing monitoring and treatment if required. I support this recommendation. It is important to strengthen communication and therapeutic monitoring between multiple clinicians and services, including GPs, to support care and minimise the risk of treatments not being followed through appropriately.

Conclusion

70. The system at CCDHB did not support the coordination of care that Ms A required across a number of different teams. The SAR found issues with a lack of clarity about roles and responsibilities, with no formal protocol for the prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy at CCDHB. The only protocol available was informal and in draft, and did not specify responsibilities for managing viral hepatitis prophylaxis. There was also no clear plan to ensure that Ms A stayed on lamivudine following chemotherapy. Medicine prescribing was paper based, and there was no provision for alerts. The information provided to Ms A regarding the need to continue her lamivudine medication was inadequate, being only verbal in nature, with no reinforcement via patient information pamphlets, clinic letters copied to her, or medication labelling on the lamivudine. The toxicity review was deferred, and no "end of treatment" summary was provided to Ms A or her GP.

71. These system issues meant that the stopping of lamivudine went un-noticed, and Ms A's hepatitis B reactivated. Accordingly, I find that CCDHB breached Right 4(1) of the Code of

Health and Disability Services Consumers' Rights (the Code) for failing to provide Ms A services with reasonable care and skill.[29]

72. The system also failed to ensure quality and continuity of services between teams at CCDHB and with Ms A's GP. Further, I note the telephone call Ms A received from CCDHB reminding her of an appointment, while she was in hospital recovering from her transplant surgery. I acknowledge how upsetting and disenfranchising this would have been for Ms A. Accordingly, I find that CCDHB also breached Right 4(5) of the Code. [30]

Other comment

73. I note that Ms A identifies as Cook Island Māori. Ms B has raised issues regarding institutional racism and the poorer outcomes experienced by Pacific peoples in New Zealand's health system. CCDHB has stated that "[t]he DHB recognises it has an obligation to do better for Māori and Pacific patients who unquestionably do experience inequitable health outcomes". I agree. Māori and Pacific peoples experience poorer health outcomes compared to non-Māori and non-Pacific in many areas of health.

74. I have commented above about the lack of information provided to Ms A regarding the need to continue her lamivudine medication. The level of communication was inadequate, being only verbal in nature. I note that CCDHB has taken a number of steps to improve its communication with Ms A, and has made process changes to improve its communication with other patients. I would also encourage CCDHB to consider whether communication is culturally appropriate, particularly for people where English is a second language (as was the case for Ms A).

75. It is appropriate that CCDHB consider the Ministry of Health's Ola Manuia Pacific Health and Wellbeing Action Plan 2020–2025 in its work on improving health outcomes for Pacific peoples. I commend CCDHB for its appointment of a Māori Health Cancer Nurse Coordinator, as part of its work to improve health outcomes for Māori and Pacific peoples.

Opinion: Dr D — adverse comment

76. When Ms A's condition deteriorated on 19 April 2019, CCDHB staff consulted the on-call liver transplant clinician at DHB2, Dr D, and were told that Ms A was not a candidate for a liver transplant because of her lymphoma diagnosis. Ms A's whānau were informed. Ms A subsequently experienced liver failure and, following a further more in-depth discussion between DHB2 and CCDHB, DHB2 accepted Ms A for a liver transplant on 29 April 2019.

77. On 19 April 2019, the on-call liver transplant clinician did not explore Ms A's lymphoma prognosis in enough detail to determine her suitability for a liver transplant. I acknowledge

[29] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[30] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

that this did not affect Ms A's care or delay her transplant, as at that point she was not eligible for a transplant. However, I am critical that this initial advice caused a lot of anguish for Ms A's whānau. I strongly encourage clinicians to ask questions and gather sufficient information about a patient's condition when consulting with colleagues.

Changes made

Protocol

78. The Department of Infectious Diseases has written a new protocol on hepatitis B in patients with cancer (the protocol) and provided this to HDC. In May 2021, the protocol was in the final stages of being uploaded to the DHB-wide protocol and guideline repository. The protocol:

- defines roles and responsibilities, with clearly assigned specialty responsibility (ie, identifying the lead service);
- has been updated with the first-line drugs consistent with international standards; and
- recommends that hepatitis B positive patients be discussed with the Infectious Diseases team prior to starting chemotherapy.

Electronic care management system

79. CCDHB is implementing an electronic care management system for Medical Oncology and Haematology (Mosaiq). Within this system, chemotherapy and supportive care treatment plans can be set up for patients who are to remain on medication for a certain time period, with prompts for the medication to be continued. CCDHB will consider adding the DHB-wide protocol to Mosaiq.

Appointment of Māori Health Cancer Nurse Coordinator

80. As part of trying to achieve improvements in health outcomes for Māori and Pacific patients, CCDHB advised that it has appointed a Māori Health Cancer Nurse Coordinator.

Information

81. Staff have been given resources on the principles of writing letters that will be sent to patients as well as GPs. Patients have been provided copies of their clinic letters to GPs from the Medical and Radiation Oncology Services since 5 October 2020, and from the Haematology Service since 16 November 2020.

82. A patient information and instruction sheet about the duration of prophylaxis treatment for hepatitis B has been written in line with the new protocol, and will be available via the DHB-wide repository.

83. The CCDHB services involved in Ms A's continuing care will explicitly state the ongoing plan of medical management of care, with documentation of critical drug regimens and their

planned duration. Ms A has ongoing follow-up in Medical Oncology, Radiation Oncology, Gastroenterology, and Renal Clinics. The letters to her GP from these appointments are being copied to her, and expressly state her ongoing medication regimen and the schedule for blood-test monitoring.

84. CCDHB will include in the treatment summary to GPs and patients a clear delineation of the handover for high-risk patients, to ensure that the patient knows who to contact if they have a problem, and the threshold for contacting their primary care provider. CCDHB told HDC that as at May 2021, this is largely being done, with ongoing definition of the requirements and further implementation.

85. I commend CCDHB for its response and actions to the matters raised by Ms A's care.

Recommendations

86. I recommend that CCDHB provide Ms A with a written apology. The apology is to be sent to HDC within three weeks of the date of this report being issued, for forwarding to Ms A.

87. I also recommend that CCDHB undertake the following, and report back to HDC within three months of the date of this opinion:

a) Provide an update on the changes identified in the "changes made" section of the report.

b) Use an anonymised version of this report as a case study, to encourage reflection and discussion during education sessions for the CCDHB services that were involved in Ms A's care, including consideration of responsibilities for managing viral hepatitis prophylaxis, patient information, and "end of treatment" summaries for patients and GPs.

Follow-up actions

88. A copy of this report with details identifying the parties removed, except CCDHB, will be sent to ACC, DHB2, the Health Quality & Safety Commission, the Royal Australasian College of Physicians, and the Royal Australian and New Zealand College of Radiologists, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Draft policy

CCDHB's draft "Prevention of Hepatitis B reactivation in patients undergoing immunosuppressive therapy: Discussion document", Standard Operating Procedure Detail states:

> "2.0 HBsAg positive patients irrespective of chemotherapeutic regimen should have investigations to determine activity of hepatitis and evaluate for presence of chronic liver disease:
>
> 2.1 Laboratory evaluation for HBeAg, HBV DNA assay, liver function tests and radiological evaluation with liver USS/fibroscan if not already performed
>
> 2.2 If HBV DNA >2000 IU/m1 and HBeAg positive or abnormal ALT or evidence of fibrosis — refer to hepatologist or ID physician
>
> 2.3 Otherwise commence on lamivudine 100mg/day po preferably one week before chemotherapy if able
>
> 2.4 Monitor liver function tests monthly and HBV DNA every three months.
>
> …
>
> 4.0 Duration of lamivudine:
>
> 4.1 Timing of lamivudine cessation is best determined in conjunction with a hepatologist based on patient and viral factors, but in general, duration of lamivudine should be 6–12 months following WCC recovery."

Appendix B: Lamivudine prescriptions and dispensing for Ms A

23 August 2018	Three-month supply prescribed, but lamivudine commenced as an inpatient.
31 August 2018	On discharge prescribed one-month supply. Dispensed as seven-day supply with other medication in a blister[1] pack (31 August, 4, 11 and 18 September 2018).
27 September 2018	Three-month supply prescribed by the oncology registrar. Dispensed as seven-day supply with other medication in a blister pack (27 September, 1, 8, 15, 22 October).
1 November 2018	Three-week supply prescribed by the oncology registrar. Dispensed as seven-day supply with other medication in a blister pack (1[2], 8, and 13 November 2018).
22 November 2018	One-month supply prescribed by the oncology registrar. Dispensed as seven-day supply with other medication in a blister pack (22, 27 November, 3 December 2018).
13 December 2018	Three-week supply prescribed by the oncology registrar. Dispensed as seven-day supply with other medication in a blister pack (13, 21, and 29 December 2018).

[1] Ms A said that she requested her medicines be put into blister packs as she was taking 12–15 pills each day.
[2] The pharmacy starts a new prescription, but from the pharmacy records there are still seven repeats left from the 27 September three-month prescription.

Appendix C: CCDHB's Systems Analysis Review — May 2020

CCDHB undertook a review into the discontinuation of lamivudine for Ms A. The review findings were:

a) There was a lack of clarity about roles and responsibilities:

- Clinicians from Gastroenterology, Infectious Diseases, Medical Oncology, and Radiation Oncology were involved in Ms A's care. None of them saw it as their primary responsibility to manage the prevention of hepatitis B reactivation for Ms A once she had finished chemotherapy.
- There was no plan in place to ensure that Ms A remained on prophylactic lamivudine for one year after she completed chemotherapy.
- There was no formal protocol for prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy at CCDHB.
- A discussion document and draft clinical protocol was circulated in 2013 for "Prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy".
    - This had not yet been approved as part of CCDHB's document management system. The draft protocol was being followed unofficially by those with access to it.
    - The draft protocol did not specify responsibilities for managing viral hepatitis prophylaxis.

b) There is a paper-based system for prescribing of medication within Medical Oncology:

- Chemotherapy and other medication prescribing is currently paper based, with copies of previous prescriptions stored in a patient's oncology paper file.
- The current paper-based system does not contain prompts for when a patient will require a new prescription for a medication.

c) Information about hepatitis B reactivation was communicated to Ms A only verbally:

- Patient information leaflets to reinforce this were not available.
- Ms A did not receive copies of her clinic letters in which the treatment plans to take lamivudine during chemotherapy and for one year afterwards were specified.
- The medication label for lamivudine did not have the instruction to continue on the medication for one year following chemotherapy.

d) Ms A did not have a Medical Oncology toxicity review:

- The Medical Oncology follow-up appointment to review treatment-related toxicity, and discuss survivorship issues, including disease monitoring and ongoing treatment plans, was deferred at the request of Ms A, via the Radiation Oncologist, and this was agreed to verbally by the Medical Oncologist.

The review team recommended:

a) Implementation of a CCDHB-wide clinical protocol, with clearly assigned specialty responsibility (ie, a lead service), for the management of patients with hepatitis B at risk of reactivation due to immunosuppression.

b) The Medical Oncology and Haematology (should they be the lead service for the patient) electronic care management system incorporate the clinical protocol for prevention of hepatitis B reactivation in patients undergoing immunosuppressive therapy (once approved), and that this include instructions to patients about the duration of prophylaxis treatment.

c) Appropriate patient information for patients with hepatitis B taking immunosuppressants be developed and uploaded to the CCDHB document management system, to be printed and given to the patient.

d) Patients receive a copy of their Medical Oncology and Radiation Oncology clinic letters.

e) Medical Oncology provide patients and their GP an "end of treatment" summary so that survivorship issues can be highlighted for ongoing monitoring and treatment if required. The Medical Oncology and Haematology electronic care management system should be configured to support this. This should also support and highlight higher risk situations, such as after the last cycle of chemotherapy, where there are changes to the frequency of monitoring and/or different specialty teams become involved in patient management.