Waikato District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC00306)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mrs A (then aged 77 years) was admitted to a public hospital (the Hospital). She was frail and underweight, and had consistently lost weight over the previous three months. On admission, her serum liver function tests (LFTs) were mostly normal. She was charted paracetamol 1g PRN (as required) for pain relief, with a maximum dose of 4g per day.

2. On Day 13[1], Mrs A underwent a right hemicolectomy[2] without complication. The operative findings confirmed colon cancer. Mrs A was transferred to a general surgical ward for post-surgical recovery.

3. By Day 16, Mrs A was being considered for discharge, but fluid began leaking from her surgical wound. Blood tests taken on Day 18 indicated that her LFTs were deranged (abnormal). That night, the on-call house officer, Dr G, crossed paracetamol off the PRN medication chart and signed the cancellation date as Day 18. He then charted regular paracetamol (1g four times a day).

4. Between Days 19 and 23, nursing staff withheld Mrs A's prescribed regular paracetamol owing to her deranged LFTs, and this is documented on the medication charts and in the clinical notes. Mrs A's LFTs reached peak derangement on Day 20.

5. On Day 23, Mrs A was reviewed by consultant gastroenterologist Dr C. Dr C was unable to identify a specific cause for Mrs A's deranged LFTs, and noted: "No specific recent drugs to explain LFTs but a drug-induced hepatitis[3] most likely."

6. Mrs A's medications were re-charted by house officer Dr E on Day 23. Dr E charted paracetamol, 1g, four times daily as a regular medication, and the prescription was signed off by a ward pharmacist. Dr E was not aware of any request to stop paracetamol. The Day 23 medication chart has "Not for paracetamol" written under the adverse reactions heading. However, it appears that this was written retrospectively.

7. Between Days 24 and 30, Mrs A was administered paracetamol as a regular medication.

8. Mrs A began to deteriorate from Day 26, and was transferred to the high dependency unit on the afternoon of Day 29. The recorded plan included optimising Mrs A's fluid and nutrition status, and searching for the cause of her acute liver deterioration.

9. On Day 30, Mrs A was reviewed by consultant gastroenterologist Dr H, who noted that she had acute liver derangement post-surgery, and ascites.[4] Dr H queried whether

[1] Relevant dates are referred to as Days 1-33 to protect privacy.
[2] A right hemicolectomy involves removing the right side of the colon and attaching the small intestine to the remaining portion of the colon.
[3] Inflammation of the liver caused by medication.
[4] The accumulation of fluid in the space between the lining of the abdomen and abdominal organs.

a drug such as paracetamol had caused her deranged LFTs. He recorded in the progress notes: "[S]top paracetamol." Mrs A received no further paracetamol.

10. Mrs A died a few days later.

Findings

11. Mrs A's prescribed paracetamol dose was too high for an underweight, frail patient with liver failure. Waikato District Health Board (the DHB) staff did not think critically and adjust Mrs A's paracetamol prescriptions in light of her circumstances. The DHB has a responsibility to ensure that its staff provide services of an appropriate standard. It did not provide services to Mrs A with reasonable care and skill and, accordingly, it breached Right 4(1)[5] of the Code.

12. The nursing staff did well to withhold paracetamol, on occasion, in response to Mrs A's deteriorating liver function. However, there was inadequate communication between nursing and medical teams regarding the withholding of paracetamol in response to Mrs A's deranged LFTs, and inadequate recording of communications. Furthermore, Mrs A's medications were re-charted exactly the same as the previous medication chart, including paracetamol 1g four times daily, because Dr E was not aware of any request to stop paracetamol, as the request had not been documented or communicated, and the prescription was signed off by a ward pharmacist with no issues raised. The DHB staff did not communicate effectively to ensure quality and continuity of the services provided to Mrs A and, accordingly, the DHB breached Right 4(5)[6] of the Code.

13. Other comment is made about Mrs A's perioperative care and communication with her family.

Complaint and investigation

14. The Commissioner received a complaint from Mrs B regarding the services provided to her late mother, Mrs A, at the Hospital.

15. An investigation was commenced on 24 April 2014. The following issue was identified for investigation:

Whether Waikato District Health Board provided appropriate care to Mrs A in 2012.

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

16. The parties directly involved in the investigation were:

Mrs B	Complainant
Waikato District Health Board	Provider

17. Information was also received from:

The Coroner's Office	
Dr C	Gastroenterologist
Dr D	General surgeon
Dr E	House officer

18. Independent expert advice was obtained from clinical pharmacologist Associate Professor Matt Doogue (**Appendix C**), colorectal surgeon Dr John Keating (**Appendix D**), and registered nurse Ms Dawn Carey (**Appendix E**).

19. Other parties mentioned in this report:

Dr F	General surgeon
Dr G	House officer
Dr H	Gastroenterologist

Information gathered during investigation

Introduction

20. This report relates to the care provided to Mrs A during her time in the Hospital, with a particular focus on the adequacy and appropriateness of the prescribing of paracetamol. Mrs A underwent uneventful surgery at the Hospital on Day 12, but her liver function deteriorated postoperatively. She died after a month in hospital.

Background

21. On Day 1, Mrs A (then aged 77 years) presented to the Emergency Department at the Hospital. She had been experiencing abdominal pain for six days with some vomiting. She was frail and underweight (around 39kg, according to Mrs B), and clinical notes record that she had consistently lost weight over the previous three months. Mrs A had a number of complex co-morbidities, including a history of Crohn's disease[7] and ischaemic heart disease.[8]

22. On Day 2, Mrs A was admitted to the Hospital under the care of consultant general surgeon Dr F. On admission, Mrs A's serum liver function tests (LFTs) (tabled in

[7] Crohn's disease is a type of inflammatory bowel disease. Symptoms often include abdominal pain, diarrhoea, fever and weight loss.

[8] Ischaemic heart disease is the most common type of heart disease and cause of heart attacks. The disease is caused by plaque building up along the inner walls of the arteries of the heart, which narrows the lumen of the arteries and reduces blood flow to the heart.

Appendix A) were mostly normal. She was charted various PRN (as required) pain relief medications, including paracetamol 1g, with a maximum dose of 4g of paracetamol per day (prescribed and administered doses of paracetamol are tabled in **Appendix B**).

23. On Days 5 and 8, Mrs A was reviewed by a clinical dietician, who noted that Mrs A was malnourished and recommended a low fibre, high protein diet supplemented by Fortisip.[9] Nursing notes taken during her admission indicate that Mrs A refused additional snacks, and was reluctant to drink nutritional supplements at times,[10] and that incidences of nausea affected her appetite.[11]

24. Dr F requested a magnetic resonance imaging (MRI) scan[12] of Mrs A's small bowel on Day 6. The results identified an obstructing lesion at the hepatic flexure[13] of Mrs A's colon, consistent with a colonic cancer.

25. On Day 7, Mrs A's care was transferred to consultant gastroenterologist Dr C, who performed a colonoscopy on Day 9. Dr C was unable to progress the colonoscope past the mid-transverse colon owing to excessive bowel looping. As Dr C was unable to reach the lesion during the colonoscopy, it was decided that Mrs A would require surgical intervention in order to complete further investigations.

26. On Day 12, Mrs A's care was transferred to consultant general surgeon Dr D. The following day, Mrs A underwent a right hemicolectomy[14] without complication. The operative findings confirmed a large, partially obstructive colonic cancer.

Transfer to general surgical ward

27. On Day 13, Mrs A was transferred to a general surgical ward, for post-surgical recovery. She remained under the care of Dr D. Clinical notes indicate that Mrs A had low blood pressure post-surgery, with her systolic blood pressure ranging between 72mmHg and 82mmHg[15] on Day 13. Her blood pressure then improved with intravenous fluids and, on Day 14, it was noted that her systolic blood pressure had increased to 90mmHg.

28. On Day 15, Mrs A was assessed by the Inpatient Pain Service (IPS), which recommended oral analgesia including paracetamol.[16] Dr D told HDC that Mrs A had progressed well in the early post-surgical period, and that by Day 16 she was being

[9] A high energy, nutritionally complete, oral nutritional supplement.
[10] It is recorded in the progress notes of Day 16 that Mrs A reported that Fortisip would "go straight through her".
[11] It is recorded in the progress notes of Day 22: "Inadequate oral intake as related to low appetite due to abdominal cramps, nausea/vomiting."
[12] MRI is a medical imaging technique used in radiology.
[13] The sharp bend between the ascending and transverse colon.
[14] A right hemicolectomy involves removing the right side of the colon and attaching the small intestine to the remaining portion of the colon.
[15] Systolic blood pressure is the maximum arterial pressure during contraction of the left ventricle of the heart. Normal systolic blood pressure is less than 120mmHg, but hypotension is generally considered when systolic blood pressure falls below 90mmHg.
[16] As stated, paracetamol 1g (up to 4g per day) was charted as a PRN medication.

considered for discharge. Dr C reviewed Mrs A that day and reported that she was "looking well". However, on Day 17, Mrs A began leaking fluid from her wound.

29. Dr D assessed Mrs A's condition on Day 17 and decided to delay discharge. Dr D told HDC that the leaking fluid through the wound meant that it was appropriate to keep Mrs A in hospital. He said that his main concern at that time was to investigate the possibility of an anastomotic leak.[17] A wound swab was sent to the laboratory for testing that day, and a wound bag was applied to drain the leaking fluid.

30. Nursing notes taken later that night record that 300ml of blood-stained fluid had drained from Mrs A's wound, and that she was feeling "tired [and] lethargic, nauseous at beginning of night, settled now".

31. Medication charts indicate that Mrs A was administered 4g paracetamol in divided doses on Day 17.[18]

Investigation and management of deranged LFTs — Days 18 to 23

Day 18

32. Blood tests taken on Day 18 indicated a normal white blood cell count but deranged[19] LFTs. In particular, Mrs A had a significant rise in ALP, GGT and ALT.[20] The blood test results were reported on Day 18 at 10.50am, and acknowledged by house officer Dr E the following day.

33. Medication charts show that Mrs A was administered 1g of paracetamol at 2.00am and a further 1g of paracetamol at 1.00pm on Day 18.

34. Dr D assessed Mrs A on Day 18. The time of his review is not recorded in the progress notes, but he noted that Mrs A was "upset as [she] feels like [a] burden". There is no specific written record in the progress notes of Dr D having reviewed the paracetamol prescription at that time.

35. Dr D told HDC that he attended a paper round[21] at the end of the day. He said: "I was directly involved in the decision to withhold Mrs A's charted paracetamol due to her abnormal liver function tests."[22] Dr D could not confirm why the decision to withhold Mrs A's charted paracetamol was not clearly recorded in her clinical notes, but he said that the decision was communicated to the team members who attended the paper round.

[17] A serious complication of colorectal surgery where there is a breakdown of the connection of digestive system structures and subsequent leakage of digestive system fluid.
[18] This is discussed further at paragraph 85.
[19] Abnormal.
[20] See **Appendix A**.
[21] Dr D told HDC that paper rounds are patient rounds conducted to review the results of tests that were ordered earlier in the day (during the course of the ward round). He said that consultants attend these rounds when they are available to do so.
[22] Excessive use of paracetamol can cause hepatotoxicity (damage to the liver). Malnourished patients are at higher risk of hepatotoxicity from paracetamol.

36. Dr D told HDC that while waiting for a consultation with the gastroenterologist with regard to Mrs A's deranged LFTs, "it was decided that paracetamol would be withheld as a precaution". HDC asked Waikato District Health Board (the DHB) to explain how the decision to withhold paracetamol was communicated amongst staff. The DHB told HDC that "there may have been some discussion between nursing and medical to withhold as the nursing staff have alluded to in their nursing notes … and the drug chart". However, there is no record in the clinical notes that discussion between medical and nursing staff took place.

37. Nursing notes record that 500ml of blood-stained fluid had drained from Mrs A's wound, and that she was "feeling miserable, not eating, needing a lot of encouragement to drink". The timing of this review is not documented, and the notes do not refer to paracetamol or deranged LFTs.

38. At 8.20pm, Mrs A was assessed by the on-call house officer, Dr G, as she was feeling "generally unwell". Dr G noted that Mrs A appeared "stable, no acute concerns", and recorded a treatment plan to provide intravenous fluids and to optimise analgesia.

39. Dr G crossed paracetamol off the PRN medication chart and signed the cancellation date as Day 18. Dr G did not record the timing of this change. Dr G then charted regular paracetamol (1g four times a day).

Day 19

40. On the morning of Day 19, a registered nurse recorded that Mrs A initially reported feeling "much better", but that she experienced a sudden onset of pain at around 4am. The nurse recorded in the progress notes: "Noted panadol crossed off on [Day 18] then recharted ? initially stopped due to deranged LFTs. Tramadol given instead of Panadol — for [review this morning]."[23]

41. The nurse told HDC that she did not contact the on-call house officer regarding the decision to withhold paracetamol overnight, because she was conscious that one house officer covered approximately nine surgical wards between 10.00pm and 8.00am. She told HDC:

> "I felt that it was more appropriate that I withhold one dose of Paracetamol and give an alternative and have [Mrs A's] medical team, who were more familiar with her case, review her bloods and Paracetamol charting on the morning ward round which would be occurring in a few hours."

42. The nurse stated that when she completed the bedside handover at the end of her shift, she told her colleague that she had withheld the paracetamol in response to Mrs A's deranged LFTs, and asked that the medical team be informed during their ward round.

43. At 8.30am, Dr D reviewed Mrs A. Progress notes record that Mrs A was experiencing "severe abdominal cramps", and that Dr D called for a CT scan of her abdomen, with OxyNorm as required for pain. The notes taken of Dr D's review do not mention

[23] Tramadol was a charted PRN medication for Mrs A.

withholding of paracetamol. Details of Mrs A's deranged LFTs were recorded in the margin of the notes.

44. At 1.30pm, it was recorded in the progress notes that Mrs A's wound had stopped leaking, and that she had gained 7kg in the previous ten days. She was encouraged to mobilise, and took three walks of the corridor.

45. The CT scan was performed at 5pm that evening.

46. At 11.45pm, it was noted that Mrs A had been given pain relief for her abdominal cramps as charted (OxyNorm), but that paracetamol was withheld owing to her deranged LFTs. "N" is recorded on the medication chart to indicate paracetamol being withheld. However, it is not documented whether discussions occurred between nursing staff and Mrs A's medical team regarding the decision of nursing staff to withhold Mrs A's paracetamol. Notes indicate that no concerns were raised by Mrs A overnight.

Day 20

47. On Day 20, Dr D reviewed Mrs A's CT scan results. He told HDC that the results showed no evidence of an anastomotic leak. His notes record that Mrs A was afebrile with stable vital signs, and that she felt "well". The recorded treatment plan was for Mrs A to mobilise. Blood test results reported at 9.05am showed that her LFTs had reached peak derangement.[24] Dr D's notes do not make mention of paracetamol being withheld.

48. "W" is recorded on the medication chart to indicate that paracetamol was withheld owing to "deranged LFTs" at 7.30am. Again, it is not documented whether discussions occurred between nursing staff and Mrs A's medical team regarding the need to withhold paracetamol.

49. Nursing notes throughout the day record that there was minimal output from Mrs A's wound, and that paracetamol continued to be withheld.

Day 21

50. On Day 21, nursing notes record that Mrs A was "eating and drinking satisfactorily, tolerating Fortisip with ice". Her wound bag was removed, and her wound was dressed. It was noted that the wound was "healing well" with "no signs of infection". Further blood tests were taken, and Dr D noted that Mrs A had elevated LFTs,[25] although she felt well with no pain.

51. Nursing notes taken at 9.45pm record that Mrs A and her family were "tearful/frustrated" with her lack of progress, and wanted "answers to questions such as what is happening about the deranged LFTs? Why has she put on 8kg of fluid? Why has she no appetite?"

[24] See Appendix A.
[25] See Appendix A.

Day 22

52. On Day 22, Mrs A was reviewed by the clinical dietician and the rehabilitation service. Dr D told HDC that Mrs A was being considered for discharge at this time, and he recorded that her deranged LFTs[26] had been "improving over [the] last few days".

53. Nursing notes record that Dr D had discussed Mrs A's questions with her and her family, and that they had "had their questions answered". No further details of the conversation are recorded in the progress notes.

54. Mrs B stated in her complaint that she and her family were shouted at by Dr D, and he queried why they were always asking questions and asking for results. Dr D said:

> "I don't shout at patients — my voice tends to be loud which may make it seem this way … I did not mean anything seriously by telling [Mrs B] she was asking too many questions. I remember answering all questions she asked even after this."

Day 23

55. On Day 23, Dr D reviewed Mrs A's condition and noted that he would discuss her deranged LFTs with Dr C. At 2.30pm, Dr C reviewed Mrs A. He was unable to identify a specific cause for Mrs A's deranged LFTs, and noted: "No specific recent drugs to explain LFTs but a drug-induced hepatitis[27] most likely."

56. Dr C told HDC: "I noted significant liver dysfunction with a peak in the ALT of 830 on [Day 20]. However, over the subsequent three days I noted the blood tests showed a progressive improvement in liver function."

57. Dr C reviewed the CT scan results from Day 19, and he noted that Mrs A had not had paracetamol for the previous four days (Days 19–22), and that there had been no recent introduction of any potentially hepatotoxic[28] medications. Dr C told HDC that his initial consideration was that the deterioration of Mrs A's liver function was "multi-factorial".

58. After performing tests to exclude other diagnoses,[29] Dr C told HDC that he considered that Mrs A's liver abnormalities were most likely due to medication, including anaesthetic drugs and possibly paracetamol, in combination with hypotension, hepatic ischaemia, and possible sepsis. However, this is not recorded in the notes.

Re-charting and administration of paracetamol

59. On Day 23, Mrs A's medications were re-charted[30] on a new medication chart by Dr E. Dr E told HDC that he re-charted Mrs A's medications "identically to the way it

[26] See Appendix A.
[27] Inflammation of the liver caused by medication.
[28] Injurious to the liver.
[29] Hepatitis B and C, autoimmune hepatitis, cytomegalovirus, Epstein-Barr virus, and toxoplasmosis.
[30] Re-charting occurs when the medication chart is full and a new chart is required to continue the medication schedule for the period of the patient's admission. The prescriber should re-prescribe the medicine(s) and record the date of re-charting on a new medication chart. From Health Quality and Safety Commission, Medication Charting Standard, Version 3, September 2012.

was charted in the previous medication chart".[31] In particular, Dr E charted paracetamol, 1g, four times daily as a regular medication.

60. Dr E explained that the prescription was signed off by a ward pharmacist with no issues raised, and that he was not aware of any request to stop paracetamol, as "no team had yet documented or communicated this request". In particular, Dr E stated:

> "On no ward round notes was the team instructed to stop paracetamol on or before the day of recharting. The patient was reviewed by [Dr C] (Gastroenterologist) on [Day 23] the same day I recharted her medications. He noted improving liver function tests. There was no mention of paracetamol, incorrect dosing of paracetamol or the need to stop paracetamol."

61. The medication chart provided to HDC was signed by Dr E and dated Day 23. It also includes an undated handwritten note reading "Not for Paracetamol" under the heading "Adverse Drug Reactions". Dr E told HDC that this note is not in his handwriting, and submitted that it was added after he re-charted Mrs A's medications on Day 23.

Days 24 to 30

62. Between Days 24 and 30, Mrs A was administered paracetamol as a regular medication.[32]

63. Dr D told HDC:

> "[A]lthough the drug chart clearly stated 'not for paracetamol' she was administered the medication. It is unclear why she was re-administered the medication after it was clearly written that she was 'not for paracetamol' and because it had been withheld from [Day 18]. Further it is unclear whether the prescribed medication had been struck off[33] properly on the drug chart on [Day 23] and whether the particular portion of the drug chart that had been struck off was done prior to or after the paracetamol had been administered to [Mrs A]."

64. Nursing notes indicate that Mrs A remained largely stable between Days 24 and 25. From Day 26, Mrs A began to deteriorate. Dr D told HDC that Mrs A had diarrhoea and signs of developing sepsis (namely rising inflammatory markers), and that her LFTs were deranged.[34] The gastroenterology team was contacted to review Mrs A's condition. A flexible sigmoidoscopy[35] was conducted to rule out the possibility of a "flare up of colitis".[36] Dr D told HDC that the sigmoidoscopy indicated mild mucous congestion without any colitis. Mrs A was given antibiotics.

[31] As stated, paracetamol had been charted as a regular medication on Day 18.
[32] See Appendix B for total daily doses of paracetamol.
[33] Removed from the medication chart.
[34] See Appendix A.
[35] An examination of the sigmoid colon by means of a flexible tube inserted through the anus.
[36] Colitis is inflammation of the inner lining of the colon. It may cause abdominal pain and diarrhoea with or without blood. Fever may be present.

65. On Day 27, a CT scan was conducted in an attempt to localise Mrs A's developing sepsis. The results indicated a mass of fluid without air in Mrs A's abdomen. Dr D explained that this result suggested ascites[37] rather than an anastomotic leak. Dr D submitted to HDC:

> "All necessary medical investigations were carried out to investigate the cause of [Mrs A's] clinical deterioration. In particular several tests were carried out to investigate the cause of her deranged LFTs. All test results that would indicate the possibility of her deranged LFTs being due to paracetamol toxicity were negative and the gastroenterologist confirmed that paracetamol toxicity was unlikely to be the cause of her altered liver function."

66. On Day 28 at 11.05am, the fluid in Mrs A's abdomen was removed by percutaneous drainage.[38] After 1900ml of fluid had been drained, Mrs A's blood pressure dropped.[39] The drainage was stopped, and Mrs A was transferred back to the ward. Mrs B recalls that staff had to "clamp the tube because mum's blood pressure dropped so much they had to rush her back to the ward to be monitored".

67. At 1.00pm, the house officer on the ward attempted to gain intravenous access to Mrs A, because she was not tolerating oral fluids. Further unsuccessful attempts were made by the house officer, the nurse educator, and the ward nurse, to gain intravenous access. Mrs B recalls that "so many people tried at least 15 times". It was then decided that Mrs A required a peripherally inserted central catheter (PICC) line. The first attempt at inserting this was unsuccessful, and Mrs A's left basilic vein was punctured. However, at 6.00pm a central venous catheter was inserted.

68. Nursing notes record that Mrs A needed close monitoring overnight, and that no beds were available in the high dependency unit (HDU). This information was discussed with Mrs B at 1.00am on Day 29.

69. On Day 29, Mrs A was reviewed by a clinical dietician, who noted that she continued to have no oral intake and no appetite. The dietician recorded that Mrs A weighed 8kg more than when she was admitted, and that she was "very fluid overloaded".

70. Mrs A was transferred to HDU on the afternoon of Day 29. It is recorded in the progress notes that Dr D met with Mrs A's family to discuss her deterioration. The recorded plan included optimising Mrs A's fluid and nutrition status, and "searching for [the] cause of [her] acute liver deterioration".

Decision to withhold paracetamol

71. On Day 30, Mrs A was reviewed by gastroenterologist Dr H, who noted that she had acute liver derangement post-surgery, and ascites. Dr H queried the possibility of "drug eg paracetamol" as a cause of her deranged LFTs. He suggested obtaining

[37] The accumulation of fluid in the space between the lining of the abdomen and abdominal organs.
[38] A form of radiological image-guided drainage, allowing minimally invasive treatment of fluid collections.
[39] Mrs A's blood pressure was 72/56mmHg (normal adult blood pressure is 120/80mmHg).

retrospective paracetamol levels,[40] and recorded in the progress notes to "stop paracetamol". He also had a high suspicion that Mrs A had sepsis.

72. Mrs A's medications were then re-charted (on a new chart, dated Day 30), and "Not for paracetamol" was recorded under "Adverse drug reactions". The medication chart indicates that paracetamol was then stopped.

73. The senior house officer in HDU reviewed Mrs A at 8.35pm on Day 30, and noted that acute liver failure had developed postoperatively. It is recorded in the clinical notes: "? Hypotensive injury ? paracetamol related — dosing stopped today — prolonged episode hypoglycaemia yesterday, likely [secondary] to this." The recorded plan included commencing N-acetyl-L-cysteine (NAC)[41] and Vitamin K.

Clinical deterioration

74. Mrs A's condition continued to deteriorate, and on multiple occasions she was noted to have tachycardia.[42]

75. Mrs B stated that she was contacted by HDU at 6am on Day 32 and told that her mother had been asking for her all night. Mrs B is concerned that when she went in to visit her mother, she found her "cuffed to the bed". The clinical notes record that Mrs A was "restrained x2 (wrist)" overnight, owing to confusion. It is recorded that the reason for the restraints was discussed with the family after they voiced their concerns. The documented plan was to contact the family if Mrs A required further restraint.

76. The DHB told HDC: "Patients are not restrained unless they are in a medically fragile condition, where timing around medication is imperative, if they show a risk of lines being pulled out … they must be restrained for their own wellbeing in order to receive the treatment they require." The DHB said that it is standard procedure for HDU staff to explain the reasons for restraint to family when they first arrive, and apologised directly to Mrs B in writing that this was not done.

77. The following day, Mrs A was commenced on the Liverpool Care Pathway,[43] and was prescribed morphine for pain and agitation. It is recorded that Mrs A's condition was discussed with Dr C that afternoon, and that Dr C considered that, in the event of death, Mrs A's case should be discussed with the Coroner. It is recorded that Dr C considered the diagnosis to be "paracetamol toxicity → liver failure [secondary] to

[40] On Day 28, Mrs A's paracetamol levels were 235µmol/L and, on Day 30, her paracetamol levels were 229µmol/L. The normal range is 0–199µmol/L. Retrospective levels are obtained by requesting the laboratory add the test for paracetamol levels to the original blood test request.
[41] NAC is a pharmaceutical drug and nutritional supplement used in the management of paracetamol overdose.
[42] Faster than normal heart rate.
[43] The Liverpool Care Pathway for the Dying Patient is a care pathway covering palliative care options for patients in the final days or hours of life.

hypoalbuminemia",[44] and that he recommended morphine be continued for Mrs A's comfort.

78. Mrs A was moved from HDU to a room on the ward and, sadly, died that evening.

79. A death certificate completed by a house officer documented the cause of death as "a) liver failure, b) ? paracetamol toxicity, c) colon cancer". This was signed and dated Day 33.

80. However, Mrs A's case was discussed with the Coroner and the Police, and an autopsy was conducted the following day, which indicated that the cause of death was sepsis from recent bowel surgery and peritonitis.[45] The secondary cause of death was recorded as liver failure. Paracetamol levels as per the toxicology report were normal.

81. A letter was sent to Mrs A's family about two months later, advising that the Coroner had classified Mrs A's death as a natural death.

82. Mrs B complained to HDC that the DHB staff failed to recognise Mrs A's developing sepsis or identify the cause of her deranged liver function "until it was far too late for her".

Further concern

83. In her complaint, Mrs B asked: "[W]hy did my brother get shouted at by the charge nurse in [the ward] for asking questions about the food mum was getting?" The Charge Nurse Manager of the general surgical ward stated:

> "I unfortunately have no recollection of this perceived incident and genuinely apologise for this apparent behaviour which is totally out of character. This has also been discussed with the wider staff to alert them as to how their response can be perceived and to be more aware of their tone of voice."

Changes and follow-up actions undertaken by the DHB

84. The DHB told HDC:

- Processes are being put in place to ensure that when house officers document "no paracetamol" on a medication chart, the medication is correctly struck off the chart to prevent it being administered to a patient after it has been charted "not to be administered".
- Mrs A's case is to be included in an internal Mortality and Morbidity Review of all patients who have died unexpectedly.
- The Head of Surgery sent a memorandum to all senior medical officers, registrars, and house surgeons, which highlighted the need for paracetamol adjustment in

[44] Hypoalbuminaemia is a medical condition where levels of albumin in blood serum are abnormally low. Low albumin levels can be an indicator of chronic malnutrition. Hypoalbuminaemia may cause generalised swelling.
[45] Infection of the inner lining of the abdomen.

patients with low body weight and its use cautioned in those who have liver failure.

- Nursing staff on the General Surgery ward conducted an informal case review of Mrs A's care in 2012, and again in June 2014.
- The General Surgery nursing team is undertaking a pilot initiative called "Staff Stories", which is a facilitated debriefing activity that enables staff to share their experiences of incidents and their concerns.
- The SBARR communication tool[46] is being reintroduced at the DHB. It is anticipated that SBARR will be used by all clinical staff when handing over patients or contacting another healthcare professional regarding concerns about the patient's condition. SBARR is also used by nursing staff at the bedside handover.

Other information from the DHB

85. While it was charted that Mrs A was to receive 1g paracetamol four times a day as a regular medication between Days 24 and 30, the DHB emphasised that Mrs A did not receive more than 3g paracetamol on any day she was in the surgical ward at the Hospital. However, the medication charts indicate that Mrs A was administered 4g paracetamol on Day 17 (1g at 2.45am,[47] 8.45am, 2.10pm, and 9.00pm).

86. The DHB accepted that there is a lack of documentation of a review of the paracetamol prescription, including reasons for stopping or withholding the medication. It accepted that the process to withhold the medication did not meet its standard of medication management.

87. The DHB accepted that the prescribed dose of paracetamol had not been adjusted for a frail patient with liver impairment. However, it submits that serum paracetamol levels were within "normal limits" at autopsy, suggesting that if paracetamol was a factor in Mrs A's death, it was not due to excessive amounts, but of "an idiosyncratic nature".

88. The DHB "Medicines Management" policy states:

> "**4. Checking and Administering Medicines**
>
> …
>
> **4.11 Omitted and delayed medicines**
>
> - Medicines that are omitted must have the correct non-administration code clearly documented on the medication chart.

[46] SBARR stands for situation, background, assessment, recommendation, response. SBARR is an easy to remember mechanism that can be used to frame conversations, especially critical ones requiring a clinician's immediate attention and action. The tool consists of standardised prompt questions within five sections, to ensure that staff are sharing concise and focused information.
[47] This dose is recorded on a separate medication chart from the other doses.

- When a medicine is omitted … and this medication change has the potential to affect the patient's health or response to treatment, then the patient's medical team should be informed as soon as practical, and a record of the event should be documented in the patient's clinical record.

- If in any doubt advice may be obtained from the medical staff or a pharmacist to ascertain whether any further response to the omitted or delayed dose is needed.

Medicine(s) that are omitted or significantly delayed without prescriber authority or clinical justification are classified as an incident and must be reported as a medicine error."

Paracetamol monograph

89. The paracetamol monograph in the New Zealand Formulary[48] states:

"**Risk factors for hepatotoxicity**[49]
Risk of hepatotoxicity may be increased with chronic excessive alcohol use, hepatic impairment, chronic malnutrition, prolonged fasting, dehydration, and in frail elderly. Maximum daily infusion dose of 3 g in patients greater than 50 kg body-weight with risk factors for hepatotoxicity."

Responses to the provisional opinion

90. Mrs B had no comments to make in response to the "information gathered" section of the provisional opinion. Dr E and Dr D told HDC that they accepted the findings in the provisional opinion and have no further comments to make.

91. In response to the provisional opinion, the DHB stated that it "accepts the findings in the report and will continue its active work to address those issues in the manner recommended in the report." The DHB also stated:

"[It] agrees entirely that there are clear lessons to be learnt related to the potential toxicities of common medications when administered in uncommon circumstances. Low body weight/malnutrition, renal impairment and hepatic impairment are the three main potential areas where dosing adjustments may be required. Doctors usually adjust for renal impairment but adjustments for body weight/malnutrition are generally less well known. Therefore the DHB acknowledges the seminality of this case and supports the efforts of the Commissioner to maximise the learning opportunity arising from it. We believe that those learnings will be nationwide in application. There are other common perioperative medications to which the same lessons may be extrapolated, such as common anti-emetics and antibiotics, particularly gentamicin."

[48] The New Zealand Formulary is an independent resource providing healthcare professionals with clinically validated medicines information and guidance on best practice, enabling healthcare professionals to select safe and effective medicines for individual patients.
[49] Injury to the liver caused by a drug.

92. The DHB accepted that the intended/prescribed paracetamol was too high (and accepts responsibility for this intent), but noted that Mrs A received significantly less than this. It stated: "The uncertainty about the role of paracetamol inducing the liver impairment was perhaps confounded by a lack of understanding about the role of paracetamol levels in acute vs chronic toxicity. This uncertainty was evident even after expert gastroenterologic review …"

93. The DHB noted that while paracetamol toxicity is a "possible cause" of the developing liver failure, it has not been proven to be the initiating cause. It explained that there are a number of contributing factors in Mrs A's case which aggravated any hepato-cellular dysfunction, including: hypo-perfusion of the liver and kidney leading to hepato-renal syndrome; and post mortem evidence of peritonitis and an anastomotic leak, which is also indicative of the well-known association of faecal peritonitis with fulminant liver failure. It submitted that to place the entirety of cause on paracetamol toxicity alone is a "vast oversimplification of a complex and deteriorating clinical scenario".

Opinion: Waikato District Health Board — Breach

Introduction

94. Waikato DHB and the staff involved in Mrs A's care had a responsibility to take all reasonable steps to ensure that Mrs A received services of an appropriate standard, including ensuring that there was adequate communication between staff to ensure the quality and continuity of the services provided to her.[50]

95. I consider that there was a lack of critical thinking by DHB staff in prescribing paracetamol to a frail patient, and poor documentation and poor communication between the staff involved in Mrs A's care. Overall, I am most concerned at the poor communication demonstrated by and between DHB staff, for which I consider the DHB is responsible.

96. Mrs A was admitted to the Hospital on Day 2. She was frail and underweight, and a clinical dietician noted that she was malnourished. Mrs A's LFTs were mostly normal on admission. Around Day 18, Mrs A's LFTs became deranged and she deteriorated. Sadly, she died. It is not my role to determine or comment on the cause of Mrs A's death. That is the role of the Coroner. Accordingly, my findings should not be interpreted as having any implication as to the cause of Mrs A's death. Further, my findings should not be interpreted as having any implication as to the initiating cause of Mrs A's liver injury.

Paracetamol charting

97. Paracetamol is widely used for pain relief in hospital and community settings. My expert advisor, Associate Professor Matt Doogue, a specialist in clinical

[50] Code of Health and Disability Services Consumers' Rights, Right 4(5).

pharmacology and general medicine, advised me that while paracetamol is generally regarded as "safe and effective", when taken in overdose, it can cause liver failure and death. The maximum recommended adult dose for paracetamol is 1g four times daily and, when taken acutely in overdose, 10g can be sufficient to cause liver damage.

98. From admission, Mrs A was charted 1g paracetamol PRN, with a maximum dose of 4g per day, which is the standard adult dose. From Day 12 to Day 17, Mrs A received between 1g and 4g paracetamol per day. While I acknowledge that the DHB stated that Mrs A never received more than 3g paracetamol per day while in the Hospital, medication charts indicate that she received 4g in divided doses on Day 17. Therefore, I find that Mrs A received 4g paracetamol on Day 17.

99. On Day 18, Dr G crossed paracetamol off Mrs A's PRN medication chart, and signed the cancellation date as Day 18. He did not record the time of this change. Dr G then charted paracetamol as a regular medication, 1g four times a day.

100. Between Days 19 and 23, Mrs A was not administered paracetamol by nursing staff, despite this being a prescribed regular medication. Nursing staff recorded this in their nursing notes and on the medication charts, by recording "W" or "N" to indicate that the medication was withheld, and that this was because of her deranged LFTs.

101. On Day 23, Mrs A's medications were re-charted by house officer Dr E. In particular, paracetamol was re-charted as a regular medication, 1g four times a day. Between Days 24 and 30, Mrs A was administered paracetamol as a regular medication, and received between 1g and 3g per day.

102. The paracetamol monograph in the New Zealand Formulary includes the caution that the risk of hepatotoxicity may be increased in patients with malnutrition, or in frail elderly, and in such cases a maximum dose of 3g per day is recommended.

103. My expert advisor, consultant general surgeon Dr John Keating, advised that paracetamol is known to have a fairly narrow therapeutic index, but its ability to cause severe liver dysfunction and liver failure in the standard adult dose in patients with malnutrition is not widely recognised.

104. Dr Doogue advised that the maximum dose he would usually recommend in a frail severely malnourished patient is 2g per day in divided doses. Dr Doogue stated: "The prescribed doses of paracetamol were inappropriate but … such prescribing occurs frequently in our hospitals and is a significant risk to frail patients." He also noted that with evidence of liver injury, the paracetamol should probably have been ceased.

105. In my opinion, there were shortcomings in the care provided to Mrs A in relation to the prescribing of paracetamol by DHB staff. Mrs A was prescribed PRN paracetamol on Day 2 at the normal adult dose. Paracetamol was then removed from her PRN medication chart on Day 18 and added as a regular medication in the normal adult dose on the same day, despite her deranged LFTs. The paracetamol was withheld for five days then re-charted in the normal adult dose.

106. I accept Dr Doogue's advice that the prescribed paracetamol dose was too high for an underweight, frail patient, and I am critical that DHB staff did not adjust Mrs A's paracetamol prescriptions, in light of her low body weight, frail status, and deranged LFTs. The DHB accepted that the intended/prescribed paracetamol dose was too high, but noted that Mrs A received significantly less than this.

107. I acknowledge that paracetamol's ability to cause liver failure in the standard adult dose in patients with malnutrition is not widely recognised. However, given Mrs A's circumstances, a more cautious approach to prescribing paracetamol would have been appropriate. This case reinforces that paracetamol doses need to be adjusted for frail, underweight, or malnourished patients.

Communication — Decision to withhold paracetamol

108. Dr D told HDC that he was directly involved in the decision to withhold Mrs A's charted paracetamol on Day 18. He said that this decision was communicated to the team members who were also attending the paper round. However, there is no reference to this decision in the clinical notes.

109. A registered nurse told HDC that she verbally handed over to her nursing colleague at the end of the night shift on Day 19, and asked that the medical team be informed during the morning ward round that she had withheld paracetamol in response to Mrs A's deranged LFTs. There is no record that a discussion between nursing staff and the medical team occurred.

110. My nursing advisor, RN Dawn Carey, advised me that nursing staff responded well to Mrs A's deranged LFTs by not administering the prescribed paracetamol. I agree. I acknowledge that it may have been favourable that Mrs A was not administered all of the paracetamol she was prescribed, and commend the nursing staff for their critical thinking in this circumstance.

111. The DHB medicines management policy specifies that the medical team should be informed as soon as practical when a medicine is omitted and this medication change has the potential to affect the patient's health or response to treatment, and a record of the event should be documented in the patient's clinical record.

112. I consider that when nursing staff began to withhold paracetamol on Day 19 in response to Mrs A's deranged LFTs, they should have advocated for this medication to be discontinued and crossed off the medication chart, and requested a medical review at that point. While the DHB has suggested that some discussion between the nursing and medical staff may have occurred, this is not documented in the clinical notes. It appears that a critical conversation regarding withholding of paracetamol did not take place between nursing and medical staff. In the event that this communication did take place, I remain concerned, as there was no clear direction for subsequent DHB staff to see that Mrs A should not have been prescribed or administered further paracetamol, nor are the concerns that rightly caused the nurses to withhold the medication recorded.

113. It is essential that teams consistently communicate well with one another to ensure that a safe and seamless service is provided to the patient. It is also essential that clear communication is accompanied by accurate documentation. Clear communication and accurate documentation form two of the layers of protection that operate to deliver seamless care.[51]

114. In my opinion, there was inadequate communication between nursing and medical teams regarding the withholding of paracetamol in response to Mrs A's deranged LFTs. Mrs A was re-charted paracetamol on Day 23 as a regular medication, because no team had clearly documented or communicated a request to withhold it, and the regular paracetamol (charted on Day 18) had not been crossed off the medication chart. There was a missed opportunity to ensure that Mrs A was not administered further paracetamol once the nursing team began to withhold it.

Documentation — Re-charting of paracetamol

115. Mrs A's LFTs reached peak derangement on Day 20. They improved slightly but remained deranged on Day 23. The deranged LFTs were discussed with Dr C, who recorded in the clinical notes: "No specific recent drugs to explain LFTs but a drug-induced hepatitis most likely."

116. On Day 23, Mrs A's medications were re-charted by house officer Dr E, who told HDC that the medications he re-charted for Mrs A were identical to those that had been charted in the previous medication chart, including paracetamol 1g four times daily. The prescription was signed off by a ward pharmacist with no issues raised, and Dr E was not aware of any request to stop paracetamol, as "no team had yet documented or communicated this request". RN Carey advised that a pharmacist initialling the prescription is interpreted as the prescription being clinically safe and valid.

117. On Day 30, Mrs A was reviewed by gastroenterologist Dr H, who queried the possibility of paracetamol as a cause of her deranged LFTs. He requested that paracetamol be stopped, and this is recorded in the clinical notes. Mrs A's medications were re-charted on a new medication chart, and "Not for paracetamol" was recorded under the adverse drug reaction heading. The medication charts indicate that paracetamol was stopped at that point.

118. On the earlier medication chart (dated Day 23), under the adverse reaction heading, "Not for paracetamol" is written. It is not clear when this was written, or by whom. Dr E submitted to HDC that this was written after he had re-charted Mrs A's medications. Further, the statement "Not for paracetamol" appears to be in different handwriting to Dr E's. I am concerned that the medication chart appears to have been amended retrospectively, and, in my view, it is essential that retrospective entries to clinical documentation are clearly identified as such, and are signed and dated by the writer, to avoid confusion.

[51] Health and Disability Commissioner Anthony Hill, "Consumer-centered Care — Seamless Service Needed" (*NZ Doctor*, 24 August 2011) (available from www.hdc.org.nz).

Conclusions

119. Mrs A's prescribed paracetamol dose was too high for an underweight, frail patient with liver failure. In my view, the DHB staff did not think critically and adjust Mrs A's paracetamol prescriptions in light of her circumstances. I note my expert's advice that paracetamol's ability to cause liver failure in the standard adult dose in patients with malnutrition is not widely recognised. However, overall, I am concerned at the standard of care Mrs A received. The DHB has a responsibility to ensure that its staff provide services of an appropriate standard. In my view, the DHB did not provide services to Mrs A with reasonable care and skill and, accordingly, it breached Right 4(1) of the Code.

120. I consider that the nursing staff did well to withhold paracetamol, on occasion, in response to Mrs A's deteriorating liver function. However, there was inadequate communication between nursing and medical teams regarding the withholding of paracetamol in response to Mrs A's deranged LFTs, and inadequate recording of communications. Furthermore, Dr E re-charted Mrs A's medications exactly as they had been charted in the previous medication chart, including paracetamol 1g four times daily. Dr E was not aware of any request to stop paracetamol, as the request had not been documented or communicated, and the prescription had been signed off by a ward pharmacist with no issues raised. The DHB staff did not communicate effectively to ensure quality and continuity of services provided to Mrs A and, accordingly, I find the DHB in breach of Right 4(5) of the Code.

Other comment — Perioperative care

121. Around Day 18, Mrs A's LFTs became deranged, and she deteriorated. Mrs A subsequently died, and an autopsy indicated that the cause of death was sepsis from recent bowel surgery and peritonitis.

122. Dr D told HDC that all necessary medical investigations were carried out to determine the cause of Mrs A's clinical deterioration. In particular, several tests were carried out to investigate the cause of her deranged LFTs. From Day 26, Mrs A began to deteriorate, and Dr D told HDC that Mrs A had signs of developing sepsis, and she was commenced on antibiotics. On Day 27, a CT scan was conducted in an attempt to localise Mrs A's developing sepsis.

123. Dr Keating advised that in the final week of Mrs A's life there was increasing evidence of abdominal sepsis with a rising C-reactive protein, although Mrs A remained afebrile,[52] and initially her white blood cell count[53] was normal. Dr Keating stated: "It is frequently the case in elderly patients that abdominal or general sepsis may not be associated with the usual signs of fever that are demonstrated in younger patients."

124. Overall, I am satisfied that appropriate measures were undertaken to investigate the cause of Mrs A's deranged LFTs and in response to her developing sepsis.

[52] Without fever.
[53] High white blood cell count usually indicates an increased production of white blood cells to fight an infection.

125. Although Dr Keating advised that, in his view, most aspects of Mrs A's care were carried out to a high standard, he advised that Mrs A's nutritional management in the perioperative setting could have been better managed by a more proactive approach. However, Dr Keating acknowledged that considerable effort was put into trying to improve Mrs A's protein and calorie intake with Fortisip, although he noted that she appeared resistant to drinking this on occasion. Dr Keating stated: "A period of enteral feeding via a nasojejunal tube[54] or intravenous nutrition should have been considered prior to surgery."

126. I acknowledge Dr Keating's comments that Mrs A's perioperative nutritional management could have been better. However, I am satisfied that appropriate measures were undertaken in terms of regular gastroenterology and dietician review in response to Mrs A's poor nutritional status.

Other comment — Communication with family

127. Mrs B has raised concerns about the manner in which she and her family were spoken to by Dr D. She said that they were shouted at. Dr D told HDC that he does not shout at patients, but that his voice tends to be loud. In addition, he said that he did not mean anything seriously by telling Mrs B she was asking too many questions.

128. Given the evidence I have on this point, I am unable to conclude what was said to Mrs A's family, and in what tone. I trust that Dr D will take this opportunity to reflect on the way in which he communicates with patients and their families in future.

129. Mrs B also complained that the charge nurse in the general surgical ward shouted at her brother for asking questions about the food Mrs A was receiving. The charge nurse manager stated that she did not recall this incident, but she apologised in writing to Mrs B for this "apparent behaviour which is totally out of character". The charge nurse manager stated that the incident had been discussed with the wider staff to alert them of how their responses could be perceived.

130. Again, I am unable to conclude what was said to Mrs B's brother and in what tone. However, I consider it appropriate that this matter has been addressed with nursing staff, and I trust it will be reflected upon.

131. Mrs B also complained that when she went to visit her mother on Day 32, she found her "cuffed to the bed". After raising concern about this with staff members, the reasons for restraint were discussed with the family. The DHB told HDC that it is usual practice to inform the family of a patient the reasons for restraint as soon as they arrive. I note that the DHB apologised in writing to Mrs B that this was not done in this instance.

[54] Used to provide nutrition to patients who need nutritional supplementation.

Recommendations

132. I recommend that the DHB:

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

b) Within three months of the date of this decision:

i. Provide confirmation to HDC that Mrs A's case was discussed at the DHB Mortality and Morbidity Review, and provide a copy of the minutes from the discussion.

ii. Recirculate a copy of the memorandum (which was sent by the Head of Surgery to all senior medical officers, registrars, and house surgeons highlighting the need for paracetamol adjustment in patients with low body weight and cautioning its use in those with liver failure) around the DHB, and send a copy of this memorandum to HDC.

iii. Provide evidence to HDC that the SBARR communication tool has been reintroduced effectively and is being used by clinical staff when handing over patient care.

iv. Provide to HDC the results of an audit of medication charts (over a period of three months following the date of my final decision) showing whether charts have been properly updated where medications have been discontinued.

v. Provide an update to HDC on the success of the DHB "Staff Stories" debriefing initiative.

Follow-up actions

133. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waikato District Health Board, will be sent to DHB Shared Services.

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

Appendix A — Liver function test results

Date	Day 1	Day 4	Day 7	Day 12	Day 15	Day 18	Day 20	Day 21	Day 25	Day 29	Day 31	Day 33
ALT	26	21	29	27	34	308	830	209	102	141	108	45
ALP	164	113	128	110	109	592	605	483	225	433	298	164
GGT	16	13	16	15	17	205	243	209	102	169	199	154
Bilirubin	6	2	3	3	3	11	10	9	9	27	75	77
Albumin	28	20	25	22	16	15	16	14	12	8	18	18

Key	
	Outside of normal range
	Furthest outside of normal range

Interpreting LFTs

Alanine aminotransferase (ALT) normal range 0–45 U/L
Significantly elevated levels of ALT often suggest the existence of other medical problems including viral hepatitis, diabetes, congestive heart failure, liver damage, and bile duct problems, so ALT is commonly used to screen for liver problems.

Alkaline phosphatase (ALP) normal range 40–100 U/L
ALP is an enzyme in the cells lining the biliary ducts of the liver. ALP levels in plasma rise with large bile duct obstruction, intrahepatic cholestasis, or infiltrative diseases of the liver.

Gamma-glutamyl transferase (GGT) normal range 0–50 U/L
GGT may be elevated with even minor, subclinical levels of liver dysfunction. It can also be helpful in identifying the cause of an isolated elevation in ALP.

Bilirubin normal range 0–24 µmol/L
Increased bilirubin causes jaundice, and can indicate a number of problems including: haemolytic anaemias, internal haemorrhage, cirrhosis, viral hepatitis, and obstruction of the bile ducts.

Albumin normal range 36–50 g/L
Albumin is a protein made specifically by the liver. Albumin levels are decreased in chronic liver disease. The consequence of low albumin can be oedema, an abnormal accumulation of fluid under the skin.

Appendix B — Paracetamol charted and administered

Date	Paracetamol prescribed/charted	Total daily paracetamol administered	Date	Paracetamol prescribed/charted	Total daily paracetamol administered
Day 2	1g qid prn	1g	Day 19	"	0
Day 3	"	1g	Day 20	"	0
Day 4	"	0	Day 21	"	0
Day 5	"	0	Day 22	"	0
Day 6	"	0	Day 23	1g qid regular (recharted)	0
Day 7	"	0	Day 24	"	1g
Day 8	"	0	Day 25	"	2g
Day 9	"	0	Day 26	"	1.5g
Day 10	"	0	Day 27	"	3g
Day 11	"	0	Day 28	"	3g
Day 12	"	2g	Day 29	"	3g
Day 13	"	1g	Day 30	"	2g
Day 14	"	1g	Day 30	"Not for paracetamol"	0
Day 15	"	3g	Day 31		0
Day 16	"	2g	Day 32		0
Day 17	1g qid prn	4g	Day 33		0
Day 18	1g qid regular	2g			

QID — four times daily.

PRN — as needed.

Appendix C — Independent expert advice to the Commissioner

The following expert advice was obtained from Associate Professor Matt Doogue:

"I am a qualified medical practitioner with vocational registration in the specialties of Clinical Pharmacology and Endocrinology. My qualifications include MB ChE 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.

Background
I have been asked to provide advice to the Health and Disability Commissioner regarding a complaint regarding the care of [Mrs A] (deceased) at [the Hospital], date of birth […] Ref C13HDC00306. I have been provided with copies of the documents listed in the letter of 9 October 2013.

I have no personal or professional conflict of interest to declare related to this case.

This case has been reviewed by Dr Maplesden, an HDC medical advisor, and I have been asked to comment particularly on the possibility of paracetamol related hepatotoxicity and the overall medical management. In addition seven specific questions have been asked and are discussed below.

My comments are in the context of my expertise as a physician specialising in Clinical Pharmacology and Endocrinology with some experience in General Medicine. There are aspects of the case and questions that are outside my areas of expertise [and] these are noted within my comments.

Case Information

The time of events are documented in the clinical notes and well summarized in the autopsy report. Key dates are:

[Day 3] — [Mrs A] was admitted to [the Hospital]
[Day 13] — surgery, right hemicolectomy
[Day 33] — died

[Day 3] [Mrs A] was admitted to hospital with abdominal pain, anorexia and weight loss. [Mrs A's] known medical conditions at the time of admission to hospital included:

Crohn's disease (well controlled currently)
Ischaemic heart disease — inferior myocardial infarction (stent right coronary artery)
Gastro-oesophageal reflux.
Previous appendectomy and cholecystectomy.

Her usual medications at admission were recorded as:

Aspirin l00 mg daily
Clopidogrel 75 mg daily
Ferrous sulphate 325 mg daily
Atorvastatin 40 mg daily
Quinapril 2.5 mg daily
Metoprolol 23.75 mg daily
Pantoprazole 20 mg daily
Escitaloprim 20 mg daily
Domperidone 10 mg daily
Creon forte EC™ ii capsules three times daily

[Mrs A] was frail —weight 40 kg (colonoscopy worksheet), BMI 17.

Colon cancer was diagnosed and to treat bowel obstruction a right hemicolectomy was undertaken [Day 13]. Subsequently, concern about 'deranged LFTs' was recorded in the clinical notes, including [Days 22 and 23]. There was marked clinical deterioration from [Day 28] and [Mrs A] died [a few days later].

The autopsy noted:

The recent right hemicolectomy with features of peritonitis and ascites.
Liver failure with oedema and a 'normal' paracetamol level.
Diffuse alveolar damage and pleural effusions.
Cardiovascular atheromatous disease and evidence of a previous myocardial infarction.

Cause of Death: The coroner found the Cause of Death was:

1. a) sepsis, b) peritonitis and recent bowel surgery

2. Liver failure, and respiratory failure due to diffuse alveolar damage.

Toxicology: The toxicology report included 'no paracetamol' detected by GCMS and a blood morphine concentration of 0.09 mg/L. Tramadol, oxycodone, cyclizine, and citalopram were also all detected.

Documentation of death in the clinical notes:

The record of death notes: Liver failure, post hemicolectomy, fluid overload, complex post-op issues, long stay in HDU, on TPN, blood culture positive [Day 30].

The death certificate documents cause of death a) liver failure, b) ?paracetamol toxicity, c) colon cancer.

During [Mrs A's] hospital admission she was predominantly cared for on a general surgical ward. This is usual for someone having colon surgery and her care should be evaluated in that context. While care may have been different under another service the overall mix of skills on a general surgical ward are most appropriate to the care of a sick patient before and after surgery.

[Mrs A's] daughter [Mrs B] notes she was at [the Hospital] every day for the four and a half weeks of her mother's stay. She observed a number of distressing events over that time and raised a number of questions. I acknowledge the family's loss and the distress they went through. I have considered the information in her letter together with the other records provided. My responses are to the questions raised by HDC.

Paracetamol and its potential causal role in [Mrs A's] liver failure.

Background
Paracetamol is widely used for pain relief in hospital and in the community. While generally regarded as 'safe and effective', when taken in overdose it can cause liver failure and death. Intentional paracetamol overdose is common in New Zealand but because there is an effective antidote (n-acetyl cysteine) liver failure secondary to paracetamol overdose is uncommon in New Zealand. It should be noted that liver damage from paracetamol does not occur immediately, it occurs 1–4 days after acute overdose.

The maximum recommended adult dose for paracetamol is one gram four times daily. When taken acutely in overdose ten grams can be sufficient to cause liver damage. Paracetamol concentrations are routinely measured in the assessment of acute overdose and there are well established 'safe' concentrations.

When taken chronically the usual daily maximum dose of four grams can cause liver toxicity for a small number of susceptible patients. This is largely due to increased production and/or decreased removal of N-acetyl-p-benzoquinone imine (NAPQI), the toxic metabolite of paracetamol. Susceptible people include those with frailty/malnutrition and alcohol abuse. The paracetamol monograph in the New Zealand Formulary includes the caution: *maximum daily dose 3g in patients with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition or dehydration.*

Some other drug formularies available in NZ mention cautions but do not provide specific dosing advice. The maximum dose I would usually recommend in a frail severely malnourished patient is 2 g per day in divided doses.

An epidemiological study of acute liver injury (ALI) associated with therapeutic paracetamol (4g or less daily) reported the incidence of acute liver injury as 2.4 cases per 100,000 person-years of exposure with a relative risk (RR) of 7.0 (99% Cl 3.3–13.9) v non exposed patients.[1] Several case series of liver failure and death due to chronic toxicity have been reported with doses of 2–4g per day.[2] [3] [4]

[1] Sabalé M, Ibáñez L, Pérez E, Vidai X, Buti M, Xiol X, Mas A, Guarner C, Forné M Solà R Castellote J, Rigau J, Laporte JR. (2007), Risk of acute liver injury associated with the use of drugs: a multicentre population survey. Alimentary Phanuacology & Therapeutics, 25: 1401−1409.

[2] Larson, A. M., Poison, J., Fontana, R J., Davern, T. J., Lalani, E., Hynan, L. S., Reisch, J. S., Schiødt, F. V., Ostapowicz, G., Shalcil, A. O., and Lee, W. M. (2005), Acetaininophen-induced acute liver failure: Results of a United States multicenter, prospective study. Hepatology, 42: 1364−1372.

[3] Gow PJ, Jones PM, Dobson JL, Angus PW. Etiology and outcome of fulminant hepatic failure managed at an Australian liver transplant unit. *J Gastroenterol Hepatol* 2004; 19: 154−159.

[4] Maldn A, Williams R. Paracetamol hepatotoxicity and alcohol consumption in deliberate and accidental overdose. *Q J Med* 2000; 93: 341–349.

[Mrs A] was frail and malnourished with evidence of liver damage. Her prescribed and administered paracetamol doses were documented in the medication charts as follows:

Date	*Paracetamol prescribed*	*Total daily paracetamol administered*	*Date*	*Paracetamol prescribed*	*Total daily paracetamol administered*
[Day 2]	1g qid prn	1g	*[Day 19]*		0
[Day 3]		1g	*[Day 20]*		0
[Day 4]		0	*[Day 21]*		0
[Day 5]		0	*[Day 22]*		0
[Day 6]		0	*[Day 23]*		0
[Day 7]		0	*[Day 24]*		1g
[Day 8]		0	*[Day 25]*		2g
[Day 9]		0	*[Day 26]*		1.5g
[Day 10]		0	*[Day 27]*		3g
[Day 11]		0	*[Day 28]*		3g
[Day 12]		2g	*[Day 29]*		3g
[Day 13]		1g	*[Day 30]*		2g
[Day 14]		1g	*[Day 30]*	**Not for paracetamol**	0
[Day 15]		3g	*[Day 31]*		0
[Day 16]		2g	*[Day 32]*		0
[Day 17]	1g qid prn	3g	*[Day 33]*		0
[Day 18]	1g qid regular	2g			

The latter medication charts had ‘not for paracetamol’ written on them. From the notes this was effective [Day 30].

[Day 23] — review by [Dr C], her regular gastroenterologist, of the disordered liver function tests, noted a drug induced hepatitis was ‘likely’ and he requested several tests including hepatitis screen. These other tests were subsequently negative.

[Day 30] — ‘gastro r/v [Dr H]’ documented potential drug toxicity (specifically referring to paracetamol toxicity) as ‘less likely’ in the differential diagnosis. He recommended ceasing paracetamol and atorvastatin. Treatment with N-acetyl cysteine was considered and subsequently decided against pending ‘paracetamol

levels'. The paracetamol concentration was noted that evening by [a doctor] who documented discussion of the result with [Dr H] and a decision not to treat with n-acetyl cysteine was made.

Subsequently, N-acetyl cysteine was administered on [Day 32]. This is unlikely to have had any bearing on the outcome.

Liver function tests

Test	*[Day 1]*	*[Day 4]*	*[Day 7]*	*[Day 12]*	*[Day 15]*	*[Day 18]*	*[Day 21]*	*[Day 25]*	*[Day 29]*	*[Day 31]*	*[Day 33]*
ALT	26	21	29	27	34	308	209	102	141	108	45
ALP	164	113	128	110	109	592	483	225	433	298	164
GGT	16	13	16	15	17	205	209	102	169	199	154
Bilirubin	6	2	3	3	3	11	9	9	27	75	77
Albumin	28	20	25	22	16	15	14	12	8	18	18

	[Day 3]	*[Day 8]*	*[Day 12]*	*[Day 28]*	*[Day 30]*	*[Day 31]*	*[Day 33]*
INR	1.1	1.1	1.8	3.6	2.3	3.1	1.4

The rise in liver function tests began [Day 18]. Her albumin and INR, markers of synthetic function were low and high respectively prior to this, suggesting significant malnutrition and metabolic compromise. The ALT peak of 308 is not very high, with paracetamol overdoses often causing very high ALT concentrations (>1000).

Paracetamol concentrations (levels) were:

[Day 28] 09:20 235 umol/L

[Day 30] 04:30 227 umol/L

These concentrations are consistent with impaired drug metabolism due to liver impairment and are higher than usually seen with therapeutic dosing. These concentrations are plausible for the reported doses from [Days 24–30] (above) and are such that paracetamol toxicity is possible. It should be noted that paracetamol concentrations are less useful/predictive in chronic overdose than acute overdose.

That paracetamol was not detected in the post-mortem samples is expected and does not exclude toxicity. Assessing possible causality of the initial liver injury using the Naranjo scale the score is 5 (probable). The ALT subsequently declined when paracetamol was not administered and no other causes were identified. However the ALT did not increase when paracetamol was restarted with the

subsequent liver failure being biochemically evident in the albumin, INR and bilirubin results. No single item of information is definitive.

Opinion
Paracetamol is a possible cause of the initial liver injury.

Prior to the blood tests on [Day 18] [Mrs A] received 12 g of paracetamol over 6 days. This is about the maximum daily dose for a frail patient I would recommend and is less than recommended by common drug references. Given her condition paracetamol toxicity is a possible cause of liver injury and other causes were not demonstrated.

The prescribed doses of paracetamol were inappropriate but these doses were not administered. Such prescribing occurs frequently in our hospitals and is a significant risk to frail patients.

Subsequently 15.5g of paracetamol was administered over a week [Days 24-30]. As noted above, the prescribed doses were inappropriate. With evidence of liver injury the paracetamol should probably have been ceased. This is a prescribing error often seen in hospitals, which does not often cause harm but can have serious consequences.

Opinion

The progression of liver failure may have been contributed to by the second course of paracetamol. Sepsis may have been in part a consequence of the liver failure. Each increases the risk of the other. Overwhelming sepsis is a frequent final consequence of liver failure.

Answers to specific questions

Management of [Mrs A's] nutritional status
Note: While low albumin is often associated with poor nutrition the association is indirect. Hypoalbuminaemia is related to ill health and it is not a reliable marker of poor nutrition per se. Young people with severe anorexia nearly always have 'normal' albumin concentrations. Low albumin is commonly associated with systemic illness particularly inflammatory conditions and hepatic failure and occasionally failure of other organs. Anorexia is a common symptom with many systemic illnesses.

I am not an expert on nutritional management. From my reading of the case notes [Mrs A's] nutritional management was consistent with what is often seen in similar patients in our hospital.

Post operatively, nutritional supplements were provided and there was dietician assessment and advice including on [Days 15, 22 and 26]. Concerns re adequacy of oral nutrition were apparent several days after surgery. Parenteral nutrition (TPN) was initiated [Day 28] and commenced [Day 29]. These were also the dates of significant clinical deterioration. In this case the combination of hypoalbuminaemia and a raised INR were a 'flag' of poor nutrition and there were efforts to address this by the clinical staff.

Management of [Mrs A's] fluids, particularly following 'the episode of prolonged hypotension following abdominal drain insertion on [Day 28]'.
I am not an expert on intensive periprocedural management. From my reading of the case notes, [Mrs A's] fluid management was consistent with what is often seen in similar patients in our hospital. In retrospect, the management was not 'ideal' but the decisions were made on the basis of information at the time, for example when a decision was made to attempt peripheral venous cannulation it was not known that the cannulation will be successful.

Obtaining vascular access: Following abdominal drain insertion at 11:05 [Day 28] the blood pressure dropped. There were several failed attempts to establish intravenous access including several attempts at canullation on the ward by nurse and house officer and an unsuccessful attempt at PICC line insertion. Intravenous access was obtained at 18:00 on [Day 28] with a central line. The blood pressure nadir was after central access was obtained (66–96/20–40). The blood pressures prior to that were not dramatically different to previous recordings. The drain was also clamped.

Administration of fluids: [Mrs A] was small and frail with a history of ischaemic heart disease. Two boluses of 500mls of 'Hartmans' and 'Gelofusin' at 21:00 and 21:30, then 'Hartmans' was administered at 125 ml/hr. There was recovery of blood pressure.

Management of [Mrs A's] decreased responsiveness on [Day 28] and [Day 29] including hypoglycaemia.
I am a specialist endocrinologist and assessment and management of hypoglycaemia is within my expertise. [Day 28] 2 1:36 The clinical notes documented 'alert, GCS 15. Able to speak full sentences' after previously being more unwell and having had fluid resuscitation. During the night of [Day 28–Day 29] there was deterioration with increased confusion and the Adult Deterioration Detections system (ADDS) was activated triggering medical review, there was no HDU bed available and care continued on the ward.

On the morning of [Day 29] ongoing medical concerns were noted and [Mrs A] was transferred to HDU early afternoon. She was seen by [Dr D] early afternoon and a meeting with the family to discuss the serious illness and deterioration was noted. Ward round noted her confusion and rapid decline over hours.

[Day 29] 22:00, hypoglycaemia, venous blood glucose 2.2 mmol/L was recorded in the notes. 50 mls of 50% glucose was given with improvement patient now more awake and answering questions, BSL improved to 8.2. It was also noted that the glucose was 1.8 mmol/L on [Day 28]. Capillary blood glucoses were recorded for the following few days with results 5.9–16.8 mmol/L. The medication list obtained from [a medical officer] on the police report includes insulin. In the notes provided the only record of insulin administration I found was 5 units of neutral insulin (Actrapid) given on [Day 31] and there was no record of treatment with sulphonylureas (another class of medicine that can cause hypoglycaemia). The admission note did not document diabetes or any treatment of diabetes.

Hypoglycaemia in the absence of treatment with insulin or other hypoglycaemic drugs is uncommon. There is no information to suggest insulinoma or other rare

causes of hypoglycaemia. In hepatic failure there is failure of gluconeogenesis (hepatic glucose production) and hypoglycaemia can occur.

Glucose measurement is subject to several sources of error and a single result is not diagnostic. In this context I would usually ask for a repeat sample for glucose (in a fluoride tube) and insulin and c-peptide prior administration of glucose. I should note that this is commonly not done, usual practice does not equal best practice. The most important measure is administration of glucose and assessment of response, this was done.

Opinion

There were other potential reasons for her fluctuating level of consciousness. Hypoglycaemia was not proven but may have occurred due to the severity of her hepatic failure and nutritional state. The low laboratory glucose result from [Day 28] appears to have been missed and should have been followed up.

Investigation and management of [Mrs A's] impaired liver function and the likely aetiology of the deterioration in liver function

I am not a gastroenterologist (liver expert) and there were gastroenterologists involved in [Mrs A's] care. From my reading of the records, the investigation and management were consistent with what is practised in tertiary hospitals I have worked in.

Regarding the likely aetiology of the deterioration in liver function, in my view paracetamol toxicity is a possible cause of her liver injury or may have been a contributory factor. For example ischaemia post-operatively could have been another contributor.

Management of [Mrs A's] post-operative sepsis

I am not an infectious diseases specialist. The question of post operative sepsis is not clear. There were no clinical concerns re sepsis documented after the procedure and observations did not raise concerns e.g. 'afebrile'. The wound healed well with no external signs of infection.

[Day 25] Blood count showed a high neutrophil count (19.1).

The C-reactive protein (CRP) had been falling post-operatively and was markedly increased when measured on [Day 26].

[Day 26] Antibiotics: intravenous Augmentin and oral metronidazole were commenced. A dose of trimethoprim was also administered and the notes refer to a urine sample prior to commencing antibiotics.

Abdominal fluid drained was serous fluid with no suggestion of infection. This was consistent with ascites associated with severe hypoalbuminaemia rather than intra-abdominal sepsis.

[Day 32] A dose of gentamicin, 200 mg was administered.

Blood culture taken [Day 30] was subsequently reported positive for pseudomonas aeruginosa.

A focus of infection or causative organism was not known at the time of clinical and biochemical deterioration and the initiation of antibiotics was 'empiric'. At this stage the most common cause of infection would be respiratory or urinary and the Augmentin™ would have covered these. Potential anaerobes were covered with metronidazole. Coverage of gram negative infection may have been insufficient with Augmentin™ and metronidazole alone from [Day 26]. Assessment of local guidelines and evaluation against these would provide more information should this be wanted.

The documentation of the potential cause of infection and consequent treatment choice is somewhat unclear. The treatment may have been reasonable under the circumstances. However, some others would have provided greater gram negative coverage in this context e.g. with gentamicin.

Appropriateness of dose and duration of paracetamol for [Mrs A] given her condition and contemporaneous laboratory results
See above

Departures from the accepted standard of care

1. Standard not met — correct drug doses should be prescribed.

The prescribed paracetamol dose was that for a healthy adult and was too high for a frail patient with liver failure. However the prescribed dose was not administered. This is a common occurrence in hospitals. This is a moderate departure from expected standards in that such dosing could be fatal but seldom causes harm as patients don't receive prescribed doses. However, this is the dose included in several standard references. That some standard reference sources are inadequate is a factor in such prescribing.

2. Standard not met — prescribed doses should be administered or a review requested.

Some prescribed drugs were not administered. This is a moderate departure from expected standards of care. It had some favourable effects in this case. However, that patients frequently don't receive prescribed medicines is a major problem in our hospitals.

Associate Professor Matt Doogue"

Appendix D — Independent expert advice to the Commissioner

The following expert advice was obtained from consultant colorectal and general surgeon Mr John Keating:

> "[Mrs A] was admitted to the Emergency Room of [the Hospital] on the evening of [Day 1] with a history of six days of colicky abdominal pain in the centre of the abdomen associated with vomiting.
>
> There had been a history of weight loss over the preceding 18 months to 2 years, to a weight on admission of 39kg.
>
> Patient was known to have a long history of Crohn's disease for which she was under gastroenterological review with [Dr C] in the private sector. She had undergone coronary artery percutaneous intervention for ischaemic heart disease and was known to have suffered an inferior myocardial infarction.
>
> The working diagnosis on admission to [the Hospital], and supported by the plain abdominal films, was of a small bowel obstruction. The patient had previously had a cholecystectomy and gynaecological surgery and the differential diagnosis was one of adhesion obstruction or a Crohn's stricture. On that basis the patient was treated initially with intravenous fluid replacement and gut rest and after consultation with the gastroenterologist, [Dr C], an MR enterography was performed on [Day 6] to image the small bowel. That study demonstrated a lesion at the hepatic flexure of the colon suggestive of a colonic carcinoma, and the patient at that point was transferred to the care of [Dr C] and arrangements made for a colonoscopy.
>
> Attempted colonoscopy was performed on [Day 9] after bowel preparation but unfortunately a complete examination of the colon to the hepatic flexure could not be completed due to excessive bowel looping.
>
> The patient then proceeded to a staging chest, abdomen and pelvis CT scan on [Day 12], which again demonstrated the lesion at the hepatic flexure but did not show evidence of metastatic disease. On [Day 12], surgical consultation with the colorectal team at [the Hospital] was obtained and arrangements were made for a hemicolectomy to be performed the following day to deal with the obstructing colonic neoplasm.
>
> Surgery was performed via a mini-laparotomy by [Dr D] and his team on [Day 13]. A straight forward operation was performed via an open technique with a side-to-side anastomosis.
>
> In the post-operative period the patient was noted to be hypotensive with the systolic blood pressure between 75 and 80 in the early post-operative period, certainly for the first 10 hours after surgery.
>
> Despite this the patient made good volumes of urine, and on the ward round the next day was producing 35ml/kg per hour of urine, about 1ml/kg/hr, which was more than adequate in the post-operative setting.

The patient continued to make good progress in the early post-operative period and consideration for discharge home was discussed on Day 16, the third post-operative day.

The patient was reviewed on [Day 16] by [Dr C] who reported that he was happy with her post-operative progress.

At midday on [Day 17] the nursing notes record a large volume of haemoserous discharge from the middle of the wound and on [Day 18] the house surgeon notes query the presence of a peritoneal on examination of the patient but gastroenterology were consulted again in view of the patient's general malaise and blood tests which showed deteriorating liver function tests with a significant and sharp rise in the ALT, the Gamma GT and the alkaline phosphatase. Of note it was that the pre-operative INR was in fact 1.8.

In view of the fact that the patient was complaining of abdominal pain on the 18th, which was five days post-operatively, a CT scan of the abdomen was performed. This demonstrated the presence of a moderate amount of abdominal ascites and some small locules of air in the upper abdomen, which would be consistent with a recent laparotomy. The C-reactive protein at this stage was not markedly elevated at 74.

Over the succeeding four days the liver function tests continued to be significantly abnormal, although they did fluctuate, but there was significant raised ALT which reached a peak of over 800.

[Dr C] again reviewed the patient and the liver function tests on [Day 23] and in his review commented that there were 'no specific recent drugs to explain the liver function tests but the drug induced hepatitis was the most likely cause for the deranged liver function tests'. He suggested a series of viral serology tests to exclude a viral cause for hepatitis, including BC and Epstein Barr virus and a series of autoantibodies to exclude autoimmune hepatitis. On [Day 26], liver function tests showed an improvement in the drop in the alkaline phosphatase, Gamma GT and ALT but they did increase again on [Day 29]. On [Day 28] the INR was measured and found to be grossly abnormal at 3.5. Such a result suggests severe impairment of liver synthetic function. An ultrasound was performed to exclude a mesenteric venous or portal vein thrombosis, although the previous CT scan had demonstrated there appeared to be no problem with the mesenteric vessels.

The patient became confused on the evening of [Day 28] and the morning of [Day 29] and a senior house officer in the surgical unit on the HDU noted that the venous blood gas on [Day 28] was 1.8 and the patient's confusion rapidly improved after administration of 50ml of 50% glucose.

Multiple reviews by the dietetics team during the admission confirmed poor oral intake and a degree of malnutrition that would have been present since admission, and significant advice about provision of oral Fortisip had been made. [Dr C] had also suggested a high protein, low fibre diet in his early review.

Two CT scans were performed in view of the patient's post-operative deterioration, the first on day 6, which demonstrated ascites but no evidence of a

leak from the ileocolic anastomosis, neither was there evidence of intestinal obstruction. A further CT scan was performed on day 14, which showed a significant increase in the volume of ascites, but again no evidence of a primary surgical problem with the resection and anastomosis.

On [Day 28], in view of the patient's continuing deterioration and poor nutritional input, a PICC line was inserted. Diarrhoea was investigated with stool cultures and a flexible sigmoidoscopy, which showed no evidence of clostridium difficile colitis. Repeat gastro review noted the increase in C-reactive protein in liver function tests. In spite of transfer to the HDU and treatment with blood transfusion, Albumin supplementation to treat the extensive oedema and change of antibiotics, the patient became hypotensive and oliguric. Renal review confirmed there was no primary renal issue. The patient continued to deteriorate in spite of treatment of intravenous antibiotics to cover the gram-negative bacillus which was found on blood culture. The patient became confused and died after transfer out of the HDU on the evening of [Day 33].

I concur the likely cause of death was sepsis associated with acute post-operative liver failure, likely be due to Paracetamol toxicity in a malnourished patient following a seemingly uneventful emergent right hemicolectomy for a locally advanced hepatic flexure cancer, confirmed by the pathologist as a T3N1 tumour.

Was the quality of surgical care of an adequate standard?
The patient, in my view, was appropriately managed in the acute presentation. She had appropriate and timely investigations of her intestinal obstruction. When colonoscopy found to visualise the lesion, she appropriately went to surgery on the basis of her MR enterography and her staging CT scan. She had a competently performed operation with a resection of the tumour and a primary anastomosis.

I do note that the patient was hypotensive in the first 12 to 18 hours following surgery, although I do not think this had a bearing on her subsequent liver failure, in that she had an excellent urine output in the first 24 to 36 hours following her surgery and it would be very unlikely that this would have been the case had she had hypotension causing ischaemic liver disease.

When the patient became unwell in the post-operative period, gastro review was sought and a fairly standard screen for liver disease was performed to exclude the common important cases of liver disease.

It was identified that a drug cause for liver disease was the likely cause of her liver dysfunction. But Paracetamol in the early post-operative period was not identified as the likely drug.

Parecentesis was performed but I am not sure that this was necessary and may have complicated the clinical picture, in that the patient became hypotensive following paracentesis of her ascites. A diagnostic tap may have been all that was required to culture the peritoneal fluid. In the final week of her life there was increasing evidence of abdominal sepsis with a rising C-reactive protein, although the patient remained afebrile, and the white count initially was normal. It is frequently the case in elderly patients that abdominal or general sepsis may not be associated with the usual signs of fever that are demonstrated in younger patients.

The patient was started on antibiotics, initially for a presumed urinary infection, and subsequently in view of her abdominal pain, a broader spectrum combination was started of Cefuroxime, Metronidazole which was subsequently changed to Ceftazidime to increase the spectrum of coverage.

The microbiologist reported a gram-negative bacillus on microscopy of her blood culture and subsequently this was shown to be due to pseudomonas. I have little doubt the patient died from sepsis associated with acute liver failure which was likely to be drug induced secondary to a standard dose of Paracetamol.

This complex post-operative problem of drug induced liver failure and its sequelae of a peritoneal infection of ascitic fluid in the absence of a leak from a healthy anastomosis, clearly presented diagnostic dilemma.

The likely cause of the liver failure was identified by [Dr C] as being a drug induced problem on [Day 23]. I am not convinced however that if N-Acetyl Cysteine (NAC) had been administered at that stage, rather than on admission to the High Dependency Unit on [Day 30], would have significantly changed the course or the outcome of [Mrs A's] illness and subsequent demise. However this aspect of the patient's care would be best addressed by a clinical pharmacologist with an expertise in paracetamol poisoning.

The nutritional management of the patient in the perioperative setting could have been better. Her BMI at operation was less than 17 calculated from the anaesthetic record (Wt. 39kgs). According to the dietetic notes her healthy (premorbid weight) 18–24 months previously was 52 kgs and thus she had a 25% weight loss from her healthy weight. Such indices put her at high risk of perioperative complications. Although considerable effort was put into trying to improve her protein and calorie intake with supplemental drinks she appeared resistant to taking them as 'they go right through me'. A period of enteral feeding via a nasojejunal tube or intravenous nutrition should have been considered prior to surgery. Likewise a nasojejunal tube could have been placed in the operating theatre to improve her post-operative nutrition. Having said that it is far from clear whether these measures would have prevented her liver failure.

Was the general investigation, management of [Mrs A's] impaired liver function tests satisfactory?

The patient's liver function tests pre-operatively on [Day 4] were essentially normal apart from a low serum Albumin commensurate with her degree of on-going inflammation and her poor nutritional status (BMI of 16.8).

The surgical team did have an on-going review provided by the gastro team of [Dr C]. She was reviewed on at least two occasions pre-operatively and seen post-operatively on [Day 3] where he reported he was happy with her progress. He was subsequently contacted when her liver function tests deteriorated and he reviewed her liver function tests and gave her his opinion as to the cause of the deranged liver function tests, namely that it was likely to be a drug induced hepatitis. A full series of serological and autoantibody tests were performed and found to be normal. When her liver synthetic function was found to be grossly abnormal, with an INR of 3.5 on [Day 29], she was given Vitamin K and ultrasound was performed to exclude a mesenteric venous occlusion. On [Day 30] [Dr H]

reviewed the patient from a gastroenterology point of view, as [Dr C] was away, and he confirmed the presence of an acute hepatic insult with ascites in the post-surgical setting and his differential includes hypotensive or ischaemic liver disease sepsis or drug induced disease and particularly he indicated that Paracetamol was a possible culprit. A change of antibiotics to Ceftazidime was performed, Paracetamol levels were measured, the INR was further corrected with further Vitamin K and a NAC infusion was performed. To support the patient, further treatment with 20% Albumin infusions were performed, and the patient from that point on remained under joint gastroenterological and surgical management.

Would earlier treatment with N-Acetyl Cysteine have altered the course of the natural history of the acute liver injury?
This question needs to be addressed to a hepatologist/clinical pharmacologist with an interest in drug induced liver toxicity but given the post-operative setting in a very malnourished patient and a review of some of the cases in the literature, which are rare, I have my doubts as to whether earlier treatment with NAC would have altered the eventual outcome here.

Was the episode of prolonged hypotension following abdominal drain insertion on [Day 28] managed in a timely and appropriate manner?
Throughout the patient's admission she had had low systolic blood pressures, ranging from 115 to 70–80 systolic in the early post-operative period.

After insertion of the abdominal paracentesis drain, the patient did become hypotensive down to similar levels, and she was treated with an intravenous infusion initially of Gelofusine and subsequently with a bolus dose of 500ml of Hartmann's procedure and subsequently with an increased basal rate of Hartmann's procedure and 125ml now. This seems appropriate in a woman of this size. As specified earlier, I am not sure that abdominal paracentesis was required, and I don't think it contributed to her management.

Was the management of [Mrs A's] decreased responsiveness on [Days 28 and 29] appropriate?

[Mrs A] became somewhat confused and disorientated on the evening of [Day 28]. On [Day 29] it was noted that a venous blood gas taken on the previous evening had shown a blood sugar level to be low. She was then given an appropriate infusion of 50ml of 50% glucose with a rapid improvement in her level of consciousness.

A patient with severe liver dysfunction hypoglycaemia should be thought of as a primary cause of a change in level of consciousness and the patient should have had a glucose infusion on the previous evening. She appeared to recover from her hypoglycaemia without further cerebral symptoms.

General Comments and Conclusions

[Mrs A] was admitted as an emergency with a large bowel obstruction from a locally advanced obstructing colon cancer. She was significantly malnourished on presentation with a BMI of 16.8 (weight 39kg at the time of her surgery). She had pre-existing coronary artery disease, having had coronary artery intervention in

2011. Patients undergoing urgent and emergent colonic surgery for obstruction have a high mortality, particularly if they are elderly and have a high ASA grade.

The reported perioperative mortality would be at least 20% in a patient such as [Mrs A]. After extensive review of her notes and results and consultations, I think most aspects of her care were carried out to a high standard. A timely diagnosis of the cause of her obstruction was performed. She had competently performed surgery but in spite of this she died as a result of her inpatient treatment. Her death was due to a liver failure which was likely due to Paracetamol toxicity. She had Paracetamol given in the standard dose but she developed likely Paracetamol poisoning due to her severe malnutrition. An almost identical case such as this has been reported in the literature, (British Medical Journal 2010; 341:c6764).

Her nutritional management in the perioperative period could I think have been better managed by a more proactive approach. It is impossible to say whether this would have made any difference to the outcome in this case but there was no rush to operate as her obstruction settled soon after admission and in general terms addressing nutrition problems is associated with a reduced risk of perioperative complications.

Paracetamol is known to have a fairly narrow therapeutic index but its ability to cause severe liver dysfunction liver failure in the standard adult dose in patients with malnutrition is not widely recognised and certainly deserves to be highlighted as a result of [Mrs A's] death. In review of her notes in retrospect there are some aspects of her treatment which may have been improved upon. On [Day 23], when it was discussed that the likely cause of her liver failure was likely due to be drug induced, she could have had a NAC infusion, although I am sceptical as to whether this would have altered the outcome of the case. I agree that her hypoglycaemia should have been treated on the evening of [Day 28] rather than on [Day 29] and I question the value of her paracentesis, although I don't think this contributed significantly to the outcome. In terms of her antibiotics, it may have been wise to treat her with a potent broad spectrum antibiotic earlier rather than treating her with Trimethoprim on the basis of a presumed urinary tract infection. I am not convinced however, that these deviations from the optimal treatment would have altered the outcome for a very serious complication in a severely malnourished woman undergoing emergent colonic surgery.

Potential alteration of the drug chart after the event.

I am concerned by the potential for the drug chart, that was re-charted by [Dr E], to have been changed after the event. [Dr E] alleges that 'not for Paracetamol' was written on the chart sometime after he had re-charted [Mrs A's] drugs and I am convinced by the veracity of his letter claiming that this comment was not present when he re-charted her drugs on [Day 23]. In conclusion, I think there is value in highlighting the potential for severe hepatic toxicity of Paracetamol in standard dosage in adult patients with severe malnutrition. There are some deviations from ideal practice in the management of a complex post-surgical problem, but I do not believe that these deviations from ideal practice resulted in her death and having extensively studied the notes I am impressed by the quality of documentation by the nursing and ancillary staff including dieticians in [the Hospital] notes.

I do think the lack of a more interventional approach to her nutritional status in the perioperative period was a deviation from best practice but should not be considered a breach of the code.

Yours sincerely

Mr John Keating MBBS (Hons) FRCS FRACS
Consultant Colorectal and General Surgeon
Wellington Hospital
Clinical Senior Lecturer in Surgery, Wellington School of Medicine"

Appendix E — Independent expert advice to the Commissioner

The following expert advice was obtained from RN Dawn Carey:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs B] about the care provided to her late mother, [Mrs A] during her in-patient stay at [the Hospital]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the available documentation on file: complaint from [Mrs B]; response from Waikato District Health Board (WDHB) including correspondence with [Mrs B], individual staff responses, clinical notes for [Mrs A], Adult pain management handbook; coronial autopsy report. I have focussed on the documentation relevant to the scope of my advice.

3. **Background**

[Mrs A] was admitted to [the Hospital] on [Day 2] with a history of worsening abdominal pain. Past medical history included Crohn's disease. In-hospital investigations determined the presence of a tumour partially obstructing the ascending colon and [Mrs A] underwent a right hemicolectomy on [Day 13]. Discharge was planned for [Day 17] but cancelled due to a high volume of haemoserous wound discharge. Over the next two weeks [Mrs A's] condition deteriorated with abnormal liver function, dependent oedema, abdominal ascites and signs of sepsis. [Mrs A] died [a few days later]. Coronial post-mortem was performed and cause of death attributed to:

I. (a) Sepsis (b) Peritonitis and recent bowel surgery II. Liver failure and respiratory failure due to diffuse alveolar damage.

Complaint

[Mrs B] complains that [Hospital] staff failed to recognise [Mrs A's] developing sepsis or identify the cause of her deranged liver function 'until it was far too late for her'.

4. **Advice requested**

As a Nursing Advisor, I have been asked to provide clinical advice on the overall management and monitoring of [Mrs A's] post-operative condition. I have been asked to comment specifically on the:

a) monitoring and assessment of [Mrs A's] liver function and developing sepsis;
b) management and monitoring of [Mrs A's] fluid status; and
c) management and monitoring of [Mrs A's] nutritional status.

My advice is limited to the nursing management of [Mrs A].

5. WDHB has provided detailed responses. For the purpose of brevity I have not repeated the response in this advice. I have reviewed it and note that it is in keeping with the contemporaneous clinical notes. In relation to the remit of my advice, I note that

   - The WDHB Medicines Management Policy requires an effective standard of interdisciplinary communication when a medication is consistently withheld or the dose altered.
   - Nursing staff in the General Surgery ward have informally case reviewed [Mrs A's] care. This has resulted in an increased awareness of Paracetamol and the need for adjustment in patients with deranged liver function.
   - [Mrs A] never received more than 3grammes (g) of Paracetamol therapy throughout her period of hospitalisation.

6. Review of clinical records

   i. **The monitoring and assessment of [Mrs A's] liver function**
   The results of [Mrs A's] serum liver function tests (LFTs) were normal on admission to [the Hospital]. Derangement was first detected from results reported on [Day 18], which are recorded as part of the surgical ward round review on [Day 19]. 'Peak' derangement was recorded on [Day 20]. In response to the deranged results nursing staff did not administer the four times per day (QID) prescribed Paracetamol therapy to [Mrs A] from [Days 18–23] inclusive. The non-administration of Paracetamol and the reason — deranged LFTs — is recorded by nursing staff on the relevant medication chart and entries in the clinical notes.

   A new seven day Adult Medication Chart (AMC) was commenced on [Day 24]. The 'Pharm' box is initialled for this medication signifying that a Pharmacist reviewed the prescription. Responses from WDHB and staff report ambiguity as to when Paracetamol therapy was discontinued and when instructions such as *Not for Paracetamol* was added to [Mrs A's] AMC.

   Serum results indicate that [Mrs A's] liver function was deranged but improving or at least status quo between [Days 23– 27]. At approximately 2pm on [Day 29], [Mrs A] transferred from [the general surgical ward] to the High Dependency Unit (HDU). From [Day 25–30], Paracetamol was administered by nursing staff ([general surgical ward] and HDU) three times per day with some administration doses recorded as 500milligrams (mgs). This is less than the prescribed dose and frequency. Clinical notes on [Day 30] report ... *stop Paracetamol*. Whilst the time of review is not recorded, the documentation is between entries recorded at 2.55pm and 4.30pm. AMC shows that Paracetamol was last administered by nursing staff on [Day 30] at 12pm. Based on consultation with a Gastroenterologist and [Mrs A's] blood results, an Albumin infusion and N-Acetylcysteine infusion were commenced in the HDU.

   Comments: [Mrs A] was nursed on a general surgical ward and a HDU. Between [Days 18–23], nursing staff noted [Mrs A's] initial LFTs

derangement and were mindful of this as an ongoing issue. They responded well by not administering the prescribed Paracetamol. Ideally nursing staff should have advocated that this medication be discontinued and crossed off her medication chart. The administration of Paracetamol from [Days 25–30] was not excessive based on the prescription. I acknowledge and agree with the Provider that a Pharmacist initialling the prescription is interpreted as the prescription being clinically safe and valid. The incidences of dose and frequency less than prescribed is not explained in the contemporaneous notes and I am mildly critical of this. I note that WDHB acknowledges that this documentation/communication omission is contrary to their policy and organisational expectations.

In my opinion, the nursing monitoring and assessment of [Mrs A's] liver function was appropriate and in accordance with the scope of nursing and the speciality of the nurses in question.

ii. **The monitoring and assessment of [Mrs A's] developing sepsis and fluid status**

Throughout her inpatient stay, [Mrs A] had periods of blood pressure (BP) less than 100mmHg systolic. Generally this BP was associated with satisfactory urinary output.

On [Day 26], in response to results indicating the presence of infection, [Mrs A] was commenced on antibiotic therapy. The next day [Mrs A] complained of being unable to pass urine. Nursing actions included a bladder scan and the insertion of a urinary catheter. Whilst fluid balance charts are available they are generally incomplete in relation to output. The periods of incomplete output monitoring equates to when [Mrs A] did not have a urinary catheter insitu. A factor preventing the accurate calculation of output was [Mrs A] mobilising independently to the toilet. Incidences of '*UTT'* (Up to toilet) are recorded. I note that [Mrs A's] serum tests of renal function remained satisfactory.

Nursing staff recorded [Mrs A's] weight preoperatively and then regularly [Days 16– 27]. As acknowledged by the Dietician documentation, there was a marked increase in preoperative and post operative weight. On [Day 29], [Mrs A] was commenced on high dose intravenous Frusemide therapy.

Comments: Comprehensive and regular vital sign assessments are necessary to detect the early physiological signs that can indicate developing sepsis. As such, nurses play a fundamental role in helping to identify signs that a patient is becoming unwell and requires further investigations. Fluid status is an important factor in helping to evaluate patient's vital signs. [The Hospital] Standard Observation Sheet (SOS) employs an Adult Deterioration Detection System (ADDS) as a tool to help identify patients who are at risk of deterioration. In my opinion [the Hospital's] SOS is well designed and benefits from the inclusion of '4 hour urine output' measurement range. ADDS guidelines include the suggested minimum monitoring requirements for [the Hospital's] adult patients. I note that heightened monitoring of [Mrs A's] vital signs occurred in accordance with the

WDHB Adult Deterioration Detection System (ADDS) scoring guidelines and in response to medical instructions. This is appropriate.

I consider that nursing staff commenced administration of [Mrs A's] antibiotic in an appropriate time scale and as prescribed.

Following a review of the submitted documentation I consider that the nursing care in relation to monitoring and assessing [Mrs A's] developing sepsis and fluid status was appropriate and in accordance with expected standards.

iii. **The management and monitoring of [Mrs A's] nutritional status**
The need for nutritional supplements and high protein diet for [Mrs A] was recognised promptly in her hospital admission. She was reviewed regularly by a Dietician and efforts were made to increase her nutritional intake. The success of the specified interventions was variable with [Mrs A] refusing extra snacks and becoming reluctant to drink nutritional supplements due to them going ... *straight through her.* Incidences of nausea despite the administration of a range of antiemetics also adversely affected [Mrs A's] appetite. Nursing documentation reports attempts to encourage and approximate [Mrs A's] nutritional intake. Due to ongoing issues with diarrhoea and loss of appetite, [Mrs A] was commenced on Total Parenteral Nutrition (TPN) on [Day 29] with enteral feeding via a nasogastric tube (NGT) the next day.

Comments: I consider the nursing care in relation to monitoring and assessing [Mrs A's] nutritional status to be appropriate.

7. Clinical advice

In my opinion, the nursing care provided to [Mrs A] was appropriate and in accordance with expected standards in relation to the

a) monitoring and assessment of [Mrs A's] liver function and developing sepsis;
b) management and monitoring of [Mrs A's] fluid status; and
c) management and monitoring of [Mrs A's] nutritional status.

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