Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 19HDC02347)

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Introduction

1. This report is the opinion of Carolyn Cooper, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The following issue was identified for investigation:

- *Whether a district health board[1] provided Mrs A with an appropriate standard of care during Month1[2] and Month2 2019 (inclusive).*

3. The parties directly involved in the investigation were:

Mr B	Complainant/consumer's grandson
Health New Zealand|Te Whatu Ora	District healthcare provider

4. Further information was received from:

Dr C	Surgeon

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, resulting in all district health boards being disestablished. Their functions and liabilities were merged into Health New Zealand|Te Whatu Ora. All references to [the district health board] in this report will be referred to as Health NZ.
[2] Relevant months are referred to as Months 1-2 to protect privacy.

Names have been removed to protect privacy (except the advisor). Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Dr D	Gastroenterologist
Dr E	Gastroenterologist

5. Also mentioned in this report:

Dr F	Surgeon
Dr G	Surgeon
Dr H	Radiologist

6. Independent clinical advice was obtained from a general surgeon, Dr Bernd Grunewald (Appendix A).

Background

Introduction

7. On 7 Month1, Mrs A, aged in her seventies at the time of these events, underwent an outpatient elective procedure at a public hospital to remove an ampullary adenocarcinoma (cancer in the duodenum).[3]

8. Following the procedure, Mrs A was admitted to hospital and managed non-surgically. Over the course of her admission, Mrs A's condition deteriorated, and she developed sepsis.[4] Urgent surgery was performed on 28 Month1 but, sadly, Mrs A did not recover, and she passed away on 2 Month2. The referral letter to the Coroner stated that Mrs A's cause of death was sepsis secondary to the duodenal perforation.

9. I offer my sincere condolences to Mrs A's family and friends for their loss.

Surgery on 7 Month1

10. The procedure used to remove Mrs A's cancer is known as ampullectomy (removal of the ampulla) via endoscopic retrograde cholangiopancreatography (ERCP)[5] and is technically complex. Perforation, bleeding, and pancreatitis (inflammation of the pancreas) are known risks of the procedure, which can increase the risk of mortality, and this had been explained to Mrs A preoperatively. The procedure was undertaken by experienced ERCP specialist and gastroenterologist Dr D.

11. Dr D said that the risk of pancreatitis from ERCP is 5%; however, this risk increases to 20% with an ampullectomy. The risk for perforation from ERCP alone is less than 1%, but this increases to 1–3% with an ampullectomy. Dr D also said that there is a low threshold of admitting patients because of the inherent risks associated with this type of procedure, and

[3] Adenocarcinoma is a type of cancer that forms within the glands inside the organs. The ampulla is a small opening where the pancreatic and bile ducts from the liver connect to form the first part of the small intestine (duodenum).
[4] Sepsis is the body's extreme reaction to an infection, causing the body to damage its own tissues and organs. It is a life-threatening emergency.
[5] ERCP is an invasive diagnostic and treatment procedure. The procedure uses a long tube with a small camera that is inserted via the mouth through to the digestive tract.

normally he admits at least 80% of all ERCP outpatients. Prior to the procedure, Mrs A was advised that she might need to be admitted to hospital postoperatively.

12. During the procedure, Mrs A's cancer was removed successfully. However, it was recorded that Mrs A's entire common bile duct was dilated (widened) and there was a possible guidewire[6] micro-perforation (a hole) at the opening of the pancreatic duct. Dr D inserted a metal stent (a tube to open the passageway), which was a standard treatment of possible perforations.

13. Following the procedure, the plan was for Mrs A to be admitted to hospital and administered antibiotics, for her to remain nil by mouth (NBM), for the stent to be removed via ERCP in seven days' time, and to repeat the ERCP in one to two months' time.

14. Dr D did not see Mrs A after the procedure. Dr D said that the standard of care does not require the ERCP specialist to check on patients postoperatively, while also noting that this would not be possible due to limited ERCP specialists in New Zealand. Dr D stated that although not all gastroenterologists have knowledge of undertaking an ERCP procedure, which is a technical issue, they still have significant experience in managing post-ERCP patients. Dr D said that the public hospital has an ERCP specialist on call 24 hours a day, seven days a week, and the ERCP specialist is readily available should any complications arise.

Postoperative care

7–10 Month1 — initial postoperative care and pancreatitis diagnosis

15. Initially, Mrs A was transferred to the gastroenterology ward for management, under the care of gastroenterologist Dr E. As Mrs A did not speak English, often family members were present in the hospital or could be contacted by telephone to interpret. Dr D told HDC that a senior gastroenterology fellow observed the procedure and subsequently completed the post-procedure admission, including handover of the plan (as per paragraph 13). The postoperative admission note recorded a likely perforation, and for a CT scan to be considered if Mrs A's condition worsened over the next two to three days.

16. From 7 to 9 Month1, Mrs A experienced vomiting, nausea, bloating, and abdominal pain. To address these symptoms, Mrs A was given intravenous (IV) fluids, anti-nausea medication, and pain relief. Abdominal and chest X-rays completed on 8 Month1 reported that there was 'no free air' or evidence of obstruction in the bowel. Dr D told HDC that the X-rays were normal and did not show evidence of perforation. On 9 Month1, Mrs A's blood tests showed that her inflammatory markers[7] were elevated, and she had a fever of 38°C.[8]

17. On 10 Month1, Dr E reviewed Mrs A and queried whether she had a peri-pancreatic collection[9] and pancreatitis. A plan was made to complete further investigations, including a CT scan of the abdomen and pelvis, seek a surgical review, and consider antibiotics.

[6] A guidewire is a thin wire used to control the movement of other equipment during surgery.
[7] Elevated inflammatory markers can signify inflammation or infection within the body.
[8] The normal body temperature ranges from 35.5°C to 37.5°C.
[9] Collection of fluid around the pancreas resulting from inflammation.

Subsequently, the CT scan reported a swollen pancreas with mild to moderate amounts of free fluid, but no drainable collection. Health NZ told HDC that the CT scan showed no retroperitoneal[10] gas suggestive of perforation. Similarly, Dr D told HDC that the CT scan did not support perforation but was consistent with moderately severe pancreatitis.

18. Later in the evening of 10 Month1, a surgical registrar reviewed Mrs A and explained to her that the CT scan had shown pancreatitis. The registrar suggested the insertion of a nasogastric tube (NGT)[11] if there was significant vomiting and requested an 'accurate fluid balance[12]' and daily blood tests to help determine the severity of the pancreatitis.

11–17 Month1 — transfer of care to general surgery

19. From 11 to 17 Month1, Mrs A was managed under the care of general surgeon Dr F.[13] During this period, Mrs A experienced fluctuating symptoms, and from 12 Month1 Mrs A's early warning score (EWS)[14] chart showed that she was spiking temperatures at least once a day.

20. On 11 Month1, Mrs A was seen by Dr F, who explained to her that she had pancreatitis. It was recorded that she was for 'supportive management', but the rationale for this was not noted. Supportive management included monitoring of her fluid balance status (including IV fluids administered and oral fluids taken), monitoring of her food intake, with a dietitian review and nutritional supplementation, and for further investigations to be completed.

21. From 11 to 14 Month1, Mrs A experienced abdominal pain, nausea, and fatigue. She was reviewed four times by a house officer (HO) or a registrar, who noted that despite her pancreatitis she was managing to eat and drink, and that she was 'bloated but a lot better'. Secondary diagnoses of constipation and dehydration were made, and the plan was for laxatives, mobilisation, and eating and drinking. A dietitian recorded a plan for nutritional supplementation and daily weighs[15] due to Mrs A's poor intake.

22. On 14 Month1, Mrs A's case was reviewed at the Gastroenterology and Hepatology multidisciplinary team (MDT) meeting. The MDT note recorded that Mrs A had developed post-ERCP pancreatitis and that the entire adenocarcinoma had been removed successfully, but that she might need further surgery to prevent cancer reoccurrence.

23. On 15 Month1, Mrs A was seen by Dr F. It was recorded that Mrs A had had a fever overnight, but that her other observations were 'acceptable' and that she looked comfortable. A plan was made for a CT scan of the abdomen and chest, as Mrs A's investigations indicated that she had an invasive type of cancer, and for an upper gastrointestinal MDT review. A family meeting (the first family meeting since admission) was held later in the day with the registrar

[10] The retroperitoneum is the area behind the abdomen.
[11] A tube that is inserted through the nose, down the throat, and into the stomach. An NGT is used to remove substances from the stomach, which can improve comfort, and minimise and prevent recurrent vomiting.
[12] The fluid monitoring charts provided to HDC covered the period 11 Month1 onwards and did not consistently record volumes related to vomiting, urine output, and fluid intake.
[13] This Office requested a statement from Dr F, but Health NZ did not provide this.
[14] Early warning scores assist with the recognition of clinical deterioration through measurement of heart rate (HR), respiratory rate (RR), temperature, and blood pressure.
[15] The weight chart showed that Mrs A's weights were missed on 20, 21, 25, and 26 Month1.

and HO. During the meeting, they discussed Mrs A's pancreatitis and the possible need for future surgery to prevent cancer recurrence and advised Mrs A that her case would be discussed at the gastrointestinal MDT meeting.

24. On 16 Month1, the registrar recorded that Mrs A was spiking temperatures but that she had been mobilising and her blood results were improving. The registrar explained to Mrs A that post-procedure bloating was expected, and that if her fevers settled and she was eating and drinking normally and continuing to mobilise, then she could be discharged. Mrs A's case was discussed at the upper gastrointestinal MDT meeting. The MDT note focused on Mrs A's high risk of cancer reoccurrence and indicated that she should be offered further surgery for this (removal of the pancreatic head). Health NZ told HDC that there was also consensus that Mrs A's pancreatitis could be managed non-surgically, but this does not appear to have been recorded.

17–20 Month1 — transfer of care to upper GI specialist

25. On the morning of 17 Month1, the HO recorded the impression of 'post ERCP pancreatitis + [a]mpullectomy for duodenal adenocarcinoma', that the plan was for Mrs A to continue eating and drinking, for a CT scan to be completed, and for Mrs A to receive dietitian input. Subsequently, Mrs A was transferred to Dr C's care. Dr C said that it is likely that this was triggered by Mrs A's abdominal distension, food intolerance, and persistent fevers, and her persistent failure to progress. Dr C noted that Mrs A had pancreatitis but did not document any suspicion that a perforation might be contributing to her ongoing symptoms. Dr C explained to Mrs A that she would likely need another operation to prevent cancer reoccurrence.

26. Dr C told HDC that from 17 Month1 he felt that 'it was likely she had a contained retroperitoneal type two perforation [16] secondary to ERCP and that this was also complicated by pancreatitis'. He also said that all her CT scans had shown evidence of a contained retroperitoneal perforation. However, this impression was not recorded in Mrs A's notes at the time.[17]

27. Dr C ordered a further CT scan and dietitian input and for antibiotics to continue. The CT scan request recorded that Mrs A had pancreatitis and adenocarcinoma, with ongoing temperatures and rising inflammatory markers, and queried whether there was a collection or abscess (collection of pus). The CT scan reported no abscess but indicated progressive inflammatory change of the duodenum and pancreas, with progressive enhancing 'moderate' amount of retroperitoneal fluid. Health NZ and Dr C said that this fluid collection was confined within the retroperitoneum.

28. On 18 Month1, a registrar explained to Mrs A that the CT scan of 17 Month1 had shown pancreatitis. Health NZ stated that Mrs A had said that she was feeling better, and she appeared to be making good progress. Health NZ said that Mrs A's food charts[18] indicated

[16] Type two perforations.
[17] As discussed in paragraph 43, the first mention of perforation in her notes did not appear until 28 October.
[18] The food charts provided to HDC covered the period of 12–26 Month1. Food charts were not completed on 11, 13, 14, 19, 21, 23, 24 and 25 Month1.

that often she was finishing 100% of her meals each day, but Mrs A had reported that she was eating only up to half of the meals, and that her family members had been consuming the rest.

29. From 19 Month1, Mrs A's heart rate began to trend above 90 beats per minute (bpm) (higher than normal). Mrs A was seen by the registrar, who documented that Mrs A was well and was mobilising and eating, but that she was low in energy and had a fever at times. The plan was to '[continue] as before'.

20 to 24 Month1 — ongoing clinical deterioration and failure to progress

30. Mr B said that from 20 Month1, Mrs A's condition deteriorated significantly, and that her fever, bloating, and vomiting continued. Mr B told HDC that they were waiting for long periods of time for doctors to review Mrs A. Further, after seeing the doctors, the family felt there were no effective solutions provided, and that the family were instructed to simply wait until the next morning's ward rounds.

31. Mr B told HDC that Mrs A excreted a large amount of dark, foul-smelling fluid daily from the 'tube through [the] nose' and that the family enquired with the doctors about the reason or the excessive fluid output, including whether it was related to abdominal bloating or an important indicator of potential perforation. Mr B said the doctors did not provide a reasonable explanation for this and why the fluid continued to be expelled. At around 1am on 20 Month1, Mrs A developed a fast heart rate (100–130bpm). Mrs A was reviewed by the on-call HO, who recorded that she was clinically stable. The recorded impression was of pancreatitis and a CT scan showing retroperitoneal fluid. The plan was to complete further investigations[19] and to consider a repeat CT scan. The HO recorded that the inflammatory process was explained by the pancreatitis but questioned whether, with the increasing inflammatory markers, there was a new source of infection, possibly with the collection in the retroperitoneum. Later in the day, Mrs A was seen twice more by on-call HOs for her fever and cough. It was recorded that Mrs A was 'stable', and that the impression was possible infection secondary to pancreatitis or a retroperitoneal fluid collection, and mild hypovolaemia (low blood volume). The HOs advised staff to continue the usual plan, and to wait for Dr C's team to review Mrs A the next day and consider further investigations.

32. On 21 Month1, Mrs A was reviewed by the registrar, who noted the events overnight. The plan was for Mrs A to be NBM, for her to have IV fluids, for further investigations to be completed, including a CT scan, and for dietitian input to be sought for Mrs A's poor oral intake. The CT request queried whether there was a collection or another cause for Mrs A's postoperative symptoms. The CT scan reported stable intra-abdominal appearances when compared to the previous CT, and that while exudates[20] around the pancreas were more visible, the extent and the volume of exudate remained unchanged.

33. Also on 21 Month1, Mrs A's electronic medication record[21] shows that her antibiotics were stopped unexpectedly at 3.39pm. Dr C said that he was not aware that the antibiotics had

[19] This included a urine sample, sputum culture, IV fluids, pain relief, and repeat blood tests.
[20] Exudate is fluid that leaks out of the blood vessels into nearby tissues as a result of inflammation.
[21] This report was generated electronically and did not indicate who specifically stopped the prescription.

been stopped and did not have an explanation for this. Health NZ told HDC this was an active decision made by a junior doctor but given the passage of time and lack of clear documentation, Health NZ was unable to identify the clinical reason for this.

34. On 22 Month1, the registrar recorded that Mrs A's high heart rate and fever were secondary to the pancreatitis. The plan was to continue with IV fluids, and for Mrs A to mobilise and to eat and drink. At 4.50pm, Mrs A's heart rate increased to 122bpm, and it was noted that Mrs A had a reduced intake and was vomiting a bile-like substance. The on-call HO reviewed her and asked for her to be repositioned in bed.

35. From 23 Month1, Mrs A's EWS chart showed that her temperatures were improving. Dr C saw Mrs A during the morning ward round and recorded that she was not tolerating food. The documented impression was pancreatitis, and the plan was for a nasojejunal tube (NJT)[22] to be inserted, and for IV fluids and anti-nausea medication to be administered. At 9.00am, Mrs A's heart rate increased to 145bpm and the Patient at Risk (PAR)[23] team were called for support. The impression was 'fast atrial fibrillation' (abnormal heart rhythm) in the context of dehydration. The plan was to complete further investigations, including a CT scan of the abdomen, give IV fluids, monitor 'strict fluid balance', and administer medications to lower her heart rate. The CT abdomen request queried whether there was an obstruction or another cause for Mrs A's symptoms. The CT reported that the intra-abdominal appearances were largely stable since the previous CT scan, and the fluid component around the kidneys demonstrated 'air locules', indicating possible infection. Later in the day, Mrs A was seen by the PAR nurse and twice by HOs, and it was recorded that while Mrs A's EWS was 4, she was in '[zero] distress' and was feeling 'better than this morning', and Mrs A's usual plan was continued. From 24 Month1, Mrs A's EWS chart showed that her heart rate was consistently between 98–130bpm. Mrs A was reviewed by the registrar, who explained the need for a gastroscopy,[24] which later showed that the duodenum was filled with fluid. Mrs A was also visited by the upper gastrointestinal cancer nurse coordinator, who recorded that the family were aware of Mrs A's invasive cancer. The nurse coordinator explained to the family that the immediate concern was for Mrs A's recovery from her current acutely unwell condition,[25] and told them that surgery (to remove Mrs A's pancreas) might be required, depending on her recovery.

36. Mrs A's case was discussed during the Radiology MDT meeting of 24 Month1. The meeting note recorded that multiple CTs had shown evolving peri-pancreatic collections that persistently contained gas, and that the latest CT scan of 23 Month1 had shown a potentially drainable collection in the right retroperitoneal space. The surgical team requested percutaneous drainage,[26] but this was declined. The radiologist, Dr H, told Dr C via email

[22] An NJT is like an NGT, but the tip goes into the second part of the small bowel (the jejunum). An NJT is inserted when the stomach cannot empty properly or to get past a blockage in the small bowel.
[23] This team consists of an intensive care registrar, a registered nurse, a surgical HO, and a medical registrar, who are called to support deteriorating patients within wards.
[24] A procedure to examine the upper part of the digestive system.
[25] There was no mention of a perforation.
[26] A minimally invasive procedure to drain the collection by placing a tube through the skin.

that '[t]he particular area of concern, near the leak[27] had mixed density, and was therefore less likely to fully respond to percutaneous drainage'. This reasoning was not documented in Mrs A's clinical notes.

25 to 27 Month1 — events leading up to emergency surgery

37. From 25 to 27 Month1, Mrs A's EWS was persistently elevated, due to a high heart rate and temperature, and at times low blood pressure. She also developed significant new symptoms over this period.

38. On 25 Month1, Mrs A's dietitian noted that she was malnourished. Mrs A was reviewed by an on-call HO for abdominal distension and fevers. The HO recorded that the fever was due to pancreatitis that was 'not infective', and that the abdominal distension was due to fluid in the abdomen. The plan was for IV fluids, and it was noted that Mrs A was not for antibiotics or blood cultures. At around midnight, the PAR team was called to review an EWS score of 5 as a result of an increased heart rate, respiratory rate, and temperature. The PAR team advised nursing staff to continue with supportive cares.

39. Dr C said that on 26 Month1 he was on leave, and Mrs A's care was handed over to the on-call weekend consultant and surgeon, Dr G. Dr C said that normally, any significant clinical changes that occur for patients on weekends are discussed with the surgeon on call.

40. During the morning ward round of 26 Month1, the registrar noted that the gastroscopy had revealed swelling in the oesophagus, and the impression was recorded as pancreatitis. Later in the day, Mrs A's abdominal distension was reviewed. The HO recorded that Mrs A had intra-abdominal ascites (fluid collection in the abdomen) and a low albumin level (protein in the blood). The impression was abdominal ascites, peripheral oedema (swelling in the peripheries) with low albumin levels, and possible third spacing[28] leading to hypovolaemia. The plan was to withhold NJT feeds and give IV fluids, to consider albumin replacement if Mrs A's heart rate continued to be high and blood pressure low, and to continue to monitor her fluid balance. Overnight, Mrs A became unsteady and required a walking aid to mobilise.

41. On 27 Month1, the registrar noted that Mrs A was vomiting and had abdominal distension and pain, and that she had had multiple reviews from various medical staff. The registrar explained to Mrs A's son that there was a possible peripancreatic fluid infection and possible ileus[29] secondary to the nutritional feeds and told him that antibiotics would be restarted, and that usually an ileus resolves by itself. As per the plan, antibiotics were restarted at this point. The registrar also documented a plan to withhold the NJT feeds, give laxatives, and encourage Mrs A to mobilise gently.

[27] Disruption in the surgical connection between two structures resulting in a fluid collection. A leak can occur after perforation of the wall; however, this is not always the cause. The possibility of a perforation contributing to her symptoms was still not documented at this time.
[28] Accumulation of fluid from the blood within body cavities, intestinal areas, or areas of the body that normally contain little fluid. This can lead to low blood pressure and swelling.
[29] Inability of the intestine (bowel) to contract normally and move waste out of the body.

28 Month1 — significant deterioration and theatre

42. From 5.21am on 28 Month1 Mrs A's EWS score remained persistently elevated at 5, due to her increased heart rate and respiratory rate. Mrs A was assessed by the PAR team, who advised that Mrs A's symptoms were most likely from an ileus.

43. Later in the morning, Mrs A was reviewed by the registrar, who recorded that Mrs A had a retroperitoneal collection that may have changed in size, as well as pancreatitis. The plan was for an urgent CT scan, to continue antibiotics, and to stop her nutritional feeds. Mrs A's CT scan reported that the 'retroperitoneal gas-containing collection … ha[d] increased in size' and noted: '[F]indings are suspicious for a duodenal perforation.' This is the first recording that a perforation could be a potential or actual cause of Mrs A's postoperative symptoms.

44. In the early evening, the registrar explained to Mrs A's son that there was a perforation in the bowel, which was getting worse, and that Mrs A required an urgent operation to treat this. Health NZ said that Dr G contacted Dr C to discuss Mrs A's case, and it was clear that without surgical intervention, she would not survive because of the persistent and severe infection.

45. The risks recorded on the consent form include bleeding, sepsis, heart attack, pneumonia, stroke, death, leak, further procedures, and intensive care. A further note stated, 'mortality re-discussed', indicating that the risks of the major surgery were discussed with Mrs A.

46. Mrs A was taken to theatre at 5pm. Health NZ said that during the procedure the retroperitoneal space was opened and two drains were placed, blocking off the duodenum. Health NZ said that this was the correct operation for Mrs A and gave her the best chance of survival. The postoperative note recorded the findings of a large retroperitoneal abscess with necrosis (dead tissue) and extensive inflammation.

Subsequent events

47. Mrs A was transferred to the intensive care unit for postoperative management. However, sadly, Mrs A did not recover, and she passed away on 2 Month2. The ICU consultant recorded Mrs A's cause of death as '[s]epsis secondary to duodenal perforation secondary to ERCP on 7 [Month1]'. Mrs A's death was referred to the Coroner, and the referral noted that the surgery of 28 Month1 had confirmed that a perforation had occurred. In contrast, the operation note made no comment regarding a perforation, and Health NZ told HDC that Dr G had been unable to identify a perforation, and both Health NZ and Dr D said that most likely Mrs A's death occurred due to pancreatitis. Health NZ said that no investigation into Mrs A's care was completed.

48. On 28 Month2 a family meeting was held with Dr C and the nurse coordinator to discuss the family's concerns. Health NZ said that the family expressed dissatisfaction with Mrs A's management on the ward and felt strongly that there was an unacceptable delay in taking Mrs A to theatre. Dr C explained to the family that his overall strategy had been to manage Mrs A's post-ERCP suspected perforation and pancreatitis non-operatively, because surgical intervention carried high risks.

49. Mr B told HDC that his family had queried with medical staff the possibility of the perforation not healing, but the clinicians were persistent that it had recovered itself and focused on Mrs A's pancreatitis. Health NZ told HDC that Mrs A's symptoms were consistent with pancreatitis, and that pancreatitis can be mild or may lead to complications that are life-threatening. Further, Health NZ said that pancreatitis may take weeks to resolve, and that primarily treatment is focused on treatment of symptoms. In contrast, Dr C said that he did consider a perforation, and that his management of Mrs A was based on this and pancreatitis.

50. Health NZ told HDC that Mrs A's clinical management was appropriate, and that there was no delay in her treatment, and that even if Mrs A had received earlier surgery, it may not have changed the overall outcome due to the increased risks associated with the ERCP ampullectomy procedure. In addition, Dr D and Dr C told HDC that Mrs A's death was discussed during the mortality and morbidity (M&M) meeting, and there was consensus that Mrs A's treatment had been appropriate. However, the M&M meetings are not recorded, so there is no documentation of such consensus. Dr C told HDC that although in retrospect it is possible to recognise that perhaps earlier operation may have prevented Mrs A's deterioration, he feels that upon reviewing Mrs A's care prospectively, her management was appropriate given that she was relatively stable, and the retroperitoneal collection was contained.

51. There is no evidence that an adverse event review was completed. In response to the provisional opinion, Health NZ stated that there is a significant challenge in identifying incidents or outcomes requiring review and the correct process to be employed in each case. Health NZ said that in Mrs A's case, perforation and pancreatitis were known complications, which had been identified by the clinical teams. Health NZ emphasised that Mrs A's death was not 'unexpected' and was a result of known complications of a clinical process.

52. Health NZ's adverse event reporting policy at the time of the events states that all serious injuries or death as a result of clinical care or non-clinical care processes are to be notified to the Adverse Event Operational Group. The policy also states that all incidents occurring from clinical processes could be 'managed at the appropriate organisational, service management and clinical levels'. Health NZ told HDC that Mrs A's case had been reviewed as part of the critical care complex and general surgical department M&M meetings.

Responses to provisional report

Family

53. The family was provided with a copy of the 'information gathered' section of the provisional report and given an opportunity to comment on this. The family thanked HDC for the time and effort put into Mrs A's case. The family also stated that the statements provided by individual providers were 'biased and ten[ded] to excuse their shortcomings'. Other comments provided by the family have been integrated elsewhere in the report.

Health NZ

54. Health NZ was provided with a full copy of the provisional report and given an opportunity to comment on this. Health NZ told HDC that it 'respectfully disagree[d] with quite a number

of the individual shortcomings' and that these issues 'cannot comfortably be characterized as systemic failures'. Other comments made by Health NZ have been integrated elsewhere in the report.

Opinion: Introduction

55. On 7 Month1, Mrs A had a planned elective procedure (ERCP ampullectomy) to remove an ampullary adenocarcinoma. Mrs A had a suspected perforation during the procedure and was admitted to hospital as a precautionary measure. Over the course of her admission, Mrs A developed pancreatitis and experienced a fluctuating clinical course, with periods of improvement and periods of deterioration. She was managed non-surgically under the care of four specialists. On 28 Month1, Mrs A's CT scan indicated a possible perforation, and emergency surgery was undertaken. Sadly, she did not survive and passed away on 2 Month2.

56. Mr B complained to HDC about the services provided by Health NZ and said that Mrs A did not receive the needed concern, effort, or care from clinicians. Mr B stated that his family would like to see changes in Health NZ's system, to avoid any unnecessary loss of life and allow his family to regain trust and confidence in the health system.

57. At the outset, I reiterate my deepest sympathies to Mrs A's family. I note the tragic outcome for them, and that they were very involved in her care. Secondly, I acknowledge the complexity of this case, as evidenced by Mrs A's fluctuating clinical course and the high risks associated with the ERCP procedure.

58. I consider that several systems issues cumulatively led to Mrs A receiving a poor standard of care. However, I note that had an appropriate standard of care been provided, Mrs A's outcome may not necessarily have changed. I set out the reasons for my decision below.

Opinion: Health NZ — breach

Introduction

59. The issue for consideration is whether the postoperative care provided to Mrs A by Health NZ was of a reasonable standard. In forming my opinion, I have considered the advice from my independent clinical advisor, Dr Bernd Grunewald, and I refer to relevant aspects of his advice throughout my opinion.

Consideration of perforation as a cause for postoperative deterioration

60. On 28 Month1, Mrs A's CT scan indicated a possible retroperitoneal perforation, and she was taken to theatre to manage this.

61. Mr B expressed concern that over the course of Mrs A's admission, clinicians remained focused on the treatment of her pancreatitis rather than exploring other causes for her deterioration. Mr B said that the possibility of the initial perforation having not healed was queried by the family, but the clinicians insisted that the perforation had healed on its own.

62. Whilst it is not disputed that a perforation may have occurred during the surgery on 7 Month1, the possibility of a perforation as the cause of the postoperative symptoms was not documented until 28 Month1 (21 days after the surgery). There is conflicting evidence as to whether, prior to that date, Mrs A's clinicians were considering whether the postoperative symptoms could have been caused by a perforation (as opposed to pancreatitis).

63. On the one hand, Dr C told HDC that from 17 Month1 (the day on which he took over Mrs A's care), he had felt that Mrs A likely had a contained retroperitoneal type two perforation secondary to the ERCP procedure, which was complicated by pancreatitis. Dr C said that his consideration of a perforation was based on the fact that all four of Mrs A's CT scans had shown small amounts of gas, which was indicative of a contained retroperitoneal perforation. Dr C's statement to HDC is supported to an extent by his statement to the Coroner, which noted that he had been aware of a perforation on 24 Month1. Whilst not explicitly stated by Dr C, I note that this is when radiologist Dr H mentioned the possibility of a 'leak', which is suggestive of a perforation. In addition, I note that perforation is a recognised and known complication of the procedure Mrs A underwent, and that she had extensive MDT input. In these circumstances, it would be unusual for clinicians not to have considered a perforation.

64. However, there is also evidence that suggests that a perforation was not considered to be causing Mrs A's postoperative symptoms. First, I note that Health NZ and Dr D provided contrasting interpretations of Mrs A's CT scans when compared to Dr C. Health NZ and Dr D stated that Mrs A's CT scan results were consistent with pancreatitis and did not support a perforation. Dr D explained that after the suspected perforation during the surgery, an X-ray was ordered to check whether a perforation had occurred. As this scan showed no abnormality, a further scan was not scheduled until 10 Month1.

65. Secondly, as noted previously, the documentation does not support a finding that a perforation was being considered actively. I note that several other diagnoses were queried by clinicians, including dehydration, an ileus, a collection, an abscess, constipation, and malnourishment, and that extensive investigations were undertaken to investigate such causes. However, a perforation was not recorded within the clinical notes until 28 Month1. Further to this, I note Mr B's submission that his family queried the possibility that the perforation (from the 7 Month1 surgery) had not healed, and that the clinicians had insisted that it had healed itself. In response to the provisional opinion, Mr B again submitted that the family had queried the possibility of a perforation when Mrs A started excreting large amounts of fluid from the 'tube through [the] nose', but no reasonable explanation was provided.

66. I acknowledge the conflicting evidence presented. However, ultimately, I consider that it is not necessary for me to make a finding of fact on this matter. Based on Dr D's statement, I am reassured that the clinicians involved did take action to investigate the suspected perforation, at least immediately after Mrs A's operation. Secondly, as discussed in more detail below, knowing whether a perforation had occurred would not have changed the day-

to-day management of Mrs A's clinical symptoms or simplified the decision-making. Nevertheless, I remain concerned about other aspects of Mrs A's care, which I discuss below.

67. I now consider whether it was reasonable to manage Mrs A's condition non-surgically.

Non-surgical management of Mrs A's condition and delay in operation

68. From 7 to 27 Month1, Mrs A's condition was managed non-surgically. Mr B expressed concern over Mrs A's management and felt that there was a delay in taking Mrs A to theatre.

69. At this point, I note that Mrs A's emergency surgery was undertaken to correct a suspected perforation. However, even if a perforation had not been considered until that point, in my view this does not greatly affect the overall judgement call to be made regarding management. The decision on how to manage Mrs A was determined by whether her symptoms were severe enough to risk intervening surgically, or whether it was considered that her symptoms would resolve on their own. There are several different views on this matter.

70. Health NZ told HDC that in its opinion, Mrs A received an appropriate standard of care, and there was no delay in her treatment. Health NZ acknowledged the tragic outcome for Mrs A but stated that even had Mrs A received surgery earlier, the outcome may have been the same due to the increased risks associated with the ERCP ampullectomy procedure.

71. My independent advisor, Dr Grunewald, considers that Mrs A should have received earlier surgical intervention. He said that a delay in surgery is associated with much higher mortality rates when compared with early surgery. Dr Grunewald advised that a non-surgical approach was unlikely to succeed in Mrs A's situation due to her dilated bile duct and the fluid collection within the retroperitoneum.

72. In response to Dr Grunewald's advice, Dr C told HDC that surgical management was considered. This is supported by the fact that Mrs A's care was transferred from the gastroenterology team to the general surgery team and then later to a specialist upper gastrointestinal surgeon, which suggests that surgical intervention had not been ruled out. In addition, Dr C explained that non-surgical intervention does not equate to conservative management. He explained that percutaneous drainage (a non-surgical approach) was considered in the week of 24 Month1, but this did not occur because radiologist Dr H declined the referral, due to the fluid collection being deemed unsuitable for drainage.

73. Health NZ and Dr C told HDC that although surgical management was considered, this was not appropriate for Mrs A. They said that surgical intervention is more suitable for patients who are very unwell soon after ERCP, and Mrs A did not fall into this category as her deterioration was not clear cut. This is supported by clinical documentation, which shows that Mrs A had a fluctuating clinical course, with periods of both improvement and deterioration.

74. Dr Grunewald advised that continuing with non-surgical treatment in Mrs A's case after 16 days was a moderate departure from the accepted standard of care, because a non-surgical pathway after so many days was unlikely to succeed. Dr Grunewald also advised that when

a 'leak' was mentioned for the first time after Mrs A's procedure, continuation of non-surgical treatment for a further five days despite her worsening condition was a moderate departure from the accepted standard of care.

75. Dr C acknowledged that in retrospect it is possible to think that an earlier operation may have prevented Mrs A's deterioration; however, he stated that when reviewing Mrs A's care prospectively, the feeling was that her management was appropriate, and this was endorsed by the M&M and MDT meetings. Dr C emphasised that Mrs A's case was highly complex, and that this was one of the most challenging clinical situations the medical team had faced. Dr C provided four further reasons why surgical intervention did not occur before 28 Month1.

76. First, Dr C explained that Mrs A needed further surgery to prevent recurrence of her cancer. As surgical intervention carried high risks, the medical team tried to find a pathway for Mrs A to recover in a way that involved the least amount of risk and 'highest likelihood' that she could go on to have this definitive surgical treatment.

77. Secondly, Dr C's view is that there were still valid non-surgical options available to Mrs A, such as percutaneous drainage. He told HDC that during the radiology MDT meeting of 24 Month1, it was deemed that Mrs A's collection was suitable for drainage, and, although initially this was declined by Dr H, the medical team had intended to revisit this on the week of 28 Month1. However, by then, Mrs A had deteriorated precipitously and needed to be taken to theatre.

78. Thirdly, Dr C stated that Mrs A's condition was reviewed in several MDT meetings, which consisted of experienced clinicians from various specialties, but no one raised any concerns about non-surgical management. I note, however, that on review of the MDT notes of 14, 16, and 24 Month1, I could not find evidence of a discussion relating to the non-surgical management of Mrs A's pancreatitis or reasoning to support this decision. I also note that there is no record of which members of the MDT were in attendance during these meetings, what specialities were represented, what clinical data was presented, and who chaired the meetings. Accordingly, I am unable to make a finding on precisely what was discussed. However, in my view, noting Dr C's recollection of consensus that the treatment was appropriate, and despite the sparse recording, I consider that if there had been strong disagreement, this would have been reflected in the clinical record, and it appears that no one strongly disagreed with the plan.

79. Lastly, Mrs A had fluctuating symptoms. At times she was noted to be pain free for significant periods, and she was eating, drinking and mobilising, which encouraged the medical team to continue with non-surgical management.

80. I acknowledge Dr Grunewald's view that after 16 days of non-operative management, Mrs A's care would be unlikely to succeed. However, I also concur with Health NZ's perspective that surgical intervention carried high risks, Mrs A remained fairly stable, and Mrs A deteriorated precipitously on 28 Month1. In addition, I note that Mrs A was reviewed regularly by clinicians and was observed to be mobilising, eating, and drinking, and that she

had reported feeling better, which may have created a false reassurance that there were no major postoperative problems.

81. It is clear that Mrs A's management required many considerations, and, in such a dynamic situation, judgement calls can be challenging. In my view, regardless of whether a perforation was being considered, both surgical and non-surgical interventions were valid management options for Mrs A, with each option having its own merits and considerations. I also note the rationale for the treating clinician, who is 'on the ground' and accountable for the patient, to make the professional call as to what is most suitable in the overall context of the patient's condition. In this case, I am satisfied that Mrs A's treatment options were considered carefully, and I am of the view that non-surgical management was not an unreasonable treatment option for Mrs A. I am also reassured by the discussions within the M&M and MDT meetings, which appear not to have raised significant concerns about the non-surgical management.

82. I now consider whether Mrs A and her family were provided with an adequate level of communication.

Adequacy of communication with Mrs A and her family

83. As discussed above, Mr B raised several concerns about Mrs A's postoperative clinical management. This has raised concerns about the adequacy of the communication provided to Mrs A and her family, who were advocating for her. In particular, I am concerned that Mrs A's condition and treatment considerations were not conveyed to her family adequately.

84. Consumers have the right to be fully informed about their condition, and this includes a full explanation of their condition and what treatment options are available to them.

85. I acknowledge that Mrs A had a language barrier and that there were challenges with finding a translator. However, according to the clinical notes, family members were often available to translate, and the family did not express concern over the unavailability of translators. Therefore, my view is that the issue is not with the lack of translation, but rather the content of the information provided to Mrs A and her family.

86. Mr B told HDC that clinicians were persistent that the perforation had healed, and they remained focused on the management of Mrs A's pancreatitis. Further, Mr B told HDC that his family was waiting for long periods to see the doctor, and when they did see doctors, no effective solutions were provided, and they were simply instructed to wait until the morning ward rounds.

87. I have reviewed the clinical notes in detail and can find evidence of only one formal family meeting having occurred between 7 and 27 Month1. This occurred on 15 Month1 and did not involve Dr F, as the consultant at the time. The meeting record appears focused on Mrs A's pancreatitis and, although the need for future surgery (to prevent cancer recurrence) was discussed, the record does not mention any reasons why Mrs A was failing to progress, and whether surgical intervention for a perforation had been considered.

88. Although several other instances of communications with Mrs A occurred other than the family meeting, these took place by the bedside during routine medical reviews, which may not have been an effective environment to communicate serious information or to allow the family to engage in meaningful conversations with clinicians. I also note that on 16 Month1, Mrs A was advised by clinicians that if her eating and mobilisation improved, then she could be discharged. This may have provided false assurance to Mrs A and her family that she was improving.

89. Dr C told HDC that he found it challenging to communicate with Mrs A and her family. He said that he sensed that the events preceding his involvement had led to the family becoming apprehensive, mistrustful, and frustrated. The nursing notes also record that Mrs A and her family appeared anxious at times and raised concerns with staff.

90. As discussed above, it is understandable and expected that Mrs A's family were concerned, given her lack of progress after the surgery of 7 Month1. Under such circumstances, I would have expected more frequent updates and family meetings that involved participation from the senior consultant on duty. Family meetings are a standard practice when there is a change in the patient's medical status, or when there is concern among family members regarding the patient's prognosis, as occurred in Mrs A's circumstances. In addition, I would have expected specific communication to have been provided about Mrs A's prognosis, diagnosis (including whether a perforation was being considered), the treatment options available, the reasons for continuing with a non-surgical approach, and why Mrs A was failing to progress. However, the clinical records show limited evidence of communication.

91. In my view, the level of engagement with Mrs A and her family was poor. I take this opportunity to remind clinicians of the importance of regular communication with their patients and the importance of having a family meeting when the patient's condition changes significantly or when slow progress occurs. In this case, I consider that Mr B's concerns could have been alleviated with more frequent communication, and full disclosure of the nature of Mrs A's condition.

Failure to continue antibiotics

92. Mrs A was prescribed antibiotics as part of her treatment. An electronically generated medication record shows that Mrs A's antibiotics were discontinued at 3.39pm on 21 Month1. Doctors are responsible for prescribing medications, and although the identity of the prescriber is known, the medication report does not show who stopped the medication, and multiple clinicians were involved in Mrs A's care over the course of her admission.

93. Dr C was the senior consultant on duty when the antibiotics were stopped. He was unaware that this had happened and told HDC that antibiotics should not have been stopped on 21 Month1. His lack of awareness is supported by the ward round notes on 21 and 22 Month1, which do not mention the cessation of the antibiotics.

94. At 9.30pm on 25 Month1, the on-call HO recorded that Mrs A was 'not for [antibiotics] or blood cultures'. Although the HO documented that the pancreatitis was not infective, it is not clear how the HO came to this conclusion.

95. In response to my provisional opinion, Health NZ told HDC that the stopping of the antibiotics was an active decision made by a junior doctor. However, Health NZ could not explain why and how this decision was reached. This is supported by Dr C's comments to HDC. Dr C has no recollection of asking for the antibiotics to be ceased, and it has not been possible to discern the reason for ceasing the antibiotics.

96. Dr Grunewald also advised that Mrs A's antibiotics should not have been discontinued on 21 Month1. He said that antibiotics needed to be given for patients in whom a retroperitoneal collection has been found and whose vital signs and blood tests indicate ongoing inflammation and sepsis. Dr Grunewald advised that the failure to continue antibiotics was a mild departure from the accepted standard of care. I accept this advice and am critical that Mrs A's antibiotics were stopped.

97. Mrs A's clinical notes show that she had compelling indicators of sepsis, notably persistent fevers, abnormal vital signs and elevated inflammatory markers. Under these circumstances, I consider it was important to continue antibiotics.

98. I acknowledge Health NZ's comments that the cessation of antibiotics was an 'active decision' by a junior doctor. However, I note my clinical advisor's comments that antibiotics are an important and common aspect of post-ERCP perforation management, and that the clinical notes contain no information on who advised the cessation of the antibiotics. My advisor considers that the cessation of antibiotics was a systems failure, and I accept this advice. The limited information on the rationale for the cessation, and Dr C's lack of awareness of the antibiotics being stopped (despite their use being a common and important part of post-ERCP perforation management and despite Dr C being the lead clinician caring for Mrs A over a six-day period) illustrates a failure of Health NZ's systems, for which I find it responsible.

Absence of shared understanding between providers, leading to fragmented approach to care

99. Following the procedure on 7 Month1 and until Mrs A's transfer to intensive care, she was managed by four different consultants. Initially, Mrs A was managed by Dr E, a gastroenterologist, which was standard procedure for post-ERCP patients at Health NZ. On 11 Month1 (three days after the surgery and after she had developed pancreatitis), Mrs A's care was handed over to Dr F, a general surgeon, for consideration of surgical intervention. Then on 17 Month1 (10 days after the surgery), Mrs A's care was transferred to Dr C, an upper gastrointestinal specialist surgeon, because of her persisting symptoms and failure to progress. Finally, temporarily Mrs A's care was handed over to Dr G, who was covering for Dr C over the long weekend between 26 and 28 Month1. In addition to changes in specialists, I note that most medical reviews were carried out by HOs and registrars.

100. Whilst it is not uncommon for a consumer's care to be transferred to a specialist who is best suited to treat the consumer's evolving needs, frequent transitions to other clinicians does introduce some risk into the continuity of care. The risks include knowledge gaps in the consumer's condition and omissions in treatment pathways. Knowledge gaps can be avoided by way of thorough documentation. However, clinical documentation has several

limitations, such as the context in which care is delivered, and the values and spirit of a consumer, which usually is carried forward through the memory of providers who interact with the patient regularly.

101. From the information provided to me, it is apparent that clinicians did not share a collective understanding of Mrs A's clinical course. This is supported by the following factors:

a) Dr C's submission that the antibiotics should not have been stopped on 21 Month1 and his lack of awareness of this for six days, suggesting that clinicians did not communicate the cessation of antibiotics to Dr C. I also note that medical staff did not question the rationale for this cessation, and nursing staff, although not responsible for prescribing antibiotics, would have administered the medication regularly, and did not question the discontinuation with clinicians.

b) Differences in the interpretation of Mrs A's CT scans. Health NZ and Dr D stated that the scan on 10 Month1 did not show signs of a perforation; however, Dr C said that all the scans 'show[ed] evidence of a contained retroperitoneal perforation'.

c) Inconsistencies in the evidence in relation to whether a perforation was being considered as a potential cause of Mrs A's postoperative symptoms (see paragraphs 62–65). In my view, this suggests that the clinicians' views on a diagnosis of a perforation may not have been communicated or understood by all the clinicians involved in Mrs A's care.

d) Differences in the reasons cited for Mrs A's death. The referral to the Coroner indicated that Mrs A had passed away due a perforation; however, Dr D and Health NZ stated that it is likely that she had succumbed to pancreatitis rather than a perforation.

102. Cumulatively, the above factors suggest that Mrs A's clinicians did not have a shared understanding of her condition and, therefore, there was a fragmented approach to care. Care fragmentation can occur when the delivery of health care is spread across a large number of providers who do not communicate with one another adequately. This may have affected the communication provided to Mrs A and her family.

103. Dr Grunewald was critical that it took 10 days after the procedure of 7 Month1 before a specialist upper gastrointestinal surgeon became involved in Mrs A's care. He advised that the involvement of a surgeon with experience in managing complications following ERCP from day one would have avoided this fragmented approach. I accept this advice.

104. I acknowledge that it is usual practice for post-ERCP patients to be managed by gastroenterologists, who have experience managing post-ERCP patients. However, I note that Mrs A's case was complicated by several factors, which in my view warranted earlier involvement by Dr C. First, I note that Mrs A's procedure carried known risks. In particular, I note Dr D's comments that with an ampullectomy, the risk for pancreatitis is increased to 20%, and normally he admits up to 80% of his outpatient ERCP patients. Secondly, a perforation had been suspected during the procedure. Finally, I note Dr C's submission that Mrs A came to him when her condition was well advanced, suggesting that the timing of her transfer affected Dr C's decision on whether to manage Mrs A surgically or non-surgically. I

acknowledge that there are system-wide resourcing issues in relation to senior consultants; however, I agree with Dr Grunewald that there was a missed opportunity to involve Dr C in Mrs A's care earlier.

Insufficient documentation

105. I have identified several areas of concern within Mrs A's clinical records completed by medical and nursing staff.

106. The Medical Council of New Zealand (MCNZ) *Good Medical Practice* guidelines (2016) state that doctors must keep clear and accurate records that report relevant clinical information, the options discussed, the decisions made and the reasons for these, the information given to patients, the proposed management plan, and any treatment prescribed.

Failure to record clinical reasoning

107. I note that on 24 Month1, a decision was made by the MDT to drain Mrs A's retroperitoneal fluid. However, this was declined by radiologist Dr H. Health NZ provided a copy of email correspondence that identified that the reasoning behind the decision was that it was unsuitable to drain this fluid. However, this reasoning was not documented within Mrs A's clinical notes, as per the *Good Medical Practice* guidelines.

108. Dr C told HDC that he had had reservations about this decision and had wanted to revisit it in the week of 28 Month1. However, this intention was not documented in the clinical notes. I note that by then Mrs A's condition had deteriorated, requiring her to be taken to theatre. In response to the provisional opinion, Health NZ told HDC that Mrs A remained in an inpatient setting where she was actively being monitored by the surgical team, and that all potential treatment options were constantly being considered based on Mrs A's changing condition, irrespective of whether or not the intention to re-visit a clinical decision had been documented.

109. I acknowledge that the radiologist provided his reasoning to Dr C via email correspondence, and I acknowledge Health NZ's comments that all potential treatment options were constantly being considered. However, as stated in the *Good Medical Practice* guidelines, all relevant clinical information, including the proposed management plan, decisions made and the reasons for them, and the options discussed should be clearly and accurately documented within the clinical notes. Therefore, the reasoning for the declined referral, and Dr C's plan to revisit the decision, was relevant clinical information that should have been documented in Mrs A's clinical notes, irrespective of the clinical setting and how often she was being monitored.

Deficiencies in monitoring charts

110. In addition to the above deficiencies in documentation by medical staff, I have observed several areas of concern within Mrs A's monitoring charts, for which nursing staff were responsible.

111. First, I note that on 14 Month1, the dietitian recorded that Mrs A needed to have her weight monitored daily. This was because concerns had been raised about Mrs A's lack of food/fluid

intake and malnourishment to the point that she needed enteral nutrition. However, the weight chart shows that Mrs A's weights were not calculated daily, and these were missed on 20, 21, 25, and 26 Month1.

112. Secondly, on 10, 11, 23, and 26 Month1 the medical team recorded that Mrs A's fluid balance needed to be monitored, often emphasising the need for it to be recorded accurately or strictly. However, the fluid charts provided to HDC demonstrate that Mrs A's oral intake, volume of vomit, and NGT aspirates were not recorded consistently. At times, the fluid chart recorded '[up to toilet]' but failed to record the urine output. On other occasions, the clinical notes record that Mrs A had vomited, but the fluid balance chart does not show the volume of the vomit. In addition, I note that the total input and output volume was not always calculated at the end of the day. Again, this is concerning, given Mrs A's dehydration and limited oral intake.

113. Thirdly, I note Health NZ's comments that Mrs A's food charts show that she was eating full meals, when she was eating only a portion of her meals and her family were finishing the meals, suggesting that the recording in her food charts was inaccurate. I also note that Mrs A's food chart was not completed daily, even when clinical notes show that Mrs A had been eating.

114. I am concerned about the above deficiencies in the monitoring charts, particularly given Mrs A's fluctuating clinical course. Doctors rely on this information to formulate their treatment pathways and, as such, I consider that it was important to monitor Mrs A's weight, fluid balance, and food intake accurately.

MDT meetings

115. Health NZ told HDC that during the upper gastrointestinal MDT meeting of 16 Month1, there was consensus that Mrs A's post-ERCP pancreatitis would be managed non-surgically. However, on review of the MDT meeting note, it appears that the discussion focused on Mrs A's high risk of cancer reoccurrence and the need to complete further surgery to prevent this. In addition, I note that Dr C said that during MDT meetings, no questions or concerns were raised by his colleagues (who included specialist surgeons and specialist hepato-biliary radiologists) about continuing non-operative management.

116. I have reviewed Mrs A's MDT meeting notes of 14 and 24 Month1 carefully. Whilst I accept Health NZ's comments that the documentation of the 14 Month1 meeting does record that Mrs A's pancreatitis would hopefully settle without sequalae, in my view this does not constitute sufficient documentation of a consensus about the treatment plan, or probable reasoning to support this decision.

117. I am further concerned that there is no record of which members were in attendance during the 14 and 24 Month1 meetings, what specialities were represented, and what clinical data was discussed. The lack of documentation means that I cannot make a finding as to precisely what was discussed. However, as noted above, I accept that there was no strong disagreement with the plan.

118. In light of the above, I reiterate the importance of documenting key decisions and the clinical reasoning for such decisions. International evidence shows that multidisciplinary care is a key part of providing best-practice treatment, and I consider it important to document the discussions that take place during such meetings accurately. Transparent documentation demonstrates accountability for decisions made and promotes continuity of care. Whilst I acknowledge Health NZ's response, in which it noted that some of the meetings discussed were not formalised MDTs, in my view the rationale and importance of documenting this type of discussion remains the same, regardless of the classification.

119. The multiple examples of poor documentation reflect poorly on the system at Health NZ. Clinical records reflect a clinician's reasoning and are an important source of information regarding the patient's care. Documentation is also a key component of ensuring continuity of care, and in ensuring that the next clinician can understand the rationale behind previous clinical decisions. Clinical documentation is therefore a cornerstone of good care, and a required standard of professional practice. In addition, poor clinical notes hamper later inquiry into what happened — thereby compromising the opportunity to address issues raised by or on behalf of a consumer, as well as quality improvement measures that may flow from such inquiry. I acknowledge the changes made by Health NZ to improve its documentation systems.

Conclusion

120. While I acknowledge that there is individual accountability and obligations to provide care within accepted standards, Health NZ has an organisational responsibility to provide a reasonable standard of care to its consumers. In my view, the deficiencies in the care provided were not the result of isolated incidents involving one or two staff. They were widespread, involving many staff members, which is a reflection of Health NZ's poor systems at the time, which I consider constitutes a departure from the expected standard of care for Mrs A. In particular, I am critical of the following issues:

- Inadequacies in the communication provided to Mrs A and her family;
- The failure to continue antibiotics when this was clinically indicated;
- The absence of a shared understanding between providers, leading to a fragmented approach to care; and
- The failure to complete documentation adequately, including the recording of MDT and other key meetings.

121. Therefore, I find that Health NZ did not provide services with reasonable care and skill and breached Right 4(1)[30] of the Code of Health and Disability Services Consumers' Rights (the Code).

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

Changes made since events

122. Health NZ told HDC that on 24 June 2021 it completed an education session for the Department of General Surgery on the management of post-ERCP perforations. In addition, an education session has been incorporated into the M&M meetings, and post-ERCP perforation has been addressed within the gastroenterology meeting, which forms part of the continuous quality improvement processes that are undertaken by the clinical team.

123. Health NZ said that it has introduced an electronic notes documentation system and, as part of this, it has introduced set templates to ensure that important information is captured and documented by staff.

124. The Radiology Service has implemented a process in which the administrative team and Radiology can record a report for every declined referral, including the reason for the decline and any details of discussions between the referring doctor and the radiologist. This forms part of the patient's clinical record.

125. In response to the provisional report, a Quality Governance Group at Health NZ considered whether more explicit guidance for MDT meetings was required. The group was of the view that formalising MDT meetings was not feasible or practical, due to the many different types of MDT meetings and the frequency of such meetings, which may slow down the process and discourage MDT collaboration.

Recommendations

126. I acknowledge the above changes made by Health NZ. I recommend that in addition, Health NZ:

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

b) Provide a reminder to the relevant clinical services of the need to consider timely referrals to an upper gastrointestinal specialist for admitted post-ERCP patients when they have experienced ERCP-related complications. Confirmation that this reminder has been delivered to relevant staff is to be provided to HDC within three months of the date of this report.

c) Provide a reminder to surgical department staff about the importance of good clinical documentation, including documenting future actions as part of the treatment plan; key clinical decisions; reasons for these decisions; and clinical discussions, to ensure that there is continuity of care and documentation of rationales for treatment plans. Evidence that this reminder has been sent is to be provided to HDC within three months of the date of this report.

d) Amend the Adult ERCP inpatient guidelines to broaden the scope of the policy, to include guidance for outpatient procedures and guidance on the post-procedural management of perforations. The updated guidelines are to be provided to HDC within six months of the date of this report.

e) Review its practice in relation to communication with families, in light of this report, and develop steps to improve its practice. An update on this review with corrective actions is to be provided to HDC within three months of the date of this report.

Follow-up actions

127. A copy of this report will be sent to the Coroner.

128. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be sent to Health New Zealand|Te Whatu Ora and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following clinical advice was obtained from Dr Bernd Grunewald on 27 October 2020:

> 'I have been asked to provide an expert opinion to the Commissioner on case number C19HDC02347. I have read the HDC guidelines for Independent Advisors and endeavored to follow them in compliance with the instructions which were included in the request. I declare no conflict of interest in this case. My name is Bernd Grunewald. I am a vocationally registered General Surgeon employed by Waikato District Health Board. I graduated from Heidelberg Medical School, Germany, in 1987 and emigrated to New Zealand in 1991. I completed the General Surgical Training Scheme of the Royal Australasian College of Surgeons, obtaining Fellowship in 1999. I underwent further training in Upper Gastrointestinal Surgery at the Royal Prince Alfred Hospital, Sydney, in 2000. This included training in ERCP. I was appointed to the position of Consultant General Surgeon with a special interest in Upper Gastrointestinal Surgery at Waikato Hospital in 2001. In addition to General and Upper Gastrointestinal Surgery, my workload also includes weekly ERCP lists. I am a member of the Waikato Hospital Multidisciplinary Team dealing with Upper Gastrointestinal and Hepatobiliopancreatic tumours. My opinion is based on nearly 20 years of experience as a Consultant General Surgeon and Endoscopist.
>
> The specific questions I have been asked to comment on are:
>
> 1. Adequacy and appropriateness of the care provided by [the DHB].
> 2. The appropriateness of the ERCP and whether a Whipple's procedure should have been considered.
> 3. Whether the steps taken by staff to manage [Mrs A's] pancreatitis were appropriate.
> 4. Whether the steps taken by staff to manage the perforation were appropriate.
> 5. Any other matters I consider warrant comment.
>
> My comments are based upon a review of the information provided by your office. These are:
>
> 1. Copy of complaint dated 10 December 2019.
> 2. [District health board's] response dated 18 March 2020.
> 3. [Dr D's] response to the Coroner's Office dated 10 February 2020.
> 4. [Dr C's] response to the Coroner's Office dated 20 Month2.
> 5. Clinical records from [the district health board].
>
> **Factual Summary**
>
> [Mrs A], [a non-English speaking woman in her seventies], was diagnosed with an ampullary tumour [while overseas] as part of a routine health check. The presence of a tumour was confirmed by gastroscopy/biopsy and MRI scan on her return to New Zealand. Histology showed ampullary adenoma with low grade and focal high grade dysplasia. Her case was reviewed at a Multidisciplinary Meeting, and endoscopic ampullectomy was recommended. This procedure was explained to her in clinic by [a]

Consultant Gastroenterologist, on 1 [Month1] and possible complications like perforation, bleeding, pancreatitis, and cholangitis were mentioned. Her common bile duct was dilated to 20mm. This was thought to be caused by a type 1 choledochal cyst.

The procedure was performed on 7 [Month1] by [Dr D], Consultant Gastroenterologist. There was a localized perforation following endoscopic resection of the tumour, and a covered 10mm biliary stent was placed in addition to a pancreatic stent. The presence of a dilated common bile duct to over 25mm was noted. She was admitted under the care of the Gastroenterologists. She did not recover as quickly as expected (her clinic letter mentioned an overnight stay) because of abdominal pain, nausea, vomiting and bloating. [Dr E], Consultant Gastroenterologist, saw her on 8 [Month1]. An abdominal x-ray was requested which did not show any abnormality. She spiked temperatures to 38 degrees and her blood tests revealed a high CRP and white blood cell count and a lipase of greater than 1000. A registrar reviewed her on 9 [Month1], and the notes only mention "swelling R arm, replace iv line". [Dr E] saw her again on 10 [Month1] and mentioned "pancreatitis post procedure". He wondered if she could have a peripancreatic collection and requested a CT scan and review by the General Surgeons. The CT report showed oedema of the pancreatic head, free fluid surrounding the pancreatic head and body, the gallbladder neck and the paracolic gutter bilaterally. There was also free fluid around the liver and spleen and within the pelvis. The conclusion of the Consultant Radiologist was "Appearances in keeping with acute oedematous pancreatitis with mild to moderate amounts of free fluid. No drainable collections". The Surgical Registrar's impression was "day 3 post ERCP pancreatitis". Supportive management was continued.

[Dr F], Consultant General Surgeon, saw [Mrs A] on 11 [Month1], and his impression was "day 4 post ERCP pancreatitis, no collections, no necrosis". He took over her care. She was reviewed by the General Surgical Registrar on 12 [Month1] and 14 [Month1], and by [Dr F] on 15 [Month1]. In addition, she was seen several times by on call house officers for fevers, nausea, bloating and high blood sugar levels. [Dr F] requested a repeat CT scan and review by "Upper GI". She was seen the same day by [the] Consultant General Surgeon, who noted "generalised abdominal pain", but he was unable to communicate with her as there was no interpreter available. His impression was "post ERCP pancreatitis" and his plan was "return with interpreter". [Mrs A] continued to spike temperatures and her white blood cell count and CRP remained significantly elevated. She was eating and drinking, but she had poor appetite, intermittent pain, and constant bloating.

Her case was discussed at the Hepatobiliary Multidisciplinary Meeting on 16 [Month1]. Histology showed an early (T1) carcinoma in the resected specimen which appeared completely excised. Further surgery (Whipple's procedure) was recommended. [Dr C], Consultant General Surgeon, saw her on 17 [Month1] and took over her care from [Dr F]. A repeat CT scan was done that day, and this showed moderate amount of peripancreatic fluid and further oedema of the head of the pancreas, oedema of the second and third part of the duodenum and increase of retroperitoneal fluid and fluid around the spleen, and moderate amount of free fluid within the abdomen and pelvis.

The conclusion by the Consultant Radiologist was "Progressive inflammatory change of the duodenum and pancreas with progressive enhancing retroperitoneal fluid suggesting peritonitis but no abscess". Her current management continued.

On 20 [Month1] [Mrs A] developed sinus tachycardia, temperature spikes, and rising inflammatory markers. Another CT scan was requested which showed no significant new changes compared to the scan from three days earlier. [Dr C] reviewed her again on 23 [Month1]. Insertion of a nasojejunal feeding tube was requested because of poor oral intake and vomiting. She developed fast atrial fibrillation with a heart rate of up to 145 beats per minute and complained of worsening abdominal pain. A nasogastric tube was inserted, and another CT scan was requested. The report stated that the fluid collections were largely unchanged, but small locules of air were seen in the right anterior pararenal space, and the final comment by the Consultant Radiologist mentions that this was "worrisome for onset of infection". The response letter by [the] Chief Medical Officer [CMO] for [the district health board], mentions that on 24 [Month1] percutaneous drainage of the retroperitoneal collection was requested by the Surgical Team. This was declined by the Radiology Department as they thought this collection was not suitable for drainage. [Dr H], Consultant Radiologist, commented "The particular area of concern near the leak had mixed density, and was therefore less likely to fully respond to percutaneous drainage". I quoted this from [the DHB] response letter as I could not find any mention of it in [Mrs A's] clinical notes. The nasojejunal feeding tube was placed endoscopically on 24 [Month1] and feeding was commenced the following day. She was seen by house officers and registrars several times between 25 [Month1] and 28 [Month1] for increasing abdominal distension, abdominal pain, chest pain, shortness of breath and generalised oedema. Her condition failed to improve, and another CT scan was requested on 28 [Month1]. There was a significant increase of retroperitoneal gas from adjacent to the posterior aspect of the second part of the duodenum that extended around the right anterior pararenal space. A definite defect was not visible although there was ectopic gas in very close proximity to the distal end of the bile duct stent. The impression by the Consultant Radiologist was "The retroperitoneal gas-containing collection predominantly within the right anterior pararenal space has increased in size. Given the clinical setting of recent ERCP and CBD stenting, and the volume of gas, findings are suspicious for a duodenal perforation".

[Mrs A] was taken to theatre the same day and the on-call Consultant General Surgeon, [Dr G], performed a laparotomy, duodenal exclusion, drainage of retroperitoneum and gastrojejunostomy. Postoperatively, she was admitted to the Intensive Care Unit. She was extubated on 29 [Month1], but she remained unwell. She had increasing noradrenaline requirements, generalized oedema, sepsis, and vasodilatory shock. In addition to ICU staff, she was also reviewed by [Dr C] on 30 [Month1]. A large amount of bile was noted in one of her two retroperitoneal drains which was "likely at the ampullectomy site". On 31 [Month1], she was again reviewed by [Dr C]. She was off her noradrenaline and her drain output was less bilious. She remained tachycardic, and ICU staff noted that her breathing was laboured with a high respiratory rate and poor cough. She was oedematous and her level of consciousness had decreased. A family meeting

was held, and the seriousness of her condition was explained to her relatives. Her condition continued to deteriorate, and she passed away on 2 [Month2].

Specific Commentary

1. Adequacy and appropriateness of the care provided by [the DHB]

This section includes my comments on management of pancreatitis and perforation (Point 3 and Point 4 of your specific questions), as these points are inseparable.

[Mrs A's] assessment and the decision to perform an endoscopic ampullectomy was appropriate. It appears that she was adequately informed about the procedure including possible risks and complications. The procedure was performed by [Dr D], but he did not see [Mrs A] again after her procedure. Her care was initially provided by another Gastroenterologist, [Dr E]. After three days her care was transferred to a General Surgeon, [Dr F]. After another four days, [Dr F] requested review by a Specialist Upper Gastrointestinal Surgeon, and [the consultant general surgeon] saw her the same day. His plan was to return with an interpreter, but when the interpreter became available [Mrs A] was only seen by a Surgical Registrar. It took another two days (10 days after the procedure) before a Surgeon with a special interest in Upper Gastrointestinal and Biliary/Pancreatic disease, [Dr C], saw [Mrs A] and took over her care.

I find this a rather fragmented approach to a patient who had a high risk procedure with intra and post procedural complications. I would expect the Endoscopist, [Dr D], to remain involved with her immediate post procedure care, and discuss any concerns about her recovery directly with a Specialist Upper Gastrointestinal Surgeon. This fragmented approach is a mild departure from the standard of care.

[Dr D] wrote in his procedure report that "dye entered tissue from localized perforation so biliary stent placed to cover likely small perforation". The stent was a fully covered 10mm by 4cm metal stent. [Mrs A's] bile duct was very dilated. The MRCP report says 20mm, [Dr D] himself mentioned a size of over 25mm. Covered metal stents are used to try to seal small periampullary perforations but a 10mm stent within a 20 to 25mm bile duct was unlikely to succeed. As soon as [Mrs A] did not recover from her procedure as expected, the differential diagnosis should have included the possibility of perforation and ongoing leak. The elevated lipase level, oedema of the pancreatic head and fluid around the pancreas on CT was consistent with pancreatitis, but there was also a moderate amount of fluid in the retroperitoneum and within the abdomen, and the possibility of a perforation should have been mentioned in the first CT report on 10 [Month1]. Early surgery is recommended for significant periampullary (type 2) perforations. It is well documented that delay in surgery is associated with much higher mortality rates than early surgery. It is possible to manage small type 2 perforations without surgery, especially if there are no significant fluid collections and the patient's clinical condition improves rapidly, including improvement of the CT findings on follow up scans. A non-surgical approach however was unlikely to succeed in [Mrs A's] case due to risk factors like dilated bile duct and moderate amounts of fluid in the abdomen

and retroperitoneum. The possibility of perforation was not even considered after the first CT scan on 10 [Month1], and she was treated for pancreatitis only.

Her second post procedure CT scan on 17 [Month1] showed worsening of her inflammatory changes, increasing amount of abdominal fluid and progressive enhancement of retroperitoneal fluid. This was again attributed to pancreatitis, and the possibility of perforation was not mentioned in her clinical notes or in the CT report. [Dr C] took over her care, but there were no changes in her overall management for presumed pancreatitis, although her clinical condition did not improve.

Her third CT scan was performed on 20 [Month1]. No new changes were observed, and management for presumed pancreatitis continued. Her clinical condition deteriorated over the next three days, and her fourth CT was done on 23 [Month1]. This showed new locules of gas. Percutaneous drainage was contemplated, but this was not attempted as the fluid collections were thought to be unsuitable for such a procedure. According to the response letter written by [the CMO], [Dr H] mentioned a "leak" when communicating this to [Dr C], but nothing further was done when percutaneous drainage was declined. A fifth post procedure CT scan on 28 [Month1], done for further deterioration of [Mrs A's] clinical condition, showed findings that were reported as "suspicious for a duodenal perforation". Surgery was performed, but [Mrs A] did not survive.

Continuation of pancreatitis management for 16 days in a patient who had a high risk procedure, documented perforation during the procedure, and risk factors for ongoing leak without taking into consideration that her clinical condition could have been caused by perforation is a moderate departure from the standard of care. When a leak was mentioned for the first time 16 days after her procedure, continuation of non-surgical treatment for another five days, despite worsening of her clinical condition and worrisome CT findings, is a moderate departure from the standard of care.

As far as [Mrs A's] nursing care and involvement of allied health professionals is concerned, I find that all of this was adequate and appropriate.

When [Mrs A] was taken to theatre on 28 [Month1], the appropriate operation was performed. Her post operative management in ICU and HDU was adequate and appropriate.

2. The appropriateness of the ERCP and whether a Whipple's procedure should have been considered.

[Mrs A] had a 43mm ampullary tumour which was discovered incidentally. It was associated with a dilated common bile duct, but the dilatation was not caused by obstruction but by a type I choledochal cyst. Biopsies showed areas of high grade dysplasia, but no invasive carcinoma. Her case was reviewed at a Multidisciplinary Meeting including Gastroenterologists, Radiologists, Pathologists, and Surgeons. The decision to proceed with an endoscopic ampullectomy was made. This procedure is accepted practice in patients without proof of invasive carcinoma. Surgical resection

(Whipple's procedure) is recommended for patients with biopsy proven carcinoma. It is accepted that some patients with high grade dysplasia will have evidence of invasive carcinoma on final histological examination of the specimen, and a Whipple's procedure may be required following initial endoscopic resection.

3. Whether the steps taken by staff to manage [Mrs A's] pancreatitis were appropriate.

See comments under Point 1.

4. Whether the steps taken by staff to manage the perforation were appropriate.

See comments under Point 1.

5. Any other matters I consider warrant comment.

[Dr D] wrote in his report to the Coroner that [Mrs A] developed "pancreatitis which resulted in some necrosis around the pancreas which became secondarily infected". I do not agree with this comment. [Mrs A's] clinical course was entirely consistent with a periampullary perforation, ongoing leak, and sepsis. She had evidence of pancreatitis as well, but this did not cause her fatal outcome.

[Dr C] wrote in his report to the Coroner that when he first saw [Mrs A] on 17 [Month1] she had been treated over the preceding 10 days for a "tentative diagnosis of post ERCP pancreatitis/perforation". The clinical notes however only mention pancreatitis. According to his Coroner's report [Dr C] was aware of a perforation on the 24 [Month1], the same time as [Dr H] mentioned a "leak", and [Dr C's] goal was "to manage this retroperitoneal perforation of the bile duct as conservatively as possible because it was highly likely that [Mrs A] would need to go on to have an extensive and major operation to remove the rest of her pancreatic head at some point in the future, and a laparotomy at this time would delay and complicate that definite treatment." It is understandable that [Dr C] wanted to avoid surgery in this situation, but surgery should have been performed because of [Mrs A's] deteriorating condition and failure of non-surgical management.

Recommendations

I strongly recommend better communication between the Endoscopist and a Specialist Upper Gastrointestinal/Biliary/Pancreatic Surgeon, as soon as a patient who had a high risk procedure like an endoscopic ampullectomy does not recover as expected.

I recommend an education session on current management of post ERCP perforations, and indications for surgery in this setting. Both Gastroenterologists and General Surgeons should attend.

The Radiology Department should have a similar education session on CT imaging of patients post ERCP, with the emphasis on CT findings in patients with perforations.

Yours sincerely,

BERND GRUNEWALD FRACS
General Surgeon

Relevant literature

1. Management of endoscopic retrograde cholangiopancreatography-related perforations. J Korean Surg Soc. 2011 Sep;81(3):195–204.
2. Endoscopic retrograde cholangiopancreatography-related perforations: Diagnosis and management. World J Gastrointst Endosc. 2015 Oct 10;7(14):1135–1141.
3. Value of temporary stents for the management of perivaterian perforation during endoscopic retrograde cholangiopancreatography. World J Clin Cases. 2014 Nov 16;2(11):689–697.
4. Cross-sectional imaging of common and unusual complications after endoscopic retrograde cholangiopancreatography. Insights Imaging. 2015 Jun;6(3):323–338.
5. Management of duodeno-pancreato-biliary perforations after ERCP: outcomes from an Italian tertiary referral centre. Surg Endosc 2013;27(6):2005–2012.'

The following clinical advice was obtained from Dr Bernd Grunewald on 6 May 2022:

'Thank you for sending me further documents regarding this case as listed in your letter dated 29 March 2022. You wanted me to respond to these four questions:

1. If any additional responses and/or statements cause me to change my original opinion and provide reasons for this
2. Whether previous and/or new departures from accepted practice are attributable to the system or individual clinicians
3. The adequacy of the [DHB] Adult In-patient ERCP guidelines
4. Any other matters that I consider warrant comment

I will comment on the relevant documents first, and then summarize my response.

Involvement in [Mrs A] post ERCP care

[Mrs A] was a high-risk patient for post-procedural complications. In this situation, I would expect that the proceduralist provides hand-over to the team who will manage the patient on the ward including concerns about the procedure and possible complications. The initial statements did not provide any evidence that [Dr D] had any involvement with [Mrs A's] care following the procedure. [Dr D] has now explained that hand-over to the ward gastroenterology team occurred with the help of his fellow, who was present during the procedure, and that a management plan was put in place. However, it would have been prudent to also inform a surgeon with experience in managing complications following ERCP. It would have provided more streamlined care for [Mrs A]. Instead, [Dr E] (Gastroenterologist) looked after her for four days. Her care was transferred to [Dr F] (General Surgeon) on day 4. [The] (Upper GI Surgeon) was asked to see her on day 8 and eventually, on day 10, [Dr C] took over her care.

Use of a 10mm self-expanding metal stent

The possibility of a "micro-perforation" was mentioned by [Dr D] in the original procedure report dated 7 [Month1], in his report to the Coroner dated 10/2/2020, and in his letter dated 14/7/2021. This meant that [Mrs A], a high-risk patient, became an even higher-risk patient for complications post-procedure. It is standard practice to insert a covered metal stent in this situation but it does not eliminate the risk of a post-procedure leak in a patient with a large bile duct whose ampulla had been resected. 60 to 70% of all post ERCP perforations are not diagnosed during the procedure. They only become obvious on imaging when a patient fails to recover as expected. While [Dr D] saw no evidence of a large leak at the time of ERCP, this did not rule out the presence of a clinically significant leak in the post-procedure period.

Pancreatitis and Perforation

[Dr C] explained in his additional comment that [Mrs A] presented to him "9 days post ERCP ampullectomy complicated by pancreatitis and type 2 perforation". He came to this conclusion based on [Dr D's] report, the first CT scan on 10 [Month1] and the raised serum lipase. According to [Mrs A's] clinical notes, she was managed for presumed pancreatitis for 16 days.

Outcome of non-surgical management versus surgery

[Dr C] mentioned that the papers I quoted favour non-surgical management over surgical intervention in type 2 periampullary perforations. Patients who undergo surgery are usually those who are very unwell soon after ERCP or deteriorate with non-surgical management. These patients are very likely to die without intervention and undergoing surgery can improve their chances of survival. However, the mortality rate is high among this group of patients. Those patients who remain clinically well or improve rapidly with non-surgical management clearly do not need surgery.

Timing of surgical intervention

[Dr C] stated that [Mrs A] was referred to him because of "persistent failure to progress, abdominal distention, food intolerance and febrile episodes". Between 16 [Month1] and 23 [Month1] "she showed signs of clinical deterioration". After 17 days of non-surgical management, it was unlikely that [Mrs A] would recover from her condition without intervention. Radiological drainage of the retroperitoneal collection was requested on 24 [Month1]. This was declined by the interventional radiologists as it was not thought to be feasible. This left surgery as the only option.

Statements by [three radiologists]

Gas on a CT scan post ERCP indicates that at least a micro-perforation has occurred but it does not help with clinical decision-making. Most patients who only have gas around the duodenum and in the retroperitoneum on CT remain well and do not need any intervention. Retroperitoneal and free intraabdominal fluid can be present in patients with pancreatitis but can also be found in patients with perforations. The absence of gas on a CT scan in patients with retroperitoneal fluid does not rule out perforation.

One case series reported that 7 out of 41 patients with perforations only had evidence of fluid on CT. Another case series of patients who were symptomatic following ERCP reported that both pancreatitis and perforation were present simultaneously in 17%. Another paper mentioned that 43% of all patients with perforations also had features consistent with pancreatitis on CT. CT reports should have mentioned that retroperitoneal fluid can also be seen in patients with perforations, and a perforation could not be ruled out. I do not think that administration of oral contrast would have contributed to the detection of a leak as, clinically, [Mrs A] did not have a large leak from her duodenum. The leak was, most likely, a small retroperitoneal leak from either the bile duct or the pancreatic duct.

Comments

1. Do any additional responses and/or statements cause me to change my original opinion?

[Dr D] explained that he handed over the care of [Mrs A] to the ward gastroenterologist with the help of a gastroenterology fellow who was present at the time of the ERCP procedure and therefore had a clear picture of the events. I accept this was satisfactory as far as [Dr D's] involvement in [Mrs A's] care is concerned. It would have been prudent to involve a surgeon with experience in managing complications following ERCP from day one. This would have avoided the "fragmented" approach to [Mrs A's] care which included [Dr D], [Dr E], [Dr F], [the consultant general surgeon] and [Dr C]. This is a criticism, but not a departure from accepted practice as at least adequate hand-over after her procedure had occurred.

Placement of a 10mm stent is an adjunct to try to prevent possible post-procedure leaks. It does not guarantee that there will be no leak post ERCP especially in [Mrs A's] case, given the specific risk factors.

[Dr C] stated that he took over [Mrs A's] care nine days after ERCP "complicated by pancreatitis and type 2 perforation". I could not find any support of this statement in [Mrs A's] notes or CT reports as only pancreatitis was mentioned for 16 days. However, I accept Mr [Dr C's] explanation that he considered the possibility of simultaneous pancreatitis and perforation. This is therefore not a departure from the accepted standard of care. The fact that there is no documentation about this in the clinical notes should be criticized.

Not all patients who are being managed without surgery for pancreatitis and perforation improve with supportive management. There is a significant failure rate of 20 to 30% of non-surgical management in patients with type 2 perforations. Delay in surgery increases mortality. Many papers, including the two papers provided by [the DHB], mention that retroperitoneal fluid collections and lack of improvement of the patient's clinical condition are indications for intervention either by radiological drainage or by surgery. [Mrs A] fulfilled these two criteria. [Dr C] himself stated that [Mrs A] initially "failed to progress" and then "showed signs of deterioration". It can be argued that an intervention should have been considered within the first 14 days given

the lack of improvement and clinical deterioration. The fact that percutaneous drainage was requested on day 17 indicates [Dr C] was aware that the management strategy needed to change. As interventional radiologists were unable to help, surgery should have been performed at that time. I accept [Dr C's] report that he deliberated on the decision to continue non-operative management or to perform surgery given [Mrs A's] circumstances including the need for further surgery for her ampullary carcinoma. However, guidelines for intervention exist and they should have been followed. Non-intervention in a patient who failed to improve and then deteriorated is, in my opinion, a moderate departure from the standard of care.

Are previous and/or new departures from accepted practice attributable to the system or individual clinicians?

Following review of the additional statements, while the approach to [Mrs A's] care was fragmented, I no longer consider there was a departure from the accepted standard as at least appropriate hand-over had occurred. I accept [Dr C's] statement that he felt that [Mrs A] suffered from pancreatitis and simultaneous perforation. I therefore consider there was no departure from standard of care given that perforation was considered after ERCP.

In my opinion, one departure remains. This is the continuation of non-surgical management for 21 days in a patient who failed to improve and subsequently deteriorated. Many clinicians were involved in [Mrs A's] care. Non-operative management was initiated and continued by four gastroenterologists and surgeons. Her CT scans were reported by three radiologists. This is a moderate departure from accepted practice and is attributable to systemic failure and not to any individual clinician.

The adequacy of the [DHB] Adult ERCP Inpatient Guideline.

These guidelines cover ERCP procedures for inpatients. They are adequate but I don't think they are relevant in this case as [Mrs A] was admitted for her procedure as an outpatient.

4. Any other matters that I consider warrant comment.

I am satisfied that this case has been extensively discussed amongst [the DHB] surgeons, gastroenterologists and radiologists. Hopefully this review will provide further guidance in managing a complex case like this in the future.

I also would like to apologize to [Dr C] for spelling his name incorrectly in my first report.

Yours sincerely

BERND GRUNEWALD FRACS
General Surgeon

Relevant literature

Cross-sectional imaging of common and unusual complications aftrer endoscopic retrograde cholangiopancreatography. Insights Imaging. 2015;6:323–338.

Complications of endoscopic retrograde cholangiopancreatography: Spectrum of abnormalities demonstrated with CT. RadioGraphics. 2001;21:1441–1453.

Management of duodenal perforations post-endoscopic retrograde cholangiopancreatography. When and whom to operate and what factors determine the outcome? A review article. J Pancreas (Online). 2012;13:18–25.

Post ERCP perforations. UptoDate 2022. Accessed 25/4/2022.

Computed tomography classification of endoscopic retrograde cholangiopancreatography-related perforation. The Kaohsiung Journal of Medical Sciences. 2019;36:129–134.'

The following clinical advice was obtained from Dr Grunewald on 27 October 2020:

'Thank you for asking me to provide further comments regarding this case. I have received the documents listed in your letter dated 31 July 2023. The four topics requiring clarification are:

Cessation of antibiotics

1. Whether the cessation of antibiotics over the period of 21–27 [Month1] was appropriate for the conservative management of ERCP complications, including pancreatitis, potential perforation and/or leak.
2. Whether this new information changes my previous opinion on the standard of care.

Adverse event review

1. Whether in my view an adverse event review should have been carried out following [Mrs A's] deterioration and death.
2. If I identify any departures in the expected standard of care, whether I consider those departures to be attributable to individual staff and/or systemic failures.
3. Management of ERCP adverse events
4. Whether there is a particular algorithm for the management of ERCP complications which I would recommend.
5. Any other matters I consider warrant comment.

Specific Commentary

Cessation of antibiotics

[Mrs A] was commenced on intravenous antibiotics on 7 [Month1] following her ERCP and ampullectomy complicated by a perforation. The surgical ward round notes from 19 [Month1], read "Continue as before". She was reviewed by the on-call house officer

several times on 20 [Month1] because of an elevated temperature, a fast heart rate and increasing inflammatory markers (white cell count and CRP). A septic screen was requested and antibiotics were continued. The antibiotics were discontinued on 21 [Month1]. The ward round notes from 21 [Month1], and from 22 [Month1], do not mention that antibiotics were to be stopped or had been stopped. I could not find any entry in [Mrs A's] clinical notes to indicate who advised cessation of intravenous antibiotics.

[Dr C] saw [Mrs A] on two occasions before her operation on 28 [Month1]. On 17 [Month1] the consultant ward round notes only mention "Erythromycin" which is commonly used to stimulate peristalsis rather than treating an infection, and on 23 [Month1] there is no mention of antibiotics.

I do not believe that her antibiotics should have been discontinued on 21 [Month1]. Although antibiotics are not routinely used in the treatment of pancreatitis, they need to be given to a patient who is being managed conservatively for post-ERCP perforation, especially if a retroperitoneal collection is found, and whose vital signs and blood tests indicate ongoing inflammation and sepsis. It is impossible to know if continuation of intravenous antibiotics would have influenced [Mrs A's] clinical course but most general surgeons would have continued intravenous antibiotics in this situation. The fact that they were stopped is a mild departure from accepted practice.

Adverse event review

An adverse event is defined as an incident which results in unintended harm to a patient. A serious adverse event is one which has led to significant additional treatment, is life-threatening or has led to an unexpected death or major loss of function (1). The Health Quality & Safety Commission New Zealand includes "Delayed recognition of patient deterioration resulting in permanent disability or death" as an example for a SAC 1 case review (Severity Assessment Code 1). I believe that [Mrs A's] death would have justified an adverse event review under this definition.

Responsibilities for any departure

As I stated in my previous response letters, there were many clinicians involved in [Mrs A's] care. I do not believe that the departure from accepted standards, i.e. discontinuation of intravenous antibiotics and continuation of non-surgical management when [Mrs A] failed to progress and showed signs of deterioration should be attributed to any particular person. This should be attributed to systemic failure.

Management of ERCP adverse events

I do not believe that an algorithm will be helpful in managing post-ERCP complications as there are too many variables to consider. More important than an algorithm is close collaboration between endoscopists and surgeons in managing these complex patients. All ERCP patients with suspected or proven complications should be discussed with a general surgeon who should get involved in the patient's care from the time of admission. This specifically applies to all cases where the endoscopist suspects that a

perforation might have occurred during the procedure. If the patient is being treated non-surgically but fails to recover rapidly then a surgeon with a special interest in biliary and pancreatic surgery should be notified and take over care. This surgeon should review the patient regularly to decide if, based on the clinical condition and CT scans, an emergency operation needs to be performed before the situation becomes unsalvageable.

Yours sincerely

BERND GRUNEWALD FRACS
General Surgeon

Relevant literature

Health Quality & Safety Commission New Zealand (https://hqsc.govt.nz).'

The following clinical advice was obtained from Dr Grunewald on 25 September 2023:

'It was not appropriate to continue non-surgical management of a septic and deteriorating patient for 21 days. Appropriate guidelines for such cases can be found in review articles. I have attached two such articles, there are more in the surgical literature.

Article 1: Page 1139, last paragraph: "Delayed surgery is performed in patients who remain septic despite non-operative treatment, and debridement and drainage of the retroperitoneal space is required".

Article 2: Page 201, paragraph 4: "We believe that fluid collection in the intra- or retroperitoneal cavity is a significant operative indication of type II injuries." Also page 203, Figure 2 "Algorithm for the management of ERCP related perforations".

The [DHB] Adult Inpatient ERCP guidelines are irrelevant in this situation. I am sure most specialist biliary and pancreatic surgeons would agree that [Mrs A's] non-surgical management did not achieve any improvement and surgery should have been performed much earlier. Intravenous antibiotics are an important part of non-surgical management of post ERCP perforations, and pretty much all biliary and pancreatic surgeons would have continued antibiotics. [The CMO] wrote on page 19 of his response letter that "these patients are typically managed with nutritional support, intravenous antibiotics, and sometimes a CBD or PD stent and percutaneous drainage of collections". I was not aware that [Mrs A's] antibiotics had been stopped until this was pointed out to me.

Regards

Bernd Grunewald.'