HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Care of woman in relation to a gastroenterology procedure

Background

1. On 22 December 2021, Mrs B underwent endoscopic retrograde cholangio-pancreatography[1] (ERCP). After being discharged that day, she developed pain and was readmitted to Middlemore Hospital (Health New Zealand | Te Whatu Ora – Counties Manukau (Health NZ)) where she was diagnosed with pancreatitis. Mrs B experienced significant complications, and her condition deteriorated. Sadly, she suffered multiorgan failure and passed away in January 2022. I express my sincere condolences to Mrs B's family.

2. On 27 January 2022, Mrs B's son, Mr A, raised concerns with this Office about the care provided to his mother by gastroenterologist Dr C and Health NZ. In particular, Mr A was concerned that the procedure took place without recent imaging to inform the procedure and that the procedure caused Mrs B's pancreatitis. Mr A also raised other concerns that are not the focus of this opinion, although they are commented on at the end of this report.[2]

3. Having considered all the available information, I make adverse comment about Dr C for failing to document cannulation of the pancreatic duct. However, given my findings, based on independent advice and responses from Health NZ, I am more concerned with the systems issues identified as outlined below.

4. I have found Health NZ in breach of Right 4(1)[3] of the Code of Health and Disability Services Consumers' Rights (the Code) for a series of systemic failures in triage and referral processes that did not prompt consideration of the need for recent imaging before scheduling patients for ERCP procedures and did not stipulate that recent imaging was a requirement before undertaking ERCP.

Issues to be determined

5. I must determine whether Mrs B was provided services with reasonable care and skill according to applicable standards at the time of her ERCP. In making this determination, I must guard against the bias that comes with hindsight and knowing the

[1] A procedure that uses X-ray to diagnose and treat problems with the biliary system (bile ducts, gallbladder, and related structures, including the pancreas).
[2] A delay in the administration of pain relief in the Emergency Department (ED) following presentation; difficulties Mr A faced when discussing his concerns with Middlemore Hospital during Mrs B's admission; and comments from surgical and Intensive Care Unit (ICU) staff about the ERCP procedure and the cause of the pancreatitis.
[3] Right 4(1) of the code states that every consumer has the right to have services provided with reasonable care and skill.

outcome. To assist me, I have obtained independent clinical advice from Dr Richard Stein, gastroenterologist. The issues for me to consider are:

(a) whether Mrs B's referral was adequately reviewed and triaged and whether she was appropriately directed to ERCP;

(b) whether it was appropriate to proceed with the ERCP in the absence of recent imaging;

(c) whether an inadvertent pancreatic duct cannulation should have been documented and whether, given such cannulation, prophylactic treatment for pancreatitis should have been administered.

Factual background

6. On 6 December 2021, after Mrs B had experienced gastrointestinal pain for two weeks, her General Practitioner (GP) referred her to Middlemore Hospital for 'specialist advice only'. The referral included Mrs B's history of gallbladder removal in 2013 and subsequent gallstones identified by ultrasound in 2014.

7. On 8 December 2021, Dr D, surgical consultant, reviewed the referral and noted on it 'gastro for ERCP'. Dr D explained that, as the grading clinician for General Surgery e-referrals, she was required to redirect referrals that had been inappropriately forwarded to General Surgery. Mrs B's referral fell into this category and was accordingly redirected to the Gastroenterology service. In noting 'gastro for ERCP', she understood that the appropriate consultant in the gastroenterology team would make appropriate allocations for clinical management.

8. Dr E, gastroenterologist, then triaged the referral on 14 December 2021 and graded it for an urgent ERCP procedure.

9. Dr E explained his rationale for the ERCP grading, including that he considered, among other factors, the significant risk of complications and heightened risk if treatment were to be delayed, together with the potential treatment delays during the upcoming holiday season.

10. When Mrs B presented to Dr C at Health NZ on 22 December 2021, the expectation of both Mrs B and Dr C was that an appropriate assessment and triage had taken place and that an ERCP would be performed that day.

11. At the time of the consultation, Dr C was aware of Mrs B's history of cholecystectomy in 2013 and that an ultrasound in 2014 had revealed likely small bile duct stones. He accessed the 2014 imaging report while he was undertaking the consenting process with her.

12. Dr C told the Health and Disability Commissioner (HDC) that he was surprised that recent cross-sectional imaging had not been undertaken and that it was not his usual practice to perform ERCP without more recent imaging. This, in his view, made the situation difficult, but he took into consideration that Mrs B had been reviewed and

referred for the ERCP by two other clinicians (the general surgeon and grading gastroenterologist) and that she was presenting at Health NZ ready to undergo the procedure.

13. Dr C told HDC that the decision to proceed to the ERCP was a joint one between himself and Mrs B after a long and fulsome discussion. He believes the discussion included the option to reschedule the procedure until more recent imaging had been obtained and that there was consideration of the surgical and specialist wait times if she was to start the referral process again. He also said Mrs B described pain that he considered warranted ERCP and that they agreed the procedure would be abandoned if difficulty was encountered. Ultimately, Mrs B agreed to the procedure and signed the consent form. This discussion and agreement are confirmed in the clinical records.

14. During the ERCP, while Dr C was cannulating the common bile duct, the guidewire initially entered Mrs B's pancreatic duct, and a small amount of contrast was injected. Dr Stein advised that pancreatic duct cannulation is not uncommon during this procedure. Health NZ's Adverse Event Report (AER) referred to research that shows inadvertent cannulation of the pancreatic duct occurs in at least 10% of ERCP procedures.

15. Dr C did not document in Mrs B's clinical records that this had occurred, nor did he administer prophylactic treatment in the form of nonsteroidal anti-inflammatory drugs (NSAIDs) to guard against pancreatitis.

16. Health NZ confirmed that, at the time of Mrs B's care, there was no process mandating prophylactic treatment in the event of inadvertent pancreatic cannulation.

17. Regrettably, Mrs B developed post-ERCP pancreatitis and had significant complications. She was admitted to hospital in the early morning of 23 December, several hours after her ERCP, but, despite intensive treatment over several weeks, died in January 2022.

Responses to provisional opinion

18. The parties to this investigation were provided the opportunity to comment on relevant sections of the provisional opinion and their responses have been considered and incorporated where appropriate.

19. Following receipt of the final decision, Mr A sought an opportunity to comment. This was granted, and his comments were considered and incorporated within this amended version of the final report where appropriate.

Decision Dr C – adverse comment

Decision to proceed without recent imaging – no breach

20. I am satisfied on the evidence that both Dr C and Mrs B anticipated that an ERCP would proceed on 22 December. It is also clear that Dr C would have expected more recent imaging than was available to him, and I accept that he was surprised when he

discovered it was not. Other specific contextual matters relevant to the decision-making on that day were that Mrs B's referral had been triaged for an urgent ERCP by an ERCP specialist (notwithstanding the absence of recent imaging), there was an upcoming holiday (Christmas), and there were pressures affecting obtaining timely imaging/radiology in the post-COVID environment that were likely to affect the timing of care should the ERCP be deferred. Health NZ also advised HDC that, at the time, there were no protocols or guidelines on the accepted maximum amount of time between imaging and undertaking an ERCP.

21. I have little difficulty concluding that Mrs B's presentation on Dr C's ERCP list, in light of the factors above, placed both Mrs B and Dr C in a difficult position.

22. I accept that, given the circumstances, Dr C had a substantial and detailed discussion with Mrs B about the concerns regarding the lack of recent imaging, including discussing options of whether to proceed or delay. This discussion was noted in the clinical record: 'careful consent was obtained noting no hepatobiliary imaging and recent [liver function tests] so very low probability of bile duct stones or other abnormality'. Mr A provided a brief account of this conversation, saying that his mother told him that Dr C had said 'we've got this far so we might as well complete the procedure'. In my view, the quote shared by Mr A indicates that Mrs B was aware of some issues on the day, but I also accept the contemporaneous documentation, which supports Dr C's evidence that the conversation was more fulsome. That said, Mrs B had prepared herself for ERCP, and her own decision-making would have undoubtedly been affected by the situation that was presented.

23. Of course, notwithstanding the discussion, it was within Dr C's remit to have considered whether an ERCP was clinically indicated or whether it would have been more appropriate to defer to seek further imaging. He has accepted this responsibility but has also provided a clinical rationale for why he decided to proceed (noting the pain Mrs B described to him and that the older imaging did show evidence of small stones) and identifying why he did not consider her normal liver enzyme tests to be determinative of whether to proceed to ERCP or not. This last point is supported by Dr E (the grading ERCP clinician), who commented that liver function tests can be normal despite clinically significant stones.

24. My advisor, Dr Stein, initially stated (without the benefit of specific statements from the clinicians involved) that Mrs B should have had a recent imaging study before her ERCP (that an MRCP[4] or endoscopic ultrasound would likely have confirmed or, if negative, made the presence of the gallstones questionable or suggested another cause of her pain). He did not consider that the description of Mrs B's pain in the written information was convincing of biliary colic, and he identified a discrepancy in the pain being documented as either left or right. He also commented on the need for a detailed history from the patient. Given this, Dr Stein's view was that the failure to obtain further imaging was a severe departure from the standard of care – though in

[4] Magnetic resonance cholangiopancreatography (an imaging technique to visualise the pancreatic duct and common bile duct).

doing so, he tempered his findings with reference to the systems issues at play (which are discussed later in this opinion).

25. After considering further evidence provided by Drs C, D, and E, Dr Stein maintained his view that not seeking further imaging and information before undertaking an ERCP was a severe departure but stated that this represented a systems failure rather than a breach of the standard of care by Dr C. He considered that Dr C was placed in a 'no-win' situation. Likewise, noting that Dr E had recommended the ERCP, he considered the systems issues to be most relevant. He stated, 'I should stress the impact ... of the pressure on doctors to rapidly triage patients and reduce waitlist times. While it would be difficult to argue that this ERCP should have proceeded as scheduled, doctors also must weigh the impact on the patient and their whānau who have been waiting or have prepared themselves emotionally for the procedure. If the procedure is then cancelled, the patient would likely have to wait several weeks for a specialist appointment or further imaging studies. Attention therefore should be focused on how to relieve doctors of the pressures of modifying their clinical decisions to deal with the repercussions of "systems issues".'

26. I agree with Dr Stein's clarified opinion and conclude that Dr C did not breach the Code in deciding to proceed with the ERCP without seeking further imaging. In reaching this conclusion, I have considered the contextual issues described in the foregoing discussion but also that Dr C had a clinical rationale for proceeding, which was consistent with Dr E's view, and he described balancing the competing contextual interests in discussion with Mrs B. In my view, criticisms of Mrs B's care are more appropriately directed to the system.

Failure to administer prophylactic treatment to prevent post-ERCP pancreatitis or reduce its severity.

27. During the procedure, Mrs B's pancreatic duct was cannulated with a small amount of contrast dye. Dr Stein has acknowledged that this is not uncommon but, in his view, noting this inadvertent cannulation, it would have been advisable to administer an NSAID rectally to reduce the risk of post-ERCP pancreatitis. Dr Stein referenced European Guidelines to support his view, noting that this was the practice at most centres in New Zealand but also acknowledging that some endoscopists did not adhere to this practice. He considered this to be a mild to moderate departure from the standard of care.

28. Both Dr C and Health NZ provided alternative evidence that, at the time, neither the international guidelines nor Middlemore Hospital policies contained specific recommendations for prophylactic treatment as part of routine ERCP procedures. Dr C also reiterated that he was trained in an era where NSAIDs were not used for prophylaxis against pancreatitis and, at the time, NSAIDs were administered based on clinical assessment of the risk of pancreatitis. In Dr C's view, Mrs B did not meet the criteria of high risk for pancreatitis warranting the administration of NSAIDs.

29. The AER contained slightly different information suggesting that Mrs B's risk profile changed from low to medium/high once the contrast was injected into the pancreatic duct. Nevertheless, the AER identified that international guidelines on prophylactic treatment were inconsistent at the time because studies had reported conflicting findings.

30. Dr Stein's advice is also relevant to my determination. In his first set of advice, Dr Stein advised, "failure to administer a rectal NSAID (or place a stent) would be a mild to moderate departure from standard care (although there are some endoscopists in New Zealand who do not give rectal NSAIDs)."

31. In Dr Stein's second set of advice after reviewing the additional information, he changed his view. His re-evaluation was based on the following context: the year in which the ERCP was performed, that this case would not be deemed to be one where there was a high or moderate risk of pancreatitis, and that there was no policy in place at the time regarding their use. He concluded, "it is now my opinion that Dr C was not in breach of the standard of care (including not administering NSAIDs pre- or post-procedure), but rather the breach was due to a systems failure of scheduling elective ERCPs without adequate assessment; a perception by medical staff of significant delays in obtaining imaging studies; and the absence of hospital guidelines regarding the medical management of patients undergoing ERCP."

32. Dr Stein maintained his advice that there was a severe departure from the standard of care, linking it to a failure to undertake a full assessment before proceeding with the ERCP. This failure has been appropriately deemed a systems failure, and a breach decision has been made against Health NZ Counties Manukau, as outlined below.

33. Accordingly, for the above reasons, including my reliance on Dr Stein's opinion, I am not critical of Dr C for not administering NSAIDs in the circumstances of this case. This issue is also briefly discussed in relation to the system later in this opinion.

Documentation – adverse comment

34. Dr Stein identified Dr C's failure to document the inadvertent cannulation of the pancreatic duct as a moderate departure from the accepted standard of care. Dr C told HDC that he did not intentionally omit this cannulation from Mrs B's clinical records, and he disputed Dr Stein's opinion that this was a moderate departure. His view was that neither he nor his peers would routinely document this kind of incident and that it was not his normal practice to document 'minor pancreatic duct contrast injections at the time of Mrs B's procedure'. He further commented that usual practice would have been to document major cannulation episodes. Dr Stein disagreed that the requirement to report cannulation of the pancreatic duct applied only to major cannulation episodes.

35. I acknowledge Dr Stein's advice. In my view, documenting the cannulation of the pancreatic duct was required, noting the potential relevance of that information to the subsequent clinical course. It was, therefore, potentially important information for

other clinicians and her family. However, in light of the evidence before me that, at the time of these events, minor cannulations such as occurred in this case may not have been routinely reported, and further information about the systems issues discussed below, I do not consider Dr C's omission to document this complication as at the level required for a breach finding. That said, I am critical that Dr C did not document the cannulation and request that he reflect on Dr Stein's comments in this respect.

Decision Health NZ – Counties Manukau – breach

36. One of the key issues in this matter was that Mrs B was referred directly to ERCP by the gastroenterology triaging doctor without obtaining more recent imaging or specific information to characterise her pain (beyond that identified in the GP referral). The ERCP then proceeded in the absence of such imaging. In Dr Stein's view, it was a severe departure from the standard of care for further evaluation not to have taken place. In this respect, Dr Stein noted that ERCP is not without associated morbidity and mortality risks, and it carries a 3% risk of pancreatitis. Health NZ's AER reported a 0.5% mortality rate for ERCP procedures.

37. Dr Stein identified three systems failures:

(a) the scheduling of elective ERCPs without adequate assessment;

(b) a perception by the medical staff of significant delays in obtaining imaging studies; and

(c) the absence of hospital guidelines regarding the medical management of patients undergoing ERCP.

Process for triaging and scheduling ERCP procedures

38. Dr C advised both the internal review process and my investigation that he was surprised by the lack of recent imaging and that this was not in accordance with usual processes. I further note that, at the time of Mrs B's procedure, Middlemore Hospital did not have in place any protocol or guidelines establishing the maximum amount of time between imaging and undertaking an ERCP.

39. Dr Stein advised HDC that both the triaging surgeon and the triaging gastroenterologist should have recommended initially obtaining more history and another imaging study rather than scheduling Mrs B directly for an ERCP. Doing so may have provided clarification on whether an ERCP was clinically indicated. After considering feedback from Drs D and E and Health NZ, Dr Stein acknowledged that the referring surgeon was not recommending ERCP but rather redirecting the referral to the appropriate service.

40. Dr E told HDC that the decision to refer Mrs B for an urgent ERCP was made in good faith and with the intention of preventing adverse outcomes from delayed care and that it complied with guidelines for ERCP referrals at Middlemore Hospital. Both Dr E and Health NZ noted limitations on the usefulness of imaging to detect common bile duct stones. Dr Stein advised that ERCP is a procedure that carries a significant risk of

morbidity and mortality and that pancreatis is not a 'rare' complication. He maintained that Mrs B should have been evaluated further before being referred for ERCP and that the failure to do so amounted to a severe departure from the standard of care.

41. Dr Stein considered that the failure to proceed to ERCP without further imaging or evaluation was a systems issue. I agree. I am in no doubt that the standard of care was for more recent imaging to be available before undertaking ERCP.

42. In my view, responsibility for nonadherence to that standard in Mrs B's situation falls to the system, which needed appropriate checks and balances to ensure patient safety. I consider that failings at numerous points occurred at Middlemore Hospital, which together resulted in Mrs B not receiving appropriate evaluation before undergoing the ERCP.

(a) Clinicians at Middlemore's Gastroenterology Department were placed under significant pressure to triage multiple referrals for ERCP in a limited amount of time. ERCP lists at the time were oversubscribed.

(b) No processes were in place at Middlemore Hospital requiring imaging before undertaking ERCP procedures or providing guidance about the length of time between imaging and ERCP procedures.

(c) Dr C was assigned to carry out an ERCP on the understanding that the patient had been appropriately triaged and assessed as suitable to undergo the procedure. He was unaware that this was not the situation until immediately before the scheduled procedure.

(d) Mrs B was scheduled for the procedure and arrived expecting that it would proceed that day.

43. As a consequence of these failures, Mrs B underwent the ERCP procedure without appropriate imaging or adequate evaluation of the necessity for the procedure and was therefore exposed to its risks. In saying this, I am unable to conclude that, had the imaging and evaluation occurred, Mrs B would not have later had the procedure undertaken in any event. Nevertheless, the imaging and evaluation should have occurred.

44. Accordingly, for the failures outlined in the above paragraphs, I find that Health NZ failed to provide services to Mrs B with reasonable care and skill, in breach of Right 4(1) of the Code.

Failure to administer NSAIDs

45. During the procedure, Mrs B's pancreatic duct was cannulated with a small amount of contrast dye. Dr Stein has acknowledged that this is not uncommon but, in his view, it would have been advisable to administer an NSAID rectally to reduce the risk of post-ERCP pancreatitis. Dr Stein referenced European Guidelines to support his view, noting that this was the practice at most centres in New Zealand, although also acknowledging

that some endoscopists did not adhere to this practice. He considered this to be a mild to moderate departure from the standard of care.

46. Health NZ provided alternative evidence that, at the time, neither the international guidelines nor Middlemore Hospital policies contained specific recommendations for prophylactic treatment as part of routine ERCP procedures. The AER acknowledged that Mrs B's risk profile changed from low to medium/high as a result of contrast being injected into the pancreatic duct. Nevertheless, the AER identified that the international guidelines regarding prophylactic treatment were inconsistent at the time because studies had reported conflicting findings.

47. Although I note Mr A's submissions that other studies and European advice showed that prophylactic treatment could reduce the risk of post-ERCP pancreatitis (and I accept this to be the case), other international guidelines applicable at the time did not direct such treatment. Given this, the different practices between endoscopists, and the lack of stipulated or mandated processes in New Zealand at the time of Mrs B's care, it would not be fair to hold Health NZ or indeed Dr C to a standard that had not yet been definitively established.

48. I acknowledge the changes Middlemore have made to strengthen their policy and procedures in relation to ERCP and the steps they took after Mrs B's tragic passing to work with her family after they made their complaint.

Other matters

49. When Mr A first submitted a complaint to this Office, he also advised of concerns about the wait time in the ED and the delay in pain relief being administered when Mrs B presented with significant pain after her procedure. This aspect of the complaint was not the subject of this investigation. Nevertheless, those concerns offer an opportunity for Middlemore Hospital to consider how it can better support patients who present to the ED after a procedure.

50. Mr A also expressed concern about Middlemore Hospital's management of Mrs B's pancreatitis. Noting my expert advisor's comments that he found nothing of concern in relation to this matter, I have not taken this any further.

51. Mr A was also concerned about comments staff made about the cause of Mrs B's pancreatitis when she presented to the ED and during her subsequent admission to the surgical ward and then ICU. A review of the information provided shows differing accounts of these comments, and I have been unable to make a finding as to what was or was not said. However, noting Mr A's concerns in this respect, I suggest Health NZ Counties Manukau – in its reflection on this case and the complaint – take opportunities to remind staff of the impact that comments can have on a consumer or their family, particularly in times of concern and distress.

52. Lastly, Mr A described the difficulties he faced when attempting to discuss his concerns with Middlemore Hospital and Dr C at the time of Mrs B's admission. However, I note that Middlemore Hospital's AER indicates that this issue was resolved.

Changes made since events

53. I acknowledge the steps Middlemore Hospital has taken in response to this incident and Mr A's complaint. I appreciate that Middlemore Hospital has actively engaged with Mr A as part of its AER and that, in response to this complaint, it has implemented actions to prevent the occurrence of a similar event, which is an important aspect of quality assurance.

54. Middlemore Hospital has confirmed that all recommendations in the AER have been implemented:

- All patients referred for outpatient ERCP will first be assessed in clinic or will be discussed by the Gastroenterology multidisciplinary team (MDT) before an ERCP is booked.
- If the pancreatic duct is cannulated and injected, then all such patients will receive Voltaren suppositories and a pancreatic stent to reduce the risk of pancreatitis. These patients may be admitted to hospital for a period of observation at the endoscopist's discretion.
- If a patient re-presents with complications after a procedure, a review of the potential for the pathway/notification process to the proceduralists will be undertaken.
- Regular audits of ERCP procedures on a two- to three-yearly basis will be undertaken to ensure that ERCP lists are performing as per international standards.

Recommendations

Health NZ Counties Manukau

55. Provide a written apology to Mr A for the issues outlined in above. The apology is to be sent to HDC within three weeks of the date of this final report for forwarding to Mr A.

56. My provisional opinion to Middlemore Hospital included a further recommendation that, if not done already, it should highlight in its processes/procedures/policy, that – before referring for or proceeding with ERCP – the indication for the procedure has been confirmed adequately with appropriate and timely investigations. Middlemore has provided evidence that, in its view, this recommendation has been completed in a revised ERCP guideline. However, that guideline does not specifically address the crux of the issue in this matter: namely the requirement for recent imaging before ERCP. Accordingly, I recommend that Middlemore Hospital consider including a requirement for recent imaging before ERCP in its guideline. Evidence of this consideration should be provided to this Office within 3 months of this final report.

Dr C

57. I am satisfied that Dr C has reflected on this matter, and I have no recommendations to make to him.

Follow-up actions

58. A copy of this report will be sent to Health NZ, Dr C, and Mr A.

59. A copy of this report with details identifying the parties removed, except Health New Zealand | Te Whatu Ora – Counties Manukau Middlemore Hospital and my independent advisor, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

60. A copy of this report will be sent to Dr C's regulatory body, the Medical Council of New Zealand, as required under s 43 of the Health and Disability Commissioner Act 2004. In conclusion, it is important for me to acknowledge the dedicated advocacy of Mr A in the tragic circumstances of his mother's death to improve healthcare services in New Zealand. It is clear that his efforts have resulted in quality improvement changes for the future. As part of this, Mr A has had discussion with the National Chief, Quality and Patient Safety at Health NZ, who advised that the development of a national policy framework was under way to improve ERCP standards nationally. Unfortunately, Mr A has since advised that the ERCP working group is no longer functioning (which I have confirmed). In light of this development, I recommend to Health NZ National Office that it re-establish the ERCP working group with a focus on seeking consistency of ERCP standards nationally. I will continue to monitor progress in relation to this recommendation and request a response to this recommendation within 3 months of this report. Therefore, an anonymised copy of this report will be provided to the National Chief, Quality and Patient Safety at Health NZ in support of these changes.

Morag McDowell

Health and Disability Commissioner

Appendix A: Independent advice

The following independent advice was obtained from Dr Richard Stein, consultant gastroenterologist:

'22 March 2024

I have been asked to provide an opinion by the Health and Disability Commissioner on case number C22HDC00215. I have read and agree to the Commissioner's Guidelines for Independent Advisors.

I am a gastroenterologist, trained in the United States at the University of Illinois Hospital and Emory University. I have vocational registration in New Zealand, where I have practised since July 2007. I am a Fellow of the Royal Australasian College of Physicians, the American College of Gastroenterology, and the American Gastroenterological Association. I have worked as a consultant gastroenterologist at Hutt Valley DHB (nine years) and Wairarapa DHB (nine years). I have managed the gastroenterology clinic at Kaitaia Hospital since 2016 and am currently doing locum work as a consultant at Rotorua and Hawke's Bay hospitals. I am a Senior Clinical Lecturer at the University of Otago in Wellington, and, while in the States, was Assistant Clinical Professor of Medicine at the University of Washington in Seattle. I was trained in ERCP during my Fellowship at Emory University in Atlanta and actively performed ERCPs in the States for over 20 years. As a Senior Medical Officer at Hutt Hospital, one of my responsibilities was collecting and reporting adverse events of all endoscopic procedures at the hospital, including ERCP, on a quarterly basis. I am currently Chairman of the NZ Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy.

I was asked by the Commissioner to review the following documents and provide an opinion on the questions listed below:

1. Letter of complaint dated 26 January 2022
2. Te Whatu Ora Counties Manukau response dated 30 May 2022
3. Clinical records from Te Whatu Ora Counties Manukau covering the period 22 December 2021 onwards.
4. Te Whatu Ora Counties Manukau ERCP guidelines.

I additionally requested a copy of the original referral from the General Practitioner, which I received on 4 March 2024.

I was asked to comment on the following after my review of the above documents:

1. The standard of care provided to [Mrs B] prior to her ERCP, during the procedure, and post procedure. In particular, to comment on the informed consent process and whether the decision to discharge [Mrs B] following the procedure was appropriate.
2. Whether a CT scan was indicated before the ERCP procedure.
3. Whether pancreatitis is a known risk factor of ERCP, and if so, whether it appears that staff were aware of and appropriately managed this risk.
4. Whether the management of [Mrs B]'s pancreatitis was of accepted standard.
5. Whether you can identify any improvements or recommendations; and

6. Any other matters that warrant comment.

For each of the above six items, I was asked to advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe)?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar outcome in the future.

Summary of events: C22HDC00215

[Mrs B] was a 69-year-old woman who was referred to the General Surgery-UGI/Hepatobiliary Service on 6 December 2021 for 'Specialist Advice Only'. The reason for the referral was 'intermittent RUQ pain for the past 2 weeks, worst last WE, no apparent trigger, nil associated, no N&V, no jaundice, no fevers or sweats, settles with rest. Otherwise well. Past lap cholecystectomy 2013. Subsequent choledocholithiasis on ultrasound Jan 2014'. No imaging reports or lab tests were attached.

The referral was triaged by the surgical department on 8 December 2021 by Dr [D] with the note: 'Gastro for ERCP. Kind regards'. It was noted on the referral that the waiting list for a first specialist appointment was 57 days.

The referral was passed on to be triaged by the gastroenterology department by Dr [E]. The only notation was 'for ERCP', and the procedure was placed on Dr [C]'s list to be performed on 22 December 2021.

When [Mrs B] met Dr [C] on the day of the procedure, the family noted 'When she met with Dr [C], he asked where the CT scan results were, and my mum advised him that there had not been a CT scan completed. Dr [C] said that he always had a CT scan booked in before doing an ERCP but said that "we've got this far, so we might as well complete the procedure". So, my mum had the procedure done and was sent home at roughly 4 pm the same day.'

On the procedure report, Dr [C] wrote 'careful consent obtained, noting that no prior hepatobiliary imaging and recent normal [liver function tests] so very low probability of bile duct stone or other abnormality'. He also noted in the 'indication section' of the procedure: 'Abdominal pain was in the left upper quadrant; past cholecystectomy 2013 and USS demonstrated choledocholithiasis Jan 2014 but no recent cross-sectional imaging. Normal [liver function tests]. Diagnostic'

It was decided to proceed with the procedure with the information provided. The procedure was uncomplicated, although (not documented in the report), in the process of cannulating the common bile duct, the guidewire initially entered the pancreatic duct, and a small amount of contrast was injected. No stones were subsequently identified in the biliary tree, and the patient was sent to the recovery area. She was discharged to home at 4pm.

That evening, according to the family, she was in a little pain when dropped off at home but developed severe abdominal pain at 11pm. She was brought by ambulance to Middlemore ED at 00:55 on 23 December 2021 and given a diagnosis of post-ERCP pancreatitis.

She was seen by the surgical registrar at 05:00 and admitted to the surgical floor with the plan to place her on clear liquids and give [intravenous] IV fluids.

At 02:15 on 25 December 2021, [Mrs B] was found to be in multiorgan failure and had a progressive downhill course. A CT scan on 28 December 2021 showed severe pancreatitis, but without necrosis, with a large volume of free peripancreatic fluid, bilateral pleural effusions and diffuse subcutaneous oedema.

She was intubated the next day, developed *Staphylococcus aureus* sepsis from a catheter site, and started on dialysis on 1 January 2022. On 3 January, she grew Klebsiella in blood cultures and was on pressor support. Despite IV antibiotics and aggressive measures in the ICU, her CT scan on 10 January showed multiple fluid collections with rim enhancement and a suspected small perforation of the transverse colon. An attempt at trans-gastric drainage of the peri-pancreatic fluid collection was made on 14 January but was unsuccessful. Her follow-up CT scan on 17 January showed a large perforation of the transverse colon, retroperitoneal extension of the inflammatory mass, and multiple areas of located gas. The patient was taken to the theatre at that point and had a right hemicolectomy with ileostomy and a partial necrosectomy of the pancreas but [later] passed away.

These are the points above on which I was asked to comment:

1. **The standard of care provided to [Mrs B] prior to her ERCP, during the procedure, and post procedure. In particular, please comment on the informed consent process and whether the decision to discharge [Mrs B] following the procedure was appropriate.**

While I do not have a copy of the signed consent, there is documentation that risks of the procedure were explained and all questions were answered on the procedure report. The procedure appears to have been performed with good technique. While the pancreatic duct was cannulated, this is not uncommon. Post-procedure, however, it would have been advisable to administer an NSAID rectally (especially in view of the guidewire being passed into the pancreatic duct and dye injected) to reduce the risk of post-ERCP pancreatitis. Routine administration of rectal NSAIDs either before or immediately after ERCP is a recommendation by the European Society of Gastrointestinal Endoscopy and is the practice at most centres in New Zealand.

(https://www.esge.com/assets/downloads/pdfs/guidelines/2014_prophylaxis_post_ercp_pancreatitis.pdf)

There is also no mention in the report that the pancreatic duct was cannulated. This was apparently noted on review of the X-ray films.

If a patient is doing well after an ERCP and, in the setting of an uncomplicated procedure, it is usual practice to discharge the patient following a recovery period in the department if they are doing well. From the family's letter, it appears that [Mrs B] had only mild discomfort when she arrived home after the exam.

Failure to administer a rectal NSAID (or place a pancreatic stent) would be a mild–moderate departure from standard of care (although there still are some endoscopists in New Zealand who do not give rectal NSAIDs).

The failure to mention cannulation of the pancreatic duct in the report is a moderate departure of standard of care, although this likely was an unintended omission.

2. Whether a CT scan was indicated prior to the ERCP procedure.

Firstly, I think it is unlikely that Dr [C] suggested [Mrs B] should have had a CT scan. I suspect he referred to an MRCP. Regardless of what imaging test was discussed, [Mrs B] should have had a recent imaging study prior to performing the ERCP. The ultrasound referred to in the GP's referral was almost eight years old, and results were being relayed second-hand.

Furthermore, the description of [Mrs B]'s pain from the information received was never entirely convincing for biliary colic. In the ERCP report, it states that the location was in the left rather than right upper quadrant as described by the GP. There is no documented detailed description anywhere of the pain. In the GP referral, it states only that there was no associated nausea or triggering factors and that it was relieved with rest. In the ERCP note, it specifically notes 'very low probability of common duct stones or other abnormality'.

In short, an MRCP (or endoscopic ultrasound) would likely have confirmed or, if negative, made the presence of the stone questionable or suggested another cause. The ERCP may have been avoided. The need for more information in the form of a detailed history from the patient cannot be understated. I disagree with the opinion of the reviewing committee at Middlemore Hospital that the patient would have undergone an ERCP even if the above studies were normal. Nowhere is there a detailed enough description of the pain that would be convincing enough of biliary colic to compel an endoscopist to proceed with an ERCP in a patient with a normal MRCP or endoscopic ultrasound.

Obtaining more history and another imaging study, specifically an MRCP or endoscopic ultrasound if a common bile duct stone was suspected, should have been the initial recommendation of both the triaging surgeon and the triaging gastroenterologist, rather than recommending the patient be scheduled directly for an ERCP.

The failure to obtain further imaging is a severe departure from standard of care. I would temper this finding, however, by pointing out that there are system failures at play as well. Doctors are under tremendous pressure to process referrals quickly and reduce wait list times. Openings for specialist appointments are extremely limited. When a patient arrives ready to have a procedure with insufficient data, doctors often find themselves under pressure to perform the procedure regardless of their best judgement in the interest of reducing pressure on the entire system.

The recommendations from the excellent Root Cause Analysis group at Middlemore Hospital addressed these issues very well and require patients to have a formal appointment or be discussed in an MDT meeting prior to scheduling an outpatient ERCP.

3. Whether pancreatitis is a known risk factor of ERCP, and if so, whether it appears that staff were aware of and appropriately managed this risk.

Pancreatitis is a well-known risk factor of ERCP.

(https://bmcsurg.biomedcentral.com/articles/10.1186/s12893-023-01953-4).

Especially given the cannulation of the pancreatic duct, a rectal NSAID should have been administered or a pancreatic stent placed. While I do not have the records from the recovery area, it is standard to monitor for pain post-procedure, and this was very likely done. The diagnosis of post-ERCP pancreatitis appears to have been made quickly on [Mrs B]'s presentation to the ED.

Failure to manage the risk of pancreatitis with a rectal NSAID (or with a pancreatic stent) was, as stated above, a mild–moderate departure from standard of care.

This was addressed in the recommendations that came out of the Root Cause Analysis and will be standard practice in the future.

4. Whether the management of [Mrs B]'s pancreatitis was of accepted standard.

This question is difficult to answer without more information about [Mrs B]'s inpatient management. I did not receive any documentation about what transpired between the time of admission early in the morning of 23 December 2021 and when she was found to be in multiorgan failure early in the morning two days later. Patients admitted with pancreatitis need to be carefully managed with IV fluids within the first 48 hours (with very close monitoring of patients who are elderly and have comorbidities).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9994841/

5. Whether you can identify any improvements or recommendations.

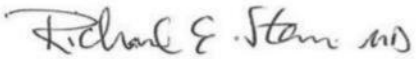
I concur with the recommendations from the group that did the excellent Root Cause Analysis. The only recommendation I would consider modifying is that an audit of procedures be done every two to three years. Regular review of all significant adverse complications should be an ongoing process, with discussions of major complications at every EUG meeting.

6. Any other matters that warrant comment.

I should stress the impact, as noted above, of the pressure on doctors to rapidly triage patients and reduce wait list times. While it would be difficult to argue that this ERCP should have proceeded as scheduled, doctors also must weigh the impact on the patient and their whānau who have been waiting or have prepared themselves emotionally for a procedure. If the procedure is then cancelled, they are forced to take into account that the patient may

have to wait several weeks for a specialist appointment and often end up being re-scheduled for the same procedure, only several months later. Attention therefore should be focused also on how to relieve doctors of the pressures of modifying their practices to deal with these 'system issues'.

Respectfully submitted,



Richard Stein, MD,
FRACP, FACG, AGAF'

Appendix B: Subsequent independent advice

I have been asked to review the additional information re: C22HDC00215, specifically the statements of Dr [C] dated 17 February 2025 and 25 July 2025, a letter from Health New Zealand to the patient's family dated 7 June 2024, and Health New Zealand's response to the Deputy Health and Disability Commissioner dated 17 September 2025.

I would preface this with the following points:

1. The additional statements above were very helpful in sorting out whether the outcome was more related to systems issues, rather than individual decisions.
2. There does not seem to be any argument that [Mrs B] should have been evaluated further prior to the ERCP being performed. The recommendations concerning the changes implemented by Health New Zealand acknowledge this: 'All patients referred for outpatient ERCP will be first assessed in clinic or will be discussed in the Gastro MDT first before an ERCP is booked'.
3. Dr [C] writes, 'With all due respect to Dr Stein, I also query whether he is in a position to comment on the standard of ERCP in New Zealand in 2021 given his background and performance of ERCP appears to only ever have been in the US'. I performed ERCPs in the States for over 20 years, from the time when interventional ERCP was in its infancy. I have been a hospital-based gastroenterologist in New Zealand for over 19 years and, for approximately five years, until one year prior to this case, was the sole reviewer of all ERCP complications at my hospital (in addition to triaging referrals for the procedure).
4. I was involved in developing current standards for training in ERCPs in my role as a committee member and current Chair of the New Zealand Committee for the Recognition of Training in Gastrointestinal Endoscopy.
5. Dr [C] implies the notion that injection of the pancreatic duct need not be reported unless it is a 'major contrast injection' and that not documenting 'minor injections' is standard of care. He states that the majority, if not all, of his contacts would agree. I disagree with this assertion.
6. There is reference in Dr [C]'s statement from June 2025 that [Mrs B] had 'biliary colic'. Again, there is nowhere in the records in which her pain is described in any detail. In fact, on the ERCP report it is noted that her pain was left, rather than right sided, and that there was 'very low probability of bile duct stone or other abnormality.'
7. Regarding the use of rectal NSAIDs, I did note in my original assessment that, at the time, some doctors in New Zealand were not routinely prescribing them, despite the fact that European guidelines have recommended their use routinely in all patients undergoing ERCP since 2014. In reevaluating this case in the context of (1) when it was performed, (2) that this particular case would not be deemed to be one where there was a high or moderate risk of pancreatitis, and (3) that there was no policy in place at the time regarding their use, I have amended my assessment (below).
8. I was always of the opinion that Dr [D] was just forwarding the referral to the appropriate service for triaging rather than recommending an ERCP. Dr [C], on the other hand, asserted that 'two experienced professionals had listed her for ERCP' (Dr [D] and [Dr E]).

9. As for the statement by Dr [C] that 'I am unsure how Dr Stein decided the ERCP was performed with good technique as that is something that can only be determined by direct observation', my report states 'The procedure ***appears*** to have been performed with good technique'. This was based on the written procedure note. It is unclear to me why he would challenge this statement.

In short, my assessment that there was a severe departure of standard of care has not changed. ERCP is a procedure that carries a significant risk of morbidity and mortality. If [Mrs B] had been fully assessed prior to being scheduled for the ERCP, the outcome may have been entirely different.

Notwithstanding the above, on re-evaluating this case in light of the further information provided, I will concede that this represents more of a system failure, rather than a breach of standard of care by Dr [C]. It is my opinion that Dr [C], at the time [Mrs B] presented for the procedure, was placed in a 'no-win' situation. He made a judgement which, only in retrospect, led to an unfortunate outcome. This is in line with my closing statement from my original assessment:

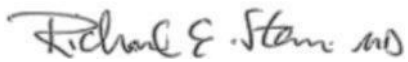
'I should stress the impact ... of the pressure on doctors to rapidly triage patients and reduce wait list times. While it would be difficult to argue that this ERCP should have proceeded as scheduled, doctors also must weigh the impact on the patient and their whānau who have been waiting or have prepared themselves emotionally for the procedure. If the procedure is then cancelled, the patient would likely have to wait several weeks for a specialist appointment or further imaging studies. Attention therefore should be focused on how to relieve doctors of the pressures of modifying their clinical decisions to deal with the repercussions of "system issues".'

In conclusion, it is now my opinion that Dr [C] was not in breach of standard of care (including not administering NSAIDs pre- or post-procedure), but, rather, the breach was due to a **system failure** of:

1. **Scheduling elective ERCPs without adequate assessment.**
2. **A perception by the medical staff of significant delays in obtaining imaging studies.**
3. **The absence of hospital guidelines regarding the medical management of patients undergoing ERCP.**

All of the above items appear to have been addressed by Health New Zealand.

Kind regards,



Richard Stein, MD, FRACP, AGAF, FACG
4 February 2026

Appendix C: Subsequent independent advice – Comment on Dr [E]'s and Dr [D]'s statements

Re: Review of Statements from Dr [E] and Dr [D]
C22HDC00215

I was asked to review the statements of Drs [E] and [D], dated 10 September 2025 and 8 August 2025, respectively, and to make any necessary additions to my previous review.

In my previous review, I did not specifically mention Dr [E] or Dr [D], but this review gives me the opportunity to do so.

Review of Dr [D]'s statement

Regarding Dr [D] and her statement, at no point in my previous review of the records did I think that Dr [D] was recommending an ERCP. The referral for ERCP was inappropriately sent to the surgical service, and I agree with Dr [D]'s statement that she was simply forwarding the referral to the appropriate service (gastroenterology) for review and triaging. In my opinion, she acted correctly and there was no deviation from standard of care.

Review of Dr [E]'s statement

Even taking into account the 'system issues' that Dr [E] mentions, that there were 'resource limitations and potential treatment delays during the holiday season', I do not agree with his statement that 'grading was consistent with professional standards and supported by two other senior consultants who independently reached similar conclusions based on the information available'.

In the report from Middlemore's Investigational Team, based on 'feedback from Dr A (Dr [C])', they write,

When [Mrs B] arrived for her ERCP procedure, Dr A did consider cancelling the procedure as there was no recent images available. He was ***concerned as this is not the normal process.*** *He could not look at the previous images as they were not available on clinical portal as they were performed in the private sector, but it was documented in the report that there was the presence of stones in the old scan of 2014. As these stones could be an explanation of her current symptoms, he decided to continue with the procedure. He did question if the referral from Surgery to the Gastro Dept for an ERCP was the correct judgement but as it was also confirmed by another Gastroenterologist at grading (14 December 2021) for an ERCP, he felt comfortable to continue.*

Dr [C] also wrote in his initial response,

I recall being surprised that she had not had any recent cross-sectional imaging, and I discussed that with her. I spent more time than I usually do in these meetings explaining to [Mrs B] that the lack of imaging put me in a difficult position, particularly in the circumstances of her having been referred to ERCP by two professionals, and she had arrived ready for the procedure.

Even with limited resources and the systemic failures that have been already mentioned, [Mrs B] should have been evaluated further to characterise her pain and possibly to investigate, for instance, why no decision was made to intervene in 2014 when she had her ultrasound. Instead, the decision to proceed urgently was based on the very limited information provided by her GP, who simply referred to her pain as 'biliary colic', never characterising the quality of the pain or identifying any features convincing for biliary colic. In fact, in Dr [C]'s ERCP report, [Mrs B]'s pain is described as left, rather than right sided, and, following his discussion with her pre-procedure, Dr [C] wrote in his report, 'very low probability of bile duct stones or other abnormality'.

Pancreatitis is not a 'rare' complication. The risk, even in the best of hands, is around 3%. Further evaluation, even just obtaining a history from the patient, may have avoided the outcome.

Dr [E]'s recommendation to perform an urgent ERCP still needs to be taken in the context of 'system issues' at the time: limited resources at his hospital and, importantly, having to triage multiple referrals in a limited period of time. Given these issues, in my opinion, there was only a minor deviation from standard of care.

Richard E. Stein, MD, FRACP, FACG, AGAF
19 February 2026