

A Decision by the Deputy Health and Disability Commissioner (Case 21HDC01892)

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Introduction

- 1. This report is the opinion of Carolyn Cooper, Aged Care Commissioner, and is made in accordance with the power delegated to her by the Commissioner.
- 2. The report discusses the care provided to Mr A by Health New Zealand|Te Whatu Ora (Health NZ).
- 3. Mr A underwent heart surgery in 2018. During his postoperative recovery period, an attempt was made to insert a chest drain, to drain fluid from his lungs. However, this was unsuccessful, and subsequently it was found that Mr A had suffered an iatrogenic splenic injury during the procedure.¹ Sadly, Mr A's condition deteriorated, and he passed away in hospital.



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¹ An injury to the spleen caused by medical examination or treatment.

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- 4. The following issues were identified for investigation:
 - Whether Te Whatu Ora/Health New Zealand² provided Mr A with an appropriate standard of care in relation to the chest drain procedure on 21 Month3 2018.
 - Whether Dr C provided Mr A with an appropriate standard of care in relation to the chest drain procedure on 21 Month3 2018.
- 5. The parties directly involved in the investigation were:

Mrs B	Complainant/daughter
Health NZ	District healthcare provider
Dr C	Individual provider

6. Independent advice was received from cardiothoracic surgeon Dr David Andrews (Appendix A).

Events leading up to complaint

Background

7. In Month1³ Mr A, in his seventies at the time, was placed on the waitlist for cardiac surgery to repair his mitral valve.⁴ His cardiac diagnoses and history included severe mitral regurgitation,⁵ ischaemic cardiomyopathy,⁶ atrial fibrillation,⁷ dilated atria,⁸ hypertension, and placement of two cardiac stents⁹ and a permanent pacemaker.

Surgery and postoperative recovery

- 8. On 15 Month3 Mr A underwent a mitral valve repair and coronary artery bypass grafting under the care of a cardiothoracic surgeon. The operation note recorded that following the surgery Mr A was transferred to the intensive care unit (ICU) in a 'stable and satisfactory condition'. A chest X-ray taken that afternoon noted: '[A]telectasis¹⁰ is present in the left lower lobe. The lungs are otherwise clear.' Bilateral chest drains were in place. Mr A was discharged back to the cardiology ward the following morning. Health NZ said that Mr A was thought to be progressing well.
- On 16 Month3 a chest X-ray showed 'more pronounced atelectasis in the left lower lobe'.
 On 18 Month3 a chest X-ray showed a 'small left pleural effusion¹¹ and left basal atelectasis



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² Now called Health New Zealand | Te Whatu Ora.

³ Relevant months are referred to as Months 1–3 to protect privacy.

⁴ Surgery to replace a poorly functioning mitral valve (the valve between the left atrium and the left ventricle of the heart) with a mechanical valve or a valve made from animal tissue.

⁵ A backward flow of blood to the heart when the flaps of the mitral valve do not close properly.

⁶ Damaged heart muscle from a lack of blood flow.

⁷ An irregular heart rhythm that begins in the heart's upper chambers (atria).

⁸ Abnormally large upper chambers (atria) of the heart.

⁹ Tubes inserted into narrowed arteries to keep them open.

¹⁰ Collapse of a lung or part of a lung.

¹¹ An abnormal accumulation of fluid between the layers of tissue that line the lungs.

slightly improved'. The X-ray report noted that the chest drains were to be removed that day, although there is no documentation of this in the clinical notes.

- 10. At 12pm on 21 Month3 Mr A was reviewed by the physiotherapy team to assess whether he was ready for discharge. He was noted to be feeling well generally and to be moving independently, although he was limited by fatigue and had increased shortness of breath on moderate exertion. Mr A's oxygen saturations were documented at 96%, but this decreased to 93% on moderate exertion. Following this assessment, Mr A was discharged from care of the physiotherapy team.
- 11. At 2pm on 21 Month3 a chest X-ray showed 'persistent moderate left basal pleural effusion with adjacent atelectasis'.

Sentinel event

- 12. At around 5.45pm on 21 Month3, a junior cardiothoracic registrar,¹² Dr C, unsuccessfully attempted to insert a chest drain. It was later discovered that during the procedure Mr A suffered an injury to his spleen.
- 13. In a statement provided to the Coroner, the cardiothoracic surgeon outlined the reason for the chest drain procedure:

'On [21 Month3] (sixth post-operative day) it was thought that [Mr A] was becoming a little more short of breath on exertion. On physical examination it was thought that he was somewhat fluid overloaded, and his diuretics were increased. A chest X-ray showed that there appeared to be a moderate left sided pleural effusion and it was considered this may have also been contributing to his shortness of breath.

It was therefore decided that this should be drained (by insertion of a Seldinger drain) and this was subsequently performed by [Dr C].'

- 14. Health NZ said that the timing of the attempted chest drain insertion (around 5.45pm) would not be considered out of hours for this type of procedure on the specialist ward.
- 15. There is no documentation of a consent process for the procedure, including whether the risks and benefits of the procedure were explained to Mr A.
- 16. In response to the provisional opinion, Dr C told HDC that Mr A received information regarding the mitral valve repair/replacement and coronary artery bypass surgery and, as part of this, he also received information regarding a chest drain and the possibility that it might need to be inserted.¹³
- 17. Dr C said that he discussed the finding of fluid on the lungs, referred to as a large pleural effusion, with both Mr A and his daughter prior to proceeding. Dr C stated that he discussed



¹² A doctor who has a minimum of two years' post-qualification experience (PQE) and is training in a specialty field.

¹³ While a consent form was completed for the earlier cardiac procedure by another doctor, it did not mention chest drains or any discussion about chest drains.

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the expected risks, side effects, and test results. There were no alternative options for Mr A, other than leaving the fluid, and Mr A agreed to the procedure. Further, Dr C said that at that stage it was not practice at the hospital to state that the procedure might end the patient's life.

^{18.} Following Mr A's passing, Mrs B gave a statement to Police about the events leading up to her father's death. A Police report dated 18 February 2021 included the following summary of Mrs B's statement:

'[Mrs B] was present when [Dr C] explained what he was planning to do. He did not seek consent or outline any risks for the procedure and "downplayed" it.'

- 19. On the other hand, an adverse event review (AER) conducted by Health NZ following the events (discussed at paragraphs 49–52) stated that '[t]he registrars, when interviewed as part of the AER, believed that they explained the procedure and that it did carry risk'.
- 20. Health NZ said that at the time of events it was not usual practice to gain written consent for this type of procedure on the ward. Health NZ also stated: 'Currently, there is not a stated requirement to seek written consent although it is implied by our policy.'¹⁴
- 21. Dr C did not document the chest drain procedure in the clinical records at the time. However, he outlined the procedure in a retrospective entry in the clinical notes at 10.30pm on 21 Month3 (after the splenic injury had been identified):

'Attempted chest drain insertion [with] 18Fr by seldinger technique. Noted pleural effusion on [chest X-ray]. Area prepped and draped.

Administered [local anaesthetic]. Aimed for line of nipple [approximately] intercostal space #5. Advanced needle. Blood returned back into syringe. Nil haemoserous fluid¹⁵ in syringe.

Senior registrar called in. Advised to abandon procedure with plan to [ultrasound scan] effusion tomorrow. [Observations] remained stable [with oxygen saturation levels] of 95% room air.'

- 22. Dr C recollected the events in a statement to HDC. He said that at the time of events he had performed 'approximately a dozen chest drains (predominantly Seldinger drains¹⁶)', and that 'more than half of these' were performed unsupervised, with no complications.
- 23. Dr C said that he first discussed with Mr A and Mrs B the finding of fluid (pleural effusion) on the chest X-ray, and Mr A agreed to the procedure. Dr C said he then took Mr A into the treatment room and proceeded as follows:

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¹⁴ This policy is described at paragraphs 40–43.

¹⁵ Bodily fluid that appears clear to yellow with a pink tinge.

¹⁶ A technique for inserting a chest drain.

'After setting up the trolley, I connected [Mr A] to a saturation and blood pressure monitor. He was positioned at 45 degrees on the bed, and following this, I aimed for the "safe triangle" (bordered by pectoralis major, latissimus dorsi, and 5th intercostal space). Due to [Mr A's] increased body mass index and body habitus, the intercostal spaces were not easily palpable. Considering this, in conjunction with palpating down the spaces, I also used his nipple line as a guide to locate his 5th intercostal space. Once I believed I had identified the right level, I prepped and draped.'

24. Dr C continued:

'Using the needle from a 18Fr seldinger drain set, I infiltrated the intended space. I was cautious regarding trajectory of the needle to pass it posteriorly as to avoid injury to the heart. I can normally feel a "popping" sensation as the needle passes through as it is tougher and more fibrous. I hadn't quite entered the pleura,¹⁷ I continued to pass the needle until I did so. However, I found that I was aspirating¹⁸ frank blood,¹⁹ rather than haemoserous fluid. I therefore called my senior registrar to come into the room to assist me. I was initially advised to attempt to advance the guidewire, for which it was met with resistance. We realised that the fluid aspirated was fresh blood rather than collected blood, and therefore we removed the needle.'

- ^{25.} Dr C said that the senior registrar then made one more attempt to aspirate in the 4th intercostal space but could not aspirate any fluid. The registrars abandoned the procedure with a plan to perform the procedure with ultrasound guidance the next day. Dr C said that the plan was to ask a radiologist to perform an ultrasound scan to mark on the skin exactly where the needle should be inserted to drain and aspirate the fluid in the lungs.
- 26. Dr C said that Mr A was informed that they could not proceed with the procedure that day. Dr C stated that Mr A was haemodynamically stable²⁰ throughout the procedure. Dr C said that he continued to observe Mr A for half an hour after the procedure had been abandoned, and Mr A remained stable with no complaints of chest or abdominal pain. Dr C said that Mr A was alert and oriented, and his blood pressure, heart rate, and oxygen saturations remained stable.
- 27. Dr C said that following this period of observation, he took Mr A back to his room on the ward and instructed nursing staff to monitor Mr A's observations closely over the next 2–4 hours. There is no documentation of this instruction in the clinical records. Dr C said that as Mr A appeared clinically well and haemodynamically stable, he considered that 'while [he] had not entered the pleura it seemed unlikely that [he] had damaged any major structure'. Dr C said that his involvement in Mr A's care ended following the procedure as he was not



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¹⁷ Serous membranes (membranes covered by a thin layer of serous fluid) that line the lungs and thoracic cavity.

¹⁸ Drawing out by suction.

¹⁹ Clinically evident presence of blood.

²⁰ Stable blood pressure and heart rate.

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on call. There is no evidence that Dr C completed a handover of care to the evening team before finishing his shift.

^{28.} In response to the provisional opinion, Dr C told HDC that there is a failure to recognise that, as a cardiothoracic registrar at the hospital in Month3, he was required to be on call 24/7. Dr C said that he was not the on-call registrar. The on-call registrar was the senior registrar (who was almost a consultant at that stage). The senior registrar gave advice on the drain being undertaken, and Dr C called the senior registrar when he was concerned about the way the procedure was unfolding. Dr C said that the senior registrar attended, and it was the senior registrar who made the decision to abandon the procedure. Dr C told HDC that the on-call registrar was well aware of the status of Mr A, and the on-call team present in the room were fully appraised of the situation. Dr C also said that after the procedure was abandoned, he advised the nurse directly to monitor Mr A closely. Dr C stated that in these circumstances, he is unsure what more could have been done by way of a handover.

Clinical deterioration

- 29. An entry in the clinical notes at 7.50pm that evening documents that Mr A was reviewed by a house officer as he was experiencing severe abdominal pain and left shoulder pain. The abdominal pain was said to have been present for 'several days', while the left shoulder pain had been present for approximately an hour. It was noted that there had been an attempt to insert a chest drain earlier that day. On examination, Mr A's respiratory rate was 24 breaths per minute²¹ and his pupils were noted to be small but equal and reactive to light. His abdomen was soft and non-tender, he was alert, he did not have a fever, and his other observations were noted to be stable.
- ^{30.} The house officer's impression was of a possible pneumothorax,²² and it was noted that the cause of the abdominal pain did not appear to be peritoneal.²³ A plan was made to administer low-dose morphine, monitor Mr A's observations closely, and take a chest X-ray to investigate the possibility of a pneumothorax.
- 31. At around 9pm a cardiac arrest call was made as Mr A had been found collapsed on the ward. He was transferred to the intensive care unit (ICU), where his condition was stabilised. At 10.13pm a CT scan²⁴ of Mr A's chest and abdomen showed no pneumothorax but did show bleeding from the spleen. He was diagnosed with an iatrogenic splenic injury with extravasation²⁵ of blood from the splenic artery.



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²¹ A normal respiratory rate in healthy adults is around 12 to 20 breaths per minute.

²² A collapsed lung, which occurs when air escapes from the lung and enters the space between the lung and the chest wall (the pleural cavity).

²³ The peritoneum is a continuous membrane that lines the abdominal cavity and covers the abdominal organs.

²⁴ A computerised tomography (CT) scan combines a series of X-ray images taken from different angles around the body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside the body.

²⁵ The leaking of fluid outside its contained space into the surrounding area/tissues.

- ^{32.} Mr A was reviewed by the general surgery team, and it was felt that surgical intervention at that time carried a high risk of morbidity. Angioembolism²⁶ of the splenic artery was therefore recommended. This was undertaken at 1am on 22 Month3, after which Mr A was transferred back to ICU.
- ^{33.} Sadly, despite ongoing care in ICU, Mr A's condition deteriorated. On 25 Month3, following discussion with Mr A's family, supportive measures were withdrawn, and Mr A died later that day.
- 34. In a statement to the Coroner, the cardiothoracic surgeon summarised the events as follows:

'[Mr A] therefore was a gentleman who had relatively routine cardiac surgery, who was mobilising on the ward and not too far away from being discharged. He developed shortness of breath which was thought at least in part to be contributed to by a significant left sided pleural effusion. Attempted insertion of a chest drain resulted in damage to a splenic artery which subsequently initiated a train of events that led to [Mr A's] demise.

It was my view that the indications for the [chest drain procedure] were sound. The technique used, as described by [Dr C], was appropriate. It was thought that he was, either with or without supervision, appropriately experienced to perform the procedure. However, despite this, an injury did occur and certainly the cause of death of [Mr A] was an iatrogenic injury.'

Responses to provisional opinion

Mrs B

^{35.} Mrs B was provided with an opportunity to comment on the 'information gathered' section of the provisional opinion and did not have any comment.

Dr C

- ^{36.} Dr C was provided with an opportunity to comment on the provisional opinion as it related to him, and his comments have been incorporated throughout the report where relevant. Dr C disputed that informed consent was not obtained for the procedure. He considers that the procedure was documented properly, and that he provided a handover to the evening team.
- ^{37.} Dr C acknowledged that there were deficiencies in the care he provided, which contributed to this tragic outcome. Dr C stated that he was extremely troubled when reading through the provisional decision, and he accepted the recommendations proposed.
- ^{38.} Dr C stated: 'I am so sorry that this was the outcome for the patient and offer my sincere condolences to the family.'



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²⁶ A minimally invasive procedure used to stop the blood flow to a certain part of the body by blocking a small artery or vein.

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Health NZ

^{39.} Health NZ was provided with an opportunity to comment on the provisional decision, and it advised that it accepted the provisional opinion.

Relevant policies and procedures

Informed consent policy

- 40. Health NZ provided HDC with the 'Informed Consent for Health Care Procedures Policy' ('Informed Consent Policy') that was applicable in 2018. The purpose of the policy is to '[inform] staff about their responsibilities in relation to obtaining informed consent for health care procedures'.
- ^{41.} The Informed Consent Policy states that, in general, it is the responsibility of the person who is to perform the healthcare procedure to gain informed consent from the consumer and to ensure that full and correct information is given regarding the procedure.
- 42. The Informed Consent Policy provides that consent may be verbal or written. If verbal consent to healthcare procedures is obtained, this must be documented in the health record. Further, written consent on an approved Informed Consent Form must be obtained in the following circumstances: 1) if the consumer is to participate in research; 2) if the procedure is experimental; 3) the consumer will be under general anaesthetic; or 4) there is a significant risk of adverse effects on the consumer. The completed Informed Consent Form must be completed before the procedure begins and is to be attached to the consumer's health record.
- 43. The Informed Consent Policy states that before making a choice or giving consent, every consumer has the right to information that would be reasonably expected under the circumstances they face. This includes, but is not limited to, the following:
 - An explanation of his or her condition, including the results of any relevant tests and investigations;
 - An explanation of the options available, including an assessment of the expected risks, side effects, and costs and benefits of each option; and
 - Notification of any proposed participation in teaching or research, including whether the research requires, and has received, ethical approval.

Resident Medical Officer Handbook 2018

- 44. Health NZ provided HDC with the 2018 Resident Medical Officers Handbook ('RMO Handbook').
- 45. The RMO Handbook outlines the rights set out in the Code of Health and Disability Services Consumers' Rights (the Code), including Right 6 (the right to be fully informed) and Right 7 (the right to make an informed choice and give informed consent).
- ^{46.} In a section titled 'Informed Consent', the RMO Handbook refers to the Informed Consent Policy and outlines (among other things) that the primary responsibility for ensuring that



information is imparted to the patient or their legal representative lies with the person who is responsible for the procedure.

- 47. The RMO Handbook also contains information about the 'RMO Handover' application, with guidance about how to enter patient handover information into an electronic system. The RMO Handbook states:
 - 'Please try and update your handover list at the end of your shift for the person the next day', and
 - '[T]he handover tool is a working, open document that is NOT part of the clinical records. You must ensure that you document in the clinical records also. This is a legal requirement.'
- 48. The RMO Handbook refers to the Health Record Documentation Standards policy, which contains guidelines aimed at all clinical, nursing, and allied health staff, including all trainee practitioners and students.

Adverse Event Review

- ^{49.} Health NZ undertook an AER in July 2018. The AER report was completed in February 2020. The following seven issues were raised in the review:
 - 1. **Informed consent**: The AER report noted that the policy required written consent to be obtained for a procedure to be carried out under anaesthesia or for a procedure with 'significant risk of adverse effects on the consumer'. Mr A was not asked to sign a written consent, and there is no clear record that consent was obtained. The registrars, when interviewed as part of the AER, believed that they explained the procedure and that it did carry risk.
 - 2. Risks of Seldinger chest drain: The AER report noted that this procedure does carry risk and therefore the operator should be experienced and competent. Dr C and the senior registrar had performed this procedure previously (15 times and over 100 times, respectively). The AER report noted that there was no system to record training and experience in this procedure nor to formally credential doctors to undertake it independently. It was noted that pleural procedures should be learned initially by observation, then skills should be developed under supervision until the supervisor is satisfied that independent practice level and skill has been attained. The supervisor sign-off should be required.
 - 3. Use of ultrasound: The AER report stated that undertaking the procedure with ultrasound guidance may reduce the risks, but this was not readily available out of hours. It was noted that this can be done using portable ultrasound, but this was not a formal part of the procedural requirement.
 - 4. **Registrar numbers**: On the day of events the number of registrars was one less than usual staffing, and this meant that there was not a doctor available to perform the procedure during the day. The report noted that, in hindsight, the procedure was not urgent and could have waited until the next day.



- 5. **Documentation**: The procedure was not recorded in the clinical record at the time, although it was stated that this did not affect the outcome directly.
- 6. **Post-procedure X-ray**: The AER report stated that it is usual practice to arrange a chest X-ray post a thoracic procedure such as the one undergone by Mr A. It was noted that there was no written guideline or protocol for this, and this was not performed. This meant that the on-call house officer did not have the benefit of the X-ray when called to see Mr A. However, it was noted that this may not have affected the outcome as the bleeding was intra-abdominal.
- 7. **Handover**: There was no oral or written handover about the procedure to the evening team.
- ^{50.} The AER identified the root cause of the adverse event as: 'Failure to fully appreciate the risks of a common procedure and thereby to minimise risk and plan for all contingencies.'
- 51. The following contributory factors were identified:
 - A non-urgent chest drain insertion conducted out of hours when staffing is less than during the day.
 - Lack of availability of ultrasound and/or training in portable ultrasound to support the procedure.
 - Lack of clarity of handover of follow-up plan and plan for X-ray.
- 52. The AER report made the following recommendations:
 - 1. All pleural procedures, including pleural aspiration and chest drain insertion, should be preceded by bedside pleural ultrasound by an experienced sonographer or clinician, or chest CT scan to accurately define the problem.
 - 2. Education should be provided for the indications for chest drain insertion in pleural effusions.
 - 3. Resident doctors should be reminded of the importance of discussing important clinical decisions with senior doctors before proceeding with a treatment or intervention.
 - 4. Staff who perform a pleural procedure should obtain prior written consent from the patient and explain all associated risks clearly.
 - 5. Resident doctors should be reminded of the importance of handing over patients to their on-call colleagues.

Relevant standards

^{53.} The Medical Council of New Zealand's (MCNZ's) *Good Medical Practice* sets out standards expected of a competent doctor. The standards set out in the 2016 version of *Good Medical Practice* applied at the time of Mr A's care in Month3.



^{54.} In the section 'Caring for patients', under the heading 'Keeping records', paragraph 5 states:

'You must keep clear and accurate patient records that report:

- relevant clinical information
- options discussed
- decisions made and the reasons for them
- information given to patients
- the proposed management plan
- any medication or other treatment prescribed.'
- ^{55.} In the same section, paragraph 6 states: 'Make these records at the same time as the events you are recording or as soon as possible afterwards.'
- ^{56.} In the section 'Working in partnership with patients and colleagues', under the heading 'Information, choice of treatment and informed consent', paragraph 31 states that doctors must familiarise themselves with the Code. Further, paragraph 32 states:

'With rare and specific exceptions you should not provide treatment unless:

- the patient has received all the information that a reasonable patient, in that patient's circumstances, would expect to receive about their condition and treatment options, including the expected risks, side effects, costs and benefits of each option; and
- you have determined that he or she has an adequate understanding of that information; and
- you have provided the patient with an opportunity to consider and discuss the information with you; and
- the patient has made an informed choice; and
- the patient consents to treatment.'
- 57. Under the heading 'Going off duty', paragraph 45 states:

'When you are going off duty, make suitable arrangements for your patients' medical care. Use effective handover procedures and communicate clearly with colleagues.'

Opinion: Introduction

^{58.} I extend my sincere condolences to Mr A's family for the loss of their loved one. Prior to the events that led to his passing, Mr A was thought to be recovering well from heart surgery and he was being considered for discharge. Health NZ's AER identified that there was a failure to minimise the risk of the attempted chest drain procedure and plan for all



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contingencies. In these circumstances, it is understandable that Mr A's family would request an independent review of the care Mr A received.

- ^{59.} To aid in my assessment of Mr A's care, I sought independent advice from cardiothoracic surgeon Dr David Andrews.
- 60. Following a thorough assessment of the information gathered in light of Mrs B's concerns, I have found Dr C in breach of Rights 4(2), 6(1)(b), and 7(1) of the Code. The reasons for my decision are set out below.

Opinion: Dr C — breach

Informed consent — breach

- 61. Right 6(1) of the Code gives consumers the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive. This includes an explanation of the consumer's condition and an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option.
- ^{62.} Further, Right 7 gives consumers the right to make an informed choice and give informed consent. Right 7(1) provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.²⁷
- ^{63.} The clinical records contain no documentation of an informed consent discussion prior to the chest drain procedure.
- ^{64.} In response to the provisional opinion, Dr C said that Mr A had received full written and verbal information regarding the mitral valve repair/replacement and coronary artery bypass surgery and, as part of this, Mr A received information regarding a chest drain and the possibility that one might need to be inserted. Dr C stated that prior to this incident, Mr A had had bilateral postoperative chest drains and a mediastinal drain inserted, and Mr A 'had consented to these and was well informed of the procedure'.
- ^{65.} Dr C said that he discussed the finding of fluid on the lungs, referred to as a large pleural effusion, with both Mr A and his daughter prior to proceeding. Dr C stated that he discussed the expected risks, side effects, and test results. He said that there were no alternative options for Mr A, other than leaving the fluid, and Mr A agreed to the procedure. Further, Dr C said that at that stage it was not practice at the hospital to state that the procedure might end the patient's life.
- 66. As per the Informed Consent Policy and the RMO Handbook, as the person performing the proposed chest drain procedure, Dr C was responsible for gaining informed consent from Mr A. I do not accept that Dr C can rely on what was allegedly discussed and provided prior to Mr A's earlier operation on 15 Month3 (by another doctor) as a basis for informed consent for the subsequent procedure. Dr C was required to give Mr A an explanation of his condition, including the results of any relevant tests and investigations, and an explanation

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²⁷ Except where any enactment, or the common law, or any other provision of the Code provides otherwise.

of the options available, including an assessment of the expected risks, side effects, and costs and benefits of each option. With respect to the possible risks, in my view, a reasonable consumer in Mr A's circumstances would expect to receive an explanation of the common risks as well as any rare but serious risks of the procedure.²⁸ My advisor, Dr Andrews, advised that the injury experienced by Mr A is a known but rare complication of the procedure. As such, I consider that Mr A should have been advised of this risk during the informed consent discussion.

- ^{67.} In her statement to Police, Mrs B said that Dr C explained 'what he was planning to do' but did not seek consent or outline any risks for the procedure. On the other hand, the AER noted that when interviewed, the registrars said that they believed that they explained the procedure and that it did 'carry risk'. Further, Dr C told HDC that prior to proceeding with the procedure, he discussed with Mr A and his daughter the findings of fluid on the chest X-ray, and that Mr A then agreed to the procedure.
- ^{68.} On review of this information, as well as the fact that Mr A allowed the procedure to take place, I consider it more likely than not that Dr C gave Mr A an explanation of his condition with reference to the results of the chest X-ray of 21 Month3, as well as an explanation of the proposed chest drain procedure and how this would be expected to improve Mr A's condition.
- ^{69.} However, despite Dr C's contention, I am not satisfied that Dr C explained the specific risks of this specific procedure to Mr A. The only evidence that supports that a discussion of risks occurred is the reference in the AER that the registrars recalled explaining that the procedure did 'carry risk'. I do not consider this persuasive evidence that Mr A was provided with a clear explanation and assessment of the particular risks of the procedure. In addition, Mrs B recalled that Dr C did not outline any risks, Dr C's statement to HDC does not mention having explained any risks, and there is no contemporaneous documentation of a discussion about risks.
- 70. On balance, I consider it more likely than not that Dr C did not provide Mr A with an explanation of the particular risks of the chest drain procedure, including the risks of damage to another organ, a major bleed, or death. In not providing this information, I find that Dr C failed to provide Mr A with information that a reasonable consumer in his circumstances could expect to receive, in breach of Right 6(1)(b) of the Code. It follows that, without this information, Mr A was not able to make an informed choice and give informed consent. Accordingly, I find that in carrying out the chest drain procedure Dr C also breached Right 7(1) of the Code.

Clinical documentation/handover — breach

71. Right 4(2) of the Code provides that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards. In previous



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²⁸ The WDHB 'Respiratory: Chest Drain' policy, discussed at paragraph 113, lists common risks as: 'Pain, infection, pneumothorax, blockage of drain, failure of procedure, need for further procedure', and lists rare but serious risks as: 'Visceral puncture (damage to another organ), re-expansion breathlessness, major bleed, death.'

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reports, HDC has made numerous comments stressing the importance of good record-keeping and the accuracy of clinical records.²⁹

Documentation of consent

- 72. I have considered whether Mr A's written consent was required for this procedure. The AER noted that the Informed Consent Policy required that written consent be obtained where a procedure is performed under anaesthesia or if there is 'significant risk of adverse effects on the consumer'. Health NZ told HDC that '[c]urrently, there is not a stated requirement to seek written consent although it is implied by [its] policy'.
- 73. My independent advisor, Dr Andrews, advised that although a chest tube insertion carries a risk of serious adverse events, the rate of occurrence is low. Dr Andrews said that he would therefore expect that documentation of Mr A's verbal consent would be acceptable, without requiring a written consent form. He stated that documentation of verbal consent should include indications for the procedure, alternative options, and the risk and benefits of the proposed procedure. Dr Andrews noted that the exchange of information between Mr A and Dr C regarding the procedure was not documented in the clinical record, and he considered this to be a moderate deviation from the accepted standard of care.
- 74. I accept Dr Andrews' advice that the risk of serious adverse events from the procedure in question is low. As such, I do not consider that this procedure meets the threshold of carrying a 'significant risk of adverse effects'. Although the potential adverse event may be significant, it is the significance of the risk rather than the event itself that is relevant in this assessment. Accordingly, as the procedure is not performed under general anaesthesia, I agree with Dr Andrews' assessment that documentation of the patient's verbal consent would be sufficient. This documentation in the clinical notes should include a summary of the risks, benefits, and options discussed with the patient.
- 75. Unfortunately, this did not occur. While Dr C has submitted that Mr A's consent to the previous chest drains (inserted at the end of the surgery on 15 Month3) covered this procedure, as discussed above, I disagree.

Documentation of procedure

- ^{76.} Dr C did not document the procedure in the clinical record until 10.30pm that evening, after Mr A had been found collapsed and was transferred to the ICU.
- 77. Dr Andrews considered that the failure to document the procedure was a 'major oversight' and a severe deviation from standard practice. He stated that it is basic standard medical practice to document significant events in the patient file, and the failed chest drain procedure would be considered a significant event. Dr Andrews noted that Dr C's request that Mr A's observations be monitored for 2–4 hours implies that he was aware of the potential for problems, and this is further evidence that the procedure should have been documented in the clinical record.



²⁹ For example: Opinions 19HDC02166 and 19HDC01547.

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^{78.} In response to the provisional opinion, Dr C told HDC that the procedure was documented fully. While I accept that the procedure was documented retrospectively, this was not until after Mr A had been found collapsed and transferred to ICU. It remains my view that given the significance of the procedure, this should have been documented contemporaneously or as soon as possible after the procedure.

Handover

- 79. Dr C's involvement in Mr A's care ended following the procedure. However, it appears that Dr C did not complete handover about the failed procedure to the evening team before finishing his shift, as there is no evidence of an oral or written handover. Dr Andrews said that handover should have occurred as standard practice, as Mr A should have been considered a patient of concern to watch. Dr Andrews said that handover was even more important in light of the lack of clinical documentation of the procedure. Dr Andrews considered that the lack of handover was a minor deviation from standard practice.
- ^{80.} In response to the provisional opinion, Dr C told HDC that he disputes that there was no handover to the evening shift following the procedure.
- ^{81.} Dr C told HDC that there is a failure to recognise that, as a cardiothoracic registrar in Month3, he was required to be on call 24/7. Dr C said that he was not the on-call registrar. The on-call registrar was the senior registrar (who was almost a consultant at that stage). The senior registrar advised on the drain procedure being undertaken, and Dr C called the senior registrar when he had concerns about the way the procedure was unfolding. Dr C said that the senior registrar attended, and it was the senior registrar who made the decision to abandon the procedure. Dr C told HDC that the on-call registrar was well aware of the status of Mr A, and the on-call team present in the room were fully appraised of the situation. Dr C also said that after the procedure was abandoned, he advised the nurse directly to monitor Mr A closely. Dr C said that in these circumstances, he is unsure what more could have been done by way of a handover.
- ^{82.} I acknowledge Dr C's view that he did verbally hand over Mr A's care to the next shift, because the on-call registrar and the nurse looking after Mr A were appraised of the situation. However, I remain concerned that there is no documentation of this, and I note that the AER also found that there was no written or oral handover to the evening shift.

Conclusion

- ^{83.} I accept Dr Andrews' advice. In my view, effective communication between healthcare providers, including through clinical documentation and handover, is essential to the provision of adequate patient care. I am critical that Dr C did not document any details of an informed consent discussion with Mr A, did not document the clinical indications or a description of the failed procedure in the contemporaneous clinical notes, and did not document a handover to the evening team before finishing his shift.
- ^{84.} I consider that in failing to document an informed consent discussion and any details about the chest drain procedure itself, Dr C failed to comply with the expectations in the RMO Handbook and Informed Consent Policy, as well as the standards set out in paragraphs 5 and



6 of the MCNZ's *Good Medical Practice* 2016. This remains my view despite Dr C's submission that Mr A had provided consent to have a chest drain prior to his surgery on 15 Month3. I am also critical that Dr C did not document a handover to the evening team before finishing his shift, and therefore he did not comply with the expectations in the RMO Handbook. On this basis, I find that Dr C did not provide Mr A with services that complied with professional and other relevant standards and, accordingly, that Dr C breached Right 4(2) of the Code.

No post-procedure chest X-ray — adverse comment

- 85. After Dr C and the senior registrar decided to abandon the attempted chest drain procedure, Mr A was taken back to the ward and Dr C asked the nursing staff to monitor Mr A's observations closely over the next 2–4 hours. No post-procedure X-ray was arranged.
- ^{86.} Dr Andrews advised that a follow-up chest X-ray should have been performed after the failed attempt. He considered that failure to do so was a moderate deviation from accepted practice. However, Dr Andrews advised that a chest X-ray would not have identified the complication or led to earlier diagnosis of Mr A's splenic injury. Dr Andrews considered that it was appropriate that Dr C requested nursing staff to monitor Mr A's observations for 2–4 hours following the procedure.
- ^{87.} I accept Dr Andrews' advice, and I am concerned that a post-procedure X-ray was not arranged. However, I note that at the time of events there was no written guideline or protocol recommending that a chest X-ray be undertaken following an unsuccessful chest drain procedure. Further, it does not appear that the assisting senior registrar recommended a chest X-ray once it was decided to abandon the procedure. While I accept Dr Andrews' advice that a chest X-ray should have been arranged, in my view, as a junior registrar with no written guideline or senior advice to follow, it was not unreasonable that Dr C did not recognise the need for a post-procedure X-ray, especially as Mr A's condition appeared stable during Dr C's observation of him in the 30 minutes following the procedure.

Clinical indication and care/skill — no breach

- ^{88.} The AER found that the chest drain insertion was a non-urgent procedure conducted out of hours when staffing was reduced, and that there was a lack of availability of ultrasound to support the procedure. On the other hand, Health NZ told HDC that the timing of the procedure (at around 5.45pm) would not be considered out of hours for this type of procedure on the specialist ward.
- ^{89.} Dr Andrews considered that the insertion of a chest drain on 21 Month3 was clearly indicated, noting that Mr A had been becoming increasingly short of breath that morning, his oxygen saturations were documented as low at 93%, and the chest X-ray that afternoon showed a moderate left-sided pleural effusion.
- ^{90.} Based on the information from Dr C and Health NZ's AER, at the time of events Dr C had performed the procedure approximately 15 times, and around half of these had been performed without supervision and without complications. Dr Andrews advised that it is standard practice in cardiothoracic surgery units for registrars to be taught the chest drain



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procedure early and then progress to performing this on their own. He said that it appears that Dr C was competent and well trained in the procedure, and that attempting the procedure at 5.45pm is in line with standard practice in all cardiothoracic units in New Zealand.

- 91. Further, Dr Andrews considered that the procedure as outlined in Dr C's retrospective clinical note and statement was 'a textbook description' and what would be expected by a competent doctor. Dr Andrews said that the fact that assistance was sought from a senior registrar and that subsequently the procedure was abandoned after inability to enter the pleural space was also what he would expect from a competent doctor.
- 92. With respect to whether the procedure should have been performed without ultrasound guidance, Dr Andrews said that while there has been a 'steady increase' in the use of ultrasound to guide chest drain insertion, 'it is by no means a universally accepted requirement'. Dr Andrews said that if the 'safe triangle' is used (as described in Dr C's statement), it is not considered necessary to use ultrasound as well, and there is little evidence that ultrasound makes insertion safer in these cases.
- ^{93.} I accept Dr Andrews' advice. On this basis, I consider that it was reasonable for Dr C to attempt the procedure independently and without ultrasound guidance at 5.45pm on 21 Month3. While I acknowledge that the AER identified that there were fewer staff available at the time of the procedure, I note that the senior registrar from whom Dr C sought assistance had performed this procedure over 100 times. I am therefore satisfied that there was sufficient senior support available at the time. Further, despite the complications experienced, I consider that the procedure appears to have been performed with adequate care and skill, including that timely and appropriate senior assistance was available.
- ^{94.} I acknowledge Dr C's response to the provisional opinion in which he told HDC that there has been no investigation into the cause of the iatrogenic injury to the splenic artery. It is therefore unclear whether it was a result of his attempt during the procedure or the attempt made by the senior registrar.

Opinion: Health NZ — adverse comment

95. Health NZ was responsible for ensuring that clinical services at the hospital were of an appropriate standard. This included ensuring that there were appropriate systems, policies, and guidelines in place and that staff had adequate training and experience to enable the provision of safe and appropriate care.

Chest drain policy/guideline — adverse comment

^{96.} It appears that at the time of events Health NZ did not have a policy/guideline for chest drain procedures. The AER noted that at the time of events there was no procedural requirement for chest drain procedures to be performed with ultrasound guidance.



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

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- 97. Dr Andrews advised that at the time of the events, use of ultrasound for chest drain procedures was an 'evolving technique' that was not the accepted standard of care in most cardiothoracic services. He explained that although there has since been an increase in the use of ultrasound, there is no mandate to use this, and, if the 'safe triangle' is used (as described in Dr C's statement), there is little evidence that ultrasound makes insertion safer. Dr Andrews indicated that the absence of a written requirement for ultrasound guidance would not be a departure from accepted standards at the time.
- 98. However, Dr Andrews considered that there should be a written policy with advice that following a failed attempt at a chest drain procedure, or at times of increased concern, there should be increased consideration of the need for a post-procedure chest X-ray.
- ^{99.} Dr Andrews explained that the need for a post-procedure chest X-ray is variable and therefore difficult to mandate. He stated that if the chest drain is inserted easily and draining appropriately, this would not require a chest X-ray. Dr Andrews advised that a post-procedure chest X-ray would likely not have shown Mr A's splenic injury. However, he explained that a chest X-ray is required in these circumstances to exclude other pathology related to a failed chest drain insertion, such as a pneumothorax or the presence of fluid or blood in the pleural space, which would require further treatment.
- 100. I accept Dr Andrews' advice. I am critical that at the time of events Health NZ did not have in place a sufficient system to ensure a post-procedure X-ray for Mr A. I note that Health NZ had no written policy about when the use of ultrasound guidance should be considered and when to arrange a post-procedure X-ray, and that multiple staff (Dr C and his assisting senior registrar) failed to recognise the need for a post-procedure X-ray for Mr A.
- In my view, written protocols and guidelines are an important component in the provision of safe patient care, particularly in supporting junior clinicians to make appropriate clinical decisions. I accept Dr Andrews' advice that a chest X-ray would not have identified Mr A's splenic injury. However, I note that if a policy had been available to guide Dr C to arrange a post-procedure chest X-ray, the results would have been available to the house officer who reviewed Mr A at 7.50pm that evening. While it is not possible to know how this would have changed the pathway of care or the outcome for Mr A, based on Dr Andrews' advice it appears that a chest X-ray would have enabled the house officer to exclude a pneumothorax as the cause of Mr A's symptoms and consider alternative diagnoses and investigations. Considering this, I am concerned that an opportunity for earlier diagnosis may have been lost.

Training and experience record — educative comment

- 102. Based on the information from Dr C and Health NZ's AER, at the time of events Dr C had performed the procedure approximately 15 times and around half of these had been performed without supervision and without complications.
- 103. Dr Andrews advised that it is standard practice in cardiothoracic surgery units for registrars to be taught the chest drain procedure early and then progress to performing this on their own. He also said that it appears that Dr C was competent and well trained in the procedure.



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On this basis, I am satisfied that Dr C was adequately trained and experienced to perform the chest drain procedure independently.

- 104. However, the AER noted that at the time of events there was no system to record training and experience in the chest drain procedure nor to formally credential doctors to undertake it independently. The AER identified that supervisor sign-off should be required to confirm that a registrar has obtained an independent practice level and skill, although this was not included as a recommendation.
- 105. Dr Andrews advised that the lack of a system to record training and credentialling is a mild deviation from accepted practice, and this is a common issue for most hospitals. He stated that junior staff should be encouraged to maintain logbooks to record their experience, as this allows better governance over the training and credentialling of junior staff in various procedures.
- ^{106.} I accept Dr Andrews' advice. Accordingly, I intend to recommend that Health NZ consider implementing a system to record training, experience, and supervisor sign-off for common procedures taught on the cardiothoracic surgery unit.

Clinical documentation/handover — no breach

107. Lastly, based on the information in the RMO Handbook I am satisfied that Health NZ had a system in place for clinicians to record patient handover information, and that RMOs were made aware of their responsibilities to record handover information and document clinical information in the patient clinical records, in accordance with the Health NZ Health Record Documentation Standards policy.

Changes made since events

- 108. Health NZ outlined several changes that have been made since these events.
- 109. Health NZ noted that the AER recommended both obtaining written consent and utilising imaging (CT/ultrasound) prior to chest drains being inserted. To assess compliance with these recommendations, in July 2022 Health NZ conducted an audit of a four-month sample period in 2021. The results of the audit showed that of 31 patient files reviewed, a CT or ultrasound was taken before a pleural procedure in 26 cases, with the remaining five procedures having been undertaken during surgery. It was concluded that the current practice was compliant with the recommendations.
- ^{110.} Further, the audit showed that patient consent was documented in 29 cases, of which 18 were on a written consent form. The remaining two cases were performed as part of lifesaving procedures involving unconscious victims of severe trauma. The audit report concluded that the recommendation from the review that written consent should be mandatory for pleural procedures had not been implemented. However, it was noted that the audit had identified that the need for informed consent is clearly understood, and compliance was 'very high and well documented'.



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- 111. Health NZ stated that it intended to notify medical staff that obtaining written informed consent for inserting a chest drain is required to ensure that the patient is fully informed about the risks and benefits of this procedure. A further audit was planned to monitor compliance with obtaining written informed consent for inserting a chest drain.
- 112. Health NZ provided HDC with a copy of the 2022 Informed Consent for Health Care Procedures Policy. This document provides that consent may be verbal or written except where written consent is required under the Code, any other law, or as otherwise required by Health NZ. There is no mention in this policy of a requirement to obtain written consent for pleural procedures.
- 113. Health NZ provided HDC with a copy of a Waitematā District Health Board (WDHB) 'Respiratory: Chest Drain' policy and advised that it was considering whether to adopt the framework. In a section titled 'Risks/Safety', the WDHB policy states (among other things):
 - Thoracic ultrasound should be available and used where a pleural drain is inserted for drainage of pleural fluid.
 - Do not insert a pleural drain outside the safety triangle or mid clavicular line (pneumothorax) without ultrasound guidance.
 - Ensure that a post insertion chest X-ray is performed within one hour of insertion and reviewed promptly by the Medical Officer who inserted the pleural drain.'
- 114. An updated RMO Handbook was issued in 2022. The 2022 version now lists the 'Health Record Documentation Standards' policy as a 'Key Employment Policy' and emphasises that it is the responsibility of RMOs to read and familiarise themselves with the expectations in that policy.

Recommendations

- 115. I recommend that Health NZ:
 - a) Provide an update/evidence of whether recommendations 1–5 in the AER have been implemented, along with an evaluative report on the effectiveness of the recommendations since their implementation. The evaluative report should include any further corrective actions implemented or to be implemented. This is to be provided to HDC within six months of the date of this report.
 - b) Provide HDC with a copy of the report from the further (2022) audit undertaken to monitor compliance with obtaining written informed consent for inserting a chest drain. This to be provided within four months of the date of this report.
 - c) Undertake the following, within eight months of the date of this report:
 - (i) Develop a written policy for chest drain procedures, including when to use radiological assessment/guidance and in what circumstances a post-procedure X-ray is recommended.



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- (ii) Conduct an evaluation of the effectiveness of the new policy three months after its introduction via an audit of compliance and provide HDC with a report, including any corrective actions to be implemented.
- d) Undertake the following, within eight months of the date of this report:
 - (i) Develop a process to record training, experience, and supervisor sign-off for common procedures taught on the cardiothoracic surgery unit.
 - (ii) Conduct an evaluation of the effectiveness of the new process three months after its introduction via an audit of compliance and provide HDC with a report, including any corrective actions to be implemented.
- 116. I recommend that Dr C:
 - a) Provide a written apology to Mrs B and her family for the issues identified in this report relating to his actions. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs B.
 - b) Complete HDC's online learning course on informed consent (Module 2: what you need to know about informed consent). Evidence of completion is to be provided to HDC within two months of the date of this decision.
 - c) Reflect on the deficiencies identified in this case, particularly around documentation standards and handover, with reference to MCNZ's *Good Medical Practice* 2021.³⁰ Dr C is to provide a written report on these reflections and the changes to practice he has instigated as a result of this case, within two months of the date of this report.

Follow-up actions

- 117. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name.
- 118. A copy of this report with details identifying the parties removed, except the advisor on this case, will be placed on the Health and Disability Commissioner website, <u>www.hdc.org.nz</u>, for educational purposes.



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

³⁰ https://www.mcnz.org.nz/assets/standards/b3ad8bfba4/Good-Medical-Practice.pdf

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr David Andrews, a cardiothoracic surgeon:

'Dr David R Andrews MBBS FRACS FCSANZ

...

19th September 2023

Expert advice to the Health and Disability Commissioner re:

Care provided by [Dr C] and Te Whatu Ora ... to [Mr A] from 15 [Month3] to 25 [Month3].

Complaint: [Mr A] Our ref: 21HDC01892

Dear Commissioner

As per the instructions given to me, I will now provide my opinion on the following points regarding the management of the care provided by [Dr C] and Te Whatu Ora ... to [Mr A] from 15 [Month3] to 25 [Month3]. I have read all the information available to me listed in the materials used in preparing this report below.

I have been given by your department a brief summary of [Mr A]'s care in the letter of instruction provided to me.

In order of their request, I present my opinions based on my now 30 years of experience in Cardiothoracic Surgery, 23 years as a qualified consultant performing initially Adult and Paediatric Cardiothoracic Surgery (including Heart and Lung Transplantation, Thoracic and Adult Congenital), for the last 12 years purely Paediatric Cardiothoracic and Adult Congenital Heart Surgery more recently recommencing Transplantation and routine Adult Cardiac Surgery again. I am a Fellow of the Royal Australasian College of Surgeons (RACS), current Member of the Board of Cardiothoracic Surgery Training, of the RACS, current examiner in Cardiothoracic Surgery of the RACS and retired Senior Examiner.

1. Whether the attempted chest drain insertion was performed with reasonable care and skill, and was clinically indicated?

The notes and attached information clearly indicated that [Mr A] was becoming increasingly short of breath on the morning of the attempted drainage of effusion. This was documented along with increasing fatigue by the physiotherapist. His saturations were also documented as being low at 93%. The chest X ray clearly shows a moderate sized Left sided pleural effusion. All of this implies that insertion of a chest drain was indicated, and we would expect it to make him clinically better. It is not uncommon for



this to occur at this stage post cardiac surgery especially in patients who have had a Left Internal Mammary Artery harvested.

The procedure, as described in the letter from [Dr C], and in the patient's file (retrospectively) outlines the procedure as I would expect a competent doctor to perform. The fact that senior help was [sought], and that the procedure was abandoned after inability to enter the pleural space or effusion is appropriate and what I would expect from a competent doctor. The ability to realise that the blood aspirated was clotting also implies good knowledge of the procedure and the potential complications.

2. Was it reasonable for [Dr C] to perform the chest drain procedure independently?

I can only deduce from the information supplied by [Dr C] that he was competent and well trained in how to undertake insertion of a chest drain. The procedure as outlined is a textbook description of the procedure. It is standard practice in Cardiothoracic Surgery units for registrars to be taught early the procedure of chest drain insertion and then grade up to performing on their own. It is the area of the hospital where most chest drains are inserted and considered a standard skill to teach whilst on the unit.

3. Was it appropriate to perform the chest drain procedure without ultrasound guidance?

Whilst there has been a steady increase in the use of ultrasound to guide chest drain insertion it is by no means a universally accepted requirement. As outlined in the resident handbook, and the guideline for chest drain management as long as the safe triangle is used it is not considered necessary to use ultrasound as well. (Enclosure [2.12 to 2.14]). The procedure as described did not deviate from the policies and guidelines provided.

There is no mandate to use ultrasound and little evidence that it makes insertion safer if the insertion is in the safe triangle as described. More recently a guideline from the British Thoracic Society suggests strong consensus for the use of ultrasound at the time of chest tube insertion. This Guideline was developed in July 2023. (Enclosure 4) The issue addressed, is it is not always possible to safely identify the safe triangle in all patients. Hence the changing in guidelines and practice we have been seeing over the last few years to increasing use of ultrasound. It is however still not mandated in either the hospital or society guidelines.

Other important points in the guideline were followed by [Dr C] in that it is recommended that before the tube is inserted fluid is aspirated with the needle used to infiltrate the local anaesthetic. This is why he stopped and asked for help as the aspirate was blood or blood stained. There was also a plan to introduce the catheter using the Seldinger technique as advocated in the guideline. (Enclosure 4)

4. Was it appropriate not to arrange a post procedure chest X-ray?

This was an oversight, and a follow up Chest Xray should have been performed after the failed attempt at drain insertion. It should have been done as it is standard and accepted



practice. It should however be noted it would not have demonstrated the complication that had occurred or led to earlier diagnosis of the splenic artery injury.

I would consider this a moderate deviation from standard practice as would most of my peers. My recommendation to avoid this in the future would be to include it in the standard of care of the health department/hospital chest tube management guidelines. A line that mentions in cases of unsuccessful chest tube placement then a routine post procedure chest Xray should occur to exclude post procedure complications.

The observations that [Dr C] ordered be kept on [Mr A] post procedure for 2 to 4 hours are considered standard of care.

5. Was it reasonable for the chest drain procedure not to be documented in the clinical records or communicated in the hand over to the evening team?

The lack of documentation in the clinical record is a major oversight and should not have occurred. It is basic standard medical practice to document significant events in the patient's file. This would have to be considered a significant event and should have been documented. The request to the nursing staff to monitor his observations closely over the next 2 to 4 hours implies awareness of the potential for problems. This is further evidence that documentation in the patient's clinical record should have occurred.

I would consider this a severe deviation from standard practice as would most of my peers. The way to avoid this in the future is to remind, at orientation and in manuals, of the absolute requirement for documentation of major events in the patient's stay to junior medical staff.

Handover to the evening team should also have occurred as he would be considered a patient to watch. It is standard practice to hand over patients of concern/interest to the after-hours team and this should have occurred. Even more important as there was no documentation in the file of what had occurred to [Mr A] leaving the after-hours team unaware, except for nursing handover which one would assume did occur.

I would consider this a minor deviation from standard care as would most of my peers. The way to avoid this in the future is to ensure all junior staff are reminded of the need to hand over patients of concern to the afterhours team.

6. Was appropriate informed consent obtained for the chest drain procedure?

This is an issue that is much more complex than at first it seems, and hospitals and health services have struggled with this issue and continue to do so. Is a signed/written form consent [required]? In my opinion no, which is why it is generally only required when patients are having procedures performed in an operating/procedural room usually under general anaesthetic. This however is not consent, consent is the exchange of information regarding a procedure between the patient and the treating clinician. It takes in the indications, options, and risks so the patient can make an informed opinion. It should then be documented; this can be either a note in the patient's file or a signed written consent form. Neither of these occurred.



I would consider this a moderate deviation from standard care as would most of my peers. The way to avoid this in the future is to mandate that there is documentation in the file outlining the discussion that occurred at the time of consent. This should include the usual things discussed such as indications, alternatives available and the risks and benefits of the proposed procedure.

One must assume since [Mr A] was an adult, without any language or mental barriers to understanding what was happening, that he understood and consented to the procedure. Was he fully informed of the risks and benefits? We cannot be sure this occurred as there is no documentation in the file from [Dr C] regarding this discussion.

This is contrary to the ... District Health Board Policy (2017) for informed consent which states:

"Consent may be verbal or written.

Verbal consent to health care procedures must be documented in the health record. Although informed consent for a health care procedure may be given verbally, it must be written consent that is granted in the following circumstances:

- 1. The consumer is to participate in any research, or
- 2. The procedure is experimental, or
- 3. The consumer will be under general anaesthetic, or
- 4. There is a significant risk of adverse effects on the consumer."

Although there is a risk of serious adverse events at the time of chest tube insertion, the rate of occurrence is low, and I would expect that documentation would be acceptable and not necessarily requiring a written consent form.

The lack of documentation therefore means we can only assume that as [Mr A] allowed the procedure to occur, he was consenting to the procedure. This is however a deviation from standard medical care and current guidelines that consent should be sought and clearly documented.

- 7. Were the District's policies and procedures at the time regarding chest drains adequate? In particular, please consider their process around obtaining informed consent for chest drains; and note that the adverse event review found that:
 - a. there was no procedural requirement for chest drains to be conducted with assistance of an ultrasound;

This is discussed above in question 3. Thus, the District's policies at the time are adequate. The policy as in attachment 16 is slightly confusing as it states that the use of ultrasound is the gold standard but then in the next paragraph talks about the safe triangle being not used if an ultrasound shows a better position. This is discussed in point 3 above.



At this time, it was also an evolving technique which was not standard of care, especially in most Cardiothoracic services. Subsequently, it has been increasingly accepted as the preferred acceptable standard.

At the time the procedure was performed the policies of the District and Hospital were adequate.

b. there was not a system to record a doctor's training and experience in the procedure nor to credential doctors to perform it independently; and

This is a common issue for most hospitals in credentialing junior staff for most procedures. It is a gap in the Policies of the hospital and should be addressed. Junior staff should be encouraged to maintain logbooks outlining their experience. This allows better governance over the training credentialing and outcomes of many of the procedures they can and do perform.

I do think this is an inadequacy in the Governance processes and one which is shared amongst most hospitals. It should be addressed for all procedures performed by junior medical staff. This includes but is not limited to practices such as arterial line insertion, central line insertion, epidurals, spinal taps, chest tubes, pleural aspiration, pericardial aspiration etc. The area, in my experience where this is most deficient is in junior medical staff training and in particular physician training.

I and most of my peers would consider this a mild deviation from standard practice, only in as much as to the best of my knowledge very few hospitals do this as standard practice. This is an issue that could be easily addressed by hospitals through the Credentialing Committee and would assist in its avoidance in the future.

c. there was no written guideline or protocol to arrange a chest X-ray post procedure.

There is no mention in the hospital guidelines of the need for a post insertion chest Xray. The need for one is variable and thus difficult to mandate. A chest drain inserted for draining of pleural fluid that was easily inserted and draining appropriately does not require a chest X-ray.

The procedure as described by [Dr C] should have had a chest X-ray performed to ensure there was no unknown complication that would require further management. As I have mentioned above, I do not believe in this instance it would have provided any further information to avoid the subsequent series of events that occurred in [Mr A]. It should however have been done as it may have shown other pathology related to a failed chest drain insertion such as increased fluid/bleeding into the pleural space or a pneumothorax. These would mandate further treatment and cannot be reliably excluded without a chest X-ray.

Therefore, the policies of the hospital should be improved to include the advice that following a failed attempt or at times of increased concern there should be increased thought around the need for a post procedure chest X-ray. This is also discussed in point 4 above.



8. Any other matters that you consider warrant comment.

The hospital's policies do outline that chest tubes should not be placed out of hours. This I disagree with as the need should mandate the timing. It is also a common procedure in a busy cardiothoracic service and attempting the procedure at 1745 at night is completely in line with standard practices in all units in Australia and New Zealand.

As far as the issue of consent I do believe that [Mr A] was aware of what was happening to him and the need for the procedure.

The major fault in this process, is the lack of contemporaneous documentation that consent was taken, and the procedure was attempted and abandoned. The lack of handover to the afterhours staff is also a concern to me. This can happen in a busy time [and is] poor service, but I cannot comment on the acuity of the service at the time of the procedure. Acts of omission are difficult to negate by policies and guidelines. The management of the patient and the recommendation for regular observations is in keeping with standard practices.

Finally, I do not understand how the damage to the splenic artery occurred when the technique used was as described by [Dr C]. It is hard to know how the splenic artery was injured from a needle and guidewire using a Seldinger technique inserted via the safe triangle. The body habitus could have led to a misunderstanding of the surface markings outlining the safe triangle and in fact the needle must have been inserted lower than intended. This may have been avoided using ultrasound guidance. Understanding that using ultrasound may mean the attempted needling could be lower than the safe triangle thus closer to the splenic artery, not necessarily decreasing the risk.

The injury that occurred in [Mr A] is a known but rare complication of insertion of a chest tube. These complications can occur despite our best intentions and efforts to avoid them.

Summary

[Mr A] was admitted for elective cardiac surgery which progressed well. He was noted to have increased shortness of breath and had a chest X-ray demonstrating a significant pleural effusion (not uncommon after this type of surgery). He then had an attempted insertion of a chest drain using a described technique (without the use of ultrasound) that was and still is standard of care in most cardiothoracic units. There was a lack of documentation around the time of the procedure. The technique as described was unlikely to lead to the complication that occurred.

Subsequently, [Mr A] suffered a large bleed into his abdomen (a known but rare complication) that set up a series of events ultimately leading to his untimely death.

I do not believe there was any deviation from hospital policies or guidelines that may have changed this outcome. There is, however, an opportunity to provide more governance and support around the documentation of training experience and outcomes for all junior staff. This will support them and provide the hospital, health



service, government and patients a level of assurance that suitably qualified doctors are performing their care after appropriate training.

This is my opinion based on the facts provided to me regarding the above case that the contents of this report are true and genuine opinions held by me. I have reviewed and sought all information required and have listed all the matters that I consider significant. In so doing I have complied with my duty to the commissioner.

Dr David Ray Andrews MBBS, FRACS, FCSANZ

Materials Used in Preparing This Report:

- 1. Letter to Dr Andrews 21HDC01892.
- 2. Te Whatu Ora response 26 July 22.
 - 2.1. Enclosure 1 Discharge Summary 08 Month1.
 - 2.2. Enclosure 2 Referral letter to CTS from Cardiology 08 [Month1].
 - 2.3. Enclosure 3 Lung Function Results 14 [Month1].
 - 2.4. Enclosure 4 Letter from Mr ... re Surgery 22 [Month1].
 - 2.5. Enclosure 5 Cardiology outpatient letter 07 [Month3].
 - 2.6. Enclosure 6 Operation notes 15 [Month3].
 - 2.7. Appendix 7.0 [Mr A] Electronic copy.
 - 2.7.1. Appendix 7.1 [Mr A] Part one.
 - 2.7.2. Appendix 7.2 [Mr A] Part two.
 - 2.8. Enclosure 10 Informed Consent for Health Care Procedures Policy 21638 (District) 2017.
 - 2.9. Enclosure 11 Informed Consent for Health Care Procedures Policy 21638 (District) 2022.
 - 2.10. Enclosure 12 Informed Consent Form for Health Care Procedures (Long Form) 2018.
 - 2.11. Enclosure 13 Informed Consent Form for Health Care Procedures (Long Form) 2022.
 - 2.12. Enclosure 14 Registrar Medical (RMO) Handbook 2018.
 - 2.13. Enclosure 15 Registrar Medical (RMO) Handbook 2022 (district).
 - 2.14. Enclosure 16 Waitematā DHB Respiratory Chest Drain.
- 3. Statement [Dr C] 15 Sept 2022.
- 4. British Thoracic Society Clinical Statement on pleural procedures. Asciak R, et al. Thorax 2023;78(suppl 3):43–68. doi:10.1136/thorax-2022-219371.
- 5. Thoracostomy tubes and catheters: Placement techniques and complications. Up to Date 2023.
- 6. Thoracostomy tubes and catheters: Indications and tube selection in adults and children. Up to Date 2023.'

