Northland District Health Board
(now Te Whatu Ora|Health New Zealand Te Tai Tokerau)

House Officer, Dr D

Senior Medical Officer, Dr C

Registered Nurse, RN E

A Report by the

Health and Disability Commissioner

(Case 20HDC01979)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman in her eighties by a house officer, a senior medical officer, a registered nurse, and Te Whatu Ora Te Tai Tokerau, Northland District (formerly Northland District Health Board (NDHB)).

2. The woman had a severe allergy to penicillin. She was admitted to Whangārei Hospital in 2020 with a fever and abdominal pain subsequent to elective surgery two weeks previously. During her five-day admission to hospital, she was transferred between a surgical ward and a general medicine ward.

3. Despite her allergy, the woman was inappropriately prescribed and administered Augmentin, a penicillin antibiotic. As a result, she suffered a severe anaphylactic reaction and died.

Findings

4. The Commissioner considered that when the senior medical officer directed the house officer to prescribe the Augmentin without first checking for adverse reactions or allergies, and when the house officer prescribed the Augmentin for the woman without first checking for adverse reactions or allergies, the woman was not provided services with reasonable care and skill. The Commissioner found both the senior medical officer and the house officer in breach of Right 4(1) of the Code.

5. The Commissioner considered that when the nurse administered Augmentin without checking adequately for adverse reactions or allergies, the woman was not provided services with reasonable and skill. The Commissioner found the nurse in breach of Right 4(1) of the Code.

6. The Commissioner considered that because of Te Whatu Ora Te Tai Tokerau's lack of policies and lack of adherence to existing procedures; the lack of flexibility to enable adequate staffing during a busy period with a number of high acuity patients; and the handover process, which did not consistently support the sharing of important information such as allergies, the woman was not provided services with reasonable skill and care. The Commissioner found Te Whatu Ora Te Tai Tokerau in breach of Right 4(1) of the Code.

Recommendations

7. The Commissioner recommended that the senior medical officer, the house officer and the nurse provide a written apology to the woman's family for the breach of the Code. The senior medical officer provided an apology in response to the provisional opinion.

8. The Commissioner recommended that Te Whatu Ora Te Tai Tokerau provide the woman's family with a written apology; consider how it can improve recognition of documented drug allergies, and implement improvements that mitigate the risk of inadvertent administration of a drug to which the patient is allergic; consider methods for improving the process and documentation of medical handover between different disciplines and between on-call and

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destination ward-based teams; amend its medication prescribing policy to make it clear that the prescriber must inform the patient of a recommended change in medication and enquire about drug allergy, and also consider amending the policy to add clarity on completion of the National Medication Chart in full; consider improving the quality of ward rounds by allowing clinicians access to electronic clinical information at the bedside; and provide HDC with an update on the implementation and effectiveness of the recommendations set out in the serious event review.

9. The Commissioner recommended that Te Whatu Ora|Health New Zealand liaise with Te Whatu Ora Te Tai Tokerau on how to support it to implement electronic prescribing.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided by Northland District Health Board (NDHB) (now Te Whatu Ora|Health New Zealand Te Tai Tokerau)[1] to her mother-in-law, Mrs A. Specifically, Mrs A was administered Augmentin (a broad-spectrum penicillin antibiotic), to which she was allergic. Sadly, Mrs A died after suffering an anaphylactic reaction to the drug.

11. At the outset I extend to Mrs A's family and friends my sincere condolences for her loss in such tragic circumstances.

12. The following issues were identified for investigation:

- *Whether Northland District Health Board provided Mrs A with an appropriate standard of care in 2020.*
- *Whether Dr C provided Mrs A with an appropriate standard of care in 2020.*
- *Whether Dr D provided Mrs A with an appropriate standard of care in 2020.*
- *Whether RN E provided Mrs A with an appropriate standard of care on in 2020.*

13. The parties directly involved in the investigation were:

Mrs B	Complainant/consumer's daughter-in-law
Dr C	Senior medical officer (SMO)
Dr D	House officer
RN E	Registered nurse
Northland District Health Board (NDHB)	District health board

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to NDHB now refer to Te Whatu Ora Te Tai Tokerau.

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14. Further information was received from:

Forensic pathologist	
Dr F	Medical registrar
Dr G	House officer
RN H	Registered nurse
RN I	Registered nurse
RN J	Registered nurse

15. Independent advice was obtained from a general physician, Dr David Cole (Appendix A), a general physician and systems advisor, Dr Margaret Wilsher (Appendix B), and a registered nurse, RN Rosalind Jackson (Appendix C).

Information gathered during investigation

Background

16. Mrs A (in her eighties at the time of the events) had a long-standing allergy to penicillin, and was known to go into anaphylactic shock in response to it. The allergy was documented on the national patient Medical Warning System[2] and in her admission documentation for the hospital admission that is the subject of this investigation.

17. Since Mrs A's first reaction to penicillin around 2002/2004, she had worn a medical alert necklace that said "Penicillin anaphylactic shock". Mrs A's daughter-in-law, Mrs B, told HDC that every time Mrs A went to the doctor or pharmacy, she asked whether the medication she was being prescribed contained penicillin.

Surgery

18. In 2020, Mrs A was admitted to Whangārei Hospital for an elective pelvic floor repair.[3] She was discharged two days later following the successful surgery. She continued to recover at home.

19. Mrs B noted that she was impressed with how quickly Mrs A was recovering, but a few days later Mrs A began to feel cold and was shivering. The following day she was still feverish and, because it was only two weeks since the operation, Mrs B decided to take Mrs A to the hospital.

[2] The Medical Warning System is an alert service linked to National Health Index numbers. It warns healthcare providers of known risk factors that could be important when making clinical decisions about patient care. This includes drug allergies or medical conditions.
[3] Posterior vaginal repair and perineorrhaphy.

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Admission to Emergency Department

20. Mrs A presented to the Emergency Department (ED) at Whangārei Hospital with a fever. It was noted that she had been recovering well from her surgery but had recently developed lower abdominal pain. It was initially suspected that she might be suffering an infection related to her surgery.

21. Mrs A's ED care summary and ED triage assessment form contained a note recording her allergy to penicillins. The national patient Medical Warning System (accessible at NDHB) also recorded a warning note of severe allergy alongside all penicillins.

22. ED nurse RN J told HDC that Mrs A had been placed on the sepsis pathway, and an intravenous (IV) line had been inserted, and bloods had been sent for testing. Mrs A was prescribed IV antibiotics (cefuroxime [4] and ertapenem [5]) following advice from the microbiology service.

23. RN J told HDC that she was aware of Mrs A's penicillin allergy, although she cannot remember how she came to learn of this. She said that her standard practice was always to check the alerts page that is printed and stored in the patient's folder stating medicine allergies, along with the triage form, which also has the patient's alerts printed. RN J noted that she also informs the patient of the medication that she gives them in order to check for allergies. In this case, RN J administered the cefuroxime slowly due to the allergy to penicillin.

24. ED house officer Dr G (a junior doctor) assessed Mrs A and noted that Mrs A had an allergy to penicillin that caused anaphylaxis. She recorded this on an ED admission note in Concerto[6] and on the front page of the 8 Day National Medication Chart[7] (the medication chart), although the medication chart does not include the reaction as being anaphylaxis. Subsequent pages of the chart (in relation to allergy status) have not been completed. The area of the chart where the allergy should be noted on subsequent pages states: "[R]efer to front page for detail about allergy." Dr G went back to Mrs A while filling out the hard copy medication chart to clarify her allergy status. Dr G told HDC that she informed her team of the allergy status during handover. She said that while Mrs A was under the care of the gynaecology team (discussed below), she discussed Mrs A with the consultant

[4] Cefuroxime is a second-generation cephalosporin antibiotic used to treat and prevent a number of bacterial infections; cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from gram-positive and gram-negative bacteria. The five generations of cephalosporins are useful against skin infection, resistant bacteria, meningitis, and other infections.

[5] Ertapenem is a carbapenem antibiotic medication for the treatment of infections of the abdomen, the lungs, the upper part of the female reproductive system, and diabetic foot; carbapenems are a class of very effective antibiotic agents most commonly used for the treatment of severe bacterial infections. Usually this class of antibiotics is reserved for known or suspected multidrug-resistant (MDR) bacterial infections.

[6] The electronic medical record system.

[7] A medication chart developed by the Health Quality & Safety Commission (HQSC) and used across New Zealand.

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microbiologists to ensure that they were treating her infection adequately without the use of penicillin.

25. ED nurse RN I received the handover from RN J at 3pm on Day 1, and recalls being informed of Mrs A's allergy to penicillin. RN I also recalled that Mrs A informed her of the allergy. RN I said that it was practice at the time for patients with allergies to wear red wristbands, but she does not remember the colour of Mrs A's wristband. RN I noted that Mrs A was to be transferred to the surgical ward, but she does not remember taking Mrs A to the ward or handing her over to the ward staff. RN I told HDC that she does recall seeing the doctor's admission summary, which documented Mrs A's allergy, and she said that this summary is always emailed to the ward prior to the ward accepting the patient for transfer.

Transfer to surgical ward

26. Mrs A was transferred to a surgical ward under the care of the gynaecology team in the evening. She continued on the sepsis pathway with the administration of IV ertapenem, and remained clinically stable. Mrs B noted in her statement to the police[8] that as at Day 3 Mrs A was still wearing her medical alert necklace.

Transfer to general medicine ward

27. By Day 5 it was thought that Mrs A was suffering from urosepsis (an infection of her urine and kidneys) that was unrelated to her earlier surgery. Accordingly, she was transferred to the general medicine ward for ongoing management. Mrs A was reviewed by a general medicine registrar, Dr F, who identified that Mrs A had a urinary tract infection and ongoing pain, and that there was concern that her situation was not improving.

28. Dr F told HDC that she was aware of the penicillin allergy as it was documented on the front of the medication chart in the allergy section and was present on the admission note. Dr F discussed the appropriateness of antibiotics with the microbiology service in view of the immediate sensitivity to cephalosporin antibiotics and, knowing that she should not prescribe a penicillin-based antibiotic, this was documented in Mrs A's notes as to "continue IV cefuroxime for now".

29. RN H cared for Mrs A from 7am until 3.30pm on Day 6, alongside three other patients. RN H told HDC that they were understaffed, as the healthcare assistant was working as a dedicated patient watch, and therefore was not able to work in the usual capacity, leaving the registered nurses to cover those duties.

30. RN H received her four patients in a group handover from the staff who had worked the night shift, as per usual practice. She told HDC that in respect of Mrs A, she would have been told that Mrs A had been transferred from a surgical ward the previous day with a kidney infection[9] and was on IV antibiotics, and that Mrs A was to be monitored for loose bowel movements. RN H said that no information was handed over regarding allergies, but that "it

[8] The police were involved in investigating Mrs A's death for the Coroner.
[9] Pyelonephritis (an inflammation of the kidney due to a bacterial infection).

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is not usual practice to handover such information". She told HDC that night shift to morning shift do not do individual handovers, so the only handover she received was the group handover. She stated that she did receive Trendcare[10] notes, which include general information about each patient, but said that allergies are not usually included in the Trendcare notes.

31. RN H told HDC that in addition to the allergy usually being noted in the top left corner of each page of the medication chart, it is her experience that if an allergy is present, then a yellow sticker is placed on the printed patient information sheet in the clinical file, with details of the allergy. There was no such sticker in Mrs A's notes.

32. Once RN H had reviewed the information, she checked on Mrs A. RN H administered Mrs A's regular medications, and at 10am she administered Mrs A's cefuroxime. RN H told HDC that when she administers medication, she checks for allergies as part of the process.

33. General medicine senior medical officer (SMO) Dr C[11] and his team reviewed Mrs A on the morning ward round. Dr C told HDC that this was his team's first contact with Mrs A. Her case was presented verbally and, following an examination, Dr C reviewed Mrs A's laboratory results and microbiology report at a computer that was away from her bedside. Dr C said that the portion of medical registrar Dr F's note that discussed the antibiotic (cefuroxime) did not contain a date, so they did not know whether the note had been written before or after the laboratory results (including the results of the urine test) had been received.

34. General medicine house officer Dr D[12] told HDC that he does not recall seeing any obvious medical alert bracelet on Mrs A during her examination, or any documentation at the bedside about a serious allergy. He said that his attention was on writing the ward round note as Dr C completed the consultation.

35. Dr C told HDC that the urine test results showed that the bacteria present (*E. coli*) was of intermediate sensitivity to the IV cefuroxime Mrs A was receiving, and fully sensitive to Augmentin (a penicillin-type antibiotic). He therefore made the decision to switch Mrs A's antibiotics to IV Augmentin. Dr C told HDC that he did consider a penicillin allergy, but was reassured because Mrs A was already receiving IV cefuroxime, and traditional teaching is that if someone has an allergy to penicillin, cefuroxime would not be prescribed. Dr C did not check whether Mrs A had an allergy before giving Dr D prescribing instructions.

36. As is his usual practice, Dr C then instructed Dr D to prescribe the Augmentin on the medication chart. Dr C told HDC that it is part of the house officer's role to check the notes for any allergies or contraindications. Dr C said that the recorded penicillin allergy on the front of the medication chart was not seen or noted by Dr D.

[10] A workplace planning and workload management system.
[11] Dr C is a Fellow of the Royal Australasian College of Physicians.
[12] House officers are junior doctors.

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37. Dr D told HDC that at 10.55am on Day 6, following the discussion with Dr C regarding the antibiotic, he prescribed the Augmentin. He did this by writing the prescription in the medication chart. Dr D told HDC that at this stage he had worked 59.5 hours across the previous seven days. He said that he did not see the penicillin allergy written on the front cover of Mrs A's medication chart. In addition, the inside cover of the medication chart regarding allergies had not been completed. He said that they did not return to Mrs A's bedside to discuss this change with her.

38. Dr D told HDC that it was not his role to assess the suitability of charting Augmentin, but rather for him to prescribe on the request of the consultant, Dr C, which he did.

Administration of Augmentin

39. RN E began her shift at 2.45pm and attended the common handover. Common handover provides a handover of all of the patients in the ward. The nursing staff receive a handover sheet containing the admission date, admission diagnosis, any past medical history, and resuscitation status. The handover does not include any allergy history for the patients.

40. RN E was allocated four patients, including Mrs A, and shift coordination duties. The morning shift team leader advised that Mrs A had been charted a new antibiotic, Augmentin, and that this was to commence that evening, eight hours after the morning dose of cefuroxime.

41. RN E told HDC that normally they have two folders containing medical records for each patient. Folder one is a small folder containing the medication chart and other monitoring charts. The second folder contains the full medical record, including the admission notes, progress notes, and past history.

42. RN E also received a bedside handover from RN H, where she was told that Mrs A had been stable during the morning shift, and there had been a change of antibiotic from cefuroxime to Augmentin. RN H advised RN E that the Augmentin was to be given at 6pm. RN E noted that she understood that Mrs A had been transferred from a surgical ward the previous day.

43. RN E told HDC that usually nurses would carry the first folder during bedside handover, and, in this case, the folder contained Mrs A's medication chart that had been transferred from the surgical ward. RN E said that at the bedside handover it was her normal practice to check the medication chart quickly and confirm with the nurse handing over that all the regular medications had been given to the patient, and she did this for Mrs A.

44. RN E told HDC that ideally nurses should read the entire medical records in the second folder, but in reality there is not sufficient time to do this due to heavy workload. RN E said that she had a heavy workload on Day 6, partly because it was a busy weekend. In Mrs A's case, RN E quickly checked the last 24 hours of progress notes that were in the second folder, but she did not review the entire medical records.

RN E told HDC that when Mrs A was due for her Augmentin, she checked the front cover of the medication chart again, and does not remember seeing any documentation for allergic reactions to medication. RN E said that she then checked the medication chart to confirm

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that Augmentin had been prescribed, as per the prescribing policy. She also noted the doctor's initials for the prescription, and the dosage, route, and frequency. RN E told HDC that Augmentin does not require an independent second check.

45. After checking the medication chart and IV antibiotic protocol, RN E went to the medication room and prepared the Augmentin. While preparing the medication she checked the notes on injectable drugs for instructions on how to prepare the medication, and she rechecked the name of the medication, the dose, and the expiry date of the ampoule. RN E told HDC that Mrs A was very tired and sleepy the whole time.

46. RN E administered the Augmentin to Mrs A at approximately 6.00pm on Day 6. RN E told HDC that prior to this she had asked Mrs A if she had any known allergies to medication, to which Mrs A had responded that she was not aware of any. RN E said that she also double checked Mrs A's identity. RN E stated that in hindsight she cannot be certain that Mrs A understood the question regarding her allergy status, or whether it did not occur to her to mention the penicillin allergy.

47. Halfway through the administration of Augmentin, Mrs A started to feel nauseous, and RN E noticed that she was experiencing shortness of breath. The administration was stopped and Mrs A was repositioned. RN E suspected that Mrs A was showing signs of anaphylaxis, so she rang the emergency bell immediately and asked the staff to initiate a "code blue" for a possible anaphylactic reaction.

48. Dr D was the first doctor in attendance, and verbally confirmed the initiation of resuscitation, as he recalled Mrs A's admission notes stating "for full resus". Dr D left to find the anaphylaxis protocol, while a medical registrar took over leading the resuscitation. Dr D found Mrs A's medical records and confirmed her resuscitation status as being "for full resus", although this was recorded as not having been discussed with Mrs A on admission. Mrs B told doctors after the event that Mrs A did not wish to be resuscitated.

49. Dr D told HDC that if it is documented that a patient is for full resuscitation, or if there is uncertainty, then it must be assumed that the patient is for full active resuscitation.

50. Resuscitation continued for over two hours, until Mrs A passed away at 9.10pm on Day 6.

Further information

Dr D

51. Dr D told HDC that during the ward round, he and Dr C read the progress note written by Dr F, but upon reflection they may not have read the note in its entirety, as it was across two pages. In hindsight, the portion they read was at the end of the note, and it contained a plan to stay on the current antibiotic, cefuroxime.

52. Dr D told HDC that he agreed that his care provided that day was suboptimal. He said that his reasoning and practice at the time was shaped by the culture of the hospital. He stated that he cannot defend his oversight in not seeing the penicillin allergy and not double checking for allergies prior to prescribing the Augmentin.

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53. Dr D said that it was common to see medication charts with the "Allergies — No" box unticked, if the patient had no allergies. This relied on the initial prescriber filling out the form, but it was common enough for him to have become used to it. Dr D acknowledged that this does not defend his reasoning, and that this should have prompted further enquiry into Mrs A's allergy status, but it is merely an observation about the general culture of practice in the hospital at the time.

54. Dr D told HDC that he felt under pressure at the time to complete the many tasks for the day, and he did not check the medication reconciliation note on Concerto, as this was not common practice amongst his colleagues at that time.

Dr C

55. Dr C told HDC that another factor relevant to the time of Mrs A's admission was workload pressure on weekends. As the on-duty senior doctor for acute general medicine, his role involved post-acute ward rounds, on an average of 10–15 new admissions and in the absence of the other medical teams on the weekend, and review of unwell patients, with up to 20–25 patients to see in total. Clinical interactions are further interrupted by telephone calls from other doctors and hospitals requesting advice or referring patients for admission.

56. Dr C told HDC:

> "[A]t the time we made the decision to change antibiotics we had left the patient bedside to seek out a ward computer to access the lab results. We did have the opportunity to go back to the patient bedside to discuss medication changes but tragically missed this chance when faced with the rest of the weekend post acute ward round list of patients to see. If fully staffed I would have dispatched either the house surgeon or registrar to discuss this with the patient, but we were short staffed, the registrar had gone to the Emergency Department to deal with incoming acute admissions."

57. Dr C told HDC that hospital policies exist in the background as a check-in process, and he provided the example of coloured wristbands to flag an allergy, which had been abandoned by NDHB, although he did not know the reasons why. My independent advisor, RN Jackson, noted that visual cues such as the "yellow alert sticker" (as noted by RN H) and red patient wrist label (noted by RN I) were not evident, and it is suggested that the wrist label is no longer used. RN Jackson advised that if processes such as this had been used consistently, there would have been additional opportunities to learn of Mrs A's allergy.

58. Dr C told HDC that he has continued to reflect on this case and has embedded the learnings into his practice to reduce the possibility of such an event occurring again. He said that he deeply regrets his part in this tragically avoidable death. He stated that from the outset he took responsibility for the prescribing error and, while it was part of a junior doctor's role to check the notes for drug allergies, he accepts that as a senior doctor he had a responsibility to be aware of what is being prescribed by junior colleagues under his supervision.

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59. Dr C told HDC that while he accepts overall responsibility, it is important to note that there are additional checks in the process, which regrettably did not identify Mrs A's allergy after he made the decision to change to IV Augmentin. These include the usual checks by the junior doctor who is physically prescribing the medication before putting pen to paper, the pharmacist's check of the prescription sheet, the nurse's check of the prescription to identify allergies prior to administration, and the nurse's check with the patient.

NDHB

60. NDHB had in place a Medicine Reconciliation on Admission policy (dated August 2019), to ensure that health practitioners accurately documented and communicated all medication changes for patients on admission, transfer, and discharge from NDHB via the electronic medicine reconciliation process in Concerto. This is described in the policy as "a proven strategy to reduce medication errors and medication related patient harm at the transition points of care (admission, transfer, and discharge)". NDHB told HDC that Mrs A was unlikely to have had her medication reviewed by a pharmacist over the weekend, due to pharmacist workload.

61. NDHB stated that this event occurred over a weekend, during which there was an unprecedented number of high acuity patients across all services. NDHB said that the unanticipated complexity created excessive demands on the registrars, and that this work was through the ED and did not reflect the ward levels of occupancy.

62. NDHB acknowledged that this was an extremely sad event that was entirely avoidable. The DHB stated that it took the event very seriously, and wanted to explore all feasible options to prevent it ever happening again. NDHB unreservedly apologised to Mrs A's family for the distress and sadness they must have felt from the untimely loss of a much-loved mother and wife. NDHB said that it accepts that systemic factors contributed to the error.

63. NDHB's prescribing policy noted:

> "Both the allergy and adverse reaction status boxes must be completed (including prescriber/pharmacist signature and date) on the NMC front page as per Northland DHB policy 'Allergies and adverse drug reactions: documenting and reporting'. Allergy and adverse reaction status is valid for a period of up to 3 months per admission, at which time it must be reviewed and re-signed and dated."

NDHB — Serious Event Analysis Review (SEA)

64. NDHB conducted an SEA, which found the following:

a) The absence of completely adhering to prescribing and medication administration protocols resulted in the patient receiving antibiotic to which she had a known anaphylaxis.

b) The absence of documented resuscitation status discussions resulted in the patient receiving resuscitation that was potentially against her wishes.

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c) The absence of flexibility with staffing provision within the hospital out-of-hours led to the inability to increase staffing levels during times of high demand, resulting in this requirement to triage and manage patient care of multiple critically unwell patients.

65. The review also incidentally found that there was a limited awareness amongst staff that allergies should be noted on the culture request forms for the laboratory to avoid testing against antibiotics that are contraindicated.

66. The SEA noted that without this error they had every expectation that Mrs A would have left the hospital and continued to live an active life, as she did not have a life-threatening condition.

67. Five recommendations were made as a result of the findings:

1. NDHB explore expediting the introduction of electronic prescribing across all DHB hospitals.
2. Pharmacy reconciliation of all in-patient drug charts.
3. Implementation of the HQSC-led shared goals of care programme.[13]
4. Surveillance audit of correct completion of resuscitation treatment orders on admission documentation.
5. Review of processes for co-ordination and oversight of the hospital as a whole.

Responses to provisional opinion

Mrs B

68. Mrs B was given the opportunity to respond to the provisional opinion. Where appropriate, her comments have been incorporated into the report. In addition, Mrs B told HDC that she does not accept that a high workload is an excuse for what happened to her mother-in-law.

Dr C

69. Dr C was provided the opportunity to comment on the provisional decision. He had no objections or comments to make.

Dr D

70. Dr D was provided the opportunity to comment on the provisional decision. He told HDC that he did not have anything new to add.

[13] Shared goals of care are when clinicians, patients, and whānau explore patients' values and the care and treatment options available, and agree on the goal of care for the current admission and if the patient deteriorates. See: https://www.hqsc.govt.nz/our-work/advance-care-planning/acp-information-for-clinicians/shared-goals-of-care/.

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RN E

71. RN E was provided with the opportunity to comment on the provisional decision. Her comments have been included throughout the report where relevant. In addition, RN E told HDC:

a) She does not recall Mrs A wearing a medical alert bracelet or necklace, and said that had she been wearing one, she would not have missed it.

b) She believes that she followed all policies and procedures related to medication administration, including checking the identification band prior to administering the medication to Mrs A. She said that she was constantly busy from the start of the shift with another quite unwell patient, and did not get the time to review all Mrs A's other clinical records. RN E stated that this was not due to her negligence. She reiterated that working on a busy shift under pressure would have affected her decision-making process on that day and hindered her from re-checking Mrs A's other clinical records.

NDHB

72. NDHB was provided with the opportunity to comment on the provisional decision, and it accepted the breach finding against it. NDHB again expressed its profound regret to Mrs A's family for the errors that led to her untimely and unexpected death.

73. NDHB submitted that the pressures (resourcing limitations and staffing issues) that led to this occurring at the time are still being experienced and are not unique to Northland, and reflect significant workforce vacancies across multiple professions.

74. NDHB agreed that electronic prescribing is the key to prevention, and stated that it had been requesting this to be prioritised for many years. NDHB noted that this represents an organisational risk, which is on its risk register and was highlighted to the NDHB Board and regionally.

75. NDHB considered that informing patients of changes in their prescribing is a good idea and consistent with shared decision-making practice, but noted that while this is feasible on ward rounds, it may not be possible when decision-making is happening remotely from the patient.

76. NDHB advised that in relation to visual cues (coloured wristbands), these were abandoned owing to the frequency with which the bands were being triggered for multiple reasons, including, for example, food intolerance. As the patient management system was unable to distinguish the nature of the alert to identify drug allergies, and in the absence of evidence to support their efficacy, the decision was taken by the Clinical Governance Board to withdraw coloured wristbands from practice.

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Opinion: Introduction

77. At the outset it is important to acknowledge, and it is not in dispute, that Mrs A's death was not an expected outcome from admission to hospital, and the medication error was avoidable. Her death clearly had a devastating impact on her family, and I again express my condolences to them. I also have no doubt that staff intended to do their best for Mrs A, and that they were affected by her death and have reflected on the circumstances. It is important that lessons are learned to prevent such an error occurring again.

78. This opinion discusses the role of individuals in the event, and also NDHB's overall responsibility to provide safe and appropriate care. I note and agree with the comments of my independent advisor, Dr Margaret Wilsher, that it is accepted that hindsight allows clarity of perspective that foresight can never achieve. Humans by their very nature are fallible and can err, and work done is not the same as work imagined. In reality, clinical practice in a busy acute admitting hospital will mean that there is potential for distraction and interruption, for shortcuts and lack of adherence to process, so the system and its processes must be sufficiently robust to protect patients at such times.

79. However, it is also important to recognise that individuals have professional responsibility in their practice, and that it is appropriate to hold individuals to account for departures from the expected standard of care. This is not intended to be punitive but to reflect the rights to which consumers are entitled, and to identify breaches of those rights where appropriate.

80. Lastly, I note that in addition to Dr Wilsher, I obtained independent advice from a general physician, Dr David Cole, and from a registered nurse, RN Rosalind Jackson, to assist my investigation of whether the Code of Health and Disability Services Consumers' Rights was breached.

Factual finding — documentation of allergy

81. I am satisfied that the front page of the 8 Day National Medication Chart was completed by the admitting house officer, Dr G, on Day 1. She recorded the word "penicillin" in the allergy box in the top left-hand corner of the chart, and signed and dated the entry. She did not record the allergic "reaction" to penicillin (for which there is space in the same box).

82. There is an adjacent but separate box entitled "adverse reactions", which is ticked "no" and initialled by Dr G (but which is undated).

83. I do not accept any suggestion that the allergy box did not contain Dr G's notations at the time the medication was administered. This is because of the weight of evidence to the contrary.

84. It is also accepted that the 8 Day National Medication Chart was the chart in folder 1 at Mrs A's bedside at the time the Augmentin was administered.

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Opinion: Dr C — breach

85. As noted by Dr C above, as the senior member of staff he had the overall responsibility to be aware of what was being prescribed by junior doctors under his supervision. While Dr C was not the prescribing doctor, it was at his direction that Dr D changed Mrs A's antibiotic from cefuroxime to Augmentin.

86. The morning ward round of Day 6 with Dr D was the first time Dr C had met Mrs A, as she had been transferred from the surgical ward the previous night. Dr C examined Mrs A and reviewed her laboratory reports, which indicated the presence of *E. coli* in her urine. *E. coli* was of intermediate sensitivity to the cefuroxime she was receiving, and fully sensitive to Augmentin. Based on this information, Dr C made the decision to change Mrs A's antibiotic to Augmentin.

87. Dr C told HDC that he did not physically prescribe the Augmentin himself, nor did he have physical access to the drug chart, and he did not see the allergy warning. He said that he was reassured that the penicillin would not cause a reaction because Mrs A was already receiving IV cefuroxime and, conventionally, if someone has anaphylaxis to penicillin, the risk of cross-reactivity to cephalosporin is too high, and cefuroxime would not be prescribed.

88. In his independent advice to HDC, general physician Dr David Cole noted that more recent data indicates that cross-reactivity is uncommon, between 2–5%. He advised that this assumption should not have precluded checking for an allergy to penicillin, and it would have been important to know of any reaction.

89. Dr Cole noted that the expected standard of practice would be to check for an allergy prior to directing (or prescribing) a medication, and that this is stated explicitly in the Medical Council of New Zealand statement on good prescribing practice.[14] Steps to check for drug sensitivities may have included asking the patient directly, checking for a medical alert bracelet or necklace, checking the drug chart, and/or checking alerts on the electronic record.

90. Dr Cole advised that if the National Medication Chart had been checked by Dr C, and the allergy status had been recorded on the front page, it would have been important to ascertain what that reaction was prior to deciding on treatment. Pending this, the drug should not have been prescribed.

91. Dr Cole's opinion is that the care provided by Dr C is likely to have been suboptimal, and likely fell below the expected standard of care. Dr Cole noted that he would regard this as a moderate to severe departure from the accepted standard of care.

92. I agree with Dr Cole's advice. While there were further checks that failed in this case (discussed below), the first step in this unfortunate event was the directive to change the

[14] https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing-practice.pdf at clauses [1] and [13].

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antibiotic cefuroxime to Augmentin. Dr C did not actually prescribe the Augmentin, but he did direct Dr D to do so without having first checked for any adverse reactions or allergies. As the senior member of the team working that day, it was Dr C's responsibility to ensure that his direction to Dr D was both reasonable and safe. Dr C failed to ensure that this was the case.

93. I note that Dr Wilsher also commented on Dr C's decision to change Mrs A's antibiotic without informing her first. Dr Wilsher advised that it would be the usual standard of care to advise a patient of a change to their medication management, and a moderate departure not to do so. I accept this advice and agree that Dr C should have informed Mrs A of this change.

94. In my view, Dr C failed to provide services to Mrs A with reasonable skill and care when he directed Dr D to prescribe the Augmentin without first checking for adverse reactions or allergies. Accordingly, I find Dr C in breach of Right 4(1) of the Code.[15]

95. It is important to acknowledge that when Dr C was made aware of the critical situation following the administration of Augmentin, he did all that could be done to address it. He communicated directly and openly with the family, and there was full disclosure of the events to both the family and the Coroner. This action was entirely appropriate in the circumstances.

Opinion: Dr D — breach

96. At the time of this event, Dr D was a house officer working on the general medicine ward. He joined Dr C on his morning ward round when he met Mrs A for the first time. Following the examination of Mrs A and the discussion regarding the microbiology report, Dr C instructed Dr D to prescribe Augmentin, which he then did.

97. Dr D told HDC that he did not see the penicillin allergy written on the front cover of Mrs A's medication chart. In addition, the boxes on the subsequent pages of the medication chart regarding allergies had not been completed. He also noted that during the examination he did not see any obvious medical alert bracelet. In response to the provisional opinion, Mrs A's family indicated that Mrs A had a medical alert necklace with a long chain rather than a bracelet.

98. HDC's independent advisor, general physician Dr David Cole, noted that the "No (allergy)" tick boxes on the internal pages of the 8 Day National Medication Chart were unchecked, and that if this was being used as an alternative source of information regarding allergy

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

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status, then the box being unticked should have prompted further enquiry into Mrs A's allergy status.

99. Dr Cole advised that under both the Medical Council of New Zealand statement on good prescribing practice (March 2020) and the NDHB Medication Prescribing Policy (March 2019), Dr D had a duty to check for allergies or other reactions. When prescribing on the ward, Dr D would have had to use the National Medication Chart. Dr Cole noted that it would be standard practice to review this at the time to check for documentation of allergies, which appeared on the front page. While there are additional sources of allergy information, the medication chart would be the default at the point of prescribing.

100. Dr Cole considers that the care provided by Dr D is likely to have been suboptimal, and likely fell below the expected standard of care. Dr Cole said that he would regard this as a moderate to severe departure.

101. I accept Dr Cole's advice, which primarily I rely upon in relation to whether Dr D met the appropriate standard of care. Dr D told HDC that he did not see the penicillin allergy written on the front page of the medication chart, and the internal pages of the chart were not completed. Whilst the internal pages were not completed, both the Day Stay Chart and the 8 Day National Medication Chart had "penicillin" written on the front cover in the "allergies" section. Even had this not been the case, the incomplete allergy boxes on the internal pages of the medication chart should have prompted further investigation by Dr D before the Augmentin was prescribed.

102. For the sake of completeness, I note that Dr Wilsher also provided an opinion identifying that Dr D's failure to ascertain whether Mrs A had an antibiotic allergy was a serious departure from accepted standards. Dr Wilsher was also critical of the failure to advise Mrs A of the intended change to her medication management. I accept this advice and agree that Dr D should have informed Mrs A of this change.

103. In my view, Dr D missed several opportunities to learn of Mrs A's allergy status, including reading the notes, reviewing the drug chart, noting the medical alert necklace, and asking Mrs A whether she had any allergies. I acknowledge that the ward was busy and that Dr D was directed by Dr C to prescribe the Augmentin. Nonetheless, notwithstanding his junior doctor status, Dr D holds some individual responsibility, and needed to take the necessary steps to ensure that the antibiotic he was prescribing was appropriate. By failing to do so, Dr D did not provide services to Mrs A with reasonable care and skill. Accordingly, I find Dr D in breach of Right 4(1) of the Code.

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Opinion: RN E — breach

104. During handover on Day 6, RN E was made aware that Mrs A's antibiotic had been changed to Augmentin, and she was advised that the Augmentin was to be administered at 6.00pm, as per the pharmacist's instruction. Before administering the Augmentin, RN E reviewed the 24-hour progress notes that were contained in the folder at hand, but she did not review all Mrs A's medical records. RN E noted that Mrs A appeared very tired and was sleeping most of the time.

105. When Mrs A was due to receive the Augmentin, RN E checked the notes on injectable drugs for instruction on how to prepare the medication. She said that she prepared the medication, then rechecked the name of the medication, the dose, and the expiry date on the ampoule. RN E also told HDC that she remembers checking the front cover sheet of the medication chart again, and did not see any documentation for any allergic reaction.

106. NDHB's Medication Administration policy requires the person administering the medication to confirm the allergy/adverse drug reaction status at the bedside. While RN E notes that she did not see any documentation, I have previously concluded that there was a record of penicillin in the allergy box on the front page of the medication chart. This was available to RN E at the time, and, in my view, should have prompted RN E to take pause.

107. In response to the provisional opinion, RN E told HDC that she acknowledges the fact that penicillin was recorded in the allergy box of the 8 Day National Medication Chart, but no adverse reactions were documented. She said that the busy shift and the shift coordination role she had on that day affected her decision-making, and is why she did not pause to check any allergy issues with the doctors. She stated that medication charts are still incomplete at times, and she feels that they need an electronic system to prevent these errors occurring in the future.

108. RN E also stated that she asked Mrs A whether she had any known allergies to medication, and that Mrs A responded that she was not aware of any.

109. Mrs A was described by her family as a good historian who would always ask a clinician whether any new medication prescribed contained penicillin. I note that RN E recalled that Mrs A was very tired and sleeping most of the time and, following Mrs A's death, questioned whether Mrs A had heard or understood the earlier questions regarding known allergies.

110. In response to the provisional opinion, RN E told HDC that she acknowledges that she may have asked the question about any allergies at a faster pace, which Mrs A probably did not understand.

111. I am satisfied, based on the evidence of Mrs A's family and other evidence indicating communication from her to other staff, that Mrs A was proactive in disclosing her allergy status, and that had she been asked directly she would have disclosed it. Allowing for the possibility that RN E did ask Mrs A about allergies, it follows that RN E did so in such a way that Mrs A did not understand, or in circumstances where Mrs A was not sufficiently alert

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or able to answer as she would have normally. This calls into question the effectiveness of RN E's communication.

112. RN Jackson advised that whilst RN E did administer the Augmentin that was a direct cause of Mrs A's anaphylactic reaction, she is not entirely at fault. RN E was the last step in the process, and unfortunately was the last line of defence across a system that ultimately failed. RN Jackson considers that RN E was thorough and consistent in her documentation and Datix recording, and logical in her reasoning. RN Jackson stated that RN E's administration of IV Augmentin to Mrs A would be considered a severe departure from accepted standards, but noted that taking into account the systems that failed, the departure should be mitigated to a mild departure.

113. While I acknowledge and discuss below the systems that failed in the care provided to Mrs A, and note that these failures did not support the individual clinicians in their decision-making, I consider that RN E had an individual professional responsibility to assure herself of, and adequately confirm, Mrs A's allergy status prior to the administration of medication. As the last check in the process, RN E's role was as crucial as the steps before her involvement. RN E failed to notice or otherwise act on the allergy documented on the front page of the medication chart, and there are concerns about the effectiveness of her communication with Mrs A regarding that status. In any event, while asking the patient is one checking factor, other important checks should have been made (namely checking for allergy status in the clinical record, and/or checking for a medical alert bracelet or necklace). By not undertaking these steps, RN E did not provide services to Mrs A with reasonable care and skill and, accordingly, I find that RN E breached Right 4(1) of the Code.

Opinion: Northland District Health Board — breach

Introduction

114. Throughout Mrs A's admission to Whangārei Hospital, there were a number of points at which a safeguard failed, leading to her being administered Augmentin, to which she had a well-known allergy. While individuals played a role in the event, the overall responsibility to provide an appropriate level of care sat with NDHB, which should have had in place robust systems to support good clinical decision-making. Systems issues and breakdowns contributed to the administration of Augmentin in error.

115. The SEA conducted by NDHB noted that deficiencies in care led to Mrs A being administered Augmentin. These included the absence of complete adherence to prescribing and medication administration protocols, and the absence of flexibility with staffing provision within the hospital out-of-hours. This was found to have led to the inability to increase staffing levels during times of high demand, resulting in the requirement to triage and manage patient care of multiple critically unwell patients.

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Systems

116. One element that led to this event is that NDHB had policies and processes that did not support safe care and, in some cases, there was a lack of adherence to policy. The serious event review noted that the absence of complete adherence to prescribing and medication administration protocols resulted in Mrs A receiving the Augmentin.

117. NDHB's medication prescribing policy required that allergy and adverse reaction status boxes be completed on the front page of the National Medication Chart, but no comment was made about the additional pages of the chart.

118. As noted by Dr D, his reasoning and practice at the time was shaped by the culture of the hospital. He said that it was common to see medication charts with the "Allergies — No" box unticked if the patient had no allergies. While this was dependent on the initial prescriber filling in the form, it was common enough that he had become used to it. He also said that he did not check the medication reconciliation note on Concerto, as this was not common practice amongst his colleagues at that time.

119. Once Dr C and Dr D had reviewed Mrs A, they returned to the ward computer station to review the laboratory results. This was where Dr C made the decision to change the antibiotic to Augmentin. Dr D then prescribed the medication. Neither Dr C nor Dr D returned to Mrs A's bedside to discuss this change with her. This was another missed opportunity to ascertain Mrs A's allergy status.

120. As my independent advisor, Dr Wilsher, noted, Mrs A's family are adamant that she was fully cognisant of her penicillin allergy, and communicated this to any clinician prescriber. The allergy was documented by both the Emergency Department assessing doctor and the inpatient admitting doctor, so it appears that Mrs A discussed her allergy with them. RN I also told HDC that she was aware of the allergy, as it had been communicated to her by Mrs A.

121. Nowhere in her notes is Mrs A ever described as confused or compromised in her ability to respond to questions. Therefore, it is reasonable to infer that she remained able to give information about her allergy if asked in an appropriate way and in appropriate circumstances. This is strongly corroborated by the statement of her daughter-in-law, who commented generally about Mrs A's diligence in disclosing her allergy to health professionals, and of witnessing, during this admission, the efforts she made to alert people to her allergy.

122. These breakdowns in policy/procedure and the lack of adherence to them meant that there were lost opportunities to ascertain Mrs A's allergy status, and this contributed to Mrs A being prescribed and administered Augmentin.

Management of high ward acuity

123. NDHB noted that over the weekend in which this event occurred there was an unprecedented number of high acuity patients across all services in the hospital. This led to

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insufficient staffing levels, placing pressure on the health professionals who were caring for Mrs A.

124. Dr D told HDC that he worked the 8.00am to 9.00pm shift on Day 5 and Day 6. He was rostered on for 68.5 hours that week, and on the morning of Day 6 he had worked 59.5 hours over the previous seven days. I note that this is a high workload, and with that comes the potential for fatigue.

125. NDHB found in the SEA that the absence of flexibility with staffing provisions within the hospital out-of-hours led to the inability to increase staffing levels during times of high demand, resulting in the requirement to triage and manage patient care of multiple critically unwell patients.

126. Dr Cole noted that the registrar is an important component of a medical team ward round, providing the hands-on expertise of a more experienced junior doctor as well as providing an additional level of direct supervision for the less experienced house officer, reducing the risk of management errors. The high number of presentations was cited as a factor that resulted in the medical registrar having to leave the ward round. Dr Cole commented that there will always be exceptions, but to an extent the increased workload at such times is predictable, and staffing levels should be adjusted to ensure that adequate cover is available. He stated that medical rosters should be devised to facilitate continuity wherever possible.

127. Taking into account the findings of the SEA and Dr Cole's advice, I conclude that NDHB lacked flexibility to increase staffing levels to cover higher workload and acuity of patients. This impacted the provision of safe staffing levels, during which time Mrs A's allergy was overlooked.

Handover

128. Regarding the handovers between staff, Dr Wilsher noted that the handover documentation in the clinical record progress notes is within the accepted standard of care, with the exception that the penicillin allergy is not recorded as part of the handover communication, either in the nursing or medical notes. She advised that the standard of care would be to communicate information that is of importance to the safe care of the patient in question. It is not known what verbal information was provided at handover, but the handover section of the admitting documentation does not contain information about drug allergies.

129. RN Jackson advised that the bedside handover document provided is evidence of good practice, although it appears to have focused on process rather than content. She said that relying on verbal handovers as a "stand alone" is not reliable, as this becomes person-dependent safety as opposed to system safety. She considers that a handover protocol that includes process and standardised content may provide a safer system for staff to work within. For example, the registered nurses stated that "allergies are not included" in handover. RN Jackson noted that if allergy status is not included in verbal handover and has

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not been transcribed reliably throughout admission, the risk of missing this information is high, and the opportunity to consider allergy status as part of standardised handover is lost.

130. RN Jackson noted that whilst not including review of allergy status as part of handover was inadequate, the handovers that did occur did not depart from NDHB practice.

131. I accept this advice and am concerned that the handover process at NDHB did not consistently support the effective sharing of important information such as allergy status.

Documentation

132. One issue at the core of this event was the documentation of Mrs A's penicillin allergy. Her allergy was documented in the ED care summary and on the front page of the 8 Day National Medication Chart. The allergy was also listed on Mrs A's patient alerts. HDC's independent advisor, Dr Wilsher, noted that it is not clear how visible to clinical staff the alert is on the Concerto system, or even how aware clinical staff are of this reporting system.

133. Dr G documented Mrs A's allergy to penicillin in the ED admission note and on the 8 Day National Medication Chart, although the medication chart did not describe the reaction of anaphylaxis. Mrs A's penicillin allergy was not recorded on the subsequent pages on the medication chart.

134. Dr Wilsher considers that the failure to record the allergy on the subsequent pages of the medication chart was a mild departure from the usual standard of care, and said that in real life practice, this section of the drug chart is not always completed.

135. Dr Wilsher advised that the factors that underpin the failure to notice documentation of the penicillin allergy are broad. However, the 8 Day National Medication Chart appears to have a design flaw in that documentation of medication allergy is not routinely carried through to every page, and the allergy section on the front page is not apparent to anyone with the chart open for review of either modification or change of medication. This means that staff who are working with the chart in everyday practice do not receive a prompt regarding drug allergy.

Conclusion

136. Three core issues contributed to the error that occurred with Mrs A, all of which led to missed opportunities to ascertain her allergy status. These were:

1. The lack of policies and procedures (for example, requiring completion of the internal pages of the medication chart, and visual indicators of allergy), and the lack of adherence to existing procedures, in particular the incomplete recording of information on the 8 Day National Medication Chart by multiple staff;
2. The lack of flexibility in staffing provision during a busy period with a number of high acuity patients; and
3. The handover process, which did not consistently support sharing of important information such as allergies.

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137. In addition, adequate continuity of care across different areas of the hospital did not occur. Mrs A's allergy status was known to the system at NDHB, but this information managed to slip through the cracks as Mrs A was transferred across wards.

138. For the reasons set out above, I consider that NDHB failed to provide services to Mrs A with reasonable skill and care. Accordingly, I find NDHB in breach of Right 4(1) of the Code.

Resuscitation status — other comment

139. Following the administration of the Augmentin, staff commenced resuscitation of Mrs A. Mrs A's clinical records noted that she was to be resuscitated, but this was not discussed with her. Mrs B told doctors after the event that Mrs A did not wish to be resuscitated.

140. NDHB noted in the SEA that the absence of documented resuscitation status discussions resulted in the patient receiving resuscitation that was potentially against her wishes.

141. RN Jackson advised that whilst resuscitation was potentially against Mrs A's wishes, to conduct a full and rigorous resuscitation in the presence of hospital treatment error is entirely appropriate. While it may have been appropriate, I note that it is important to discuss resuscitation status with patients at the outset in order to avoid ambiguity. In making this comment, I acknowledge that resuscitation was not expected to be an outcome of Mrs A's hospital admission.

Opinion: Dr G — other comment

142. My independent general physician advisor, Dr Cole, was critical of the way Dr G documented Mrs A's allergy on the medication chart. However, taking into consideration Dr G's very junior doctor status, together with the steps she in fact took to alert the treating team of Mrs A's allergy (recording it in the admission document and on the front page of the medication chart, and verbally advising the team), together with the lack of clarity in the policy as to what should be recorded where, and the practice at the time, I am not critical of Dr G's care.

Changes made since event

Dr C

143. A pharmacist now accompanies Dr C on his ward rounds and provides support to him and the junior staff. This occurs during the weekdays, and he plans to extend it to the weekend.

144. Dr C now ensures that he pauses and asks junior staff on his team to check the allergy box before advising a change in medication.

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Dr D

145. Dr D has changed his practice for checking for allergies, and will take time to do this even if he is under pressure to complete tasks.

146. Dr D now double checks for allergies, looking twice at the allergy box and making time to ask the patient if they are aware of any allergies.

147. Dr D also double checks the clinical regional portal to see whether any previous medication reconciliations have been completed for the patient, and checks the national alerts on the patient's clinical regional portal front page.

NDHB

148. This case has been presented and discussed at the mortality and morbidity review and at the handover review as a salient reminder to all medical staff to check for allergies before prescribing.

149. Dr C told HDC that within a few weeks of this case, weekend staffing was bolstered with an extra SMO for ward reviews, and extra house surgeons and registrars for ward rounds and admissions.

150. In response to the provisional decision, NDHB submitted that over recent years it had increased after-hours medical staffing significantly. However, NDHB stated that during the weekend when Mrs A died there was an unprecedented number of high acuity patients, and the nature of health care is not to staff routinely for rare, extraordinary events. NDHB also told HDC that the National Medication Chart has been modified to remove the requirement to chart the allergy in two locations. The allergy section is now visible from all pages of the prescription.

RN E

151. In response to the provisional opinion, RN E told HDC that she now pauses and takes time to check a patient's allergies, and ensures that patients fully understand her questions or explanations.

152. RN E is undertaking a graduate diploma to update her knowledge and skills. She has also become a New Zealand Nurses Organisation (NZNO) delegate to support her colleagues and raise concerns with the NZNO about the impact of working conditions for nurses.

HQSC

153. The layout of the National Medication Chart has been altered, with the allergy box now immediately above the prescribing columns to enhance visibility to the prescriber. The allergy box is now also visible when the chart is scanned to the pharmacy.

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Recommendations

154. In response to the provisional recommendations, Dr C provided HDC with a written apology for forwarding to Mrs A's family.

155. I recommend that Dr D provide a written apology to Mrs A's family for the breach of the Code identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

156. I recommend that RN E provide a written apology to Mrs A's family for the breach of the Code identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

157. I recommend that Te Whatu Ora Te Tai Tokerau:[16]

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

b) Consider how it can improve recognition of documented drug allergies, and implement improvements that mitigate the risk of inadvertent administration of a drug to which the patient is allergic. Evidence of this is to be sent to HDC within four months of the date of this report.

c) Consider methods for improving the process and documentation of medical handover between different disciplines and between on-call and destination ward-based teams, particularly handover of information that is of importance to the safe care of the patient in question. Evidence of this is to be sent to HDC within four months of the date of this report.

d) Amend its medication prescribing policy to make it clear that the prescriber must inform the patient of a recommended change in medication and enquire about drug allergy, and also consider amending the policy to add clarity regarding the filling out of the National Medication Chart in full, as discussed above. The new policy is to be sent to HDC within four months of the date of this report.[17]

e) In my provisional opinion I recommended that consideration be given to improving the quality of ward rounds by allowing clinicians access to electronic clinical information at the bedside. In response, NDHB submitted that bedside laptops are available on all medical wards and have been so for more than a decade. Acknowledging this information, I recommend that NDHB provide evidence to HDC that staff have been orientated to, and use, the available laptops for accessing relevant clinical information at the bedside.

[16] On 1 July 2022, NDHB was disestablished, and therefore these recommendations apply to Te Whatu Ora|Health New Zealand Te Tai Tokerau.

[17] In response to the provisional decision, NDHB submitted that it was happy to review the policy and hoped to achieve regional consistency of such documents as it transitioned into the new Te Whatu Ora structure.

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f) Within four months of the date of this report, provide HDC with an update on the implementation and effectiveness of the recommendations set out in the Serious Event Analysis Report on this event.

158. I note that Te Whatu Ora Te Tai Tokerau agreed that electronic prescribing is the key to prevention of medication errors, and asked for this to be prioritised (see paragraph 74). I recommend that Te Whatu Ora (National Office) liaise with Te Whatu Ora Te Tai Tokerau (Northland District) in respect of how it can support Te Tai Tokerau to implement electronic prescribing.

Concluding comment

159. In its response to the provisional opinion, Te Whatu Ora Te Tai Tokerau (Northland District) highlighted resource limitations — in particular staff shortages and pressures — which were evident at the time of this case, and are ongoing. While I note that shortly after Mrs A's episode of care, after-hours staffing was increased (which signals that improvement in after-hours staffing levels could be, and was, improved), I nevertheless acknowledge that such workforce pressures are evident both regionally and across the sector in multiple professions. Mrs A's case is a salutary reminder of the potential for patient harm when there are inadequate staffing levels to meet service demand. It also highlights the importance, in such circumstances, for robust systems and tools to support staff and clinical decision-making.

Follow-up actions

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

161. A copy of this report with details identifying the parties removed, except the advisors on this case, NDHB (now Te Whatu Ora|Health New Zealand Te Tai Tokerau), and Whangārei Hospital, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's and Dr D's names in covering correspondence. A copy of this report will also be sent to the Nursing Council of New Zealand, and it will be advised of RN E's name.

162. A copy of this report with details identifying the parties removed, except the advisors on this case, NDHB (now Te Whatu Ora|Health New Zealand Te Tai Tokerau), and Whangārei Hospital, will be sent to the Health Quality & Safety Commission and the New Zealand Pharmacovigilance Centre, and published on the HDC website (www.hdc.org.nz) for educational purposes.

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Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from general physician Dr David Cole:

"Complaint: [Mrs A]/Whangārei Hospital [2020]

Report produced 23rd October 2021

Your Ref: 20HDC01979 — NHI …

My name is Dr David Cole. I have been asked to provide an opinion to the Commissioner on case number 20HDC01979 regarding the care that the late [Mrs A] received from Whangārei Hospital during her admission [in] 2020. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I have no conflicts of interest to declare in this case.

I am a Consultant General Physician employed by Canterbury District Health Board. I graduated from Sheffield University Medical School, England, in 1982 with a Bachelor of Medicine and Surgery awarded with honours (MB, ChB, Hons). My postgraduate qualifications comprise Membership of the Royal College of Physicians (MRCP, UK), Doctor of Medicine (MD, Sheffield University) and Fellowship of the Royal Australasian College of Physicians (FRACP). I have subspecialty interests in endocrinology, diabetes and obstetric medicine. I am an honorary Clinical Senior Lecturer at the University of Otago.

I have been requested by the Commissioner to provide expert advice on the following issues:

Please review the enclosed documents and advise whether you consider the medical care provided to [Mrs A] by Whangārei Hospital was reasonable in the circumstances, and why.

In particular, please comment on:

A. [Dr C] — Medical SMO

1. The adequacy of steps taken by [Dr C] to assess the suitability of antibiotics, prior to making the decision to switch [Mrs A] to Augmentin;

2. If not answered above, the adequacy of steps taken to assess [Mrs A's] penicillin allergy status. From the information provided, we note there are differing versions of the events about whether [Mrs A's] allergy status was recorded on the front cover page of the 8 days national medication chart. For this, please provide your advice in the alternative. In other words, what would your advice be if:

a. [Mrs A's] allergy status was recorded on the front cover page of the 8 day national medication chart; and

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b. [Mrs A's] allergy status was not recorded on the front cover page of the 8 day national medication chart.

3. Any other comments you wish to make about [Dr C's] care.

B. [Dr D] — House officer who charted IV Augmentin

4. The adequacy of steps taken by [Dr D] prior to prescribing Augmentin for [Mrs A];

5. If not answered above, the adequacy of steps taken to assess [Mrs A's] penicillin allergy status. From the information provided, we note there are differing versions of the events about whether [Mrs A's] allergy status was recorded on the front cover page of the 8 days national medication chart. For this, please provide your advice in the alternative. In other words, what would your advice be if:

a. [Mrs A's] allergy status was recorded on the front cover page of the 8 day national medication chart; and

b. [Mrs A's] allergy status was not recorded on the front cover page of the 8 day national medication chart.

6. Any other comments you wish to make about [Dr D's] care.

C. [Dr F] (medical registrar)

7. The adequacy of documentation of [Mrs A's] allergy, and communication to the team about [Mrs A's] allergy; and

8. Any other comments you wish to make about [Dr F's] care.

D. [Dr G] — (house officer)

9. The adequacy of steps taken by [Dr G] to chart [Mrs A's] 8-Day National Medication Chart;

10. The adequacy of documentation of [Mrs A's] allergy; and

11. The adequacy of the handover process to surgical wards (gynaecology).

E. Whangārei Hospital

12. Any other comments you wish to make about the overall care provided to [Mrs A] by the medical team as it relates to her eventual penicillin reaction.

For each question, please advise:

a. What is the standard of care/accepted practice?

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b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

c. How would it be viewed by your peers?

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Sources of information reviewed in the preparation of this report:

1. Letter of complaint dated [2020]
2. Police Statement from complainant, [Mrs B]
3. Northland District Health Board's response letter dated [2021]
4. Serious Event Analysis (SEA) Report, incident reference [number]
5. Code Blue record sheet
6. Policy — Medication Prescribing
7. Policy — Management of Anaphylaxis in the Inpatient Setting
8. Policy — Code Blue Calls and Medical Emergency
9. All ED presentations, [Days 5–6]
10. Timeline for SEA
11. [Mrs A's] Clinical records from Whangārei Hospital covering the period [Days 1–6].
12. 8 Day National Medication Chart — coloured
13. Northland District Health Board's response letter dated [2021]
14. Statement from [Dr D] (house officer, first response)
15. Statement from [Dr D] (house officer, second response)
16. Statement from [Dr C] (SMO)
17. Statement from [Dr F] (registrar)
18. Statement from [Dr G] (house officer)
19. Postmortem report — coroner's reference no …
20. New Zealand Medical Council Statement on Good Prescribing Practice (March 2020). https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing-practice.pdf

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Background

On [Day 1] [Mrs A] presented to the Emergency Department at Whangārei Hospital with fever. She was admitted under the care of the gynaecology service and transferred to a surgical ward.

The source of presumed infection was initially unclear, but thought possibly related to her recent surgery. She had been recovering from a posterior vaginal wall repair and perineorrhaphy done [two weeks' previously]. Ertapenem, a broad spectrum intravenous antibiotic effective against resistant organisms of a type [Mrs A] had previously had ('ESBL' or 'extended spectrum beta lactamase' producing E coli) was prescribed pending further investigation. Infections of this type can recur. A CT scan of the chest, abdomen and pelvis raised the possibility of a right sided pyelonephritis rather than a gynaecological infection. An ultrasound scan of the pelvis done to help exclude gynaecological infection found no drainable collection (pus). A urine sample taken on the day of admission produced a mixed growth of organisms, predominantly E coli. Ertapenem is usually reserved for resistant organisms. The microbiology laboratory report generated on [Day 3] indicated the E coli to be sensitive to alternative antibiotics, including cefuroxime. The ertapenem was stepped down to intravenous cefuroxime on [Day 4]. With the investigations indicating a kidney and urine infection (pyelonephritis) a request to transfer to general medicine was made and accepted ([Day 5]). The general medicine service would normally manage this condition. The patient was moved to [a general medical ward] for ongoing management of the pyelonephritis.

With ongoing symptoms a further change in antibiotic was made, and on [Day 6] at around 1800 hrs, despite having informed ED staff that she was allergic to penicillin, [Mrs A] was administered Augmentin by intravenous injection. Sadly she passed away the same day due to acute anaphylactic shock. It is disputed whether her penicillin allergy was recorded on the front page of the 8 day National Medication Chart.

A. [Dr C] — Medical SMO

1. The adequacy of steps taken by [Dr C] to assess the suitability of antibiotics, prior to making the decision to switch [Mrs A] to Augmentin;

The care provided by [Dr C] was likely to have been suboptimal, and likely fell below the expected standard of care. I would regard this as a moderate to severe departure, but subject to the mitigating factors detailed below. I would expect my professional colleagues to concur with this.

On his morning ward round [Dr C], a senior medical officer (SMO or consultant) in general medicine, directed that the antibiotic being given [Mrs A] be changed to Augmentin. There was a responsibility for the senior doctor making this direction to ensure that it was both reasonable and safe to do so. The actual prescribing was delegated to the House Officer on the team, [Dr D].

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[Mrs A's] care had been transferred to the General Medicine service from the Gynaecology service on [Day 5]. [Mrs A] was reviewed by [Dr C], who met her for the first time on [Day 6]. The ward round entry for [Day 6] stated the diagnosis of pyelonephritis and urinary tract infection, together with the antibiotic being used to treat this, which at that point was intravenous cefuroxime. Back pain and mild right flank tenderness was noted and with ongoing symptoms a change of antibiotic was made on the basis of the earlier antimicrobial sensitivities. The organism was fully sensitive to Augmentin and of intermediate sensitivity to cefuroxime. The plan was made to switch to intravenous Augmentin. The entry was without a time and was unsigned, written between nursing notes made at 0700 and 1345hrs.

In his statement [Dr C] admitted that no check for an allergy to Augmentin was done by him. Augmentin contains amoxicillin, a form of penicillin. [Dr C] points out that the use of a cephalosporin antibiotic, such as the cefuroxime which [Mrs A] was taking without problem, would not usually be considered in someone known to have a severe allergic reaction to penicillin. Historically cross reactivity was generally quoted of between 10 to 30%, although more recent data indicates cross reactivity is uncommon (2–5%). However, this assumption should not have precluded checking for an allergy to penicillin, and any reaction would be important to know. Not everyone with anaphylaxis to penicillins will have a reaction to cephalosporins. The reason [Mrs A] had been initially stepped down to cefuroxime was that she was known to have taken a cephalosporin in the past without any reaction.

The expected standard of practice would be to check for an allergy prior to directing (or prescribing) a medication. This is explicitly stated in the New Zealand Medical Council Statement on Good Prescribing Practice (March 2020). Steps to check for drug sensitivities might have included asking the patient directly, checking for a Medical Alert bracelet or necklace, checking the drug chart and/or checking alerts on the electronic record. Any or all of these would be reasonable, depending on the circumstances. Although the right to informed consent to treatment may be considered to require a detailed discussion with the patient prior to the administration of any new medication, which would have to include nature of treatment, risks, benefits and alternative options, and this would be best practice, this level of detail is not routine as it is often impractical in the setting of a busy acute service.

Recommendations for improvement:

Substantial efforts continue to be made to minimise the risks of this type of event happening, as it is too easily done. Heavy workloads, fatigue, incomplete staffing and the frequent distractions of an acute care hospital environment contribute to human errors in critical decision making. By addressing these factors and adding additional layers of safety these events can be reduced. Regrettably, at the present time, a foolproof system to prevent inadvertent administration of drugs known to cause allergies has proven elusive, but there are steps to help reduce this risk.

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At a personal level, [Dr C] has changed his practice, recording allergies routinely in medication lists and being especially vigilant when directing the prescribing of junior staff. He will never forget the potential consequence of not doing so.

To support this, regular ongoing education including real life examples is important. Prescribing, including the recognition and recording of allergies, should be periodically audited and fed back to medical staff (senior and junior).

The premature departure of the Medical Registrar from the ward round was a result of urgent service requirements elsewhere. If the Registrar was the same as had seen [Mrs A] the previous day then this may have been particularly important, as she was already aware of the penicillin allergy and this information would have been immediately available. Likely this tragic event would then have been avoided. Continuity of care adds to safety as important details can be lost in the process of handovers, which by their nature can only be an outline of the complete picture. Even were this not the same Registrar, the Registrar is an important component of a medical team ward round, providing the hands-on expertise of a more experienced junior doctor as well as providing an additional level of direct supervision for the less experienced House Officer, reducing the risk of management errors.

The high number of presentations on what was [a weekend] was cited as a factor which resulted in the Medical Registrar having to leave the ward round. There will always be exceptions, but to an extent the increased workload at such times is predictable and staffing levels should be adjusted to ensure adequate cover is available, and medical rosters should be devised to facilitate continuity of care wherever possible.

2. If not answered above, the adequacy of steps taken to assess [Mrs A's] penicillin allergy status. From the information provided, we note there are differing versions of the events about whether [Mrs A's] allergy status was recorded on the front cover page of the 8 days national medication chart. For this, please provide your advice in the alternative. In other words, what would your advice be if:

a. [Mrs A's] allergy status was recorded on the front cover page of the 8 day national medication chart; and

b. [Mrs A's] allergy status was not recorded on the front cover page of the 8 day national medication chart.

In his statement [Dr C] admits that he does not recall any steps taken by himself to ascertain [Mrs A's] penicillin allergy status.

If the National Medication Chart had been checked by him and allergy status had been recorded on the front page it would have been important to ascertain what that reaction was prior to deciding on treatment. Pending this, the drug should not have been prescribed.

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If the allergy status was not recorded this should prompt further enquiry. There is a tick box for 'Allergies — No' which was empty. If unchecked this should have prompted an enquiry about allergy prior to prescribing. The 'Adverse Reactions — No' box adjacent, which covers non-allergic reactions, was ticked and signed, although not dated. However, these boxes, as for the 'Miniboxes' for allergies on the inside pages of the National Medication Chart in use at that time, do not necessarily function well and may be missed.

3. Any other comments you wish to make about [Dr C's] care.

When [Dr C] was made aware of the critical situation following administration of Augmentin he did all that could be done to address it. Not knowing the resuscitation wishes of [Mrs A] in a situation that was potentially reversible he helped with her care whilst attempts were made to clarify this. He communicated directly and openly with the family during this time. There was full disclosure about the circumstances. He reported the event directly to the coroner.

B. [Dr D] — House officer who charted IV Augmentin

4. The adequacy of steps taken by [Dr D] prior to prescribing Augmentin for [Mrs A];

The care provided by [Dr D] was likely to be suboptimal, and likely to fall below the expected standard of care. I would regard this as a moderate to severe departure, but subject to the caveats detailed below. I would expect my professional colleagues to concur with this.

[Dr D] was in his … year as a House Officer. As the actual prescriber of medication there is a duty to check for allergies or other reactions (New Zealand Medical Council Statement on Good Prescribing Practice, March 2020 and Northland District Health Board Medication Prescribing Policy March 2019). [Dr D] would have to prescribe using the National Medication Chart, and it would be standard practice to review this at the time for documentation of allergies, which is on the front page. Although additional sources of information on allergy status might be sought, the Medication Chart would be the default at the point of prescribing.

The 'No (allergy)' tickbox on the internal pages of the National Medication Chart were unchecked and, if being used as an alternative source of information to the main allergy entry on the front page, being unchecked this should have prompted an enquiry into allergy status.

5. If not answered above, the adequacy of steps taken to assess [Mrs A's] penicillin allergy status. From the information provided, we note there are differing versions of the events about whether [Mrs A's] allergy status was recorded on the front cover page of the 8 days national medication chart. For this, please provide your advice in the alternative. In other words, what would your advice be if:

[Mrs A's] allergy status was recorded on the front cover page of the 8 day national medication chart;

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If the front page of the National Medication Chart had been checked and allergy status had been recorded it would have been important to ascertain what that reaction was prior to deciding on treatment. Pending this the drug should not have been prescribed.

[Mrs A's] allergy status was not recorded on the front cover page of the 8 day national medication chart.

There is a tick box for 'Allergies — No' which was empty. If unchecked this should have prompted an enquiry about allergy prior to prescribing. The 'Adverse Reactions — No' box adjacent, which covers non-allergic reactions, was ticked and signed, although not dated.

However, these boxes, as for the 'Miniboxes' for allergies on the inside pages of the National Medication Chart in use at that time, do not necessarily function well and may be missed.

Recommendations for improvement:

The recommendations for improvement include those made in section A above. In addition, the following are particularly relevant to the actual prescriber at the point of prescribing:

'Medication Reconciliation' employs trained pharmacists to check the accuracy of prescribing charts, including the identification of allergies and correct notification. This acts as a 'double check' for the charting, supporting and auditing compliance with standards and providing another level of safety. This did not appear to have been available here. In practice resource limitations may preclude hospitals from being able to apply this in a timely fashion to all the medication charts that might be in use. It would be completed one or two days into the admission, and is usually unavailable out of hours or at weekends. [Mrs A] had been admitted several days before the event. Medicines Reconciliation would have helped ensure the medications chart had been completed correctly. Medications Reconciliation, by providing constant feedback, also acts as a reminder of the requirements and potential pitfalls around prescribing.

New Zealand hospitals use a mix of paper and electronic charts for prescriptions. Electronic Medication Charts (e-prescribing) can offer a valuable technological safety aid. Electronic Medication Charts usually include prompts to guide good prescribing practice. Information about allergies can be carried over from one admission to the next. They can offer inbuilt protections to reduce prescribing errors. The system I am familiar with, 'MedChart', has this technology built into it, but at the cost of it taking much longer to complete than would a traditional paper chart. For a complex patient it may take 20 minutes to complete a new prescription chart electronically when it would have taken perhaps a third of that time to complete a traditional paper chart. This is such as to preclude the use of electronic charts in our Emergency Department, where that delay would be unacceptable and could be dangerous in itself, although they are used on most inpatient wards. Electronic prescribing systems may introduce other problems. For

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example, MedChart is not intuitive. Poor displays show only part of the prescription within a given screen view. It is difficult to see whether a medication has been given or not. These systems need considerable investment and refinement to make them function better. However, the current technology is able to help protect against inadvertent prescribing of a drug known to cause an allergic reaction. If it had been available here this unfortunate event, almost certainly, would not have occurred.

Whilst National databases and alerts on electronic records can be helpful, for these to be really effective they need automatically linking to the patient record and to the point of prescribing.

6. Any other comments you wish to make about [Dr D's] care.

[Dr D] was the first doctor attending following the emergency bell and appropriately activated the emergency response 'Code Blue' directly. At that time the patient's request not to be resuscitated was not known. He did all he could to help.

C. [Dr F] (medical registrar)

7. The adequacy of documentation of [Mrs A's] allergy, and communication to the team about [Mrs A's] allergy;

I believe the care provided by [Dr F] was reasonable.

[Dr F], Medical Registrar, saw the patient on [Day 5], prior to transfer of care to General Medicine. In her statement she says she was aware of a penicillin allergy from documentation on the front of the National Medication Chart and from the admission note. This was not expressly stated in her entry into the hospital record but is fully consistent with the actions taken. It would be reasonable to expect others to have been aware of this by checking for allergies recorded on the National Medication Chart before prescribing.

I cannot tell if the penicillin allergy was communicated directly to the medical team. There is a note from her entry on [Day 5] as follows, 'Dr … Agree for medicine take care' suggesting a discussion with a senior clinician. The contents of the discussion are not stated. It is not clear to me if she was the same Registrar as would have been on [Dr C's] ward round on [Day 6], and who was called away prior to [Mrs A] being seen. There is no documentation relating to a handover between [Dr F] and [Dr C] or his team, but if she were his Registrar then it wasn't to be expected that she would be called away. The need for a formal handover would not have been anticipated. Handovers of patients between inpatient teams are often verbal, may not be done when the patient record is at hand and may not be recorded.

8. Any other comments you wish to make about [Dr F's] care.

[Dr F's] review appears succinct but comprehensive and management reasonable. Recognising penicillin allergy as a restriction on antibiotic choice it would have been helpful to have put this in the entry, but it was not wrong not to have done so, as she had

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found this to be identified elsewhere in the expected location on the National Medication Chart.

D. [Dr G] — (house officer)

9. The adequacy of steps taken by [Dr G] to chart [Mrs A's] 8-Day National Medication Chart;

The care provided by [Dr G] was likely to be suboptimal, and likely to fall below the expected standard of care. I would regard the charting overall as a moderate departure, but subject to the mitigating factors noted below. I would expect my professional colleagues to concur with this.

The National Medication Chart as copied to me had 'penicillin' properly and legibly identified as an allergy on the front page. There is an adjacent column to identify the type of allergy. This was not completed although anaphylaxis had been recorded in the Emergency Admission note also written by [Dr G]. The entry for the penicillin allergy was dated and signed. [Mrs A] was also known to have an allergy, angioedema, to the class of drugs known as 'ACE Inhibitors'. This was not recorded on the National Medication Chart front page, although it had been documented in the Emergency Admission note.

The allergies 'Minibox' on the inside pages was not completed. There are tick boxes for both NO and YES. Neither were ticked.

In the 'as required' section Sevredol (a strong pain reliever) and Laxsol (a laxative) were charted. There was no entry for the maximum dose/24 hours, nor a stated indication for either. These are 'brand names' and the generic name, which for Sevredol would be morphine, was not stated.

Standard practice is to accurately record allergies, and this should include the type of reaction. Not to record an allergy is a moderate to severe departure from the standard of care. Not to record the type of allergy is a moderate departure from the standard of care.

The failure to complete the 'Minibox' might be considered a minor deviation from the standard of care. However, others might disagree, in that in practice it appears not to have been useful or practical and I understand has been removed from subsequent iterations of the chart.

When prescribing 'as required' medication this should include a maximum dose for a given period. This is especially important for narcotics such as morphine. This would be considered a mild departure from the standard of care. The use of generic drug names, such as 'morphine', is strongly encouraged. Writing the indication for which the drug is to be used is also recommended.

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Prescribing requirements and guidelines are detailed in the New Zealand Medical Council Statement on Good Prescribing Practice, March 2020 and in the Northland District Health Board Medication Prescribing Policy March 2019.

Recommendations for improvement:

The recommendations for improvement include those made in both sections A and B above.

The heavy workload, stress of competing demands and frequent work related distractions of an acute medical hospital are particularly problematic at the point of admission, which is the time when [Mrs A] was first seen by [Dr G]. The resulting challenges to completing documentation and doing so accurately, a process that takes time and concentration, are considerable. As a consequence incomplete documentation and inaccuracies in medication charts are, regrettably, not uncommon. In this type of work environment other layers of safety need to be built into the care model to guard against errors, which are inevitable.

Electronic prescribing systems include prompts to guide good prescribing practice and can oblige completion of important information. Here the type of penicillin allergy would be an example of this. The daily maximum dose of an 'as required' medication would be another. Information about allergies can be carried over from one admission to the next. These systems have their own problems, some of which have been mentioned in the earlier recommendations above (section B).

Medical staffing levels need to be sufficient to manage the demands, but often are not. Staffing needs to be sufficient to cope with surges in demand, and not just the average demand. Whether this was a factor at this point or not isn't evident from the information available to me.

10. The adequacy of documentation of [Mrs A's] allergy;

As above

11. The adequacy of the handover process to surgical wards (gynaecology).

The Emergency Admission note on [Day 1] written by [Dr G] details the known allergies 'Angiotensin converting enzyme (ACE) inhibitors Angioedema' and 'Penicillins Anaphylaxis'. In her statement she reports she informed 'her team' of her allergy status, presumably this refers to the other medical staff covering gynaecology. There is no formal record of this, but the Emergency Admission note may also have been considered a handover document. Verbal handovers are not necessarily recorded and may be done away from the patient record. The information needed is clearly displayed in the Admission Note, however. [Dr G] was on the gynaecology team the following day and wrote the entry on the consultant ward round, so at that point there was direct continuity of care.

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E. Whangārei Hospital

12. Any other comments you wish to make about the overall care provided to [Mrs A] by the medical team as it relates to her eventual penicillin reaction.

I have not been asked specifically about the administration of the Augmentin, which is a nursing issue, and assume this is being reviewed elsewhere. I have no further comments.

Dr David Cole, MB, ChB, MD, MRCP, FRACP
Consultant Physician, Canterbury District Health Board
23rd October 2021"

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Appendix B: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr Margaret Wilsher:

"Ref: 20HDC01979

I have been asked to provide an opinion to the Commissioner on case number 20HDC01979 and I have read and followed the Commissioner's Guidelines for Independent Advisors.

My qualifications are as follows: MB ChB, University of Otago; MD, University of Otago; Fellow, Royal Australasian College of Physicians; Distinguished Fellow, Royal Australasian College of Medical Administrators. I am currently the Chief Medical Officer for Auckland District Health Board and an Honorary Professor of Medicine, Faculty of Medical and Health Sciences, University of Auckland. I am accountable for the clinical practice and professional standards of nearly 1500 doctors employed by ADHB and have been involved in medical leadership and health management for over 15 years. I am a practising physician in public and private sectors, a clinical researcher and teacher. I also hold membership of the New Zealand Institute of Directors and sit on a number of external health related governance and advisory committees and boards.

My referral instructions from the Commissioner are to provide an opinion on the care provided by Whangārei Hospital to [Mrs A] in [2020].

I have read and considered the following material supplied by the Commissioner:

Letter of complaint dated [2020]

Police Statement from complainant, [Mrs B]

Northland District Health Board's response letter dated [2021] and attachments:

Serious Event Analysis (SEA) Report, incident reference [number]

Timeline for SEA

Policy — Medication Administration

Policy — Management of Anaphylaxis in the Inpatient Setting

Policy — Medication Prescribing

Policy — Code Blue Calls and Medical Emergency Notification

Code Blue record sheet

8 Day National Medication Chart

ED presentations [Days 5–6]

[Mrs A's] Clinical records from Whangārei Hospital covering the period [Days 1–6].

Northland District Health Board's response letter dated [2021] and attachments:

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a. High risk medications requiring second check (ED & Medical wards)

b. Organisation filing and storing of medication charts — [the general medical ward] layout

c. Augmentin administration guideline (NoIDs)

d. RN handover process

IX. Statement from the following RNs involved in [Mrs A's] care:

[RN E]
[RN H]
[RN I]
[RN J]

X. Statement from the following doctors involved in [Mrs A's] care:

a. [Dr D]
b. [Dr C]
c. [Dr F]
d. [Dr G]

Background as provided by the HDC

[In 2020], this Office received a complaint from [Mrs B] about the care provided to her late mother in law, [Mrs A], at Whangārei Hospital.

[Mrs A] had a known previous anaphylactic reaction to penicillin and wears a medical alert necklace recording the allergy. On [Day 1], she presented to the Emergency Department with fever, and was admitted. She was subsequently transferred to surgical ward and then to [general medical ward].

On [Day 6] at 6pm, despite informing ED staff that she was allergic to penicillin and wearing a medical necklace, [Mrs A] was administered Augmentin IV injection. Sadly, she passed away the same day due to acute anaphylactic shock. It is disputed whether her penicillin allergy was recorded on the front page of the 8 day national medication chart.

Expert advice requested

I have been asked to review the documents sent to me and advise whether I consider the care provided to [Mrs A] by Whangārei Hospital was reasonable in the circumstances, and why.

In particular, I was asked to comment on:

1. [Mrs A's] patient journey through the hospital leading up to her serious adverse drug event and any systemic issues identified.

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2. The appropriateness of relevant policies and procedures in place at the time of the events, including:
    a. Medications & Fluids Requiring an Independent Second Check in ED and Medical wards
    b. Medication Administration
    c. Management of Anaphylaxis
    d. Medication Prescribing
    e. Code Blue Calls and Medical Emergency
3. Any other comments I might wish to make on the systems in place and the care provided to [Mrs A] by Whangārei Hospital as it relates to her adverse drug reaction.

On 21st October 2021, I wrote to the HDC seeking further clarification on those instructions and was provided with amended advice:

'In this case we would like to invite you to comment on the overall adequacy of the system and process in place, up until the point of penicillin administration to the patient. i.e. The fact that penicillin was prescribed and administered. We are not looking at the management of the anaphylaxis. We would also welcome any recommendations you would like to make in relation to Whangārei Hospital's system and process in place (sic).'

OPINION

The patient journey

[Mrs A] presented to Whangārei Hospital at 1223 on [Day 1]. She was assessed in the Emergency Department (ED) and assessed as having an infective complication of recent surgery (posterior vaginal wall repair and perineorrhaphy). She was prescribed IV cefuroxime and metronidazole, her previous anaphylaxis to penicillin being noted and documented in the ED Care Summary. The penicillin anaphylaxis is also documented on the front page of the Day Stay National Medication Chart. Penicillin allergy is also listed on the patient alerts but it is not clear how visible that alert history on the electronic Concerto system is to all clinical staff or how aware all clinical staff are of this reporting system. The cefuroxime was administered at 1410 and the metronidazole at 1539 but the antibiotic prescription was later changed to substitute metronidazole with ertepenam on the advice of microbiology. The first dose of ertepenam was given at 1654. [RN J] administered the cefuroxime slowly because of history of allergy. The ED admission note was completed by [Dr G] and she documented anaphylaxis to penicillin. [Dr G] made arrangements for [Mrs A] to be admitted to the ward and signed her letter at 1703. [Dr G] also documented penicillin allergy on the front page of the 8 Day National Medication Chart (NMC) but did not describe anaphylaxis in that section. The subsequent pages of the 8 day NMC chart do not contain documentation of penicillin allergy but the box where that information would be placed states 'refer to front page for details'.

Documentation to ward staff in the handover section of the nursing progress notes did not specifically note drug allergy. The handover form was completely filled out but there is no specific section for drug allergy to be noted. The patient was enrolled in the adult

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sepsis action pathway but the document does not indicate penicillin allergy — there is no section on which to do so.

[Mrs A] appears to have arrived on the ward around 2045. She was assessed by the senior house officer (SHO) at 2200. No mention is made in the treatment and progress notes about penicillin allergy. However, it is documented several times that microbiology cultures were awaited and that reconsideration of antibiotic choice would occur once microbial sensitivities were known. By [Day 4] it is documented that [Mrs A] was improving and that ultrasound had revealed an insignificant pelvic fluid collection. A decision was made to transfer care from gynaecology to medicine presumably in light of no surgical intervention being required. On [Day 5], documentation 'transfer to medics' is made by the gynaecology team and it is recorded that the patient was 'accepted' implying handover discussion. Details of that handover are not available as it was likely verbal, doctor to doctor.

[Mrs A] was subsequently reviewed by the Saturday ([Day 5]) rostered medical registrar ([Dr F]) who discussed the case with [the microbiologist]. The decision was to continue cefuroxime. Nursing notes from the same day indicate transfer (the surgical ward nurse) and then receipt of the patient by respective medical ward nurse at 1600 hours [Day 5]. No comment is made about penicillin allergy by either nurse in the treatment and progress notes.

[Mrs A] was seen by [Dr C], physician, on the ward round Sunday [Day 6]. [Dr C] was the acute medicine consultant on call for the weekend. It is not clear what handover occurred from the accepting medical registrar to the destination ward admitting team but there appears to have been a different medical registrar working on Sunday [Day 6] according to the statement of [Dr D].

It was noted on [Dr C's] ward round that [Mrs A] was currently prescribed cefuroxime but that the culture of E.Coli exhibited intermediate sensitivity to that antibiotic. The decision was made to change the antibiotic to Augmentin, the culture sensitivity being higher. It would appear that decision was made in the office setting as [Dr C] describes moving from [Mrs A's] bedside to the ward computer station to review lab results. It is not clear if the medical team had access to the drug chart on the ward round. The date of prescription is recorded but not the time.

It is not documented in the clinical record whether the decision to prescribe Augmentin was communicated to or discussed with [Mrs A]. [Dr D] states that the medical team did not return to the bedside to discuss the change of management with the patient. The nursing note at 1345 on the same day does not indicate a change of antibiotic. It is not clear if the medical team communicated that decision directly to the nursing team. The next medical attending note in the treatment and progress notes is written by [Dr C] after the anaphylaxis event.

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All subsequent entries are made after that event with the exception of an incomplete nursing note written by [RN E]. This note is dated [Day 6] 1745. It appears to be a progress note written in advance of the shift completing. No mention is made of decision to change antibiotic or drug allergy.

[RN E] continues her note in retrospect at 2336hrs. It is recorded that the morning nurse had indicated a different antibiotic was to be given. [RN E] describes checking the medication chart for drug allergies noting that none was documented, and also checking with the patient whether she had allergies recording 'stated she wasn't aware of any allergies, this was checked prior to administration'. [RN E] goes on to describe the patient collapse half way through the infusion, and the subsequent resuscitation events.

Handover and documentation

Documentation of [Mrs A's] penicillin allergy is appropriate in that it is clearly written on the front page of both the Day Stay and 8 Day National Medication Charts used during the admission. It is also documented in the ED case summary and in the Admission note by the respective attending doctors. [Dr F], the weekend reviewing medical registrar, confirms that penicillin allergy was documented on the front of the medication chart and in the admission note. Penicillin allergy is not recorded on the subsequent pages of the 8 Day NMC but I consider this is a mild departure from usual standard of care because the chart is somewhat misleading in referring to the front page for details about allergy. In real life practice, this section of the drug chart is not always completed.

[RN H] makes comment in her statement about a usual practice to present a yellow sticker on the printed patient information sheet in the clinical file with details of the allergy. It is not clear from the documentation supplied if this is in fact a standard process at Whangārei Hospital or an additional alert at ward level.

Handover documentation in the clinical record progress notes is within standard of care with the exception that the penicillin allergy is not recorded as part of the handover communication either in nursing or medical notes. The standard of care would be to communicate information that is of importance to the safe care of the patient in question. It is not known what verbal information was provided at handover. It is noted that the handover section of the admitting documentation does not contain information about drug allergy.

Recommendation: the handover to ward staff section of the ED nursing progress notes should have a tick box for drug allergy.

The clinical record does not contain evidence of a weekend handover process from one medical team to another. This does not mean that a verbal handover or separate handover process is not used at Whangārei Hospital but any handover process should ensure that important clinical information such as penicillin allergy is passed onto the new clinical team. [Dr C], in his statement, indicates that he had a large number of new patients to assess on the Sunday morning ([Day 6]) ward round. That would be usual in

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any busy acute medicine service in NZ. Formal handover tools are designed to enable safer transfer of patient care between teams.

Recommendation: Whangārei Hospital considers methods for improving the process of and documentation of medical handover between different disciplines and between on call and destination ward based teams.

It is unclear if [Dr C] and his team had access to the medication chart at the time of the Sunday morning ([Day 6]) ward round. It would be the usual standard of care to review all relevant documentation regarding the patient including the medication chart at the time of ward round, particularly if new information necessitated a change in medication.

Recommendation: Whangārei Hospital ensures processes allow for the medication charts to be available to clinicians on ward rounds.

Communication

It is not possible to comment fully on communication between staff, or between staff and patient without interview.

[Mrs A's] family are adamant that she was fully cognisant of her penicillin allergy and communicated this to any clinician prescriber. [The ED assessing doctor] and the inpatient admitting doctor ([Dr G]) documented both penicillin allergy in the relevant drug charts and the respective ED discharge and inpatient admission documents. It would appear that both doctors had communicated with [Mrs A] regarding whether she had any drug allergy. It is possible that they viewed the alert history on Concerto but more likely they asked because both documented a history of anaphylaxis which is not documented in the information on alerts. [RN I], who was the ED nurse caring for [Mrs A], states that her patient was aware of her penicillin allergy and communicated this. She also describes the practice of patients with drug allergies wearing red wristbands but she does not recall what colour [Mrs A's] wristband was. [RN I] also recalls seeing penicillin allergy being documented in the admission summary.

Nowhere is it documented in the clinical record that [Mrs A] was confused or obtunded. It seems reasonable to assume therefore that she remained able to give information about her antibiotic allergy if so asked.

It is would appear from [Dr D's] and [Dr C's] statements that the decision to change antibiotic was made away from the bedside and neither doctor returned to advise [Mrs A] of that change. If they had it is likely she would have advised them of her allergy to penicillin. It would be usual standard of care to advise a patient of a recommended change to pharmacologic management, and a moderate departure from usual care not to advise of such given there can be extenuating circumstances such as the patient's ability to understand such information, the significance of the change or the urgency of such.

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Recommendation: Whangārei Hospital gives consideration to improving the quality of ward rounds by allowing clinicians access to electronic clinical information at the bedside. This could obviate the need to leave the bedside in order to make important clinical decisions which might not subsequently be communicated to the patient and/or family. Bedside prescribing should form part of such improvement process. Electronic prescribing tools can further mitigate the risk of inadvertent prescribing of a drug to which the patient has a documented allergy.

[RN H] was the attending nurse for [Mrs A] on the Monday morning. Whilst she was aware of the change in antibiotic she did not discuss this with the patient, but in effect had no reason to given she was not to administer Augmentin during her shift. [RN H] points out that the Team Leader would normally attend the medical ward round but did not do so on that day. It is possible that had the change in antibiotic been discussed with nursing staff at the ward round this would have provided additional opportunity to communicate the decision to the patient and/or to ascertain the history of drug allergy.

Recommendation: Whangārei Hospital gives consideration to making all ward rounds multidisciplinary in nature and where that is not possible e.g. in weekends, having a checklist of significant management changes that can be shared with the senior nurse on the ward.

Prescribing and administration of medication

In prescribing a change of antibiotic, it would be standard of care to ensure there was no known drug allergy. [Dr D], in his second statement to the HDC, wrote that it was not his role to assess the suitability of charting Augmentin but rather to prescribe at the request of the consultant. The MCNZ published guideline 'Good Medical Practice' sets out the principles and values that define good medical practice and provides guidance to doctors on the standards expected of them.

https://www.mcnz.org.nz/assets/standards/85fa1bd706/Good-Medical-Practice.pdf

In relation to prescribing, doctors may prescribe only when they are satisfied that the medication or treatment is in the patient's best interests. [Dr D] as [an] RMO is qualified to prescribe independently. The standard of care would be to ensure that in changing an antibiotic, the patient did not have an allergy to the new antibiotic. [Dr D] states he did not see the documentation of the penicillin allergy in the front page of the medication chart, although he did provide a sample signature on the front page. Human factors science shows that people do not always see what they are not looking for.

Failure to ascertain whether a patient had an antibiotic allergy before prescribing an antibiotic would be considered by most peers to be a severe departure from usual care.

[RN E] states that prior to administering Augmentin, she asked [Mrs A] whether she had any known allergies to penicillin. She recalls earlier looking at the front cover sheet of the medication chart and did not see any documentation for allergic reaction to medication. This would be the usual standard of care and is the recommended practice according to the Medication Administration protocol published by NDHB.

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Failure to ascertain if a patient had a penicillin allergy prior to administering the first infusion of a penicillin containing antibiotic would be considered a severe departure from usual care.

The factors that underpin the failure to notice documentation of the penicillin allergy are beyond the scope of this review including workload, workplace distractions and other human factors. However, the 8 day NMC would appear to have a design flaw in that documentation of medication allergy is not routinely carried through to every page and the allergy section on the front page is not apparent to anyone with the chart open either for review or modification or change of medication. This means that staff who are working with the chart in every day practice do not receive a prompt regarding drug allergy, a potential factor in respect of [Dr D] and [RN E].

Recommendation: Whangārei Hospital considers how it can improve the recognition of documented drug allergy and implement improvements that mitigate the risk of inadvertent administration of a drug to which the patient is allergic. The introduction of a check list for first dose of newly prescribed antibiotic is one example.

Policies and protocols

The NDHB Medication Prescribing Policy states that allergy and adverse reaction status boxes must be completed on the NMC front page referencing a further policy on Allergies and Adverse Drug Reactions (not supplied). No comment is made about the additional pages in the NMC. There is no reference to the prescriber communicating directly with the patient regarding drug allergies.

Recommendation: NDHB amend its Medication Prescribing Policy to make clear that the prescriber must inform the patient of a recommended change in medication and enquire about drug allergy.

The Medication Administration Protocol contains a clear medication administration flow chart. On page 4 the responsibilities of the staff member administering the medication are listed and confirmation of allergy/adverse drug reaction status is such a responsibility.

Whangārei Hospital uses bedside handover with the ISBAR tool for morning to afternoon nursing shift handover. Information about allergy appears not to be standard practice for every shift handover. It is not clear if the ISBAR tool is used for transfer between clinical areas or services and whether background information about drug allergy forms part of that handover.

Recommendation: Whangārei Hospital consider using ISBAR for nursing handover for transfer or transition of care, and that drug allergy is provided as part of the background information.

Medication and fluids requiring an independent second check are documented for both ED and Medical wards. It is not clear where that documentation is kept. Augmentin is not on either list.

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Recommendation: Whangārei Hospital pharmacy gives consideration as to whether first IV dose of penicillin containing antibiotic be listed as requiring independent second check.

Other comment

There are potential improvements to system and processes that can be made as a result of the findings in the Whangārei formal adverse event review. This advice is provided in the context of the family complaint which focused on how [Mrs A] could have been prescribed a penicillin containing antibiotic when she clearly described her allergy history to any clinician that enquired. The advice from HDC was to constrain the review up until the point of penicillin administration. However, the family also raise concerns in their complaint about the decision to perform prolonged resuscitation when [Mrs A] had indicated to them that she did not want such. In the serious adverse event analysis report, the reviewers recommend roll out of Advance Care Planning. It might be useful for Whangārei Hospital to consider the place of the Health Quality and Safety Commission 'Shared Goals of Care' principles in the setting where otherwise well patients, who are not in the last year of life, are admitted acutely to hospital.

It is accepted that hindsight allows clarity of perspective that foresight can never achieve. Humans by their very nature are fallible and can err, and work done is not the same as work imagined. In reality, clinical practice in a busy acute admitting hospital will mean that there is potential for distraction and interruption, for short cuts and lack of process adherence, so the system and its processes must be sufficiently robust to protect patients at such times. Several of the staff involved indicated heavy workload as a factor influencing their ability to provide good care over the weekend in question but it was beyond the scope of this review to consider workload in relation to the events that occurred.

It is clear that the staff involved in the care of [Mrs A] have reflected on their actions, and that her sad outcome has affected some deeply. Under a Just Culture, an organisation would focus on understanding why certain staff choices were made rather than the outcome, and then work to improve the likelihood that staff will make the correct choices in similar circumstances in the future, whether that be by education and training, or engineered system change. I have no doubt that all of the staff involved intended to provide the very best care for [Mrs A] but sadly her outcome was far from what would have been desired.

I extend my sympathy to the family of [Mrs A] and acknowledge the loss of a much loved mother, mother in law and grandmother.

Yours sincerely

Dr Margaret Wilsher MD, FRACP, FRACMA
Chief Medical Officer, Auckland District Health Board"

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Appendix C: Independent clinical advice to Commissioner

The following independent advice was obtained from RN Rosalind Jackson:

"[Mrs A] (dec) (Northland District Health Board)

Thank you for the opportunity to provide opinion to the Commissioner on this case, number 20HDC01979. I confirm that I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. By reviewing this case I confirm that I have identified no conflict of interest.

My name is Rosalind Clare Jackson and I am a New Zealand trained Registered Nurse (NZRN comp, reg 120875) and hold a Master's Degree in Health Science. Since 2006 I worked full time as a Nurse Service Leader (Anaesthesia and Surgical Services) in a secondary district health board, with responsibility and accountability for operational management and professional leadership to nursing in the surgical inpatient setting.

In November 2017 I was seconded to a programme manager role responsible for organisational development of our staff engagement and culture programme. In February 2019 I was appointed into the permanent role as Associate Director of Nursing which includes responsibility for the nursing practice development team, care capacity demand management, infection prevention control and occupational health services.

Other training that I have completed that is relevant to the role of an Independent Advisor includes,

Institute for Healthcare Improvement (IHI) — Patient Safety Programme

New Zealand Incident Management System — Root Cause Analysis Training (Clinical event/investigation review)

IHI Open School (completed) — six modules on quality improvement methodology

1.0 Background

A complaint was received from [Mrs A's] family about the care provided to [Mrs A] at Whangārei Hospital.

[Mrs A] had a known previous anaphylactic reaction to penicillin and wore a medical alert necklace recording the allergy. On [Day 1] [Mrs A] presented to the Emergency Department with fever, and was admitted. She subsequently transferred to the surgical ward and then to [the general medical ward].

On [Day 6] at 1800 hrs, despite [Mrs A] informing ED staff that she was allergic to penicillin and wearing a medical necklace, [Mrs A] was administered Augmentin IV injection and passed away that same day due to acute anaphylactic shock. It is disputed whether her penicillin allergy was recorded on the front page of the 8 day national medication chart.

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The Commissioner is seeking my opinion on whether the nursing care provided by Northland District Health Board (NDHB) to [Mrs A] was reasonable under the circumstances, and why. That is:

The adequacy of steps taken by [RN E] prior to the administration of penicillin; in particular,

The adequacy of steps taken to assess [Mrs A's] penicillin allergy status.

My advice if [Mrs A's] allergy was recorded on the front cover page of the 8 day national medication chart; and

My advice if [Mrs A's] allergy was not recorded on the front cover page of the 8 day national medication chart;

My advice if [RN E] did ask [Mrs A] about her allergy status and she did not disclose her penicillin allergy to [RN E] prior to administering Augmentin.

My advice if [RN E] did not ask [Mrs A] about her allergy status and she did not disclose her penicillin allergy to [RN E] prior to administering Augmentin.

Any other comments I wish to make about [RN E's] care.

The adequacy of the handover process from [RN H] to [RN E]

The adequacy of the handover process/transfer to the surgical ward.

The adequacy of the handover processes between [RN J] (Emergency Department) and [RN I] (Emergency Department).

Any other comments I wish to make about the care provided to [Mrs A] as it relates to her eventual penicillin reaction.

For each question I will consider and advise,

What is the standard of care/accepted practice?

If there has been a departure from the standard of care or accepted practice, how significant a departure do I consider this to be (mild, moderate or severe departure)?

How would it be viewed by my peers?

Recommendations for improvement that may help to prevent a similar occurrence in the future.

In forming my opinion on the matters requested I have reviewed the following documents provided by the Commissioner,

Letter of complaint dated [2020]

Police Statement from complainant, [Mrs B]

Northland DHB's response dated [2021], including:

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Serious Event Analysis (SEA) Report, incident reference [number].

Timeline for SEA

Policy — Medication Administration

Policy — Management of Anaphylaxis in the Inpatient Setting

8 day medication chart

[Mrs A's] clinical records from Whangārei Hospital covering the period [Days 1–6]

Northland DHB's response letter dated [2021] and attachments

Statement from RNs involved in [Mrs A's] care; [RN E], [RN H], [RN I] and [RN J].

On request, HDC provided additional information from Northland DHB, that is,

Final anonymised SEA report.

Evidence of Handover protocol or similar controlled document (original document provided)

Copy of a Patient Care Plan document as part of the record (risk assessment tools and ED record noted) or blank copy if not completed.

Evidence of Ward VRM (Variance Response Assessment) for [Day 6]? (Mauve, green, yellow, orange or red)

NDHB's Trend Care operational guidelines or document that guides allocation of time to the ward shift leader role?

2.0 The adequacy of steps taken by [RN E] prior to the administration of penicillin.

2.1 The adequacy of steps taken to assess [Mrs A's] penicillin allergy status.

From [RN E's] statement, she has described the steps taken to assess allergy status as part of the medication administration process. That is,

Checked medication chart (8-day chart), noted that any allergic reaction was 'not recorded'. In the adjacent box, adverse reaction was ticked 'No'

Correct prescription details were checked.

Checked NOIDS (Notes of Injectable Drugs)

[RN E] prepared the medication appropriately and according to NDHB policy.

Checked against the 5 rights of medication administration.

[RN E] states that she asked [Mrs A] about any known allergies and understood [Mrs A] to have answered 'not that she was aware of'.

On the onset of symptoms, [RN E] took appropriate action, stopped administering medication and sought help.

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At that time [RN E] asked [Mrs A] again a specific question about any allergy to antibiotics however [Mrs A] was unable to answer.

As reported by [RN E], steps taken to assess [Mrs A's] penicillin allergy status were adequate and consistent with expected standard of practice.

My advice if [Mrs A's] penicillin allergy was recorded on the front cover page of the 8 day national medication chart.

In addition to the drug 'Penicillin' being recorded, if the allergic reaction was recorded as 'anaphylaxis', like what was recorded on the day stay admission medication chart, I would have expected [RN E] to have noted this when checking the medication, not continued with preparation and inform the medical team or pharmacist. It is important that both the drug and reaction are recorded.

My advice if [Mrs A's] allergy was not recorded on the front cover page of the 8-day national medication chart.

Documentation of [Mrs A's] allergy status was incomplete. Appropriate documentation would have recorded both the penicillin allergy AND reaction. It is clear that 'Penicillin' was recorded as a medication allergy however there is no documentation of reaction. On the adjacent box it is recorded that there is no adverse reaction. On the inside pages of the medication chart the allergy section is blank.

With the benefit of hindsight, noticing Penicillin as a documented allergy should at least have occurred and been enough to cause [RN E] to stop and seek advice. However, from review of [RN E's] statement (paragraph 19, 20) and clinical notes, [RN E] did look to see if there was evidence of any reactions. When she did not see this she took this at face value and did not explore further. This is further evidenced in [RN E's] statement that she rechecked the 8 day medication chart and confirmed that she had not missed any detail for an allergic reaction to any medication (paragraph 28). This demonstrates to me that [RN E] remained focused on there being no allergic or adverse reaction being recorded rather than the medication itself.

My advice if [RN E] did ask [Mrs A] about her allergy status and she did not disclose her penicillin allergy to [RN E] prior to administering Augmentin.

If this scenario occurred, as was reported by [RN E], then this would have been the last opportunity for [RN E] to realise that a penicillin allergy causing anaphylaxis existed.

[RN E] states that she did ask [Mrs A] about any known allergies to medication and that she replied 'no'. This is unusual as [Mrs A] was reported to be proactive in declaring her allergy status. This is evident in her family's police statement and in [RN I's] (Emergency Department) statement. [RN E] notes that [Mrs A] had been sleeping and questions whether she heard or understood [RN E's] earlier question to any known allergies or

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allergy to antibiotics. As there does not appear to be any evidence provided that contradicts [RN E's] statement, on balance, [RN E's] version of events should be accepted.

My advice if [RN E] did not ask [Mrs A] about her allergy status and she did not disclose her penicillin allergy to [RN E] prior to administering Augmentin.

If [RN E] did not ask [Mrs A] about her allergy status then she would have been acting outside of NDHB's medication administration policy and right 2 (right medication) of the 5 rights of medication administration applicable to Registered Nurses. This would constitute a serious departure from accepted standards however cannot be considered in isolation of other system contributors to error.

I would not have expected [Mrs A] to have been required to disclose her penicillin allergy to [RN E] although she is reported to have been proactive in this regard. In the context of other system failures, I would not expect [Mrs A] to be responsible for this aspect of her own care.

Any other comments I wish to make about [RN E's] care.

[RN E] demonstrated professional diligence in a number of ways,

Rapid escalation to medical team immediately on onset of an adverse reaction occurring.

Initiation of life support measures conducting two cycles of CRP prior to medical team arriving

Prompt escalation to the medical team of the possibility that anaphylaxis was occurring

Participation in ongoing resuscitation efforts

Completing shift documentation.

Returning to the hospital at 0252 hrs to complete the Datix (reportable event form). [RN E] states she was tired, confused and shaken by the event. Whilst it is appropriate that a Datix reportable event form is completed when information was fresh in her mind this would not be expected to occur in the middle of the night.

Evident reflection on her practice and consideration of possible contributing factors.

Paragraph 35 of [RN E's] statement reads logically and is a credible explanation of where information was recorded about [Mrs A's] allergy. It also explains that the records were separated between folders 1 (bedside record) and 2 (clinical file).

My advice has focused on [RN E's] practice individually. This is appropriate however before arriving at a final assessment of departure from accepted standards, of equal importance is to consider wider system impacts that [RN E] was working in and any possible influence on her practice.

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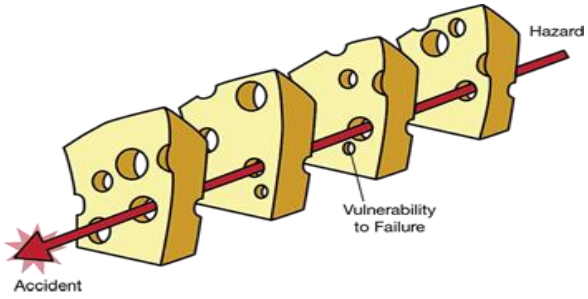
2.7 System Influences

James Reason (1997) developed a well-known model (Swiss Cheese) which represents visually how an organisation's defences against failure are modelled as a series of barriers, represented as slices of cheese. The holes in the slices of cheese represent weaknesses in individual parts of the system and are continually varying in size and position across the slices. The system produces failures when a hole in each slice momentarily aligns, permitting (in Reason's words) 'a trajectory of accident opportunity', so that a hazard passes through holes in all of the slices, leading to a failure.



From my review of the case notes provided to me I can identify a number of vulnerability to failures that contributed to this adverse event. In the presence of system vulnerabilities processes of safety can become overly person dependent.

Examples include:

On admission, [Mrs A's] allergy to penicillin well recorded on the ED record, source data patient management system with alerts page printed out. It is noted that in ED the 'day stay' medication chart was used (as part of 12 page admission 'booklet') with penicillin allergy and reaction noted (not signed or dated). This document appears not to be used for inpatient admission so a reliable transfer of care of information needs to occur.

As this was Emergency Department admission documentation, this part of the record is kept in [the ward] Folder two and is not included in the bedside documentation. It is not uncommon for 'bedside' records to be kept separate from the main clinical record. This is because this documentation is most required at the bedside, leaving the main health record held in the central staff area.

The 8-day medication chart for inpatient admission was completed on [Day 1] however the allergy status was not completed in full, i.e., reaction not noted, and 'adverse reaction' ticked 'No'.

This 8-day medication chart was held separately in Folder 1 and kept at the bedside.

Alert/allergy fields inside the 8 day medication chart were blank. This was a lost opportunity to alert staff to check the front cover for further details.

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It is not uncommon for nursing staff not to review the entire record (folders 1 and 2) when they commence shift. Review of the previous 24–48 hours' records is usual, accepted practice. It is a reasonable deduction that the most relevant information is reflected in the previous 24 hours. This chart review combined with verbal 'common handover' and bedside handover provides sufficient information to commence the shift until there is time to review the main record in more detail. Without review of the entire record, [RN E] only had the 8 day medication chart to refer to.

From the records provided, there is no evidence that a patient care plan had been completed. Whilst a blank record provided does not include a field for allergies, if it had been completed it may have been another prompt, opportunity for handover continuity of information to occur between wards and shifts. [Mrs A] was wearing a medic alert necklace and there is no reference to this in the clinical record. The Patient Care plan would have been an appropriate place to record this.

Visual cues such as the 'yellow alert sticker' (noted by [RN H]) and red patient wrist label (noted by [RN I]) were not evident and there it is suggested that the wrist label is no longer used.

Whilst the Emergency Department RN included allergy status in her handover, and this was emailed to the admitting ward there is no evidence that this was communicated verbally or in writing in a handover between wards.

[RN H] (am shift) knew there had been a change to the medication, referred to the pharmacist about time of administration and handed over the change to the PM [RN E], however, did not realise or recall [Mrs A's] allergy status.

Augmentin was discussed with the medical team and prescribed with none of the medical team noting allergy status.

Handover process does not include allergy status and other than SBAAR communication methodology there does not appear to be a standard of handover content.

Further consideration is under similar circumstances, could other caregivers do the same thing? Given the extent of system vulnerabilities I believe so therefore the underlying issue here is one of safe systems.

Regarding [RN E's] culpability I refer to an incident decision tree or culpability matrix. This is an evidence based framework approach (this one is a NHS version) to assessing adverse events.

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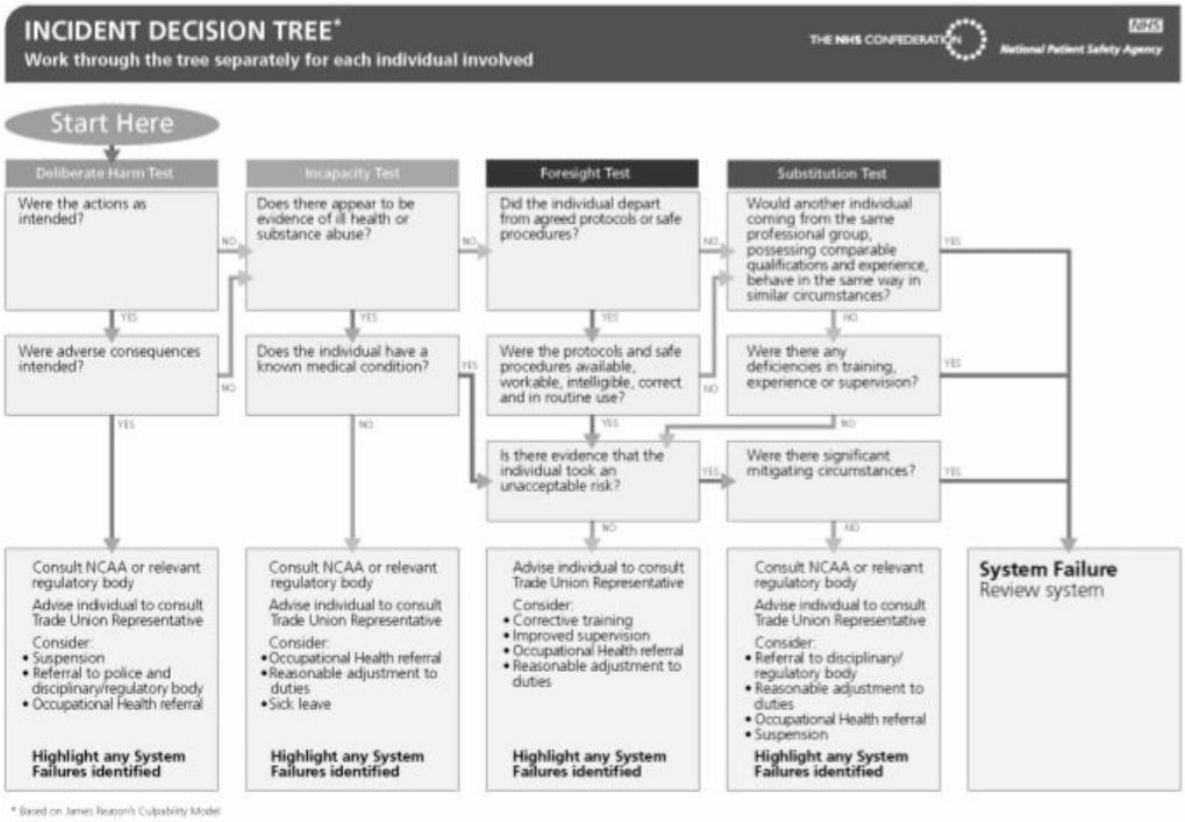

Considering system variables identified, there is no evidence of intention to cause deliberate harm or employee incapacity. [RN E] states she acted within current policy and common interpretation, and it is likely that a comparable staff member may make a similar decision.

Therefore, whilst [RN E] did administer IV medication that [Mrs A] was allergic to which was a direct cause of her anaphylactic reaction she is not entirely at fault. [RN E] was the last step in the process and unfortunately was the last line of defence across a system which ultimately failed. [RN E] appears to have acted consistently with standards of practice expected of her before, during and after medication was administered. Furthermore [RN E] was thorough and consistent in her documentation and Datix recording and logical in her reasoning. Therefore, whilst administration of IV Augmentin to [Mrs A], of which she was allergic, would be considered a serious departure from accepted standards, system failures that contributed to this reduce [RN E's] culpability to a mild departure from accepted standards.

3.0 The adequacy of the handover process from [RN H] to [RN E]

The handover process as described in [RN H's] statement is consistent with [RN E] in that allergies are not routinely handed over between shifts and not considered normal practice. In the context of this case, not including allergy status as part of handover, especially with a reaction of anaphylaxis is inadequate. As part of bedside handover, I would expect review of Folder 1 to occur including the medication chart where allergies

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should be noted as part of the review. [RN E] stated that check of the medication chart occurred however the focus was on whether prescribed medications had been given. At this point in the handover, neither [RN E] nor [RN H] noticed the penicillin allergy.

Departure from accepted practice considers whether the handover occurred as per NDHB standard. The handover between night to morning and morning to afternoon nurse appears to have occurred according to the 'Handover Process in [the general medical ward]' provided in the case file. Therefore, whilst not including review of allergy status as part of handover was inadequate, handover did not depart from accepted NDHB practice. Therefore there was no departure from accepted practice.

4.0 The adequacy of the handover process/transfer to the surgical ward between ED and the Surgical Ward including documentation of [Mrs A's] allergy.

[Mrs A] was transferred to the surgical ward according to standard practice at NDHB, i.e. a patient may be escorted to the ward and handed over by a nurse other than that allocated to her care. This is not uncommon practice in Emergency Departments where patients of lower or stable acuity can be safely transferred by another member of staff. [Mrs A's] clinical record accompanied her as well as admission summary emailed ahead to [the surgical ward]. Therefore, information about [Mrs A's] allergy status was clearly included in the clinical records and the process of handover appears adequate.

5.0 The adequacy of the handover processes between [RN J] (ED) and [RN I] (Surgical Ward).

[Mrs A's] allergy status was well documented and evident on the printed alerts page and Triage page of the ED Assessment form as well as being informed by [Mrs A]. The handover process between [RN J] and [RN I] appears adequate in the context of this case however whether this occurred within an ISBAR framework is not evident. There is no evidence that the [surgical ward] nurse acknowledged [Mrs A's] allergy status and there is no evidence of a completed nursing care plan. There is no evidence of the type of content of handover between [the surgical ward] and [the general medical ward].

6.0 Any other comments I wish to make about the care provided to [Mrs A] as it relates to her eventual penicillin reaction.

6.1 I note a statement made in letter of [2021] between NDHB CMO to HDC, i.e., 'it is the prescriber's duty to check for incompatibilities like allergies'. Medical statements were not included in the case file for my review however I expect this is being assessed elsewhere.

6.2 From the Serious Event Analysis Report Executive Summary.

'At the medical ward round on [Day 6] neither the senior nor junior doctor present had met [Mrs A] previously. A decision was made by the SMO to change her antibiotic to Augmentin to which the organism was fully sensitive. The penicillin allergy was not noted by either doctor.'

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'The absence of completely adhering to prescribing and medication administration protocols resulted in the patient receiving an antibiotic to which she had a known anaphylaxis'.

It is noted to have been a busy weekend … however, staff directly involved in incident reported not feeling time pressured. The Hospital Status at a Glance report provided states Green 100% of the period for [the general medical ward] which suggests optimal staffing to meet demand. Therefore, whilst resources out of hours are typically less than during business it does not suggest that this was a significant distraction or variable for Augmentin being prescribed or administered.

[Mrs A] was reported to be a good historian, mindful of her allergy and the consequences. Therefore it is suggested that the plan to change antibiotic may not have been discussed between her and the medical team. Whilst systems should not be solely reliant on patient disclosure, if discussion of the change in care was not discussed with [Mrs A] it was another lost opportunity to be alerted to her allergy status.

6.3 Bedside handover document provided is evidence of good practice however appears to have focused on process rather than content. Relying on verbal handovers 'stand alone' is not reliable as it becomes person dependent safety as opposed to system safety. A handover protocol that includes process and standardised content may provide a safer system for staff to work within. For example, RNs stated that 'allergies are not included' in handover. If allergy status is not included in handover and has not been reliably transcribed throughout admission, the risk of missing this information is high. The opportunity to consider allergy status as part of standardised handover is lost. It is recommended that a handover/clinical communications protocol is developed which will provide guidance on both process and content of clinical handover.

6.4 Medication administration protocol, (in date). Appendix B is a useful reference to when medication errors can occur. I would assess that this error is aligned to the Design section and systems that did not support continuity of information from admission, throughout two ward moves.

6.5 Despite evidence that anaphylaxis was suggested early as a potential cause of the arrest, recognition of anaphylaxis as the most likely cause was delayed. However, the significance of this and impact on the final outcome for [Mrs A] is not within the scope of this review. However what this does indicate is that [Mrs A's] penicillin allergy was not easily noted by any of the attending medical (or nursing) team but eventually found on the Emergency Department admission note.

It is stated that whilst resuscitation was potentially against [Mrs A's] wishes, to conduct a full and rigorous resuscitation in the presence of hospital treatment error is entirely appropriate.

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7.0 Any other matters for consideration.

I acknowledge the extent of regret and apology conveyed by Northland District Health Board and willingness to meet with [Mrs A's] family. I recommend this offer be extended again maybe in the context of Health and Disability review outcome and resolution.

The Serious Investigation Analysis report has been completed and was timely however the main systems recommendation appears to be longer term and is dependent on resource, i.e., implementation of electronic prescribing and administration system and medication reconciliation of all inpatient drug charts. These strategies are the strongest system measures to eliminate risk however the commitment to measures of compliance appears indecisive ('decision to proceed or … And business case considering options …'). Therefore, what will NDHB do in the shorter term to mitigate the risk of prescribing and administration error that is still present?

8.0 Summary and Recommendations for Improvement

I identified one mild departure from standards by [RN E] however more impactful outcome is to focus on systems improvements.

As an outcome of this review I have identified three opportunities for quality improvement.

A handover/clinical communications protocol is explored which will provide guidance on both process and content of clinical handover.

It is recommended that utilisation of the allergy alert red wrist label is clarified.

NDHB demonstrate commitment to implementation of the serious investigation report recommendations.

Rosalind Jackson
Associate Director of Nursing
Bay of Plenty District Health Board

1 November 2021

References

Meadows, S., Baker, J., Butler, J (2005). *The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents*. Advances in patient safety: from research to implementation (Vol 4). Programs, Tools and Products, Agency for Healthcare Research and Quality (US).”

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Appendix D: Medical Council of New Zealand: Statement on good prescribing practice (2020)

"Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines you prescribe.

Take an adequate history of the patient, including: family history of the disease or condition; any previous adverse reactions to medicines; previous and current medical conditions; and concurrent or recent use of medicines (including non-prescription, complementary and alternative medicines).

There are often changes to a patient's medicines when their care is transferred between health professionals or between care facilities. Transitions of care can result in medication errors and cause harm to the patient. You should ensure that the health professional taking over the patient's care is supplied with the patient's current list of medicines, allergies and adverse drug reactions, and that any changes are documented, reconciled and explained."

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