

Inadequate care and oversight of respiratory patient

1. First, I express my sincere condolences to the [consumer's] whānau for the passing of Mr A since this complaint was opened in March 2021.
2. At the outset, I apologise for the delay in communicating the outcome of my decision. For context, HDC has experienced a significant and unprecedented increase in complaint volume, which has lengthened our assessment timeframes. I apologise on behalf of this Office for the delays and lack of communication. I appreciate that significant time has passed since the events outlined in the complaint.

Complaint background

3. On 3 December 2020 Mr A (90 years old) was admitted to North Shore Hospital (Health New Zealand|Te Whatu Ora (Health NZ) Waitematā) with a working diagnosis of infective bronchiectasis.¹ Mr A spent a prolonged period in hospital, eventually being discharged on 14 January 2021. During his stay, Mr A experienced multiple exacerbations of his bronchiectasis; Pseudomonas pneumonia; an unwitnessed fall resulting in superficial wounds and a head injury; 'fluid overload'; and an 11% body weight loss (74kg on admission but 66kg on discharge).
4. On 29 March 2021 this Office received a complaint from Mr A's daughter, Dr C, regarding the care provided to Mr A during his stay in hospital, and regarding the care provided by Health NZ Waitematā's outpatient respiratory clinic in the lead-up to his admission. Dr C raised the following concerns:
 - Medication management:
 - Failure to check medication interactions (itraconazole,² digoxin,³ and dabigatran⁴)
 - Inappropriate antibiotic administration (Augmentin⁵ and doxycycline⁶) on admission and on subsequent relapse (Mr A's previous infection had been resistant to Augmentin)
 - Incorrect duration of appropriate antibiotic (ceftazidime⁷) with no further oral antibiotics as prescribed, resulting in relapse
 - No offer of prophylactic antibiotics post discharge
 - Inadequate assessment and response to Mr A's hospital fall and injury

¹ A long-term condition in which the airways of the lungs become widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection.

² A broad-spectrum antifungal medication used to treat a variety of fungal infections.

³ A medication used to help the heart to beat more strongly and with a more regular rhythm.

⁴ A medication used to treat or prevent clots in the blood.

⁵ An antibiotic.

⁶ An antibiotic.

⁷ An antibiotic used to treat or prevent a variety of bacterial infections.

- Inadequate respiratory observations
- Inadequate nutritional observation and weight loss

Independent advice

5. Independent advice was obtained from Dr Ben Brockway, a respiratory physician and senior lecturer in respiratory medicine (Appendix A). After review of Dr C's complaint letters, clinical records, and Health NZ Waitematā's responses to HDC, Dr Brockway reported the following departures from the expected standard of care provided by Health NZ Waitematā to Mr A:
 - **Mild departures:** the delay in recognising and responding to drug interaction between itraconazole and digoxin; the 'near miss' of prescribing a second anticoagulant⁸ (Clexane); and not providing an X-ray after Mr A's fall.
 - **Moderate departures:** failing to administer ceftazidime and further oral antibiotics for the appropriate duration; administering Augmentin after Mr A suffered further exacerbation of his bronchiectasis following cessation of IV ceftazidime; and the decision to escalate oral Augmentin to IV Augmentin.
 - **Severe departure:** paucity of neurological observations following Mr A's fall.

Health NZ response

6. Health NZ Waitematā was provided with a copy of Dr Brockway's report, and Health NZ commented on the identified departures from the expected standard of care and responded to the concerns raised in the complaint. Health NZ also provided relevant standards, guidelines, and clinical records for my assessment.
7. Health NZ Waitematā acknowledged and accepted the departures as outlined in Dr Brockway's report. Health NZ also offered an apology for not providing Mr A with an X-ray after his fall, and for not meeting the expected standards in its care of Mr A.

Investigation findings

Medication management — drug interactions

8. Mr A did not receive an appropriate standard of care regarding management of drug interactions.
9. Itraconazole is known to interact with digoxin by increasing its concentration in the individual. The Health NZ Waitematā digoxin protocol specifies that itraconazole can increase digoxin levels, and subsequently digoxin levels should be monitored and adjusted

⁸ Blood thinner.

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as needed.⁹ Itraconazole is also known to increase dabigatran levels, and it is recommended to monitor for bleeding or anaemia.¹⁰

10. The Medical Council of New Zealand's statement on good prescribing outlines that doctors must '[b]e familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, [and] effectiveness' of the medicines they prescribe.¹¹
11. In 2020 electronic prescription checks/flags were not in place in the Health NZ Waitematā outpatient setting. Responsibility to check for interactions sat with the individual prescriber. On 27 October 2020, when prescribing itraconazole for Mr A in the community respiratory clinic, Dr B did not check for drug interactions with digoxin or dabigatran. Subsequently, Mr A's digoxin levels were not monitored in the lead-up to his admission to hospital. Dr B has acknowledged this.
12. On 4 December, after admission to hospital, the itraconazole drug interactions were flagged correctly on the inpatient system and identified by the hospital pharmacist, with a recommendation to test digoxin levels and monitor for blood loss or anaemia. However, this did not occur.
13. Dr D (registrar) accepted the flagged interaction and advised that Mr A could remain on itraconazole. Dr D did not order digoxin blood tests or advise to monitor Mr A for bleeding or anaemia.
14. Dr D prescribed Clexane on 4 December when Mr A was already taking another anticoagulant (Pradaxa). This prescribing mistake was picked up by a different house officer on 5 December before the prescription was filled.
15. On 8 December, digoxin levels were taken and Mr A was found to be 'supratherapeutic' with higher than therapeutic levels of digoxin (2.4 when the range is 0.6–2.00). Mr A's medication was adjusted, and he received regular monitoring of digoxin levels moving forward. Health NZ Waitematā was unable to explain why the flags on the inpatient system did not trigger a digoxin level earlier.

Medication management — administration of antibiotics

16. It was reasonable for Mr A to be placed on Augmentin and oral doxycycline initially on admission. Health NZ Waitematā's Empiric Antibiotic Protocols recommends this initially until a review of sputum cultures has been completed. Sputum was collected on 4 December and reported on 7 December. Acknowledging that Mr A had experienced a previous

⁹ Medsafe New Zealand data sheet: Itraconazole:

<https://www.medsafe.govt.nz/profs/datasheet/s/sporanoxsol.pdf>; NZ Formulary — drug interactions — [New Zealand Formulary - New Zealand Formulary](#); The Health NZ Waitematā Digoxin protocol.

¹⁰ Medsafe New Zealand data sheet: Itraconazole:

<https://www.medsafe.govt.nz/profs/datasheet/s/sporanoxsol.pdf>; NZ Formulary — drug interactions — [New Zealand Formulary - New Zealand Formulary](#)

¹¹ The Medical Council of New Zealand's statement on good prescribing:

<https://www.mcnz.org.nz/assets/Archive/Statements/Prescribing/Statement-on-good-prescribing-practice-March-2020.pdf>

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resistance to Augmentin, independent advisor Dr Brockway noted that in people with bronchiectasis, different organisms may appear in sputum over time, especially when there has been recent antibiotic use. Subsequently, clinical responses should be determined based on the sputum results at the time of presentation. I am guided by Dr Brockway's advice in finding that this approach was appropriate.

17. On 7 December, after consulting with the Infectious Diseases team, Mr A was appropriately prescribed IV ceftazidime to be followed by oral ciprofloxacin, after sputum cultures identified fully susceptible *Pseudomonas aeruginosa*.¹² This advice/plan was repeated on 9 December in the ward round care plan and should have guided staff moving forward.
18. Although correct, the Infectious Diseases referral advice was insufficient, as it did not specify the duration of the treatment. Health NZ Waitematā has acknowledged that this advice should have been more specific.
19. Mr A was not provided with the correct duration of antibiotic treatment. International guidelines (provided by Health NZ Waitematā) specify that treatment should take place for a minimum of 14 days.¹³ IV ceftazidime ceased after one week (14 December) and Mr A was not provided with oral ciprofloxacin as had been directed and outlined in his care plan. Health NZ Waitematā has acknowledged that it did not complete the appropriate duration of treatment. It is not clear why this occurred.
20. On 21 December Dr E (a general medicine registrar) inappropriately placed Mr A on oral Augmentin when he deteriorated after the ceftazidime was stopped. In providing good clinical care, doctors are required to assess the patient adequately, including reading the patient's notes.¹⁴ Mr A's prior *Pseudomonas* infection and shortened antipseudomonal course were not considered appropriately at the time. It is not clear whether specialist advice was sought at this time. The use of oral Augmentin in a person with bronchiectasis with recent *Pseudomonas*-positive cultures is not clinically preferred, recommended, or appropriate.¹⁵ Independent advisor Dr Brockway views this decision as a departure from the standard of care, and Health NZ Waitematā has acknowledged that this was inappropriate.
21. Sputum cultures taken on 21/22 December and reported on 24 December demonstrated that Mr A again had a *Pseudomonas* infection. Mr A's medication was not adjusted in response to this. From the information provided, it is not clear whether Health NZ Waitematā had an electronic alert system to flag new results with the care team.
22. On 26 December, after Mr A did not improve, Dr F (general medicine house officer) inappropriately escalated Mr A's oral Augmentin to intravenous administration. Mr A's recent sputum cultures were available, but it appears that these were not considered at the time of this decision. It is not clear whether specialist advice was sought. Independent

¹² A common disease-causing bacteria.

¹³ British Thoracic Society Guideline for bronchiectasis in adults.

¹⁴ New Zealand Medical Council, *Good Medical Practice* (2016):

<https://www.mcnz.org.nz/assets/Archive/Statements/Good-Medical-Practice/2016-December-Good-Medical-Practice.pdf>

¹⁵ Independent advisor Dr Brockway's report (Appendix A).

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advisor Dr Brockway highlighted that in Mr A's circumstances, the 'wrong agent [antibiotic] is more likely than inadequate bioavailability'¹⁶ to explain antibiotic treatment failure.

23. It appears that the appropriate treatment for Mr A (IV ceftazidime) was delayed for a week because of the incorrect decision to administer oral then IV Augmentin. On 28 December the Infectious Diseases team was consulted and Mr A was placed back on one week of IV ceftazidime followed by two weeks of oral ciprofloxacin.
24. Independent advisor Dr Brockway is of the view that it was appropriate to recommend that Mr A discuss prophylactic antibiotics in an outpatient setting/respiratory clinic on the basis that this is a specialist decision (rather than generalist). I agree with this view.

Assessment and response — Mr A's fall

25. Health NZ Waitematā falls policy¹⁷ required that after a fall, vital signs were to be monitored every eight hours. Where a head injury occurred, neurological assessment was to occur every 2 hours for the first 12 hours, every 3 hours for the next 24 hours, and every 4 hours for the following 24 hours.
26. Mr A did not receive appropriate neurological observation/assessment after experiencing a fall on 5 December just before midnight. Mr A injured his left shoulder, and although not reported at the time, the left side of his head.¹⁸
27. The initial assessment noted superficial skin tears and requested 'neuro observations in a few hours'. A neurological assessment was undertaken at 1.40am but not performed again until 4.04pm. No further neurological assessments occurred throughout Mr A's stay.
28. Acknowledging that the initial report did not mention a head injury, it was apparent by the evening of 6 December that Mr A had suffered a head injury from the fall, with nursing staff recording a haematoma over the left side of his forehead. No neurological assessments occurred once this injury was identified.
29. Independent advisor Dr Brockway considers that the failure to undertake these observations in a patient with this history (unwitnessed fall, possible head strike, on anticoagulation, with neurological observations recommended) is a departure from accepted practice. I agree. Health NZ Waitematā acknowledged that the neurological assessment and monitoring of Mr A was inadequate.
30. Health NZ Waitematā also acknowledged that an X-ray was not provided for Mr A after he and his whānau continued to report Mr A's left shoulder pain on 7 December and requested an X-ray. Health NZ Waitematā apologised for this and acknowledged that this would have provided Mr A and his whānau with reassurance that there was no permanent damage.

¹⁶ The rate and extent of drug absorption from a dosage.

¹⁷ Falls Prevention Strategies — Reducing Harm.

¹⁸ Head strike was confirmed the following day by the presence of a haematoma over the left side of his forehead.

Respiratory observations

31. An Early Warning Score (EWS) helps to identify acutely ill and deteriorating patients by calculating a score based on core mandatory vital signs. Respiratory rate (breaths per minute) is one of these vital signs and must be recorded.¹⁹ A respiratory rate between 12–20/minute scores zero and is considered normal.
32. Mr A's respiratory rate was recorded in a timely manner as required by policy. However, it is not possible to establish the accuracy of Mr A's respiratory rate recordings, noted as sitting between 18–20/minute for most of his six-week stay.
33. Dr C and independent advisor Dr Brockway raised concerns about the lack of variance in Mr A's recorded respiratory rate, considering that he experienced several acute exacerbations of bronchiectasis throughout his stay, and at times Mr A's respiratory rate was observed by whānau as 30/minute throughout his stay.
34. Health NZ Waitematā advised that it would work with a ward educator to ensure that staff orientation and respiratory training includes clear direction that all respiration rates be counted for a full minute.

Nutrition observations

35. The Health NZ Waitematā policy²⁰ outlines that adults requiring oral nutrition/support should have their Malnutrition Universal Screening Tool (MUST) completed to determine risk and subsequent required action, including any referral to a dietician.²¹
36. Mr A's admission chart summary appears to suggest that Mr A was assessed under MUST seven times²² throughout his stay, recording a score of 0 (low risk/routine care) each time. However, the clinical records contain only one completed MUST form from 13 January 2021 (at the end of Mr A's stay), which appears to have been completed incorrectly. It records Mr A's 'usual weight' as 66.7kg, which was his weight at discharge (not admission/'usual'), and subsequent records show only a 1% unplanned weight loss.
37. Mr A lost 8.4kg during his six-week stay (74.4kg at admission and 66kg at discharge — 11% of his body weight). It is noted that Mr A was placed on fluid restrictions and diuretics during his stay. Subsequently, it is not possible to establish clearly whether Mr A experienced loss of muscle mass versus fluid loss.
38. Regardless, I consider that there was an unreasonable delay in consulting a dietician to address whānau concerns regarding food intake and weight loss. On 7 December whānau raised concern about Mr A's reduced fluid and food intake. Mr A's care plan subsequently included a request for dietician input, but this did not occur.

¹⁹ Health NZ Waitematā policy 'Observations Vital Signs, Early Warning Score (Adult) & Escalation Pathway'.

²⁰ Dietician referrals — inpatients.

²¹ 0 = low risk/routine care; 1 = medium risk/observe; 2 or more = high risk/treat, refer to dietician.

²² On 5, 12, 19, 28, and 31 December and 7 and 13 January.

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39. From 10 December, Mr A's care plan included daily weight recording. It appears that this did not start until 18 December, at which point he weighed 73.47kg (1kg lighter than admission). This is an unreasonable delay.
40. On 26 December a further note for dietician input was requested by the on-call house officer, and a referral was made on 29 December. Mr A was assessed by a dietician on 30 December with a subsequent plan made to increase his food intake.
41. It is not clear whether Mr A's malnutrition risk was monitored adequately via the MUST assessment. If the charted assessment is accurate, Mr A was assessed regularly throughout his stay and did not meet the criteria for referral to a dietician under Health NZ Waitematā policy. This appears to conflict with the information provided by Mr A's whānau that he did not have adequate food intake and was experiencing rapid weight loss.
42. Regardless of the MUST assessment, I consider that the direct request from Mr A's doctors for dietician input should have prompted a consultation or formal referral, which did not occur until late December and only after a further request. This is clearly an unreasonable delay, and I am critical of Health NZ Waitematā for this.
43. I am also critical that Mr A's plan included daily weights, but this was delayed for eight days. Based on this, I consider that Mr A did not receive adequate oversight of his nutrition and weight until the dietician assessment.

Fluid balance observation

44. Mr A's fluid balance was not monitored adequately throughout his stay, in particular throughout the period he experienced 'fluid overload'. On 14 and 15 December it was identified that Mr A had fluid on his lungs and bilateral pedal oedema.²³ He was started on daily frusemide²⁴ and fluid restrictions of 1.2L/day and remained on this until his discharge one month later, 14 January 2021. Clinical records show one completed fluid balance sheet during Mr A's stay, covering 7 January 2021, and then 10–13 January.
45. The Medsafe data sheet for frusemide²⁵ specifies that 'all patients receiving furosemide therapy should be observed for signs of fluid or electrolyte imbalance'.
46. Whilst in the care of Health NZ Waitematā Mr A was on frusemide for four weeks. His fluid balance was monitored for five days in total, across two different weeks. This is clearly inadequate, and I am critical of Health NZ for this.

Decision

47. Having reviewed all the information, including Health NZ's responses and Dr Brockway's independent advice, I have formed my decision as outlined below. Health NZ Waitematā was provided with the opportunity to comment on my provisional decision and advised that it has accepted my findings.

²³ A build-up of fluid in the feet, ankles, or legs.

²⁴ A medication used to help the body get rid of excess fluid and salt.

²⁵ Medsafe data sheet on frusemide: <https://www.medsafe.govt.nz/profs/Datasheet/i/lpca-Frusemidetab.pdf>

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Health NZ Waitematā — breach

48. Mr A's antibiotic management was inadequate, and at times incorrect, resulting in a delay in appropriate treatment, exacerbation of his bronchiectasis, and deterioration of his wellbeing. Mr A did not receive adequate assessment following his fall and injury, including neurological observations, and he did not receive adequate oversight of his fluid balance during treatment for fluid overload.
49. It is not clear how Mr A's malnutrition risk was assessed throughout his admission, or whether his weight loss was directly attributable to nutrition issues. I am critical of the substantial delay in obtaining dietician advice and assessment after it was requested within the first week of his stay.
50. I acknowledge the concerns raised by Dr C and independent advisor Dr Brockway about the lack of variance in Mr A's recorded respiratory rate, considering that he experienced several acute exacerbations of bronchiectasis throughout his stay. I intend to follow up on the actions Health NZ Waitematā has taken to ensure that respiratory rates are recorded accurately.
51. I note with concern that at times Mr A's history and care plans were not reviewed adequately by successive staff members and subsequently were not considered or actioned. This included the requests for daily weights, the request for dietician input, and consideration of Mr A's recent (inpatient) Augmentin resistance. I am critical of Health NZ Waitematā for this.
52. I consider that there were multiple gaps in the oversight and coordination of Mr A's care. Health NZ Waitematā acknowledged that 'respiratory medicine at Waitematā has not reached the degree of inpatient specialisation that other similar sized Districts have achieved'. In the absence of such specialisation at the hospital, I consider that there was a lack of engagement/consulting with appropriate specialists in the respiratory clinic and/or Infectious Diseases team regarding Mr A's care, and I am critical of Health NZ in this regard.
53. For the reasons outlined above, it is my opinion that Health NZ Waitematā did not uphold Mr A's right to have services provided with reasonable care and skill, and, accordingly, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

Dr B (outpatient respiratory clinic) — adverse comment

54. Dr B had an obligation to be familiar with the drug interaction between itraconazole and digoxin²⁶ and subsequently to monitor Mr A's digoxin levels after itraconazole was prescribed on 27 October 2020.²⁷ This did not occur, and I am critical of Dr B for this. I note that since this event, Dr B has moved to e-scripts, which should improve drug interaction checks.

²⁶ The Medical Council of New Zealand's statement on good prescribing:

<https://www.mcnz.org.nz/assets/Archive/Statements/Prescribing/Statement-on-good-prescribing-practice-March-2020.pdf>

²⁷ New Zealand Formulary — Interactions: <https://nzformulary.org/>; Medsafe New Zealand data sheet on itraconazole: <https://www.medsafe.govt.nz/profs/datasheet/s/sporanoxsol.pdf>

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Dr D (inpatient registrar) — adverse comment

55. Dr D had an obligation to be familiar with the drug interactions between itraconazole, digoxin, and dabigatran.²⁸ On 4 December 2020, after Mr A's admission to hospital, this interaction was flagged correctly by the inpatient system and identified by the hospital pharmacist, with a recommendation to test digoxin levels and monitor for blood loss or anaemia. Dr D accepted the flagged interaction and recommendations but advised that Mr A could remain on itraconazole. Dr D did not order digoxin blood tests or advise staff to monitor Mr A for bleeding or anaemia. Accordingly, I am critical of Dr D for this failure.

Dr E (inpatient general medicine registrar) — adverse comment

56. Health NZ Waitematā's Empiric Antibiotic Protocols outline that oral Augmentin in a person with bronchiectasis with recent *Pseudomonas*-positive cultures is not appropriate. In providing good clinical care, doctors are required to assess the patient adequately, including reading the patient's notes.²⁹ In the circumstances of this case, it appears that Mr A's recent positive (post-admission) culture was not considered adequately, and subsequently the empirical guidelines were not followed. Independent advisor Dr Brockway and Health NZ Waitematā acknowledged that prescription of Augmentin for Mr A was a departure from standard practice. Accordingly, I am critical of Dr E.

Dr F — adverse comment

57. As noted above, Health NZ Waitematā's Empiric Antibiotic Protocols outline that Augmentin in a person with bronchiectasis with recent *Pseudomonas*-positive cultures is not appropriate. In providing good clinical care, doctors are required to assess the patient adequately, including reading the patient's notes. In the circumstances of this case, Dr F had available to him the most recent sputum cultures identifying that Mr A had *Pseudomonas*-positive cultures. It appears that this was not considered adequately when Dr F decided to administer IV Augmentin, and subsequently the empirical guidelines were not followed. Dr Brockway identified this as a moderate departure from accepted standards. Accordingly, I am critical of Dr F.

Health NZ Waitematā's proposed changes

Health NZ Waitematā outlined that it would undertake the following changes:

- Ensure that respiratory rate training is included in staff orientation to ensure better compliance;
- Remind prescribers to be vigilant of interactions and warnings triggered in electronic prescribing systems;
- Remind prescribers to be vigilant of interactions and required monitoring, where electronic systems are not available;

²⁸ The Health NZ Waitematā Digoxin protocol; The Medical Council of New Zealand's statement on good prescribing:

<https://www.mcnz.org.nz/assets/Archive/Statements/Prescribing/Statement-on-good-prescribing-practice-March-2020.pdf>

²⁹ New Zealand Medical Council — Good Medical Practice 2016:

<https://www.mcnz.org.nz/assets/Archive/Statements/Good-Medical-Practice/2016-December-Good-Medical-Practice.pdf>

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- Follow up on implementing the interaction checker in the community setting (noting that this sits at regional level);
- Advise Dr D of this review and highlight the issue of drug interaction checking;
- Facilitate a reflection session and follow through with the pharmacy team regarding blood requests from pharmacists;
- Review current antibiotic guidelines with the Infectious Diseases team, to improve clarity around anti-pseudomonal therapy and duration.
- Follow up on whether the respiratory service can support the development of a bronchiectasis guideline; and
- Present Mr A's case at a 'morbidity and mortality' meeting.

Dr C and whānau's response to my provisional opinion

58. Dr C raised some new issues that had not been considered by this investigation, including monitoring of blood, including CRP levels, albumin, and anaemia, as well as concerns that heart failure was not investigated adequately. Dr C also reiterated concerns regarding the nursing care provided, including the prevention of pressure sores, responsiveness to call bells, and the overall attention to symptoms and early warnings, and she provided a series of suggested recommendations for improvement.
59. I have provided Health NZ Waitematā with a copy of Dr C's response and have made an addition to recommendation b), to include that Health NZ Waitematā consider meeting with Dr A to discuss the above issues and suggested recommendations.

Recommendations

Health NZ Waitematā

60. I recommend Health NZ Waitematā:
- a) Provide an apology to Dr C and the wider whānau for the issues outlined in this investigation. Please include in this letter any actions taken as a result of this complaint and any systemic improvements. The written apology is to be sent to HDC within three weeks of the date of the final opinion, for forwarding to Dr C.
 - b) Provide HDC with an update and evidence of the outcomes of its proposed changes outlined above, within three months of the date of this decision, and consider meeting with Dr C to discuss the issues and suggested recommendations raised in response to my provisional opinion.
 - c) Undertake an audit of 30 drug interactions flagged in the electronic system, to determine the degree of compliance with warnings/recommendations. The summary of findings with corrective actions is to be provided to HDC within three months of the date of this opinion.
 - d) Develop a policy or clearly documented process on referral pathways for General Medicine to Respiratory/Infectious Diseases specialists and provide an update to HDC within three months of the date of this opinion.

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- e) Remind all staff of their obligations to read patient notes and provide clear and unequivocal directions on care plans and provide evidence of this to HDC within three months of the date of this opinion.

Dr B

61. I recommend that Dr B:

- a) Reflect on the circumstances of this case and provide a written summary of these reflections and the changes to practice instigated as a result of this case.
- b) Provide a written apology to Dr C for not having checked the drug interactions before prescribing itraconazole to Mr A, and thereby not monitoring him appropriately. The apology is to be sent to HDC within three weeks of the date of this decision, for forwarding to Dr C.

Dr D

62. I recommend that Dr D:

- a) Reflect on the circumstances of this case and provide a written summary of these reflections and the changes to practice instigated as a result of this case.
- b) Provide a written apology to Dr C for not having checked the drug interactions before prescribing itraconazole, thereby not monitoring Mr A appropriately. The apology is to be sent to HDC within three weeks of the date of this decision, for forwarding to Dr C.

Dr E

63. I recommend that Dr E:

- a) Reflect on the circumstances of this case and provide a written summary of these reflections and the changes to practice instigated as a result of this case.
- b) Provide a written apology to Dr C for having not considered Mr A's notes adequately, and subsequently prescribing Mr A oral Augmentin inappropriately against empiric protocols. The apology is to be sent to HDC within three weeks of the date of this decision, for forwarding to Dr CA.

Dr F

64. I recommend that Dr F:

- a) Reflect on the circumstances of this case and provide a written summary of these reflections and the changes to practice instigated as a result of this case.
- b) Provide a written apology to Dr C for not having considered Mr A's notes and recent results adequately and subsequently continuing to prescribe Mr A IV Augmentin against empiric protocols. The apology is to be sent to HDC within three weeks of the date of this decision, for forwarding to Dr C.

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Follow-up action

65. A copy of this report with details identifying the parties removed, except Health NZ Waitematā and the independent advisor on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Carolyn Cooper
Aged Care Commissioner

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Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr Ben Brockway:

‘Complaint: [Mr A]/Te Whatu Ora Waitematā

Ref: C21HDC00718

I am a vocationally registered Respiratory Physician and Senior Lecturer in Respiratory Medicine employed by Te Whatu Ora Southern at Dunedin Public Hospital, and the University of Otago Dunedin School of Medicine. My qualifications are: BSc (Hons) University of London 1995; MB, BS University of London 1996; MRCP (London, 2001), FRACP (2012), and I am an elected Fellow of the Royal College of Physicians (2020). I hold Certificates of Completion of Training in General (Internal) Medicine and Respiratory Medicine from the Joint Committee on Higher Medical Training in the UK (2008). I was appointed as a Consultant in Dunedin in 2008 and am Clinical Director for Respiratory Medicine for Te Whatu Ora Southern.

I have read and agreed to follow the Commissioner’s guidelines for independent advisors, and believe I am appropriately trained and experienced to provide an expert opinion regarding the requested case review C21HDC00718.

I have been provided with the following information to base my review on:

1. Letters of complaint dated 31 March 2021
2. Te Whatu Ora Waitematā’s response dated 23 July 2021
3. Clinical records from Te Whatu Ora Waitematā covering the period 3 December 2020 until 14 January 2021
4. Family response to Te Whatu Ora Waitematā’s response

I have also reviewed Te Whatu Ora Waitematā’s Empiric Antibiotic Protocols. Aspects of the case have been discussed in confidence and anonymised with my colleagues [...], Pharmacy Manager Te Whatu Ora Southern, and Dr [...] FRACP, Consultant Respiratory Physician.

Background of complaint

Mr [A] was admitted to Ward 10 at North Shore Hospital with a diagnosis of infective bronchiectasis. Mr [A] spent a protracted time in hospital and his family raise concerns that he would have died without their intervention.

I have specifically been asked to comment on:

- (i) delays in recognizing the potential interaction between digoxin and itraconazole — Mr [A]’s supratherapeutic digoxin levels recognised five days after admission;
- (ii) documented clinician advice to commence prophylactic clexane (4 December 2020) when Mr [A] was already taking dabigatran (error recognised by registrar at point of prescribing);

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- (iii) choice of initial antibiotic therapy and whether sufficient consideration was given to Mr [A]’s historical sputum culture results. Was it then appropriate to stop IV ceftazidime after one week with no extended course of oral antibiotics?;
- (iv) choice of antibiotic therapy (oral then IV Augmentin) when Mr [A] had a further exacerbation of his bronchiectasis following cessation of IV ceftazidime;
- (v) was there appropriate and timely involvement of specialist respiratory and infectious diseases services?;
- (vi) was sufficient heed given to the specialist advice that Mr [A] might require prophylactic antibiotics (as 3x weekly azithromycin) on discharge?;
- (vii) was there timely and appropriate involvement of the DHB dietetic service?;
- (viii) was the documented assessment and management of Mr [A]’s injuries following a fall in 6 December 2020 clinically appropriate noting nursing staff reported Mr [A] having a left forehead haematoma later on 6 December 2020 and his wife requesting X-ray of his shoulder because of ongoing pain on 7 December 2020?; and
- (ix) Any additional comment on clinical issues raised in the complaint or noted by yourself on review of the clinical documentation and provider response?

(1) Delays in recognizing the potential interaction between digoxin and itraconazole — Mr [A]’s supratherapeutic digoxin levels recognised five days after admission

On admission (Thursday 3 December), Mr [A] was on itraconazole 200mg bd (commenced 27 October) and digoxin 125mcg daily. His digoxin levels were satisfactory in June 2020 (pharmacist note, 8 December) prior to commencing itraconazole. There is no record of any digoxin levels being done in the community after commencing itraconazole but before admission to hospital, and thus the duration of supratherapeutic/potentially toxic digoxin levels is uncertain (but may have been weeks and not solely during his period of admission). On Friday 4 December at 0814 the pharmacist noted *“Please note itraconazole is a CYP3A4 inhibitor — caution with use of other medication that are CYP3A4 substrates — in Mr [A]’s case — digoxin and dabigatran. Suggest take a digoxin level [one has not been taken since itraconazole has started] — itraconazole may increase digoxin levels 2–6 fold, may need a digoxin dose decrease”*.

The post acute ward round (PTWR) entry from 0843 same day mentions that the patient reported not receiving his itraconazole, but not the recommendation for digoxin levels from earlier in the day. Mr [A]’s digoxin levels were supratherapeutic (2.4, target range quoted as 0.6 to 2.0) when checked on Tuesday 8 December. Given the timing of these events it is plausible that a blood form was put out for digoxin levels on the next working day after the PTWR (Monday 7th) for the phlebotomy round on Tuesday 8th.

I would expect most medical staff to consider interactions between itraconazole and digoxin as a possibility. Itraconazole is not a commonly prescribed drug, so heightened awareness of potential interactions is needed. Checking this on the New Zealand Formulary flags the interaction as Severe and supported by study evidence. While exhaustive checking of all potential interactions is often impractical for admitting

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teams, electronic prescribing systems should flag the interaction at the point of prescribing (our local MedChart system clearly flags this interaction to the prescriber). Without further interrogation of Waitematā's MedChart system I am unable to comment on whether the prescriber had an alert flagged at the time of prescribing (and interaction configuration is site specific in MedChart). Thus the question is of timing of tests; turnaround time for digoxin levels at our local laboratory is an hour and the assay can be run at any time i.e. urgent levels can be processed 24 hours a day.

I view the interval between the recommendation for levels to be done on 4th December prior to the PTWR, and the results being available on 8th December to be a mild departure from standard of care. In terms of recommendations for preventing similar occurrences in the future, I am unaware of a reason why pharmacists should not be able to add on tests for bloods already drawn in this circumstance. Where a pharmacist has a high index of suspicion for drug toxicity, my belief is that they should be able to request a drug assay and alert the medical team accordingly. Relying on one group of professionals to be responsible for patient safety is inherently unsafe, and any professional should be able to contribute to improving patient safety.

(2) documented clinician advice to commence prophylactic clexane (enoxaparin) (4 December 2020) when Mr [A] was already taking dabigatran (error recognised by registrar at point of prescribing);

Again, this should be picked up by an electronic prescribing system. Mr [A] was also on itraconazole which is noted to increase the effect of dabigatran. The PTWR note contains the information "Atrial Fibrillation, on Pradaxa" above the plan to give prophylactic clexane 20mg so this appears an error of commission, which was noted by the house officer on Saturday 5 December. This near-miss event resulted in no harm and is overall a mild departure from accepted practice, with electronic prescribing systems being key to reducing risk. Of note the importance of preventing venous thrombosis in unwell medical patients was recognised, the issue was that Mr [A] was already adequately anticoagulated.

(3) choice of initial antibiotic therapy and whether sufficient consideration was given to Mr [A]'s historical sputum culture results. Was it then appropriate to stop IV ceftazidime after one week with no extended course of oral antibiotics?;

Protocols are provided by Waitematā's Antimicrobial stewardship group for empiric treatment. First line recommendation is for amoxicillin/clavulanic acid 1.2g q8h with review of sputum cultures and clinical response. There is a caveat comment that *Bronchiectasis patients colonised with Pseudomonas may require specific anti-pseudomonal antibiotics if systemically unwell*. At the point of admission it was not proven (although clinically highly likely) that Mr [A] was chronically infected with pseudomonas. It is reported that a prior sputum sample (date unknown) had grown haemophilus resistant to augmentin (amoxicillin/clavulanic acid) and sensitive to tetracycline. People with bronchiectasis may have different organisms in their sputum over time, especially when there has been recent antibiotic use. The use of IV Augmentin plus oral doxycycline at admission is therefore not unreasonable, although from a specialist perspective I would highlight that prior pseudomonas infection is a

strong predictor of subsequent pseudomonal infection even after a prolonged course of treatment, reflecting the inherent resistance of the organism and difficulty in clearing infection from structurally abnormal lung. I note a sputum sample was sent to the lab for culture within 24 hours of admission. This allowed identification of pseudomonas, which was noted on the ward round entry of Monday 7 December.

An Infectious Diseases referral was then sent regarding use of tazocin (restricted antibiotic) and an appropriate antibiotic regime was used (ceftazidime) although recommendations for duration of treatment were not given. I note the reference to the BTS Guidance for Bronchiectasis in Adults in the empiric protocols [Hill, A. T. *et al.* British Thoracic Society Guideline for bronchiectasis in adults. *Thorax* **74**, 1 (2019)]. These guidelines also state *“In general, antibiotic courses for 14 days are standard and should always be used in patients infected with P. aeruginosa”*. I also note the ID advice was for IV ceftazidime followed by oral ciprofloxacin. This was reiterated in the ward round note of 9 December.

On Monday 14 December the plan was to “complete 7 days of ceftazidime”. No further antipseudomonal therapy (e.g. oral ciprofloxacin) was provided. Under some clinical circumstances a team may consider it appropriate to provide a week of IV antipseudomonals followed by “consolidation” treatment e.g. with oral ciprofloxacin or inhaled aminoglycoside antibiotics (if available) but again these are to extend duration of therapy.

The week of IV antipseudomonal treatment is in my view a moderate departure from the BTS Guidelines. Waitematā does not have a clinical pathway for the management of bronchiectasis in adults. I would suggest this would be a good way to improve management of this common clinical scenario. Similarly the empiric guidance for treatment should be reviewed to consider the routine need for 2 weeks of antipseudomonal treatment which the BTS statement unambiguously recommends.

(4) choice of antibiotic therapy (oral then IV Augmentin) when Mr [A] had a further exacerbation of his bronchiectasis following cessation of IV ceftazidime);

Oral amoxicillin/clavulanic acid was started on Monday 21 December after Mr [A]’s family raised concerns he was developing a further chest infection. The weekend plan of 24 December states *“If ... clinically deteriorates ... discuss with ID re optimal antibiotic choice”*. On Saturday 26 December the decision was made to switch from oral to IV after the family raised concerns for his condition; the RMO also notes a further rise in CRP. On Monday 28 December further concerns were raised by the family and the CRP was now further elevated (>200). After discussion with ID on call, a plan for 1 week of IV ceftazidime followed by two weeks of oral ciprofloxacin was agreed. Thus the interval between the family raising concerns and Mr [A] receiving appropriate antibiotics was one week, despite two sputum samples (taken on the night of 21/22 December and reported 24 December) again demonstrating pseudomonas.

For the reasons given above, the use of oral amoxicillin/clavulanic acid orally *in a person with bronchiectasis with recent pseudomonas positive cultures* is not appropriate. It is possible that the responding RMO was considering the symptoms to be consistent with

hospital acquired pneumonia, where the empiric guidance is for amoxicillin/clavulanic acid (but given intravenously). Either way, the empiric guidance was not followed, and the significance of the prior pseudomonas isolate and shortened antipseudomonal course was not recognised. Escalating to intravenous amoxicillin/clavulanic acid for treatment failure is an inappropriate step — of the many potential reasons for treatment antibiotic failure, in this scenario wrong agent is more likely than inadequate bioavailability. Again, I view this as a moderate departure from standard practice.

(5) was there appropriate and timely involvement of specialist respiratory and infectious diseases services?;

ID advice was sought on 7 December (consideration of tazocin for pseudomonas, recommendation for ceftazidime and subsequently oral ciprofloxacin) — this was the first normal working day after the sputum results were available, and so timely. There is also a comment that “... wouldn’t reattempt pseudomonas clearance unless there is a strong wish to do so from respiratory”. This advice is reasonable but perhaps in interpretation missed the distinction between eradication therapy (a period of intensive antibiotic treatment to clear pseudomonal infection) and suppression therapy (the use of usually inhaled or pulsed intravenous antibiotics, with or without an anti-inflammatory macrolide to reduce risk of exacerbation). Repeated attempts at eradication, especially in people with structurally highly abnormal lungs, are rarely helpful, but in people who exacerbate more than 2–3 times a year with pseudomonas, suppression treatment improves quality of life and decreases exacerbation rates (BTS guidelines).

Respiratory services were contacted by phone on Thursday 10 December, a week after admission, as the treating team were appropriately concerned about lack of improvement despite appropriate antibiotics. Recommendations were given around possible pulmonary haemorrhage and a CT scan performed. No further entries are visible from respiratory services, but I note the Waitematā response to the complainant states that Mr [A] was seen by Dr [...], Respiratory Consultant (point 15). It is unclear to me if Dr [...] is a respiratory physician — his name is not on the Waitematā Respiratory Department webpage or on the NZMC’s registration page as a respiratory trained physician, and the role identified in the electronic record was as a General Medicine Consultant. Thus I am unable to otherwise comment on timeliness of respiratory service review.

A recommendation was made on 23 December to discuss the use of antibiotic prophylaxis (i.e. suppression therapy) with Dr [B] in outpatients. There does not appear to have been any physical review by respiratory services (but it is unclear if this was requested). My view is that in hospitals with generalist admission policies it is prudent to have strong pathways to support non-specialists, and a bronchiectasis clinical pathway might help define appropriate early therapy and antibiotic choice, duration, and route as well as red flags for referral to specialist services.

(6) was sufficient heed given to the specialist advice that Mr [A] might require prophylactic antibiotics (as 3x weekly azithromycin) on discharge?;

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This is a specialist decision as there are some potential traps, particularly around ensuring no mycobacterial infection is present prior to commencing long term anti-inflammatory macrolide therapy. Macrolides have no intrinsic anti-pseudomonal activity, but probably reduce exacerbation rates by anti-inflammatory activity; however, atypical mycobacterial infection is a contraindication to their use. Mr [A] appears to have had previous mycobacterial infection; I would not expect a non-specialist to instigate anti-inflammatory macrolides without discussion with respiratory services. As such the recommendation to discuss with Dr [B] in outpatients is prudent and the decision is generally non-urgent (and mycobacterial cultures take 4 to 6 weeks to return, so again this may be best addressed in outpatients after discharge). I do not think the decision not to commence prophylactic antibiotics in hospital was a departure from accepted practice. This is not to say that they were not needed — I am pleased to see since they were started Mr [A]’s family report a period of good respiratory health — but decision making on this is reasonably complex.

(7) was there timely and appropriate involvement of the DHB dietetic service?;

Ward round notes of Monday 7 December suggest dietetic input. I cannot see a response to this — it is possible this was not actioned. Nursing staff report sporadically on oral intake. A further ward round plan on Saturday 26 December again flags dietetic input as needed, with nursing entry on Tuesday 29 December showing a referral was made. A dietitian reviewed Mr [A] on Wednesday 30 December, and a plan made to increase food intake in the first instance. Follow up on 6 January 2021 and 13 January showed ongoing weight loss but concomitant use of diuretics cloud the issue as to loss of muscle mass vs loss of fluid. There is an appropriate discharge letter from dietetic service to GP on discharge.

Thus as far as I can tell from the available records medical staff requested a dietetic referral be made on 7 December and he was seen on 30 December, clearly an unreasonable delay. I am unable to comment on specifics of the dietetic advice as this is outside of my specialist area.

(8) was the documented assessment and management of Mr [A]’s injuries following a fall in 6 December 2020 clinically appropriate noting nursing staff reported Mr [A] having a left forehead haematoma later on 6 December 2020 and his wife requesting X-ray of his shoulder because of ongoing pain on 7 December 2020?;

The first mention of a fall was by the on-call house officer shortly after midnight on the morning of Sunday 6 December. The record states “on his way back from toilet then felt legs give way”, “fell on to right side. Didn’t hit his head ... sore left shoulder otherwise feeling OK”. It was recorded that “no facial droop” was seen, implying the face had been observed. Superficial skin injuries were noted and a (rather loose) suggestion made “neuro obs in a few hours page if concerns”. Neuro observations were recorded at 0140 and again at 1604. There was no change in Mr [A]’s GCS; his initial neuro obs document mild weakness of the left arm (potentially related to pain limiting) whilst the second neuro obs later that afternoon record mild weakness of both legs.

Although the recommendation for neuro obs was unclear as to how frequently and for how long they should be made, 14 hours between observations appears to be a

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departure from reasonable standard care. I am unaware of Waitematā's protocols for this scenario. Locally our protocol is after head strike neuro obs are done half hourly for 2 hours, then hourly for four hours, then review if need is still ongoing. A failure to undertake these observations in a patient with this history (unwitnessed fall, possible headstrike on anticoagulation, with neuro obs recommended) is a departure from accepted practice; if they were undertaken but not documented my view is that would be a moderate departure from the required standard of documentation. It is possible that in some patients in this circumstance the disruption of performing observations exceeds the potential benefits, especially in patients who are not candidates for neurosurgical intervention, but if that was the case here it was not documented.

Dressings were recorded as changed on left elbow and left back of hand on the afternoon of Sunday 6 December. At 2157 that day the nursing team reported "Haematoma over L) side of forehead" confirming headstrike had occurred. The family raised concerns re Mr [A]'s sore left shoulder (documented immediately after fall by RMO as sore, but *"moving all 4 limbs with normal power bilaterally"* whilst the neuro obs record mild weakness of the left arm). Nursing notes from early Monday 7 December state *"inform team mane [re shoulder XR]"*. This does not appear to have occurred. I am not aware of guidance as to shoulder X-rays (unlike e.g. ankle x-rays where the "Ottawa Rules" make judging who needs an x-ray relatively easy) and in this situation X-rays tend to be low risk, low cost investigations that are easily performed in hospital, and a reasonable step to take in symptomatic patients.

Nursing notes on Tuesday 8 December show Mr [A] was mobile with a low walking frame, suggesting no serious shoulder pathology likely. A physiotherapy assessment on Tuesday 5 January found no significant shoulder impingement, although this was four weeks later.

It appears the paucity of neuro obs was a significant departure from accepted practice. There is no guidance on practice for shoulder injuries that I am aware of in common use, but generally in this circumstance a precautionary x-ray in symptomatic patients is reasonable — especially when the injury will potentially impair rehabilitation and chest physiotherapy. As such I think this is a minor departure from reasonable care.

(9) Any additional comment on clinical issues raised in the complaint or noted by yourself on review of the clinical documentation and provider response?

Reviewing the initial complaint, the institutional response, and subsequent response to Waitematā's letter it is clear that there are a number of areas where I am unable to comment on provision of care — such as response times to call bells, or an inability to capture subtleties of communication retrospectively. Mr [A]'s advocate expresses surprise that his respiratory rate was recorded as being 18–20 throughout his stay on ward 10 whilst experiencing several acute exacerbations of bronchiectasis, to which I can only concur. However there are few instances of *"tachypnoea"*, *"dyspnoea"* or *"breathlessness"* in the clinical record to cross check respiratory rate to. I am therefore unable to comment further on these.

I have no further comments to make regarding care provided at this time but would be happy to discuss further as required.

Dr Ben Brockway
NZMC 31536'

The following further advice was received from Dr Brockway:

'Thank you for asking me to comment further on the care of Mr [A], **C21HDC00718**.

I have had no change in my professional status and remain vocationally registered as a respiratory physician. I have no conflicts of interest.

I have reviewed:

Clinical records from Te Whatu Ora Waitematā covering the period 3 December 2020 until 14 January 2021

Internal review of the antibiotic choices, conducted by Dr [...], Clinical Director of Infectious Disease

Dr [...] admission to Fellowship of the RACP

Appendices of STOT and HFNO documentation from Waitematā as well as EWS and neurology monitoring guidance, Falls prevention, digoxin guidance, and dietitian processes.

The response by Dr [...] to [...] on behalf of Te Whatu Ora Waitematā.

I note the extensive efforts that have been made to address the clinical issues identified. I have been asked to comment on:

1) Whether Health NZ's comments change any aspects of your initial advice;

No changes to comments regarding digoxin/itraconazole interaction, anticoagulation prescribing, timeliness of specialist services input, use of macrolides in the anti-inflammatory setting for patients with chronic colonisation with *P. aeruginosa*, dietetic referral, or comments on fall and subsequent management.

In regards to comments regarding antibiotic choice and duration, the only additional comment I would make is to draw attention to the admission document. This is provided in the pdf of clinical records from Waitematā. On page 69 (the General Medicine admission note by Dr [...]) it states "previously had sputum +ve for pseudomonas, cleared with 6/52 course of ciprofloxacin" which is reiterated on page 70. The post take ward round note by [...] also mentions "had a growth of pseudomonas, now cleared with ciprofloxacin". Thus a history of pseudomonas infection was reported at admission and on the PTWR. However, if there were negative sputums between the prior reported pseudomonas positive sample this would be falsely reassuring — clearance of pseudomonas chronic infection is often difficult and not commonly sustained. However this specialist understanding may not be widely known and so the choice of initial antibiotic is not unjustifiable.

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2) Whether there are any other matters in this case that you consider warrants comment;

I have no further comments to make.

3) Any recommendations that you could think of for future improvements at Health NZ Waitematā, if applicable.

The provided updated protocols are of high quality and demonstrate commitment to service improvement. I have no further comments to make.'