Hutt Valley District Health Board
Medical Centre 1

A Report by the Deputy
Health and Disability Commissioner

(Case 19HDC02039)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This case concerns the care provided to a man who presented to an emergency department with a suspected allergic reaction. The case highlights inconsistencies around the way medication allergies and reactions are recorded across the country, and the lack of governance over the national Medical Warning System. This report also highlights the importance of district health boards having adequate systems for ensuring that allergies are recorded and flagged to facilitate continuity of care for patients' future interactions with health services.

2. The man presented to Hutt Valley District Health Board (HVDHB) via ambulance, after having taken expired flucloxacillin tablets for a sore toe and experiencing itchy skin and shortness of breath, and then collapsing. He was discharged from the DHB with a possible allergy to flucloxacillin. This information was not recorded in any database, and the level of detail provided to the man about his new possible allergy is unclear.

3. Three weeks later, the man was on holiday when he presented to a different DHB with a sore toe. He was asked whether he had any allergies, and he advised staff that he did not. There was no alert on the national Medical Warning System of the man having any allergies. He was administered intravenous flucloxacillin as treatment for his sore toe, and, sadly, he died of anaphylactic shock shortly afterwards.

Findings

4. While acknowledging the weaknesses that exist in the current national Medical Warning System and with information sharing between DHBs, the Deputy Commissioner found HVDHB in breach of Right 4(5) of the Code for having an inadequate system for ensuring that allergies were recorded and flagged, and for its inadequate communication with the man's usual general practice. The Deputy Commissioner also reminded the DHB of the importance of ensuring that all communication with patients, particularly in relation to advice as vital as allergy information, is fulsome and documented, and that patients have a good understanding of the implications.

5. Adverse comment was made about the Emergency Department registrar at HVDHB, for her documentation and communication in this case.

6. The Deputy Commissioner also made adverse comment about the man's usual general practice, as it was provided with notes from the man's presentation to HVDHB, but the man's new allergy information was not added to the Practice Management System, and was instead filed without action.

Recommendations

7. The Deputy Commissioner recommended that HVDHB:

a) Develop an "end-to-end" process for both the ED and general hospital setting, for when a patient presents with, or experiences, a new actual or suspected drug/medication allergy;

b) Consider designing and implementing a new discharge form;

c) Create a package of educational material to be used throughout departmental teaching sessions and staff inductions at HVDHB, to address the general standards of practice expected in relation to medication allergy reporting and follow-up actions;

d) Undertake intermittent audits of the adequacy and observance of HVDHB policies relating to new allergies that require action; and

e) Provide the man's family with a written apology.

8. The Deputy Commissioner recommended that the medical centre undertake a further audit to ensure that important information in patient discharge summaries is being actioned; provide training to its staff on its electronic reporting tool; and provide the man's family with a written apology.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a referral from the Coronial Services of New Zealand about the services provided to Mr A prior to his death. The following issues were identified for investigation:

- *Whether Hutt Valley District Health Board provided Mr A with an appropriate standard of care in 2019.*
- *Whether Medical Centre 1 provided Mr A with an appropriate standard of care in 2019.*

10. This report is the opinion of Deputy Health and Disability Commissioner Dr Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

11. The parties directly involved in the investigation were:

Mr B	Complainant/Mr A's brother
Hutt Valley District Health Board (HVDHB)	Provider
Medical Centre 1	Provider/medical centre

12. Further information was received from:

Ms C	Mr A's partner
Mr D	Mr A's friend
DHB2	
Medical Centre 2	
The Ministry of Health	
The Health, Quality & Safety Commission (HQSC)	
The Royal New Zealand College of General Practitioners (RNZCGP)	

13. Also mentioned in this report:

Dr E	ED registrar
Dr F	GP

14. Independent clinical advice was obtained from a health management specialist, Mrs Julie Patterson (Appendix A), and an emergency medicine specialist, Dr Vanessa Thornton (Appendix B). In-house clinical advice was obtained from general practitioner (GP) Dr David Maplesden (Appendix C).

Information gathered during investigation

Background

15. Mr A (aged in his fifties at the time of these events) had a medical history that included asthma, gout (a form of arthritis), and recurrent cellulitis (a bacterial skin infection) for which he had been prescribed flucloxacillin[1] in 2014.

16. This report concerns the care provided to Mr A when he presented to the HVDHB Emergency Department (ED) with a suspected allergic reaction. The report also highlights issues with the governance and inconsistent use of the national Medical Warning System (MWS), and with information sharing between district health boards (DHBs) and medical centres.

National Medical Warning System[2]

17. The MWS is an alert service linked to the patient National Health Index numbers, and is designed to warn health and disability support services of any known risk factors that may be important when making clinical decisions about individual patient care. The MWS contains the following features: medical alerts (such as health conditions), healthcare event summaries, contact details, donor information, and medical warnings (such as allergies).

18. The responsibility for maintaining the content of the MWS rests primarily with its users, ie, healthcare providers. However, currently there is inconsistency in the way in which warnings are managed, with each DHB having adopted its own processes and delegations as to what notifications can be added and by whom.

19. As well as adding an alert to the system directly, another way for information to be added to the MWS is to report any adverse drug reactions to CARM (the Centre for Adverse Reactions Monitoring).

[1] Flucloxacillin is a penicillin-based antibiotic used most commonly to treat skin and wound infections, chest infections, and bone infections.
[2] https://www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/medical-warning-system.

ED visit — Day 1[3]

Assessment and discharge

20. Mr A complained of a sore foot at home and asked his partner, Ms C, if they had any antibiotics. Ms C found some flucloxacillin that had been prescribed for a family member but had expired two years previously, and gave Mr A two tablets. Shortly after taking them, Mr A began to experience itchy skin and shortness of breath, and collapsed. Ms C telephoned 111 for an ambulance, and Mr A was taken to the ED, along with Ms C, arriving at 2.30pm. He was given oxygen and allergy medication during his ambulance journey.

21. Mr A was seen by ED registrar Dr E, who documented Mr A's presentation as:

> "Patient presented after a collapse without [loss of consciousness]. Has had a sore toe and decided to take some out of date flucloxacillin. Went cleaning the house and about thirty minutes afterwards started developing itchiness of his ears. Itchiness spread throughout body. Started to feel [short of breath] and constricting of his neck … [W]ent to the bathroom feeling nause[ou]s and collapsed to the ground because he felt so weak."

22. It was noted by Dr E that Mr A's symptoms had since improved, and the plan was made for a blood and urine test to be taken, along with an ECG (a test for heart abnormalities) and a chest X-ray, and to monitor Mr A for any re-developing symptoms.

23. Mr A's blood tests came back unremarkable, and his X-ray appeared similar to previous X-rays that had been undertaken. His sore foot (for which he had taken the flucloxacillin) was examined, and a wound on it was washed and dressed and topical antibacterial cream applied. A period of observation and an examination found nothing abnormal, and his vital signs were "reassuring", and Dr E cleared him for discharge at 4.48pm.

24. The discharge was documented as: "Advised if chest pain/abdo[minal] pain to represent to ED. Topical chlorsig [antibacterial cream] on wound. ?? advised possible allergy to flucloxacillin."

25. Dr E told HDC that she cannot remember exactly what she told Mr A and his family about his presentation to ED. She stated that she advised Mr A that his presentation was most likely due to an allergic reaction to the flucloxacillin, and she would have suggested a GP follow-up, and also return precautions (when to return to the ED) for other symptoms such as chest pain or further difficulty breathing, as well as return precautions in regard to developing signs of cellulitis on his toe. Dr E stated:

> "At the time I 100% believed that [Mr A] had understood that his presentation was most likely due to an allergy to flucloxacillin and not related to the medication being outdated. I also believe that I discussed that this would represent an allergy to penicillin and that he should not take these medications again."

[3] Relevant dates are referred to as Days 1 and 21 to protect privacy.

26. Ms C confirmed to HDC that both she and Mr A were told in the ED that Mr A had had an allergic reaction to flucloxacillin. However, Dr E did not provide Mr A with information regarding flucloxacillin coming in different forms (ie, that he would also be allergic to the intravenous form of flucloxacillin as well as the tablet form), and no written discharge advice was provided to Mr A or his partner.

27. There is no documentation of what Mr A and his partner were told, and also no discharge summary for Mr A's presentation to the ED.

Recording of allergy and follow-up actions

28. Mr A's new potential drug allergy to flucloxacillin was not added to the national Medical Warning System, or HVDHB's own drug alert system.

29. HVDHB told HDC that all doctors (both RMOs and SMOs[4]) are able to add a drug alert onto "Concerto" (the DHB's electronic patient management system), with a tick box option to make the alert a "National Alert" via the Medical Warning System. However, no guidelines or policies were in place at the DHB on when and how to enter a drug alert to a patient record directly.

30. Dr E told HDC:

> "In regards to my knowledge of reporting adverse reactions at the DHB, I was aware of the incident form processes for adverse events that occur in the workplace. I was not aware of any system for reporting allergic reactions. My practice at the time was to inform the patient that they had experienced an allergic reaction and the importance of avoiding this medication/allergen."

31. HVDHB acknowledged that an "end-to-end" process for suspected and actual drug allergic reaction to a medication is required at the DHB, and stated: "[T]his also needs to be supported by comprehensive policy and protocol which includes effective communication with the patient as well as the use of national alert systems."

32. A copy of the clinical notes from this ED presentation was sent to Mr A's GP practice — Medical Centre 1 — for its information. However, despite Mr A noting down the name of his usual GP, the information was addressed only to "Dr [Medical Centre 1]" and not directly to his GP. There was nothing in the information sent to the GP practice to specifically flag that Mr A had a newly discovered allergy to flucloxacillin, other than Dr E's note "?? advised possible allergy to flucloxacillin", and the diagnosis was listed as "Allergic reaction NOS [not otherwise specified]".

33. In particular, the "advice to GP/patient" section of the notes was blank.

[4] Resident medical officers (junior doctors) and senior medical officers.

Medical Centre 1

34. At the time of events, Mr A was a registered patient of Medical Centre 1, and had been since 2011. As such, the electronic summary of Mr A's visit to the ED was automatically sent to Medical Centre 1 as his GP practice.

35. The usual process at Medical Centre 1 at the time of events was that the patient's usual GP would read the discharge letter, and in the case of an allergy being the discharge diagnosis (as was the case for Mr A's ED visit), this allergy would be added to the "alert" tab in the patient's medical record. In the case of medication-related side effects, reporting to CARM was to be done as indicated.

36. However, Mr A's usual GP was on leave at this time, and as the electronic summary was not addressed to a specific GP, it was sent to an "unmatched" inbox and accidently filed by a practice nurse without being actioned. At the time of events, Medical Centre 1's "Managing Test Results Policy" did not have a process for the management of unassigned results or correspondence.

37. Medical Centre 1 stated:

> "The best explanation we have is that it was a system failure, where the original document was not sent directly to the provider by the hospital and the nurse filed it accidentally as it had appeared in an unmatched provider inbox."

38. Medical Centre 1 told HDC that it was expected that the nurse would forward the letter to the responsible doctor (in this case, the locum covering for Mr A's usual GP), but this did not occur. Medical Centre 1 stated that this case was discussed with the practice nurse, who has no recollection of having filed the summary, as it was a considerable time ago.

39. As a result, the information about Mr A's new potential allergy to flucloxacillin was not reconciled with his patient record at the medical centre, and it was not reported to CARM.

Presentation to Medical Centre Day 21

40. Mr A and his family took a trip to another region with family friends. However, Mr A became lethargic and started to feel unwell.

41. At 9am on Day 21, Mr A presented to Medical Centre 2 accompanied by Ms C, and was seen by Dr F.

42. Dr F noted that Mr A had cellulitis on his right lower leg, possibly originating from the interdigital infection between his toes. Mr A was documented to have chills, a headache, and diarrhoea, and he was unable to drink much because of nausea.

43. On examination, Mr A appeared unwell and had a fever of 38.9°C,[5] a fast heart rate, and low blood pressure.

[5] Usually, a high temperature is considered to be 38°C or above.

44. Dr F told HDC that at this presentation she definitely remembers asking Mr A at least twice whether he had any allergies. She stated that she is sure of this because she was considering giving him oral flucloxacillin in the consultation room, and so asked him before she began to prescribe it. She said that she then changed her mind and considered a "loading dose"[6] of flucloxacillin by injection and asked him again about allergies, and he said no, so she began to prescribe it.

45. However, Dr F stated that she then considered that because Mr A was unwell and on holiday, it could be difficult for people to look after him, so she changed her mind and considered that admittance to ED would be best.

46. The plan was made for Mr A to present to the ED at DHB2 to be admitted for intravenous fluids and antibiotics. Under the "Medical Warnings/Allergies" section of the referral form to the ED, Dr F noted "No adverse reactions known". In a note on Mr A's file made subsequent to these events, Dr F documented that she "had asked [Mr A] and his wife regarding allergies and [they] had said no".

DHB2 ED visit — Day 21

47. Mr A presented to the ED at DHB2 for review of his right lower leg cellulitis at approximately 10am on Day 21, accompanied by his friend, Mr D. It was noted that Mr A had chills, a headache, diarrhoea, and nausea. DHB2 told HDC that at triage, Mr A was assessed for any previous allergies, and Mr A did not advise that he had any. It was documented on the triage form that Mr A had "NKDA" — no known drug allergies.

48. DHB2 told HDC that the usual process at DHB2 is that when a patient presents to the ED, they are seen first by the Triage Nurse, who obtains the patient's full name and date of birth. The patient is then seen by the Clinical Unit Administrator, who double checks the details with the patient and registers their visit into the ED. If the patient is outside of the catchment area of the DHB, their details are searched on the national system.

49. The DHB stated that if there is an alert for the patient, a "red alert triangle" will appear on the system, which would then be brought to the attention of the attending clinical staff.

50. At the time of this presentation, the national database showed three national hospital visits for Mr A, in 2007, 2009, and 2015 respectively. DHB2 told HDC that there was nothing in the database to show that Mr A had visited HVDHB on Day 1, and there were no alerts logged against Mr A's NHI number.

51. The impression was that Mr A had right leg cellulitis and fungal toes. He was assessed by a nurse practitioner, who told HDC that he asked Mr A if had any allergies and if he was on any medications before commencing him on 2g intravenous flucloxacillin as per the DHB's "cellulitis pathway". The nurse practitioner stated that at this time, Mr A noted only that he used inhalers for his asthma. Mr D told HDC that he does recall Mr A being asked by the

[6] A "loading dose" is an initial higher dose of a drug that may be given at the beginning of a course of treatment before dropping down to a lower maintenance dose.

nurse if he was allergic to anything prior to administering the antibiotic, but stated that he could not hear Mr A's response, as Mr A was very quiet and lethargic at this time.

52. Very soon after Mr A was administered the intravenous flucloxacillin, he made a noise as if he was going to vomit, and complained that he was itchy. The nurse told HDC that she then heard Mr A being asked again by the nurse practitioner if he was allergic to anything, and that the nurse practitioner was told that he had no allergies. The flucloxacillin was stopped and Mr A was administered intramuscular adrenaline. The emergency alarm bell was activated and Mr A was then moved to the resuscitation area.

53. Mr D told HDC:

> "It was almost instantaneous [Mr A] started dry wrenching [sic] and coughing so the nurse gave him what looked like an upside down bowler hat in case he spewed …
>
> During [Mr A's] coughing fit the nurse asked me if I knew if [Mr A] was allergic to anything all I could think was our period of time [working together] and to my recollection nothing like this happened with [Mr A] so I said 'No! he shouldn't be' then the nurse took off somewhere then returned not long after. Whilst the nurse was away [Mr A] had gotten off his bed and was standing and using the bed to support himself still having a fit his legs gave out and I caught him by this time I saw the nurse returning so I yelled out to him that [Mr A] has dropped he said we need to get him on the bed which we did."

54. At this point, the emergency medicine consultant took over the resuscitation effort of Mr A. The consultant told HDC that the working diagnosis was of a life-threatening anaphylactic reaction with likely severe bronchospasm (when the airways go into spasm and contract), giving rise to a respiratory arrest and collapse. Efforts were made to oxygenate Mr A using nasal prongs, but his oxygen saturations decreased and so he was anaesthetised and intubated.[7]

55. Very soon after this, no pulse could be found, and CPR[8] was commenced. After nearly an hour of CPR, increasing doses of adrenaline, and direct-current shocks,[9] it was apparent that continuation was futile and CPR was ceased. Sadly, Mr A died at 12.25pm, with his cause of death noted as an acute anaphylactic reaction, secondary to a flucloxacillin allergy.

Further information

Mr A's family

56. When asked about Mr A's knowledge of his allergy to flucloxacillin, Ms C told HDC that both she and Mr A were aware of the allergy. She stated that on Day 21 Mr A was in extreme pain and was not oriented, and hence was not in a state to answer correctly about his drug

[7] Intubation is the process of inserting a tube through the mouth and then into the airway. This is done so that a patient can be placed on a ventilator to assist with breathing during anaesthesia, sedation, or severe illness.
[8] Cardiopulmonary resuscitation.
[9] A treatment that aims to return an abnormal heart rhythm back to a normal pattern.

allergies when asked. Ms C stated: "A lot happened that day, we were on holiday and the day he died was on the day of [a family anniversary], a day we will never forget."

Hutt Valley DHB

57. HVDHB told HDC that this case has highlighted the issues associated with the processes and governance of drug allergy alerts at HVDHB. It stated that the current system was developed over ten years ago and management of alerts was undertaken by a single clinician. The DHB stated that following that clinician's retirement, the system became fragmented.

58. The DHB also stated that from its review of the case, it is reasonably clear that the event that led to Mr A's presentation to HVDHB was an allergy to flucloxacillin. However, it noted that according to the ED notes at the time, there was a doubt in the assessing doctor's mind whether this was a true allergy (as she had documented "possible allergy"). HVDHB stated that it is possible that a "possible allergy" may not have reached the threshold of creating an alert as defined by a medical practitioner, and noted that documenting non-allergies as allergies can create issues with the future use of antibiotics.

59. HVDHB stated:

> "Therefore good governance of drug allergy needs to include an end to end process incorporating education regarding entering alerts, and removing alerts that are not appropriate. Hutt Valley District Health Board is undertaking the work required to develop such a system.
>
> We do sincerely apologise for the distress created for [Mr A's] family."

Medical Centre 1

60. Medical Centre 1 told HDC that it was clear from reviewing Mr A's records that the person who filed his discharge summary did not act appropriately and omitted a potentially serious allergic reaction to the patient's medical warning module on the Practice Management System (PMS). Medical Centre 1 stated:

> "We unreservedly apologise to the family and appreciate the opportunity for the practice to review and improve our policies and procedures to minimise future harm and optimise quality of care."

HQSC

61. HQSC's Medication Safety Expert Advisory Group (MSEAG) met in May 2019 to discuss the governance arrangements for the MWS, the inconsistent use of the MWS, the implications for medication safety, and what the MSEAG should do about the situation. The MSEAG agreed that it is concerned that the MWS is compromised because of the inconsistency in the way warnings are managed between DHBs. The MSEAG noted the lack of government and national oversight to be an issue.

Ministry of Health

62. Dr Ashley Bloomfield, Director-General of Health, told HDC that the Ministry of Health's expectation is that DHBs would report a severe adverse event related to a medicine to

CARM. In turn, CARM will record a "warning" or "danger" alert for individual patients against their unique National Health Index number on the national MWS.

63. Dr Bloomfield stated that this information is accessible to secondary healthcare facilities in New Zealand, and that ED doctors are expected to check the MWS for drug alerts for their patients prior to prescribing. He also noted that DHBs are able to add warnings directly to the MWS in situations where healthcare providers need to be aware of the presence of any known risk factors that may be important when making clinical decisions about patient care.

64. Dr Bloomfield told HDC that there is no centralised governance over MWS data,[10] and that processes and standards for recording medical warnings vary across DHBs. He stated:

> "The lack of centralised governance over the MWS is acknowledged and the Ministry has convened a MWS Working Group to make recommendations for improving MSW data quality, and with an initial focus on drug alerts. This is likely to involve the development of a Health Information Standards Organisation standard for recording drug alerts to the MWS and the promotion of more consistent processes across DHBs."

Royal New Zealand College of General Practitioners

65. The Royal New Zealand College of General Practitioners (RNZCGP) was approached regarding its expectations of a GP practice when notified (by way of an ED discharge summary) of a new drug-related allergic reaction. RNZCGP told HDC that if notification came back to a GP that there had been an ED presentation because of a significant drug-related allergic reaction, then the expectation would be that this patient information would be reconciled in the patient's PMS file.

66. RNZCGP stated:

> "Indicator 10.1 of the Colleges Foundation Standards states that 'the practice ensures all medicines prescribed, administered or supplied are recorded in the Practice Management System (PMS). Medical Warnings are noted.' Indicator 10.4 states that 'The practice undertakes medical reconciliation in a timely manner'. As such, recording an allergic reaction would be an expected standard."

67. When asked if a GP or GP practice would be expected to report the reaction to CARM, RNZCGP said that this would not necessarily be the case. If it was considered serious enough to warrant a CARM report, then the assumption would be that this would be done or completed by the service to which the patient presented — in this case ED or the DHB service. RNZCGP stated: "[A]gain, there is no clarity as to where responsibility sits however generally it would be the service the patient first presented to that would be considered for reporting."

[10] With the exception of Child Protection Alerts and CARM's role in verifying and creating alerts for adverse reactions about which it is advised.

68. RNZCGP told HDC that it is not aware of any expectations that GPs should enter patient allergy information against a patient's NHI number via the national MWS, and stated that most GPs would be unaware and unable to access the MWS or add information to it.

Responses to provisional opinion

69. Mr A's brother, Mr B, and Ms C were provided with the opportunity to comment on the "information gathered" section of the provisional opinion. Both Mr B and Ms C told HDC that they had no additional information to add, but noted that they would like to see changes to the MWS as a result of this case.

70. HVDHB was provided with the opportunity to comment on the sections of the provisional opinion that relate to the DHB, and it acknowledged and accepted the findings and recommendations. HVDHB stated:

> "It is pleasing to see HDC acknowledges the weaknesses that exist within the current national alerts system. Although as an organisation we will continue progressing actions to achieve an end-to-end alerts management process, we rely on the implementation of a robust national system to frame our DHB processes and policies that adequately govern alerts ongoing."

71. Dr E had no comments to make on the sections of the provisional opinion that relate to her.

72. Medical Centre 1 was provided with the opportunity to comment on the relevant sections of the provisional opinion, and it noted that it has since undertaken a formal process for change in its policies and alerts.

Opinion: Preliminary comment

73. From the outset, I wish to acknowledge the national systems issues at play in this case, and express my concern about the inconsistencies around the way medication allergies and reactions are recorded across the country. The purpose of the MWS is to warn health and disability support services of any known risk factors such as allergies that may be important when making clinical decisions about individual patient care. The system has been linked to patient National Health Index numbers so that these alerts can be accessed and viewed throughout New Zealand. However, this case is an example of the weaknesses that exist within the current system.

74. My health management specialist advisor, Mrs Julie Patterson, told HDC that regrettably, in spite of national strategies aimed at improving the ability to share health information electronically across all DHBs, this has not yet been achieved. She noted that whilst an alert can be placed against a patient's National Health Index number, it is her understanding that this is not universally used to check patient status. Mrs Patterson stated:

> "Although recognizing it is far from ideal, there is a wide range of issues preventing national sharing of patient health information and it seems that it will be some time before this desired status is achieved."

75. My in-house GP advisor, Dr David Maplesden, also shared these concerns and stated that he believes the main issues at stake in this incident revolve around inconsistencies in use of the reporting systems (which may relate in part to the systems themselves) and the inability to share important health information easily between health providers. Dr Maplesden also noted that research indicates that, at best, only one in ten adverse reactions are being reported in New Zealand.

76. On behalf of the Ministry of Health, Dr Bloomfield acknowledged that there is no centralised governance over MWS data, and that processes and standards for recording medical warnings vary across DHBs. He noted that the Ministry has convened an MWS Working Group to make recommendations for improving MWS data quality, with an initial focus on drug alerts.

77. I note that it is not my role to determine cause of death, and my findings should not be construed as implying that any provider was responsible for, or could reasonably have prevented, the tragic outcome of Mr A's passing. Although without doubt issues with the national system contributed to these events, I nonetheless consider it vital for individual medical centres and DHBs to have their own adequate systems and processes in place for drug and medication allergies, to ensure that staff are supported adequately in their decision-making and reporting requirements. In addition, staff are required to communicate clearly to their patients in a way that allows the patient to fully understand the information being provided, as per the Code.

78. I will draw upon advice from Dr Maplesden, Mrs Patterson, and emergency medicine specialist Dr Vanessa Thornton when considering the care provided to Mr A by HVDHB and Medical Centre 1.

Opinion: Hutt Valley DHB

Introduction

79. Mr A presented to the ED on Day 1, after taking two tablets of expired flucloxacillin for a sore foot and experiencing itching and shortness of breath. He was seen at the ED by Dr E, and the following tests were taken: blood, urine, ECG, and a chest X-ray. Mr A's foot was examined, and a wound was washed and dressed and topical antibacterial cream applied. He was cleared for discharge by Dr E that same day, after a period of observation and an examination found nothing abnormal and his vital signs were "reassuring".

80. In this case, I consider that the clinical care provided to Mr A in response to his presentation was appropriate. In particular, I note the advice from health management specialist Mrs Patterson that the medical care provided to Mr A for his physical condition appeared to be

well organised and well executed, and Dr Thornton's advice that the care provided by Dr E was within the expected level of care for an ED registrar (with the exception of documentation, which I will address further below).

81. My opinion will therefore focus on the systemic context in which care was provided to Mr A — most notably, the actions (or lack thereof) taken in response to Mr A's newly discovered allergy and the lack of cooperation between HVDHB and other providers.

Cooperation between providers — breach

Lack of "end-to-end" process for allergies

82. As noted above, the MWS is an alert service linked to patient National Health Index numbers, and is designed to warn health and disability support services of any known risk factors that may be important when making clinical decisions about individual patient care. This includes, but is not limited to, medical warnings such as allergies.

83. The responsibility for maintaining the content of the MWS rests primarily with its users, the healthcare providers. Dr Bloomfield, on behalf of the Ministry of Health, stated that its expectation is that DHBs would report a severe adverse event related to a medicine to CARM. In turn, CARM will record a "warning" or "danger" alert for individual patients against their unique National Health Index number on the national MWS. Dr Bloomfield also noted that DHBs are able to add warnings directly to the MWS in situations where healthcare providers need to be aware of the presence of any known risk factors that may be important when making clinical decisions about patient care.

84. On Day 1, Mr A presented to the HVDHB ED after having an apparent reaction to flucloxacillin. However, Mr A's new potential drug allergy to flucloxacillin was not added to the national MWS, or HVDHB's own alert system. Mr A then presented to DHB2 on Day 21, but there was nothing in the database to show that Mr A had visited HVDHB on Day 1, and there were no alerts logged against Mr A's NHI number to show that recently he had had an allergic reaction to flucloxacillin. Mr A was administered intravenous flucloxacillin as per DHB2's "cellulitis pathway", and, sadly, he died of an acute anaphylactic reaction.

85. HVDHB told HDC that all doctors are able to add a drug alert onto "Concerto", with a tick-box option to make the alert a "National Alert" via the MWS. However, no guidelines or policies were in place at the DHB on when and how to enter a drug alert into a patient record directly. Dr E told HDC that she was not aware of any system for reporting allergic reactions.

86. Mrs Patterson advised:

> "It would be expected that the DHB would have clinical policy, (or protocol arising from policy), providing direction as to what is expected of staff when a patient experiences an actual or suspected allergic reaction to a medication. Whilst this is a clinical matter, from a systems perspective it is expected that there would be an 'end to end' process to deal with such events. The scope of that process should cover from effective communication with patient, family/whānau and the general practitioner, through to notation in the patient's medical file, and making national notification."

87. HVDHB told HDC that this case has highlighted the issues associated with the processes and governance of drug allergy alerts at HVDHB, and it acknowledged that an "end-to-end" process for suspected and actual drug allergic reaction to a medication is required at the DHB.

88. Mrs Patterson stated that in her view, the HVDHB policy setting does not direct staff adequately as to the actions required when a patient experiences an actual or suspected allergic reaction to a medication. Further, she noted that HVDHB does not have an "end-to-end" process to be implemented in such cases, which she stated should be supported by comprehensive policy and protocol, commencing with effective communication with the patient through to use of the national alert systems. Mrs Patterson advised:

> "It is my assessment that current policy settings will not adequately direct clinical staff as to the expected practice standards and therefore is inadequate to protect patient safety. I consider this to be a significant departure from what should be expected of any DHB."

89. Mrs Patterson noted that policy and protocols need to be developed to guide staff to implement this process successfully, thus protecting patients who experience an allergic reaction to a medication from future harm. I agree.

90. I do acknowledge that Mr A's initial reaction was not definitively indicative of a severe anaphylactic reaction. HVDHB told HDC that it is possible that a "possible allergy" (as the allergy was documented at HVDHB) may not reach the threshold of creating an alert by a medical practitioner as defined, and noted that documenting non-allergies as allergies can create issues with the future use of antibiotics. I accept that the cause and nature of Mr A's allergy was not fully understood at that time.

91. However, I consider that with the ambiguity of possible allergies, it is all the more important to have a process in place at the DHB to assist staff with these decisions. Dr Thornton noted that "good governance of 'possible allergies' [is] important in the care of patients and their future use of antibiotics", and I agree. In this case, the lack of policy meant that there was a lack of clarity around what steps were needed on how to distinguish between the types of allergies (possible or actual, and mild or severe) and the consequent action required.

Communication with GP

92. It is usual practice for summaries of a consumer's presentation to a secondary healthcare facility to be forwarded to the consumer's usual GP. This is done (usually via a discharge summary) to ensure that any important new information can be reconciled in the patient's record at the GP practice, and for the GP to follow up if necessary. It is also done in the interest of continuity of care.

93. In this case, there was no discharge summary of Mr A's presentation to ED on Day 1, and, instead, a copy of the ED clinical notes was sent to Mr A's GP practice. Despite Mr A noting down the name of his usual GP, the information was instead sent to "Dr [Medical Centre 1]", which meant that the information was not sent directly to his GP's inbox.

94. My in-house GP advisor, Dr Maplesden, advised:

> "If a report is received from secondary care noting the patient has had an adverse drug reaction in hospital, I would expect this information to be prominent in any DHB report and to be transcribed into the PMS [of the GP practice]."

95. However, this information was not "prominent" in the HVDHB report. There was nothing in the information sent to the GP practice to flag that Mr A had a newly discovered allergy to flucloxacillin, other than Dr E's note, "?? advised possible allergy to flucloxacillin", which was amongst all the other notes, and the diagnosis was listed as "Allergic reaction NOS [not otherwise specified]". In addition, the "advice to GP/patient" section of the notes was blank.

96. I consider that in this case (in the context of a newly discovered allergy), the diagnosis should have been specifically flagged to Mr A's GP to ensure that the information would be seen, reconciled in Mr A's patient notes at the practice, and reported to CARM if it was felt to be necessary. In my opinion, this was especially crucial considering that the allergy was not acted upon at HVDHB. I consider that this was a missed opportunity by the DHB to provide for good continuity of care between HVDHB and Mr A's GP.

Conclusion

97. Right 4(5) of the Code stipulates that every consumer has the right to co-operation among providers to ensure quality and continuity of services. In Mr A's case, there was no system in place to guide staff in the actions to take when a patient presents with a suspected or actual medication allergy, including whether Mr A's allergy warranted entry into the MWS. There was an inadequate system for ensuring that allergies were recorded and flagged to facilitate continuity of care for Mr A's future interactions with health services.

98. In addition, HVDHB's communication with Mr A's GP was inadequate. There was no succinct discharge summary of the presentation, and the clinical records were sent to the practice instead of Mr A's GP. The information about his new allergy was not flagged clearly, and there was no advice to the GP.

99. I note Mrs Patterson's advice that a DHB would be expected to have a clinical policy providing direction as to what is expected of staff when a patient experiences an actual or suspected allergic reaction to a medication. She advised that the scope of that process should cover effective communication with the patient and family/whānau (discussed further below) and the general practitioner, through to notation in the patient's medical file, and making national notification.

100. No such policy was in place at HVDHB and, as a result, there was a lack of clarity around the nature of Mr A's allergy and whether it should have been entered into the MWS. There was also a missed opportunity for this information to be flagged clearly to Mr A's GP and acted upon. It is clear that the system in place at HVDHB at the time, in regard to allergic reactions, did not allow for co-operation among providers to ensure quality and continuity of services. It follows that I find HVDHB in breach of Right 4(5) of the Code.

Communication with Mr A — adverse comment

101. Dr E told HDC that at the time of Mr A's discharge from HVDHB, she told Mr A that his presentation was most likely due to an allergic reaction to flucloxacillin. She stated that she believed that Mr A had understood that his presentation was likely due to an allergy to flucloxacillin and not related to the medication being outdated. She also believes that she discussed with him that this would represent an allergy to penicillin, and that he should not take penicillin medications again.

102. The clinical records for this conversation state: "??advised possible allergy to flucloxacillin." There is no evidence in the documentation as to what other information was provided, or of Mr A's understanding of the information he was given.

103. Ms C told HDC that both she and Mr A were told in the ED that Mr A had had an allergic reaction to flucloxacillin. However, she said that Dr E did not provide Mr A with information regarding flucloxacillin coming in different forms, and no written discharge advice was provided to Mr A or his partner to supplement any verbal information that he was given.

104. Mr A presented to both Medical Centre 2 and DHB2 on Day 21, and was asked multiple times about his allergy status. However, Mr A did not inform any of the providers at these facilities of his allergy to flucloxacillin, and, sadly, he died after being administered intravenous flucloxacillin for the treatment of cellulitis.

105. Mrs Patterson noted that in the context of a new allergy, it is the patient and their family/whānau who are most reliably able to carry and communicate their own information on allergies. She stated:

> "Therefore, the health system has an absolute responsibility to ensure that patients who experience an adverse reaction, or are suspected of having experienced an adverse reaction, to a medication:
>
> - Have a full understanding of their experience.
> - Understand the possible implications if they were to have that medication in the future.
> - Are able, when being prescribed medications in the future, (whether or not they are questioned about allergies), to advise the prescriber of the details of their allergy i.e. name the medication and their previous adverse reaction to the medication/s."

106. HVDHB acknowledged to HDC that an "end to end" process for suspected and actual drug allergic reaction to a medication is required at the DHB, and that this needs to be supported by comprehensive policy and protocol that includes effective communication with the patient.

107. Mrs Patterson noted that while Mr A was informed of his allergy, HVDHB failed to ensure that he fully understood what he had experienced, its cause, and the possible implications of this for the future. She considered this to be "a moderate departure from accepted practice when communicating critical information to a patient".

108. It is difficult to establish what exactly Mr A understood about the nature of his allergy. However, I note that contemporaneous documentation supports a discussion having taken place with Mr A about his allergy, and Ms C has confirmed that she was aware of the allergy. I also note her statement that Mr A was in considerable pain on Day 21 and hence was not in a state to answer correctly about his drug allergies when asked.

109. Based on the above, I consider it is more likely than not that Mr A understood that he had a flucloxacillin allergy. However, I am unable to determine the extent to which he understood the implications of the diagnosis, or the risks if he took flucloxacillin in the future. Mr A did not advise DHB2 staff that he had any allergies on the day he presented. I acknowledge that he was in significant pain, which may have affected his ability to respond fully.

110. While I am satisfied that HVDHB had a discussion with Mr A about his allergy, I cannot make a finding about the detail discussed or whether HVDHB's communication was appropriate in the circumstances, particularly in the context of Mr A's history of recurrent cellulitis, which is usually treated with flucloxacillin. I remind HVDHB of the importance of ensuring that all communication with patients, particularly in relation to advice as vital as allergy information, is fulsome and documented, and that patients have a good understanding of the implications.

Opinion: Dr E — adverse comment

111. Dr E was the ED registrar who saw Mr A at HVDHB on Day 1 when he presented with a reaction after taking flucloxacillin tablets. My independent health management specialist, Mrs Patterson, advised that from a systems perspective, it appears that the medical care provided to Mr A for his physical condition by the ED staff was well organised and well executed.

112. In addition, my independent emergency medicine specialist advisor, Dr Thornton, stated that in the ED, Dr E completed a full physical examination and a full work-up of other systems, including an ECG, blood tests, and a period of observation to ensure that there was not another cause for the collapse. Dr Thornton advised:

> "[Dr E] noted a mild allergic response to flucloxacillin which resolved with loratadine and oxygen prior to arrival in the ED. [Dr E] concluded that this response was likely to be as a result of flucloxacillin and she decided the best advice was to tell the patient that flucloxacillin could be the cause of the allergy in ED and to avoid this in the future. This is at the expected level for this type of presentation to ED."

113. Taking the above into consideration, I am not critical of the care that Dr E provided to Mr A directly. I also note Dr E's statement that at the time of these events, she was not aware of any system in place at the DHB for the reporting of allergic reactions, and, as outlined above, I consider that the lack of process in place at HVDHB was the main factor in this case.

114. However, I am critical of Dr E's documentation and communication in this case.

115. In her response to HDC, Dr E stated that she advised Mr A that his presentation was most likely due to an allergic reaction to flucloxacillin, and that she would also have suggested GP follow-up. Dr E stated that she also would have discussed that this would represent an allergy to penicillin, and that Mr A should not take penicillin medications again.

116. The only note in Mr A's clinical record about this conversation is "?? advised possible allergy to flucloxacillin". There is nothing in the documentation that summarises what information about the newly discovered allergy Mr A and/or his partner were given upon discharge, or of Mr A's understanding of his allergy.

117. In addition, no information was provided about flucloxacillin coming in different forms, and the verbal advice given to Mr A was not supplemented with written information, such as a copy of his clinical record from the presentation.

118. Dr Thornton considered both the lack of communication and the lack of documentation by Dr E to represent a "mild deviation from the standard of care", and I accept this advice. I remind Dr E of the importance of ensuring that all advice provided to patients, particularly in relation to advice as vital as allergy information, is fulsome and documented.

Opinion: Medical Centre 1 — adverse comment

119. Mr A was a registered patient of Medical Centre 1 at the time of these events, and had been since 2011. On Day 1, Mr A presented to HVDHB's ED after having a reaction to some out-of-date flucloxacillin tablets he had taken. There was a query regarding a possible allergy to flucloxacillin, and he was discharged.

120. A copy of the record of Mr A's ED visit was sent automatically to Medical Centre 1, as his registered GP practice. However, it was addressed to "Dr [Medical Centre 1]" instead of Mr A's usual GP and, as a result, the record was sent to an "unmatched" inbox at the practice as opposed to the GP's inbox.

121. My in-house advisor, GP Dr David Maplesden, advised that in the primary care setting, a suspected drug reaction would normally be entered in the Allergy/Alert module of the practice's PMS. This information would then be pre-populated in any subsequent e-referrals (eg, to secondary care) and would also transfer to another PMS if the patient transferred to another practice. In addition, Dr Maplesden stated that best practice would be for the reaction to be notified to CARM.

122. Dr Maplesden advised:

> "If a report is received from secondary care noting the patient has had an adverse drug reaction in hospital, I would expect this information to be prominent in any DHB report and to be transcribed into the PMS."

123. Medical Centre 1's usual process at the time of events was consistent with Dr Maplesden's expectation, with the patient's usual GP being expected to read any discharge documentation received from a secondary care facility, and, if applicable, add to the "alert" tab in the patient's medical record the details of any allergy. In the case of medication-related side effects, reporting to CARM was also to be done as indicated.

124. However, in this case, a practice nurse looking after the unmatched inbox filed the documentation without actioning it. Medical Centre 1 told HDC that it was expected that the nurse would forward the letter to the responsible doctor (in this case, the locum covering for Mr A's usual GP), but this did not occur. As a result, the information about Mr A's new potential allergy to flucloxacillin was not reconciled in his patient record at the medical centre, and it was not reported to CARM.

125. Dr Maplesden advised:

> "Given the content of the ED discharge summary (presentation with possible/likely anaphylactoid reaction to flucloxacillin) I believe the reaction needed to be promptly coded into the allergy module of the PMS once the discharge summary was reviewed. The failure to do this … I believe would be met with moderate disapproval by my peers."

126. Dr Maplesden noted that while the failure to record the allergy in the appropriate module of the PMS was not relevant to Mr A's death, there was potential for harm if he was subsequently prescribed flucloxacillin at the practice because the allergy had not been recorded, or if records were sent to other providers with the current code of NKA (no known allergies). In addition, Dr Maplesden noted that this incident raises the issue of whether important information contained in non-assigned clinical correspondence has been appropriately incorporated into the relevant PMS module for other patients.

127. I accept this advice, and I also note that Indicator 10.1 of the RNZCGP "Foundation Standards" states that "the practice ensures all medicines prescribed, administered or supplied are recorded in the Practice Management System (PMS). Medical Warnings are noted", and that Indicator 10.4 stipulates that "[t]he practice undertakes medical reconciliation in a timely manner".

128. There was clearly a failure by Medical Centre 1 in this case, in that Mr A's new allergy information was not added to the PMS as it should have been, and instead was filed without action. I also note that at the time of the events, the practice had no process for the management of unassigned results or correspondence to guide its nursing staff. As noted by Dr Maplesden above, this omission allowed for potential future harm to Mr A. It was also a missed opportunity for Mr A's allergy to be reported to CARM.

129. However, I acknowledge that the electronic record of the hospital visit was sent to the practice rather than to Mr A's GP, and that information about Mr A's new allergy to flucloxacillin was not prominent. In particular, the diagnosis was listed as "Allergic reaction NOS [not otherwise specified]" and the "advice to GP/patient" section of the notes was blank.

130. Additionally, I note Dr Maplesden's advice that as there was no request for the GP practice to notify CARM, it was reasonable for the practice to assume that the ED clinicians had done this themselves.

131. This case highlighted a weakness in the system in place at Medical Centre 1 at the time, in particular in relation to the management of documentation sent to its unmatched provider inbox. Medical Centre 1 has since made relevant changes to its policy (as outlined below).

Changes made since events

Hutt Valley DHB

132. HVDHB stated that significant progress improvement is planned regarding the process and governance of drug allergy alerts at HVDHB. HVDHB stated:

> "This work will occur in the context of any enhancements to the systems advised by the Ministry of Health, the Health Quality and Safety Commission and the Centre for Adverse Reactions Monitoring (CARM) … Local improvement will be informed by the national work regarding changes and enhancements to the existing MWS system and the proposed establishment of permanent national governance arrangements for national medical warning and alerts."

133. Since this incident, HVDHB's Clinical Head of Department has recommended to its RMOs that they include in their documentation a generic statement such as "patient and/or family member has verbalized understanding of the discharge instructions".

134. In addition, the Clinical Director for Medical and Acute Services now gives registrars from all specialities yearly face-to-face training on drug allergy alerts, including showing them how to load drug allergy alerts into the system.

Medical Centre 1

135. Medical Centre 1 told HDC that as a result of this serious and tragic incident, the practice reviewed and altered its relevant policies and procedures, and undertook a clinical staff meeting to ensure that all staff were aware of this case. Medical Centre 1 noted that the staff member who filed the discharge summary was present at the meeting.

136. In particular, the practice amended its inbox policy to include a procedure for addressing discharge summaries and correspondence that includes information about possible/ confirmed allergic reactions or medication side effects/reactions. Of note, the policy now

stipulates that "all unassigned results/correspondence that enter this inbox are checked by a nurse daily and these are then forwarded to the doctor responsible for that patient".

137. Medical Centre 1 also undertook an audit to ensure that the necessary actions in a discharge summary had been carried out in other cases. Using a sample of 20 randomly selected filed discharge summaries, 17 had been assessed correctly to have information in them that required action, while the other three did not require further action. Medical Centre 1 stated:

> "As a result of this audit, I feel our clinicians are providing a high level of care when it comes to following through on actions required for patents who have had care provided in secondary care. There is always room for improvement, but we hope that our amended and updated policy will provide our clinicians with direct procedural guidance."

Recommendations

138. I recommend that HVDHB:

a) Develop an "end-to-end" process for both the ED and general hospital setting, for when a patient presents with a new actual or suspected drug/medication allergy in the ED and for when a patient experiences an actual or suspected drug/medication allergy at the DHB. Using the guidance provided by my independent advisors, this process should be supported by comprehensive policy and protocol, and the scope of the process should cover from effective communication with the patient, family/whānau, and the general practitioner, through to notation in the patient's medical file, and making national notification.

   The process should also include guidance for staff on how to counsel patients about new allergies, including the type of information (both written and verbal) that should be given (ie, that the drug can be in different forms, and is a part of a larger group of medication, if applicable).

   The process (and the supporting policies and protocols) should then be updated and amended accordingly in light of any changes and amendments made to the national MWS.

   Evidence that the process has been developed is to be sent to HDC within nine months of the date of this report.

b) Consider designing and implementing a new discharge form that incorporates the following:

- A prompt about any information given to a patient at discharge (both written and verbal, including whether a copy of the discharge summary was given the patient);
- A section that specifically flags any findings that the patient's GP should be made aware of and/or action; and
- A "problem list/clinical issues/diagnoses schedule" that could be pasted into discharge summaries to avoid omissions.

The outcome of this consideration is to be sent to HDC within six months of the date of this report.

c) Undertake an internal review into why Mr A's ED clinical record was sent to the Medical Centre (under "Dr [Medical Centre 1]") rather than Mr A's usual GP, and consider how HVDHB can make changes to ensure that future records are sent directly to a patient's GP. The outcome of this review, and details of the changes made as a result, are to be sent to HDC within three months of the date of this report.

d) Create a package of educational material to be used throughout departmental teaching sessions and staff inductions at HVDHB, to address the general standards of practice expected in relation to medication allergy reporting and follow-up actions, as well as the importance of communication with patients and whānau, and with a patient's GP. The package should include the new "end-to-end" process developed in (a) above, as well as an anonymised version of this report as a case study. Evidence that this has been done is to be sent to HDC within nine months of the date of this report.

e) Undertake intermittent audits of the adequacy and observance of HVDHB policies relating to new allergies that require action. This audit should observe:

- Whether the allergy was entered into HVDHB's own alert system and/or the national MWS and/or reported to CARM;
- Details of whether there is adequate documentation of the information provided to the consumer and/or the consumer's family/whānau, including if there is adequate documentation of the consumer's understanding of the allergy; and
- Whether the allergy was specifically flagged to the consumer's GP.

The outcome of the audits is to be sent to HDC within 12 months of the date of this report. If the audit data indicates that there are still weaknesses in the process, HVDHB is to report to HDC on the further changes that will be made to address this.

f) Provide Mr A's family with a written apology for the breaches 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.

139. I acknowledge that Medical Centre 1 has made changes to its policies as a result of this case, and that it has provided training to its staff on the new policies and undertaken an audit to ensure that the necessary actions in a discharge summary had been carried out in other cases. In addition, I recommend that Medical Centre 1:

a) Undertake a further audit of 20 randomly selected unassigned discharge summaries (or other unassigned items of clinical correspondence if there are insufficient discharge summaries) and report on whether management of these items is in accordance with the relevant practice policy, to ensure the long-term adherence of staff to its new policies.

   The outcome of the audit is to be sent to HDC within four months of the date of this report. If the audit data indicates that there are still weaknesses in the process, Medical Centre 1 is to report to HDC on the further changes that will be made to address this.

b) Provide training to its staff on its electronic reporting tool and the BPAC article referred to in Dr Maplesden's advice. Evidence that this has been done is to be sent to HDC within four months of the date of this report.

c) Provide Mr A's family with a written apology for the aspects of the care that it provided that fell below accepted standards. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

Follow-up actions

140. In January 2022, the Ministry of Health wrote to HDC with an update on the improvements being made to the Medical Warning System. It stated:

> "The Medical Warnings Working Group has endorsed work to categorise warnings in the MWS so they can be more consistently identified and used by clinical decision support systems … In addition, the Ministry has recently approved the development of a user interface to demonstrate the approach that should be taken to categorise warnings when they are added to the MWS."

I will be writing to the Ministry of Health to request a further update on the working group's progress on improvements after their next meeting.

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

142. A copy of this report with details identifying the parties removed, except the experts who advised on this case and HVDHB, will be sent to HQSC, the Australasian College for Emergency Medicine, the Ministry of Health, the Centre for Adverse Reactions Monitoring (CARM), Medsafe, and the Royal New Zealand College of General Practitioners, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

143. At the time of sending HQSC an anonymised copy of this report, I will be requesting an update on any further meetings held by the Medication Safety Expert Advisory Group about the MWS. I will also ask whether, in light of this case and the concerns identified in this report, the group has any further recommendations or ideas for improvements in the way allergies are reported and actioned nationally.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from health management specialist Mrs Julie Patterson:

"Advice to the Health and Disability Commissioner
Complaint: Hutt Valley DHB
HDC Reference: C19HDC02039
Independent Advisor: Julie Patterson

1.0 Introduction

I have been asked by the Health and Disability Commissioner (HDC) to provide non-clinical advice on the service provided to [Mr A] (deceased) at Hutt Valley District Health Board (HVDHB) on [Day 1].

I am not aware of any personal or professional conflicts in relation to advising the Commissioner on the service provided to [Mr A].

I have recently completed over 45 years in the New Zealand public health service over which time I worked as a registered nurse, a clinical manager, a general manager of hospital services, a manager and advisor within the Ministry of Health and as a general manager planning and funding. For the last eleven years I worked as a DHB Chief Executive.

I hold the qualifications — NZ Registered General and Obstetric Nurse (RGON), Bachelor of Arts (BA) and Master of Business Administration (MBA). I have a longstanding interest and active involvement in, improving patient safety and the quality of service across health providers.

The HDC has asked that I advise *'from a systems perspective, whether I consider the care provided to [Mr A] by HVDHB and [DHB2] was reasonable in the circumstances, and why'.*

In particular I have been asked to comment on:

For HVDHB:

1. The adequacy of the care provided to [Mr A] at [the public hospital] on [Day 1], from a systems perspective.
2. The adequacy of HVDHB's existing policies and procedures related to notifying and recording adverse reactions, and whether these were adhered to in this case.
3. Any other matters in relation to the care provided by [the public hospital], from a systems perspective, that I consider warrant comment or amount to a departure from accepted practice.

For Both DHBs:

1. My perspective on the ability of HVDHB and [DHB2] to share important health information between them in the circumstances of this case.
2. Whether I consider there may be systemic shortcomings in the way the nationwide Medical Warning System is being utilized by DHBs.
3. My recommendations for any system improvements to either or both DHBs to guard against a reoccurrence of a similar case in the future.

The HDC provided me with the following documents to review:

1. Referral from [the Coroner] dated 21 October 2019
2. HVDHB's response to HDC dated 18 November 2019
3. [DHB2's] responses to HDC dated 28 November 2019 and 26 August 2020
4. Clinical records from HVDHB covering the period [Day 1]
5. Clinical records from [DHB2] covering period [Day 21]
6. Relevant policies of HVDHB
7. Relevant policies [DHB2]

I have read and believe I have complied with the HDC's Guidelines for Independent Advisors.

2.0 Background

On [Day 1], [Mr A], [in his fifties], was taken to the HVDHB Emergency Department (ED), by ambulance, following collapse at his home. [Mr A] reported that prior to his collapse he had taken for a sore toe, some expired flucloxacillin, which he had at home. Shortly after taking the medication he experienced symptoms including itching, shortness of breath and nausea leading to his collapse. Ambulance staff administered oxygen and oral loratadine, an anti-histamine used to treat allergic reactions.

[Mr A] was assessed by ED medical staff, with the most likely cause of his collapse identified as an allergic reaction. A plan was made to administer adrenaline if required. Following a period of observation [Mr A] was discharged, having not required adrenaline.

On discharge [Mr A] was advised that he had possibly experienced an allergic reaction to the flucloxacillin he had taken and was 'told not to take any more of the flucloxacillin tablets'. No allergy alert was entered in the national data base.

[Mr A's] clinical notes record diagnosis as 'Allergic Reaction NOS'. NOS is assumed to mean 'not otherwise specified'.

Twenty days later, on [Day 21], [Mr A] who was [on holiday], was referred from primary care to [DHB2] feeling unwell and with a sore toe. This referral recorded no known allergies. [Mr A] was assessed and diagnosed by [an] ED nurse practitioner as having cellulitis.

[Mr A] again reported having no drug allergies and was given intravenous flucloxacillin as per the hospital's cellulitis protocol. [Mr A] immediately experienced a severe anaphylactic reaction and following extensive, unsuccessful resuscitation attempts, [Mr A] died.

Following his death [Mr A's] wife reported that she was unaware of [Mr A] having any allergies.

3.0 Scope

From a systems perspective this advice is presented in line with the specific questions posed by the HDC in relation to both HVDHB and [DHB2]. Limited comment is offered in relation to DHBs' ability to share patient information and the use of the national databases as I do not have expertise, or in depth knowledge, in this area.

4.0 Advice — [Mr A's] Care at [the public hospital] and HVDHB's policy settings.

4.1 Care at [the public hospital]

In my view, from a systems perspective, it appears that the medical care provided to [Mr A] for his physical condition, by the ambulance staff and the ED staff, was well organised and well executed.

From the information provided I am less confident about the effectiveness of the communication with [Mr A] and whether or not the advice provided to [Mr A], at the time of his discharge, was adequate.

The [HVDHB] ED nursing notes for [Mr A] at 1447 hours state 'wife at bedside'. It is unclear whether or not [Mr A's] wife was still present at 1646 hours when [Mr A] was cleared for discharge. At this time the medical ED notes record '?? advised possible allergy to flucloxacillin'. It is not stated who was advised, i.e. [Mr A] alone or he and his wife. Further, it is unclear what the two question marks relate to. Is there a question as to whether or not advice was given? Or, do the question marks relate to the possibility of an allergy?

It is reasonable to assume the latter since … HVDHB's response … dated 18 November 2019 … states 'This discussion [at discharge] included the advice to avoid further use of flucloxacillin given the suspected allergy'. However, it is not stated whether 'this discussion' took place with [Mr A] alone, or if his wife was also present, to receive this advice.

From the tragic events which occurred only 20 days later it appears that neither [Mr A], nor his wife, had any idea that he had a possible allergy to flucloxacillin. From the information provided, one could well imagine that [Mr A] was left with the impression that his reaction related to the expired nature of the drug he had taken, and/or that it had been prescribed for someone else, rather than his adverse reaction being due to the drug itself.

The system should expect any communication with a patient, which is as important as a possible allergy, would take account of the patient's language competency and health literacy. [Mr A's] ethnicity is stated [and] English may not have been his first language. There is no evidence in the documentation as to [Mr A's] understanding of the information he was given.

4.2 Policy Settings HVDHB

From the material provided the expectations on clinical staff relating to possible allergic reaction to a medication cannot be ascertained.

It would be expected that the DHB would have clinical policy, (or protocol arising from policy), providing direction as to what is expected of staff when a patient experiences an actual or suspected allergic reaction to a medication. Whilst this is a clinical matter, from a systems perspective it is expected that there would be an 'end to end' process to deal with such events. The scope of that process should cover from effective communication with patient, family/whānau and the general practitioner, through to notation in the patient' s medical file, and making national notification.

There is no evidence of such an 'end to end' process from the material provided. The only policy provided by HVDHB is a Policy for entering and reviewing potentially sensitive electronic patient alerts. Although it seems unlikely that HVDHB's policy expectations are limited to a single policy, covering only one aspect of what should be the 'end to end' process described above, this has to be considered the case, since the HDC requested 'relevant policies'.

Now, turning to the policy provided. This policy, whilst it does not outline its scope or coverage, relates primarily to notifications, (and deactivation) of alerts on the DHB's patient management system, WebPAS, (which in turn provides basic demographic information to the national dataset), and its clinical information system Concerto. Excluding the national data set, these data bases, although shared by some other central region DHBs, are not able to be accessed beyond that region.

Further, the policy (which in its content and form is more akin to a protocol) is unclear. Importantly it seems that the scope of the policy does cover drug alerts as, in the background, it states 'The use of the Alerts facility in WebPAS for Drug and Food sensitivities and allergies, and for infection control issues is well established at HVDHB'. It goes on however, to deal with 'other alerts' and in the Policy section explicitly states 'All requests for an alert (other than Drug or infection control alert) to be placed on an individual patient record should be passed to the quality unit'. No information is provided as to who should manage these exclusions and how, other than in Appendix 1, (a flow chart for alert addition and an alert request form) does include Allergy and Possible Allergy as categories for alerts.

In addition to the absence of direction on the explicit exclusions, Appendix 1 provides different direction on the commencement steps of the process. The flowchart directs the alert to the Quality Department whereas the Alert Request Form directs the reader

to an Alert email (which may be the Quality Department) or to a specific staff member in the Emergency Department.

The policy provided gives no insight as to HVDHB's expectations as to alerts for inclusion in the national data set or notifications to the national Centre for Adverse Reactions Monitoring. It appears from a screen shot (provided by [DHB2]) that [Mr A's] presentation to [HVDHB] ED was not recorded in the national database, so an alert was not recorded in that database. In addition in a Report to the Coroner, [HVDHB] states 'With respect to the documentation of Alerts, it is not the ED policy to have registrars enter Alerts on our DHB system. In addition these are not national alerts'.

In my view, HVDHB policy setting does not adequately direct staff as to the actions required when a patient unfortunately experiences an actual or suspected allergic reaction to a medication. Further based on the material provided, including the written responses to both the Coroner and the HDC, it appears that HVDHB does not have an 'end to end' process in place to assist staff to lessen the possibility of future harm to patients as a result of an allergic reaction.

6.0 National Systems

Regrettably, in spite of national strategies aimed at improving the ability to electronically share health information across all DHBs this has not yet been achieved. Whilst an alert can be placed against the patient's National Health Index number, it is my understanding that this is not universally used to check patient status, especially given this system is not a system used for clinical information. Unless a reaction to a drug is notified to the Centre for Adverse Reactions Monitoring, then there is no electronic means of a hospital outside of the patient's usual DHB, or maybe region, accessing this information.

I am not able to provide advice on how DHBs generally use these systems or to how sharing of clinical information between DHBs could be improved. I do know that it is an extremely complex issue, given the wide range of systems already in place across DHBs and to be achieved would require significant investment.

7.0 Conclusion

Although recognizing it is far from ideal, there is a wide range of issues preventing national sharing of patient health information and it seems that it will be some time before this desired status is achieved.

In this context it is the patient and their family/whānau who are most reliably able to carry and communicate their own information on allergies. It is the patient and their family/whānau who are in the best position to protect their safety through preventing adverse reactions to medications they know they are allergic to.

Therefore, the health system has an absolute responsibility to ensure that patients who experience an adverse reaction, or are suspected of having experienced an adverse reaction, to a medication:

- have a full understanding of their experience.
- understand the possible implications if they were to have that medication in the future.
- are able, when being prescribed medications in the future, (whether or not they are questioned about allergies), to advise the prescriber of the details of their allergy i.e. name the medication and their previous adverse reaction to the medication/s.

In my view it appears that whilst [the public hospital], from a systems perspective, provided appropriate physical care to [Mr A] and did inform him (possibly in the presence of his wife) of his possible allergy to flucloxacillin they failed to ensure that he fully understood what he had experienced, its cause and the possible implications of this for the future. I consider this inadequate communication to be a moderate departure from accepted practice when communicating critical information to a patient.

Further, based on the information provided, it appears that HVDHB does not have an 'end to end' process to be implemented when a patient experiences, or is suspected of having, an allergic reaction to a medication. This 'end to end' process should be supported by comprehensive policy and protocol, commencing with effective communication with the patient through to use of the national alert systems. In my opinion, from a systems perspective, HVDHB policy and process, based on the information the DHB has provided, is inadequate. It is my assessment that current policy settings will not adequately direct clinical staff as to the expected practice standards and therefore is inadequate to protect patient safety. I consider this to be a significant departure from what should be expected of any DHB.

It is encouraging that HVDHB has advised the Coroner it intended to 're-evaluate how and by whom Alerts are entered, to ensure allergies are recorded for future care providers'. In my view however, HVDHB needs to take considerably more action in that it needs to design an 'end to end' process. Policy and protocols need to be developed to guide staff to successfully implement this process, thus protecting their patients who experience allergic reaction to a medication, from future harm. [DHB2] could be requested to share their quality policies and protocols with HVDHB.

I consider the most critical component of this 'end to end' process to be effective communication with patients and their family/whānau. National alerts are important but as they may not always be accessed, patient knowledge will always be the most reliable 'safety net'.

I recommend that to avoid similar tragedy in the future DHB staff need to empower their patients through effective communication. Clinical staff need to not only tell patients of their possible drug allergy but to also make every effort to ensure the patient has the language competency and health literacy to understand the message and therefore be able to actively protect themselves should the situation arise.

Julie Patterson"

Appendix B: Independent clinical advice to Commissioner

The following expert advice was obtained from emergency medicine specialist Dr Vanessa Thornton:

> "I have been asked to provide an opinion to the commissioner on case number C19HDC0209 and I have read and agree to follow the commissioner's Guidelines for Independent advisors.
>
> I am the Clinical Director of Middlemore Hospital Emergency Department New Zealand the largest Emergency Department in Australasia. I have been the CD since 2019. Prior to this I was the HOD of MMH since 2008. My qualifications are FACEM (Fellow of the Australasian College of Emergency Medicine) and MBChB at Auckland University. I have been a fellow of the college for 20 years and graduated as a Doctor in 1992. I am drawing on my experience as an Emergency Physician.
>
> I have reviewed the following documentation:
>
> 1. Referral from [Coroner]
> 2. Hutt Valley DHB dated 18 November 2019 and attachments
> 3. Hutt Valley DHB's response dated 22 February 2021 and attachments (includes statements from Dr E)
> 4. [DHB2's] response dated 28 November 2019 and 26 August 2019 and attachments
> 5. Clinical records [Medical Centre 2]
> 6. Clinical records [Medical Centre 1]
> 7. Statements from [Ms C] dated 22 April 2021
> 8. Statement from [Mr D] dated 21 May 2021
> 9. Response form Ministry of Health
> 10. Response form HQSC and attachments
> 11. Hutt Valley District Health Board
>
> I have been advised to provide advice and will comment on the Emergency Department aspect of this presentation in particular on the following:
>
> 1. The adequacy of the communication provided to [Mr A] and his family by [Dr E] during his ED presentation at Hutt Valley DHB
> 2. Whether [Dr E's] actions in this case were consistent with accepted practice when a new allergy is discovered in the ED
> 3. The adequacy of [Dr E's] documentation
> 4. Any other comments you wish to make on the care provided by [Dr E] to [Mr A]
> 5. Any comments you wish to make on the care provided to [Mr A] at Hutt Valley [DHB]
> 6. Any comments on the care provided to [Mr A] at [DHB2] ED
> 7. Any comments you wish to make about allergy alerts in ED in general and the MOH warning system

8. Any other matters that you consider warrant comments or are a departure from standard of care

Summary of case

[Mr A] was brought to Hutt Valley ED on [Day 1] by ambulance at 1447. The history from the ambulance was [Mr A] had noted a toe infection and took a relative's antibiotic. After 30mins he felt nauseated and SOB collapsing to the ground. At the time the ambulance recorded him to be flushed and sweaty with sats of 80% HR 66 BP 123/81 and GCS of 15. The ambulance noted pink skin on the R arm and abdomen and itchiness to the skin. The ambulance immediately treated him with loratadine, oxygen and 1 Litre of saline. Noted in ambulance report was that [Mr A] had no known allergies.

On arrival at ED at 1443 the triage nurse notes a history of an allergic reaction after taking 2 expired flucloxacillin and that [Mr A] was initially hypoxic and hypotensive with the ambulance. The triage nurse also reported a history of no known allergies. [Mr A] was given a triage category 2 and placed in Resus 1 (R1). The nurse in R1 noted a raised red rash and RR 16 BP 106/56 and sats of 100% on 2 L of oxygen. An ECG was taken along with blood tests including a venous blood gas.

[Dr E] an Emergency Medicine registrar reviewed the patient at 1500hrs. She noted a history of collapse without loss of consciousness after taking some flucloxacillin that was in the house. Thirty minutes after taking the fluclox he noted itchiness over the ears and started to feel SOB with constriction in the throat. He took his symbicort which didn't help and felt nauseated went to the bathroom and felt so weak went to the ground. [Dr E] noted the hypoxia in the ambulance.

On exam [Dr E] noted no tongue swelling no wheeze the abdomen was soft and the sats were 100% on 2 L of oxygen.

The investigations completed at the time of arrival showed an ECG with T wave inversion a normal FBC, Urea and electrolytes and CXR.

The impression was of an allergic reaction and the plan was for a period of observation and [Mr A] was to be discharged if he remained well otherwise if he was deteriorating then adrenalin.

At 1646 [Dr E] reviewed [Mr A] who remained well and discharged him with topical Clorsig for the toe. He was told to represent if abdo or chest pain and advised of a possible allergy to flucloxacillin.

On [Day 21] [Mr A] presented to [DHB2] ED at 1001. He was referred from a GP in [Medical Centre 2] for cellulitis of his leg to the orthopaedic team. The GP noted a red lower leg extending to the knee with nausea and diarrhoea associated and a fever of 39 degrees. He noted no allergies. He had a past history of asthma and his observations in ED were HR 96 Temp 37.8 RR 20 and saturations 95%. It was noted that he had no allergies and he was given a triage category 4.

He was seen by [a nurse practitioner] and a history of 2 days of infection on his toe was noted. He had been unwell with nausea and seen by GP who referred to ED. He was noted to be alert and ambulating and did not have obvious cellulitis of the leg.

He was treated as cellulitis and given 2gm of flucloxacillin IV at 1120 and subsequently experienced SOB, urticaria and collapse and was given IM adrenalin at 1126. He was moved to resus and the full ACLS protocol was completed. Despite aggressive resuscitation he was unable to be resuscitated and he unfortunately died due to anaphylaxis.

The adequacy of the communication provided to [Mr A] and his family by [Dr E] during his ED presentation at Hutt Valley DHB

[Dr E] noted in her discharge summary that she thought the collapse on the presentation on [Day 1] was related to the use of the antibiotic flucloxacillin. [Dr E] reports she verbally communicated this to [Mr A] and his partner [Ms C], at the time of discharge on [Day 1]. [Dr E] did not write this advice for [Mr A] in the discharge papers. It seems [Mr A's] partner [Ms C] had heard this communication as I note in her email dated 22/04/21 she says she was aware of the allergy so we can assume that [Dr E] communicated her concerns about flucloxacillin verbally to [Mr A] and [Ms C] at the time of discharge. Unfortunately [Ms C] did not present with [Mr A] on [Day 21] to [DHB2].

The adequacy of the communication was below expected level for an ED registrar as [Dr E] did not write in the discharge summary her concerns. This is a mild deviation from the expected level for a registrar.

Whether [Dr E's] actions in this case were consistent with accepted practice when a new allergy is discovered in the ED

[Dr E] noted a mild allergic response to flucloxacillin which resolved with loratadine and oxygen prior to arrival in the ED. In ED [Dr E] completed a full physical examination and at the time in ED there was no evidence of an ongoing allergic response. She completed a full work up of other systems including an ECG, blood tests and a period of observation to ensure there wasn't another cause for the collapse. [Dr E] concluded that this response was likely to be as a result of flucloxacillin and she decided the best advice was to tell the patient that flucloxacillin could be the cause of the allergy in ED and to avoid this in the future.

This is at the expected level for this type of presentation to ED.

The adequacy of [Dr E's] documentation

[Dr E's] documentation of clinical notes provided a full history examination and investigation as to the cause of the collapse and is accurate around a response to flucloxacillin which is a mild response only requiring antihistamine and oxygen and the result was complete resolution of symptoms.

The discharge summary discusses the potential that Flucloxacillin was the cause of the presentation but it doesn't say for the patient to avoid this in the future. [Dr E] notes in her report that she told the patient to avoid but this was not documented as clearly as it could have been for the patient. [Dr E] reflects on this documentation in her summary of events and retrospectively feels she could have been clearer in the written notes.

In terms of the clinical history examination and subsequent reviews [Dr E's] notes were at the level expected for an ED registrar.

The lack of documentation of the verbal advice is a mild deviation from the standard of care as [Dr E] has verbally told the patient her opinion on the consultation and to avoid flucloxacillin but this was not documented in the discharge summary.

Any other comments you wish to make on the care provided by [Dr E] to [Mr A]

No further comment.

Any comments you wish to make on the care provided to [Mr A] at [HVDHB]

[Dr E's] statement reports that she is unaware of the national reporting system for allergies in New Zealand. It is unclear how long she has worked as an ED registrar but it is uncommon for an ED registrar to see an allergic response to medication that requires a report to the national warning system. This report would usually be in discussion with the ED SMO as reporting requires careful consideration of the risks and benefits. Since this event the HVDHB has started face to face training on how to report and load a drug allergy. This is a good systemic change that all hospitals should provide for their teams.

Any comments on the care provided to [Mr A] at [DHB2] ED

[DHB2] used the appropriate treatment for cellulitis where the patient is presenting with systemic symptoms and signs of cellulitis. [Mr A] was unwell with fever at GP of 39.8 and blood tests indicating a CRP of 224 and WCC 17. The best treatment for cellulitis, if no known allergies, is 2 gms IV flucloxacillin.

In administering medication at any time a nurse should perform the 5Rs (right patient, right medicine, right dose, right route, right time, right indication, right documentation and right to refuse). Finally the nurse should confirm if the patient has any allergies to flucloxacillin. This is the standard expected at all hospitals. Unfortunately in this case [Mr A] did not relay the possible reaction to Flucloxacillin from [Day 1] and he received a large dose of flucloxacillin resulting in [Mr A's] severe shock and subsequent death from anaphylaxis despite early aggressive therapy.

Assuming all the questions were asked and answered by [Mr A] at the time of presentation to ED then the care delivered in [DHB2] ED was at the level expected by any ED when delivering care to a patient.

Any comments you wish to make about allergy alerts in ED in general and the MOH warning system

The national alert system CARM is available to all patients across DHBs but usually the DHB will enter this data when there has been a severe reaction or response to an allergen. When a severe reaction occurs the CARM system attaches an alert where there is a known risk and this may be a risk for future care of the patient in any DHB.

In general allergy alerts reported to CARM require careful consideration of the risks. The risk of not reporting a severe allergic response is high but the risk of reporting an allergy which is not an allergy creates ongoing issues for patients where they present with life threatening infections and the first line therapy or antibiotics is said to be unavailable due to allergy. Many patients present to EDs with a rash and itchiness often without obvious cause which makes the assessment of the allergen harder. [Dr E] did consider the mild allergic response to be due to flucloxacillin and warned [Mr A] about further use but did not consider this to be a severe event based on the symptoms and recovery. As noted no adrenalin was used for [Mr A] and he did have a history of using penicillins without any allergic response. Good governance of 'possible allergies' are important in the care of patients and their future use of antibiotics.

[Dr E] did document the possible allergy in the clinical notes, unfortunately clinical notes are not available across DHBs in New Zealand and thus we were unable to view previous presentations if the patients are not from your DHB. This complicates the care provided to patients. Ensuring patients understand their health needs is very important but this can be supported by electronic systems visible to all health practitioners.

Any other matters that you consider warrant comments or are a departure from standard of care

This is a very rare case as usually early treatment of anaphylaxis with adrenalin will result in an excellent response. In a fatality series described previously, only '14 percent of the 164 patients dying from anaphylaxis received adrenalin before respiratory or cardiac arrest, although 62 percent of the 164 patients eventually received it before demise[1]' supporting early adrenalin use as in the case of [Mr A] usually resolves the anaphylaxis and prevents progression to shock and subsequent death**.** [Mr A] had used penicillin based drugs at other times without concern including amoxil and augmentin. The CARM system records severe life threatening conditions and in this case [Mr A] presented in retrospect with a mild self limiting response to flucloxacillin.

There is no national health record so when patients move around New Zealand it makes it hard to see the care delivered in other DHBs. Unifying the clinical record would help to reduce the risk of events of this nature occurring in the future as clinicians would review previous interactions patients have had with the health system.

1. Pumphrey RS. Lessons for management of anaphylaxis from a study of fatal reaction."

Appendix C: In-house clinical advice to Commissioner

The following expert advice was obtained from GP Dr David Maplesden:

"1. Brief synopsis

a. [Mr A] presented to [HVDHB] ED by ambulance on [Day 1] having collapsed at home after taking a flucloxacillin capsule previously prescribed for another family member. Ambulance officers found him to be hypoxic and hypotensive. He had a transient rash in ED. He had been administered an oral antihistamine at home and did not require adrenaline. He was managed as having a suspected flucloxacillin drug reaction (not anaphylaxis, possible anaphylactoid reaction) and was discharged later in the day.

b. It is unclear precisely what advice [Mr A] was given regarding his reaction eg importance of notifying any health providers in the future. As far as I can determine, the reaction was not entered on any alert database (DHB/national). The ED discharge summary is reported as being sent to a GP although subsequent ([DHB2]) notes record [Mr A] as having no GP (you may want to confirm to whom the summary was sent) [**See addendum s8**]. The consultation and diagnosis was evidently not entered on the national visit database and was not visible to [Mr A's] [DHB2] providers at his attendance on [Day 21]. I am not familiar with this database or process for data entry and this may require further detail.

c. [Mr A] attended a primary care after-hours service in [Medical Centre 2] on [Day 21]. He was diagnosed with cellulitis of his leg and referred to [DHB2] ED. The GP referral letter has a section on drug sensitivities which is usually pre-populated from the patient record. This states 'No Known Drug Allergies'. The attending GP ([Dr F]) is not currently available for comment but it is probably worth gaining a response from her as to the basis for the drug allergy entry. If the patient had previously attended the medical centre, this could be a historical entry and does not necessarily mean there was a fresh enquiry regarding allergies prior to the referral. As there was no medication being prescribed by [Dr F], she would not necessarily have made a new enquiry regarding allergies. Clarification on this issue would be helpful. **Addendum 29 July 2020: On review of the [Medical Centre 2] notes there is an entry by [Dr F] made after [Mr A's] death which states: I had asked him and his wife regarding allergies and said no**.

d. ED triage notes have recorded NKDA (no known drug allergy). I am not sure if this was transposed from the GP letter or if the patient was asked directly again if he had any allergies. If he was asked directly by either the GP or triage nurse and denied any drug allergy, questions might be raised as to the quality of information he received about his condition on discharge from [HVDHB] ED three weeks previously. There was no record of his reaction on any accessible adverse drug reaction database.

e. [Mr A] was administered IV flucloxacillin as standard management of his cellulitis. He suffered a severe anaphylactic reaction and despite prompt and appropriate resuscitation and treatment measures, tragically he could not be revived.

2. The current national drug reaction monitoring system includes the Centre for Adverse Reactions Monitoring (CARM) in Dunedin which is the national repository for adverse reaction reports. The Centre's current website enables prompt on-line reporting of suspected adverse drug reactions by health professionals or consumers. A comprehensive guide to the process was published in 2001. At that stage reporting was done manually using a specific paper form. One form was supplied annually to most GPs inside the widely used MIMS prescribing manual. In 2001, 65% of the reports CARM received were from community doctors (mostly general practitioners) while hospital doctors contributed 17% and pharmacists (community and hospital) submitted 2.3% of the reports.

3. Reporting to CARM can contribute to individual patient safety through the **Medical Warning System** (MWS) module in the Health Statistic Collection of the Ministry of Health's Information Group which enables the recording of an electronic alert. For severe and life-threatening reactions CARM records warning or danger alerts for medicines for individual patients against their unique National Health Index number which is accessible to health care facilities in New Zealand. This means that when the patient is next seen and the system is accessed (usually at a hospital), the information is displayed. Medical Warnings are usually entered for medicines that have caused serious or potentially serious allergic reactions or other reactions likely to lead to serious illness or distress if re-administered. Medical Dangers are entered for medicines that are likely to cause life-threatening or fatal reactions if re-administered. I would assume that all DHBs have a process and protocol for entering reactions into this system (although see section 8) but see discussion below regarding accessing this system in primary care.

4. An electronic reporting tool was launched in 2009 and this was publicised to GPs in a BPAC article, and the reporting tool was linked with some practice management systems via the BPAC dashboard to facilitate access. I am not sure how well the electronic reporting system was publicised in secondary care or how easy it is to access. The BPAC article noted that at that stage CARM received on average 4000 spontaneous adverse reaction reports a year. General Practice accounted for approximately 60% of these adverse reaction reports. Some other interesting aspects of the reporting are noted below (from the BPAC article):

- *The World Health Organisation rates New Zealand as having the highest number of adverse reaction reports submitted per capita compared to other countries in their programme. In addition, reports from New Zealand are also regarded as being of the highest quality. This is because New Zealand has one of the best reporting systems in the world. It is also apparent that New Zealand's healthcare professionals, who are interested in the safety of medicines, are motivated to report and understand that adverse reaction reporting is part of their professional responsibility.*

- *Although our adverse reaction reporting is rated highly, research indicates that at best only one in ten adverse reactions are being reported in New Zealand i.e. the*

rate of under-reporting is in excess of 90%. Moreover, recent research conducted in New Zealand examined the data stored in the Patient Management Systems of 30 General Practices. Of the 725 entries in the medical warnings files, that recorded an adverse reaction or allergy to at least one medicine, only 21 were reported to CARM.

5. In 2014 BPAC published an updated article on adverse drug reaction reporting noting the following points:

- CARM receives, on average, 4000 spontaneous adverse reaction reports each year. *Approximately half of these adverse reaction reports are submitted from general practice.*

- *Although New Zealand's adverse reactions reporting system is highly regarded internationally, it is thought that, at most, one-in-ten adverse reactions are reported.*

- *There are a number of reasons why an adverse reaction might not be reported. These include the absence of a prompt to initiate reporting, failing to realise that an adverse reaction has occurred, assuming that a reaction is already well known and the time required to manually fill in reaction forms.*

- *While the total number of adverse reactions reported to CARM via any method has remained stable from 2009 to 2013, the percentage of reports received from general practice has increased from 46% in 2009 to 55% in 2013. This suggests that the eADR tool may be encouraging reporting from the general practice sector especially among nurses; 20% of reporters in 2009 were nurses compared to 33% in 2013. [NB this differs from previously published statistics]*

6. In June 2019, Medsafe published an updated article on adverse drug reaction reporting encouraging use of the on-line reporting module and noting a recent study of medication-related harm in New Zealand hospital settings estimated that 28% of patients experienced one or more medicine-related harms. However, I could not find any statistics related to the current rate of CARM notifications from within secondary care.

7. While I would expect primary care health providers to be familiar with the CARM reporting process, I am not aware of the process for directly notifying the MWS of a severe adverse drug reaction and I do not believe there is any integration of this system with primary care practice management systems. In the primary care setting, a suspected drug reaction would normally be entered in the Allergy/Alert module of the PMS, and this module is generally pre-populated in any subsequent e-referrals (eg to secondary care). The information would also transfer to other PMSs if the patient transfers practices. Best practice would be for the reaction to be notified also to CARM but as noted in the previous discussion, this is thought to occur in fewer than 10% of cases although the percentage may be higher with potentially serious reactions. If the drug reaction is severe, best practice is to arrange for the patient to have a Medic-Alert

identifier as an additional safety precaution, and to ensure the patient is appropriately educated and informed about their reaction. If a report is received from secondary care noting the patient has had an adverse drug reaction in hospital, I would expect this information to be prominent in any DHB report and to be transcribed into the PMS. In some DHBs and PHOs there is the ability to access (with patient consent) components of a patient's primary care health record (including drug reactions) by other health providers in both primary and secondary care (and vice versa primary care access to secondary care records) but this is not consistent throughout the country.

8. [Mr A] was registered at [Medical Centre 1] but had not been seen there since 14 August 2017. On reviewing GP notes and response from the practice, it appears [Mr A] had been prescribed penicillins on at least three previous occasions over the preceding six years (amoxicillin 5 March 2013, flucloxacillin 11 April 2013, flucloxacillin 8 July 2014). There is no record of any adverse reaction to the antibiotics on these occasions. The practice Incident Reporting Policy required notification to CARM of adverse drug reactions recorded during care provided by the practice. The [HVDHB] ED summary was received at the medical centre on [Day 2] and is marked as being filed by [a provider]. The ED summary gives a coded diagnosis of Adverse reaction NOS and in the body of the report describes possible allergy to penicillin. There is no request in the ED summary to notify CARM. I am unable to confirm that the suspected drug reaction was transcribed into the adverse reaction/alert module of the PMS but my expectation is that this would be done although I think it is reasonable to assume the ED clinicians had notified CARM. It may be worth checking with the medical centre whether the allergy had been transcribed from the ED summary and, if not, recommending they raise the incident with relevant staff.

Addendum 12 May 2021: In a response from the practice dated 20 January 2021 it is confirmed the suspected flucloxacillin allergy recorded in the [HVDHB] discharge summary was not added to the Allergies module of the PMS. The discharge summary was addressed to Dr [Medical Centre 1] (not assigned to a specific GP). There is no clear reason given why the allergy was not entered, but possibilities of the discharge summary not being reviewed prior to [Mr A's] death (due to the holiday period) or being inadvertently filed by nursing staff are proposed.

Comments: Review of the in-box audit record for the discharge summary should enable confirmation of who filed the record and when it was filed. The clinical notes suggest the summary was filed on [Day 2]. [Mr A] died on [Day 21] and the practice was notified of his death (per enquiry from the Coroner) [the following month]. Given the content of the ED discharge summary (presentation with possible/likely anaphylactoid reaction to flucloxacillin) I believe the reaction needed to be promptly coded into the allergy module of the PMS once the discharge summary was reviewed. The failure to do this (or the alternative scenario of the discharge summary not having been reviewed prior to notification [the following month] of [Mr A's] death) I believe would be met with moderate disapproval by my peers. While the failure to record the allergy in the appropriate module of the PMS was not relevant to [Mr A's] death, there was potential for harm if he was subsequently prescribed flucloxacillin at the practice

because the allergy had not been recorded, or if records were sent to other providers with the current code of NKA (no known allergies) as was recorded in the notes on 13 July 2016. This incident also raises the issue of whether important information contained in non-assigned clinical correspondence has been appropriately incorporated into the relevant PMS module for other patients.

Recommendations:

- **The practice carry out further investigation as to the circumstances of the omission and notify the Commissioner of any remedial actions resulting from the investigation.**

- **The practice confirm its current management process for unassigned clinical correspondence and any changes to this process as a result of the incident in question.**

- **The practice undertake an audit of twenty randomly selected unassigned discharge summaries (or other unassigned items of clinical correspondence if there are insufficient discharge summaries) and report on whether management of these items is in accordance with the relevant practice policy.**

9. I think the bottom line is that the current systems are imperfect and it is important to recheck with the patient regarding adverse drug reactions prior to any prescribing. The MWS in particular appears to have some issues and minutes from the HQSC medication safety expert advisory group dated 22 May 2019[1] included:

- *[A member] tabled a briefing paper relating to National Medical Warnings. The paper recommended the EAG discuss the governance arrangements for the Medical Warning System (MWS), the inconsistent use of the MWS and the implications for medication safety, and what, if anything the EAG should do about the situation.*

- *The EAG agreed that they are concerned that the MWS system is compromised due to the inconsistency in the way warnings are managed between DHBs. We need to understand what is happening across DHBs, with a baseline measure of the extent of the issue. Lack of Governance or national oversight appears to be an issue. Should the medical warning system be a fundamental Ministry service? Should the governance sit with the Ministry?*

This suggests the HQSC are actively involved in attempting to rationalise and improve current reporting systems and the HQSC may be best placed to use incidents such as the one in question to try and improve current systems and reduce the risk of further such critical medication errors.

[1] https://www.hqsc.govt.nz/assets/Medication-Safety/Group-info-and-minutes/EAG-minutes-22-May-2019.pdf Accessed 21 July 2020

9. I believe the main issues at stake in this incident revolve around inconsistencies in use of the reporting systems described (which may relate in part to the systems themselves), inability to easily share important health information between health providers (lack of an effective true shared electronic health record), and perhaps the quality of information provided to [Mr A] on discharge from [HVDHB] ED such that he was evidently unware of the significance of his diagnosis on [Day 1]. The systems level issues might be best addressed in conjunction with HQSC although external expert advice on the adequacy of HVDHB policies/processes related to notification and recording of adverse drug reactions, and whether these were adhered to, is probably required."