District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC01413)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns a CT scan performed on a man by a DHB's radiology service using iodine contrast, despite the man's previous adverse reaction to iodine contrast having been recorded as a medical warning by his GP.

2. The report highlights the importance of adequate communication between providers (in this case GP to DHB) to capture patient medical warnings safely. I note that the man's allergy was not entered on the national Medical Warnings System by any health provider. There is opportunity to align expectations and systems better across primary and secondary sectors at a national level to improve the quality and safety of health services.

Findings

3. The Deputy Commissioner made adverse comment that the man's adverse reaction to contrast was not added to the DHB's systems in September or October 2018, considering that the reaction warning related specifically to a radiology procedure.

Recommendations

4. The Deputy Commissioner recommended that the DHB provide an update on its work to develop an interface between the GP e-referral system and the DHB's radiology system, and consider what additional measures the DHB can take to improve the reconciling of GP e-referral medical warnings with its radiology system.

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her father, Mr A, by a district health board (DHB). The following issue was identified for investigation:

- *Whether the district health board provided Mr A with an appropriate standard of care between September 2018 and May 2019 (inclusive).*

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

7. The parties directly involved in the investigation were:

Ms B	Complainant
District health board	Provider

8. Dr C, a radiologist, is also mentioned in the report.

9. Further information was received from the Ministry of Health, the Royal New Zealand College of General Practitioners, and a medical centre.

10. In-house clinical advice was obtained from GP Dr David Maplesden (Appendix A), and independent clinical advice was obtained from radiologist Dr Gabriel Lau (Appendix B).

Information gathered during investigation

Background

11. This report concerns the communication of allergy information from Mr A's GP to the DHB. Mr A had an allergy to contrast containing iodine,[1] which is a chemical substance used in medical X-ray imaging. However, at the DHB's radiology service (Radiology) he was subsequently given a CT[2] scan using intravenous[3] contrast containing iodine.

12. Mr A, aged in his eighties, was diagnosed with cancer of the blood and bone marrow[4] (non-Hodgkin's lymphoma) in September 2016, and was treated with chemotherapy. Mr A had CT scans at Radiology involving the use of iodine contrast on 20 September 2016, 9 August 2017, and 19 February 2018. There is no record of Mr A experiencing an adverse reaction to the use of contrast after the first two scans but, after the third, his GP recorded a reaction on 24 February 2018, as set out in further detail below.

2018

19 February 2018

13. On 19 February 2018, Mr A underwent a CT scan of the neck, chest, abdomen, and pelvis (CT CAP)[5] at Radiology using an idodine-based contrast .[6] This was the last occasion on which Mr A received contrast before the events of May 2019.

24 February 2018

14. On 24 February 2018, Mr A's GP documented the following in Mr A's "Medical Warnings" table on the GP Practice Management System: "[R]adio-opaque contrast causes A[cute] K[idney] I[njury] and skin peeling."

15. The medical warning was provided on referrals from the GP to Older People's Health at the DHB on 27 February 2018,[7] and to Radiology on 4 September 2018 (see below). However, the warning was not entered on the National Medical Warning System (MWS), which includes warnings on allergies and medical alerts.

[1] Omnipaque 350 contrast, which is used to enhance the visibility of internal structures during imaging.
[2] Computerised tomography scan, combining X-ray images to create cross-sectional images.
[3] Within the vein.
[4] Small lymphocytic lymphoma/chronic lymphocytic leukaemia.
[5] CT Neck/CAP C+.
[6] Intravenous contrast media are water-soluble compounds containing iodine. The iodine absorbs X-rays and enhances visibility.
[7] DHB Older People's Health Referral for Outpatient Appointment.

4 September 2018

16. On 4 September 2018, Mr A's GP sent a referral to Radiology for a chest X-ray[8] and a hip/pelvis X-ray.[9] The referral documents included a copy of the "Medical Warnings" table, including the note about radio-opaque contrast.

17. Mr A was to receive plain film X-rays with no contrast involved, but on 26 October 2018 Mr A requested that the X-rays be cancelled.

2019

18. In 2019, Mr A's kidney[10] function began to deteriorate, and an ultrasound (US) scan on 9 April 2019 showed swelling of the left kidney[11] and dilation of the ureter.[12] A CT scan of the kidney, ureter, and bladder (CT KUB) was then organised by Haematology.

11 April 2019

19. On 11 April 2019, a booking clerk contacted Mr A to arrange the CT scan. After the conversation, the booking clerk documented in the DHB's radiology system: "[Patient] says he was very sick at home after last contrast scan [and patient] thinks it was a reaction."

17 April 2019

20. Mr A had the CT KUB scan on 17 April. No contrast was used, and the scan was uneventful. The scan showed a new nodal mass [13] in the left pelvis, and a CT CAP scan was recommended.

6 May 2019

21. On 6 May 2019, a Haematology registrar at the DHB referred Mr A to Radiology for the CT CAP scan. There was no specific instruction on the referral for pre- or post-scan intravenous fluids to be administered, as Mr A did not have a history of diabetes, and his kidney function[14] was to be checked before the scan. The referral document had a field entitled "Previous reaction to intravenous contrast media?", which was marked "N[o]". The DHB commented that its records from the three previous scans contain no documentation of an adverse reaction,[15] and Mr A had a rash present before the CT scan.[16]

7 May 2019

22. On receiving the referral, Dr C, the DHB radiologist, noticed the booking clerk's note in the radiology system: "[Patient] says he was very sick at home after last contrast scan [and

[8] To investigate a cough that had persisted for at least eight weeks after an upper respiratory tract infection.
[9] To investigate hip pain and the extent of Mr A's osteoarthritis.
[10] Renal function.
[11] Hydronephrosis (swelling caused by a build-up of urine).
[12] Hydroureter (distension of the duct (ureter) through which urine passes from the kidney to the bladder).
[13] A lump affecting a lymph node.
[14] eGFR — estimated glomerular filtration rate.
[15] On 20 September 2016, 9 August 2017, and 19 February 2018.
[16] The Dermatology clinic letter dated 4 July 2018 notes: "He describes a rash since the end of August/beginning of September 2017. This is itchy with a burning sensation and started on his legs before spreading elsewhere [Mr A] has an eczematous rash on the lower legs bilaterally, most likely on the basis of venous stasis eczema with autosensitisation."

patient] thinks it was a reaction." Dr C was not aware of the GP's "Medical Warning" table on the 4 September 2018 referral.

23. Dr C asked Ms D, a senior medical radiation technologist, to investigate the nature of Mr A's reaction in case he required pre-medications[17] for the CT scan.

10 May 2019

24. Ms D emailed Dr C and reported:

> "[Mr A] vomited when he got home after his last CT. He was also having chemo[therapy] at the same time so may have just been that. Prior to that he had had scans with the contrast with no problem. He does however need IV [intravenous] hydration cr140 eGFR 39."

25. Dr C emailed Ms D saying that the vomiting "[s]eems to be Chemorelated", and concluding, "so yes for contrast with hydration[18] but don't think premed[ication]s needed". Ms D stated that vomiting was "not recognised as a reaction to the contrast", so "pre-medications were not charted for [Mr A's] planned CT".

15 May 2019

26. Mr A had a kidney function test on 15 May. The test indicated that Mr A's eGFR was 47. Based on this result, Radiology determined that Mr A did not require intravenous hydration for the CT scan, in line with the DHB's guidelines,[19] which require intravenous hydration where eGFR is lower than 45.

24 May 2019 CT scan

27. Ms D stated[20] that on 24 May 2019, she obtained Mr A's consent before the CT scan. She said:

> "I asked about any rash, swelling, numbness, shortness of breath or vomiting that occurr[ed] after the patient's last scan. He said no, that he was totally fine after the actual scan and the only issue was that he vomited several hours later."

28. Ms D discussed with Mr A that "this [reaction was] not what [they] would consider a reaction to the contrast". In response to the provisional opinion, Ms B told HDC that her father was aware of his increasing allergy to iodine-based contrast, but Ms D had led him to believe that he was incorrect and that the symptoms he had experienced were unrelated to any allergy caused by the contrast.

[17] Medication to neutralise or mitigate poor reactions to contrast.
[18] Hydration was not needed by the time of the scan, as Mr A's eGFR had improved from 39 to 47mL/min/1.73m2 (as discussed below).
[19] Guidelines for Contrast Induced Nephropathy (CIN) Risk Stratification and Prophylaxis (Appendix C).
[20] In an email dated 28 May 2019.

29. Mr A had a CT scan of the neck and CAP, using intravenous contrast containing iodine. The contrast was administered without any pre-medication or intravenous hydration. The DHB told HDC that the Radiology protocol was followed based on the information available.

30. There was no immediate contrast reaction following the scan, and Mr A returned home. However, shortly afterwards he became nauseous and started to vomit.

25–29 May 2019

31. On 25 May, Mr A developed a rash on his face. The following day, the nausea and vomiting persisted and the rash had spread, and Mr A was admitted to hospital with an acute kidney injury post allergic reaction to the contrast. By 29 May 2019, blood tests showed that Mr A's kidney function had returned to baseline levels.

Further information

Ms B

32. Ms B told HDC:

> "Whilst I acknowledge [the public hospital] may have been unaware of my father's previous allergy to non-ionic iodine based contrast due to absence on the hospital allergy register, I cannot excuse the lack of clinical comprehension and prior evidence presented which caused my father to require ambulance admission to [the hospital] suffering acute kidney injury secondary to administration of Omnipaque 350."

DHB

33. The DHB apologised for the reaction Mr A experienced following the CT scan on 24 May 2019 and for the distress caused to Mr A and his family.

34. The DHB told HDC: "[I]n this instance we believe that our clinical team have provided appropriate and professional care at all times." The DHB stated that there may have been other causes for the symptoms Mr A experienced after the CT scan in February 2018. Mr A's vomiting may have been caused by the antibiotic erythromycin he was taking,[21] and a rash was present before the CT scan (see paragraph 21).

<u>Information sharing</u>

35. The DHB told HDC:

> "[T]here are many ways for GPs to share allergy and adverse drug reaction information with the hospital but none other than the national medical warning system is pulled into our clinical systems in a useful way."

36. The DHB described the GP e-referral[22] as essentially an electronic version of a paper referral, which is filed in a document directory.

[21] A district nurse noted on 19 February 2018 that Mr A had "just vomited x2 (had taken [e]rythromycin 20–30 mins previously)".
[22] Electronic referral.

37. The DHB acknowledged the fundamental challenge of integrating data between primary care and secondary care, and local, regional, and national data sources. The DHB stated:

> "The health system has defaulted to a multiple platform model that leads to such vulnerabilities being almost unavoidable. Information is handed over between systems in a form that is little better than paper based systems."

38. The DHB said that an administrative clerk reconciles basic patient details[23] at the time of registration of the e-referral. It stated:

> "The Grading Clinicians or the Specialist who sees the patient at the First Specialist Appointment reviews the referral and transfers the information from the GP into our medical records, and if required also transfers it to the National Medical Warnings (NMWs) system."

39. The DHB said that its expectation is that GPs enter relevant information about their patient into the national MWS directly.

Ministry of Health

40. The Chief Medical Officer at the Ministry of Health told HDC that a working group has been established to progress improvements to the National MWS database. This includes potential integration of the MWS to GP and pharmacy systems, as currently it is available only to DHBs and the Centre for Adverse Reactions Monitoring.[24]

Royal New Zealand College of General Practitioners

41. The Medical Director of the Royal New Zealand College of General Practitioners (RNZCGP) told HDC:

> "[O]ur expectation would be that relevant clinical information received from a specialist GP to a DHB would be reconciled in the patient's hospital notes. We would expect the DHB to have appropriate systems in place to ensure relevant clinical information from the GP is entered in a timely way into clinical records."

Responses to provisional opinion

Ms B

42. Ms B was given an opportunity to respond to the "Information gathered" section of the provisional opinion. Where appropriate, changes have been made to the report in response to her comments.

43. Ms B also commented that there was opportunity for the DHB to transfer her father's medical warnings into the national MWS.

[23] National Health Index (NHI) number, name, date of birth, and address.
[24] The national repository for adverse reaction reports.

DHB

44. The DHB was given an opportunity to respond to the provisional opinion. The DHB acknowledged that no entry of Mr A's adverse reaction to contrast was made on its systems in September or October 2018, but stated:

> "It is our view that … [Mr A] was afforded standard care when referred for X-Rays, and that staff took appropriate precautions to investigate and follow up [Mr A's] past experiences of radiology procedures."

45. The DHB reiterated its apology to Mr A's family, and added that it is continuing to work towards improvements in its systems, and is contributing to improvements in the national MWS.

Opinion: District health board — adverse comment

Introduction

46. When Mr A had a CT scan on 24 May 2019 at Radiology, the scan was undertaken using iodine contrast, despite Mr A's previous adverse reaction to iodine contrast having been recorded as a medical warning in a referral to Radiology by Mr A's GP. In this report I have considered how the breakdown in communication occurred between the DHB and the GP, and whether in the circumstances, the DHB considered Mr A's presentation adequately before giving him contrast. In forming my opinion I have considered in-house clinical GP advice and expert advice from a radiologist, and have canvassed the views of the Ministry of Health and the RNZCGP.

Communication of Mr A's allergy and the national MWS — adverse comment

47. In February 2018, Mr A had an adverse reaction to contrast, and this was recorded by his GP in the GP practice management system as: "Radio-opaque contrast causes A[cute] K[idney] I[njury] and skin peeling." In September 2018, when the GP referred Mr A to Radiology for X-rays, the "Medical Warnings" table was included in the e-referral. The "Medical Warnings" table was also shared with the DHB by the GP in another referral letter. However, the allergy was not recorded by the DHB in the radiology system or medical records, and it was not recorded by the GP or DHB staff in the national MWS.

48. Unfortunately, over a year later on 24 May 2019, Mr A had CT scans at Radiology that used contrast. The referral for these scans came from Haematology, and so did not include the "Medical Warnings" table that would have been generated from an e-referral from the GP practice management system. I have considered what is the expectation and standard practice for how GPs communicate allergy warnings to DHBs, and how DHBs would be expected to reconcile this with its systems.

49. My in-house clinical advisor, GP Dr David Maplesden, expressed concern that DHB staff did not reconcile the medical warning with the DHB's own records, after the e-referral on 4 September 2018. Dr Maplesden advised:

> "[T]here is a reasonable assumption by referrers that this is an effective means of informing other health providers of any changes in a patient's health status (including allergies and alerts) and that some form of reconciliation takes place when the referral is received."

50. Dr Maplesden's view is echoed by RNZCGP, which stated:

> "[O]ur expectation would be that relevant clinical information received from a specialist GP to a DHB would be reconciled in the patient's hospital notes. We would expect the DHB to have appropriate systems in place to ensure relevant clinical information from the GP is entered in a timely way into clinical records."

51. I accept that the GP advised the DHB of the allergy in an appropriate way in correspondence and referrals, and that it is not usual practice for GPs to enter medical warnings in the national MWS. I turn next to the question of reconciliation by the DHB. The DHB told HDC:

> "[T]here are many ways for GPs to share allergy and adverse drug reaction information with the hospital but none other than the national medical warning system is pulled into our clinical systems in a useful way."

52. The DHB described e-referrals as an electronic version of paper referrals, which are filed in a document directory. It is clear that as the IT systems are not integrated between the GP practice and the DHB, other measures are required to reconcile or enable information sharing.

53. The DHB told HDC that an administrative clerk reconciles basic patient details like name and date of birth at the time of registration of the e-referral. The clinician assessing the e-referral is the one who transfers information from the GP into DHB medical records (and the national MWS if required). I note that the X-rays in 2018 would not have required the use of contrast and were cancelled by Mr A. However, I am concerned that the medical warning was not recorded in the DHB's medical records.

54. I also note that the DHB's expectation is that GPs enter relevant information about their patient into the national MWS directly. My radiology advisor, Dr Gabriel Lau, takes a similar view, and advised that the standard of care would be to review the national MWS and to discuss with the patient to ascertain the symptoms. However, Dr Maplesden advised:

> "In my experience there is limited awareness of this capability or how to access this system and I would not regard use of this system as common practice. However, it is common and accepted practice for allergies and alerts to be recorded in the relevant [practice management system] module and transferred to other health providers electronically when referrals are made or the patient changes practices."

55. Dr Maplesden's view is supported by RNZCGP. As noted above, the College told HDC that its expectation was that relevant clinical information received by a DHB from a GP would be reconciled in the patient's hospital notes, and the College would expect the DHB to have appropriate systems in place to ensure that relevant clinical information is entered in a timely way into clinical records.

56. Clearly there is a disconnect of expectations between the primary and secondary care sectors in New Zealand, and this is a much broader issue than the DHB alone. It is a system issue at a national level that goes beyond a system failing at the DHB. I am satisfied that the DHB has adequate policies in place to manage e-referrals, and I acknowledge that Mr A's X-rays would not have required contrast and were cancelled by Mr A. However, I am concerned that Mr A's adverse reaction to contrast was not added to the DHB's systems in September or October 2018, considering that the reaction warning related specifically to a radiology procedure.

57. I note that the Ministry of Health has advised HDC that a working group has been established to progress improvements to the national MWS database, including potential integration of the MWS to GP and pharmacy systems, as currently it is available only to DHBs and the Centre for Adverse Reactions Monitoring. As Dr Lau states, a nationwide uniform health information system would reduce the chance of information not being communicated. I endorse the importance of this national work to improve patient safety.

Adequacy of checking symptoms reported and decision-making in May 2019 — other comment

58. Despite any shortcomings in a national medical warning system, the practitioner administering the contrast has a duty of care to assess symptoms and to check allergy status.

59. In April 2019, DHB Haematology requested a CT scan for Mr A, and on 11 April 2019 a booking clerk spoke to Mr A and documented in the DHB's radiology system: "[Patient] says he was very sick at home after last contrast scan [and patient] thinks it was a reaction." This scan was performed on 17 April, without contrast, and was uneventful.

60. Mr A then required a further CT scan, and a referral was sent by Haematology to Radiology on 6 May 2019. The referral did not include specific instruction for pre- or post-scan intravenous fluids to be administered, as Mr A did not have a history of diabetes and his kidney function was to be checked before the scan. The referral was marked "No" for "Previous reaction to intravenous contrast media?". I note the DHB's comment that its records contain no documentation of an adverse reaction from the three previous scans,[25] and that a skin rash was present before the CT scan.

61. The DHB's radiologist was not aware of the GP's "Medical Warning" table from the 4 September 2018 referral, but did notice the booking clerk's note from 11 April 2019. A medical radiation technologist then investigated the nature of Mr A's reaction and reported:

[25] On 20 September 2016, 9 August 2017, and 19 February 2018.

> "[Mr A] vomited when he got home after his last CT. He was also having chemo[therapy] at the same time so may have just been that. Prior to that he had had scans with the contrast with no problem."

62. This led the radiologist to conclude that the vomiting "[s]eem[ed] to be Chemorelated", and to use contrast without requiring pre-medications. Mr A's kidney function test on 15 May indicated that his eGFR was 47, so intravenous hydration during the CT scan was not required, in line with the DHB's guidelines.

63. On 24 May 2019, a medical radiation technologist obtained Mr A's consent before the CT scan. She said that she "asked about any rash, swelling, numbness, shortness of breath or vomiting that occurring after the patient's last scan. He said no, that he was totally fine after the actual scan and the only issue was that he vomited several hours later." She stated that she discussed with him that "this [was] not what [they] would consider a reaction to the contrast".

64. Dr Maplesden was not critical of the DHB's consideration of Mr A's symptoms and the decision to provide contrast to Mr A. Dr Maplesden advised that Mr A's "history [of vomiting after a previous contrast CT scan] was not a contraindication to further contrast procedures nor an indication for pre-procedure IV hydration". Dr Maplesden considers that Mr A's "management in terms of no pre-contrast IV hydration on 24 May 2019 was consistent with accepted practice".

65. Dr Lau was similarly not critical of the decision-making in May 2019. In his view, the decision not to administer pre-medications or intravenous hydration to Mr A before or after the CT scan was appropriate. Dr Lau advised:

> "Vomiting and nausea are considered mild contrast reactions (as per attached RANZCR [26] Iodinated Contrast Media Guidelines) — the decision to administer premedication for mild contrast reactions, would be based on the degree of symptoms.
>
> No intravenous hydration is recommended for patients whose eGFR is greater than 45 mL/min/1.73m2 (as per attached RANZCR Iodinated Contrast Media Guidelines)."

66. In my opinion, DHB staff acted appropriately in considering Mr A's symptoms, asking him about his experience, and undertaking an eGFR test prior to the scan. The decision-making was appropriate with the information they had before them, which included no record in the DHB's system of an adverse reaction from the three previous scans. What was missing was the GP's "Medical Warning" table from the 4 September 2018 referral, which recorded an adverse reaction to contrast. The communication issues that led to this information not being added to the DHB's records have been addressed in the previous section of my opinion.

[26] The Royal Australian and New Zealand College of Radiologists.

Conclusion

67. Mr A was given contrast with the CT scan of 24 May 2019 in error, and, as a result, he suffered an allergic reaction and was hospitalised with an acute kidney injury. Before using the contrast, DHB staff assessed Mr A appropriately from the information they had available. What was not available was the GP Medical Warning table, which specifically documented that "[r]adio-opaque contrast cause[d] AKI[27] and skin peeling" for Mr A. I am concerned that Mr A's adverse reaction to contrast was not added to the DHB's systems in September or October 2018, considering that the reaction warning related specifically to a radiology procedure.

68. I am also concerned that Mr A's allergy was not entered on the national MWS by any health provider. This is a matter I will be raising further with the Ministry of Health, as I believe there is an opportunity to better align expectations and systems across primary and secondary sectors to improve the quality and safety of health services provided to consumers.

Changes made since events

69. The DHB told HDC:

- Mr A's allergy to contrast has been entered onto the DHB's clinical records and radiology system, and the national MWS.
- It no longer uses the older ionic contrast agents for CT scans, and vomiting is now extremely uncommon.
- It is planning work on an interface between the GP e-referral system and the DHB's radiology system.

Recommendations

70. In the provisional opinion, I recommended that the DHB:

a) Provide an update to HDC on the work to develop an interface between the GP e-referral system and the DHB's radiology system.

In response, the DHB told HDC that work has commenced to load GP e-referral information into the Radiology Information System and work through issues. Adding in allergies will require work on algorithms and storage considerations, and a national solution involving the use of MWS may be preferable.

[27] Acute kidney injury.

b) Consider what additional measures the DHB can take to improve the reconciling of GP e-referral medical warnings with its radiology system, while an IT solution is being developed.

In response, the DHB told HDC that information from referral forms concerning medical warnings is manually typed into the Radiology Information System alert system. The Administration Team Leader is responsible for maintaining the alert systems, and inputs the information immediately upon receiving it. As stated above, the DHB is exploring options to transfer allergy information and adverse reactions from GP e-referrals into the DHB's electronic medical record. The DHB will also request that GPs advise Radiology if patients present to them with a contrast reaction following contrast administered during an outpatient procedure.

71. I note that in a letter dated 25 June 2019, the DHB apologised to Ms B for the distress caused.

72. Taking into account the actions taken by the DHB in response to the provisional recommendations, I consider that no further recommendations are necessary.

Follow-up actions

73. I will be writing to the Ministry of Health to request an update on the working group's progress on improvements to the national MWS database, including the potential integration of the MWS to GP and pharmacy systems.

74. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Ministry of Health, the Royal New Zealand College of General Practitioners, and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house clinical advice to the Commissioner

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

> "I have reviewed the information on file.
>
> 1. Leaving aside the issue of [Mr A's] previous possible contrast induced acute kidney injury (CI-AKI), his management in terms of no pre-contrast IV hydration on 24 May 2019 was consistent with accepted practice[1] taking into account renal function tests performed on 15 May 2019, nine days prior to the procedure, which showed an eGFR of 47 mL/min/1.73m^2. The reported history of vomiting after a previous contrast CT was explored and was felt possibly related to concurrent chemotherapy. The history was not a contraindication to further contrast procedures nor an indication for pre-procedure IV hydration. The history of rash was not clearly related to use of IV contrast as noted in the response and dermatologist letters on file.
>
> 2. I think the main concerning issue in this case is the apparent failure by DHB staff to reconcile the allergies listed on the radiology e-referral dated 4 September 2018 with allergies listed in [Mr A's] DHB record. The DHB response notes that *GPs can enter key alerts, such as allergies and drug reactions, into a national warning system linked to the patient's NHI number … These are then visible to DHB users.* In my experience there is limited awareness of this capability or how to access this system and I would not regard use of this system as common practice. However, it is common and accepted practice for allergies and alerts to be recorded in the relevant PMS module and transferred to other health providers electronically when referrals are made or the patient changes practices. Primary care to DHB e-referrals have a dedicated area for patient allergies which in most DHBs must be completed (either 'no allergies' or listed allergies) before the form can be submitted. There is a reasonable assumption by referrers that this is an effective means of informing other health providers of any changes in a patient's health status (including allergies and alerts) and that some form of reconciliation takes place when the referral is received. Similarly, I would expect a GP to update the patient's practice record (PMS) if a DHB discharge summary is received noting a new allergy or diagnosis. I think this oversight is a significant cause for concern and the DHB might want to elaborate on what measures are in place to ensure such referral information is reconciled in the future."

[1] The Royal Australian and New Zealand College of Radiologists. Iodinated Contrast Media Guideline. Sydney: RANZCR; 2018. https://www.ranzcr.com/documents/573-iodinated-contrast-guidelines-2016/file Accessed 13 July 2020

Appendix B: Independent clinical advice to the Commissioner

The following expert advice was obtained from radiologist Dr Gabriel Lau.

"Comment on the care provided to [Mr A] at [the DHB] between September 2018 and May 2019.

Dr Gabriel Lau MB ChB, FRANZCR, EBIR
Director of Interventional Radiology,
Dunedin Hospital,
Dunedin

TERMS OF REFERENCE

I have been asked to comment on:

1. The failure of [DHB] staff to reconcile the GP's 'Medical Warning' note about radio-opaque contrast on the e-referral dated 4 September 2018 with [the DHB's] own records for [Mr A]. Please include in this a consideration of the adequacy of systems and procedures in place at [the DHB] to support staff accessing medical warnings.
2. The adequacy of radiology staff's investigation into whether [Mr A] required pre-medications or intravenous hydration when being given contrast.
3. The appropriateness of the decision by radiology staff not to administer pre-medications or intravenous hydration before or after the CT scan.
4. The length of time after administering contrast that an allergic reaction could occur.
5. Whether nausea and/or vomiting is a recognised reaction to iodine contrast.
6. Any other matters in this case that you consider warrant comment.

For each question, I have been asked to advise:

1. What is the standard of care/accepted practice?
2. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
3. How would it be viewed by your peers?
4. Recommendations for improvement that may help to prevent a similar occurrence in future.

INFORMATION PROVIDED

In order to do this I have been provided with the following information to assist with the review:

1. Letter of complaint dated 31 July 2019 and attachments.
2. [The DHB's] response dated 9 October 2019.

3. Clinical records relevant to the radiology care provided from [the DHB], from 2017 onwards.
4. Email dated 28 August 2020 with further information from [the DHB].
5. GP referrals to [the DHB] dated 27 February 2018, and two for 4 September 2018.
6. Response to notification from [the DHB] dated 18 December 2020, and six attachments.

WHO AM I

I am Gabriel Buong Hung LAU, MB ChB, FRANZCR, EBIR. I am employed as a Consultant Radiologist at Dunedin Hospital and Pacific Radiology Otago. I work at Dunedin Public Hospital as a diagnostic and interventional radiologist, where I am the Director of Interventional Radiology. I also work in private practice as a diagnostic and interventional radiologist at Pacific Radiology Otago.

I trained in Diagnostic and Interventional Radiology in New Zealand, and worked as a Diagnostic and Interventional Radiologist at the National University Hospital in Singapore for just over 4 years, before returning to Dunedin, to work in the capacity as described above, in 2006. I have a Radiology Fellowship from the Royal Australian and New Zealand College of Radiology (FRANZCR) and also have attained the European Board of Interventional Radiology (EBIR). As well as this I am a member of the Interventional Radiological Society of Australasia (IRSA), a corresponding member of the Cardiovascular and Interventional Society of Europe (CIRSE), a corresponding member of Society of Interventional Radiology (SIR) and a founding member of Society of Interventional Oncology (SIO). I am a corresponding member of the European Society of Radiology (ESR), the European Society of Gastrointestinal and Abdominal Radiology (ESGAR), and the Radiological Society of North America (RSNA).

I am the past Chief Censor of the RANZCR. I am currently the Editor of Diagnostic and Interventional Radiology for the *Journal of Medical Imaging and Oncology*. I am the co-lead examiner for the Abdominal component of the Part 2 RANZCR examinations and an examiner for the European Board of Interventional Radiology. I currently have a position on the Board of RANZCR, and I am the Chair of the New Zealand branch of RANZCR.

RESPONSE

1. The failure of [DHB] staff to reconcile the GP's 'Medical Warning' note about radio-opaque contrast on the e-referral dated 4 September 2018 with [the DHB's] own records for [Mr A]. Please include in this a consideration of the adequacy of systems and procedures in place at [the DHB] to support staff accessing medical warnings.

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

Standard of care would be to review the National Health Index Warning system and to discuss with the patient to ascertain the symptoms, which can be performed by a trained Radiology staff, such as Radiology Nurse, Medical Radiation Technologist.

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

No departure from standard of care.

c. How would it be viewed by your peers?

No departure from standard of care.

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

Already actioned by [the DHB].

2. The adequacy of radiology staff's investigation into whether [Mr A] required pre-medications or intravenous hydration when being given contrast.

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

Standard of care would be to review the National Health Index Warning system and to discuss with the patient to ascertain the symptoms, which can be performed by a trained Radiology staff, such as Radiology Nurse, Medical Radiation Technologist.

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

No departure from standard of care.

c. How would it be viewed by your peers?

No departure from standard of care.

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

Already actioned by [the DHB].

3. The appropriateness of the decision by radiology staff not to administer pre-medications or intravenous hydration before or after the CT scan.

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

Vomiting and nausea are considered mild contrast reactions (as per attached RANZCR Iodinated Contrast Media Guidelines) — the decision to administer premedication for mild contrast reactions, would be based on the degree of symptoms.

No intravenous hydration is recommended for patients whose eGFR is greater than 45 mL/min/1.73m2 (as per attached RANZCR Iodinated Contrast Media Guidelines).

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

No departure from standard of care.

c. How would it be viewed by your peers?

No departure from standard of care.

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

None as already follow guidelines.

4. The length of time after administering contrast that an allergic reaction could occur.

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

The length of time is categorised as per attached RANZCR Iodinated Contrast Media Guidelines.

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

See above.

c. How would it be viewed by your peers?

See above.

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

See above.

5. Whether nausea and/or vomiting is a recognised reaction to iodine contrast.

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

Vomiting and nausea are considered mild contrast reactions (as per attached RANZCR Iodinated Contrast Media Guidelines).

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

Mild departure from standard of care.

The patient should be informed that they have had a contrast reaction, and the severity.

c. How would it be viewed by your peers?

Mild departure from standard of care.

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

Staff should be aware of the degrees of severity of contrast reactions.

6. Any other matters in this case that you consider warrant comment.

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

There are two areas of uncertainty, which would raise the level of severity of the contrast reaction from mild.

1. Rash post CT scans

The patient has had CT scans on 20 September 2016 and 9 August 2017, with no documented contrast reaction.

The patient then had a CT scan on 19 February 2018, with no documented contrast reaction.

The patient was seen in Haematology clinic 1 May 2018, where there was documentation of possible contrast reaction after both the 9 August 2017 and 19 February 2018 CT scans, taken from the history.

The rash was then assessed and diagnosed by the Dermatologist as most likely on the basis of venous stasis eczema and autosensitisation and not due to contrast reaction.

The patient was referred by the GP for plain X-rays on 4 September 2018, with a note on the GP referral system, dated from 24 February 2018 of Radio-opaque contrast causes AKI and skin peeling.

It is unclear if when the patient had developed AKI after the CT scan on 9 February 2018, what action was taken to alleviate the symptoms of the rash.

2. AKI

The patient was referred by the GP for plain x-rays on 4 September 2018, with a note on the GP referral system, dated from 24 February 2018 of Radio-opaque contrast causes AKI and skin peeling.

It is unclear if when the patient had developed a rash after the CT scans on 9 August 2017 and 19 February 2018, what action was taken to alleviate the symptoms of the rash. Or if the rash was the same as when seen by the Dermatology team.

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

Mild departure from standard of care.

When the rash and AKI was diagnosed and treated by the GP, it should have been entered on the National Health Index warning system.

Furthermore the patient did not appear to be aware of the nature of his contrast reaction, when questioned by Radiology staff.

c. How would it be viewed by your peers?

Mild departure from standard of care.

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

It is difficult for a GP to be aware of all drug reactions, however there is access to a common alert system, the National Health Index warning system.

It is more difficult for patients to be aware of their drug reactions and the implications.

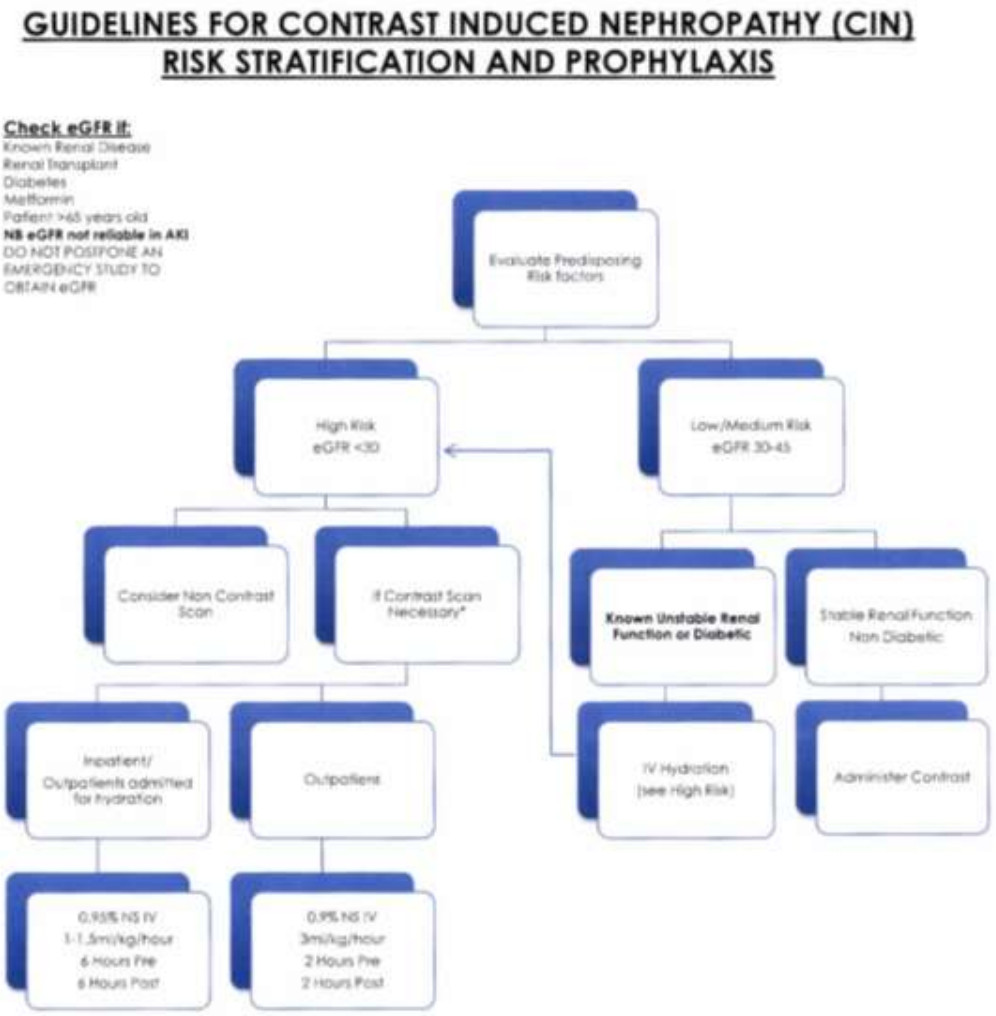
A nationwide uniform health information system as opposed to each individual DHB/region using their own system, where information could be documented and accessed by healthcare providers would reduce the chance of information not being communicated.

Within a DHB/region, there are multiple different information systems being used between primary care and Hospitals.

From a nationwide perspective, there are different information systems used by different DHB/Hospitals throughout the country, and at primary care level as well.

G. B. H. Lau"

Appendix C: Relevant policies



Adverse Reactions to Intravenous Iodinated Contrast Media: Prevention, Recognition and Treatment (excerpt)

"Contrast-induced nephropathy (CIN) is an acute decline in renal function after the administration of a contrast agent in the absence of an alternative cause.

…

(1) INCREASED RISK OF NON-RENAL ADVERSE REACTION

Patients with a history of

• Previous moderate or severe acute reaction to iodine contrast agent.

• Asthma.

• Allergy requiring medical treatment.

Consider:

• an alternative test not requiring an iodinated agent

• use of premedication.

Clinical evidence of the effectiveness of premedication is limited.

…

ACUTE ADVERSE REACTIONS (within 1 hour of contrast medium injection)

Mild: Nausea, mild vomiting, Urticaria, Itching

Moderate: Severe vomiting, Marked urticaria, Bronchospasm, Facial/laryngeal edema, Vasovagal attack

Severe: Hypotensive shock, Respiratory arrest, Cardiac arrest, Convulsion.

LATE ADVERSE REACTIONS (occur 1 hr to 1 wk after contrast injection)

Nausea, vomiting, headache, musculoskeletal pain, fever have been described following contrast administration, but many are not related to the contrast medium.

True late skin reactions are similar type to other drug reactions; they are usually mild to moderate and self-limiting."

Guidelines for the administration of contrast material in radiology (excerpt)

"Our suggested Renal Hydration Protocol is:

eGFR <30:
Consider non contrast scan. If contrast is required, consider discussion with renal team;
Give IV fluids: Outpatient — Normal saline 3mL/kq/h 2 hours pre and 2 hour post scan;
Inpatient or if admitted for hydration — 1–1.5mUkci/h 6 hours pre and 6 hour post scan.

eGFR 30–44
Administer contrast if renal function stable and not diabetic. If renal function unstable or if diabetic, give IV hydration as for the EGFR<30 group above."

Procedure: Medication Allergies and Adverse Drug Reactions (ADRs) Procedure (excerpt)

"All allergies and ADRs which will impact on clinical decision making about individual patient care need to be reported to the National Medical Warnings system which will document these as 'warnings'.

…

Nurses and pharmacists: Can document allergies and ADRs already documented in clinical records or from patient feedback."

Appendix D: The National Medical Warning System

"The [National Medical Warning System] MWS[1] 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 allows data from other sources to be available where it could be important. It is not designed to be a replacement for a service's own clinical information system.

…

The MWS contains the following:

- Medical warnings. These warn the provider of any known dangers relating to the specific individual and the administration of therapeutic medicines (eg, allergies, drug sensitivities, or adverse medical reactions). Warnings are categorised as 'warnings' or 'dangers'. Doctors submit an incident, such as an allergic reaction, as a warning.

…

Like the NHI, the MWS contains information of operational-level significance, and the responsibility for maintaining the content of the MWS rests with health and disability support services."

[1] https://www.health.govt.nz/our-work/health-identity/national-medical-warning-system, accessed 1/9/2021.