Radiologist, Dr B Radiology Service

A Report by the Deputy Health and Disability Commissioner

(Case 19HDC02399)



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Executive summary

- 1. This report concerns the care provided to a woman by a radiologist and a district health board (DHB).
- 2. On 27 May 2019, the woman underwent a surveillance CT scan of her chest and abdomen. A radiology service was contracted by the DHB to perform the scan, which was reviewed and reported by the radiologist. The radiologist reported that he saw no metastases on the woman's lungs, and that there was no evidence of recurrence.
- 3. On 9 December 2019, the woman underwent a further surveillance CT scan of her chest and abdomen, which showed a 25mm lesion with the appearance of metastases in the left lower lobe of her lung. The report also noted that the lesion could be observed in previous scans, including the scan reported by the radiologist on 27 May 2019.
- 4. Following this diagnosis, the woman was immediately referred to the cardiothoracic and oncology departments at the DHB for further assessment and treatment, and underwent surgery in January 2020.

Findings

- 5. While acknowledging the complex nature of radiology reporting, the Deputy Commissioner considered that the woman's lung lesion should have been detected by the radiologist when he reported the scan on 27 May 2019. The Deputy Commissioner found that the radiologist did not provide the woman services with reasonable care and skill, in breach of Right 4(1) of the Code.
- 6. The Deputy Commissioner considered that the radiology service had appropriate systems in place to ensure the quality control of its imaging, and did not find the radiology service vicariously liable for the radiologist's breach of the Code.

Recommendations

- 7. The Deputy Commissioner recommended that the radiologist continue to implement the changes made to his practice as a result of this complaint to ensure that images reconstructed with soft tissue and lung algorithms are compared directly at the time of reporting, and also continue to have a self "second look" to improve accuracy. The radiologist has provided a written apology to the woman for the failing identified.
- 8. The Deputy Commissioner recommended that this case be used for shared learning for educational purposes (e.g., for discussion in review meetings with colleagues or students), and that the anonymised copy of this report be shared with all of the radiology service's branches.



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Complaint and investigation

- 9. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the radiology services provided to her by Dr B at the radiology service and the DHB. The following issues were identified for investigation:
 - Whether Dr B provided Mrs A with an appropriate standard of care on 27 May 2019.
 - Whether the radiology service provided Mrs A with an appropriate standard of care on 27 May 2019.
- 10. This report is the opinion of Deputy Commissioner Deborah James, and is made in accordance with the power delegated to her by the Commissioner.
- 11. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer
Dr B	Provider/radiologist
Radiology service	Provider
DHB	Provider

12. Also mentioned in this report:

Dr C	Radiologist
Dr D	Radiologist
Dr E	Respiratory physician

- 13. Further information was received from the Accident Compensation Corporation (ACC).
- Independent expert advice was obtained from a radiologist, Dr Graeme Anderson (Appendix A).

Information gathered during investigation

Introduction

15. This report discusses the care provided to Mrs A (aged in her thirties at the time of events), prior to her diagnosis of colorectal liver metastases¹ in her lung in December 2019 and, in particular, errors that occurred during the reporting of a CT² scan of her chest and abdomen on 27 May 2019.



¹ The spread of cancer cells from the place where they first formed to another part of the body.

² Computed tomography.

- ^{16.} In 2017, Mrs A was diagnosed with low rectal cancer and underwent radiotherapy and, subsequently, an abdominoperineal resection.³
- 17. Following Mrs A's diagnosis with cancer, she underwent surveillance scans on a regular basis to monitor her condition.

CT scan on 22 May 2018

^{18.} On 22 May 2018, Mrs A underwent a PET/CT⁴ scan of her whole body, which was reported by radiologist Dr C at the radiologist service. The scan demonstrated that Mrs A had liver metastases, but reported that there were no suspicious nodules⁵ in Mrs A's lungs. The scan also noted:

"Mediastinum⁶ and thoracic⁷ nodes: No enlarged nodes. Subcentimetre short axis mediastinal⁸ and hilar⁹ nodes with moderate update, probably reactive."

^{19.} Mrs A underwent liver resection surgery¹⁰ in June 2018.

CT scan on 26 November 2018

20. On 26 November 2018, Mrs A underwent a surveillance CT scan of her chest and abdomen at the DHB, which was reported by radiologist Dr D. The report stated that there were no suspicious lesions¹¹ in Mrs A's lungs.

CT scan on 27 May 2019

21. On 27 May 2019, Mrs A underwent another surveillance CT scan of her chest and abdomen. The radiology service was contracted by the DHB to perform this scan, and it was reviewed and reported by Dr B. Dr B reported that a comparison was made with previous CT scans performed on 7 March 2019¹² and 26 November 2018, and that he saw no metastases on Mrs A's lungs. Dr B recorded that there was no evidence of recurrence, and no further imaging was recommended.

CT scan on 9 December 2019 and diagnosis

22. On 9 December 2019, Mrs A underwent a further surveillance CT scan of her chest and abdomen, which showed a 25mm lesion with the appearance of metastases in the left lower lobe of her lung.

¹⁰ Surgical removal of all or a portion of the liver.



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³ Surgery in which the anus, rectum, and sigmoid colon are removed.

⁴ Positron Emission Tomography.

⁵ A growth of abnormal tissue.

⁶ The anatomical region located between the lungs and containing the principal tissues and organs of the chest except the lungs.

⁷ Pertaining to the chest.

⁸ The area between the lungs.

⁹ A depression or recess at the exit or entrance of a duct into a gland or of nerves and vessels into an organ.

¹¹ An area of abnormal tissue.

¹² This was a CT scan of the abdomen and pelvis.

- ^{23.} This was the first time the lesion had been reported. However, the report noted that the lesion could be observed in all of the three previous scans.
- 24. The report stated:

"... Metastases

Interval increase in size (47% since 27/05/2019) for the now bilobulated speculated mass at the medial aspect of the apex of the left lower lobe.

Date/Location	Left lower lobe
09/12/2019	25mm
27/05/2019	17mm
26/11/2018	7mm
22/05/2018	7mm
02/05/2017	0mm

•••

Comment

Interval 47% increase in the bilobulated lesion in the left lower lobe when compared to 27/05/2019 ..."

25. Following this diagnosis, Mrs A was immediately referred to both the cardiothoracic and oncology departments at the DHB for further assessment and treatment, and underwent a left lower lobe segmentectomy¹³ in January 2020.

DHB review

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- ^{26.} Mrs A raised concerns with the DHB for failing to diagnose the lesion in her lung when, based on the scan of 9 December 2019, it first presented on the imaging on 22 May 2018.
- 27. The DHB undertook a review of the imaging and prepared a Clinical Incident Report dated 26 August 2020 (the Incident Report). Each of the relevant scans were reviewed by the radiologist who undertook the original reporting. The scans were also reviewed by the Clinical Director of the radiology service and the DHB's Clinical Leader of Radiology, and an independent review was obtained from another radiology service. Feedback was also sought from Dr E, a respiratory physician and Clinical Director of Respiratory Services at the DHB at the time.

CT scans on 22 May 2018 and 26 November 2018

28. Based on commentary provided by the reporting radiologists, the radiology service, and Dr E, the Incident Report concluded that with hindsight, the nodule is detectable on the CT scans of both 22 May 2018 and 26 November 2018, but there were reasonable grounds for the failure to detect the nodule. This finding is based on the radiology service's explanation that it was in part a "perceptual discrepancy", in that the abnormality was not seen, and

¹³ A procedure to remove diseased lung tissue.



also in part an "interpretive discrepancy", in that the abnormality was seen, but explained as something different to the final diagnosis.

29. The Incident Report noted:

"[A] visualisation tool called maximum intensity projection (MIPS) is used to make small nodules more obvious. Unfortunately, when nodules are sitting up against blood vessels ... using MIPS can merge the nodule and vessel together, giving the impression they are one structure. In turn, the reporting radiologist may not realise that there is a nodule, thinking instead that it is part of the blood vessel ..."

- ^{30.} The radiology service's external reviewer also found that the "nodule could therefore be a pulmonary metastasis or also reactive intrapulmonary¹⁴ node¹⁵".
- 31. The Incident Report also noted:

"While in retrospect the pulmonary nodule is visible, the small size of the nodule, location of the nodule immediately adjacent to vascular structures ... and the multiple FDG avid¹⁶ adjacent lymph nodes does significantly impair the ability to detect the lesion."

- 32. The Incident Report stated that perceptual errors account for 60–80% of radiologists' errors, and appears to be a feature of the "extremely complex" system in which radiologists operate. It stated that in this case, the perceptual error was consistently reported as arising from the small size of the lung nodule and its close proximity to a blood vessel. The Incident Report noted that lung nodule detection is acknowledged to be among the more difficult of radiologists' tasks, and there is evidence that reliability of lung nodule detection falls with decreasing size of the nodule. Although medium to large lung nodules are detected consistently, inter-reader agreement and reader sensitivity for lung nodule detection diminish substantially as nodule size falls below 8–10mm.
- ^{33.} Dr E commented that "these observations are only made with the benefit of hindsight", and "it would be an unrealistic expectation for any radiologist to have detected them".

CT scan on 27 May 2019

^{34.} The Incident Report concluded that the nodule was detectable on the CT scan of 27 May 2019, despite the close proximity to the left hilum,¹⁷ and that it had grown in comparison to previous imaging.



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¹⁴ Situated within the lungs.

¹⁵ Normal lymph nodes. Commonly they are found during the assessment of CTs of the chest, and sometimes are difficult to distinguish from pulmonary nodules.

¹⁶ "FDG avid" is a term primarily used by radiologists to describe structures in PET scans that have taken up and concentrated fluorodeoxyglucose more than surrounding tissues.

¹⁷ A depression or fissure where structures such as blood vessels and nerves enter an organ.

Dr B

- ^{35.} Dr B told HDC that he received a Fellowship from the Royal Australian and New Zealand College of Radiologists (RANZCR) and has been working as a consultant radiologist.
- ^{36.} Dr B acknowledged the error on his part for failing to detect the nodule on the CT scan on 27 May 2019. Dr B stated:

"The normal practice would be to review both the images reconstructed with a lung algorithm, which is better for detecting lung nodules and the images reconstructed with a soft tissue algorithm, which is better for assessing the mediastinum (heart and major blood vessels). In hindsight, on review of the images, it was most likely a perception error on my part, with the lung nodule being close to vessels, and my interpretation was that the 'altered tissue' was a blood vessel."

- 37. Dr B said that he has learnt from his error and has changed his practice to ensure that images reconstructed with the soft tissue and lung algorithms are compared directly at the time of reporting, as well as having a self "second look" for improving accuracy.
- ^{38.} Dr B apologised to Mrs A for his role in the delayed diagnosis and the additional trauma and distress it has caused to her and her family.

Radiology service

- ^{39.} The radiology service accepts that the non-reporting of the pulmonary lesion on the CT scan of 27 May 2019 was a perceptual error on Dr B's part. The radiology service said that a perceptual error is deemed to have occurred when retrospectively an abnormality is determined to have been present on a diagnostic image, but not seen by the interpreting radiologist at the time of primary interpretation.
- 40. The radiology service said that with the passage of time, it is extremely difficult to determine what may have contributed to the error, as radiologist fatigue, workload, distractions, or interruptions (such as urgent clinical matters, conversations, or emails) may all play a role. The radiology service stated: "[W]hilst striving for perfection, any system with human involvement will be vulnerable to error."
- ^{41.} The radiology service also said that it has systems in place to minimise perceptual errors. At the time the error was made, the radiology service had a full quota of radiologists to meet the volume of imaging reporting. The radiology service stated that the reporting station Dr B was using satisfied Medical Physics and IANZ¹⁸ requirements in relation to monitor resolution and luminescence, and attention was given to the ambient light and ergonomic set-up of the reporting room. The radiology service said that it is a quiet space, protected as much as possible from interruption.

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¹⁸ International Accreditation New Zealand.

42. The radiology service stated that it has considered employing computer-aided detection for reviewing imaging, and is awaiting validation of products by RANZCR for widespread use before proceeding.

Further information — ACC

43. A radiologist, Dr David Milne, provided external clinical advice to ACC in relation to Mrs A's treatment injury claim. Dr Milne noted:

"Suspicion of a small lung metastasis was raised on subsequent CT PET and CT examinations but in fairness, this is a difficult call on grounds of small size of the lung nodule and the confounding¹⁹ mild FDG avidity seen in the hilar²⁰ and mediastinal²¹ nodes at the time of the CT PET of 22/5/18. There was uncertainty about whether the nodule had increased in size on the imaging of 26/11/18 but unanimous agreement that there was an enlarging nodule likely a lung metastasis in the left lower lobe on the CT of 27/5/19. My impression is that it would have been reasonable to expect that the nodule be detected on this imaging of 27/5/19 and to assume that the nodule was a lung metastasis from the prior rectal cancer ..."

- ^{44.} Dr Milne said that the lung metastasis was there to be seen on the CT scan of the chest and abdomen on 27 May 2019, but that errors of observation and interpretation are common in clinical radiology and should not give rise to concerns about competence in respect of the reporting radiologist if isolated.
- 45. ACC also obtained external clinical advice from an oncologist who acknowledged that the delay in diagnosing the lung lesion would have been very stressful for Mrs A, but considered that the delay would not have affected the long-term prognosis significantly. The oncologist advised that although the lung metastasis had increased in size over time, it had not caused any other physical injuries to the lung or other organs, and had not caused any further detectable spread.

Responses to provisional opinion

- ^{46.} Dr B was given an opportunity to respond to the provisional opinion. He provided Mrs A with a written apology for the failing identified, and for the impact this has had on Mrs A's subsequent care.
- 47. Dr B said that he has learnt from his error and has changed his practice to avoid recurrence.
- ^{48.} The radiology service and Dr C were provided with an opportunity to respond to the provisional opinion, and, where relevant, their responses have been incorporated into this report.



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¹⁹ To confuse something with something else.

²⁰ Relating to or located near a hilum, which is a depression or fissure where structures such as blood vessels and nerves enter an organ.

²¹ The area between the lungs.

²³ February 2022

- ^{49.} The radiology service accepted the provisional opinion and said that it was "considered and balanced".
- ^{50.} The radiology service commented on the blind review that was conducted by Dr Anderson, a radiologist who provided independent expert advice to HDC, and said that "a truly blind review would be to analyse studies in the setting of a normal day's workload, with no further context". It said that while this may not be reasonable or possible in practice, it believes that the distinction should be made, as the scrutiny such a case will receive will be greater than for a "routine" case.
- 51. The DHB and Dr D were provided with an opportunity to respond to the provisional opinion.
- 52. Dr D sincerely apologised to Mrs A for not diagnosing the lung nodule on 26 November 2018. Dr D told HDC that since she has been made aware of this case, and the difficulty in detecting nodules around blood vessels, she has made "a point to look at these areas even more carefully" to try to reduce observation and perception errors.
- 53. Mrs A was provided with an opportunity to respond to the "information gathered" section of the provisional opinion. She reiterated her concerns that the tumour was not found earlier. She stated:

"Had the tumour been removed at the time of my liver resection it would not have been growing in my chest for 18 months requiring them to take a wedge out of my lung. It would have not resulted in the spread to the rest of my lung, which this year resulted in another surgery resulting in the total removal of the bottom left lobe of my lung."

Opinion: Dr B — breach

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- 54. As set out above, Mrs A's CT scan on 27 May 2019 was reviewed and reported by Dr B, who saw no metastases on Mrs A's lungs.
- 55. Dr B explained that because of the location of the lung nodule in close proximity to the blood vessels, he incorrectly interpreted it to be a blood vessel. Dr B accepts that most likely he made a perceptual error.
- ^{56.} The nature of radiology reporting is complex, and it is widely accepted that due to perceptual errors, radiologists may from time to time miss what, with hindsight, may be obvious.
- 57. Previously this Office has noted that just because it is widely accepted that errors of perception (such that a radiologist misses an apparent abnormality that would have been detected by most of his or her peers in similar circumstances) occur in a small but persistent

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number of radiology interpretations, that is not determinative in assessing whether the standard of care has been met in a particular case.²²

- ^{58.} Whether the standard of care has been met will be assessed on a range of factors, including the clinical history of the patient and how obvious the abnormality is. The standard of care applicable in the present case is the care and skill that an ordinarily careful radiologist would exercise under similar circumstances.
- ^{59.} I sought external clinical advice on this issue from a radiologist, Dr Graeme Anderson. Initially, Dr Anderson completed a review of Mrs A's scans without any clinical history (a "blind review").
- 60. In his blind review of the CT scan on 27 May 2019, Dr Anderson identified the lung nodule and metastasis. He reported "LLL nodule 16 x 14mm" and a "solitary enlarging left lower lobe pulmonary metastasis". His blind review concluded that the scan showed further growth in the pulmonary metastasis compared with the previous scan.
- ^{61.} I acknowledge that perceptual errors do occur in radiology. However, having considered Dr Anderson's advice, and given the size of the lung nodule at that time, I consider that it should have been detected by Dr B. In this case, there is unanimous agreement between the DHB's reviewers, the ACC advisors, the radiology service, and Dr B that the lung nodule was visible on the CT scan on 27 May 2019. At that time, the lung nodule measured approximately 17mm in size.
- 62. While the lung nodule on the previous two CT scans was obvious only in hindsight, this was not the case with the CT scan on 27 May 2019. Further, Mrs A's clinical history indicated that she was at high risk of developing metastases, and Dr B was on notice that she was being screened specifically for this purpose. Dr B has accepted that his reporting technique may have contributed to the perceptual error.
- 63. I consider that an ordinary radiologist in these circumstances exercising reasonable care and skill would have detected the lung nodule on the 27 May 2019 scan. Accordingly, I find that Dr B failed to provide Mrs A with an appropriate standard of care on 27 May 2019, in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights ²³ (the Code).
- ^{64.} While it is uncertain whether earlier detection would have affected the long-term prognosis, later detection meant that Mrs A and her family were subject to further trauma and distress, which could have been avoided.
- ^{65.} I acknowledge that Dr B has apologised to Mrs A and expressed regret for his role in the delayed diagnosis and the additional trauma and distress this has caused to her and her family.



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²² See opinions 15HDC00685 and 17HDC00415.

²³ Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

²³ February 2022

Opinion: Dr C — other comment

- ^{66.} The CT scan on 22 May 2018 was reported at the radiology service by Dr C, who noted that there were no suspicious nodules in Mrs A's lungs, but that there were "short axis mediastinal and hilar nodes with moderate update, probably reactive".
- 67. My expert advisor, Dr Anderson, completed a blind review of the CT scan taken on 22 May 2018 and detected a small nodule, but noted that it "could represent a solitary pulmonary metastasis or also a reactive intrapulmonary node".
- 68. Dr Anderson advised:

"It is well recognised that colorectal metastases can indicate a Sarcoid²⁴ like reaction in especially mediastinal and hilar lymph nodes. However the question should always be asked 'could they be malignant?' Unfortunately the small nodule in the left lower lobe is also avid however could be interpreted as an intrapulmonary lymph node (which can also be avid in Sarcoid like reaction)."

- ^{69.} Dr Anderson advised that although the small lung nodule in the left lower lobe is visible, it could also be interpreted as a lymph node, as commonly lymph nodes are found during the assessment of CT scans of the chest.
- 70. Dr Anderson's blind review of the 22 May 2018 CT scan is consistent with that of the radiology service's external reviewer, who also considered that the "nodule could therefore be a pulmonary metastasis or also reactive intrapulmonary node".
- I accept that at that time it was difficult for the lung nodule to be characterised definitively.
 I also accept the consensus view expressed in the Incident Report that it is challenging to detect lung nodules that measure below 8–10mm in size.
- 72. Dr Milne, who provided external clinical advice to ACC, also concluded that while suspicion of a small lung metastasis was raised on the 22 May 2018 CT scan, it would be "a difficult call" because of the small size of the lung nodule, and it having the appearance of something else. There was also only "mild FDG avidity" seen in the area between the lungs, which means that the nodule may have lit up on the CT scan, but the activity level was mild. Active cancerous nodules are more likely to show a higher degree of activity.²⁵
- 73. At the time of the CT scan on 22 May 2018, the lung nodule was small and measured approximately 7mm in size. This was further complicated by the location of the lung nodule, being in close proximity to a blood vessel and therefore having the appearance of a blood vessel.

²⁵ Global Resource for Advancing Cancer Education Forum accessed on 9 December 2021.



²⁴ An inflammatory disease marked by the formation of small nodules of immune cells in the lungs, lymph nodes, and other organs.

74. Given the size and location of the lung nodule, I consider it was reasonable for Dr C not to have detected the intrapulmonary lung nodule on the CT scan of 22 May 2018.

Opinion: Dr D — other comment

- 75. The CT scan on 26 November 2018 was reported on by Dr D, who reported that there were no suspicious lesions in Mrs A's lungs.
- 76. Dr Anderson's blind review of the CT scan taken on 26 November 2018 noted that the left lower lobe nodule had increased in size slightly since the previous scan, and that it was "now most likely a metastasis". Dr Anderson measured the nodule at 9mm at that time.
- 77. Dr Milne, who provided external clinical advice to ACC, was uncertain as to whether the nodule had increased in size on the imaging of 26 November 2018. According to the CT scan report of 9 December 2019, the nodule had measured 7mm in size on 26 November 2018, with no increase in size since the CT scan on 22 May 2018.
- 78. While there is some inconsistency in relation to the interpretation of the size of the nodule on the scan taken on 26 November 2018, it still measured below 10mm. I accept the consensus view expressed in the Incident Report that it is challenging to detect lung nodules that measure below 8–10mm in size. I also note that detection was further complicated by the location of the lung nodule, being adjacent to a blood vessel.
- 79. Given the size and location of the lung nodule, I consider that it was reasonable for Dr D not to have detected the nodule on the CT scan taken on 26 November 2018.

Opinion: Radiology service — no breach

- 80. As a healthcare provider, the radiology service is responsible for providing services in accordance with the Code.
- ^{81.} Dr Anderson reviewed the relevant imaging and found that all of the reports follow standard international or RANZCR guidelines for oncology reports, and that all of the scans were performed using standard protocols. Dr Anderson considers the quality of the reports to be appropriate, and advised that his peers would agree.
- ^{82.} In this case, I consider that Dr B's independent perceptual error did not indicate broader systems or organisational issues at the radiology service. Accordingly, I consider that the radiology service did not breach the Code directly.



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²³ February 2022

- ^{83.} In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) of the Act if it can prove that it had taken such steps as were reasonably practicable to prevent the acts or omissions.
- 84. The radiology service is an employing authority for the purposes of the Act, and Dr B is an employee of the radiology service. As set out above, I have found that Dr B breached Right 4(1) of the Code for failing to provide services to Mrs A with reasonable care and skill.
- 85. I accept that the radiology service had systems in place to ensure the quality control of its imaging, and that in this case the error was an independent perceptual error by Dr B. Accordingly, I find that the radiology service is not vicariously liable for Dr B's breach of the Code.
- ^{86.} I also note that currently the radiology service is instituting a programme that helps to manage a radiologist's workload and is also used for image review and interpretation. The programme will incorporate a peer review module, which will require a percentage of all reported studies to be reviewed by another radiologist for quality control purposes.

Recommendations

- 87. As recommended in the provisional decision, Dr B provided a written apology to Mrs A. I recommend that Dr B:
 - a) Continue to adopt the changes made to his practice by ensuring that images reconstructed with the soft tissue and lung algorithms are compared directly at the time of reporting, as well as having a self "second look" to improve accuracy. Dr B is to provide HDC with evidence of having done so over a three-month period from receipt of this decision.
 - b) Use this case as the basis of shared learning for educational purposes (e.g., for discussion in review meetings with colleagues or students).
 - c) Share HDC's anonymised report with all branches of the radiology service, within three weeks of the date of the anonymised report being placed on the HDC website.

Follow-up actions

- 88. A copy of this report will be sent to the DHB.
- 89. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand and the Royal Australian and New Zealand College of Radiologists, and they will be advised of Dr B's name.
- ^{90.} A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, <u>www.hdc.org.nz</u>, for educational purposes.



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Appendix A: Independent clinical advice to Commissioner

Blind review

The following report was prepared by radiologist Dr Graeme Anderson following a blind review of [Mrs A's] CT scans:

"I have read the Guidelines for Independent Advisors

Case Review: Patient: [Mrs A], GBA2526.

*I reviewed these exams without what would be usual practice: Review of relevant old imaging or evaluation of local staging examinations eg MRI.

No history was provided either. This would not be normal practice when reporting complex imaging.

The SECTRA viewer provided was 'Windows only' so I loaded the DICOM images into a free Mac compatible viewer 'Horos' and viewed on my laptop.

Please note that images would normally be viewed on a dedicated IANZ approved workstation, when reporting.

1. PET CT 30/5/2017

The PET scan shows an avid (SUV max not available on the provided images) low rectal tumour measuring 40mm craniocaudally on PET. 1 x 9mm mildly avid mesorectal node (2 o'clock) and 1 x 8mm mildly avid superior rectal node.

No other avid nodes.

Avidity in Right iliac fossa secondary to physiological ovarian uptake.

No metastatic disease elsewhere.

Impression: Rectal tumour with mesorectal lymph node involvement but no distant disease.

2. PET CT 22/05/18

Abdomen:

Post-operative changes in the Pelvis with colostomy in situ.

Small focus of avidity adjacent to Rt iliac bifurcation again thought to be physiological ovarian uptake.

40mm Segment 4 Hepatic Metastasis, nil other abdominal disease.

Chest:

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Development of bilateral mildly avid but borderline size significant hilar and mediastinal lymph nodes (largest level 7 node 14 x 8mm (SUV max not provided)

6mm nodule centrally in LLL superior segment, with similar avidity to nodes.

This nodule is new since the 30/5/17 PET CT.

No other pulmonary nodules.

No disease elsewhere

Impression: Solitary hepatic metastasis

Chest nodal changes suggest reactive granulomatous/sarcoid like reaction sometimes seen with colorectal tumours. Endoscopic Bronchial Ultrasound Sampling (EBUS) if it will alter management to differentiate

The 6mm left lower lobe nodule could represent a solitary pulmonary metastasis or also a reactive intrapulmonary node.

3. CT CAP 26/11/18

This was compared to the PET CT imaging as above

Hepatic resection cavity (Segment 4/8) measures 65 x 30mm. Similar enhancement and small sub capsular collection/seroma

No new liver lesion or changes in pelvis at resection site.

<u>Chest:</u> Left lower lobe nodule slightly bigger than previous PET at 9mm.

Prominent mediastinal and hilar nodes similar to slightly smaller

No other pulmonary nodules

Impression:

9mm Left lower lobe nodule now most likely a metastasis.

Post treatment changes in hepatic metastasis.

No disease elsewhere.

4. CT CAP 27/5/19

Persistent post resection cavity in Liver appears a little larger 70 x 42mm, no enhancing components or new areas of enhancement.

In the Pelvis stable post-surgical changes (slight levator thickening appears stable)

Chest: LLL nodule 16 x 14mm. Nodes stable, not size significant. No further nodules.

Impression

Solitary enlarging left lower lobe pulmonary metastasis.

Post treatment changes in the liver, slightly larger. An MRI to differentiate between post treatment change and local recurrence.



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5. CT CAP 9/12/19

Liver: Post resection changes stable 64 x 39mm

Pelvis: Stable post treatment changes.

<u>Chest:</u> LLL metastasis 27x 19mm has further increased in size.

Impression: Enlarging left lower lobe metastasis. No new disease.

Case summary:

PET (5/17) showed rectal tumour and 2 small mesorectal nodes, no distant metastases

PET (5/18) showed solitary hepatic metastasis and reactive changes in chest, small nodule in LLL in retrospect was a metastasis but possibly a reactive intrapulmonary node.

CT (11/18) showed post-operative changes in Liver and Pelvis and slight increase in size of LLL nodule (now likely a metastasis)

CT (5/19) showed further growth in pulmonary metastasis and lack of resolution of hepatic resection cavity but no definitive tumour bed recurrence.

CT (12/19) Also showed further growth in LLL metastasis, but stable changes in the liver.

Dr Graeme Anderson Radiologist BHB MBChB FRANZCR

1/10/2020"

Expert advice

The following expert advice was obtained from Dr Anderson following his blind review:

"Overview

I was asked by the Commissioner to provide an opinion on Case Number C19HDC02399.

This was initially a blind review of the imaging (completed 30/09/20).

This report has been requested after details of the case have been provided, including copies of radiology reports and clinical information (received 1/11/20).

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I have no conflicts of Interest around this case, although I would state that I was asked to perform a similar blind read for this case for ACC (sent 13/04/20).

Qualifications:

I am a Radiologist who has been qualified for over 20 years.

Degrees: BHB (Auckland) 1987 MBChB (Auckland) 1990. FRANZCR 2000.

<u>Post graduate training</u>: Chest Imaging Brompton Hospital London 2007. ACR PET Course (Reston VG) 2009.

Positions:

Radiologist Counties Manukau Health 1999 to present.

Radiologist co-lead CMH/NDHB Lung Cancer MDM 2014 to present.

Network Training Director Northern Region Radiology Training Program (2018 to present)

Radiologist Ascot Radiology 2007 to present (Current Lead of PET CT)

Northern Region PET Variance Committee Chair 2013 to Dec 2019.

I have been reporting PET CT for nearly 10 years and have primary or second read over 10,000 examinations.

Referral Instructions from the Commissioner:

'Provide a blind review of the scans undertaken on [Mrs A] by [the DHB] and [the radiology service]'

'In light of this review and with the provided further information about the complaint and the clinical circumstances of [Mrs A's] treatment identify whether the care provided was consistent with accepted practice.'

Documents provided:

- 1. Memory stick containing the imaging files: PET CT 30/05/17, PET CT 22/05/18, CT CAP 26/11/18, CT CAP 27/05/19, CT CAP 9/05/19)
- 2. Letter of complaint 18/12
- 3. [DHB] response 19/02/20
- 4. [Radiology service] response 4/02/20
- 5. Relevant clinical records from [the DHB] covering the period 2017–2020
- 6. Radiology Reports from [the radiology service] covering the period 2017–2020

I have been asked to comment on:

[Radiology service];

- 1. The quality of the radiology report dated 22/5/18
- 2. The quality of the radiology report dated 27/5/19



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

3. The reasonableness of the response from [the radiology service], including explanations given by the reporting radiologists.

[DHB].

- 1. The quality of the radiology report dated 26/11/18
- 2. The quality of the radiology report dated 27/5/19
- 3. The reasonableness of the response from [the DHB], including explanations given by the reporting radiologists.

For each answer provide.

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

Background

[Mrs A] was diagnosed with low rectal carcinoma in April 2017 and underwent a short course of radiotherapy prior to an abdominal-perineal resection.

Pre-operative staging imaging identified a locally advanced tumour with mesorectal lymph node involvement but no distant metastatic disease (PET CT 30/05/17).

Various imaging was undertaken between 2017 and 2019. In December 2019, [Mrs A] was diagnosed with lung metastasis and underwent further treatment.

May 2018.

On 07/05/18 a CT CAP (Chest, Abdomen and Pelvis) was performed due to rising CEA levels.

A metastasis was identified in the liver which was subsequently confirmed on MRI liver (2/5/18) and PET CT (22/05/18).

A small left lower lobe nodule was not identified on either the CT CAP or the PET CT.

November 2018.

A CT CAP (18/09/18) was undertaken and did not identify the pulmonary nodule.

May 2019.

A CT CAP was performed (27/05/19) and reported no evidence of recurrence or metastatic disease.



December 2019.

A CT CAP was performed and the left lower lobe pulmonary nodule was detected and reported.

[Radiology service] Reports:

22/5/2018 FDG PET CT.

The report follows a standard oncological template that is widely used in New Zealand and overseas (especially ... Hospital where the Radiologist received their fellowship training).

The template used in the original PET CT report (30/5/2017) also uses a template although more tailored to staging colorectal tumours that is outlined in RANZCR reporting guidelines.

Template reports have been shown to improve errors in especially oncologic reporting as they provide an inbuilt checklist as the Radiologist reports.

The report states 'Lungs and pleura: No suspicious nodule' and 'Mediastinum and thoracic nodes: No enlarged nodes. Subcentimetre short axis mediastinal and hilar nodes with moderate uptake, probably reactive'.

Impression;

Right Hepatic Metastasis. No other metastatic disease demonstrated.

The report is judged as clear and concise and well laid out.

On reading this case myself, I noted that there was avid mediastinal and hilar lymph nodes (well above mediastinal background although no SUV measured).

SUV or 'Standard Uptake Values' measure how much uptake of radioactive tracer various tissues have, eg normal heart and brain are usually high and tumors are often visible because they have high SUV values.

It is usual practice to measure SUV values of tumors and sometimes other abnormal structures (eg hilar and mediastinal lymph nodes in this patient).

No SUV values are given for the liver metastasis or the lymph nodes (and I could not find any measured on the images).

Measuring an SUV value not only brings validity to the statement 'probably reactive' but also concentrates the reporting Radiologist on the area of abnormal uptake.

It is well recognised that colorectal metastases can incite a Sarcoid like reaction in especially mediastinal and hilar lymph nodes. However the question should always be asked 'could they be malignant?'.



Unfortunately the small nodule in the left lower lobe is also avid however could be interpreted as an intrapulmonary lymph node (which can also be avid in Sarcoid like reaction).

One last statement about the report.

There is no indication whether PET reports are double read at [the radiology service] (I see no note of a double reader).

In the 2 large [city] PET practices all PET CT scans are double read, even when the primary Radiologist is very experienced.

There is a lot of information and a large number of images on a PET CT (4–5000).

Double reading has been shown to improve accuracy of all Radiology reporting.

Comments on PET technique.

Detailed Fused MPR (Multiplanar Reconstructions) images have been performed through the liver, this is an excellent way of identifying liver metastases that might be quite subtle as the liver is normally avid and small metastases difficult to see.

Liver MRI (which the patient also had) has been shown to be more sensitive for identifying hepatic metastases however.

With lung nodules there is not a technique that is better than PET CT. Fused lung reconstructions are very useful in staging of lung carcinomas and can make small lung nodules much easier to perceive, especially if they lie centrally adjacent to vessels.

27/5/2019. CT CHEST, ABDOMEN/PELVIS.

The report also follows a standard format, it is clear and concise.

Comparison was made with previous CT scans but not with the previous PET CTs.

It is standard practice to compare with the most recent imaging. Sometimes older examinations are reviewed but most often this is where there is a new question of progression (eg a rising CEA) or the last scan was indeterminate for progression.

The report is very brief, but important sites of possible local recurrence in the surgical bed and in the liver are described correctly.

Other potential sites of common spread (eg Lungs and lymph nodes are also reported).

The left lower lobe nodule is not reported despite it now being 16 x 14 mm.

<u>In Summary</u>: A brief but structured report which compared with appropriate previous imaging.

[Radiology service] Response:

A. [Dr C]:

Summary:

- 1. Appropriate qualifications and experience of Radiologist.
- 2. Radiologist Peer review occurring via Multidisciplinary Meetings.
- 3. Acknowledges that the lung metastasis was not identified and reported.
- 4. Outlines some of the concepts of perceptual and interpretive discrepancies.
- 5. Outlines some of the limitations of MIP images in small lung nodules close to vessels.
- 6. Provides details of an internal blinded review that notes the difficulty of identifying the lung nodule on the PET CT.
- B. [Dr B]

Summary:

- 1. Provides a sincere apology.
- 2. Outlines experience.
- 3. Notes the perceptual error (and also notes the difficulty of identifying small nodules close to central blood vessels).

Comments:

No suggestions as to how things could change in the practice or in [Dr C's] Reporting to reduce the likelihood of this occurring again.

[Dr B] offers a solution of 'reviewing soft tissue and lung windows in tandem.' A self 'second look' is a recognised method for improving one's accuracy.

Both responses are adequate, offer an apology for the metastasis not being identified on the scans, and some of the recognised reasons that small lung nodules may not be identified on CT and PET/CT.

Only [Dr B] suggests a change in practice to help prevent this occurring again.

[DHB] reports.

25/11/18 CT Chest Abdomen and Pelvis.

The report is very detailed and compares the current examination with all previous imaging including the PET CT from 22/05/18.

The report answers the clinical question which was raised in the previous CT (18/09/18) of the abdomen, ie whether colitis had resolved.

No specific comment is made regarding whether the hilar and mediastinal nodes at the PET/CT on 22/05/18 which were avid, had changed in size.



But it did note a thymic remnant and some dependent sub pleural changes in the lung indicating that these structures were actually viewed as part of the radiologist's search pattern.

The left lower lobe nodule (now measuring 9mm by my measurement) is not reported.

<u>In Summary:</u> A clear well laid out, and detailed report that answers the clinical question. Clear evidence that the radiologist used routine search patterns and 'check areas' when reporting.

The Report has two radiologist names at the end. [Dr D] and ... I am unsure whether this examination was double read.

27/05/2019 CT Chest Abdomen and Pelvis.

The assessment of this report has been outlined in [the radiology service] section.

[DHB] Response:

Summary:

- 1. Includes an assessment by a Respiratory Consultant, [Dr E], who notes that the lesions are only readily visible with the benefit of hindsight, and notes that the nodule was not identified at the GI MDM.
- 2. Includes a statement by the Radiologist [Dr D].
- 3. Includes a sincere apology.
- 4. Outlines the process of reviewing the images for the patient's benefit, and offers explanations of why the nodule was not identified (perceptual and alliterative bias).

Comments

No comment as to whether the case was to be discussed at a department discrepancy meeting in order to educate other radiologists as to the reasons for not detecting the nodule and improve detection in future cases.

What is the Standard of Care?

The scans have been reported by well trained and experienced Radiologists. All RANZCR Fellows and subspecialty trained.

All of the reports in question from [the radiology service] and [the DHB] follow standard International or RANZCR guidelines for Oncology Reports.

All of the scans have been performed using standard protocols.

The quality of the reports would be seen as appropriate by peers.



Recommendations for Improvement:

1. Lesion detection improvements.

Studies evaluating Radiologist accuracy in identifying small pulmonary nodules on CT scans demonstrated a mean accuracy of only 49 percent for nodules measuring 5mm in size.

Some methods for improving accuracy include the utilization of Maximum Intensity Projection (MIP) lung Images (which were utilized in this case).

Double Reading of examinations including PET CT (which is utilized routinely at the 2 large [city] PET practices ...) also improves nodule detection.

In some practices formal double reading of PET is not practical, however automated 'double reading' using computer assisted diagnosis (CAD) and other Artificial Intelligence techniques are becoming more available (and are used routinely already in some situations eg CT colonography).

2. Educating about Radiological Discrepancies:

Shared discussion of Radiological Discrepancies in departments via formal meetings, the Radiological Mortality and Morbidity Meeting equivalent, has also been shown to reduce all forms of Radiological error.

Formal double reading also works in this way with more lesions being detected and the differences in perception and search techniques between readers benefitting both parties.

3. Measuring and recording SUV values in abnormal tissues.

Documenting the actual SUV in the report can be useful to avoid ambiguity with qualitative statements that may be interpreted variably and providing a measurable baseline for follow up.

4. Using Fused Lung Images to improve conspicuity of small lung lesions.

By fusing PET images with matched lung reconstructions, small even faintly avid lung nodules have increased perspicuity and the increased anatomical detail of lung structures improves differentiation of vascular and bronchial structures and hilar nodes and perihilar nodules.

Final Statements:

There is little understanding amongst non-Radiologist clinicians about the limitations of Radiological examinations (and some ignorance amongst Radiologists themselves).

CT and PET CT particularly of the Lungs have significant error rates, correctly called 'false negatives'. Unlike so much of clinical practice for example clinical examination, every pixel of the investigation is recorded in perpetuity, and then may be subject to intense retrospective analysis that was not available at the time to the reporting Radiologist.



The following retrospective analysis that occurs once a lesion is finally perceived on a follow up examination may be reflected back to the patient in a clinic visit as a 'mistake', rather than the test which has a known false negative rate (like all tests) failing to provide the answer early on in the disease process as is so often the case.

It behoves all Radiological practices and the patients they serve to discuss such 'false negatives' in an open manner both amongst themselves in formal discrepancy meetings. This is the forum to discuss improvements that can be made in the practice.

Examples that are pertinent to this case, Formal double reading of PET, Computer Aided Detection, PET protocol changes, including Fused lung reconstructions and recording of SUVs for abnormal lesions.

Dr Graeme Anderson Radiologist. BHB MBChB FRANZCR. 17/11/20

References:

- 1. Lung Nodule and Cancer Detection in CT Screening. Geoffrey D Rubin, MD. J Thorac Imaging. 2015 Mar; 30(2): 130–138.
- 2. How We Read Oncologic FDG PET/CT. Michael S. Hofman & Rodney J. Hicks. Cancer Imaging 35 (2016).
- 3. Common patterns in 558 diagnostic radiology errors. Jennifer J Donald. Stuart A Barnard. Journal of Medical Imaging and Radiation Oncology Volume 56, Issue 2. First published: 13 April 2012.
- 4. Perceptual error and the culture of open disclosure in Australasian radiology. Pitman AG. Australas Radiol 2006; 50: 206–11."

