General Practitioner, Dr B

A Report by the
Health and Disability Commissioner

(Case 19HDC01320)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman by a general practitioner (GP) in 2017 when the GP surgically removed a lesion[1] from behind the woman's left ear. The report highlights the importance of taking the necessary steps to confirm that the characteristics of a presumed benign epidermoid/sebaceous[2] cyst (including the cyst contents) are typical for the suspected pathology, particularly if no histology is requested. The woman preserved the excised lesion and, nearly two years later, histology was carried out and the woman was diagnosed with stage 4 metastatic melanoma (skin cancer).[3]

2. The GP now sends all excised tissue for histology (with the exception of skin tags[4]), and advised that in future, if he makes a decision not to send excised tissue for histology, he will document the decision and his reasons in the clinical notes.

Findings

3. The Commissioner considered that by omitting to transect the woman's excised lesion to confirm its cystic nature before deciding not to send it for histology, which delayed the woman's diagnosis, the GP did not provide services with reasonable care and skill, in breach of Right 4(1) of the Code.

Recommendations

4. The Commissioner recommended that the GP provide a written apology to the woman, and provide relevant evidence to demonstrate appropriate management of minor surgery and histological analysis of surgical samples. The GP has provided the requested information and letter of apology.

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her by Dr B. The following issue was identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care in March 2017.*

6. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	Provider/GP
Medical centre	Provider/general practice

[1] In this report, the lesion is also referred to as a "lump" and a "cyst".
[2] Sebaceous cysts, also known as epidermoid cysts, are benign and usually painless and slow-growing, and normally form around a hair follicle. Sometimes the cyst can become inflamed and tender.
[3] Stage 4 indicates that the melanoma has spread to other parts of the body, making it harder to treat.
[4] A small, typically benign growth on the skin.

7. Also mentioned in this report:

Dr C	GP
Dr D	Clinical Director

8. Further information was received from:

District Health Board (DHB)
The Accident Compensation Corporation (ACC)

9. In-house clinical advice was obtained from GP Dr David Maplesden (Appendix A).

Information gathered during investigation

10. This report discusses the care provided to Mrs A (in her eighties at the time of events) in relation to the removal of a lesion behind her left ear by GP Dr B at the medical centre, and subsequent follow-up care. Nearly two years after the lesion was removed, histology of the excised sample was carried out, and Mrs A was diagnosed with stage 4 metastatic melanoma (skin cancer).

Background

11. Mrs A told HDC that she had had a lump behind her ear for several years and first mentioned it to her GP, Dr C, on 17 June 2015. At that time, Dr C recorded that the lump had been present for years and had become bigger and sore in the last two weeks, but that "today [the lump] is reducing and not tender". Dr C diagnosed the lump as a sebaceous cyst and documented: "Not inflamed or red, not tender. No discharge. ~2cm [diameter]." Dr C recorded that she offered to remove the cyst but that Mrs A "declines if not necessary", and that Mrs A was aware to request a review if the cyst became painful or increased in size. In response to my provisional opinion, Mrs A said that she declined removal at that time as she was due to travel abroad four days later and understood from the consultation that the cyst "was not of any undue concern or urgency".

Lesion removal and follow-up care

12. Almost two years later, on 24 February 2017, Mrs A was seen by Dr C again in relation to the lesion behind her ear. Dr C documented: "Mod large seb cyst behind left ear ~2cm diam, not inflamed, mobile from underlying tissue." The records note that she discussed removal of the cyst with Mrs A, and then asked a colleague, Dr B, to review Mrs A.

13. Dr B told HDC that prior to these events, he had spent "many years in hospital surgical rotations", which provided him with confidence in surgical techniques. He stated that his colleagues at the medical centre were aware of this and, as a result, "would refer more complex surgical cases" to him.

14. Dr B said that when Dr C requested his opinion on Mrs A's case, he was in a consultation with another patient. Dr B stated that Dr C provided him with a brief history of Mrs A's lesion and asked if he agreed with the diagnosis of a sebaceous cyst. Dr B said that after examining the lesion and taking into account the history, he agreed with the diagnosis.

15. Dr B told HDC that he was then asked whether he would be able to excise the lesion at Mrs A's request, and Dr C documented that Dr B would be "happy to remove [it] for her". Dr B stated that he told Mrs A that although removal of the lesion was not necessary owing to the benign diagnosis, excision was an option, and Mrs A could make an appointment if she wished to proceed.

16. The clinical records show that on 3 March 2017, Mrs A was seen by Dr B for "excision of left-auricular[5] lesion", and that Dr B carried out an "elliptical[6] excision" of the lesion after having obtained Mrs A's written consent for the procedure. Mrs A told HDC that she then asked Dr B what he was going to do with the cyst. She said that Dr B replied that he would "dispose of it", and she asked to keep it. Dr B stated that although he does not recall that conversation, he does not dispute Mrs A's recollection, "considering the specimen entered her possession". Although it is not evident from the clinical notes, Mrs A subsequently retained the specimen in a container of formalin.[7]

17. Dr B documented the plan to review the surgical site "as required". Although it is not documented, Dr B told HDC that he also would have "reiterated post-surgical complications to watch for such as infection and bleeding".

18. Dr B stated that he did not consider disrupting the cyst capsule to confirm characteristic contents, and did not send the excised specimen for histology.[8] He did not document that decision. In relation to this lack of documentation, Dr B stated:

> "Normally, when a request for histology is made, a copy of the request is available in the notes, as is the case for any other laboratory request. There is an absence of this for [Mrs A], which indicates that it was not sent for histology. Hence I did not think to actively record the decision not to do so."

Subsequent events

19. Mrs A told HDC that in 2018, the area where the cyst had been removed started to itch and feel tender. She re-presented to the medical centre on three occasions for review of this issue — on 2 May, 29 June, and 26 September 2018 — and was seen by Dr C, Dr B, and another GP, respectively.

20. On 31 October 2018, Dr C reviewed Mrs A again and noted ongoing issues with swelling and pain at the surgical site, as well as a further lesion around the site. Dr C recorded subcutaneous thickening of around 1.5cm, photographed the area of concern, and

[5] Relating to the ear.
[6] Oval-shaped.
[7] A clear solution used as a preservative.
[8] The study of the microscopic structure of cells and tissues.

documented the plan to refer Mrs A to a plastic specialist for review. On 6 November 2018, Dr C sent an urgent referral to Plastics Department at the public hospital, in which she noted the previous removal of a "large post auricular cyst March 2017" and requested possible "further biopsy/removal". In the referral, Dr C also stated that no histology appeared to have been sent for the previously excised cyst.

21. One week later, the referral to Plastics was declined with a note to Dr C that the history was unclear, and for Dr C to re-refer if she suspected malignancy. On 21 November, Dr C re-referred Mrs A to the Plastics Department, and again noted that it did not appear that a histology sample had been sent upon initial excision of the cyst, and as such the diagnostic nature of the lesion was uncertain. In the referral, Dr C noted: "Given the tissue in this area is now growing ??scar tissue/??other, and painful, I feel further review is warranted."

22. Subsequently, Mrs A's referral to the Plastics Department was accepted, and on 18 December 2018 she attended the Plastics Clinic and presented the original excision specimen that she had kept in formalin. The sample was sent for histology, and on 4 January 2019 Mrs A was diagnosed with stage 4 metastatic melanoma.

Further information

Dr B

23. Dr B stated that he "can only speculate" as to his reasoning at the time for his decision not to send Mrs A's excised tissue for histology, but knows that at one point in his practice he "did not think histological confirmation of a sebaceous cyst necessary and was not practiced in disrupting the cyst as a way of confirming it".

24. In relation to his education and experience at the time of these events, Dr B stated:

> "At the time I was still a training GP registrar and so my expertise in management decisions was still in development. … My knowledge specifically in this case on whether to send a sebaceous cyst for histology was based on mentor education. I do vaguely recall [the medical centre Clinical Director, Dr D] advising me that it is not necessary to send a sebaceous cyst for histology but I cannot recall the secondary part about disrupting the cyst to confirm its contents. I also recall the Medical protections society's casebook which contained a couple of similar cases of sebaceous cysts not being sent for histology and being malignant and the letters in response to those cases disputing the recommendation and arguing that it is not an uncommon practice. I am quite sure that particular letter did not mention disrupting the cyst to confirm sebaceous contents. Whether these events occurred before or after [Mrs A's] excision I cannot say."

25. Dr B further stated:

> "At that time, I would only have sent tissue for histological analysis if the provisional diagnosis was that of malignancy or if the diagnosis was uncertain or if anything unusual was encountered during surgery."

26. Despite the above, Dr B acknowledged that he made an error by not confirming cystic contents prior to his decision not to send the specimen for histology, and told HDC that he is "prepared to learn from this and change [his] practice so that this does not happen again".

27. Dr B stated that since 12 January 2017 he has participated in the Skin Cancer Audit and Research Database[9] (SCARD) for the auditing of skin cancer surgery. He noted that this has allowed him to monitor the number of minor surgery cases he is performing, any surgical complications, and the level of agreement between his clinical diagnosis and subsequent histological diagnosis. Dr B said that although initially he did not use this audit tool for what he "thought were obviously benign lesions such as sebaceous cysts", since Mrs A's complaint he has started recording benign cysts in the audit as well. Dr B told HDC that since 1 January 2019 he has recorded 177 surgical procedures, 22 of which were for cosmetic reasons (as was the case for Mrs A), and noted that histological analysis was requested for all cases.

28. In response to my provisional opinion, Mrs A stated: "I do not consider that the procedure was cosmetic as the cancer was causing great irritation and causing constant discomfort due to its proximity to [my] hearing aid."

Medical centre

29. The medical centre said that the history of Mrs A's lesion was "quite inconsistent" with a malignant cause, and that Dr B's operation was carried out with this history in mind. It further stated that at the time of these events, the medical centre did not have a policy regarding sending all tissue removed from a patient to the laboratory for histological analysis. In relation to its usual practice at that time, it stated:

> "[W]e have always sent the vast majority of tissue samples to the lab. However it has been accepted that the pusy contents of boils, sebaceous cysts and maybe a few other examples were not expected to be sent. Sebaceous cysts often present as infected lesions and the removal of them is frequently messy and limited tissue is present. This situation has historically been extended to intact sebaceous cysts; these have just been cut open and the diagnosis confirmed visually before they are discarded."

30. The medical centre said that in retrospect, in this case it was wrong not to send the lesion for histology, and apologised for that shortcoming.

Changes made since these events

31. The medical centre stated that since these events it has implemented a policy of sending all tissue samples to the laboratory for histological analysis, and that this change has been "widely discussed and accepted by all doctors and surgical assistants".

32. Dr B said that he now sends all excised tissue, except for skin tags, for histology. In addition, Dr B said that in future if he makes a decision not to send excised tissue for histology, he will document that decision and his reasons in the clinical notes.

[9] Available online at http://scard.skincanceraudit.com/int/reports-pool.php.

Responses to provisional opinion

33. Mrs A and Dr B were given the opportunity to respond to relevant sections of my provisional opinion.

34. Mrs A accepted the "information gathered" section of my provisional report, and her comments have been incorporated above where relevant.

35. Dr B provided a letter of apology in line with the recommendation of my provisional report, but did not make further comment in relation to the proposed findings.

Opinion: Dr B — breach

36. On 3 March 2017, Dr B surgically removed a lesion from behind Mrs A's left ear. However, Dr B did not disrupt the cyst capsule to confirm its contents before making the decision not to send the excised specimen for histology, nor did he document that decision in the clinical notes. Mrs A recalled that Dr B said that he intended to dispose of the specimen, so she asked to keep it. In 2018, Mrs A started to notice changes in the area where the cyst had been removed, including itchiness, tenderness, swelling, and pain. In November 2018, Dr C referred Mrs A to the local Plastics Department for review of her surgical site, and at the resulting specialist appointment Mrs A presented the original excision specimen that she had kept in formalin since the March 2017 surgery. Following histological analysis of the sample, Mrs A was diagnosed with metastatic melanoma.

37. In relation to the lack of documentation regarding his decision not to send the specimen for histology, Dr B stated that normally when a request for histology is made, a copy of the request is available in the notes, but as no request was made, he did not think to actively record the decision not to send for histology.

38. The medical centre told HDC that before sebaceous cysts are discarded, it is standard practice to cut them open and confirm the diagnosis visually. Dr B acknowledged that he made an error by not confirming cystic contents prior to his decision not to send the specimen for histology. He told HDC that looking back at these events now, he can "only speculate" about his reasoning at the time for the decision not to send Mrs A's excised tissue for histology, but said that he "did not think histological confirmation of a sebaceous cyst necessary and was not practiced in disrupting the cyst as a way of confirming it". Dr B further stated that at the time, he would have sent tissue for histological analysis only if the provisional diagnosis was malignant or uncertain, or if something unusual was encountered during surgery.

39. My in-house clinical advisor, GP Dr David Maplesden, advised that Dr B departed from accepted practice by not disrupting Mrs A's cystic lesion before making the decision not to send the excised specimen for histology.

40. While Dr Maplesden noted that some of his peers would not send a presumed sebaceous cyst for histology, he stated that this would be only "providing the cyst capsule had been disrupted and revealed classic contents of sebum". He advised that if Dr B had disrupted the cyst membrane to confirm that the nature of Mrs A's cystic lesion was consistent with his clinical diagnosis of a sebaceous cyst, his failure to send the sample for histology would not be a departure from widely accepted practice. Dr Maplesden concluded:

> "However, I feel the failure by [Dr B] to establish the nature of the cyst by disrupting the capsule to confirm characteristic cyst contents before making the decision to forgo histology of the lesion, was a moderate departure from accepted practice."

41. Dr Maplesden further advised that Dr B should have documented the fact that he did not send the excised tissue for histology, along with his reasons for that decision.

Conclusion

42. Dr B made an error by not confirming cystic contents of the excised specimen before making the decision not to send it for histology, and by not documenting that decision in the clinical notes. This resulted in a delayed diagnosis for Mrs A.

43. Accordingly, I find that Dr B failed to provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

44. Dr B stated that he now sends all excised tissue for histology (with the exception of skin tags), and that in future if he makes a decision not to send excised tissue for histology, he will document that decision and his reasons in the clinical notes. I support these actions.

45. It is also appropriate that the medical centre has since put in place a policy to ensure a consistent approach to management of minor surgery samples such that all tissue samples will now be sent for histological analysis.

Recommendations

46. In my provisional opinion I recommended that Dr B provide evidence of his SCARD audit in relation to minor surgery undertaken since 1 January 2019 and histological analysis of surgical samples, to demonstrate appropriate management of surgical cases. In his response to my provisional opinion, Dr B provided that evidence and, as such, this recommendation has been met.

47. In my provisional opinion I also recommended that Dr B provide a written letter of apology to Mrs A for his breach of the Code. Dr B sent the apology to HDC, and this has been forwarded to Mrs A.

Follow-up actions

48. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

49. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

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

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mrs A]; response from [Dr B] of [the medical centre]; response from [Dr D] of [the medical centre]; [medical centre] clinical notes; [DHB] response and clinical notes.

2. [Mrs A] states that she had a lump behind her left ear for several years and mentioned it to her GP, [Dr C], in June 2015 and December 2016. On 3 March 2017 [Dr B] removed the lump and stated he was going to dispose of it so [Mrs A] asked if she could keep it which she did. The area around the removal site subsequently became itchy, thickened and tender and was reviewed by [Dr B] in May and June 2018 (no action), September 2018 (*'tapped with 22G needle'*) and November 2018 (urgent referral letter sent to DHB plastic surgical service). After the referral was initially declined then resent, [Mrs A] was seen by the plastic surgeons on 18 December 2018 and after further investigations she was diagnosed with widespread metastatic melanoma. The tissue from the 2016 removal was sent for histology which revealed a *malignant spindle cell tumour, incompletely excised.* [Mrs A] is concerned that her management and outcome may have been quite different had the specimen been sent for histology in December 2016. She notes [Dr C] has discussed the case with [Dr B] and the practice has implemented a policy that all tissue surgically removed will be sent for histology.

3. In his response, [Dr B] states he had diagnosed [Mrs A's] lesion as a sebaceous cyst on clinical grounds and excised the lesion with a large ellipse of skin to avoid rupturing the cyst. *I did not encounter anything out of the ordinary when performing the excision … at the time there was no policy at [the medical centre] for sending all excised tissue for histological analysis At that time, I would only have sent tissue for histological analysis if the provisional diagnosis was that of malignancy or if the diagnosis was uncertain or if anything unusual was encountered during surgery. Since this happened, it is now policy to send all excised tissue for histological analysis.*

4. The response from [the medical centre] complaints officer [Dr D] confirms that [the medical centre] now has a written policy regarding sending all excised lesions for histology. He notes that prior to this complaint, *we have always sent the vast majority of tissue samples to the lab. However it has been accepted that the pus content of boils, sebaceous cysts and maybe a few other examples were not expected to be sent. Sebaceous cysts often present as infected lesions and the removal of them is frequently messy and limited tissue present. This situation has historically been extended to intact sebaceous cysts; these have been cut open and the diagnosis is confirmed visually before they are discarded …* [Dr D] notes that the history of [Mrs A's] lesion — a longstanding (years) cystic swelling that varied in size (swelling up then shrinking) was not characteristic of a malignant lesion but does occur with sebaceous cysts. [Dr D]

notes that post-surgical scar changes are not rare with a majority caused by keloid scarring (benign).

5. Available GP notes commence with a consultation ([Dr C]) on 17 June 2015 which includes: *Lump behind left ear, present for years but increased in size last 2/7, was sore, today is reducing and not tender. Sebaceous cyst behind left ear, not attached to scalp, typical appearance of overlying skin. Not inflamed or red, not tender, no discharge ~2cm diam. Sebaceous cyst behind left ear, not currently infected so will monitor, aware to bring for review if pain or increase in size, offered removal, declines if not necessary.*

Comment: Management was consistent with accepted practice. The history and clinical description of the lesion is quite consistent with epidermoid (sebaceous) cyst and appropriate safety-netting advice was provided. Removal of an epidermoid cyst is usually undertaken at patient request or if the cyst becomes recurrently infected. Epidermoid cysts are encountered commonly in primary care. One large study of cutaneous cysts of the head and neck removed from patients found epidermoid cysts accounted for 49% of cases followed by pilar cysts (27%) and dermoid cysts (22%). These are all benign pathologies. Cystic lesions with malignant pathology are very rare.

6. [Mrs A] evidently requested removal of the cyst on 24 February 2017 ([Dr C]). Notes include: *Mod large seb cyst behind left ear ~ 2cm diam, not inflamed, mobile from underlying tissue. Discussed removal, reviewed by* [Dr B] *who is happy to remove for her.*

Comment: It was reasonable to consider removal of the lesion at patient request. The lesion had evidently not changed significantly since previous review almost two years previously, and retained characteristics consistent with the sebaceous cyst diagnosis.

7. Excision was undertaken by [Dr B] on 3 March 2017. Notes include: *Infiltrated with local anaesthetic and adrenaline, elliptical excision, 4-O monosyn for continuous deep and subcuticular sutures, Fixomul to skin. Plan: Review as required.*

Comments:

(i) Best practice is to document obtaining of consent (verbal or copy of written consent) for a minor surgical procedure. The fact the excised tissue was not sent for histology (and the reasons for this) should also have been documented. Documentation was otherwise adequate.

Addendum 24 February 2020: [Dr B] confirms in a further response dated 24 January 2020 that written consent for the procedure was obtained and is scanned separately into the patient notes. A copy is available if required.

(ii) The issue of failure to send the specimen for histology is discussed later in this report. There is nothing to suggest [Dr B] incised the removed cyst to confirm the

expected sebaceous contents/provisional diagnosis (see later comments and [Dr D's] response in s 4 in this regard). The excision process otherwise appears consistent with accepted practice.

8. On 2 May 2018 [Mrs A] presented to [Dr C] — *Prev seb cyst removed from left post auricular region — last month or two noticing scar quite tender, occ itchy and sl thickened. OE Raised scar post auricular region with thickening underlying. Plan: Try with locoid* [steroid cream], *if not settling recommend further review with* [Dr B].

Comment: I think it was reasonable to consider a keloid type reaction as a possible diagnosis in this situation although most keloid formation would be evident within a year of the original skin insult (in this case excision) and [Mrs A's] symptoms had started at about a year post-excision. Patients with keloid formation may complain of pain, itching or burning and trial of topical steroid is an accepted initial intervention[1]. With the benefit of hindsight, this was a missed opportunity to confirm [Mrs A's] specimen had not been sent for histology but there remained the opportunity to do so, as she had retained the specimen in formalin (although this was not evident from the notes).

9. On 29 June 2018 [Dr B] reviewed [Mrs A] noting: *seen regarding irritable scar in the left post-auricular region, started up in the last couple of months, was fine for a long time after surgery. OE Raised scar in the left post-auricular, thick underlying tissue Imp: possible keloid developing Plan: No intervention for keloid, see how it develops, might consider steroid injections?*

Comment: I believe keloid formation was still a reasonable differential diagnosis for [Mrs A's] symptoms and clinical findings as recorded, and would be a common explanation for the scenario presented. However, in the absence of a reassuring histology report in relation to the underlying lesion originally removed, the differential might have included possible atypical (?malignant) skin lesion with a low threshold for biopsy or specialist review if the area failed to settle, or did not progress in a characteristic manner for keloid scarring. This was again a missed opportunity to seek histological review of the original lesion although [Dr B] would have had to recall that the lesion had been given to [Mrs A] and confirmed that she had retained it in the original container.

10. On 26 September 2018 [Mrs A] was reviewed by [another provider at the medical centre] in relation to the scar. Notes include: *scar behind left ear — burning pain, itch. March 2017 — sebaceous cyst excised from behind left ear. Firm raised scar behind left ear — yellow colour — dry tap with 22G needle, lots of resistance like scar tissue. Plan: consider plastics private referral for painful scar re-excision (could be recurrent sebaceous cyst??). [Mrs A] will consider …*

[1] McGinty S et Siddiqui W. Keloid. StatPearls [Internet] (last updated March 2019). https://www.ncbi.nlm.nih.gov/books/NBK507899/ Accessed 16 September 2019

Comment: Progressive keloid scarring remained a possible diagnosis although it is unclear whether the macroscopic appearance of the area in question was consistent with this diagnosis. There was no obvious fluid collection on dry-needling (that might have suggested recurrence of sebaceous cyst). It was certainly appropriate to consider specialist referral at this point, and this was apparently discussed with [Mrs A] but deferred until she confirmed consent.

11. [Dr C] reviewed [Mrs A] on 31 October 2018 noting ongoing issues with swelling and pain at the original excision site and a (?new) papillomatous lesion adjacent to the site. There was significant subcutaneous thickening noted and [Dr C] photographed the area of concern and provided a referral and images to the plastic surgical service at [the DHB] on 6 November 2019. The referral was marked urgent and noted [Mrs A's] previous sebaceous cyst removal and subsequent development of *abnormal scar tissue.* There was no reference to the fact the original excision sample was not sent for histology. The images provided show a classic warty keratosis and some tissue swelling around the original scar. The original referral was declined with a note to the referrer dated 13 November 2018 stating: *The history here is unclear. I cannot see the histology report for the cyst removal March 2017. I hope it was sent for histology as is accepted standard of practice. The photo shows some swelling, a scar and a warty keratosis. Try liquid nitrogen to the keratosis. If you think it is something worse like malignancy, please re-refer.*

Comment: [Dr C's] decision to make an urgent referral for specialist review was clinically appropriate and she was conscientious in providing images of the area of concern. It would be accepted practice to attach any relevant histology reports and, in this case, to note (from the outset) that the original lesion had not been sent for histology. This was important clinical information as in the absence of a formal histology report it could not be confidently assumed that the original lesion was benign. I am mildly critical this information was not provided in the original referral and I think it was reasonable, on the basis of the information provided, for [the DHB] to decline the original referral and request re-referral with more supporting information if the issue was felt likely to be related to malignancy.

Addendum 24 February 2020: Following a response from [the medical centre] dated 5 February 2020 it has been brought to my attention that the original referral letter dated 6 November 2018 does include the statement '*no histology appears to have been sent*' although [the DHB] response to the referral as noted above implies this statement was not seen. I apologise to [Dr C] for my oversight and retract any criticism of her referral which, on review, was of a good standard.

12. On 21 November 2018 [Dr C] re-referred [Mrs A] to [the DHB's] plastic surgical service. On this occasion she noted the diagnostic uncertainty as *it does not appear that a histology sample was sent at initial excision of the cyst. Given the tissue in this area is now growing ??scar tissue ??other and painful, I feel further review is warranted.* The referral was accepted and [Mrs A] attended the plastic surgical service on 18 December 2018.

Comment: Management by [Dr C] was consistent with accepted practice. [Mrs A] was seen by [the DHB's] plastic surgical service within a month of the referral which appears consistent with accepted practice for an urgent (unable to determine of high suspicion of cancer) skin lesion referral.

13. At the clinic review on 18 December 2018 [Mrs A] presented her original excision specimen which she had kept at home in formalin. This was sent for delayed histology in addition to a fine needle biopsy of the current mass. Subsequent histology of the fine needle biopsy was of insufficient cellularity to confirm a diagnosis but was suggestive of spindle cell morphology. Examination of the original excision biopsy revealed a spindle cell tumour, most likely malignant melanoma, at least 12mm thick and incompletely excised, extending into subcutaneous tissue. PET-CT revealed widespread metastatic disease (nodes and bones — stage IV melanoma) and [Mrs A] subsequently underwent palliative immunotherapy and radiotherapy although her prognosis is poor. Plastic surgical clinic report dated 11 January 2019 includes the comment: *[Mrs A] was certainly upset … that the lesion was not processed two years ago and I certainly agree that this is unusual practice.* I understand an ACC Treatment Injury claim has been lodged in relation to the delayed diagnosis of melanoma.

14. There is no requirement for a general practice to have a formal policy regarding processing of skin lesions removed by minor surgery[2] with that decision generally being a clinical one with assumed competence of individual health providers in this regard. BPAC included the following statements in a 2015 article on anatomic pathology tests in New Zealand: *Tier 1 tests for histology include the majority of specimens clinicians send for histological examination. In primary care this predominantly consists of shave, punch, incisional and excision biopsies of superficial soft tissue lesions of the skin. Specimens may therefore include: tissue from the biopsy or excision of basal or squamous cell carcinomas, pigmented naevi, lipomas and sebaceous cysts as clinically indicated … There are no specific referral guidelines for anatomic pathology in the Laboratory Schedule. All tissue and aspirated fluid recovered by a medical procedure should ideally be submitted for examination. However, in practice, there are a number of exceptions to this, although these are of more relevance in a secondary care setting. Tissues that are not usually submitted for testing include tonsils, hernia and hydrocele sacs, femoral heads from patients undergoing hip joint replacement and placentas from women who have normal vaginal deliveries at term.* ***The Laboratory Schedule therefore makes no recommendation to clinicians over which tissues or fluids not to submit, but leaves this as a clinical judgement.***

15. On a defensive note, the American Academy of Family Physicians noted the following recommendation in a 2013 article[3]: *Send everything for histopathology. You*

[2] Foundation Standard & Interpretation Guide. RNZCGP. 2016. https://oldgp16.rnzcgp.org.nz/assets/Foundation-Standards-Interpretation-Guide-APR-2016.pdf Accessed 16 September 2019

[3] Fox G et McCann L. 12 Errors to Avoid in Coding Skin Procedures. Fam Pract Manag. 2013 Jan-Feb;20(1):11–16

never want to be in a situation where a patient develops metastatic melanoma, has no obvious primary symptoms, and is asked whether he or she has had anything removed (especially anything 'pigmented') that was not sent for histopathology. Your word that it was a seborrheic keratosis may not protect you, because sometimes even the world's greatest experts cannot make that differentiation with complete assurance. Histology is your ally and your defense. Skin tags that are soft and absolutely typical, as well as typical verrucae in younger patients, can be exceptions.

16. The clinical diagnosis of skin lesions is an imperfect process. A 2005 study[4] comparing the diagnostic accuracy of various health provider groups concluded: *Dermatologists diagnosed twice the number of neoplastic and cystic skin lesions correctly (75%) than nondermatologists (40%). The clinical diagnosis rendered by family practitioners matched the histopathologic diagnosis in only 26% of neoplastic and cystic skin lesions. Plastic surgeons, who performed the largest number of cutaneous surgical procedures among the nondermatologists, did better in the recognition of skin tumors than family physicians, but still had a diagnostic accuracy rate of only 45%.* A later meta-analysis showed diagnostic accuracy of pigment and non-pigmented skin lesions can be improved with use of dermoscopy, but diagnostic accuracy was still significantly limited[5].

17. A UK study published in 2016[6] examined the concordance between clinical and histological diagnosis of specimens submitted as sebaceous (epidermoid) cysts. Comments include: *The diagnosis of epidermoid cyst is seldom in doubt, and associated malignancy extremely rare, yet it is commonplace for the lesion to be sent to the pathology laboratory for analysis. The aim of this study was to evaluate our current practice with regards to diagnostic accuracy among clinicians, and assess risk of not routinely sending suspected epidermoid cysts for histological examination. Potential cost savings were also estimated and calculated … There is anecdotal evidence to suggest an intra- and inter-departmental variation in surgical practice when clinically apparent benign skin lesions, including epidermoid cysts, are excised. While some routinely request histological examination of these specimens, others are confident enough in the clinical diagnosis to discard such specimens in the absence of concerning features. The practice of routine histological examination of epidermoid cysts may therefore incur an additional cost with no consequent benefit to patient care or prognosis. With finite healthcare resources, this brings into question the justification for such practice. ...* The study examined records of 536 patients referred for removal of suspected sebaceous cysts removed over a four year period. The cyst was discarded by the operator in 140 cases. Around 80% of patients sent in by GPs with suspected diagnosis of epidermoid cyst had the diagnosis confirmed histologically while the remainder was other benign diagnoses (lipoma, pilomatrixoma and dermatofibroma).

[4] Sellheyer K et Bergfiled W. A retrospective study of the clinical diagnostic accuracy of common skin diseases by different specialties compared with dermatology. J Am Acad Dermatol 2005;52(5):823–30

[5] Jones O et al. Dermoscopy for melanoma detection and triage in primary care: a systematic review. BMJ Open. 2019;9(8)

[6] Apollos J et al. Routine histological examination of epidermoid cysts; to send or not to send? Ann Med Surg (Lond). 2017 Jan; 13: 24–28.

There were no reports of malignant histology (and no reports of malignancy found later on reviewing records of patients in whom the lesion had been discarded). The investigators concluded: *There was close agreement between clinical and final histological diagnosis of epidermoid cyst.* ***Where a characteristic, odorous, toothpaste-like material is present on transection intra-operatively, the diagnosis is confirmed and the lesion can be discarded.*** *We argue that significant cost savings can be achieved by adopting this approach.*

18. Final comments

(i) There is some controversy regarding whether all cutaneous excision/biopsy specimens should be sent for histology reporting and to what degree clinical judgement may/should be applied when making this decision. I believe there is concordance that where there is any doubt regarding the nature of the lesion being excised, the lesion must be sent for histology. Furthermore, noting the limited clinical diagnostic accuracy of health providers in general (and particularly primary care physicians) in relation to cutaneous skin lesions, even with use of dermoscopy, I believe all pigmented skin lesions should be sent for histology and on consultation with a number of my colleagues there was universal agreement with this principle. I am therefore somewhat concerned at [Dr B's] comment that prior to the case in question he *would only have sent tissue for histological analysis if the provisional diagnosis was that of malignancy or if the diagnosis was uncertain or if anything unusual was encountered during surgery.* If the implication from this comment is that [Dr B] relies on macroscopic (and/or dermoscopic) assessment of a skin lesion he is removing to determine whether or not it should be sent for histological examination, I would regard this as a moderate departure from accepted practice.

Addendum 24 February 2020:

- **In his response dated 21 January [Dr B] has clarified his practice at the time of the events in questions which was: I did not feel it necessary to send benign cystic lesions and skin tags for histological examination where the history and clinical examination was consistent with a benign lesion … I would send all pigmented lesions for histological analysis to ensure that melanoma is excluded, in contradiction to my statement. This would include benign naevi and seborrheic keratosis … I was also sending lipomas for histological examination because of the possibility of malignancy in the form of liposarcoma. Taking into account his revised statement and the discussion below, I believe [Dr B's] practice at the time of the events in question was largely consistent with that accepted by some primary care providers with the exception of his failure to routinely open an apparent cystic lesion to confirm the cystic nature of the lesion prior to determining need for histology.**

- **[Dr B] describes his use of dermoscopy which is consistent with accepted practice. I did not wish to imply in the discussion above that the limitations of dermoscopy meant that all pigmented lesions should be removed and sent for histology. If the presumed benign lesion remains in situ, it can be observed for**

further change that might alter the diagnosis and eventual management. If a lesion presumed to be benign (but actually malignant) is removed and the sample not examined histologically, the opportunity to reconsider the benign diagnosis in a timely fashion may be lost with the first signs that the original diagnosis was in error being presentation with metastatic disease.

- **[Dr B] explains why he did not open [Mrs A's] cystic lesion prior to making a decision regarding need for histology as being due to his interpretation of his previous education in this regard, and his understanding the practice of sending all sebaceous cysts for histology was controversial. However, I remain of the view that while there may be some controversy over sending sebaceous cysts for histology when they have a typical cystic appearance following transection, the failure to send an intact cystic lesion for histology (no transection attempted or considered) represents a moderate departure from accepted practice.**

(ii) On discussion with colleagues, there are some limited situations where not all providers would send a biopsy sample for histology (although others would). These situations were: following curetting of a clinically diagnosed seborrheic keratosis or verruca (provided the curettings were consistent in macroscopic appearance with the provisional diagnosis) and simple skin tag (acrochordon) snip removal. Given accepted management of these lesions includes destructive treatment with no tissue obtained (eg cryotherapy), such an approach seems not unreasonable. Some of my colleagues surveyed would not send a presumed sebaceous cyst for histology providing the cyst capsule had been disrupted and revealed classic contents of sebum. Others send every sample obtained, including one colleague who excised what was felt to be a 'classic sebaceous cyst' from a patient's scalp that histology revealed to be a metastatic deposit from an undiagnosed renal carcinoma. This finding is in keeping with [Dr D's] comments (s4) and the study conclusions noted in s17. My conclusion is that if [Dr B] had confirmed the nature of [Mrs A's] cystic lesion to be consistent with his clinical diagnosis of sebaceous cyst, by disrupting the cyst membrane to reveal characteristic contents, his failure to send the sample for histology would not be a departure from practice that is accepted by some primary care providers. However, I feel the failure by [Dr B] to establish the nature of the cyst by disrupting the capsule to confirm characteristic cyst contents before making the decision to forgo histology of the lesion, was a moderate departure from accepted practice. Mitigating factors are that the lesion was evidently non-pigmented and cystic in nature, and the documented history was suggestive of a benign cyst (slow growth with fluctuations in size).

(iii) I think it is appropriate the practice has put in place a policy to ensure a consistent approach to management of minor surgery samples. There may be some concern at [Dr B's] previous practice in this regard but he has not provided much detail in his response. There is an opportunity for shared learning from this incident (possible HQSC report), emphasizing the importance of either sending all cutaneous cysts for histology even if the history and pre-removal findings appear characteristic of a benign cyst, or at least confirming the presence of classic epidermoid cyst contents before making any decision to dispose of the specimen without histology."