SCOTTISH PUBLIC SERVICES OMBUDSMAN

People Centred | Improvement Focused

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: South of Scotland

Case ref: 202200588, Ayrshire and Arran NHS Board

Sector: Health

Subject: Hospitals / Clinical treatment / diagnosis

Summary

The complainant (C) had a family history of breast cancer and was referred to the high risk/family history service for monitoring. C attended appointments with the high risk/family history service to have regular mammogram scans carried out. In 2019, C had symptoms in their left breast. They received a mammogram scan from the symptomatic service and appropriate investigations were carried out to establish the nature of the symptoms in C's left breast which was confirmed to be a cyst. At this time, C's right breast was reported as normal. In 2021, a mammogram scan identified abnormalities in the right breast which led to the diagnosis of advanced (stage 3) cancer. C was told that there were abnormalities present in the right breast on the scan in 2019.

C complained that the Board did not follow up on these abnormalities at the time. In light of C's complaint the Board carried out an internal review, which C was unhappy with as they thought the review would be independent.

The Board said that mammogram scans are reviewed by two consultant radiologists or consultant radiographers who report independently to ensure there are two clinical opinions. The Board's response to C's complaint indicated that the abnormalities were considered and discussed at the time but it was decided that they should not be biopsied.

I took independent clinical advice from a consultant radiologist with specific experience in breast radiology (the Adviser). The Adviser highlighted that the Board's response did not match the medical records, specifically that the abnormalities were not discussed in 2019 and that these were missed. The Adviser said that it was reasonable for the Board to carry out an internal review but the conclusions reached by the review were not reasonable.

I found that the Board failed to provide reasonable care and treatment to C as abnormalities were missed in 2019. Therefore, the opportunity for early diagnosis was missed. I found that the internal review was unreasonable due to the conclusions reached and that the Board did not appear to be holding appropriate meetings in line with relevant standards. I do not consider that the Board demonstrated they have learned from what happened in this case.

My investigation identified some issues with the way in which the Board investigated and responded to C's complaint. As mentioned above, I found the medical records did not support the Board's response. On seeing a draft version of this report, the Board clarified that the abnormalities were not identified or discussed in 2019, and that they were referring to a meeting that was held in 2021. I considered that this should have been made clearer in the complaint response. I found the Board's handling of C's complaint to be unreasonable.

As such, I upheld C's complaints.

Redress and Recommendations

The Ombudsman's recommendations are set out below:

What we are asking the Board to do for C:

Complaint number	What we found	What the organisation should do	What we need to see
(a) and (b)	• Calcifications present in 2019 were missed and not biopsied. Therefore, an opportunity to make an early diagnosis was missed. • If the calcifications were biopsied in 2019 a diagnosis of cancer would have been achieved. • An appropriate internal review was not carried out as the conclusion reached in relation to the impact of the failings was unreasonable. • The Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings. • Information included in the final response to C's complaint was not supported by the medical records.	Apologise to C for: • the failure to identify and biopsy calcifications in 2019, the opportunity to make an early diagnosis, and the significant, detrimental impact this has had on C and their prognosis • the failure to carry out an appropriate internal review; and • for the failures in complaint handling. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets	A copy or record of the apology By: 31 August 2023

We are asking Board to improve the way they do things:

Complaint number	What we found	Outcome needed	What we need to see
(a)	• Calcifications present in 2019 were missed and not biopsied. Therefore, an opportunity to make an early diagnosis was missed. • If the calcifications were biopsied in 2019 a diagnosis of cancer would have been achieved.	When mammograms are undertaken on patients presenting with issues in one breast, radiologists should consider and fully report on the findings in both breasts. There should be appropriate consideration given to carrying out a biopsy when abnormalities such as definite and sizeable calcification are present on a mammogram and the decision in this regard recorded.	• Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again. • Evidence that learning is reflected in policy and guidance By: 2 September 2023
(b)	• The internal review that was carried out in this case was unreasonable as the conclusion reached in relation to the impact of the failings was incorrect. • The Board failed to reasonably	An urgent meeting (or meetings) held in line with the Standards to discuss a sample of breast radiology cases from 2021 to date (at least six per year, pro rata for the current year). These cases should be selected in line with the Standards i.e. that are clinically important and have an educational message	This office and the complainant should be informed of • the results of the radiology meetings • any learning points and action plan to implement and share

Complaint number	What we found	Outcome needed	What we need to see
	demonstrate that as an organisation they learned from what happened in this case. • The Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings.	that would benefit their colleagues. The meeting(s) should be chaired by an independent person external to the Board, with the appropriate level of expertise and experience. This is to provide assurance about the independence of the meeting(s). The meeting(s) should • record the outcome on each case in line with the Standards, including any "good spots" and learning points and/ or follow-up action • identify and share any learning • encourage constructive discussion and reflection • produce a consensus on structured learning outcomes, learning points, and follow-up actions, supported by an overall, clear implementation plan.	findings (as appropriate) Meeting held by: 31 October 2023 Results of meeting and (as relevant) any action plan by: 1 November 2023

Complaint number	What we found	Outcome needed	What we need to see
(b)	We found that the Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings.	Systems and arrangements should be in place to support all radiology staff and ensure radiology education and learning meetings are held in line with the Standards. Assurance that the Board will follow the Standards consistently in the future.	• Evidence the Board has in place an action plan to ensure that the Standards are in place for all radiology staff. • Evidence of how the Board will ensure the Standards will continue to be met in the future. • Evidence that the Board has communicated the outcome with the complainant. By: 2 September 2023

We are asking the Board to improve their complaints handling:

Complaint number	What we found	Outcome needed	What we need to see
(a)	We found that information included in the final response to C's complaint was not supported by the medical records.	Complaint investigations should be carried out in line with the NHS Model Complaints Handling Procedure. They should be: accurate in their findings and conclusions, clear, and supported by relevant evidence, such as, medical records.	Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again. Evidence that demonstrates how the Board ensure decisions are accurate and based on available evidence. By: 2 September 2023

Feedback

Points to note

1. In this case, the complainant was given the impression that an independent review would be carried out as part of the complaints investigation process. However, it was an internal review that was carried out. Whilst it was reasonable for an internal review to be carried out, I consider that better and clearer communication about this in advance of the review would have been beneficial for the complainant. This would likely have set the complainant's expectations about what action the Board would be taking and what type of outcome they could expect.

2. I would ask that the Board reflect on this point and consider this feedback when handling similar situations in the future.

Complaints handling – responding to an SPSO investigation

3. When organisations are notified of our intention to investigate a complaint they are asked to provide all information relevant to the complaint, including any relevant policies or procedures.

4. It is disappointing that the Board provided information about radiology meeting standards only once my draft report was issued for comment, and further information only when provided with details about adjustments made to my report in light of that information. This information was relevant to the complaint and particularly important to our investigation of head of complaint (b). This information could have, and should have, been provided at an earlier stage.

5. I draw the Board's attention to this point and ask that when responding to enquiries by my office in the future they ensure all relevant available information is provided at the start of our investigation.

6. In this case, the failure to do this resulted in avoidable delay in finalising my report, and I ask the Board also to reflect on the impact this would have on the complainer and the Board's own staff.

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. C complained to my office about the failure by Ayrshire and Arran NHS Board (the Board) to follow up on abnormalities in a mammogram (an x-ray imaging method used to examine the breast for the early detection of cancer and other breast diseases) they received in 2019. C also said that the Board failed to carry out an appropriate review into the situation after they complained.

2. The complaint from C I have investigated is that:

   (a) The Board failed to provide C with reasonable care and treatment *(upheld)*; and

   (b) The Board failed to carry out an appropriate review into C's complaint *(upheld)*.

Investigation

3. In order to investigate C's complaint, I and my complaints reviewer gathered further evidence from the Board and sought independent clinical advice from a consultant radiologist with specific experience in breast radiology (the Adviser). In considering the case, the Adviser had sight of C's relevant medical records and the Board's complaint file.

4. In this case, I have decided to issue a public report on C's complaint because of the significant personal injustice suffered by C and my significant concern about the failings I have identified. I also consider there is the potential for wider learning from the complaint.

5. This report includes the information that is required for me to explain the reasons for my decision on this case. Please note, I have not included every detail of the information considered. My complaints reviewer and I have reviewed all of the information provided during the course of the investigation.

6. C and the Board were given an opportunity to comment on a draft of this report. In light of comments (and new information from the Board), the parties were given an opportunity to comment on adjustments made to the draft report, at which point the Board provided yet further information. It is of significant concern to me that the Board did not provide this information earlier and I have included feedback for them at the end of this report.

Background

7. Services offered by the Board in relation to the monitoring and management of breast cancer are:

i. The Scottish Breast Screening Programme (SBSP), that invites women without symptoms between the ages of 50 – 70 to attend screening every three years.

ii. The high risk/family history service, where individuals attend to have a mammogram scan at varying frequencies (dependent on their individual risk level).

iii. The breast symptomatic service, where individuals are referred if they present with symptoms e.g. a lump.

8. C did not meet the age criteria for the SBSP, however, they told SPSO they had a family history of breast cancer which was included in the GP's referral for C to attend the high risk/family history service. C attended appointments with the high risk/family history service to have a mammogram in 2014 and 2017. Later, after experiencing symptoms, C received further mammograms in 2019, and 2021. These were carried out by the symptomatic service. In 2019, the mammogram was reported as normal for the right breast. The mammogram taken in 2021 identified abnormalities in the right breast which led to the diagnosis of advanced (stage 3) cancer.

9. C was told that there were abnormalities present in the mammogram taken in 2019. C complained that the Board did not follow up on these abnormalities at the time. In light of C's complaint the Board carried out an internal review, but C was unhappy with this review. They said they were led to believe it would be independent. Despite this, the radiologists who missed the abnormalities in 2019 were a part of the group included in the review.

(a) The Board failed to provide C with reasonable care and treatment

Concerns raised by C

10. C told us the reasons they considered the Board had failed to provide them with reasonable care and treatment were that:

i. C had a mammogram in 2019 which was reported as normal

ii. C presented at the breast unit in April 2021 with a lump in their right breast and was diagnosed with advanced breast cancer (grade 3). C required a mastectomy and total lymph node clearance, six months chemotherapy and radiotherapy, and adjunct treatment (treatment given in addition to the primary treatment to lessen the chance of cancer returning)

iii. When C was diagnosed with cancer they also found out that the mammogram in 2019 was not normal, and should not have been reported as such; and

iv. C has recently confirmed to my office that their condition has deteriorated and that they have been advised they will not survive beyond October 2023.

Ayrshire and Arran NHS Board's response

11. I do not intend to repeat the content of the Board's original response to C's complaint, as all parties are aware of the content. However, the main points of their response were that:

i. The radiology service has a robust system in place whereby mammograms are reviewed by two consultant radiologists or consultant radiographers who report independently. This is to ensure two separate clinical opinions and to identify any discrepancies

ii. In C's case, it was agreed by both parties at the time that there were some abnormalities in C's mammogram but that they did not feel it was anything sinister, and therefore, decided not to carry out a biopsy

iii. The mammogram was discussed at a multi-disciplinary team meeting which is normal process when there are abnormalities and again it was not felt there was clear evidence of possible malignancy

iv. Following C presenting again in April 2021, a review was carried out internally which is normal procedure. The review identified that:

v. The right-sided microcalcification was new on the 2019 mammogram when compared to the 2017 mammogram

vi. Appearances were not suspicious at the time, but it was felt this should have been further assessed

vii. However, even if this was biopsied in 2019, there is no guarantee that they would have found malignancy at the time, it may have still been too early to pick it up.

12. In response to my complaints reviewer's enquiries, the Board reiterated that:

i. On review of the 2019 mammogram, there were new indeterminate microcalcifications seen in the right breast. It is accepted that these should have been further investigated at the time; and

ii. Following review of the case at a multi-disciplinary meeting in 2021, there was consensus that there is no way to prove that further investigation at the time would have shown malignancy or affected the outcome.

Medical advice

13. My complaints reviewer and I sought independent advice from a consultant radiologist with particular experience in breast radiology (the Adviser). The Adviser told us that:

i. C visited the breast unit in October 2019 with a lump in their left breast which was confirmed to be a cyst

ii. The mammogram taken at the time, in addition to showing a cyst on the left breast also revealed a finding of 15 mm cluster of calcifications in the opposite breast (right breast)

iii. There is no mention of this finding in the mammogram report of 3 October 2019 and hence, no biopsy was performed

iv. Although the finding of calcification in the right breast was incidental and on the opposite side to what C presented with, a breast radiologist/ reader with adequate training and qualification would be expected to pick this up

v. Had those calcifications been identified, a biopsy would have been performed which did not happen in this case.

14. On reviewing the Board's letter to C dated 16 November 2021, which was their final response to C's complaint the Adviser noted that:

i. The letter said some abnormalities were detected by both parties (when commenting on a draft of this report the Board confirmed the mammogram

was read by a consultant radiologist and a consultant mammographer) on the mammogram in 2019 but they did not feel there was anything sinister, and therefore, the decision was made not to biopsy

ii. The Adviser found no evidence on the mammogram report from 2019 that this was the case. There was no mention that calcification was present on the report and there is no documentation of a discussion that took place between the parties about the possibility of biopsy. The letter said that the case was discussed in a multi-disciplinary team meeting but there was no evidence of this in the medical records

iii. The letter also said, even if the calcifications had been biopsied in 2019 there is no guarantee that malignancy would have been found at that time, it may still have been too early to pick this up from a biopsy

iv. The Adviser said they disagree with the Board's position on this point. It is the Adviser's view that there was clearly an abnormality in 2019 which progressed over time and diagnosed as high-grade cancer in 2021

v. When reading mammograms, calcification is one of the important findings that is looked for as carrying out a biopsy on the calcification leads to diagnosis of breast cancer in the early stage, especially the 'in situ' stage when cancer cells are still localised to milk ducts and not invaded into the breast tissue. This is important as clinical outcome is far superior when detected at this stage

vi. Making early diagnosis of breast cancer from calcification forms the core of the breast screening processes. The finding of calcification in this case is very definite and sizable (15 mm) and there is no reason to think that a biopsy may not have yielded a diagnosis of cancer at that time

vii. Benign calcifications do not later turn malignant, therefore, given that the calcification in this case has since developed into invasive cancer, had a biopsy been carried out at the time, this would have led to a diagnosis of cancer

viii. This was a missed opportunity to make an early diagnosis which could have potentially affected the extent of surgery and prognosis for C

ix. There was a failure to detect the early abnormality, and as such, the care and treatment was unreasonable; and

x. This miss occurred as a result of human error which led to a missed opportunity in making an early diagnosis and potentially achieving a better prognosis for C. The Board should acknowledge this and provide a full and sincere apology.

(a) Decision

15. C complained to my office about the failure by the Board to follow up on abnormalities in a mammogram in 2019. I wish to pay testament to C in continuing with their complaint while also dealing with their illness. Their most recent prognosis will have been devastating for them. They have my utmost sympathy.

16. The advice that I have received is set out above. In particular, the Adviser told me that:

i. The 2019 mammogram had findings of 15 mm calcifications in C's right breast. These were not reported in the mammogram report

ii. The Board's final response letter makes reference to abnormalities being discussed by radiologists and at a multi-disciplinary meeting but there is no evidence to support this position in the medical records (I consider this in more detail below and under complaint handling)

iii. From the evidence available the calcifications were missed by the clinicians carrying out the mammogram

iv. As the calcifications were missed they were not biopsied. This was a missed opportunity to make an early diagnosis; and

v. If this calcification was picked up in 2019 and a biopsy performed, there is no reason to think that a biopsy may not have yielded a diagnosis of cancer at that time, and therefore, a diagnosis of breast cancer would have been achieved in 2019.

17. In making my decision I have taken into account that the Board said, in their final response to C, that the abnormalities in the 2019 mammogram were discussed by the clinicians carrying out the mammogram and at a multi-disciplinary meeting. It was decided that a biopsy was not required. However, as noted above the advice I received highlighted that the medical records did not support the Board's position on this point.

18. Having checked the medical records, I can see that the mammogram report from 3 October 2019 highlighted that there was a palpable lesion in C's left breast, which appeared to be a cyst. The report goes on to say that there were also smaller opacities elsewhere in the left breast which had developed since the last mammogram (2017). The report states that an ultrasound should clarify what was happening in the left breast, and that, there was no focal lesion in the right breast.

19. There was no mention of abnormality or calcifications in the right breast. There were no notes of a discussion between the clinicians carrying out the mammogram and there was no record of C's case being discussed at a multi-disciplinary meeting in 2019.

20. I do not consider the Board's position, that the right breast abnormalities were discussed at the time, to be reasonable or supported by the medical records.

21. I accept the advice I have received as noted above. In particular I accept that the right breast calcifications were missed, and therefore, the opportunity for early diagnosis was missed. That these findings were missed is of significant concern. It is even more so given that, because of C's family history, they had been referred by their GP to the high risk/family history service. In the circumstances, I consider the care and treatment provided to C was unreasonable.

22. As such, I uphold this complaint. The impact of these failings for C is immense. I cannot begin to imagine how painful reading this report will be for them and I am truly sorry for this.

23. My recommendations, which I urge the Board to implement as a matter of urgency, can be found at the end of this report.

(b) the Board failed to carry out an appropriate review into C's complaint

Concerns raised by C

24. C told us the reasons they felt the Board failed to carry out an appropriate review were that:

i. C was told an independent review would be carried out

ii. An internal review was carried out

iii. The review included the two staff members who originally reported on C's mammogram in 2019. C finds it to be upsetting that these staff members

missed the abnormalities in 2019, however, now they agree that the mammogram showed abnormalities.

Ayrshire and Arran NHS Board's response

25. The main points of the Board's response to these concerns were that:

i. Internal review is normal procedure for the service to review their own systems as they are responsible for implementing changes where required

ii. All internal reviews are approached from an open honest perspective in order to identify service improvements

iii. C's case has been recorded on the internal incident reporting system (Datix).

Medical advice

26. I asked the Adviser whether or not it was reasonable for the Board to carry out an internal review of what happened. The Adviser said:

i. The case was reviewed by the radiology discrepancy meeting and in the multi-disciplinary team meeting which is in line with normal practice

ii. It is not unreasonable for involved clinicians to be present in the review

iii. The case was also recorded on Datix.

27. The radiologists who carried out the internal review unanimously agreed that the calcification would have been graded M3 if it had been picked up in 2019. However, using their criteria for interval cancers, they felt the discrepancy would be graded at 2, which acknowledges that there was an anomaly present on the mammogram but it was not obviously cancer. In light of this, I asked the Adviser to consider the conclusions reached by the Board as a result of their internal review, and whether or not these were reasonable. The Adviser said:

i. The calcification present in 2019 was a new finding from the previous mammogram in 2017, which made it compelling for a biopsy

ii. They agree with the M3 grading, and consider that they (and most radiologists) would grade the calcification at least M3 (indeterminate) which means a biopsy was indicated

iii. The Adviser explained that the grading of abnormalities follows The Royal College of Radiologists Breast Group Classification for Breast Imaging descriptor table. All calcification graded at M3 or above must be biopsied. In routine practice, most calcifications which are recalled and biopsied are M3. Only a small proportion of cancerous calcification actually show suspicious features on mammography. The majority of calcifications are M3 or indeterminate and must be biopsied to determine their nature, and therefore, agreed with the conclusion that using the criteria for interval cancers, the discrepancy should be graded at 2

iv. However, it was of concern to the Adviser that the Board concluded that there was no guarantee they would have found malignancy at the time. As discussed at complaint (a) above, it is the Adviser's view that this conclusion is wrong. The Adviser explained that benign calcifications do not later turn malignant, therefore, given that the calcification in this case has since developed into invasive cancer had a biopsy been carried out at the time, this would have led to a diagnosis of cancer

v. The Adviser said, as an outcome to the discrepancy meeting, the Board should have recognised and accepted that had the abnormality been identified in 2019 and a biopsy carried out this would have: confirmed malignancy, resulted in an early diagnosis, and the outcome for C would have been different.

(b) Decision

28. I understand fully why C was concerned about the review that was carried out, given that they were under the impression that the review would be independent. However, the advice I have received, and accept, is that it is reasonable for an internal review to be carried out, and that it was not unreasonable that involved clinicians were present.

29. I accept that it was reasonable for the discrepancy meeting to conclude that the calcification should have been graded M3 if it had been identified at the time, and that further investigations should have been carried out then. I also accept it was reasonable for the discrepancy meeting to agree this was a grade 2 discrepancy.

30. However, I accept the advice that the ultimate conclusion reached by this review did not appreciate or accept the significance or impact of what happened as it should have done. It is of the utmost concern to me that the Board and an internal review have not recognised that the calcification missed, would have been identified as malignant had a biopsy been carried out in 2019.

31. In conclusion, I accept that it was reasonable to hold an internal review, for the clinicians involved to be a part of the review and that the gradings agreed by the review were reasonable. However, I also accept that the review failed to acknowledge or accept that the abnormality would have been identified as cancerous had it been biopsied in 2019, and therefore, I consider the review to have been unreasonable. For this reason, I consider the Board failed to carry out an appropriate review into what happened.

32. As such, I uphold this complaint.

33. These findings will undoubtedly be devastating for C and they have my heartfelt sympathy. They also raise wider concerns about the way in which the Board are carrying out discrepancy meetings and whether or not the conclusions reached reasonably identify and accept the impact of the failings being discussed.

34. When commenting on a draft version of this report the Board told my office that they have not held a breast radiology discrepancy meeting since the meeting in 2021. When I asked the Board for clarification of this they further explained that they hold general department meetings of this sort. However, breast cases are not discussed at these meetings as they are a "very subspecialist area of practice". As such, a symptomatic breast radiology meeting was set up in 2021 to discuss cases where there has been a discrepancy.

35. The Board said there has not been a further discrepancy case since, and so, the symptomatic breast radiology meeting has not been held since 2021. The Board expressed their concern that my investigation was seeking to apportion blame on those involved and referred me to the Standards for radiology events and learning meetings[1].

36. I assure the Board that there is no question about the purpose and outcome of my investigation; it is to establish what happened and to objectively weigh evidence to make findings about the body under jurisdiction, in this case the Board. It is not about apportioning blame. In doing this, my investigations take into account relevant standards, in this case the Standards for radiology events and learning meetings (the Standards). I am mindful of the aim of the Standards, the aim of which, as stated in their concluding paragraph, is "… to learn from both mistakes and excellence; to use those with expertise to educate their colleagues, encourage good team working and

[1] https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr201-standards-for-radiology-events-and-learning-meetings.pdf

raise the quality of radiology reporting. As always, the ultimate aim is improved patient care."

37. As things stand, I do not consider that the Board have demonstrated that, as an organisation, they have learned from what happened in this case, and that in respect of breast cases, I remain unconvinced that good practice is being identified for learning.

38. Upon reviewing the standards, I note that Standards 1 and 2 set out that there should, as a minimum, be six meetings held per year (referred to as radiology education and learning meetings-REALMs). All radiologists should attend a minimum of 50% of departmental REALMs and should contribute at least one case a year to their REALM. The Standards also set out that REALMs should be viewed as learning events that should not solely consider discrepancies but also consider "good spots"[2]. Excellent diagnoses are equally important. A successful meeting should be focused on shared learning, encouraging constructive discussion and reflection, producing a consensus on structured learning outcomes, learning points and follow-up actions, and should provide a comprehensive method for independent reflection and review of cases through learning points for those unable to attend the meetings.

39. I note the Board's position that they hold REALMs at a general radiology department level, in particular that these meetings do not consider breast cases given this is a very subspecialist area of practice. However, the Standards do not specifically exclude breast radiology cases (or subspecialist areas of practice) from REALMs. In addition, while I note the Board's position that there have been no further symptomatic breast discrepancy cases since 2021, the Standards also advise that REALMs should not just consider discrepancies but should also focus on "good spots". Given this, I am not satisfied that the Board are meeting the relevant standards for radiology. I also do not consider the Board have reasonably demonstrated learning from the meeting they held to discuss C's case.

40. I have, therefore, made a number of urgent recommendations based on this finding which can be found at the end of this report. I also recognise that C was under the impression this review would be independent when it was, in fact, internal. I consider that better and clearer communication about this in advance of the review would have been beneficial for C. Therefore, I have included some feedback on this point for the Board to consider. This can also be found at the end of this report.

[2] Under the Standards a "good spot" occurs when a retrospective review, subsequent imaging or information leads to recognition that an observation or diagnosis has been made that might readily have been overlooked.

Complaints handling issues

41. During our investigation of this complaint we noted that the Board's final response to C's complaint said:

42. 'It was agreed by both parties at the time that there were some abnormalities but they did not feel that there was anything sinister, and therefore, the decision was made not to biopsy. C's mammogram report was also discussed at the multi-disciplinary team meeting which is normal process when there are abnormalities and again it was not felt there was clear evidence of a possible malignancy'

43. Paragraph 42 above suggests that the abnormalities in the right breast were identified and considered by the radiologists at the time. It further suggests that a decision was made not to biopsy. However, as explained in complaint (a) above, this statement from the Board is not supported by the medical records. The evidence shows that the abnormalities in the right breast were, in fact, missed.

44. Paragraph 42 above also indicates that the mammogram report was discussed at a multi-disciplinary team meeting although, as noted under point (a), there is no evidence one was held in 2019. When commenting on a draft of this report the Board advised that this was in reference to the multi-disciplinary meeting following C's attendance in 2021. I consider that this should have been made clearer in the complaint response.

45. The NHS Model Complaints Handling Procedure should be followed when investigating complaints. It is important that complaint investigations, and ultimately complaint responses, are accurate, clear, and can be supported by relevant evidence, such as, medical records. It is also important that the Board is clear on the subject of the complaint to avoid mistakes and confusion. The statements made by the Board in the complaint response referred to above are not evidenced by the medical records.

46. It is also of concern to me that the Board's complaint handling did not identify the concerns my investigation has identified at paragraph 30 above.

47. In light of this, I consider the Board's response to C's complaint to be unreasonable.

48. Therefore, under section 16G of the SPSO Act, which requires the Ombudsman to monitor and promote best practice in relation to complaints handling, I have made a recommendation to the Board in relation to complaints handling. This can be found at the end of this report.

Recommendations

Learning from complaints
The Ombudsman expects all organisations to learn from complaints and the findings from this report should be shared throughout the organisation. The learning should be shared with those responsible for the operational delivery of the service as well as the relevant internal and external decision-makers who make up the governance arrangements for the organisation, for example elected members, audit or quality assurance committee or clinical governance team.

What we are asking the Board to do for C

Complaint number	What we found	What the organisation should do	What we need to see
(a) and (b)	• Calcifications present in 2019 were missed and not biopsied. Therefore, an opportunity to make an early diagnosis was missed. • If the calcifications were biopsied in 2019 a diagnosis of cancer would have been achieved. • An appropriate internal review was not carried out as the conclusion reached in relation to the impact of the failings was unreasonable.	Apologise to C for: • the failure to identify and biopsy calcifications in 2019, the opportunity to make an early diagnosis, and the significant, detrimental impact this has had on C and their prognosis • the failure to carry out an appropriate internal review; and • for the failures in complaint handling. The apology should meet the standards set out in the SPSO guidelines on apology	A copy or record of the apology. By: 31 August 2023

Complaint number	What we found	What the organisation should do	What we need to see
	• The Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings. • Information included in the final response to C's complaint was not supported by the medical records.	available at www.spso.org.uk/information-leaflets	

We are asking the Board to improve the way they do things

Complaint number	What we found	Outcome needed	What we need to see
(a)	• Calcifications present in 2019 were missed and not biopsied. Therefore, an opportunity to make an early diagnosis was missed. • If the calcifications were biopsied in 2019 a diagnosis of cancer would have been achieved.	When mammograms are undertaken on patients presenting with issues in one breast, radiologists should consider and fully report on the findings in both breasts. There should be appropriate consideration given to carrying out a biopsy when abnormalities such as definite and sizeable calcification are present on a mammogram and the decision in this regard recorded.	• Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again. • Evidence that learning is reflected in policy and guidance. By: 2 September 2023
(b)	• The internal review that was carried out in this case was unreasonable as the conclusion reached in relation to the impact of the failings was incorrect.	An urgent meeting (or meetings) held in line with the Standards to discuss a sample of breast radiology cases from 2021 to date (at least six per year, pro rata for the current	This office and the complainant should be informed of • the results of the radiology meetings

Complaint number	What we found	Outcome needed	What we need to see
	• The Board failed to reasonably demonstrate that as an organisation they learned from what happened in this case. • The Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings.	year). These cases should be selected in line with the Standards i.e. that are clinically important and have an educational message that would benefit their colleagues. The meeting(s) should be chaired by an independent person external to the Board, with the appropriate level of expertise and experience. This is to provide assurance about the independence of the meeting(s). The meeting(s) should • record the outcome on each case in line with the Standards, including any "good spots" and learning points and/ or follow-up action • identify and share any learning • encourage constructive	• any learning points and action plan to implement and share findings (as appropriate) Meeting held by: 31 October 2023 Results of meeting and (as relevant) any action plan by: 1 November 2023

Complaint number	What we found	Outcome needed	What we need to see
		discussion and reflection • produce a consensus on structured learning outcomes, learning points, and follow-up actions, supported by an overall, clear implementation plan.	
(b)	The Board's practice of excluding breast radiology cases from radiology education and learning meetings does not appear to be in line with the Standards for Radiology Events and Learning meetings.	Systems and arrangements should be in place to support all radiology staff and ensure radiology education and learning meetings are held in line with the Standards. Assurance that the Board will follow the Standards consistently in the future.	• Evidence the Board has in place an action plan to ensure that the Standards are in place for all radiology staff. • Evidence of how the Board will ensure the Standards will continue to be met in the future. • Evidence that Board has communicated the outcome with the complainant. By: 2 September 2023

We are asking the Board to **improve their complaints handling**

Complaint number	What we found	Outcome needed	What we need to see
(a)	We found that information included in the final response to C's complaint was not supported by the medical records.	Complaint investigations should be carried out in line with the NHS Model Complaints Handling Procedure. They should be: accurate in their findings and conclusions, clear, and supported by relevant evidence, such as, medical records.	Evidence that the findings of this investigation have been fed back to relevant staff in a supportive way for learning and improvement and to avoid a similar mistake being made again. Evidence that demonstrates how the Board ensure decisions are accurate and based on available evidence. By: 2 September 2023

Feedback for Ayrshire and Arran NHS Board

Points to note

1. In this case, the complainant was given the impression that an independent review would be carried out as part of the complaints investigation process. However, it was an internal review that was carried out. Whilst it was reasonable for an internal review to be carried out, I consider that better and clearer communication about this in advance of the review would have been beneficial for the complainant. This would likely have set the complainant's expectations about what action the Board would be taking and what type of outcome they could expect.

2. I would ask that the Board reflect on this point and consider this feedback when handling similar situations in the future.

Complaints handling – responding to an SPSO investigation

3. When organisations are notified of our intention to investigate a complaint they are asked to provide all information relevant to the complaint, including any relevant policies or procedures.

4. It is disappointing that the Board provided information about radiology meeting standards only once my draft report was issued for comment, and further information only when provided with details about adjustments made to my report in light of that information. This information was relevant to the complaint and particularly important to our investigation of head of complaint (b). This information could have, and should have, been provided at an earlier stage.

5. I draw the Board's attention to this point and ask that when responding to enquiries by my office in the future they ensure all relevant available information is provided at the start of our investigation.

6. In this case, the failure to do this resulted in avoidable delay in finalising my report, and I ask the Board also to reflect on the impact this would have on the complainer and the Board's own staff.

Terms used in the report **Annex 1**

adjunct treatment	Treatment given in addition to the primary treatment to lessen the change of cancer returning
the Adviser	a consultant radiologist with specific experience in breast radiology who provided independent advice on this case
benign	non-cancerous abnormalities or tumours
biopsy	tissue sample
the Board	Ayrshire and Arran NHS Board
C	the complainant
calcification	deposits of calcium salts that can be detected by imaging
chemotherapy	a treatment where medicine is used to kill cancerous cells
focal lesion	abnormal area of tissue
malignant	cancerous
mammogram	an x-ray of the breast
mastectomy	a surgical operation to remove a breast
M3	the grading of calcifications found in the breast. M3 is an indeterminate (i.e. cannot be determined from the mammogram) abnormality that requires further investigation
radiotherapy	a treatment using high-energy radiation
Stage 3 / Grade 3	a classification of cancer. Stage 3 is a larger cancer that may have started to spread into surrounding tissue and there are cancer

	cells in the lymph nodes nearby
SBSP	Scottish Breast Screening Programme