Northern Ireland
Public Services
Ombudsman

Investigation Report

Investigation of a complaint against Southern Health & Social Care Trust

NIPSO Reference: 202000453

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The Role of the Ombudsman

The Northern Ireland Public Services Ombudsman (NIPSO) provides a free, independent and impartial service for investigating complaints about public service providers in Northern Ireland.

The role of the Ombudsman is set out in the Public Services Ombudsman Act (Northern Ireland) 2016 (the 2016 Act). The Ombudsman can normally only accept a complaint after the complaints process of the public service provider has been exhausted.

The Ombudsman may investigate complaints about maladministration on the part of listed authorities, and on the merits of a decision taken by health and social care bodies, general health care providers and independent providers of health and social care. The purpose of an investigation is to ascertain if the matters alleged in the complaint properly warrant investigation and are in substance true.

Maladministration is not defined in the legislation, but is generally taken to include decisions made following improper consideration, action or inaction; delay; failure to follow procedures or the law; misleading or inaccurate statements; bias; or inadequate record keeping.

The Ombudsman must also consider whether maladministration has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. A remedy may be recommended where injustice is found as a consequence of the failings identified in a report.

Reporting in the Public Interest

This report is published pursuant to section 44 of the 2016 Act which allows the Ombudsman to publish an investigation report when it is in the public interest to do so.

The Ombudsman has taken into account the interests of the person aggrieved and other persons prior to publishing this report.

TABLE OF CONTENTS

Page

SUMMARY ………………………………………………………… 4

THE COMPLAINT ……………………………………………… 6

INVESTIGATION METHODOLOGY ………………………… 7

THE INVESTIGATION ………………………………………….. 9

CONCLUSION ………………………………………………... 43

APPENDICES ………………………………………………….

Appendix 1 – The Principles of Good Administration

Appendix 2 – The Principles of Good Complaints Handling

SUMMARY

I received a complaint about the actions of the Southern Health and Social Care Trust (the Trust). The complainant raised concerns about the Trust's investigation of a Serious Adverse Incident (SAI). The SAI investigation was about care and treatment provided at Daisy Hill Hospital (DHH) to the complainant's mother (the patient) in April 2018. The complainant said the level of investigation undertaken was not in accordance with the Health and Social Care Board (HSCB) Guidance on the Procedure for the Reporting and Follow Up of Serious Adverse Incidents, published in November 2016. She also said the Trust failed to provide her with the minutes of a meeting held with the family on 13 August 2020. The complainant said the report into the SAI failed to clearly outline what happened and that the Trust failed to include its response to the family's queries in the final report. The complainant also raised concerns about the recommendations outlined in the report. She said the report did not clarify what these were based on. She also said the report did not make the recommendation to improve the process mandatory. The complainant raised a further concern that the Trust failed to refer her to my office in its final response.

The investigation examined the details of the complaint, the Trust's response, and relevant local and national guidance. I obtained independent professional advice from a Consultant in Emergency Medicine.

The investigation established several failings on the Trust's part to adhere to relevant guidance. It established failings in respect of the manner in which the SAI process was commenced, the manner in which the investigation was conducted and concluded and the appropriateness of the learnings and recommendations outlined. It also established that the Trust failed to signpost the complainant to my Office at the conclusion of the process.

The investigation identified these failing as maladministration that caused the complainant to experience the injustice of uncertainty and frustration regarding the SAI process adopted, as well as the time and effort of bringing this complaint to my Office.

I recommended that the Trust apologise to the complainant directly for the failures

identified within one month of the date of the final report. I made six further recommendations for the Trust to address under an evidence-supported action plan to instigate service improvement and to prevent future reoccurrence of the failings identified – and recommended the Trust update my Office in this respect within six months of the date of the final report.

I will share a copy of my final investigation report with the Department for Health, which has assumed responsibility for the function and role of the former HSCB.

THE COMPLAINT

1. I received a complaint about the actions of the Southern Health and Social Care Trust (the Trust). The complainant raised concerns about the Trust's investigation of a Serious Adverse Incident[1] (SAI). The SAI investigation was about the care and treatment at Daisy Hill Hospital (DHH) the Trust provided to the complainant's mother (the patient) in April 2018.

Background

2. The patient attended DHH emergency department (ED) on 16 April 2018 complaining of chest pains. Staff performed a chest x-ray, which a locum ED doctor reviewed. He documented that the x-ray did not show '*consolidation*[2] *or pneumothorax*[3]'. The ED doctor diagnosed the patient with musculoskeletal chest wall pain[4] and discharged her from the ED within three hours of her arrival. On 22 April 2018, radiology staff produced the formal x-ray report for the patient. It documented, *'a subtle abnormality identified in right side lung. Requested follow up x-ray (6-8 weeks)*'. Staff did not book this follow up x-ray. It is not known if radiology staff forwarded the report to ED staff for review.

3. The patient attended DHH ED on 3 June 2019 again complaining of chest pain. Staff performed an x-ray for the patient and identified a mass on her right side lung. The patient and her family attended her General Practitioner (GP) on 24 June 2019. The GP informed the patient that DHH staff diagnosed her with lung cancer. He also informed the patient of DHH staff's failure to invite her for a follow up x-ray following her ED attendance in April 2018. The patient sadly passed away on 1 June 2020 of lung cancer.

4. The patient's family submitted a complaint to the Trust on 10 July 2019. It issued its response on 25 October 2019. The family were not satisfied with the Trust's response and contacted my office. As part of my office's assessment of that complaint, the Trust offered to conduct a SAI investigation into the care and treatment it had provided to the patient. As a result, the complaint to my

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[1] Any event or circumstance that led or could have led to serious unintended or unexpected harm, loss or damage to patients.
[2] Where the alveolar airspaces are filled with fluid, cells, tissue, or other material. It can often be a sign of infection/pneumonia.
[3] When air gets into the space between the outside of the lung and the inside of the chest wall (collapsed lung).
[4] Pain that affects the muscles, ligaments, tendons, and bones; often caused by injury or a chronic condition.

office was discontinued to allow the SAI to proceed. The Trust then initiated the SAI process on 10 July 2020. The Trust issued its final report for its investigation on 11 March 2021. The complainant was dissatisfied with the SAI process undertaken and submitted a fresh complaint to my office.

Issue of complaint

5. I accepted the following issue of complaint for investigation:

Whether the Southern Health and Social Care Trust managed the Serious Adverse Incident (SAI) investigation process appropriately and in accordance with relevant guidelines.

INVESTIGATION METHODOLOGY

6. In order to investigate this complaint, the Investigating Officer obtained from the Trust all relevant documentation together with its comments on the issues the complainant raised. This documentation included information relating to the Trust's handling of both the complaint and the SAI process.

Independent Professional Advice Sought

7. After further consideration of the issues, I obtained independent professional advice from the following independent professional advisor (IPA):

    - **Consultant in Emergency Medicine (IPA)**, FRCEM, FRCSEd (A&E) MBBS, LLM (Medical Law), RCPathME; with over 14 years' experience in the role.

    The IPA provided advice in respect of the findings and recommendations the Trust made in the final SAI report, as well contextual information.

    The clinical advice received is enclosed at Appendix two to this report.

8. The information and advice which informed the findings and conclusions are included within the body of this report and its appendices. The IPA provided 'advice'; however how I weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards and Guidance

9. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those which are specific to the circumstances of the case. I also make reference to relevant regulatory, professional and statutory guidance.

   The general standards are the Ombudsman's Principles[5]:

   - The Principles of Good Administration

10. The specific standards and guidance referred to are those which applied at the time the events occurred. These governed the exercise of the administrative functions and professional judgement of those individuals whose actions are the subject of this complaint.

    The specific standards and guidance relevant to this complaint are:

    - The Health and Social Care Board's (HSCB[6] Guidance on the Procedure for the Reporting and Follow Up of Serious Adverse Incidents, November 2016 (HSCB Guidance); and
    - Review Team Report by Sir Liam Donaldson, Dr Paul Rutter and Dr Michael Henderson – The Right Time, The Right Place, December 2014 (the Donaldson Report).

    Relevant sections of the guidance considered are appended at Appendix three to this report.

11. I did not include all information obtained in the course of the investigation in this report. However, I am satisfied I took into account everything I considered relevant and important in reaching my findings.

12. A draft copy of this report was shared with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations. I gave careful consideration to the comments I received from both the complainant and the Trust, before I finalised this report.

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[5] These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

[6] The HSBC closed on 31 March 2022 and responsibility for its functions transferred to the Department of Health. All references to HSCB in this report should be read in this context.

THE INVESTIGATION

Whether the Southern Health and Social Care Trust managed the Serious Adverse Incident (SAI) investigation process appropriately and in accordance with relevant guidelines.

Detail of Complaint

13. The complainant said the level of investigation undertaken (level one - Serious Event Audit[7] [SEA] – an analysis of the review stages is included at Part 5 of the HSCB Guidance, and set out in Appendix three to this report) was not in accordance with the HSCB Guidance. She also said the Trust failed to provide her the minutes of a meeting held with the family on 13 August 2020.

14. The complainant referred to the Trust's final SAI report. She said it failed to clearly outline what happened to the patient's x-ray report produced in April 2018, and why staff did not arrange for a follow up x-ray. She explained the family asked questions of the Trust following the second draft of the report. However, the Trust failed to include its response to the queries in the final report, and instead responded to them in a separate letter. The complainant also raised concerns about the recommendations outlined in the report. She said the report did not clarify what these were based on. She also said the report did not make the recommendation to improve the process mandatory. The complainant raised a further concern that the Trust failed to refer her to my office in its final response.

Evidence Considered

Legislation/Policies/Guidance

15. I considered the following guidance:
    - The HSCB Guidance
    - The Donaldson Report

    In addition, I considered the IPA's advice regarding the findings and recommendations the Trust made in the final SAI report.

[7] A method of formally assessing significant events with a view to improving patient care and services.

The Trust's response to investigation enquiries

Decision to undertake a Level one (SEA) investigation

16. The Trust said the screening team[8] determined the level of investigation, and not its review team. It explained that most SAI investigations will '*enter the review process at Level 1 with a view to determining what happened, why it happened and what will change*'. The Trust said it categorised the incident as a '*catastrophic incident*'.

17. I asked the Trust why it set terms of reference (TOR) for the review. It explained the HSCB Guidance states TOR are not required for a Level one review. However, the Trust said it agreed to set TOR for its review because the family requested them. It explained the review team shared the TOR with the family on 4 September 2020. It said the complainant confirmed the family agreed to the TOR on 9 September 2020.

18. I asked the Trust why it followed a root cause analysis (RCA) approach for its review when this is normally only taken for Level two (or above) investigations. It explained that all Level one reviews within the Trust '*will have a structured review to incorporate other contributing factors merely to determine why it happened*'.

19. The Trust explained its staff receive training on how to undertake a SAI investigation. However, the training does not cover how to draft TOR.

Failure to share minutes of the meeting in August 2020

20. The Trust said the review team did not provide a formal minute of the meeting to the family. It explained that the team considered its own notes taken during the discussion. The Trust said the complainant provided a written document during the meeting, which outlined the issues the family wished the review team to consider during its SAI review. It shared this document with all members of the review team, which they considered during the review. The Trust said the

[8] The team consists of consists of the Assistant Director of Acute Services, Associate Medical Director, and three Clinical Directors.

review team acknowledged it did not provide the family a formal minute of the meeting, and apologised for failing to do so in its responses to my Office.

The SAI review investigation content of the reports

21. I asked the Trust if it took written statements from the staff involved in the incident. It explained it did not, '*as all information that was required by the Review Team was available*'. I also asked the Trust to provide evidence of the review team's consideration of the evidence it collated during its investigation. It explained '*there are no formally documented notes of meetings which would specifically record which evidence had been considered*'.

22. I asked the Trust if the review team considered the patient's x-ray, and whether it would prompt medical staff to take action in addition to the follow up x-ray. It explained that had a clinician had sight of the report, they would have performed a further x-ray. It further explained that the clinician would have made a decision as to the '*most appropriate form of investigation to follow*' based on the outcome of that further x-ray.

23. I asked the Trust if the review team considered whether the radiologist should have marked the x-ray as '*urgent*'. It said it did consider this issue. It explained the review team concluded the radiologist did not have a '*high index of suspicion for cancer*'. Therefore, '*it was reasonable to not mark the report for urgent communication*'. The Trust further explained that the clinical outcome would likely have been the same for the patient, regardless of whether staff identified it as urgent/red flag, or not. It said all radiology reports should be read and acted upon, and '*the debate here is only one of urgency'*.

24. In relation to the review team's findings, the Trust explained the process for the sign off of radiology reports '*was not fit for purpose*'. It said the process was '*not incapable of error*'. It explained it is a paper based system and there is no ability to check that relevant staff progressed the recommended actions noted on each radiology report. The Trust further explained that the review team knew this before it met to consider the case.

25. The Trust explained the review team did not obtain independent advice as part of its investigation.

26. I referred the Trust to the concern that its written response to the complaint (in October 2019) and three drafts of the report contained conflicting information. It said it '*accepts there is a difference in what the family were advised as a result of their complaint and what they were advised in the SAI report*'. However, the Trust considered the information contained in all three versions of the report consistent.

27. The Trust explained the review team provided the first draft report to the family on 9 October 2020. It said this draft *'focused on a timeline of events, identified system failures and extracted learning from the incident*'. It explained the complainant said the first draft report '*did not make much reference to the impact the incident had on [the patient] and her family*'. The Trust said its staff found it difficult to elicit from the complainant '*exactly the points which she wished to be addressed*'. It explained the complainant forwarded photographs of the draft report with her handwritten comments. However, they were difficult to read, and staff asked the complainant to resend them. It said the complainant did not do so. The Trust explained staff had a '*number of conversations*' with the complainant. However, she '*did not seem to be in a position to provide any further clarity*'. It also said it offered the complainant two meetings with the Chair of the SAI Review Team. However, she declined these offers.

28. In her written comments, the complainant challenged the Trust's perspective. The complainant's position was that whilst the first draft of the report was dated 9 October 2020, she did not receive it until 28 October 2020, under a cover letter dated 15 October 2020. The complainant also challenged the Trust's '*narrative*' that she didn't '*engage*' and didn't provide '*clarity*'. The complainant's position was that when she received the first draft of the report, she explained to the Trust that she was unwell at the time and requested an extension of time to provide her comments on it. The complainant said when she later contacted the Trust to say she was still working on her comments, the Trust asked her to submit the comments she had made so far. The complainant explained at this

stage she had handwritten comments in the margin of the report, and so she took photographs of these and submitted them. The complainant said that when she contacted the Trust again in December 2020 about her comments, the Trust told her that it had used her handwritten comments to produce a second draft of the report, and that additional comments were not necessary at that stage. The complainant said she did not refuse to send comments to the Trust, and was willing to clarify her comments.

29. The Trust said the review team amended the report to '*include all the details of the clinical care provided to [the patient] during her attendance on 16 April 2018*'. It explained the family also requested an acknowledgement of the impact the incident had on the patient and her family. The review team issued its second draft on 28 January 2021.

30. The Trust said it received further correspondence from the complainant on 21 February 2021. It explained the complainant said the second draft report *'takes a strong focus on my mother's medical assessment*'. The Trust said the review team felt the second draft report clearly outlined the impact the failing had on the patient and her family.

31. The Trust said the review team issued the final SAI review report and covering letter on 11 March 2021. It explained it considered this '*as concluding this issue*'. The Trust said the former HSCB advised the Acute Professional Group[9] at the HSCB, whose role it is to assess SAI reports shared with the HSCB, reviewed the report and were '*satisfied based on the information provided that this incident can be closed from their perspective*'.

32. The Trust said point 12 of the final report '*provides clarity*' as to what happened to the patient during her visit to DHH ED on 16 April 2018. It explained it also provided the family a copy of the ED documentation for her attendance. The Trust said '*there is no further information available that will provide any further clarity*'.

[9] A group of Assistant Directors for Acute Services, Associate Medical Directors and Clinical Directors. It is chaired by the Director of Acute Services.

33. I asked the Trust why it did not refer to the patient's history of chronic obstructive pulmonary disease (COPD) in the report. It said the review team were '*sorry that COPD…is not listed under Patient Factors*'.

34. I referred the Trust to the review team's finding that staff missed an opportunity for earlier diagnosis of lung malignancy. I asked if it considered the report outlined the impact this finding had on the patient's pathway. The Trust explained the review team were clear that had malignancy been detected, the patient's treatment would have been different. It said '*it is regrettable'* the family consider the report did not fully outline the impact this had on the patient.

35. I referred the Trust to the complainant's concern that the review failed to clarify several issues. I put these issues to the Trust and it responded as follows:

    - In relation to the error in the patient's ED clinical record relating to the left/right side chest pain, the Trust said it considered this resolved. It explained both the doctor's note and the request for an x-ray documented the correct side the patient experienced chest pain. The Trust said the triage nurse incorrectly documented 'right sided chest pain' in the notes. It apologised the review team did not make this clear in its report;
    - The Trust said the review team did not consider that the ED doctor who reviewed the patient's x-ray on 16 April 2018 was '*in training*';
    - The Trust explained the diagnostic reporting time is 28 days for routine and planned reports (radiology staff completed the x-ray report within six days);
    - The Trust explained radiology staff printed the report on 23 April 2018. However, despite its investigation, it cannot conclude if radiology staff left the x-ray report for an ED Consultant to review, if ED staff received it, who received it, when they received it, whether staff placed it in the box in the ED, who accessed it and when;
    - The Trust said it cannot determine who in the ED screened the x-ray report;

- The Trust said it does not have a check sheet for returned x-ray reports to show that a consultant reviewed it;
- The Trust explained that unchecked reports remain in the designated box in the ED;
- The Trust said it did not find the hard copy x-ray report and it remains missing;
- The Trust explained reports that are no longer required are put into a confidential waste bin, which is removed for shredding when full;
- The Trust explained the review team considered staff may have placed the report into the confidential waste bin in error. However, it had no way to verify this; and
- The Trust explained the process failed as an ED Clinician did not see the printed report.

36. I referred the Trust to the section of its review report that documented the outcome of the review was '*no area of service failure*'. It explained the HSCB requires the Trust to categorise the outcome of SAI investigations as per the agreed Donaldson (2012) scheme[10]. It said the review did not *'fit into any of the 6 areas of service failures listed*'.

The recommendations and the failure to include responses to the family's queries in the final report

37. The Trust said its Radiology Service wishes to develop a Speciality Safety Net Team in response to concerns regarding '*non-action of recommendations made on radiology reports and impact on clinical care for our patients*'. It explained the team will '*review and track patients reports, initially focusing on those reports that contain the word "follow up" or that have been communicated urgently to the clinical teams*'. This will ensure staff take appropriate action and follow-up for the patient.

38. The Trust said it would also like the team to ensure that '*all cancelled inpatient examinations following justification process, is fed back to the Clinical Teams*

[10] Information relating to this scheme is enclosed at Appendix six to this report.

timely'. This will ensure that '*onward management of the patient is not delayed*'. The Trust said it will develop a team will involve a '*significant financial investment in the system which will undoubtedly improve patient care*'.

39. I referred the Trust to the concern that despite the complainant's request, it did not conduct a sample audit of the radiology reports left for the ED consultant that same day. The Trust explained it did not undertake an audit as it did not know what day staff provided the report to the ED.

40. I referred the Trust to the report's recommendation to improve communication between secretarial staff and the medical team. I asked what finding led to this recommendation. The Trust said it did not identify any failing that led to this recommendation. It explained the review team considered it '*beneficial to review communication between the teams*'.

41. I asked the Trust what timeline the review team attached to its recommendations. It explained the recommendations were '*a long term goal of Radiology, Clinicians and NIECR systems*'. Therefore, the review team did not specify any timeframe for their implementation. I also asked the Trust why it did not make the recommendations mandatory. It explained that if the recommendations proceeded with the current technology, they are unlikely to be successful. I asked the Trust how it is 'encouraging' staff to use the digital sign off outlined in the recommendations. It said it does so at medical staff inductions and during Morbidity and Mortality Meetings.

42. I referred the Trust to its revised Standard Operating Procedure (SOP) for x-ray reports. I asked how it is expected to prevent this failure from recurring. The Trust said the revised SOP will not '*guarantee*' it. However, it is '*an attempt to reduce the likelihood*'. It explained that under the revised process, staff will leave abnormal x-rays '*for the Consultant to review*'. Following review, the Consultant will indicate what follow up is required and administrative staff will make necessary arrangements. Staff will also notify the Consultant's Secretary if a patient is referred.

43. The Trust said the review team considered the family's questions relating to how it would progress its recommendations. It explained the review team had not yet concluded on how it would implement the recommendations at the time it issued the report. The Trust said its Operational Teams continue to work to amend the current process '*to ensure the failsafe for radiological investigation follow up is more robust and it will be closely audited'*.

The failure to refer the complainant to my office

44. The Trust said it accepted it did not provide information to the family regarding further recourse options in its final letter issued on 11 March 2021. It explained it amended its letter templates to ensure the option for recourse is provided.

Relevant excerpts from Trust records

45. Relevant excerpts from the Trust's records are detailed in the Analysis and Findings section of this report.

Analysis and Findings

Decision to undertake a Level One (SEA) investigation

46. The complainant said that the level of investigation the Trust undertook in respect of the SAI review was not in accordance with the HSCB Guidance.

47. The Trust's positon was that its Screening Team determined the level for the review, and that most investigations commence at level one.

48. *Part 5* of the HSCB Guidance sets out that when a SAI review is commenced, it '*should be conducted at a level appropriate and proportionate to the complexity of the issue under review*'. It goes on to state that '*it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event*'. *Part 5* goes on to state that whilst '*most*' SAIs will be subject to a level one review, a level two or three review can be instigated immediately in '*more complex*' SAIs. It provides that the HSC Regional Risk Matrix, which forms appendix 16 to the HSCB Guidance, is used to assist in the Trust's consideration of the '*seriousness*' of a SAI, and therefore level of review.

49. *Part 5.1* of the HSCB Guidance relates specifically to level one reviews. It states that a level one review consists of a significant event audit (SEA). The purpose of the SEA is to assess what has happened, why the events happened in terms of what went wrong and what went well, assess what has been changed or agree what will change, and identify local and regional learning. The possible outcomes are listed as closed with learnings, closed with no learning, or that the SAI requires a review at levels two or three.

50. *Part 5.2* of the HSCB Guidance relates specifically to level two reviews. It states that a level two reviews consists of a root cause analysis (RCA). At the outset of a level two review, a terms of reference is produced and agreed prior to the investigation taking place.

51. *Part 5.3* of the HSCB Guidance relates specifically to level three reviews. It states that a level three review consists of an independent review, and is appropriate for complex SAIs involving multiple organisations, SAIs which are technically complex and require independent expert advice, or where the events are '*high profile*' and attracting considerable attention from the general public and/or the media.

52. The Trust's positon is that a level one review took place. This SAI report is entitled '*Level 1 – Significant Event Audit Including Learning Summary Report and Service User/Family/Carer Engagement Checklist*'. I am satisfied that the review the Trust undertook was a level one review.

53. However, I note that at the outset of the SAI process, the Trust produced a terms of reference. That TOR was provided to the complainant for agreement and was subsequently finalised. *Part 5* of the HSCB Guidance states that a terms of reference is only provided as part of a level two review. In addition, the agreed terms of reference then states that a review will take place using a '*Root Cause Analysis (RCA) Methodology'*. *Part 5* of the HSCB Guidance also states that a RCA takes place as part of a level two review, rather than as part of a level one review.

54. I reviewed the final SAI Report. The agreed terms of reference are not included as part of that report. In addition, the investigation that took place was an SEA, and not a RCA, despite the content of the terms of reference.

55. Therefore, whilst I am satisfied that it was a level one review that took place, this review was inconsistent with the approach agreed with the complainant at the outset of the SAI.

56. I consider that at the outset of the process, the Trust's external actions with and towards the complainant were more consistent with a level two review being undertaken, rather than a level one review – despite the internal level one classification, and the initial information provided to the HSCB that a level one review was to take place. However, the SAI process the Trust subsequently adopted, including the SAI report, were in line with a level one review. It is clear, therefore, that the Trust did not fully adhere to the HSCB Guidance in the manner in which it commenced the SAI process.

57. I consider that the Trust's initial actions in agreeing a terms of reference, and agreeing to carry out a RCA established a level of expectation for the complainant in terms of what the review would consist of. I consider that it was reasonable for the complainant to have formed this expectation – based on the terms of reference agreed. The Trust did not meet these expectations, as no RCA took place.

58. I note the Trust's position that a terms of reference was only produced at the patient's family's request. I accept that this may be the case. However, the Trust has a responsibility under *Part 3 of the Addendum* to the HSCB Guidance (set out in Appendix three to this report) to be open and honest with the complainant regarding the SAI process. I find that the Trust failed to be open and honest with the complainant about the exact nature of the SAI process that was to be applied, following its initial actions.

59. In terms of the Trust's decision-making regarding the level one review classification, I note the Trust's position is that its screening team determined the level at which the review was to take place, and not the review team itself. The Trust provided my Office with the screening form for this SAI in support of

this position. I am satisfied, therefore, that it was the screening's team's role to determine the level of review to take place.

60. In terms of the screening team's decision in this respect, I reviewed the screening form in detail. Under the section entitled '*summary of discussions*' it documents that on 20 May 2020 the team decided to complete a level one SAI '*as per HSCB request*'. However, no further information is provided regarding when this request was made, or the terms of the request. Furthermore, the Trust has not provided any documentation from the HSCB regarding this request. I note an email from HSCB to the Trust dated 24 June 2020 that acknowledges receipt of the Serious Adverse Incident Notification[11] the Trust issued. That email also acknowledges the Trust's confirmation that a level one review will take place. Taking the evidence provided into consideration, I find that, on balance, it is more likely than not that the screening team decided the level of review that was to take place, rather than HSCB requesting that a specific level of review was to take place.

61. I also note the section of the screening form entitled '*Decision on level review type AND rationale for this*' on the form is blank. The only indication, therefore, that the screening team set at the review at level one is the entry in the '*summary of discussions*' section, which does not provide any detail regarding the rationale for that decision being made. On this basis, I consider that whilst the Trust recorded the level for the review in its records, it did not record its rationale for reaching this decision.

62. In terms of the decision itself, the Trust's Governance Team (IR2) Form lists the '*actual impact/harm*' as being '*catastrophic*'. *Appendix 16* of the HSCB Guidance defines a catastrophic impact on a person as being an event that causes '*permanent harm/disability (physical/emotional trauma) to more than one person*' or '*incident leading to death*'. Given that the patient's lung cancer potentially went undiagnosed for a year, I am satisfied that the decision to

[11] The standard form the Trust must use to notify the HSCB that a SAI review is to be undertaken – contained in Appendix One to the HSCB Guidance

classify the harm as '*catastrophic*' is in line with the matrix set out in *Appendix 16* to the HSCB Guidance.

63. *Part 5* of the HSCB Guidance states that the screening team must assess the complexity of the issues at hand when determining the level at which a review should commence. *Part 5* also clarifies that complexity is not limited to the seriousness of the incident itself, and that most reviews commence at level one. Whilst the Trust classified the issues as '*catastrophic*', there is nothing in the HSCB Guidance which states that a '*catastrophic*' event must be investigated at a higher level than one. *Part 5* sets out that a complex issue may be one in which multiple organisations are involved, or where there is technical complexity in the matters being reviewed. In this case, the issues under review involved only one organisation, and involved an internal assessment of administrative processes. I am satisfied, therefore, that whilst the events under review were very serious in terms of the impact on the patient, the practical parameters of the review were not particularly complex, when viewed in the context of *Part 5* of the HSCB Guidance.

64. The First Principle of Good Administration, '*getting it right*' requires that public bodies must act in accordance with their own polices and guidance. I find that in failing to adequately communicate with the complainant regarding the level of review to be undertaken, the Trust failed to follow the *Addendum* to the HSCB Guidance.

65. The Second Principle of Good Administration, '*being customer focused*', requires a public body to inform service users what they can expect from a process, and to keep to its commitments. I find that by establishing a terms of reference and agreeing to carry out a RCA, but subsequently carrying out a SEA, the Trust failed to inform the complainant about the exact nature of the SAI process being followed. I further find that in agreeing to carry out a RCA, but in fact carrying out a SEA, the Trust failed to keep its agreed commitment to the complainant.

66. The Third Principle of Good Administration, '*being open and accountable*', requires a public body to be open and clear about the policy its applying and to

ensure that information provided is clear and accurate. I find that the Trust failed to provide clear and accurate information to the complainant about the level of review that was to be undertaken. The third Principle also requires public bodies to provide honest, evidence-based explanations, giving reasons for its decisions, and keeping full and accurate records. This principle underscores the need for records of decisions to be created and maintained by a public body. This is a key principle of good administration. To comply with this principle adequate and contemporaneous records must be retained of matters considered by the public body, decisions made and the reasons for the decisions including the weight given to relevant factors. Without such records being maintained it is impossible for public bodies to defend its actions and the decisions it makes when challenged. It can also have the effect of diminishing the public's confidence that decisions made are not arbitrary and outside of due process. I find that the Trust failed to record its rationale for deciding a level one review would take place on the screening form, and therefore failed to explain its reasons for making that decision.

67. I find that the failures identified constitute maladministration. Nevertheless, I consider the Trust's decision to commence the SAI review at level one was in line with the HSCB Guidance. As a result of these failings, the complainant suffered the injustice of uncertainty and frustration as to the parameters of the review being undertaken – in terms of how the level of review was established, what the review would consist of, and what the SAI report would contain. These failings also caused the complainant the time and effort of bringing this complaint to my Office.

68. Therefore, I uphold this element of the complaint.

Failure to share minutes of the meeting in August 2020

69. The complainant was concerned that the Trust did not provide minutes of the meeting held with the patient's family as part of the SAI review process on 13 August 2020.

70. The Trust acknowledged that handwritten notes were taken of that meeting that were used internally, but that no minutes were provided to the family. The Trust offered its apologies to the complainant for this in its replies to my Office.

71. On foot of the Trust's acknowledgement, I am satisfied that the Trust did not provide minutes of that meeting to the patient's family.

72. *Part 4.4* of the *Addendum* to the HSCB Guidance (set out in Appendix four to this report) states that a written record should be kept of discussions with a service user's family as part of a SAI process, and a copy of that written record shared with the service user's family. In addition, *Part 4.6* and *Appendix 4* of the *Addendum* of the HSCB Guidance sets out that following a meeting with a service user's family, staff must document all meetings with a service user's family and circulate minutes to all relevant parties for timely verification. I find that the Trust failed to adhere to these aspects of the HSCB Guidance when it failed to share a copy of its handwritten notes with the patient's family.

73. As set out above, the First Principle of Good Administration, '*getting it right*' requires that public bodies must act in accordance with their own polices and guidance. The Second Principle of Good Administration, '*being customer focused*', requires a public body to keep to its commitments, including any published service standards. The Third Principle of Good Administration, '*being open and accountable*', requires a public body to keep proper and appropriate records. I find that in failing to provide the patient's family with a copy of the minutes of the meeting on 13 August 2020, the Trust failed to follow *Part 4.4* of the Addendum to the HSCB Guidance, and therefore keep to the commitments set out in that Guidance in a proper and appropriate manner.

74. I find that the failures identified constitute maladministration. As a result of these failings, the complainant suffered the injustice of frustration in not receiving a copy of the minutes of the meeting the complainant took part in. These failings also caused the complainant the time and effort of bringing this complaint to my Office.

75. I therefore uphold this element of the complaint.

The SAI review investigation and content of the reports

76. The complainant was concerned that the Trust's methodology in conducting its investigation was inconsistent with the HSCB Guidance. The complainant was also concerned that the final SAI report did not clearly address the concerns she raised at the outset of the process – and in particular what had happened to the patient's x-ray report after it left the radiology department, and why the follow-up x-ray was not ordered

77. As analysed in detail above, the Trust carried out a level one review under an SEA, despite initially establishing a terms of reference under agreeing to conduct a RCA – which are required for a level two review rather than a level one. I found previously that the Trust's actions in this respect resulted in a failure to comply with the HSC Guidance, and created uncertainty for the complainant regarding what the investigation would consist of.

78. In the agreed terms of reference, the Trust undertook to carry out a RCA. Therefore, it is appropriate and necessary to determine whether or not the investigation the Trust undertook met the standards required of a RCA, and whether it met the standards of a SEA in its investigation and subsequent SAI report.

79. *Part 5.1* of the HSCB Guidance (set out in Appendix three to this report) sets out the standards required for a level one review. It states that as part of a level one review the Trust must assess what has happened, assess why an event happened with reference to what went wrong and what went well.

80. *Appendix 5* of the HSCB Guidance relates to level one reviews, and provides guidance notes for staff seeking to assess what has happened and why. In terms of '*What Happened*', Appendix five states the Trust should '*consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user, the team, organisation and/or others*'. In terms of '*Why Did It Happen*', Appendix five states the Trust should '*consider, for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge, or the complexity and uncertainty associated with an event'*.

81. *Part 5.2* of the HSCB Guidance (set out in Appendix three to this report) sets out the standards required for a RCA. It states that the review should be conducted to a '*high level of detail*' and '*include use of appropriate analytical tools*'. It must also be untaken by a '*multidisciplinary team*' and chaired by someone '*independent to the incident*'.

82. *Appendix 7* to the HSCB Guidance provides further guidance in respect of a methodology for a RCA. It provides a non-exhaustive list, but states the following to be considered:

- Review of service user's records and compile a timeline, if relevant;
- Review of witness statements, if available;
- Interviews with relevant staff concerned;
- Specific reports provided by staff;
- Outline engagement with involved parties;
- Review of local, regional and national policies, procedures and codes of conduct; and
- Review of documentation.

83. In terms of the service user's records and the compilation of a timeline, I am satisfied from my examination of the review team's SAI file that the team did compile a timeline, and did include the patient's medical records as part of its investigation. In terms of documentation reviewed, I note the Trust's position that there that there is no formally documented notes of any meetings that record exactly what evidence the review team took into consideration as part of its investigation. As a result, it cannot be determined what, if any, consideration was given to the individual pieces of evidence contained in the SAI file, or what weight was applied to pieces of evidence when decisions were being made. The SAI report does not make reference to specific pieces of evidence in support of the conclusions reached in it.

84. In terms of witness statements, staff reports and engagement with involved parties, I am satisfied from my examination of the review team's SAI file that the team did include the complainant's initial statement submitted as part of the SAI process. I note that this was the only statement or report in the SAI file.

85. In the initial statement the complainant outlined that she wanted the SAI review to include the following:

- A review of the patient's pathway through the Hospital ED on 16 April 2018 clearly showing where errors occurred and identifying the cause of those errors;
- Identify, where appropriate, additional processes/safeguards to prevent reoccurrence of these errors and/or put in place learning mechanisms to reinforce existing processes;
- Completion of a sample review of other patient journeys through the ED on 16 April 2018 to ensure others were not affected in a similar manner;
- Review of the Trust's response to the complainant's initial internal complaint dated 28 October 2019 to identify further best practice. The complainant felt the original response showed no '*humanity*' or '*corporate responsibility*' – and failed to identify '*where responsibility lay*' for the errors that occurred.

86. In terms of additional processes/safeguards, these will be addressed alongside my analysis of the recommendations of the report – set out below. I will address the remaining aspects of the initial statement here.

87. The SAI report refers to this initial statement, and so I am satisfied that it was reviewed to an extent as part of the investigation process. However, there is no documentation in the SAI file to show when or how that statement was considered, and what weight was applied to its contents in the context of the investigation as a whole.

88. In terms of the review of the patient's pathway through the ED, I reviewed the three versions of the SAI report. I note that as the drafts progressed, additional

information in respect of the patient’s pathway through the ED were included. I am satisfied that by the third and final draft the Trust provided an account of the patient’s pathway through the ED on 16 April 2018, and did provide significant detail of events on that day. However, I note there are relevant factors that were still not addressed in the final report, which the complainant identified and queried as part of the SAI process.

89. When discussing the patient’s medical history, the report does not refer to the patient’s COPD. The Trust acknowledged that this was the case and has apologised for this in its replies to my Office. The patient presented with chest pain, and COPD is a lung condition. On that basis, I consider that this was a relevant factor that should have been identified as part of the patient’s ED pathway, and that should have been reflected in the SAI report. I note the complainant’s comment to my Office that the patient was on several medications for her COPD, which I consider bolsters the relevance of this factor, and the importance of its reflection in the report.

90. When discussing the triage stage of the patient’s pathway, the report does not refer to the triage nurse’s error in recording the side of the patient’s chest where she was experiencing pain. The Trust acknowledged this, and said this was resolved when the ED doctor recorded the correct information. I accept that the error was corrected. However, I consider that this is nonetheless a relevant factor in the patient’s overall ED pathway that the Trust ought to have identified during the investigation, and reflected in the SAI report.

91. When discussing the ED doctor who reviewed the patient on 16 April 2018, I note the report does not refer to this individual being a doctor ‘*in training*’. The Trust’s position was that this was not considered as part of the review. Whilst the fact that the attending doctor was ‘*in training*’ does not in and of itself justify an assumption being made regarding clinical skill and judgment, I nonetheless consider that it was a potentially relevant factor that ought to have been identified and considered as part of the investigation and reflected in the SAI report.

92. I consider that it would have been preferable for the first draft of the SAI report to include all the necessary details of the patient's pathway through ED on 16 April 2018. The fact that it did not do so caused the complainant to question the thoroughness of the investigation carried out. I consider that it was reasonable for the complainant to form this opinion. However, I also note that purpose of a draft is to incorporate feedback from the parties, and I note that the Trust did take the complainant's feedback on board regarding the detail of the patient's pathway. Nonetheless, I refer to my findings above that further relevant factors ought to have been investigated and addressed in the final SAI report regarding the patient's ED pathway.

93. In terms of where errors occurred and the cause of those errors, I note the Trust's position that the errors occurred after the radiology department issued the x-ray report, and not during or immediately after the patient's ED attendance.

94. I note the SAI report identified that the x-ray report issued on 22 April 2018 stated a follow-up x-ray should take place in 6-8 weeks' time. The SAI report also identified that this follow-up x-ray was not requested, and that as a result there was a missed opportunity for the patient to have received an earlier diagnosis. The Trust further identified that this diagnosis resulted in the patient's death. The SAI report identified that the x-ray report had not been marked as urgent by the radiology department, which meant that its findings were not highlighted to the ED team.

95. The SAI report set out the usual process adopted for x-ray reports is that the radiology department report prints them in hard copy and sends them to referring department, which in this case was the ED, for appropriate follow-up. The report is placed in a box in the ED reception for the consultant to review. The SAI report explained that if an x-ray presents an '*abnormal*' investigation, the onus is on the referrer to follow-up on this. The report identified that this system was not '*fit for purpose*'.

96. The SAI report states that the x-ray report was not reviewed, and this resulted in the patient being denied the opportunity for earlier treatment. The report goes

on to state that had the ED consulted reviewed the x-ray report, either a follow-up x-ray would have taken place, or a red flag referral would have been made to the respiratory team for an urgent CT scan. The report acknowledges that this did not take place because the x-ray report was not reviewed.

97. I am satisfied that during the investigation the Trust identified that the error in the patient's overall pathway was that the ED had not reviewed the x-ray report following its despatch by the radiology department. However, the report does not provide any detail as to why the report had not been reviewed, or at which stage in the chain the error occurred after the x-ray report was issued. The Trust acknowledged to this Office that it could not determine if and when the x-ray report was reviewed, but this was not set out in the SAI report. The report does not provide any detail as to what the chain of events was following the production of the x-ray report. It is possible that the error may have occurred at the point of despatch, during transit or at the point of delivery in ED. I consider that this aspect of the SAI ought to have been investigated in more detail – as per the HSCB Guidance on both SEAs and RCAs (*Parts 5.1* and *5.2* respectively). In addition, whilst the SAI report identifies that the x-ray report was not marked as '*urgent*', there is no detail provided to demonstrate whether the Trust investigated whether it should have been marked as '*urgent*'. The IPA advised that it was not necessary for the x-ray report to have been marked urgent. I consider that this is something the Trust ought to have investigated and concluded on itself as part of the review.

98. In addition whilst the SAI report identifies that the system in place was not '*fit for purpose*', there is no analysis presented regarding whether or not the errors were preventable within the system that was in place. I consider that this ought to have been investigated and addressed in the SAI report, even if the outcome was that the errors were not preventable. This would have potentially provided some clarity for the family.

99. In terms of the impact of the errors on the patient and her pathway, the IPA advised that in addition to the patient's loss of opportunity for earlier diagnosis and treatment, the errors resulted in the patient being '*left without knowing the real cause of her symptoms*'.

100. I consider that whilst the final SAI report does identify the ultimate outcome of the error on the patient, it does not go into detail in respect of the ongoing impact on the patient. The report does not discuss the impact of the patient being unaware of the cause of her symptoms. Furthermore, the report does not consider the impact of the terminal diagnosis on the patient or her family in an empathetic manner. I consider details in respect of impact to be a relevant factor in the investigation that should have been given further consideration and reflected in a clearer and more open basis in the final SAI report.

101. I note the complainant's concern that the second draft of the SAI report did not provide sufficient detail to show the impact of the errors on the patient had been investigated and addressed. I also note the Trust's position that the final draft did sufficiently address the impact. Based on my findings above, I do not accept the Trust's position in that respect. The absence of an analysis of the impact caused the complainant to question the thoroughness of the investigation, and I consider this response on the complainant's part was reasonable.

102. As a result, I do not consider that the investigation was sufficiently thorough to determine where errors occurred, the cause of those errors and the extent of the impact of those errors on the patient. The outcome of the errors is presented, but the chain of events leading up to and causing that outcome has not been established, or presented in the final SAI report. As a result, the Trust failed to adhere to the requirements of *Parts 5.1* and *5.2*, and *Appendices 5* and *7* of the HSCB Guidance. Furthermore, the Trust failed to provide the complainant with full facts and an understanding of what happened, as required by *Parts 1 and 3.4* of the *Addendum* to the HSCB Guidance.

103. In terms of the sample review of other patients' journeys on 16 April 2018, I note the Trust's position in the SAI report that whilst this was considered, it was not actioned on the basis that the errors occurred after this date, when the x-ray report was produced and despatched by the radiology department on 22 April 2018. I am satisfied that the Trust gave sufficient consideration to this request, and that its conclusion in this respect was reasonable and appropriate. In reaching this conclusion, I also note the IPA's advice that ED assessment and examination were appropriate and in line with relevant standards.

104. I also note the Trust's position that it could not conduct an audit of other X-Ray reports reviewed by ED administration staff on the day the patient's X-ray was reviewed, as it could not determine when exactly the patient's report was reviewed. Whilst I note the Trust's position in this respect, I consider that an audit could have taken place to review a sample of x-ray reports despatched by the radiology department to the ED for the months of March 2018 – June 2018 – as the Trust is in possession of records to show what X-ray reports were sent during that period. I consider this was a missed opportunity to potentially identify any further failings with the process being followed.

105. In terms of the Trust's response to the complainant's original complaint being addressed as part of the SAI review, I note that the SAI report does refer to this aspect. In the SAI report, the Trust says that it has '*taken on board*' the family's comments regarding the initial complaints process. The Trust acknowledged that its initial response did not '*convey*' the '*sense of sympathy*' that it should have, and that the '*brevity*' of that response was not normal practice. The Trust provided an apology for this in the SAI report.

106. I consider that an analysis of the original internal complaints procedure does not form part of a typical SAI review conducted in line with either *Parts 5.1* or *5.2* of the HSCB Guidance. This is because it has no specific impact on the SAI itself. Despite this, the Trust did address the family's concerns regarding that complaints procedure in the final version of the SAI. I consider that this was appropriate for the Trust to have done, in order to meet the family's expectations, and to ensure openness and transparency in the review process. I note that the Trust identified its failings in that respect and apologised for them. I consider the Trust's actions in this respect to be reasonable and appropriate.

107. Regarding interviews carried out, I note the Trust's position that no interviews with staff took place, as it felt all relevant information was already available to the review team. Therefore, the review team did not conduct any interviews with the ED doctor who initially requested the x-ray in 2018, the radiologist who compiled the x-ray report, or the administration staff who may have received and handled the x-ray report that subsequently could not be located. I consider

that statements from these staff members would be information relevant to the investigation – particularly in light of my finding above that the report does not detail the chain of events following the x-ray report being produced by the radiology department. I do not accept the Trust's position that, in the absence of interviews with these staff members, the review team had access to all relevant information to allow them to conduct their investigation. I find that interviews with these staff members would have been necessary to ensure the investigation was conducted to a '*high level of detail*', as required by *Part 5.2* of the HSCB Guidance. I conclude that the use of staff interviews would have been an appropriate '*analytical tool*' in the investigation. I consider that in deciding not to conduct interviews with these staff members, the Trust lost the opportunity to potentially determine exactly what happened to the X-ray report after the radiology department produced it - to determine exactly what went wrong, and when it went wrong. I find that in opting not to conduct these interviews, the Trust failure to thoroughly and robustly investigate what went wrong in the patient's care pathway.

108. In terms of local, national and regional policies, I note that none are included as part of the review team's SAI file, and there is no reference to any polices in the SAI Report that were in place at the time of the patient's initial x-ray in 2018. It cannot be determined, therefore, whether there were any relevant policies in place – and if there were, it cannot be determined what, if any, consideration was given to them as part of the investigation process. I consider an examination of any relevant polices would be an appropriate '*analytical tool*' as part of the investigation. If no applicable policies existed, I consider it would have been appropriate for this to be been identified as part of the investigation, and recorded in the review team's SAI file and report – to ensure the investigation was conducted to a '*high level of detail*', as required by *Part 5.2* of the HSCB Guidance.

109. In terms of the Trust's conclusion in the final SAI report, I note its position that there was '*no area of service failure*' identified, and that as a result, the SAI would not proceed to further investigation. The Trust's position was that the HSCB requires the Trust to categorise the outcome of SAI investigations as per

the agreed Donaldson (2012) scheme. It said the review did not *'fit into any of the 6 areas of service failures listed*'.

110. *Part 4.4.2* of the Donaldson Report states that to be regarded as a serious adverse incident for reporting purposes, the incident must fall into one of the following six categories:

- the serious injury or unexpected/unexplained death of a service user, staff member, or visitor;
- the death of a child in health and social care;
- unexpected serious risk to a service user, staff member, or member of the public;
- an unexpected or significant threat to service delivery or business continuity;
- serious self-harm or assault by a service user, staff member, or member of the public;
- serious self-harm or assault by a person in the community who has a mental illness of disorder, and who in receipt of mental health or learning disability services, or has been within the last 12 months; and
- any serious incident of public interest.

111. The IPA advised that whilst the patient's case may not fit specifically into one of these categories, the Trust considered it sufficiently significant to commence a SAI review. The IPA further advised that whilst the patient's case may not amount to a SAI, it is an example of failure in care and treatment the Trust provided.

112. Having reviewed the Trust's position, the Donaldson Report and the IPA's advice, I am not satisfied that the Trust's conclusion that the patient's case did not constitute a serious adverse incident is reasonable in the prevailing circumstances. The final SAI report states that the missed opportunity to

diagnose the patient's lung cancer '*regrettably resulted in her demise*'. This conclusion was reached despite the failures in the investigation process that have been identified in this report. I consider that the Trust's acknowledgment of this is inconsistent with its overall conclusion that this case is not a serious adverse incident under the Donaldson criteria. I further consider that the Trust's actions may have caused significant injury to the patient, and may have presented a serious risk to the patient and her opportunity for treatment. I find this to be a further failure in the robustness of the investigation process, and in the accuracy of the final SAI report.

113. I note the Trust's position that the HSCB endorsed the conclusion they reached. I consider the HSBC's position in this respect must be viewed in the context of the procedural failures now identified in this report, which were not necessarily apparent to the HSCB at the time. Furthermore, I consider that the HSBC's endorsement does not absolve the Trust from the responsibility to get the process right.

114. In summary, the agreed terms of reference for the investigation set out that a RCA would take place to review the care provided to the patient on 16 April 2018. In reference to my findings above, the Trust's investigation and subsequent final SAI report also failed to meet the standards set out in *Part 5.2* and *Appendix 7* of the HSNC Guidance for a RCA. Furthermore, the investigation and final report failed to meet the standards set out in *Part 5.1* and *Appendix 5* of the HSCB Guidance for a level one review by way of SEA. The conclusion was also inconsistent with *Part 4.4.2* of the Donaldson Report.

115. The Trust also agreed in the terms of reference to engage with the family in an open and transparent manner, to consider their experience and address their concerns in a sensitive and empathetic manner. I find that whilst steps were taken to engage with the family and to act upon their comments in respect of the draft SAI reports, the final draft of the report failed to address all relevant factors in the patient's ED pathway, and failed to fully demonstrate that a thorough investigation into the cause and impact of the errors had taken place. Therefore, the Trust failed to meet the expectations it set for the complainant in the terms of reference, and also failed to ensure a sufficiently thorough

investigation to the standards required by *Part 5.1* and *Appendix 5*, and *Part 5.2* and *Appendix 7* of the HSCB Guidance.

116. In the terms of reference, the Trust undertook to take a multidisciplinary approach to the investigation. However, the Trust failed to obtain relevant information from radiology and ED department staff as part of its investigation. I consider that this impacted upon the thoroughness, openness and transparency of the investigation. As such, the Trust failed to keep this undertaking and failed to ensure a sufficiently thorough investigation to the standards required by *Part 5.1* and *Appendix 5*, and *Part 5.2* and *Appendix 7* of the HSCB Guidance.

117. In the terms of reference, the Trust undertook to provide a chronology of events based on documented evidence and staff accounts, and to identify factors which may have had an influence on x-ray report not being followed-up. I am satisfied that a chronology was produced as part of the investigation process, and that it was reflected in the final SAI report. However, I refer to my findings above that the Trust failed to record the documentation it reviewed as part of the investigation and failed to conduct interviews with staff which I consider would have been materially relevant to the investigation. I refer also to my finding above that material factors which ought to have been investigated and reflected in the final SAI report were not identified and considered. As such, the Trust failed to keep these undertakings and failed to ensure a sufficiently thorough investigation to the standards required by *Part 5.1* and *Appendix 5*, and *Part 5.2* and *Appendix 7* of the HSCB Guidance.

118. It may be that the Trust has been unable to determine exactly what happened, or exactly what went wrong. If that was the case, in the interests of openness and transparency, I consider the Trust ought to have stated that in the SAI report.

119. The First Principle of Good Administration, '*getting it right*' requires that public bodies must act in accordance with their own polices and guidance. The Trust failed to follow *Part 5.1* and *Appendix 5* of the HSCB Guidance in the manner in which it investigated the SAI under its own classification of the review as level

one. The Trust also failed to follow *Part 5.2* and *Appendix 7* of the HSCB Guidance in respect of the RCA it undertook to carry out. The First Principle also requires a public body to take reasonable decisions, based on all relevant considerations. I find that the Trust failed to ensure that all relevant considerations were identified and consider as part of the investigation, and addressed in the final SAI report – and failed to reach a conclusion consistent with *Part 4.4.2* of the Donaldson Report.

120. The Second Principle of Good Administration, '*being customer focused*', requires a public body to inform service users what they can expect from a process and to keep to its commitments. I find that the Trust failed to meet the expectations and commitments it set for the SAI process when it agreed a terms of reference with the complainant, and agreed to carry out a RCA in line with its policy. I further find that the Trust failed to meet the expectations set for a SEA in the HSCB Guidance.

121. The Third Principle of Good Administration, '*being open and accountable*', requires a public body to keep accurate and proper records and to give its reasons for making decisions. I find that the Trust failed to record the evidence, information, and relevant policies it considered as part of the SAI process and any weight it was applying to these. Therefore, it failed to provide a sufficient rationale for the conclusions it reached, including its decision that the patient's case did not meet the criteria for a serious adverse incident in *Part 4.4.2* of the Donaldson Report. The Third Principle also requires public bodies to take responsibility for its actions. I consider that in seeking to rely on the HSCB's endorsement of its decision on foot of the Donaldson Report, the Trust has failed to take full reasonability for its decision that the patient's case did not amount to a SAI.

122. I find that the failures identified constitute maladministration. As a result of these failings, the complainant suffered the injustice of uncertainty and frustration as to the SAI process adopted. These failings also caused the complainant the time and effort of bringing this complaint to my Office.

123. I therefore uphold this element of the complaint.

The recommendations and the failure to include responses to the family's queries in the final report

124. The complainant was concerned that the final SAI report did not clarify what the recommendations in it were based on, and that the recommendation to improve the process was not a mandatory one. The complainant was also concerned that the queries and comments the family raised in respect of the contents of the second draft SAI report were not reflected in the final version of the SAI report. The complainant stated that they were handled in a separate letter instead.

125. The SAI report provides that to prevent reoccurrence, a standard operating procedure has been put in place to govern how x-ray reports are reviewed on receipt by the ED department. The report goes on to say that if this SOP had been in place on 22 April 2018, the error would not have occurred. I consider the Trust's finding in this respect to be inconsistent with the Trust's position that it could not determine the precise cause of the error.

126. The final SAI report goes on to explain that the new SOP requires that official x-ray reports sent by the radiology department will be segregated into '*normal*' and '*abnormal*' findings. A consultant will review an abnormal x-ray report and decide what follow-up action is required. No further information in respect of the new SOP is provided in the final SAI report.

127. After the second draft of the SAI report was issued, the complainant submitted some comments to the Trust, which included queries about the new SOP. The complainant queried whether the new SOP would in fact address the issue of human error – and queried whether an audit system should be set up. The Trust responded to this query, but in a separate letter to the complainant, rather than in the final version of the SAI report. In its response the Trust outlined what the procedure was prior to the new SOP being introduced. However, I do not consider that it addressed the actual query the complainant put forward. I consider that a more detailed explanation of what the new SOP was designed to do and how it was intended to improve service delivery ought to have been included in the SAI report, following the complainant's queries.

128. The complainant also commented that the second draft of the SAI report said the purpose of the new SOP was to improve communication between secretarial and clinical staff. The complainant queried why the SAI report did not identify what had gone wrong in respect of that communication which caused the patient's x-ray report not to be reviewed. The Trust responded to this query to say that it was '*unclear*' as to what exactly happened to the x-ray report. However, this acknowledgement was not included in the final SAI report. I consider that, in the interests of openness and transparency required by *Part 3* of the *Addendum* to the HSCB Guidance, this admission should have been included in the final SAI report as part of the explanation of what happened and why. Furthermore, I consider that the Trust's response to this query did not address why the Trust considered communication between secretarial and clinical staff was particularly relevant in the patient's case, and therefore necessary to prevent re-occurrence. The Trust therefore failed to explain in sufficient detail what this improvement was based on.

129. In respect of the new SOP, the IPA advised that under the new SOP, the Trust continued to rely on non-clinical staff to assess and filter the x-ray reports. The IPA further advised that the GMC Guidance states that a person to whom tasks are delegated needs to have the '*knowledge, skills and experience*' and meet '*defined standards of competence*' to complete a task such as this. The IPA queried why the SOP did not set out that a clinician should review all x-ray reports, irrespective of whether they are normal or abnormal. The IPA advised that the new SOP would ensure that all abnormal x-ray reports are reviewed by a consultant, but could not prevent x-rays being misfiled or miscategorised by non-clinical staff. The IPA advised that the Trust ought to carry out an audit to determine the effectiveness of the new SOP in light of that position.

130. *Part 8* of the HSCB Guidance states that a key aim of the SAI procedure is to '*improve services and reduce the risk of incident reoccurrence*'. In respect of the new SOP, I am not satisfied that this is sufficiently robust to meet this key aim.

131. On foot of the IPA's advice, I consider that if the aim of the new SOP is to reduce or eliminate human error and prevent recurrence, then it would be

reasonable and appropriate for a clinician to review all x-ray reports, rather than for the Trust to rely on staff without clinical training. I consider that the Trust ought to review its new SOP in light of the IPA's advice – which is set out in Appendix two to this report. As per the IPA's advice, this review should include an audit to determine its current effectiveness.

132. In addition to the complainant's queries regarding the new SOP, the complainant queried about the second draft of the SAI report not clarifying the position regarding the triage nurse's recording of the patient's pain as being right-sided instead of left-sided. The Trust responded to this query, but did not update the SAI report in this respect in its final version. I also note that this query was not related to the recommendations in the report. As a result, I consider the report should have been amended to include this.

133. The complainant also queried the position in the second draft SAI report that the abnormality found was '*incidental*' to the reason for the patient's ED attendance on 16 April 2018. The Trust responded to this query, but did not update the SAI report in this respect in its final version. I also note that this query was not related to the recommendations in the report. As a result, I consider the report should have been amended to include this.

134. In addition, the complainant queried why the patient's medical history of COPD was not included in the report. The Trust responded to this query, but did not update the SAI report in this respect in its final version. I also note that this query was also not related to the recommendations in the report. As a result, I consider the report should have been amended to include this.

135. *Appendix 4* to *the Addendum* to the HSCB Guidance requires that the Trust should allow for amendments to the draft SAI report if required. I consider that the additional comments the complainant provided on the second draft of the SAI report ought to have been incorporated into the final version. This would also ensure the investigation and reporting process was fully open and transparent, as required by *Part 3* of the *Addendum* to the HSCB Guidance.

136. In terms of the stated recommendation in the final SAI report, the report states that '*the Trust implements the electronic sign off of radiology reports on*

NIECR'. In the body of the final SAI report, the Trust set out that NIECR stands for the Northern Ireland Electronic Care Record. The Trust set out that all radiology reports are currently available on the NIECR, and that the ability to sign-off on having viewed these reports is set up in the system. The Trust concluded that the use of this system would be a '*failsafe*' way of *'reducing governance issues*' and '*the amount of clerical time needed*'. The Trust said that it would 'encourage' staff to use the digital sign-off system. It is noted the recommendation was not a mandatory one. In addition, no timeline for implementation was included as part of the final SAI report.

137. I note the Trust's position to this Office that the digital sign-off system will '*review and track patients reports, initially focusing on those reports that contain the word "follow up" or that have been communicated urgently to the clinical teams*'. The Trust's position was that the recommendation could not be mandatory at this point, as the technology is not yet sufficient to facilitate it.

138. In respect of this recommendation, the IPA advised that the digital sign-off system will be able to confirm whether an x-ray report was viewed and checked, but not whether it was subsequently actioned. The IPA further advised that digital sign-off can be more '*burdensome*' than review of physical copies, which can lead to a delay in service provision. The IPA advised that implementing this recommendation would not '*fully prevent reoccurrence of this failure*', but may help identify who the clinician was that ought to have actioned the x-ray report. The IPA further advised that a digital sign-off system is susceptible to a report being opened in error, giving a false result that a document had been viewed. The IPA also advised that whilst staff can be trained to use the digital sign-off system and reminded to use it, it is difficult to force staff to make appropriate use of the system. The IPA's ultimate advice was '*I do not consider the recommendation to implement electronic sign off of radiology reports will necessarily address the issue of failing to act on an abnormal report although it should allow any un-reviewed reports to be identified more easily. It will, however, prevent reports from being lost which appears to have been a factor in this case*'. The IPA advised that the

recommendation being mandatory would have little impact on the practicality of its implementation.

139. I accept the IPA's advice that the recommendation identified in the final SAI report is likely to prevent an x-ray report being mislaid, it is not likely to ensure that a report is actioned once viewed. The Trust's investigation has been unable to determine whether the report was mislaid on its route to the ED, or during its time in the ED, or whether it was misfiled on arrival at the ED, or whether it was correct filed, but not acted upon. It has been noted above that this position was not fully outlined in the final SAI report.

140. As a result, I consider that whilst it was worthwhile to make this recommendation as part of the SAI process, the recommendation will not necessarily prevent a reoccurrence of this incident. I am satisfied that the Trust sufficiently clarified why it was making this recommendation in the final SAI report, but failed to be open and transparent about its potential shortcoming, which have been identified in the IPA's advice. On foot of the IPA's advice, I am satisfied that it was not essential that the recommendation was made mandatory in the SAI report.

141. On this basis, I am not satisfied that the recommendation made fully meets the key aim set out in *Part 8* of the HSCB Guidance. It may be the case that that this is the extent of the steps which can be taken to reduce human error. If this is the case, I consider this ought to have been identified as part of the investigation, and reflected in the final SAI report.

142. I consider that the Trust ought to review this recommendation in light of the IPA's advice – which is set out in Appendix two to this report.

143. To summarise, I consider that in respect of the new SOP, the Trust was not sufficiently open and transparent with the complainant about why the new SOP was relevant to the errors identified in the patient's care, how the new SOP was to operate, and how the SOP was intended to prevent or limit future reoccurrence. In addition, on foot of the IPA's advice, I am not satisfied that the new SOP in its current form will be sufficient to address the errors identified in the patient's care – and therefore meet the key aim identified in *Part 8* of the

HSCB Guidance. I also found that the Trust ought to have updated the final SAI report to include the clarifications the complainant requested – in line with *Part 3* and *Appendix 4* to the *Addendum* to the HSCB Guidance. I further found that the Trust ought to have been sufficiently open and transparent with the complainant about the limitations of its recommendation, and why it was not appropriate for that recommendation to be mandatory – to ensure compliance with *Part 3* to the *Addendum* to the HSCB Guidance.

144. The First Principle of Good Administration, '*getting it right*' requires that public bodies must act in accordance with their own polices and guidance. The Third Principle of Good Administration, requires a public body to be '*being open and accountable*', regarding its processes and decisions. The Trust failed to meet its key aim in *Part 8* of the HSCB Guidance in the manner in which it made recommendations and identified service improvements. In addition, the Trust failed to adhere to *Part 3* of the *Addendum* to the HSCB Guidance which requires the Trust to be open and transparent about the SAI investigation – and *Appendix 4* of the *Addendum* to the HSCB Guidance, regarding the family's comments being reflected in the final SAI report.

145. I find that the failures identified constitute maladministration. As a result of these failings, the complainant suffered the injustice of uncertainty and frustration as to the SAI process adopted. These failings also caused the complainant the time and effort of bringing this complaint to my Office.

146. I therefore uphold this element of the complaint.

The failure to refer the complainant to my office

147. The complainant was concerned that the Trust had not informed her that she could refer a complaint to my Office at the conclusion of the SAI process.

148. The Trust acknowledged this, and apologised for this in its replies to my Office.

149. I note that the complainant had previously submitted a complaint to my office regarding the care and treatment provided to the patient, the investigation of which was discontinued following the Trust's offer to commence the SAI review.

I reviewed the Trust's response to the complainant's original internal complaint, and note that in that letter, the Trust did not signpost the complainant to my office. That letter should have signposted the complainant to my Office, and I note the Trust's position that it has now amended its templates to do so.

150. I also reviewed the HSCB Guidance, and note that it does not specifically require the Trust to signpost the complainant to my Office following case closure.

151. Despite this, I find that, in line with the Principles of Good Complaint Handling, the Trust ought to have informed the complainant of her right to bring a complaint to my Office. I consider this to be a failing on the Trust's part.

152. The First Principle of Good Complaint Handling, '*getting it right*', requires a public body to signpost a complainant to my Office at the conclusion of a complaints process. I am satisfied that the SAI review process commenced as a result of the complainant's complaint. Therefore, it would have been appropriate for the Trust to have signposted the complainant to my Office, despite the complainant being aware of my Office from previous usage.

153. I find that is failure constitutes maladministration. As a result of this failing, the complainant suffered the injustice of uncertainty and frustration as to what avenues remained open to her.

154. This element of the complaint is therefore upheld. However, I welcome the Trust's confirmation it has since amended its templates.

Conclusion

155. I received a complaint about the manner in which the Trust approached the SAI process – specifically whether the process adopted met the standards required in the HSCB Guidance.

156. The investigation established the following:

- The Trust failed to be clear and open about the level of review it undertook to complete;

- The Trust failed to provide the complainant with a copy of the minutes of the meeting held on 13 August 2020, as required by the HSCB Guidance;
- The Trust failed to ensure it completed a sufficiently thorough investigation to comply with the standards set out in the HSCB Guidance;
- The Trust failed to ensure that all material factors were identified, considered and addressed in the final SAI report;
- The Trust failed to ensure that it met the undertakings it made to the complainant in the agreed terms of reference;
- The Trust failed to meet the requirements of the HSCB Guidance in respect of the service improvements it identified and the recommendations it made in the SAI report;
- The Trust failed to address the queries the complainant made in respect of the second draft of the SAI report in the final SAI report; and
- The Trust failed to signpost the complainant to my Office at the conclusion of the SAI process.

157. I am satisfied that the maladministration identified caused the complainant to experience the injustice of uncertainty and frustration regarding the SAI process adopted, as well as the time and effort of bringing this complaint to my Office.

158. I therefore uphold the complaint.

Recommendations

159. I recommend that the Trust provides the complainant with a written apology in accordance with NIPSO 'Guidance on issuing an apology' (June 2016), for the injustice caused as a result of the maladministration/failures identified within **one month** of the date of the final report.

160. I further recommend for service improvement and to prevent future recurrence, that the Trust:

    I. Takes steps to ensure that all staff responsible for carrying out this SAI process have the opportunity to consider the findings in this report and demonstrate that those individuals have reflected on how they can

improve their practice in future and are aware of their responsibilities under the HSCB Guidance;

II. Provides appropriate and adequate training to any and all staff involved in handling SAI reviews to ensure that HSCB Guidance is followed in all cases – to include the drafting of terms of reference;

III. Introduces a sign-off sheet in the ED for staff delivering physical x-ray reports to sign on deposit to demonstrate delivery of the report to the ED – to reduce the chance of a report being misplaced;

IV. Provides my Office with evidence of the Trust's operational team's work so far, as of the date of this final report, to implement the new SOP and digital sign-off ox X-ray reports – as the Trust stated in the final SAI report that work in this respect has already begun;

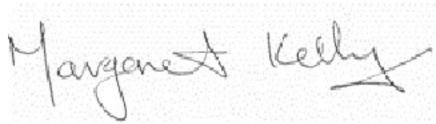
V. Reviews its new SOP regarding the handling of x-ray reports in light of the IPA's advice, which is contained in Appendix two to this report – including carrying out an audit into the impact and effectiveness of the new SOP; and

VI. Reviews the current iteration of the digital sign-off of x-ray reports in light of the IPA's advice.

161. I recommend that the Trust implement an action plan to incorporate these recommendations and should provide me with an update within **six months** of the date of my final report. That action plan should be supported by evidence to confirm that appropriate action has been taken (including, where appropriate, records of any relevant meetings, training records and/or self-declaration forms which indicate that staff have read and understood any related policies).

162. In light of the Trust's decision on foot of the Donaldson Report, and in the context of the findings in this report, my Office will share a copy of my final investigation report with the Department of Health, which has assumed responsibility for the former HSCB's function and role.

163. Finally, I wish to pass on my condolences to the complainant, and her family, on the death of her mother.



MARGARET KELLY
Ombudsman
5 September 2022

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

- Acting in accordance with the law and with regard for the rights of those concerned.
- Acting in accordance with the public body's policy and guidance (published or internal).
- Taking proper account of established good practice.
- Providing effective services, using appropriately trained and competent staff.
- Taking reasonable decisions, based on all relevant considerations.

2. Being customer focused

- Ensuring people can access services easily.
- Informing customers what they can expect and what the public body expects of them.
- Keeping to its commitments, including any published service standards.
- Dealing with people helpfully, promptly and sensitively, bearing in mind their individual circumstances
- Responding to customers' needs flexibly, including, where appropriate, co-ordinating a response with other service providers.

3. Being open and accountable

- Being open and clear about policies and procedures and ensuring that information, and any advice provided, is clear, accurate and complete.
- Stating its criteria for decision making and giving reasons for decisions
- Handling information properly and appropriately.
- Keeping proper and appropriate records.
- Taking responsibility for its actions.

4. Acting fairly and proportionately

- Treating people impartially, with respect and courtesy.
- Treating people without unlawful discrimination or prejudice, and ensuring no conflict of interests.
- Dealing with people and issues objectively and consistently.
- Ensuring that decisions and actions are proportionate, appropriate and fair.

5. Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Putting mistakes right quickly and effectively.
- Providing clear and timely information on how and when to appeal or complain.
- Operating an effective complaints procedure, which includes offering a fair and appropriate remedy when a complaint is upheld.

6. Seeking continuous improvement

- Reviewing policies and procedures regularly to ensure they are effective.
- Asking for feedback and using it to improve services and performance.
- Ensuring that the public body learns lessons from complaints and uses these to improve services and performance.

Appendix 2

PRINCIPLES OF GOOD COMPLAINT HANDLING

Good complaint handling by public bodies means:

1. Getting it right

- Acting in accordance with the law and with regard for the rights of those concerned.
- Ensuring that those at the top of the public body provide leadership to support good complaint management and develop an organisational culture that values complaints.
- Having clear governance arrangements, which set out roles and responsibilities, and ensure lessons are learned from complaints.
- Including complaint management as an integral part of service design.
- Ensuring staff are equipped and empowered to act decisively to resolve complaints.
- Focusing the outcomes for the complainant and the public body.
- Signposting to the next stage of the complaints procedure in the right way and at the right time.

2. Being customer focused

- Having clear and simple procedures.
- Ensuring that complainants can easily access the service dealing with complaints, and informing them about advice and advocacy services where appropriate.
- Dealing with complainants promptly and sensitively, bearing in mind their individual circumstances.
- Listening to complainants to understand the complaint and the outcome they are seeking.
- Responding flexibly, including where appropriate co-ordinating responses with any other bodies involved in the same complaint, where appropriate.

3. Being open and accountable

- Publishing clear, accurate and complete information about how to complain, and how and when to take complaints further.

- Publishing service standards for handling complaints.
- Providing honest evidence-based explanations and giving reasons for decisions.
- Keeping full and accurate records.

4. **Acting fairly and proportionately**

- Treating the complainant impartially, and without unlawful discrimination or prejudice.
- Ensuring that complaints are investigated thoroughly and fairly to establish the facts of the case.
- Ensuring that decisions and actions are proportionate, appropriate and fair.
- Ensuring that complaints are reviewed by someone not involved in the events leading to the complaint.
- Acting fairly towards staff complained about as well as towards complainants

5. **Putting things right**

- Acknowledging mistakes and apologising where appropriate.
- Providing prompt, appropriate and proportionate remedies.
- Considering all the relevant factors of the case when offering remedies.
- Taking account of any injustice or hardship that results from pursuing the complaint as well as from the original dispute.

6. **Seeking continuous improvement**

- Using all feedback and the lessons learnt from complaints to improve service design and delivery.
- Having systems in place to record, analyse and report on learning from complaints.
- Regularly reviewing the lessons to be learnt from complaints.

Where appropriate, telling the complainant about the lessons learnt and the changes made to services, guidance or policy.