Investigation of a complaint against the Western Health & Social Care Trust

Report Reference: 202002249

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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.

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SUMMARY

This complaint was about care and treatment the Western Health and Social Care Trust (the Trust) provided to the complainant's late husband (the patient). The patient underwent treatment within the Trust for cancer from July to September 2019, and again in early September 2020 after his cancer metastasised[1]. The patient sadly died on 16 September 2020.

The investigation established the following failings in the care and treatment the Trust provided to the patient:

- The Oral Maxillofacial Facial Surgeon Consultant incorrectly downgraded the patient's red flag referral in July 2019;
- The ENT Consultant did not effectively communicate to the patient the need for a biopsy;
- The Cardiologist should have recognised the patient required urgent treatment for a pericardial effusion and arranged this procedure at an earlier point;
- The quality of the Cardiology records for 7 and 8 September 2019 fell below the GMC Standard; and
- The Consultant's communication with the patient and the lack of a referral for palliative care in September 2020.

The investigation also identified maladministration in the Trust's record keeping and in its handling of the family's subsequent complaint.

I recognised the impact these failings had on the patient and his family at an already difficult time. I wish to convey my heartfelt condolences to the family on the loss of their husband and father.

I recommended the Trust provide the complainant with a written apology for the

[1] The cancer had spread to other sites in the body.

injustice caused as a result of the failure in care and treatment. For service improvement to prevent future reoccurrence, I recommended the Trust brings the contents of this report to the attention of staff so they can reflect on the learnings identified. I made further recommendations for the Trust to address under an evidence-supported action plan to instigate service improvement and to prevent further reoccurrence of the failings identified.

THE COMPLAINT

1. This complaint was about care and treatment the Western Health and Social Care Trust (the Trust) provided to the complainant's late husband (the patient) during the period July 2019 to September 2019, and during September 2020. The complainant raised additional concerns about the Trust's communication with the patient's family during this time. It was also about how the Trust handled the subsequent complaint.

Background

2. The patient was diagnosed with oesophageal cancer[2] in 2015. He received treatment and was later assessed as 'cancer free'. In June 2019 the patient began to feel a restriction when he opened his mouth, and had difficulty eating. On 18 July 2019 the patient's GP referred the patient to the Maxillofacial Team[3] within the Trust as a red flag referral[4].

3. Over the next few weeks the patient began to feel intense pain and had visible swelling around his jaw. The patient attended a consultation appointment with the Consultant ENT Surgeon (ENT Consultant) in the Trust on 23 August 2019. The ENT Consultant referred the patient for a CT scan, which occurred on 5 September 2019. On the same day, following the CT scan, the patient began to deteriorate. The complainant telephoned the patient's GP for advice who contacted the Trust and arranged for an ambulance to take the patient to hospital. The Trust admitted the patient to South West Area Hospital for treatment on the same day (5 September 2019).

4. On 6 September 2019 the patient and the complainant requested the results of the CT scan taken on 5 September 2019. The results showed the need for the patient to receive a fine needle aspirate[5](FNA) which the Radiologist booked for 9 September 2019. The CT results also detected a large pericardial effusion[6]. As a result of this, an urgent echocardiogram[7] was ordered and confirmed the presence of the pericardial effusion. The Trust transferred the

[2] Cancer arising from the esophagus – the food pipe that runs between the throat and stomach.
[3] Medical team specifically focused on jaws and face.
[4] Red Flag referrals are only for cases of suspected cancer (patient to be seen within 2 weeks).
[5] Fine needle aspiration is a diagnostic procedure used to investigate lumps or masses.
[6] A condition with the accumulation of too much fluid in the pericardium, a sac surrounding the heart.
[7] An imaging test that uses ultrasound to monitor the heart function.

patient's care to the Cardiologist in Altnagelvin Hospital on 6 September 2019. On 9 September 2019 the patient received an urgent pericardiocentesis[8] procedure which drained fluid from around the patient's heart. The Trust suspected the patient's facial swelling to be a tumour seeding[9] (metastasis[10]) and on 10 September 2019, the patient received an ultrasound-guided biopsy[11].

5. The Trust did not identify the patient's swelling was a tumour seeding but as a diagnosis of cancer. The Oncologist informed the patient on 16 September 2019 his cancer had returned. The patient requested the Trust transfer his care to St James's Hospital in Dublin. The Trust discharged the patient on 19 September 2019 to allow him to continue his care and treatment in Dublin.

6. On 3 September 2020 the patient attended the Emergency Department (ED) in South West Acute Hospital presenting with a sudden severe shortness of breath. The ED Consultant admitted the patient to hospital for treatment, and the patient received a CT scan. Upon review of the patient's CT scan, the Ward Consultant (the Consultant) informed the patient his cancer had spread. The patient requested that he continue his care and treatment in St James's Hospital, Dublin. The Trust discharged the patient from its care on 7 September 2020. The patient sadly passed away on 16 September 2020.

7. The complainant raised concerns to the Trust on 19 November 2020 about the patient's care and treatment. The complainant received the Trust's final response to her complaint on 14 February 2022.

Issues of complaint

8. I accepted the following issues of complaint for investigation:

Issue 1: Whether the Trust provided appropriate care and treatment to the patient in July to September 2019, and in September 2020.

[8] Procedure to drain excess fluid from the pericardium, the sac around the heart.
[9] Malignant cells are deposited along the tract of a biopsy needle.
[10] A word used to describe the spread of cancer from the original tumor site to other parts of the body.
[11] Image-guided biopsy performed by taking samples of an abnormality under some form of guidance such as an ultrasound or MRI.

Issue 2: Whether the Trust provided the patient's family with the appropriate communication in September 2019.

Issue 3: Whether the Trust addressed all issues of the complaint in accordance with its policy and relevant standards.

INVESTIGATION METHODOLOGY

9. 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 complaints process.

Independent Professional Advice Sought

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

- A Consultant Oral and Maxillofacial Surgeon with subspecialist interest in head and neck cancer (M IPA);
- A Consultant ENT Surgeon with specialist interest in head and neck cancer (ENT IPA);
- A Senior Nurse with 21 years' experience across primary and secondary care (N IPA);
- A Consultant Cardiologist with over 30 years' experience (C IPA);
- A Consultant Radiologist with 18 years' experience working in a tertiary cancer centre. The IPA has special interests in cancer procedures including biopsies (R IPA);
- A Consultant Oncologist with almost 30 years' experience (O IPA); and
- A Consultant Physician with over 40 years' experience (Con IPA).

I enclose the clinical advice received at Appendix three to this report.

11. The information and advice which informed the findings and conclusions are included within the body of this report. The IPAs 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

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

    The general standards are the Ombudsman's Principles[12]:

    - The Principles of Good Administration; and
    - The Principles of Good Complaint Handling.

13. 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 General Medical Council's Good Medical Practice, updated April 2014 (the GMC Guidance);
    - Royal College of Physicians National Early Warning Score (NEWS) 2, 19 December 2017 (RCP NEWS guidance);
    - The National Institute for Health and Care Excellence's Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition, Clinical Guideline 32, updated 4 August 2017 (NICE CG32);
    - Nursing and Midwifery Council The Code, 10 October 2018 (the NMC Code);
    - Northern Ireland Referral Guidance for Suspected Cancer – Red Flag Criteria 2015 (Red Flag Referral Criteria); and
    - The National Institute for Health and Care Excellence's End of Life

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

Care for Adults: Service Delivery [B] Evidence Review; Timing of referral to palliative care services NICE guideline NG142 October 2019 (NICE NG142).

I enclose relevant sections of the guidance considered at Appendix four to this report.

14. 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.

15. I shared a draft copy of this report with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations. The complainant and the Trust submitted comments in response. I considered all comments I received before finalising this report.

THE INVESTIGATION

Issue 1: Whether the Trust provided appropriate care and treatment to the patient in July to September 2019, and in September 2020.

Detail of Complaint

Patient's red flag referral

16. The complainant was dissatisfied that the Maxillofacial team downgraded the patient's referral to routine on 18 July 2019.

17. The complainant said the ENT Consultant failed to offer the patient treatment, and told the patient his jaw pain was *'only an infection'*. The complainant said the ENT Consultant did not discuss the need for a biopsy with the patient.

Evidence Considered

Legislation/Policies/Guidance

18. I considered the following policies/guidance:
    - GMC Guidance; and
    - Red Flag Referral Criteria.

Trust's response to investigation enquiries

19. The Trust stated the patient was *'initially referred by his GP to the Maxillofacial Team on 18 July 2019 as a Red Flag referral'*. It stated, *'whilst this referral was downgraded to routine, this was in line with the Regional Red Flag referral criteria'*.

20. The Trust stated the patient's GP referred the patient as a Red Flag referral to the ENT Department on 11 August 2019. It said *'this referral was triaged on the Electronic Care Record (ECR) in a timely fashion on 12 August 2019'*.

21. The Trust stated the patient's ENT consultation (23 August 2019) was within *'14 days of the Red Flag referral received on 11 August 2019'*. This was in accordance with the Northern Ireland Referral Guidance for Suspected Cancer – Red Flag Criteria.

22. The Trust stated the consultation records on 23 August 2019 document the ENT Consultant found a mass upon clinical examination of the patient and discussed the patient's scans with a Radiologist. The Radiologist recommended a CT scan of the patient's neck in contrast[13] as a Red Flag referral. It cannot account for the conversation between the ENT Consultant and the patient on 23 August 2019, as there is no record of the conversation within the patient's medical notes. However, it *'confirmed that there is no reference to a diagnosis of infection in the ECR'*.

Relevant Trust records

23. The Trust provided this Office with the patient's medical records for the period 1 July 2019 to 31 August 2019. These include records of the patient's consultation with the ENT Consultant on 23 August 2019. I enclose a summary of the records provided at Appendix five to this report.

Relevant Independent Professional Advice

M IPA

24. The M IPA advised the GP's referral stated the patient's main symptom was temporomandibular joint[14] (TMJ) pain. The *'only indicator was previous oesophageal cancer for which he was still under active review'*. The Oral and Maxillofacial Surgery (OMFS) Consultant considered these factors along with the patient's x-ray results in his decision *'that the referral did not meet the red flag pathway guidelines…On that basis, it was triaged as a TMJ referral which was not red flag'*.

25. The M IPA advised the OMFS Consultant downgraded the patient's referral to routine/non-urgent. However, based on the patient's clinical history and red flag guidance criteria, '*the referral clearly meets the red flag referral criteria'*. This is because one of the red flag symptoms criteria was *'unilateral unexplained pain in the head and neck area for more than 4 weeks, associated with earache but a normal otoscopy (examination of the canal /drum)'*. The OMFS Consultant's

[13] A contrast dye is used to show blood flow in the carotid arteries and other vessels in the head and neck.
[14] The hinge joint between the sliding hinge, connecting the jawbone to the skull.

decision to downgrade the patient's referral *'was therefore not compliant with the red flag symptoms/criteria'*.

26. The M IPA advised had the OMFS Consultant triaged the patient as red flag, the patient *'would have been seen earlier and all the investigations he has had would have occurred a few weeks earlier'.* If the Trust had detected *'the multi metastatic deposits'* earlier*,* it could have *'improved the patient's experience and quality of life'*. For example, a *'less symptomatic pericardial effusion which could have been detected and treated earlier'*. However, these delays *'would not have altered his prognosis due to the widespread pattern of recurrence of the oesophageal cancer'*. However, it *'would have had a detrimental impact on his experience during his care in hospital and quality of life'*.

ENT IPA

27. The ENT IPA advised the ENT Consultant *'took an appropriate history and conducted a relevant examination during the consultation [23 August 2019]'*. The ENT Consultant noted the patient's past medical history of oesophageal carcinoma[15].

28. The ENT IPA advised the ENT Consultant took advice from the Radiologist and *'the CT was a reasonable thing to do first'*. This is because *'it is possible to get a CT scan done more quickly than an MRI as they are much quicker to do and can give as much information'*.

29. The ENT IPA advised the ENT Consultant could have requested an ultrasound-guided biopsy at the time of the clinic visit. However, if the ENT Consultant requested the biopsy on 23 August 2019, it would *'only'* have brought the diagnosis forward by *'a few days'*. Given the patient had *'metastatic disease[16] at this point'* it would have made *'no difference to the treatment altered or the prognosis…in the end this was not done'*. It is *'not clear whether the patient was informed of the request'*. There is no guidance in this area, however '*usually you would inform the patient so they would not be surprised if a biopsy was done'*.

[15] Esophageal caner is a cancer arising form the esophagus (the food pipe).
[16] In metastasis, cancer cells break away from where they first formed and form new tumors in other parts of the body.

Analysis and Findings

Maxillofacial team

30. The Red Flag Referral Criteria states a red flag is a patient with *'unilateral unexplained pain in the head and neck area for more than 4 weeks, associated with otalgia (earache) but a normal otoscopy*[17]*'*. I note the GP's referral on 18 July 2019 to the Maxillofacial team states *'Pain left jaw x 2 months, noticed it swollen. Sore to open jaw and eat. Pain radiates to eye and ear at times'*. The referral also documents the patient's background of oesophageal cancer.

31. The M IPA advised *'the referral clearly meets the red flag referral criteria'* and the OMFS Consultant's downgrading of the referral *'was therefore not compliant with the red flag symptoms guidance/criteria'*. I accept this advice. I note an appointment made under the Red Flag Referral Criteria should take place within two weeks (before 1 August 2019 in the patient's case). However, the patient did not attend an appointment (with ENT) until 23 August 2019. I consider the OMFS Consultant's decision to downgrade the patient's referral to routine/non-urgent a failure in the patient's care and treatment. I uphold this element of the complaint.

32. I note the M IPA's advice that *'these delays would not have altered his [the patient's] prognosis due to the widespread pattern of the oesophageal cancer'*. However, the M IPA also advised this failure had a *'detrimental impact'* on the complainant's quality of life and experience of care. I consider the identified failure in the patient's care and treatment caused the patient a loss of opportunity to receive earlier investigations. I do not doubt it also caused the patient to sustain the injustice of discomfort, and both him and the complainant stress and uncertainty due to the time they waited for the appointment.

ENT

33. The complainant said the ENT Consultant failed to offer the patient treatment. I refer to the GMC guidance which requires doctors to *'adequately assess the patient's conditions, taking account of their history'*. I note this guidance also

[17] Medical device used to look into ears.

requires doctors to *'promptly provide or arrange suitable advice, investigations or treatment where necessary'*.

34. The medical records document the patient attended a consultation with the ENT Consultant on 23 August 2019. I note the records for this consultation document the patient's symptoms, history of oesophageal cancer, and the appearance of a mass in the masseteric muscle[18] on the left hand side. Therefore, I accept the ENT IPA's advice *'the ENT Consultant took an appropriate history and conducted a relevant examination during the consultation'*.

35. The medical records document the ENT Consultant sought advice from a Radiologist on 23 August 2019 on how to proceed. The records document the Radiologist recommended the ENT Consultant refer the patient for a CT scan of the neck as a red flag. I accept the ENT IPA's advice *'the CT was a reasonable thing to do first'*.

36. I note the ENT IPA advised the ENT Consultant could have requested an ultrasound-guided biopsy on 23 August 2019, which may have brought the diagnosis forward by a few days. However, I accept the ENT IPA's advice this *'would have had no positive effect on the patient's treatment options or prognosis'* as the patient already *'had metastatic disease at this point'.*

37. The complainant said the ENT Consultant did not discuss the need for a biopsy with the patient. The ENT IPA advised the ENT Consultant requested a biopsy following the CT scan. I note the ENT IPA advised it is not clear whether the ENT Consultant informed the patient of the request. I also note the medical records do not record that the ENT Consultant informed the patient of the biopsy referral.

38. I note the ENT IPA advised there is no guidance in this area. However, I refer to Standard 32 of the GMC guidance which requires doctors to *'give patients the information they want or need to know in a way they can understand'*. I also refer to Standard 49, which requires doctors to work in partnership with

[18] Muscle located in the jaw used for chewing.

patients, sharing information they need to make decisions about their care. This includes options for treatment.

39. I accept the ENT Consultant's advice that an ENT Consultant would usually *'inform the patient so they would not be surprised if a biopsy was done'*. I consider that in this instance, by not communicating this to the patient, the ENT Consultant did not act in accordance with Standards 32 and 49 of the GMC Guidance. I am satisfied this lack of communication represents a failure in the patient's care and treatment. While I do not consider this failure impacted the patient's clinical pathway, I consider it caused both the complainant and the patient to sustain the injustice of uncertainty. This is because the Trust did not provide them with full information about the patient's planned treatment. I partially uphold this element of the complaint.

40. The complainant said the ENT Consultant told the patient his jaw pain was *'only an infection'*. I note the records do not document the patient had an infection on 23 August 2019. I also note the medical records do not document a record of this conversation. In the absence of any additional documentary evidence, I am unable to conclude on this element of the complaint.

Detail of Complaint

Early Warning Score 6 September to 11 September 2019

41. The complainant said the patient's National Early Warning Score (NEWS) during the period 6 September to 11 September 2019 *'did not reflect the acuity of his condition'*. The complainant said the patient was unable to take care of himself and had difficulty breathing.

42. In response to the draft Investigation Report the complainant said the nursing staff did not complete a pain assessment of the patient upon his admission to hospital on 6 September 2019.

Evidence Considered

Legislation/Policies/Guidance

43. I considered the following policies/guidance:
    - RCP NEWS guidance; and

- The NMC Code.

The Trust's response to investigation enquiries

44. The Trust did not provide a response to this investigation enquiry.

Relevant Trust records

45. The Trust's medical records contain the patient's NEWS charts for the timeframe 6 September 2019 to 11 September 2019. These records are summarised within the N IPA's advice.

Relevant Independent Professional Advice

46. The N IPA advised the nursing staff assessed the patient's pain using NEWS from admission until discharge which was in line with national nursing standards.

47. The N IPA advised on 6 September 2019, *'the patient was scoring between 2 and 3. This was due to a respiratory rate of 22-23 (with normal being up to 20) and an oxygen saturation of 94% (with normal being above 95%)'*. For these scores the RCP guidance *'advocates a minimum of 4-6 hourly repeat and local clinical response is for a registered nurse to assess'*. The nursing documentation documents *'a registered nurse reviewed the patient in line with local escalation guidance'*.

48. The N IPA advised on 7 September 2019 the patient's NEWS was between one and three, *'however nurses repeated his NEWS in the early hours because the patient complained of shortness of breath'*. The patient's NEWS of three was due to *'raised respirations and low oxygen saturations that had been unchanged all day'*. The nursing staff reviewed the patient's NEWS between 4-6 hourly in line with RCP guidance.

49. The N IPA advised on 8 September 2019 the patient's NEWS rose to five at 06.15 and the patient reported feeling short of breath on exertion. Nursing staff escalated the patient's condition to a doctor. A *'pericardial effusion causes*

shortness of breath and palpitations, which would explain the patient's NEWS from admission'.

50. The N IPA advised on 9 September 2019 the patient's NEWS rose to five at 06.15 and returned to three at 07.00. The patient's NEWS remained between three and four throughout the rest of that day. The patient was comfortable during the evening *'which is reflected within stable respiration rates and pulse documented on NEWS charts'*.

51. The N IPA advised on 10 September 2019, the patient's NEWS spiked to five, which was the same time the patient complained of *'unbearable pain'* at the *'drain site'.* The Nursing staff escalated the patient's NEWS to medical staff and the nursing staff planned to repeat NEWS as two-hourly (rather than RCP guidance of NEWS frequency of hourly with a score of five). However I note the nursing records documented *'the patient was checked frequently'*. The patient slept until 06.20 *'and given that he had been in unbearable pain, it is reasonable to delay NEWS'*. The *'decision however should be documented, and it was not'*. At 10.50, nursing staff documented the patient as being *'more comfortable'*. As *'NEWS settled to between 3-4, there was no impact of this on the patient'*.

52. The N IPA advised on 11 September 2019, the patient's NEWS was between two and three. *'This is reflected within the nursing documentation, noting that he was 'peaceful' and 'slept fairly well overnight''*. The *'frequency of NEWS was in line with RCP guidance and escalation was not needed'*.

53. Overall, the N IPA advised the NEWS for the patient remained steady from admission but was not 'normal'. *'NEWS reflected that the patient was unwell secondary to a painful facial/jaw swelling and pericardial effusion. There was no acute deterioration over this timeframe'.*

Analysis and Findings

54. The NMC requires nursing staff to *'observe and assess the need for intervention for people…identify, assess and respond appropriately to uncontrolled symptoms of distress including pain'*. I note the records document

the patient's NEWS charts contains an assessment of the patient's pain score. The nursing records document this was assessed throughout his admission. I accept the N IPA advice *'the patient's pain was assessed from admission through to discharge and therefore nursing actions were in line with national nursing standards'*.

55. The RCP NEWS guidance requires nursing staff to review patients with a total score of one to four a minimum of four to six hourly. The guidance states if a patient scores three in a single parameter, or a total of five or more, then staff should review the patient hourly as a minimum.

56. I accept the N IPA's advice the nursing staff reviewed the patient and his NEWS *'at a frequency advocated within RCP guidance'* between 6 and 11 September 2019, with the exception of the morning of 10 September 2019.

57. For this date, the nursing records document the patient's NEWS was five at 04:00. It also documents that the patient complained he was in *'unbearable pain'*. I note the RCP NEWS guidance requires nursing staff to review a patient with a NEWS of five, hourly as a minimum. However, the nursing records document the nursing staff did not take the patient's NEWS again until 06.20 when he awoke from sleeping.

58. I acknowledge there was a delay in NEWS recording, and the nursing staff deviated from the RCP guidance. However the N IPA advised this deviation was *'reasonable'* as the patient was asleep and *'the nursing documentation shows that the patient was checked frequently'*. Having reviewed the records I note the nursing staff checked the patient at 04.00, 04.40, 06.20 and 07.00. I am satisfied nursing staff frequently monitored the patient during this time. I do not consider the delay in the patient's NEWS a failure in his care and treatment. I am also satisfied the nursing staff assessed the patient's pain throughout his admission. I do not uphold this element of the complaint.

59. However, I note the medical records do not document the nursing staff's decision to delay the patient's NEWS on the morning of 10 September 2019. I accept the N IPA's advice, *'the decision however should be documented, and it*

was not'. I refer to Standard 10 of the NMC code which requires nursing staff to maintain full and accurate records. I consider without such records it is impossible for nursing staff to defend their actions and decisions when challenged. I consider the absence of this record constitutes a service failure. I would ask the Trust to remind its nursing staff of the importance of maintaining records of their decisions.

Detail of Complaint

Delay in fluid being drained from the patient's heart

60. The complainant was dissatisfied the patient waited from Saturday 7 September 2019 to Monday 9 September 2019 to receive a pericardial effusion. The complainant believed the Trust had no sense of urgency to perform the procedure.

Evidence Considered

Legislation/Policies/Guidance

61. I considered the following guidance:
    - GMC Guidance.

Trust's response to investigation enquiries

62. The Trust stated the patient was transferred from South West Area Hospital to Altnagelvin Hospital on 6 September 2019 following discovery of a large amount of fluid surrounding his heart. Upon his arrival to Altnagelvin, his blood pressure and heart rate were normal, and his NEWS was two.

63. The Trust stated the Cardiologist reviewed the patient on 7 September 2019 and in her opinion, there was *'no requirement for urgent removal of the fluid (pericardiocentesis)'*. The Cardiologist documented discussions with the on call Interventional Cardiologist who agreed at this stage the patient did not require pericardiocentesis.

64. The Trust stated the patient's condition began to worsen on the morning of 9 September 2019, and the Cardiologist brought the patient in for pericardiocentesis at approximately 12.05.

Interviews

65. On 15 December 2022 the Cardiologist attended an interview with this Office to provide her account of the care and treatment she provided to the patient. I enclose a transcript of the Investigating Officer's interview with the Consultant Cardiologist at Appendix six to this report.

Relevant Trust records

66. The Trust provided this Office with the patient's medical records. I enclose a summary of these records at Appendix five to this report.

Relevant Independent Professional Advice

67. The C IPA advised the Trust usually provides a catheterisation laboratory[19] for emergency/urgent work at weekends. This is because, the laboratory may not be fully staffed; the Trust would normally call the staff required in from home when an emergency arises. She advised as the Cardiologist did not consider *'the pericardial tap to be urgent, it was appropriate to plan the tap for the next available routine slot in the lab'*.

68. The C IPA advised the patient's observations were relatively normal until the oxygen requirement started to increase. The *'patient actually presented with cardiac tamponade[20], based on the appearance of the right atrium and right ventricle on the echo performed in the referring hospital'*. In addition to the patient's raised respiratory rate, he complained of breathlessness; *'I would have considered it appropriate to undertake an urgent pericardiocentesis, as soon as it could be arranged'*. As the Trust transferred the patient to Altnagelvin for this procedure, the C IPA would have expected the Trust to plan the pericardiocentesis for 7 September 2019.

69. The C IPA advised the medical records document the patient began to deteriorate on 8 September 2019 which *'should have prompted pericardiocentesis that day'*.

[19]Catheterisation laboratory is an examination room in a hospital or clinic with diagnostic imaging equipment used to visualize the arteries and chambers of the heart.
[20] Compression of the heart due to pericardial effusion.

70. The C IPA advised the Cardiologist originally planned the pericardiocentesis as a diagnostic procedure. However, as the patient's condition suddenly deteriorated on 9 September 2019, it became an '*urgent therapeutic procedure'*. A diagnostic pericardiocentesis is '*not an emergency'*. A therapeutic pericardiocentesis is '*usually urgent'* and '*may be an emergency'*. The Trust should have *'recognised sooner that the pericardial effusion required urgent treatment, despite the initial observations which suggested no haemodynamic instability, and gave a false sense of reassurance'.*

71. The C IPA advised *'if the pericardiocentesis had been performed earlier it is unlikely that the patient would have become so unwell so quickly'*. However, *'the delay had…no impact on the long term outlook'*.

72. In relation to the Trust's decision to bring the procedure forward to 12.05 the C IPA provided advice on how catheter lab provides urgent and emergency treatment work. In her advice she advised *'any given time for a procedure scheduled for an urgent lab is approximate and a 'best guess''*. She advised *'three was no need for explanations regarding the timing of the procedure'*.

73. I also note in response to the draft Investigation Report the complainant raised concerns that the interventional cardiologist that preformed the pericardial effusion was not aware of the patient's medical history or current condition. The C IPA advised the pericardial drain was undertaken as an emergency and lifesaving. *'The delay of even a few minutes could affected the outcome'*. She advised there was no time for the interventional cardiologist to take a detailed history or review the notes *'indeed, it would have been inappropriate to do so'*.

Analysis and Findings

74. The clinical records document the Trust transferred the patient from South West Area Hospital to Altnagelvin Hospital on 6 September 2019 following the discovery of a large amount of fluid surrounding his heart. The records document the Cardiologist saw the patient at 07.30 on 7 September 2019 and planned to list the patient for a pericardial drain/tap on 9 September 2019 for diagnosis. I am disappointed to note that the records of this consultation are not

legible. As a result, I am unable to determine what the Cardiologist discussed with the patient or decipher the records to determine what decisions the Cardiologist made. I consider this further below.

75. The C IPA advised the Trust usually provides a catheterisation laboratory for emergency/urgent work at the weekends. I note the Trust transferred to the patient to Altnagelvin hospital on a Friday, and the Cardiologist saw him on Saturday morning, 7 September. I accept the C IPA's advice *'it was appropriate to plan the tap for the next available routine slot in the lab'*. The Cardiologist arranged this for Monday 9 September 2019.

76. However, the C IPA advised *'the patient actually presented with cardiac tamponade, based on the appearance of the right atrium and right ventricle on the echo preformed in the referring hospital'*. In addition, the C IPA advised the records document a rise in the patient's respiratory rate and the patient complained of breathlessness. In consideration of the patient's prognosis at that time, I accept the C IPA's advice *'I would have considered it appropriate to undertake an urgent pericardiocentesis, as soon as it could be arranged after the echo had been performed. As the patient had to be transferred from one hospital to another for this, I would have expected the pericardiocentesis to have been planned for 7 September 2019'*.

77. On 8 September 2019 the clinical records document a junior doctor attended to the patient as his NEWS increased, and he experienced breathlessness. I note the medical records also document the Cardiologist attended to the patient during her ward round on the same day. I accept the C IPA's advice the patient's increase of NEWS *'should have prompted pericardiocentesis that day'*. The Cardiologist's records of this consultation are not legible, and I am unable to consider the Cardiologist's rationale for not arranging a pericardial drain for 8 September 2019, given the patient's deterioration. I consider this further below.

78. On 9 September 2019, the records document a junior doctor reviewed the patient due to his increasing NEWS and arranged for the patient's pericardial drain. The records also document upon the patient's arrival to the

catheterisation laboratory on the same day, the patient collapsed, and the pericardial drain became an urgent therapeutic procedure.

79. I accept the C IPA's advice that the Cardiologist should have recognised sooner that the patient required urgent treatment for a pericardial effusion. I consider this a failure in the patient's care and treatment. I uphold this element of the complaint.

80. I note in response to the draft Investigation Report the complainant raised concerns that she was dissatisfied that the Trust brought the patient's pericardial procedure forward to 12.05 and neither herself nor the patient were provided with an explanation for this. I note the clinical records do not document a reason for this change of time in procedure. I also note the records do not document that a clinician advised the patient and the complainant of the reasoning for the change of time for the procedure.

81. In her advice (Appendix Three) the C IPA provides an explanation of how Catheterisation Laboratories provide emergency treatment. She advised that any given time for an urgent procedure within a catheterisation laboratory is approximate, and it would not have been appropriate to leave a staffed lab vacant. She advised for this reason *'there was no need for explanations regarding the timing of the procedure'*. I accept this advice however I consider the absence of an explanation regarding the timing of the procedure may have been confusing and distressing for the patient and the complainant. Whilst there is no requirement for clinicians to provide an explanation when this happens, I would ask the Trust to be mindful of the patient and their family when this occurs.

82. I also note in response to the draft Investigation Report the complainant raised concerns that the interventional cardiologist who preformed the pericardial effusion was not aware of the patient's medical history or current condition. The C IPA advised the pericardial drain was undertaken as an emergency and *'the delay of even a few minutes could affected the outcome'*. She advised there was no time for the interventional cardiologist to take a detailed history or

review the notes *'indeed, it would have been inappropriate to do so'*. I accept this advice.

83. I am concerned that the illegibility of the records for 7 and 8 September 2019 prevents me from considering the Cardiologist's rationale for the decision to plan the patient's pericardiocentesis for 9 September 2019. The C IPA also raised concerns about the quality of the handwritten cardiology records. Standard 19 of the GMC Guidance requires clinicians to keep '*clear, accurate and legible records'*. During my investigation I wrote to the Trust on two occasions to request a transcript of these records. I am surprised and disappointed that at the time of writing this report, the Trust is yet to provide this. I consider the illegibility of the Cardiologist's records for 7 and 8 September 2019 a failure in the patient's care and treatment. This is because other clinicians rely on patients' records when providing care and treatment. These records also make it very difficult for my Office to appropriately investigate the complainant's concerns when they avail of their right to bring their complaint to my Office. I uphold this element of the complaint.

84. I consider this failure in the patient's care and treatment caused the patient to sustain the injustice of a loss of opportunity to receive the pericardial effusion at an earlier point. The C IPA advised had the Cardiologist done so, *'it is unlikely that the patient would have become so unwell so quickly'*. In response to the draft Investigation Report the complainant considers the delay in the procedure caused the patient to suffer *'unnecessary'*. Therefore, I am satisfied this failure also caused the patient and the complainant great concern given how suddenly he became unwell on 9 September 2019. I note the C IPA advised *'as the effusion was tapped so quickly after the patient's collapse* [on 9 September]*, the delay had no impact, and certainly no impact on the long term outlook'*. I hope this advice goes some way to reassure the complainant.

Detail of Complaint

Pain management post heart surgery

85. The complainant said the Trust left the patient in severe pain following the fluid drain (9 September 2019). She explained the nurse advised that medical staff said they could not prescribe any further pain relief as it would override

medication administered earlier that day. The complainant said the nurse did not contact a senior doctor to request a change in the patient's medication.

Evidence Considered

Legislation/Policies/Guidance

86. I considered the following guidance:
    - GMC Guidance.

Trust's response to investigation enquiries

87. The Trust acknowledged the complainant was upset that the patient was in pain during the pericardiocentesis[21] procedure. It stated the procedure *'can be painful for a variety of reasons'* and *'care was taken to address his pain'*. The patient *'received 6mls of 2% lidocaine as a local anaesthetic at the pericardiocentesis site'*. Medical staff provided the patient with 2.5mg of intravenous diamorphine during the procedure which is a potent opioid pain relieving medication.

88. The Trust stated *'nursing documentation in the Coronary Care Unit at 1pm, immediately after return form the Catheterisation Lab notes that [the patient] had no pain at the drain site'*.

Interviews

89. I enclose a transcript of the Investigating Officer's interview with the Consultant Cardiologist at Appendix six to this report.

Relevant Trust records

90. The medical records document that following his procedure, the patient returned to the Ward at 13.00 on 9 September 2019. I enclose a summary of the patient's records at Appendix five to this report.

[21] Pericardiocentesis is an invasive procedure that uses a needle and catheter to obtain fluid from the membrane enclosing the heart.

Relevant Independent Professional Advice

Nurse IPA

91. The N IPA advised *'the nurse's response to the patient on the 9th was appropriate and in line with national guidance and nursing standards'*.

92. The N IPA advised nursing records document the patient received pain relieving medication at 03.15 and 03.50. At 04.00, records document the patient was in *'unbearable'* pain, and *'this was escalated'*. Medical records document the Registrar told the nurse to *'wait for the given painkillers'*. Records further document the patient's pain was easing and at 04.40 he was sleeping.

93. The N IPA advised medical records document upon waking up at 06.20, the patient complained of pain and nursing staff administered analgesia and informed the doctor. The nursing records document, *'the patient was settled with no reports of uncontrolled pain after this date'*.

Cardiologist

94. The C IPA advised medical records document the patient was comfortable and pain free *'for most of the time after the drain was inserted'*. The records document *'an appropriate level of background analgesia, including paracetamol and opiates was given. When he complained of pain he was given additional analgesia'*.

95. The C IPA advised the Cardiologist could have increased the patient's dosage of opiates. However, the patient's GP referral letter (5 September 2019) stated the patient declined tramadol because it made the patient drowsy, so he *'may not have tolerated doses of opiates'*.

96. The C IPA advised controlled drugs were initially not available; drugs that were available were out of date. Another Ward had supplies. However, staff could not move medication without a nurse manager's consent. The nurse manager stated it was not their responsibility to provide this consent. There was no on call pharmacist available. It is *'unacceptable that drugs cannot be accessed when required. It is unacceptable that the chain of responsibility appeared to be*

unclear; it was unacceptable that an on call pharmacist was not available'. However, this had *'no impact to the patient, who was prescribed other drugs'*.

97. In response to the draft Investigation Report the complainant queried why the Registrar told the nurse to wait for the given pain killers to take effect on 10 September. The C IPA advised *'my interpretation of the truncated comments of the registrar…is that the patient already was taking recommended doses of two analgesics, oxycodone and paracetamol, and in addition in the hour before the comment was recorded had been given additional oxycodone, and codeine'*. She advised as the additional oral doses given would not be expected to be effective immediately *'it was therefore appropriate that no further analgesia was given at that time'*.

98. The complainant raised concerns that the Registrar did not review the patient at 04.00 on 10 September. The C IPA advised the records do not document that the Registrar reviewed the patient at that time, however *'it is unlikely that a further clinical review would have found anything of note, and indeed the patient went to sleep shortly after this'*. She also raised concerns that the Registrar did not provide the patient with IV pain relief at this time. The C IPA advised *'further intravenous analgesia eg with opiates would have been inappropriate, af [sic] the patient had received appropriate additional doses of oral opioid analgesics in the hour before this. Further intravenous opioids could have led to overdose'*.

Analysis and Findings

99. Medical records document the patient returned to the Ward following his procedure at approximately 13.00 on 9 September 2019.

100. The records further document that overnight (at 03.15 on 10 September 2019), the patient informed nursing staff he felt pain at the drain site. At 04.00, the records document the patient was in '*unbearable pain'* before it eased, and he was sleeping at 04.40. At 06.20, records document the patient was in pain before settling and sleeping again at 07.00. At 10.50, records document the

patient as comfortable, and at 21.20 the records document the patient said he did not feel any pain at the drain site.

Nursing

101. The RCP NEWS guidance states *'the symptom of pain should be recorded and responded to by the clinical team'*. The NMC Code requires nursing staff to *'take appropriate action to reduce or minimise pain or discomfort'*. The NMC Code also requires nursing staff to *'make a timely referral to another practitioner when any action, care or treatment is required'*.

102. Records document the patient was in pain at 14.40 on 9 September and nursing staff administered analgesia. The records document a doctor attended the patient due to left parotid shooting pain and prescribed Gabapentin[22]. The N IPA advised *'the nurse's response to the patient on 9th was appropriate and in line with national guidance and nursing standards'*. I accept this advice.

103. Records document nursing staff administered the patient pain relief at 03.15 and 03.50. At 04.00, when the patient's pain became *'unbearable'*, nursing records document a nurse escalated the patient's pain to the Registrar. The records document the patient was in pain at 06.20 and the nursing staff administered analgesia and informed the Doctor. The N IPA advised *'the records show that nursing staff responded promptly to the patients' complaints of pain and they escalated this to medical staff in a timely manner'*. I accept this advice and consider the nursing staff's actions meet the NMC Code requirements.

Cardiology

104. The records document medication the patient received on 9 and 10 September 2019. I note the medication received included: oxycodone[23], gabapentin[24], codeine[25] and IV paracetamol. The C IPA advised the records evidence the patient received all medications as prescribed.

[22] Used to Treat neuropathic pain.
[23] Treats sever pain in adults.
[24] Can treat neuropathic pain.
[25] Pain relief.

105. I accept the C IPA's advice the patient received *'an appropriate level of background analgesia...when he complained of pain he was given appropriate additional analgesia.'* She also advised the Cardiologist appropriately managed the patient's pain post-surgery.

106. The C IPA advised the Cardiologist could have increased the opiates dosage for the patient. However, I refer to the Investigating Officer's interview with the Cardiologist who stated that, at times, the patient refused medication as it made him drowsy. I note the records also document the patient refused tramadol due to the effect of drowsiness.

107. The nursing records document the patient complained of pain at 04.00 on 10 September and the nursing staff escalated this to the Registrar who advised the nurse to wait until the given painkillers had taken effect. In response to the draft Investigation Report the complainant queried why the Registrar made the decision to wait until the painkillers had taken effect. The C IPA advised the patient was already receiving recommended doses of two analgesics, oxycodone, and paracetamol. In addition the clinical records document in the hour before the Registrar made this comment, the patient received additional oxycodone and codeine. The C IPA advised *'it was therefore appropriate that no further analgesia was given at that time, as the additional oral doses given would not be expected to be effective immediately'*.

108. In her response to the draft Investigation Report the complainant raised concerns that the Registrar did not review the patient at 04.00 on 10 September nor did they offer the patient with IV pain relief. I note the clinical records do not document the Registrar reviewing the patient at this time. However it does document that a Consultant reviewed the patient within the previous hours and that the patient had received a chest X-Ray which had excluded any serious complications relating to the pericardial drain. The C IPA advised *'the observations were stable. It is unlikely that a further clinical review would have found anything of note, and indeed the patient went to sleep shortly after this'*. I accept this advice. In relation to the IV pain relief I note the clinical records document the patient was receiving IV paracetamol on a regular basis

on 9 and 10 September. The C IPA advised *'further intravenous analgesia…would have been inappropriate, af [sic] the patient had received appropriate additional doses of oral opioid analgesics in the hour before this'*. I am satisfied the Registrar provided the patient with the appropriate care and treatment. This is because the C IPA advised *'further intravenous opioids could have led to overdose'*.

109. The records document at 04.40 the patient was sleeping. At 06.20 he awoke and complained of pain, and the nursing staff provided him with IV paracetamol. The records document at 07.00 the patient was sleeping again. I consider the patient's pain eased to the point where he could sleep. I therefore do not consider it a failing that the patient did not receive increased dosage of opiates.

Overall

110. I considered all available evidence. I accept the N IPA's advice that *'the records show that nursing staff responded promptly to the patient's complaints of pain and they escalated this to medical staff in a timely manner'*. I am also satisfied the Cardiologist prescribed appropriate medication to alleviate the patient's pain. I do not uphold this element of the complaint.

111. I am concerned that staff were unable to access controlled drugs when required. The medical records attribute this to a number of causes as outlined above. The C IPA advised this did not impact the treatment provided to the patient. However, I would ask the Trust to reflect on its process for staff gaining access to controlled drugs during the night, and that it clarifies its chain of responsibility in this respect.

Detail of Complaint

Facial biopsy

112. The complainant said the patient's facial biopsy was a very painful procedure. She said the patient received one core biopsy, as during the second biopsy, the Radiologist did not consider it appropriate to continue. This was due to a complication during the second procedure. The complainant said the Radiologist did not complete the second procedure on a later date to obtain a

second core biopsy, and did not inform the patient he was only able to obtain one core biopsy during this procedure.

113. The complainant believed the Radiologist did not administer to the patient a local anaesthetic with a nerve block[26] during his biopsy procedure. She considered a nerve block would have allowed the Radiologist to proceed with the second biopsy procedure. The complainant was also dissatisfied the Radiologist did not review the patient following his biopsy.

114. In response to the draft Investigation Report the complainant said the ENT Consultant did not review the patient following his biopsy. She said the records document on 10 September that the Radiologist recommended the patient receive an ENT review following his procedure.

Evidence Considered

Trust's response to investigation enquiries

115. The Trust stated it took two biopsies from the patient: a fine needle aspirate for cytology[27], and a core biopsy for histopathology[28]. The patient tolerated the first pass of the core biopsy, however on attempt at a second pass, the patient developed facial pain and a facial nerve palsy[29]. It did not complete the second biopsy pass. The Radiologist *'did not think it was safe, or appropriate to perform any more biopsies in this case as the patient had developed a complication'*. It considered, *'the core biopsy was sufficient for diagnosis of recurrence and exclusion of new primary cancer'*.

116. The Trust stated the patient would have received *'the local anaesthetic as the first part of the procedure before the fine needle aspiration (FNA) cytology specimens were obtained'*. The FNAs were *'tolerated well'* and the Radiologist proceeded to obtain the core biopsy. The patient developed facial pain on the second core biopsy attempt which was likely due to *'the needle touching the facial nerve in the biopsy tract'*. This *'does not mean the local anaesthetic*

[26] Nerve block is any deliberate interruption of signals traveling along a nerve often for the purpose of pain relief.
[27] Presence of cells which may be used for diagnosis or for screening.
[28] Refers to the microscopic examination of tissue in order to study the manifestations of disease.
[29] Damage or disease of the facial nerve.

administered into the skin and superficial soft tissues did not work'. When the patient developed facial nerve pain, the Radiologist withdrew the needle.

117. In response to the draft Investigation Report the Trust stated the Radiologist contacted the ENT Registrar to arrange a follow up of the patient following his biopsy. It stated the ENT Registrar reviewed the patient on the evening of 10 September 2019 and contacted the Radiologist to advise the patient's symptoms had resolved. It further stated the ENT Registrar informed the Coronary Care Team of their review.

Relevant Trust records

118. The Trust provided this Office with the patient's clinical records for the period July 2019 to September 2019. The clinical records document the Trust referred the patient for an ultrasound-guided biopsy on 10 September 2019. The clinical records also document the Radiologist performed two FNA biopsies and one core biopsy. The Radiologist attempted to obtain a second core biopsy but terminated the procedure due to a complication.

Relevant Independent Professional Advice

R IPA

119. The R IPA advised a FNA is a type of biopsy that uses a very small needle to try and aspirate individual cells from suspect tumour tissue. It differs from a core biopsy which uses a larger needle which has a special mechanism to core out a cylinder of tissue from the tumour.

120. The R IPA advised *'the yield of FNA is very low'* and would require at least two to three passes in order to gather enough cells for analysis. Most Radiologists would undertake two or more core biopsy passes to ensure the lab has enough tissue. The medical records document the Radiologist undertook two passes for FNA cytology. The R IPA advised *'only an FNA was requested. However, as the yield from this appeared inadequate'*, the Radiologist attempted to take a core biopsy as well *'in order to optimise the result from the procedure'*. The records document the Radiologist undertook a third sample as a core biopsy for histology.

121. The R IPA advised the Radiologist abandoned the fourth sample (second core biopsy) because the patient experienced significant nerve irritation. *'If the first core looked good enough for diagnosis, this was appropriate'*.

122. The R IPA advised *'the branches of the facial nerve spread out like rays of the sun from the parotid gland to supply many muscles of the face'*. Nerves cannot be identified and therefore cannot be entirely avoided. *'As soon as one of these was irritated by the biopsy needle, the procedure was concluded. This cannot be faulted, especially, as the operator managed to yield enough tissue for a diagnosis'*.

123. The R IPA advised *'the decision to abandon the procedure was done appropriately and the samples were sufficient to confirm the suspected diagnosis of disseminated oesophageal cancer'*.

124. The clinical records do not document the Radiologist informed the patient that he had only taken one core biopsy. However the R IPA advised *'it is safe to assume that the radiologist discussed the termination of the procedure, when the patient could not tolerate the second attempt'*. He advised this is because the Radiologist would have had to explain he withdrew the needle without obtaining a second core biopsy. The R IPA advised *'this is explained in great detail in the report from the procedure…there was no need for additional entries in the patient's notes'*.

125. The R IPA advised *'suitability and eligibility for inclusion in a clinical trial is only made after the diagnosis has been established'*, and after the MDT established the available treatment options for the respective diagnosis. He advised at the time of the patient's biopsy it was not clear whether the tumour in the patient's cheek was a non-cancerous lump or the recurrence of the previous oesophageal cancer, or a second unrelated cancer. He advised *'getting a second core – which was attempted – was neither feasible nor necessary, as a clinical trial would not have been considered at that stage…a claim that the patient could not be included in a trial because of the lack of a second core can therefore not be made'*.

126. The Trust stated the Radiologist completed the procedure using local anaesthetic. The R IPA advised this *'was entirely correct'*. The *'exact doses of local anaesthetic were not documented, which is in keeping with standard practice…this level of detail is rarely recorded for biopsies'*. Other than local anaesthetic*, 'no drugs are given for these procedures'*.

127. The R IPA advised the clinical records do not document the patient experienced pain or discomfort during the first three biopsies *'indicating that adequate local anaesthesia had been achieved'*. During the fourth biopsy (the second core biopsy), *'a nerve branch seemed to have been directly irritated by the needle and the procedure was terminated appropriately to avoid permanent damage'*.

128. The R IPA advised a nerve block *'is virtually never applied for this type of procedure'*. The use of a nerve block *'would even have been dangerous, as it would have caused paralysis of that side of the face, potentially causing damage to the eye from an inability to close it'*. A nerve block *'in this anatomical area is inappropriate'*.

129. The R IPA advised Radiologists are *'not usually expected and are not usually given the time to review their patients after superficial biopsies'*.

ENT IPA

130. The ENT IPA advised the medical records document the ENT Registrar seen the patient at 17.35 on 10 September 2019. During the review he advised the ENT Register documented the patient had no haematoma[30], and the facial nerve was working appropriately. He advised *'the review was therefore appropriate'*.

Analysis and Findings

Radiology Care

131. The complainant said the patient only received one core biopsy, as during the second core biopsy procedure, the Radiologist did not consider it appropriate to

[30] Collection of blood outside of blood vessels. It can occur from surgery. When a blood vessel is cut or torn, blood and other fluids leak from the damaged vessel and collect in a mass.

continue due to a complication. The complainant said the Trust did not take a second core biopsy on a later date.

132. I note the medical records document the Radiologist successfully performed two FNA biopsies, and one core biopsy on 10 September 2019. The medical records also document the Radiologist attempted to take a second core biopsy but abandoned the procedure as the patient experienced significant nerve irritation. The R IPA explained facial nerves are *'spread out like rays of the sun'* within the face, and I accept the R IPA's advice *'they cannot be identified and thus not entirely avoided'*.

133. The R IPA advised the Radiologist took two FNA biopsies, however *'this technique did not appear to yield adequate samples'*. Therefore the Radiologist changed the procedure to a core biopsy. The R IPA advised most operators take two or more core biopsies to ensure there is enough tissue for diagnosis. However on this occasion, the patient began to experience pain, and the Radiologist terminated the procedure.

134. The R IPA advised the Radiologist took enough tissue during the first core biopsy to make a diagnosis. Therefore, they did not need to perform a second core biopsy procedure at a later date. The R IPA advised this was appropriate. I accept this advice.

135. In response to the draft Investigation Report the complainant said the Radiologist did not inform the patient that he did not take a second core biopsy. I accept the medical records do not document the Radiologist provided the patient with this information during and following the procedure. However the R IPA advised the Radiologist *'would have had to explain, why the needle was withdrawn without getting a second core. This was for pain from nerve irritation, which the patient would have been acutely aware of'*. He also advised *'this is explained in great detail in the report from the procedure… there was no need for additional entries in the patient's notes'*. I accept this advice.

136. The complainant said the patient needed the second biopsy to participate in a clinical trial. The R IPA advised *'suitability and eligibility for inclusion in a clinical*

cancer trial is only made after the diagnosis has been established' and after the MDT established the available treatment options for the respective diagnosis. The R IPA advised the records document the ENT Consultant referred the patient for an FNA procedure, and not a core biopsy. He advised the yield from the FNA appeared inadequate and so the Radiologist attempted to undertake core biopsies as well in order to optimise the result from the procedure. As the clinical records document at the time of the procedure no diagnosis had been established, and no core biopsy was requested, I accept the R IPA's advice *'getting a second core – which was attempted was either feasible nor necessary, as a clinical trial would not have been considered at that stage'*.

137. The complainant raised a further concern that the Radiologist did not provide the patient with adequate local anaesthesia using a nerve block for the biopsy procedures. The complainant said if the Radiologist did so, it would have made the patient comfortable enough to continue with the second core biopsy.

138. The Trust stated the Radiologist completed the procedure using local anaesthetic. The R IPA advised this *'was entirely correct'*. I note the medical records do not document the exact doses of the local anaesthetic the Radiologist used for the procedure. The R IPA advised this *'is in keeping with standard practice'* as *'this level of detail is rarely recorded for biopsies'*.

139. The R IPA advised the medical records do not document the patient experienced pain or discomfort during the first three biopsies. I accept the R IPA's advice that this indicated *'adequate local anaesthesia had been achieved'*.

140. In relation to administration of a nerve block for the core biopsy, I note the R IPA advised this *'is virtually never applied for this type of procedure'*. He further advised that administering a nerve block was *'inappropriate'*. This is because it may cause *'paralysis of that side of the face, potentially causing damage to the eye from an inability to close it'*. I accept this advice and consider the Radiologist's decision not to administer a nerve block in this instance appropriate.

141. The complainant said the Radiologist did not review the patient following the biopsy procedure. The R IPA advised *'Radiologists are not usually expected and are not usually given the time to review their patients after superficial biopsies'*. I accept this advice. I note the medical records document that following the procedure, the patient returned to the Ward and the nursing staff and Consultants monitored the patient.

142. Based on the evidence available to me, I am satisfied the Radiologist provided the patient appropriate care and treatment. I accept the R IPA's advice that *'a sufficient diagnostic result was obtained'*, and the Radiologist did not need to perform the second core biopsy procedure on another date. I accept the patient was aware the Radiologist terminated the second core biopsy procedure, and the biopsy was not required at that time for a clinical trial. I am satisfied the patient received the appropriate dosage of local anaesthetic and it was acceptable that the Radiologist did not review the patient following the procedure. I do not uphold this element of the complaint.

ENT Care

143. In response to the draft Investigation Report the complainant said the ENT Consultant did not review the patient following his biopsy procedure.

144. Following the patient's procedure on 10 September 2019, the records document the Radiologist recommended the patient receive an ENT review. The Trust stated the ENT Registrar reviewed the patient on 10 September 2019 and informed the Radiologist that the patient's symptoms had resolved.

145. I note the medical records document that the patient received a review from the ENT Registrar at 17.35 on 10 September 2019, and the ENT Registrar documented the patient did not have a hematoma and his facial nerve was fully functional. I accept the ENT IPA's advice *'the review was therefore appropriate'*. I do not uphold this element of the complaint.

146. In response to the draft Investigation Report the complainant raised concerns about the quality of the clinical records, particularly the clinical record of 10 September 2019 where the patient's name is incorrect on the clinical notes. I

would ask the Trust to remind its staff of the importance of completing patients' clinical records with the correct personal details.

Detail of Complaint

Results and cancer advice

147. The complainant said the Cardiologist did not refer the patient for Oncology input at the appropriate time. She also said the Cardiologist did not inform the patient nor the family about the discussions of the 11 September 2019 MDM meeting.

148. The complainant also said the Trust's Oncologist did not meet with her and the patient to offer advice on the patient's clinical pathway and treatment. The complainant believed the Trust did not provide the patient with oncology advice because he previously received treatment in Dublin. The complainant also said the Oncologist did not review the patient until 16 September 2019, and believed if the Oncologist reviewed the patient prior this date, he may have prescribed the patient with effective pain relief medication.

Evidence Considered

Legislation/Policies/Guidance

149. I considered the following policies and guidance:
    - GMC Guidance.

Trust's response to investigation enquiries

150. The Trust stated the *'Oncologist was made aware of patient the preceding week as investigations were ongoing by [the Cardiologist] who was also in discussion with his treating team in Dublin'*. The Oncologist reviewed the patient on the evening of 16 September 2019 as the family wanted to explore treatment options in both Northern Ireland and the Republic of Ireland.

151. The Trust stated the Oncologist reviewed the patient's *'MRI scans of Parotid*[31] *and spine pre assessment'* along with the patient's pain in parotid, trismus[32] and spine. The Oncologist *'did not recommend palliative radiotherapy to parotid*

[31] Parotid gland is a major salivary gland present on either side of the mouth.
[32] Commonly known as lockjaw. Contraction of the jaw muscles causing a difficulty in opening the mouth.

or spine as this would delay systemic treatment and would also delay potential entry into clinical trial'.

Relevant Trust records

152. The Trust provided this Office with the medical records for the period June 2019 to September 2019.

153. The medical records document an MDM meeting took place on 11 September 2019 which discussed the patient, and MDM agreed to request an MRI scan of the patient's head and neck to further assess the parotid swelling.

154. The medical records document the Oncologist saw the patient on 16 September 2019. The records further document the patient and the complainant wished for the patient to continue his care and treatment in Dublin, and the Trust discharged him from its care on 19 September 2019.

Relevant Independent Professional Advice

C IPA

155. The C IPA advised the clinical notes document that the Cardiologist informed the patient and family of the MDM discussions of 11 September 2019, and the request for the patient to receive an MRI scan of his head and neck.

156. In relation to a referral to Oncology, the C IPA advised it is unusual to wait until there is a firm diagnosis before an Oncology diagnosis is made. *'Although metastatic cancer was strongly suspected, the histology diagnosis was received at 1743 on 12/09/19'*. She advised an Oncology referral would not be expected to be made out of hours, so referral the next morning *'as was done, was timely and appropriate'*. The C IPA advised the clinical records document that the Cardiologist discussed Oncology input with the patient and the complainant on 13 September 2019. The Cardiologist made an Oncology referral on behalf of the patient by email on the same day. She advised *'it would not have been appropriate to refer earlier, before a histological diagnosis had been made'*.

O IPA

157. The O IPA advised *'the case notes document near daily discussion about the investigation and treatment plan as would reasonably [be] expected bearing in mind the available information'*.

158. The O IPA advised the Trust's Oncologist attended to the patient on 16 September 2019 and the records document the Oncologist was *'aware of metastasis[33] on masseter[34], bone metastases[35], pericardial effusion'*. The records document *'the symptoms described and possible treatment options and a request made for molecular markers[36] to guide treatment'*.

159. In response to this Office's enquiries the Trust stated *'the Oncologist 'did not recommend palliative radiotherapy to parotid or spine as this would delay systemic treatment and would also delay potential entry into clinical trial'*. The complainant said the Oncologist did not provide this information to the patient. The O IPA advised he cannot find this information within the clinical records. However in response whether the Oncologist should have provided this information to the patient the O IPA advised *'No. All treatment was planned in Dublin no treatment was planned in the Trust'*.

160. The O IPA advised the Oncologist recorded investigations, possible treatment within a clinical trial and prognosis, and the role of radiotherapy. *'As an oncologist this represents a complete view of where the patient was from an oncological point of view and is of the expected standard competent oncologist'*.

161. The O IPA advised *'communication between the patient and the oncologist on this one visit is appropriately recorded in the notes…there was no further or different relevant information or advice to be offered'* at this consultation.

162. The O IPA advised the Oncologist did not examine the patient until 16 September 2019, however *'even if the oncologist had seen the patient earlier,*

[33] The spread of cancer.
[34] Muscle located in the jaw used for chewing. Covers the sides of the jaw.
[35] Bone metastasis is a category of cancer metastases that results from primary tumor invasion to bone.
[36] An identifiable molecular characteristic usually DNA, RNA, or protein in a patient or a tumor that can be used to provide prognostic or predictive information about the cancer or about a particular treatment.

[it] would have made no material difference to the events on the ward or the outcome which followed accepted practice'. In relation to whether the Oncologist could have prescribed the patient with pain relief at an earlier stage, the O IPA advised *'oncology is a treatment speciality administering systemic treatments and radiotherapy to alter the course of cancer. It is not a diagnostic speciality neither can it provide or is it appropriate for the oncologist to provide all palliative and medical care'*.

163. The O IPA advised there is no evidence in the records that the patient's treatment in Dublin impacted the care and treatment the Trust provided to the patient. The O IPA advised *'the care was at an expected standard'*.

164. Overall the O IPA also advised *'from an oncology point of view the patient was appropriately managed and there is clear evidence of appropriate communication with both the patient and his wife in the records'*.

Analysis and Findings

Cardiology Care

165. In response to the draft Investigation Report the complainant said the Cardiologist did not inform the patient of the 11 September 2019 MDM meeting. I note the 11 September 2019 MDM meeting discussed the patient and it was recorded that it requested an MRI scan of the patient's head and neck to further assess the parotid swelling. The C IPA advised *'it is clearly documented that the patient and the family were informed'*.

166. The complainant does not consider the Cardiologist referred the patient to the care of Oncology at the appropriate time. The C IPA advised it is usual to wait until there is a firm diagnosis before an oncology diagnosis is made. The clinical records document the Cardiologist received the patient's histology diagnosis at 17.43 on 12 September 2019. The C IPA advised *'An oncology referral would not be expected to be made out of hours, so referral the next morning, as was done, was timely and appropriate'*. The records also document on 13 September 2019 the patient's formal report of the pericardial effusion cytology was available. The medical records document the Cardiologist spoke to the patient and his wife about Oncology input and she made a referral for

this input via email on the same day. The C IPA advised *'the timing of the referral was appropriate'*. I accept the C IPA's advice. This is because she advised *'it would not have been appropriate to refer earlier, before a histological diagnosis had been made'*. I consider the Cardiologist's care and treatment to the patient was appropriate. I do not uphold this element of the complaint.

Oncology Care

167. The complainant was concerned the Oncologist did not meet with her and the patient to offer advice on the patient's clinical pathway and treatment. She was also concerned that the Oncologist did not see the patient until 16 September 2019. I refer to the GMC Guidance which requires clinicians to *'give patients the information they want or need to know in a way they can understand'*. The GMC Guidance also requires clinicians to *'be considerate to those close to the patient and be sensitive and responsive in giving them information and support'*.

168. The medical records document that when the Oncologist visited the patient on 16 September 2019, he discussed his medical history and diagnoses. The records also document the Oncologist informed the patient his progress was dependent on the chemo/immunotherapy[37] response. Based on these records, I accept the O IPA's advice that the Oncologist was aware of the patient's diagnosis and prognosis at that time.

169. In response to this Office's enquiries the Trust stated *'the Oncologist 'did not recommend palliative radiotherapy to parotid or spine as this would delay systemic treatment and would also delay potential entry into clinical trial'*. The complainant said the Oncologist did not provide this information to the patient. I note the clinical records do not document the Oncologist provided the patient with this information. However the patient made a request to continue his care and treatment in Dublin and I accept the O IPA's advice there was no requirement for the O IPA to provide the patient with this information.

[37] Type of cancer treatment that helps a patient's immune system fight cancer.

170. I note the Trust admitted the patient to hospital on 5 September 2019 and the Oncologist did not attend to the patient until 11 days later. The complainant said this left the patient *'believing that he had no options and that he was not a priority and that his pain could not be controlled'*. However, the records evidence the patient was under the care of the Cardiologist during that time. The records also document the Oncologist attended to the patient following his cancer diagnosis and his request to transfer his care to a Dublin hospital.

171. I note the O IPA did not raise any concerns with this timeline. The O IPA advised it is not *'appropriate for the oncologist to provide all palliative and medical care'*. He also advised *'even if the oncologist had seen the patient earlier* [during the week], *he would have made no material difference to the events on the ward or the outcome which followed accepted practice'*. I accept this advice.

172. Having reviewed the records and O IPA advice, I have not identified any evidence to suggest the patient's decision to undergo treatment in Dublin impacted the Oncologist's care and treatment of the patient.

173. The complainant also raised concerns with the Oncologist's communication with her and the patient. I consider the records provide evidence of the Oncologist's discussions with the patient and the complainant. I also note the O IPA's advice that the Oncologist could not have offered any *'further or different relevant information or advice'*. Based on the evidence provided I consider the Oncologist's communication met the relevant GMC standards.

174. I accept the O IPA's advice that the Oncologist *'appropriately managed'* the patient. I have not identified any failings in the care and treatment the Oncologist provided to the patient. I do not uphold this element of the complaint.

Detail of Complaint

Referral to McMillan nurses

175. The complainant said the Oncologist did not refer the patient to the care of McMillan nurses and as a result she did not receive their support.

Evidence Considered

Trust's response to investigation enquiries

176. The Trust stated it discussed the patient at two MDMs[38] in September 2019, and *'it was noted' 'the patient was receiving treatment for his cancer in Dublin'*. For this reason, it did not consider the patient for a new referral to the McMillan nurses.

Relevant Trust records

177. The Trust provided this Office with the patient's medical records for September 2019 including email correspondence both internally, and externally. The Trust also provided this Office with the notes of the MDM meetings held on 11 and 18 September 2019. I enclose a summary of these records at Appendix five of this report.

Relevant Independent Professional Advice

178. The O IPA advised McMillan nurses are palliative care nurses who provide patients diagnosed with cancer assistance with their symptoms and psychosocial support. The O IPA advised any health professional can refer a patient for McMillan nurses' advice.

179. The O IPA advised *'since this patient's care was predominantly in Dublin it is not clear to me why this is deemed a loss of opportunity within the Trust'*. He advised *'the assumption would be that specialist nursing support came from the treating hospital in Dublin which would be appropriate'*.

180. However the O IPA advised *'it may be argued that the involvement of the palliative care team may have helped with symptom control and perhaps assisted patient's wife and coming to terms with his terminal illness'*. Nevertheless, *'the assumption would be that specialist nursing support came from the treating hospital in Dublin which would be appropriate'*.

[38] Multidisciplinary Team Meeting is a meeting of group of professionals from one or more clinical disciplines who together make decisions regarding recommended treatment of individual patients.

181. The O IPA also advised *'the medical notes are well-written with frequent interaction'* and did not identify any failings.

Analysis and Findings

182. The Trust stated it did not consider a referral to McMillan nurses as the patient chose to receive care and treatment in Dublin following his diagnosis. I note the O IPA advised that as St James's Hospital, Dublin, predominantly provided the patient's care, he did not consider the complainant, nor the patient missed the opportunity to receive care from McMillan nurses. He advised *'the assumption would be that specialist nursing support came from the treating hospital in Dublin which would be appropriate'*. I accept this advice.

183. I consider the Trust's decision not to refer the patient and the complainant to McMillan reasonable. The records document the Oncologist informed the complainant and the patient of the patient's cancer diagnosis on 16 September 2019. On the same day, the complainant and the patient requested the Oncologist transfer his care to St James's Hospital, Dublin. The Trust discharged the patient on 19 September 2019, three days (inclusive) following his cancer diagnosis. Therefore, the patient was no longer under the Trust's care. I do not uphold this element of the complaint.

Detail of Complaint

Clinical trials

184. The complainant said the Oncologist did not refer the patient for clinical trials, and as a result, *'the patient missed his opportunity'*.

Evidence Considered

Trust's response to investigation enquiries

185. The Trust stated: *'within the Trust all patients are offered NICE[39]/NHS approved cancer treatment for their cancer type'*. When these treatments are exhausted the *'Consultant Oncologist will consider open trials for the cancer type within the North West Cancer Centre, Northern Ireland and UK wide'*. The Oncologist checked both Northern Ireland and Republic of Ireland clinical trial

[39] National Institute of Care and Excellence.

websites for possible studies open to the patient. However, there were no trial options specific to the patient's diagnosis.

186. The Trust stated a *'keynote[40] immunotherapy'* clinical trial appeared open in Dublin. However, upon review of published literature, this study appeared to have closed its recruitment in June 2019.

Relevant Trust records

187. The Trust provided this Office with the patient's oncology records for September 2019. Within those records the Oncologist recorded the possibility of a keynote trial on 16 September 2019. The records for 16 September 2019 also document the Oncologist discussed with the patient the possibility of a clinical trial.

Relevant Independent Professional Advice

188. The O IPA advised clinical trials *'are effectively experiments of treatment in patients…not all new treatments are better than existing treatment'*. The O IPA advised *'it cannot be said that any individual patient will actually benefit from participation within a clinical trial'*.

189. The O IPA advised the records document the Oncologist checked for clinical trials on behalf of the patient on 16 September 2019. It also documents the Oncologist and the patient discussed the possibility of a clinical trial.

190. The O IPA advised *'the loss of an opportunity to participate in a trial which no more than 5% of patients doing any event will not have altered the major treatment options of systemic treatments of palliative radiotherapy'*. The O IPA advised as the patient did not receive his treatment with the Trust, he could not identify any failings in the patient's care and treatment.

191. In response to the draft Investigation Report the complainant queried if the MDM discussed the patient's intention to participate in a clinical trial and whether the Oncologist informed the patient of these discussions. The O IPA

[40] Type of reference for clinical trials.

advised as the patient was intending to continue his care and treatment in Dubin there was *'no requirement to discuss at the local MDT OR consider trial entry. This would have been pointless since no care was planned in the Trust as per patient wishes'*.

192. The complainant also raised concerns in her response to the draft Investigation Report that the Oncologist did not inform the patient that the Radiologist only obtained one core biopsy sample on 9 September 2019. The O IPA advised the aim of the biopsy was to make a diagnosis of either cancer or an infection. The biopsy was not taken to obtain tissue for a clinical trial which typically requires additional consent once enrolment has taken place. He advised *'it is not clear to me that additional biopsy would have to have been taken on 09 September 2019 to render clinical trial admission possible'*. He advised this is because *'original pathological material from the primary can be used. There would always have been the opportunity to take further tissue at a later date if needed in any event'*.

Analysis and Findings

193. I note the Trust stated the Oncologist checked the Northern Ireland and Republic of Ireland clinical trial websites on 16 September 2019. However, the patient did not meet the eligibility criteria for clinical trials available in September 2019, and as such the Oncologist did not refer the patient for a clinical trial. I am unable to access information about clinical trials that were available in September 2019. Therefore, I cannot test the patient's eligibility. However, I note the Trust's attempts to search for a suitable trial. Also, the O IPA advised if there was a loss of opportunity, it would *'not have altered the major treatment options of systemic treatments of palliative radiotherapy'*. I hope this brings an element of reassurance for the complainant.

194. In response to the draft Investigation Report the complainant queried if the MDM discussed the patient's intention to participate in a clinical trial and whether the Oncologist informed the patient of these discussions. I note the clinical records document the MDM met to discuss the patient on four occasions during this hospital admission. The records of these meetings do not

document the patient's request to participate in a clinical trial. However the O IPA advised as the patient was intending to continue his care and treatment in Dubin there was *'no requirement to discuss at the local MDT OR consider trial entry. This would have been pointless since no care was planned in the Trust as per patient wishes'*. I accept this advice.

195. The complainant also raised concerns in her response to the draft Investigation Report that the Oncologist did not inform the patient that the Radiologist only obtained one core biopsy sample on 9 September 2019. Upon my review of the clinical records I am satisfied the Oncologist did not provide this information to the patient. However the O IPA advised *'it is not clear to me that additional biopsy would have to have been taken on 09 September 2019 to render clinical trial admission possible'*. He advised this is because *'original pathological material from the primary can be used. There would always have been the opportunity to take further tissue at a later date if needed in any event'*. I accept this advice.

196. Overall, I am satisfied the Oncologist researched clinical trial availability on behalf of the patient and provided him with the appropriate care and treatment in relation to his request to participate in a clinical trial. I do not uphold this element of complaint.

Detail of Complaint

Treatment as an inpatient

197. The patient attended ED on 3 September 2020 and the ED Consultant admitted the patient to hospital for treatment that same evening. The complainant believed the Consultant did not understand the seriousness of the patient's condition during his admission on 3 September 2020 and ignored the complainant's concerns. The complainant also said when she asked the nurse about the patient's symptoms, the nurse advised her the doctor was *'not concerned'.*

198. The complainant said the Consultant did not prescribe adequate pain relief for the patient, and his left pleural drain[41] stopped functioning during the hospital admission (3 September 2020 to 7 September 2020).

Evidence Considered

Legislation/Policies/Guidance

199. I considered the following policies and guidance:

- GMC Guidance; and
- NICE NG142 Guidance.

Relevant Trust records

200. The Trust provided this Office with the patient's medical records for September 2020 which include his ED records. I enclose a summary of these records in Appendix five to this report.

Trust's response to investigation enquiries

201. The Trust stated the patient attended ED with a history of sudden severe shortness of breath whilst coming down the stairs lasting approximately 15 minutes with no chest pain. The patient received a chest drain four weeks prior to this ED attendance as he had a pleural effusion[42] *'and reported that the output had reduced from approximately 700mls to 30-70mls a day for the past two weeks'*. The patient received radiotherapy and was soon to commence chemotherapy.

202. The Trust stated the patient's blood results showed his CRP[43] was *'elevated'* which confirmed infection. The ED Consultant commenced an intravenous antibiotic of tazocin[44] and ordered a chest X-Ray and ECG[45].

203. The Trust stated it admitted the patient to the Ward at 20.10 on 3 September 2020. On the afternoon of 5 September 2020, the complainant reported she was concerned the patient's condition deteriorated and his abdomen remained

[41] A flexible plastic tube that is inserted through the chest wall into the pleural space.
[42] An excessive collection of fluid in the pleural cavity, the fluid-filled space that surrounds the lungs.
[43] C-reactive protein is a protein made by the liver that is released into the blood. The concentration of this protein rises in response to inflammation.
[44] An antibiotic that is given via drip to treat serious bacterial infections.
[45] Electrocardiogram test is used to check a person's heart rhythm and electrical activity.

swollen. The on-call Consultant reviewed the patient and the medical records document *'there was some swelling in left lateral flank*[46] *however the abdomen was not distended*[47]*, soft not tender on palpitation, no rash present'*. The patient did not complain of discomfort and the on-call Consultant referred the patient for an abdominal and chest x-ray. The *'chest X-Ray revealed left pleural effusion and that chest drain above fluid level and not draining correctly hence fluid overload'*.

204. The Trust stated the Consultant prescribed the patient with *'a single dose of Intravenous Furosemide (used to treat fluid retention) and to commence hourly observations'*. However, the patient requested not to receive Furosemide *'as it would leave him having to pass urine frequently overnight'*, and he wished to sleep. It respected this request and administered the drug the following morning (6 September 2020) at 07.00.

205. The Trust stated on 6 September 2020 the patient received another CT of his chest, abdomen, and pelvis. On the same day a nurse from St James's Hospital in Dublin telephoned to advise it was ready to receive the patient for chemotherapy either on 9 or 10 September 2020.

206. The Trust stated on 7 September 2020, the ED Consultant spoke to the patient to advise of the CT scan findings which showed the disease had progressed. The ED Consultant communicated this by telephone to the complainant. The patient wished to contact St James's Dublin from home regarding his admission and the Trust made plans to share the radiology report with the patient to bring to Dublin. The Trust discharged the patient from its care on 7 September 2020 to allow him to continue his care in St James's Hospital, Dublin.

Relevant Independent Professional Advice

207. The Con IPA advised the medical records document the complainant's concern about the patient's abdominal swelling and *'he was seen by the F1 doctor*[48]

[46] Side of the body between the ribcage and the iliac bone of the hip.
[47] Swollen due to pressure on the inside of the body.
[48] Foundation Year 1 Doctor

specifically concerning the abdominal swelling'. However, the medical records did not provide evidence that the Consultant said he was *'not concerned'*.

208. The Con IPA advised the patient received appropriate pain relief and *'there was no early warning signs of deterioration'*.

209. The Con IPA advised the records document the patient's left pleural drain stopped working on 2 September 2020 (the day before his ED attendance). During his hospital admission; the ED Consultant referred the patient to the respiratory team who obtained a chest x-ray. This x-ray discovered the patient's pleural drain was above fluid level, meaning *'the fluid level had fallen below the tip of the [drain]'*. This meant the fluid level had reduced and there was less to drain. The records also document *'the pleural effusion was getting smaller'*.

210. The Con IPA advised the records document on 5 September 2020 the output from the chest drain reduced over the past four days and the patient felt well; he had no pain or discomfort, and his NEWS score was 1. There was no requirement for the Consultant to offer the patient treatment for the drain because *'the pleural collection had reduced substantially…soon after, he was discharged and allowed to leave hospital…So, it was deemed that nothing else by way of action, was necessary'*. He was *'satisfied that he [the patient] had all necessary interventions given the nature and severity of his illness, there was little else that could have been done for him'*.

211. The Con IPA advised he identified a failure in the Consultant's communication to tell both the patient and the complainant *'it was futile to persist in treatment when the cancer was disseminated'*. A palliative care specialist *'should have been brought in to make it easier for the patient and his family'*.

Analysis and Findings

212. The medical records document the Trust admitted the patient to the Ward on 3 September 2020 at 20.10. He continued to receive care and treatment on the Ward until his discharge on 7 September 2020.

213. The complainant said when she visited the patient in the Ward *'I emphasised my worry of [the complainant's condition deteriorating each time I saw him'*. However, the Consultant '*ignored*' her concerns. I note the medical records do not document the complainant's concerns during the period 3 September to 7 September 2020. I have no reason to doubt the complainant raised her concerns to the Consultant. However, in the absence of any documentary evidence, I am unable to ascertain what concerns she reported, and how the Consultant responded. In the absence of additional evidence, I am unable to determine if the Consultant's response was appropriate or what impact it may have had on the patient's care and treatment (if any).

214. The medical records document the patient's NEWS was zero on 5 September 2020. The Con IPA advised this implied *'there were no early warning signs of deterioration'*. I accept this advice.

215. In relation to abdominal swelling, the complainant said the nurse advised her that the Doctor was *'not concerned'*. However, the nurse did not document this interaction within the patient's medical records.

216. The complainant said she had concerns that the patient had abdominal swelling. The patient's medical records document this concern. The Con IPA advised the medical records document the complainant reported the patient had abdominal swelling and the F1 doctor attended to the patient specifically for this. The Con IPA advised the F1 doctor examined the patient but did not offer any intervention *'because there was no real swelling detected'*.

217. The complainant said the patient's pleural drain was not working during his hospital admission in September 2020. The Con IPA advised the medical records document the drain stopped working the day before admission (2 September 2020). The records document the ED Consultant referred the patient to the respiratory team upon admission to the ED on 3 September 2020. The respiratory team then performed a chest x-ray. The Con IPA advised the x-ray showed the drain in place and the pleural effusion reducing in size. As a result, the pleural tube was draining progressively less fluid. The Con IPA advised, as the fluid level within the drain reduced, there was less fluid to drain.

218. The Con IPA advised the records document on 5 September the chest drain output reduced over the past four days. The *'patient felt well; he had no chest pain or discomfort; the NEWS score was 1'*. He advised, for these reasons *'no treatment was required and soon after, he was discharged and allowed to leave hospital'*. I accept this advice.

219. Although the complainant did not raise a concern with the Consultant's communication, I note the Con IPA advised the Consultant should have informed the patient and family *'it was futile to persist in treatment when the cancer was disseminated'*. He further advised the Consultant should have arranged for a palliative care specialist to attend to the family in order to provide support to the patient and his family. I refer to Standard 49 of the GMC Guidance, which requires clinicians to share information with patients to enable them to make decisions about their care. I consider the Consultant's lack of communication in this respect, and the subsequent referral, a failure in the complainant's care and treatment. I consider this was a difficult time for both the patient and the complainant. I accept the Con IPA's advice *'the clinicians appear to have lost sight of the fact that this young man was [with] (sic) disseminated malignancy was entering the final phase of his life'*.

220. I am satisfied the Trust was aware of the patient's condition and provided the patient with appropriate care and treatment in relation to his pleural drain. I am unable to conclude on the nurses' comments and I am unable to determine whether the clinicians considered all of the complainant's concerns. However I am satisfied the Trust appropriately responded to the complainant's concern relating to the patient's abdomen swelling. I found a failing in care and treatment regarding the Consultant's communication with the patient and a lack of referral for palliative care. For this reason, I partially uphold this element of the complaint.

221. I do not consider this failure impacted the patient's clinical pathway. However I consider it caused both the patient and complainant to sustain the injustice of a loss of opportunity. This is because I do not consider the Consultant provided

the patient and complainant with the information required for the patient to make informed decisions about his palliative care.

Issue 2: Whether the Trust provided the patient's family with the appropriate communication in September 2019.

Detail of Complaint

222. The complainant said the Cardiologist was dismissive towards family members and would not allow them to ask questions regarding the patient's condition.

Evidence Considered

Legislation/Policies/Guidance

223. I considered the following guidance:

- The GMC Guidance.

Interviews

224. I enclose a transcript of the Investigating Officer's interview with the Consultant Cardiologist at Appendix six to this report.

Relevant Trust records

225. The Trust provided this Office with the patient's medical and nursing records for September 2019. I enclose a summary of these records at Appendix five to this report.

Relevant Independent Professional Advice

226. The C IPA advised the Cardiologist frequently recorded communication with the patient and his family in the medical records. The nursing records document the patient's wife and other relatives were present with the patient in his room *'for much of the time, including during ward rounds'. This would have allowed frequent informal communication between the staff, patient and family'*.

227. The C IPA advised *'The consultant cardiologist had multiple discussions with the patient and his family about his investigation and treatment'*. The Cardiologist's communication was *'appropriate, and of the highest standard'*.

Analysis and Findings

228. The GMC Guidance requires clinicians to give *'patients the information they want or need to know in a way they can understand'*. This guidance also requires clinicians to be *'considerate to those close to the patient and be sensitive and responsive in giving them information and support'*.

229. I note the medical records document the Cardiologist regularly saw the patient and complainant during the period 9 September to 14 September 2019. The records also document the Cardiologist advised them both of the patient's clinical pathway and causes for pericardial effusion. In the interview held with the Cardiologist, she spoke of how the family and the patient's wife were regularly in the patient's room when the Cardiologist attended. I note the C IPA advice supports this. The records also document the Cardiologist's discussions with members of the patient's family.

230. I note the complainant considers the Cardiologist was dismissive towards the patient's family members and did not allow them to ask questions regarding the patient's condition. The Cardiologist stated during the interview that she regularly engaged with the patient's family. Upon my review of the clinical records, there is documentary evidence of frequent interaction between the Cardiologist, the complainant, the patient and members of his family. While I have no reason to doubt the complainant, the records do not support that the Cardiologist was dismissive towards the family.

231. During an interview with my Office the Cardiologist stated *'my duty of care was to [the patient], and I tried to involve [the patient] and [the complainant] at every step'*. The Cardiologist stated she explained to the family she wished to speak to the patient and the complainant first to discuss his clinical pathway, before relaying this information to the rest of the family. I note the C IPA advised this *'was sensible'*. While I recognise these private conversations may have caused the family to feel excluded, I consider this a reasonable approach.

232. I accept the C IPA's advice that the Cardiologist's communication as documented within the clinical records *'was appropriate, and of the highest standard'*. I am satisfied the Cardiologist's communication with the patient and

his family met the standards set by the GMC Guidance. I note the C IPA advised the Cardiologist went *'above and beyond what is required in the circumstances'*. I do not uphold this element of the complaint.

Issue 3: Whether the Trust addressed all issues of the complaint in accordance with its policy and relevant standards.

Detail of Complaint

233. The complainant was dissatisfied she waited 15 months for a response to her complaint. The complainant said when the Trust provided her with a response, it overlooked some of her issues of complaint.

Evidence Considered

Legislation/Policies/Guidance

234. I considered the following policies and guidance:
    - The Trust's Complaints Process; and
    - DoH Complaints Guidance.

The Trust's response to investigation enquiries

235. The Trust acknowledged the *'extensive'* delay in providing the complainant with a written response to her complaint.

236. The Trust stated it wished to assure the complainant *'that it carried out a full and detailed investigation of all the issues raised in [the complainant's] letter of complaint'*. Its investigating team consisted of staff from the ENT, Cardiology and Oncology specialties. It sought consent from the complainant to contact staff at the St James's Hospital in Dublin where the patient received treatment. It felt it would provide it with information to assist in its investigation. However, in an email dated 31 October 2021, the complainant declined consent for the Trust to approach St James's Hospital in Dublin for this information.

Relevant Trust records

237. The Trust provided this Office with the complaints file and relevant correspondence. I enclose a summary of the complaints file at Appendix five of this report.

Analysis and Findings

238. The complainant was dissatisfied the Trust provided her with a response to her complaint 15 months following its submission.

239. I refer to the DoH Complaints Guidance which states the Trust should provide a complainant with a full response to their complaint *'within 20 working days'*. I note the complaint records document the Trust received the complaint on 19 November 2020 and provided its response on 14 February 2022.

240. The DoH Complaints Guidance states *'as soon as the HSC organisation becomes aware that the relevant response timescale is not achievable they must provide the complainant with an explanation'*. The complaint records document the Trust contacted the complainant via telephone on 6 January 2021 and informed her of the delay to its written response. The Trust stated the delay was due to the complexity of the complaint and the impact of the Covid-19 pandemic.

241. I refer to the Trust's complaints process, which states *'a holding letter will be issued, if necessary explaining that the response will be delayed and providing a reason for the delay'*. The Trust's complaint records document it issued a holding letter to the complainant on 15 April 2021. This letter informed the complainant that the written response was with the Assistant Director for approval. The letter attributed the delay to the Assistant Director's workload at that time. The complainant received this letter four months following submission of her complaint.

242. The Trust issued the complainant with a second holding letter on 26 May 2021. It said the Trust was not in a position to provide the complainant with a full response. It attributed the delay to awaiting a response from staff in Altnagelvin hospital. The Trust issued a third and final holding letter to the complainant on 24 June 2021. This letter documented the Trust still awaited information from one doctor which it needed to complete the response to her complaint. The complainant received the Trust's final response eight months later.

243. I accept it may not always be possible for a Trust to fully respond to a complaint within the stated 20 working day timeframe. However, I expect bodies to take immediate and appropriate action to investigate and respond to the issues raised. Having reviewed the records, I do not consider those involved in the investigation process demonstrated sufficient urgency to respond to the complaint within an acceptable timescale. I acknowledge this also made it difficult for the complaints team to provide sufficient updates to the complainant.

244. I acknowledge this complaint was complex. I also acknowledge the unprecedented impact of Covid-19 on healthcare departments. However, I consider 15 months a significant and unacceptable period of time for the complainant to wait for a response to her complaint.

245. The complainant also said the Trust did not address the following issues of her complaint:

- *'[the patient] had to wait three weeks to see a surgeon – why was there no sense of urgency?'*;
- *'How many procedures should you put in place to ensure that a misdiagnosis would not happen again'*;
- *'how many procedures should you put in place to ensure a seriously ill patient receives prompt medical attention regardless of the day or time'*;
- *'how many procedures should you put in place to educate medical and nursing staff on how to care for a patient suffering with cancer and appropriately manage their symptoms'*; and
- *'how many procedures should you put in place to ensure that medical do not cause greater distress, turmoil and emotional torture to a patient and family dealing with cancer'*.

246. The DoH guidance requires the Trust to consider all aspects of a complaint. In response to my Office's enquiries, the Trust stated it wished to assure the complainant *'that it carried out a full and detailed investigation of all the issues raised in [the complainant's] letter of complaint'*.

247. I consider the issues outlined above are open questions about how to remedy the situation. I find it difficult to determine the specific issues of complaint within these questions.

248. I reviewed the Trust's final written response to the complainant dated 14 February 2022. I consider the Trust addressed the complainant's substantive concerns raised within the original complaint in November 2021, and within correspondence during the period November 2021 to February 2022.

249. However I note the records do not evidence that the Trust informed the complainant that it could not specifically address the questions outlined above. I consider that had it communicated this to the complainant, it would have reduced any uncertainty that occurred by not acknowledging them.

250. The First Principle of Good Complaint Handling, 'getting it right', requires bodies to act in accordance with *'relevant guidance and with regard for the rights of those concerned'*. The Second Principle of Good Complaint Handling, 'being customer focused', requires bodies to deal with complaints promptly and avoid unnecessary delays. It also requires bodies to respond to all elements of complaint. I consider the Trust failed to act in accordance with these Principles in its handling of the complaint. I consider this maladministration and uphold this element of the complaint. I consider the identified maladministration caused the complainant to suffer the injustice of frustration and uncertainty.

CONCLUSION

251. I received a complaint about care and treatment the Trust provided to the patient during the period July 2019 to September 2019, and in September 2020. I upheld elements of the complaint for the reasons outlined in this report. I considered the failures identified constituted a failure in the patient's care and treatment. I also found the record keeping for this case was at times of a poor standard.

252. I also received a complaint about the Trust's handling of the subsequent complaint. I identified maladministration in the Trust's failure to provide the

complainant with a response to her complaint within an appropriate time frame, and failed to address all issues of her complaint.

253. I recognise the impact of the identified failures had on both the patient and the complainant. I especially recognise the distressing situation for the patient and the family. In response to the draft Investigation Report the complainant said the identified failures caused the patient to suffer unnecessarily. I understand the issues in the complaint are a great source of concern for the complainant, and I hope the findings and recommendations provide some closure for her. The patient sadly passed away on 16 September 2020. I offer my condolences throughout this report to the complainant for the loss of her husband.

Recommendations

254. I recommend the Trust provides to the complainant a written apology in accordance with NIPSO's 'Guidance on issuing an apology' (July 2019), for the injustice caused as a result of the failures and maladministration identified (within **one month** of the date of this report).

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

    i) Discusses the findings of this report with all clinicians involved in the patient's care, and staff members reflect on the case and discuss it as part of their next appraisal;
    ii) Provides training to relevant Oral and Maxillofacial Surgical staff to include triaging of referrals in accordance with relevant guidance;
    iii) Provides training to relevant staff about the importance of communicating clinical pathways to patients, and the completion of appropriate referrals to palliative care;
    iv) Provides training to relevant Cardiology staff about the importance of recognising when a patient requires urgent treatment for pericardial effusion and consider arranging this procedure at an earlier stage;
    v) Reminds all staff of the importance of maintaining proper and appropriate records, and to ensure these records are legible, in accordance with Standard 19 of the GMC Guidance; and

vi) Reminds relevant staff of the importance of fully responding to complaints, and communicating with complainants, during the complaints process in accordance with the DoH Procedure.

256. I recommend the Trust implements an action plan to incorporate these recommendations and should provide me with an update within **six** months of the date of my final report. The Trust should support its action plan with evidence to confirm it took appropriate action (including, where appropriate, records of any relevant meetings, training records and/or self-declaration forms which indicate that staff read and understood any related policies).

Margaret Kelly
Ombudsman

June 2024

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

- Acting in accordance with the law and relevant guidance, 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 relevant guidance, 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