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

Report Reference: 202003412

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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 & Social Care Trust (the Trust) provided to the patient. The patient attended hospital on 7 March 2021 with symptoms of a Bartholin's abscess[1]. The Trust performed an incision to treat the abscess. The patient raised concerns about the provision of her informed consent for the procedure, an absence of follow-up care, and the decision to continue with a type of antibiotic.

The patient continued to experience symptoms of the abscess and returned to hospital on 18 March 2021 where the Trust performed a second incision. She raised concerns about the decision to perform this incision and the provision of her informed consent. She was also concerned the Trust did not notify her or her GP about the results of a swab taken on 7 March 2021. The patient believed the treatment provided caused her to contract sepsis in the hours following the second procedure.

The investigation identified failures in care and treatment. It found the Trust did not obtain informed consent from the patient for both attendances. It also found the Trust failed to inform the patient of the risk of recurrence and to discuss with her the option of an alternative treatment.

The patient also raised concerns about the Trust's decision not to consider her case under the Serious Adverse Incident (SAI[2]) process. The investigation identified maladministration in the process the Trust followed when it made its decision.

I recommended that the Trust apologise to the patient for the failings identified. I also recommended actions for the Trust to take to prevents future recurrence of the failings.

[1] A painful, pus-filled infection of the Bartholin's gland.
[2] Incidents that result in serious risk or harm.

THE COMPLAINT

1. This complaint was about care and treatment the Western Health and Social Care Trust (the Trust) provided to the patient on 7 and 18 March 2021. It was also about whether the Trust appropriately considered if it ought to have investigated the matter as a Serious Adverse Incident (SAI[3]).

Background

2. The patient phoned the Out of Hours GP on 5 March 2021 after she experienced symptoms of a Bartholin's abscess[4]. The GP prescribed the patient Flucloxacillin[5]. The patient continued to feel unwell and attended the Emergency Department (ED) at Altnagelvin Area Hospital on 7 March 2021. The ED subsequently referred the patient to Gynaecology[6] who performed the first incision. Clinicians advised the patient to complete the course of antibiotics her GP previously prescribed. They also took a swab prior to discharging the patient the same day.

3. The patient visited her GP on 18 March 2021 again with symptoms of a Bartholin's abscess. The GP referred the patient to Gynaecology for a second incision. The Trust prescribed the patient Metronidazole[7] following the second incision, as swab results reported presence of Escherichia coli (E. coli[8]). Following discharge on 18 March 2021, the patient's partner phoned Gynaecology reporting she was unwell. An ambulance transported the patient to the ED in the early hours of 19 March 2021, shortly after receiving the second incision. The ED transferred the patient to Gynaecology.

[3] Serious Adverse Incidents (SAIs) are defined as any untoward medical occurrence (s) that at any dose results in death, hospitalisation or prolongation of existing hospitalisation, persistent or significant disability/incapacity or a congenital anomaly or birth defect.
[4] A Bartholin's abscess is a painful, pus-filled infection of the Bartholin's gland, which is located on either side of the opening of the vagina. The gland can become blocked and form a cyst, which may become infected and form an abscess.
[5] Flucloxacillin is an antibiotic. It's used to treat: skin and wound infections.
[6] Gynaecology is the area of medicine that involves the treatment of women's diseases, especially those of the reproductive organs.
[7] Metronidazole is an antibiotic. It's used to treat skin infections, rosacea and mouth infections, including infected gums and dental abscesses. It's also used to treat conditions such as bacterial vaginosis and pelvic inflammatory disease.
[8] An E. coli infection is any illness you get from strains of E. coli bacteria.

4. On 19 August 2021, the patient submitted a complaint to the Trust regarding care and treatment received on 7 and 18 March 2021. The Trust issued the patient a final response letter dated 5 September 2022.

Issues of complaint

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

   Issue 1: Whether the Trust provided appropriate care and treatment to the patient on 7 March and 18 March 2021.

   Issue 2: Whether the Trust appropriately considered if the matter ought to have been investigated as a Serious Adverse Incident (SAI).

INVESTIGATION METHODOLOGY

6. In order to investigate this complaint, the Investigating Officer obtained from the Trust all relevant documentation together with its comments on the issues the patient raised.

Independent Professional Advice Sought

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

   - A Gynaecology Consultant with 34 years experience in the field.

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

8. I include the information and advice which informed the findings and conclusions within the body of this report. The IPA provided ‘advice’. However, how I weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards and Guidance

9. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those 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[9]:

- The Principles of Good Administration

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

    The specific standards and guidance relevant to this complaint are:

    - The General Medical Council's Good Medical Practice, updated April 2014 (the GMC Guidance);
    - The General Medical Council's Decision making and consent, November 2020 (Decision making and consent guidance);
    - The General Medical Council's Intimate examinations and chaperones, January 2024 (Intimate examinations guidance);
    - National Institute for Health and Care Excellence's Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use, NICE Guideline 15, August 2015, (Antimicrobial stewardship);
    - National Institute for Health and Care Excellence's Inserting an inflatable balloon to treat a Bartholin's cyst or abscess (information leaflet), December 2009 (NICE information leaflet);
    - National Institute for Health and Care Excellence's Balloon catheter insertion for Bartholin's cyst or abscess, December 2009 (Bartholin's abscess interventional guidance);
    - The Health and Social Care Board's Procedure for the Reporting and Follow up of Serious Adverse Incidents, November 2016 (SAI guidance); and
    - The British Medical Association's Consent and refusal by adults with decision-making capacity, September 2019 (Consent for adults with decision-making capacity guidance).

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

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

11. In investigating a complaint of maladministration, my role is concerned primarily with an examination of the Trust's administrative actions. It is not my role to question the merits of a discretionary decision. That is unless my investigation identifies maladministration in the Trust's process of making that decision.

12. 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.

13. A draft copy of this report was shared with the Trust and the patient to enable them to comment on its factual accuracy and the reasonableness of the findings and recommendations.

THE INVESTIGATION

Issue 1: Whether the Trust provided appropriate care and treatment to the patient on 7 March and 18 March 2021 in relation to the first and second incision procedures, notification of swab results, obtaining written consent prior to the incisions and the continuation of Flucloxacillin.

Evidence Considered

Legislation/Policies/Guidance

14. I considered the following guidance:
    - The GMC guidance;
    - Decision making and consent guidance;
    - Intimate examination guidance;
    - Antimicrobial stewardship;
    - NICE information leaflet;
    - Bartholin's abscess interventional guidance; and
    - Consent for adults with decision-making capacity guidance.

a) Treatment provided to the patient on 7 March 2021.

Detail of Complaint

15. The patient raised the following concerns regarding care and treatment provided to her on 7 March 2021 in Altnagelvin Area Hospital:
    - The Trust did not explain the risks before the procedure or obtain her written consent for it. The Trust told the patient to continue with the Flucloxacillin antibiotics rather than change to Metronidazole.
    - The Trust did not arrange any follow-up treatment for her after the procedure.

The Trust's response to investigation enquiries

16. The Trust stated it is normal practice for verbal consent to suffice for minor procedures requiring local anaesthetic and where patients are awake and alert throughout. The clinician '*would have'* explained the benefits, risks and side effects prior to commencement of a procedure.

17. The Trust said it took a swab from the patient on 7 March 2021, which it sent for Organisms and Sensitivity (O&S).

18. A microbiologist[10] from the Trust said, '*Flucloxacillin was a reasonable choice as it was empirical treatment for a soft tissue infection'*. The Trust felt it reasonable to continue with the prescribed treatment provided the patient remained well.

19. The Trust said the Morbidity and Mortality (M&M) meeting[11] on 6 April 2022 confirmed the treatment provided to the patient on 7 March 2021 was reasonable. This is because the patient was well between 7 and 18 March 2021.

[10] A microbiologist is a scientist who studies microscopic life forms and processes.
[11] Morbidity & Mortality (M&M) meetings are a critical component of clinical governance. They have the potential to improve patient outcomes, quality of care, attitudes towards patient safety and they contribute to the education of clinical staff.

Relevant Trust records

20. I considered records the Trust and patient provided. I enclose a chronology of the care and treatment the patient received at Appendix five to this report.

Relevant Independent Professional Advice

21. The IPA advised the Trust attempted insertion of a Word catheter[12] for the patient on 7 March 2021. This is a '*routine first line intervention'* for a Bartholin's abscess.

22. The IPA referred to the Bartholin's abscess interventional guidance. He advised that in addition to administration of local anaesthesia, clinicians are expected to obtain '*at least a verbal consent and to document the same'*. He further advised, '*presumably verbal consent was undertaken'*. However, he did not identify any evidence that the Trust documented the patient's consent. In relation to the Trust informing the patient of risks for the procedure, the IPA advised the records evidence '*limited information documented'*. Therefore, he found this '*difficult to assess'*.

23. The IPA advised clinicians are expected to sterilise the perineal skin with antiseptic. Clinicians should document this in the records. The records evidence the '*skin was sterilised (?product used), LA was administered'*.

24. The IPA advised the Word catheter insertion failed. However, the clinician was content they drained the abscess. The clinician discharged the patient with safety netting[13] to return if she had any concerns. However, as the Word catheter failed, the Trust should have '*warned*' the patient and her GP of the increased risk of recurrence. The records do not evidence the Trust did so.

25. The IPA advised it was appropriate for the Trust to tell the patient to continue with Flucloxacillin. This was because the swab result was not available at the

[12] A Word catheter is a flexible tube with a small balloon at its tip that is inserted into a Bartholin cyst or abscess to allow drainage and healing.
[13] Information shared with a patient or their carer designed to help them identify the need to seek further medical help if their condition fails to improve, changes, or if they have concerns about their health.

time of incision. Therefore, the '*best course of action'* was to complete the previously prescribed course of antibiotics.

26. In relation to follow-up care, the IPA advised the Trust acted appropriately. This was because the patient's GP was responsible for follow-up care for the patient following her discharge from the hospital.

The patient's comments on the draft report

27. The patient said the Trust told her to continue with the first course of antibiotics (Flucloxacillin) as she was 'well'. She questioned if this prolonged the sepsis.

Analysis and Findings

Informed Consent

28. The patient raised concern that the Trust did not inform her of the risks associated with the incision, or obtain her written consent, prior to performing the procedure on 7 March 2021.

29. The GMC's Consent guidance states that clinicians do not always require written consent for minor procedures. I note the NICE information leaflet, which outlines the incision procedure the Trust undertook for the patient, does not state that clinicians should obtain written consent. Furthermore, the IPA advised that verbal consent from the patient was sufficient for this particular procedure. Based on the information available, I do not consider the Trust was required to obtain written consent from the patient on this occasion.

30. However, this does not negate the requirements for obtaining informed verbal consent. The NICE information leaflet states that clinicians can offer the treatment provided they ensure '*the patient understands what is involved and agrees to the treatment'*. I also note that both the GMC's and BMA's Consent guidance are clear on the importance of informed consent and documenting it in the patient's records. Specifically, the BMA Guidance states records should include '*discussions about the treatment options, including potential harms and benefits of any treatment, any specific concerns the patient had and any other*

information that was given to them'. Therefore, I would expect the Trust's records, as a minimum, to document this information.

31. I considered the Trust's record for the procedure undertaken on 7 March 2021. It documented, '*counselled pt [patient] re word catheter, acceptance of same'*. While this record alludes to a discussion with the patient about the procedure, I am disappointed it does not contain the level of detail outlined in the GMC's and BMA's guidance. I also note the IPA found it difficult to '*assess*' whether the Trust provided the patient with appropriate information about the procedure or whether it obtained her verbal consent. In the absence of an appropriate record, I cannot be satisfied the Trust obtained informed consent from the patient for the procedure on 7 March 2021.

32. I consider this a failure in the Trust's care and treatment of the patient and uphold this element of the complaint. I am satisfied this failure caused the patient the loss of opportunity to have full knowledge of the procedure before agreeing to the incision. I also consider she sustained the injustice of uncertainty.

The decision to continue with Flucloxacillin

33. The patient was concerned that during her attendance on 7 March 2021, the Trust continued the Flucloxacillin antibiotic her GP prescribed days earlier. She believed the Trust should have prescribed Metronidazole at that stage rather than when she re-attended on 18 March 2021.

34. I note the Trust prescribed Metronidazole on 18 March 2021 based on the results from the wound swab. The results showed anaerobes[14] which were resistant to Co-Amoxiclav and sensitive to Metronidazole. However, the Trust only took the swab when the patient attended on 7 March 2021 and did not know the result until 12 March 2021. Therefore, it was not aware the anaerobes were sensitive to Metronidazole.

[14] Any organism that does not require molecular oxygen for growth.

35. The IPA advised that due to this, it was appropriate for the Trust to advise the patient to complete the course her GP prescribed. I accept his advice and consider the decision to continue with Flucloxacillin on 7 March 2021 appropriate. I have not identified a failure in care and treatment and as such, do not uphold this element of the complaint.

Follow-up treatment

36. The patient said the Trust discharged her following the first incision for the Bartholin's abscess without advice or arrangements for follow-up treatment. The records evidence the Trust told the patient to '*keep area clean'*, complete the course of antibiotics, and return if she becomes unwell or concerned.

37. The NICE Bartholin's abscess interventional guidance states that a balloon catheter can remain in place for four weeks prior to removal. However, the Trust's records document that the procedure failed. Therefore, the catheter was not in place when the Trust discharged the patient and there was no requirement for her to return. The IPA advised that in this event, the patient's care returned to her GP and the Trust was not required to follow-up with additional treatment. He further advised the Trust provided the patient '*safety-netting advice'*, which he considered appropriate.

38. However, the IPA advised that as insertion of the Word catheter failed, the patient was at increased risk of the abscess recurring. He further advised that the Trust should have informed both the patient and the GP of this increased risk. However, the records do not evidence it did so.

39. Standard 49 of the GMC Guidance requires clinicians to *'work in partnership with patients, sharing with them the information they will need to make decisions about their care'*. This includes sharing information about the condition and its '*associated risks and uncertainties'*. While the safety-netting advice provided went some way to inform the patient, it did not give her full and complete information about what may occur following her discharge. By not sharing this information with the patient, I consider the clinicians involved failed to act in accordance with this GMC standard. I am satisfied this represents a

failure in the Trust's care and treatment of the patient and I uphold this element of the complaint.

40. I am satisfied the failure identified caused the patient to sustain the injustice of worry and uncertainty. Had the Trust provided this information to the patient, I do not doubt it would have helped alleviate her concerns when the abscess did recur just over a week later.

b) Treatment provided to the patient on 18 March 2021.

Detail of Complaint

41. The patient raised the following concerns about the incision procedure performed on 18 March 2021 in Altnagelvin Area Hospital:
    - Whether the Trust should have performed the incision given her swab results showed the presence of E. coli.
    - The clinicians again did not inform her of the risks of the procedure or ask for her written consent.
    - The Trust did not inform her or her GP of the swab results.

42. The patient said that following her discharge from hospital on 18 March 2021 at 22:40, she returned a few hours later, at 02:00 on 19 March 2021. Clinicians diagnosed her with sepsis[15]. The patient was admitted to hospital and spent some of that admission in the Intensive Care Unit. She said she continues to recover from this '*traumatic experience'*.

The Trust's response to investigation enquiries

43. The Trust said its M&M meeting on 6 April 2022 concluded it was the second incision on 18 March 2021 that may have initiated the '*septic storm'*.

44. The Trust stated the swab results were a '*commonly seen phenomenon in the ano-genital region*[16]'. It was not uncommon to detect several strains of E. coli. It is not required to treat all strains identified if the patient was clinically well.

[15] Sepsis is a potentially life-threatening condition that arises when the body's response to infection causes injury to its own tissues and organs.
[16] Anogenital refers to the anus and external genitalia, irrespective of gender.

45. The Trust said '*when [the patient] was seen on 18 March 2021, the doctor documented that the wound swab had anaerobes, which were resistant to Co-Amoxiclav*[17] *and sensitive to Metronidazole. As a result, [the patient] was then commenced on Metronidazole at that time.*'

46. The Trust said there was no evidence the anaerobes[18] sensitive to Metronidazole caused the patient to become unwell as these were not detected in the blood cultures[19].

47. In relation to the patient not being advised of the possibility of acquiring the illness she experienced, the Trust said '*it would not be normal practice to inform a patient that, by having this procedure, they might develop overwhelming sepsis as it is such a rare complication'.*

48. The Trust stated it does not automatically send swab results to the GP. They are readily available for health care professionals on the Electronic Care Records system.

49. The Trust advised, '*an information leaflet has since been written so this can be provided to patients who require this procedure. This is currently awaiting approval and it is hoped that this will be available soon'*.

Relevant Trust's records

50. I considered records the Trust and the patient provided. I enclose a chronology of the care and treatment the patient received at Appendix five to this report.

Relevant Independent Professional Advice

51. The IPA advised the Trust again attempted to pass a Word catheter on 18 March 2021. However, it failed. Therefore, the Trust only performed an I&D[20]. Given the procedure failed a second time, the Trust should have offered the

[17] Co-amoxiclav is a penicillin-based antibiotic that can treat various bacterial infections, such as respiratory tract, bone and joint, genito-urinary and abdominal infections.
[18] Anaerobic bacteria are bacteria that can grow only in the absence of oxygen.
[19] Blood culture is a test that checks for bacteria, yeast, or other germs in your blood.
[20] Incision and drainage is a common procedure used to drain an abscess.

patient a '*formal Marsupialisation*[21]' under general anaesthetic. If accepted, the Trust should have performed the procedure within 24 hours.

52. The IPA advised the clinicians should have checked the patient's swab results prior to making the second incision. However, the records did not document they did so.

53. The IPA reiterated his advice regarding informed consent as outlined previously in this report. He advised the records from 18 March 2021 do not document that clinicians obtained verbal consent for the procedure.

54. The IPA advised the results of the swab taken on 7 March 2021 were available from 12 March 2021. It is routine for the Trust to issue a letter outlining the results of the swab to both the patient and a GP within seven days (by 19 March 2021). However, the patient returned to hospital before that date.

The patient's comments on the draft report

55. The patient referred to the Trust's findings from its M&M meeting on 6 April 2022 in which it confirmed the treatment provided to the patient on 7 March 2021 was reasonable. This is because the patient was well between 7 and 18 March. The patient confirmed this and said this is further evidence that it was the second incision on 18 March 2021 that caused her to go into septic shock. She also questioned if the Trust should have made the second incision if it was aware that E. coli was present.

The Trust's comments on the draft report

56. The Trust explained that if there is a result that warrants a change in treatment, it will send the results electronically to the patient's GP. It will contact the patient by telephone and advise them of the change in treatment. It is not Trust policy to send patients their results in writing.

[21] A procedure where the cyst is first opened with a cut and the fluid drained out. The edges of the skin are then stitched to create a small "kangaroo pouch", which allows any further fluid to drain out.

Analysis and Findings

Decision to perform the procedure

57. The patient was concerned with the Trust's decision to perform a second incision on 18 March 2021 given the swab taken over a week earlier showed the presence of E. coli.

58. The IPA advised the clinicians should have checked the swab results before they performed the procedure. However, he could not confirm from the records that they did so. The record from 18 March 2021 documents that the '*wound swab result'* showed anaerobes resistant to Co-amoxiclav but sensitive to Metronidazole. Based on this record, and on the balance of probabilities, I consider the clinicians did have knowledge of the swab results prior to performing the incision. However, there is insufficient evidence to determine if the clinicians were aware that E. coli was present before they made the second incision.

59. The IPA did not identify a failing in the decision to perform the incision initially. However, he advised that given the clinicians' second attempt to insert a Word catheter failed, they should have considered performing a marsupialisation procedure for the patient under general anaesthetic. I note the NICE Bartholin's abscess interventional guidance states this is a more invasive procedure. However, I consider that given the recurrence of the abscess, it was appropriate for the clinicians to discuss this alternative treatment with the patient prior to her discharge.

60. I refer again to Standard 49 of the GMC Guidance which requires clinicians to share with patients the '*information they will need to make decisions about their care'*. I consider that in failing to discuss this alternative treatment with the patient, the clinicians did not act in accordance with this standard. I am satisfied this represents a failure in the Trust's care and treatment of the patient. I uphold this element of the complaint.

61. I note the IPA's advice that performing the procedure may not have prevented the onset of sepsis. However, I consider it caused the patient to sustain the

injustice of a loss of opportunity to be made aware of the alternative treatment and make an informed decision on her care.

Informed Consent

62. The patient raised concern that the Trust did not inform her of the risks associated with the second incision, or obtain her written consent, prior to performing the procedure on 18 March 2021.

63. I have outlined previously in this report standards the Trust was required to meet and the relevant IPA advice regarding consent. My finding that the Trust was not required to obtain written consent from the patient does not change for this element of the complaint. However, I again consider that, as a minimum, the Trust should have documented the information it provided to the patient to allow her to give her verbal consent, and that it obtained consent.

64. The Trust's record for the procedure undertaken on 18 March 2021 documents that the patient verbally consented to the clinician performing a '*PV exam'*[22]. However, it is of great concern to me that there is no evidence in the record to suggest the clinicians discussed the procedure with the patient, or obtained her verbal consent, prior to performing the incision. I note the IPA also did not see within the record any evidence that the Trust obtained informed consent. Therefore, I cannot be satisfied the Trust obtained informed consent from the patient for the procedure on 18 March 2021. I consider in failing to do so, the Trust failed to act in accordance with relevant guidance for obtaining informed consent.

65. I consider this a failure in the Trust's care and treatment of the patient and uphold this element of the complaint. Patients have a fundamental right to be involved in decisions about their treatment and to make informed decisions (if they can). I am satisfied this failure caused the patient the loss of opportunity to have this right provided to her. I also consider she sustained the injustice of uncertainty.

[22] A vaginal examination.

66. The Trust informed this office that it now considers it reasonable to obtain written consent for this procedure. I welcome the Trust's decision and change to its process. I am hopeful this will minimise the risk of this failing recurring.

Notification of the swab results

67. The patient said the Trust did not make her aware of the results from the swab taken on 7 March 2021 until she attended a meeting with the Trust on 29 March 2022. The records evidence the results of this swab were available from 12 March 2021. As outlined previously, these results led to a change in the type of antibiotics prescribed to the patient.

68. I note the Trust said it retains swab results on its Electronic Care Record (ECR), which health professionals can access. Therefore, it does not routinely notify GPs of such results.

69. I note the IPA advice that the Trust should have informed the patient of the results, in writing, within seven days. However, the Trust stated this is not its current practice. It explained that if there is to be a change in a patient's treatment, they will notify their GP electronically and telephone the patient, if required.

70. The records for the patient's attendance on 18 March 2021 refer to the swab results. However, it is not clear from the records if the clinicians notified the patient of the results by telephone or during her attendance. I also note the Trust did not provide evidence that it notified the patient's GP of the results. I would ask the Trust to ensure that in communicating such results, it does so in accordance with relevant policy and guidance.

Issue 2: Whether the Trust appropriately considered if the matter ought to have been investigated as a Serious Adverse Incident (SAI).

Detail of Complaint

71. The patient contacted the Trust on various occasions between September 2021 and January 2022 to ask if it would investigate the case as an SAI. She explained the Trust informed her the case did not meet the criteria for an SAI

investigation and instead it would review her case at an upcoming M&M meeting. The patient believed the Trust should have investigated her complaint under the SAI process.

Evidence Considered

Guidance

72. I considered the following legislation/policies/guidance:
    - SAI guidance.

The Trust's response to investigation enquiries

73. The Trust said the patient's concerns did not initially meet the SAI criteria. Following the patient's enquiry about the SAI process, it first had to consider her concerns as part of its M&M process.

74. The Trust initially notified the patient of its decision during a telephone call in January 2022. It told the patient that the '*M&M forum would have a group of relevant professionals present, who would review the information around her case'*. If it believed the case met the threshold for an SAI, it would take the process forward.

75. The Trust reiterated its position when it met with the patient on 29 March 2023. The Consultant Gynaecologist explained the patient's case was a '*rare event'*. However, as learning, the Trust devised a leaflet to advise future patients of possible risks associated with the procedure.

76. The Trust held an M&M meeting on 6 April 2022. It also discussed the matter internally and agreed the patient's case '*did not fall into any of the criteria groups'*.

Relevant Trust's records

77. I considered the minutes of Trust's meeting with the patient in March 2022 and its response to the patient issued in September 2022. I also considered the minutes from the M&M meeting in April 2022. I enclose a summary of the relevant records at Appendix five to this report.

The patient's comments on the draft report

78. The patient again referred to the Trust's findings from its M&M meeting on 6 April 2022. She believed her sudden deterioration met the definition of an SAI.

Analysis and Findings

79. The patient believed the Trust should have investigated her concerns as an SAI. However, the Trust did not consider the patient's case met the relevant criteria. This investigation did not seek to question this discretionary decision. Instead, it considered the process the Trust followed when it applied the criteria and made its decision.

80. The Trust said it applied the criteria for an SAI outlined in the 2016 SAI Guidance to the patient's case. Section 4.1 of the guidance defines an adverse incident as '*any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation'*.

81. Section 4.2 lists the criteria for an SAI. Of the criteria listed, I consider it reasonable to find that 4.2.2 may apply to the patient. That being, '*unexpected serious risk to a service user*'. Section 4.2 also states that '*any adverse incident which meets one or more of the above criteria should be reported as an SAI'*. Given the patient contracted sepsis and was admitted to hospital following the incision procedures, which included a period in the Intensive Care Unit, it is not immediately clear to me why the Trust decided this case did not meet the threshold for an SAI.

82. In this event, I would have expected the Trust to outline how it considered the guidance and applied the SAI criteria. I also would have expected it to document its decision and the rationale for it.

83. I considered the Trust's records regarding this issue. I refer to an internal email from September 2021 which documented that the Trust decided not to report the case as an SAI at that time. It said this was because it had '*not completed the investigation'*. It agreed to complete its investigation and share its findings

in the written response. I do not consider this the Trust's final decision on the matter or its rationale for that decision.

84. The Trust provided a handwritten note of its meeting with the patient in March 2022. It documented that the Trust informed the patient her case did not fall under the SAI process. However, it did not document how it applied the criteria or its rationale for this decision.

85. The patient contacted the Trust again in April 2022 and queried whether it should consider her case as an SAI. I consider this indicates that by this time, the patient remained uncertain about the Trust's positions and its reasons for it. I note the Trust did not respond to the patient's query. I also note that while the Trust reiterated its decision in its written response to the patient's complaint, issued in September 2022, it again did not explain the reasons for it. I consider the above instances represent various missed opportunities for the Trust to explain to the patient its rationale for its decision that her case did not meet the threshold for an SAI investigation.

86. In its response to this office, the Trust explained it discussed the patient's case at its M&M meeting in April 2022 and decided it did not meet the SAI criteria. Having considered the minutes of this meeting, I accept the Trust discussed the patient's case in detail. However, the minutes do not evidence it discussed the patient's SAI query, whether the case met the relevant criteria, or reasons for its decision.

87. The Trust explained that two of its Assistant Directors discussed the matter and agreed the patient's case '*did not fall into any of the criteria groups'*. However, the Trust did not provide any information about when this discussion took place. It also did not provide a note of the meeting outlining what the Assistant Directors discussed, how they applied the SAI criteria, and the reasons for their decision.

88. I expect public bodies to be open and truthful when accounting for their decisions. In this case, I consider the Trust ought to have documented how it applied the SAI criteria and the rationale for its decision that it did not meet the

required threshold. By not doing so, it prevented this office from considering if its reasons were appropriate and in accordance with the SAI Guidance.

89. The Third Principle of Good Administration requires public bodies to 'k*eep proper and appropriate records'* and to '*give reasons for its decisions'*. I consider the Trust failed to meet this Principle in its consideration of the patient's case. I am satisfied this failure constitutes maladministration. I therefore uphold this element of the complaint.

90. I consider the failure identified caused the patient to sustain the injustice of frustration and uncertainty. This is evidenced by her repeated enquiries to the Trust about the SAI process. I consider that had the Trust clearly outlined to the patient its decision and the reasons why it did not meet the threshold for an SAI, the patient would not have felt she needed to reiterate her enquiry on so many occasions.

CONCLUSION

91. I received a complaint about whether the Trust provided appropriate care and treatment for the patient on 7 and 18 March 2021. I upheld elements of the complaint. The investigation did not identify any evidence to suggest the Trust discussed with the patient the risks of the procedure on 7 March 2021, which would have allowed her to provide her informed consent. It also found the Trust did not obtain the patient's informed consent prior to the procedure on 18 March 2021. Furthermore, the investigation established that the Trust did not inform the patient of the risk of the abscess recurring on 7 March 2021 or discuss marsupialisation as alternative treatment.

92. The investigation also identified maladministration in the process the Trust followed when it decided the case did not meet the threshold for an SAI investigation. As outlined previously in this report, it is not my role to question the merits of a discretionary decision unless my investigation identifies maladministration in the process of making that decision. In this case, I consider the maladministration identified does give me cause to question the merits of Trust's discretionary decision that the case did not meet the threshold

for an SAI investigation. This is because with the information available, I cannot be certain the Trust applied the SAI criteria appropriately and fairly. I address this further in my recommendations below.

93. I recognise the failures caused the patient to sustain the injustice of a loss of opportunity, worry, frustration, and uncertainty. I was sorry to hear about the patient's admission to hospital due to sepsis and appreciate the worry she experienced during this time. I hope this report and the recommendations outlined below go some way to address her concerns.

94. I was concerned to note the IPA for this case raised concerns about the Trust's records for both procedures. I would ask the Trust to remind relevant staff of the importance of creating and retaining records in accordance with GMC Guidance.

Recommendations

95. I recommend the Trust provides to the patient 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 identified (within **one month** of the date of this report).

96. I recommend the Trust reviews its decision that the patient's case does not meet the threshold for an SAI investigation. In doing so, the Trust should document how it applied the SAI criteria and the rationale for its decision. The Trust should provide both this Office and the patient with its outcome and its rationale (within **three months** of the date of this report).

97. I also recommend, for service improvement and to prevent future reoccurrence, that the Trust:

    i. Shares this report with relevant staff involved in the patient's care as part of their appraisal process and for future development and understanding;
    ii. Provides training to relevant staff to include:
        - The importance of obtaining informed consent in accordance with relevant standards;

- The importance of informing patients of the increased risk of the abscess recurring if the Word catheter procedure fails; and
- Consideration of performing a marsupialisation procedure under general anaesthetic if abscesses reoccur.

98. I recommend the Trust implements an action plan to incorporate these recommendations and provides 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 **July 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.