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

Report Reference: 202003016

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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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Appendix 1 – The Principles of Good Administration

Case Reference: 202003016
Listed Authority: Western Health and Social Care Trust

SUMMARY

I received a complaint about the Western Health and Social Care Trust's (the Trust) care and treatment of the complainant during three periods of care between 18 September and 30 November 2020. The complainant underwent two surgeries on her hip, following a fall.

The complainant believed the Trust did not perform the first operation correctly. She also said the operations changed her life, including affecting her ability to do her job, as well as causing her ongoing pain, anxiety and depression.

The investigation established there were several failings in the complainant's care and treatment related to two of the three periods of care in the complaint.
The failings identified were:

- Consent for the hip fixation procedure was not undertaken by a senior doctor;
- The Trust failed to provide appropriate advice to the complainant about weight-bearing;
- The x-rays performed post-surgery did not include a lateral view, which would have assisted in considering the extent to which the fracture had displaced;
- The Trust did not maintain appropriate records of the review of the complainant's x-ray; and
- The Trust did not arrange appropriate testing to identify if infection was an underlying cause of the failure of the first operation.

I recommended the Trust provide the complainant with a written apology for the injustice caused by the failures in care and treatment. 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.

I recognise the complainant found her experience distressing, with her ongoing pain impacting on her daily life. I hope, however, this report provides the complainant with reassurance that the decisions to undertake the operations and how these were carried out were appropriate.

THE COMPLAINT

1. This complaint was about the actions of the Western Health and Social Care Trust (the Trust). This related to the care and treatment provided to the complainant following a fall which resulted in a fracture at the neck of her femur and issues with her hip following two operations during the period 18 September to 30 November 2020. From the complainant's correspondence, it is clear her experience following the fracture of her hip has deeply affected her life on an ongoing basis.

Issue(s) of complaint

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

Whether the Trust provided appropriate care and treatment to the complainant between 18 September and 30 November 2020.

INVESTIGATION METHODOLOGY

3. 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

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

   - A Consultant Orthopaedic Surgeon for 15 years, MBBS, MRCSEd, MRCSGlas, MSc, FRCS (Tr. & Orth.) MBA (CO IPA).

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

5. The information and advice which informed the findings and conclusions are included within the body of this report. The IPA provided 'advice'. However,

how I weighed this advice, within the context of this complaint, is a matter for my discretion.

Relevant Standards and Guidance

6. 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[1]:

   - The Principles of Good Administration.

7. 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 British Orthopaedics Association, The Care of Patients with Fragility Fracture, September 2007 (BOA Guidance);
   - The General Medical Council's Ethical Guidance for Doctors, Decision Making and Consent, November 2020 (GMC Decision and Consent Guidance); and
   - The General Medical Council's Good Medical Practice, April 2019 (GMC Guidance).

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

8. I did not include all information obtained during the investigation in this report. However, everything relevant to the investigation has been considered in reaching my findings.

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

9. 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 INVESTIGATION

Detail of Complaint

10. The report into the complaint has been divided into three periods of care and treatment. Period one relates to the initial surgery following a fracture on 18 September 2020. This period also includes the complainant's post-operative review on 2 November 2020. Four distinct elements were considered as part of the investigation of this period of care; (i) the decision to perform the fixation procedure, (ii) obtaining consent, (iii) the operation and (iv) post-operative care. Period two from 9 to 12 November 2020 relates to the complainant's total hip replacement which was performed on 10 November 2020 and period three, 28 to 30 November 2020, which relates to the complainant's treatment for an infection.

i. Care and treatment 18 September to 2 November 2020

11. The complainant said the procedure, on 18 September 2020, left her in ongoing pain. She believed, because of this, she then had to have a full hip replacement. She said both procedures left her in ongoing pain with a scar which is an '*eyesore*' and she had to stop working in a job which she had held for 38 years. She believed these procedures also caused '*depression, anxiety, hair loss and weight gain*' and *'fundamentally changed her life'.*

Evidence Considered

Trust's response to investigation enquiries

12. As part of investigation enquiries, the Trust had an opportunity to respond to the complaint. The Trust's response to the enquiries related to all elements of the complaint is at Appendix two to this report.

Legislation/Policies/Guidance

13. I considered the BOA Guidance, the GMC Decision and Consent Guidance and the GMC Guidance.

Relevant records

14. I considered the complainant's medical records for the period 18 September to 2 November 2020.

Relevant Independent Professional Advice

15. The CO IPA provided advice about the decision to perform the procedure on 18 September 2020, the consent process around this, the conduct of the procedure and post-operative care. The CO IPA's full advice is enclosed at Appendix three to this report.

Responses to the Draft Investigation Report

16. The complainant, the Trust and those individuals within the Trust, who were cited within the complaint, were given an opportunity to provide comments on the Draft Investigation Report. Where considered appropriate, comments are either reflected in changes to the report or are outlined in paragraphs 17 to 21 and 49.

Consultant Orthopaedic Surgeon A's response

17. Consultant Orthopaedic Surgeon A explained the reasons he was unable to speak with the complainant before and after the surgery, including his delegation of the consent process to a CT1. Consultant Orthopaedic Surgeon A said, at the time of the complainant's referral to him, after she presented to ED, he was preparing to begin a '*major operation'* with the StR and neither could leave the operating theatre. He said, as this was '*a Friday afternoon … the Higher Surgical Trainees (HST) …. were attending their core curriculum teaching as part of their higher surgical training so there was limited medical cover available at a more senior level'.* Consultant Orthopaedic Surgeon A said he discussed with the CT1 what was required for the complainant in depth and provided the CT1 with detailed instructions for the complainant's care and treatment with a plan for an urgent operation. He also said, although he could

not *'recall for sure'* he is '*almost certain*' he spoke to the complainant in the anaesthetic room, '*if for no other reason but to introduce'* himself'. He also referred to the GMC Guidance on responsibility and delegation of consent; but, while he accepted the CT1 undertook the consent process, he said he was *'content' t*his particular CT1 was competent to undertake this process. Consultant Orthopaedic Surgeon A further stated, as neither he nor StR '*could …be in two places at the one time and there was no other senior doctor available',* the alternative would have delayed the complainant's care. Specifically, the complainant was *'an emergency trauma case… in significant pain who had been administered analgesia and need[ed] a surgical procedure expediently'.* He said she would have had to be admitted to the ward prior to being brought to theatre, where he would have spoken to the complainant, but only after he had completed the other operation, then completed the consent process. Consultant Orthopaedic Surgeon A said he believed the decisions taken were correct and, in the complainant's best interests.

18. In relation to the complainant's post-operative care, Consultant Orthopaedic Surgeon A explained he had performed the procedure as he was the consultant on-call at the time of the complainant's presentation; however, this role transferred to another person later that day and over the ensuing weekend. He said the complainant's care was delegated to an appropriate person in the new consultant on-call. He also said his instructions following surgery were that full weight-bearing was permitted but referred to the CO IPA's advice that there are conflicting, and therefore not definitive, views on this practice. Further, as he had no further involvement with the complainant, he did not know about her x-ray on 20 September 2020. Consultant Orthopaedic Surgeon A agreed that a lateral hip x-ray of the operated side would have been useful but, as the complainant was no longer under his care, the responsibility for such a request lay elsewhere.

19. Consultant Orthopaedic Surgeon A said that the complainant did not contact him or his secretary at any point to report any problems post-surgery but if she had, he '*would have made arrangements for her to be seen at the earliest opportunity'*.

20. Consultant Orthopaedic Surgeon A said the complainant's care and treatment occurred at the height of the Covid pandemic during a '*very challenging time to reinstate services due to significant restrictions on clinic numbers and reduced workforce'.*

StR's response

21. The StR accepted the findings and recommendations in the Draft Investigation Repot, with particular reference to consent. He said, although he '*would always ensure to see patients the morning of surgery ... due to the emergency nature of this case, regrettably this was not possible'.*

Analysis and Findings

Period One: Care and treatment 18 September to 26 September 2020

The decision to perform the fixation procedure

22. I refer to the BOA Guidance, relevant to treatment options for hip fractures, and the associated risks and benefits. The guidance states patients with hip fractures, who are medically fit, should have surgery within 48 hours of admission. I note the BOA Guidance details the risks associated with hip surgery. Specifically, only half of those treated '*will return to their previous level of independence*', with most experiencing '*at least some long-term hip discomfort'*; and half experiencing '*deterioration in their walking ability'*, including the necessity of a walking aid or physical help with mobility. Further, up to 20 percent of those treated will have to move into residential care. The BOA Guidance states, for displaced intracapsular fractures[2], there are several potential advantages and disadvantages to carrying out an internal fixation[3] procedure, which was the procedure carried out on the complainant. The potential benefits are the patient retains part of the hip, with the *'lesser surgical trauma'* potentially reducing the risk of death, further ill-health and wound bleeding and infection. The risks of this procedure in these cases, as outlined in

[2] A displaced intracapsular fracture occurs within the capsule of the hip joint when the pieces of the bone moved so much that a gap forms around the fracture when the bone broke. As the blood supply to the femoral head in a hip joint travels via the capsule, any fracture within the capsule could be likely to damage this blood supply.
[3] Internal Fixation is when implants are used to stabilize the broken bone and hold it together. Internal fixation of the hip can be performed using screws, wires, pins, rods, or other hardware to promote stability in the hip.

the BOA Guidance, include up to 33 percent chance the fracture will not heal; up to 20 percent likelihood of bone tissue death because of problems with blood supply; and up to two percent chance of a fracture around the implant. These risks result in a further operation in up to 36 percent of cases. I note, however, the BOA Guidance states for patients younger than 65, '*fixation is the most appropriate treatment'.*

23. I refer to the CO IPA's advice. In relation to the complainant's care from 18 September to 2 November 2020, the CO IPA advised, when the complainant presented to AH ED on 18 September 2020 following her fall, she had a *'displaced intracapsular left-sided neck of femur fracture*'. He explained, on the same day, the Trust carried out a fixation of the hip fracture using a Dynamic Hip Screw[4]. I note the CO IPA referenced the BOA Guidance and advised, the decision to operate and the timing of this was '*correct'.* The CO IPA further described the possible options for treatment of such a condition as fixation or total hip replacement. He explained there were differing perspectives on this; however, in younger patients, in which category the CO IPA advised the complainant was, '*attempts are made to fix the hip fractures to try and save the native hip'.* The CO IPA advised *'the advantages of preserving the hip joint outweigh the risks of a second operation*' should the fixation fail and require conversion to a full hip replacement. The CO IPA advised, because of the complainant's age, the decision to perform the fixation was appropriate.

24. I consider the records evidence the Trust provided the complainant with treatment for her hip fracture on 18 September 2020 in accordance with the timelines stipulated in the BOA Guidance. Therefore, I am satisfied the intervention of care and treatment was timely. Having considered the BOA guidance, and with the benefit of the CO IPA's advice, I am satisfied fixation of the complainant's hip was an appropriate treatment option.

[4] A dynamic hip screw is a pin and plate fixed to the thigh bone. In this operation, a screw is passed into the ball of the hip and a plate is passed over it and fixed to the thigh bone. The plate is secured with screws.

The consenting process for the fixation procedure

25. I refer to the GMC Decision and Consent Guidance which states, when delegating elements of the decision-making process to another doctor, you must consider if this is appropriate in the context of '*the nature of the intervention and the complexity of the information about'* the treatment and *'the level of uncertainty surrounding the outcome*'. Further, I note the GMC Decision and Consent Guidance states the person undertaking the task must be *'suitably trained and competent*' and has *'sufficient knowledge of the intervention and its associated benefits and harms, as well as alternative options for treatment and care'.* The GMC Decision and Consent Guidance also states, if a doctor delegates aspects of the decision-making, the doctor with responsibility for a patient remains responsible for ensuring a patient has all the information needed to decide and '*has a realistic expectation of the outcome'.*

26. I also refer to the GMC Guidance. I note it states, when a doctor delegates care of a patient, the doctor must '*be satisfied that the person providing care has the appropriate qualifications, skills and experience'.*

27. I refer to the records cited in paragraph 14. The complainant presented to the AH Emergency Department (ED) at 10:02 on 18 September 2020, with surgery performed on the same day at 15:30. Consultant Orthopaedic Surgeon A performed the surgery, assisted by a Speciality Doctor/Registrar (StR). The form for the '*Consent for examination, treatment or care*' for the procedure on 18 September 2020 lists several risks and benefits. The benefits included mobilisation and pain management. The risks included infection, bleeding, wound healing and scarring. A CT1[5] doctor signed the consent form. I note there are no records of either Consultant Orthopaedic Surgeon A or the StR meeting with the complainant prior to, or after, the surgery.

28. The CO IPA considered the consent process for the complainant's fixation procedure. He advised, on 18 September 2020, the complainant signed a consent form which detailed '*all the usual and accepted complications*

[5] A CT1 is a doctor who is in his/her third year after completing the medical degree. It will be the doctor's first year within a specialty, for example, orthopaedic surgery.

associated with the hip surgery'. The CO IPA further advised, however, the consultant surgeon is responsible for discussing care and treatment options with a patient. Further, if a doctor delegates this, the doctor should be '*an experienced member of the surgical team who has the time and skill to gain sufficient understanding of the patient's views and wishes'.* The CO IPA specified that the doctor involved in the consenting process should *'have sufficient knowledge of the associated risks and complications, as well as any alternative treatments available for the patient's condition'.* I note the CO IPA explained the doctor who undertook the consent process with the complainant, a CT1, '*is considered a junior member of the surgical team and although their experiences can vary, they would not be expected to have full knowledge of the treatment options to undertake a comprehensive discussion with the patient'.* The CO IPA advised, whoever undertakes the appropriate discussion with a patient *'should also complete and sign the consent form at the end of that discussion. Therefore, the CT1 must have discussed the procedure with the patient and not the senior surgeon responsible for her care.'*

29. The CO IPA referenced the GMC Decision and Consent Guidance and advised, when delegating the consent process, it is the consultant surgeon's responsibility to ensure they delegate this to an appropriate person. Further, the consultant surgeon is ultimately responsible for ensuring a patient *'has been given the information they need to make the decision, has had time and support to consider it, and has given their consent before the treatment or care is provided'.* The CO IPA advised, Consultant Orthopaedic Surgeon A, who performed the fixation procedure, did not speak to the complainant at any point prior to the surgery. I note he concluded, in the context of '*the complexity of the surgery and the expected knowledge level'* of a CT1, the consent process was not appropriate.

30. I refer to Consultant Orthopaedic Surgeon A's comments on the Draft Investigation Report at paragraph 17. I consider it was reasonable that, in the circumstances described, Consultant Orthopaedic Surgeon A was unable to undertake the consent process at that time. I also refer to the CO IPA's advice the decision to perform the procedure urgently was correct. I also consider,

however, the arrangements the Trust had in place at that time for senior cover in this department were inadequate to ensure the facilitation of appropriate consent. Although I consider it is evident the complainant signed a consent form on 18 September 2020 prior to her surgery, a CT1 completed the consent process. I accept the CO IPA's advice the consenting process, and the provision of relevant information, should be facilitated by an appropriately knowledgeable person and a CT1 would not have the necessary knowledge for a comprehensive discussion with a patient. Therefore, I am satisfied the Trust did not carry out the consent process for the procedure on 18 September 2020 in accordance with either the GMC Decision and Consent Guidance or the GMC Guidance cited at paragraphs 25 and 26 above respectively.

The conduct of the fixation procedure

31. The BOA Guidance highlights the *'sliding hip screw'* as *'the foremost implant and should be regarded as the gold standard'* with a '*superiority'* over other implant types. I note the complainant received a dynamic hip screw and which the BOA Guidance categorises as a '*sliding hip screw'.*

32. The CO IPA provided advice about the conduct of the procedure of 18 September 2020. He advised, the Trust performed the surgery *'in accordance with current relevant guidance and standards'* and the care was timely, for which the Trust '*should be commended'*. I note the CO IPA advised, however, it is good practice for the operating surgeon to discuss the surgery with a patient and, if this is not possible, to have a conversation with a patient following the surgery; however, neither Consultant Orthopaedic Surgeon A nor the StR spoke with the complainant before or after the surgery.

33. I consider the Trust's use of a dynamic hip screw for this procedure was in accordance with the BOA Guidance. I also accept the CO IPA's advice about the conduct of the surgery on 18 September 2020. Therefore, I am satisfied the fixation procedure was performed appropriately.

Post-operative care

34. I note the GMC Guidance states, '*recording your work clearly, accurately, and legibly … patients' records should usually include: relevant clinical findings … the information shared with patients … decisions made, actions agreed (including decisions to take no action) and when/whether decisions should be reviewed ... who is creating the record and when'.* The GMC Guidance states when a doctor delegates care of a patient, the doctor must '*be satisfied that the person providing care has the appropriate qualifications, skills and experience'.*

35. I note the records indicate there was a change in the consultant-on-call for this department on 18 September 2020. The records also indicate the complainant was reviewed by consultants on 19, 20, 22, 23 and 25 September 2020. On 20 September 2020, she was reviewed by a Consultant Orthopaedic Surgeon and by a Consultant Orthopaedic Physician on the other dates. She was also reviewed by a StR on 21 to 23 and 26 September 2020.

36. There is no evidence in the records the Trust informed the complainant about the need for care in weight-bearing after her procedure, either before or after the x-ray on 20 September 2020. Further, there is only one record which relates to review of the complainant's x-ray of 20 September 2020. This record is documented in the nursing care records of 21 September 2020. The record states, '*check x-ray 20th'*. I note this record does not clearly indicate who reviewed the x-ray results, including if this was an appropriate clinician. Neither does the record provide any detail of any consequential decisions or whether the complainant was informed of the x-ray results.

37. The CO IPA advised that the Trust told the complainant post-operatively to *'mobilise'* with '*full weight-bearing*'. He advised that, following a procedure such as this, *'many surgeons opt for protected weight-bearing to prevent fracture displacement[6]'* and which is '*usual practice*'. The CO IPA explained, this approach is more important in cases such as for the complainant, when

[6] In a displaced fracture, the bone snaps into two or more parts and moves so that the two ends are not lined up straight.

'the comminution[7] of the posterior cortex of the femoral neck … is visible on the fluoroscopy[8] images from the theatre'. I note the CO IPA concluded the Trust should have informed the complainant about '*protective weight-bearing … if [the] patient [was] able to comply'*. He advised this is particularly important '*to prevent early displacement'* when, as in this case, '*there is posterior comminution of the fracture'.*

38. The CO IPA advised the Trust appropriately performed an x-ray on 20 September 2020, but this was only a single view (anteroposterior (AP))[9] x-ray. He explained, when compared to the fluoroscopy images taken during the procedure, this x-ray indicates '*the de-rotation screw has already backed out … and there was some loss of reduction of the fracture with some collapse'.* He advised, '*this would imply some movement of the fracture but does not imply failure of [the] fixation'*. He advised it was '*essential to take a lateral view[10] [x-ray] to check this movement'.* I note the CO IPA concluded the Trust should have performed a lateral view x-ray to check fracture fixation and position.

39. In relation to the subsequent need to inform the complainant about weight-bearing following the x-ray results, the CO IPA advised that the Trust should have informed the complainant about protected weight-bearing *'to prevent further collapse of the fracture'.* Further, '*all of this information should have been given to the patient with a warning that fixation could fail*'. I note the CO IPA advised he could not conclude that the absence of caution about weight-bearing led to the failure of the fixation procedure.

40. I note Consultant Orthopaedic Surgeon A's comments in paragraph 18 that the complainant's care was transferred to a consultant when his period of acting as consultant-on-call ended. I consider this was reasonable and appropriate in consideration of the GMC Guidance cited in paragraph 34.

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[7] A comminuted fracture is one where the bone is broken in two or more places.
[8] Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, like an X-ray movie. During a fluoroscopy procedure, an X-ray beam is passed through the body. The image is transmitted to a monitor so the movement of a body part or of an instrument or contrast agent ("X-ray dye") through the body can be seen in detail.
[9] A single view anteroposterior (AP) hip x-ray includes images of both sides of the hip on the same film.
[10] A lateral view x-ray provides an unobscured picture of the femoral head-neck junction, a view that cannot be seen on the single AP view. In addition, the lateral view excels in the ability to demonstrate the femoral head's spherical level as it should be, together with any joint space narrowing and femoral neck deformities.

41. I note there is no documented record the Trust informed the complainant about either protected weight-bearing or the results of the x-ray. I accept the CO IPA's advice the Trust should have informed the complainant about protected weight-bearing after the procedure on 18 September 2020, particularly after the x-ray on 20 September 2020, and there is no evidence it did so. I also accept the CO IPA's advice the Trust should have undertaken a lateral view x-ray.

42. I refer to the GMC Guidance cited in paragraph 34. Although I cannot definitively conclude that the complainant's x-ray results were not reviewed by an appropriate clinician, I consider the Trust failed to act in accordance with the GMC Guidance in relation to record-keeping and associated continuity of care.

43. In consideration of the failings outlined in paragraphs 41 and 42, I am satisfied that, following the fixation procedure on 18 September 2020, the post-operative care and treatment provided to the complainant was not fully in accordance with GMC Guidance and good practice.

44. I consider the findings in paragraphs 41 and 42 constitute failings in care and treatment; therefore, I uphold these elements of the complaint.

Injustice

45. I considered carefully whether the failings caused an injustice to the complainant. I consider the complainant sustained the injustice of the loss of opportunity for making an informed decision about the fixation procedure on 18 September 2020, including the range of possible treatment options. I also consider the complainant sustained the injustice of uncertainty because she did not have a full understanding of the procedure, including the potential both for failure of the fixation and the necessity for further surgery. Further, I consider the complainant sustained the injustice of the loss of opportunity for an improved chance of an optimum outcome from the procedure. This is because, as the CO IPA advised, the x-ray of 20 September 2020 indicated deterioration at that point yet, neither prior to nor after, the x-ray, did the Trust caution the complainant about weight-bearing; and a lateral view x-ray was not undertaken to further identify the condition of the fixation. I also consider the complainant sustained the injustice of the loss of opportunity for discussion about her

procedure with the operating surgeon and which may have provided her with reassurance. The BOA Guidance indicates the fixation procedure carries up to 33 percent chance that the fracture will not heal and, in up to 36 percent of cases, patients will require a further operation. I also note the CO IPA advised he could not conclude that the absence of caution about weight-bearing led to the failure of the fixation procedure; however, I am concerned about how the failings I have outlined may have impacted on the effectiveness of the fixation procedure, particularly the lack of advice regarding the need to avoid weight bearing and the lack of a lateral view X ray.

Detail of Complaint

Period Two: Care and treatment 9 to 12 November 2020

46. The complainant said, at her post-operative review held approximately six weeks after her procedure, she still experienced '*excruciating'* pain. She said, at the review, the consultant told her the cause of her pain was the '*plate had lowered and the screw with a jagged edge was penetrating her thigh'.* The complainant said, within a few days, she received a full hip replacement. She said she understood the surgeon planned to '*line up the wounds'* from the two procedures; however, the remaining scar is significant, and she has continued pain in this area, even after the hip replacement.

Evidence Considered

Legislation/Policies/Guidance

47. I considered the BOA Guidance, the GMC Decision and Consent Guidance and the GMC Guidance.

Relevant records

48. I considered the complainant's medical records from 2 to 12 November 2020.

Relevant Independent Professional Advice

49. The CO IPA provided advice about the decision to perform a hip replacement and the associated consent; the conduct of the procedure; and the

complainant's post-operative aftercare and review. The full CO IPA advice is enclosed at Appendix three to this report.

Consultant Surgeon B's response

50. Consultant Surgeon B accepted the findings and recommendations in the Draft Investigation Report.

Analysis and Findings

51. I refer to the GMC Decision and Consent Guidance in paragraphs 25 and 26 that a patient's surgeon is responsible for ensuring a patient is given the information and the time needed to make an informed decision. I note the BOA Guidance, cited in paragraph 22, that the fixation procedure carries up to 33 percent chance the fracture will not heal and up to 20 percent likelihood of bone tissue death because of problems with blood supply with a further operation required in up to 36 percent of cases.

52. I refer to the records cited in paragraph 48. The consent form for the hip replacement lists a range of risks and benefits. The benefits include pain management and improvement of symptoms with relevant risks including, pain, infection, bleeding, scar, swelling and the need for further procedures. The complainant signed the consent form on 9 November 2020, one day before the operation. Another CT1 doctor signed this form on the Trust's behalf. I note, however, the records of the review clinic appointment on 2 November 2020 document that Consultant Orthopaedic Surgeon B discussed and explained the hip replacement procedure to the complainant, including the benefits and risks and Consultant Orthopaedic Surgeon B performed the hip replacement procedure. Further, the records indicate, following this discussion at the review clinic, the Trust planned the complainant's surgery for 10 November 2020.

53. The CO IPA advised the complainant's post-operative review was on 2 November 2020. He advised, because of the complainant's pain, due to the screw projecting into the hip joint and avascular necrosis of the hip joint, Consultant Orthopaedic Surgeon B recommended a hip replacement procedure *'as soon as possible'.* The complainant was admitted to AH on 9 November

2020 and the operation took place on 10 November 2020. The CO IPA advised the second procedure was necessary at this point because '*the femoral head had started to collapse and the metalwork was failing'.* The complainant was in pain, with mobility loss and '*there was no scope of this improving with time'.* The CO IPA advised this is a *'recognised complication'* of the first fixation procedure. I note the CO IPA advised the decision to perform a hip replacement was '*appropriate and reasonable'.*

54. I note the CO IPA advised the clinic letter of 2 November 2020 '*clearly states'* Consultant Orthopaedic Surgeon B informed the complainant about the complications of the procedure and the complainant consented to the surgery. I refer to the CO IPA's advice in paragraph 29 above, related to element (i) that the responsible consultant surgeon must ensure a patient is given the information and time to make the decision by someone who has the appropriate level of knowledge. The CO IPA also advised that the Trust did not omit any actions in relation to consent and decisions for this procedure. The CO IPA also advised that the Trust '*correctly'* performed the hip replacement surgery, with satisfactory post-operative x- rays. He advised both the complainant's aftercare and the planned six-week review were '*appropriate'.*

55. The CO IPA also advised, however, the Trust did not send any samples to rule out infection as the cause of *'the collapse of the previous fracture'*. Although *'there were no obvious signs of infection noted'*, it would be good practice to send samples to exclude the presence of any infection. Further, *'sometimes the entire extricated metalwork is sent to the laboratory to rule out any infection*' with the complainant kept on antibiotics until tests '*definitively exclude infection'.* I note the CO IPA concluded it was *'incorrect'* to not conduct these tests. The CO IPA further explained the complainant's later infection *'was not a deep infection*' and which settled with intravenous (IV) antibiotics. He concluded it was, therefore, *'unlikely*' there was any deep infection at the time of the hip replacement. Further, it was '*unlikely'* the complainant's later infection was caused by any underlying infection present at the time of the hip replacement; however, in the absence of the expected sample tests, *'it would be difficult to confirm [this] with absolute certainty'.*

56. I consider the records indicate, whilst the surgeon who performed the procedure on 10 November 2020 did not sign the consent form, he discussed and explained the procedure with the complainant on 2 November 2020. This discussion included relevant risks and benefits in line with those detailed in the BOA Guidance. I accept the CO IPA's advice the operating surgeon provided the complainant with the required information about the surgery, and this was in line with the GMC Decision and Consent Guidance. Further, the Trust did not omit any actions in managing the decision and consent process for this procedure. Therefore, I am satisfied the Trust appropriately managed the decision and consent process in line with the GMC Decision and Consent Guidance.

57. I accept the CO IPA's advice, when the Trust reviewed the complainant on 2 November 2020, the presentation of her hip at that point, and on which the Trust based the decision to perform a hip replacement, represented a '*recognised complication'* of the original procedure. I consider this reflects the BOA Guidance. I also accept the CO IPA's advice the decision to perform the hip replacement was '*appropriate and reasonable'*; the Trust '*correctly*' performed the surgery; and the Trust provided appropriate post-operative care, including *'satisfactory'* post-operative x- rays and follow-up review.

58. I accept the CO IPA's advice that the Trust's failure to send samples to check for an underlying infection, when it identified the fixation had failed, was *'incorrect'*. Therefore, I am satisfied this constitutes a failing in care and treatment and uphold the aspect of the complaint relating to the lack of testing to ensure infection did not play a role in the failure of the fixation procedure.

Detail of Complaint

ii. Care and treatment 28 to 30 November 2020

59. The complainant said, a couple of weeks after her hip replacement, she attended her general practitioner (GP) as her wound was '*weeping*' and she was then re-admitted to AH for another period of three days.

Evidence Considered

Legislation/Policies/Guidance

60. I considered the BOA Guidance.

Relevant records

61. I considered the complainant's records from 28 to 30 November 2020.

Relevant Independent Professional Advice

62. The CO IPA provided advice about the treatment of the complainant's wound infection during the period of care and any causal link to the operations of 18 September and 10 November 2020. The full CO IPA's advice is at Appendix three to this report.

Analysis and Findings

63. The complainant's records indicate the Trust prescribed 2g IV Flucloxacillin[11] to the complainant. The prescription stipulated administration four times per day. This antibiotic's use includes treatment of skin and wound infections. The Trust administered the first dose at 22:00 on 28 November 2020, with four doses on 29 November 2020 and two doses on 30 November 2020 at 06:00 and 10:00. I note AH admitted the complainant to the ward at 22:00 on 28 November 2020 and discharged her on 30 November 2020. The records indicate the Trust discharged the complainant with an ongoing prescription until 6 December 2020 of Flucloxacillin, with a planned review on 22 December 2020.

64. I refer to the BOA Guidance which states, '*deep wound infection'* is a serious complication, which occurs in up to five percent of cases, and which can lead to death or significant loss of permanent mobility. Treatment requires deep cleaning of the wound and sometimes removal of the implant. I note the BOA Guidance also states, '*superficial wound'* infection is *'more common'* with effective treatment using antibiotics and, if required, deep cleaning of the wound.

[11] Flucloxacillin is an antibiotic used to treat skin and wound infections, among other infections.

65. The CO IPA explained, following several days' treatment of oral antibiotics which the complainant's GP prescribed, the complainant presented to AH ED on 28 November 2020 with a *'wound infection around the left hip replacement'.* She was admitted to AH at this time. The CO IPA advised, initial assessment indicated it might be a '*deep infection'* which would require a theatre '*washout'*, to which the complainant consented. The CO IPA further advised, however her symptoms settled with IV antibiotics; therefore, it was '*likely*' to be a *'superficial wound infection*'. The CO IPA explained the complainant was discharged from AH with oral antibiotics and a review planned for three weeks later. The CO IPA advised the wound infection required prompt intervention which the Trust provided. Further, whilst the wound infection occurred because the complainant had surgery, '*infection is a well-recognised … complication of hip replacement surgery'* with a higher risk associated with a second procedure, as in this case. I note the CO IPA advised the care given between 28 and 30 November 2020 was '*appropriate'.* I also refer to the CO IPA's advice at paragraph 55 it was '*unlikely*' this infection stemmed from any previously undiagnosed infection from the time of the hip replacement. However, because the Trust did not carry out sample tests at that time, this could not be determined.

66. I consider the complainant's records indicate, when she presented to AH ED on 28 November 2020, the Trust assessed her as having a wound infection. I consider the records indicate the Trust considered a deep clean of the wound as a possible treatment for the infection, should the infection be '*deep'* and for which the complainant gave consent. I consider this is in keeping with the BOA Guidance.

67. I consider the records indicate the Trust commenced treatment of the infection with an IV antibiotic of a type associated with wound infections. I consider the records indicate the Trust administered this in line with the prescription and it scheduled a review three weeks after the complainant's discharge. I consider the BOA Guidance indicates a wound infection is an expected risk of hip surgery, with antibiotics suggested as an effective treatment when the infection is not deep. I accept the CO IPA's advice, although the Trust planned for a

possible deep clean of the wound, the complainant's symptoms settled with the IV antibiotics; therefore, it was *'likely'* to be a *'superficial wound infection'.* Further, I accept the CO IPA's advice, although it was '*unlikely'* her infection began before 10 November 2020, this could not be determined because the Trust did not carry out tests for infection at the time of the procedure on 10 November 2020. I also accept the CO IPA's advice the Trust provided appropriately prompt intervention for the infection which is '*a well-recognised … complication of hip replacement surgery'.* Therefore, I am satisfied the care and treatment the Trust provided between 28 and 30 November 2020 was appropriate and do not uphold this element of the complaint.

CONCLUSION

68. I received a complaint about the care and treatment the Trust provided the complainant during three periods of care from 18 September to 30 November 2020. I upheld aspects of the complaint.

69. The investigation has established:
    - The Trust failed to act in accordance with national standards and guidance in undertaking the consent process with the complainant in relation to her first operation on 18 September 2020;
    - The Trust failed to both inform the complainant about protected weight-bearing and perform lateral view x-rays after the procedure on 18 September 2020;
    - The Trust failed to maintain appropriate records of either the review of the complainant's x-ray of 20 September 2020 or any consequential decisions and actions; and
    - The Trust did not test for evidence of infection to verify that infection was not the cause of the failure of the first operation.

70. The investigation concluded that the decisions to perform both operations were appropriate and timely and the Trust performed these procedures correctly. The investigation also established the Trust appropriately managed the consent process for the hip replacement procedure of 10 November 2020 and the

Trust’s care and treatment during the third period of the complainant’s care from 28 to 30 November 2020 was appropriate.

Recommendations

71. I recommend the Trust provides the complainant with a written apology in accordance with NIPSO’s ‘Guidance on issuing an apology’ (July 2019), for the injustices caused because of the failures identified (within **one month** of the date of this report).

72. I recommend the Trust should remind relevant staff of the importance of the GMC Guidance, paragraphs 45, the GMC Decision and Consent Guidance, paragraphs 42 to 45 and the BOA Guidance. These should be evidenced by records of information sharing and/or training.

73. I recommend the Trust reviews the arrangements to ensure there is adequate senior cover in this department in consideration of GMC Decision and Consent Guidance. This should be evidenced by documented records of the review and copies of any amended policies or guidance.

74. I recommend the Trust should remind relevant staff of the importance of GMC Guidance, paragraph 70. This should be evidenced by records of information sharing and/or training. Further, I recommend the Trust undertakes a sample audit in this department related to the documentation of review of scans and investigations and consequent decisions and actions. The Trust should take action to address any identified trends or shortcomings and provide this Office with an update of findings and corrective actions as appropriate.

75. I recommend the Trust undertakes a sample audit in relation to the testing of samples for infection when fixations or similar procedures fail. The Trust should take action to address any identified trends or shortcomings and provide this Office with an update of findings and corrective actions as appropriate.

76. I further recommend the Trust should ensure relevant staff are given the opportunity to reflect on the findings of this report and the full CO IPA’s advice in consideration of their own practice. This should be discussed at staff’s next

appraisal and noted in appraisal documentation. This should also be evidenced by records of information sharing.

77. 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 staff read and understood any related policies).

78. I recognise the complainant found her experience distressing, with her ongoing pain impacting on her daily life. I hope, however, this report provides her with reassurance that the decisions to carry out the operations and how the Trust carried out these procedures were appropriate.

79. I note the Trust's engagement with the complainant on an ongoing basis in relation to the management of her pain, with particular reference to the area around her wound and scar.

MARGARET KELLY
Ombudsman

26 March 2024