Northern Ireland
Public Services
Ombudsman

Investigation Report

Investigation of a complaint against Belfast Health & Social Care Trust

NIPSO Reference: 202000029

The Northern Ireland Public Services Ombudsman
33 Wellington Place
BELFAST
BT1 6HN
Tel: 028 9023 3821
Email: nipso@nipso.org.uk
Web: www.nipso.org.uk

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 2 – The Principles of Good Complaints Handling

Case Reference: 202000029

Listed Authority: Belfast Health & Social Care Trust

SUMMARY

I received a complaint about the actions of the Belfast Health and Social Care Trust (the Trust). The complaint is about the care and treatment the Knockbreda Health and Wellbeing Centre (Sexual and Reproductive Clinic) provided to the complainant's daughter (the patient) on 9 October 2019. The complainant said that when removing the patient's Nexplanon[1] implant the nurse asked the patient questions about her sexual health, and the reasons for wanting the implant removed. The complainant believed this made the patient feel uncomfortable. The complainant said that the Doctor also asked the patient for the reasons for wanting the contraceptive implant removed. The complainant also said that the Doctor did not wait for the anaesthetic to work before beginning the procedure to remove the implant from the patient. He also raised further concerns about the Doctor's failure to use an antiseptic prior to the beginning the removal procedure.

The investigation examined the details of the complaint, the Trust's response, and relevant internal guidance and national standards. I also sought advice from an Independent Clinical Advisor (IPA). The investigation established the Trust carried out the correct procedure on 9 October 2019 to remove the Nexplanon implant from the patient. The investigation also established that there was a service failure in the record keeping by the Trust. I asked the Trust to reflect on action to prevent the failure recurring.

[1] Birth control implant inserted into arm of patient.

THE COMPLAINT

1. I received a complaint about the actions of the Belfast Health and Social Care Trust (the Trust). The complainant is about the care and treatment the Knockbreda Health and Wellbeing Centre (Sexual and Reproductive Clinic) provided to the complainant's daughter (the patient) on 9 October 2019 in relation to the removal of a Nexplanon implant.

Issue of complaint

2. The issue of complaint accepted for investigation was:

   Whether the care and treatment provided to the patient in relation to the removal of a Nexplanon implant on 9 October 2019 was appropriate and in accordance with relevant procedures and standards.

INVESTIGATION METHODOLOGY

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

Independent Professional Advice Sought

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

   - **General Practitioner**, MRCGP MBBS BDS FDS RCS DFSRH (LoC IUD &SDI)

   The IPA is a registered GP that holds a Letter of Competence in Intrauterine[2] Techniques and Subdermal Contraceptive Implant Techniques.

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

[2] Intrauterine means 'inside the uterus'. An intrauterine device is also known as a contraceptive device or coil that is inserted into the uterus to prevent pregnancy.

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

Relevant Standards and Guidance

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

   The general standards are the Ombudsman's Principles[3]:

   - The Principles of Good Administration
   - The Principles of Good Complaints Handling

7. The specific standards and guidance referred to are those that 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 (GMC) Good Medical Practice, as updated April 2014 (the GMC Guidance);
   - Faculty of Sexual and Reproductive Health Clinical Guidance: Progestogen-only Implants (February 2014) (FSRH Guidance); and
   - NICE Guidance NG125 Surgical site infections: Prevention and treatment (NICE Guidance).

8. I did not include all of the information obtained in the course of the investigation in this report but I am satisfied that everything that I consider to be relevant and important was taken into account in reaching my findings.

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

9. A draft copy of this report was shared with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations.

THE INVESTIGATION

Whether the care and treatment provided to the patient in relation to the removal of a Nexplanon implant on 09 October 2019 was appropriate and in accordance with relevant procedures and standards.

In particular, this will consider:

- Communication about the procedure.
- The administration of an anaesthetic.
- The use of an antiseptic.

Detail of Complaint

10. The complainant said the Doctor and Nurse both questioned the patient regarding her sexual health, and reasons for wanting the implant removed. The patient said this made her feel uncomfortable.

11. The complainant said that the Doctor did not use an antiseptic during the removal of the patient's implant, and did not check if the anaesthetic had taken effect before making an incision. The complainant said the Doctor continued the procedure despite the patient stating the procedure was causing her pain. He also said the patient cried out in pain.

Evidence Considered

Legislation/Policies/Guidance

12. I considered the following policies and guidance:

- The GMC Guidance;
- The FSRH Guidance; and
- NICE Guidance.

Relevant sections of the guidance are enclosed at Appendix four to this report.

The Trust's response to investigation enquiries

Communication about the procedure.

13. The Trust said that the Nurse recalled that her consultation with the patient covered routine topics, such as previous sexual history. The Trust stated: *'[the Nurse] was not aware of any evidence that [the patient] was upset or distressed by this interaction'*. The Trust also stated, *'[the Nurse] also notes that, in the best interest of the patient, it is important to take a thorough history and discuss all topics required to ensure best care is provided'*.

14. The Trust stated, *'[the Nurse] has advised that on reviewing [the patient's] notes it was recorded that she had been advised, at a visit to [another clinic], to attend genitourinary medicine services'*. The Trust said, *'it is good nursing practice to follow up on previous planned or suggested treatments.'* The Trust also stated, *'[the Nurse] advises that regular screening is encouraged as part of good sexual health and that health promotion is an integral part of the role of all staff in sexual and reproductive health services'*.

15. The Trust stated that the Nurse advises enquiring why the patient wanted a contraceptive implant removed is *'a component of the history taking required when a request to remove and implant is made'.* The Trust said, *'staff would routinely check the reasons for the request, and plans for future contraception, to ensure the patient is making an informed choice about their treatment'*.

16. The Trust stated that the usual clinical procedure at that time was to see the patient at the drop-in clinic, discuss any problems and agree a course of action. A further appointment would then be arranged with the patient for the removal of an implant. The Trust said because the patient was not able to attend twice, the Trust was aiming to accommodate the patient and complete the consultation and remove the implant at this appointment. The Trust stated, *'[the Doctor] has advised that patients often request removal of an implant due to underlying health reasons and on many occasions, the patient finds the removal of the implant does not resolve their underlying health condition.'* The

Trust also stated, *'it is vital that there is a thorough discussion prior to an implant being removed'*.

The administration of an anaesthetic.

17. The Trust explained, *'It would be standard practice to wait a few minutes and then test the injected area with the tip of a needle or tip of the Nexplanon introducer prior to attempted insertion.'* The Trust stated, *'[the Doctor] advises that she waited for more than one minute prior to making the incision in [the patient's] arm. [The Doctor] advises that the procedure lasted approximately two minutes and she does not recall [the patient] complaining of pain or discomfort'.*

The use of an antiseptic.

18. The Trust said, *'[The Doctor] has described how she followed the protocol for implant removal using a sterile swab and waiting more than one minute before making a small incision into [the patient's] arm'*. The Trust said, *'it is standard practice to use a simple chlorhexidine wipe prior to venepuncture for aseptic technique and that would not usually be documented in the patient's notes.'*

Relevant Trust records

19. The patient's medical records document that the patient attended Sexual & Reproductive Clinic at the Knockbreda Health & Wellbeing Centre on 09 October 2019 for a removal of an implant.

20. The patient's medical record documents that 2 ml 1% Lidocaine HC1[4] was used as a local anaesthetic for the procedure. Batch number and expiry date of the anaesthetic was included within the medical notes.

Relevant Independent Professional Advice

Communication about the procedure.

21. The IPA advised that it is standard practice at a preliminary stage that information is taken from the patient prior to removal of the contraceptive

[4] Type of local anaesthetic.

implant. This information includes; age, previous contraception used and problems encountered, menstrual history, any serious illness/gynaecological problems/surgery, coital and sexual history.

22. The IPA advised it is common practice to ask the patient for the reasons for wanting an implant removed. The IPA also advised that the doctor needs to illicit the patient's own ideas, concerns or expectations prior removal of the implant.

23. The IPA advised, *'during the assessment for sexual health services a preliminary history/checks taken by the nurse may well be repeated for verification by the Dr/clinical operator. It is usual and expected good clinical care to enquire about sexual health in detail'*.

The administration of an anaesthetic.

24. The IPA advised that a waiting time of one minute is an appropriate waiting time for checking if the anaesthetic had taken effect. The IPA advised the procedure *'still required a prior check with the patient and if they were experiencing pain the procedure would be delayed and additional analgesia may be given if needed an another 1min of waiting instituted before another attempt at procedure.'* The IPA also advised that she would not document an anaesthetic check with the patient within the procedure notes. However, the IPA would confirm verbally with the patient that the area was fully anaesthetised. The IPA advised that she would ensure *'the patient was agreeable to the continuation and completion of the procedure'*.

25. The IPA advised, *'it isn't a failing that the analgesia check was not documented, it is not a Faculty (FRSH) requirement in documentation but there is an expectation that a check would have been done verbally and the area was anaesthetised'*.

26. The IPA advised, *'there is no clear description from the notes supplied a detailed description of the procedure from start to finish but this is a factor of the software used at the clinic and perhaps a free text box could have been used to circumnavigate this'*.

27. The IPA advised on some recommendations the Trust could reflect on in order to allow a record of a more detailed description. These recommendations are enclosed in the IPA's advice at Appendix three to this report.

The use of an antiseptic.

28. The IPA advised, *'the sterile swab on its own would not constitute appropriate disinfection unless it was soaked in a disinfectant or antiseptic solution.'* The IPA advised, *'if it was used as an antiseptic then it should have been documented in the notes'*.

29. The IPA concluded, *'this is a rather unfortunate example of communication breakdown in a very straight forward procedure. The patient has a strong sense that she was judged and disrespected but the doctor and nurse says that was not their intention'*.

Analysis and Findings

30. I examined the Trust's care and treatment provided to the patient on 9 October 2019 for the removal of a Nexplanon implant.

Communication about the procedure.

31. I note the complainant believed the patient was made to feel uncomfortable by the Trust staff for being asked questions about her sexual health, and reasons for wanting the implant removed. I note the Trust said that the Nurse covered routine topics with the patient such as previous sexual history. I note the Trust also said the nurse was not aware of any evidence that the patient was upset or distressed by this interaction. I also note the Trust said *'in the best interest of the patient, it is important to take a through history and discuss all topics required to ensure best care is provided.'* I note the Trust said that enquiring why a patient wants an implant removed is *'a component of the history taking required when a quest to remove an implant is made'*.

32. I note that FRSH Guidance states, *'the reasons for requesting implant removal should be discussed with each individual patient'*. I note the IPA's advice that it is standard practice that detailed information is taken from a patient prior

implant removal. I also note that the IPA advised it is usual and expected good clinical care to enquire about sexual health in detail, and that these checks that are taken by the nurse may well be repeated by the doctor for verification. I accept the IPA's advice on this matter, and I am satisfied that the Trust staff appropriately asked the patient questions relating to her sexual health and reasons for wanting the implant removed. After consideration of all the evidence available to me I do not uphold this element of the complaint.

The administration of an anaesthetic.

33. I note the complaint said the doctor performed the procedure on the patient without checking that the anaesthetic had worked. I note the complainant said this caused the patient to cry out in pain. I note the Trust said the doctor waited for more than one minute prior to making the incision in the patient's arm. I also note the Trust advised that the procedure lasted approximately two minutes and the doctor does not recall the patient complaining of pain or discomfort.

34. I note that patient medical records for 9 October 2019 documents that 2mls 1% Lidocaine HCL of local anaesthetic was used. FRSH Guidance February 2014 documents *'The insertion site should be anaesthetised using lidocaine 1%*.' No comment is made in the patient's medical records on how the anaesthetic was administered.

35. I note that the Trust said, *'it would be standard practice to wait a few minutes and then test the injected area with the tip of a needle or tip of the Nexplanon introducer prior attempted insertion'*. I note that FSRH Implants Guidance states: *'The point of a needle should be used to check that adequate analgesia has been provided.'*

36. I note and accept the IPA's advice that the Trust's procedure in the administration of the anaesthetic was correct. The IPA also advised that the Trust's waiting time of one minute for the anaesthetic to take effect was appropriate.

37. I have no reason to disbelieve the complainant that the patient experienced pain during this procedure. I note that the IPA advised verbal confirmation

would be required from the patient, and an assumption is made that the skin would have been checked verbally with the patient before proceeding the incision. However this check is not documented by the Trust within the patient's medical records. It is not a failing that this verbal confirmation is not documented, and it is not an FRSH requirement to record this information. After consideration of all evidence available to me, I do not consider there was a failing in the care and treatment.

38. Although I did not identify a failing about this matter I note that the IPA advised there is no clear description from the patient's notes of the procedure from start to finish. The IPA has suggested some learning improvements, and I will refer to this further in the conclusion of this report.

Use of an antiseptic

39. I note the complainant said that the doctor did not use an antiseptic prior to commencing the procedure to remove the implant. I note that FRSH Guidance states, *'the insertion/removal site should be cleaned with antiseptic solution'*. I note that the Trust in its response to the complainant dated 12 October 2020 said that a sterile swab was used during the implant removal procedure. I also note that the Trust said in its correspondence to this Office on 28 September 2021 *'it is standard practice to use a simple chlorhexidine wipe prior to venepuncture for aseptic technique and that would not usually be documented in the patient's notes'*. I note that the NICE Guidance states *'0.5% chlorhexidine in 70% alcohol solution was licensed for 'preoperative skin disinfection prior to minor surgical procedures''*.

40. I note the use of an antiseptic is not documented within the medical records. I note the GMC guidance: *'clinical records should include: relevant findings, the decisions made and actions agreed, and who is making the decisions and agreeing the actions, information given to patients, any drugs prescribed or other investigation or treatment'*. I note the IPA advised that a sterile swab on its own would not constitute appropriate disinfection unless it was soaked in a disinfectant or antiseptic solution.

41. I note the complainant said no antiseptic was used in this instance, and the Trust maintains that an antiseptic was used. The NICE Guidance indicates that the type of antiseptic the Trust used was appropriate for use in this type of procedure. I note there is no record of the type of antiseptic used within the Trust's notes, and the IPA advised that it should be documented. As there are conflicting accounts on whether an antiseptic was used I am unable to determine whether an antiseptic was used in this case. However I am satisfied there is a service failure in the record keeping in this instance as it is not documented if an antiseptic was used. For this reason I partially uphold this element of the complaint.

CONCLUSION

42. I received a complaint about the care and treatment the patient received from the Trust relating to the removal of a Nexplanon implant on 9 October 2019.

43. The investigation of the complaint did not find a failure in the Trust's care and treatment of the patient. However the investigation established that the recording of the removal procedure in this instance fell below the expected standards. The IPA concluded that as a service improvement better software interface could be introduced. This would allow more description to be added to the patient's medical records to include details of the procedure, its checks and balances and documented patient consent and contentment with the procedure. The IPA recommended a consent form to be introduced that states: *'despite good intentions, discomfort may be felt during the procedure and the patient should declare this clearly and verbally with the clinician*'. I would ask the Trust to reflect on this. I would also ask the Trust to reflect on including the use of an antiseptic during procedures within the patient's medical records.

44. I wish to highlight the IPA's observation as a service improvement in relation to appointment bookings. The IPA recommended that a text or written documentation should accompany the appointment booking as a reminder of the appointment time and date and the conditions under which the patient will be received.

45. I recognise this was not a pleasant experience for the patient and the IPA has acknowledged that. The IPA concluded *'this is a rather unfortunate example of communication breakdown in a very straight forward* procedure'. I hope this report goes some way to address the patient's concerns. I recognise the complainant may not totally agree with all of my conclusions. However, I wish to reassure him that I reached them only after full consideration of the facts of this case.

MARGARET KELLY
Ombudsman **January 2022**

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

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

2. Being customer focused

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

3. Being open and accountable

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

4. Acting fairly and proportionately

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

5. Putting things right

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

6. Seeking continuous improvement

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

Appendix 2

PRINCIPLES OF GOOD COMPLAINT HANDLING

Good complaint handling by public bodies means:

1. **Getting it right**

   - Acting in accordance with the law and with regard for the rights of those concerned.

   - Ensuring that those at the top of the public body provide leadership to support good complaint management and develop an organisational culture that values complaints.

   - Having clear governance arrangements, which set out roles and responsibilities, and ensure lessons are learned from complaints.

   - Including complaint management as an integral part of service design.

   - Ensuring staff are equipped and empowered to act decisively to resolve complaints.

   - Focusing the outcomes for the complainant and the public body.

   - Signposting to the next stage of the complaints procedure in the right way and at the right time.

2. **Being customer focused**

   - Having clear and simple procedures.

   - Ensuring that complainants can easily access the service dealing with complaints, and informing them about advice and advocacy services where appropriate.

   - Dealing with complainants promptly and sensitively, bearing in mind their individual circumstances.

   - Listening to complainants to understand the complaint and the outcome they are seeking.

   - Responding flexibly, including where appropriate co-ordinating responses with any other bodies involved in the same complaint, where appropriate.

3. **Being open and accountable**

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

- Publishing service standards for handling complaints.

- Providing honest evidence-based explanations and giving reasons for decisions.

- Keeping full and accurate records.

4. Acting fairly and proportionately

- Treating the complainant impartially, and without unlawful discrimination or prejudice.

- Ensuring that complaints are investigated thoroughly and fairly to establish the facts of the case.

- Ensuring that decisions and actions are proportionate, appropriate and fair.

- Ensuring that complaints are reviewed by someone not involved in the events leading to the complaint.

- Acting fairly towards staff complained about as well as towards complainants

5. Putting things right

- Acknowledging mistakes and apologising where appropriate.

- Providing prompt, appropriate and proportionate remedies.

- Considering all the relevant factors of the case when offering remedies.

- Taking account of any injustice or hardship that results from pursuing the complaint as well as from the original dispute.

6. Seeking continuous improvement

- Using all feedback and the lessons learnt from complaints to improve service design and delivery.

- Having systems in place to record, analyse and report on learning from complaints.

- Regularly reviewing the lessons to be learnt from complaints.

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