Northern Ireland
Public Services
Ombudsman

Investigation Report

Investigation of a complaint against Belfast Health & Social Care Trust

NIPSO Reference: 201917138

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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

The complaint concerned the care and treatment the Belfast Health and Social Care Trust (the Trust) provided to the complainant (the patient) in relation to the replacement of her pacemaker.

The patient cited a number of concerns related to the pacemaker replacement. She said that, both because she was informed that as it was her third pacemaker procedure there were higher risks and a Consultant Cardiologist was named on her appointment documentation, she expected that a Consultant Cardiologist should have carried out the operation. The patient also said that, during the procedure, medical staff discussed the approach to be taken about the pacemaker leads. The patient noted her concern about this discussion and whether she should have been consulted and informed about the discussion outcome. The patient also said that the Trust Cardiology Associate Specialist positioned the new pacemaker in a different position from her previous one and that this caused her discomfort and that the Trust Cardiology Associate Specialist told her *'to make sure that the pacemaker did not flip'* which caused the patient additional stress and anxiety. The patient said that the Trust denied that the pacemaker was in a different position. The patient also said that the Trust stated both that the device would not flip and that the patient had not been told that it might. The patient also said that the Trust did not appropriately address the questions and concerns contained within her written complaints of 20 December 2019 and 15 June 2020.

There were elements of the complaint that the investigation did not uphold. The investigation, however, established that there was a failure in care and treatment because the Trust failed to obtain consent for the procedure in accordance with the General Medical Council's Guidance: *Consent: patients and doctors making decisions together.* The investigation also found that, in dealing with the patient's written complaints of 20 December 2019 and 15 June 2020, the Trust did not provide answers to and address all her queries and concerns. The investigation established that the Trust provided a written response to only one of the queries and concerns raised in the patient's two complaint letters.

The investigation established that, as a result of the failings identified, the patient did not have the opportunity: - for timely consideration of her options in making a decision, to ask questions and clarify concerns and to be provided with additional information about the procedure, those involved in it, the decisions made about the leads and the implications of these decisions. The investigation also established that the patient experienced worry, uncertainty and frustration as she did not have her concerns appropriately addressed.

I made four recommendations, including an apology to the complainant for the failings identified. I also recommended that the Trust provides a full written response and detailed information to the patient about those involved in the procedure; and clear information about the discussions during the procedure, the decisions made and the reasons for these and the correlation between these decisions and ongoing issues with the patient's pacemaker leads. I also recommended that the Trust ensures that relevant staff are reminded of the importance of the GMC Consent Guidance, particularly in relation to: - the timing of consent; and providing information to the patient about who will be involved in the treatment, what will happen in the procedure and, where decisions about the course of action are to be made during the procedure, the outcomes of these decisions and any associated impact on the patient. I have recommended that the Trust should provide evidence of how these staff have reflected on this and how they can improve their practice in the future. I also recommended that the Trust should share the findings in this report with relevant staff about how the Trust responded to and addressed the patient's written complaints and the concerns and queries therein. I recommended that the Trust should provide a record of the information-sharing.

THE COMPLAINT

1. I received a complaint about the actions of the Belfast Health and Social Care Trust (the Trust). The complaint related to the care and treatment associated with the replacement of the patient's pacemaker and to the Trust's actions when she raised concerns.

Issues of complaint

2. The issues of complaint accepted for investigation were:

Issue 1: Whether the care and treatment the Trust provided to the patient between 13 August 2019 and 9 November 2020 was appropriate, reasonable and in accordance with relevant policies and standards.

Issue 2: Whether the clinical responses which were provided by the Trust to the patient's questions were appropriate and reasonable.

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 complainant's issues. This documentation included information relating to the Trust's handling of the complaint.

Independent Professional Advice Sought

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

- Consultant Cardiologist MD FRCP LLM RCPathME; with 29 years' experience as a Consultant Cardiologist and career-long experience in the management of patients with a permanent pacemaker in situ.

The professional advice received is enclosed at Appendix four 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 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[1]:

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

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:

- General Medical Council (GMC) Guidance: Consent: patients and doctors making decisions together, June 2008 (GMC Consent Guidance);
- British Heart Rhythm Society (BHRS) Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults, January 2018 (BHRS Standards);
- Belfast Health and Social Care Trust Integrated Care Pathway for Cardiology Device Procedure, October 2016 (Trust Cardiology Device Procedure);
- Department of Health Guidance in Relation to the Health and Social Care Complaints Procedure, April 2019 (DoH HSC Complaints Procedure); and

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

- Belfast Health and Social Care Trust Consent form for Examination, Treatment or Care, October 2011 (Trust Consent Form).

Where appropriate, relevant extracts from the guidance considered are enclosed at Appendix three to this report. Appendix three also includes the full BHRS Standards and the Trust Consent Form.

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

THE INVESTIGATION

Issue 1: Whether the care and treatment the Trust provided to the patient between 13 August 2019 and 9 November 2020 was appropriate, reasonable and in accordance with relevant policies and standards.
In particular:

- The care and treatment which was planned at the Pacing and Implantable Cardioverter Defibrillator Clinic (ICD) on 13 August 2019;
- The procedure on 24 September 2019 to replace the Pacemaker; and
- The care and treatment provided to the patient in the period from when she expressed concerns on 28 November 2019 to the further replacement of the pacemaker on 9 November 2020.

Detail of Complaint

9. The patient said that a Consultant Cardiologist (TCC) did not carry out the procedure to replace her pacemaker, even though she was told that, as this was her third pacemaker procedure, there were higher risks. The patient said that the Trust Cardiology Associate Specialist (TCAS) positioned the pacemaker in a different place from her previous pacemakers and that this caused her both discomfort and anxiety but that the Trust stated that the pacemaker was in the same position as previous pacemakers.

10. The patient also said that, during her procedure, there were discussions among medical staff about the pacemaker leads but that she did not know what this discussion was about and she was not consulted in relation to this discussion.

11. The patient said that the TCAS told her to *'make sure that the pacemaker did not flip*' and that this caused additional stress and worry for her. The patient also said that the Trust staff denied both that the pacemaker would flip and that the patient had been told that it would.

12. The Trust subsequently carried out a procedure to reposition the pacemaker on 9 November 2020.

Evidence Considered

Legislation/Policies/Guidance

13. I considered the GMC Consent Guidance, the BHRS Standards and the Trust Consent Form. Relevant extracts are enclosed at Appendix three.

The Trust's response to investigation enquiries

14. As part of investigation enquiries, the Trust was provided with an opportunity to respond to the complaint.

The care and treatment which was planned at the Pacing and Implantable Cardioverter Defibrillator Clinic (ICD) on 13 August 2019

15. The Trust stated that when it is identified that a pacemaker should be replaced, patients are placed on a waiting list. The Trust stated that patients are assigned an operator with the next available theatre list based on clinical urgency and chronological order.

The procedure on 24 September 2019 to replace the Pacemaker

I. The competence of the TCAS

16. The Trust stated that the doctor who carried out the replacement procedure is a Cardiology Associate Specialist and is not a trainee. The Trust stated that the TCAS had more than ten years' experience in device implantation. The Trust referenced the BHRS Standards and stated that staff are authorised to perform a procedure based on the number of procedures that individual carried out on annual basis, following appropriate training. The Trust further stated that, in addition, an individual must work in a centre with a minimum of two implanting cardiologists and a minimum total implant number for that centre. The Trust stated that in the year in question (1 April 2019 to 31 March 2020), the TCAS performed 311 pacemaker procedures and in this same period, the Trust undertook 2073 pacemaker procedures. The Trust further stated that the TCAS is appraised and revalidated in line with GMC recommendations.

II. The procedure

17. The Trust stated that the procedure on 24 September 2019 went smoothly with no complications. The Trust stated that the pacemaker leads were checked for fractures but there were none and the sensing parameters were checked and these were all satisfactory. The Trust stated that the patient's wound was checked before her discharge with all parameters satisfactory.

III. The position of the replacement pacemaker

18. The Trust stated that the patient's discharge summary of 24 September 2019 records that the '*incision was made on [the patient's] old scar … the existing dual chamber pacemaker was explanted and a new pacemaker implanted into the left pre-pectoral pocket*.'

19. The Trust stated that on 9 November 2020, when a further procedure was carried out to re-site the pacemaker at the patient's request, it was recorded that, '*a new deeper sub-pectoral pocket was created to house the same generator and leads*.'

The care and treatment provided to the Patient from when she expressed concerns on 28 November 2019 to the further replacement of the pacemaker on 9 November 2020

20. The Trust stated that, when the patient expressed concerns, the Trust's Lead Cardiology Clinical Physiologist (TCCP) arranged an urgent review with the TCC. The Trust stated that the TCC, and the TCAS who carried out the procedure, both met with the patient at this appointment and addressed each of the patient's five concerns. The Trust stated that the concerns expressed and addressed were that the replacement device was more prominent; the patient was worried that the device might flip; the patient had a painful left scapula, which the Physiotherapist informed the patient was related to her pacemaker; and the device was not sitting in the same place. The Trust provided records of, and referenced, the TCC's examination of the patient's pacemaker site at this appointment on 4 December 2019. The Trust stated that it is recorded that the TCC, "*examined [the patient's] pacemaker area and confirmed that the wound is well healed. There was no evidence of any other wound to indicate that the device has not been placed in the same area."*

21. The Trust stated that the TCC's clinical assessment was that the risk to the patient to reopen the pocket for a new device outweighed any potential benefits.

22. The Trust stated that, on 19 March 2020, another Trust Consultant Cardiologist (TCC B) met with the patient and explained to the patient that a repositioning might not resolve her discomfort and carried potential risk of infection. The Trust further stated that at a review, held on 24 September 2020, TCC B agreed with the patient to proceed with repositioning despite clinical assessment of risks '*in the hopes of satisfying the patient's needs.'*

Relevant records

23. I considered the patient's records from the period 13 August 2019 to 20 November 2020.

Relevant Independent Professional Advice

The care and treatment which was planned at the Pacing and Implantable Cardioverter Defibrillator Clinic (ICD) on 13 August 2019

24. The CC IPA advised that, on 13 August 2019, the '*contemporaneous clinical record'* of the patient's attendance at the Trust clinic highlighted potential problems related to the pacemaker's leads. The CC IPA advised that, at this clinic, it was planned to replace the pacemaker and that this *'was appropriate and reasonable.'*

25. The CC IPA advised that, although the consent form for the procedure was *'completed appropriately in terms of the disclosure of risks, however it was signed on the day of the procedure itself. This is not in accord with GMC guidelines on consenting … in which it is recommended that the consenting process should incorporate that the treatment options are explained, including who will be involved in the treatment and that this information should be shared in a place and at a time when the patient is best able to understand and retain it and gives the patient time to reflect, before and after they make a decision. The guidelines state that the patient should be given the time and support they need to maximise their ability to make the decisions for themselves and consider all the options and to ask questions. In practice, this so-called cooling off period should be at least 24 hours and so the evidence would suggest that a consenting process initiated "on the day" in this case fell below an acceptable standard.'*

26. The CC IPA concluded that '*many of the [patient's] concerns related to her expectations of the procedure in September 2019'*. He further advised that as the patient '*was consented for this planned procedure on the same day. This is unsatisfactory'* and '*outside GMC guidance'*. The CC IPA advised that the patient's '*concerns and expectations might have been better clarified with full and documented preoperative discussion. This particularly relates both to the issue of whether the leads would need replacing (rather than explanting) and who would be involved in her procedure. Discussion around how the leads would be checked during the procedure, the actions taken in specific*

circumstances and the key medical staff performing the procedure, would have been helpful.'

The procedure on 24 September 2019 to replace the Pacemaker

I. The competence of the TCAS

27. The CC IPA advised that it was appropriate for the TCAS to perform the procedure. He advised that the TCAS' and the Trust's volume of activity exceeded the requirements of the related BHRS Standards.

28. The CC IPA advised that the consent form stated that the patient understands that whilst the individual obtaining consent cannot, '*guarantee that a particular person will perform the procedure … The person will however have appropriate experience'.*

II. The procedure

29. The CC IPA advised that the procedure on 24 September 2019 was undertaken to an acceptable standard. He further advised that '*due care and attention was paid to the possibility that the leads may need replacing. Appropriate measures were taken during the procedure to investigate this and it was decided that replacement was not required.'*

30. The CC IPA advised that *'there is a contemporaneous written record of the procedure on 24 September 2019.'* He advised that the clinical steps taken during the procedure were detailed and that these *'were all appropriate'.* The CC IPA advised that the outcome was that the *'same leads'* were to be used. The CC IPA advised that discussion with the patient during this procedure *'cannot be undertaken'.*

III. The position of the replacement pacemaker

31. The CC IPA advised that the pacemaker was placed in the same position as the previous device. The CC IPA also advised that the device was placed in a

new position from the siting of previous pacemakers at the follow-up procedure on 9 November 2020.

The care and treatment provided to the patient from when she expressed concerns on 28 November 2019 to the further replacement of the pacemaker on 9 November 2020

32. The CC IPA advised that he could not comment on whether the TCAS had told the patient to make sure that the pacemaker did not flip as there were '*no contemporaneous records of a discussion about this'.* He further advised, however, that '*this possibility was felt to be highly unlikely when the [patient] was reviewed after the procedure.'*

33. The CC IPA advised that the TCC explained clearly to the patient that repositioning the pacemaker was '*not an approach to be taken lightly'* and that the TCC offered to refer the patient for another opinion. The CC IPA also advised that the Trust facilitated another clinical opinion and which supported the TCC's view. The CC IPA further advised that TCC B then offered the patient a further review to see if she still wished to have a further procedure. The CC IPA also advised that there were '*understandable challenges … around this time because of the effect of the Coronavirus pandemic, and the timing of actions was therefore appropriate when considered against that backdrop.'* The CC IPA advised that the Trust's care and treatment during the period of 28 November 2019 to 9 November 2020 was appropriate, reasonable and in accordance with relevant standards and policies.

Responses to the Draft Investigation Report

34. Both the patient and the Trust were given an opportunity to provide comments on the Draft Investigation Report. Where appropriate, comments have been reflected in changes to the report. Other comments in relation to issue one are outlined in paragraphs 35 to 39 and at paragraph 72 about issue two.

Patient's Response

35. The patient said that on the day of the procedure, the TCAS said that she was '*very sorry that she did not have the English to explain to [the patient] what was being discussed'.* The patient queried whether it was appropriate to have someone performing a procedure who does not have enough English to explain what is happening to a patient.

36. The patient challenged the CC IPA's advice that she could not have been consulted about the leads during the procedure because she would have been sedated. The patient said that she was awake during the procedure and conversed with the nurse.

37. The patient queried whether it was reasonable that the pacemaker was replaced in the same pocket with the result that it was more superficially sited than previously, given that the original pocket was made 28 years ago and this was the third pacemaker.

38. The patient queried if it was appropriate that the documentation associated with arrangements for her procedure stated that the Consultant was the TCC, if the TCC was not to carry out the procedure.

39. The patient referred to research she had undertaken in which it was asserted that a pacemaker could 'flip' if placed in a loose pocket, and which she believed was as in her case and that "Twiddlers Syndrome" could also cause a device to 'flip'.

Further Independent Professional Advice following Draft Investigation Report Responses

40. Following the patient's comments on the Draft Investigation Report, I sought further advice from the CC IPA. Key extracts are detailed in paragraphs 41 to 45 in relation to issue one and paragraph 73 in relation to issue two. The full additional advice is at Appendix five.

41. The CC IPA advised that, if the TCAS was unable to explain what was happening to the patient this was not appropriate. He referred to his previous

advice that both the consenting process and provision of information to the patient was not in keeping with GMC Guidance or good practice and advised that this included information about what decisions were made about the leads. The CC IPA advised that '*the discussion about the procedure should take place face-to-face and be clearly communicated in a language that the patient understands'.*

42. The CC IPA advised that, although patients are usually sedated during such procedures and which would render consultation with a patient impossible, even if the patient is awake, any decisions to which the patient agreed would not constitute an ideal consenting process. He advised that a patient draped, instrumented, and lying on an operating a table surrounded by nurses, technicians, and doctors, cannot be seen to be able to give free and informed consent, in the absence of any pressure, intimidation or obligation. The CC IPA referred to his original advice around consent and provision of information to the patient which, if managed according to GMC guidance, would have avoided this issue, including consideration that it '*would have been reasonable to have updated and clearly informed the patient thereafter about any decisions which were made about the leads'.*

43. The CC IPA advised that there is no reason that a pacemaker needs to be re-sited when replacing it. The CC IPA also advised that bodily changes over the intervening time between procedures may lead to thinner '*overlying tissues'* which may result in the replacement appearing to be more superficial.
44. The CC IPA advised that patient documentation will include the Consultant with overall responsibility for the patient. He advised that *'ideally both the individual performing the procedure and the responsible Consultant should be identified for completeness'.* The CC IPA referred again to his previous advice about the consenting process and the provision of information to the patient about those to be involved in her care and which was not in accordance with GMC Guidance or good practice.

45. The CC IPA advised that it would be 'u*nusual for a device to "flip" spontaneously'.* He further advised that the reference to "*Twiddler Syndrome"*

relates to the occasional patient who tends to '*fiddle and pick*' at the device or wound and which should be discouraged. The CC IPA advised that, given this was the patient's third pacemaker, "*Twiddler Syndrome*" seemed an unlikely scenario. The CC IPA also advised that there was '*no indication in the records*' that the pacemaker was placed in a loose pocket.

Analysis and Findings

46. In relation to issue one of the complaint, I carefully examined the care and treatment the Trust provided to the patient between 13 August 2019 and 9 November 2020.

The care and treatment which was planned at the Pacing and Implantable Cardioverter Defibrillator Clinic (ICD) on 13 August 2019

47. The GMC Consent Guidance stated that you should '*share information in a way that the patient can understand and, whenever possible, in a place and at a time when they are best able to understand and retain it … give the patient time to reflect, before and after they make a decision … give the patient the time and support they need to maximise their ability to make decisions for themselves'.* The GMC Consent Guidance also stated that, in supporting the patient in making decisions about their treatment, you should '*listen to their concerns, ask for and respect their views, and encourage them to ask questions'* and in how you discuss the treatment with the patient you should ensure that the patient should be able to raise '*any questions or concerns*.' I note that the GMC Consent Guidance stated that the patient should be given information about '*the people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved'.*

48. The CC IPA advised that the consent form for the procedure '*was signed on the day of the procedure itself'.* I note that the CC IPA referred to the GMC Consent Guidance and advised that the Trust did not obtain consent in accordance with this guidance. The CC IPA also advised that '*a consenting process initiated "on the day" in this case fell below an acceptable standard',* that this was '*unsatisfactory'* and '*outside GMC guidance'*. The CC IPA further advised that the patient's '*concerns and expectations might have been better*

clarified with full and documented preoperative discussion … Discussion around how the leads would be checked during the procedure, the actions taken in specific circumstances and the key medical staff performing the procedure, would have been helpful.' He also advised that the discussion *'should take place face-to-face and be clearly communicated in a language that the patient understands',* that this should have included information about what decisions were made about the leads and who was to be involved in the patient's care. The CC IPA further advised that consent and the provision of information to the patient had been managed appropriately, it would also *'have been reasonable to have updated and clearly informed the patient thereafter about any decisions which were made about the leads'.*

49. Following consideration of the GMC Consent Guidance and the CC IPA's advice, I find that this constitutes a failure in care and treatment. Therefore, I uphold this element of the complaint.

Injustice

50. I considered carefully the impact that the failure in care and treatment had on the patient. I consider that because of this failure, the patient did not have the opportunity: - for timely consideration of her options in making her decision, to ask questions and clarify concerns and to be provided with additional information about the procedure, those involved in it, the decisions made about the leads and the implications of these decisions.

The procedure on 24 September 2019 to replace the Pacemaker

I. The competence of the TCAS

51. I note that the BHRS Standards state that, depending on the complexity and type of device, the highest number of implants per year cited as a baseline for an appropriately trained individual is 60 and for a centre this is 100.

52. The Trust stated that the TCAS was a Cardiology Associate Specialist with more than ten years' experience in device implantation and was therefore not a

trainee. I note that the Trust referenced the BHRS Standards and stated that in the year in question, 1 April 2019 to 31 March 2020, the TCAS performed 311 pacemaker procedures and the Trust undertook 2073 pacemaker procedures. The Trust also stated that the TCAS is appraised and revalidated in line with GMC recommendations.

53. The CC IPA advised that it was appropriate for the TCAS to perform the procedure and that both the TCAS' and the Trust's volume of activity exceeded the requirements of the BHRS Standards. I note that the CC IPA advised that the consent form states that the patient understands that whilst the individual obtaining consent cannot, '*guarantee that a particular person will perform the procedure … The person will however have appropriate experience'.* I note that the patient signed consent form.

54. I consider that the level of performance of implants, both for the TCAS and the Trust as a Centre, was in accordance with the BHRS Standards. I also accept the CC IPA's advice that it was appropriate for the TCAS to perform the procedure. Therefore, I do not uphold this element of the complaint.

II. The procedure

55. The CC IPA advised that '*the procedure was undertaken to an acceptable standard.*' I note that the CC IPA advised that the clinical steps taken were detailed in the *'contemporaneous written record'* of the procedure and that these '*were all appropriate'.* I accept the CC IPA's advice and therefore do not uphold this element of the complaint.

56. The CC IPA advised that, in relation to the discussion and actions taken about the pacemaker leads during the procedure, *'appropriate measures were taken during the procedure'*. I note that the CC IPA advised that a discussion with the patient '*cannot be undertaken'* in these circumstances. I refer to paragraphs 47 to 50 above about the timing of consent for the procedure and the associated

impact of this in relation to the patient's understanding of what the procedure entailed.

III. The position of the replacement pacemaker

57. The Trust stated that, on 24 September 2019, the *'incision was made on [the patient's] old scar … the existing dual chamber pacemaker was explanted and a new pacemaker implanted into the left pre-pectoral pocket.* I note that the Trust also stated that at the further procedure on 9 November 2020, '*a new deeper sub-pectoral pocket was created to house the same generator and leads.'* The medical records associated with each of the two procedures confirm these statements.

58. I note that the CC IPA advised both that, on 24 September 2019 the pacemaker was placed in the same position as the previous device, and on 9 November 2020 the pacemaker was repositioned to a different site.

59. I note the patient's comments related to the superficial position of the replacement pacemaker; however, I refer to the CC IPA's further advice about the siting of the pacemaker. Following review of the medical records and the IPA's advice, I am satisfied that on 24 September 2019, the device was replaced in the same position as the previous pacemaker and it was reasonable to do so. Therefore, I do not uphold this element of the complaint.

The care and treatment provided to the Patient from when she expressed concerns on 28 November 2019 to the further replacement of the pacemaker on 9 November 2020

60. The Trust stated that, in response to the patient's concerns, it arranged an urgent consultation review for the patient with the TCC. I note that this was arranged for 4 December 2019, four working days after the patient contacted the Trust with her concerns. The Trust provided records of the TCC's examination of the patient's pacemaker site at this appointment. These records support the Trust's statement that '*there was no evidence of any other wound to indicate that the device has not been placed in the same area.'* I also refer to

paragraphs 78 to 81 below in issue two in relation to the Trust's responses to the patient's concerns and questions. The Trust stated that the TCC's clinical assessment was that the risk of surgery to reposition the pacemaker outweighed any potential benefits. The records document that the TCC offered to refer the patient for another opinion on this matter.

61. The Trust stated that TCC B undertook a clinical assessment with the patient on 19 March 2020, to provide a further opinion at the patient's request. The medical records confirm this. I note that the records evidence that at this consultation, TCC B's clinical assessment reflected that of TCC and that TCC B then offered the patient a further review in six months. At this further review which took place on 24 September 2020, TCC B agreed to reposition the device and that this took place on 9 November 2020. The Trust stated that it offered this procedure '*in the hopes of satisfying the patient's needs'.* The Trust also stated that 'a *new deeper sub-pectoral pocket was created to house the same generator and leads*.' This was also recorded in the letter of the same date from the Trust to the patient's General Practitioner (GP); specifically *'a new sub pectoral pocket was created.'*

62. The CC IPA advised that, as there were '*no contemporaneous records of a discussion about'* the TCAS telling the patient to make sure that the device did not flip, he could not conclude whether this was the case. The CC IPA further advised that '*this possibility was felt to be highly unlikely when the [patient] was reviewed after the procedure*'. I note that the CC IPA also advised that spontaneous 'flipping' of a device would be unusual and that, although there is a risk that a patient might 'twiddle' with the device and that this would be discouraged, given that this was the patient's third pacemaker this would be unlikely. The CC IPA advised that there was '*no indication in the records'* that the pacemaker was placed in a loose pocket. Whilst in consideration of the records and the CC IPA's advice, I cannot conclude whether the TCAS told the patient to make sure that the device did not flip, I note the patient's comments on this matter. I am satisfied, however, that on 4 December 2019, the TCC provided clear reassurance to the patient that the device would not flip. I refer

to paragraph 64 below that the Trust offered this reassurance in a timely manner.

63. The CC IPA advised that, at the consultation review on 4 December 2019, the TCC explained the risks of repositioning the device clearly to the patient and also that the TCC offered to refer the patient for another opinion. The CC IPA advised that the Trust then did facilitate another clinical opinion with a different cardiologist. I note that the CC IPA advised that, at this further consultation, TCC B's clinical assessment supported TCC's clinical opinion. The CC IPA further advised that, at this consultation, TCC B offered the patient a further review to see if she still wished to have another procedure.

64. The CC IPA advised that the Trust's care and treatment during this period were appropriate and reasonable. I note that the CC IPA advised that there were '*understandable challenges … around this time because of the effect of the Coronavirus pandemic, and the timing of actions was therefore appropriate when considered against that backdrop.'* I consider that the consultation review appointment of 4 December 2019, which the Trust arranged to resolve the patient's concerns, was made in a timely manner. I accept the CC IPA's advice that the timing of actions during the Covid-19 pandemic was appropriate and that the Trust's care and treatment was appropriate and reasonable. I therefore do not uphold this element of the complaint.

Issue 2: Whether the responses which were provided by the Trust to the patient's questions were appropriate and reasonable.

Detail of Complaint

65. The patient said that, despite numerous attempts to obtain answers to all her questions and concerns about the procedure on 24 September 2019, the Trust failed to resolve and address these. The questions and concerns which the patient said were detailed in her complaint documentation and were unanswered related to: - the change and delay of an appointment with TCC B; the patient being told by TCAS that the pacemaker might flip; why a Consultant Cardiologist did not carry out her procedure, the discussions about the leads

during her procedure; and that the pacemaker was situated in a different position to the previous one.

Evidence Considered

Legislation/Policies/Guidance

66. I considered the DoH HSC Complaints Procedure and the Trust's Complaints Leaflet. Relevant extracts are enclosed at Appendix three.

The Trust's response to investigation enquiries

67. The Trust stated that it facilitated a number of clinical assessments with the patient, and which involved three different doctors, to endeavor to answer the patient's questions and address her concerns. The Trust also stated that further explanations were provided to the patient in the Trust's complaint response letters of 7 August 2020 and 4 September 2020.

68. The Trust stated that it believes that the clinical responses from the TCC, TCAS and TCC B who all met with the patient were appropriate. The Trust stated that, at each point, staff both provided sound clinical reassurance to the patient and discussed risks and benefits with her.

Relevant Records

69. I reviewed the patient's records for the period under investigation and all documentation related to the patient's complaint, including that provided by the patient and the Trust.

70. It was documented in the records that, on 28 November 2019, the patient telephoned the Trust. The records documented that the patient contacted the Trust because she had concerns about the procedure to replace her pacemaker and, following a referral from her GP for a review, the Trust had scheduled a review appointment for her to take place in four months. The records documented that the patient felt that this time period was not acceptable as she believed the device was not replaced correctly and she wished to have another medical opinion. The records documented that the

Trust then provided the patient with an earlier review consultation and that this took place on 4 December 2019.

71. The records documented that the patient submitted a complaint on 20 December 2019 and that this was received by the Trust on 23 December 2019. The records documented that in this complaint, the patient said that she was not satisfied with the review consultation of 4 December 2019 in relation to provision of answers to her questions and resolution of her concerns and she wished to have another review by an independent Consultant Cardiologist. The records documented that the patient submitted a further written complaint on 15 June 2020 in which her queries and concerns were reiterated.

Responses to the Draft Investigation Report

Patient Response

72. The patient said that, at the appointment on 4 December 2019, her concerns and queries were not addressed to her satisfaction which then led to her formal complaint to the Trust. She said that the appointment left her with more queries and concerns. The patient also said that the Trust did not provide her with a written response to her written queries and that she has continued to be subject to ongoing investigations about the leads which has added to her anxiety about those queries and concerns which remain unanswered.

Further Independent Professional Advice following Draft Investigation Report Responses

73. The CC IPA advised that, given that the patient has continued to be reviewed in relation to issues with the pacemaker leads and she remains uncertain about the reasons for this, '*it is likely that the patient's continued uncertainty around this would also have been resolved if the patient had been given clearer and more timely information about the procedure and decisions made concerning the leads.'*

Analysis and Findings

74. In its response to investigation enquiries, the Trust enumerated the concerns which it stated the patient raised. I note that the Trust stated that it addressed each of these concerns with the patient at the appointment on 4 December 2019.

75. I refer to the review consultation appointment of 4 December 2019 and the analysis and findings at paragraphs 60 to 64 above. I note from the review of records, including the contemporaneous handwritten notes and the letter to the patient's GP on 4 December 2019, that at this appointment, a number of the concerns which were later included in the patient's complaint were discussed and addressed. The concerns addressed at that time were about the pacemaker being in a different position from the previous device and concerns that the pacemaker would flip. The CC IPA advised that at that appointment, those concerns the patient raised '*were documented and each addressed to an acceptable standard.'*

76. I consider that the records referenced in paragraphs 69 and 70 above evidence that the patient's concerns and questions about the position of the device and the risk of the pacemaker flipping were verbally addressed during the appointment on 4 December 2019. I also accept the CC IPA's advice that the concerns which were addressed at the appointment were *'addressed to an acceptable standard.'* I therefore do not uphold the element of the complaint that the Trust did not address the patient's concerns and questions about the position of the device and the risk of it flipping. I also, however, refer to my findings in paragraphs 81 to 83 below about the issues associated with the Trust's provision of a written response to the range of enquiries and concerns detailed in the patient's written complaints.

77. In reference to one aspect of the concern related to the device flipping, which was that the patient said that the TCAS told her previously to make sure that the device did not flip, I refer to paragraph 62 above that I cannot conclude whether the patient was previously told this.

78. Following the review consultation appointment of 4 December 2019, the patient then submitted her complaint to the Trust. Within the complaint, the patient detailed three additional questions and concerns but which the records indicate were not discussed at the review consultation appointment. The first of these related to the change and delay in the patient's appointment to obtain another opinion about the placement of the pacemaker, specifically with TCC B. I note that, in the letter from the Trust of 14 September 2020 to the patient, the Trust addressed this and explained that, following the facilitation of the urgent review consultation appointment on 4 December 2019, the Trust understood that this had remedied the patient's concerns but when the patient expressed continued dissatisfaction and requested another opinion on the position of the pacemaker, the Trust made an appointment for her with TCC B for March 2020. In the intervening period between December 2019 and the appointment in March 2020, the Trust came under increasing pressure from the growing Covid-19 pandemic. This impacted on timelines for appointments and the Trust explained this in its letter of 14 September 2020. The CC IPA advised that '*understandable challenges … around this time because of the effect of the Coronavirus pandemic, and the timing of actions was therefore appropriate when considered against that backdrop.'*

79. I consider that there is evidence that the Trust provided a written response to and addressed the patient's question about the delay and change in her appointment with TCC B. I also accept the CC IPA's advice that the timescales for actions were appropriate in the context of the escalating Covid-19 pandemic. Therefore, I do not uphold this element of the complaint that the Trust did not provide a written response or address the patient's question about the delay in her appointment.

80. The two other points the patient made in her written complaints but which were not raised at the review appointment, were related to why a Consultant Cardiologist did not carry out her procedure and the discussions about the leads which took place during her procedure.

81. In relation to the former of these two queries, the records documented that, in a telephone call from the Trust to the patient on 5 May 2020, the Trust explained to the patient the credentials under which it was appropriate that the TCAS performed the procedure. The record stated that the Trust '*reassured [the patient] that [TCAS] is an Associate Specialist and has the training and necessary knowledge to carry out procedures like her's'*. I note, however, that following this, the patient continued to raise this question in her correspondence with the Trust, yet the Trust made no attempt to address this in any further correspondence. I consider that this indicates both that the verbal explanation was not adequate and there is no evidence that the Trust provided a written response to this aspect of the patient's written complaint. In relation to the latter of the two points referenced in paragraph 80, I note that there is no reference in any of the records to the Trust addressing the patient's concerns and questions about the discussions about the leads, either verbally or in writing. I also refer to the CC IPA's follow-up advice that, if the patient had been given appropriate information about the procedure and the decisions made concerning the leads, it is probable that her ongoing uncertainty about this would have been alleviated. I accept the CC IPA's advice.

82. I consider that the findings in paragraph 81 above in relation to addressing the relevant patient's concerns and queries constitute maladministration. This is because the failures do not accord with the third principle of the Principles of Good Complaints Handling, 'Being Open and Accountable' which requires public bodies to provide honest evidence-based explanations and give reasons for decisions. I therefore uphold this element of the complaint.

83. In referring to my findings at paragraph 76, although I consider that the issues about the placement of the device and the device 'flipping' were appropriately addressed at the review appointment on 4 December 2019, this was done verbally. I consider that it is clear that the patient's concerns were not satisfied by this as she continued to raise these issues, along with others, in the written complaints of 20 December 2019 and 15 June 2020. I also refer to my findings at paragraphs 81 and 82. I consider that, with the exception of the patient's question about the delay and change in her appointment with TCC B, the Trust

did not provide a written response to any of those queries and concerns detailed in her written complaints. I consider that this constitutes maladministration. This is because the failures do not accord with the fourth principle of the Principles of Good Complaints Handling, 'Acting fairly and proportionally' which stipulates that complaints are investigated thoroughly and fairly to establish the facts of the case.

Injustice

84. I considered carefully the impact that the maladministration had on the patient. I consider that this caused the patient to experience worry, uncertainty and frustration because she did not have her concerns appropriately addressed.

CONCLUSION

85. I investigated the complaint and found both a failure in care and treatment and maladministration in relation to the Trust's actions.

- There was a failure in care and treatment for the patient because the Trust did not obtain consent for the patient's procedure on 24 September 2019 in accordance with GMC Consent Guidance.

- The Trust failed to fully answer and address all of the patient's concerns and queries which were detailed in her written complaints of 20 December 2019 and 15 June 2020. The Trust also failed to provide a written response to all but one of those queries and concerns.

    - I am satisfied that the failure and maladministration had a negative impact on the patient as she did not have the opportunity for timely consideration of her options in making her decision or to ask questions and clarify concerns or to be provided with additional information about the procedure, those involved in it, the decisions made about the leads and the implications of these decisions; and she experienced worry, uncertainty and frustration as her concerns were not appropriately addressed.

86. Whilst the investigation did identify issues of a failure in care and treatment and maladministration, I hope that this report gives the patient reassurance in relation to her concerns about the procedure on 24 September 2019, including the placement of the pacemaker, the competence of the TCAS; and the follow-up care and treatment provided by the Trust from 28 November 2019 to 9 November 2020.

Recommendations

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

2. I recommend that the Trust provides a full written response to the patient's queries related to the role and positions of those involved in the discussions and decisions about the pacemaker leads during the procedure on 24 September 2019. I also recommend that the Trust provides the patient with full and clear information about the nature of the discussions about the leads, which occurred during the procedure; the decisions and outcomes arising from these discussions, including the reasons for these decisions; and the correlation between the decisions made at and the outcomes of the procedure and the ongoing issues with the patient's pacemaker leads. I recommend that the written response and information is provided to the patient within one month of the date of this report.

3. I refer the Trust to the GMC Consent Guidance and recommend that relevant staff are reminded of the importance of the GMC Consent Guidance, particularly in relation to: - the timing of consent; and providing information to the patient about who will be involved in the treatment, what will happen in the procedure and where decisions on the course of action are to be made during the procedure, the outcomes of these decisions and any associated impact on the patient. I also refer the Trust to the CC IPA's advice and recommend that discussions with patients about the latter two points should be documented. The Trust should provide evidence of how these staff reflected on the key

points of the GMC Consent Guidance and how they can improve their practice in the future.

4. The Trust should ensure that the findings in this report, in relation to issue two, are shared with relevant staff who deal with complaints; in particular, the findings related to how the Trust responded to and addressed the patient's written complaints and the concerns and queries detailed in these. The Trust should provide records of the information-sharing.

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

MARGARET KELLY
Ombudsman **25 July 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

6. 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.

7. 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