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

Report Reference: 202003384

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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.

TABLE OF CONTENTS

Page

Case Reference: 202003384

Listed Authority: Belfast Health and Social Care Trust

SUMMARY

This complaint was about care and treatment the Belfast Health and Social Care Trust (the Trust) provided to the complainant when he received a nerve root injection[1] for leg pain. It was also about the Trust's subsequent Clinical record Review (CRR).

The investigation identified the Trust performed the procedure appropriately. However, it failed to fully explain to the complainant the possibility that it may lead to symptom worsening. I considered this a failure in care and treatment.

In relation to the CRR, the investigation did not find any evidence to suggest the review sufficiently considered the complainant's perspective regarding the impact the procedure had on him. I considered this maladministration. The investigation did not find any reason to question the CRR's finding that the Trust conducted the procedure appropriately.

I recommended the Trust apologise to the complainant for the injustice sustained. I also recommended learning for the Trust to implement to prevent these failures recurring.

[1] An injection combining a local anaesthetic and a steroid.

THE COMPLAINT

1. This complaint was about care and treatment the Belfast Health and Social Care Trust (the Trust) provided to the complainant in March 2022 when he received a nerve root injection[2] for leg pain. It was also about the Trust's subsequent Clinical Record Review (CRR).

Background

2. The complainant suffers from right leg pain. In June 2021, a Trust Consultant administered a nerve root injection to his back with the hope of gaining relief from his pain. The complainant reported that the injection did not relieve his pain and he received a second injection.

3. The complainant attended for a second injection on 28 March 2022, which a registrar[3] administered, under the supervision of a Consultant. The complainant reported that upon receiving this injection, he experienced temporary paralysis and his pain worsened.

4. The complainant raised his concerns with the Trust in April 2022. The Trust conducted a CRR dated 6 July 2022 and issued its final response regarding the complaint on 13 September 2022.

Issues of complaint

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

   Issue 1: Whether the Trust appropriately administered a lumbar nerve root injection to the patient on 28 March 2022.

   Issue 2: Whether the Trust conducted its Clinical Record Review (CRR) appropriately and in accordance with relevant guidance.

[2] An injection combining a local anaesthetic and a steroid.
[3] Medical grade below Consultant.

INVESTIGATION METHODOLOGY

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

Independent Professional Advice Sought

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

    - A Consultant Interventional Radiologist (CIR IPA) with experience of administering nerve root injections in an NHS Trust in Great Britain.

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

8. 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

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

    The general standards are the Ombudsman's Principles[4]:

    - The Principles of Good Administration

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

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

The specific standards relevant to this complaint are:

- The General Medical Council's Decision Making and Consent, September 2020 (GMC Guidance).

11. The CIR IPA also referred to the following articles within his advice, which I consider are relevant to this complaint:
    - Complications associated with Lumbar Transforaminal Epidural Steroid Injections – Andrew Chang, September 2020;
    - Interventional Pain procedures: A Narrative Review focusing on Safety and Complications – Lo Bianco, Tinirello et al, Journal of Pain Research 2023; and
    - A Prospective Evaluation of Complications of 10,000 Fluroscopically Directed Epidural Injections – Laxmaiah Manchikanti, March 2012

    I enclose these articles at Appendix three to this report.

12. I did not include all information obtained in the course of the investigation in this report. However, I am satisfied I took into account everything I considered relevant and important in reaching my findings.

13. A draft copy of this report was shared with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations. Whilst not changing my findings and conclusions, I have made certain changes to the report in light of the comments received.

THE INVESTIGATION

Whether the Trust appropriately administered a lumbar nerve root injection to the patient on 28 March 2022.

In particular, this will consider:

- The supervision of the registrar during the procedure; and
- The complainant's concern that he experienced temporary paralysis and severe constant pain as a result of the injection.

Detail of Complaint

14. The complainant believed the Consultant did not appropriately supervise the registrar who undertook the procedure on 28 March 2022. As a result, the registrar incorrectly undertook the procedure.

15. The complainant said the procedure caused him to experience temporary paralysis and increased pain. He said he experiences *'debilitating*' pain daily.

16. The complainant stressed his differing experience between the injection he received in June 2021 with that of March 2022.

Evidence Considered

Legislation/Policies/Guidance

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

The Trust's response to investigation enquiries

18. The Trust stated the registrar was a *'Senior Radiology Registrar'* who had performed the same procedure under supervision on *'multiple occasions'*.

19. The Trust stated that its records evidenced the complainant provided his consent for the procedure. It explained the procedure and technique, which included *'intended benefits and risks'.* The risks included '*infection, bruising, allergy, temporary numbness and weakness'*. The complainant '*agreed*' to the procedure described and '*understood*' the person undertaking the procedure had '*appropriate experience'*.

20. The Trust stated the complainant '*reported pain during the procedure and loss of power in his leg following the procedure'.* It reviewed the imaging from the procedure and determined the needle was *'in a satisfactory position with outline of the L3 nerve[5] following injection of iodinated contrast[6].'* The supervising

[5] L2, L3 and L4 spinal nerves provide sensation to the front part of the thigh and inner side of the lower leg.
[6] A means of enhancing the ability to see blood vessels and organs during radiographic procedures.

Radiologist reassured the complainant at the time that leg weakness was a normal post injection occurrence.

Relevant Trust records

21. **20 June 2021** – The complainant signed Form 3 Consent for examination, treatment or care which states 'Rt L5 Nerve Root Injection.
Explanation: technique, Benefit: Pain relief, Risk: Infection, bruising, Allergy, temporary leg numbness and weakness.

22. **28 March 2022 – Request** – Fluoro guided nerve injection[7] lumbar. Right leg pain. Worst anterior thigh. MRI scan 10/8/20 reported potential irritation of the right exiting nerve root at L3/4 level which would correlate potentially symptomatically. Persistent pain. Previous L5 NRI [*nerve root injection*] and physio. Right L3 NRI injection. (requested in past but L5 nerve root was injected and did not give any ease). MRI scan most significant changes at L3/4 level and potential surgical target.

23. **Form 3 Consent for examination, treatment or care 28 March 2022**

The complainant signed this form which states 'Right L3 Nerve Root Injection.
Explanation: technique, Benefit: Pain relief, Risk: Infection, bruising, Allergy, temporary leg numbness and weakness.

24. **Report** – 28/03/2022, 09:42, Fluoro guided nerve injection lumbar Right L3 nerve root injection. Technique: Informed written consent. Aseptic technique. 1% Lidocaine to subcutaneous[8] tissue. Under fluoroscopic guidance a 22-gauge spinal needle was placed within the right L3 neural exit foramen[9]. Safe perineural[10] position confirmed with Omnipaque[11]. Subsequent checks with

[7] Injection directly into a joint using special imaging.
[8] Beneath the skin
[9] An opening that allows the passage of structures such as nerves from one region to another
[10] Area surrounding a nerve
[11] Contrast agent used for x ray imaging

Kenalog[12] 40 mg and Chirocaine[13]. No immediate complication. Post procedure advice given.

Relevant Independent Professional Advice

25. The CIR IPA advised he considered the treatment provided '*appropriate'* following the results of an MRI scan carried out on 10 August 2020. This indicated a possible compromise of the exiting L3 nerve root at the L3/4 exit. '*This report specifically refers to the symptoms and suspected L3 origin and a previous L5 root block'*.

26. The CIR IPA advised it is common for fifth year registrars to conduct these types of procedures. Such registrars *'usually have passed their exams'* and in are in their final year of training before taking up a consultant post. At this stage, registrars *'work without direct supervision'*. This means their supervisor is not physically present. However, there should be a consultant available if the registrar is unfamiliar or unsure about the procedure.

27. The CIR IPA advised the risks of this procedure includes '*transient and permanent pain / paralysis / symptom worsening including the risk of paraplegia for lumbar injections and tetraplegia and stroke for cervical injections.'* These complications are rare. However, worsening of the symptoms is reported with an incidence of less than 1%, but up to 5%. '*Consent was not taken for permanent symptom worsening.'*

28. The CIR IPA advised that '*Transient symptom worsening after nerve root blocks is not at all rare'.* It not occurring following the previous injection does not mean the registrar did not conduct the second procedure correctly. The records evidence that permanent symptom worsening was *'well described'.*

29. The CIR IPA advised the image taken during the procedure did not *'demonstrate an obvious problem'.* He did not identify any concerns with the performance of the procedure. However, the records do not evidence the Trust

[12] A type of steroid hormone.
[13] A type of anaesthetic.

informed the complainant about the rarer or severe complications when obtaining consent.

Analysis and Findings

Supervision of the registrar

30. I accept the advice of the CIR IPA that the lumbar nerve root procedure carried out on 28 March 2022 was appropriate in an attempt to alleviate the complainant's leg pain. This was based on the results of an MRI scan carried out on 10 August 2020 which indicated a possible compromise of the nerve exiting the spine at the right L3/4 foramen[14]. The referral referenced the previous L5 injection which had not provided relief and I accept that there were valid clinical indications that an injection at the L3/4 site had the potential to provide pain relief. I note the advice of the CIR IPA that, *'the most optimistic publications report improvement in up to 75% of patients.*

31. The complainant questioned the level of supervision over the clinician who carried out the procedure on 28 March 2022. I note an ST5[15] registrar carried out the procedure.

32. I refer to Standard 44 of the GMC Guidance. It states that when delegating work, the clinician should ensure the person they delegate to is *'suitably trained and confident'*. The Trust stated the registrar *'was within his last 6 months of specialty training and had performed this procedure under supervision on multiple occasions'.*

33. The CIR IPA advised it is common practice for a fifth-year registrar to carry out this type of procedure. I accept the CIR IPA's advice that it is not necessary for a consultant to oversee the treatment that such an experienced clinician provides. I do, however, note that a consultant was present at the clinic at the time and spoke with the complainant and his wife following the procedure.

[14] An opening which allows nerves and blood vessels to travel from one area to another.
[15] A specialty registrar in their 5th year of training.

34. Based on the evidence available, I consider the decision for the registrar to administer the injection without direct supervision from the consultant was appropriate and in accordance with Standard 44 of the GMC Guidance. Therefore, I have not identified a failure in care and treatment and do not uphold this element of the complaint.

Administration of the injection

35. The complainant believed the registrar '*botched'* the procedure, which resulted in him experiencing constant and debilitating pain. I note that short term pain and leg numbness are known temporary side effects of nerve root injections through a combination of local anaesthetic and nerve irritation. However, the complainant said he continues to suffer pain at an enhanced level almost two years later.

36. In relation to the procedure itself, the CIR IPA advised that the imaging of the procedure, which showed the needle position, did not demonstrate a clear and '*obvious problem'*. The CIR IPA also advised that because the complainant's experience after the first injection was different from that of the second, it does not necessarily indicate that the registrar performed the procedure incorrectly.

37. I have not identified any failure in how the registrar administered the injection as there is no evidence to suggest he did so incorrectly. Both the CIR IPA and the subsequent CRR identified that the correct needle was used and it was in the correct position. I note and accept the advice of the CIR IPA that unfortunately '*permanent symptom worsening is a recognised but very rare complication'* of this procedure. Indeed, his advice is that '*permanent symptom worsening is well described'* and '*worsening of symptoms is reported with an incidence of …up to 5%.'* I accept that unfortunately, nerve root blocks can lead to permanent worsening of symptoms in a small number of patients. x

38. I note the complainant signed *Form 3 – Consent for Examination Treatment or Care* prior to the registrar performing the procedure. This stated that the clinician explained the nerve root injection procedure including the risks of infection, bruising, allergy, temporary leg numbness and weakness. However, I

note this document does not reference the possibility that the complainant's pain or symptoms may worsen following the procedure. While I note that such an outcome may be a very rare consequence of nerve root injections, as referenced in the preceding paragraph, I accept the advice of the CIR IPA that '*permanent symptom worsening is a recognised but very rare complication'*. As such, I consider the clinician obtaining consent should have explained this risk to the complainant. I see no evidence he did so.

39. Standards 21-24 of the GMC guidance, under the heading '*Discussing benefits and harms'* states '*you must give patients clear, accurate and up to date information, based on the best available evidence about the potential benefits and risks of harm of each option, including the option to take no action*'. This includes '*recognised risks of harm that you believe anyone in the patient's position would want to know. You will know these already from your professional knowledge and experience'*. I consider the failing to fully explain to the complainant the possibility, however slight, that the nerve root block procedure may potentially lead to symptom worsening to represent a failure in care and treatment. I am satisfied this caused him to sustain the injustice of a loss of opportunity to make a fully informed decision on the procedure subsequently performed. This has undoubtedly contributed to his frustration and uncertainty over the appropriateness of the care and treatment he received at that time. I partly uphold this element of the complaint. I discuss my remedy at the conclusion of this report.

Issue 2: Whether the Trust conducted its Clinical Record Review (CRR) appropriately and in accordance with relevant guidance.

Detail of Complaint

40. The complainant emphasised his view that the procedure and the pain he is experiencing are connected. He considered the Trust '*glossed over'* this information in its CRR of his care.

Evidence Considered

The Trust's response to investigation enquiries

41. The Trust stated the Clinical Record Review categorised the care provided during the procedure and post operatively as *'satisfactory'.* Experiencing pain and weakness is '*not uncommon'* following nerve root or any image guided injection. Pain with a perineural[16] injection of local anaesthetic and steroid is possible. Also, leg and temporary numbness is '*expected*' when patients received a local anaesthetic injected correctly to a nerve root.

Relevant Trust record

42. The Trust document titled '*Clinical Record Review'* is dated 6 July 2022. I enclose a copy of this document at Appendix 4. It detailed a factual analysis of the care provided to the complainant. Section 2 of the form, entitled 'Assessment', is blank. Under the heading '*Investigation',* it documented, '*There is evidence of degeneration in the lower lumbar spine particularly at the L3/4 and L4/5 levels. At L3/4 in particular there is potential for irritating the exiting right sided nerve root which may account for the patient's symptoms.'*

43. Under the heading '*Treatment'* it documented '*Dr (registrar) does remember the procedure but does not recall the patient experiencing undue discomfort during the procedure…… On review of images of the procedure the needle is in a satisfactory position with outline of the L3 nerve following injection of iodinated contrast. Dr (Consultant) does remember speaking to patient and wife following procedure to explain that the leg weakness was a normal post injection occurrence. This confirms the needle position was in appropriate position. Patient was provided with a wheelchair to leave the department'.* It further documented, '*Patient had previous Right L5 nerve root injection and did not have these symptoms. This was performed on the 28 June 2021 at Musgrave Park Hospital'.*

44. The document, under the heading '*Communication'* continues '*Patient received information leaflet explaining that he may experience flare of symptoms following procedure. Patient was consented for temporary leg numbness and*

[16] Around the nerve.

weakness which is consistent with appropriately administered local anaesthetic to nerve'. The review concluded, under the heading Overall/Assessment '*This is not an uncommon situation following nerve root or any image guided injection. MSK*[17] *Radiologists and spinal surgeons who also perform nerve root injections, would deal with this not infrequently. Pain and weakness are known effects of nerve root injection. Patient may experience pain with perineural injection of local anaesthetic and steroid. Leg numbness and temporary numbness is an expected effect of local anaesthetic injected correctly to a nerve root…. '.*

Relevant Independent Professional Advice

45. The CIR IPA advised the CRR signed on 6 July 2022, summarised the chain of events leading to the complaint. The complainant contacted his treatment team on 8 April 2022 after the nerve root block on 28 March 2022 because of worsening pain. The team informed the complainant this may happen.

46. The CIR IPA did not raise any concerns with the content of the CRR.

Analysis and Findings

47. The complainant said the CRR determined the registrar carried out the procedure in March 2022 in a '*satisfactory manner'*. However, he believed the CRR '*glossed over'* his continuing pain. I note the purpose of a CRR is to provide an independent retrospective analysis of clinical management with a view to identifying potential gaps in care, aiming for future practice improvement.

48. Having reviewed the CRR report, I note its findings are broadly in line with that of the CIR IPA. That is, it did not identify a failure in how the registrar carried out the procedure in March 2022. Given my investigation reached the same conclusion, I have no reason to question the CRR's findings that the registrar conducted the procedure '*satisfactorily*'.

[17] Musculoskeletal

49. In relation to the complainant's concern that the CRR report '*glossed over'* the pain he experiences, I note it contained references to the complainant's increased leg pain. However, I am disappointed it does not place any focus on the full impact of the procedure that the complainant reported to the Trust. That being that he continues to experience '*debilitating*' pain daily. I would have expected the Trust to have included the complainant's report in section (2) of the form. This is entitled, 'Assessment' and should include '*history taking, examination and diagnoses'*. However, this section is blank.

50. I do not consider that referencing the impact on the complainant would have changed the outcome of the CRR. However, I consider it would have demonstrated to the complainant that the Trust took it into account when it conducted its review.

51. When investigating complaints, either by way of clinical review or other investigation, I expect public bodies to take a personalised approach, giving appropriate consideration to the effect on the complainant. I also expect bodies to base their decisions on all available facts and evidence, which in this case should have included a consideration of the complainant's account. I do not consider the Trust did so in this case. In not doing so, I am satisfied the Trust did not act in accordance with the fourth Principle of Good Administration, 'acting fairly and proportionately'. I consider this constitutes maladministration. I am satisfied this caused the complainant to sustain the injustice of uncertainty and frustration.

CONCLUSION

52. This complaint was about care and treatment the Trust provided to the complainant in March 2022 when he received a nerve root injection for leg pain. The investigation did not identify a failure in how the registrar administered the injection. However, it identified that the Trust failed to fully explain to the complainant a possibility that the nerve root block procedure may lead to symptom worsening.

53. The complainant also raised a concern about a CRR the Trust undertook following receipt of his complaint. The investigation identified that the Trust did not appropriately consider the impact the procedure had on the complainant. However, I had no reason to question the CRR's finding that the registrar performed the procedure appropriately.

54. I consider the failings identified caused the complainant to sustain the injustice of frustration, uncertainty, and a loss of opportunity to make an informed decision about his treatment.

55. I note the complainant spoke with the Trust's [18]ICATS team for further review on two occasions, in November 2022 and August 2023. Based on his experience to date, the complainant fears the effect of any future treatment. While I appreciate the complainant's apprehension, I would strongly encourage him to consider re-engaging with the Trust to help alleviate the pain he experiences daily.

Recommendations

56. I recommend the Trust provides a written apology to the complainant, in accordance with NIPSO's Guidance on Issuing an Apology (July 2019), for the injustice identified at paragraph 51. The Trust should provide the apology to the complainant within **one month** of the date of my final report.

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

    i) Discusses the findings of this report with all clinicians involved in the patient's care, and staff members reflect on the case and discuss it as part of their next appraisal;

    ii) Provides training to relevant staff to include explaining to patients, when obtaining consent, the possibility that a nerve root block procedure may lead to symptom worsening; and

[18] Integrated Clinical Assessment and Treatment Services

iii) Provides training to relevant staff about the importance of considering a complainant's perspective when conducting a CRR, and of documenting their consideration.

58. I recommend 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. The Trust should support its action plan with evidence to confirm it took appropriate action (including, where appropriate, records of any relevant meetings, training records and/or self-declaration forms which indicate that staff read and understood any related policies).

MARGARET KELLY
OMBUDSMAN **28 March 2024**

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

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

2. Being customer focused

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

3. Being open and accountable

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

4. Acting fairly and proportionately

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

5. Putting things right

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

6. Seeking continuous improvement

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