



Northern Ireland

**Public Services**  
Ombudsman

# **Investigation of a complaint against Belfast Health & Social Care Trust**

**Report Reference: 202006154**

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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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**Case Reference:** 202006154

**Listed Authority:** Belfast Health and Social Care Trust

## **SUMMARY**

This complaint was about care and treatment the Belfast Health and Social Care Trust's Regional Fertility Centre (the RFC) provided to the complainant between June 2023 and October 2023.

The complainant was referred to the RFC for In-Vitro Fertilisation (IVF)<sup>1</sup> treatment. She said that during her initial consultation, the RFC assured her she was ovulating as she had regular cycles. However, she believed the RFC should have confirmed this by tracking her follicles at this early stage. The complainant underwent two cycles of IVF. She was concerned that following the second transfer, the RFC did not prescribe her sufficient progesterone<sup>2</sup>. She also said the RFC should have monitored her progesterone levels post transfer. The complainant believed not doing so caused her IVF treatment to fail.

The investigation did not identify any failings. It found there was no requirement for the RFC to track the patient's follicles to confirm ovulation. It also found the RFC prescribed progesterone in line with relevant guidance and there was no requirement for it to monitor her progesterone levels.

Living with infertility and undergoing IVF treatment is an emotional and distressing experience. Throughout my consideration of this complaint, I recognised how important a positive outcome was to the complainant. I was very sorry to learn the treatment did not result in a positive outcome for the complainant and her partner. While this investigation did not identify any failures in the treatment provided, I hope it helps to remove any uncertainty they had about the process.

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<sup>1</sup> IVF - In vitro fertilization (IVF) is one of several techniques available to help people with fertility problems have a baby.

<sup>2</sup> Progesterone - Progesterone is a sex steroid hormone which is elevated after ovulation. Its main function is to support uterine quiescence (inactivity), and health of womb lining and therefore implantation and early pregnancy.

## THE COMPLAINT

1. This complaint was about care and treatment the Belfast Health and Social Care Trust's (the Trust) Regional Fertility Centre (the RFC) provided to the patient between June 2023 to 23 October 2023.

### Background

2. The complainant lives with endometriosis. She started receiving fertility treatment from the RFC in 2021. The complainant initially underwent a Fresh Embryo Transfer<sup>3</sup> in October 2022. Unfortunately, this was unsuccessful.
3. The Trust added her to the Frozen Embryo Transfer (FET)<sup>4</sup> waiting list in February 2023. The transfer occurred on 11 July 2023. Unfortunately, this again did not result in a successful pregnancy. The RFC reviewed the complainant on 24 October 2023 and subsequently discharged her on that date.

### Issue of complaint

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

**Whether the care and treatment provided by the Trust to the complainant between June 2023 – 24 October 2023 was adequate, appropriate and in accordance with guidance and relevant standards.**

## INVESTIGATION METHODOLOGY

5. 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. This documentation included information relating to the Trust's complaints process.

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Fresh Embryo Transfer - <sup>3</sup>the embryo is transferred to the uterus immediately after fertilization and development in the lab, typically 3-5 days after egg retrieval. The process aligns with the natural cycle and the hormonal stimulation used for egg retrieval.

<sup>4</sup> Frozen Embryo Transfer - The transfer of frozen thawed embryos from a previous IVF cycle gives another opportunity to achieve a pregnancy without undergoing another full IVF cycle.

## **Independent Professional Advice Sought**

6. After further consideration of the issues, I obtained independent professional advice from the following independent professional advisor (IPA):
- A Reproductive Consultant (MD FRCOG) with more than 10 years' experience in reproductive medicine.

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

7. 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**

8. 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<sup>5</sup>:

- The Principles of Good Administration
9. 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:

- National Institute for Health Care and Excellence Clinical Guidance cg 156b Fertility problems: assessment and treatment updated September 2016 (NICE Guidelines).
- Research Paper - Luteal Phase Support in IVF: Comparison Between Evidence-Based Medicine and Real-Life Practices published August 2020 (Research Paper Article).
- Guideline of the European Society of Human Reproduction and Embryology; Ovarian Stimulation for IVF /ICSI October 2019 (ESHRE).

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<sup>5</sup> These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

- Guideline of the European Society of Human Reproduction and Embryology; Ovarian Stimulation for IVF /ICSI Volume 2 Issue 2 2020 (ESHRE V2).
- The British National Formulary (the BNF).

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

10. 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.
11. 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. I have carefully considered all of the comments I received.

## THE INVESTIGATION

**Whether the care and treatment the Trust provided to the complainant between June 2023 – 24 October 2023 was adequate, appropriate and in accordance with guidance and relevant standards. In particular this will examine:**

- **The prescribing of Lubion<sup>6</sup>**
- **The measurement of Progesterone levels; and**
- **Follicle tracking.**

### Detail of Complaint

12. The complainant raised the following concerns:
  - The RFC should have prescribed her Lubion by injection during the luteal phase<sup>7</sup> in addition to the progesterone already prescribed.
  - Due to her having low levels of progesterone, the RFC should have monitored her progesterone levels during the luteal phase.
  - The RFC advised her that she was ovulating during her first appointment on 8 April 2021, but it failed to conduct follicle tracking to confirm this.

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<sup>6</sup> Lubion is for women who need extra progesterone while undergoing treatment in IVF.

<sup>7</sup> The luteal phase happens in the second part of your menstrual cycle (post embryo transfer in IVF cycles).

## Evidence Considered

### Legislation/Policies/Guidance

13. I considered the following guidance:

- The BNF
- The NICE Guidance
- ESHRE

I have included relevant sections of this guidance at Appendix three of this report.

### The Trust's response to investigation enquiries

14. I made enquiries of the Trust about the issues the complainant raised. Relevant extracts of the Trust's response to my enquiries are at Appendix four to this report.

### Independent Professional Advice

15. I considered the advice I obtained from the IPA. The advice related to fertility treatment the complainant received. The IPA's full advice report is at Appendix two to this report.

## Analysis and Findings

### *The prescribing of Lubion*

16. The IPA advised the main function of progesterone during the luteal phase '*is to support uterine quiescence<sup>8</sup>, health of womb lining and therefore implantation and early pregnancy*'. He also advised '*If progesterone levels are low, then the womb lining may break down and/or increase uterine contractility<sup>9</sup> resulting in failed implantation and/or miscarriage.*' I therefore appreciate the complainant's concern about her progesterone levels post embryo transfer. This is especially given her first IVF cycle was unsuccessful.
17. The records evidence the patient was prescribed Crinone during the luteal phase. The IPA advised this '*is a routinely prescribed progesterone vaginal pessary for luteal phase supplementation*'.
18. The ESHRE guidance recommends a dose of 90mg of Crinone once daily. The BNF states that '*one applicatoRFCI daily should commence from the day of embryo*

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<sup>8</sup> Uterine quiescence – dormancy of the womb

<sup>9</sup> Uterine contractility - muscle contractions of the uterine smooth muscle that can occur at various intensities in both the non-pregnant and pregnant uterine state.



*transfer and continue for a total of 30 days once pregnancy is confirmed’.*

19. The records evidence that the complainant administered 90mg of Crinone every 12 hours. The IPA advised that therefore, the complainant was *‘receiving two applications of Crinone daily.’*
20. The complainant believed the RFC should have prescribed her Lubion alongside the Crinone it had already prescribed. This is another type of progesterone; however, it is administered by injection. The IPA advised that prescribing Lubion alongside Crinone has been adopted by some providers. However, it is not reflected in current guidelines. I therefore accept the IPA advice that the Crinone the RFC prescribed *‘was in line with the relevant guidelines.’*
21. Based on the evidence available, there was no requirement for the RFC to prescribe the complainant both Crinone and Lubion post transfer. As such, I have not identified a failure in the care and treatment provided to the patient. Therefore, I do not uphold this element of the complaint.
22. The complainant was concerned that by not receiving the Lubion injection, her progesterone levels would have been too low to support implantation. The IPA advised that as the complainant administered two doses of Crinone daily, she was *‘by all accounts on [a] double dose’*. This would have sufficed to raise her progesterone levels.
23. I also note that paragraph 16.1 of the ESHRE states that a more recent clinical trial *‘reported no difference in clinical pregnancy rate’* when it compared administration of progesterone via a subcutaneous<sup>10</sup> route with the vaginal route. I hope this brings the complainant an element of reassurance.

#### *The measurement of progesterone levels*

24. The complainant believed the RFC should have monitored her progesterone levels during the luteal phase, as she has *‘medically documented low progesterone levels’*.
25. In its response to enquiries, the Trust explained that *‘monitoring and treatment of the Luteal phase progesterone levels is outside of the current ESHRE guidance’*. The ESHRE guidance does not specifically refer to the monitoring of progesterone levels

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<sup>10</sup> By injection.

during the luteal phase. However, paragraph 16.1 of the guidance states that *'luteal support has not been studied properly'* and that further studies are needed in this area.

26. The IPA advised that clinicians may routinely test progesterone levels *'immediately prior to medicated FET (frozen thaw embryo transfer).'* However, this is not in the luteal phase of the cycle.
27. Given the absence of guidance on the monitoring of progesterone levels, I do not consider there was any requirement for the RFC to conduct such a test for the complainant during the luteal phase of the cycle. As such, I have not identified a failure in the care and treatment of the complainant for this issue. I do not uphold this element of the complaint.

#### *Follicle tracking*

28. The complainant said that during her first consultation appointment with the RFC in 2021, the Consultant told her she was *'definitely ovulating'* as she had regular cycles. The complainant believed the RFC should have offered her follicle tracking to confirm she was ovulating naturally.
29. In its response to enquiries, the Trust stated that follicle scan tracking falls outside the guidance *'for the investigation of subfertility'* for patients living with endometriosis. I reviewed both the ESHRE and NICE guidance and have not identified any recommendation for providers to conduct follicle tracking to confirm ovulation at this stage of the process.
30. The IPA also advised *'this is not standard practice and not indicated for purposes of IVF'*. I accept the IPA advice. Taking account of the NICE guidelines, and the IPA advice, I am satisfied that follicle tracking prior to IVF treatment was not a requirement in the complainant's case. As such, I have not identified a failure in the complainant's care and treatment regarding this issue. I do not uphold this element of the complaint.
31. I wish to draw to the Trust's attention the IPA advice regarding the double dose of Crinone prescribed to the complainant. He advised the Trust should consider incorporating *'progesterone testing immediately prior to medicated FET treatments and adjust dose of progesterone accordingly.'* I would ask the Trust to note and

consider this advice.

## **CONCLUSION**

32. I received a complaint about care and treatment the Trust's RFC provided to the complainant. I do not uphold the complaint for the reasons outlined in this report.
33. I wish to recognise the grief and disappointment the complainant and her partner experienced when this difficult process ended unsuccessfully. While I appreciate my investigation may not have delivered the outcome they wished for, I hope this report removes any uncertainty the complainant and her partner had about the RFC's process.

**MARGARET KELLY**

**Ombudsman**

**April 2025**

## **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.

