# Investigation Report

## Investigation of a complaint against a GP practice in the South Eastern Health and Social Care Trust area

**NIPSO Reference: 17396**

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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. She may also investigate and report 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.

Where the Ombudsman finds maladministration or questions the merits of a decision taken in consequence of the exercise of professional judgment she must also consider whether this has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. The Ombudsman may recommend a remedy where she finds injustice as a consequence of the failings identified in her report.

The Ombudsman has discretion to determine the procedure for investigating a complaint to her Office.

## 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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# THE COMPLAINT

1. I received a complaint about the actions of The Surgery, Comber (a GP practice in the South Eastern Health and Social Care Trust area) in relation to the care and treatment it provided to a patient. The patient attended the practice on three occasions complaining of a lump in her right breast. She stated that she was not adequately examined on each occasion. The patient stated that she told the GP that the lump could be better detected standing up, however she stated she was examined whilst lying down. The patient indicated that her doctor did not detect a lump until the third visit, when she was referred to the breast clinic.

**Issue of complaint**

2. The issue which I accepted for investigation was:

Whether appropriate care and treatment was provided to the patient by the practice following her discovery of a lump in her breast?

# INVESTIGATION METHODOLOGY

3. In order to investigate the complaint, the Investigating Officer obtained from the practice all relevant documentation together with their comments on the issues raised by the patient. This documentation included information relating to the practice's handling of her complaint and her medical records. The Investigating Officer also sought and received information from the South Eastern Health and Social Care Trust (the Trust) in relation to the patient's treatment at the breast clinic. As part of my process I shared a draft report with the patient and the practice. I considered responses from both before arriving at my conclusion.

**Independent Professional Advice Sought**

4. After further consideration of the issues, I obtained independent professional advice (IPA) from a General Practitioner (GP). The IPA is a GP with over 20 years'

experience with a particular interest in women's health. The relevant information and advice which have informed my findings and conclusions are included within the body of my report. The IPA has provided me with 'advice'; however how I have weighed this advice, within the context of this particular complaint, is a matter for my discretion.

**Relevant Standards**

5. 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.

The general standards are the Ombudsman's Principles[1]:

- The Principles of Good Administration
- The Principles of Good Complaints Handling
- The Public Service Ombudsmen's Principles for Remedy

6. The specific standards are those which applied at the time the events occurred, and which governed the exercise of the administrative and professional judgment of those organisations and individuals whose actions are the subject of this complaint.

The specific clinical standards relevant to this complaint are:

- The Oxford Handbook of General Practice, 3rd edition, Chapter 20, Breast disease (the Oxford Handbook)
- Good Medical Practice, General Medical Council (GMC) Guidelines 2013
- Patient.info website
- NICE guidance on referral for suspected cancer

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

7. I have not included all of the information obtained in the course of the investigation in this report but I am satisfied that everything that I consider to be relevant and important has been taken into account in reaching my findings.

## MY INVESTIGATION

**Detail of Complaint**

8. The patient complained about the actions of the practice in relation to the care and treatment she received from her GP. She stated that she attended the practice in April 2016 complaining of a lump in her right breast and believes that she was not adequately examined by her doctor. She stated that she was advised to apply evening primrose oil and return in one month. She returned later that month and again explained that the lump could only be detected whilst standing. However she was again examined whilst lying down. She was then asked to attend again a month later as the doctor advised that the lumpiness was less than first examined.

9. The patient attended for the third time at the end of May 2016 and stated she informed the doctor that she was very concerned, and that the lump could be better detected whilst standing. She stated that she was again examined whilst lying down, however this time was told that a lump had been detected. She stated that the doctor advised her that she would be referred to the breast clinic, however, as there was not a history of breast cancer within the family, the referral could not be 'red-flagged'. She stated she was subsequently diagnosed with two areas of cancer in her right breast and the lump was a Grade 3 tumour. She underwent a mastectomy followed by chemotherapy, radiotherapy and hormone therapy.

10. In response to investigation enquiries, the practice stated that the doctor carried out the examination with the patient in a semi-reclined position and noted lumpiness in both breasts. The practice added it is important that patients are examined in this position as all areas of the breast can be examined thoroughly. It referred to the

Oxford Handbook of General Practice and stated conservative measures were recommended initially, in accordance with this guidance. These included; evening primrose oil, light analgesia, a soft brassiere at night, and observation. The practice confirmed that primrose oil was recommended as it was clinically documented that it helps reduce lumps within breast tissue. The practice disputed that the doctor had conducted an inadequate examination, as it considered best medical practice was adhered to.

11. In relation to the second consultation, the practice stated that the doctor had examined the patient in a semi-reclined position and asked her to raise her arms above her head. As the lumpiness was noted to have decreased, she was advised to continue with the primrose oil and return in one month. They added that even if she was examined in a standing position, a referral would not have been made at this stage as her symptoms of lumpiness had improved. At the third consultation the practice stated the patient was again examined in a semi-reclined position by the doctor, and it was noted that unfortunately the lumpiness could be felt in both breasts. The practice stated that this 'lumpiness' as described by the doctor was not a lump as stated by the patient. Therefore as initial conservative measures seemed unsuccessful, an urgent referral was made to the Trust's breast clinic.

12. The practice explained that a potentially cancerous lump is generally unilateral, hard, irregular, discrete and/or tethered to neighbouring tissue. It may also involve discharge from the breast or an inverted nipple. They stated that despite the very unfortunate outcome, these were not the patient's symptoms in this case. The practice confirmed therefore a 'red flag' referral was not deemed appropriate and the patient's negative family history was not a factor in this decision. They stated that the patient attended the breast clinic in June 2016 and the Trust's Associate Specialist stated in the outpatient letter that *'it felt like what she is palpating was her normal tissue over a prominent rib'.* The practice stated that the Trust's Associate Specialist therefore also indicated that the area was not clinically suspicious. They also highlighted that the Trust's Consultant Surgeon indicated that the abnormalities that were detected via mammogram would not have been palpable clinically. In the practice's opinion, the patient was referred to the breast clinic at the appropriate stage and was examined according to their protocol.

13. A letter from the Outpatient Clinic was issued to the patient's GP by the Associate Specialist who examined her that day at the breast clinic. The letter stated that mammography had *"shown two small areas in the upper inner quadrant of the right breast with micro-calcification and on scanning looked like prominent ducts... We have proceeded to a core biopsy of this area and she will also have a vacuum assisted biopsy of a second area on 13 July. We have explained to her that these areas would not be clinically palpable and we will review her when the results of both biopsies are available."*

14. However, the patient disputed that her tumour was not clinically palpable and suggested the Trust's Consultant Surgeon who subsequently arranged her treatment would confirm this. The Investigating Officer therefore sought clarification on this issue from the Trust's Consultant Surgeon. The Consultant Surgeon stated *"I have reviewed my notes and dictated letters from the patient's care in 2016. There is no evidence in these records that her tumour was clinically palpable."*

15. To assist in the investigation, in relation to the initial consultation in April 2016, the IPA advised that *"there is clear evidence of a history and examination of the breast and also of the other breast. This is consistent with Good Medical Practice."* In relation to the method for examining the breasts, the IPA referred to the Oxford Handbook which *"states a process of observation then examination with the patient in a semi reclined position and the hands above the head."* The IPA also referred to guidance contained on 'patient.info', a peer reviewed and referenced website widely used by medical professionals. The IPA advised *"it states 'there is no proven best method to examine the breast. Different people have different techniques and the following description is by no means the only approach'. The approach described is with the patient lying flat, examining both breasts and examining all the breast tissue. This is consistent with the Oxford Handbook of General Practice and Patient.info."* The IPA further advised *"Doctors learn and are assessed on the techniques of breast examination in their training. There is no standardised method…"* The IPA concluded *"…the examination of the breasts performed by the doctor in April 2016 was consistent with Good Medical Practice and also with two reputable sources of clinical practice guidelines, the Oxford Handbook of General Practice and*

*Patient.info."*

16. I note that the IPA was satisfied with the practice's adherence to the Oxford Handbook of General Practice. However, the IPA suggested the practice provides further explanation *"as to why a referral was not made at the first consultation as the nodularity (lumpiness) was asymmetrical and the patient is over 30 years of age."* In relation to the appropriateness of oil of evening primrose, the IPA did not consider it was an appropriate measure as there was no indication for it because of the absence of cyclical breast pain.

17. In relation to the second consultation, the IPA advised that *"the decision to continue to recommend oil of evening primrose was unlikely to do harm and did not affect ongoing clinical care although was not given for the indication of cyclical pain."* The IPA concluded further that *"However, the care given, that is assessment of the breasts, reviewing the clinical progress of signs and arranging follow up, was in consistent (sic) in accordance with clinical guidelines and good practice."* The IPA advised that the practice's explanation as to why it did not examine the breasts standing up was reasonable in the circumstances. The IPA advised that *"While it may have reassured the patient that her concerns were being taken seriously, it would have been clinically unreliable and not the usual technique and as no lump was palpable, would not have changed the course of the clinical decision making."*

18. In relation to the final consultation, the IPA noted that the breast lumpiness was found to have persisted and deteriorated and that an urgent referral was made. The IPA advised that *"The doctor's urgent referral was consistent with NICE guidance."* In relation to whether the patient should have been referred earlier, the IPA advised that *"The doctor could have referred the patient to the breast clinic at the first consultation following the Oxford Handbook of General Practice. However, it was reasonable and consistent with Good Medical Practice and NICE guidelines on referral for suspected cancer* [to arrange] *regular follow up and review with referral in May 2016."*

19. The IPA also did not believe that the doctor failed to detect the breast cancer. The IPA referred to the breast surgeon's letter which clearly states it was not clinically palpable and it was therefore not possible to detect it. The IPA distinguished

between lumps and lumpiness and advised *"there is no evidence during the examinations that the lumpiness was clinically suspicious. It was therefore not possible for the doctor to detect the breast cancer…"* Overall, the IPA considered *"the care and treatment provided … has been appropriate and been consistent with Good Medical Practice and NICE guidelines on referral for suspected cancer…"*

20. In response to the IPA, the practice stated that 'observation' is always carried out. However they also confirmed that observation is only documented if something abnormal is observed. The Investigating Officer sought clarification from the practice regarding the absence of a referral at the first consultation as outlined in the Oxford Handbook. They responded that; *"the Oxford Handbook states that a 'referral should be made for woman over 30 with asymmetrical nodularity'. The referral was not made at this stage as clinically the doctor viewed what was described by the patient as a 'lump', more as lumpiness. Women with breast lumpiness commonly have more lumpiness in one side than the other. Although a slightly greater amount of lumpiness was found on one side during the consultation we find this is often the case, and there was not enough of a disparity to constitute truly asymmetrical findings which would have been more concerning.*

21. The practice responded to the IPA advice to confirm that the doctor did follow the advice of the Oxford Handbook as at the patient's first attendance the lumpiness was not truly asymmetrical or suggestive of malignancy. The practice concurred with the IPA's conclusion that the treatment was reasonable and consistent with Good Medical Practice and NICE guidelines for suspected cancer. They also indicated it would consider the recommendations of the IPA and where necessary will make changes to protocols following receipt of the Ombudsman's final report.

22. The Investigating Officer sought further advice from the IPA regarding the practice's compliance with the Oxford Handbook. The IPA considered their response to be reasonable as *"they have provided a full explanation of the findings with reference to the Oxford Handbook and a clear explanation of the difference between clinically significant asymmetrical lumpiness and normal findings which are rarely completely symmetrical*." The IPA further advised that a referral was not indicated at the first consultation as the lumpiness could not be described as persistent. The IPA also confirmed that having reviewed the additional response from the Consultant

Surgeon, *"…I do not* consider *that the tumour was clinically palpable."* In relation to service improvements, the IPA suggested that it may be useful to include observation in the practice protocol. The IPA added that clarification has been provided by the practice and the original advice remains unaltered.

23. In response to my draft report, the patient stated that she did not accept her doctors' reasons for a non-referral at the first consultation. She reiterated that she did not present with 'lumpiness' in her breasts but rather a specific lump in her right breast. She showed the doctor exactly where it was and how it could be best detected whilst lying down. She stated that she was advised to take evening primrose oil, when she had a specific hard lump that she knew wasn't going to go away with evening primrose oil. She also stated she does not accept that her finding a lump in her right breast and the subsequent diagnosis of cancer in two areas of the same breast was merely a coincidence. She added that had she taken on board her doctor's assurances of being '95% certain' that there was nothing to worry about, she may have been satisfied taking evening primrose capsules and not returned for a review. However because she was so concerned about the lump she returned for further examination but her concerns were dismissed.

## ANALYSIS AND FINDINGS

24. The patient complained that at the consultation in early April 2016 her doctor did not adequately examine her, as she explained the lump could be better detected when standing up. However the doctor asked her to lie down and having detected lumpiness in both breasts, told her to take oil of evening primrose and return in one month. I accept the advice of the IPA that there is no proven best method of breast examination and that the examination performed was consistent with good practice and relevant standards. In terms of the treatment given, the doctor recommended conservative measures and to return in three weeks. I accept the advice of the IPA that although oil of evening primrose was not warranted, there is no evidence that it led to any harm and had no effect on the patient's ongoing care. I am also satisfied that the practice has provided a reasonable explanation as to why it did not refer the patient at the first consultation, in accordance with the Oxford Handbook. I therefore

accept the advice of the IPA that the doctor followed the practice outlined in the Oxford Handbook and that there were no symptoms to indicate a referral to the Trust's breast clinic after the first consultation.

25. At the second consultation the patient complained that she again told the doctor that the lump could be better detected whilst standing. However she complained that she was again examined lying down. I accept the advice of the IPA that it was reasonable in the circumstances that the doctor did not carry out the examination on the patient while she was standing up. I also accept that although it may have provided reassurance to the patient that her concerns were taken seriously, this approach would have been clinically unreliable and was not the usual technique. In terms of the care given, I accept the advice of the IPA that arranging follow-up was in accordance with clinical guidelines and good practice.

26. The patient also complained about the consultation at the end of May 2016. As previously stated, I accept the advice of the IPA that it was reasonable in the circumstances that the doctor did not examine the patient standing up. I note that at this consultation the doctor did not detect a lump but noted that the lumpiness in both breasts had deteriorated. An urgent referral to the Trust's breast clinic was arranged. I accept the advice of the IPA that this was consistent with the relevant clinical standards and there was no indication to refer the patient as a 'red flag referral' under the cancer pathway.

## CONCLUSION

27. I am satisfied that the care and treatment provided by the doctor in this case was consistent with good practice and relevant clinical standards. I acknowledge that there was an unfortunate outcome for the patient and that she has maintained she found a lump. However I accept the advice of the IPA that the evidence points to it not being clinically detectable by palpation and there is no evidence to suggest that the doctor should have made the referral sooner. **I have not found any evidence of a failure in the care and treatment provided. I therefore do not uphold this issue of complaint.**

28. I arrived at my final decision following careful consideration of responses from both parties on the content of my draft report. I am conscious that the patient may be disappointed with the outcome of my investigation of her complaint. However I hope that she will accept that I have reached my decision only after the most careful examination, consideration and testing of all available evidence.

**Service Improvements**

29. Although I have not found any evidence of a failure in care and treatment, I am however of the view that the practice should use the IPA's suggested service improvements as an opportunity to improve its service. I therefore suggest it considers implementing the following service improvements, as outlined by the IPA:

- The practice should review its protocol for breast examination to include also specifically noting that where a woman has a site of concern that this has been acknowledged and examined. Patient.info states '*If you have difficulty finding a discrete lump, ask the patient to demonstrate it for you'.*

- The use of oil of evening primrose should be reviewed, particularly as NHS Clinical Knowledge summaries '*do not routinely recommended evening primrose oil for cyclical breast pain'* and there is no indication in breast nodularity.

- The practice should review evidence for referral of women with asymmetrical nodularity, and select evidence-based guidance which they will adopt. In this case the guidance they use was not followed, but alternative guidance suggests an alternative evidence-based pathway.

- The practice should ensure that notes record the full history, which includes the relevant history of the presenting complaint, the relevant personal or other history and the site of concern. In this case the duration and site of the breast lump were not noted which was clinically relevant when the signs were in another site.

I am pleased to report the practice has indicated in response to my draft report that it will be reviewing each of the service improvements recommended by the IPA and giving consideration to its current policies.

**MARIE ANDERSON**
**Ombudsman** **June 2018**

**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.