

Investigation Report

Investigation of a complaint against Western Health and Social Care Trust

NIPSO Reference: 201916858

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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: 201916858

Listed Authority: Western Health and Social Care Trust

SUMMARY

I received a complaint about the care and treatment provided to the complainant's mother at Altnagelvin Area Hospital from 23 August 2019 until 14 October 2019. The Western Health and Social Care Trust manage this hospital. The complainant said she was disappointed that the patient's initial MRI¹ was declined. She expressed concern that Trust staff had presumed that the patient's ovarian mass² was not malignant. The complainant said that a MRI subsequently taking place on 11 October 2019 was too long a timeframe to wait, given the size of the ovarian mass. In addition, the complainant was unhappy that she had not been made aware of the patient's pulmonary sepsis³ diagnosis until she read it on her mother's death certificate. The complainant felt that she had not received an acknowledgement or answer from the Trust as to why this was the case in the Trust's reply to her original complaint. Furthermore, the complainant was dissatisfied with the pain relief the Trust staff provided to her mother on 14 October 2019, and challenged the honesty of the Trust's response to her on this issue.

The investigation examined the details of the complaint, the Trust's response, and relevant local and national guidance. I obtained independent professional advice from a Consultant Physician, a Consultant Radiologist and a Consultant in Obstetrics and Gynaecology.

The investigation uncovered that the Trust had mislaid or lost certain parts of the patient's medical records. Whilst sufficient records were provided to enable the independent professional advisors to provide advice that I could rely upon in this specific investigation for the most part, this cannot be said of all elements. I considered this loss of records to be maladministration on the part of the Trust, causing the injustice of frustration, upset and mistrust for the complainant.

The investigation did not find a failing in terms of the care and treatment provided to the patient regarding the cancellation of the initial MRI scan. Regarding the malignancy of the

¹ MRI stands for Magnetic Resonance Imaging – and is a type of scan which uses magnetic fields and radio waves to produce images of the inside of the body.

Abnormal growthson the ovaries.

³ Sepsis is a potentially life-threatening condition caused by the body's response to an infection. Pulmonary sepsis refers to such an infection of the lungs and/or respiratory system.

patient's ovarian mass, the investigation found while the treatment plan was ultimately in line with relevant standards, there were failings in the care and treatment provided to the patient. These related specifically to the recording of the patient's RMI score, together with the calculation method used to determine it, and observations relating to the vascularity of the ovarian mass. I consider this resulted in the injustice of uncertainty for the patient and the complainant. The investigation was unable to reach a conclusion regarding communication from the Trust in terms of the patient's sepsis diagnosis because the Trust had lost or mislaid key medical records. The investigation did not find a failing in care and treatment in respect of the pain management provided to the patient on 14 October 2019.

The investigation also established maladministration in relation to the Trust's handling of the complainant's queries regarding the diagnosis of sepsis, and pain relief administered on 14 October 2019. I consider the failures identified caused the complainant to suffer the injustices of upset, frustration and having to take the time and trouble to bring a complaint to this Office.

I recommended that the Trust apologise to the complainant directly for the failures in complaint handling identified. Regarding failures in record-keeping and in care and treatment provided to the patient, I made six further recommendations for the Trust to address under an evidence-supported action plan to instigate service improvement and to prevent future reoccurrence of the failings identified.

THE COMPLAINT

Background

- The patient had a medical history of Crohn's Disease⁴. On 23 August 2019 the 1. patient was admitted to Altnagelvin Hospital (the Hospital) with suspected complications connected to that condition. A CT scan⁵ took place which incidentally uncovered an ovarian mass. As a result of the mass being uncovered, a MRI scan was arranged for the patient as an 'urgent priority'. The patient was subsequently discharged from the Hospital and the MRI scan was given an outpatient⁶ designation. Before the scheduled MRI scan took place, the patient returned to the Hospital to undergo an Ultrasound scan⁷, at the request of her GP. The results of the patient's CT and Ultrasound scans were reviewed by a Consultant Radiologist, who made the decision to cancel the previously arranged MRI scan. Instead, the patient was referred for a Gynaecological (gynae) Clinic Review⁸ (the Review), and the patient's case was discussed at a Local Gynaecological and Oncology Multidisciplinary Meeting⁹ at the Hospital.
- 2. The patient attended the Review, at which she was informed by a Consultant Obstetrician and Gynaecologist that the mass was not 'overtly malignant¹⁰' at that time, but that potential malignancy could not be excluded. As a result, surgery was recommended to the patient. Before a decision in respect of surgery was made, the patient was readmitted to the Hospital with suspected symptoms connected to a stroke¹¹. A second MRI scan was requested. This scan took place and unfortunately showed a rapidly progressing malignancy. The patient and her family were informed that the patient was suffering from terminal 12 cancer on 10 October 2019. Unfortunately the patient passed away on 14 October 2019 whilst in the Hospital. The cause of death was recorded as pulmonary sepsis due to, or as a consequence of, metastatic ovarian cancer¹³ on the patient's death certificate.

⁴ Crohn's Disease is a type of inflammatory bowel disease which causes inflammation to the digestive tract. Symptoms can include abdominal pain, severe diarrhoea, fatigue, weight loss and malnutrition.

⁸ An appointment with a Gynaecologist to discuss female health-related matters.

Computerised tomography scan - creates cross-sectional images of the bones, blood vessels and soft tissue in the body using a series of X-rays taken from different angles around the body.

A patient who comes to hospital for a short appointment without requiring an overnight stay.

A procedure that useshigh-frequency sound waves to create an image of part of the inside of a body – also known as a sonogram.

⁹ A meeting of a group of medical professionals from one or more clinical disciplines who together make decisions regarding treatment for individual patients.

Tendency of a medical condition to become progressively worse - often used as a characterisation of cancer.

¹¹ A life-threatening medical condition that happens when the blood supply to part of the brain is cut off.

¹² Incurable, predicted to lead to death.

Advanced stage of malignancy that has spread from cells in the ovaries to distant areas of the body.

3. The complainant made a complaint to the Trust on 23 October 2019 about the care and treatment the patient received, and also about the communication between the Trust staff and the patient's family. The complainant felt the Trust's actions were humiliating, damaging and unnecessary for the patient's family. The Trust responded by letter dated 13 March 2020.

Issues of complaint

4. The issues of complaint accepted for investigation were:

Issue One: Whether the care and treatment the Trust provided to the patient between 23 August 2019 and 14 October 2019 was appropriate, reasonable and in accordance with relevant policies and standards?

Issue Two: Whether the Trust has investigated and responded to the complaint in accordance with relevant policies and 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. The Investigating Officer also obtained written comments from individuals at the Trust who were identified as part of this investigation as having, or potentially having, information relevant to this investigation. All these individuals were informed in writing of their rights under the 2016 legislation prior to their comments being sought. Documentation gathered included information relating to the Trust's handling the complaint.

Independent Professional Advice Sought

- 6. Independent professional advice was obtained from the following independent professional advisors (IPAs):
 - Consultant Radiologist (R IPA), Dr med, MRCP, FRCR: who has over 16
 years' experience working in a specialist cancer centre with a high load
 of cross-sectional imaging.

- Consultant in Obstetrics and Gynaecology (OG IPA), BSc, MB, ChB, FRCOG, MD: who has been practicing since 2000 and is an accredited Minimal Access Surgeon¹⁴ and Colposcopist¹⁵ with the BSCCP, and has been appointed gynaecology cancer lead.
- Consultant Physician (P IPA), MB, MSc, MD, FRCP, FRCPEd, FRCPI,
 Dip Card RPMS Lond: who has been practicing for over forty years, and
 who has been an accredited geriatrician¹⁶ since 2001.
- 7. The information and advice which informed the findings and conclusions are included within the body of this report. The IPAs provided 'advice'; however how this advice was weighed, 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 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 17:

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

- Northern Ireland Cancer Network (NICAN) Regional Gynaecology Group
 - Imaging Guidelines for Suspected and Confirmed Gynaecological

¹⁴Surgeon who complete surgery with one or more small insertions rather than a large insertion.

¹⁵ A trained specialist in the use of a colposcope to examine the cervix, vagina and vulva.

¹⁶ Doctor who specialises in providing primary care to older adults aged 65 years and up.

¹⁷ These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

- Malignancy, August 2014 (Cancer Imaging Guidelines).
- Royal College of Obstetricians and Gynaecologists (RCOG) Guideline
 Management of Ovarian Cysts in Post-Menopausal Women, July 2016 (RCOG Guideline);
- National Cancer Waiting Times Monitoring Dataset Guidance,
 September 2020 (Dataset Guidance);
- The National Institute of Care and Excellence (NICE) Clinical Guideline
 122 Ovarian Cancer: Recognition and Initial Management, April 2011
 (NICE NG122);
- Department of Health: Guidance in relation to the Health and Social Care
 Complaints Procedure (April 2019) (DoH Guidelines);
- Western Health and Social Care Trust 'Policy for Management of Complaints', March 2015 (Trust's Complaints Policy); and
- The General Medical Council's (GMC) Good Medical Practice, April 2013 (GMC Guidance).
- 10. I did not include all of the information obtained in the course of the investigation in this report but I am satisfied that I took into account everything I consider to be 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 gave careful consideration to the comments I received from both the complainant and Consultant B, on the part of the Trust, before I finalised this report. In addition, I sought further independent professional advice on foot of the comments received.

THE INVESTIGATION

Issue One: Whether the care and treatment the Trust provided to the patient between 23 August 2019 and 14 October 2019 was appropriate, reasonable and in accordance with relevant policies and standards?

Detail of Complaint

- 12. The complainant raised the following concerns regarding the care and treatment provided to the patient by the Trust between 23 August 2019 and 14 October 2019:
 - That the MRI scan for the patient which was arranged on 24 August 2019 was cancelled by the Consultant Radiologist on 30 August 2019 without valid reason for doing so;
 - That as a result a MRI scan did not take place until 11 October 2019, which
 was too long of a time period for the patient to have waited for that scan,
 given her sizeable ovarian mass;
 - That the Trust staff had presumed that the patient's ovarian mass was not malignant;
 - That the patient's family had not been informed about the patient's sepsis diagnosis until it appeared on the patient's death certificate; and
 - That the patient was not provided with adequate pain relief on 14 October 2019.

Evidence Considered

Legislation/Policies/Guidance

- 13. I refer to the following policies and guidance which were considered as part of investigation enquiries:
 - · Cancer Imaging Guidelines
 - RCOG Guideline;
 - NICE NG122;
 - Dataset Guidance.

The Trust's response to investigation enquiries

14. The Trust provided written responses to both the complainant and this Office in respect of the above mentioned concerns.

- 15. In addition, written statements were provided to this Office by three individuals who had been identified as having information relevant to this investigation, as follows:
 - The Consultant Radiologist who cancelled the original MRI scan (Consultant A);
 - The Consultant Obstetrician & Gynaecologist who met with the patient on 12
 September 2019 (Consultant B); and
 - The Medical Consultant with responsibility for the patient's care and treatment at the time of her death (Consultant C).

Cancellation of MRI on 24 August 2019

- 16. The Trust stated that such a scan is not part of the 'recommended Ovarian Cancer pathway', and made reference to the Cancer Imaging Guidelines in support of that position. The Trust explained that the results of the CT scan and the Ultrasound scan, when combined, were sufficient to result in the patient's case being discussed at the Multi-Disciplinary Team Meeting and ultimately referred for review at the Gynae Clinic. The Trust's position, therefore, was that the MRI scan was no longer necessary, and that it was on this basis that it was cancelled.
- 17. In Consultant A's statement she explained that 'the cystic/solid lesion had been characterised sufficiently', so she cancelled the MRI scan and advised a referral to the Gynaecology department for 'definitive diagnosis and treatment'. Consultant A also explained that she approached Consultant B about the results, which led to the case being discussed at the Multi-Disciplinary Team Meeting.
- 18. In Consultant B's statement he said that there was 'no indication at this stage for a MRI, as it would not have added to the overall clinical picture'. Consultant B went on to say that 'even if overt malignancy was suspected at this stage a CT would be the imaging of choice for a suspected ovarian cancer'.

Delay in subsequent MRI

19. The Trust said that this scan was requested by the Hospital's medical team, without any consultation with the Gynaecology team or with staff during a Multi-Disciplinary Team Meeting. The Trust explained that the timing of the scan was delayed due to the patient being discharged from hospital and later readmitted. The Trust stated that when the MRI scan took place, the results showed that the 'the disease had

unfortunately progressed significantly' since the CT scan had been carried out on 23 August 2019. The Trust went on to say that even if the MRI scan had been performed earlier 'it is unlikely that it would have shown disease progression in such a short interval from the CT [scan] (23 August 2019) or given us any significant additional information'.

20. Consultant C said in his statement that he requested a MRI scan because of the patient's existing status as an outpatient with 'suspected malignancy'. Consultant C explained that the results of that MRI showed 'extensively metastatic disease and significant increase and progression of the disease of ovarian cancer'. Consultant C said that it 'looks like very aggressive disease, not amenable for biopsy and treatment'

Consideration of malignancy of ovarian mass

- 21. The Trust stated that results of the CT scan and Ultrasound scan raised a 'suspicion of malignancy'. As a result, the patient's case was discussed at the Multi-Disciplinary Team Meeting and ultimately referred for review at the Gynae Clinic. The Trust's position was that if malignancy had not been 'suspected', then such a discussion and referral would not have taken place.
- 22. Consultant B said in his statement that he informed the patient that 'while it [the ovarian mass] was not overtly malignant, I was unable to completely exclude a focus of abnormal cells within it', and so he recommended surgery. In respect of it not being overtly malignant, Consultant B said that a CA-125 test¹⁸ had been carried out on 16 August 2019 which showed a "normal" result of 25. Consultant B explained that the patient was hesitant to proceed with surgery, due to a fear of requiring a colostomy bag¹⁹ but agreed to consider the surgical options. Consultant B said that following the MRI scan that took place he reviewed the results and noted a 'rapidly progressing malignancy', but the patient had already passed away at that point.

¹⁹ A bag that collects fecal matter from the digestive tract through an opening in the abdominal wall called a stoma.

¹⁸ A test to measure the level of cancer antigen 125 in the blood – with a result between 0-35 units/ml being normal, and a result over 35 units/ml being an indicator of potential cancer.

Communication with the family about sepsis

23. The Trust apologised for 'any additional distress caused', and highlighted that an offer had been made to the complainant to meet with the staff who provided care and treatment for the patient. The Trust repeated that offer to the complainant.

Pain relief on 14 October 2019

24. The Trust said that Oramorph²⁰ was administered to the patient at 04.00, and again at 20.45. The Trust explained that the patient was 'retching' on the two occasions that the drug was administered, and as a result was 'not able to swallow it fully'. The Trust explained that the patient was asked by nurses in the interim if she was in pain that day, and that the patient 'denied that she was'.

Relevant excerpts from medical records

25. Relevant excerpts from the patient's medical records were studied.

Relevant Independent Professional Advice

Cancellation of MRI 24 August 2021

R IPA (Radiologist)

26. The R IPA confirmed that the patient's ovarian mass was first detected incidentally during a CT scan aimed at treating the patient's Crohn's Disease symptoms. The R IPA advised that a MRI scan was requested and subsequently cancelled in August 2019. The R IPA also advised that the patient received an ultrasound scan on 30 August 2019.

27. The R IPA said 'the patient was planned for surgery and further imaging would not have a bearing on this and therefore was – arguably – redundant'. The R IPA went on to say that 'the decision had been made to operate and remove the tumour. The operation could potentially have been delayed by another scan, the result of which probably would not have altered management anyway'. The R IPA advised that

²⁰ A strong painkiller taken by mouth which is a form of Morphine.

- 'once the decision to proceed to surgery was made, the [MR] scan was no longer required but could have potentially delayed surgery'.
- 28. In relation to the care and treatment pathway, the R IPA advised that 'the decision to operate obviated the need for further imaging'. The R IPA went on to advise that 'it was decided to list the patient for surgery, which was an appropriate course of action for both a benign as well as a malignant tumour. An MRI scan at this stage would have been of academic interest only'. The R IPA advised that 'it was within the remit of the consultant radiologist to decide whether sufficient information had been obtained from the US and CT scans and to cancel the MRI'. The R IPA advised that the decision to cancel the MRI 'was justified', had 'no detrimental impact' on the patient's care and treatment, and was a reasonable decision for the consultant to have made. In his supplementary advice, the R IPA advised that it was 'good practice that an attempt was made to cancel an unnecessary examination'.
- 29. The R IPA noted that there could have been better communication between the Trust and the patient and/or their family regarding the reasons for cancelling the MRI scan at the time and further noted that better communication may have been 'reassuring' for the complainant. The R IPA said 'I believe the complaint is based on the assumption that the patient came to harm because the MRI scan was cancelled or delayed. To reiterate, the MRI scan was no longer required and it was cancelled appropriately. It would appear that the reasons for this may not have been adequately relayed to the family'.

OG IPA (Obstetrician and Gynaecologist)

30. The OG IPA advised that this decision was 'entirely reasonable' — on the grounds that 'RCOG guidelines do not recommend the use of MRI as an initial modality to assess ovarian cancer', and that in the 'vast majority' of cases, CT and ultrasound scans are 'adequate to give sufficient information concerning a mass'. The OG IPA advised that 'it is extremely unlikely that MRI would have provided any further information at that point'. The OG IPA added that 'MRI is an expensive resource and generally in demand throughout the hospital. It is inappropriate to perform unnecessary investigations'. The OG IPA advised that the decision made by

Consultant A to contact the patient's GP about an 'urgent referral to gynaecology' instead was 'appropriate'.

31. The OG IPA noted that Consultant A then had an informal discussion with Consultant B which resulted in the patient's case being discussed at the Multidisciplinary Team Meeting on 10 September 2019. The OG IPA explained that under National Guidelines²¹, a patient with a referral for suspected cancer should be seen within two weeks, and have their treatment commence within 62 days. The OG IPA stated that the approach taken by the Trust staff following the ultrasound was 'entirely within National Guidelines' and 'well within acceptable timeframes'. The OG IPA said that due to the 'informal conversation' between Consultants A and B, the patient's case was discussed 'approximately one to two weeks earlier in the expected timeline'.

Delay in subsequent MRI

R IPA

32. The R IPA said that it was 'unclear' why a second MRI scan was later scheduled as 'surgery could and should have been undertaken without it'. The R IPA advised that the scan had become 'immaterial', and that 'the diagnosis of possible cancer needing an operation had already been made on the basis of the US and CT scan. Little additional information was to be gained from a third scan'.

OG IPA

33. The OG IPA advised that 'delaying the MRI has not had an effect on the patient's care', and that an earlier MRI 'would not have provided further information' on the patient's overall medical status.

Consideration of malignancy of ovarian mass

OG IPA

34. The OG IPA advised that following the Multidisciplinary Team Meeting, the patient attended a consultation with Consultant B at which surgery was discussed, including the potential for joint surgery with a Consultant Colorectal Surgeon. The OG IPA referred to this treatment plan being devised for what was thought to be likely to be a *benign*; mass rather than a malignant one. The OG IPA advised that

²¹ National Cancer Waiting Times Monitoring Dataset Guidance, September 2020.

- the 'referral to a colorectal surgeon to discuss a joint procedure was entirely appropriate' in these circumstances.
- 35. However, regarding the ovarian mass being considered not to be 'overtly malignant', the OG IPA raised a point in their advice in respect of there being no referral made to an Oncology Centre following the Multidisciplinary Team Meeting stating 'I am surprised that the patient was not referred to an oncology centre following this meeting'. The OG IPA explained that this was due to the 'complexity of the potential surgery', the patient's Risk of Malignancy Index (RMI) score of 225, and the 'vascularity of the mass'.
- 36. Regarding the RMI score, the OG IPA explained that under the RCOG Guideline, this score is used to determine the risk of an ovarian mass being malignant. The score is the result of a calculation using ultrasound findings, menopausal status and the level of CA125 as the variables. Under the RCOG Guideline, a RMI score of 200 or more is considered to be a higher risk of cancer. The OG IPA advised that in contrast to the RCOG Guideline, the NICE NG122 recommends an alternative calibration of the scoring, where a score of 250 or more is considered high risk of cancer. The OG IPA advised out that the patient's score of 225 would be considered high risk under the RCOG approach, but low risk under the NICE approach.
- 37. The OG IPA also made reference to the RCOG Guideline regarding the features of an ovarian mass which can be determined from a CT scan, and which are likely to indicate malignancy. The OG IPA referred in particular to the blood flow feature, and advised that the mass had been described as 'vascular' following the CT scans. The OG IPA advised that 'the CT scan was described as a vascular mass and this should have raised a suspicion of malignancy' and as a result, 'features on the CT scan report do not seem to have been factored into the discussion in assessing the risk of malignancy'. The OG IPA was of the opinion that given the RMI score exceeded the RCOG threshold, and the description of the mass as 'vascular', he was 'surprised' that a referral to Oncology was not made following the Multidisciplinary Team Meeting.

- 38. The OG IPA was asked if the care and treatment provided to the patient was appropriate, reasonable, timely and in line with relevant standards. The OG IPA advised 'there does not seem to be any acknowledgement that the RMI is above 200 and I am surprised that a referral to the regional Gynaecological oncology team was not made'. However, the OG IPA went on to advise that 'given the patient's rapid deterioration from her disease and co-morbidities, it is unlikely that a referral to a tertiary centre would have affected the outcome'.
- 39. The OG IPA further advised that 'even if the diagnosis had been a likely malignancy, the patient would usually be referred to a cancer centre for MDM review discussion and surgical planning. The timeline for this is usually 3-4 weeks. Given the patient's rapid deterioration over that time frame, she would not have been fit of extensive surgery and therefore in my opinion this has not altered the eventual outcome'. The OG IPA advised that 'given the rapid progression of the disease it is highly unlikely that any treatment would have been effective in controlling the disease'.
- 40. The OG IPA raised concerns regarding the medical notes and records the Trust supplied stating that they were 'far from complete' and 'barely adequate'. In particular, the OG IPA identified the following concerns in this respect:
 - a) The patient's discharge letter dated 25 August 2019 makes reference to an out-patient referral to gynaecology being made, but the OG IPA stated that 'there is no evidence from the notes I have which confirms if this appointment was made':
 - b) The medical notes refer to the outcome of the Multidisciplinary Team Meeting at which the patient's case was discussed, but 'there is no documentation as to who attended the MDM, only an outcome letter'. It should be noted, however, that the Trust subsequently provided this information as part of the supplementary written statement of Consultant B;
 - c) There were no clinical ward notes from the patient's initial admission or from her 'multiple medical admissions'. It should be noted, however, that the Trust subsequently provided this documentation at the request of this Office;
 - d) There was no 'documentation of a calculation of the RMI to assess the mass and a consequent treatment plan based on that calculation'. Furthermore,

there was no indication as to whether the Trust follows the RCOG or NICE model in making its RMI calculations. The OG IPA advised that 'I would consider it mandatory to calculate and document the RMI as recommended by the RCOG with an outcome plan'.

In the supplementary written statement of Consultant B he accepted that the RMI had not been 'explicitly documented', but said that it had been considered when the patient's care pathway was being determined. Consultant B confirmed that the patient's RMI score was '225'. Consultant B referred to the RCOG Guideline, but did not clarify exactly which model was used for the calculation for the patient – only referring to '250' being the score to demonstrate higher risk of malignancy. Consultant B said that as a result of this score, and the imaging results, the patient was "felt to have a low likelihood of ovarian malignancy", but was offered surgery by way of "pelvic clearance²²" in any event.

In his supplementary advice, the OG IPA advised that 'if an RMI of 250 was used this is fine, but this needs to be a documented region wide protocol to ensure that all patients receive the same level of assessment and care'. The OG IPA explained this this is particularly important and relevant in this case, where a score of 225 yields a different outcome, depending on which model was applied. The OG IPA concluded that the absence of a documented, region-wide management protocol in this respect was 'sub optimal'.

OG IPA's Overall Conclusion

41. The OG IPA concluded that 'the fact that a MRI scan was not performed initially, has had no effect on this patient's disease process. Nor in effect has the lack of documentation of the RMI or management of the disease as probably benign'. The OG IPA went on to conclude that even if the mass had been identified as being malignant on 10 September 2019, it is unlikely the patient could have had surgery before the end of October 2019, at which point she would have been 'unfit for surgical intervention' due to the 'effects of advanced disease'. This position was reiterated in the OG IPA's supplementary advice.

²² An operation to remove the internal reproductive organs from the pelvic region.

Communication with the family about sepsis P IPA (Physician)

- The P IPA advised that he did not consider the patient developed any of the 'red flag' symptoms of sepsis syndrome – namely – 'high fever, fast heart rate, rapid, shallow breathing, and low urine output. The P IPA advised that there are none of the 'classical manifestations' of sepsis and the patient's 'clinical presentation was not like sepsis' - stating that 'there is no record of blood cultures showing growth of organisms in the blood either. Neither did she have any features of acute respiratory distress syndrome which would have been expected in the presence of severe sepsis'. The P IPA advised that he considered that the patient had instead contracted 'hospital acquired pneumonia (HAP)' - and that this is likely what caused the patient's death as 'her immunity had been rendered so low by the cancer and she easily caught a bug in hospital. The P IPA went on to advise that the drugs being administered to the patient indicated she was receiving treatment for HAP. As a result, the Death certificate 'could instead have said she died of HAP due to ovarian cancer. The P IPA advised that 'it is possible that the possibility of sepsis in her diagnoses was considered in the last few hours before death, in view of rapid deterioration'.
- 43. Regarding the communication element specifically, the P IPA advised that the signed DNAR²³ form states that the reason it was being signed was due to the diagnosis of 'disseminated malignancy. Sepsis' and that records state this was discussed with the patient's daughter. The P IPA advised 'I take it that' Consultant C mentioned sepsis at this time, but it cannot be determined for certain. Furthermore, the P IPA advised that 'it cannot be certain whether her [the patient's] daughter took in all that she was being told by the consultant' due to her understandable concerns about the patient's poor health at the time. The P IPA accepted that the family were likely 'taken aback' by the word 'sepsis' appearing on the death certificate, and suggested that 'perhaps it would have been easier if the MCCD had said 'hospital acquired pneumonia' instead of 'pulmonary sepsis' on the basis that the patient had not exhibited any signs of sepsis in the medical records provided. The P IPA concluded that when the family had complained to the Trust about the communication issue regarding sepsis, the Trust ought to have realised

²³ Do Not Attempt Resuscitation Form

that the family were confused about the death certificate and explained what had been put onto it. Doing so may have 'served to avoid considerable angst and worry' for the family.

Pain relief on 14 October 2019

P IPA

- 44. The P IPA advised that the Trust had not supplied the drug administration record for this date to this Office. The P IPA explained that, as a result, his advice was based on information he obtained '*indirectly*' from nursing records and NEWS²⁴ charts. The matter of missing records is addressed in detail later in this report at paragraphs 46-55.
- 45. The P IPA identified that on 14 October 2019 the NEWS charts had eight entries throughout the day where the patient's pain was recorded as being '0/10' which meant that the patient did not report experiencing any pain on that day. The P IPA also advised that nursing records referred to the patient specifically declining pain medication that day, 'thus corroborating the pain scores available in the NEWS charts'. The P IPA advised that the patient was administered 5ml of morphine liquid at 03.30 that day. The P IPA was asked if the pain relief administered that day was appropriate, reasonable and in line with relevant standards. The P IPA advised that it was. The P IPA advised that it was not necessary to prescribe long-acting regular morphine when the patient was not requiring 'repeated doses of oral morphine'. The P IPA did advise, however, that he cannot comment on any other drugs that may have been administered that day, as the record was not there to be reviewed.

Analysis and Findings

Preliminary Matter – Mislaid or Lost Medical Records

- 46. The following medical notes and records in respect of the patient were not provided to this investigation when requested on the basis that the Trust could not locate them:
 - Medicine Kardex²⁵;
 - Drug Administration Records for 14 October 2019; and

²⁴ National Early Warning Score – standardised system for recording routine medical data

²⁵ Prescription and Administration Record

- Consultant C's Medical Notes for the period 11 October 2019 14 October 2019.
- 47. Both the OG IPA and the P IPA identified the absence of these medical records as a matter of concern, and as an impediment to the provision of their professional advice.
- 48. The P IPA in particular identified the absent drug administration records and Consultant C's notes for the period. 11-14 October 2019. The P IPA advised that 'not having access to the relevant medical notes has been a challenge' and that this was 'not satisfactory'. The P IPA further advised that as a result, 'one can only make speculative comments/conclusions. This is not a desirable situation'.
- 49. This Office asked the Trust for these medical notes and records both at the outset of this investigation under a general request for all relevant medical notes and records, and under specific requests on foot of the IPAs' advice.
- 50. When these could not be located, this Office encouraged the Trust to follow its internal procedures in respect of lost or misplaced documentation. There has been no confirmation from the Trust in terms of any steps taken on foot of this Office's suggestion. I am therefore unable to determine whether the Trust has commenced an investigation into the missing records, whether the investigation has been conducted in line with any specific guidance or standards, or what the outcome of any such investigation might have been. I consider it important for the Trust to have been in a position to provide this Office with an evidence-based explanation for the missing records. I am concerned that Trust has not done so.
- 51. Where records are missing, it adversely impacts not only the Trust's ability to investigate and respond to complaints directly, but also this Office's ability to investigate complaints. This includes the ability of the independent professional advisors engaged by this Office to provide complete and accurate advice. Missing records also have the potential to cause a complainant to feel that openness, transparency, fairness and justice is being denied to them. These are barriers to both Good Administration and Good Complaints handling. I consider it is a fundamental principle of information governance that public sector bodies,

- especially those providing health and social care services, can easily identify, locate and retrieve information relating to their service users.
- 52. In this specific investigation, the independent professional advisors set out in their responses to this Office that they have been able to form perspectives they can endorse from ancillary and supporting medical records which were available primarily nursing notes and NEWS charts. On this basis, I have, for the most part and unless otherwise stated, been able to rely on the independent professional advice they have provided in making my findings on this complaint.
- 53. The First Principle of Good Administration, 'getting it right' requires bodies to act in accordance with 'relevant guidance and with regard to the rights of those concerned'. The Third Principle of Good Administration 'being open and accountable' requires bodies to 'handle information properly and appropriately' and to 'keep proper and appropriate records'. I consider the Trust failed to act in accordance with these principles when it lost or mislaid parts of the patient's medical notes and records. I further consider that the Trust failed to act in accordance with these principles when it failed to provide an evidence-based explanation for the missing records, on foot of a documented investigation. I am satisfied that these failures constitute maladministration on the Trust's part.
- 54. While this is not a matter for the Information Commissioner's Office (ICO), on the basis that the patient is deceased, this maladministration has impeded my ability to provide full answers on all elements of the care and treatment provided by the Trust to the patient, as set out further below in this report.
- 55. I am satisfied that the maladministration identified caused the complainant to experience the injustice of frustration and upset as a result of not being able to receive full answers to all elements of her complaint in a timely manner, upset at the loss of personal information relating to her mother, as well as mistrust towards the Trust regarding its record handling processes.

Cancellation of MRI on 24 August 2019

56. The complainant was concerned that the decision by the Trust not to proceed with the initial MRI scan meant that the malignancy of the patient's ovarian mass was

- not identified as early as it could have been. As a result, the patient did not have the opportunity to commence a treatment programme as early as she could have.
- 57. In its reply to the complainant's original complaint, the Trust stated the rationale for the initial MRI scan being cancelled was that following a review of the images from the previous CT scan by the Consultant A, she 'felt the cyst/solid lesion had already been characterised sufficiently and was advised there was a referral to Gynae for definitive diagnosis and treatment'. The Trust also stated that Consultant A spoke with Consultant B about the patient's case being discussed at the upcoming Multidisciplinary Team Meeting.
- 58. In particular, I note the OG IPA's advice that the Trust's decision to cancel the initial MRI was 'entirely reasonable' on the basis that the RCOG Guideline states that such a scan is not recommended for as an 'initial modality' to 'assess ovarian cancer'. I reviewed the RCOG Guideline on foot of the OG IPA's advice and note that position within them. I also reviewed the Cancer Imaging Guidelines in light of the OG IPA's advice, which I consider to be line with each other. I further note the OG IPA's advice that the CT and ultrasound scans which had already taken place were 'adequate to give sufficient information concerning a mass', and that it was 'extremely unlikely' that a MRI scan would have provided any more information. In this respect, the OG IPA's advice is in line with the rationale put forward by the Trust. I further note that OG IPA's advice that cancelling the initial MRI scan did not have any effect on the care and treatment provided to the patient by the Trust.
- 59. I note the R IPA's advice that the initial MRI scan became 'redundant' once the CT and ultrasound scans were analysed, and a treatment plan was put in place on foot of those scan results. As such, the R IPA's advice is also in line with the Trust's rationale, and with both the RCOG and Cancer Imaging Guidelines. I further note the R IPA's position that cancelling the initial MRI scan was 'justified' and 'reasonable' and had 'no detrimental impact' on the care and treatment provided to the patient by the Trust.
- 60. Having reviewed all relevant evidence I do not consider that the MRI scan was cancelled without a valid reason. I am further satisfied that the decision to cancel the scan did not have any negative impact upon the care and treatment the Trust

- provided to the patient. On that basis, my finding is that I do not uphold this element of the complaint.
- 61. However, I accept the R IPA's concern that there could have been better communication between the Trust and the patient and her family regarding the Trust's rationale for cancelling the initial MRI scan at the time of its cancellation. Had the Trust done so, it would have provided clarity for the patient and her family regarding the decisions being made about the patient's care. I would ask that Trust staff reflect on this.

Delay in subsequent MRI

62. I note that this MRI scan was requested by Consultant C, and not by those Consultants who had previously discussed the patient's care, and made a decision regarding the original MRI scan. I refer to the R IPA's advice which sets out that the scan had become 'immaterial', as a suitable treatment plan was already set out - and the scan was not necessary for the discussed surgery to take place. I refer also to the OG IPA's advice that 'delaying the MRI has not had an effect on the patient's care'. On this basis, my finding is that I do not uphold this element of the complaint.

Consideration of the malignancy of the ovarian mass

- 63. The complainant was concerned that the Trust had presumed that the patient's ovarian mass was not likely to be malignant, and as a result did not place the patient on the optimal treatment plan at an early enough stage.
- 64. The Trust set out in its reply to the complainant's original complaint to the Trust that following Consultant A's analysis of the CT and ultrasound scan results, an informal conversation was had with Consultant B, which resulted in the patient's case being discussed at the Multidisciplinary Team Meeting on 10 September 2019. The patient then met with Consultant B on 12 September 2019. At that meeting, whilst Consultant B described the patient's mass as not being 'overtly malignant at that time', they could not 'completely exclude a focus on abnormal cells within it'. As a result, Consultant B recommended surgery, and suggested joint surgery could take place with a Consultant Colorectal Surgeon.

- 65. In terms of the treatment pathway, I note the OG IPA's advice that the initial diagnosis following the CT scan was that the patient's ovarian mass was benign but that Consultant A questioned this diagnosis following the ultrasound scan. This resulted in the patient bring referred to the gynaecology department. This referral led to the informal discussion between the Consultants A and B, as well as the patient's case being discussed at the Multidisciplinary Team Meeting. This in turn led to the consultation between the patient and the Consultant B, and a surgical plan being discussed. I note the OG IPA's advice that this initial treatment pathway was in line with National Guidelines regarding treatment times for cancer. I reviewed the National Guidelines on foot of the OG IPA's advice and note that position within them. I also note the OG IPA's advice was that the Trust addressed the patient's case 'approximately one to two weeks earlier in the expected timeframe' due to the actions of Consultant A. I consider that Consultant A ought to be commended for their actions in this respect.
- 66. I also note the R IPA's advice that the surgery the Trust proposed as part of the patient's treatment plan was an 'appropriate course of action' for both a malignant and a non-malignant, or benign, mass.
- 67. In terms of the Trust's considerations regarding malignancy, I note the OG IPA's advice that he was 'surprised' a referral was not made to an Oncology Centre for the patient given the patient's RMI score of '225' and the recorded vascular nature of the ovarian mass.
- 68. In respect of the RMI score, I reviewed the RCOG Guideline the OG IPA referred to, and also the NICE NG122. I am satisfied that there are two medically accepted mechanisms for determining malignancy of an ovarian mass one where a score of '200' or above indicates malignancy, and another where a score of '250' or above indicates malignancy. This is of particular relevance in respect of the patient, as she received a result of '225' meaning that she would be considered at likely risk of malignancy under the RCOG mechanism, but at an unlikely risk of malignancy under the other mechanism.
- 69. I note the OG IPA's advice that the Trust's medical records do not show what consideration, if any, the Trust gave to RMI when considering the malignancy of the

- patient's mass. Furthermore, if consideration was given there is no indication of which mechanism was applied.
- 70. I note both the supplementary written statement of Consultant B, and the OG IPA's subsequent supplementary advice on foot of that further statement. Consultant B accepted that no record was made of the RMI score for the patient, but said that consideration was given to the score of '225' when reaching a treatment plan. Consultant B also makes reference to the score being under '250', which he said indicated that it was unlikely the patient's mass was malignant. This suggests the NICE mechanism had been applied. However, I also note the OG IPA's position that if the Trust adopted the NICE mechanism, that was 'fine' but that nonetheless, the RCOG Guideline states that the mechanism used, and the score worked out, must be recorded in the patient's records. Furthermore, there must be in place a 'documented region-wide protocol' in the approach to RMI to ensure consistency in care for all within the region.
- 71. In respect of the vascularity of the ovarian mass, I note the OG IPA's advice that the fact that the CT scan showed the mass was vascular should have raised a 'suspicion' that it was malignant, based on the RCOG Guideline on the importance of blood flow in determining malignancy. I further note the OG IPA's advice that there is no record of vascularity being a factor considered when the Trust was determining the malignancy or otherwise of the patient's ovarian mass.
- 72. I refer to the GMC Guidance, which requires clinicians to provide a good standard of practice and care to patients. This includes clinicians' duty to record their work clearly, accurately and legibly. It further requires clinical notes to include, amongst other things, 'relevant clinical findings', 'the information given to patients', 'any drugs prescribed or other investigation or treatment', and 'who is making the record and when'.
- 73. In my view clinical notes should precisely record the dates on which examinations referred to are performed, details of those examinations, the findings of them, and the subsequent treatment plan to be followed. This is to ensure clarity for those clinicians who will later rely on the information that is recorded in the patient's medical record.

- 74. In respect of the RMI score, I consider that Consultant B failed to clearly record the patient's score, and to clearly record the RMI calculation model being applied to reach that score. As a result, I find that these omissions in record keeping constitute a failing in the care and treatment the Trust provided to the patient.
- 75. As part of the Trust's comments on the draft report, Consultant B said that as either the RCOG Guideline or the NICE mechanism can be applied when calculating the RMI score, use of one over the other cannot be considered a failure in care and treatment. Nonetheless, Consultant B did accept that the score had not been documented in the patient's medical records. I have given full consideration to Consultant B's comments in this respect. I concur that the application of either mechanism is suitable. The use of one mechanism over the other does not, in and of itself, result in a failure in care and treatment. It is also noted that there is no regional policy currently in place regarding which mechanism to be applied with the introduction of such being a recommendation contained within this respect. However, I have found that the failure in care and treatment in this respect relates specifically to Consultant B's failure to record the mechanism being applied in the patient's medical notes, and Consultant B's failure to record the patient's RMI score in those notes. I am satisfied, therefore, with my finding in this respect.
- 76. In respect of the vascularity of the ovarian mass, it cannot be concluded with certainty whether or not this observation, available from the CT scan, was taken into consideration by Consultant B when determining the malignancy of the patient's ovarian mass. Whilst it is noted that Consultant A escalated the patient's case to Consultant B on foot of the CT scan and ultrasound results, there is no reference made to such observations of vascularity in the patient's medical notes and records. I consider that the Consultant B's failure to clearly record what consideration, if any, was given to the vascularity of the mass also fell short of the abovementioned standards set out in the GMC Guidance. As a result, I find that this omission in record keeping also constitutes a failing in the care and treatment provided by the Trust to the patient.
- 77. As part of the Trust's comments on the draft report, Consultant B said that it was the role of the Consultant Radiologist, Consultant A, to record observations relating to the vascularity of the mass in the patient's medical notes, and to address this

factor at the multidisciplinary team meeting. Consultant B challenged the finding in the draft report that it had been their responsibility to record observations on the vascularity of the mass, and the potential implications of the vascularity, in the patient's medical notes and records. Consultant B also said that the decisions made at the multidisciplinary team meeting were reached by quorum, and not by Consultant B alone.

- 78. On foot of Consultant B's comments, I sought further independent professional advice on the matter of this responsibility from the OG IPA. The OG IPA advised that the role of the Consultant Radiologist is to "describe the findings on the CT scan". The OG IPA advised that Consultant A did so in respect of the patient's scan. The OG IPA further advised that "the interpretation of the nature of the mass is the responsibility of the MDT as a whole, but this should be lead by the Consultant Gynaecologist". The OG IPA went on to advise that the final responsibility sits with the MDT lead gynaecologist who in this matter is Consultant B. the OG IPA advised that Consultant A had documented the vascularity of the mass in the initial report but that there was "absolutely no record of this finding in the MDT documentation or that the implication of the finding had been considered". The OG IPA advised that it was the responsibility of Consultant B to ensure that "the discussion concerning each patient is appropriately documented with history, findings and outcome".
- 79. Having given detailed consideration to both Consultant B's comments, and the further advice provided by the OG IPA, I am satisfied with my finding in this respect.
- 80. However in respect of the impact on the patient, I note that despite the OG IPA's concerns regarding the approach of the Trust set out above, the OG IPA advised that 'given the patient's rapid deterioration from her disease and co-morbidities, it is unlikely that a referral to a tertiary centre would have affected the outcome'. I further note the OG IPA's advice that had such a referral been made, it would have prolonged the treatment plan by 3-4 weeks, at which point the patient would no longer have been fit for surgery due to the progression of the disease. In particular, I note the OG IPA's advice that the absence of a referral to an Oncology Centre 'has not altered the eventual outcome' for the patient. I also note the OG IPA's advice that 'given the rapid progression of the disease it is highly unlikely that any

treatment would have been effective in controlling the disease. I note also the position of both the OG IPA and the R IPA that the ultimate decision of the Trust to recommend surgery for the patient, irrespective of the malignancy or otherwise of the mass, was the appropriate treatment pathway.

- 81. To conclude on this element I consider that, whilst the ultimate treatment plan put in place was reasonable, appropriate and in line with relevant standards, there were nonetheless failings in the care and treatment provided by the Trust specifically regarding Consultant B's recording of the factors and considerations which resulted in that treatment plan being set. These failings in care and treatment resulted in the injustice of uncertainty for the patient regarding the malignancy, or otherwise, of the mass she was living with, as well as uncertainty for both the patient and her family regarding treatment decisions made about the ovarian mass. Furthermore, it is noted that it was not until 10 October 2019 that the malignancy of the mass was communicated to the patient's family.
- 82. On that basis, my finding is that I uphold in part this element of the complaint to acknowledge that whilst the ultimate treatment plan was in line with relevant standards, there were nonetheless failings in care and treatment in recording of factors taken in to consideration when putting that treatment plan in place.

Communication with the family about sepsis

- 83. The complainant was concerned about the standard of communication between the Trust and the patient's family, on the basis that the family had not been made aware that the patient was diagnosed with sepsis until the family saw the patient's death certificate.
- 84. I refer to the Trust's reply to the complainant's original complaint, and I note that there was no reference to sepsis or its appearance on the death certificate in that reply. I refer also to the Trust's replies to this Office's enquiries on this concern. In that reply the Trust apologised for not addressing the complainant's concern, but did not provide any information regarding the sepsis diagnosis or the communication of that diagnoses to the patient's family. The complainant's specific concern regarding the Trust's reply in this respect will be addressed under 'Issue Two' in this report.

- 85. I note the P IPA's advice that there is no evidence available in the patient's medical records to show that the patient had, in fact, contracted pulmonary sepsis. The positon of the P IPA is that, based on the medical records available, it is more likely that the patient contacted Hospital Acquired Pneumonia (HAP) as a result of a low immune system due to the severity of the patient's cancer. The P IPA's recommendation was that the death certificate ought to have cited HAP, rather than pulmonary sepsis. However, I also note the P IPA's advice that sepsis may have been considered in the patient's final hours, as her condition deteriorated. As discussed above, unfortunately the Trust has lost or mislaid Consultant C's medical records for the last 4 days of the patient's life. It is therefore possible that observations regarding the onset of sepsis in the patient's final hours may be contained within those missing records. Therefore, neither the P IPA nor I have been able to definitively conclude on this either way. I also find this concerning in terms of the impact of uncertainty this will cause the complainant.
- 86. In terms of the treatment provided to the patient, I note the P IPA's advice that the patient did receive treatment for what he considers to have been HAP, and that the treatment received was in line with the accepted treatment programme for HAP.
- 87. In terms of communication between the Trust and the patient's family, I note the contents of the DNAR which states 'sepsis' as part of the rationale for putting the notice in place. In addition I refer to the entry in the nursing records which states that the Medical Consultant discussed the contents of the DNAR 'in length' with the complainant on 14 October 2019. I also note, however, the P IPA's advice that the Consultant C's medical notes were not made available, and therefore it cannot be determined whether Consultant C specifically discussed sepsis with the complainant. The P IPA also advised that the complainant may not have been in a position to have fully taken in all that Consultant C was saying, due to the nature of the conversation and the patient's condition at the time.
- 88. Having reviewed all relevant evidence relating to this element of the complaint, I accept the advice of the P IPA that it is likely that the patient was suffering from HAP towards the end of her life due to the treatment plan being followed and the medication being administered. However, as also indicted by the P IPA, I am not in possession of sufficient evidence to rule out the potential that an appropriate

diagnosis of pulmonary sepsis was made in the patient's last hours when her condition was rapidly deteriorating due to the Trust having lost or mislaid Consultant C's medical notes for that time period. I am nonetheless satisfied from the advice of the P IPA that the patient was receiving appropriate care for her respiratory symptoms in her last days.

89. In terms of communication with the family at the time of the patient's diagnosis, there are indications in the medical notes the Trust provided to suggest that a diagnosis of sepsis may have been discussed to some extent with the complainant as part of the explanation of the DNAR notice. If this conversation did take place, it would not be unreasonable for the complainant to have potentially not fully taken in all aspects of what being said, given the patient's condition at the time and the purpose of the DNAR being discussed which would clearly have been a distressing conversation for the complainant. However, as advised by the P IPA, in the absence of the Consultant C's medical notes from the conversation in question, it cannot be said with certainty that sepsis was discussed with the complainant at the time – particularly where this is specifically denied by the complainant. On that basis, there is insufficient evidence available to enable me to reach to finding in respect of whether or not sepsis was discussed with the complainant in advance of it appearing on the patient's death certificate. As a result, I cannot conclude on this element of the complaint. The absence of the full medical notes and records for the patient for the relevant time inhibited me from making a finding on this element. This is because the Trust has lost or mislaid Consultant C's medical notes for the period 11-14 October 2019. Regarding the lost or mislaid medical records, I refer to my conclusions regarding the maladministration and associated injustice which resulted from the Trust's actions, at paragraphs 46-55 of this report.

Pain Relief on 14 October 2019

- 90. The complainant was concerned that the patient did not receive appropriate pain relief on the last day of her life, and as a result spent that day in pain despite the complainant requesting pain relief for the patient.
- 91. In its reply to the complainant's original complaint, the Trust stated the patient received two doses of Oramorph on 14 October 2019, one at 04:00 and another in the evening. The Trust went on to say that nurse in charge of the patient's care that

day asked the patient throughout the day whether she was in pain, and that patient replied that she was not. The Trust referred to the nursing records for 14 October 2019 in support of that position.

- 92. I note the P IPA's advice that the Trust had not provided the Medicine Kardex and drug administration records for 14 October 2019. It transpires that the Trust were not able to be locate these, as discussed previously in this report. I further note the P IPA's position that, as a result of these documents being unavailable, his advice was obtained "indirectly" from nursing records and NEWS charts.
- 93. I refer to the P IPA's advice that the nursing records and NEWS charts are in agreement that the patient did not make any requests for pain relief. Furthermore, when asked about wanting pain relief, the patient rejected the option. As a result, the patient received two doses of Oramorph on 14 October 2019 one in the early hours of the morning, and one in the evening. I note that this reflects the position put forward by the Trust in its reply to the complainant's original complaint. I further note the P IPA's advice that, based on the records available to him, the pain relief provided to the patient throughout the day was appropriate, reasonable and in line with relevant standards.
- 94. I also refer to the concerns the complainant raised with this Office in which she said that the patient was 'too weak' to respond to the nurses questions about pain relief, and that she had asked for pain relief on behalf of her mother as a result. The complainant said that the evening dose of Oramorph was administered only after she complained about the lack of pain relief for the patient stating that the patient suffered 'terminal restlessness and distress'. I fully acknowledge the complainant's perspective in this respect and the concern that she had to advocate for pain relief for her mother. The medical records supplied by the Trust do not provide a complete account of the care and treatment provided to the patient on 14 October 2019, however there are nursing records and NEWS charts which support that Trust staff sought to establish the patients level of pain and need for pain relief.
- 95. Having reviewed all relevant available evidence, I accept the P IPA's concern about the Trust being unable to locate the Medicine Kardex and drug administration records for 14 October 2019, and the impact this has had on the P IPA's ability to fully advise on this element of the complaint. Regarding the lost or mislaid medical

- records, I refer to my conclusions regarding the maladministration and associated injustice which resulted from the Trust's actions, at paragraphs 47-56 of this report.
- 96. However, in terms of the impact of those absent records, I note that the P IPA was nonetheless satisfied that there were sufficient ancillary medical records available to enable them to assess the pain management provided to the patient that day. Based on my analysis of the P IPA's advice, as well as the nursing records and the NEWS charts, I consider that it is more likely than not that Trust staff did take reasonable steps to manage the patient's pain in line with the patient's wishes. On that basis, I conclude that it is more likely than not that the care and treatment provided to the patient in this respect was appropriate, reasonable and in line with relevant standards. As a result, whilst acknowledging the absence of the Medicine Kardex and drug administration record, my finding is that I do not uphold this element of the complaint.

Issue Two: Whether the Trust has investigated and responded to the complaint in accordance with relevant policies and standards?

Detail of Complaint

- 97. The complainant raised the following concerns regarding the manner in which the Trust responded to her original complaint:
 - That the Trust failed to answer the question of why the family had not been made aware of the patient's sepsis diagnosis at the time;
 - That the Trust had failed to explain in their response why the initial MRI scan had been cancelled; and
 - That the Trust had not been honest in its response in respect of pain management for the patient on 14 October 2019.

Evidence Considered

Legislation/Policies/Guidance

- 98. I refer to the following policies and guidance which were considered as part of investigation enquiries and which I consider the appropriate standard upon which to base my investigation:
 - DoH Guidelines; and

Trust's Complaints Policy

The Trust's records & responses to the investigation enquiries

Awareness of the Sepsis Diagnosis

99. I considered the Trust's written response to the complainant's original complaint dated 13 March 2020. In the complaint received by the Trust, the complainant stated as an element of her complaint that 'At NO point were we advised that [the patient] had contracted Sepsis, until we read the death certificate'. Upon review of the Trust's response, I note that the Trust had not addressed this element at all. This Office put that issue to the Trust again as part of this investigation. In the Trust's response to this Office, the Trust acknowledged this failing, and apologised for 'any additional stress caused by not having fully addressed the concerns raised in her complaint'. However, when asked by this Office to address the issue, the Trust did not do so at that time. The Trust subsequently confirmed that Consultant C, who would be able to answer this question, has left the employment of the Trust since being informed of this investigation and providing a statement in respect of it. No further information was provided to address the concern.

Reason for Initial MRI Being Cancelled

100. In the complaint the Trust received, the complainant raised concerns regarding the Trust's decision to cancel the initial MRI scan. In the subsequent complaint submitted to this Office, the complainant raised the concern that the MRI scan had been cancelled 'without a valid reason for doing do'. The complainant was therefore putting forward the position that she felt the Trust's initial response had failed to outline its rationale for the cancellation sufficiently clearly. Upon review of the Trust's response, I note that the following position put forward, 'felt the cyst/lesion had already been characterised sufficiently and was advised there was a referral to Gynae for definitive diagnosis and treatment'. In the Trust's response to this Office's enquiries, the Trust reiterated this rationale, and provided the written statement of Consultant A in support of that rationale. The Trust also provided the extract entry from its Request Notes System, which stated 'Mass characterised on US²⁶ as cystic/solid, no indication for MRI. Please refer to Gynae

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²⁶ Ultrasound

for definitive diagnosis and treatment. I note that this reflects the response given to the complainant's original complaint.

Honesty Regarding Pain Management

101. In the complaint the Trust received, the complainant had raised concerns regarding the management of the patient's pain on 14 October 2019. The complainant stated that she had to take proactive steps to seek pain relief for the patient, as she felt the patient had been left in pain by Trust staff. The complainant further put forward that there was a delay in the pain relief she sought for the patient being administered. Upon review of the Trust's response, I note that the Trust put forward that the nurse looking after the patient asked the patient if she required pain relief, but that the patient said she did not. Therefore the only pain relief that was administered was two doses of Oramorph, one in the early hours of the morning, and one in the evening. The Trust referred to nursing records in support of their position. In the complainant's subsequent complaint to this Office, she challenged the honesty of the Trust's account and reiterated that she had to proactively ask for pain relief for the patient as the patient was in pain and distress by mid-afternoon. In the Trust's response to this Office's enquiries, the Trust reiterated the position it put forward to the complainant previously.

Analysis and Findings

Awareness of the Sepsis Diagnosis

- 102. I am satisfied that the Trust did not respond to the complainant's query in this respect neither in its original reply to the complainant directly, nor in its reply to this Office's enquiries. I considered the records contained within the complaints file, which includes the admission of the Trust, in reaching this conclusion. I noted the Trust's apology in its reply to this Office's enquiries, but that despite the apology, the query remained substantively unanswered.
- 103. The Trust's complaints procedure states that it should 'aim to answer all the issues raised in the complaint, be open and honest explaining the situation, why it occurred and reporting the action taken or proposed. Furthermore, the DoH Guidelines require the Trust to 'address the concerns expressed by the complainant and show that each element has been fully and fairly investigated.

104. As a result, I find that the Trust failed to act in accordance with its own complaints policy, and also failed to act in accordance with the DoH Guidance in respect of how it addressed this element of the complainant's original complaint.

Reason for Initial MRI Being Cancelled

105. I am satisfied that the response provided to the complainant did provide a valid reason to account for why the initial MRI scan was cancelled – namely – that Consultant A noted the ovarian mass had already been ;*characterised sufficiently*; by the CT and ultrasound scans, and that a referral to gynaecology had already been made. I am satisfied that in addressing this element of the complaint, the Trust acted in accordance with its own complaints policy, as well as the DoH Guidance. It should be noted that this matter is separate from that relating to the Trust's communication at the time of the cancellation of the scan, which I have addressed under Issue one in this report.

Honesty Regarding Pain Management

- 106. I refer to both the Trust's own complaints policy and the DoH Guidance where the importance of honest investigation of complaints and honest responses are set out in detail. I note the opposing perspectives the complainant and the Trust put forward in respect of the patient's wishes for pain relief. As set out in my analysis of this matter under Issue one in this report, I fully acknowledge the complainant's perspective in this respect. The nursing records referred to by the Trust in their response to the original complaint indicate that pain was managed and pain relief provided. I do not, however, consider that this means that the complainant did not make a request for pain relief for her mother that day.
- 107. As noted in my analysis under Issue one, I also recognise that the medical records the Trust provided relating to pain relief for 14 October 2019 are incomplete. I consider that the fact the Trust lost or mislaid the Medical Kardex and the patient's drug administration records for 14 October 2019 ought to have come to the Trust's attention when it conducted its investigation into this element of the complainant's original complaint. If this information had come to the Trust's attention at that time, this ought to have been communicated to the complainant, in the interests of open and honest investigation. However, this was not done.

108. Whilst there is insufficient evidence available to reasonably conclude that the Trust was deliberately dishonest in its response to this element of the original complaint, the fact that the missing records were not discovered and/or identified in the response raises legitimate questions and concerns as to the thoroughness of the Trust's internal investigation into this element of the complaint and their candour on the issue.

Impact

- 109. I find, therefore, that I partially uphold Issue two of the complaint. I identified several failures on the Trust's part regarding its internal investigation into the original complaint, and the content of its response to the complainant. I identified that the Trust failed to respond to the complainant's query regarding their awareness of the sepsis diagnosis. I also identified that the Trust lost or mislaid certain of the patient's medical notes and records, and did not bring this to the complainant's attention when it discovered this or in the alternative the Trust did not conduct a thorough enough investigation into the complainant's query about pain relief to discover these records were missing at the time of response. The complainant said that she considered the Trust's failures regarding communication to be humiliating, damaging and unnecessary.
- 110. The First Principle of Good Administration, 'getting it right', requires bodies to act in accordance with 'relevant guidance and with regard for the rights of those concerned', and in accordance with its own policies and guidance. The Fourth Principle of Good Complaint Handling, 'acting fairly and proportionately', requires bodies to ensure 'complaints are investigated thoroughly and fairly to establish the facts of the case'. I consider the Trust failed to act in accordance with these Principles in its handling of the complainant's original complaint. I am satisfied this constitutes maladministration. As a consequence, I am satisfied the maladministration identified caused the complainant to experience the injustice of frustration, uncertainty, and the time and trouble of bringing his complaint to this Office.

CONCLUSION

111. I received a complaint about the care and treatment provided to the patient from 23 August 2019 until 14 October 2019. The complaint also relating to the standards of complaint handling on the part of the Trust.

Lost or Mislaid Medical Records

- 112. The Investigation established maladministration in relation to the Trust having lost or mislaid parts of the patient's medical records, and also in relation to the Trust's failure to provide this Office with an evidence-based explanation for the missing records, on foot of a documented investigation.
- 113. I am satisfied that this maladministration identified caused the complainant the injustice of frustration, upset and mistrust.

Issue one

- 114. The investigation established the following failings in the care and treatment the Trust provided to the patient, which resulted in the Issue one of the complaint being partially upheld:
 - The Trust failed to keep clear, accurate and legible records relating to relevant clinical findings, information given to patients and investigations carried out regarding recording the patient's RMI score, identifying the RMI calculation method being used, and recording any consideration given to the vascularity of the patient's ovarian mass
- 115. I am satisfied that the failings identified caused both the patient and the complainant the injustice of uncertainty.

Issue two

- 116. The investigation established maladministration in relation to the following elements, which resulted in Issue two being partially upheld:
 - The Trust's failure to provide a response to the part of the complaint relating to communication of the patient's sepsis diagnosis to the patient's family; and
 - The Trust's failure to inform the complainant that parts of the patient's

medical notes and records were lost or mislaid, or in the alternative, failed to conduct a sufficiently thorough investigation into the pain relief element of the original complaint so as to identify that certain medical notes and records were missing.

117. I am satisfied that the maladministration identified caused the complainant the injustice of frustration, uncertainty, and time and trouble of bringing a complaint to this office

Recommendations

- 118. 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 injustice caused as a result of the failures in complaint handling identified within one month of the date of this report.
- 119. I further recommend, for service improvement and to prevent future reoccurrence, the Trust:
 - Reminds all staff involved in patient complaints handling of the importance of providing full, clear and thorough responses to each and every element of a complaint raised by, or on behalf of a patient;
 - II. Carries out a review of their record management policies and processes to ensure that patient medical notes and records can be tracked and located at all times, and to ensure a procedure for reporting mislaid or lost records forms part of that dossier;
 - III. Provides appropriate and adequate training to any and all staff involved in handling medical notes and records regarding the record management policies and procedures in place;
 - IV. Takes steps to ensure that all clinicians involved in the patient's care have the opportunity to consider the findings in this report and demonstrate that those individuals whose actions have been criticised have reflected on how they can improve their practice in future and are aware of their responsibility to document patient management decisions in relation to GMC Guidance.

- V. Carry out a random sampling audit of ovarian cancer patients' medical notes and records, with a particular emphasis on the presence of RMI scores and the calculation method applied to determine those scores – and take action to address any identified trends or shortcomings.
- VI. Undertakes a review, at Trust governance level, of its approach to RMI to ensure the Trust has in place a 'documented region-wide protocol' regarding the approach to RMI, as well as engaging with the regional centre on this to ensure clarity and consistency in care for all within the region, and to ensure that necessary referrals for patients to tertiary centres are made, and made timeously. With this in mind, a copy of this report will be shared with the Chief Medical Officer by this Office under the Ombudsman's powers set out in Section 43(2)(d) of the Public Services Ombudsman Act (NI) 2016.
- 120. I recommend that the Trust implements an action plan to incorporate these recommendations and should provide me with an update within **six 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).
- 121. Finally, I wish to pass on my condolences to the complainant, and her family, on the death of her mother. Throughout my examination of this complaint I fully recognise the evident care and devotion shown by the complainant to ensure that her mother received the appropriate care and attention. I hope that my report has gone some way to address the complainant's concerns. I acknowledge that the complainant may not agree fully with all of my findings, but I wish to assure her that I have reached them only after the fullest consideration of all the facts of this case.

MARGARET KELLY

Ombudsman March 2022

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, coordinating 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.

PRINCIPLES OF GOOD COMPLAINT HANDLING

Good complaint handling by public bodies means:

Getting it right

- Acting in accordance with the law and relevant guidance, 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 learnt from complaints.
- Including complaint management as an integral part of service design.
- Ensuring that staff are equipped and empowered to act decisively to resolve complaints.
- Focusing on 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.

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

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.

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 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.

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.

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 the learning from complaints.
- Regularly reviewing the lessons to be learnt from complaints.
- Where appropriate, telling the complainant about the lessons learnt and changes made to services, guidance or policy.