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

Report Reference: 202001646

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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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Appendix 1 – The Principles of Good Administration

Case Reference: 202001646

Listed Authority: The Western Health and Social Care Trust

SUMMARY

I received a complaint about the Western Health and Social Care Trust's (the Trust) care and treatment of the complainant's brother (the patient) between 16 December 2020 and 5 January 2021.

The complainant raised several concerns. This included the time taken to treat the patient's condition and the impact this had on the patient's prognosis; the conduct of the endoscopic retrograde cholangiopancreatography[1]; the treatment given to the patient, including continued treatment within the Trust rather than transfer to the regional Hepatobiliary unit; the liaison with the regional Hepatobiliary unit; the impact of Covid on the patient's care; and communications with, and information provided to, the patient's family.

The investigation established there were significant failings in the patient's care and treatment and that, on the balance of probabilities, these failings contributed to the patient's death, as well as leaving the patient in severe pain. The failings identified were:

- the Trust failed to appropriately manage the patient's pain, including leaving the patient without pain relief for a nine-hour period;
- the Trust failed to insert a catheter in a timely manner, and not until 18 hours after he was admitted and this '*had a small but significant impact on the poor outcome for the patient';*
- the Trust failed to ensure timely transfer of the patient to the critical care unit; and
- the Trust failed to take appropriate and timely decisions and actions in relation to the patient's sepsis, including drainage in a timely manner which '*would have likely prevented further deterioration'.*

[1] Endoscopic retrograde cholangial pancreatography is a procedure that combines upper gastrointestinal (GI) endoscopy and x-rays. It is used to diagnose and treat problems with your biliary system.

I recommended the Trust apologises to the patient's family for the injustices caused by the failures in care and treatment. I made further recommendations for the Trust to address under an evidence-supported action plan to instigate service improvement and to prevent recurrence of the failings identified.

I would also wish to convey my sincere condolences to the complainant and her family on the sad loss of their loved one.

THE COMPLAINT

1. This complaint concerned the care and treatment the Western Health and Social Care Trust (the Trust) provided to the complainant's brother (the patient) from 16 December 2020 and 5 January 2021.

Background to Complaint

2. The patient presented to Altnagelvin Hospital at the emergency department (ED) late evening on 16 December 2020 with severe abdominal pain. The patient was admitted to the surgical ward on the afternoon of 17 December 2020. The patient deteriorated quickly, and within 24 hours, he was transferred to the critical care unit (CCU).

3. An Endoscopic Retrograde Cholangiopancreatography (ERCP) was planned for 22 December 2020 but was performed on 18 December 2020 because of the patient's clinical deterioration. Despite treatment, the patient remained critical. A computed tomography[2] (CT) scan on 22 December 2020 indicated necrosis of the pancreas[3]. The Trust stated it discussed the patient's case with the regional Hepatobiliary team (HPB team) in the Belfast Health and Social Care Trust (BHSCT) Mater Infirmorum Hospital (MIH). The Trust stated the HPB team advised surgical intervention was not required as the CT scan did not show any bowel ischaemia[4]. The patient, therefore, continued in CCU where he remained unstable.

4. On 29 December 2020, a further CT scan showed necrotising pancreas with fluid collection. The Trust stated this was discussed with the HPB team and the HPB team advised drainage was not necessary at this stage. The patient remained unwell. On 4 January 2021, a further CT scan indicated stable necrotising pancreas, less fluid collection but ischaemic changes. The Trust stated it again discussed the case with the HPB team and the HPB team advised a laparotomy[5] should be performed, as this presented the only chance

[2] A computerised tomography scan uses X-rays and a computer to create detailed images of the inside of the body.
[3] Sometimes people with severe acute pancreatitis can develop a complication where the pancreas loses its blood supply. This can cause some of the tissue of the pancreas to die (necrosis). When this happens, the pancreas can become infected, which can spread into the blood (sepsis) and cause organ failure.
[4] Bowel ischaemia occurs when blood flow to the bowel is blocked. It can affect the small or large intestine.
[5] Laparotomy is a surgical incision into the abdominal cavity. It is carried out to examine the organs and structures of the lower

for the patient's survival, although there was also a high risk associated with the surgery. The laparotomy revealed severely necrotised pancreas and non-viable ischaemic large bowel. The patient returned to CCU and his condition deteriorated. Sadly, the patient died on 5 January 2021.

Issues of complaint

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

Issue 1: Whether the care and treatment provided to the patient by the Trust during the period 16 December 2020 to 5 January 2021 was appropriate, reasonable and in accordance with relevant standards and guidance.

Issue 2: Whether the communication with, and information provided to, the patient's family was appropriate and consistent with the patient's condition and care.

INVESTIGATION METHODOLOGY

6. To investigate this complaint, the Investigating Officer obtained all relevant documentation from the Trust, together with its comments on the issues the complainant raised. This documentation included information relating to the Trust's complaints process.

Independent Professional Advice Sought

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

- A Consultant in Emergency Medicine (MBChB FRCS FRCEM DIMC); with 20 years' experience as a consultant in emergency medicine; involved in the daily management of acute abdominal pain cases; and
- A Consultant Hepatobiliary Surgeon (MBBS, MS (Gen Surg), FRCS (Ed), FRCS (Glasg), FRCS (eng)); with more than 12 years' experience as a consultant hepatobiliary and pancreatic surgeon.

abdomen, such as the appendix, intestines, kidneys, liver, pancreas, gallbladder, bladder, uterus, etc. It is performed under general anaesthetic and may be merely exploratory or may include another surgical procedure if necessary.

I enclose the Consultant in Emergency Medicine's professional advice at Appendix three and the Consultant Hepatobiliary Surgeon's professional advice at Appendix four.

8. I included the information and advice that informed the findings and conclusions within the body of this report. The IPAs provided 'advice'. However, how I weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards and Guidance

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

The general standards are the Ombudsman's Principles[6]:

- The Principles of Good Administration.

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

The specific standards and guidance relevant to this complaint are:

- National Institute for Health and Care Excellence (NICE): NICE Guideline 104 Pancreatitis, 2018 (NICE Pancreatitis Guideline);
- British Medical Journal UK Guidelines for the Management of Acute Pancreatitis, UK Working Party on Acute Pancreatitis, April 2005 (UK Acute Pancreatitis Guidelines);
- World Journal of Emergency Surgery Guidelines for the Management of Severe Acute Pancreatitis, 2019 (WJES Acute Pancreatitis Guidelines); and

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

- General Medical Council, Good Medical Practice, April 2019 (GMC Guidance).

11. I did not include all information obtained during the investigation in this report. However, I am satisfied I considered everything relevant and important in reaching my findings.

12. I shared a draft copy of this report with the patient and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations.

THE INVESTIGATION

Issue 1: Whether the care and treatment provided to the patient by the Trust during the period 16 December 2020 to 5 January 2021 was appropriate, reasonable and in accordance with relevant standards and guidance.
In particular, this considered:

(i) The timeliness of the assessment, diagnosis, care and treatment of the patient in relation to both the period in the Emergency Department (ED) and in the ward. This includes the Trust's actions in consideration of advice sought and received from the HPB team; and

(ii) The conduct and aftercare of the ERCP.

Trust's response to investigation enquiries

13. As part of investigation enquiries, the Trust had an opportunity to respond to the complaint. The Trust's response to the enquiries related to the complaint is at Appendix two to this report.

Detail of Complaint

14. The two elements of Issue one of the complaint are addressed separately below.

The timeliness of the assessment, diagnosis, care and treatment of the patient in relation to both the period in the Emergency Department (ED) and in the ward, including the Trust's actions in consideration of advice sought and received from the HPB team

15. The complainant said the patient was not admitted to a ward until more than 12 hours after his presentation at ED. She queried whether the timing of the treatment and intervention impacted on his prognosis, including the administration of appropriate antibiotics in a timely manner. The complainant queried whether the patient received lesser and incorrect care because this happened during the Covid pandemic. The complainant said the patient died after admission for gallstones and she believed, if the patient had been treated more promptly and appropriately, he would have survived.

16. The complainant queried why the patient was not sent to the HPB team for treatment when the Trust sought advice from the HPB team. She also queried if the Trust had the capacity to appropriately treat the patient.

Evidence Considered

Legislation/Policies/Guidance

17. I considered the NICE Pancreatitis Guideline; the UK Acute Pancreatitis Guidelines; the WJES Acute Pancreatitis Guidelines; and the GMC Guidance. Key extracts from the relevant policies and guidance are included, as appropriate, within either the Consultant Hepatobiliary Surgeon Independent Professional Advisor's advice at Appendix four or at Appendix five which details extracts of relevant guidance.

Relevant Trust Records

18. I reviewed the patient's medical records, including his Northern Ireland Electronic Care Record (NIECR) and records from CCU, for the period of 16 December 2020 to 5 January 2021. I also examined records of a Trust Morbidity and Mortality[7] (MM) meeting, at which the Trust discussed the

[7] Within healthcare, a key component of workplace-based learning is the 'morbidity and mortality' meeting. The goal of this meeting is to provide clinicians with the opportunity to discuss errors and adverse events in an open manner, review care

patient's case, and an email from the Trust to the HPB team dated 4 January 2021.

Third-Party Information

19. I requested the HPB team provide a copy of all records related to the HPB team's liaison with the Trust about the patient during the period 16 December 2020 to 5 January 2021, including records of any of the HPB team's advice to the Trust about the management of the patient; details of any follow-up by the HPB team with the Trust, particularly on 18 December 2020 related to review of the patient's CT scan; and any discussions related to consideration of transferring the patient to the HPB team.

20. The HPB team did not provide any documentation. In response to the request for information. The HPB team stated that, following discussion with the staff in both the MIH and the Royal Victoria Hospital (RVH), *'there is no documentation held within the Belfast Trust regarding this. Both secretaries have stated that it may have been a telephone conversation and advice was given verbally however not documented'.* The HPB team stated*, 'unfortunately until recently they did not keep records of any advice given to other hospitals in relation to their patients and so cannot provide any assistance with this enquiry.'*

Relevant Independent Professional Advice

Consultant in Emergency Medicine's Advice (ED IPA)

21. The ED IPA provided advice on the patient's care and treatment from the time he presented at ED until his admission to the ward. I refer to the ED IPA's advice which is at Appendix three to this report.

Consultant Hepatobiliary and Pancreatic Surgeon's Advice (HPS IPA)

22. The HPS IPA provided advice on the patient's care and treatment from the time of the patient's admission to the ward, including that related to the Trust's interactions with the regional hepatobiliary unit. I refer to the HPS IPA's advice which is at Appendix four to this report.

standards, and make changes if required.

Responses to the Draft Investigation Report

23. The complainant, the Trust and those individuals within the Trust, who were cited within the complaint, were given an opportunity to provide comments on the Draft Investigation Report. Where considered appropriate, comments are either reflected in changes to the report or are outlined in paragraphs 24 to 37.

The Trust's response

Fluid resuscitation-Insertion of a Catheter

24. The Trust stated the ED doctor's initial diagnosis was the patient had suffered a bowel perforation. On receipt of the patient's blood test and x-ray results, a revised and correct diagnosis was then made of acute pancreatitis. The Trust acknowledged that either diagnosis should have led to prompt catheterisation of the patient to facilitate an accurate assessment of his urine output. The Trust offered apologies to the patient's family for this failing.

25. The Trust outlined a proposed action plan to address this failing in line with the recommendations made in the Draft Investigation Report. The specific actions are outlined in the Recommendations section below.

Management of the patient's pain in ED

26. The Trust acknowledged that, while in ED, the patient should have been provided with morphine sooner. The Trust also stated, however, that the patient '*was in a high degree of pain and that this was largely resistant to morphine, which is our most commonly used strong analgesic'.* The Trust provided details of the pain relief provided to the patient during this period and stated, '*given [the patient's] age and condition with impaired renal function there must have been concern about toxic effects from large and repeated doses of morphine'.* The Trust referred to the later involvement of the pain team, when morphine was administered using Patient Controlled Analgesia[8], (PCA) and explained, PCA could not begin during the patient's time in ED because the ED staff were not trained in providing care for this form of pain

[8] Patient Controlled Analgesia is a method of pain relief in which the patient controls the amount of pain medicine that is used. When pain relief is needed, the person can receive a preset dose of pain medicine by pressing a button on a computerized pump that is connected to a small tube in the body.

management. The Trust stated the PCA *'did eventually provide some pain relief but the onset was slow and incomplete'.* The Trust stated, morphine PCA is frequently used for severe pain management, in combination with other non-opioid medications such as paracetamol and non-steroidal anti-inflammatory drugs[9] (NSAIDS); however, although paracetamol was administered intravenously, given the patient's impaired renal function, NSAIDS could not be given.

27. The Trust further stated, '*in our experience it would be extremely unusual to escalate to more advanced analgesic techniques … for acute pancreatic or gall-bladder pain'. T*he Trust accepted, and stated it very much regretted, both the delay in pain relief and the pain relief was not fully effective. The Trust also stated, however, the patient's pain was resistant to the *'commonly used strong analgesic techniques'* available to the hospital.

Transfer to CCU

28. The Trust stated the patient was referred to critical care on the afternoon of 17 December 2020 and the Critical Care Outreach Service (CCOS) assessed the patient at 17.50. The Trust stated CCOS gave advice on patient management *'appropriate to the patient's condition*'; however, CCOS did not assess him as needing critical care at that time. Further, an *'anaesthetic/critical care registrar was contacted … [and] advice given'* related to pain management and about the use of oxygen and fluid therapy; however, the patient was not escalated to the consultant for critical care. The Trust stated the patient was not escalated to the consultant-on-call until 04.00 on 18 December 2020, after the patient's National Early Warning Score[10] (NEWS) rose to seven. At approximately 06.30, the patient was reviewed. The Trust accepted there was no evidence the repeat blood gas, which was requested, was performed prior to the patient's admission to critical care. The Trust stated, sometime after 08.30, senior staff in the

[9] Non-steroidal anti-inflammatory drugs are medicines that are widely used to relieve pain, reduce inflammation, and bring down a high temperature. Common examples used include ibuprofen; naproxen; diclofenac; and mefenamic acid.
[10] The National Early Warning Score is a system for scoring routinely recorded physiological measurements of patients to identify acutely ill patients, including those with sepsis. The NEWS scoring system measures six physiological parameters: respiration rate; oxygen saturation; systolic blood pressure; pulse rate; level of consciousness or new-onset confusion; and temperature. A score of 0, 1, 2 or 3 is allocated to each parameter. A higher score means the parameter is further from the normal range. A culminative score of seven or more indicates high risk with the requirement for emergency assessment by a critical care team, usually leading to patient transfer to higher-dependency care area.

surgical unit contacted critical care directly and a critical care consultant became involved. The Trust stated, although junior surgical staff initiated a referral to critical care on 17 December 2020, this did not result in a transfer but, when there was consultant to consultant liaison, transfer was expedited.

29. The Trust stated its critical care guidelines indicate patients should be referred to critical care through senior doctors from both referring and receiving departments. The Trust stated the standard process should not, however, prevent admission to critical care when a patient requires urgent escalation; therefore, if a patient is causing concern, there should be escalation within a team to ensure direct senior to senior consultation. The Trust accepted there were no records of escalation until approximately 08.30 on 18 December 2020. The Trust stated it deeply regretted that, although there were earlier referrals to critical care, concerns did not result in an earlier escalation and transfer to critical care.

30. The Trust also stated, at the time of the patient's care, the hospital and critical care were operating under an unprecedented Covid-19 surge with critical care at elevated capacity. Specifically, on 17 December 2020, there were nine patients in the critical care unit, including five with life-threatening Covid-19. The Trust accepted admission to critical care should be timely and according to clinical need; however, the Trust stated, *'it must be acknowledged that staff were working under considerable and sustained pressure from the effects of a COVID19 surge [which] … should be recognised as a factor [which] played a role in the timeliness of acceptance and transfer to critical care'.*

31. The Trust outlined a proposed action plan to address the identified issues in relation to the failure to transfer the patient to critical care earlier. The specific actions, which reflect the recommendations made in the Draft Investigation Report, are outlined in the Recommendations section below.

Decisions and actions related to drainage and surgical interventions including reference to the HPB team's advice to the Trust

32. The Trust acknowledged the appropriateness of the HPS IPA's advice in relation to drainage. It also referred to the stipulations in the NICE Pancreatitis Guideline about seeking advice from a specialist pancreatic centre. The Trust stated, the CT scan of 18 December 2020 did not identify necrosis; therefore *'there was no indication for drainage'.* The Trust stated it discussed the patient's case with the HPB team on 23 December 2020 and 30 December 2020. The Trust provided records from the patient's NIECR, which it had not previously provided, and in which the Trust documented these discussions. On 23 December 2020, it is documented the patient's elevated intra-abdominal pressure was discussed with the regional hepatobiliary team, along with suggestion of necrosis. The documented advice from the regional hepatobiliary team was *'to sit tight and continue ICU management as long as no signs of bowel ischemia. Currently no indication to surgical drainage'*.

33. On 30 December 2020, because the CT scan of the patient's abdomen and pelvis indicated, *"progressive necrotising pancreatitis with enlarging lesser sac fluid collection contiguous with the pancreatic body necrosis", t*he Trust again liaised with the HPB team. This documented discussion indicates the Trust stated to the HPB team that the CT scan showed '*?pneumatosis of right colon + Fluid collection beside pancreas'* and the HPB team advised, '*Fluid collection does not require surgical intervention*'. The Trust also stated that the CCU Consultant involved with the patient on both 30 and 31 December 2020 stated, in addition to his discussion with the HPB team, he discussed the CT scan with a Consultant Radiologist in the Trust who '*was not convinced that there was definite pneumatosis on the CT scan'*. Further, the CCU Consultant stated that, on both days when he reviewed the patient, he *'decided that there was not enough evidence to suggest abdominal compartment pressure … [and] that the patient did not need a laparotomy to inspect the right colon for ischaemia or to decompress the abdomen.'* This CCU Consultant also emphasised '*the management of the necrotic pancreas and associated fluid collections was directed by the HPB team'.*

34. The Trust provided a copy of an email sent to the HPB team on 4 January 2021 which refers to information the Trust provided to the HPB team about the patient and the HPB team's advice. The email record indicates the Trust informed the HPB team that the patient, *'has necrotising pancreatitis … his IAP has markedly increased during last weekend and today it is almost 25mmHg … Now ICU team feels he is not going to improve with such IAP and they ask if there is any chance for possible surgical decompression+ / necrosectomy and drainage'*. The Trust stated that, prior to this email, the Trust discussed the patient on the phone with the HPB team and the HPB team advised the Trust to proceed with a laparotomy procedure. The Trust stated this procedure was carried out on 4 January 2021.

35. The Trust stated the additional records evidence the surgical team was familiar with the management guidelines for severe acute pancreatitis. The Trust stated this evidence included the Trust's prompt discussions with the HPB team, following changes to the patient's condition throughout his admission, and the evidence of the HPB team's advice. The Trust stated this advice, in conjunction with *'thorough consideration, directed the management decisions made'.*

36. In providing additional records of the Trust's engagement with the HPB team in relation to the patient, the Trust apologised for its earlier failure to provide all relevant records. The Trust stated it documented the initial discussion with the HPB team in the patient's records but did not document the resulting HPB team's advice there. The Trust stated the advice was not recorded in the patient's notes '*due to [the] rapid deterioration of the patient on that day*' which required communications with multiple teams, including the CCU and the endoscopic team to facilitate the emergency ERCP outside planned ERCP times. The Trust agreed documentation of advice is '*important for continuity of care';* therefore, the surgical team documented the HPB team's advice on the handover sheet on 18 December 2020 and on an email to the consultant who was on call during the period of 18 to 21 December 2020. The Trust provided these records. The Trust also referred to the records provided in response to the Draft Investigation Report which included the NIECR records. The Trust

stated these records are accessible to any NIECR user who has the authority to access a patient's electronic records.

37. The Trust stated it has consequently introduced a template for recording referrals and advice which involves parties external to the surgical team which reflects the recommendations in the Draft Investigation Report. This includes decisions and actions agreed and by whom as well as details of medication prescribed, or other investigations or treatments agreed. The Trust provided a copy of this new documentation. The Trust also stated it would require external parties to provide a point of contact to facilitate instant dissemination of these forms to both enhance record-keeping and keep track of advice given in case further advice or changes to advice are needed. The Trust stated the form would be added to the NIECR and would be visible to all service users.

Further Independent Professional Advice following Draft Investigation Report Responses

38. Following receipt of the Trust's comments on the Draft Investigation Report, both the ED and HPS IPAs provided further advice. The ED IPA provided advice on the Trust's management of the patient's pain and the HPS IPA provided advice about the Trust's liaison with the HPB team about the patient. Key extracts from the ED and HPS IPAs' further advice are detailed in paragraphs 39 and 40 respectively. The ED and HPS IPAs' full advice are enclosed at Appendices six and seven, respectively.

ED IPA's Advice

39. The ED IPA advised that his original advice remained unchanged following the Trust's comments. Specifically, although the patient's pain score was eight out of ten at triage, the Trust did not administer pain relief for two hours and '*this was not appropriate'.* After the patient's first dose of morphine, it was again two hours before a further dose was given, which '*was not appropriate'* and then no other pain relief was administered for a further nine hours. The ED IPA advised, the patient '*did not receive analgesia which was effective at alleviating his pain. This was not appropriate'*. Further, the Trust did not take appropriate actions in response to the patient's continued pain, *'more morphine should have been*

given at an earlier stage … the acute pain team should have been contacted at an earlier time … analgesia was … inadequate during his time in the emergency department.'

HPS IPA's Advice

40. The HPS IPA advised that the Trust discussed the patient with the HPB team in a timely manner; however, there was *'no evidence'* the Trust informed the HPB team of the patient's full clinical condition, including the indications of sepsis. The HPS IPA referred to the UK Acute Pancreatitis Guidelines and advised '*this is vital, as the indication for decompression/ drainage is not only elevated intra-abdominal pressure, but also control of sepsis … This patient was clearly septic on 23rd December … and … the CT was suggestive of necrosis. Similarly, on 29th/30th December, … there was progressive necrosis with a temperature of 39.4 C, and the CRP from the day before was 202. With evidence of sepsis and progressively increasing lesser sac collection, the priority is to control sepsis with drainage of collection, even should the intra-abdominal pressure not be elevated'.* The HPS IPA referred to the Trust's comments on the Draft Investigation Report that the Trust's actions were based on the HPB team's advice. The HPS IPA advised that the Trust was correct to seek the HPB team's advice, in accordance with pancreatitis guidance; however, pancreatitis guidance also provides *'clear guidance on management of this condition and what needs to happen when symptoms escalate'.* The HPS IPA also advised that the Trust *'did not apparently recognise the need to manage the presenting danger of the patient's sepsis, as indicated in the'* UK Acute Pancreatitis Guidelines.

Analysis and Findings

Overall Patient Care in ED

41. The ED IPA advised, in ED, the patient was triaged as category three and which was *'appropriate*' and a Ranson score was calculated, which is the correct scoring system for pancreatitis severity assessment. I note the ED IPA advised, whilst in ED, the patient was assessed appropriately and in a timely manner and investigations undertaken were appropriate. The ED IPA also

advised, the patient was *'correctly diagnosed [with] pancreatitis at an early stage … [and] appropriately referred … to the receiving surgical team'.* The ED IPA advised, although there was a delay from the patient's arrival in ED until his admission to the ward, because there was no bed available, this was outside the control of medical and nursing staff. The ED IPA advised he could not identify any impact on the patient's care and treatment arising from the Covid pandemic. I accept this advice and am satisfied the patient's overall care in ED was appropriate.

Management of the Patient's Pain in ED

42. The ED IPA advised the patient was '*in severe pain throughout his time in the emergency department*' with analgesia not administered until two hours after he presented and which, as outlined in the ED IPA's further advice, *'was not appropriate'.* Also, in the ED IPA's further advice, two hours elapsed before another dose of morphine was administered, which '*was not appropriate*'. Further, no other pain relief was administered for another nine hours which was *'not appropriate*'; and the Pain team was not contacted until 10:50 on the morning after the patient's admission but this should have occurred earlier. I note the ED IPA advised '*the failure to manage the patient's pain during his time in ED was not reasonable or appropriate.'* I accept this advice and am satisfied the patient's pain was not managed appropriately while in ED.

Fluid resuscitation-Insertion of a Catheter

43. The ED IPA advised, the patient did not appear to be catheterised until after 16:00 on 17 December 2020 and the patient should have had a urinary catheter inserted at an earlier stage to monitor his urine output. I note the ED IPA advised *'this failure was not appropriate or reasonable.'* The HPS IPA also provided further advice about fluid resuscitation in relation to management of acute pancreatitis. He confirmed the patient's catheter was not inserted until 18 hours after the patient first presented to the hospital, at 17:50 on 17 December 2020 and when the catheter was inserted, the indications were the patient required more fluids. The HPS IPA advised this was confirmed later by blood tests and *'this has had a small but significant impact on the outcome'* for the

patient. I accept both the ED and HPS IPAs' advice and am satisfied the Trust did not insert a catheter in a timely manner.

Initial Patient Care on the Ward

44. The HPS IPA advised, at 09:15 on 17 December 2020, the patient '*had a confirmed diagnosis of acute pancreatitis secondary to gallstones'* and at 10:00, *'it was confirmed that there was no evidence of mesenteric ischaemia.*' I note the HPS IPA advised, the patient *'was assessed appropriately with laboratory blood tests, arterial blood gas analysis and CT scan in a timely manner*' in line with appropriate management of acute pancreatitis. The HPS IPA concluded the Covid pandemic '*did not affect the initial management of this patient'.* I accept this advice and am satisfied the patient's initial care on the ward was appropriate.

Transfer to CCU

45. I note the WJES Acute Pancreatitis Guidelines which state, '*patients with organ failure … need an urgent transfer to an ICU*'.

46. The HPS IPA advised, at 19:00 on 17 December 2020, the patient's blood results clearly indicated the patient was *'progressing to develop renal failure from pre-renal failure'* and the Trust should have requested urgent CCU review to facilitate his transfer to CCU for '*heamofiltration, central line insertion and other organ support'*. The HPS IPA advised there was no record of the planned repeat arterial blood gas tests which were suggested at 06:30 on 18 December 2020, to be reviewed by the CCU team and, therefore, the CCU team did not accept the patient for transfer until 09:40 on 18 December 2020, with transfer at 10:32 on 18 December 2020. I note this transfer took place over 15 hours later than the HPS IPA's advice indicated this should have occurred. The HPS IPA advised the delay in transferring the patient to CCU was another factor '*which contributed to the negative outcome in this patient'.*

47. Although I recognise the patient's period of admission coincided with significant pressures from the Covid-19 pandemic and acknowledge this would have had an impact on CCU capacity, I refer to the HPS IPA's advice that, at 19:00 on 17

December 2020, the patient was moving into renal failure. I accept the HPS IPA's advice. I consider the Trust did not act in accordance with the WJES Acute Pancreatitis Guidelines in ensuring the patient's transfer to CCU when he began to experience renal failure. I also refer to the Trust's comments on the Draft Investigation Report in which it acknowledged both that the escalation of concerns about the patient to senior staff did not occur until later, and the standard process of senior-to-senior referral to CCU should not prevent transfer of a patient when necessary. I am satisfied the Trust did not manage the patient's transfer to CCU in a timely manner.

Decisions and actions related to drainage and surgical interventions including reference to the HPB team's advice to the Trust

48. I note the UK Acute Pancreatitis Guidelines state, in relation to treatment of acute pancreatitis, *'the minimum manoeuvre would be external tube drainage of the common bile duct'* and '*the decision to intervene depends on the clinical picture (evidence of sepsis) and demonstration by CT of pancreatic or peripancreatic necrosis. There is agreement that all patients with infected necrosis require intervention by radiological or surgical drainage'.* The WJES Acute Pancreatitis Guidelines state, '*clinical deterioration with signs or strong suspicion of infected necrotizing pancreatitis is an indication to perform intervention (percutaneous endoscopic Drainage)'* and *'signs or strong suspicion of infected necrosis in a symptomatic patient requires intervention … When a patient deteriorates a step-up approach starting with percutaneous or endoscopic drainage is indicated'.*

49. I note the GMC Guidance states doctors must '*promptly provide or arrange suitable … investigations or treatment where necessary'* and *'provide effective treatments based on the best available evidence'.*

50. I refer to the further information and records the Trust provided in relation to advice sought and received from the HPB team. On 23 December 2020, the Trust discussed the patient's intra-abdominal pressure and the suggestion of necrosis with the HPB team. The HPB team advised, in the absence of bowel ischemia, there was no requirement for drainage. On 30 December 2020, the

Trust discussed possible pneumatosis of the patient's right colon, and fluid collection beside the pancreas, with the HPB team. The HPB team advised, *'fluid collection does not require surgical intervention'.* I note, although the Trust CCU consultant stated '*the management of the necrotic pancreas and associated fluid collections was directed by the HPB team*', he also stated that, on 30 and 31 December 2020, he '*decided that there was not enough evidence to suggest abdominal compartment pressure … [and] that the patient did not need a laparotomy to inspect the right colon for ischaemia or to decompress the abdomen'.*

51. The HPS IPA advised, although on 23 December 2020, Surgical team review confirmed acute necrotising pancreatitis with multi-organ failure and there was clear indication of *'ongoing sepsis and the need for intervention … however [the patient was] just given antibiotic*s'. I note the HPS IPA advised the CT scan of 23 December 2020 indicated a need for intervention through '*drainage*', yet the Trust did not do this and therefore, '*the sepsis [was] not addressed appropriately'.* He also advised the CT scan on 29 December 2020 '*confirmed progressive necrotising pancreatitis'* and there were indications of *'poorly controlled sepsis'.* The HPS IPA advised the CT scans from 22 December 2020 indicated 't*he lesser sac collection should have been drained percutaneously'* by 29 December 2020 '*at the latest'.* The HPS IPA further advised, *'although surgery was not the ideal solution, it would have been better than doing nothing in the absence of drainage*'. The HPS IPA advised *'timely drainage in this patient would have likely prevented further deterioration'.*

52. The HPS IPA advised that the Trust discussed the patient with the HPB team in a timely manner but there was no evidence the Trust informed the HPB team of the patient's full clinical condition, including the indications that the patient had sepsis. The HPS IPA advised, in accordance with the UK Acute Pancreatitis Guidelines, patients with this condition who also have sepsis require drainage. On 23 December 2020, the patient '*was clearly septic'* with indications of necrosis and on 29-30 December with evidence of sepsis and increasing fluid, *'the priority is to control sepsis with drainage … even should the intra-abdominal pressure not be elevated'.* The HPS IPA also advised, although the

Trust acted in line with NICE Pancreatitis Guideline by referring to the HPB team for advice, pancreatitis guidance also clearly details the steps needed to manage this condition when symptoms escalate. I note the HPS IPA further advised, the Trust '*did not apparently recognise the need to manage the presenting danger of the patient's sepsis, as indicated in the'* UK Acute Pancreatitis Guidelines. The HPS IPA concluded, *'the appropriate course of action was drainage',* which was straightforward; therefore, the Trust could have undertaken this without a need to transfer the patient to the HPB team.

53. I consider both the UK Acute Pancreatitis Guidelines and the WJES Acute Pancreatitis Guidelines indicate, in cases of acute pancreatitis, drainage is an essential treatment, with the UK Acute Pancreatitis Guidelines specifying the role of both sepsis and necrosis in determining the need for drainage. Although on 23, 30 and 31 December 2020, the HPB team's advice was surgical intervention was not required, I consider the Trust did not respond to the patient's clinical condition in accordance with the UK Acute Pancreatitis Guidelines and, consequently, did not act in line with the GMC Guidance detailed in paragraph 49. Further, I accept the HPS IPA's advice there is no evidence the Trust informed the HPB team about the patient's indications of sepsis. I also accept the HPS IPA's advice that the Trust should have considered the UK Acute Pancreatitis Guidelines in cognisance of the patient's clearly indicated ongoing sepsis, which was not addressed appropriately. I accept the HPS IPA's advice drainage should have occurred by 29 December 2020 at the latest, and which treatment the Trust had the capacity to perform; and timely drainage *'would have likely prevented further deterioration'.* I am satisfied the Trust did not take appropriate and timely decisions and actions in relation to the patient's sepsis, including drainage and surgical interventions for the patient.

54. I also accept the HPS IPA's advice, however, the Trust discussed the patient with the HPB team in a timely manner and in seeking this advice acted in accordance with the NICE Pancreatitis Guideline.

55. In consideration of the findings in paragraphs 42, 43, 47 and 53 above, I uphold this element of the complaint.

56. I am extremely concerned about the failings in care and treatment I identified in this case.

57. I also note with serious concern the failure of the Trust, at a MM meeting, to raise any points of learning about the patient's care and treatment and cannot understand, given the significant failings in care and treatment and their impact on the outcome for this patient, how this could be the case.

Injustice

58. I considered carefully whether the failings caused an injustice to the patient and his family and consider, on the balance of probabilities, that the failings contributed to the patient's death. I refer, in particular, to the HPS IPA's conclusion that, whilst severe pancreatitis carries uncertainty of outcome for patients and therefore there is no certainty the outcome would have been different for the patient with the recommended care and treatment, there were, however, '*a number of factors which have contributed to the negative outcome in this patient'.* I considered, in particular, the HPS IPA's advice the failure to '*perform any urgent radiological or surgical intervention'* was a '*significant contributory factor to the patient's deterioration and the final outcome'*. I consider the patient lost the opportunity to have optimal possible treatment options and, on the balance of probabilities, the failings contributed to the patient's death. I also consider, because of the failings, the patient experienced the unnecessary distress of severe pain.

59. In her complaint to this office the complainant said she was '*sickened, frightened and stressed'* by the experience and which had *'eroded [her] confidence in care'* by the hospital. I consider the failings caused the patient's family uncertainty, in not knowing what difference appropriate care and treatment may have made to the outcome for the patient. I also consider the failings caused the patient's family distress, in both the loss of their loved one, and watching them suffer unnecessary and severe pain.

Detail of Complaint

(ii) The conduct and aftercare of the ERCP

60. The complainant said necrosis of the pancreas was not identified until after the ERCP. She therefore queried if the ERCP was correctly performed and if the ERCP contributed to the necrosis.

Evidence Considered

Legislation/Policies/Guidance

61. I considered the UK Acute Pancreatitis Guidelines and the WJES Acute Pancreatitis Guidelines.

Relevant Trust Records

62. I considered the patient's medical records for 16 December 2020 to 5 January 2021.

Relevant Independent Professional Advice

HPS IPA's advice

63. The HPS IPA advised, at 12:34 the Surgical team reviewed the patient again, following discussion with the Gastroenterologist about an ERCP. The HPS IPA advised the ERCP was originally scheduled for 22 December 2020; however, it was noted, if the patient developed jaundice or became *'unstable due to biliary sepsis'*, an urgent ERCP would be arranged. The HPS IPA advised, the patient was referred to Gastroenterology for an urgent ERCP intervention in response to the patient's deterioration. The HPS IPA advised the ERCP was '*clearly indicated*'. The HPS IPA further advised, at 10:32, the patient transferred to CCU for '*type 1 respiratory failure, acute kidney injury and pain management'.* The HPS IPA advised, at 14:00, the patient then transferred to theatre for an emergency ERCP which was performed by '*specialists'*, two Consultant Gastroenterologists. The HPS IPA advised the ERCP was performed in an '*timely, appropriate manner*' and, although the stone could not be removed, *'the procedure was successful in decompressing the bile duct by the sphincterotomy and insertion of stent'.* The HPS IPA further advised, the removal of a bile duct stone is not always possible at a first attempt, especially

in an acute inflammatory setting and '*the aim of ERCP for acute gallstone pancreatitis is to relieve the sphincter pressure and decompress the bile duct'.* The HPS IPA advised the Trust provided '*appropriate'* post-ERCP care.

Analysis and Findings

64. I note the UK Acute Pancreatitis Guidelines state an urgent ERCP should be undertaken when there are indications of *'jaundice, or a dilated common bile duct'* in patients with acute pancreatitis. The UK Acute Pancreatitis Guidelines also state, '*all patients undergoing early ERCP for severe gall stone pancreatitis require endoscopic sphincterotomy whether or not stones are found in the bile duct*' and '*facilities and expertise should be available for ERCP to be performed at any time for common bile duct evaluation followed by sphincterotomy and stone extraction or stenting, as required'.* The WJES Acute Pancreatitis Guidelines state, '*ERCP in patients with acute gallstone pancreatitis and cholangitis is indicated'* and '*ERCP in acute gallstone pancreatitis with common bile duct obstruction is indicated'*.

65. The HPS IPA advised an ERCP was scheduled for 22 December 2020, but it was agreed an urgent ERCP would be arranged if the patient developed jaundice or became *'unstable due to biliary sepsis*. The HPS IPA advised the Trust arranged an urgent ERCP intervention in response to the patient's deterioration and the ERCP was '*clearly indicated'.* I note the HPS IPA advised two '*specialists*' performed the ERCP in a '*timely*, *appropriate manner*' and *'the procedure was successful in decompressing the bile duct by the sphincterotomy and insertion of stent',* which the HPS IPA advised was the aim of an ERCP in these circumstances. The HPS IPA also advised the Trust provided '*appropriate'* post-ERCP care.

66. I consider the Trust acted in accordance with both the UK and WJES Acute Pancreatitis Guidelines in performing the ERCP. I accept the HPS IPA's advice the ERCP was correctly performed by appropriate professionals; was successful in its primary aim, in this case at that time; and the post-ERCP care was appropriate. Therefore, I do not uphold this element of the complaint; however, I hope the HPS IPA's advice provides the complainant with some

reassurance that this aspect of the patient's care and treatment was appropriate.

Issue 2: Whether the communication with, and information provided to, the patient's family was appropriate and consistent with the patient's condition and care.

Detail of Complaint

67. The complainant said the Trust's communications and information were *'very misleading, incorrect and confusing, condescending'*. The complainant referenced several examples. She said a consultant asked if the patient drank alcohol; the complainant queried why the consultant would assume the patient had drunk alcohol; a doctor informed the family they were '*going to try and waken the patient up'* but a nurse later told her this was not likely to be possible; the Trust informed her the patient's medication was working, yet he died; the Trust informed her they should be able to take the patient's tube out the following day but the next day the Trust informed the tube could not yet be withdrawn; and the Trust informed her the patient had deteriorated and advice would be sought from the HPB team about surgery which would then proceed that afternoon but in the afternoon the Trust informed her there would be no surgery yet and instead treatment with antibiotics would continue.

Evidence Considered

Legislation/Policies/Guidance

68. I considered the NICE Pancreatitis Guideline, the UK Acute Pancreatitis Guidelines and the WJES Acute Pancreatitis Guidelines.

Relevant Trust records

69. I reviewed the patient's records for 16 December 2020 to 5 January 2021.

Relevant Independent Professional Advice

ED IPA's Advice

70. The ED IPA advised one of the main causes of pancreatitis is excessive alcohol consumption. The ED IPA advised, it is therefore both routine and necessary to enquire about a patient's alcohol consumption for assessing pancreatitis. The ED IPA advised *'it is entirely appropriate to ask this question.'*

HPS IPA's Advice

71. The HPS IPA advised, the Surgical team did ask the patient's family if the patient drank alcohol; however, this was '*appropriate as alcohol is the second most common cause of acute pancreatitis*.

72. The HPS IPA advised, on 28 December 2020, there was a plan to '*wean'* the patient from sedation because the patient's '*respiratory parameters were marginally improving'*; however, the patient did not tolerate withdrawal of the sedation. The HPS IPA advised the Trust tried this again on both 29 and 30 December 2020 but failed for the same reason. The HPS IPA advised, the Trust's communication with the family that attempts were being made to waken the patient was *'appropriate and consistent with the patient's clinical condition'.* The HPS IPA advised *'there was no evidence on the documents of any conflicting information being given to the family'.*

Analysis and Findings

73. I note the complainant referenced examples of the Trust's communications with the family, including the query about the patient's alcohol consumption, the changes in reports of the patient's progress and information about the patient's treatment plan.

74. I note the NICE Pancreatitis Guideline states, '*people with acute pancreatitis usually present with sudden-onset abdominal pain. Nausea and vomiting are often present and there may be a history of gallstones or excessive alcohol intake',* '*Identifying the cause … If gallstones and alcohol have been excluded as potential causes of a person's acute pancreatitis'* and '*the incidence in the UK [of acute pancreatitis] is approximately 56 cases per 100,000 people per*

year. Around 50% of cases are caused by gallstones, 25% by alcohol and 25% by other factors.' The UK Acute Pancreatitis Guidelines refer to patient history in relation to investigating the cause of acute pancreatitis and this specifically details *'alcohol intake*'. The WJES Acute Pancreatitis Guidelines state, '*acute pancreatitis is an inflammatory condition of the pancreas most commonly caused by bile stones or excessive use of alcohol*', *'on admission, the etiology of [acute pancreatitis] should be determined, to project the need of definitive treatment (e.g., gallstone disease) and to avoid recurrence (e.g., alcohol intake, hypertriglyceridemia)'* and *'in the absence of gallstones or significant history of alcohol use, serum triglyceride and calcium levels should be measured'.*

75. I note both the ED and HPS IPAs advised one of the main causes of pancreatitis is alcohol and it was *'appropriate'* to ask this question.

76. I note the HPS IPA advised the Trust's communication with the family about trying to waken the patient was *'appropriate and consistent with the patient's clinical condition'* and *'there was no evidence on the documents of any conflicting information being given to the family'.*

77. I consider the NICE Pancreatitis Guideline and both the WJES and UK Acute Pancreatitis Guidelines indicate alcohol consumption is a key cause of acute pancreatitis and this should be identified or eliminated as the cause from the beginning. I also accept the ED and HPS IPAs' advice this enquiry was appropriate. Further, I accept the HPS IPA's advice the information the Trust provided to the family was consistent with the patient's condition. Therefore, I do not uphold this issue of complaint. I refer to Issue one (i) for additional comments about the plans for surgery.

CONCLUSION

78. I received a complaint about the care and treatment the Trust provided to the patient for acute pancreatitis. The investigation established there were significant failings in the patient's care and treatment and that, on the balance of probabilities, these failings contributed to the patient's death, as well as leaving the patient in severe pain.

79. The investigation identified the following failings:

- the Trust failed to appropriately manage the patient's pain, including leaving the patient without pain relief for a nine-hour period;
- the Trust failed to insert a catheter in a timely manner, and not until 18 hours after he was admitted and this '*had a small but significant impact on the poor outcome for the patient';*
- the Trust failed to ensure timely transfer of the patient to the critical care unit; and
- the Trust failed to take appropriate and timely decisions and actions in relation to the patient's sepsis, including drainage in a timely which *'would have likely prevented further deterioration'*.

Recommendations

80. I recommend the Trust provides the complainant a written apology in accordance with NIPSO's 'Guidance on issuing an apology' (July 2019), for the injustice caused because of the failures identified (within **one month** of the date of this report).

81. At the Ombudsman's request, the Trust reviewed the Draft Investigation Report, reflected on the CED and HPS IPAs' advice and then provided a detailed plan of actions it would take to ensure the learning and improvements in managing and treating acute pancreatitis, identified in the investigation, are shared within the Trust, including at Trust governance level. The Trust's plan included specific and timebound actions, with roles and responsibilities for these clearly allocated to appropriate individuals. These are detailed below.

82. The Trust will: -

- ensure relevant staff are reminded of the importance of timely catheterisation in the management of acutely unwell patients;
- encourage relevant staff to attend further training relevant to appropriate care of critically ill surgical patients;
- include the requirement for timely catheterisation in the surgical team's induction material;

- include the NICE Pancreatitis Guideline, the UK Acute Pancreatitis Guidelines and the WJES Acute Pancreatitis Guidelines in teaching sessions for relevant staff;
- ensure those staff involved in the care of acute pancreatitis are familiar with current relevant guidance. This will be reflected within the personal appraisal/ revalidation process;
- remind the surgical team of the critical care referral and escalation process;
- revise the Trust's critical care guidance to make the referral, escalation, handover and recording processes clearer; and
- introduce a new referral template for all parties external to the surgical unit.

83. I also recommend the Trust should ensure relevant staff are given the opportunity to reflect on the findings of this report and the full ED and HPS IPAs' advice in consideration of their own practice. This should be reflected in the personal appraisal / revalidation process with appropriate development plans identified as required.

84. I recognise how difficult and upsetting this may be for patient's family to read and wish to offer my heartfelt condolences to the complainant and her family.

MARGARET KELLY
Ombudsman

May 2024

Appendix 1

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

- Acting in accordance with the law and 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.