SCOTTISH PUBLIC SERVICES OMBUDSMAN

People Centred | Improvement Focused

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

SPSO
Bridgeside House
99 McDonald Road
Edinburgh
EH7 4NS

Tel **0800 377 7330**
Web **www.spso.org.uk**

Scottish Parliament Region: Central Scotland

Case ref: 202100979, Lanarkshire NHS Board

Sector: Health

Subject: Hospitals / Clinical treatment / diagnosis

Summary:

The complainant (C) complained to my office about the treatment provided to their late spouse (A) by Lanarkshire NHS Board (the Board).

Following a period of ill health, A attended University Hospital Wishaw's (UHW) Emergency Department (ED). A was diagnosed with primary biliary cirrhosis (PBC) by the gastroenterology department. A continued to be seen by the gastroenterology department as an outpatient over a period of months. It was noted that A's liver function had deteriorated over this period.

A then presented to UHW's ED where they were reviewed and noted to have worsening liver failure. A was subsequently admitted to the Emergency Care Unit (ECU). A was transferred to a specialist liver unit in another NHS Board's area four days later and sadly died there.

C complained that the Board had failed to adequately investigate and treat A's condition; that they provided A with inadequate in-patient care and treatment in UHW; and that they failed to treat A with dignity when transferring them to the ECU.

The Board reviewed A's care by undertaking a Significant Adverse Event Review (SAER). In their SAER, and their written response to C's complaint, the Board identified service failures. These were failures to timeously refer A to a specialist liver unit, in waiting times, the organisation of A's care, in the medication prescribed to A, and in staff attitude for which they apologised and identified learning. However, they found no failures in the in-patient care and treatment provided to A in UHW.

During my investigation I sought independent advice from a consultant hepatologist and gastroenterologist. Having considered and accepted the advice I received, I found that:

- A presented with clinical symptoms that were not typical of PBC, and that A had clear indicators of another underlying liver condition.

- Given A's clinical symptoms the Board have arranged urgent tests and / or a referral to a specialist liver centre / transplant hepatologist within a few weeks of their presentation, and definitely by the time their condition deteriorated several months later.

- In terms of A's treatment for PBC it is clear that there was a failure to have adequate regard to relevant guidelines. This had significant consequences to As' health. Six of the seven service standard measures of the PBC guidelines were not met.

- The symptoms that A presented with were also not in keeping with the additional condition that was considered of autoimmune hepatitis (AIH).

- A biopsy should have been offered to A much earlier. When this was subsequently offered, the Board should have done more to actively facilitate A's attendance for a biopsy. Other appropriate tests to diagnose AIH were not carried out.

- In terms of A's treatment for AIH, there was a failure to follow the relevant guidelines. In particular in relation to the use of contraindicated steroid medication and a failure to carry out regular blood checks.

- A's steroid medication was continued, although they were exhibiting side effects, without considering either referral to a specialist, or a liver biopsy or other treatment. There was also a failure to consider if the side effects of the medication were a sign of deterioration of A's liver disease.

- Although an additional condition of primary sclerosing cholangitis appears to have been suspected and an Magnetic Resonance Cholangiopancreatography (a medical imaging technique) was considered, this was not carried out early enough to exclude or confirm such a diagnosis. Nor were other important tests to differentiate between liver conditions carried out.

- As A's condition deteriorated acute severe AIH should have been considered and this should have triggered frequent clotting tests and a referral to a transplant unit. This was not done. The clinical team should have recognised that A's presentation was not in keeping with PBC nor standard AIH.

- If standard treatment guidelines for PBC and AIH had been followed then the outcome for A would have been significantly different and it is possible, if not likely, that A would still be alive.

- There were failures in communication and to adequately take into account A's personal circumstances.

- There was a failure to provide A with an appropriate level of dignity and person centred care following their admittance to UHW.

- There were significant failings in A's in-patient care and treatment in UHW. There were failures in the management of A's ascitic drain, steroid medication, and constipation. There was a failure to trigger a medical review in light of a fall A experienced on a ward.

- Despite significant signs of deterioration and infection during their in-patient admittance at UHW, A's condition was not given sufficient priority and there was a lack of urgency in making a diagnosis and ensuring that A was provided the correct treatment.

- The Board's SAER did not adequately address and identify the failings in A's care and treatment that occurred from their initial presentation.

- There had been a failure to meet the requirements of the Duty of Candour process.

Taking all of the above into account, I upheld all of C's complaint.

In investigating this case it is of significant concern to me that that I issued an earlier critical public report into the gastroenterology service at UHW on 22 June 2022 (case reference 202001373). In that report I was critical of the care and treatment the patient received from the gastroenterology service for PBC and other clinical issues. In particular I found serious failings in identifying and treating the patient's deteriorating liver disease between 2017 and 2018. I am concerned that I have found similar failings over a similar timescale in this case.

My recommendations are set out below:

What we are asking the Board to do for C:

Rec number	What we found	What the organisation should do	What we need to see
1	Under complaint point a) I found that there was a failure to investigate and/ or diagnose A's condition. In particular I found that: i. there was a failure to make an appropriate and timely diagnosis; ii. there was a failure to appropriately refer A to a specialist liver service/ transplant hepatologist at an early stage in their treatment; iii. there were significant and sustained failures in the consideration, management and treatment of A's	Apologise to C for the failings identified in this investigation and inform C of what and how actions will be taken to stop a future reoccurrence. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets	A copy or record of the apology.

Rec number	What we found	What the organisation should do	What we need to see
	deteriorating condition including a failure to take into account relevant guidance; and iv. there were failures in communication and to adequately take into account A's personal circumstances. Under complaint point (b) I found that the Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019. Specifically: i. there were failures in the management of A's ascitic drain, steroid medication and constipation; and ii. there was a failure to trigger a medical review in		

Rec number	What we found	What the organisation should do	What we need to see
	light of A's fall and a failure to follow relevant guidelines in the management of patients with decompensated liver disease. I also found that there were failures in the Board's handling of C's complaint and the subsequent Significant Adverse Event Review.		

We are asking the Board to improve the way they do things:

Rec number	What we found	Outcome needed	What we need to see
2	complaint point a) I found that the there was a failure to investigate and/ or diagnose A's condition. In particular I found that:	Patients showing signs of advanced liver disease should receive appropriate and timely care and treatment that is in line with relevant guidance	Evidence that the Board have arranged, as a matter of urgency, independent external audit of the treatment of patients by the gastroenterology outpatient service at UHW with

Rec number	What we found	Outcome needed	What we need to see
	i. there was a failure to make an appropriate and timely diagnosis; ii. there was a failure to appropriately refer A to a specialist liver service/ transplant hepatologist at an early stage in their treatment; iii. there were significant and sustained failures in the consideration, management and treatment of A's deteriorating condition including a failure to take into account relevant guidance; and iv. there were failures in communication and to adequately take into		PBC/ AIH or an overlap syndrome from 2018 to date to ensure there is no systemic or individual issue which may have affected other patients The audit should be completed independently by individual(s) with the appropriate experience and expertise My office should be provided with an update on the progress of the audit. My office and the complainant should be informed of the results of the audit including all learning points and any required action plan to implement and share findings Evidence that the findings of my investigation have been shared with relevant staff in a supportive

Rec number	What we found	Outcome needed	What we need to see
	account A's personal circumstances		manner for reflection and learning Evidence that learning from these events and the external audit is reflected in policy guidance and staff training
3	Under complaint point b) I found that the Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019. Specifically there were failures in the management of A's ascitic drain, steroid medication, and constipation. We also found that there was a failure to trigger a medical review in light of A's fall and a failure to follow relevant guidelines in the management of	Patients admitted to hospital showing signs of advanced liver disease should receive appropriate and timely care and treatment that is in line with relevant guidance	Evidence that: My findings have been shared with staff in a supportive way for reflection and learning and to ensure similar mistakes are not made again; and That the learning from these events and the external audit is reflected in policy/ guidance and staff training

Rec number	What we found	Outcome needed	What we need to see
	patients with decompensated liver disease.		

We are asking the Board to improve their complaints handling:

Rec number	What we found	Outcome needed	What we need to see
4	I found that the Board's complaint handling was unreasonable. Specifically: i. there was a failure to meet the requirements of the Duty of Candour process; and ii. a failure to undertake a reasonable Significant Adverse Event Review that identified key learning and improvements	When an incident occurs that falls within the Duty of Candour legislation, the Board's Duty of Candour processes should be activated without delay. Local and Significant adverse event reviews should be reflective and learning processes that ensure failings are identified and any appropriate learning and improvement taken forward. Adverse event reviews should be held in line with relevant guidance.	Evidence that the Board have reviewed their Duty of Candour processes, including timescales for activating the process and; Evidence that the Board have reviewed their process for carrying out adverse event reviews to ensure these reviews properly investigate, identify learnings and develop system improvements to prevent similar incidents occurring

We are asking the Board for evidence of action already taken

Rec number	What we found	Outcome needed	What we need to see
5	Under complaint point c) I found that there was a failure to provide A with an appropriate level of dignity and person centred care on 4 August 2019.	The Board said that they had reminded staff of the professional and caring manner they would expect from them at all times.	Evidence of the action taken.

Feedback

Points to note

As noted at paragraph 81, A should have been referred to a tertiary liver service/ transplant hepatologist within a few weeks of presentation. The failure to do so raises the question in my mind as to whether there is a sufficiently open and transparent culture that encourages clinical staff at all levels to identify when they may require internal or external specialist support in treating complex cases and that enables them to request this. I urge the Board to consider how they can support clinicians to identify and raise when they may require internal or external specialist support when providing care and treatment.

This report will be as difficult for staff to read, as it no doubt is for the family. It is incumbent on the Board to ensure staff are supported and that it is clear to them that my findings reflect failures in systems that should have been there to support them.

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. The complainant (C) complained to me about the care and treatment provided to their late spouse (A) by Lanarkshire NHS Board (the Board).

2. Following a period of ill health, A attended University Hospital Wishaw's (UHW) Emergency Department (ED) on 25 September 2018. A was noted to have abnormal liver function tests. An urgent referral was made to the gastroenterology department.

3. A was diagnosed with Primary Biliary Cirrhosis (PBC) by the gastroenterology department on 5 October 2018. A continued to be seen by the gastroenterology department as an outpatient. A's last outpatient gastroenterology appointment (prior to admission to hospital) was on 30 July 2019. It was noted that A's liver function had deteriorated between October 2018 and July 2019.

4. A presented to UHW's ED on 4 August 2019 where they were reviewed and noted to have worsening liver failure. A was subsequently admitted to the Emergency Care Unit (ECU).

5. On 8 August 2019, A was transferred to a specialist Liver Unit in another NHS Board's area (the specialist Liver Unit) and sadly died there several days later.

6. C has complained to my office about aspects of A's care and treatment. In particular, that there was a failure to adequately investigate and/ or diagnose A's condition from 2018 and in relation to their admission to UHW between 4 August 2019 and 8 August 2019.

7. The complaint from C I have investigated is that:

   (a) The Board failed to adequately investigate and / or diagnose A's condition (***upheld***);

   (b) The Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019 (***upheld***); and

   (c) The Board failed to treat A with dignity on 4 August 2019 when transferring them from University Hospital Wishaw's Emergency Department to UHW's Emergency Care Unit (***upheld***).

Investigation

8. In order to investigate C's complaint, I and my complaints reviewer considered all of the documentation submitted to us by C and by the Board including A's medical and nursing records, and complaint correspondence. I also obtained medical advice from an appropriately qualified medical adviser (the Adviser: a consultant hepatologist and gastroenterologist). In advising on the case, the Adviser had full access to A's relevant medical records, including the relevant outpatient records and the Board's complaint file.

9. In this case, I have decided to issue a public report on C's complaint to reflect my concerns about the failings identified in A's care and treatment; the significant personal injustice caused by the failings identified, and the potential for wider learning from the complaint.

10. This report includes the information that is required for me to explain the reasons for my decision on this case. It also contains some technical medical terms and descriptions which I have considered necessary to include in order to provide the appropriate level of detail both in relation to A's condition, and to the advice I have received and taken into account. Wherever possible, explanations for these terms are provided in the report and / or in annex 1.

11. While I have not included every detail of the information considered, my complaints reviewer and I have reviewed all of the information provided during the course of the investigation. C and the Board were given an opportunity to comment on a draft of this report.

Background

12. I have set out below the background and key events that relate to points (a) (b) and (c) of the complaint.

13. A had a background of chronic liver disease and was diagnosed with PBC in October 2018.

14. A was seen by the gastroenterology department as an outpatient from October 2018. A's last outpatient appointment was on 30 July 2019 prior to being admitted to UHW on 4 August 2019.

15. A presented to ED on 4 August 2019 at 17:08 with increasing ascites (a condition in which fluid collects in spaces within the abdomen) and jaundice.

16. A was seen at 20:40 and was noted to have worsening liver failure.

17. A was admitted to ECU at 23:25 hours and remained there until 8 August 2019 when they were transferred to the specialist Liver Unit due to the continued deterioration in their condition.

18. A, who was aged 41 years at the time, sadly died in the specialist Liver Unit on 12 August 2019.

19. A's cause of death was listed as 1a multi organ failure, 1b septic shock, 1c necrotising fasciitis, 2 chronic liver disease.

20. In February 2020, following receipt of C's complaint, the Board commissioned a Severe Adverse Event Review (SAER) into the circumstances of A's death. A SAER is a national approach to learning from adverse events through reporting, review, and the sharing of learning.

21. The SAER was completed on 30 October 2020. The main findings of the SAER were;

i. The assessment and management of the A's clinical deterioration during their admission to UHW and the specialist Liver Unit in August 2019 was appropriate and reasonable with involvement of specialist teams in gastroenterology, liver transplantation and intensive care.

ii. There is no evidence from the information considered by the review team, including discussions with representatives of the intensive care staff at the specialist Liver Unit, that A had evidence of necrotising fasciitis when they were transferred from UHW in August 2019. (C complains that there was poor wound care at UHW, and they question whether this led to A developing necrotising fasciitis - see complaint point b)

iii. In January 2019 following outpatient review there was a plan to undertake endoscopy to determine the presence of varices (varicose veins) which would indicate a concern about the possibility of underlying cirrhosis. It is recognised that budesonide (a steroid used to treat inflammation) is contraindicated in the treatment of autoimmune chronic active hepatitis because of shunting budesonide away from the liver in cirrhosis causing steroid side effects and loss of response. At this stage it would have been appropriate to change budesonide to prednisolone an alternative steroid not contraindicated in cirrhosis.

iv. A's budesonide dose was reduced below 9mg per day whilst Liver Function Tests (LFT) were still abnormal. This would normally only be done when remission had been achieved (normalisation or near normalisation of

LFT's). This situation should have prompted a review and consideration of switching to an alternative immunosuppressant.

v. The fibroscan (a scan of the liver) indicated the presence of cirrhosis and shunting in July 2019 and at the subsequent clinic visit in July 2019. Cirrhosis was also confirmed clinically when there was evidence of ascites. It would have been appropriate to discontinue budesonide and an alternative steroid substituted.

vi. Earlier discussion and referral of the patient to the specialist Liver Unit may have resulted in earlier consideration of liver transplantation and a different outcome for the patient.

vii. A attended unscheduled care services on several occasions. This was largely related to symptoms of chronic liver disease and abnormal liver function tests. Improved co-ordination of care between the unscheduled care services and liver services in the form of better multidisciplinary team working, and in particular a clearly defined role for the liver nurse specialists team, may have resulted in earlier intervention and more co-ordinated care.

viii. A more robust multidisciplinary approach including discussions within a local liver MDT may have resulted in more coordinated care between emergency ambulatory care staff and the outpatient gastroenterology services. It may also have facilitated outpatient investigations and monitored the decision making around the provision of liver biopsy for the patient. It was identified that a liver biopsy would have helped in clarifying the diagnosis.

22. The recommendations of the SAER were;

i. A local review of liver services should be undertaken including defining the roles and responsibilities of team members and the processes that support the liver MDT. The development of a weekly local liver MDT supported by clinical and nursing staff should be established. A pan-Lanarkshire MDT has been implemented following this incident.

ii. Review of the liver nurse specialist roles should be undertaken to facilitate the development of robust communication pathways between other specialties, in particular acute physicians providing unscheduled care, and the liver team for patients admitted with worsening liver disease who require urgent liver review in the outpatients.

iii. Learning from the SAER should be shared with the gastroenterology team and the case reviewed at the local mortality and morbidity meeting.

Relevant policies, procedures

- The British Society of Gastroenterology - BASL Decompensated Cirrhosis Care Bundle – First 24 hours 2014
- The British Society of Gastroenterology PBC primary biliary cholangitis treatment and management guidelines 2017 (the PBC guidelines)
- Philip N Newsome et al. (2018): Guidelines on the management of abnormal liver blood tests. Gut 67(1):6-19.
- American Association for the Study of Liver Diseases Diagnosis and Management of Autoimmune Hepatitis November 2010 (the AIH guidelines)

(a) The Board failed to adequately investigate and/ or diagnose A's condition

Concerns raised by C

23. The following paragraphs set out the concerns C raised.

24. A was diagnosed with PBC approximately 10 months before they died. After diagnosis, A was prescribed steroid medication to treat PBC.

25. They questioned whether A should have been referred for specialist care and / or treatment much earlier.

26. When A was admitted to the specialist Liver Unit, they were advised that A was not presenting as someone with PBC. They, therefore, questioned whether A had been misdiagnosed with PBC.

27. The death of A has devastated their whole family. They feel that if A had received appropriate care they would have survived.

The Board's response

28. I do not intend to repeat the content of the Board's original responses to C's complaint, as all parties are aware of the content.

29. The main points of their response dated 19 February 2021 were that:

i. They had been required to await the completion of the SAER before being able to respond to the complaint. The information gathered by the SAER team enabled them to respond as follows.

ii. A had gone through a series of tests before a clinical diagnosis of PBC was made in November 2018.

iii. Following a review of A's outpatient and unscheduled care attendances there was evidence of progressive liver disease despite the interventions that had been undertaken. A's worsening liver function was felt to be due to their underlying liver disease and by July 2019 they had developed decompensated liver failure.

iv. Despite the treatment in place, A's liver function deteriorated leading to liver failure and, ultimately, their admission to UHW in August 2019.

v. From review of the documentation in A's medical records through the SAER process, they believe that A had PBC or autoimmune hepatitis (AIH) or an overlap syndrome. The absence of a liver biopsy had contributed to this uncertainty. The SAER identified that a liver biopsy would have helped in clarifying the diagnosis.

vi. It was agreed that earlier referral to the specialist Liver Unit would have resulted in a different management plan and early transplantation may have resulted in a different outcome for A.

vii. They accepted it was clear there were issues with waiting times, the organisation of A's care, their medication and staff attitude for which they apologised.

30. In response to my enquiries, the Board also said that:

i. The SAER found that there was a specific failure to refer A to appropriate specialists and specialist care timeously and that such a referral may have resulted in a different outcome.

Medical advice received

PBC diagnosis and PBC guidelines

31. The Adviser was asked to review A's clinical records including the SAER, and to comment on the reasonableness of the Board's diagnosis and treatment prior to A's admission to UHW on 4 August 2019. The Adviser said:

32. There was evidence of A having significant liver damage far beyond PBC in October 2018. They noted that on the initial tests and in subsequent outpatient reviews there were clear indicators of A having an additional liver condition other than the immunological markers of PBC. These were: AMA (anti-mitochondrial antibodies) positivity and raised IgM immunoglobulins (antibodies that defend against bacteria and viruses).

33. The signs that A had another undiagnosed condition which led to their deterioration were: their presentation with right upper quadrant pain, having intermittent jaundice with fluctuating bilirubin (a byproduct of red blood cell breakdown that helps make bile for digestion), clay-coloured stools and highly elevated liver transaminases (an enzyme found in the liver) levels, which were often over 200. A also had marked fluctuations in cholestatic tests (bilirubin). All of these symptoms were not typical for PBC and strongly suggested A had another liver problem.

34. However, even if PBC was the diagnosis, A's young age at diagnosis (which was an indication of a poor prognosis) and a bilirubin level of over 100 should have triggered a referral at that time to a liver transplant unit in accordance with the PBC guidelines.

35. Because PBC is typically an extremely slowly progressive disease, treatment success is typically reviewed after one year of treatment. The rapid progression of A's condition should have triggered a critical review of the diagnosis at each outpatient clinical review and urgent tests and / or a transplant referral should have been arranged within the first couple of months of the diagnosis.

36. A rapid deterioration within a couple of months, as seen in A, would be extremely rare in a patient with PBC. However, A's clinical team did not do any risk stratification as recommended in the PBC guidelines.

37. Assuming that PBC was the main or one condition that A had, then there were other failures in the management of A's PBC. A was not tested for osteoporosis / vitamin deficiencies, they were not evaluated for typical symptoms of PBC (in particular itch and fatigue) and were not referred to a patient support group in accordance with the PBC guidelines.

38. In summary, none of the seven service standard measures[1] of the PBC guidelines were met. (See paragraphs 77 and 85)

[1] See Annex 3 for the complete text of the 7 PBC Guidelines service standard measures.

Additional diagnosis and diagnostic testing

39. The Adviser stated that A's case was diagnostically challenging. They advised that A should have been reviewed by, or referred to, an experienced liver centre prior to initiating therapy and this did not happen. At the latest, by December 2018, A's case should have been discussed with a tertiary liver service / transplant hepatologist.

40. The Adviser noted a gastroenterology clinic letter in December 2018. This detailed a presumed diagnosis of the additional, and separate, condition of AIH. However, the Adviser found no evidence in A's clinical notes of any diagnostic scores or algorithms being used to make a diagnosis of AIH.

41. The Adviser advised that A's level of bilirubin should have prompted consideration of acute severe AIH and this also should have triggered frequent clotting tests and a referral to the transplant unit. This was not done.

42. However, they advised A's symptoms were not in keeping with a diagnosis of AIH alone because of A's significant and fluctuating biliary damage. The Adviser found no evidence in A's clinical notes to suggest that any diagnostic criteria was used to consider if they had AIH-PBC overlap syndrome.

43. The Adviser advised that AIH guidelines state that a biopsy is necessary for diagnosis. They noted that a biopsy is also recommended in the PBC guidelines if an overlap autoimmune condition is considered likely. This was not done in A's case. Nor were the other appropriate tests highlighted by the AIH guidelines, such as a Magnetic Resonance Cholangiopancreatography (MRCP) performed in the clinical context. An MRCP is used as a diagnostic tool to differentiate between different liver conditions. (See paragraphs 73 and 81)

44. The Adviser stated that, in addition to PBC and AIH, primary sclerosing cholangitis (PSC) as a differential diagnosis (or as overlap) appeared to have been suspected because the clinicians mentioned carrying out an MRCP relatively early. However, this important test was delayed by several months. Given the cholestatic picture and A's jaundice this should have been requested with urgency in 2018.

45. The Adviser advised that no screening was carried out for other autoimmune related conditions which they would have expected from the AIH guidelines. Other recommendations of the AIH guidelines were not followed or not documented, such as carrying out a bone density test and offering pregnancy counselling.

46. The Adviser advised that there was also no evidence at any time of an assessment of the severity of A's liver disease being done (such as calculation of a

MELD score which ranks the patient's degree of sickness and shows how much they need a liver transplant). This is vital to balance the risk of continuation of steroid treatment which has the risk of infection and delays diagnosis and definite treatment such as a liver transplant.

47. A also had abnormal tests of copper metabolism which were not followed up. Also, no urinary tests, nor as noted above, a liver biopsy, nor relatively simple tests to investigate whether A had destruction of the red cells (haemolysis) as a cause of their jaundice were carried out.

Treatment

48. In December 2018 A was started empirically on treatment with the steroid budesonide. The Adviser advised that empirical treatment with budesonide is only indicated and licensed in patients with non-decompensated and / or non-cirrhotic autoimmune hepatitis (which should be proven by liver biopsy). Budesonide results in a high concentration to the liver, but in advanced liver disease it bypasses the liver through shunts which can lead to unacceptable side effects. Therefore, budesonide is only given in patients with neither cirrhosis nor acute severe hepatitis. In A's circumstances, the Adviser advised that they should not have been prescribed budesonide and that an alternative steroid (prednisolone) should have been considered if AIH had been confirmed on biopsy.

49. The Adviser advised that A continued to be treated with budesonide despite several senior reviews and without considering a referral to a specialist, a biopsy or other treatment. This was even though A presented with steroid side effects on two consecutive clinic visits.

50. The Adviser advised that normally a large amount of budesonide is metabolised in the liver and does not enter the general circulation, but when liver disease deteriorates the medication bypasses the liver, and side effects occur. The side effects experienced by A should have been seen as a sign of deterioration of A's liver disease.

51. In addition, the AIH guidelines recommend that regular follow up blood tests are done after the start of steroid treatment. The recommended blood checks are every 12 to 24 hours in acute severe AIH and every 1 to 2 weeks in other AIH. These were not done in A's case. Each of these blood tests would, and should, have triggered reflection on whether deviation from the guidelines (not referring for a liver transplant) was still appropriate and whether the presumed diagnosis was still correct.

52. The Adviser noted that A was not tested for thiopurine methyltransferase (TPMT) to be able to start treatment with azathioprine which should have been started after 2 weeks of steroids as recommended in the AIH guidelines. A was prescribed budesonide in December 2018 and azathioprine was only prescribed in August 2019 during an in-patient hospital admission to UHW.

53. A was also prescribed with ursodeoxycholic acid (UDCA - medication used in the management and treatment of liver disease). The Adviser noted the clinical team caring for A increased their prescription to a level much higher than recommended in the PBC guidelines. The recommended level is 13 – 15 mg / kg / day, but A's consultant increased this to over 20 mg / kg / day. They also did not consider a second line agent, which should be given in non-responsive PBC on treatment failure in accordance with the PBC guidelines.

54. The increased dosage of UDCA was escalated to a level where there was clearly no benefit and with the possibility of a worse outcome. Treatment continued without considering either referral to a specialist, or a biopsy or other treatment. This was even though A presented with steroid side effects on two consecutive clinic visits. The side effects should have been seen as a sign of deterioration of A's liver disease.

Communication

55. The Adviser also considered how staff had communicated with A. From their review of the clinic letters, the communication with A seemed to be extremely brief. Where handwritten notes of the consultant in charge were available, this was limited to very few lines and the initial review of A seemed to have been made by a relatively junior trainee, with no evidence of consultant discussion or supervision.

56. For example, there was mention in the clinical notes that a liver biopsy had been discussed with A who had agreed to have the biopsy done. However, several months later (and the biopsy should have been done within weeks), they noted there were discussions that A found it difficult to attend a different hospital for the biopsy and the communications suggested that A was not sufficiently aware of what the biopsy entailed. Around that time (several months after presentation) there was the first mention that A might have challenging personal and social circumstances including anxieties around their large family, two of whom had health issues. This suggested that A's personal circumstances had not been considered or discussed with them earlier and, therefore, patient centred care was not provided.

Overall conclusions

57. In the Adviser's view, mistakes had been made throughout from the time of A's initial presentation.

58. A did not have a typical presentation. The clinical team should have recognised that A's presentation was not in keeping with PBC nor standard AIH which can be treated without obtaining external specialist advice.

59. The treating consultant in charge and their team including junior doctors should have been aware of their limitations. The junior doctor who had reviewed A in clinic should have had an opportunity to adequately discuss A's case with a clinical supervisor.

60. The treating consultant in charge and their team should also have been aware of the relevant guidelines including the natural history, differential diagnosis, and management of patients with the different types of autoimmune liver disease (and jaundice in general including haemolysis and Wilson's disease).

61. They should have recognised A's deterioration and the urgency for further assessment and should have asked for specialist liver advice. A should have been referred to a tertiary liver service / transplant hepatologist within a few weeks of their presentation.

62. The mistakes in making a timely diagnosis should have been obvious to clinical team members with general gastroenterology training without specific liver training.

63. It was unclear whether there was a culture issue in the treating clinical team(s) with regards to asking for help within the Board and getting help from outside the Board.

64. The medical management of A went against clear medical guidelines, and this should have been picked up during any of the clinical liver reviews. These reviews should have explicitly mentioned that there had been significant failures in A's management rather than that management could have been better and a referral could have been made earlier.

65. If standard guidelines had been followed then the outcome for A would have been significantly different and it is possible, if not likely, that A would still be alive.

66. These failings should have been mentioned clearly in the event reviews for the consultant and any trainees involved to reflect on.

67. Under a duty of candour,[2] all of these failings should have been clearly explained to A's family. The Board's comment that an earlier referral to the transplant unit 'might have made a difference' to A's outcome did not reflect the extent of the failings and that an earlier referral would have made a significant difference to A's outcome.

68. In their view, the reviewing gastroenterologist (with more liver experience / interest than the clinical team who managed A, should have identified these failings in the course of conducting the SAER.

69. The Adviser also considered that the SAER should have looked at A's full care from their initial presentation in 2018 and not only the most recent care and treatment they had received.

The Board's response to the proposed public report

70. I provided the Board with a copy of my proposed public report. In response they made the following comments.

71. The Board said that the treating team did recommend a biopsy to A. They said that a letter was sent to A, and their GP, on 25 January 2019 advising this would take place in University Hospital Hairmyres (UHH).

72. The Board said that, regrettably, C was unable to travel to UHH. This was discussed further with A at an outpatient appointment on 25 April 2019, and on this occasion, A was concerned about having the procedure under local anaesthetic, therefore consideration was given to general anaesthetic. The Board said that A was advised to contact the gastroenterology service to arrange a suitable date, but this did not happen.

73. The Board also said that an MRCP was performed on 1 May 2019.

74. The Board disagreed that there was a failure to undertake a reasonable SAER.

75. The Board said that the failings identified by the Adviser in relation to the prescription of budesonide, the discussion and referral of A to the Liver Unit, and the multidisciplinary approach to A's care were identified as key findings by the SAER.

[2] The duty of candour is a legal requirement for all NHS organisations in Scotland to be open and transparent with service users and/or the relevant person when an unintended or unexpected incident has occurred that results in death or harm

76. The Board commented that the SAER was commissioned following the complaint about A's care. Initially, the review's scope was to consider events between 4 August 2019 to 8 August 2019. However, this was extended to comment on A's care and the management of their chronic condition from their initial presentation in September 2018. The Board said that five of the seven key findings from the SAER pertained to this earlier period.

77. The Board commented that the first of the 7 service standards of PBC is for an ultrasound to be carried out. They said that this was met. They noted that the SAER recorded that A had an abdominal ultrasound which showed; a normal liver, absent gallbladder, common bile duct (CBD) with normal calibre.

78. The Board said that the SAER identified that this incident did trigger a Duty of Candour. However, they said that this only became apparent after the full investigation had been carried out. In these circumstances, they said that it was not reasonable to expect candour to be activated prior to full investigation. The Board said that candour was implemented as part of the SAER process and that A's family were offered an opportunity for a meeting in the final report letter, but did not take up the offer. The Board said that they were satisfied that they had followed local and national policy in this regard.

Additional advice

79. I asked the Adviser for additional advice in light of the Board's comments.

80. The Adviser advised that it was correct for the Board to say that A had been offered a liver biopsy. However, they advised that the biopsy should have been pursued at a much earlier stage (in 2018), because of clear diagnostic difficulty. The Adviser considered that the Board should have facilitated the biopsy if necessary by admitting A to hospital and referring them to an appropriate unit. The Adviser reiterated their advice that, where the diagnosis is unclear, it is inappropriate to initiate steroid treatment.

81. The Adviser accepted that an MRCP was undertaken in May 2019. However, they advised that this should have been considered and undertaken at a much earlier stage (in 2018). They advised that a biopsy and MRCP could have potentially led to a diagnosis several months earlier when A would have likely been a candidate for liver transplant.

82. The Adviser noted the Board's comments about the SAER, but advised that they considered that it had inadequately addressed the early management of A's care. The Adviser advised that the SAER should have concentrated on the early

management of A's condition as soon as failures in this area were identified. They considered that the decision not to do so significantly limited the learning from A's experience.

83. In response to the Board's statement that five of the seven key SAER findings pertained to the period beginning September 2018; they advised that no key finding specifically referred to events and A's clinical deterioration in 2018. The Adviser considered that the SAER should have specifically addressed these. In particular the absence of investigations into A's ongoing clinical deterioration. They said key finding six mentioned "earlier discussions" but did not specify timing and it should have emphasised that discussions should have taken place months before. Key finding seven referred to unscheduled care services but is not specifically related to the events in 2018. The Adviser reiterated their advice that A's deteriorating condition in 2018 should have triggered face-to-face reviews, immediate hospital admission (in relation to A's bilirubin level of over 100) and referral to a liver transplant unit.

84. The Adviser advised that, from the clinical course in 2018, it was clear that the management of A's condition should have been far more aggressive and collaborative, involving a tertiary care hepatologist and the Liver Unit. They advised that this was inadequately addressed by the SAER and its key findings.

85. The Adviser accepted the Board's point that A had received an ultrasound. However, they advised that the findings of the ultrasound scan (in the context of the liver biochemistry) should have triggered urgent further investigations.

86. The Adviser said that the duty of candour trigger should have been clear to the Board at the time of the SAER's initial instruction. They advised that the unwillingness of A's family to meet with the Board did not mean that the duty of candour could be ignored. The Adviser considered that the Board still needed to inform A's family about what had gone wrong with their treatment from the date of their initial presentation in 2018.

Decision

87. The basis on which I reach conclusions and make decisions is 'reasonableness'. My investigation looks at whether the actions taken, or not taken, were reasonable in the circumstances and in light of the information available to those involved at the time.

88. In investigating this complaint, I have obtained professional advice from the Adviser (as outlined above). I have carefully considered this advice, which I accept.

89. While PBC was initially diagnosed, it is clear that A was presenting with clinical symptoms that should have alerted the treating clinical team that this was not a typical presentation of PBC, and that A had clear indicators of another underlying liver condition. The rapid progression of A's condition should also have triggered critical reviews of the PBC diagnosis at each of the clinical reviews carried out. Crucially, urgent tests and / or a referral to a specialist liver centre / transplant hepatologist should have been arranged within a few weeks of A's presentation in 2018, and definitely by December 2018 when their condition deteriorated. It is of deep concern to me that this did not happen.

90. In terms of A's treatment for PBC it is clear that there was a failure to have adequate regard to the relevant guidelines, which had significant consequences. Medication was prescribed at much higher than recommended levels to a point where there was clearly no benefit and a potentially worse outcome. Second line agents were not considered and given as they should have been in non-responsive PBC.

91. Furthermore, A was not tested for osteoporosis / vitamin deficiencies; nor were they evaluated for typical symptoms of PBC such as itch and fatigue, and they were not referred to a patient support group in accordance with the PBC guidelines

92. It is of significant concern to me that the Adviser has said that six of the seven service standard measures of the PBC guidelines were not met.

93. The symptoms that A presented with were also not in keeping with the additional condition that was considered in December 2018 of AIH. The advice I have received is that for AIH on its own, but, in particular, in PBC with overlap autoimmune condition, a liver biopsy is necessary for diagnosis. While a biopsy was offered in early 2019, this should have been offered to A much earlier in their presentation in 2018.

94. When offered in 2019, the Board should have done more to actively facilitate A's attendance for a biopsy. Nor were the other appropriate tests to diagnose AIH carried out such as diagnostic scoring / algorithms and screening used in line with AIH guidelines. Although an additional condition of PSC appears to have been suspected and an MRCP considered this was not carried out early enough to exclude or confirm such a diagnosis. Nor were other important tests to differentiate between liver conditions carried out.

95. The Adviser has told me that, as A deteriorated, acute severe AIH should have been considered and this should have triggered frequent clotting tests and a referral

to a transplant unit. This was not done. The clinical team should have recognised that A's presentation was not in keeping with PBC nor standard AIH.

96. In relation to A's treatment for AIH, my investigation has established that there was again a failure to follow the relevant AIH guidelines. In particular in relation to the use of budesonide in December 2018 which was contraindicated; the failure to commence azathioprine and the failure to carry out regular blood checks in line with AIH guidelines. A's steroid medication was continued, although A was exhibiting side effects, without considering either referral to a specialist, or a liver biopsy or other treatment. There was also a failure to consider whether the side effects of the medication prescribed were a sign of deterioration of A's liver disease.

97. I recognise that A's diagnosis would have been extremely challenging. Equally, it is apparent from the evidence and the advice I have received that A's complex liver condition required specialist input from an early stage in their presentation; yet this was not recognised as it should have been from the outset. It is also apparent that there were a number of significant and sustained failures in relation to A's ongoing diagnosis and treatment. As such, I am in no doubt that A's care and treatment was unreasonable

98. It is of particular concern to me that those treating A did not appear to have fully taken into account the relevant guidelines in relation to the treatment of PBC and AIH . Nor does there appear to have been appropriate and adequate reflection as to the severity of the symptoms A was presenting with. The advice I have received and accept is that if standard guidelines had been followed then the outcome for A would have been significantly different and it is possible, if not likely, that A would still be alive. This will be extremely difficult for C to read, and they have my utmost sympathy.

99. As noted above, A should have been referred to a tertiary liver service / transplant hepatologist within a few weeks of presentation. The failure to do so raises the question in my mind as to whether there is a sufficiently open and transparent culture, supported by clear procedures that encourage clinical staff at all levels to identify when they may require internal or external specialist support in treating complex cases, and that enables them to request this. I have provided feedback for the Board on this point at the end of my report.

100. I am also critical of how staff appeared to have communicated with A about their condition and treatment. I note that the Adviser considered there had been a failure to take a patient centred approach towards A, especially in relation to their particular needs and taking into account their challenging personal circumstances.

101. While I note a SAER was carried out that identified some failings, it is of significant concern that the SAER did not identify all the significant and sustained failings that occurred particularly when A presented in 2018 . I have considered this in more detail under complaint handling.

102. Taking account of the advice I have received and in view of the failings identified, I uphold this point of the complaint. My recommendations for action are set out below.

(b) The Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019

Concerns raised by C

103. The following paragraphs set out the concerns C raised.

104. They consider there was a failure to provide A with adequate care and treatment as a patient in UHW between 4 August 2019 and 8 August 2019.

105. In particular, they consider there was poor wound care and they question whether this led to A developing necrotising fasciitis.

The Board's response

106. I do not intend to repeat the content of the Board's original responses to C's complaint, as all parties are aware of the content.

107. The main points of their response dated 6 March 2020 were that:

i. They were sorry for the delays which had occurred in the ED due to the high number of patients who had presented there at the time.

ii. A had remained in the ECU due to the unavailability of beds within Ward 5. The length of stay there is variable. However, A's management was guided by the gastroenterology team and, therefore, their care was not impacted while they were in the ECU.

108. The main points of their response dated 19 February 2021 were that:

i. They had required to await the completion of the SAER which had been carried out after A's death before being able to respond to this complaint.

ii. On A's admission on 4 August 2019, a number of tests and investigations were carried out and they were diagnosed with acute on chronic decompensation of their liver disease.

iii. An ascitic tap was undertaken. The fluid that was drained showed no signs of bacterial infection in the peritoneum (a membrane that lines the abdominal cavity and covers the abdominal organs). There was a persistent leakage of fluid from the tap which is a recognised complication.

iv. Changes were made to A's medication and there were plans to insert a drain to allow continuous drainage of the remaining fluid; and to discuss A's case with the specialist Liver Unit. As A was not keen to have a new drain inserted without a general anaesthetic it was agreed to wait the outcome of discussions with the specialist Liver Unit.

v. After A suffered a fall on 8 August 2019, there was concern that they had a loss of brain function as a result of the failure to remove toxins in the blood as a result of liver failure. Further discussions took place with the specialist Liver Unit, and A was transferred to them for assessment of a liver transplant.

vi. There was no clinical evidence that A had developed necrotising fasciitis prior to leaving UHW on 8 August 2019. Having consulted with staff at the specialist Liver Unit they have confirmed there were no signs of A having necrotising fasciitis on their arrival there.

109. In response to my enquiries, the Board also said that:

i. The SAER found no evidence of wound infection or necrotising fasciitis when A was transferred from UHW to the specialist Liver Unit.

ii. The investigation also noted that the assessment and management of A's clinical deterioration in August 2019 was appropriate and reasonable, with the involvement of specialist teams.

Medical advice received

110. The Adviser was asked to review A's clinical records and the SAER. They were asked to comment on the reasonableness of the care and treatment provided to A between 4 August 2019 and 8 August 2019. The Adviser said:

111. They considered there were failures in A's care and treatment in UHW between 4 August 2019 and 8 August 2019.

112. A had presented on admission on 4 August 2019 with lower abdominal pain and tenderness making them reluctant to turn over.

113. An ascitic drain was inserted which then leaked. A was reluctant to have the drain inserted. The wound care, the way the leakage from the ascitic drain site was dealt with, was not adequate. The leak was described as a large amount over several days and there were significant complications of the ascitic drain which had been inserted by a junior doctor and which was not adequately managed for over two days. Leakage was not stopped adequately. The leaking site should have been stitched closed because of the high risk of infection which carries a high mortality risk.

114. It seemed that doctors treating A were not aware that patients with decompensated liver disease often do not display typical signs of sepsis because of the liver dysfunction and that infection is often the main cause of deterioration.

115. The gastroenterologists involved in A's care should have advised early with regards to the correct medication treatment. The budesonide steroid medication (which had previously been prescribed to A and referred to at complaint point (a) above) should have been stopped because of its contraindication.

116. The constipation (present on A's admission) should have been managed with stool charts and an increase in lactulose, thus aiming for frequent bowel motions to prevent hepatic encephalopathy (a loss of brain function as a result of failure in the removal of toxins from the blood due to liver damage).

117. A's fall on 8 August 2019 and their comment immediately afterwards that they wanted to sleep, were not considered as a sign of their deterioration with hepatic encephalopathy. This should have triggered a medical review.

118. During A's admission, the attempts of the doctors to identify the causes of A's deterioration were not given enough priority. The presence on A's admission with lower abdominal pain and tenderness making them reluctant to turn over, their reluctance to have an ascitic drain inserted, as well as their constipation should have led the team to concentrate on the abdomen / abdominal wall in searching for causes of A's deterioration. They considered that there was a lack of thorough daily examination to search for a cause of A's acute worsening clinical status. For example, they did not find evidence of a gastroenterology consultant examining A.

119. As A had decompensated cirrhosis, infection should have been strongly considered, aggressively searched for, and treated including with empirical/

prophylactic antibiotics in line with relevant guidance for patients with decompensated liver disease[3].

120. In the Adviser's view, the clinical team caring for A should have been much more proactive with regards to discussing A with the hepatology / liver transplant team.

121. From their review of the medical records, the assessment of A immediately before their transfer to the specialist Liver Unit was brief and centred around A's consciousness. There was no documentation showing that A was examined by doctors before their transfer to the specialist Liver Unit (as stated in the Board's SAER), and they were unable to say if there were any signs of necrotising fasciitis or wound infection on transfer.

122. Overall, there was a failure to appreciate the urgency of the need to make a diagnosis and ensure A was on the correct treatment plan despite the significant signs of deterioration and infection.

123. They, therefore, disagreed with the Board's view (as set out in paragraph 109 ii above) that the assessment and management of A's clinical deterioration during their admission was 'appropriate and reasonable' with involvement of specialist teams in gastroenterology, liver transplantation and intensive care. They considered this view was not justified by the evidence of failings they had identified. They were critical that these failures had not been identified during the SAER and that insufficient learning has been drawn from these.

124. They noted there was no apology given to A's family from the Board with regards to the failure to manage the leaking drain adequately, nor the inappropriate treatment with the steroid, budesonide.

Decision

125. I have carefully considered the advice I have received from the Adviser on this complaint. I accept this advice.

126. From the evidence provided it is clear to me that there were significant failings in A's care and treatment in UHW between 4 August 2019 and 8 August 2019.

127. The Adviser has told me the leakage from an ascitic drain was not dealt with adequately. There was a failure to effectively and timeously manage the leakage, the leaking site being high risk for infection and which carried a high mortality risk.

[3] BSG-BASL Decompensated Cirrhosis Care Bundle- First 24 hours

128. Further failings my investigation has identified include the management of A's steroid medication which was inappropriate and should have been stopped. There was also a failure to manage A's constipation. Furthermore, the fall that A suffered and their desire to sleep was a sign of a potentially more serious condition and should have triggered a medical review

129. I consider that A's deterioration was not given sufficient priority and there was a lack of urgency in making a diagnosis and ensuring A was provided the correct treatment despite the significant signs of deterioration and infection. The Adviser also considered that there had a failure to be more proactive in discussing A with the hepatology/ liver transplant team and, as in complaint point (a), there was a failure to follow relevant guidance. I accept this advice and consider there were serious and significant failings in the care provided to A over this period. I am extremely critical of this.

130. I recognise C's concerns about A developing necrotising fasciitis while in the UHW. The Adviser was unable to determine whether or not there were signs of necrotising fasciitis or wound infection at the point of transfer as the documentation was brief and centred on A's consciousness. Given this I am unable to confirm the position definitively. Although I note the Board's position that they have consulted with staff at the specialist Liver Unit who have confirmed there was no evidence A was suffering from this on arrival. Nevertheless, given it is stated in the SAER that A was examined prior to transfer I am critical that there is no documentation in the medical records relating to a physical examination.

131. Taking account of the evidence and the advice I have received, and in view of the failings identified, I uphold this point of the complaint. My recommendations for action are set out below.

(c) The Board failed to treat A with dignity on 4 August 2019 when transferring them from UHW's Emergency Department to UHW's Emergency Care Unit

Concerns raised by C

132. C complained there was a failure to treat A with dignity when they were being transferred from the ED to the ECU.

The Board's response

133. I do not intend to repeat the content of the Board's original responses to C's complaint, as all parties are aware of the content.

134. The main points of their response dated 6 March 2020 were that:

i. They were sorry that a nurse had shown no consideration for A's dignity or the pain they were suffering when getting them dressed to transfer from the ED to the ECU. They had reminded staff of the professional and caring manner they would expect from them at all times.

135. In response to my enquiries, the Board also said that:

i. With regard to C's concerns that there was a failure to treat A with dignity when being transferred to the ECU, this did not fall within the scope of the SAER.

ii. An apology for this failing was given in their complaint response of 6 March 2020. However, they were willing to reiterate their apologies for failing to maintain A's dignity when they were transferred from the ED to the ECU.

Medical Advice received

136. The Adviser was asked to review A's clinical records and the comments received from C and the Board.

137. The Adviser said that it is always difficult to determine the extent of dignity provided without being present in the situation. However, from the clinical notes, they could not see any entry indicating that attempts were made to treat A with dignity.

Decision

138. C has complained staff failed to treat A with dignity on 4 August 2019 when transferring them from ED to ECU.

139. It is important that patients (and staff) feel respected and are treated with dignity.

140. I appreciate this was a stressful and difficult time for A. I also recognise this has caused C concern.

141. I accept that it is difficult to determine the extent of how a patient has been treated without being present when the situation complained about occurred. I also accept that medical notes and entries by their very nature will not always convey the humanity in the way in which a patient was cared for and whether or not the patient was treated with dignity. I also recognise that when under pressure it can be challenging to document this detail in the time available.

142. Nevertheless it is clear the Board have acknowledged there was a failure to provide appropriate consideration for A's dignity and the pain they were suffering when getting them dressed to transfer from the ED to the ECU. Overall, I consider that, on balance, there was a failure to provide A with an appropriate level of dignity and person centred care and, I, therefore, uphold this point of complaint.

143. I acknowledge and welcome that the Board have apologised for this when responding to C's complaint, and I have asked for evidence of the action the Board say they have taken to address this as part of my recommendations.

Complaint handling/ SAER

144. Section 16 G of The Scottish Public Services Ombudsman Act 2002 requires me to monitor and promote best practice in relation to complaints handling.

145. Following receipt of C's complaint, the Board conducted a SAER. The findings of the SAER were relied upon when responding to C's complaint. As noted above, the purpose of the SAER is to investigate, identify learnings and develop system improvements to prevent similar incidents occurring. I also consider that complaints, handled well, provide similar opportunities for enduring learning and improvement. While it is appropriate to account the outcome of other investigations, like SAERs, when responding to complaints, the complaint investigation should be objective, evidence based, and balance the evidence. It is not apparent the extent to how this was done in this case.

146. As noted at paras 64 and 82 the Adviser considered the medical management of A went against clear medical guidelines. They considered the significance of this particularly during A's early presentation should have been picked up in more detail during the SAER process, including that there had been significant failures in A's management rather than that management could have been better and a referral could have been made earlier.

147. The Adviser also explained that under of a duty of candour, all of these failings should have been clearly explained to A's family. They considered the Board's comment that an earlier referral to the transplant unit 'might have made a difference' to A's outcome did not reflect the extent of the failings and that an earlier referral would have made a significant difference to A's outcome.

148. In the Adviser's view, the reviewing gastroenterologist (with more liver experience / interest than the clinical team who managed A) should have identified these failings in the course of carrying out the SAER.

149. I have carefully considered the Board's comments in relation to the SAER and their position that a reasonable SAER was conducted. I note that the scope of the SAER included diagnosis as well as subsequent management, and that the findings include that a referral to a specialist service could have been made earlier. However, I am of the view that the SAER did not adequately address and identify the failings in A's care and treatment that occurred from their initial presentation in 2018 through to the most recent care provided.

150. In view of this I consider that the complaints review process, including the SAER was not sufficiently thorough and needed to be improved.

151. The SAER should have identified and acknowledged that A's medical management did not follow clear medical guidelines and had been significantly wrong rather than that management could have been better and a referral could have been made earlier.

152. While I note the Board's comments in relation to duty of candour, I do not consider the Board's review of these events appropriately identified what went wrong and the extent of the failings that occurred. Nor do I consider there was the appropriate learning that I would expect to see when the duty of candour process is activated. I consider there has been a failure to meet the requirements of the duty of candour process.

153. By the time of C's complaint and the SAER it was too late to change the outcome for A but, at the very least, the Board should have ensured an appropriate and thorough review in response to C's complaint that fully identified all the appropriate learning and improvement required so that A's family could be assured that there would be lasting learning from the tragic circumstances of A's case. I have therefore made recommendations in relation to the Board's investigation of C's complaint and the SAER that was subsequently carried out.

Previous Public Report / Recommendation for external audit

154. In investigating this case and making my findings and recommendations it is of significant concern to me that that I issued an earlier critical public report into the gastroenterology service at UHW on 22 June 2022 (case reference 202001373). In that report I was critical of the care and treatment the patient received from the gastroenterology service for PBC and other clinical issues. In particular I found serious failings in identifying and treating the patient's deteriorating liver disease between 2017 and 2018. I am concerned that I have found similar failings over a similar timescale in this case.

155. In light of this, I am taking the unusual step of recommending that the Board arrange for an independent external audit of the treatment of patients by the gastroenterology outpatient service at UHW with PBC, AIH or an overlap syndrome, from 2018 to date to ensure there is no systemic or individual issue which may have affected other patients, and inform my office of the results. This recommendation and all my recommendations for action are set out below.

156. Finally, I extend my heartfelt sympathy to C and their family for their loss. I commend them for their fortitude in pursuing their complaint during what must have been, and still be, the most difficult of times. I hope that they can take some comfort from knowing their actions will benefit others.

Recommendations

Learning from complaints

The Ombudsman expects all organisations to learn from complaints and the findings from this report should be shared throughout the organisation. The learning should be shared with those responsible for the operational delivery of the service as well as the relevant internal and external decision-makers who make up the governance arrangements for the organisation, for example elected members, audit or quality assurance committee or clinical governance team.

What we are asking the Board to do for C

Rec number	What we found	What the organisation should do	What we need to see
1	Under complaint point a) I found that the there was a failure to investigate and/ or diagnose A's condition. In particular I found that: v. there was a failure to make an appropriate and timely diagnosis; vi. there was a failure to appropriately refer A to a specialist liver service/ transplant hepatologist at an early stage in their treatment; vii. there were significant and sustained failures in the consideration,	Apologise to C for the failings identified in this investigation and inform C of what and how actions will be taken to stop a future reoccurrence. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets.	A copy or record of the apology. By: 19 July 2024

Rec number	What we found	What the organisation should do	What we need to see
	management and treatment of A's deteriorating condition including a failure to take into account relevant guidance; and viii. there were failures in communication and to adequately take into account A's personal circumstances. Under complaint point (b) I found that the Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019. Specifically: iii. there were failures in the management of A's ascitic drain, steroid medication and constipation; and iv. there was a failure to trigger a medical review in light of A's fall and a failure to follow relevant guidelines in the management of patients with decompensated liver disease.		

Rec number	What we found	What the organisation should do	What we need to see
	I also found that there were failures in the Board's handling of C's complaint and the subsequent Significant Adverse Event Review.		

We are asking the Board to improve the way they do things

Rec number	What we found	Outcome needed	What we need to see
2	Under complaint point a) I found that the there was a failure to investigate and/ or diagnose A's condition. In particular I found that: v. there was a failure to make an appropriate and timely diagnosis; vi. there was a failure to appropriately refer A to a specialist liver service/ transplant hepatologist at an early stage in their treatment; vii. there were significant and sustained failures in the consideration,	Patients showing signs of advanced liver disease should receive appropriate and timely care and treatment that is in line with relevant guidance.	Evidence that the Board have arranged, as a matter of urgency, independent external audit of the treatment of patients by the gastroenterology outpatient service at UHW with PBC/ AIH or an overlap syndrome from 2018 to date to ensure there is no systemic or individual issue which may have affected other patients;

Rec number	What we found	Outcome needed	What we need to see
	management and treatment of A's deteriorating condition including a failure to take into account relevant guidance; and viii. there were failures in communication and to adequately take into account A's personal circumstances		The audit should be completed independently by individual(s) with the appropriate experience and expertise. My office should be provided with an update on the progress of the audit. My office and the complainant should be informed of the results of the audit including all learning points and any required action plan to implement and share findings. Evidence that the findings of my investigation have been shared with relevant staff in a supportive manner for reflection and learning.

Rec number	What we found	Outcome needed	What we need to see
			Evidence that learning from these events and the external audit is reflected in policy guidance and staff training. By: 19 March 2025 (with an update on progress to be provided by 19 December 2024)
3	Under complaint point b) I found that the Board failed to provide A with adequate care and treatment as a patient in University Hospital Wishaw between 4 August 2019 and 8 August 2019. Specifically there were failures in the management of A's ascitic drain, steroid medication, and constipation. We also found that the there was a failure to trigger a medical review in light of A's fall and a failure to follow relevant guidelines in the management of patients with decompensated liver disease.	Patients admitted to hospital showing signs of advanced liver disease should receive appropriate and timely care and treatment that is in line with relevant guidance	Evidence that: My findings have been shared with staff in a supportive way for reflection and learning and to ensure similar mistakes are not made again; and That the learning from these events and the external audit is reflected in policy/ guidance and staff training.

Rec number	What we found	Outcome needed	What we need to see
			By: 18 October 2024

We are asking the Board to improve their complaints handling:

Rec number	What we found	Outcome needed	What we need to see
5	I found that the Board's complaint handling was unreasonable. Specifically: iii. there was a failure to meet the requirements of the Duty of Candour process; and iv. a failure to undertake a reasonable Significant Adverse Event Review that identified key learning and improvements	When an incident occurs that falls within the Duty of Candour legislation, the Board's Duty of Candour processes should be activated without delay. Local and Significant adverse event reviews should be reflective and learning processes that ensure failings are identified and any appropriate learning and improvement taken forward. Adverse event reviews should be held in line with relevant guidance.	Evidence that the Board have reviewed their Duty of Candour processes, including timescales for activating the process and; Evidence that the Board have reviewed their process for carrying out adverse event reviews to ensure these reviews properly investigate, identify learnings and develop system improvements to prevent similar incidents occurring. By: 18 October 2024

We are asking the Board for evidence of action already taken

Rec number	What we found	Outcome needed	What we need to see
4	Under complaint point c) I found that there was a failure to provide A with an appropriate level of dignity and person centred care on 4 August 2019.	The Board said that they had had reminded staff of the professional and caring manner they would expect from them at all times.	Evidence of the action taken. By: 19 July 2024

Feedback for the Board

As noted at paragraph 81, A should have been referred to a tertiary liver service/ transplant hepatologist within a few weeks of presentation. The failure to do so raises the question in my mind as to whether there is a sufficiently open and transparent culture that encourages clinical staff at all levels to identify when they may require internal or external specialist support in treating complex cases and that enables them to request this. I urge the Board to consider how they can support clinicians to identify and raise when they may require internal or external specialist support when providing care and treatment.

This report will be as difficult for staff to read, as it no doubt is for the family. It is incumbent on the Board to ensure staff are supported and that it is clear to them that my findings reflect failures in systems that should have been there to support them.

Terms used in the report **Annex 1**

A	the aggrieved
ascites	the build-up of fluid in the abdomen
ascitic drain	a drain to remove fluid from a patient's abdomen
azathioprine	medicine used to treat inflammatory and autoimmune conditions
the Adviser	the consultant hepatologist and gastroenterologist who provided independent advice on this case
AIH	autoimmune hepatitis, a disease that harms the liver's ability to function
the Board	Lanarkshire NHS Board
bilirubin	a byproduct of red blood cell breakdown that helps make bile for digestion
budesonide	a steroid used to treat inflammation
C	the complaint
Decompensation	the clinical deterioration of a structure or system
ECU	Emergency Care Unit
ED	Emergency Department
ERI	Edinburgh Royal Infirmary
Gastroenterology	the branch of medicine focused on the digestive system and its disorders

hepatic encephalopathy	a loss of brain function as a result of failure in the removal of toxins from the blood due to liver damage
haemolysis	destruction of red blood cells
LFT	Liver Function Test
Magnetic Resonance Cholangiopancreatography	a medical imaging technique used to visualize the biliary and pancreatic ducts non-invasively.
necrotising fasciitis	a life-threatening soft-tissue infection
PBC	Primary Biliary Cirrhosis, a disease that harms the liver's ability to function
UHW	University Hospital Wishaw
UDCA	medication used in the management and treatment of liver disease
SAER	Severe Adverse Event Review, a national approach to learning from adverse events through reporting, review and the sharing of learning

List of guidelines considered Annex 2

The British Society of Gastroenterology - BASL Decompensated Cirrhosis Care Bundle – First 24 hours 2014

The British Society of Gastroenterology PBC primary biliary cholangitis treatment and management guidelines 2017 (the PBC guidelines)

Philip N Newsome et al. (2018): Guidelines on the management of abnormal liver blood tests. Gut 67(1):6-19.

American Association for the Study of Liver Diseases Diagnosis and Management of Autoimmune Hepatitis November 2010 (the AIH guidelines)

The 7 PBC guidelines service standard measures **Annex 3**

1. To exclude alternative aetiologies for cholestasis, all patients with suspected PBC should have an abdominal ultrasound as part of their baseline assessment (standard 90%).

2. All patients should be offered therapy with UDCA. UDCA at 13–15mg/ kg/ day is recommended for first-line use in all patients with PBC (standard 90% of patients receiving therapy at adequate dose or documented to be intolerant).

3. To facilitate the identification of patients at risk of progressive disease, individualised risk stratification using biochemical response indices is recommended following 1 year of UDCA therapy (standard 80% of patients receiving UDCA therapy to have their response status recorded in the notes and the criteria used recorded).

4. To highlight the impact on QoL and to ensure appropriate investigation and treatment, all patients should be evaluated for the presence of symptoms, particularly fatigue and itch (standard 90% of patients have the presence/ absence of fatigue and pruritus recorded in the notes in the last year).

5. To maximise the opportunity for all patients to be considered in a timely way for liver transplantation, all patients with a bilirubin >50 μmol/ L or evidence of decompensated liver disease should be discussed with a hepatologist linked to a transplant programme (standard 90% documentation that discussion has taken place within 3 months of the bilirubin exceeding 50 μmol/ L and the actions taken recorded).

6. To optimise prevention of osteoporotic bone fractures, all patients with PBC should have a risk assessment for osteoporosis. Treatment and follow-up should be according to national guidelines (standard 80% assessment within the last 5 years).

7. To ensure timely but considered diagnosis and treatment, overlap with AIH should be recognised as rare and, when suspected, liver biopsy with expert clinicopathological assessment is recommended to make the diagnosis (standard 90% of patients in whom the diagnosis of overlap is made having had liver biopsy confirmation and the clinicopathological assessment discussion noted).