



Northern Ireland

Public Services
Ombudsman

Investigation Report

Investigation of a complaint against the Northern Health and Social Care Trust

NIPSO Reference: 17783

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The Role of the Ombudsman

The Northern Ireland Public Services Ombudsman (NIPSO) provides a free, independent and impartial service for investigating complaints about public service providers in Northern Ireland.

The role of the Ombudsman is set out in the Public Services Ombudsman Act (Northern Ireland) 2016 (the 2016 Act). The Ombudsman can normally only accept a complaint after the complaints process of the public service provider has been exhausted.

The Ombudsman may investigate complaints about maladministration on the part of listed authorities. She may also investigate and report on the merits of a decision taken by health and social care bodies, general health care providers and independent providers of health and social care. The purpose of an investigation is to ascertain if the matters alleged in the complaint properly warrant investigation and are in substance true.

Maladministration is not defined in the legislation, but is generally taken to include decisions made following improper consideration, action or inaction; delay; failure to follow procedures or the law; misleading or inaccurate statements; bias; or inadequate record keeping.

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

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

Reporting in the Public Interest

This report is published pursuant to section 44 of the 2016 Act which allows the Ombudsman to publish an investigation report when it is in the public interest to do so.

The Ombudsman has taken into account the interests of the person aggrieved and other persons prior to publishing this report.

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Appendix 1 – The Principles of Good Administration

EXECUTIVE SUMMARY

I received a complaint about the actions of the Northern Health and Social Care Trust in relation to the treatment and care of the complainant's late wife following admittance to the Causeway Hospital, Coleraine, on 31 August 2015. The patient was diagnosed with decompensated fatty liver disease. Unfortunately her condition deteriorated and she died on 26 September 2015.

Issues of Complaint

I accepted the following issues of complaint for investigation:

- i. The clinical care and treatment received by the patient. This issue has been dealt with in a number of respects:
 - a. Paracentesis – the use of this technique to draw a sample of fluid from the patient's abdomen.
 - b. The use of antibiotics
 - c. Consent for treatment
 - d. The nutrition and hydration provided to the patient
- ii. The extent of any learning derived by the Trust as a result of this complaint.

Findings and Conclusion

The investigation of the complaint identified failures in the care and treatment provided to the patient in respect of the following matters:

- I. Delay in carrying out paracentesis
- II. Failure to attempt further paracentesis following the failed attempt on 11 September 2015
- III. Failure to commence the use of antibiotics prior to 12 September 2015 and delay in seeking microbiological advice
- IV. A delay of 11 days before the patient was reviewed by a Dietitian on 10 September 2015
- V. A failure to be proactive and to promote 'aggressive nutritional therapy rich in

calories and proteins'

- VI. A failure to commence or consider nasogastric feeding of the patient
- VII. The imposition of a fluid restriction represents a failure in the care and treatment provided to the patient with regard to hydration
- VIII. A failure to communicate with the family regarding the paracentesis procedure.

I am satisfied that the failures in care and treatment which I have identified caused the complainant to experience the injustice of upset, frustration and the injustice of the loss of opportunity for him and his family to participate in the decision regarding paracentesis.

Recommendations

I recommended:

- An apology from the Chief Executive of the Trust and from each of the clinicians involved to the complainant for the failures in care and treatment and maladministration which this report has identified.
- A payment to the complainant and his three daughters of £10,000, in solatium, for the injustice referred to above.
- I note that the Trust has conducted an audit with regard to paracentesis and the evaluation of patients with ascites to demonstrate compliance with guidelines. I recommend that the Trust carry out a similar audit with regard to numbers of patients with decompensated liver disease screened for malnutrition with evidence of appropriate intervention and a similar audit with regard to hydration to provide evidence of learning with regard to inadequacies of nutrition and hydration from the independent report and the CH IPA. The Trust should complete this audit within a period of 6 months of the date of my final report and provide my office with evidence that this has occurred.

I am pleased to report that the Trust has accepted my findings and conclusions

THE COMPLAINT

1. The complaint concerns the treatment and care the complainant's late wife (the patient) received following admittance to the Causeway Hospital, Coleraine, on 31 August 2015. The patient was diagnosed with decompensated fatty liver disease. Unfortunately her condition deteriorated and she died on 26 September 2015. The complainant and his family have significant concerns regarding the care and treatment she received while in the hospital.

2. As part of the Trust's complaints process, the Trust engaged an independent review of the care the patient received. A consultant hepatologist and gastroenterologist from the Belfast Trust reported in March 2016 and found a number of faults in the clinical care provided by the Trust. I have considered this report as part of my investigation and note that my findings of failures by the Trust are similar to those found by the report's author. The complainant however requested that I investigate the issues and give further independent consideration to the care and treatment his wife received. The Trust stated that lessons had been learned from the report.

Issues of complaint

3. Following a review of the documentation and information available, the following issues were accepted for investigation.

Clinical care – there are a number of aspects to this element of the complaint:

- (i) **Paracentesis** – The complainant contends that this technique, (to draw a sample of fluid from the patient's abdomen) ought to have been completed sooner. He was particularly concerned with the comment in the report that 'It is possible that the delay in seeking a sample of fluid and subsequent treatment with antibiotics made a material difference in the outcome.'
- (ii) **Use of antibiotics** – The complainant stated that antibiotics were not administered to his wife until 11 September 2015. He complained that the antibiotics she received then were generic and not specifically targeted for her

infection. He contends that a delay in giving antibiotics from 2 September 2015 until 11 September 2015 and the type prescribed was to his wife's detriment and led to a weakened state which made her ultimate death more likely.

- (iii) **Consent for paracentesis** – He complained that consent was not sought from his wife or the family for the paracentesis procedure.
- (iv) **Nutrition and Hydration** – He complained that the lack of nutrients and poor hydration (and indeed a fluid restriction) over an extended period of time would have weakened his wife's condition and would have had a detrimental effect on her chances of survival.
- (v) **Lessons learnt** – As a result of the report commissioned by the Trust and the complaints process, the Trust has informed the complainant that lessons have been learned and that processes have been improved. Neither the complainant nor his family have confidence in this statement.

INVESTIGATION METHODOLOGY

In order to investigate the complaint, the Investigating Officer obtained from the Trust all relevant documentation together with the Trust's comments on the issues raised. The Investigating Officer met with the complainant, his daughters and a representative from the Patient and Client Council on the circumstances of their complaint. I have shared a copy of this draft report with the Trust, the doctor involved in the patient's care, and with the complainant for the purposes of comment on the factual accuracy and the reasonableness of the conclusions.

Independent Professional Advice

5. After further consideration of the issues, I obtained independent professional advice from an independent professional advisor, a Consultant Hepatologist (CH IPA).

7. The information and advice which have informed my findings and conclusions are included within the body of my report. The IPA has provided me with 'advice'.

However, how I have weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards

8. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those which are specific to the circumstances of the case.

9. The general standards are the Ombudsman's Principles¹:

- The Principles of Good Administration
- The Principles of Good Complaints Handling
- The Public Services Ombudsmen Principles for Remedy

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

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

THE INVESTIGATION

Issue 1 – The clinical care and treatment provided to the patient

(i) Paracentesis

13. The complainant contends that this technique, (to draw a sample of fluid from the patient's abdomen) should have been completed at an early date in her admittance.

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

He is also of the opinion that paracentesis should have been attempted under ultra sound guidance but that this was not done as the hospital did not have an interventional radiologist. The complainant states that his wife should have been transferred to Belfast to have this procedure done if it could not be done in the Causeway Hospital. The complainant is particularly concerned with the comment in the report commissioned by the Trust that ‘It is possible that the delay in seeking a sample of fluid and subsequent treatment with antibiotics made a material difference in the outcome’

14. The CH IPA advised that the European Association for the Study of the Liver (EASL) guidelines for ascites² from 2010 states ‘*A diagnostic paracentesis with an appropriate ascitic fluid analysis is essential in all patients investigated for ascites prior to any therapy to exclude causes of ascites other than cirrhosis and rule out spontaneous bacterial peritonitis (SBP) in cirrhosis*’. These guidelines are followed by most liver and gastroenterology units.

15. The severity of ascites and subsequent management are outlined in the EASL guidelines from 2010 and are shown below.

Grade of ascites	Definition	Treatment
Grade 1 ascites	Mild ascites only detectable by ultrasound	No treatment
Grade 2 ascites	Moderate ascites evident by moderate symmetrical distension of abdomen	Restriction of sodium intake and diuretics
Grade 3 ascites	Large or gross ascites with marked abdominal distension	Large-volume paracentesis followed by restriction of sodium intake and diuretics (unless patients have refractory ascites)

² Excess fluid in the peritoneal cavity, the space between the 2 layered membrane that lines the inside of the abdominal wall and which covers the abdominal organs

16. The British Society of Gastroenterology (BSG) and British Association for the Study of Liver disease (BASL) developed a 'care bundle' for patients admitted with decompensated cirrhosis to ensure that effective evidence-based treatments are delivered within the first 24 hours of admission to hospital. This care bundle provides a simple checklist of key investigations, and clear guidance on the management of cirrhosis-related complications, such as spontaneous bacterial peritonitis (SBP), variceal bleeding and acute kidney injury. The bundle is designed to help junior doctors and non-specialists provide effective care for these patients, who frequently have complex medical needs, in the first 24 hours, when specialist advice may not be available.

17. Based on EASL guidelines, the care bundle states: *'It is, therefore, recommended that all patients presenting with ascites have a diagnostic ascitic tap to exclude SBP on admission to hospital, or if there is deterioration in their clinical status. Diagnosis of SBP is made when the absolute number of PMN cells is >250/mm³ of ascitic fluid. Upon diagnosis, SBP should be empirically treated with broad spectrum antibiotics, such as third-generation cephalosporin (cefotaxime or ceftriaxone), co-amoxiclav or ciprofloxacin, according to hospital policy, with modifications made in light of subsequent culture results. Patients with SBP are at high risk of developing hepatorenal syndrome (HRS) and should have intravenous albumin administered to prevent worsening of renal function.'*

18. The CH IPA advised that data from a recent study (Orman ES, Hayashi PH, Bataller R) states that performing a paracentesis at the time of hospital admission in patients with cirrhosis and ascites may decrease mortality rates. This database study of 17,711 patients with cirrhosis and ascites demonstrated that patients who underwent paracentesis had significantly lower in-hospital mortality rates than those who did not (6.5 versus 8.5 percent, adjusted odds ratio 0.55, 95% CI 0.41-0.74).

19. I refer to the following entries in the patient's clinical notes relevant to this issue:

1 September 2015 – 'US (ultra sound) abdomen requested'

- 2 September 2015** – ‘US abdo ...free fluid throughout abdo and pelvis’.
- 4 September 2015** – ‘Ascites on US’
- 5 September 2015** – Daily evaluation of nursing care - ? ascetic tap IV abx – no obvious source of infection.’
- 6 September 2015** – ‘Oedema³ up to abdomen’
- 8 September 2015** – again noted ‘USS mobile gallstones + free fluid in abdomen + pelvis’
- 9 September 2015** – ‘Abdominal ascites’ ‘Ascites oedema up to abd’
- 11 September 2015** – ‘diagnostic tap to exclude SBP’
‘attempted diagnostic tapaspiration attempted @ various angles with blue and green needles without success.....tap under US guidance on Monday’
- 12 September 2015** – Failed diagnostic tap yesterday, commenced on I/V tacozin to cover SBP’

20. The CH IPA explained that abdominal paracentesis is a simple bedside procedure in which a needle is inserted into the peritoneal cavity (within the abdomen) and the fluid within the cavity, known as ascites, is removed. Diagnostic paracentesis refers to the removal of a small quantity of fluid for testing. Therapeutic paracentesis refers to the removal of five litres or more of fluid to reduce intra-abdominal pressure and therefore relieve symptoms of breathlessness and abdominal pain. An ascitic tap is not usually attempted when there is a trace of ascites (grade 1).

21. The IPA advised that in the patient’s case, when an ultrasound was performed on 2 September 2015, free fluid in the abdomen and pelvis was demonstrated and documented in the notes. In addition, there is a reference on 2 September 2015 regarding the continued use of spironolactone⁴. Both these two entries suggested to the CH IPA that there was significant (grade 2) ascites. The CH IPA advised that according to the EASL & BSG guidelines together with study data, a diagnostic paracentesis should have been performed by 2 September 2015 on the patient when

³ Abnormal fluid accumulation in body tissues

⁴ Spironolactone, is a medication that is primarily used to treat fluid build-up due to heart failure, liver scarring, or kidney disease.

ascites was confirmed by ultrasound and that at a very minimum pre-marking of a suitable site with ultrasound should have been requested following a failed 'blind' diagnostic paracentesis.

22. In response to investigation enquiries, the Trust stated that the patient was admitted on 31 August 2015. An ultrasound scan was undertaken on 2 September 2015 which confirmed the presence of ascites. The patient's radiology report did not quantify the volume of ascites. A doctor considered undertaking a diagnostic ascitic tap soon after the scan was completed. However, it was his clinical judgment that there was insufficient fluid to be drained from the peritoneal cavity, which was later confirmed by the radiologist.

23. The Trust stated that between the ultrasound scan on 2 September 2015 and the attempted diagnostic paracentesis on 11 September 2015, there were a number of clinical notes recording the presence of ascites, detected by examination at the bedside, particularly from 8 September 2015 onward. In conjunction with deteriorating liver function tests and rising white cell counts the overall clinical picture suggested further liver decomposition and raised the possibility of infected ascites. A second doctor therefore attempted a diagnostic tap to attempt to confirm this diagnosis prior to commencing antibiotics. The attempt at fluid aspiration was unsuccessful, in most part due to the patient's habitus and therefore the doctor considered that it was the correct course of action to proceed with broad spectrum antibiotic therapy rather than delay further awaiting a radiologically guided aspiration. When the patient was reviewed on 16 September 2015, she had already commenced on antibiotics and a further attempt for ascitic tap would not have resulted in any greater clinical benefit.

24. A copy of the CH IPA advice was shared with the Trust. In relation to this element of the complaint the Trust commented on the independent advisors statement that in cases where no fluid is obtained by blind paracentesis, either because there is only a small volume of fluid or due to difficult body habitus such as obesity, either ultrasound guided or real time ultrasound drainage should be performed. The Trust stated that *'the patient was morbidly obese and that an ultrasound scan highlighted there was insufficient fluid to attempt a further paracentesis. It was [the doctor's] opinion at the*

time that a diagnostic tap even if carried out under marking would not have been effective. Therefore [he] requested an interventional radiologist to carry out the procedure. The Trust confirmed also that there has been a recent clinical audit undertaken into the practice of paracentesis, covering the test period May to October 2017. This highlights practice in Causeway Hospital which is now in line with BSG guidelines. A copy of this clinical audit was provided by the Trust.

Analysis and Findings

25. The patient attended the Emergency Department of Causeway Hospital on 31 August 2015. She presented with recent jaundice and an 'angry' rash on her right shin. The patient stated that she had felt unwell for over a month and had felt weak and off her food. The patient was admitted to hospital and her clinical notes recorded that she had previously had a CT scan in 2008 showing a 'fatty liver'. A preliminary diagnosis of decompensated liver disease was made and she was assessed using the Childs Pugh score. This is an assessment tool to evaluate the prognosis of chronic liver disease using five clinical measurements. The patient was assessed as having a Childs Pugh score of C, which is the highest measurement on the scale and indicates a high level of mortality within one year. The CH IPA used other scoring systems to assess her prognosis. He advised that at this time she had a UKELD score of 61 (19% 3 month mortality) and MELD Na score of 26 (25% mortality at 3 months). Using the CLIFc AD score, which is best for predicting hospital mortality, the CH IPA advised that the patient was indicative of a 23% mortality at 1 month and 51% mortality at 3 months.

26. After admittance, an ultrasound scan of the patient's abdomen was requested on 1 September 2015 and the results received on 2 September 2015. The report on the scan stated '*Indication liver failure. Findings suboptimal examination due to the patient's size. The gallbladder contains mobile gallstones...There is free fluid throughout the abdomen and pelvis...Conclusion gallstones. Ascites*'. The presence of ascites was then noted in the clinical record over the next seven days, up to 9 September 2015.

27. The CH IPA has advised that his examination of the ultrasound results and the continued use of spironolactone suggest the presence of significant (grade 2) ascites

28. The CH IPA has advised that EASL guidelines for ascites in 2010 states '*A diagnostic paracentesis with an appropriate ascitic fluid analysis is essential in all patients investigated for ascites prior to any therapy to exclude causes of ascites other than cirrhosis and rule out spontaneous bacterial peritonitis (SBP⁵) in cirrhosis*'. He also advised that a care bundle based on EASL guidelines states '*It is, therefore, recommended that all patients presenting with ascites have a diagnostic ascitic tap to exclude SBP on admission to hospital, or if there is deterioration in their clinical status*'.

29. I note that a diagnostic tap/paracentesis was unsuccessfully attempted on 11 September 2015. The clinical record states that it was attempted using various sized needles and from different angles but that a sample of the fluid was not obtained. The Trust has attributed this failure to obtain a sample of fluid to the patient's obesity and an opinion that there was insufficient fluid present. I also note that a 'tap' under ultrasound guidance was planned for the following Monday but that this was not ultimately attempted as by this stage the patient had been started on an antibiotic.

30. In examining this aspect of the complaint, I consider that there was a failure in the care and treatment received by the patient in two respects. Based on the advice of the CH IPA and an examination of the clinical record, I consider that there was a delay in attempting to obtain a sample of ascetic fluid by means of paracentesis following admission until 11 September 2015. Once this attempt had proved to be unsuccessful, I further consider that there was then a failure to attempt to obtain a sample by other means. I shall consider each of these issues in turn.

31. When the patient was admitted to hospital on 31 August 2015, she was severely ill from liver disease as evidenced by her jaundice and the high scoring she received on the Childs Pugh measurement scale and by other scoring systems referenced by

⁵ Spontaneous bacterial peritonitis (SBP) is the development of a bacterial infection in the peritoneum, despite the absence of an obvious source for the infection. It is specifically an infection of the ascitic fluid – an increased volume of peritoneal fluid.

the CH IPA. By 2 September 2015, the presence of ascites had been detected following an ultrasound scan and its presence was further noted over the following number of days. The Trust has stated its view that the amount of ascites present was insufficient to obtain a sample and of the difficulty caused by the patient's size. The CH IPA has suggested, based on his examination of the documentation that there was significant ascites (grade 2) present. Irrespective of the amount of ascites present, the EASL guidelines for ascites in 2010 are clear. '*A diagnostic paracentesis with an appropriate ascitic fluid analysis is essential (my emphasis) in all patients investigated for ascites prior to any therapy to exclude causes of ascites other than cirrhosis and rule out spontaneous bacterial peritonitis (SBP).*

32. The CH IPA explained the reason behind the importance of obtaining a diagnostic sample of ascetic fluid of patients with decompensated liver disease as the fact that bacterial infections are common in such patients and that these infections can cause life threatening complications. Therefore, careful assessment for infection is important, as is prompt treatment with antibiotics. The CH IPA explained that it is recognised that the progression of infections can lead to multiple organ failure and is associated with a short-term mortality. Infections are recognised as a major trigger of systemic inflammation and organ failure in advanced cirrhosis leading to a four-fold increased mortality. The CH IPA also advised that the increasing prevalence of multiresistant bacteria underlines the importance of obtaining samples for microbiological culture and sensitivity to guide antibiotic therapy. (I consider the use of antibiotics at a later stage of this report) I was advised that early recognition and accurate diagnosis of sepsis are key factors to improve outcome.

33. The care bundle, based on EASL guidelines quoted at paragraph 17 was developed for patients admitted with decompensated liver disease to ensure that effective evidence based treatments are delivered within the first 24 hours of admission to hospital. In this case it was strongly suspected that the patient had liver disease upon admittance to hospital and that ascites was present yet paracentesis was not attempted until 12 days later. I accept the advice of the IPA that a diagnostic paracentesis should have been attempted by 2 September 2015 when ascites was confirmed by ultrasound. I consider that the delay in attempting to carrying out this

procedure represents a failure in the care and treatment provided to the patient. I consider this delay to have caused her the injustice of not having a timely assessment of her condition in line with the guidelines in place at the time. I consider it to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

34. There had been an unsuccessful attempt to perform diagnostic paracentesis on 11 September 2015. I accept the difficulty which may have presented itself due to the patient's obesity. Therefore, the issue became the action which ought to have followed this failed 'blind' attempt. The complainant has complained that he was informed that paracentesis should have been attempted under ultra sound guidance, however, this could not be undertaken because Causeway Hospital did not have an interventional radiologist. The Trust has stated that when a Doctor reviewed the patient on 16 September 2015, by that stage she had already commenced on antibiotics and a further attempt at paracentesis would not have resulted in any greater clinical benefit.

35. The CH IPA has advised that ultrasound guided paracentesis can be performed by pre-marking an ideal site for paracentesis. This method does not require an interventional radiologist; the pre-marking can be done by a sonographer. Another method of carrying out paracentesis is that it is undertaken while performing ultrasound – the latter called 'real time ultrasound'. It is the latter method which would be generally performed by an interventional radiologist. The CH IPA advised that if the patient has a large volume of ascites and the operator is experienced in performing paracentesis then there is probably no advantage in 'blind' versus ultrasound guided paracentesis. However, in cases where no fluid is obtained by blind paracentesis either because there is only a small volume of fluid or due to difficult body habitus such as obesity either ultrasound guided or real time ultrasound drainage should be performed.

36. The CH IPA advised that in this case the complainant's understanding was that the lack of an interventional radiologist was the stated mitigation for not performing an ultrasound guided paracentesis. However the CH IPA advised that pre-marking a suitable site for paracentesis is possible without an interventional radiologist and this

should have been attempted in this case. In general, diagnostic paracentesis is not performed by an interventional radiologist. However, when fluid cannot be obtained either by 'blind' paracentesis or by pre-marking with ultrasound guided then an interventional radiologist may be required to perform real time ultrasound and paracentesis. In the patient's case, the IPA's advice is that at a very minimum pre-marking of a suitable site with ultrasound should have been requested following a failed 'blind' diagnostic paracentesis.

37. I accept the advice of the CH IPA that, following the failed attempt at diagnostic paracentesis, on 11 September 2015, further efforts to obtain a sample of ascetic fluid should have been made. I note that the Trust considered this option as evidenced by the clinical note of 11 September 2015 '*Tap under US guidance on Monday.*' However I note also that no further attempt was subsequently made. I accept that after this date the patient's condition continued to deteriorate in that her liver function was failing and she had experienced hepatic encephalopathy⁶. I accept the IPA advice that '*at a very minimum pre-marking of a suitable site with ultrasound should have been requested*'. If a further attempt had been requested and proved to be unsuccessful, then further consideration ought to have been given to an attempt to obtain a sample with the assistance of an interventional radiologist either at Causeway or elsewhere. However I note that neither of these methods were attempted by the Trust. I conclude that the initial delay in attempting paracentesis represents a significant failure in the care and treatment afforded to the patient. I also consider the failure to attempt further paracentesis to represent an additional significant failure in the care and treatment provided to the patient. These failings caused her the injustice of loss of opportunity to have her condition fully assessed. I am also satisfied that these failures caused the complainant and his family injustice by way of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

38. I shall consider the consequences of this finding at the conclusion of this report.

(ii) Use of antibiotics

⁶Hepatic encephalopathy (HE) is an altered level of consciousness as a result of liver failure.

39. The complainant has complained that antibiotics were not administered to his wife until 11 September 2015. He complained that when administered these were generic antibiotics and not specifically targeted for the patient's infection which would have been the case if fluid had been obtained by paracentesis and a culture grown. The complainant contends that a delay in giving antibiotics from 2 September 2015 until 11 September 2015 and the type prescribed weakened his wife and made her ultimate death more likely.

40. I refer to the following summary of entries in the patient's clinical records:

31 August 2015 -Emergency Department Clinical record – 'Noted jaundice today – denies abdo pain – no nausea – feels weak and off food since April. Angry rash to right shin now worse.'

2 September 2015 – 'US abdo ...free fluid throughout abdo and pelvis'.

4 September 2015 – 'Ascites on US'

5 September 2015 – Daily evaluation of nursing care - ? ascetic tap IV abx – no obvious source of infection.'

9 September 2015 - 'Bilateral oedema abdominal ascites'

11 September 2015 – 'diagnostic tap to exclude SBP. T/D Tazocin if tap WCC/neut '

11 September 2015 – 'Attempted Diagnostic Tap.....Aspiration attempted @various angles with blue and green needles with no success...C/o Tazocin for SBP cover empirically. ?Tap under US guidance on Monday.'

12 September 2015 - 'failed diagnostic tap yesterday, commenced on Tazocin to cover SBP'

14 September 2014 – 'Discussed with husband and 2 daughtersabx (antibiotics) already started for SBPmod volume of ascites – tap would not be of benefit...'

19 September 2015 – 'day ? iv tazocin. No improvement in inflame markers'

41. In response to investigation queries, the Trust stated that the patient had an ultrasound scan on 2 September 2015. This confirmed the presence of ascites. A doctor considered taking a diagnostic tap soon after the scan was completed. However, in his professional judgement, there was insufficient fluid to be drained from the peritoneal cavity. A number of clinical notes in the days following the scan recorded

the presence of ascites detected at the bedside. Together with deteriorating liver function tests and rising white cell counts, the overall clinical picture suggested further liver decompensation and raised the possibility of infected ascites (SBP). A diagnostic tap was therefore attempted on 11 September 2015 which was unsuccessful. A doctor then considered that the correct course of action was to proceed with broad spectrum antibiotic therapy rather than delay further awaiting radiologically guided aspiration. When the patient was reviewed on 16 September 2015 she was already commenced on antibiotics and a further attempt at an ascetic tap would not have resulted in any greater benefit.

42. The CH IPA, having examined the patient's medical records, advised that three possible sources of sepsis had been identified by 3 September 2015. Firstly, the clinical notes on presentation in the emergency department comment on a red rash on the patient's right leg which could be indicative of cellulitis.⁷ Secondly, a potential source of infection was confirmed on 2 September 2015, namely ascites. Finally, at presentation, the patient's urine analysis was positive for nitrates suggestive of a urine infection, this subsequently confirmed as E coli producing ESBL on 3 September 2015, a third potential source of infection. However the CH IPA has noted that treatment of sepsis was only contemplated on 11 September 2015, in the context of worsening liver failure; a persistently elevated CRP⁸ and white cell count together with progressive acute kidney injury. The source of infection at this time was thought to be in the patient's ascites, possibly due to SBP.

43. The CH IPA advised that a diagnostic paracentesis ought to have been attempted on 2 September 2015 followed by the instigation of a broad-spectrum antibiotic as per the BSG care bundle and the EASL 2010 guidelines. If cellulitis of the leg or infection of the urinary tract were thought to be the source of infection, then appropriate antibiotics after microbiological advice should have been instigated by 3 September 2015. The IPA noted that treatment for urinary bacteria producing ESBL was not commenced on the high dependency unit until 20 September 2015.

⁷ Cellulitis is a bacterial infection involving the inner layers of the skin. It specifically affects the dermis and subcutaneous fat.

⁸ C-reactive protein (CRP) is a protein in blood plasma, whose levels rise in response to inflammation

44. The CH IPA advised that in about 60% of cases with SBP no organism is grown (culture negative) from fluid culture, despite an elevated white cell count in the ascitic fluid, which is the major diagnostic criterion of SBP. In general, tazocin would be an appropriate antibiotic for SBP, since gram negative bacteria are a common cause. Although EASL guidelines stipulate the use of a third-generation cephalosporin, co-amoxiclav or ciprofloxacin as the ideal antibiotics, the actual antibiotic used will be dependant of local microbiology policy. This policy is determined by the local resistant profiles of bacteria.

45. However the CH IPA advised that in the patient's case the diagnosis of SBP, although a possibility was never confirmed. Since two alternative sources of infection had been identified and since tazocin would be ineffective against E Coli ESBL, best practice would be to seek microbiological advice. He advised that possibly the use of ciprofloxacin (effective against ESBL and non-harmful to kidney function) may have been more appropriate in this situation.

46. The CH IPA advised that he agreed with the conclusion of the independent report on the patient's treatment that the delay in obtaining a sample of ascitic fluid and more importantly the timing of instigation of antibiotics possibly made a material difference to the patient's ultimate outcome. This opinion is on the basis of EASL, BSG and BASL guidelines together with clinical study data. The CH IPA advised that the type of antibiotic initially used is less significant however, the choice, in this instance, may have been flawed for the reasons outlined. Overall the CH IPA advised that the delay in instigation of appropriate antibiotic treatment may have contributed to the patient's death. However the CH IPA also advised that it should be noted that the patient's prognosis was poor at presentation, but optimal treatment of sepsis may have improved her chances of survival.

47. In response to receipt of the IPA advice the Trust stated that upon reflection and given the absence of a confirmed diagnosis of SBP, it accepts that it may have been helpful to seek microbiology advice.

Analysis and Findings

48. As referenced in preceding paragraphs, the patient was severely ill with

decompensated liver disease when admitted to Causeway Hospital on 31 August 2015. By 3 September 2015, three possible sources of infection and potential sepsis⁹ had been identified. A rash on her right leg, ascites and a urine infection. The CH IPA has explained the importance of careful assessment for infection in patients with decompensated liver disease and how prompt treatment with antibiotics can lead to improved prognosis. His advice that infections are recognised as a major trigger of systemic inflammation and organ failure in advanced cirrhosis and can lead to a fourfold increase in mortality is particularly stark. It is for this reason that early recognition and accurate diagnosis of sepsis are key factors to improve outcome.

49. I found a failure in the care and treatment received by the patient relating to paracentesis. I accept the advice of the CH IPA that in addition to the delay in attempting paracentesis from 2 September 2015, there was also a delay in instigating broad spectrum antibiotic treatment from 3 September 2015 until 12 September 2015. This ought to have been commenced at the earliest possible date with appropriate microbiological advice being sought to identify the most effective antibiotic to use. I note that the antibiotic tazocin, was not prescribed to the patient until 12 September 2015, 13 days after admission. This was despite the three potential sources of infection having been identified early in the admission and on a background of worsening liver failure, a persistently elevated CRP and white cell count together with progressive acute kidney injury. I consider this excessive delay in instigating the use of antibiotics to constitute a failure in the care and treatment received by the patient.

50. I consider this failure to commence the use of antibiotics at an earlier stage in the care and treatment of the patient to have caused her the injustice of loss of opportunity in not having her condition adequately assessed and treated at an earlier time. I consider it to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

51. The antibiotic, tazocin was used from 12 September 2015 until a change on 20

⁹ Sepsis is a life-threatening condition that arises when the body's response to infection causes injury to its own tissues and organs.

September 2015 when the type of antibiotic was changed to metronidazole and levofloxacin. This was following a microbiological review and it being noted on 19 September 2015 in the clinical record that after a number of days of tazocin there had been no improvement in the inflammatory markers. The CH IPA has advised that in general tazocin would be an appropriate antibiotic for SBP, however he noted that in this case a diagnosis of SBP, while a distinct possibility, had never been positively diagnosed. As two alternative sources of infection had been identified by 3 September 2015, and tazocin may have been ineffective against one of them, the CH IPA advised that best practice would have been to seek microbiological advice to avoid the possibility of a flawed choice of antibiotic. I agree with this advice and consider that, in conjunction with a delay in the use of antibiotics, there was a delay in seeking microbiological advice as to the specific type of antibiotic which would be most effective for the patient's condition. I consider that this ought to have been sought at an earlier date than 20 September 2015. I consider this excessive delay to constitute an additional failure in the care and treatment received by the patient. I consider this failure to have caused her the injustice of the loss of opportunity to have her condition properly assessed and treated at an earlier time. I consider it to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

52. I address the consequences of this finding at the conclusion of this report.

(iii) Consent for paracentesis.

53. The complainant complains that consent was not sought from his wife or the family for the paracentesis procedure. He complains that this was a failing and that if his consent had been sought, he would have refused to permit this intervention if it was to be carried out without ultra sound guidance. He complains that the opportunity to participate in this decision making was denied by the Trust.

54. I refer to the patient's clinical records as follows

7 September 2015 – (04.00) Daily Evaluation of Nursing Care – ‘remains confused

and vague...Ammonia level back (?) 165.'

(18.25) comfortable evening, no evidence of confusion noted.'

8 September 2015 – (4.20) no anxieties expressed at time of report.

Clinical Notes (10.35) – 'periods of encephalopathy over weekend'

9 September 2015 - Clinical Notes – '...encephalopathy improving, feels ok'

11 September 2015 - Daily Evaluation of Nursing Care – (15.30) 'I spoke to [the patient's] daughters who were concerned regarding her confusion. I then spoke to [the patient] and she was able to tell me where she was and what the date and the month was. Dr [...] and Dr [...] both spoke to [the patient's] daughters regarding same.'

11 September 2015 – Clinical Notes – '...grade 1 encephalopathy'

'Patient informed of plan for tap.....diagnostic tap to exclude SBP. T/D Tazocin if tap WCC/neut '

11 September 2015 – Daily Evaluation of Nursing Care - (19.30) 'Dr [...] attempted diagnostic tap with no success'

Clinical Notes – 'Attempted Diagnostic Tap.....Aspiration attempted @various angles with blue and green needles with no success...C/o Tazocin for SBP cover empirically. ?Tap under US guidance on Monday.'

12 September 2015 –Daily Evaluation of Nursing Care – (10.15) [Patient] remains quite confused this morning. Uncoordinated and non-compliant with instructions. '

(17.00) Clinical notes – 'Spoke with daughter, explained ongoing deterioration + prognosis not good at present.'

(22.30) 'Worsening encephalopathy today'

16 September 2015 – No confusion evident today

55. The CH IPA advised that General Medical Council (GMC) 2008 Consent guidelines state that 'written consent should be obtained from a patient if:

- a) The investigation or treatment is complex or involves significant risks or
- b) There may be significant consequences for the patient's employment, or social or personal life'

56. The CH IPA advised that a diagnostic paracentesis is not a complex investigation and is a low risk procedure. A prospective study of 1100 therapeutic paracenteses documented no bleeding complications. A higher complication rate (1.6% percent) was

reported in a prospective study of 515 paracentesis in-patients with cirrhosis but most of these were related to therapeutic rather than diagnostic paracentesis. Thus, most hepatologists regard diagnostic paracentesis as a low risk safe procedure. As a result, in the UK, written consent for diagnostic paracentesis is not usually sought. The CH IPA also advised that most clinicians would explain the procedure to the patient and will obtain informed consent.

57. The CH IPA advised in this case, there is a note on 11 September 2015 that the 'patient was informed of tap'. He advised that by 11 September 2015 the patient was encephalopathic (a neuro-psychiatric disorder associated with liver failure due to the effects of excess ammonia on brain function). No formal assessment of capacity was made in the notes but the CH IPA was of the opinion that the patient did not have capacity to make decisions regarding paracentesis.

58. The CH IPA advised that the Mental Capacity Act (MCA) for England & Wales 2005, section 5, applies in connection with the care or treatment by another person. According to section 1 of the Act a person lacks capacity in relation to a matter if at the material time she is unable to make a decision for herself in relation to the matter because of an impairment of, or a disturbance in, the functioning of the mind or brain. If the patient lacks capacity, then a decision may be implemented by the senior clinician in charge of the patient's care. However, carers should be involved in discovering any wishes formerly expressed by the patient, but in this instance, this discussion regarding diagnostic paracentesis did not occur. The CH IPA advised that the equivalent Northern Ireland legislation did not apply at the relevant time in this case and that the substantive content is reflected in the Mental Capacity Act for Northern Ireland of 2016. Although the final decision regarding paracentesis would be with the senior clinician in charge, good clinical practice would be to explain the rationale for paracentesis with her family.

59. I shared the CH IPA advice regarding this issue with the Trust. However no comments were made by the Trust.

Analysis and Findings

60. On the basis of the advice received from the CH IPA I am satisfied that formal written consent from the patient was not required in this instance. I note the advice that 'diagnostic' paracentesis is not a complex investigation and is a low risk procedure for which written consent is not usually sought from clinicians. I note and accept the recording in the clinical notes for 11 September 2015 that the patient was informed of the plan to carry out diagnostic paracentesis. I note however the advice of the CH IPA that in the days preceding 11 September 2015, confirmed in the clinical and nursing notes, the patient experienced a period of hepatic encephalopathy which in his opinion robbed her of the capacity to make an informed decision regarding paracentesis.

61. I note that no formal test regarding the patient's mental capacity or ability to make an informed decision was made. However at the time she was informed of the plan to carry out the diagnostic tap, she was questioned by nursing and clinical staff in response to the family's concerns over confusion. The record of this is noted in the Daily Evaluation of Nursing Care Record of 11 September 2015 at 15.30hr, after the plan for a diagnostic tap is noted. At that time the patient is recorded as being able to understand and communicate where she was. She was aware of date and month, thereby showing a level of awareness. However, on 12 September 2015, (10.15) she was described as being 'quite confused'. From an examination of the clinical records I am satisfied that during this period the patient experienced confusion brought on by hepatic encephalopathy. However these periods of confusion were transitory. The IPA has concluded that the patient did not have capacity and therefore informed consent could not be obtained from her.

62. From the records, it is clear that clinical staff were aware that the patient was experiencing hepatic encephalopathy. I made further enquiries to the CH IPA with regard to this matter and enquired if, in these circumstances, a mental health assessment ought to have been carried out by a mental health professional. The CH IPA advised that it would not be normal practice to have a mental health assessment carried out when a patient has hepatic encephalopathy. This is because it is clinically apparent that the patient cannot retain information and thus by definition give informed

consent. The CH IPA advised that the clinical records evidence that the patient was encephalopathic from 7 September 2015 both clinically with supportive biochemical evidence of raised serum ammonia. Therefore I am satisfied that she was unable to give informed consent. I accept this advice from the CH IPA together with the advice that although the final decision regarding whether or not to carry out the diagnostic tap would be for the senior clinician, good clinical practice would have required discussion and explanation of the process of paracentesis and its rationale with the complainant and his family in order to seek their views and respect their rights to participate in that decision making.

63. I refer to paragraph 28 of the GMC Guidance on Consent: “patients and doctors making decisions together” (June 2008) states that, *‘Clear, accurate information about risks of any proposed investigation or treatment, presented in a way patients can understand, can help them make informed decisions. The amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussion with patients should focus on their individual situation and the risk to them.’* Paragraph 76 of this guidance on ‘Making decisions when a patient lacks capacity’ states that *‘clinicians must consider the views of people close to the patient on the patient’s preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient’s best interests’*

64. The Trust are obliged to have regard to the human rights of the patient and her family in the context of the delivery of care and treatment when a patient does not have the capacity to decide on treatment. Although ultimately a clinical decision, it is important to ensure that the patient and where appropriate the family have an opportunity to participate in that clinical making process. The participation principle is a key tenet of the human rights based approach to patient care. In circumstances where the patient had no capacity to provide informed consent to the proposed paracentesis procedure, I consider that the complainant and his family ought to have been consulted. The failure to involve the family in this decision making process does not reflect good practice and fails to respect the participation principle. The Trust failed in this regard to have regard to the rights of the complainant and his family. I consider this lack of consultation to have caused the complainant and his family the injustice of

loss of opportunity to participate in the decision making process regarding the paracentesis procedure.

Nutrition and Hydration

65. The complainant states that the independent report concluded that the nutrition and hydration provided to his wife was inadequate. He complains that lack of nutrients and poor hydration (and indeed a fluid restriction) over an extended period of time would have weakened her condition and would have had a detrimental effect on her chances of survival. He is concerned that a referral to a dietician was not made earlier and that when it was made subsequent input was not vigorous or effective.

66. I refer to the relevant clinical records as follows

2 September 2015 – Daily Evaluation sheet (16.30) ‘.....Fluid restrict 1.5 litre’
Clinical notes ‘ ...Fluid restrict 1.5L.’

3 September 2015 – Daily Evaluation sheet (20.00) ‘.....Plan – encourage pt intake up to (1200ml scored out) 1500ml restriction...’

4 September 2015 – Clinical Notes (14.10) ‘.....Fluid restrict 1.5 litre’

5 September 2015 – Daily Evaluation sheet (16.50) ‘.....Fluid restriction adhered to...’

6 September 2015 – Daily Evaluation sheet (08.20) ‘.....Fluid restriction 1500mls continued’

8 September 2015 – Clinical Notes (16.00) ‘.....phone call from Dr [...]; advises dietitian input ? supplements etc’

9 September 2015 – Daily Evaluation sheet (4.50) ‘.....Pt referred to dietitian’

10 September 2015 – Clinical Notes (16.55) ‘Dietitian.....Patient referred 04.49 9.9.15 dietetics department did not receive this referral until 08.50. Pt referred Wednesday not Tuesday. Pt not seen yesterday due to one member of staff for whole hospital yesterday afternoon & also other high priority patients requiring review.’

12 September 2015 – Daily Evaluation sheet (22.30) ‘.....Consider NGT if becomes too drowsy to take laxative orally’

14 September 2015 – Clinical Notes (16.30) Dietitian review’

67. The CH IPA advised that protein-energy malnutrition is common in patients with cirrhosis and is associated with poor survival. Malnutrition is reported in 20% of patients with compensated cirrhosis and in more than 50% of patients with decompensated liver disease. The progression of malnutrition is associated with the progression of liver failure and is easily recognizable in decompensated patients with cirrhosis. Poor dietary intake has been found to be an independent predictor for in-hospital mortality. The European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines recommend that energy and protein intake should be 35-40 kcal/kg of body weight per day and 1.2-1.5 g/kg of body weight per day, respectively for patients with chronic liver disease.

68. In answer to specific questions from the Investigating Officer, the CH IPA advised as follows

- i. A dietician should have been involved in the patient's care from admission. However, she was only reviewed by a dietician on 10 September 2015 (day 11 of her admission).
- ii. The patient did not receive substantial nutrition according to accepted guidelines as noted in the food intake recorded by the dietician from 12 September 2015 onwards. The recorded intake of 400 –700 kcal/day from 12 – 14 September 2015 is well below recommended intake from the dietician of 2714 kcals/day from 10 September 2015. A review of the food charts prior to 12 September 2015 and after 14 September 2015 confirm an intake below the daily calorific recommendations throughout the patient's admission.
- iii. Nasogastric feeding ought to have commenced in view of the patient's poor intake which was exacerbated by her encephalopathy and ascites. Although there is no firm guidance on when to implement nasogastric feeding, it would have been good clinical practice to commence nasogastric feeding 2-3 days after initial review by the dietician, when it was noted that The patient's calorific intake was only 700 kcal/day. Indeed, nasogastric feeding was suggested by a junior doctor on 12 September 2015.
- iv. There was no indication for fluid restriction in a patient with decompensated cirrhosis and ascites. The CH IPA advised that from the notes it seems the indication

for the fluid restriction was to treat the patient's ascites – this is not a recognised treatment for ascites. Fluid restriction can be applied for patients with hypervolemic hyponatremia (a large circulating volume of fluid associated with a low serum sodium) according to EASL guidelines as follows - *'Fluid restriction to 1000 ml/day is effective in increasing serum sodium concentration in only a minority of patients with hypervolemic hyponatremia but may be effective in preventing a further reduction in serum sodium levels'*. The CH IPA advised that as noted in the guideline, fluid restriction is only used with hyponatremic cirrhotic patients with ascites but even in these cases it is seldom effective. Indeed, most hepatologists would not use fluid restriction as a therapy. Therefore fluid restriction was not indicated in the patient's circumstances since:

- (i) The patient was not hyponatraemic and
- (ii) Fluid restriction was contraindicated in view of the progressive rise in urea, indicative of acute kidney injury with concomitant use of diuretics.

69. On reviewing the patient's clinical notes the CH IPA advised that fluid intake was on average 1200 mls/day until 11 September 2015, which would lead to dehydration (reduced circulating intravascular volume) when progressive renal impairment was noted. This was the only objective assessment which the CH IPA could make from a notes review. The acute kidney injury observed was probably multifactorial, with sepsis, diuretic therapy and progressive liver failure also contributing to kidney failure.

70. The CH IPA advised that best practice in this case required an immediate dietetic assessment on day 1 with protein and calorific intake targets aided by oral supplements such as fortisips. If this was unsuccessful after 2-3 days then nasogastric feeding ought to have been commenced with a fluid intake of 2-3 litres/day titrated carefully according to renal function and clinical assessment of hydration. The CH IPA advised that poor hydration and nutrition would have been detrimental to the patient's outcome.

71. The CH IPA advice was shared with the Trust for comment. In response the Trust stated that feedback from the CH IPA was in line with the Trust's own conclusion, dietetic support was insufficient therefore it had nothing further to add. During the

course of local resolution and following receipt of the Trust's report, the Trust accepted that it had failed to provide adequate screening of nutritional risks, there had been a delay in referral to dietetics and that enteral feeding ought to have been more rigorously pursued and the rationale for not doing so discussed and documented.

Findings and Analysis

72. The complainant has expressed his severe concerns over the care and treatment his wife received with regard to both nutritional input and hydration. I consider the issues of nutrition and hydration below.

73. The complainant complained to both the Trust and me that his wife was not fed or fed inadequately for over a period of 12 days. He complained that she was not assisted with feeding and because of her condition she frequently fell asleep at meal times which resulted in her not being fed. He considers that a lack of sufficient nutrition during her admission at Causeway Hospital led to her weakened state which reduced her chances of survival.

74. The CH IPA has advised that protein energy malnutrition is a common factor in patients with cirrhosis and that malnutrition is reported in more than 50% of patients with decompensated liver disease. I note his advice that poor dietary intake has been found to be a predictor for in-hospital mortality. I also note the quote in the independent report taken from EASL Guidelines 'Current clinical management of alcoholic cirrhosis focuses on alcohol abstinence, aggressive nutritional therapy rich in calories and proteins (my emphasis)...'. I accept the fact that the complainant disputes the role of alcohol in his wife's health complications but irrespective of the cause of the patient's liver problems, I am satisfied that nutritional input should play an important part in its treatment.

75. I accept the advice of the CH IPA and also taking into consideration the content of the independent report, I consider there to have been a number of failings by the Trust to provide adequate nutritional support to the patient.

76. The presence of malnutrition in patients with decompensated liver disease is a recognised factor associated with this condition. It is for this reason that the EASL Guidelines recommend an aggressive nutritional therapy as part of a treatment plan. I note with concern that the patient was not referred for review by a dietitian until 10 days after admittance, being thereafter seen on day 11. I accept the advice of the CH IPA that this referral ought to have taken place upon admission or very shortly afterwards. I consider the delay of 11 days before she was attended by a dietitian to constitute a failure in the care and treatment. I consider this failure to have caused her the injustice of the loss of opportunity to have her nutritional needs properly assessed and appropriately treated at an earlier time. I consider this failing to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received.

77. When the patient was seen by a dietitian, the Dietetic Nutritional Assessment form completed on 10 September 2015 calculated that she had lost 9.12% of her body weight over the previous 6 months. This was considered to be a 'significant' weight loss. The CH IPA noted that the recommended daily intake was to exceed 2700Kcals and 90 – 113g of protein per day. However, on review on 14 September 2015 by the dietitian it was noted that the patient's intake was only 400Kcals/12g protein on 12 September 2015, 700 Kcals/25g protein on 13 September 2015 and 700/25g protein Kcals on 14 September 2015.

78. I conclude that therefore the patient's recommended daily intake was not being adequately met to a significant degree. There is evidence of her reduced appetite and limited amount of feeding with notations in the Daily Evaluation of Nursing Care sheets which record her refusing meals. There is further confirmation of the family's dissatisfaction with the feeding regime in the record of 23 and 24 September 2015. This record noted that a complaint was likely to be received from the family due to a failure to assist the patient with feeding. At this time the dietitian recorded that she had informed the family that this was a nursing issue and not a matter for dietetics. Sadly the patient passed away two days later. I have considered the evidence carefully. I conclude that the Trust failed to be proactive and to promote 'aggressive nutritional therapy rich in calories and proteins' as recommended in EASL Guidelines.

I consider this to constitute a failure in the nutritional care and treatment received by the patient. I consider this failure to have caused her the injustice of the loss of opportunity to benefit from receiving her recommended calorific and protein intake for a sustained period of time. I consider this injustice to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received.

79. At the dietetic review on 14 September 2015, it was noted that the patient's intake was well below that recommended. It was also noted that she had experienced periods of confusion caused by encephalopathy and that she had on occasion refused food. However the option of nasogastric feeding does not appear to have been considered by the Trust or if it was, this consideration was not recorded. I note that there was a query in the clinical notes on 12 September 2015 whereby it was suggested that a nasogastric tube might be a method of providing medication to the patient but that there was no follow up, either to provide medication or nutrition. The CH IPA has advised that it would have been good practice to commence nasogastric feeding 2/3 days after the initial review when it was noted that the patient's intake was so deficient. I agree with this advice and consider that the failure to commence or consider nasogastric feeding at this time constitutes a failure in the care and treatment provided to the patient. I consider this failure contributed to the injustice to the patient of not receiving her recommended calorific and protein intake for a sustained period of time. I consider it to have caused the complainant and his family the injustice of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

80. A short time after admission to Causeway, on 2 September 2015, the patient was placed on a fluid restriction of 1500ml per day. This is recorded in the clinical notes. I note that Daily Fluid balance and Prescription Charts were completed documenting her daily fluid input and output. I note that the Daily Fluid Balance and Prescription Chart for 12 September 2015 in the special instructions section states that the fluid restriction imposed was 1200mls per day. The records evidence that the amount of fluid intake recorded varied from a low of 815ml on 14 September 2015 to a high of 2948ml on 17 September 2015. The patient was admitted to ICU on that date.

81. The detail of the relevant Daily Fluid balance and Prescription Charts are set out below.

Date													
7/9	9/9	10/9	11/9	12/9	13/9	14/9	17/9	18/9	19/9	20/9	21/9	23/9	24/9
MI													
1290	1204	1175	1250	1100	1650	815	2948	1256	2609	1116	1427	1108	870

82. I note the comments in the independent report in examining the issue of hydration. The report states ‘a confounding issue was the fluid restriction of 1200mls applied to the patient. This appears to have been arbitrary and based on the presence of ascites’. The CH IPA advice is similar in this respect. The CH IPA advises that the records are poor in relation to the rationale for applying a fluid restriction. The CH IPA has also advised that from his examination of the notes, it appears that the indication for the fluid restriction was to treat the patient’s ascites. However I was advised that this is a form of treatment which is applied to patients with hypervolemic hyponatramia¹⁰ but even then this form of treatment is seldom effective. I was advised that the patient was never hyponatraemic. The CH IPA advice is that there was no indicator for imposing a fluid restriction, in this case the patient was being treated for decompensated liver disease and ascites and that most hepatologists would not use fluid restriction as a therapy. The CH IPA advice on fluid restriction states that a fluid restriction would be contraindicated in light of the ‘progressive rise in urea, indicative of acute kidney injury’ with the associated use of diuretics. The CH IPA also advised that his clinical review of the notes revealed that the patient’s fluid intake up to 11 September 2015 was on average 1200mls and this would lead to dehydration. At this time progressive renal impairment was noted. I note that the patient’s average fluid intake increased on occasion after this date but not significantly or consistently, neither was the fluid restriction lifted. However the CH IPA could not attribute the acute kidney injury noted to the application of a fluid restriction and limited intake, as this was probably multifactorial with sepsis, diuretic therapy and progressive liver failure all contributing.

¹⁰ Hyponatremia is a low sodium level in the blood.

I am satisfied however that poor hydration combined with the use of diuretics would not have benefited the patient. I accept the advice of the CH IPA in this regard and consider that a fluid restriction in these circumstances was a failing in the care and treatment provided to the patient. I consider this failure led to her receiving inadequate hydration from 2 September 2015 for a sustained period of time. This failing has in my view caused the patient the loss of opportunity for optimal recovery. I consider the complainant and his family have also suffered the injustice of frustration and uncertainty over the appropriateness of the care and treatment received by the patient.

83. I have considered carefully and accept the advice of the CH IPA that good practice, with regard to the patient's treatment in the fields of nutrition and hydration required immediate dietetic assessment on admission with protein and calorific intake targets. This ought to have been supplemented by oral supplements. If this has proved to be unsuccessful after two to three days, then nasogastric feeding ought to have been commenced with a fluid intake of 2-3 litres/day adjusted carefully according to renal function and clinical assessment of hydration. This plainly did not happen. I consider the consequences of the failures regarding nutrition and hydration at the conclusion section of this report.

(iv) Lesson learnt following the outcome of the review

84. As a result of the independent report and following completion of the complaints process, the Trust has informed the complainant that lessons have been learnt by it and by relevant staff and that processes have been improved. Neither the complainant nor his family have confidence in this statement. The complainant has no confidence that anything has been learned from the report into the care of his wife and believes that no changes will be made or have been made.

85. In response to investigation queries the Trust stated that the review highlighted three areas where the management of the patient's case by the clinicians involved could have been improved. The report also noted that early in the clinical course it seems there was a lack of consultant led communication with the family. It highlighted

the need for good consultant engagement with patients and relatives and detailed documentation to support this. The Trust also stated that there has been specific learning for the Trust's Dietetic Service as a result of the review. The Nutrition and Dietetic service has provided further education at ward level, which emphasises the importance of timely and appropriate referrals from nursing colleagues to the service. The Trust Dietetic Service has produced a guide for their management of patients with liver disease and a leaflet to support individuals with liver disease who require a 'no added salt' diet to assist with their management of ascites.

86. I consider it important that where significant failings have occurred, as in this case, that individual clinicians reflect personally on the lessons learned and provide evidence of this.

87. The Trust stated that it acknowledged the need to share learning on a regional basis and that it would, at a senior level, contribute to the work of a regional nutritional review steering group. It also stated that was revising its 'Nutrition and Hydration strategy'. The Trust also confirmed that it had purchased hand dynamometers for use by nutrition and dietetic staff to assist in identifying malnutrition and muscle loss. Finally, as referenced previously in this report, the Trust stated that there had been a recent clinical audit undertaken into the practice of paracentesis, covering the test period May to October 2017, which highlights the practice in Causeway Hospital is now in line with BSG guidelines.

88. The CH IPA advised that the actions taken by the clinicians and the Trust as a result of this complaint have been governed by the independent report and were appropriate and reasonable in the circumstances.

89. The CH IPA advised that only audit data from these actions would demonstrate compliance with the learning points. Compliance with the first 24 hours of actions for patients with acute or chronic hepatic decompensation from the BSG and BASL may be a useful audit tool to demonstrate compliance with regard to the management of decompensated cirrhosis. An audit of the numbers of patients with decompensated cirrhosis screened for malnutrition with evidence of appropriate intervention would

provide evidence of learning with regard to inadequacies of nutrition from the independent report. I have asked the Trust to provide evidence of the actions taken by it in order that I can, as far as practicable, assess whether lessons have been learned from this case.

Findings and Analysis

90. I accept the advice of the CH IPA that the action points taken by the Trust to date have been driven by the contents of the independent report. I accept that they are appropriate and reasonable. I make no findings of maladministration with regard to the action points taken by the Trust to date. As regards systemic failings I asked the Trust whether any of the circumstances involved in this case ought to be referred to the General Medical Council. The Trust have indicated that it did not consider there were fitness to practice issues arising from this case. Having carefully considered the issues, I have made a number of recommendations based on the advice of the CH IPA. The complainant advised the Investigating Officer of his hope that lessons will be learned from his complaint and that other families will not have to suffer as he and his family have done. I urge the Chief Executive and the Medical Director, as the responsible persons, to consider my report and the advice of the CH IPA and to reflect on the lessons for learning and the promotion of good clinical practice in the treatment of patients with decompensated liver disease.

CONCLUSION

91. The complainant submitted a complaint to me about the actions of the Trust. I have investigated the complaint and have identified a failure in the care and treatment provided to the patient in respect of the following matters:

- (i) Delay in carrying out paracentesis
- (ii) Failure to attempt further paracentesis following the failed attempt on 11 September 2015
- (iii) Failure to commence the use of antibiotics prior to 12 September 2015 and delay in seeking microbiological advice

- (iv) A delay of 11 days before the patient was reviewed by a Dietitian on 10 September 2015
- (v) A failure to be proactive and to promote 'aggressive nutritional therapy rich in calories and proteins'
- (vi) A failure to commence or consider nasogastric feeding of the patient
- (vii) The imposition of a fluid restriction with regard to hydration
- (viii) A failure to communicate with the patient's family regarding the paracentesis procedure.

92. In the course of this investigation, I have identified significant and repeated failures by the Trust in the care and treatment provided to the patient. The significant failures identified in this report were also identified for the most part in the independent report. This report and the advice provided by the CH IPA reveals that upon admission to the Causeway Hospital on 31 August 2015, the patient was severely ill with decompensated liver disease. In 2008, the patient had been noted to have a 'fatty liver' and such was the progress of her illness that by August 2015, she was admitted to hospital with a severe life threatening condition. The CH IPA has noted, and I accept, the poor prognosis which the patient presented with and the high percentage rates of patients who do not survive this condition. I note and accept the advice that the combination of the patient's age, obesity and advanced presentation of liver failure would have ruled out the option of her receiving a liver transplant.

93. The multiple and serious failures in the care and treatment provided to the patient were in relation to a delay in the paracentesis procedure, a delay in the instigation of an antibiotic therapy, the receipt of microbiological advice, nutritional failures and the unnecessary fluid restriction imposed. The failures identified lead me to conclude that the patient was not given the best possible chance of survival. The Trust failed to provide adequate care and treatment to her and while I cannot conclude that her death was avoidable, given the patient's complex health conditions, these failures reduced her chances of survival. Upon arrival in Causeway Hospital on 31 August 2015, the patient was seriously ill with a condition from which many patients do not survive. I consider that her limited chances for survival from this illness were dependent on her receiving timely and appropriate supportive care. Having said this and in spite of the

failures identified, such was the level of the patient's illness that I cannot conclude that her death was avoidable. However I do agree with the advice of the CH IPA and am satisfied that prompt treatment of potential sepsis in combination with the provision of appropriate fluids and nutrition would have improved her chances of survival and that the failures identified may have made a material difference to the outcome.

Recommendations

94. I recommend:

- A personal apology from the Chief Executive of the Trust and from each of the clinicians involved to the complainant and his family for the failures in care and treatment which I have identified. That apology should follow my guidance on making an apology.
- A payment, in solatium, of £10,000 in total to the complainant and his three daughters for the injustice of upset, frustration, distress for the failures identified and the loss of opportunity to participate in the decision making process.
- I note that the Trust has conducted an audit with regard to paracentesis and the evaluation of patients with ascites to demonstrate compliance with guidelines. I recommend that the Trust carry out a similar audit with regard to numbers of patients with decompensated liver disease screened for malnutrition with evidence of appropriate intervention and a similar audit with regard to hydration to provide evidence of learning with regard to inadequacies of nutrition and hydration from the independent report and the CH IPA. The Trust should complete this audit within a period of 6 months of the date of my final report and provide my office with evidence that this has occurred.

95. In response to receipt of a draft of this report and when asked to provide comments the Trust accepted the failings identified. It also confirmed that it accepted my recommendations and, upon receipt of the final report would act upon them. The Trust further stated that the consultant in charge also accepts the findings of the report. He asked that the Trust pass on his unreserved apology to the complainant and to all his family and friends for the shortcomings encountered by the patient while under his care in Causeway Hospital. He commented that four doctors had assessed the patient

between 31 August 2015 and 2 September 2015 with input from radiology and none of these doctors had detected grade one ascites. The Trust stated that, with regard to the consultant's clinical practice, he has undertaken and documented a personal reflection of this case, including my conclusions. This has been shared with the Trust's Medical Director, who met with the consultant to discuss his reflections in person. He assured me that the consultant's reflections are comprehensive and insightful, and that he is satisfied that learning has been identified and that the consultant has changed his practice. I accept this assurance and I therefore do not propose to make a referral to the General Medical Council.

Marie Anderson

MARIE ANDERSON
Ombudsman

July 2019

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.

