Investigation Report

Investigation of a complaint against the South Eastern Health and Social Care Trust

NIPSO Reference: 20136

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The Role of the Ombudsman

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

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

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

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

The Ombudsman must also consider whether maladministration has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. A remedy may be recommended where injustice is found as a consequence of the failings identified in a report.

Reporting in the Public Interest

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

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

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SUMMARY

The complainant raised concerns about the actions of the South Eastern Health and Social Care Trust (the Trust). He was being treated for a low platelet blood count[1] (otherwise called thrombocytopenia) from March 2012. The complaint concerns the care and treatment he received from the Trust prior to his diagnosis of Primary Biliary Cholangitis[2] (PBC). The complainant was diagnosed with PBC by clinicians in the Belfast Health and Social Care Trust (BHSCT) on 13 March 2018.

The investigation established the care and treatment provided to the complainant was in accordance with good medical practice. Upon consideration of the guidelines for the diagnosis of PBC, I do not consider the complainant's ALP levels were persistently elevated which would have prompted an earlier referral to Hepatology by the Consultant Haematologist. Furthermore, I consider it was not the role or within the clinical expertise of a Consultant Haematologist to diagnose PBC which is generally diagnosed by a Hepatologist. Therefore, I have not found failures in the care and treatment provided by the Haematology service prior to the complainant's diagnosis of PBC.

The South Eastern Health and Social Care Trust accepted my findings and recommendations.

[1] Low platelet blood count is when you don't have enough **platelets** in your **blood**, your body can't form clots. A **low platelet count** may also be called **thrombocytopenia**. This condition can range from mild to severe, depending on its underlying cause.

[2] **Primary biliary cholangitis (PBC)**, previously called **primary biliary cirrhosis**, is a chronic disease in which the bile ducts in your liver are slowly destroyed. Bile is a fluid made in your liver. It aids with digestion and helps your body get rid of cholesterol, toxins and worn-out red blood cells.

THE COMPLAINT

1. The complainant raised concerns about the actions of the South Eastern Health and Social Care Trust (the Trust). The complainant was referred by his GP to a Consultant Haematologist[3] in the Trust for management of his low platelet blood count in March 2012. He believed he was neglected by his medical team in the Trust and as a result of this neglect there was a delay in his diagnosis of PBC. The complainant was diagnosed with PBC by clinicians in the Belfast Health and Social Care Trust (BHSCT) on 13 March 2018. The complainant believes had he been diagnosed sooner with PBC, he may not have developed cirrhosis of the liver[4].

Issues of complaint

2. The issues of complaint which I accepted for investigation were:

   i. Whether the care and treatment the complainant received prior to his diagnosis of Primary Biliary Cirrhosis was appropriate and reasonable.

INVESTIGATION METHODOLOGY

3. 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 by the complainant. This documentation included information relating to the Trust's handling of the complainant's complaint. I have also examined the complainant's medical records from the BHSCT and GP. The actions of the BHSCT and the GP were not part of this complaint.

[3] Consultant **Haematology** (doctor) **Haematologists** diagnose and clinically manage disorders of the blood and bone marrow. They also provide clinical support for the **haematology** diagnostic laboratory including the blood bank.
[4] **Cirrhosis** is a late stage of scarring (fibrosis) of the **liver** caused by many forms of **liver** diseases and conditions, such as hepatitis and chronic alcoholism. ... As **cirrhosis** progresses, more and more scar tissue forms, making it difficult for the **liver** to function (decompensated **cirrhosis**).

Independent Professional Advice Sought

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

- Consultant Haematologist (CH IPA) MD; RFCP; FRCPath; LLM with 25 years experience treating patients with Immune Thrombocytopenia[5] (ITP) or with a low platelet count.

6. 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

7. 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.

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

- The Principles of Good Administration
- The Principles of Good Complaints Handling
- The Public Service Ombudsman Principles for Remedy

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

10. The specific standards relevant to this complaint are:

[5] **Immune (Idiopathic) thrombocytopenia (ITP)** is a disorder characterized by a blood abnormality called **thrombocytopenia**, which is a shortage of blood cell fragments called platelets that are needed for normal blood clotting. **ITP** is an **immune** disorder in which the blood doesn't clot normally. This condition is now more commonly referred to as **immune thrombocytopenia** (**ITP**). **ITP** can cause excessive bruising and bleeding. An unusually low level of platelets, or thrombocytes, in the blood results in **ITP**

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

- Autoimmunity Review, the Diagnosis of Primary Biliary Cirrhosis, Bowlus & Gershwin et al (2014) (The Diagnosis of PBC);
- British Journal of Haematology, Guidelines for the Investigation and Management of Idiopathic Thrombocytopenic Purpura (ITP) in Adults, Children and in Pregnancy (2003) (Guidelines for the Investigation and Management of ITP);
- British Guidelines for Primary Biliary Cirrhosis (PBC) (2017 & 2018) (Guidelines for PBC); and
- American Academy of Family Physicians www.aafp.org/afp Thrombocytopenia American Family Physician (2012) (AFP Guidance for Thrombocytopenia)

11. 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.

12. In accordance with the NIPSO process, a copy of this draft report was shared with the Trust and the complainant for comments on factual accuracy and the reasonableness of the findings and recommendations.

INVESTIGATION

Issue one Whether the care and treatment the complainant received prior to his diagnosis of Primary Biliary Cirrhosis was appropriate and reasonable.

Detail of Complaint

13. The complainant stated that a Consultant Haematologist had been treating him for a low platelet count since March 2012. However, he stated he had a raised alkaline phosphatase (ALP[7]) level in June 2016 which he believes his

[7] **Alkaline phosphatase** (**ALP**) is an enzyme in a person's blood that helps break down proteins. The body uses **ALP** for a wide range of processes, and it plays a particularly important role in liver function and bone development

Consultant Haematologist ignored and neglected to act upon resulting in a delay in testing him for PBC. The complainant further complained that had he been tested earlier for PBC then he may not have gone on to develop cirrhosis of the liver. The complainant was diagnosed in the BHSCT with PBC on 13 March 2018.

Evidence Considered

14. I have considered the following extracts of the Diagnosis of PBC:

'The diagnosis of PBC should be suspected when there is an elevation of serum alkaline phosphatase (ALP) other signs of cholestasis[8] including jaundice[9] or pruritus[10] and cirrhosis of unknown cause. The diagnosis of PBC can be established if two or three objective criteria are present: (i) serum anti-malignin antibody *(AMA's) at titers>1:40, (ii) unexplained elevated ALP > 1.5 times the upper normal values for over 24 weeks and (iii) compatible liver histology, specifically non supportive cholangitis and interlobular bile duct injury'.*

15. I have considered the following extracts of the guidelines for the investigation and management of ITP:

'The diagnosis of ITP is based principally on the exclusion of other causes of thrombocytopenia[11] using the history, physical examination, blood count, peripheral blood film, autoimmune profile and other investigations. Further investigations are not indicated in the routine work-up of patients with suspected ITP if the history, examination, blood count and film are typical of the diagnosis of ITP and do not include unusual features that are uncommon in ITP, or suggestive of other causes'.

16. I have considered the following extracts of the guidelines for PBC:
'*Primary biliary cholangitis (formerly known as primary biliary cirrhosis, PBC) is an*

[8] **Cholestasis** is defined as a decrease in bile flow due to impaired secretion by hepatocytes or to obstruction of bile flow through intra-or extrahepatic bile ducts.
[9] **Jaundice** is a term used to describe a yellowish tinge to the skin and the whites of the eye. Body fluids may also be yellow. The color of the skin and whites of the eyes will vary depending on levels of bilirubin. Bilirubin is a waste material found in the blood
[10] **Pruritus** or itch is defined as an unpleasant sensation of the skin that provokes the urge to scratch.
[11] **Thrombocytopenia** is a condition characterized by abnormally low levels of thrombocytes, also known as platelets, in the blood.

autoimmune[12] liver disease in which a cycle of immune mediated biliary epithelial cell injury, cholestasis and progressive fibrosis[13] can culminate over time in an end stage biliary cirrhosis. Both genetic and environmental influences are presumed relevant to disease initiation. PBC is most prevalent in women and those over the age of 50 but a spectrum of disease is recognized in adult patients globally….As the disease is increasingly diagnosed through the combination of cholestatic serum liver tests andthe presence of antimitochondrial antibodies[14] most presenting patients are not cirrhotic and the term cholangitis is more accurate'.

'*Diagnostically, PBC should always be considered in patients with otherwise unexplained repeated elevation of usually serum alkaline phosphatase (ALP), but also gamma-glutamyl transferase (GGT)[15]'.*

Clinical Records

17. I considered the following relevant extracts from the complainant's clinical records:

21 June 2016: '*I note since the last review platelets are 81 x 10^9/L. The patient has no bruising or bleeding tendencies and is feeling clinically well. As his platelet count is stable we will continue to review him and see him again in one years time'.*

21 June 2016: ALP level 141 U/L[16] (30-138)

25 June 2017: '*This gentleman's platelet count is much better today at > 100 x 10^9/L. He has no bleeding symptoms. As you know I put this down to perhaps alcohol ingestion which he still consumes and certainly his haemoglobin and white cell count[17] (WCC) has remained normal and largely excluding myelodysplasis[18]. The*

[12] An **autoimmune disease** is a condition in which your **immune** system mistakenly attacks your body. The **immune** system normally guards against germs like bacteria and viruses.
[13] **Fibrosis** is the formation of excess fibrous connective tissue in an organ or tissue in a reparative or reactive process. This can be a reactive, benign, or pathological state.
[14] **Antimitochondrial antibodies** (AMAs) are an example of an autoimmune response that occurs when the body turns against its own cells, tissues, and organs. ... T
[15] **Gamma-glutamyl transferase** (GGT) is an enzyme found mainly in the liver
[16] U/L Units per Litre
[17] A **white blood cell** (WBC) **count** is a test that measures the number of **white blood cells** in your body.
[18] **Myelodysplastic** syndromes (MDS) are a group of cancers in which immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells.

other differential is a mild ITP'.

The Trust's response to investigation enquiries

18. In response to investigation enquiries regarding the management of the complainant's condition, the Trust stated '[*the complainant] was referred to his Consultant Haematologist for management of his low platelet count, which was managed accordingly. [The complainant's] GP noted a raised ALP level in April 2016, which led to [the complainant's] referral to the hepatology*[19] *unit* [in the BHSCT] *on 8 September 2017 and the subsequent diagnosis of PBC'*. The Trust stated '*The Consultant Haematologist was not informed of [the complainant's] referral to the hepatology unit…. he was subsequently seen in January 2018 by the hepatology unit in the Royal Victoria Hospital (RVH). [The complainant] did not present at the (haematology) clinic with raised ALP until the summer of 2016 when there was a slight rise detected prior to the diagnosis of PBC being made…had he presented at the clinic with a significantly raised ALP, his Consultant Haematologist would have contacted hepatology for advice'*.

19. The Trust further confirmed '[*The complainant] was initially referred to Haematology by his GP in 2012, with a low platelet count…..during the complainant's initial appointment, his Consultant Haematologist took his history….. [the complainant] was frank about having a long history of heavy drinking, which was also documented within his medical records, and that he was taking quinine*[20]*, which can cause low platelet counts. Initial differential diagnoses included drug induced thrombocytopenia, caused by taking the drugs quinine, aspirin*[21]*, perindopril*[22] *and adalat*[23] *which the complainant was on, combined with his alcohol consumption. The Consultant Haematologist also considered mild immune thrombocytopenic purpura ('ITP') as a differential diagnosis. The Consultant Haematologist advised the complainant to stop drinking alcohol. In the absence of any other abnormal results, the Consultant*

[19] **Hepatology** is a branch of medicine concerned with the study, prevention, diagnosis and management of diseases that affect the liver, gallbladder, biliary tree and pancreas.
[20] **Quinine** is a common treatment for malaria. Some people believe that it can also help with leg cramps and restless legs syndrome
[21] **Aspirin** is an everyday painkiller for aches and pains
[22] **Perindopril** is a medicine used to treat high blood pressure and heart failure
[23] Nifedipine, sold under the brand name Adalat among others, is a medication used to manage angina, high blood pressure.

Haematologist did not consider it necessary to undertake further screening/investigation, or to pursue active treatment. The Consultant Haematologist was however, mindful that [the complainant] may require steps to increase his platelet count, if, for example, he was to require surgery. The Consultant Haematologist gave the GP advice which included when to stop aspirin, and that she had alerted [the complainant] to present to his GP if there was any bleeding or bruising and arranged to see him in one year'.

20. The Trust further stated '[*The complainant] attended the Consultant Haematologist's clinic annually in 2013, 2014 and 2015 and at each visit the ALP was checked and found to be normal with raised GGT. The first rise in ALP appears to have been noted by [the complainant's] GP in April 2016, which was sent to the BHSCT. [The complainant's] GP subsequently referred [the complainant] to hepatology, following which a diagnosis of PBC was made* [in March 2018}*. The first time the ALP was noted to be above the normal limits at the Consultant Haematologist's clinic was on 21 June 2016 when it was 141.*

21*. [The complainant] was contacted by his Consultant Haematologist after the diagnosis of PBC was reached and an early review appointment was arranged at her outpatient clinic, which took place on 26 June 2018. During this appointment, his Consultant Haematologist looked at the platelet levels and enquired whether he had stopped drinking. The Consultant Haematologist also checked his liver function tests (LFTs) and informed him that she would contact hepatology in respect of the PBC, as this was an area outside her expertise. The Consultant Haematologist spoke with, and subsequently received a letter dated 10 July 2018, from hepatology in the BHSCT, which set out when [the complainant's] liver enzymes first became cholestatic (that is when there was first a rise in ALP)'.*

22. In response to the complainant's belief that had he been tested earlier for PBC he may not have developed cirrhosis, the Trust stated '*The Consultant Haematologist did not make the diagnosis of PBC, and it was not within her expertise to do so as a Consultant Haematologist. The Consultant Hepatologist* [from the BHSCT] *notes in his letter of 10 July 2018 "On review of his* [the complainant's] *liver function tests, his liver enzymes became cholestatic for the*

first time in April 2016 and therefore I believe that the PBC is likely to be of relatively recent onset….It is fairly clear cut that his liver cirrhosis has largely resulted from fifty years of alcohol misuse and that the PBC in his case developed within the last couple of years and is almost certain to be mild and that mild rises in ALP are often seen in patients with alcohol related liver cirrhosis and therefore, the fact that PBC was not considered as a differential diagnosis, is not surprising".

23. The Trust also stated *'It is not within the Consultant Haematologist's area of expertise to comment on whether earlier testing would have led to a diagnosis of PBC, although it will be noted from the Consultant Hepatologist that he was of the view that the PBC was of relatively recent onset. It is also not within the Consultant Haematologist's area of expertise to comment on whether an earlier diagnosis of PBC would have had an impact on either the complainant's life expectancy or quality of life'.*

24. The Investigating Officer made further enquiries in regards to the complainant's ALP levels. The Trust stated *'the treatment was not altered because the slight raise in the ALP was consistent with [the complainant's] declared alcohol intake (mild rises in ALP are often seen in patients with alcohol related liver cirrhosis). The platelet count was slightly improved….[The complainant] was reviewed at the Consultant Haematologist's clinic on 21 June 2016 and 25 July 2017, as he was being seen once per year only. The ALP was only slightly raised in keeping with alcohol intake and therefore, it was assessed that there was no need for a referral elsewhere'.* The Trust further confirmed '*that given [the complainant's] clinical history, a slightly raised ALP is most likely to indicate alcoholic liver damage…..between June 2016 up and until January 2018, the complainant attended his Consultant Haematologist's clinic on 21 June 2016 and 25 July 2017, continuing the annual review for the very stable platelet count. As part of these outpatient attendances, the complainant will have been asked about bleeding symptoms, alcohol intake and had his full blood count (FBC) and haematology profile bloods taken. Active surveillance is the strategy for chronic mild thrombocytopenia.*

Earlier review may be triggered as a result of haemorrhagic[24] symptoms or preparation for a surgical procedure etc. Patients are advised if there are any bleeding symptoms, to seek medical advice. This was not required in the complainant's case as he never had any bleeding symptoms'.

Independent Professional Advice

25. In response to investigation enquiries about ITP the CH IPA advised '*Immune Thrombocytopenia: (ITP) is a lowering of the platelets in the blood due to the formation of auto-antibodies which 'recognise', attach to, and destroy the circulating platelets, resulting in a low platelet count'.* The CH IPA also advised '*The complainant never actually required treatment for ITP since his platelet count never fell to a sufficiently low number to cause bleeding and hence make treatment necessary. However, his platelet counts were being monitored with this possible diagnosis in mind (the diagnosis is one of exclusion – there is no one reliable test used to make a diagnosis of ITP which is often made on the basis of other causes of a low platelet count, such as drugs, having been excluded), from 2012. He would only have required treatment for ITP if his platelet count had fallen ….. he was taking a drug for cramps – quinine – which can cause low platelets, and this was stopped. Aspirin, which he was also taking, does not cause low platelets but interferes with platelet function so that the platelets do not clump together normally. Thus, in a person who has a low platelet count and is also taking aspirin, this may well be stopped as it could precipitate bleeding'.* The CH IPA confirmed '*they (the complainant's platelet levels) were being monitored on a yearly basis by the haematology department, along with his platelets. It is possible that his GP also requested some ALP blood tests but I do not have this information'.*

26. In response to investigation enquiries regarding the complainant's ALP levels, the CH IPA advised '*On 23 June 2015 his* [the complainant's] *ALP was 124 U/L (normal) although the GGT was significantly raised at 338 which would be in keeping with alcohol toxicity. A year later on 21 June 2016, his ALP was 141 U/L (30-138 is between normal range), slightly above the normal range, Again, the GGT was significantly raised at 412. I could not identify any further ALP reading's in the clinical*

[24] 'accompanied by or produced by haemorrhage'.

notes until 18 January 2019 when it was well within the normal range at 84 U/L (30-138). His GTT was also well down at 43 U/L although the platelets remained low at 54x10^9/L'.

27. In response to enquiries regarding the complainant's Consultant Haematologist diagnosing PBC, the CH IPA confirmed it was not within her expertise to do so. The CH IPA specifically advised '…*there was nothing to suggest PBC as a diagnosis. The low platelets were much more readily explained by either liver disease resulting from alcohol abuse, since the very raised GGT and only very slightly raised ALP were in accordance with this diagnosis, or ITP. His haematologist had ruled out other causes of a low platelet count such as myelodysplasia*[25] *of a deficiency of folic acid or vitamin B12……The complainant's ALP was not high enough at the time it first rose to even raise the possibility of PBC as a diagnosis'.*

28. In response to enquiries made regarding the complainant's ALP levels in April 2016 and June 2016 being indicative of a PBC diagnosis the CH IPA advised '*No, they would not. As stated earlier, on 21 June 2016 his ALP was 141 U/L, with a normal range of 30-138, so it barely exceeded the limits of the normal range. It would need to be consistently higher than this for the possibility of a diagnosis of PBC to be entertained. At the same time his GGT was significantly elevated at 412, and his AST*[26] *(another liver enzyme) was 48 with a normal range of 15-40. The bilirubin*[27] *was 10. Given his history of alcohol abuse these results were most consistent with a diagnosis of alcohol-induced liver impairment. In June 2016 there was nothing in the results which should have led his Consultant Haematologist to suspect a diagnosis of PBC, an auto immune disorder. Cirrhosis caused ethanol ingestion was a much more likely cause of any biochemical and haematological abnormalities. His platelets remained on the low side at 81x10^9/L which was consistent with either a diagnosis of alcohol-induced platelet toxicity or ITP. I do not have his ALP result from April 2016 as I understand this was from a blood sample taken by his GP'.*

29. The CH IPA further advised '*I do not think an earlier referral to a Consultant*

[25] **Myelodysplastic** syndromes (MDS) are a group of cancers in which immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells.
[26] **AST** is an **enzyme** your **liver** makes. ... **AST** is also called SGOT (serum glutamic-oxaloacetic transaminase
[27] Bilrubin is an orange-yellow pigment formed in the liver by the breakdown of haemoglobin and excreted in bile.

Hepatologist was indicated …..PBC is much commoner in women than men…essentially there was nothing to suggest a diagnosis of PBC in either his history or the results of his laboratory investigations'.

30. In response to investigation enquiries regarding the complainant's care and treatment prior to his diagnosis of PBC, the CH IPA advised '*In my opinion and based on my reading of the clinical documentation, the care and treatment that the complainant received prior to his diagnosis of PBC was appropriate and reasonable….it was in line with good medical practice. If the complainant has cirrhosis of the liver, on balance of probabilities the principle cause of this is long standing alcohol abuse rather than PBC, which is of relatively recent onset. There is nothing in the documentation that I have seen to suggest that an earlier diagnosis of PBC could/should have been made by his haematologist given that the enzyme mild elevations of his ALP and AST apparent in his blood from June 2016 and the earlier more pronounced elevations in his GGT were consistent with changes expected following long-term alcohol abuse'.*

The Trust's response to IPA

31. The Investigating Officer provided an opportunity for the Trust and the Consultant Haematologist to comment on the CH IPA advice. The Trust confirmed it reviewed the CH IPA advice and '*does not have any comments to make on the CH IPA advice'.*

The complainant's response to the draft report

32. The complainant provided a detailed response to the draft report and expressed his dissatisfaction with the process. The complainant stated he still felt that he had been let down by the Haematology Service of the Trust and now by NIPSO also. The complainant provided additional comments regarding the CH IPA advice and why he did not have access to the GP test results which I will deal with in my analysis and findings.

The Trust's response to the draft report

33. Upon receipt of the draft report the Trust stated '*Thank you for sharing the*

Ombudsman's draft report with the Trust for comments. It has been shared with staff, including the Consultant Haematologist and the Trust welcomes the findings of the report and has no further comments to make'.

Analysis and Findings

34. The complainant questioned why the CH IPA did not have access to '*all the medical records and GP records'.* As noted in paragraph 3, all the relevant medical records were obtained including relevant GP records and the Trust clinical records. These records were considered as part of the investigation but were not provided to the CH IPA as they were not records that were available to the Consultant Haematologist reviewing the complainant. While the records were considered they were not subject to review by the CH IPA as the actions of the BHSCT and GP were not part of this complaint.

35. I established the complainant was being treated in the Haematology clinic in the Trust for a low platelet blood count since March 2012. I also established the complainant was reviewed annually at the clinic on 8 May 2012, 25 June 2013, 24 June 2014, 23 June 2015, 21 June 2016 and 25 July 2017. I note the complainant's ALP levels were being monitored annually at the clinic by his Consultant Haematologist. The monitoring by the Consultant Haematologist was in addition that being undertaken by the complainants GP who managing the complaints overall health. Upon examination of the complainant's clinical notes, the first indication that his ALP levels had risen was noted by the complainant's GP in April 2016. On 21 June 2016, the Trust stated the complainant's '*ALP level was noted to be above normal limits'* at his Consultant Haematologist's clinic and this slight rise in his ALP was '*in keeping with the complainant's alcohol intake'.* I note the complainant was diagnosed with PBC in the BHSCT in March 2018.

36. I note from examination of the complainant's GP records that he was being reviewed by his GP. This included regular monitoring of his LFT's by his GP in addition to being under the care of his Consultant Haematologist in relation to his low platelet count. I further established that as the complainant's LFT's had showed a slight rise in September 2017 and November 2017, the GP made on onward referral

to the BHSCT for further investigation. The care and treatment provided by the complainant's GP and BHSCT were not part of the complaint to my office and were not part of this investigation.

37. I have considered and I accept the advice of the CH IPA that on 21 June 2016 the complainant's ALP was only slightly above the normal range at 141 U/L. I further accept the CH IPA advice that '*the rise in ALP needs to persistently be at least 1.5 above the normal range which was not the case with the complainant…the complainant's ALP was not high enough at the time it first rose to even raise the possibility of PBC as a diagnosis'.* I have also considered and I accept the CH IPA advice that nothing was indicated in the results of his ALP tests that would have led his Consultant Haematologist to consider PBC as a diagnosis. I refer to extracts of the diagnosis of PBC by Bowlus & Gershwin et al *'that the diagnosis of PBC can be established if two or three objective criteria are present: serum AMA's and unexplained elevated ALP > 1.5 times the upper normal values for over 24 weeks….'*. Furthermore, I note the guidelines for PBC state '*diagnostically, PBC should always be considered in patients with otherwise unexplained repeated elevation of usually serum ALP but also GGT'.* I consider the complainant's ALP levels on 23 June 2015 at 124 U/L was normal and on 21 June 2016 at 141 U/L was only slightly above average. I am satisfied that the complainant ALP levels were not '*persistently'* 1.5 times the upper value which has been identified by the CH IPA as ranging between 30-138 U/L. I do not consider the complainant had any unexplained or repeated elevations in his ALP that would have led to an earlier referral by the Consultant Haematologist to Hepatology for consideration of a potential diagnosis of PBC.

38. The Trust stated the Consultant Haematologist did not make the diagnosis of PBC as it '*was not within her expertise to do so as a Consultant Haematologist'*. I note this was a view supported by the CH IPA. I further accept the CH IPA advice that '*there was nothing to suggest PBC as a diagnosis…..the low platelets were much more readily explained by either liver disease resulting from alcohol abuse since the raised GGT and only very slightly raised ALP were in accordance with this diagnosis or ITP'.*

39. I note the complainant believes that had he been tested earlier for PBC then he may not have been diagnosed with Cirrhosis of the liver. However, I have considered and I accept that CH IPA advice that '*any alleged delay in diagnosing PBC will not have caused permanent hepatic impairment given the very mild increase in his LFT's which only became apparent in 2016…if the complainant has cirrhosis of the liver, on balance of probabilities the principle cause of this is long-standing alcohol abuse rather than PBC, which is of relatively recent onset'.*

40. In response to the draft report, the complainant commented on the CH IPA advice. In particular, the complainant stated '*already assuming that the thrombocytopenia is purely related to the consumption of alcohol even though after the complete abstinence from alcohol the platelet levels have continued to drop contrary to his statement that they will (return to normal in one week of abstinence*)'. I note the CH IPA advised '*Alcohol-related thrombocytopenia generally is transient, and platelet counts usually return to normal within 1 week of abstinence'.* I further note the CH IPA advised '*the complainant was never actually being treated for ITP since his platelet count never fell to a sufficiently low number to cause bleeding and hence make treatment necessary….he would only have required treatment for ITP if his platelet level count had fallen below around 15 X 10 L with attendant evidence of bleeding'.* Therefore, it is my view that as the complainant's platelet count never dropped sufficiently low to warrant treatment for ITP, I consider his Consultant Haematologist was monitoring his condition and adapting treatment accordingly, hence stopping the drug quinine.

41. In response to the draft report, the complainant presented a sample of his blood results and tests from 2012 – 2018 where he considers the results highlighted he had continued liver problems which he states his '*Consultant Haematologist should have been explored further*'. I note the complainant also stated '*The Consultant Haematologist should have known about his ongoing liver disease and she should have attempted to rule out PBC'*. However, upon examination of the clinical records, I have been presented with no evidence to support the complainant's assertions that his Consultant Haematologist should have explored further his ongoing liver problems or diagnosed his PBC. The purpose of the complainant attending the Haematology Service was for the management of his low platelet count. However if

the Consultant Hematologist noted blood test results that were concerning and were outside their area of expertise it would be for the consultant to refer back to the GP for onward referral or to make contact with another specialism. As the complainant's ALP levels were not persistently elevated in the tests carried out by the Consultant Haematologist this situation did not arise.

42. I have considered and I accept the CH IPA advice that '*the care and treatment that [the complainant] received prior to his diagnosis of PBC was appropriate and reasonable and in line with good medical practice*'. In light of the CH IPA advice, it is clear that it was not the role of a Consultant Haematologist to make a diagnosis of PBC. Rather if review of the patient and tests they considered such a diagnosis possible, the role of the Consultant Haematologist would have been to either refer back to the GP for onward referral to a Hepatologist or make such an onward referral themselves. I consider the care and treatment provided to the complainant by the Trust prior to being diagnosed with PBC to have been appropriate and reasonable. Therefore, I do not uphold the complaint. I note the complainant considers that if he received an earlier diagnosis of PBC he may not have developed cirrhosis of the liver. I have not identified any evidence that this is the case.

CONCLUSION

43. The complainant submitted a complaint to me about the actions of the South Eastern Health and Social Care Trust.

My investigation established the care and treatment provided to the complainant was appropriate and reasonable and in accordance with good medical practice. Upon consideration of the guidelines for the diagnosis of PBC, I do not consider the complainant's ALP levels were persistently elevated which would have prompted an earlier referral to Hepatology. Furthermore, I consider it was not within the clinical expertise for the complainant's Consultant Haematologist to have subsequently diagnosed the complainant's PBC. Therefore, I have not found failures in the care and treatment provided to the complainant prior to his diagnosis of PBC.

PAUL MCFADDEN **12 March 2020**
ACTING OMBUDSMAN

Appendices

APPENDIX ONE

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.