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The investigation of a complaint against Betsi Cadwaladr University Health Board

A report by the
Public Services Ombudsman for Wales
Case: 202206250

Contents	Page

Introduction

This report is issued under s23 of the Public Services Ombudsman (Wales) Act 2019.

In accordance with the provisions of the Act, the report has been anonymised so that, as far as possible, any details which might cause individuals to be identified have been amended or omitted. The report therefore refers to the complainant as Mrs L.

Summary

Mrs L complained about the care and treatment her late mother, Mrs K, received from the Health Board between January 2021 and her death on 31 January 2022 from biliary sepsis (a serious infection of the bile ducts). In particular whether monthly blood tests were an appropriate way to monitor her condition from January 2021, and the follow-up care for Mrs K following a biliary stent in November 2021.

Mrs K had pancreatitis (inflammation of the pancreas) in January 2021. An ultrasound scan was undertaken but the Ombudsman found that the scan was inadequate as Mrs K's bile duct was not visible, so it could not be seen whether gallstones were present. The Ombudsman found that given Mrs K's clinical history the most likely cause for pancreatitis was gallstones, but the Health Board had concluded it was steroid induced pancreatitis despite the scan being unclear. The failure to identify Mrs K's gallstones in January 2021 meant her condition remained untreated.

In August, Mrs K developed other symptoms. Scans undertaken in the autumn showed evidence of a blocked bile duct which required surgery in November. The Ombudsman found that she should have been treated sooner and these were further missed opportunities by the Health Board to identify the seriousness of Mrs K's condition.

The surgery did not fully resolve Mrs K's condition, and she sadly died in January 2022.

The Ombudsman concluded that if Mrs K had been treated appropriately at the outset, her pancreatitis would have been treated successfully and her deterioration and death may have been prevented. This was a grave injustice to Mrs K and her family. The Ombudsman also found little to no evidence that the seriousness of Mrs K's condition was appropriately communicated in October to her and her family either before or after treatment.

The Ombudsman found that although the surgery in November was carried out too late for Mrs K, the procedure was performed to the required standard. A further procedure was scheduled for 8 weeks' time, and this was a reasonable amount of time for Mrs K to wait.

The Ombudsman was concerned at the Health Board's seeming lack of candour in its complaint response to Mrs L, and its lack of objective reflection by its clinicians during the Ombudsman's investigation in that it continued to fail to identify and acknowledge failings in Mrs K's care.

The Ombudsman made a number of recommendations, which the Health Board accepted. These included to:

- Provide Mrs L with a full apology from the Chief Executive for the failings identified in this report.

- Pay Mrs L £4,000 financial redress reflecting the serious failings found and the resulting and lasting significant impact upon her and her family.

- Review this case, in line with its legal requirements under the Duty of Candour, to determine how Mrs K's presentation in January 2021 was misdiagnosed owing to inadequate assessment/imaging. The Health Board to report its findings to its Quality and Patient Safety Committee and in its Annual Report on the Duty of Candour.

- Share the Ombudsman's report with the Clinical Director responsible for the consultants involved in Mrs K's care so that its findings are reflected upon and discussed with those consultants.

- Review its handling of Mrs L's complaint in line with the Duty of Candour.

The Complaint

1. Mrs L complained about the care and treatment her late mother, Mrs K, received from the Health Board between January 2021 and her death on 31 January 2022 from biliary sepsis (infection of the biliary tract). In particular:

- Whether, following Mrs K's discharge from hospital in January 2021, monthly blood tests were an appropriate way to monitor her condition.

- Whether there was a lack of follow-up care for Mrs K following a biliary stent being fitted in November 2021.

Investigation

2. I obtained comments and copies of relevant documents from Betsi Cadwaladr University Health Board ("the Health Board") and considered them in conjunction with the evidence provided by Mrs L. I also sought the advice of one of my Professional Advisers, Professor Stephen Ryder, an experienced consultant gastroenterologist ("the Adviser").

3. The Adviser was asked to consider whether, without the benefit of hindsight, the care and treatment had been appropriate in the situation complained about. I determine whether the standard of care was appropriate by making reference to relevant national standards or regulatory, professional or statutory guidance which applied at the time of the events.

4. I have not included every detail investigated in this report, but I am satisfied that nothing of significance has been overlooked.

5. Both Mrs L and the Health Board were given the opportunity to see and comment on a draft of this report before the final version was issued.

Relevant guidance, legislation and literature

6. Reference is made within this report to the following national guidance:

- British Society of Gastroenterology ("BSG"): UK guidelines for the management of acute pancreatitis 1998 ("the BSG Pancreatitis Guidelines"). These guidelines address the initial steps in diagnosis, investigation and treatment of acute pancreatitis. Specifically, it states that an ultrasound examination of the abdomen might be helpful in confirming a diagnosis but cannot be used for a definitive diagnosis. A computerised tomography scan ("CT scan" - the use of X-rays and a computer to create an image of the inside of the body) is also recommended when there is diagnostic uncertainty.

- BSG: UK guidance on re-starting endoscopy services during the COVID-19 pandemic ("the BSG Endoscopy Guidance") April 2020. This guidance outlines when emergency procedures should still go ahead.

- Steroid Induced Pancreatitis: A Challenging Diagnosis (2020) ("the Case Study"). This case study concluded that increasing doses of steroids may increase the risk of acute pancreatitis.

- Welsh Government - The Duty of Candour Statutory Guidance (2023). This guidance requires local health boards in Wales to talk to service users about incidents that have caused harm, apologise and support them through the process of investigating the incident, and then to learn and improve and find ways to stop similar incidents happening again.

- Public Services Ombudsman for Wales: Groundhog Day 2 - An opportunity for cultural change in complaint handling? (2023). This thematic report built on my predecessor's report from 2017 ("Ending Groundhog Day - Lessons in Poor Complaint Handling"), focusing on how our complaints standards training and the requirements of the Duty of Candour provide a fresh opportunity for change to the ways health boards engage with their patients and respond to complaints.

- Welsh Government National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Regulations") and accompanying Putting Things Right guidance ("the PTR Guidance"). The Regulations set out specific actions that health bodies should complete when considering complaints, together with timescales for completion. The PTR Guidance says that there may be occasions when it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. This may include, for example, obtaining a second opinion to aid a patient's understanding of the care they have received.

The background events

7. Mrs K underwent a cholecystectomy (a procedure to remove the gallbladder) in **2013**. She was also known to have rheumatoid arthritis, psoriatic arthropathy (a type of arthritis linked to chronic skin disease) and primary biliary cholangitis (autoimmune disease in which the bile ducts become inflamed and destroyed).

8. On 31 December **2020** Mrs K was admitted to Wrexham Maelor Hospital ("the Hospital") with stomach pains and a raised temperature. She was seen by a consultant in colorectal surgery ("the First Consultant") and was treated conservatively for steroid induced pancreatitis (inflammation of the pancreas) with antibiotics and a double dose of prednisolone (a steroid to reduce inflammation). Mrs K's condition improved and, after stopping antibiotics, she was discharged on 5 January **2021** with instructions to come back for an ultrasound on 8 January. Mrs K was prescribed 10mg of prednisolone, but this was to be reduced over time.

9. Mrs K underwent an ultrasound on 8 January which did not show any biliary obstruction. Mrs K was discharged back to the care of her GP with instructions to carry out monthly blood tests. Mrs L said these were carried out at home by Mrs K's GP.

10. In August, Mrs K appeared jaundiced, and she saw her GP. She was referred to the Gastroenterology Team on 3 September as her blood tests identified elevated liver enzymes (high levels indicate inflammation). Mrs K underwent a CT scan which showed a gallstone in the common bile duct.

11. Mrs K, accompanied by Mrs L, saw a consultant gastroenterologist ("the Second Consultant") in an outpatient clinic on 6 October. She reported recurrent episodes of abdominal pain and a high temperature since her pancreatitis episode in December. Mrs K was noted to be in a poor physical condition and had limited mobility. Mrs K had been given a number of courses of antibiotics and was due to finish a second course of ciprofloxacin (a broad-spectrum antibiotic to treat bacterial infections) the following day. The Second Consultant explained to Mrs K her options to manage her bile duct stones:

- she could do nothing

- attempt an endoscopic retrograde cholangiopancreatography ("ERCP" - an examination of the pancreatic and bile ducts using a thin tube with a light and camera on the end) to try and remove the stone

- an ERCP to put a stent in to prevent bile duct blockage or laparoscopic surgery (a type of keyhole surgery using a camera) to try and remove the stone.

12. The Second Consultant explained to Mrs K the risks and benefits of each option and that she was at very high risk of not surviving the operation in view of her mobility. Additionally, in view of her immunosuppression for her rheumatoid arthritis, Mrs K was at risk of infections causing further significant complications. The Second Consultant said he would also speak to a consultant surgeon regarding Mrs K's options, and he would see her again in a few months.

13. On 15 October Mrs K was admitted to the Hospital by her GP owing to a high temperature, vomiting and pain in her upper abdomen. Mrs K was diagnosed with biliary sepsis. Mrs K underwent an ERCP procedure

on 3 November. It was not possible to remove the bile duct stone owing to its size, so 2 stents were placed to assist the flow of bile into Mrs K's small bowel. The plan was to repeat the ERCP in 8 weeks. Mrs K was discharged on 5 November.

14. Mrs K's liver enzymes were noted to be at normal levels on 22 November, 20 December and 17 January **2022**.

15. On 25 January Mrs K was admitted to the Hospital with further sepsis and COVID-19. The plan to carry out a further ERCP on 26 January was therefore deferred. Mrs K's condition subsequently deteriorated and sadly, she died on 31 January. Her death certificate noted biliary sepsis with rheumatoid arthritis and COVID-19 as contributing factors.

16. Mrs L complained to the Health Board in April. The Health Board responded on 26 August. Mrs L approached me in December.

Mrs L's evidence

17. Mrs L said that there had been opportunities to treat the stones in her mother's bile duct sooner and that her condition was not treated as the medical emergency it should have been.

18. Mrs L said that her mother was not given a discharge letter on 5 January 2021 with information about the bile duct stones or information about how her condition should be monitored and treated. Mrs L said that there was no follow-on care for the 2 stents her mother had fitted in November.

The Health Board's evidence

19. The Health Board said that, although the ultrasound carried out in January 2021 was difficult, there was no evidence of a blocked bile duct at the time. As Mrs K had previously undergone a cholecystectomy, had a normal liver function test ("LFT") prior to admission and had normal LFTs following discharge on 19 January, the likelihood of residual biliary stones was not considered "very high" and an invasive procedure such as an ERCP was not felt to be justified at the time.

20. The Health Board said that the subsequent CT scan and ultrasound in September and October 2021 did show evidence of a blocked bile duct, though it was not totally blocked as Mrs K was not jaundiced and her blood tests did not raise any concerns until September.

21. The Health Board said that there was no indication for Mrs K to undergo an ERCP until the scans evidenced the blocked bile ducts. There was also no indication for these scans until the blood tests in September showed significantly raised liver enzymes, having been normal in April and May. Mrs K underwent her CT scan on 11 September and was seen in clinic just under 4 weeks later. The Health Board said that even had Mrs K been seen earlier, it was debatable whether her ERCP would have taken place sooner. Following her ERCP, the Health Board wrote to Mrs K's GP with details of her care and treatment and the need for a repeat ERCP in 6-8 weeks.

The Health Board's comments on the Ombudsman's Professional Advice

22. Following receipt of the Adviser's advice I shared it with the Health Board. Despite its critical nature, the Health Board's position remained unchanged. It said that as Mrs K had normal LFTs before and after her admission in January 2021, the likelihood of residual biliary stones was not considered to be "very high". The ultrasound was not reported by the Ultrasonographer as "inadequate". The Health Board continued that the diagnosis of "steroid induced pancreatitis" was reasonable in the absence of excess alcohol intake coupled with Mrs K's intake of oral steroids and her not having a gallbladder. Overall, the Health Board commented that it felt the Adviser's comments had been made with the benefit of hindsight and were not supported by the evidence base.

Professional Advice

23. The Adviser said that Mrs K presented with acute pancreatitis in January 2021. He said that whilst the BSG Pancreatitis Guidelines for managing acute pancreatitis were applied generally, there was a very significant deficiency in how the Health Board dealt with Mrs K. The

Adviser said that the ultrasound that Mrs K underwent was inadequate. He said that the point of the ultrasound was to rule out gallstones as a possible cause for Mrs K's pancreatitis. This was a significant issue for Mrs K, as she had previously had a cholecystectomy, but critically there had been a procedure to explore her bile duct for a previous bile duct stone. As such, the probability of her January 2021 pancreatitis being caused by gallstones was very high. The Adviser said that the ultrasound did not see the bile duct owing to overlying bowel gas and the report did not comment on the presence or absence of bile duct dilatation (widening) within the liver. He said that the Clinical Team appear to have accepted this as a "normal" examination. The Adviser said that the diagnosis the Clinical Team arrived at, steroid induced pancreatitis, while being possible, seemed highly unlikely in the clinical context.

24. The Adviser said that steroid induced pancreatitis is a very rare condition and, given Mrs K had been treated on a number of occasions previously with steroids for her arthritis, he did not believe she met the criteria for its diagnosis (see the Case Study, paragraph 6). He added that there was no doubt that, if further imaging by magnetic resonance imaging ("MRI" - the use of strong magnetic fields and radio waves to produce detailed images of the inside of the body) or endoscopic ultrasound had been undertaken in January/February 2021, the common bile duct stone which caused Mrs K's pancreatitis would have been seen at that time. The Adviser said that accepting an inadequate ultrasound examination as "normal" in this clinical context was not an appropriate standard of care. He added that if a diagnosis of steroid induced pancreatitis was thought to be correct, then treating it with a double dose of steroids was incomprehensible.

25. The Adviser said that if a diagnosis of gallstones in the bile duct had been made in January/February 2021, then Mrs K should have been offered an ERCP. Given that Mrs K presented with pancreatitis this would have been an urgent procedure and therefore, even with the COVID-19 restrictions on endoscopy services (the BSG Endoscopy Guidance) she would have accessed an ERCP within a few weeks. The Adviser said this would then have avoided the jaundice and episodes of infection which occurred until she presented again to her GP in August. He said Mrs K's

episodes of infection were cholangitis which was a direct result of a gallstone blocking bile flow out of the bile duct and allowing bacterial infection to lodge in the bile duct.

26. The Adviser said that monthly blood tests were not an appropriate way to monitor Mrs K's condition following her discharge on 5 January. Her underlying primary biliary cholangitis would also potentially elevate her liver enzymes. Liver enzyme abnormalities are not a good predictor of the risk of cholangitis. Mrs K should have undergone proper investigations and had the problem dealt with in January 2021.

27. The Adviser said that he would also be critical of the delay which occurred following Mrs K's presentation to her GP in August with jaundice and being seen in clinic in October. He said jaundice is a "2-week-wait" symptom and Mrs K should have been referred on a cancer pathway. Even if the cause was not cancer, the underlying pathology in someone like Mrs K who was jaundiced could be serious. He added that gallstone obstruction of the bile duct also carries a high mortality rate if untreated, particularly in someone on high levels of immunosuppression.

28. The Adviser said that Mrs K's admission to the Hospital on 15 October owing to cholangitis, and before the ERCP procedure, would have been avoided by either the initial January admission being properly investigated, or a 2-week wait referral being made in August. He added that there was a delay before Mrs K underwent the ERCP, between 20 October and 3 November. He said that, although this was a long wait for someone with a potentially life-threatening illness, it was probably just within the bounds of acceptable practice considering Mrs K was being treated with antibiotics and seemed clinically stable.

29. The Adviser said that Mrs K's ERCP procedure was carried out appropriately. It is not always possible to remove large gallstones from the bile duct during the first procedure. The placement of a stent is usually successful, however, there is small chance (10%) of developing further cholangitis which, sadly, Mrs K did before a further ERCP could take place. The Adviser added that an interval of 3 months to carry out a follow-up ERCP was not unreasonable.

30. The Adviser concluded that there were significant issues with Mrs K's investigations in January 2021. He said that the Health Board needed to recognise this, and that with appropriate investigations and interventions at the time, Mrs K would have almost certainly been treated successfully and not died when she did. He added that the Health Board did not explain the seriousness of the diagnosis clearly when it was made during her admission in October and did not communicate to Mrs K and Mrs L the potential seriousness of cholangitis in someone with background liver cirrhosis and who was immunosuppressed.

The Adviser's views on the Health Board's comments

31. The Adviser reviewed the Health Board's comments on his advice. He said he had considerable concerns that the Health Board's views reflected neither expert opinion nor showed adequate reflection. He said the ultrasound report clearly did not answer the clinical questions posed which were: "is there bile duct dilatation?" and "are there gallstones visible with the bile duct?" The common bile duct was not seen and there was no comment on the intrahepatic duct (within the liver) calibre (its quality) at all. The Adviser said that to assume "no comment" was normal is not justifiable. Ultrasonographers rarely, if ever, report investigations as "inadequate", it is therefore up to the expertise of the referring team to decide if the investigation and its report have answered the clinical questions posed. The Adviser said that he did not think there could be any realistic debate that it did not, and that further imaging to exclude bile duct stones was mandated here.

32. The Adviser added that most people presenting with gallstone pancreatitis have already passed their bile duct stone or will do so without further problems. This does not negate the need to prove whether the stone causing the pancreatitis is still in place. This requires adequate imaging which Mrs K did not have. If a stone is still present in the bile duct on imaging, then removal would normally be recommended. This is not because it will alter the outcome of the present episode of pancreatitis but because it will prevent further later complications, recurrent pancreatitis or cholangitis.

Analysis and conclusions

33. Firstly, I would like to offer my condolences to Mrs L on the sad loss of her mother.

34. The advice I have received is very clear, which is why I have set it out in some detail above. This enables me to be relatively brief in what I have to say here. While accepting that advice in full, the findings set out below are my own. I will address each of Mr L's concerns in turn.

Whether, following Mrs K's discharge from hospital in January 2021, monthly blood tests were an appropriate way to monitor her condition

35. Before I consider whether monthly blood tests were an appropriate way to monitor Mrs K's condition following her discharge from the Hospital in January 2021, I must consider the decisions surrounding Mrs K's ultrasound. Although this specific complaint was agreed with Mrs L at the start of this process, it was the Adviser who raised concerns about the ultrasound when he was asked to comment on the overall care Mrs K received from January 2021 until her sad death.

36. Performing an ultrasound in January 2021 was in line with BSG Pancreatitis Guidelines, however, the ultrasound report is clear that the bile duct was not visible. It could not therefore be seen whether gallstones were present, and I accept the advice that further imaging was required to rule that out. This did not happen. Owing to Mrs K's previous medical history, it seems most likely that her pancreatitis was caused by gallstones, and it was a significant service failure that this was not determined in January 2021, and she was misdiagnosed. I am also concerned that, having shared the Adviser's comments with the Health Board, it remains of the view (paragraph 22) that the outcome of the ultrasound was acceptable and that gallstones were unlikely.

37. The failure to identify Mrs K's gallstones in January 2021 was, in my view, unacceptable and a service failure. I accept the advice that this failure by the Health Board caused Mrs K a continued injustice as her condition remained untreated. In saying this, I am mindful that the episode of care happened during a time when there were still some restrictions in place as a result of the COVID-19 pandemic. As set out in

my Clinical Standards,[1] in arriving at any conclusions, I take full account of the impact that the restrictions in place because of the pandemic would have had. Having done so, I am reassured by the Adviser's comment in paragraph 25 that, even with the COVID-19 restrictions on endoscopy services, Mrs K would have accessed an ERCP within a few weeks.

38. Mrs K subsequently developed jaundice and cholangitis and she endured further delays (paragraphs 27 and 28) before she finally received 2 stents in November. This, however, did not fully resolve Mrs K's condition as she sadly died 6 days after being re-admitted on 25 January 2022. These were further missed opportunities by the Health Board to identify sooner the seriousness of Mrs K's condition.

39. Overall, I am saddened to conclude that, had Mrs K been treated appropriately at the outset, her acute pancreatitis would have been treated successfully and on balance, her deterioration and death might have been prevented. This is a grave injustice, not just to Mrs K, but as an enduring source of distress for Mrs L and her family. It therefore follows that monthly blood tests were not an appropriate way to monitor Mrs K's condition upon her discharge, as there were clearly more appropriate investigations that should have taken place and for that reason I **uphold** this part of the complaint.

Whether there was a lack of follow-up care for Mrs K following a biliary stent being fitted in November 2021

40. As I have identified above, the 2 stents fitted in November were carried out too late for Mrs K, although the procedure was performed to the required standard. However, a further ERCP was scheduled for 8 weeks' time, and I accept that this was a reasonable amount of time for Mrs K to wait. Therefore, I **do not uphold** this complaint.

41. However, I agree with the Adviser (paragraph 30) that there is little to no evidence that the seriousness of Mrs K's condition was appropriately communicated in October to her and her family, including Mrs L, either before or after the ERCP procedure. By November, Mrs K was extremely unwell, and although her chances of developing further cholangitis were,

[1] Clinical Standards - Public Services Ombudsman Wales

in the Adviser's opinion, small, she did develop cholangitis and biliary sepsis prior to her death. This poor communication compounds the injustice for Mrs L that the care and treatment her mother received during the period in question was below the required standard. Although it was not specifically outlined within the scope of the complaint (paragraph 1), I **invite** the Health Board, and relevant clinicians, to consider how they can better ensure patients are fully informed of the seriousness of their illnesses and possible outcomes.

42. I am also concerned at the Health Board's seeming lack of candour in its complaint response to Mrs L, and its lack of objective reflection even during this investigation when it had sight of my Adviser's advice. It is disappointing that the Health Board has still failed to identify and acknowledge the failings in Mrs K's care. In my thematic report on complaint handling last year (see paragraph 6) I recommended that health boards consider whether to provide staff investigating complaints with independent medical advice to provide an independent clinical view to inform complaint responses. It is my view that the Health Board should have undertaken this option as Mrs K's death should have prompted a thorough review. Although not specifically outlined within the scope of the complaint, I will be recommending that the Health Board reviews its handling of Mrs L's complaint in line with its Duty of Candour.

Recommendations

43. I **recommend** that the Health Board, within **1 month** of the date of this report:

a) Provides Mrs L with a fulsome apology, from the Chief Executive, for the failings identified in this report. The apology should make reference to the clinical failings, the impact of these on Mrs K's outcome and the impact on Mrs L and her family.

b) Offers Mrs L financial redress in the sum of £4,000 reflecting the serious failings I have found and the resulting and lasting significant impact upon her and her family.

44. I **recommend** that the Health Board, within **4 months** of the date of this report:

c) Reviews this case, in line with its legal requirements under the Duty of Candour, to determine how Mrs K's presentation in January 2021 was misdiagnosed owing to inadequate assessment/imaging. The Health Board should then report its findings to its Quality and Patient Safety Committee and include its findings in its Annual Report on the Duty of Candour.

d) Shares this report with the Clinical Director responsible for the relevant consultants involved in Mrs K's care so that its findings are reflected upon and directly discussed with those consultants as part of their regular supervision.

e) Reviews its handling of Mrs L's complaint in line with the Duty of Candour. Any improvements it identifies should be fed back into its complaints handling procedure and shared with my office.

45. I am pleased to note that in commenting on the draft of this report **the Health Board** has agreed to implement these recommendations.

Michelle Morris

Michelle Morris 15 August 2024
Ombwdsmon Gwasanaethau Cyhoeddus/Public Services Ombudsman

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