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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: 202301141

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Introduction

This report is issued under s.23 of the Public Services Ombudsman (Wales) Act 2019.

We have taken steps to protect the identity of the complainant and others, as far as possible. The name of the complainant and others has been changed as well.

Summary

Ms A complained about the care she received from Betsi Cadwaladr University Health Board ("the Health Board") and Liverpool University Hospitals NHS Foundation Trust ("the First English Trust"). Her concerns included her management and care following surgery for her inflammatory bowel disease in 2019, whether she was properly consented for surgery to address her fluid collections and pelvic infection in March 2022, as well as the post-operative care and treatment and the handling of her complaint.

The investigation found that following Ms A's surgery in 2019 the Health Board's management of her post-operative fluid collections was appropriate, but there were failings in the colorectal care provided by the First English Trust. The Ombudsman noted that Ms A should have been reviewed and monitored more closely, although it could not be definitively said that this would have prevented sepsis.

The Ombudsman also found issues with gynaecological referrals made to another NHS Trust, the appropriateness of an investigative procedure and the lack of preventative antibiotics given. These failings led to persistent infection and ill health for nearly 3 years before definitive surgical treatment in March 2022.

The investigation identified shortcomings in the consent process, and the Ombudsman concluded that Ms A did not give informed consent for the surgery in March 2022. This raised human rights considerations, particularly regarding personal autonomy and the right to respect for private and family life. The injustice for Ms A included not having an opportunity to reconcile herself to the likely outcome of the surgery or to explore options to have biological children in the future. The impact on Ms A, both physically and psychologically, was significant.

The investigation also highlighted a failure to provide information and advice about hormone replacement therapy, leaving Ms A to experience menopausal symptoms without clear management.

In respect of the handling of Ms A's complaint, the Ombudsman found delays in complaint handling but did not consider the delay unduly excessive. The Health Board relied on the First English Trust to handle parts of the complaint which it was able to do, but there were shortcomings in the First English Trust's response.

The Ombudsman was concerned that in its contract monitoring of commissioned care, the Health Board prioritised financial reporting over patient safety and service quality. She considered that effective contract monitoring might have prevented some failings in Ms A's care.

The Ombudsman made a number of recommendations, which the Health Board accepted.

Within **1 month**:

a) Apologise to Ms A for the failings identified in the report.

b) Share the report with the Chair of the Health Board and the other Board members and its Patient Safety and Clinical Governance Group.

Within **2 months**:

c) As part of its commissioning arrangements, request the First English Trust undertake and evidence the following:

i. a review of Ms A's case to see what additional learning could be identified to improve the patient experience;

ii. a reminder to its clinicians of the relevant guidance around informed consent and their professional obligations when it comes to record keeping to ensure that discussions with patients are documented;

iii. as a point of learning, it shares with clinicians an anonymised case study of the clinical failings identified in the case at an appropriate clinical forum;

iv. the Colorectal Surgeon is asked, as part of learning and reflection, to share a copy of this report and discuss the steps that she has put in place to improve her clinical practice at her next professional revalidation;

v. a copy of the report is shared at its relevant patient safety governance committee.

In addition, the Health Board should:

d) Seek written assurances from the First English Trust's Chief Executive that it has taken steps to address the clinical failings identified in the report.

e) Share the compliance evidence relating to recommendations c) and d) with the Ombudsman's office.

Within **6 months**:

f) Prioritise, complete and implement a Commissioning Assurance Framework.

The Complaint

1. Ms A complained about care she received from Betsi Cadwaladr University Health Board ("the Health Board") and also care commissioned by the Health Board from an NHS Trust in England, the Liverpool University Hospitals NHS Foundation Trust ("the First English Trust"). The investigation looked at whether Ms A received:

a) Appropriate review and treatment of her post-operative fluid collections and pelvic sepsis (when the body overreacts to an infection originating in the pelvis, causing damage to the organs and tissue) following surgery in 2019, including adequate gynaecological input.

b) Sufficient time and information to understand and consider the risks of the surgical removal of her post-operative fluid collections in March 2022, and to give her fully informed consent before this surgery was carried out.

c) Prompt and appropriate investigation and treatment for her pain and reduced kidney function following surgery.

d) Timely and appropriate information about her hysterectomy (surgery to remove the womb), including advice about post-operative recovery, the menopause and options for hormone replacement therapy ("HRT" – treatment that can help relieve menopause symptoms).

2. The investigation also considered whether the Health Board dealt with Ms A's complaint in line with the National Health Services (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

Investigation

3. As part of the investigation, we obtained comments and copies of relevant documents from the Health Board, Liverpool University Hospitals NHS Foundation Trust ("the First English Trust") and Liverpool Women's NHS Foundation Trust ("the Second English Trust") to which Ms A was referred by the First English Trust, and considered those in conjunction

with the evidence provided by Ms A. [In late 2024 an organisational restructure led to the First and Second English Trust coming together under a Group structure. However, this report reflects the position at the time of the events in question.]

4. We also obtained professional advice from 2 of my Professional Advisers, Mr Misra Budhoo, a consultant general and colorectal surgeon ("Colorectal Adviser") and Mr Nitish Narvekar, a consultant obstetrician and gynaecologist ("Gynaecology Adviser"). My Advisers were asked to consider whether, without the benefit of hindsight, the care or 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 complained about. We have not included every detail investigated in this report, but I am satisfied that nothing of significance has been overlooked.

5. The Health Board has commissioning arrangements in place with the First English Trust, under the terms of an "NHS Standard Contract", which I have considered. As a Welsh patient receiving treatment commissioned by a Health Board in Wales, Ms A's treatment falls within my jurisdiction as set out in Schedule 3 of the Public Services Ombudsman (Wales) Act 2019.

6. The NHS complaints process should not be seen as operating in isolation. A key part of the investigation was to look more widely at the interaction between the complaints process (referred to at paragraphs 2 and 19) and the Health Board's contract monitoring process. This was to ensure that the monitoring in place was sufficiently robust to support the way that the complaints process works with commissioned services.

7. Both Ms A, the Health Board and the First and Second English Trust were given the opportunity to see and comment on a draft of this report before the final version was issued.

Relevant legislation/guidance

8. Article 8 of the European Convention on Human Rights, as enshrined in UK law by the Human Rights Act 1998 ("the HRA"), deals with the right to respect for an individual's personal autonomy and private and family life. It also protects an individual's right to control of their body, health and treatment. Although Article 8 is not an absolute right (as a qualified right it can involve the weighing up and balancing of competing rights), a failure to obtain informed consent could contravene Article 8.

9. The FREDA Principles: a set of guiding principles (Fairness, Respect, Equality, Dignity and Autonomy) which were developed to help NHS organisations and clinicians treat patients and their loved ones in a way that protects and respects their human rights.

10. It is not part of my function, as Ombudsman, to make definitive findings about whether a public body has breached its duties under the HRA. However, when considering whether there has been maladministration or service failure on the part of a public body, as Ombudsman I may consider whether human rights have been engaged. I can then comment on whether public bodies have had regard to human rights considerations while performing their functions.

11. My office has issued statutory guidance relating to the "Principles of Good Administration" (2008, updated 2016 and again in 2022) ("the Guidance"), to which bodies within my jurisdiction are also expected to have regard, in order to deliver good administration and customer service. The Guidance sets out the principles of good administration that public sector providers are expected to adopt when it comes to service delivery and dealing with service users. These principles include, for example, public bodies being open and accountable by taking responsibility for their actions. The most recent update reinforces that in commissioning services, a public body should ensure there are "robust governance arrangements in place" since as the body with statutory responsibility for delivering the service, they remain accountable for it, regardless of who is delivering the service in practice.

12. Clinically, my Advisers and I have considered the following guidance from the National Institute of Health and Care Excellence ("NICE"):

- NG125: "Surgical site infections: prevention and treatment" (August 2020) which notes that patients should be given clear, consistent information and advice about wound management throughout all stages of their care.

- NG180 "Perioperative care in adults" (August 2020) which states that patients should be given a point of contact to provide information and support before and after their surgery. It also recommends offering an enhanced recovery programme to people having elective major or complex surgery (such as hysterectomy).

- NG23 "Menopause: diagnosis and management" (December 2019) sets out the management and information to be provided to patients prior to menopause triggering surgery (such as a hysterectomy).

13. In addition, the General Medical Council has produced various guidance for doctors on consenting patients. The 2013 "Good Medical Practice" guidance sets out what is required in terms of the consenting process for doctors to be satisfied they have valid consent from a patient for an investigation or treatment. The 2020 guidance on "Decision-making and consent" expands on this.

14. The guidance requires the discussion on consent to be documented. Where the consenting process is delegated to another person, it says what level of knowledge and training is required of that person. The guidance also makes it clear that the delegating doctor is still responsible for ensuring that the patient has been properly consented.

15. Other guidance such as "Consent: supported decision-making, a Guide to Good Practice" (November 2018), issued by the Royal College of Surgeons, reiterates the need for the consent process to begin "well in advance of the treatment" and that more than 1 discussion may be required for particularly complex or life-changing discussions. It confirms that just because a patient signs a consent form does not mean that legally valid consent for treatment has been obtained.

16. “Obtaining Valid Consent Clinical Governance Advice No. 6” (January 2015), issued by the Royal College of Obstetricians and Gynaecologists (“RCOG”), says that as part of the consenting process, if written consent is to be taken immediately before the operation, the patient must have been given the opportunity to discuss any intervention in a clinic or preoperative assessment unit visit. Otherwise, patients should be advised that they can defer or postpone their treatment to have more time to consider. If the patient’s ovaries are removed without appropriate consent, the doctor should record their decision-making, and reasoning, and ensure that the patient is informed of the event, and why it occurred, as soon as is practical.

17. Other RCOG guidance such as “Abdominal hysterectomy for benign conditions, Consent Advice No. 4” (May 2009), stresses the importance of patients being aware of the nature of the procedure and that the patient’s preferences, in relation to removing or leaving the ovaries alone should be documented, if it is not certain that the ovaries will be removed. The guidance notes that patients should also be advised about the potential psychological and physical impact of the procedure (for example in terms of fertility, sexual and bladder function, and the menopause).

18. Although the NICE and other guidance referred to above is not mandatory, clinicians are expected to have regard to relevant guidance as part of their clinical decision-making. In the event that the decision is made to depart from guidance then the rationale for doing so should be clearly documented.

19. Finally, in terms of the complaints process, I have considered the Welsh Government National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 and accompanying “Putting Things Right” guidance (collectively known as “PTR”). These set out the timescale for a complaint response. They also confirm that complaints about care provided by an English body that has been commissioned by a Welsh body should be dealt with through the English body’s own complaints procedure. However, if it becomes apparent that any care provided or arranged by the English body may have caused

harm to a patient, the English body must notify both the NHS Litigation Authority and the Welsh commissioning body. It is then for the Welsh body to consider whether any harm has been caused and take action as appropriate, although the 2 bodies should co-operate.

The background events

20. In **2016** Ms A, who has a history of chronic inflammatory bowel disease ("Crohn's disease"), had a subtotal colectomy (where the large bowel is removed) at Ysbyty Glan Clwyd ("the Welsh Hospital"). In June **2019** due to recurrent bleeding, Ms A underwent a proctectomy (surgery to remove her rectum and anal canal) at the First English Trust's Royal Liverpool University Hospital ("the English Hospital"). A percutaneous (through the skin) drain was inserted to treat an internal collection of fluid which had developed; a computerised tomography scan ("CT scan" - the use of X-rays and a computer to create an image of the inside of the body) showed that the collection had reduced, and Ms A was discharged on 2 July.

21. On 10 July Ms A attended the Welsh Hospital complaining of pain and feeling generally unwell; a CT scan confirmed that she still had a fluid collection, but it was decided not to intervene because of its small size. Ms A attended a follow-up appointment at the English Hospital on 27 August, when the colorectal surgeon responsible for her care ("the Colorectal Surgeon") noted Ms A's ongoing pain and recurrent fluid collections and planned to carry out blood tests and a further CT scan.

22. On 7 October Ms A returned to the Welsh Hospital again complaining of ongoing pain. Another CT scan showed that the fluid collection had slightly increased; it was described as a complex infection collection in the space in front of Ms A's coccyx and sacrum (bones at the base of the spine). Ms A was advised to wait for her next planned appointment at the English Hospital for review of the collection and appropriate treatment. On 30 October the Colorectal Surgeon wrote to Ms A informing her that there was "no collection seen" on her most recent CT scan and arranging to see her again in 3 months' time.

23. Ms A attended the Welsh Hospital again on 12 December complaining of pain and feeling unwell and "shivery". As the fluid collection was persisting and forming pockets within Ms A's pelvis, a drain was inserted, which reduced the collection. Ms A was discharged on 16 December with the drain still in place.

24. Ms A went to the Welsh Hospital again on 19 December reporting more pain and feeling unwell; the collection was still there and there was now infection at the drainage site. Ms A was admitted as an inpatient. On 22 December the drain was flushed out, but it was not draining much fluid. It was decided to treat Ms A with intravenous ("IV") antibiotics for which she required further interventions. A CT scan on 6 January **2020** showed there was no improvement in the collection and Ms A continued on longer-term IV antibiotics. She was eventually discharged on 15 January and arrangements were made for her to have a further 3-week course of IV antibiotics.

25. Ms A was reviewed by a gastroenterologist ("the Gastroenterologist") at the English Hospital in February when she complained of continuing pain and also urinary incontinence. An ultrasound scan (the use of high-frequency sound waves to create an image of the inside of the body) showed that Ms A had a prolapsed uterus (when the uterus slips down and bulges into the vagina) and a cyst within the area, although it was noted that the cyst had been present on previous scans and appeared unchanged. The Gastroenterologist sent a referral to the Gynaecology department of the Second English Trust on 4 March.

26. A further referral to Gynaecology at the Second English Trust was made by a urologist on 6 August **2021**, when it was noted that a CT scan had also revealed a polyp (a growth attached to the inner wall of the uterus that expands into the uterus) in Ms A's uterine cavity. Also, on 19 August the Colorectal Surgeon made a referral to a consultant gynaecologist at the Second English Trust ("the Gynaecologist" is also an Oncologist within the Oncology team). The referral noted that the top of Ms A's uterus was now possibly affected by the infection and requested a gynaecology view be obtained before proceeding to general surgery to clear the infection. On 29 October a further letter was sent to the Gynaecology department, noting that it was possible Ms A's ovaries were also affected and requesting the appointment be expedited.

27. On 16 November the Colorectal Surgeon wrote again to the Gynaecologist asking him to review Ms A's scans and see her urgently. It was noted that Ms A was unable to tolerate a magnetic resonance imaging scan ("MRI scan" - the use of strong magnetic fields and radio waves to produce detailed images of the inside of the body) owing to claustrophobia and it was suggested that the best way to proceed might be an operation with general and gynaecological involvement to clear the infection.

28. The Gynaecologist sought input from a consultant radiologist, who responded on 29 December. He had reviewed Ms A's scans and identified possible fluid build-up in her fallopian tubes and evidence of potentially infectious pockets of fluid, as well as the polyp in the inner lining of Ms A's uterus. He suggested it might be possible to try an MRI scan again with sedation.

29. The Second English Trust arranged for Ms A to undergo a hysteroscopy (where a thin lighted tube is inserted into the uterus with a camera), which would also look at whether to remove the polyp, on 22 January **2022**. The procedure could not be completed because it caused Ms A too much pain. It was noted that Ms A's uterus and cervix were pushed backwards and stuck to the front of her sacrum.

30. Later that month, Ms A was admitted to the Welsh Hospital again with pain and generally feeling unwell. A CT scan showed that she had a mass in her pelvis which was suspected to be a chronic abscess, with a thick capsule (made up of surrounding healthy cells, a wall of tissue surrounds the abscess to stop it infecting neighbouring structures) preventing further percutaneous drainage. The Welsh Hospital contacted the Colorectal Surgeon, who advised that Ms A should be admitted to the English Hospital for surgery to remove the collection. Ms A was discharged from the Welsh Hospital with another drain in place.

31. In early March Ms A received a telephone call from the Colorectal Surgeon; the telephone call was not documented by the Colorectal Surgeon, and the content of the discussion is disputed. On 9 March Ms A was admitted to the English Hospital for surgery to remove the collection. She signed a consent form (at 8:31) that morning, which was completed by a registrar training in colorectal surgery ("the Registrar"). The consent form noted that the operation might involve a total abdominal

hysterectomy and removal of both Ms A's ovaries; it listed the intended benefits of surgery, with the significant, unavoidable or frequently occurring risks also documented. These included bleeding, infection (which was detailed), menopausal symptoms (only if both ovaries were removed) and death. In terms of alternative treatment this was listed as antibiotics, radiological drainage of the tubo-ovarian abscess (a procedure to drain the abscess/inflammatory mass that develops in a fallopian tube and ovary) and no treatment. There was no separate documented consenting discussion note.

32. At 13:03, Urology carried out a procedure where bilateral stents were inserted into Ms A's ureters (a stent is a thin flexible tube that keeps open the ureter, a duct which carries urine from the kidney to the bladder) to allow for identification of the ureters in the surgery that followed.

33. The surgical operation notes indicate that the Colorectal Surgeon was the lead surgeon, supported by the Gynaecologist and the Registrar. Ms A underwent a full hysterectomy and the removal of both fallopian tubes and ovaries as well as the clearance of the collection. The bilateral ureteric stents were subsequently removed. Later, Ms A was given antibiotics and pain relief on the ward; the Registrar did not note any concerns when he reviewed Ms A the following day. A pain review noted some abdominal pain, and that Ms A was unable to breathe deeply or cough, and pain relief was continued.

34. On 12 March nursing staff recorded that Ms A complained of back pain and that she could be given pregabalin (medication used in the relief of nerve pain). It was noted that her urine was still quite blood-stained, although a good amount was being passed. Later that day, Ms A's pain seemed "a lot less severe", although by the evening nurses noted that she still had back pain when she was in bed. The following day, a doctor noted that Ms A reported left-sided "flank pain" (which generally refers to the upper abdomen, back and sides); nursing staff noted that Ms A continued to report pain, which was worse when sitting in a chair. Ms A was able to mobilise to the toilet and around her bed independently.

35. On 15 March a doctor noted that Ms A complained of back pain and was having difficulty mobilising. A pain review noted that Ms A described a "stabbing twisting sensation sometimes radiating from left to right". By the evening, nursing staff noted that Ms A's back pain was severe and uncontrolled, radiating from her lower back to both her sides, and she was unable to remain still in bed. An urgent CT scan in the early hours of 16 March showed that both Ms A's kidneys were swollen with a build-up of urine, and a urine test showed evidence of infection.

36. A referral was made to Urology, and on 17 March stents were inserted to allow urine to drain from Ms A's kidneys to her bladder. Ms A was discharged on 19 March with outpatient reviews planned with Urology and the Colorectal Surgeon.

Complaint handling

37. Ms A submitted a complaint to the First English Trust via her Advocate and copied it to the Health Board in August 2022. Internal emails confirmed that the Health Board would only respond to the concerns about the Welsh Hospital, as Ms A's other concerns had already been forwarded directly to the First English Trust.

38. In its response to Ms A, dated 28 October, the Health Board said that non-surgical treatment of Ms A's fluid collections was recommended when she first presented because it was only 4 weeks after her surgery. When she returned to the Welsh Hospital in October [2019] it advised waiting for her planned review because her symptoms at that time were "minimal". It apologised for the pain and discomfort Ms A experienced when the drains were inserted in December, but said it was agreed to continue treatment given that she was responding to the antibiotics.

39. The First English Trust responded to Ms A's complaint in February **2023**. In its complaint response it said that further surgery was not recommended for 3-6 months following a major operation because of the risk of complications. It said that Ms A's case was discussed extensively at multi-disciplinary team meetings, and that surgery was arranged as soon as it was felt that the benefits outweighed the risks.

40. The First English Trust apologised that the operation, and the possibility that Ms A might need a hysterectomy, was not discussed "closely enough" with her before her surgery. The Colorectal Surgeon had said that this, and the possibility of triggering early menopause, were "likely" discussed during the telephone conversation in early March. The First English Trust added that this "will" have been included as part of the discussion around hysterectomy and removal of the ovaries but acknowledged that it was not able to find documentation of the conversation and details of what specifically was discussed. It accepted that in terms of the telephone call that Ms A had not been given the opportunity to process the information, prepare any questions, or have the opportunity to ask questions at a later date.

41. The First English Trust also apologised that nobody had explained the operation to Ms A or the need to consider HRT after the surgery. It also noted the need to document consent discussions. The First English Trust said that it had created an action plan to address these areas of learning. It added that certain issues (consideration of the need for a hysterectomy and whether it might have been avoided if surgery had been undertaken sooner, and the lack of gynaecology follow-up and HRT advice) should be dealt with by the Second English Trust.

42. In relation to Ms A's concern that no-one had discussed her wish for a family prior to the surgery, the First English Trust commented as follows. It said that the Colorectal Surgeon had advised that family planning had been discussed with Ms A since 2017. It noted that Ms A's Crohn's disease, proctectomy and longstanding pelvis sepsis all have significant implications on the chances of becoming pregnant and that it was documented that Ms A's proctectomy was initially delayed for this reason. The First English Trust said that unfortunately Ms A had 3 emergency admissions due to bleeding and her surgery therefore had to be expedited in 2019. Similarly, the decision to undergo surgery to resolve the collections and prevent significant harm had been taken as a result of Ms A's ongoing pelvic sepsis. It added it was:

> "very sorry to hear that [Ms A] would have liked to have a conversation around the possibility of preserving her eggs and that she did not have the opportunity for this. Unfortunately, egg conservation is usually only considered when a patient is below

the age of 37. We would like to apologise that this was not discussed with her and for the distress that she has experienced as a result of not having this conversation at the time."

43. The First English Trust did not share its complaint response with the Health Board [As the First English Trust's complaint investigation did not identify that Ms A had been caused harm, there was no requirement to do so under PTR, see paragraph 19.]

44. Ms A's Advocate forwarded Ms A's complaint about her other concerns to the Second English Trust. In its response to the complaint (provided only during the course of my investigation) the Second English Trust said the Gynaecologist recalled what was a complex case and that he and the Colorectal Surgeon had discussed the "high chance" of Ms A requiring the removal of her reproductive organs, but that the extent of the inflammation and infection was not fully realised until the operation took place. It said that the Gynaecologist had planned to have a telephone conversation with Ms A to discuss the gynaecological aspects of the operation, but the First English Trust had brought the operation forward at short notice. In any event, it said that it was for the First English Trust to ensure the consenting process was appropriate as they were leading the operation and therefore responsible for Ms A's care.

45. The Second English Trust upheld Ms A's complaint that she was not reviewed by the Gynaecologist following the surgery and that HRT was not discussed with her. It said that Ms A should have been advised about HRT 6 to 8 weeks after her operation. In reaching this conclusion, it noted the Gynaecologist's statement that HRT would not be commenced until the 6 to 8 week post-operative telephone review (for out of area patients) had taken place. This was to exclude any disease that might be identified from the tissue sample taken at the time of the operation for which HRT was not advisable. It was also to ensure that Ms A had recovered from the surgery. The Second English Trust said that at the time it did not hold regular routine ward rounds at the English Hospital, but that it had subsequently introduced them to ensure patients requiring gynaecological input are reviewed and post-discharge follow-up arranged.

Ms A's evidence

46. Ms A said that the insertion of the drains was "horrific" and that having them left in situ was extremely uncomfortable and embarrassing as she needed to carry a pillow everywhere she might need to sit down.

47. Ms A said she was also very unwell with them, and felt they were causing her more harm than good. Ms A said that the drains obviously were not working, and her treatment should have been changed much sooner. She questioned whether this might have prevented the need for such radical surgery and saved her reproductive organs.

48. Ms A recalled that she was a passenger in a car with her elderly parents when the Colorectal Surgeon telephoned her unexpectedly in early March. She was therefore unprepared and unable to ask any questions about what she was told. She remembered the Colorectal Surgeon told her what a large operation it would be, confirmed Ms A did not already have children and said that she might lose an ovary which had not been visible on her last CT scan.

49. Ms A said that she signed the consent form for the surgery as she was getting ready to go into theatre and that she had been anxious and distressed at the time. She said she was unaware that a hysterectomy was a possible outcome and only found out this had happened when a nurse told her after she woke up from the surgery. She said that none of the operating team came to talk to her about it or to review her recovery and she was forced to ask clinicians who had not been involved to explain what had been done. Ms A said she had not known whether the Gynaecologist had been present during the operation until it was confirmed by my office.

50. Ms A said that the district nurse team had advised her after her discharge about what she should and should not do as she recovered as she had not been given that information by the English Hospital. She also said the district nurses had told her that she should have been advised about HRT, which she eventually sought through her GP.

51. Ms A described her whole experience as being "horrific" and said that mentally "I have had so many dark days". She said she had been significantly impacted by the way she had been treated and the outcome

of the surgery; she was devastated as she had wanted to have children. She had since sought counselling and mental health support to help come to terms with the situation. However, she said that there were still trigger points everywhere, as she saw families going out together, babies and children and she referred to the "grieving process" that she was going through. She added in terms of her situation:

> "I'm avoiding people; people ask me about my health and I've lost my confidence as I'm not steady enough to talk about this, I know I'll burst into tears and I don't want to do that. I know I'm a different person, my family keep telling me that. I feel like a shadow of my former self."

The Health Board's evidence

52. In its response to enquiries from my office, the Health Board referred to the terms of its [standard] contract with the First English Trust and other providers and explained the reporting requirements it contained. It said that reports from such providers are reviewed by the Health Board's professional leads. It added that the contract team regularly reviews external sources for any reports relating to providers that may impact on the services commissioned for Health Board patients.

53. In terms of contract monitoring, the Health Board added that it did not currently have regular contract meetings with commissioned providers, such as the First English Trust, but contacted them on an ad hoc basis for any information it might need. The Health Board said that its commissioned providers report financially to the Health Board on the contract each month. These reports are validated and reviewed and any issues arising are raised with the provider. The Health Board noted that the contract covers all aspects of the relationship including performance and quality. The Health Board commented that its Healthcare Contracts section does not receive or review reports on these other areas but would liaise with the provider on contractual issues if any were identified by the relevant department within the Health Board. The Health Board noted that its Head of Healthcare Contracting - Finance was not aware of any such request for this being made in this case.

54. The Health Board said that it was developing a Commissioning Assurance Framework ("CAF") which, when in place, would give greater clarity on the roles and responsibilities for the monitoring of external contracts. The CAF is a continuous assurance process that aims to provide confidence to internal and external stakeholders, and the wider public, that the Health Board is operating effectively to commission safe, high-quality and sustainable services within the resources available. This includes delivering on statutory duties and driving continuous improvement in the quality of services and outcomes achieved for patients. The CAF is designed to place the patient, service quality and patient safety at the heart of commissioned services.

Professional Advice

The Colorectal Adviser

55. My Adviser said that post-operative pelvic collections following a proctectomy are generally best treated non-operatively and it was appropriate to try drainage and antibiotics in the first instance. He concluded that Ms A's treatment from the Welsh Hospital up to February 2022 was clinically appropriate. At that point, consideration for surgical removal of the collection was reasonable, given that non-operative options for treatment had been unsuccessful. My Adviser also said there was no clear gynaecology condition (such as would have necessitated referral to Gynaecology at the Second English Trust) until the polyp was identified [in June 2021].

56. However, in respect of Ms A's care from the First English Trust during this time, my Adviser commented that:

- The Colorectal Surgeon's letter on 30 October 2019 was inaccurate, as every scan showed that the fluid collection was persisting and increasing. Ms A should have been reviewed at that time to consider whether to attempt drainage or monitor her more closely, which might have prevented her from developing sepsis and requiring hospital admission in December.

- It was unclear why Ms A's care seemed to be overseen by the Gastroenterologist between October 2019 and August 2021. As her ongoing problems were post-operative complications, coordination of her care should have been done jointly with the surgeons.

57. My Adviser has noted that Ms A's surgery in March 2022 was a complex operation with significant consequences for her. He said the consent form, signed on the day of her surgery, was insufficient to demonstrate appropriate, informed consent for the procedure. He also said that:

- Whilst the operation was brought forward in early 2022, possibly as a result of the hysteroscopy triggering further development of Ms A's existing infection, it was not an emergency and should only have gone ahead following appropriate discussion and consent.

- There was no apparent documented discussion prior to the day of the surgery about the nature of the operation, the potential that Ms A's reproductive organs might need to be removed, or the implications of that.

- Consent is a process - not a moment in time based on signing a form prior to surgery, with no other supporting documented discussion, prior to the day of surgery. In Ms A's case there was no reasonable discussion or time (on the day of the surgery) for Ms A to process the information.

- It was questionable whether the Registrar was a suitable clinician to take Ms A's consent, given that the Registrar was training in colorectal surgery and had no complex/major gynaecological background. In addition, the Adviser pointed to the inadequate documented discussion as well as the absence of any prior information or discussion with Ms A.

- The responsibility for consent lay primarily with the Colorectal Surgeon as the operating surgeon and the clinician with overall care of Ms A's admission. However, given that this was a planned procedure, the Colorectal Surgeon should have ensured that the consent process also had appropriate input from the Gynaecologist.

58. My Adviser said that it would not normally be within the remit of a colorectal surgeon to perform gynaecological surgery or provide appropriate gynaecological advice post-operatively. However, the Colorectal Surgeon, as the principal surgeon involved, had direct responsibility for the implications of the operation; and as such should have been directly involved in Ms A's post-operative inpatient care and should have ensured or requested appropriate gynaecological follow-up. This was particularly so, given the implications of the most radical options in terms of the surgery and the damage to Ms A's ureters, a known but uncommon complication of such surgery.

59. My Adviser also considered the action taken in relation to Ms A's complaints of back pain following her operation. He said that the records showed that Ms A was making reasonable progress; there was mention of some pain in the left flank area 4 days post-surgery, but there was little record of back pain until 16 March. He said that symptoms of damage to the ureters usually develop after 6 to 8 days. It was therefore not surprising that Ms A's pain was not reported to be significant until 16 March, and she was treated within 24 hours, which was 8 days after her operation. My Adviser concluded that, in this respect, the care provided was timely and the action taken was appropriate.

60. In reviewing Ms A's case, my Adviser also raised additional concerns. Firstly, he noted that there was no recorded discussion regarding the risks and benefits of Ms A's original surgery in June 2019, despite the proctectomy being a significant operation with serious risks including bladder dysfunction, chronic infection and infertility issues. In addition, the operation notes did not include any information about the role of the Gynaecologist, such as when he arrived and what he did. My Adviser said that the Colorectal Surgeon should have ensured that the Gynaecologist properly documented his involvement and instructions for post-operative management.

The Gynaecology Adviser

61. My Adviser said that given Ms A's case was surgically complex, it was appropriate to treat her collections non-surgically for the initial 6 months after her proctectomy operation. He felt that after that time further surgical management should have been considered and, given

the pelvic pain and other symptoms Ms A experienced, she should have been referred to Gynaecology by the middle of 2020. However, he noted that referrals and reviews at that time would have been impacted by the COVID-19 outbreak and the management of her collections would have remained with the Colorectal Surgeon because they were primarily related to the proctectomy in 2019.

62. My Adviser reflected that it is not unusual for a hysteroscopy to trigger (or exacerbate) a pelvic infection and this should have been considered before it was attempted in January 2022. However, there was no record that this risk was considered, or that alternative options to investigate the nature of the polyp were explored, such as an open MRI scan (using a type of machine with a wider opening and which is more comfortable and easier to tolerate than a traditional scanning machine). He also said that Ms A should have been prescribed prophylactic (preventative) antibiotics, which could have mitigated the risk of infection. In the event, the abandoned hysteroscopy probably caused inflammation and possibly triggered the development of further infection leading to Ms A's admission in the January. However, my Adviser has concluded that it was likely that Ms A would have needed definitive surgery in any event and thus the ultimate outcome might have been the same.

63. Turning to the decision to proceed with surgery and the operation in March, my Adviser said that:

- There was little communication or shared decision-making between the different specialities who were treating Ms A; each clinician seemed to review her in isolation so there was no joined-up thinking or holistic approach to her care.

- There was no record of Ms A's case being discussed in a multi-disciplinary meeting or that the risks and benefits of a hysterectomy were discussed in detail at any point.

- Ms A's operation was not an emergency, and the Gynaecologist was aware of the possibility that he would need to remove her reproductive organs, so he should have obtained her informed consent before it took place.

- Ms A should have been fully involved and informed of the complexity of her condition, the nature of the operation and the available treatment options.

- The complexity and persistence of Ms A's infection and fluid collections were such that open surgery and, ultimately, the removal of her reproductive organs was appropriate.

64. In relation to Ms A's post-operative care, my Adviser said that HRT should have been discussed before the operation took place. Where HRT is agreed, it is standard practice for it to start at the point of discharge, which is generally within 5 days of surgery. If Ms A's case meant there was a variance in normal practice, then the rationale for withholding HRT should have been explained to Ms A and HRT prescribed immediately at the earliest opportunity to do so.

Comments on the draft report

65. The First English Trust acknowledged that Ms A had had a very difficult time and offered its apologies to her for the distress and anxiety that she had encountered in what it acknowledged was a very complex case.

66. The First English Trust said that Ms A had consistent collaborative care at the First and Second English Trust and that the scan results given to Ms A by the Colorectal Surgeon "were true". However, with the benefit of hindsight, tubo-ovarian collection had been the cause of her recurrent infection, and the right procedure had been performed at the time.

67. The First English Trust said that the Registrar, who was a senior registrar, was appropriate to take consent. It noted that consent was completed with Ms A 2 hours prior to her going to theatre and the First English Trust added that "I can assure you there was time to discuss further with the team." The First English Trust said that it accepted that it was a "big" surgery for Ms A and that her post-operative course was not smooth, and that recollection can sometimes not be clear. It added that regular gynaecology involvement post-operatively was now routine, however, multi-disciplinary teams have always been collaborative. The First English Trust acknowledged that communication

had fallen short of the standards of excellence it aims for in its Surgery Division. It also noted that the lessons learnt from Ms A's case would be discussed more widely across teams.

68. The Second English Trust referred to the timeliness of the HRT prescribing. It said that normal practice in general gynaecology after straightforward surgery with benign pathology (no cancerous disease) is to offer HRT before discharge from hospital. However, it added that Ms A's surgery was not straightforward, and her case was complex. Ms A had a complex abdomen with extensive adhesions, and it would not have been possible to eliminate the possibility of pathology such as a low-grade ovarian malignancy or endometriosis. Therefore, it reiterated that waiting until the histology was available and discussing HRT at the post-operative appointment was the normal practice within the oncology team of which the Gynaecologist was a member.

Analysis and conclusions

69. In reaching my conclusions I have considered the advice that I have received from my Advisers, which I accept. However, the conclusions reached are my own. Where there might be slight differences in the views of my Advisers, I have given more weight to the view of the Adviser who works within the same speciality as the clinician who made, or should have made, the decision due to their expertise in this field. I will address each of Ms A's concerns in turn. The Health Board, as commissioner of the care from the First English Trust, is responsible for monitoring the performance of the contract and for any failings which I identify on the part of the First English Trust. It is also responsible for any failings on the part of the Second English Trust to which referrals were made by the First English Trust, as by extension, this care was also undertaken under the terms of the contract with the Health Board.

Whether Ms A received appropriate review and treatment of post-operative fluid collections and pelvic sepsis following surgery in 2019, including adequate gynaecological input

70. The management of Ms A's fluid collections by the Health Board was reasonable. Both Advisers agreed that it was appropriate to attempt to resolve the matter by non-surgical means, by the use of

antibiotics and drainage in the first instance. However, I conclude that there were failings in the First English Trust's care of Ms A during this period. Specifically, the Colorectal Surgeon incorrectly reported the outcome of the October 2019 scan, which affected Ms A's treatment at that time; Ms A should have been reviewed and consideration given to attempting drainage or closer monitoring. I cannot say definitively that this would have prevented Ms A from developing sepsis, but there is a possibility that it might have done. In any event, Ms A's care between 2019 and 2021 should at least have involved surgeons, rather than having been overseen by the Gastroenterologist, since her ongoing problems were related to the surgery.

71. The Gynaecology Adviser has said that Ms A should have been referred to Gynaecology by the middle of 2020. In fact, the Gastroenterologist did make such a referral in March 2020; however, I have seen nothing to suggest that any action was taken in response to that referral, but I am mindful that referrals and reviews at that time would have been affected by the COVID-19 pandemic, and this may account for why it appears to have been missed or overlooked.

72. I turn now to the input from Gynaecology once the further referrals were actioned. I am concerned that, in view of the possibility that a hysteroscopy might trigger or exacerbate a pelvic infection, there was no consideration of the advisability of carrying out this procedure, or exploration of alternative options to investigate the nature of the polyp. In addition, Ms A should have been prescribed prophylactic antibiotics to mitigate the risk of infection. The subsequent decision to proceed with surgery and the operation in March 2022 was made with seemingly little or no communication between the different specialities involved in Ms A's care, and certainly no multi-disciplinary meeting to consider the risks and benefits of a hysterectomy.

73. The failings I have identified, both from a colorectal and gynaecological perspective, amount to service failures. Ms A suffered from persistent infection and associated ill-health for nearly 3 years before definitive surgical treatment was performed. In addition, although it is not possible to say whether the outcome for Ms A would have been

any different but for these failings, Ms A will always wonder whether her hysterectomy could have been avoided. These are considerable injustices to her. I therefore **uphold** this part of the complaint.

Whether Ms A was given sufficient time and information to understand and consider the risks of the surgical removal of her post-operative fluid collections, and to give her fully informed consent before this surgery was carried out

74. I am extremely concerned about the process by which Ms A gave her "consent" for the surgery in March 2022. The relevant guidance makes it clear that consent is not simply a matter of completing and signing a form and to place reliance solely on the form does not show that consent has been adequately given. Instead, consent is a process which should begin well in advance of the day of the surgery; it should ensure the patient is fully aware of what is proposed and the options and the intended benefits and risks of the surgery and is given the opportunity to formulate and ask questions and has time to process that information. It is disappointing that the First English Trust's response does not appear to have recognised this when commenting on the time available to Ms A before she went to theatre for what it accepted was a "big" operation (see paragraph 67).

75. Any discussions should be clearly and separately recorded as part of the consenting process. This did not happen here. Guidance also makes it clear that the doctor [who carries out the surgery] is responsible for ensuring valid consent is given before the treatment. If part of the consent process, as in this case the completion and signing of the consent form, is delegated to another person, that person must be suitably trained and have sufficient knowledge to discuss the operation, alternative options and benefits and harm with the patient. There is no separate documented record that would provide some insight into the consenting discussion that took place on the day of surgery. I am also mindful that Ms A's case was complex, and from a gynaecological viewpoint not straight forward as recognised by the Gynaecologist (see paragraph 44).

76. The responsibility for obtaining Ms A's consent for the operation was primarily that of the Colorectal Surgeon as the operating surgeon and the clinician with overall care of Ms A during her admission,

although there should also have been appropriate input from the Gynaecologist. The situation was not an emergency, and appropriate, informed consent should therefore have been obtained. There is no record of a separate documented discussion that took place with Ms A prior to surgery about the nature of the operation or the possibility that her reproductive organs might need to be removed. I do not accept that the full implications of the surgery were "likely" discussed with Ms A during a telephone call - there is no evidence of this. I am also mindful that Ms A was not expecting the telephone call and had no chance to prepare for it.

77. On the evidence, I conclude that Ms A did not give informed consent for the extensive surgery which was carried out in March 2022. This is a serious failing which amounts to service failure. Although I am not able to make definitive findings of a breach of human rights, it is right that I draw attention to and comment on cases, such as Ms A's, where Article 8 rights are potentially engaged. I accept, based on the advice I have received from the Gynaecology Adviser, that Ms A would have needed definitive surgery and that ultimately the outcome might have been the same. Nevertheless, given that personal autonomy as well as the right to respect for one's private and family life underpins Article 8, Ms A had the right to have a say and to determine what was to happen in terms of her body. This is pivotal to informed consent and a rights based, person centred approach to care, that reflects the core FREDA principles and values.

78. I am mindful that had Ms A been properly consented, it would have given her an opportunity to reconcile herself to the likely outcomes, as there was no immediate urgency to carry out the procedure. It would also have meant that Ms A could have explored options that left open the possibility of having biological children in the future (for example through fertility preservation such as egg freezing and surrogacy). All of this was denied to her.

79. The impact on Ms A both physically and psychologically has been significant. Ms A has been left devastated as she wanted to have children, and she grieves the loss of that opportunity. Moreover, she has needed counselling and mental health support to come to terms with the

situation. I am satisfied that the serious failings identified in Ms A's case have caused her a significant injustice. I **uphold** this element of Ms A's complaint.

Whether Ms A received prompt and appropriate investigation and treatment for her pain and reduced kidney function following surgery in March 2022

80. Ms A's reports of pain following surgery were not thought to be significant until 16 March, some 7 days after her surgery. I accept the advice from the Colorectal Adviser that this timescale reflected the usual time for development of symptoms indicating damage to the ureters and Ms A received prompt and appropriate treatment for this. I therefore **do not uphold** this part of Ms A's complaint.

Whether Ms A received timely and appropriate information about her hysterectomy, including advice about post-operative recovery, the menopause and options for hormone replacement therapy

81. Ms A should have received advice and information about the possible consequences of the surgery before the operation took place. This should have included a discussion about HRT. I have seen nothing to indicate that such a discussion took place. This was a failing. The Colorectal Adviser said that it would not usually be the role of a Colorectal Surgeon to provide appropriate gynaecological advice post-operatively. However, the Colorectal Surgeon was the principal surgeon involved and therefore should have been directly involved in Ms A's post-operative care. If she was not able to provide gynaecological advice, the Colorectal Surgeon should have ensured relevant gynaecological input. I consider it unacceptable that Ms A was obliged to seek information regarding the surgery she had undergone from people who had not been directly involved in the operation, and this must have caused Ms A considerable uncertainty and distress.

82. The failure to provide appropriate information and advice, including HRT, meant Ms A was left to experience menopausal symptoms at the same time as recovering from complex surgery, without a clear idea of her management and why it would be felt advisable for HRT to be delayed until the results of follow-up investigations had been received (see paragraphs 45 and 68). The failings I have identified amount to

service failure and caused Ms A considerable anxiety and distress. This is a further injustice to her. I therefore **uphold** this element of Ms A's complaint.

Whether the Health Board dealt with Ms A's complaint in line with the National Health Services (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

83. Although there was a delay in the Health Board providing its complaint response to Ms A, the delay was not unduly excessive. It is clear that the Health Board did not see that it had a role to play in Ms A's complaint to the First English Trust that she had copied to the Health Board (see paragraph 37). The Health Board was entitled to rely on the First English Trust to consider the relevant elements of Ms A's complaint under its own complaints procedure, in accordance with the Regulations and guidance. I note that the First English Trust did not respond to Ms A's complaint until more than 6 months after the complaint had been received and did not address (or forward for consideration) the concerns that related to the care it had arranged at the Second English Trust. The First English Trust did identify and apologise for some failings. However, its response was not sufficiently robust and should have more fully identified and acknowledged the extent of the serious failings identified by my Advisers, especially around informed consent for the surgery. However, because the First English Trust's investigation did not identify harm it did not have to bring Ms A's case to the attention of the Health Board. Therefore, the Health Board would not have had sight of the First English Trust's complaint response.

84. Strategically and operationally the complaints process should not be seen as operating in a vacuum. Instead, it should be seen as part of an integrated, joined-up approach to improving patient safety and experience, in which an effective assurance contract monitoring process plays a vital supporting role. This is more so in the case of commissioned healthcare services outside of Wales, where effective contract monitoring provides an additional layer of patient protection/safety, in cases where, as here, the commissioned body does not identify harm.

85. In my view, the Health Board's failure to identify the poor complaint handling by the First English Trust as well as the poor care and other failings identified in Ms A's case, are a reflection of the wholly inadequate contract monitoring arrangements in place at the Health Board. I find it concerning that the Health Board has placed financial reporting at the heart of its contract monitoring, rather than the patient, their safety and the quality of the service. As a result, an important part of the Health Board's monitoring role, which requires it to have rigorous oversight and scrutiny of the commissioned body, has been lost, meaning missed opportunities to identify issues around poor performance. The Health Board should have recognised and addressed this deficiency sooner than it has. It is disappointing that this situation has been allowed to happen and continue for so long, given the Ombudsman's statutory guidance on good administration includes public bodies having both responsibility and accountability for commissioned services. I cannot discount the possibility that had an effective contract monitoring regime been in place then some, if not all of these failings, might have been avoided. This is the injustice for Ms A, as she will have to live with the uncertainty of not knowing whether her care would have been better had an effectively monitored quality assurance process been in place. To that extent, I therefore **uphold** this part of Ms A's complaint.

86. I welcome the fact that the Health Board is working to put in place a CAF. In light of this case, I would urge the Health Board to prioritise its implementation of the CAF, and I have reflected this in my recommendations below.

87. Given the serious and significant healthcare and commissioning failings in this case, I will be sharing this report with Healthcare Inspectorate Wales, the Care Quality Commission in England, and the Parliamentary and Health Service Ombudsman.

Recommendations

88. I **recommend** that the Health Board should:

Within **1 month**:

a) Apologise to Ms A for the failings identified in this report.

b) Share this report with the Chair of the Health Board and the other Board members and its Patient Safety and Clinical Governance Group.

Within **2 months**:

c) As part of its commissioning arrangements, request the First English Trust undertake and evidence the following:

i. a review of Ms A's case to see what additional learning can be identified to improve the patient experience;

ii. a reminder to its clinicians of the relevant guidance around informed consent and their professional obligations when it comes to record keeping to ensure that discussions with patients are documented;

iii. as a point of learning, it shares with clinicians an anonymised case study of the clinical failings identified in this case at an appropriate clinical forum;

iv. the Colorectal Surgeon is asked, as part of learning and reflection, to share a copy of this report and discuss the steps that she has put in place to improve her clinical practice at her next professional revalidation;

v. a copy of this report is shared at its relevant patient safety governance committee.

In addition, the Health Board should:

d) Seek written assurances from the First English Trust's Chief Executive that it has taken steps to address the clinical failings identified in this report.

e) Share the compliance evidence relating to recommendations c) and d) with my office.

Within **6 months**:

f) Prioritise, complete and implement a CAF.

89. 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 25 March 2025
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