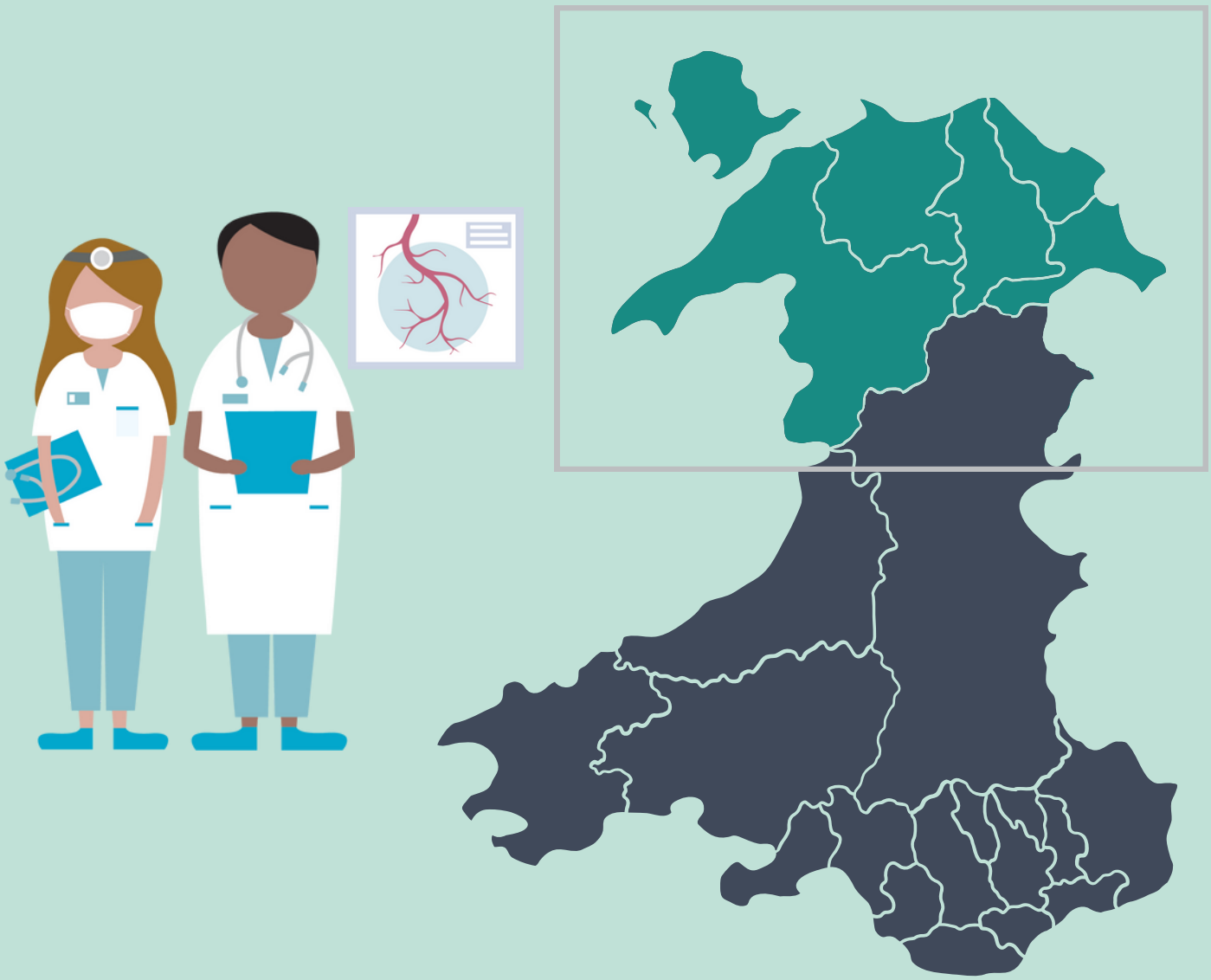
Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Vascular Services at Betsi Cadwaladr University Health Board; a review of progress



Content	Page

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales. We are responsible for inspecting and reviewing National Health Service (NHS) services and independent healthcare services throughout Wales against a range of standards, policies, guidance, and regulations to highlight areas requiring improvement.

As part of HIWs annual reviews programme for 2022-23, we undertook a local review of vascular services within Betsi Cadwaladr University Health Board (the health board). The review set out to consider the progress made by the health board in relation to the findings and recommendations highlighted in the *Royal College of Surgeons (RCS) of England Clinical Record Review Report,* published in January 2022. Details of the recommendations can be found in appendix B.

The RCS report highlights nine recommendations for improvement. The first five were highlighted as urgent recommendations to address patient safety risks. They were considered as important actions for the health board to take, to ensure patient safety is maintained. The remaining four were recommendations for service improvement and were considered important actions to be taken by the health board, to improve the service.

We explored whether the actions implemented by the health board had improved the quality of care being provided and improved patient safety, and whether vascular care was consistent across the health board for people regardless of where they live.

This report details our findings and 11 recommendations for improvement. The health board must consider all these recommendations, and it is our expectation that these are taken forward in the context of broader improvement work.

We would like to express our thanks to all the staff working within the health board, who helped inform our review by providing the requested information, participating in interviews and for completing our survey to share their views and experiences with us.

We would also like to express our thanks to those within the RCS and the Vascular Quality Panel who supported us with relevant information to help inform our review.

The Royal College of Surgeons of England will be referred to as RCS throughout the body of this report.

Executive Summary

This report highlights the findings from our review, where we considered the progress made by the health board, in addressing the findings and nine recommendations within its vascular services as highlighted in the RCS review report, to maintain patient safety and quality of care. The key findings highlighted during our review are outlined below.

It was evident that efforts had been made by the health board to implement processes and make improvements within its vascular services, with the aim to provide safe, timely and effective care to patients.

We identified that satisfactory progress has been made against all nine recommendations made by the RCS review team, and work to address the five urgent patient safety risks was commenced promptly by the health board. However, further work is still required to strengthen some aspects of clinical record keeping, and to ensure a patient's journey through the vascular pathways is consistent and robust. This is to ensure that care is equitable regardless of a patient's geographical location, that the quality of written communication is maintained, and records are filed in a timely manner and in chronological order, to maintain patient safety.

Overall, we found evidence to demonstrate that prompt actions were taken by the health board to follow-up on all patients (or next of kin), who were reviewed as part of the RCS review, in line with the duty of candour. In doing so, the health board also met its ethical and legal obligations by establishing the outcome for several patients, where the RCS team could not determine this during their review.

We found that a Vascular Quality Review Panel (VQP), was set up to undertake further scrutiny of the records reviewed by the RCS team. Consequently, this led to new information being identified for some patients, with four patients being referred by the health board to His Majesty's Coroner. The next of kin were contacted appropriately. In May 2023, the Senior Coroner for north Wales opened inquests into the four people who sadly lost their lives.

The RCS team found significant issues with the Multidisciplinary Team (MDT) Processes within vascular services. Through our review, we found the health board has made satisfactory progress with the improvements required for MDT working. Immediate 'make safes' were implemented within the vascular surgery service, which including enhanced consultant cover and closer MDT decision-making support, which was provided from Liverpool University Hospital Foundation NHS Trust (LUHFT). This also included dual consultant operating during complex arterial surgery, such as Abdominal Aortic Aneurism (AAA) repairs.

We found a process has also been implemented by the health board, to gain the required clinical support within the vascular MDT meetings, and in relation to the aneurysm pathway.

Through its service improvement process, the health board has also commissioned the support from the University Hospital of North Midlands (UHNM), to support the delivery of emergency and urgent elective AAA cases on an ongoing basis until 2024. Although marked improvements have been made with MDT working, further work is required for the health board to assure itself that MDT discussions are always documented promptly within clinical records.

We found that Standard Operating Procedures (SOP) had also been implemented to manage the MDT meetings. This is to accurately facilitate and reflect the discussions taking place and the decision-making process regarding patient care and the plans for treatment. This included the implementation of MDT forms, which are completed during the MDT meetings and filed within the clinical records.

In addition to SOPs, we found the health board had also updated and implemented several patient care pathways across the service. The management for the implementation and revised pathways process was undertaken through the health board's RCS targeted intervention plan. However, further improvement is still required to ensure that the continuity of patient care is maintained to a high standard throughout the different pathways of care, and that the standard of communication within clinical records is further improved and promoted across all MDTs.

Our review highlighted some concerns with the culture of working between teams involved within different care pathways, which may impact on patient care. This was evident through our interviews with staff, who suggested poor communication between MDT staff working within the diabetic foot pathway. In addition, that clearer working relationships must be established between diabetologists and vascular specialists, and within the orthopaedic team and podiatry services, to ensure that patients are being referred promptly when required, and patients are assessed by the most suitable team, to provide more timely advice and care. Work is needed to improve the working culture across different teams throughout the vascular pathway overall.

During our clinical records review, we found the quality of record keeping was much improved since the findings of the RCS team. However, further improvement is required, particularly in relation to our findings in Ysbyty Gwynedd (YG) and Wrexham Maelor Hospital (WMH). Whilst some improvements have been made with record keeping, as demonstrated within the health board's audit results, and staff training, questions remain as to whether progress can be sustainable. This is because several issues remain with the quality of record keeping as evidenced during our review, which may impact on the quality of patient care, most notable with filing of records chronologically and prompt insertion of surgical procedure records.

We found that satisfactory progress has also been made by the health board for the consent-taking process within vascular services. We found evidence of improvements through consent process audit results and through our clinical records review. However, further work is required to ensure the records always clearly demonstrate the entire consent process accurately and appropriately.

When we explored whether the governance arrangements in place within the health board were effective in monitoring the response to the RCS findings and recommendations, we found these to be satisfactory.

In recognition of the overall progress made against the RCS recommendations, we have de-escalated the vascular service from the Service Requiring Significant Progress (SRSI) designation. Whilst we have seen improvements across the vascular services, we have made 11 recommendations to further strengthen the arrangements in place. The health board must ensure measures are in place to assure itself that the improvements and processes implemented since the RCS review, are sustainable now and in the future.

Context

In its Operational Plan 2022-23, HIW committed to a programme of local reviews, which did not originally include the plan to undertake a review of vascular services within the health board. The decision to undertake this review, was based on our concerns relating to the findings highlighted within the RCS report on 44 clinical records relating to vascular surgery on behalf of the health board[1].

In April 2019, the decision was made by the health board to change its model of care for vascular services. The model was changed to a hub and spoke model, where the most complex procedures, such as major arterial surgery, are conducted at a specialist centre ('the hub') which is based at Ysbyty Glan Clwyd (YGC). The hub at YGC, is supported by local centres ('spoke sites'), namely Ysbyty Gwynedd (YG) and Wrexham Maelor Hospital (WMH), which conduct more straightforward treatments or non-arterial surgery. Both 'spoke sites' feed into YGC for patients who require arterial surgery. The 'hub and spoke' model is endorsed by the Vascular Society for Great Britain and Ireland[2] and the Royal College of Surgeons of England[3].

The aim of the 'hub and spoke' model is to ensure that patients within the health board have equal access to vascular services. This is regardless of which area they live in north Wales and that arterial surgery is prioritised in order, to those who need it most urgently. In addition, the model aims to ensure the sustainability of services going forward. The aim for spoke sites includes the provision of out-patient appointments, review of in-patient vascular referrals, and to undertake some less specialised procedures across the whole of north Wales.

The vascular care and treatment plans for patients are considered and prescribed through Multidisciplinary Team (MDT) collaboration within decision-making meetings. All three acute sites within the health board maintain the availability of a vascular consultant to provide clinical services. Within the spoke sites, this includes vascular clinics, vascular diagnostics and rehabilitation services, and less complex treatment, such as varicose vein procedures.

In July 2021, the RCS undertook an examination of 44 clinical records relating to vascular surgery, on behalf of the health board. Following their review, a report was published in January 2022, which set out several findings and nine recommendations for improvement by the health board. This was to ensure that the quality of care and services provided are improved, to maintain the safety of patients.

The concerns related to:

- The quality of clinical care and the risks to patient safety
- Poor MDT working
- Poor documentation and record keeping.

[1] Report on 44 clinical records relating to vascular surgery on behalf of Betsi Cadwaladr University Health Board
[2] Vascular Society
[3] Royal College of Surgeons of England

Following publication of the RCS report, HIW considered the findings which raised questions in relation to the quality and safety of patient care, and the consistency in the service provided across the health board. Consequently, in February 2022, HIW considered the vascular service under its Service of Concern process, and subsequently designated the service as a *Service Requiring Significant Improvement (SRSI)*.

Given the nature of the concerns highlighted within the RCS report, and subsequent SRSI designation for the vascular service, HIW decided to undertake its own review of the service.

The review focusses on examining the progress made by the health board in relation to each of the nine recommendations included within the RCS report. This was to gain assurances relating to patient safety and the quality of care being provided. In addition, to consider whether the health board's vascular service could be de-escalated as a SRSI, and to identify whether there were further actions required for improvement.

What We Did

Focus of Review

The focus of our review was to assess the progress made by the health board in addressing the findings and recommendations included within the RCS review report. The review considered the actions implemented by the health board and subsequent improvements within service, to determine whether progress had been made to ensure safe and quality care was being provided to patients.

The review sought to address the following overall question:

Do the current arrangements in place within the health board's vascular services support the delivery of quality care, which is safe, timely and effective?

Throughout the review we explored:

- Whether evidence was available to confirm urgent concerns identified by RCS had been addressed
- Whether evidence was available to demonstrate that actions taken to maintain patient safety and the quality of care were effective, sustainable and will aid service improvement
- The governance arrangements in place within the health board to monitor the ongoing response to the RCS findings and recommendations.

In addition to the primary focus on the health board's response to the RCS recommendations, we also engaged with the Vascular Quality Panel (VQP) to help to inform the review findings. Furthermore, we engaged with the RCS which undertook the original review and highlighted that the team would follow-up with the health board, on what action has been taken to address their recommendations.

Scope and Methodology

To assess the areas outlined above, a bespoke methodology was developed. During our review fieldwork, we:

- Requested relevant documentation from the health board, prior to and during our fieldwork, around its policies and procedures relating to the vascular service
- Held interviews with a range of health board staff
- Undertook onsite fieldwork focusing on patient case studies by undertaking a clinical record review

- Conducted an online survey for staff working within the health board's vascular service
- Undertook an exercise to collate patient views and experiences of the service.

Staff Interviews

We held multiple interviews with health board staff, which included clinical staff, managers and directors involved in the vascular service. We completed a total of 24 staff interviews, and our findings will be highlighted throughout our report.

Patient Case Study

We asked the health board to provide us with a list of 75 patients who had received care and treatment within each of the three vascular service sites within the health board (25 per site). From these lists, we randomly selected patients and reviewed the information available whilst onsite, to assess the care and treatment provided, in view of the issues highlighted within the RCS report and its recommendations.

During our onsite patient case study, we reviewed 39 patient clinical records across the three sites, which were a mixture of emergency, elective and outpatient clinical records. This included 19 from YGC, 14 from WM and six from YG. None of the patients reviewed as part of our case study review, were included in the RCS review.

Staff Survey

We launched an online staff survey, to obtain the experience and opinions of staff working within the vascular service. The survey was shared with the health board to circulate to staff working within vascular services in each of the three sites. The survey was also promoted through our stakeholders, on the HIW website and our social media channels, and was also distributed to staff during our onsite fieldwork. It was available for completion between November 2022 to January 2023. Overall, we received a total of 21 responses from staff, 12 respondents worked within YGC, 11 in YG and five in WMH.

It was disappointing to find that the response rate to our staff survey was quite low. Therefore, the quantitative results may not accurately reflect the staff views across the service as a whole. We therefore made the decision not to reflect the quantitative results within this report. However, where relevant we have included some qualitative examples of staff feedback where applicable. A summary of the survey results will be shared with the health board for it to consider the responses, however, we will redact some information we share, to maintain staff confidentiality.

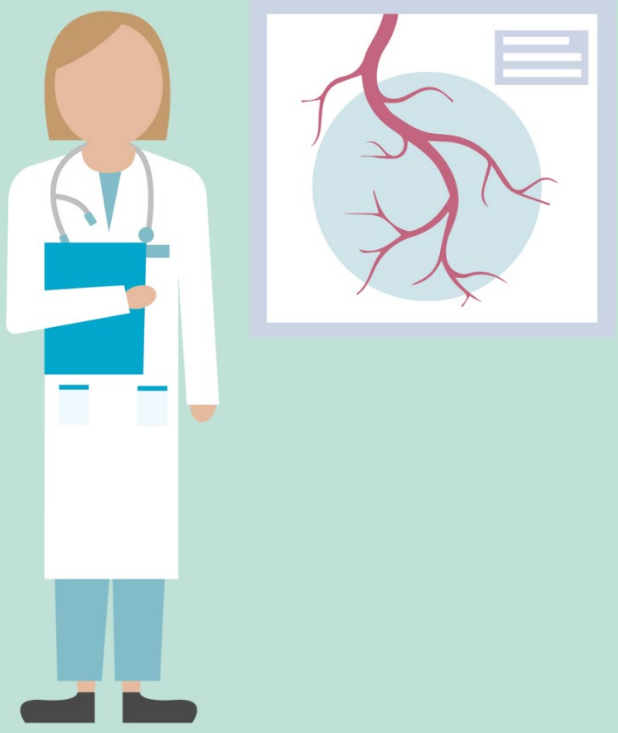
Patient Experience Engagement

As part of our onsite fieldwork, we held discussions with several patients who had received, or were receiving care and treatment from the health board's vascular services. This was to gain an understanding of their experiences during their journey. The findings form our patient engagement are highlighted throughout this report.

Review Team

Our review team consisted of the following:

- HIW Senior Healthcare Inspector (who led the review)
- HIW Healthcare Inspector (who supported the lead and review team)
- HIW Reviews Assistant (who supported the lead and review team and engaged with patients)
- Three Expert Vascular Surgery Consultants (Clinical Peer Reviewers)
- One Registered Vascular Nurse (Clinical Peer Reviewer)
- One Patient Experience Reviewer.



What We Found

We considered the evidence available across the health board and its vascular services, to establish the progress it has made in addressing the findings and recommendations highlighted within the RCS report, on the 44 clinical records reviewed relating to vascular surgery on behalf of the health board.

We have set out our findings throughout this section in line with each of the nine recommendations highlighted in the RCS report. The first five recommendations were regarded as urgent to address patient safety risks. They were important actions for the health board to take, to ensure patient safety is maintained. The remaining four were recommendations for service improvement were considered important actions to be taken by the health board, to improve the service.

Urgent RCS Recommendations to Address Patient Safety Risks:

The following five recommendations were considered as important actions for the health board to take urgently, to ensure patient safety is maintained.

RCS Recommendation: 1

The health board should consider the conclusions of this report, as well as the other information it holds, and on this basis provide further follow-up of any patients for which it considers this to be required. This should protect patient safety and ensure that patients or their families have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20[4].

HIW Summary of Findings

The health board has made satisfactory progress with addressing and implementing the required actions for this recommendation. Whilst each patient whose records were reviewed by the RCS team have been followed up appropriately in line with this action, some patients or next of kin communications have been significantly prolonged.

During the RCS clinical records review, significant shortcomings were identified by the review team in relation to patient care, which may have significantly impacted on patient safety. This included the cumulation of considerably poor record keeping, therefore, providing a lack of evidence to demonstrate that some essential decisions, treatment or care had been undertaken when necessary.

[4] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

For example, delayed or poor MDT decision making, MDT decisions not being implemented, treatment rationale not documented, such as the reason to amputate a person's limb as opposed to surgical bypassing, inappropriate treatment plans, and lack of post operative care planning.

This highlights significant concerns regarding the patient care and treatment received (or not) when they had used the vascular services. Given these issues were identified by the RCS review team retrospectively, and the significance of the impact this may have had on some people, it is pivotal that the health board followed up on those relevant.

Duty of Candour

In line with the responsibilities set out with the duty of candour within the *Health and Social Care (Quality and Engagement) (Wales) Act 2020*[5], which came in to force across within NHS Wales in April 2023, Welsh Government highlights its commitment to safe, effective, and person-centred healthcare services. The duty of candour is placed on NHS bodies and on primary care providers in Wales, in respect of services they provide under a contract or other arrangements with a local health board. Wales is not the only UK jurisdiction to have a duty of candour. As highlighted by the RCS in the recommendation above, in England, the duty is set out at Regulation 20 of the Health and Social Care Act 2008, and in Scotland, it is set out in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016[6].

The intention of the duty of candour legislation is to ensure that providers are open and transparent with people who use health and care services. The duty sets out specific requirements providers must follow when things go wrong with care and treatment. This includes informing people about the incident, providing reasonable support, truthful information, and an apology when things go wrong.

In relation to the clinical records reviewed by RCS, we explored whether the health board had contacted any of the relevant patients (or next of kin), whose records were reviewed by the RCS team, in particular, for those where issues were identified during the RCS review.

Patient Follow-up

We found that the health board did follow up with all relevant patients reviewed by the RCS team and informed them that their clinical records were reviewed as part of the RCS review. This was evidenced through our ability to review copies of the letters sent to people and through our communications with staff within the health board.

[5] Health and Social Care (Quality and Engagement) (Wales) Act 2020 (legislation.gov.uk)
[6] Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (legislation.gov.uk)

Initial communication with the patients (or next of kin) was through a formal letter, dated March 2022. The letter informed the patient that a Vascular Quality Review Panel (VQP) would undertake further scrutiny of the records.

Patients were also informed of the reason for undertaking further scrutiny, which was to ensure all improvements in the service could be identified, to ensure relevant changes were made and that the quality of care provided to patients is being maintained.

Further letters were also sent to patients in August 2022 and January 2023, providing an update where applicable, relating to the VQP review. Patients were informed that as part of the VQP process, an external independent vascular surgical expert was part of the panel, and for some patients this led to new information being identified. Consequently, through the VQP review process, this led to new information being identified for some patients, with four patients being referred by the health board to His Majesty's Coroner. The next of kin were contacted in line with the duty of candour regarding this. The Senior Coroner for north-east Wales and central, opened inquests during May 2023, into the four people who sadly lost their lives.

The next of kin of the patients who lost their lives within vascular services, were all offered a face-to-face meeting with health board staff to discuss the findings in further detail. Two families took up the offer of a meeting, and two did not request to meet with the health board.

Within its written correspondence, the health board also informed patients how it had implemented additional safety measures within the vascular services, such as implementing a two-surgeon operating model for the repair of Abdominal Aortic Aneurysms (AAAs), and the involvement of a regional specialist centre in planning treatment. Further details of this will be provided later in this report.

The health board also provided a dedicated vascular helpline for patients or families to make contact if they had any further queries, and some patients could contact a member of the Vascular Quality Team, directly when required.

Of the patient records reviewed by the RCS, in April 2022, the health board received two formal complaints from patients under the NHS Wales Putting Things Right[7] process.

The health board informed us that a full investigation has since taken place regarding the concerns, and reports will form the response, followed by a face-to-face meeting if required. The complainants have not yet received a response from the health board, and this is due to be sent to them in April-May 2023.

[7] NHS Wales complaints and concerns: Putting Things Right

The Health Board's Ongoing Actions

When considering current and future patients, the health board confirmed that its aim is to ensure that patients and/or families receive clear open and transparent communication regarding care or treatment, in line with the duty of candour.

This is for the occasions where patient care may fall below expectations or where incidents may have occurred.

We found that work is ongoing to develop the arrangements to maintain a duty of candour where applicable, through the health board's Quality Review Panel (QRP). This means that any relevant incidents are escalated to and considered by the QRP to determine the required actions as a result. In addition, where appropriate, the health board plans to provide information to families about any incident in line with duty of candour. We found that any learning or actions required for improvement are also identified and shared across teams as appropriate.

The health board has developed and implemented a Duty of Candour policy. This has been circulated to all relevant staff within the vascular services and health board. This has been cascaded to staff through email, newsletter and through the relevant team meetings.

HIW Recommendation 1

The health board must consider its responsibilities in line with the NHS Wales Putting Things Right process. This is to establish whether timelier responses could have been given following the two formal complaints it received, and whether it is assured that updates were given appropriately throughout the course of the complaint investigation. The health board should set out what action will be taken to ensure that in future, people are communicated with in a timely manner when raising concerns.

RCS Recommendation: 2

The review team were unable to determine the outcome for a number of the patients. The Health Board should review the care of these patients to ensure the Health Board are aware of the outcomes and that the Health Board has met its ethical and legal obligations, including those outlined in recommendation one.

HIW Summary of Findings

The health board has made satisfactory progress with addressing and implementing the required actions for RCS recommendation two. This was completed in the way highlighted within the health board's action response to recommendation one, where all patients were initially written to informing them of a further review, and their records would be reviewed in detail by the VQP.

As previously highlighted, significant shortcomings were identified by the RCS review team in relation to patient care, which may have significantly impacted on patient safety at the time of their care or following their discharge.

During their review, the RCS team did not interview or contact any of the patients or their next of kin, whose records they reviewed. They could therefore only make a judgement based on that documented throughout each patients' clinical records. They found that poor record keeping often created a barrier to determining the outcome for some patients.

We considered the action taken by the health board in addressing this recommendation, and whether outcomes for the patients were identified. In addition, whether any action was taken as appropriate, following this.

The Health Board's Action Following the RCS Review

We found that the health board did review the care of all the patients the RCS considered during their review. This was completed through the implementation of the VQP, as highlighted further in recommendation one. In line with its ongoing actions following the RCS review and that highlighted earlier, the health board made initial contact with all patients through a formal letter and subsequently followed up with further letters as appropriate. Further details can be found in recommendation one.

We were provided with evidence that the patients (or the next of kin) were informed that further scrutiny of their records would be undertaken by the VQP. Where appropriate, we also found that patients were candidly informed of the reason for undertaking further scrutiny, and if the care they received previously fell below the standard required to maintain their safety.

In addition, they were informed of what action the health board has taken since the RCS review, to improve patient safety and the quality of care provided. This was evidenced in the selection of letters provided to us as part of our review.

As a result of the shortcomings identified during the RCS review and the subsequent recommendations within their report, the health board immediately set out to address this recommendation as appropriate. Amongst other actions, the health board took immediate steps to strengthen clinical leadership and to enter into a service level agreement and agreeing a Memorandum of Understanding (MOU) with Liverpool University Hospital Foundation Trust (LUHFT).

This provided the health board with enhanced consultant cover and closer decision-making and planning support within MDT meetings for vascular patients who require more complex vascular surgeries.

In addition, and as detailed earlier, the health board implemented a VQP to review all the records reviewed by the RCS team, and to contact all the patients whose records were reviewed, or next of kin where applicable. As part of their review, one of the aims was to establish the outcomes of the patients where the RCS team were unable to identify this. On considering our evidence, we believe this action has been addressed appropriately by the health board through the VQPs review process.

The Health Board's Ongoing Actions

As part of the health board's action plans for improvement of quality care, patient safety and overall patient experience, it also implemented additional measures to help embed any changes or new processes in to practice.

This includes:

- Commencing a programme of ongoing improvement work with the support of Improvement Cymru[8]
- Appointing a Clinical Lead for vascular services who is supported by the Clinical Director for Surgery at YGC
- to improve the overall leadership of the surgical teams
- Commencing the recruitment process for additional Consultants for Vascular Surgery.

Overall, it is evident throughout the course of our review that the health board has achieved the requirements of this recommendation. It has met its ethical obligations through implementing the VQP, which reviewed every patient that the RCS team considered and communicated with them, or their next of kin, and were able to determine the outcome for all patients.

[8] Improvement Cymru is the improvement service for NHS Wales. Its aim is to support the creation of the best quality health and care system for Wales so that everyone has access to safe, effective and efficient care in the right place and at the right time.

RCS Recommendation: 3

The Health Board should review the comments made in this report, alongside the local information it holds, and determine if the patient records contained the information, they would expect for the patient episode(s). The Health Board should ensure that the current practice meets the agreed standards as set out in the RCS England good practice guide.

HIW Summary of Findings

The health board has made satisfactory progress with this recommendation. However, further work is required to ensure that clinical record keeping is maintained to the expected standard. Clinical record audits should also remain in place, with actions set and managed as applicable, for the health board to assure itself that patient safety and quality care is being maintained.

The RCS review team identified significant shortcomings in the clinical records they reviewed, which fed their concerns for patient safety.

Subsequently, the team recommended the health board to consider and determine whether the patient records held all the relevant data it expected for each patient, in line with the *RCS England good practice guide*.

The health board implemented a VQP to review all the records reviewed by the RCS team. Their findings were consistent with those of the RCS, concluding that not all the patient records contained the information they would expect for the patient episodes of care.

In addition, for some cases, further or more serious issues were identified by the VQP team. These additional findings were addressed with the relevant patients or their next of kin, as part of the VQP review process, and in line with the duty of candour. Further details can be found in RCS Recommendation One.

The RCS implemented the *Good Practice Guide*, to support surgical teams across the UK in delivering optimal standards of care. The guides detail the principles of the core standards within the RCS *Good Surgical Practice document*[9]. The overall guidance aims to assist employers, surgeons, and other healthcare professionals, to develop and implement models of care, which utilise the surgical care team in a consistent manner.

As part of the health board's actions to address the recommendations, we found that improvement work in relation to the significant issues identified by the RCS in relation to record keeping and consent was underway, soon after the RCS report was published.

[9] RCS: Good surgical practice

This included the appointment of a Professional Standards Vascular Lead, who is a vascular surgeon, to work closely with the clinical teams to drive improvement.

We found the health board had already commenced a pilot to implement a digital health record system in its vascular services. This is to move the process of recording clinical documentation from paper to electronic records. This is an encouraging initiative to help improve the access of information regarding patient care and treatment across the health board's vascular services. However, as this was in its preliminary stages, the records we reviewed were on paper.

We found that weekly audits of clinical records within vascular services were also implemented across all three acute sites. The audit results highlighted some pointed improvements in record keeping; further details of this will be provided later in the report. We were informed that the audit process has subsequently been extended to other surgical specialties, to review the quality of other teams' clinical record keeping. However, we did not consider the evidence for this outside of the vascular services.

During our patient case study, we did not reassess any of the cases reviewed as part of the RCS review, and instead we selected different patient records.

This included patients who had accessed the vascular services following the publication of the RCS report, from April 2022 onwards, to consider what improvements had been made since the RCS review.

When considering whether patient records were in line with the agreed standards of care, set out in the RCS G*ood Practice Guide*, we found that, overall, most records contained the expected information relevant to patient episodes of care. However, the documentation in a small number of records did not always meet the standard within the guide.

We found examples of both effective records keeping and records which did not meet the standards set out within the RCS guide. Whilst the majority demonstrated substantial improvement, some practices still require improvement in some areas of documentation. Examples of both are highlighted below:

Examples of effective record keeping:

- Detailed and complete documentation
- Contemporaneous record keeping
- Clear documentation with timely care plans following radiology reports
- Evidence of MDT discussions and decision making
- Evidence that care provided was being evaluated regularly
- Good evidence relating to inpatient care episodes.

Examples of areas that did not meet record keeping standards:

- Incomplete plan of care for one patient
- Misfiled notes (incorrect patient details in some records reviewed)
- The absence of some surgical operation records
- Records not filed in chronological order.

We found that training in medical record keeping had been provided to all medical teams in the vascular services and was delivered by the General Medical Council (GMC). We were informed that the training was based on the standards set out in the RCS good practice guides.

Whilst overall we found satisfactory progress and improvements with the clinical record keeping, some areas still required improvement as highlighted above, and detailed throughout this report. Therefore, further work is required to embed improved clinical record keeping by all staff into everyday practice. This is to ensure that all clinical records meet the standards expected for record keeping and to maintain the safety of patients.

The health board must continue with regular clinical record audits, and any issues identified, or actions needed through the results, should be addressed with individuals and learning should be cascaded throughout the teams responsible for documenting within patient clinical records. This should be routinely embedded into daily practice.

Further details on the issues highlighted within the *Good Surgical Practice Guide* can be found in Appendix C.

HIW Recommendation 2

The health board must maintain the record keeping audit process, to assure itself that the standards expected for record keeping, are consistent and are being maintained in the immediate and long term. Particularly within its vascular services, but also across the health board. This includes record keeping for all members of the MDT.

RCS Recommendation: 4

The Health Board should review the MDT and clinical pathway arrangements for those undergoing vascular surgery to ensure that there is appropriate MDT input into decision making for every patient. All MDT decisions and communication should be adequately documented in each patient's record.

HIW Summary of Findings

The health board has made satisfactory progress with this recommendation. However, further improvement is still required to ensure that the continuity of patient care is maintained to a high standard throughout the different pathways of care, and that the standard of communication within clinical records is further improved and promoted across all MDTs. In addition, work is needed to improve the working culture across different teams throughout the overall vascular pathway.

The RCS review team considered the effectiveness of the MDT in ensuring continuous and optimal patient care. They found in most cases, that there were either no MDT reports included in the patient records, or that MDT discussions were documented to have taken place, however, no decisions were documented.

Subsequently, the RCS team recommended the need for improvement with MDT input and decision-making, for every patient's journey through the clinical pathways in place.

In addition, the RCS review team highlighted that all decisions and communications should be adequately documented within the relevant clinical records. This is to ensure appropriate decisions, plans and outcomes are documented correctly within clinical records for all member of the MDT to see, to understand the decisions and plans for informing care and treatment, to maintain patient safety.

Multidisciplinary Working

As highlighted earlier, we found that in March 2022, immediate make safes were implemented in the service, which included enhanced consultant cover and closer MDT decision-making support provided from LUHFT. We found evidence that shared MDT working with LUHFT during out of hours was also implemented by the health board, and the MDT at Liverpool also supported the MDT meetings which were held every Friday. In addition, the health board also set up a service level agreement and MOU with LUHFT for additional support for surgeons from both the health board and Liverpool to work alongside each other. We also found that the vascular team in Liverpool supported the implementation of new Standard Operating Procedures (SOP), which have been implemented and are now used as part of the MDT process. This is to ensure key information is discussed and decisions are documented in a systematic way.

Since the implementation of support from Liverpool, the health board has also commissioned support from the University Hospital of North Midlands (UHNM), for the delivery of emergency and urgent elective AAA cases.

We found that a health board wide MDT meeting, which covers North Wales, is held every Friday. In addition, MDT meetings for more acute or urgent patients are also held on a Wednesday. The MDT meetings involve all available vascular consultants, interventional radiologists, and anaesthetic consultants, who consider patients from all three acute sites. Since September 2022, the vascular service has worked with the UHNM vascular service to ensure discussions and decisions have been undertaken for any patients requiring AAA surgery. The health board has also implemented a designated MDT coordinator, who records all decisions made during these meetings within the relevant clinical records.

We found that the process for surgical decision-making for AAAs is undertaken locally. The decisions made are then discussed in detail with consultants at UHNM vascular MDT meetings. This is to gain MDT assurances that treatment options and the decisions made are appropriate to each patient, and in line with best practice.

It was, overall, encouraging to find the satisfactory progress made against this recommendation, with the evidence in place demonstrating the above measures have been implemented. This confirms that the appropriate MDT input is in place, to ensure that adequate discussions, decision-making and plans of care are being implemented for vascular patients.

Record Keeping

We found that training for medical staff on clinical record keeping was provided by the GMC to all medical staff within vascular services, and of all grades. The training was based on the standards set out in the *RCS Good Practice Guides* as highlighted earlier. Following this, audit activity of clinical records was also implemented and undertaken by senior clinicians at the health board. We saw evidence that the standard of record keeping in relation to MDT discussions and decision-making is improving.

To help us establish what actions had been implemented by the health board to improve MDT working across the vascular services, as highlighted earlier, we completed a review of patient records, and considered what additional measures had been implemented to improve the quality of MDT discussions and decision making for patient care.

Since engaging with LUHFT and implementing new SOPs for the MDT process, the health board implemented MDT forms to be completed following discussions of each individual patient. When we reviewed the documentation relating to MDT discussions and decision-making, we found that the forms were being completed appropriately. The overall discussions were not always documented in the clinical records, however, the data for this was evident within the MDT forms, which were filed within the clinical records.

Clinical Pathways

The RCS report highlighted the need for clear agreed pathways to be in place, to ensure that timely and effective treatment is provided by all members of the MDT at sites across the health board.

It was evident from the documents we reviewed, through our attendance at meetings, and during our interviews with staff, that several new pathways have been developed and implemented through the Pathway Transformation Programme, to improve the quality and safety of patient care.

We saw evidence that several pathways have been revised, updated, or developed following the RCS review. These included pathways for the following:

- Patient admission
- Emergency transfer
- Ischaemic limb
- Intravenous Drug User
- Renal fistula
- Day case angioplasty
- Abdominal aortic aneurysm
- Diabetic foot
- Rehabilitation
- Repatriation
- Palliative
- Vascular escalation

We found that the management for the implementation and revised pathways process, was through the health board's RCS targeted intervention plan. We were informed in our interviews with Vascular Network staff that the implementation of the new pathways and the required changes to practice, were difficult to embed across the service. This was due to initial poor communication across the teams with some staff being slow to implement the changes to practice. To help with this, we were told that a PDCA (Plan, Do, Check, Action), process was in place for each new pathway to assist with the implementation process. Through this, any new issues, actions, or amendments can be completed as appropriate, and the aim is to complete the PDCA process on a fortnightly basis, until fully implemented.

Within our staff survey, we received some negative feedback in relation to pathways. This includes:

"There is no effective pathway in the West area. BCUHB will have potentially 3x different pathways (one for each area). Staff supporting vascular are demoralised as there is a chaotic and ad-hoc approach to the provision of patient care which is dependent on personalities (some vascular consultants will support [team redacted] and others do not). Some patients are even told to transport themselves to Ysbyty Glan Clwyd, and present to ED!"

"Pathways in place that all staff have agreed on, that all staff are aware they are on these pathways, vascular beds in YG, full time vascular consultant in YG, MDT in YG, staff are here and willing, but no accommodation, this has been promised for 3 years".

When the RCS team considered the effectiveness of clinical pathways (including referral and discharge), and more specifically the diabetic foot pathway, they focussed on whether procedures were undertaken in a timely manner, and if they were correctly undertaken. Whilst they found care was satisfactory for some patients, for the majority, they found several significant issues as highlighted in their report, hence their recommendation around clinical pathway arrangements.

During our review, we found that the health board had developed new pathways for discharge and referral and repatriation. These had been ratified and added to the health board's pathways library and linked to the vascular services webpage for ease of access for all clinicians. This was communicated to all staff through team meetings, and through email. Further details are highlighted below.

Diabetic Foot Pathway

We considered the improvements made to the diabetic foot pathway and found that transformation workshops took place in September and November 2022, and included MDT staff from the three acute sites. Through our records review and interviews with staff, we identified concerns following the implementation of this pathway, where the three acute sites were working inconsistently to each other.

Our interviews with staff indicated that in YG, there was poor communication between MDT staff working within the diabetic foot pathway. However, within WMH, the staff reported that the new pathway process was working well. The health board must explore the issues within YG and ensure improvements are made promptly, to ensure there is consistency across the health board in the provision of care through the diabetic foot pathway.

Similarly, to that highlighted above, we received feedback in our staff survey which aligned with the issues in YG regarding staff who work within the diabetic foot pathway, which states:

> *"More detailed plan [is needed] of who is responsible for diabetic foot, rather than a trail of emails passing patient from one [person] to another. Patients having their OPD appointments cancelled several times, then not being seen or re-scheduled, although urgent referrals, both legs to be scanned in YGC rather than one leg with wound, as frequently issues with the other leg on discharge, and the whole process has to start again".*

Our interviews with staff at YG identified that since the centralisation of vascular services at YGC, the clinics held at YG have not been able to run effectively. This was the result of the clinic area being removed to provide office space, and there was no longer a clinical area suitable to assess patients, or to provide post operative care, such as dressing changes. In addition, staff reported that the postoperative referral process was insufficient, and they often found that patients had been discharged from the hub site following surgery, but staff at YG had not been made aware of this.

As highlighted earlier, patients can choose where they wish to have their postoperative care undertaken. However, the current lack of clinical area within YG, to assess or provide follow up care to patients means, they may not always be able to receive post discharge care at YG. Instead, they may need to travel longer distances to other acute sites for their follow up appointments. The clinics at both spoke sites, are also intended for monitoring and screening of patients, where potential problems with the feet are identified early to help prevent the need for surgery. Staff reported a decline in the number of patients they were able to see, due to lack of clinical area to undertake this.

We also found through our staff interviews, that clearer working relationships must be established between diabetologists and vascular specialists, this is to ensure that patients are being referred promptly when required in relation to diabetic foot issues. In addition, staff also described the need for improved working relationships with the orthopaedic team and podiatry services, to ensure patients are assessed by the most suitable team, to provide more timely advice and care.

It is evident through our findings that there appears to be a cultural issue amongst different teams who may encounter a patient requiring the combined needs of different teams. In addition, within the feedback we received in our staff survey, some cultural issues were also raised with us. This includes:

"Communication between consultant [must be improved] on site, as regularly patients have 3 treatment plans, then they come home with nothing done. Realisation by vascular staff we are all under pressure, and being screamed at as they are too busy to help, does not indicate good practice!"

"The managers below them [senior management] on lower bands try their best to be supportive and always listen, however, they have no power or control over what happens within the vascular department, so as a line manager there are very little decisions that they can actually make. They are more of a listening ear which must be very frustrating to them. Our team have raised several concerns over the past 12 months surrounding lack of trained staff and our worries around things being missed or errors being made, no action has been taken. The consultants have also raised the same issues to senior management and again nothing has been done to support us. Our staff are overworked, working 6 days a week every week. Our

"Management need to develop methods of keeping skilled and experienced staff within vascular and prevent them leaving the unit".

"YGC to support staff and patients in YG, feels like that they don't care and don't want to work as a team. The system worked before they moved it all over to YGC".

"They always do everything in their power to ensure the patients are cared for in an effective and professional manner, and they always show empathy towards the patients

"I think we all work well as a team and support each other".

"Dedicated Surgical and Nursing Teams".

The health board must explore the working culture between teams involved within different care pathways, to ensure patients are receiving timely care and working relationships are functional. Issues were raised with us by staff which suggest poor communication between MDT staff working within the diabetic foot pathway, poor working relationships between diabetologists and vascular specialists, and within the orthopaedic teams and the podiatry services. The health board must also review the operational processes in place and the availability of clinical space at YG, to review and treat patients following their surgery, and for the monitoring and screening of patients with specific needs, associated with their diabetes.

HIW Recommendation 3

The health board must explore the reasons for reported inconsistencies in the implementation of the Diabetic Foot Pathway across its three acute sites.

HIW Recommendation 4

The health board must consider and address the issues reported to us regarding the lack of clinical areas at YG, to review patients pre and post operatively.

HIW Recommendation 5

The health board must consider the comments and findings in this report regarding staff culture and the perceptions of different teams. This is to establish whether there is learning, or development required to improve the working relationships across all teams, to support a positive working culture.

Referral and Repatriation Pathway

We found that the health board has implemented a referral and repatriation pathway within its vascular services. This was developed and implemented following the RCS recommendations, to improve the patient experience, the flow of patients across the vascular service and to maintain patient safety.

The pathway sets out the process that must be followed when patients require repatriation to their usual hospital near their home address, such as to YG or WMH, following their acute treatment or surgical procedures undertaken at YGC.

Whilst positive measures have been undertaken to implement a new referral and repatriation pathway, our staff survey received some negative responses regarding the effectiveness of the repatriation process.

These include:

> *"Patients need to be repatriated back to their local hospital. There are never any beds available".*

> *"Ward 3 in YGC often has patients from different specialities, so sometimes there are no available beds for vascular patients to be transferred into".*

Discharge Pathway

We found that the service has developed and implemented a discharge pathway, to improve the process and ongoing care needs beyond hospital admissions. The aim of the pathway is to ensure discharges are planned at an early stage to ensure safe and timely discharge from hospital with follow up plans in place.

The pathway also aims to help ensure that patients and clinical community teams receive information regarding their hospital treatment, and aftercare which includes the plans for follow up. In addition, as part of the new discharge pathway, patients can decide the geographical location for their follow up appointments and can also request the clinician they would like to see.

Whilst positive measures have been undertaken to implement a new discharge pathway, responses to our staff survey included some negative responses regarding the discharge process. These include:

> *"Patients have poor handover if they are admitted to Ysbyty Glan Clwyd, and community staff/ specialist staff are often unaware of their discharge, plus if they are a West patient admitted to Glan Clwyd, they are admitted on a different hospital number (West use 'D', Central use 'G' and East use 'M' numbers), thus compounding the problem of actually locating the patients!"*

> *"Patient [should] have clear discharge plans, and the district nursing team [should] be aware patients have been discharged from YGC vascular service (regular failure in this and patients do not get [surgical] dressings care following discharge). Concerns have been Datixed, [with] outcome 'unlikely to happen again', but it happens regularly."*

Given the health board has implemented new pathways to support its vascular services, it is pivotal the health board considers the comments made by staff and it should explore the reason behind the comments throughout this section. This is to ensure improvements are made where necessary.

HIW Recommendation 6

The health board must consider the comments made by staff regarding the ongoing issues following the implementation of new pathways. This is to establish whether the pathways need to be revised, or further action is required for compliance with the pathways as appropriately.

RCS Recommendation: 5

The Health Board should review the consent-taking practices within the Vascular surgery service to ensure appropriate discussion of risks, benefits and alternatives of treatment takes place and is legibly documented. Clinical records should clearly detail the giving of information and the decisions made by the patient. It should ensure that consent practices are compliant with the Montgomery ruling.

HIW Summary of Findings

The health board has made satisfactory progress with this recommendation, with improvements found within consent-taking process audits and our clinical records review. However, further work is required to ensure the records always clearly capture the entire process accurately and appropriately.

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. Acquiescence where the person does not know what the intervention entails is not consent[10],[11]. Gaining the patient's consent and documenting this sufficiently, is an issue that often presents difficulties. The recent changes in case law, such as the Montgomery ruling[12], has highlighted the crucial need to tailor information to the patient's individual needs.

We considered the health board's practices within vascular services, to establish whether an appropriate discussion of the procedure's risks, benefits and alternatives to treatment have been undertaken during the consent process, and whether this is legibly documented in the patient records.

When considering consent, and the health board's compliance with the consent process, we completed a patient case study, and reviewed the records of 39 patients within the vascular services.

It was evident in 25 out of the 30 relevant records reviewed, that information about their condition, treatment options and procedure had been discussed adequately with the patient, therefore informed consent was obtained.

All 19 records within YGC were clear and included the required information regarding patient consent. However, for five relevant records reviewed in WMH, we were unable to find the surgical procedure record from theatre, therefore, we were unable to triangulate the evidence from consent to theatre, to provide our judgement for these records.

[10] Reference Guide to Consent or Examination or Treatment - Department of Health
[11] Consent to Treatment - NHS
[12] Montgomery v Lanarkshire Health Board (2015) - Healthcare Ethics and Law

The incomplete record of the patient's journey through theatre, means that any clinician performing the follow up review, would not have the correct information available to them, to provide appropriate advice and care to the patient, therefore, potentially inhibiting the patient's recovery process and ongoing care needs. We promptly raised these issues with senior staff during our onsite fieldwork.

We also found an area for improvement within MDT discussions prior to treatment. In three records we reviewed, there was insufficient documentation to support that discussions had been held with the patient around reasons for the procedure. We did, however, feel this may have been due to the treatment being an emergency and in a life-threatening situation.

As part of our review, we engaged with patients in person. Those we spoke with during our fieldwork, were asked about their experiences during the consent process. Of the 15 patients we spoke with, 14 confirmed to us that their procedure had been sufficiently explained to them before they provided consent for their treatment. Each patient also confirmed that they had sufficient opportunity to ask questions about their procedure. The remaining one patient said, they were dissatisfied with the information that had been provided to them regarding their treatment.

To explore the consent process further, we also reviewed a recent clinical record audit report, which considered the quality of the documentation relating to consent. Twenty clinical records were reviewed during the audit, and the results highlighted a 100% compliance. This demonstrates a vast improvement in the recording of the consent process, from that found by the RCS review team. However, considering the findings from our records review, the health board must undertake further work to ensure the consent process is always completed appropriately and correctly.

In order to triangulating our evidence, we asked vascular network staff about training for consent during our interviews. We were told that all relevant staff involved in the consent process within the vascular service have completed consent training following the RCS review recommendations. In addition, that the process for monitoring training compliance for doctors is done through the Continued Professional Development Plan (CPDP) process, and training completion is reviewed quarterly. Despite the training and monitoring compliance through the CPDP process, we found a small number of non-compliance points as highlighted above.

On discussion with staff about our consent process findings, we were told that an audit pilot is scheduled to start in April 2023, as part of the quality improvement cycle. This will involve reviewing the quality of the consent process documentation of at least five vascular patients, to establish if this is in line with GMC consent guidance. This will allow the service to establish current practices on a regular basis to help ensure appropriate consistency, and to immediately address any issues where identified, and to share the learning from the results.

Overall, it is evident from our findings that the vascular service has addressed the consent taking practices as highlighted in the RCS review recommendations, and measures have been implemented to make improvements.

We found evidence demonstrating that the consent taking processes at the main hub site in YGC was satisfactory. However, improvements are required with obtaining appropriate consent and the suitable filing of clinical records at both spoke sites is needed.

HIW Recommendation 7

The health board must ensure that all staff are completing all aspects of the consent process as applicable and are documenting this within the relevant clinical records. In addition, further consent process audits must be undertaken and continue on a regular basis, with feedback provided to all staff and actions implemented as applicable.

RCS Recommendation: 6

The Health Board should audit the standard of clinical documentation to ensure there are contemporaneous and comprehensive notes of patient care at each stage of the surgical pathway.

HIW Summary of Findings

The health board has made satisfactory progress with this recommendation, alongside others relating to documentation and clinical record keeping. Whilst there is an overall improvement in record keeping, there is still more work for the health board to do, to assure itself that all staff are maintaining contemporaneous and comprehensive records for patients, and to ensure this is sustainable in the future.

During their review, the RCS team had cause for concern when reviewing several patient clinical records. They found in most records reviewed, several entries were illegible, and paperwork was frequently not filed in any form of order, which made it difficult for the team to provide a thorough assessment for each patient. This was consistent in the VQP review findings.

It is already highlighted throughout this report that work was underway from an early stage following the RCS review, to make improvements with clinical record keeping. We saw evidence of a monthly clinical records audit which considers the findings within 20 clinical records. The findings are reported to the Vascular Steering Group (VSG), and where required, any actions are discussed, and plans are developed to address these. The audit results highlight improvements in several areas, including the consent process, the quality of surgical operating notes, and the clinical record entries overall. We also saw evidence that significant improvements have been made in the quality of record keeping following vascular MDT meetings.

During our staff interviews, we noted that the audits results are also collated and are measured against the vascular improvement plan in place, which is also discussed in the VSG. From here, any issues identified are escalated to the Vascular Oversight Group. The audit results are disseminated to all relevant staff working within the vascular service, to ensure that lessons are learnt and any changes to practice are made.

Through our case study review, we considered the quality of record keeping and whether it was contemporaneous and comprehensive, to determine whether all appropriate and necessary discussions, care and treatment had taken place where expected, and was appropriately recorded and filed correctly.

The records we reviewed at YGC, were overall, well maintained and were clear and easy to navigate. Of the 19 records reviewed, four demonstrated that clinical entries were not filed chronologically, therefore, making them difficult to navigate and for the required information to be located.

The records reviewed at WMH, were found to be satisfactory, although some cases had an absence of records following surgical procedures, as they had not yet been filed into the clinical record at the time of our review. Failing to ensure notes are filed correctly and in a timely manner can mean patient care is not followed up appropriately by staff, due to the absence of procedure details. This highlights the importance of ensuring patient notes are completed and filed correctly.

The records reviewed at YG were mostly day case procedures and were not easy to navigate since they were not filed chronologically. Five of the six records we reviewed had satisfactory documentation, and entries regarding diagnostic and imaging, followed with clear timely plans made, which were documented accordingly. We found that discussions and decisions made for treatments were discussed with patients and were documented accordingly. All patient records were up to date and completed contemporaneously.

Overall, our patient record review, supported the results found in the health board's recent audits undertaken, as most records had contemporaneous and comprehensive documentation. Whilst we identified satisfactory improvements, the health board acknowledges that further work is required to ensure that the improvements are integrated into everyday practice and remain of high professional standard and must be sustained in the future.

HIW Recommendation 8

The health board must ensure that:

a) All clinical record entries are filed in chronological order
b) Surgical operation records are filled promptly after the surgical procedure

RCS Recommendation: 7

The Health Board should improve the quality of record keeping in clinical records. This should include but is not limited to:

- *(i) Information about patient admissions*
- *(ii) Descriptions of imaging investigations and reports during pre and post operations*
- *(iii) More detail in clinic notes and letters, which should document the reasoning and evidence for clinical decisions. This should include details of MDT discussions*
- *(iv) Descriptions of discussions with patients regarding diagnosis, options for treatment, risks of treatments and of non-treatment*
- *(v) More detailed information in operation notes, which should include diagrams to ensure completeness*
- *(vi) Information on final patient outcomes*
- *(vii) Details of discharge planning and care plans*
- *(viii) Details of the involvement of other health care professionals*
- *(ix) Clinical correspondence, radiology reports and investigation results*
- *(x) The filing process, which should reflect chronological events.*

HIW Summary of Findings

Overall, we found the quality of record keeping was much improved since the findings of the RCS team. However, further improvement is required, particularly for our findings for the records reviewed in YG and WMH. Whilst improvements have been made, and the health board's audit results demonstrate satisfactory improvement, more work is required to ensure the improvements are sustainable. This is because several issues remain with the quality of record keeping which may impact on the quality of patient care, most notable with filing of records chronologically and prompt insertion of surgical procedure records.

The RCS report found the quality of record keeping in the vascular service to be below the standard required for patients travelling through the health board's vascular service.

To establish whether improvements have been implemented and the progress made by the health board against this recommendation, we reviewed clinical records for each acute site. This report has already highlighted several areas regarding clinical record keeping, and will therefore, not be repeated through this section. However, in summary our work to consider this recommendation is reflective of our findings overall, including aspects highlighted elsewhere in this report.

The records we reviewed were a mixture of emergency, elective and outpatient records. The methodology used to gather evidence was developed from the RCS recommendations as listed in the RCS recommendation seven, as above.

We found that in most cases, record keeping had improved at the central hub site in YGC. However, for those reviewed within YG and WMH, further improvement is required to meet the expected standard.

We also found that some episodes of care were incomplete, as there was an absence of some surgical procedure records from theatre. In addition, we could not always identify whether some follow-up reviews had been completed, or when they had, there was insufficient detail recorded. We also found examples of misfiling in some records at each site, with the incorrect patient record filed in a different patient record. We escalated such issues immediately to the relevant staff within the vascular teams.

Central Hub Site – Ysbyty Glan Clwyd (YGC)

We reviewed 19 clinical records at YGC, which were a mix of planned admissions and emergency cases. Of the records reviewed, 15 were found to be satisfactory and easy to navigate and were well structured and in chronological order. In the remaining four records these were unsatisfactory, with episodes of misfiling, some records were not chronologically ordered, or were incomplete with the absence of surgical procedure records.

The admission documentation contained a satisfactory standard of information, with clear records of the reason for admission and plans documented on patient arrival.

For planned care admissions, we found effective communication and documentation within the MDT meeting records. This included patient diagnosis, morbidity and decision-making being discussed appropriately, prior to commencing treatment. We also found that diagnostic and imaging results were clearly documented and formed part of the MDT decision making process.

When considering discharge planning or repatriation of care, we found this to be clear and complete in most cases. We found satisfactory examples of the support being in place before discharge, for the patients who required it. For patients who required repatriation, a timely referral was made for all but one of the patients.

We found that discharge letters to the GP (and patient) contained a detailed reflection of the patient's journey through vascular services, to facilitate appropriate continuation of care following discharge. This included the requirements for ongoing anticoagulation or antibiotic therapy as appropriate and any follow up plans.

Our findings relating to admission, repatriation and discharge contradicts some of what staff told shared with us in interview or survey, as highlighted in different sections within this report.

Spoke Site (east) – Wrexham Maelor Hospital (WMH)

The records we reviewed at WMH were mostly day case patients, such as those for varicose veins treatment. Of the 11 records reviewed, two did not have surgical procedure records filed promptly within the clinical records as appropriate.

When considering the MDT process for patient care prior to treatment, the records we reviewed showed effective communication between members of the MDT, and that discussions and decisions were clearly documented in the notes. However, for three records reviewed, each had a delay from the decision to treat, to the treatment being given. This was due to delays in obtaining further radiology imaging and/ or waiting times for a bed to become available. The remaining records showed good clear documentation with timely care plans made following radiology reports. We found that patients had been discussed within the MDT meetings prior to commencing treatment.

We found that discussions with patients and next of kin regarding the reasons for treatment were well documented. All records were up to date and were completed contemporaneously. Overall, it was evident that care was planned in a way that promoted the patient's independence, and we found that care was evaluated regularly.

Upon reviewing surgical procedure notes at WMH, overall, we found the records to be clear and well documented, with clear post operative plans included. We also found evidence of one AAA repair, and this was performed in line with the dual consultant process (which was performed at YGC).

We found satisfactory documentation on the planning for discharge. Patients had received support where necessary to facilitate their discharges.

The discharge letters had been well completed to facilitate appropriate continuation of care. This included the need for ongoing medication requirements.

Spoke Site (west) – Ysbyty Gwynedd (YG)

The records we reviewed at YG were all planned episodes of care. All were difficult to navigate, and it was hard to find documentation relating to admission. Some entries were signed, but the clinicians name had not been printed. Operation notes had not been filed in the record, and not all entries were in chronological order. There was also misfiling in one set of records we reviewed.

We found that the reason for patient admissions had been clearly documented. Their care was planned prior to the patient's arrival on site, and they had been reviewed by a consultant within 24 hours of admission. Where necessary, we found satisfactory entries from the MDT members.

Most cases we reviewed at YG were day case procedures. In five of the six cases we reviewed, diagnostic and imaging results were clearly documented in the notes and timely plans were made in view of the results. We saw that decisions to operate were discussed with patients and documented accordingly.

All patient records were up to date and were completed contemporaneously. It was also evident that care was evaluated regularly and planned in a way that promoted patient independence.

Documentation to support the delivery and effectiveness and evaluation of care were found to be satisfactory at YG.

Overall, discharge and repatriation planning at YG was found to be of a good standard. All cases showed clear evidence of transfer of care or discharge planning. All cases also showed documentation that the patient was medically fit for discharge and a clear discharge letter was in place. This included plans for follow up and continued medications required.

Overall summary of records for the three acute sites

Overall, we found that the health board has implemented plans for improvements in the quality of record keeping. However, further improvement is required, particularly for the general filing of records to ensure they are kept in chronological order, the surgical procedure record from theatres should be filed promptly and in the correct place, and records should not contain any documents that relate to other patients. The records held within YG require the most attention for improvement.

In all sites, we found diagnostic and imaging results were clearly documented in the records, and timely plans of care were made in view of these results.

We found clear discharge planning documentation in all three sites, and discharge letters contained a detailed reflection of patient's journey through the vascular service, to facilitate appropriate continuation of care. This included the details for the appropriate ongoing medications, and the follow-up plans for patients, although this is in contrast to what some staff told us during interview and in our staff survey.

Overall, we consider that this recommendation has been addressed with progress made for improving the quality of clinical records. However, further improvements remain necessary to ensure compliance with regulatory record keeping standards. This is highlighted in this recommendation and within other sections of this report.

HIW Recommendation 9

The health board must address the issue where we found examples of misfiling an incorrect patient clinical record, in a different person's record.

HIW Recommendation 10

The health board must ensure that clinical documentation entries are signed with the clinician's name legibly printed for identification of the author.

RCS Recommendation: 8

The Health Board should consider Liverpool University Hospitals NHS Foundation Trust (or other centre the Health Board currently works with) having oversight of the aneurysm pathways at BCUHB. In the opinion of the review team, the aneurysm service would benefit from oversight by an external independent clinician or unit, such as Liverpool University Hospitals NHS Foundation Trust, where the vascular unit already has an informal network relationship. The review team recommend that the Health Board has an automatic referral to Liverpool Trust's (or other centre the Health Board currently works with) MDT, for review of their decisions in any case that could not be treated with a standard Endovascular Aneurysm Repair (EVAR[13]).

HIW Summary of Findings

The health board has addressed this recommendation and implemented the required actions promptly following the RCS recommendations. A new model of working relating to aneurysm treatment has been embedded in to practice within the health board, with oversight provided by LUHFT and UHNM, and for discussions and decision making of patients who require aneurysm repairs when they cannot be treated with a standard EVAR.

As highlighted earlier in the report, the health board took immediate steps to strengthen clinical leadership and entered into a service level agreement with a Memorandum of Understanding with LUHFT. This provided the health board with enhanced consultant cover and closer decision-making and planning support for patients requiring more complex vascular surgeries. Since the implementation of support from LUHFT, the health board has also commissioned support from UHNM to support the delivery of emergency and urgent elective AAA cases and within the MDT meetings related to these cases.

Following initial oversight of the MDT by staff from LUHFT, a more formal arrangement with UHNM was agreed. This included the provision of a second on call out of hours consultant surgeon for AAA procedures. As previously highlighted, the new process for the AAA service sets out the requirement for surgical decisions to be discussed within the MDT meetings prior to the surgery taking place, except for immediate life-threatening cases.

In response to the RCS recommendation, in July 2022, the health board formally introduced dual consultant operating for all 'out of hours' emergency AAA procedures.

[13] Endovascular Aneurysm Repair (EVAR)

To facilitate this, two vascular surgical consultants were required for the 'out of hours' on-call rota. Whilst the health board implemented this process following the RCS review, it has not been sustainable.

During our interviews with staff, we were informed that although the incidences of emergency AAA procedures was very low, the increase for individuals needing to undertake 'on-call' commitments, put significant strain and pressures on the health and well-being of the existing cohort of consultants. This subsequently resulted in increased sickness levels.

To mitigate against this issue and to maintain service provision, the health board explored other options, and concluded that an alternative process was required. In December 2022, very senior middle grade doctors were introduced to the rota as the second surgeon for AAA cases. This mean that senior surgical support with appropriate experience in complex vascular surgery (but not a consultant), now support as the second on-call surgeon. The health board informed us that there have not been any reported issues or concerns with the adapted rota, although close monitoring and evaluation of these procedures is ongoing.

Dual surgeon procedures are ongoing for AAA surgery undertaken within the service, and the consultants we spoke with confirmed that they were happy to have an experience colleague with them during these procedures and wanted the process to continue. We were told that on the occasions when it is determined that AAA procedure is not able to be dual operated at YGC, the patient is transferred to UHNM for the treatment.

On occasions, some patients require transfer to UHNM or LUHFT for more complex and higher risk procedures, which cannot be undertaken at YGC. During our interviews with some staff, they did not recall any recent cases which involved a patient being transferred to UHNM for surgery.

However, we were informed a small number of cases continue to be referred to LUHFT, when complexity of a patient's condition and needs falls outside of the scope of surgical practice of either YGC or UHNM.

As highlighted earlier, the health board has an MOU and service level agreement agreed with UHNM for the provision of vascular service MDT support. This sets out the responsibilities of both the health board and the UHNM for the management of patients requiring certain types of arterial surgery. We were informed that the health board is also developing an ongoing partnership with the UHNM vascular service, which aims to harmonise practices between the two organisations. This is to support the health board's vascular surgeons with treatment decision-making processes.

RCS Recommendation: 9

The Health Board must make arrangements for a member of the Liverpool Trust's (or another centre) MDT team to attend the BCUHB's MDT, in person or remotely for a period of three months, to provide feedback on the process. This could be formalised to involve the Liverpool Trust's unit (or another centre) having closer involvement in BCUHB's MDT and governance processes around the aneurysm pathway and to provide more active clinical support.

HIW Summary of Findings

The health board has made satisfactory progress with this recommendation. It immediately commenced work to address the recommendation following the RCS review and developed a working relationship with LUHFT to support them, as highlighted throughout this report. It specifically implemented a process to gain the required clinical support within the vascular MDT meetings and in relation to the aneurysm pathway. However, further work is required for the health board to assure itself that MDT discussions are documented within clinical records.

As highlighted throughout this report, the health board promptly implemented the recommended clinical support which was initially provided by the vascular service at LUHFT. In addition, since September 2022, the health board's vascular service now has a formal arrangement with UHNM. This arrangement includes involvement and oversight from UHNM of all vascular patients requiring AAA surgery and their presence within MDTs which are held every Friday. In addition, further clinical support is provided for acute urgent patient discussions and decision-making MDT meetings, which are held every Wednesday. The health board confirmed that the oversight from UHNM staff will continue until 2024.

The RCS report highlights that in most cases assessed during their review, they found no documentation from the MDT meetings detailed within the clinical records. This meant that they did not have assurance that patients were being discussed and decision were made appropriate for treatment or surgery, as there was no evidence to support this. In addition, with the lack of MDT documentation, there was no evidence to demonstrate whether robust plans were implemented based on decisions made during MDT meetings.

During the time of our fieldwork, we found that the health board's targeted intervention plan included a 2022-2023 audit programme. This included the plan to review standards of MDT processes across the health board and with the services provided by LUHFT and UHNM. This was implemented to continually monitor the MDT processes and identify any further improvement or training requirements. We reviewed the evidence which demonstrated significant improvements to the overall MDT working process within the vascular services.

As part of our patient case study review, we assessed the effectiveness of the MDT, and the quality of documentation following MDT meetings and in the provision of optimal patient centred care. This has been highlighted in several places within this report and will therefore, not be repeated in the section.

Overall, we found evidence available to demonstrate that MDT discussions and decision-making regularly takes place. The MDT forms were completed for most cases we reviewed and were filed appropriately with the relevant patient's clinical records.

We have already highlighted that on occasions, some patients require transfer to UHNM or LUHFT for more complex and higher risk procedures, which cannot be undertaken at YGC.

Oversight from UHNM of all vascular patients requiring AAA surgery and their presence within MDTs will continue until 2024. This is to ensure patient discussions and decision-making is adequately considered with experienced vascular experts.

The health board must consider and evaluate its position regarding external support for vascular surgery MDT engagement, before it concludes in 2024. This is to determine whether it is assured that the service can continue without the support currently in place. If it feels further ongoing support is required, this must be confirmed prior to the end of the current agreement, to maintain the safety of patients.

HIW Recommendation 11

The health board must ensure a process is in place to evaluate the sustainability of its vascular service support from UHNM to determine what arrangements will be in place once current agreements end in 2024.

Conclusion

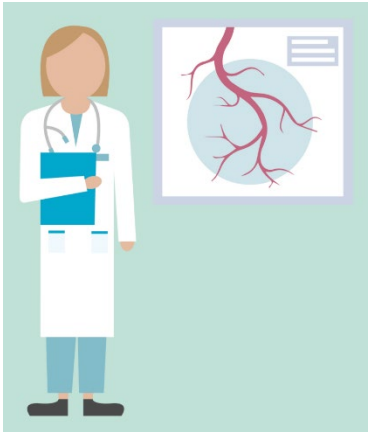
The aim of our review was to explore whether the current arrangements in place within the health board's vascular services following the RCS review, support the delivery of quality care, which is safe, timely and effective. Our review has found that adequate processes are now in place, which supports the health board's ongoing objective to provide safe, timely and effective care to patients using its vascular services.

It is clear from our findings that the health board has made satisfactory progress against all nine recommendations made following the RCS review, and work to address the issues was commenced promptly, particularly for the five urgent recommendations relating to patient safety risks. However, further work is still required to strengthen some aspects of clinical record keeping, and to ensure the patient's journey through the vascular pathways is consistent and robust. This is to ensure that care is equitable regardless of a patient's geographical location, and that the quality of written communication is maintained, and records are filed in a timely manner and in chronological order.

Overall, we found evidence to demonstrate that appropriate actions have been taken by the health board, to implement processes to improve services and the care and safety of patients. Whilst the additional support provided by LUHFT and UHNM has much improved the service provided to patients within the health board, and their overall safety, it is paramount the health board maintains a robust governance process to manage and monitor care. The health board should ensure it is adequately prepared when the support from UHNM ends in 2024, particularly for aspects of the vascular pathway, such as MDT support for patient discussions and decision making.

We also found the governance arrangements in place within the health board to monitor the ongoing response to the RCS findings and recommendations, were satisfactory. There are adequate arrangements in place to manage and monitor the progress within vascular services, which capture any issues, and address required actions to rectify any issues found. Whilst documentation is much improved, we feel that staff engagement to further progress comprehensive documentation within clinical records is pivotal. This is to ensure care episodes are captured accurately, and that ongoing care needs can be established as appropriate, in order to maintain safe and quality care for people using the health board's vascular services.

Whilst we have found improvements across the vascular service and have de-escalated it as a Service Requiring Significant Improvement, the health board must ensure it has measures in place to assure itself that the improvements and processes implemented since the RCS review, are sustainable now and in the future. In addition, the health board must take action to consider and improve the staff cultural issues we identified during our review.



What Next?

We expect the health board to maintain the progress it has made in improving its vascular service since the RCS review. We also expect the health board to carefully consider the findings from our review and act upon the 12 recommendations set out within the report and listed within Appendix A.

The health board should use the findings of this review to reflect further on what it has implemented since the RCS review, and to consider the robustness of its governance processes to ensure the improvements within the service are maintained and are sustainable for the future. This must include the need for ongoing audit processes within several aspects of the delivery of care, as patients travel through the vascular service pathways.

The health board will be required to submit an improvement plan in response to our review's findings and recommendations. This is to ensure that the issues raised by our review are being appropriately addressed.

It is our expectation that the health board will ensure that the staff working within its vascular service and those closely associated with the service have an opportunity to receive and understand the findings from out review.

Appendix A

HIW Recommendations

As a result of the findings from this review, we have made the following recommendations in the table below.

	Recommendations:
1	The health board must consider its responsibilities in line with the NHS Wales Putting Things Right process. This is to establish whether timelier responses could have been given following the two formal complaints it received, and whether it is assured that updates were given appropriately throughout the course of the complaint investigation. The health board should set out what action will be taken to ensure that in future, people are communicated with in a timely manner when raising concerns.
2	The health board must maintain the record keeping audit process, to assure itself that the standards expected for record keeping, are consistent and are being maintained in the immediate and long term. Particularly within its vascular services, but also across the health board. This includes record keeping for all members of the MDT.
3	The health board must explore the reasons for reported inconsistencies in the implementation of the Diabetic Foot Pathway across its three acute sites.
4	The health board must consider and address the issues reported to us regarding the lack of clinical areas at YG, to review patients pre and post operatively.
5	The health board must consider the comments and findings in this report regarding staff culture and the perceptions of different teams. This is to establish whether there is learning, or development required to improve the working relationships across all teams, to support a positive working culture.
6	The health board must consider the comments made by staff regarding the ongoing issues following the implementation of new pathways. This is to establish whether the pathways need to be revised, or further action is required for compliance with the pathways as appropriately.
7	The health board must ensure that all staff are completing all aspects of the consent process as applicable and are documenting this within the relevant clinical records. In addition, further consent process audits must be undertaken and continue on a regular basis, with feedback provided to all staff and actions implemented as applicable.
8	The health board must ensure that: a) All clinical record entries are filed in chronological order

	b) Surgical operation records are filled promptly after the surgical procedure.
9	The health board must address the issue where we found examples of misfiling an incorrect patient clinical record, in a different person's record.
10	The health board must ensure that clinical documentation entries are signed with the clinician's name legibly printed for identification of the author.
11	The health board must ensure a process is in place to evaluate the sustainability of its vascular service support from UHNM to determine what arrangements will be in place once current agreements end in 2024.

Appendix B

Recommendations within the RCS report

Urgent recommendations to address patient safety risks:

The recommendations below are considered to be highly important actions for the healthcare.

organisation to take to ensure patient safety is protected.

1. The Health Board should consider the conclusions of this report, as well as the other information it holds, and on this basis provide further follow-up of any patients for which it considers this to be required. This should protect patient safety and ensure that patients or their families have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20[14]
2. The review team were unable to determine the outcome for a number of the patients. The Health Board should review the care of these patients to ensure the Health Board are aware of the outcomes and that the Health Board has met its ethical and legal obligations, including those outlined in recommendation 1.
3. The Health Board should review the comments made in this report, alongside the local information it holds, and determine if the patient records contained the information, they would expect for the patient episode(s). The Health Board should ensure that the current practice meet the agreed standards as set out in the RCS England good practice guide[15]
4. The Health Board should review the MDT and clinical pathway arrangements for those undergoing vascular surgery to ensure that there is appropriate MDT input into decision making for every patient. All MDT decisions and communication should be adequately documented in each patient's record.

[14] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (legislation.gov.uk)
[15] Surgical Care Team Guidance — Royal College of Surgeons (rcseng.ac.uk)

5. The Health Board should review the consent-taking practices within the Vascular surgery service to ensure appropriate discussion of risks, benefits and alternatives of treatment takes place and is legibly documented. Clinical records should clearly detail the giving of information and the decisions made by the patient. It should ensure that consent practices are compliant with the Montgomery ruling[16].

The RCS England good practice guide[17] may be of assistance in this process.

Recommendations for service improvement

The following recommendations are considered important actions to be taken by the healthcare organisation to improve the service:

6. The Health Board should audit the standard of clinical documentation to ensure there are contemporaneous and comprehensive notes of patient care at each stage of the surgical pathway.
7. The Health Board should improve the quality of record keeping in clinical records. This should include but is not limited to:
    a. Information about patient admissions
    b. Descriptions of imaging investigations and reports during pre and post operations
    c. More detail in clinic notes and letters, which should document the reasoning and evidence for clinical decisions. This should include details of MDT discussions.
    d. Descriptions of discussions with patients regarding diagnosis, options for treatment, risks of treatments and of non-treatment
    e. More detailed information in operation notes, which should include diagrams to ensure completeness.

[16] The 2015 Supreme Court decision on Montgomery vs NHS Lanarkshire
[17] Consent: Supported Decision-Making — Royal College of Surgeons (rcseng.ac.uk)

f. Information on final patient outcomes

g. Details of discharge planning and care plans

h. Details of the involvement of other health care professionals

i. Clinical correspondence, radiology reports and investigation results

j. The filing process, which should reflect chronological events.

8. The Health Board should consider Liverpool University Hospitals NHS Foundation Trust (or other centre the Health Board currently works with) having oversight of the aneurysm pathways at BCUHB. In the opinion of the review team, the aneurysm service would benefit from oversight by an external independent clinician or unit, such as Liverpool University Hospitals NHS Foundation Trust, where the vascular unit already has an informal network relationship.

The review team recommend that the Health Board has an automatic referral to Liverpool Trust's (or other centre the Health Board currently works with) MDT, for review of their decisions in any case that could not be treated with a standard EVAR.

9. The Health Board should make arrangements for a member of the Liverpool Trust's (or another centre) MDT team to attend the BCUHB's MDT, in person or remotely for a period of three months, to provide feedback on the process.

This could be formalised to involve the Liverpool Trust's unit (or another centre) having closer involvement in BCUHB's MDT and governance processes around the aneurysm pathway and to provide more active clinical support.

Appendix C

RCS Good Surgical Practice: A guide to good practice[18]

"Record Your Work Clearly, Accurately and Legibly!"

Surgeons must ensure that accurate, comprehensive, legible and contemporaneous records are maintained of all their interactions with patients. In meeting the standards of Good Medical Practice, you should:

- Be fully versed in the use of the electronic health record system used in your organisation and record clinical information in a way that can be shared with colleagues and patients and reused safely in an electronic environment.
- Take part in the mandatory training on information governance offered by your organisation, including training on data protection and access to health records.
- Ensure that all medical records are accurate, clear, legible, comprehensive and contemporaneous and have the patient's identification details on them.
- Ensure that when members of the surgical team make case note entries these are legibly signed and show the date, and, in cases where the clinical condition is changing, the correct time.
- Ensure that a record is made of the name of the most senior surgeon seeing the patient at each postoperative visit.
- Ensure that a record is made by a member of the surgical team of important events and communications with the patient or supporter (for example, prognosis or potential complication). Any change in the treatment plan should be recorded.
- Ensure that there are clear (preferably typed) operative notes for every procedure. The notes should accompany the patient into recovery and to the ward and should give sufficient detail to enable continuity of care by another doctor.

[18] RCS Good Surgical Practice: A Guide to good practice

The notes should include:

  - Date and time
  - Elective/emergency procedure
  - Names of the operating surgeon and assistant
  - Name of the theatre anaesthetist
  - Operative procedure carried out
  - Incision
  - Operative diagnosis
  - Operative findings
  - Any problems/complications
  - Any extra procedure performed and the reason why it was performed
  - Details of tissue removed, added or altered
  - Identification of any prosthesis used, including the serial numbers of prostheses and other implanted materials
  - Details of closure technique
  - Anticipated blood loss
  - Antibiotic prophylaxis (where applicable)
  - DVT prophylaxis (where applicable)
  - Detailed postoperative care instructions
  - Signature.

- Ensure that sufficiently detailed follow-up notes and discharge summaries are completed to allow another doctor to assess the care of the patient at any time.
- Ensure that you are familiar and fully compliant with the guidelines of the Data Protection Act 1998 around the use and storage of all patients' identifiable information

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

Communications Manager
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ

Or via:

Phone: 0300 062 8163
Email: hiw@gov.wales
Website: www.hiw.org.uk

Mae'r ddogfen yma hefyd ar gael yn Gymraeg.
This document is also available in Welsh.

WG47916
Digital ISBN 978-1-83504-220-5