Clinical Record Review Report

Royal College of Surgeons of England
ADVANCING SURGICAL CARE

Report on 44 clinical records relating to vascular surgery on behalf of Betsi Cadwaladr University Health Board

Review visit carried out on: 19 July 2021

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A clinical record review on behalf of:

The Royal College of Surgeons of England

The Vascular Society of Great Britain and Ireland

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Contents

1. Introduction and background

On 24 September 2020, Dr Kate Clark, Medical Director for Secondary Care of Betsi Cadwaladr University Health Board (referred to hereafter as "BCUHB"), wrote to the Chair of the Invited Review Mechanism (IRM) to request an invited service review including a clinical record review of fifty cases relating to vascular surgery. In particular, the request highlighted the need for the review to address the standard, quality and safety of care provided by the vascular surgery service under the model of the integrated Vascular Network, since it was established in April 2019. The review would feed into and inform a wider process to improve the service and to enable greater assurance of its safety and quality. This request was considered by the Chair of The Royal College of Surgeons of England (RCS Eng) IRM and a representative of the Vascular Society of Great Britain and Ireland (VSGBI), and it was agreed that an invited service review would take place on 11-13 January 2021. It was originally intended that the clinical record review of 50 cases would be incorporated in the service review, however it was not possible for BCUHB to provide the fifty sets of clinical records in advance of the service review and, therefore, it was agreed that a subsequent, standalone clinical record review would take place.

The clinical reviewers (referred to hereafter as "the review team") who carried out the invited service review were appointed to review the cases and a site visit took place on 19 July 2021. The review team considered the care provided to the fifty patients put forward by BCUHB. This included the review of the clinical records, and supporting information, provided to the review team by the Health Board.

The appendices to this report list the members of the review team and supplementary information provided to the review team. This clinical record review was carried out with the purpose of meeting the terms of reference outlined in section two, and drew conclusions from the information provided in relation to the clinical record review only.

The review team's conclusions are based on the information provided to them, which are outlined in section three. The notes made by the clinical reviewers with regard to the individual cases are detailed in Appendix A. These represent their initial views on each case while looking at them individually and do not necessarily reflect their final conclusions. The conclusions section of this report contains the review team's views on the care provided to these patients, and recommendations based on these conclusions are outlined in section four.

1.1. Background[1]

In January 2013, following public consultation, BCUHB announced that the provision of services for major and complex in-patient arterial surgery and emergency vascular surgery would be centralised onto a single site at Ysbyty Glan Clwyd (YGC). The transition to centralisation was to involve an interim arrangement of provision services at two sites; Ysbyty Gwynedd (YG) and Wrexham Maelor (WM). The implementation of centralisation was delayed due to renovation of the YGC site and concerns raised by some clinicians and external stakeholders. To address this, in 2015, an external invited service review was commissioned from the RCS England.

This invited service review concluded that patient safety was being compromised with the provision under a two site model and that BCUHB should not delay the decision to centralise the provision of major and complex arterial surgery and emergency vascular surgery as part of delivering the vascular surgery service by an integrated network hub and spoke model[2]. This

[1] Background information provided by BCUHB as part of the invited review request.

[2] High quality urgent vascular care is best delivered by integrated vascular networks [also the central recommendation by the 2018 "Getting it right first time" (GIRFT) review of vascular services. Under this model, the arterial centre (hub) provides

integrated vascular network service model was informed and supported by the Vascular Society of Great Britain and Ireland (VSGBI), RCS England, Public Health Wales through the Welsh Abdominal Aortic Aneurysm Screening Programme (WAAASP) and Welsh Government. It was also supported by the North Wales Local Medical Committee (LMC), the majority of clinicians and the North Wales Community Health Council (NWCHC).

Prior to the request in September 2020 for an RCS England invited review, an internal review was undertaken of the vascular services provided by the integrated vascular network model established in April 2019, following concerns raised by patients, carers and staff. These concerns were included in a report by the North Wales Community Health Council, which was presented to the BCUHB in May 2020[3].

1.2. Overview of healthcare organisation and department[4]

The integrated vascular network for the provision of vascular services through a hub and spoke model of patient care was established in April 2019. This consisted of (and was still the arrangement at the time of the review), a centralised acute hub service at the YGC site and two spoke sites at YG and WM.

The vascular surgery service provided by BCUHB is a specialty focusing on the diagnosis and surgical treatment of disorders of the blood vessels, excluding the heart, lungs and brain. It provides emergency and elective treatment for patients for conditions including life-threatening emergencies such as aortic aneurysms (an abnormal dilation or ballooning of an artery caused by the pressure of blood flowing through the area) and less severe conditions such as varicose veins. Many vascular conditions are treated in a less invasive manner, using interventional radiology. Patients can be referred to the vascular service by their GP[5].

There were, at the time of the review, eight consultant surgeons within the vascular surgery service and a further three consultant general surgeons within the wider team. There were also the following non-consultant grade doctors supporting the service[6]:

- At the hub site (YGC), three specialist surgical registrar (SpR) doctors and one grade 3 specialty surgical registrar (StR3) doctor. The SpR post at YG was vacant and there was a SpR due to start at WM in January 2021.

- At the hub site (YGC), one F1 and two SHO[7] doctors. At YGC spoke site, a core training doctor (CT1) at YG. The SHO post at WM spoke site was vacant and interviews were reportedly being arranged.

The 1:8 on-call arrangement was that the consultant vascular surgeon of the week commenced Friday evening, covered that weekend and the following week (in hours), and handed over on Friday. The surgical registrar on call of 1:11 was provided by the general surgery team.

There was understood to be a vascular clinical nurse specialist (CNS) at each of the three sites and an advanced nurse practitioner (ANP) at the hub site[8].

The vascular clinical facilities available at YGC hub site included:

arterial surgery and complex endovascular interventions with the related pre and post procedure care, delivered where possible at the local non-arterial (spoke) sites. Day case peripheral angioplasty and stenting can also be performed at spoke sites. All hospitals in the network continue to provide clinical support (vascular clinics, diagnostics, some specific

interventions, review of inpatient vascular referrals and rehabilitation)]. “The provision of services for patients with vascular disease 2018 Vascular Society of Great Britain and Ireland (VSGBI). (Review date 2021).

[3] There was understood to have been a delay in this report being presented to BCUHB due to the COVID-19 pandemic.

[4] Background information provided by BCUHB as part of the invited review request and the Service Overview information.

[5] https://bcuhb.nhs.wales/health-services/health-services1/services1/services/vascular-surgery/

[6] RCS England has published general information on “who’s who in the surgical team.”

[7] The term Senior House Officer (SHO) has been replaced with specialist trainees years 1 & 2 (ST1/ST2)

[8] During interviews, CNS and ANP appeared to be referred to, at times, synonymously. Therefore, in the report, CNS/ANP is used where either of the terms was used.

- Eighteen service dedicated ward beds (ward 3).[3]
- Eight level three intensive care unit (ICU) beds and five level two high dependency unit (HDU).
- Ten major theatre sessions plus access to shared 24/7 emergency theatre.
- One and a half theatre sessions for elective day cases.

[3] The fifteen ward beds at YG were suspended in September 2019.

2. Terms of reference for the review

The following terms of reference for this review were agreed prior to the review being undertaken between the RCS England, the review team and Betsi Cadwaladr University Health Board (BCUHB).

The review will involve:

- Consideration of background documentation regarding the vascular surgery service.
- A clinical records review of 50[4] specific cases put forward by BCUHB[5].

Terms of Reference

In conducting the review, the review team will consider the standard, safety and quality of care provided by the vascular surgery service under the current integrated vascular network, including with specific reference to:

1. Both established and developing clinical pathways in providing optimal clinical care, including consideration of:

    (i) The effectiveness of referral pathways in enabling timely access for patients to effective interventions.

    (ii) The effectiveness of the "diabetic foot pathway," in the management of diabetic foot disease in line with national standards.

    (iii) Clinical decision making.

2. The effectiveness of the multidisciplinary team (MDT) in ensuring continuous and optimal patient care.

3. Clinical governance, including the effectiveness of:

    (i) Mortality and Morbidity (M&M) in discussing cases as part of learning and taking forward actions.

    (ii) The processes in place for concerns and incidents to be reported and addressed.

    (iii) The appropriate communication of outcomes following reported concerns and incidents.

4. Clinical outcomes, complications and mortality for both the service and individual surgeons in the context of accepted national and international standards/norms.

[4] The review was originally to include 50 cases; this was revised to 49 cases. 44 cases were provided for review during the review visit and this is what has been reported on.

[5] During the planning phase of the service review, it was not possible for BCUHB to provide the fifty sets of clinical records in advance of the review. A review of the clinical records, therefore, was to take place on site after the service review and a separate report to be provided.

5. The adequacy of the medical staffing and clinical facilities for the volume and type of clinical activity undertaken.

6. Behaviours, communication and team working, including specific reference to:

   (i) The team of consultant vascular surgeons.

   (ii) The wider vascular surgery service.

   (iii) The multi-disciplinary team (MDT).

   (iv) Engagement and communication between the vascular surgery service and:
   - The spoke sites,
   - The relevant community services.

7. Communication with patients and other health professionals, with specific reference to:

   (i) The effectiveness of providing information to patients in supporting and enabling shared decision-making.

   (ii) The adequacy of the provision of patient clinical information to the appropriate primary and community health care teams

Conclusions and recommendations

The review team will, where appropriate:

- Form conclusions as to the standard of care provided by the vascular surgery service including whether there is a basis for concern in light of the findings of the review.

- Make recommendations for the consideration of the Medical Director for secondary care of the Betsi Cadwaladr University Health Board as to courses of action which may be taken to address any specific areas of concern which have been identified or otherwise improve patient care.

The above terms of reference were agreed by the College, the healthcare organisation and the review team on 14th December 2020.

3. Conclusions

The following conclusions are based on the information provided to the review team from the clinical records reviewed and any other supplementary information provided. These are overall conclusions based on the cases provided and focused on highlighting areas of concern or improvement.

The review team highlighted that it appeared that there were cases where the entire patient record had not been provided for review. Where there appeared to be an absence of expected documentation, they have made a note of this in the clinical records notes in Appendix A. There were no clinical records available for the review team to assess regarding six cases[6].

There was cause for concern identified by the review team in the sample of cases reviewed. The review team noted that in the majority of the clinical records, some or many entries were illegible and paperwork was frequently not filed in any form of order, which made it difficult to provide a thorough assessment for each case. In some cases[7], there was no summary of the patient's clinical history included in the patient's record. This meant that there were instances where they were unable to draw conclusions on all domains of care as required by the Terms of Reference. The review team were strongly of the opinion that the majority of the surgical notes and supporting correspondence, results and reports were disorganised, illegible and incomplete.

The review team would like to highlight their concerns regarding the aneurysm patients reviewed, in terms of the complications, mortality, prolonged procedures and high volumes of blood transfusion. The Health Board should review these comments, alongside the local information it holds, and determine if the patient records contain the information they would expect for the patient episodes of care.

3.1. The effectiveness of clinical pathways in providing optimal clinical care

This section considers both the effectiveness of clinical pathways (including referral and discharge) generally and, more specifically, in relation to diabetic foot pathways.

In the review team's opinion, the patients' clinical assessments, investigations, and in some cases, podiatry care, appeared reasonable and appropriate in **cases A5, A6, A20, A26, A28, A32, A38, A42, A44, A46 and A48.** In these cases the review team considered that the procedures were undertaken in a timely manner and correctly administered.

In **cases A10, A12, A13, A14, A16, A17, A22, A25, A28, A37 and A39,** it was the review team's view that the patients' clinical assessments and diagnosis were satisfactory and the treatments provided to patients were considered reasonable.

The review team considered that, in most of the cases reviewed, there were certain areas of the patient's care which were not completely documented. These are highlighted below:

In **case A1**, the review team noted that the information provided indicated that the patient had a likely infected graft which appeared to not have been treated. The review team did not find any documented discussions or communications regarding the decisions made regarding the management of this patient.

[6] A23, A27, A31, A35, A41 and A50

[7] A4 and A9

case A2, it was not clear to the review team what treatment occurred in 2019 and information on the patient's final stay and cause of death was also not included in their record.

In **case A3**, The review team noted that there was limited information available regarding imaging, especially the MRI[8] scans in the early stages of treatment. The clinical records provided did not include the final outcome for this patient and there was no information about patient treatment from 2018.

In **case A11**, the review team found poor documentation of the details of the patient's presentation included in the clinical notes, and although MDT was described as taking place for some decisions, these were not recorded. The review team noted that there was a lack of documented post operation graft imaging even when the surgery was suspected to have failed.

In **case A13**, the review team noted that there were no imaging reports available and no preoperative echocardiography[9] undertaken. The review team observed that there was no postoperation discharge planning or care plan identified in the patient's clinical record. There was also no documentation of safety assessment and home needs included in the patient's notes.

In **case A18**, the review team considered that the decision to offer amputation appeared to be inappropriate and in the review team's view, palliation and conservative therapy should have been considered instead. The review team concluded that the risk from major amputation was extremely high due to the patient's age, preoperative hyponatraemia and history of vomiting. The review team considered that the surgery was likely unnecessary and futile in this case.

In **case A22**, the review team noted that there was no documentation of clinical events leading to the patient's hospital admission and no information recorded on the decisions made as an inpatient or plans for treatment.

In **case A25**, the review team considered that although the decision making appeared to be acceptable, it was not documented adequately in the patient's clinical record. This is particularly important for an iatrogenic injury.

In **case A29**, the review team noted that there was no information included regarding the assessment undertaken on the patient's first admission in hospital. The review team considered that the patient's clinical notes were all out of sequence and it was unclear to the review team why the decision to do a bypass was subsequently changed to amputation. The review team considered that the documentation of initial assessment in the clinic was inadequate.

The review team were extremely concerned about **case A34**. They were critical of the patient's pathway where there was a five day wait for an MDT decision, whilst the patient was an inpatient. The review team were also concerned by the decision to amputate the foot rather than proceed to a below the knee (BKA) amputation as the primary procedure. The review team also noted that the patient had been discharged without a care plan and that the patient's wife was having to 'carry him to the toilet'.

The review team noted that in **case A39**, there was a complete absence of pre-operative clinical documentation regarding the planned surgery. They were deeply concerned about the apparent MDT decision to proceed on the same admission to open aneurysm repair, despite there being a

[8] **Magnetic resonance imaging** (**MRI**) is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body. https://www.nhs.uk/conditions/mri-scan/

[9] **Pre-operative echocardiography** has been utilised in perioperative period in patients with active cardiac conditions scheduled for non-cardiac surgery to aid in risk stratification. Echocardiography enables direct visualization of the various chambers of the heart, valves, adjacent structures and major connecting vessels like pulmonary artery and aorta.

documented high risk. The review team also was very critical of the management of the final theatre episode, for the reasons listed in this case's summary in Appendix A.

case A40, it was the review team's view that there was a significant interval between the decision to operate and the procedure which should have been analysed against the VSGBI[10]/NAAASP[11] standards.

The review team noted that in **case A44**, the decision to offer the patient open surgery instead of the planned endovascular aneurysm repair (EVAR)[12] was not explained in their clinical notes.

The review team noted that in **case A45**, the patient diagnosis of operative threshold for abdominal aortic aneurysm (AAA) was made from the surveillance programme in January 2020, but there was no documentation provided prior to the March outpatient review which was already two months post their CT scan. The patient waited a further eight months for surgery which was not explained in their clinical notes, although the review team noted it may have been as a result of COVID-19 service changes.

In **case A47**, the review team found no information relating to the workup for abdominal aortic aneurysm (AAA) repair, in particular MDT review. In the review team's view, given the absence of an electronic patient record (EPR), there should be more frequent recording in the notes of key consultations and test results, including blood tests (e.g. renal function and Hb[13]) relevant to a patient with renal dysfunction post major surgery..

In **case A48**, the review team noted that two other consultants were called in to assist with an AAA open repair surgery. In the review team's opinion there should already be two consultants present for an open case procedure - as this is standard practice in many units - and especially in the case of a difficult aortic aneurysm neck/anatomy surgery.

From the MDT records provided in **case A49**, it appeared to the review team that a decision for open aneurysm repair had been solely based on the imaging. In the review team's view there should have been consideration of the option of endovascular surgery in this case. The review team therefore concluded that the clinicians were possibly working outside the limits of their competence.

3.2. The effectiveness of the multidisciplinary team (MDT) in ensuring continuous and optimal patient care

The terms of reference requested that the review team draw conclusions on the effectiveness of the multidisciplinary team in ensuring continuous and optimal patient care.

The review team noted that, in most cases, there were either no MDT reports included in the patient records, or MDT discussions were described to have taken place but no decisions were documented.

In **cases A1, A3, A4, A5, A6, A7, A8, A9, A11, A13, A14, A17, A21, A22, A29, A40, A45 and A48,** there were little or no records of any MDT discussions or input and it was the review team's view that the patients' treatment should have been discussed and documented more thoroughly to ensure better patient care and clinical pathways.

[10] Vascular Society of Great Britain and Ireland

[11] National Abdominal Aortic Aneurysm Screening Programme

[12] Procedure commonly used as treatment of thoracic and abdominal aortic aneurysms.

[13] **Hemoglobin**

In **case A7**, it was the review team's view that amputation should have been discussed with the patient earlier in their clinical treatment and that there should have been better MDT working shown in this case.

case A8, the review team were extremely concerned that this patient's record lacked documentation on MDT, post operation care, discharge planning and care, and follow up management.

In **case A10**, the review team were concerned that there was no documentation of any MDT discussions at any stage of the patient management between 2016 and 2021.

In **case A17**, there was no information provided to the review team to confirm whether a palliative approach was considered for this patient as no documentation relating to MDT working was included in the patient's notes.

Although MDT discussions and decision were recorded in **case A18**, the review team noted that the consultant who was familiar with the patient should have considered palliation.

In **case A29**, MDT discussions appeared to have taken place, however, no official documentation was identified by the review team.

In **case A40**, there were no documented discussions at MDT available to the review team. In the review team's opinion the inpatient surgical notes were vague.

In **case A43**, the decision was made in MDT to proceed to open repair surgery. The review team were concerned that there was no consideration of complex endovascular repair apparent in the patient's clinical notes. The review team also found it concerning that there was no documentation taken by the vascular team included in the patient's clinical record.

In **case A44**, the review team considered that there was adequate MDT working and communication during the pre and post operations, although there was lack of documentation of MDT before the operation.

The review team noted that in **case A47**, there was no information of MDT and/or consultation and communication with colleagues relating to the merits of surgery given the patient's health status.

In **case A48**, there was also an absence of documentation relating to MDT and/or consultation and communication with colleagues having taken place, apart from a note of a discussion that the patient "was…not suitable for endovascular aneurysm repair [EVAR]".

3.3. Clinical Governance

This term of reference was addressed in the invited service review report dated 15 March 2021.

3.4. Clinical Outcomes

The review team considered that the treatment and outcome for **cases A12, A13 and A15** were satisfactory and showed competence of those involved in the patients' care. The patients' clinical record entries were accurate and documented appropriately, indicating good clinical management.

The review team noted that there were instances where the clinical records did not include patient outcomes, which meant that the review team could not draw conclusions on the overall quality of care. The review team recommended that the Health Board reviews the following seven patients' care to ensure they have received appropriate follow-up. It is important that the Health Board confirm that cases **A1, A3, A4, A11, A22, A45** and **A47** had received appropriate clinical followup.

In **case A3**, the clinical record provided did not include the final outcome for this patient and there was no information about patient treatment from 2018 for the review team to review.

case A4, the review team concluded that multiple procedures were performed without any durable result. Alternatives to bypass were not recorded but should have been discussed especially if the patient decided against it. The limb remained viable at discharge but with ongoing ulceration and pain, the presenting symptoms.

In the review team's view, in **case A11**, it was hard to assess if inserting a long segment SFA[14] stent for the patient's left heel ulcer was appropriate, rather than undertaking bypass surgery, because of the lack of imaging provided. It was also unclear to the review team what the likelihood of graft failure was. The review team considered that bilateral amputation was a poor outcome for this patient and there was no documentation to support the need for AKA[15] revision. In the review team's opinion a further internal clinical review may be required due to lack of information regarding the patient's complex treatment.

In **case A20**, the review team considered it to be poor practice to have missed the femoral nail at AKA as, in their opinion, it would have been evident on pre-operation imaging. The review team were concerned that there was no frailty or sarcopenia scoring included in the patient's notes that would have helped identify patients for whom delaying surgery was likely to be a major issue.

In **case A22**, the review team noted that the outcome was not recorded in the patient's record, therefore the review team were unable to form any conclusions on the outcomes and complications regarding this patient.

In **case A25**, the review team considered that the decision to close the patient's wound at the third procedure rather than use vacuum assisted closure[16] (VAC) should be reviewed by the clinical team.

In **case A30**, the review team found that details of the post operation procedure was missing from the clinical notes and there was no information on the outcome documented.

In **case A43**, the review team questioned why an aneurysm repair took over seven hours when there were no specific problems identified in theatre and no reason recorded for the lengthy procedure in the patient's operation notes.

In **case A44**, the review team considered that the outcome was poor, with the patient dying from complications of open AAA surgery. There appeared to be significant intraoperative complications, yet there was no evidence of review in a morbidity/mortality meeting.

Case A45 was an open AAA with a prolonged operative procedure without explanation; the operation note described a straightforward tube graft operation requiring around six hours. The review team considered that the appropriate operation was undertaken and noted that the patient made excellent recovery following surgery.

In **case A47**, an inflammatory AAA appeared to have been undertaken by a single surgeon, with a four hour procedure and prolonged suprarenal cross-clamp.

[14] superficial femoral artery

[15] above the knee amputation

[16] **Vacuum-assisted closure (VAC)** is a simple but effective method to promote rapid wound-healing. In recent years it has been shown to be an effective therapy for the management of large, complex, acute wounds as well as chronic wounds that have failed to heal by conventional methods.

3.5. Medical staffing and clinical facilities available for the volume and type of clinical activity undertaken

This term of reference was addressed in the invited service review report dated 15 March 2021.

3.6. Behaviours, communication and team working

The terms of reference requested that the review team draw conclusions on behaviours, communication and team working within the vascular surgery service.

In **case A14**, the review team considered that the patient's care to treat a recurrent ischaemia appeared to have been appropriately managed prior to patient transfer by performing angioplasty and toe surgery locally at the Bangor site.

In **case A15**, it was the review team's view that there was good liaison between clinical colleagues in medicine, anaesthesia and the intensive therapy unit (ITU).

In **case A22**, the review team considered that the patient was assessed adequately by the Vascular Team and it was a reasonable decision to transfer the patient to the hub site where they received good ITU care and there was adequate involvement of relevant specialties.

In **case A26**, the review team noted that there was appropriate contact with the vascular team during the patient's treatment and the decision to manage the patient locally was correct and proved to be successful. In the review team's view, there was good liaison with the vascular hub which was adequately documented in the patient's record.

In the review team's opinion, there was good liaison with colorectal and COTE teams documented in **case A28**.

The review team concluded that there was poor management in **case A34**, compounded by insufficient record-keeping and a lack of communication with the patient pre- and post-surgery.

3.7. Communication with patients and other health professionals

The terms of reference requested that the review team draw conclusions relating to communication with patients, their family and their GP, including patient consent.

The review team considered that in **cases A26** and **A28**, patient consent was undertaken and clearly documented in the patients' clinical record.

The review team noted that in case **A28**, the communication with the patient's family was outstanding and detailed in their clinical record.

In **cases A2, A4, A5, A8, A9, A17, A22 and A40,** the review team noted that communication with the patient regarding their care and, in some cases, including informed consent, was not documented. The review team were of the strong opinion that there should be detailed recording of patient discussions which should include risks and benefits to treatment.

In **case A4**, the review team concluded that amputation should have been considered and discussed with the patient at an early stage when repeated grafts failed and the patient's pain continued. There was no information available to the review team to confirm if the options were discussed with the patient.

In **case A13**, the review team considered that there should have been an earlier communication with the patient about amputation, or even palliation and pain management as part of their treatment plan. In the review team's opinion a palliative approach should at least have been discussed and documented due to the patient's age and severe COPD[17].

In **case A18**, the review team were of the opinion that patient communication should have included discussions about futile surgery and palliative options. The review team also noted that there appeared to have been no significant discussion with the patient's family about palliation and amputation appeared to have been decided as the only option for this patient.

In **case A21**, the review team noted the patient communication that was documented did not include any discussion to consider early ceiling of care with the patient and their family in view of the patient's comorbidities.

In **case A29**, the review team found minimal discussion with the patient regarding decision making and subsequent change from planned bypass to AKA.

The review team highlighted in **case A30** that there was no discussion with the patient and/or their relatives documented, regarding the pros and cons of a conservative approach despite the patient's dementia and comorbidities.

The review team were concerned with the consent process in relation to **case A34**, as there was no information of discussions with the patient prior to surgery and the only documentation provided described that the consent was 'taken on table' which the review team found to be unacceptable.

In **case A36**, the review team concluded that primary and elective amputation should have been discussed with the patient and/or their family, along with a conservative/palliative approach.

The review team considered that there could have been better documentation regarding the communication with the patient and the patient's family in **case A37**, as the clinical records detailed that the patient's family wished to speak with the consultant but there was no information documented that this had taken place.

In **case A40**, it was concerning to the review team that there was no information of discussions with the patient prior to surgery where the risk and benefits of surgery, endovascular approach and conservative approach should have been discussed. The review team noted that the consent form also did not mention the risk of open repair surgery and death.

In **case A43,** in the review team's opinion, communication with the patient and their family fell below the expected standard as a result of a lack of documentation of patient and family discussions about the risks of surgery and the potential role of complex endovascular repair. It was unclear to the review team whether the patient knew the risk and complexity of the planned surgery and whether a discussion with the neighbouring tertiary referral centre took place.

In **case A44**, it was the review team's view that there was good ITU communication with the patient's family.

The review team considered that there was excellent communication with the patient in **case A45** where treatment options were provided and the patient was allowed to choose. The review team also noted that consent was included in the patient's notes.

Case 47 had no preoperative documentation of discussion regarding the value of surgery in a patient with known dementia, or the increased risks of surgery on an inflammatory aneurysm.

[17] **Chronic obstructive pulmonary disease** (COPD) is the name for a collection of lung diseases including chronic bronchitis, emphysema and chronic obstructive airways disease.

However, there was good communication between the ITU and the next of kin during a prolonged postoperative stay, and a well-documented discussion with the patient and next of kin prior to discharge.

In **case A48**, the review team were concerned that there was no information that a discussion had taken place with the patient as to benefits and drawbacks of open surgery versus endovascular treatment (fenestrated approach). The review team also noted that there was inadequate counselling with the patient regarding the risks of surgery.

The review team were concerned that in **case A49**, information showed that the detailed risks were explained to the patient, however, there was no mention of the mortality risk (national average 4% for open repair). In the review team's view there should have been discussion with the patient about other options, especially EVAR (an iliac aneurysm is easily treated endovascularly and is standard practice in most units) given the patient's cardiac history and previous laparotomy.

4. Recommendations

4.1. 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[18].

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[19] 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 contain 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[20].

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 decisionmaking for every patient. All MDT decisions and communication should be adequately documented in each patient's record.

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[21].

   The RCS England good practice guide[22] may be of assistance in this process.

4.2. Recommendations for service improvement

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

[18] The Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014: http://www.legislation.gov.uk/uksi/2014/2936/contents/made

[19] As highlighted in section three

[20] https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/service-standards/surgical-care-teamguidance/

[21] The 2015 Supreme Court decision on Montgomery vs NHS Lanarkshire

[22] https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/

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:

    (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.

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 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.

5. Guidance for the healthcare organisation

5.1. Responsibilities in relation to this report

This report has been prepared by The Royal College of Surgeons of England and the Vascular Society of Great Britain and Ireland under the IRM for submission to the healthcare organisation which commissioned the invited review. It is an advisory document and it is for the healthcare organisation concerned to consider any conclusions and recommendations reached and to determine subsequent action.

It is also the responsibility of the healthcare organisation to review the content of this report and in the light of these contents take any action that is considered appropriate to protect patient safety and ensure that patients have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.[23]

5.2. Further contact with the Royal College of Surgeons of England

Where recommendations have been made that relate to patient safety issues, the Royal College of Surgeons of England will follow up with the healthcare organisation to request confirmation that timely action has been taken to address these recommendations.

If further support is required the College may be able to facilitate this. Additionally, if it is considered that a further review would help to assess improvements that have been made the College's Invited Review service may be able to undertake this.

[23] The Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014: http://www.legislation.gov.uk/uksi/2014/2936/contents/made