

NATIONAL VASCULAR REGISTRY



2017 Annual Report

DRAFT – September 2017



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The Royal College of Surgeons of England is an independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this it supports Audit and the evaluation of clinical effectiveness for surgery.

The RCS managed the publication of the 2016 Annual report.



The Vascular Society of Great Britain and Ireland is the specialist society that represents vascular surgeons. It is one of the key partners leading the audit.

Commissioned By



HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the NCA Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

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Acknowledgements

The National Vascular Registry is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit Programme (NCA). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the NCA Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

We would like to acknowledge the support of the vascular specialists and hospital staff who have participated in the National Vascular Registry and the considerable time devoted to data collection.

We would also like to thank

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Foreword

As President of the Vascular Society of Great Britain and Ireland (VSGBI), it gives me great pleasure to support the publication of the National Vascular Registry report 2017. Special thanks must go to Professor Ian Loftus, Chair of the Audit Committee of VSGBI and his team and to Professor David Cromwell and his team on the Clinical Effectiveness Unit at the Royal College of Surgeons of England.

The NVR annual report is a very important document because it reassures the public that vascular surgery remains safe and that vascular units are producing good outcomes for their patients.

This year's report give details of 4153 elective aortic aneurysm repairs (AAA) in 2016 and I am pleased to see that mortality remains very low (2.9% for open repair and 0.4% for endovascular repair). It is also good to see that the NVR is starting to accumulate data on outcomes for complex aneurysm repair and ruptured AAA – this data will support the ongoing re-organisation of services. For carotid surgery, there are details of 4330 interventions in 2016 with similarly impressive results.

Of course, there are always areas for improvement. I am concerned about waiting times for elective AAA repair and carotid surgery, which continue to vary across NHS vascular units. Also, the speed with which the case ascertainment of lower limb endovascular procedures (mainly peripheral angioplasty) needs to increase.

Overall, the information in this report will be invaluable for those who commission vascular services and for local vascular specialists to drive further improvements so that all our patients have access to world-class outcomes across the range of clinical vascular services.

Professor Rob Sayers

President of the Vascular Society of Great Britain and Ireland

Executive Summary

This 2017 Annual report of the National Vascular Registry is the fourth since the new Registry was launched in 2014, to replace the National Vascular Database. The Registry is commissioned by the Healthcare Quality Improvement Partnership and is designed to support quality improvement within NHS hospitals performing vascular surgery by providing information on their performance.

Data entry into the NVR is mandatory for individual clinicians and for vascular units. For clinicians, the NVR data can then support medical revalidation; for vascular services, the information can inform local initiatives to support the quality of care and the commissioning of clinical services. This report comprises comparative Trust level information on arterial interventions across England, Scotland, Wales and Northern Ireland for the period from January 2014 to December 2016. It supplements information provided online at the dedicated vascular quality improvement website (www.vsqip.org.uk).

The report provides data on provider activity, metrics on the process of care and clinical outcomes for the major vascular interventions:

- 1) Repair of aortic aneurysms, including elective infra-renal, ruptured infra-renal, and more complex aneurysms
- 2) Carotid endarterectomy
- 3) Lower limb revascularisation (bypass and endovascular)
- 4) Major lower limb amputation

The metrics are drawn from a number of service guidelines, in particular, the Vascular Society of Great Britain and Ireland (VSGBI) "Provision of Vascular Services" document published in 2016, the VSGBI Quality Improvement Frameworks, and the National Institute for Health and Care Excellence guidelines on stroke and peripheral artery disease.

Aortic aneurysms

Aortic aneurysm repair represents one of the major aspects of vascular service provision. Aneurysms typically develop in the aorta below the renal arteries (infra-renal AAA) and elective repair is aimed at preventing their rupture. A national screening programme for AAA in men aged 65 years has operated since 2009 and aims to reduce the rate of aneurysm rupture and associated mortality. This report provides information on the provision of aortic aneurysm repair in terms of elective, emergent and complex repair.

1) *Elective infra-renal AAA*

The provision of services for the repair of elective infra-renal AAA has been the subject of a Quality Improvement Programme supported by the VSGBI. In recognition of the importance of case volume in driving better clinical outcomes, many regional vascular services have been reconfigured, with interventions being increasingly performed in high-volume 'hub' centres, with dedicated facilities and specialist multi-disciplinary services. This includes the ability to offer and perform minimally invasive endovascular repair 7 days a week.

The NVR received detailed information on 4,153 elective AAA repairs in 2016, and there appears to be a 5% decrease in activity within the NHS since 2015. The proportion of cases performed by open repair and endovascular repair (EVAR) is similar to the previous 2 years (30% open repair, 70% EVAR).

The outcomes from elective AAA repair improved dramatically following the Quality Improvement Programme and continue to be favourable when compared internationally to other countries. The in-hospital mortality was 2.9% for open repair and 0.4% for EVAR. Postoperative complications were documented for 20.5% and 6.3% for open repair and EVAR, respectively.

Most centres continue to achieve important measures of the process of care for the majority of patients. Specifically:

- 78.3% were discussed at MDT meetings
- 82.2% had pre-operative CT/MR angiography
- 96.6% of patients underwent a formal anaesthetic review (91.9% by a consultant vascular anaesthetist)
- 83.9% had documented formal fitness assessment tests

This year, the NVR undertook a snapshot audit which examined what factors influenced the time to surgery for patients with a diagnosed AAA. This found that advice from non-vascular specialists and assessments are required for between 15-18% of patients. In addition, 7-8% of patients experienced delays due to their operation being cancelled.

There remain 2 areas of potential improvement in the provision of AAA services. Firstly, there are significant variations in the timelines from diagnosis to surgery, with centres ranging from a median of under 30 days to over 100 days. The National Screening Programme has set a timeline of 8 weeks from diagnosis to repair and vascular units should strive to meet this target for the majority of patients.

Secondly, there remain a number of centres providing elective AAA services with low case volumes. Despite the ongoing regional reconfigurations of vascular services, there were 16 (check this) vascular centres with a case volume of below 30 patients in 2016. Further reconfiguration of service is desirable to ensure patients receive treatment in vascular centres with the best facilities and clinical pathways.

2) *Complex Aneurysm Repair*

Aortic aneurysms that occur above or around the renal arteries require more complex aortic procedures. Recently, endovascular repair has become the favoured approach for these more complex intervention in many centres. Between January 2014 and December 2016, there were 2,055 complex AAA repairs, comprising of 1,838 endovascular and 217 open repairs. The endovascular procedures included: 984 fenestrated repairs (FEVAR), 177 branched repairs (BEVAR) and 332 thoracic procedures (TEVAR). these represent a relatively large case volume, although it is difficult to give an accurate estimate of case ascertainment due to the complexities of coding these procedures in routine hospital data.

The outcomes remain favourable for EVAR compared to open repair, with an in hospital mortality of 3.5% and 18.4%, respectively. Direct comparison of these figures is difficult and the open procedures may represent a more complex anatomical AAA to repair. Further work is required to clarify which patients benefit most from an endovascular approach or an open repair.

Complex aortic surgery remains a relatively high risk, high cost service. It is essential to build a more detailed picture of service provision, activity and outcomes from both open and endovascular procedures. Centres should only be commissioned to perform such procedures if they have submitted complete and accurate data on case activity and outcomes to the NVR to ensure the provision of safe and effective services for patients with complex aortic disease. 57 of the 76 centres performing complex AAA repairs in 2014-2016 submitted fewer than 10 cases.

3) *Ruptured AAA*

This report documents the activity and outcomes for ruptured AAA for the three year period from January 2014 to December 2016. Despite the national screening programme for the detection of aneurysms, the number of aneurysm ruptures remain high, with 2,913 cases over the 3-year period. This, as with elective repair, represents a case ascertainment of 86%.

In contrast to elective repair, and despite clinical trial evidence of benefit from EVAR [Powell et al 2014] , the adoption of EVAR remains static for ruptured AAA (approximately 30% compared to 70% for elective repair). Patients undergoing EVAR for ruptured AAA had a lower reported in-hospital postoperative mortality compared to open repair (23.2% and 41.2%, respectively). As with complex AAA repair, direct comparison of these figures are difficult and the open procedures may represent the more complex cases. Further work is required to clarify which patients benefit most from the two approaches.

All NHS trusts demonstrated postoperative mortality rates within the expected range, given the number of procedures performed by the vascular unit. We note, though, a recent study suggested better outcomes were being achieved in the United States [Karthikesalingam et al 2014]. This may be partly due to the slow adoption of EVAR for ruptured AAA. There are a

variety of possible resource and process reasons for this but each vascular unit performing emergency AAA repair should ensure they are able to provide endovascular services 24 hours a day, 7 days a week, with appropriate skill mix, hybrid operating facilities and endovascular consumables.

Carotid endarterectomy

Disease of the carotid arteries can predispose patients to stroke. Carotid endarterectomy (CEA) can reduce that risk of a stroke for some patients if surgery is performed quickly following the onset of symptoms. It is recommended that patients have surgery within 14 days of their first symptoms.

In 2016, there were a total of 4,330 carotid interventions. The number of procedures recorded in the NVR has decreased significantly recently (a 15% drop in two years). This seems to reflect a fall in activity rather than a reduction in case-ascertainment, which has been consistently high since 2014 (>90%). The median time from symptom to surgery is unchanged in 2016 compared to 2015 (median: 13 days). However, there remains significant variation between NHS trusts, with the median delay ranging from 5 days to over 70 days.

The surgical outcomes continue to be good. Estimated rates of significant complication are:

Postoperative complication	Procedures in 2014-2016	Complication rate (%)	95% Confidence interval
Bleeding	14,133	2.3	2.1-2.6
Myocardial Infarct	14,133	1.3	1.1-1.5
Stroke within 30 days	14,134	1.8	1.5-2.0
Death and/or stroke within 30 days	14,134	2.2	1.9-2.4
Cranial nerve injury	14,043	1.8	1.6-2.0

There are two key areas for service improvement with regard to carotid endarterectomy:

- 1) Time from symptom to surgery. The benefit of surgery is much lower for most patients once 14 days have elapsed from the presenting symptoms. All trusts performing carotid endarterectomy should review their pathways of care to ensure that patient are offered surgery within this 14-day window.
- 2) Case volume. There is a documented volume outcome relationship between case volume and clinical outcomes for CEA. The provision of services document from the VSGBI recommends that centres perform a minimum volume of 40 cases per annum [VSGBI 2015]. In 2016, over 30 centres did not meet this standard. Vascular centres should only be commissioned to perform CEA if they submit complete and accurate data on case activity and outcomes to the NVR, with case

numbers that allow an appropriate comparison to national standards. Further reconfiguration of services may be required, given the decreasing national caseload.

Lower Limb Interventions for Peripheral Artery Disease

Peripheral artery disease (PAD) of the lower limb causes a range of symptoms ranging from lifestyle restricting claudication to critical ischaemia and potential limb loss. Treatment options include conservative therapy, endovascular or open surgical interventions including bypass. In cases where revascularisation is not possible or deemed unsuitable, major lower limb amputation may be required. This report outlines the processes and outcomes of lower limb revascularisation procedures between January 2014 and December 2016.

1) Lower limb bypass

NHS hospitals submitted 17,200 open surgical/bypass procedures to the NVR, with an estimated case ascertainment rate of 90%. Among these patients, 70.0% underwent bypass surgery for critical limb ischaemia, and 85.4% were recorded as being on an anti-platelet agent and 82.3% on a statin.

Surgical outcomes for bypass procedures remained good. The in-hospital postoperative mortality rate was 2.8% (95% CI 2.6 to 3.1). Overall, there were no defined complications in 86.0% of cases (95% CI 85.5-86.6%) and a further secondary procedure was required in 8.5% of cases. All the NHS trusts had a risk adjusted rate of in-hospital death that fell within the expected range given the number of procedures performed.

We observed that 1 in 10 patients had an unplanned readmission, which suggests this is an area for improvement. The NVR does not have information on the reasons for readmission but local services should review their local rates to determine the cause and examine possible pathways for improvement.

2) Endovascular lower limb procedures

The NVR has been collecting data on endovascular lower limb procedures since January 2014. The number of procedures submitted to the NVR has increased each year: 3,474 in 2014, 4,471 in 2015 and 5,941 in 2016. However, the overall case-ascertainment has not increased as much as we would like: rising from 15.7% in 2014 to 20.7% in 2015 and 27.5% in 2016.

Among the patients having endovascular interventions (angioplasty or stents), 52% patient had critical ischaemia, and roughly 3 in 4 patients were on anti-platelet medication (78.9%) or statin therapy (75.7%).

There were large variations between NHS trusts, with regard to provision of the treatment on a day case basis. Overall, there were good clinical outcomes with an in-hospital mortality rate of 1.6% and a complication rate of 5.7%.

Nonetheless, the case-ascertainment remains too low for robust conclusions to be drawn from analysis of the data. While a few NHS trusts achieved 90% ascertainment rates, there was a disappointingly large number of vascular units with very low rates, including 50% of arterial centres achieving a case-ascertainment estimates of less than 20%. Continued local efforts must be made to improve data collection.

3) *Major lower limb amputation*

Over the three-year data collection period, 9 804 major lower limb amputations were entered into the NVR (3,059 in 2014, 3,441 in 2015 and 3,304 in 2016, with a yearly increase in estimated case ascertainment from 65.2% to 69.7%). Significant variations in the level of data ascertainment remain between NHS trusts, with 20 arterial centres capturing data on less than 50% of cases.

There were a higher proportion of below-knee to above-knee amputations (6,978 procedures, 71.2% versus 2 826, 28.8%, respectively). In terms of patient characteristics, 72% were on aspirin therapy and 72% took statins; 62.6% were diabetic.

Most patients were emergency admissions but over 80% of patient underwent surgery during daytime hours (8am-6pm) – one of the key quality indicators in the VSGBI quality improvement pathway. In terms of other process measures, a consultant surgeon was present in theatre in 79.8% of below knee and 74.1 for above knee procedures, and antibiotic/DVT prophylaxis was given in around 60% of patients. The 30-day mortality for below and above knee amputations was 6.7% (95% CI 6.1 to 7.2) and 12.4% (95% CI 11.2 to 13.7), respectively.

All the NHS trusts had a risk adjusted rate of in-hospital death that fell within the expected range given the number of procedures performed. There were, however, variation in the levels achieve on the process measures (daytime operating, consultant presence, prophylactic medication). The low level of case-ascertainment for lower limb amputations limits our ability to make conclusions about the consistency of outcomes but it is unlikely to affect the observed variation on the process measures. Local services should therefore examine how improvements can be made terms of both data submission and their performance against the recommendations of the NCEPOD report and the VSGBI quality improvement pathway.

Recommendations

Vascular units within NHS trusts / Health Boards

Vascular units should review their activity, case ascertainment and outcomes to ensure care is consistent with the recommendations in national clinical guidance on patients requiring major arterial surgery. In particular, vascular units are encouraged to adopt the care pathway and standards outlined in the Vascular Society's Provision of Vascular Services document, plus Quality Improvement Frameworks for AAA and amputation.

Units should also regularly review their levels of data submission to the NVR, with the aim of ensuring it is complete, particularly in relation to major amputation and endovascular lower limb procedures. Specific areas for improvement are:

- Vascular units should assess whether all AAA patients are discussed at the vascular MDT meeting and that this is documented clearly in the medical notes. Units should also check that this information is uploaded to the NVR, including the date of discussion.
- The National AAA Screening Programme has set a target of 8 weeks for the time patients take from vascular assessment to elective AAA repair. For non-complex aneurysms, vascular units should adopt this as a target for both screen and non-screen detected AAA patients, and alter the care pathway to avoid excessive waiting time beyond 8 weeks.
- For patients requiring complex AAA repair, vascular units should also examine how the time from vascular assessment to surgery can be reduced, particularly, the process of requesting non-conventional devices for endovascular procedures. Cancellations should be kept to a minimum.
- For emergency repair of ruptured aneurysms, NHS vascular units should evaluate how access to endovascular repair can be improved. This may require review of anaesthetic as well as surgical aspects of the care pathway.
- Vascular units with low volumes of complex AAA surgery should review referral pathways within their networks in order to meet the volume thresholds recommended by the VSGBI.
- NICE recommends that carotid endarterectomy is undertaken within 14 days of a patient experiencing symptoms. NHS trusts that are not meeting this target should optimise referral pathways within their networks and implement improvements to drive down the waiting times. More generally, units should examine how their performance compares against the standards within NICE Guideline CG68.
- Vascular units should review local care pathways and patient outcomes for lower limb amputation, and adopt the care pathway and standards outlined in the Vascular Society's Quality Improvement Framework.

- Vascular units should examine how to improve their performance against the NCEPOD recommendations for amputation, specifically in relation to operating on planned lists, having a consultant surgeon present and the use of prophylactic medication. Units should also check that this information is being uploaded accurately to the NVR.

For Medical Directors of NHS trusts / Health Boards

Medical Directors should review the results for their organisation and ensure that vascular units have sufficient resources to meet the standards defined by NICE and the VSGBI for patients requiring elective and emergency arterial procedures.

In addition, there needs to be support from Medical Directors for improved case-ascertainment, and we recommend data submission to the NVR becomes an essential part of yearly appraisal and revalidation for all vascular interventionists.

For Commissioners / Regional Networks

Commissioners (in England) and Welsh Health Boards should (1) review the results for their local organisations to ensure the care provided to their patients is meeting national quality standards, and (2) should work with NHS providers to develop strategies for addressing areas of variation. In particular, the low numbers of procedures that some vascular units do for patients with complex AAA or ruptured AAA, as well as the falling numbers of carotid endarterectomies, highlights the need for further centralisation or collaboration between networks to ensure highest standards of care for these patient groups.

Commissioners / Health Boards should encourage their local providers to adopt the care pathway and standards outlined in the Vascular Society's Quality Improvement Frameworks and Provision of Vascular Services documents, including submission of data to the NVR.

For Vascular Society of GB&I / British Society of Interventional Radiology

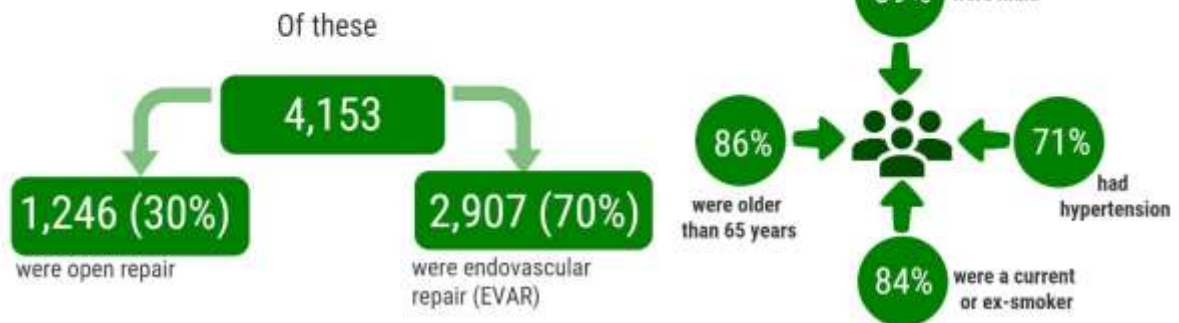
The Vascular Society of Great Britain & Ireland and the British Society of Interventional Radiology should encourage their members to collect and submit the data requested by the National Vascular Registry, in particular, the details of patients who undergo lower limb procedures.

Elective repair of infra-renal abdominal aortic aneurysm (AAA)

AAA is an abnormal expansion of the aorta. If left untreated, it may enlarge and rupture causing fatal internal bleeding. An infra-renal aneurysm occurs below the level of the renal (kidney) arteries within the aorta.

There were 4,153 elective infra-renal AAA repairs submitted to the NVR in 2016, which is approximately 86% of all procedures carried out in the UK.

Which people had surgery?



How were patients assessed?



Most patients waited 70 days between vascular assessment and AAA repair

However for 22/72 vascular units, 25% of patients waited more than 120 days

Patient outcomes after surgery

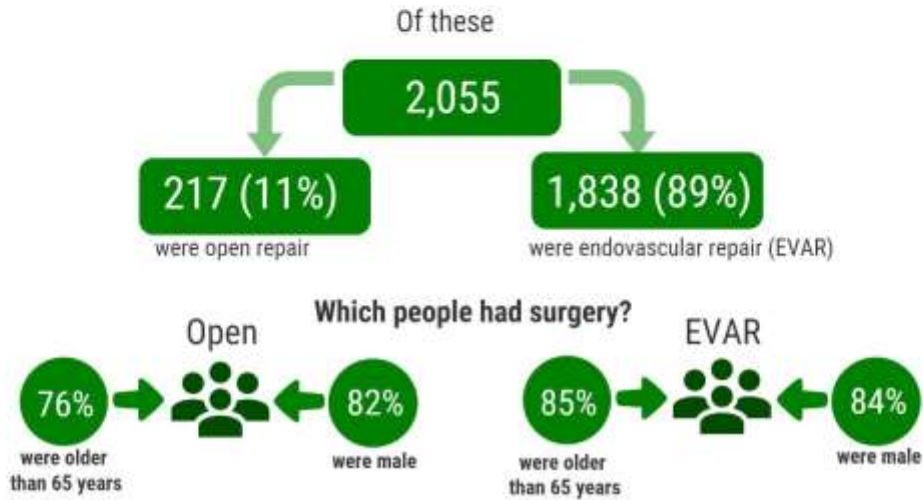


The average is the median; "typically between" is the interquartile range.

Repair of elective complex aortic aneurysms (AAA)

The term complex is used to describe those aneurysms that occur above the level of the renal (kidney) arteries.

There were 2,055 repairs of elective complex AAAs carried out in 2014-2016.



The most common complex EVAR procedures were:

Fenestrated EVARs (FEVAR), which involves a graft containing holes (fenestrations) to allow the passage of blood vessels from the aorta.

Branched EVAR (BEVAR), which involves separate grafts being deployed on each blood vessel from the aorta after the main graft has been fitted.

Thoracic endovascular aortic/aneurysm repair (TEVAR).

Patient outcomes after surgery



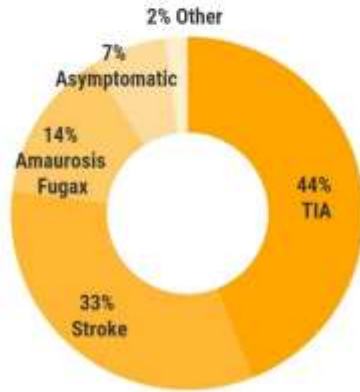
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Carotid Endarterectomy (CEA)

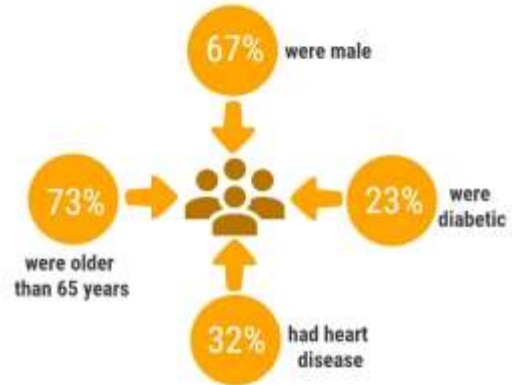
A surgical procedure in which build-up is removed from the carotid artery in the neck.

There were 4,330 carotid endarterectomies submitted to the NVR in 2016, which is approximately 90% of all procedures in the UK.

What were the reasons patients had surgery?

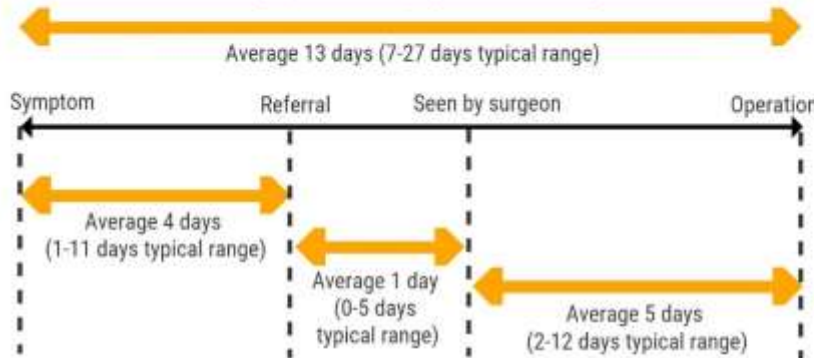


Which people had surgery?



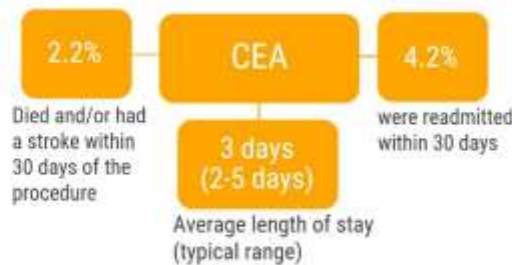
Treatment times for symptomatic patients

Recommended time from symptom to surgery is within 14 days



The average delay for symptom to surgery in NHS vascular units ranged from 4 to 74 days

Outcomes of surgery



The average is the median; "typically between" is the interquartile range.

TIA stands for transient ischaemic attack. Amaurosis fugax is the loss of vision in one eye due to an interruption of blood flow to the retina.

Lower limb angioplasty/stenting for peripheral arterial disease

Peripheral arterial disease (PAD) is a restriction of the blood flow in the lower limb arteries that can severely affect a patient's quality of life, and risk their limb.

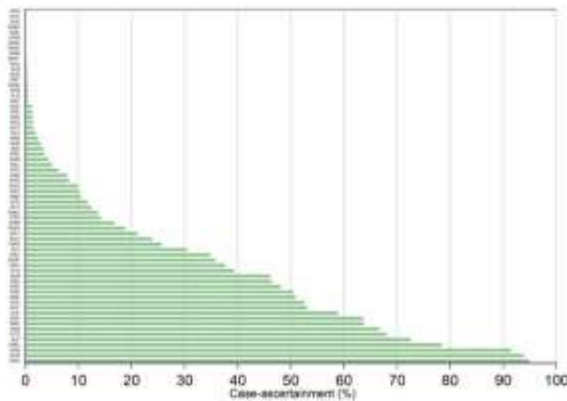
Endovascular interventions become options when conservative therapies have proved to be ineffective.

13,886

lower limb angioplasty/stent procedures carried out in the UK in 2014-2016

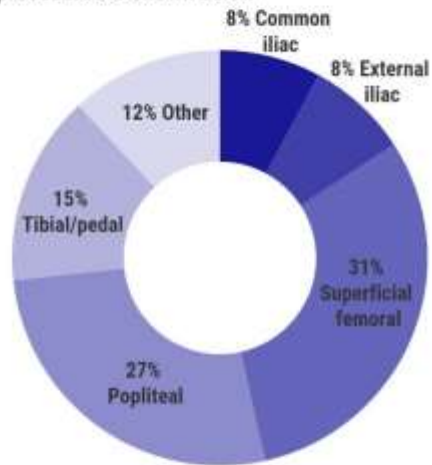
Case ascertainment

The percentage of cases entered by each trust varied, from an average of 60%, with a typical range of 38% to 73%. The breakdown of these rates for each trust is shown below.

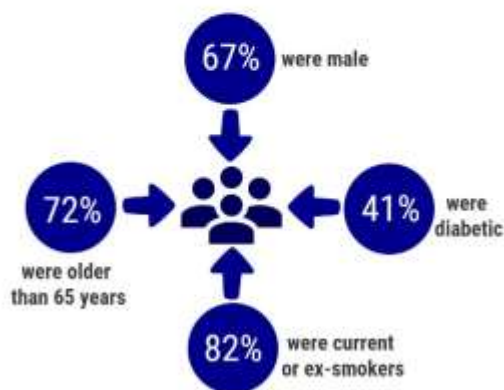


Procedures by anatomical location

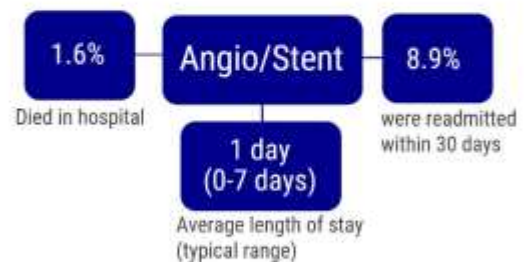
Lower limb angioplasty/stent procedures are carried out in various artery locations within the leg. The breakdown of these procedures is shown below



Patient characteristics



Patient outcomes after their procedure



The average is the median; "typically between" is the interquartile range.

Lower limb bypass for peripheral arterial disease

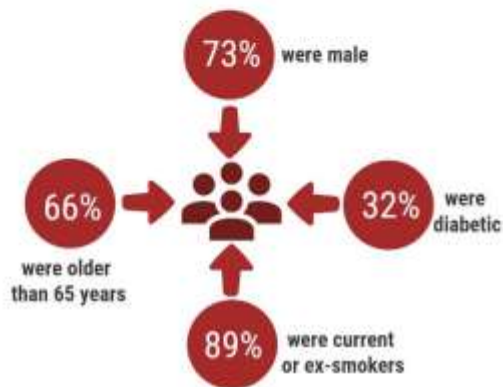
Peripheral arterial disease (PAD) is a restriction of the blood flow in the lower limb arteries that can severely affect a patient's quality of life, and risk their limb.

Open surgical (bypass) interventions become options when conservative therapies have proved to be ineffective.

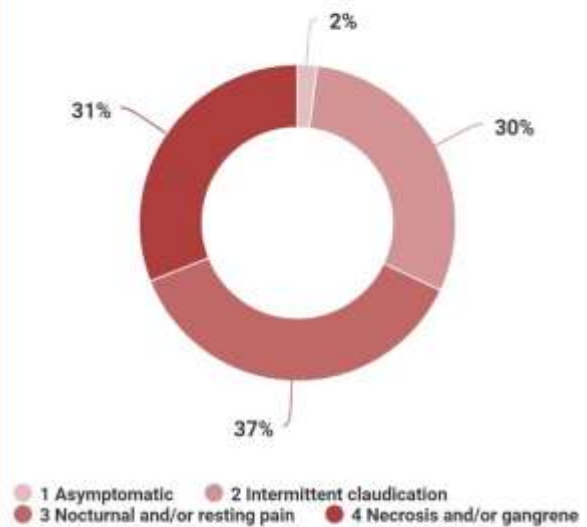
17,200

lower limb bypass procedures carried out in 2014-2016

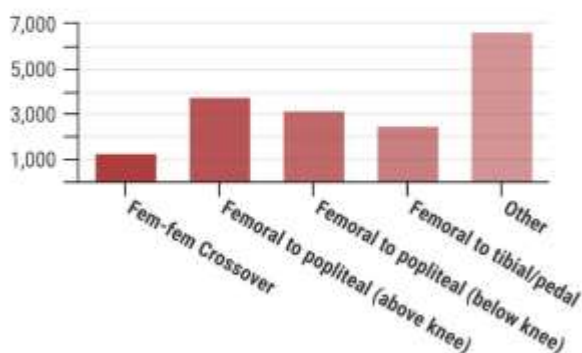
Patient characteristics



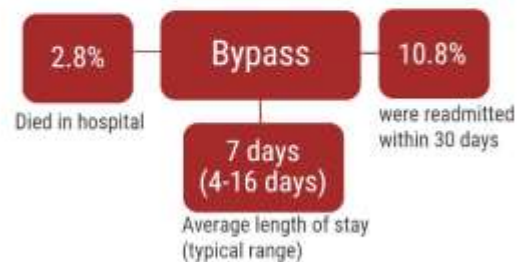
Patient severity (Fontaine Score)



Types of bypass procedures carried out



Patient outcomes after their bypass



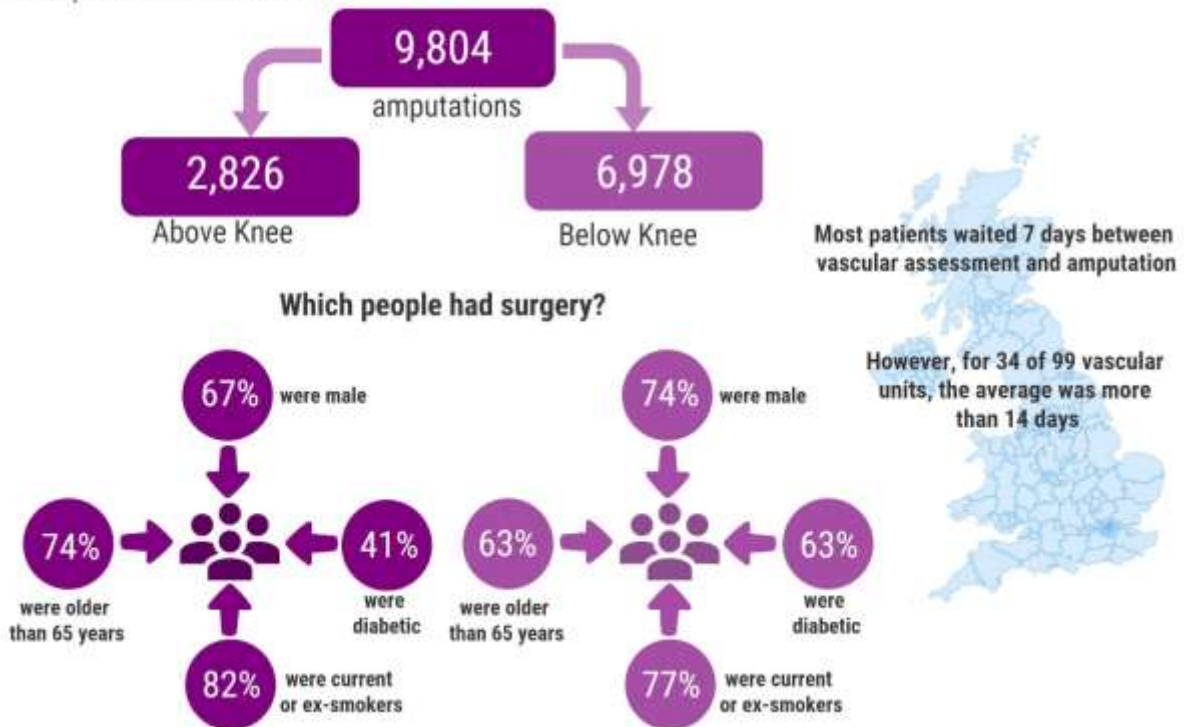
The average is the median; "typically between" is the interquartile range.

Lower limb major amputation for peripheral arterial disease

Peripheral arterial disease (PAD) is a restriction of the blood flow in the lower limb arteries that can severely affect a patient's quality of life, and risk their limb.

Despite open and endovascular revascularisation procedures, PAD can gradually progress in some patients to critical limb ischaemia. In these situations, patients will require amputation of the lower limb.

In 2014-2016 there were 9,804 major lower limb amputations submitted to the NVR, which is about 80% of the actual cases performed across the UK.



Patient outcomes after surgery



The average is the median; "typically between" is the interquartile range.

1. Introduction

The National Vascular Registry (NVR) was established in 2013 to measure the quality and outcomes of care for patients who undergo major vascular procedures in NHS hospitals, and to support vascular services improve the quality of care for these patients by publishing high-quality benchmark information. The NVR was commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

Hospital-based vascular services treat patients with conditions that affect blood circulation, and which are part of the broad spectrum of cardiovascular disease. The treatments for these conditions are typically aimed at reducing the risk of cardiovascular events such as a heart attack, stroke or the rupture of an artery. There are two principal types of vascular disease:

- serious atherosclerotic conditions, which concern the thickening, narrowing and occlusion of arteries, or
- aneurysmal conditions (outside of the heart and brain) in which an artery has widened and is at risk of rupture.

The diversity of vascular disease presents a challenge for vascular services. Treatment options will depend upon the severity of a patient's condition as well as the extent of other co-existing conditions. Some patients may only require a combination of advice on lifestyle change and medication. However, many patients have severe arterial disease that requires surgery or an invasive procedure like angioplasty.

The NVR captures data on adult patients undergoing emergency and elective procedures in NHS hospitals for the following patient groups:

1. patients who undergo carotid endarterectomy or carotid stenting
2. patients who have a repair procedure for abdominal aortic aneurysm (AAA), both open and endovascular (EVAR)
3. patients with peripheral arterial disease (PAD) who undergo either (a) lower limb angioplasty/stent, (b) lower limb bypass surgery, or (c) lower limb amputation.

Adult patients with vascular conditions who do not have surgery (including those referred but not operated on) are outside the scope of the NVR.

Clinical audits commissioned by HQIP typically cover NHS hospitals in England and Wales. The NVR encourages all NHS hospitals in England, Wales, Scotland and Northern Ireland to participate in the Registry, so that it continues to support the work of the Vascular Society of Great Britain and Ireland (VSGBI) to improve the care provided by vascular services within the UK. It is mandatory for individual clinicians to collect data on the outcomes of these

procedures for medical revalidation, and the NVR is designed to facilitate this. Outcome information also plays a crucial role in the commissioning of vascular services.

1.1 The 2017 Annual Report

The aim of this report is to give an overall picture of the care provided by NHS vascular units. It provides information on the process of outcomes of care for:

- patients undergoing the elective repair of abdominal aortic aneurysms (AAA), both infra-renal (below the kidneys) and juxta-/supra-renal (adjacent/above the kidneys)
- patients undergoing emergency repair of a ruptured AAA
- patients having a carotid endarterectomy
- patients with PAD having:
 - an endovascular intervention (angioplasty or stent insertion)
 - a lower limb bypass procedure
 - a major lower limb amputation

The information is primarily derived from information collected continuously by hospitals throughout the year. But in this report, we augment this information with the results on a snapshot audit that examined how changes from the standard care pathway for AAA patients can affect the time from initial referral to surgery.

The report is primarily aimed at vascular surgeons and their teams working within hospital vascular units. Nonetheless, the information in the report is relevant to other health care professionals, patients and the public who are interested in having an overall picture of the organisation of services within the NHS.

Being a procedure-based clinical audit, the NVR is designed to evaluate primarily the outcomes of care, with the aim of supporting vascular specialists to reduce the risk associated with the procedure. Short-term survival after surgery is the principal outcome measure for all vascular procedures, but the report also provides information of other outcomes, such as the types of complications that occur after individual procedures.

Additional contextual information is provided by the process measures. These are linked to standards of care that are drawn from various national guidelines. The “Provision of Services for Patients with Vascular Disease” document produced by the Vascular Society [VSGBI 2015] provides an overall framework for the organisation of vascular services, while a number of other sources describe standards of care for the individual procedures, including:

For carotid endarterectomy

- National Institute for Health and Clinical Excellence (NICE). Stroke: The diagnosis and acute management of stroke and transient ischaemic attacks [NICE 2008]

- National Stroke Strategy [DH 2007] and its associated publication “Implementing the National Stroke Strategy – an imaging guide” [DH 2008].

For elective AAA repair

- The Vascular Society of GB&I “Quality Improvement Framework for AAA” [VSGBI 2012]
- Standards and outcome measures for the National AAA Screening Programme (NAAASP) [NAAASP 2009]

For peripheral arterial disease

- The Vascular Society of GB&I. “A Best Practice Clinical Care Pathway for Major Amputation Surgery” [VSGBI 2016]
- National Institute for Health and Clinical Excellence (NICE). Guidance for peripheral arterial disease (CG147) [NICE 2012]

1.2 Publication of information on the VSQIP website

As well as producing these annual reports, the Registry publishes information on the www.vsqip.org.uk website for each of the five vascular procedures for all UK NHS trusts that currently perform these procedures. For each organisation, the website gives the number of operations, the typical length of stay, and the adjusted postoperative outcomes.

As part of NHS England’s “Everyone Counts: Planning for Patients 2013/4” initiative, the NVR has published outcome information for elective infra-renal AAA repairs and carotid endarterectomy procedures by individual consultants currently working at the organisation. Consultant-level information has also been published for NHS hospitals in Wales, Scotland and Northern Ireland for surgeons who consented.

1.3 Organisation of NHS hospital vascular services

The organisation of hospital vascular services within the UK continues to evolve. It is recommended that vascular services are organised into regional networks, consisting of a hub hospital providing arterial surgery and complex endovascular interventions, and spoke hospitals providing venous surgery, diagnostic services, vascular clinics, and rehabilitation [VSGBI 2016].

Achieving this network organisation of services has led to a widespread reconfiguration of vascular services within regions. The changes can be illustrated by looking at the number of NHS trusts providing vascular surgery. In 2011, elective repair of infra-renal AAA was

performed in 114 NHS trusts. By 2016, 32 of the NHS trusts had stopped performing elective AAA repairs, and in the remaining 82, the number of NHS trusts performing fewer than 30 operations had fallen to 20 (Figure 1.1). A similar pattern can be seen for NHS trusts performing carotid endarterectomy procedures: 120 trusts provided this service in 2011 but this had reduced by 2016 to 87 trusts (Figure 1.2).

Figure 1.1: Number of NHS trusts performing elective infra-renal AAA surgery

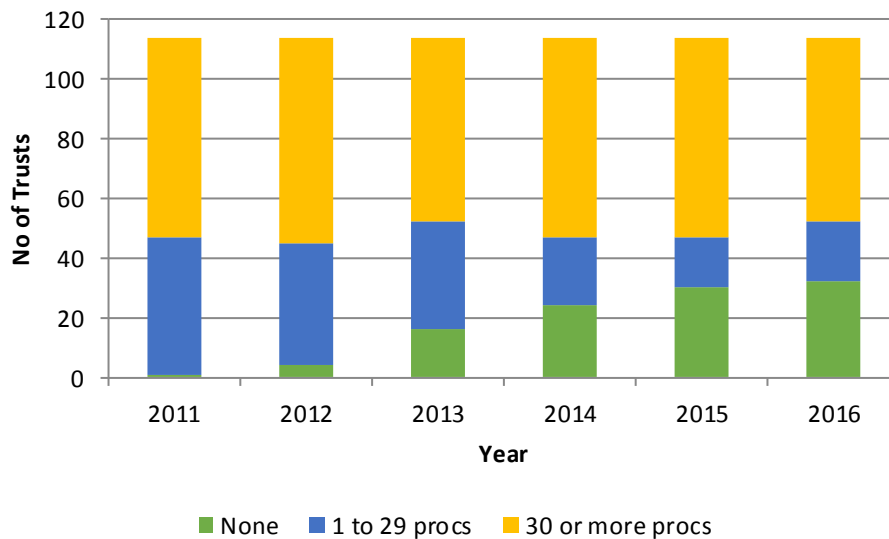


Figure 1.2: Number of NHS trusts performing carotid endarterectomy surgery



Within NHS hospitals, there have also been major changes. There has been investment to improve the operating environment for vascular specialists, with the increasing availability of theatres that incorporate radiological imaging equipment (so-called hybrid theatres), and dedicated daily vascular operating lists. Working within multi-disciplinary teams has also become common practice.

This process of reconfiguration is ongoing. In the 2015 NVR organisational survey, 48 (76%) of the responding NHS trusts / Health Boards reported that they were a part of a completely or near-completely reconfigured network. Respondents from another eight NHS organisations stated that reconfiguration was planned within the next two years.

The current location of NHS trusts performing AAA surgery is shown in Figure 1.3 overleaf.

1.4 How to read this report

The results in this report are based primarily on vascular interventions that took place within the UK between 1 January 2014 and 31 December 2016. To allow hospitals to enter follow-up information about the patients having these interventions, the data used in this report was extracted from the NVR IT system in August 2017. Only records that were locked (i.e., the mechanism used in the IT system for a hospital to indicate that data entry is complete) were included in the analysis.

The scope of the NVR extends only to patients who underwent a procedure. Details of patients who were admitted to hospital with a vascular condition (e.g. a ruptured AAA) but are not operated upon, are not captured in the Registry.

Results are typically presented as totals and/or percentages, medians and interquartile ranges (IQR). Where appropriate, numerators and denominators are given. In a few instances, the percentages do not add up exactly to 100%, which is typically due to the rounding up or down of the individual values. More details of the analytical methods are given in Appendix 11.

Where individual NHS trust and Health Board results are given, the denominators are based on the number of cases for which the question was applicable and answered. The number of cases included in each analysis may vary depending on the level of information that has been provided by the contributors and the total number of cases that meet the inclusion criteria for each analysis. Details of data submissions are given in the Appendices.

For clarity of presentation, the terms NHS trust or Trusts has been used generically to describe NHS trusts and Health Boards.

Figure 1.3: Map of vascular units in NHS trusts that currently perform elective AAA repair



2. Repair of abdominal aortic aneurysm

2.1 Background

Between 1 January 2014 and 31 December 2016, the NVR received information on AAA repairs from 90 NHS organisations: 75 in England, 5 in Wales, 9 in Scotland, and 1 in Northern Ireland. These organisations submitted data on 13,058 elective infra-renal AAA procedures. The number of these procedures identified in the routine hospitals datasets over the same period was 14,723, which gives an overall case-ascertainment of 89%. There was a slight decrease in the number of AAA repairs performed in 2016 compared to 2014 (a fall of 9%).

The estimated 2016 case-ascertainment figures for the four nations were: 87% for England, 109% for Wales, 95% for Northern Ireland and 56% for Scotland. The overall case-ascertainment has remained fairly stable over the last three years (Table 2.1).

The estimated case-ascertainment figures for individual NHS trusts may differ slightly from those published on www.VSqip.org.uk website due to the different time periods covered.

Table 2.1: Estimated case-ascertainment of elective infra-renal AAA repairs**

	2014	2015	2016	Total
Audit procedures	4,547	4,358	4,153	13,058
Expected procedures	5,098	4,813	4,812	14,723
Estimated case-ascertainment	89%	91%	86%	89%

** It is possible that a small number of complex EVAR procedures that were carried out for infra-renal aneurysms are included in the expected procedures figures due to issues related to their coding. Thus, the case-ascertainment rates shown above, and in appendix 4, may be an underestimate for those NHS trusts that carry out complex EVAR procedures.

In recent years, there has been an increasing trend in the proportion of repairs performed as endovascular (EVAR) procedures, growing from 54% in 2009 to 66% in 2013. This trend has stabilised over the last few years, with EVAR procedures accounting for 70% of the elective infra-renal AAA repairs in 2016. There were small differences in the characteristics of patients who had EVAR and open procedures (see Appendix 4), with those undergoing EVAR procedures being, on average, slightly older and having a greater burden of comorbid disease.

The majority of procedures were performed for patients with an AAA diameter between 5.5 and 7.4 cms. Few patients had AAAs with a diameter of less than 5.5cm, the typical threshold at which patients may be advised to have surgery. Patients were often rated as having poor levels of fitness, with severe systemic disease (ASA grade 3). This is to be expected given the high prevalence of other cardiovascular diseases; 7 in 10 had hypertension and about 4 in 10 patients suffered from some form of heart disease. A large proportion of patients were also on medication when assessed pre-operatively.

The suitability of patient for an EVAR depends of various aspects of an aneurysm and its relationship to the normal aorta (e.g., the length and angle of the normal aorta). Among elective infra-renal EVAR repairs:

- The neck angle was less than 60 degrees for 90.7% of procedures
- The median proximal aortic neck diameter and length were 24 mm (IQR 22 to 26) and 24 mm (IQR 18 to 30), respectively
- There were 452 (16.1%) procedures that unilaterally extended into the iliac artery and 123 (4.4%) procedures required bilateral limb extensions

Among the open repairs, the most common type of repair was with a straight 'tube' graft (63.7%), followed by a bifurcated graft (36.1%).

2.2 Preoperative care pathway for elective infra-renal AAA

The VSGBI AAA Quality Improvement Framework [VSGBI 2012] made various recommendations about the preoperative pathway of care for elective patients with infra-renal AAA. These include:

- All elective procedures should be reviewed preoperatively in an MDT that includes surgeon(s) and radiologist(s) as a minimum
- All patients should undergo standard preoperative assessment and risk scoring, as well as CT angiography to determine their suitability for EVAR
- All patients should be seen in pre-assessment by an anaesthetist with experience in elective vascular anaesthesia
- Ideally, a vascular anaesthetist should also be involved to consider fitness issues that may affect whether open repair or EVAR is offered

The results for procedures performed in 2016 are presented alongside the figures for the previous two years in Table 2.2. They suggest that the majority of patients are receiving care that is consistent with the recommended pathway. The overall proportion of patients having pre-operative CT/MR angiography and MDT assessment was lower than expected, but the figures might be conservative because patients for whom the dates were unknown were counted as equivalent to patients who did not receive these elements of care. The figures were reported in this way because, for audit purposes, hospitals should know the values.

Table 2.2. Overall compliance with standards related to the elective AAA care pathway

	Percentage of patients meeting standard		
	2016	2015	2014
Elective patients were discussed at MDT meetings	78.3 (3,251/4,153)	74.4	80.2
Patients with an AAA diameter \geq 5.5cm deemed suitable for repair had a pre-operative CT/MR angiography assessment	82.2 (3,108/3,782)	84.1	94.0
Patients underwent a formal anaesthetic review	96.6 (4,010/4,153)	96.0	98.0
Patients who had an anaesthetic review had one by a consultant vascular anaesthetist	91.9 (3,686 /4,009)	92.2	90.0
Patients had their fitness measured	83.9 (3,478/4,147)	82.2	73.7
Most common assessment methods:			
CPET	39.5	47.6	48.1
Echo +/- pulmonary function tests	38.2		

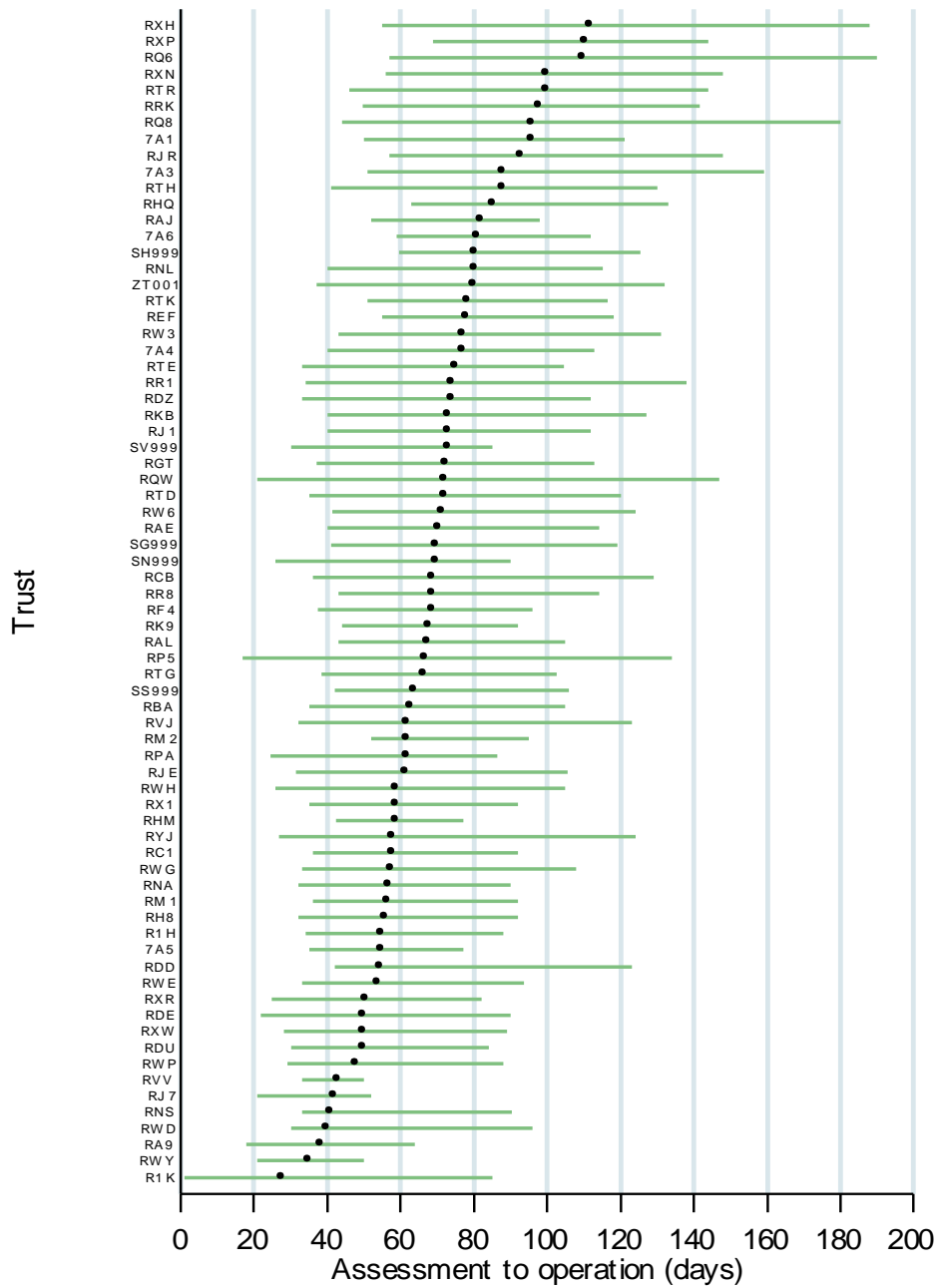
The National AAA Screening Programme has emphasised the importance of the timely scheduling of an elective repair to mitigate the risk of a patient's AAA rupturing while waiting for treatment. This is a small absolute risk of rupture, but the NAAASP recommends a target of 8 weeks from date of referral from the NAAASP to the date of the repair.

For elective infra-renal AAA repairs, the time from vascular assessment to surgery covers an important component of the referral process that is under the direct control of vascular services. Figure 2.1 (overleaf) summarises the variation among NHS trusts in the median (IQR) time from vascular assessment to surgery for procedures performed in 2016. The graph contains figures for all organisations that had 10 or more infra-renal AAA repairs cases with assessment and procedure dates. The median time is represented by a black dot. The interquartile ranges (IQRs) are shown by horizontal green lines. Any upper quartile line that is red indicates that the upper quartile value was above 200 days. This typically occurs when the number of patients with assessment and procedure dates for the NHS organisation is relatively small.

The median delay at the majority of vascular units tended to fall within the range of 60 to 90 days. Nonetheless, the upper limit of the interquartile ranges shows that, at 33% of the vascular units (24 of 72), 25% of patients operated on in 2016 waited more than 120 days. This is a reduction from 37% for 2015. While there are legitimate reasons for some patients to wait for surgery, such as the investigation and optimisation of comorbid medical conditions, we note that 120 days is well over the National AAA Screening Programme target of 8 weeks from date of referral to surgery and the analysis also only covers the period from vascular assessment to surgery.

The values for the individual organisations can be found in Appendix 4.

Figure 2.1: Median (IQR) time from assessment to treatment (days) for patients who had elective infra-renal AAA repair between January and December 2016



2.3 Snapshot audit of elective infra-renal AAA repair

In this section, we report the results from the snapshot audit into the time between referral and treatment for elective infra-renal AAA repair. The audit covered a 3-month period from June 2016 to August 2016. In this period, data were submitted on 1,021 patients, of whom 300 had an open repair and 721 had EVAR procedures.

For both types of procedures, the mean aorta size was 55mm (Table 2.3). Almost a fifth of patients for both procedures had a threshold set for the size of the aortic aneurysm to reach before treatment was considered appropriate. Often this is clinically appropriate if an aneurysm diameter is below 5.5cm at diagnosis. The most common reason for the threshold was patient anatomy, being 60.0% for open repair and 56.3% for EVAR, respectively, and the threshold was set to be approximately the same.

One reason for the time from referral to treatment being lengthened can be the need for advice from other clinical specialties. This was sought for around a fifth of patients. Advice from a cardiologist was required for 8.8% of open repairs and 6.6% of EVAR. Some of these patients were also referred for assessment by other specialists.

Another reason for delays to treatment can be the cancellation of the planned operation. The rates of cancellation were similar for open repair and EVAR, and affected 7-8% of patients. However, reasons for cancellations differed. For open repair, lack of hospital beds (63.6%) and availability of hospital facilities (22.7%) were the most common reasons. For EVAR, patient fitness (44.9%) was the most frequent reason followed by availability of hospital facilities (34.7%).

Figure 2.2 shows the time it takes for patients to be operated on from initial diagnosis or referral. Patients with an aorta greater than 55mm mostly have their AAA repaired within 12 months. Patients with an aorta of less than 45mm could have their AAA repaired up to 50 months after the original diagnosis, which reflects the need for the AAA diameter to reach the set threshold for intervention.

Once a decision is made to operate, the patient undergoes a formal assessment of fitness and anatomy. In the previous section, we highlighted the considerable variation in the times from vascular assessment to operation. The need for specialist opinion and the possible cancellation of the operation are two reasons that might contribute to this variation. Consequently, we stratified the time from vascular assessment to operation for patients in the snapshot audit by whether or not their procedure was cancelled and whether specialist opinion was needed. Figure 2.3 shows the distribution of these times by these four groups:

- The waiting times for patients who had no specialist opinion and no cancellation (group 1; 80% of patients) were the lowest, with a median wait of 62 days. However, there were still 25% of patients who waited more than 100 days

- The need for specialist opinion (group 2; 13% patients) shifted the average wait from 62 days to around 96.5 days
- The cancellation of the operation (group 3; 5% patients), coming late in the care pathway was also associated with a higher average wait, again making typical waiting times range from 75 to 150 days.
- Patients that required a specialist opinion and whose procedure was also cancelled (group 4; 1.8% patients) had a median waiting time of 116.5 days.

Table 2.3: Details of snapshot audit for elective infra-renal AAA repairs undertaken between June and August 2016

	Open (n=300)		EVAR (n=721)	
Mean aorta size	<i>Mean</i> 55.4mm	<i>IQR</i> 46 to 61mm	<i>Mean</i> 55.5mm	<i>IQR</i> 48 to 60mm
	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
% threshold set	19.3	14.9 to 24.4	17.1	14.4 to 20.1
Reason for threshold set	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
- Fitness	5.5	1.1 to 15.1	9.2	4.7 to 15.9
- Anatomy	60.0	45.9 to 73.0	56.3	46.9 to 65.4
- Both	34.5	22.2 to 48.6	34.5	26.0 to 43.7
	<i>Mean</i>	<i>IQR</i>	<i>Mean</i>	<i>IQR</i>
Size of threshold	56.1mm	55 to 57mm	56.2mm	55 to 55mm
Specialist Opinion	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
None required	82.1	77.2 to 86.4	85.8	82.9 to 88.3
Cardiology	8.8	5.8 to 12.7	6.6	4.9 to 8.7
Respiratory	2.1	0.8 to 4.5	2.9	1.8 to 4.4
Renal	2.1	0.8 to 4.5	2.2	1.2 to 3.5
Other	8.1	5.2 to 11.9	5.0	3.5 to 6.9
	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
% Cancellation of operation	7.7	4.9 to 11.5	7.1	5.3 to 9.2
Reason for cancellation	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
Device related	0.0	0.0 to 0.0	2.0	0.0 to 10.9
Lack of hospital beds	63.6	40.7 to 82.8	18.4	8.8 to 32.0
Patient fitness	9.1	1.1 to 29.2	44.9	30.7 to 59.8
Availability of hospital facilities	22.7	7.8 to 45.4	34.7	21.7 to 49.6
Patient decision	4.5	0.1 to 22.8	0.0	0.0 to 0.0

Figure 2.2: Time to procedure for elective infra-renal AAAs repair among NHS vascular units for procedures performed between Jun 2016 and Aug 2016. Graphs are stratified by size of aorta on diagnosis. The long waits for patients with aneurysms below diameter threshold for surgery (usually 55mm) are appropriate.

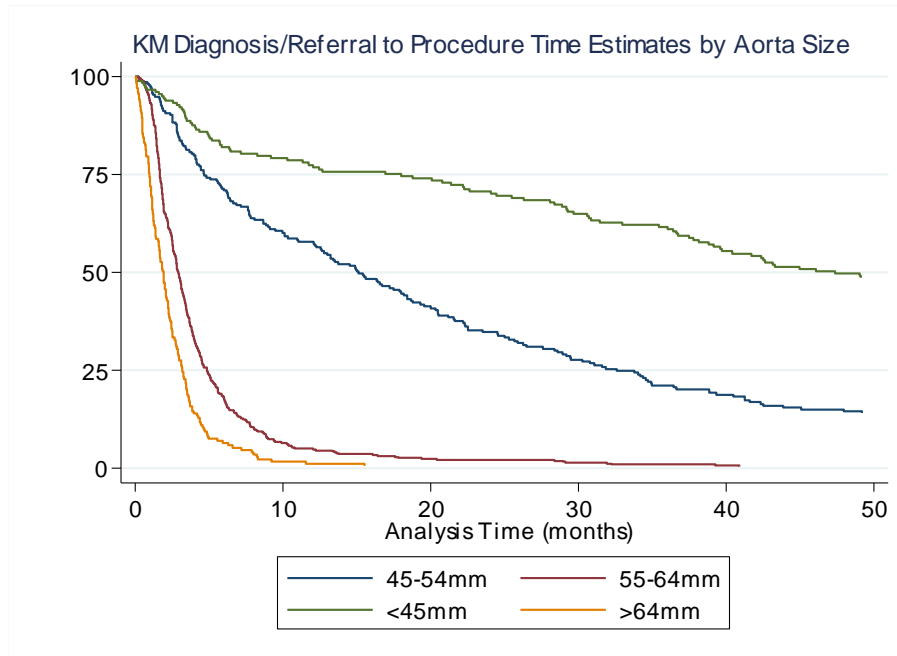
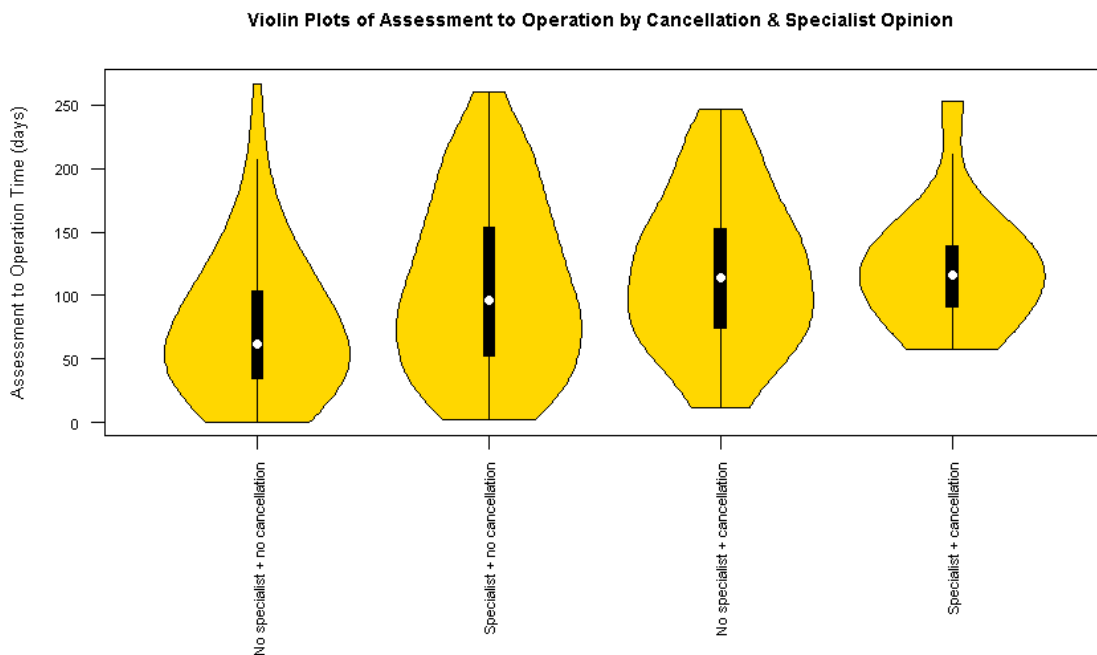


Figure 2.3: Distribution of times from vascular assessment to procedure for elective infra-renal AAA repair among NHS vascular units for procedures performed between Jun 2016 and Aug 2016. Graphs are stratified by whether patients had a specialist opinion and operation cancellation.



2.4 Postoperative outcomes after elective infra-renal AAA repair

The overall patterns of postoperative care are summarised in Table 2.4. There were some notable differences between patients having open and EVAR procedures. For EVAR procedures, over 60% of patients were returned to a normal hospital ward after surgery. Among those admitted to either level 2 or 3 critical care, the median length of stay was 1 day. The median length of the overall postoperative stay was 3 days. For patients undergoing open repair, 98% of patients were admitted to a level 2 or level 3 critical care unit. They typically remained there for 2 days, and the median total postoperative stay was 8 days, and had a comparatively high in-hospital mortality rate. Patients having open repair were more susceptible to respiratory complications, and the rate of return to theatre was also higher. The procedures had comparable 30-day readmission rates.

Table 2.4: Postoperative details of elective infra-renal AAA repairs undertaken between January and December 2016

		Open AAA (n=1,246)		EVAR (n=2,907)	
Admitted to	Ward	2.2%		63.2%	
	Level 2	58.8%		33.4%	
	Level 3	38.8%		3.5%	
		Median	IQR	Median	IQR
Days in critical care:	Level 2	2	1 to 4	1	0 to 1
	Level 3	2	2 to 4	1	1 to 2
Hospital length of stay (days)		8	6 to 10	3	2 to 4
		Rate	95% CI	Rate	95% CI
In-hospital postoperative mortality		2.9	2.0 to 4.0	0.4	0.2 to 0.8
Defined complications					
	Cardiac	4.9	3.8 to 6.3	1.4	0.1 to 1.9
	Respiratory	10.5	8.9 to 12.4	2.1	1.6 to 2.6
	Haemorrhage	1.4	0.8 to 2.2	0.9	0.6 to 1.3
	Limb ischaemia	3.1	2.2 to 4.2	1.1	0.8 to 1.6
	Renal failure	5.2	4.1 to 6.6	1.1	0.7 to 1.5
	Other	3.1	2.2 to 4.3	0.4	0.2 to 0.8
None of predefined		79.5	77.1 to 81.7	93.7	92.7 to 94.5
Return to theatre		6.8	5.5 to 8.4	2.0	1.5 to 2.6
Re-admission within 30 days		6.1	4.7 to 7.8	5.8	4.9 to 6.8

Patients undergoing EVAR procedures may experience an endoleak, in which blood still enters the aneurysm sac after the stent is inserted. Type II endoleaks (in which blood flows into the sac from other branches of the aorta) are the most common and least serious type. These may not require immediate treatment as some will resolve spontaneously. Type I endoleaks (in which blood leaks around the points of graft attachment) are potentially more serious and generally require intervention. Among the 2016 EVAR procedures:

- 2,401 (83.3%) procedures experienced no endoleak while the patient was in hospital
- Type 1 endoleaks occurred in 159 (5.5%) procedures
- 179 endoleaks (of any type) required intervention at the time of the procedure

2.5 Postoperative in-hospital mortality for elective infra-renal AAA repair

The principal performance measure used by the NVR for elective infra-renal AAA repair is the postoperative in-hospital mortality rate. In this section, we report these outcomes for NHS organisations undertaking these AAA repairs during the period from 1 January 2014 to 31 December 2016. We used this 3-year period to give robust outcome estimates.

The comparative, risk-adjusted mortality rates for individual NHS trusts are shown in a funnel plot in Figure 2.4. The horizontal axis shows surgical activity with dots further to the right showing the hospitals that perform more operations. The 99.8% control limit defines the region within which the mortality rates would be expected to fall if their outcomes only differed from the national rate because of random variation. The overall in-hospital mortality rate was 1.4%, and all NHS trusts had a risk-adjusted rate of inpatient mortality that fell within the expected range given the number of procedures they each performed.

Figures 2.5A and 2.5B show the risk-adjusted rate of inpatient mortality among NHS trusts for open repair and EVAR procedures separately. Each funnel plot is centred on the national average mortality rate for these two procedures. The overall in-hospital mortality rates for open and EVAR procedures were 3.1% and 0.6%, respectively.

Figure 2.4: Risk-adjusted in-hospital mortality rates after elective infra-renal AAA repair among NHS vascular units for procedures performed between January 2014 and December 2016. The overall in-hospital mortality rate was 1.4%.

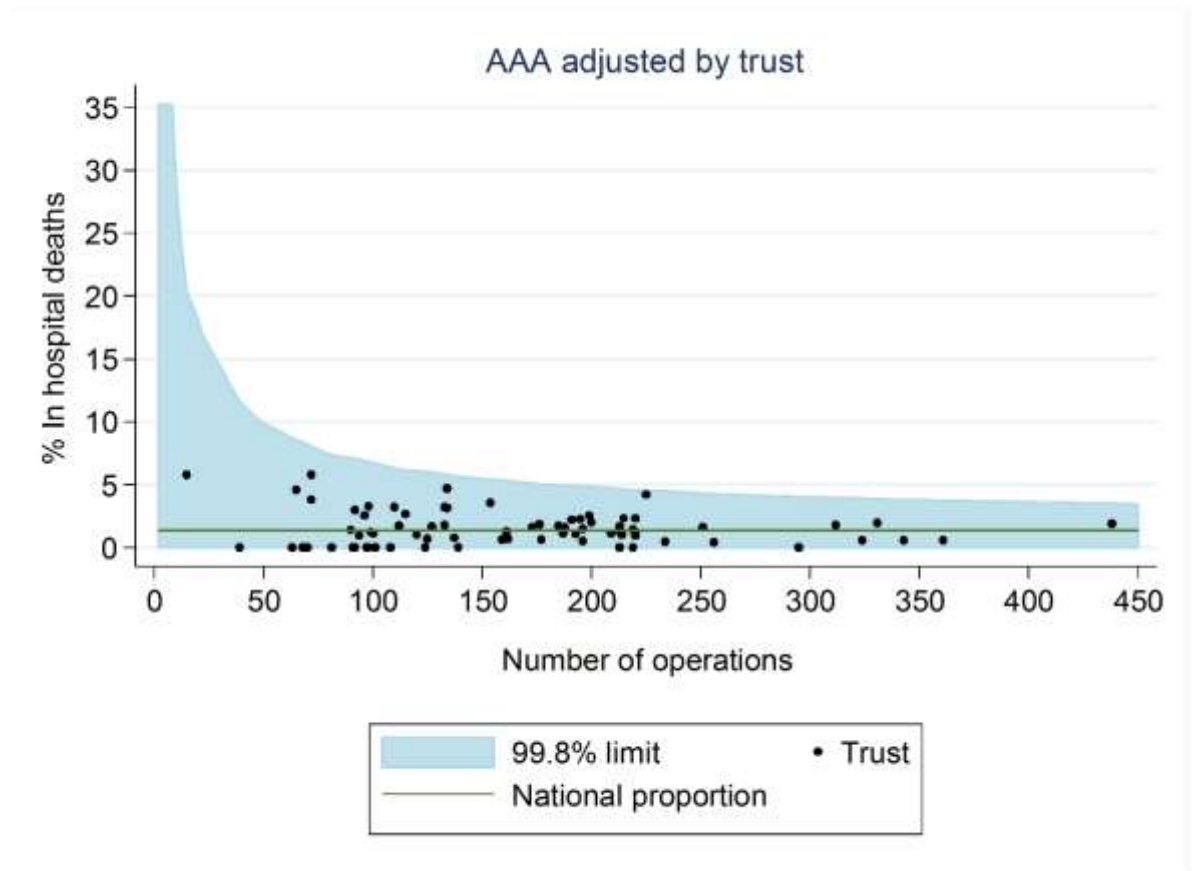
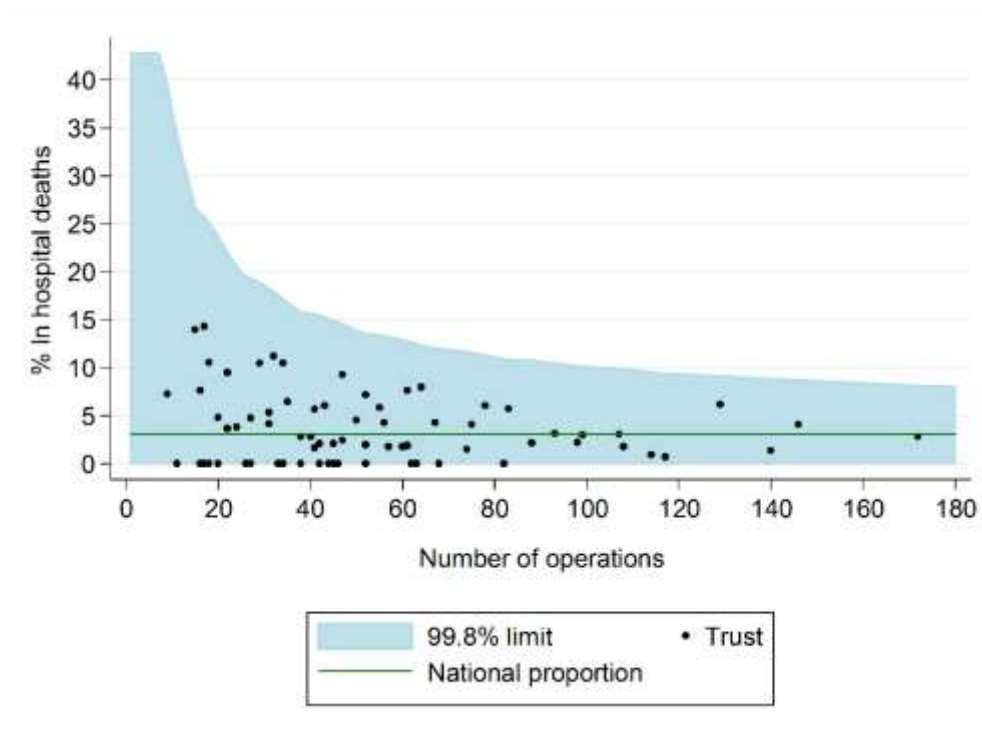
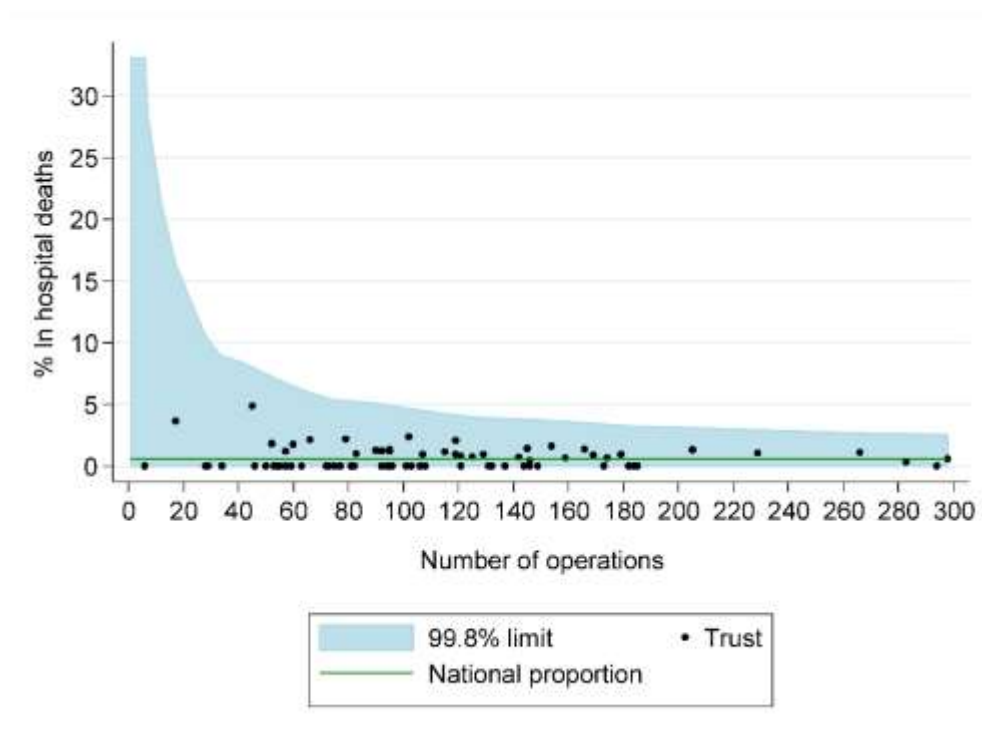


Figure 2.5: Funnel plot of risk-adjusted in-hospital mortality after elective AAA repair for open and EVAR procedures. The overall in-hospital mortality rates for open and EVAR procedures were 3.1% and 0.6%, respectively.

A: Open repairs



B: EVAR procedures



2.6 Conclusion

For many years, the focus of quality improvement around elective infra-renal AAA surgery has been to reduce postoperative mortality. In 2008, the mortality rate following elective infra-renal AAA repair in the United Kingdom was 7%; by 2013, it had fallen to 2.4%. The results in this report show that vascular units continue to improve the safety of the procedure, and all are performing at a similar standard of care.

Nonetheless, postoperative mortality only reflects one part of the spectrum of outcomes that are important to patients, and the report highlights various issues for NHS trusts / Health Boards to examine along the care pathway. On the positive side, many patients received care that met the VSGBI standards of pre-operative assessment but there are several areas for improvement. First, around one quarter of patients were not discussed at MDT. Secondly, while the time from vascular assessment to surgery may legitimately be many weeks for individual patients, the overall pattern of delay for individual vascular units should ideally be consistent with the 8 weeks referral to repair target. A significant proportion of units did not meet this standard and are recommended to examine how the time to surgery can be shortened.

3. Elective repair of complex aortic conditions

3.1 Patterns of complex aortic surgery

Most abdominal aortic aneurysms occur below the point where arteries branch from the aorta to the kidneys (infra-renal). Aortic aneurysms may occur in other locations, however, and those that occur above this point are typically more complex in their physical shape. Aneurysms that occur above this point are categorised into three types:

- Juxta-renal (that occur near to the renal arteries)
- Supra-renal (that occur above the renal arteries) and
- Thoraco-abdominal (more extensive aneurysms involving the thoracic and abdominal aorta)

Endovascular procedures are increasingly being performed instead of open surgery for complex aneurysm repair as new endovascular grafts have been developed. Collectively these procedures are known as complex endovascular repairs, but the term covers a number of techniques. The most common are:

- fenestrated EVAR (FEVAR) which involves the use of a graft which has holes (fenestrations) to allow the passage of blood vessels from the aorta
- branched EVAR (BEVAR) in which separate grafts are deployed on each blood vessel from aorta after the main graft has been fitted
- thoracic endovascular aortic/aneurysm repair (TEVAR)

The endovascular approach may also be used when an abdominal aneurysm extends down to the common iliac arteries. Here, an iliac branch device is used to preserve the blood flow to the internal iliac arteries.

In this chapter, we update last year's results to cover a 3-year period between January 2014 and December 2016. NHS trusts have submitted 2,055 records related to complex AAA procedures to the NVR (660 procedures in 2014, 695 in 2015 and 700 in 2016). These were submitted by 76 vascular units, and the volume of activity within these units ranged from 1 to 265 procedures (median=11.5). 57 of these units performed fewer than 30 procedures over the three years. Of these procedures, 1,838 (89%) were endovascular (Table 3.1), with over half being fenestrated repairs.

Table 3.1: Characteristics of patients who had an elective repair of complex AAA between January 2014 and December 2016

		Open AAA	%	EVAR	%	Total
Total procedures		217		1,838		2,055
Age group (years)	Under 66	52	24.0	279	15.2	331
	66 to 75	97	44.7	738	40.2	835
	76 to 85	66	30.4	747	40.6	813
	86 and over	2	0.9	74	4.0	76
Male		177	81.6	1,543	83.9	1,720
Female		40	18.4	295	16.1	335
Type of procedure	FEVAR			984	53.6	
	BEVAR			177	9.6	
	TEVAR			332	18.1	
	Iliac branch graft			231	12.6	
	Composite graft			19	1.0	
	Other (e.g., chimney / snorkel / periscope)			94	5.1	

The outcomes of elective repairs for patients with non infra-renal AAA are summarised in Table 3.2. For endovascular procedures, over three-quarters of patients were admitted to either level 2 or 3 critical care. For patients undergoing open repair, 98% of patients were admitted to a level 2 or level 3 critical care unit, where they typically remained there for 3-4 days. The median overall postoperative stay was 9 days. In addition, a greater proportion of patients having open repair were readmitted to critical care.

The median length of stay for endovascular repair was slightly shorter than for open repairs (5 v 9 days). However, patients having endovascular repair were more likely to be readmitted within 30 days than open repairs. There was very little difference in the outcomes for the two most common complex endovascular procedures (Table 3.3).

The in-hospital postoperative mortality rates for open and endovascular procedures were around six times greater than the rates for infra-renal AAA for both open and endovascular repair, reflecting the complex nature of the disease and surgery.

Table 3.2: Postoperative details of complex AAA repairs undertaken between January 2014 and December 2016

		Open AAA (n=217)		Endovascular (n=1,838)	
Admitted to	Ward	2.3%		19.9%	
	Level 2	47.5%		58.6%	
	Level 3	50.2%		21.4%	
	Died in theatre	0.0%		0.1%	
		Median	IQR	Median	IQR
Days in critical care:	Level 2	3	0 to 4	1	0 to 3
	Level 3	4	3 to 10	2	1 to 3
Hospital length of stay (days)		9	7 to 16	5	3 to 9
		Rate	95% CI	Rate	95% CI
In-hospital postoperative mortality		18.4	13.5 to 24.2	3.5	2.7 to 4.5
Re-admission to critical care		10.6	6.8 to 15.5	3.2	2.5 to 4.1
Return to theatre		17.1	12.3 to 22.7	7.1	6.0 to 8.4
30 day readmission rate		6.0	2.8 to 11.0	7.6	6.3 to 9.2

Table 3.3: Postoperative details of complex TEVARs and FEVARs undertaken between January 2014 and December 2016

		TEVAR (n=332)		FEVAR (n=984)	
Admitted to	Ward	13.6%		15.0%	
	Level 2	59.9%		62.3%	
	Level 3	26.2%		22.7%	
	Died in theatre	0.3%		0.0%	
		Median	IQR	Median	IQR
Days in critical care:	Level 2	1	0.5 to 3	1	0 to 2
	Level 3	2	1 to 2	2	1 to 3
Hospital length of stay (days)		5	3 to 10	6	4 to 8
		Rate	95% CI	Rate	95% CI
In-hospital postoperative mortality		3.0	1.5 to 5.5	3.9	2.7 to 5.3
Re-admission to critical care		4.2	2.3 to 7.0	2.8	1.9 to 4.1
Return to theatre		8.2	5.5 to 11.7	7.0	5.5 to 8.8
30 day readmission rate		9.7	6.3 to 14.3	8.1	6.2 to 10.4

Similar to the elective infra-renal repairs, we report the time from vascular assessment to surgery for complex repairs. Figure 3.1 shows the variation amongst trusts in the median (IQR) time from vascular assessment to surgery performed between 2014 and 2016. We chose three years in order to obtain a reasonable volume of data. The graph shows figures for all organisations where 10 or more complex repairs were undertaken with assessment and operation dates. This retained 33 of the 76 trusts.

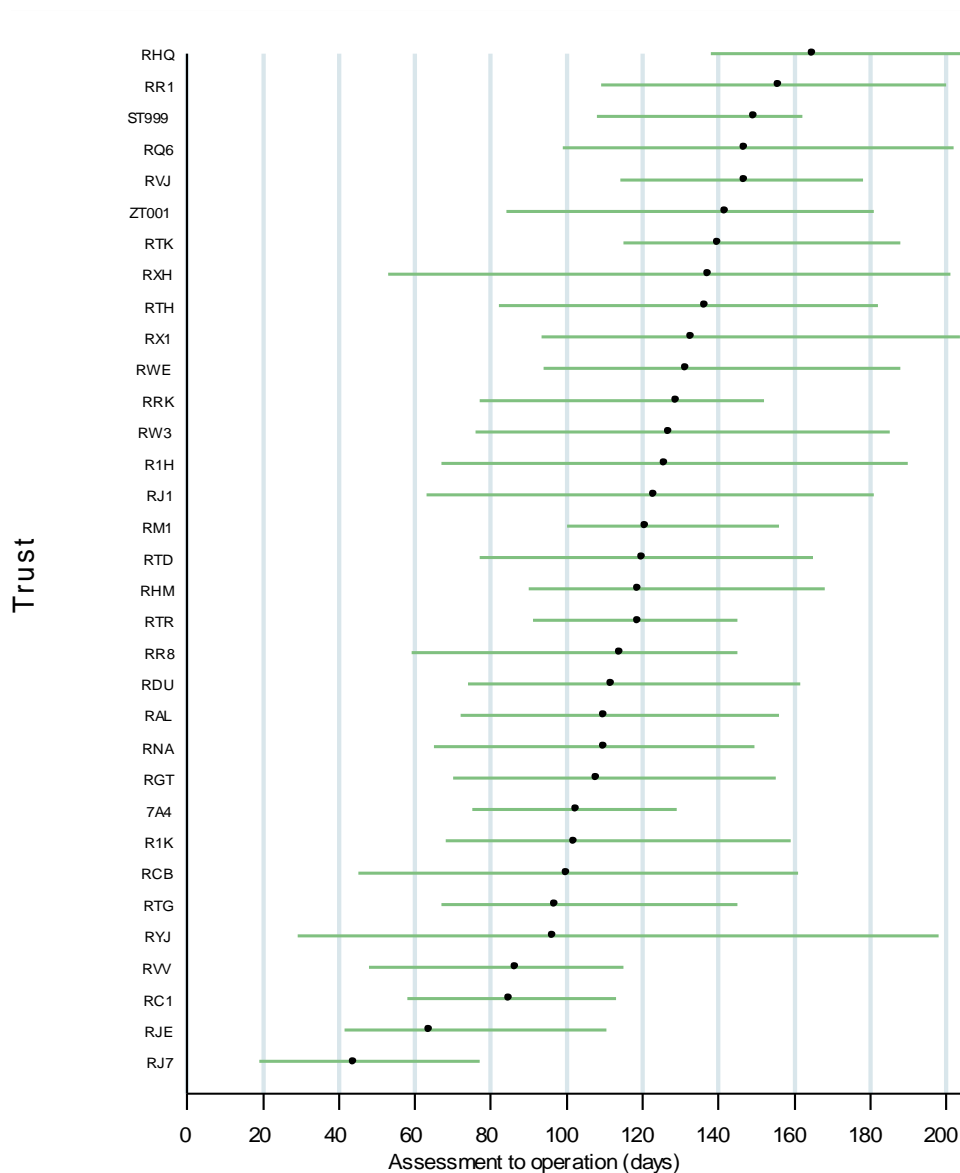
The median delay was 119 (68-170) days with the majority of vascular units tending to fall within the range of 100 to 140 days. However, the upper limit of the interquartile ranges shows that, at four vascular units, 25% of patients having a complex AAA repair between 2014 and 2016 waited more than 200 days. While there are legitimate reasons for some patients to wait for surgery, such as the investigation and optimisation of comorbid medical conditions, we note that 200 days is well over the National AAA Screening Programme target of 8 weeks from date of referral to surgery and the analysis also only covers the period from vascular assessment to surgery. Therefore the time from referral to treatment, or decision to operate to treatment will be longer.

3.2 Snapshot audit of complex aortic conditions

In this section, we report the results from the snapshot audit into the time between referral and treatment for complex AAA repairs. The audit covered a 6-month period from June 2016 to December 2016 of which 43 cases were open repair and 341 were endovascular procedures.

The mean aorta size for both procedure types was approximately 58mm (Table 3.4). As with elective infra-renal AAA patients, a threshold set for the size of the aortic aneurysm to reach before treatment was considered appropriate. Open repairs had a higher proportion of cases where a threshold was set (23.8%) compared with endovascular repairs (10.0%). The most common reason for open repairs was anatomy (70%); for endovascular procedures, it was both anatomy and fitness (50.0%). The threshold set for both groups was roughly 57mm. The most common reason for open repairs was anatomy (70%; 7 of 10); for EVAR procedures, it was both anatomy and fitness (50.0%). The threshold set for both groups was roughly 57mm.

Figure 3.1: Median (IQR) time from assessment to treatment (days) for patients who had an elective complex AAA repair between January 2014 and December 2016



One reason for the time from referral to treatment being increased can be the need for advice from doctors in other clinical specialties. A quarter of the open repairs required specialist opinion compared to 12.4% for endovascular repairs. The most common specialty involved in this process was cardiology: 6.2% for EVARs and 11.9% for open repairs. Another reason for longer waiting times can be the need for a non-conventional endovascular device; this was required in 41.9% of cases, and took on average 67 days to be obtained. Rates of operation cancellations were similar (under 5%) for both open and endovascular repairs, with lack of hospital beds being the most common reason.

Table 3.4: Details of snapshot audit for elective complex AAA repairs undertaken between June and December 2016

	Open (n=43)		Endovascular (n=341)	
Mean aorta size	<i>Mean</i>	<i>IQR</i>	<i>Mean</i>	<i>IQR</i>
	58.3mm	54 to 63mm	58.9mm	55 to 65mm
	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
% threshold set	23.8	12.1 to 39.5	10.0	6.9 to 13.8
Reason for threshold set	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
- Fitness	*	*	12.5	3.5 to 29.0
- Anatomy	*	*	37.5	21.1 to 56.3
- Both	*	*	50.0	31.9 to 68.1
	<i>Mean</i>	<i>IQR</i>	<i>Mean</i>	<i>IQR</i>
Size of threshold	57.5mm	55 to 60mm	57.0mm	55 to 60mm
Specialist Opinion	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
None required	73.8	58.0 to 86.1	87.6	83.5 to 91.0
Cardiology	11.9	4.0 to 25.6	6.2	3.8 to 9.4
Respiratory	0.0	0.0 to 8.4	2.2	0.9 to 4.4
Renal	4.8	0.6 to 16.2	0.9	0.2 to 2.7
Other	11.9	4.0 to 25.6	4.0	2.2 to 6.8
			<i>Rate</i>	<i>95% CI</i>
% non-conventional device	*	*	41.9	36.5 to 47.5
			<i>Mean</i>	<i>IQR</i>
Requested to acquired time for device	*	*	67.4 days	49 to 80.5 days
	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
% Cancellation of operation	4.8	0.6 to 16.2	4.7	2.6 to 7.6
Reason for cancellation	<i>Rate</i>	<i>95% CI</i>	<i>Rate</i>	<i>95% CI</i>
Device related	*	*	20.0	4.3 to 48.1
Lack of hospital beds	*	*	46.7	21.3 to 73.4
Patient fitness	*	*	20.0	43.3 to 48.1
Availability of hospital facilities	*	*	13.3	1.7 to 40.5
Patient decision	*	*	0.0	0.0 to 0.0

* Not published due to small numbers

3.3 Conclusion

Complex aortic aneurysm repairs comprise a relatively small part of the overall vascular surgical workload, but they consume a relatively greater proportion of the health care resources than infra-renal AAA repair. Moreover, it is an area that is evolving due to the continuing development of new complex endovascular grafts. Consequently, we primarily provide these results to support the commissioning of vascular services in this area.

We are currently unsure of the level of case-ascertainment for these procedures. The coding of complex aortic procedures in Hospital Episode Statistics (HES) prevents these procedures from being clearly identified. Consequently, we do not know if these results are representative of the country as a whole. Nonetheless, the high postoperative mortality rate, particularly for open repairs, suggests that NHS trusts and Commissioners should be focused on ensuring the care for these patients is delivered safely. We would recommend that complex aortic surgery should only be commissioned from vascular units that submit complete and accurate data on caseload and outcomes of these procedures to the NVR.

4. Repair of ruptured abdominal aortic aneurysms

4.1 Surgical activity for ruptured AAA

In this chapter, we describe the outcomes of emergency AAA repairs among patients with a ruptured abdominal aortic aneurysm. The analysis included procedures performed between 1 January 2014 and 31 December 2016. Details of 2,913 procedures were submitted to the NVR, giving an estimated case-ascertainment of 86% (compared to 73% in the previous report). The proportion of patients having an EVAR procedure over this 3-year period was 27.4% (n=798), slightly up from 25.1% in the period between 2013 and 2015.

Compared to patients who had an elective repair of an infra-renal AAA, the patients who had surgery for a ruptured AAA were older on average, with most aged over 76 years at the time of surgery and tended to have a larger diameter of the aneurysm (See Appendix 3).

In comparison to patients undergoing an open repair, patients having EVAR had a smaller AAA diameter, on average, and a greater proportion had also undergone AAA surgery previously. Almost 75% of the open grafts performed in 2014 and 2016 were tube grafts. The next most common were bifurcated iliac (19.5%) and bifurcated groin (4.9%). Uni-iliac and crossover procedures comprised only 0.6%. For the patients undergoing EVAR, the basic characteristics of their anatomy were:

- 87.5% had a neck angle between 0-60 degrees; for 7.1%, it was 60-75 degrees.
- The mean neck diameter was 23.9mm and the mean neck length was 24.0mm
- The aneurysm was extended into either the left / right iliac artery for 18.4% of procedures and was extended bilaterally for 4.6% of procedures.

The outcomes of the surgical repair for patients with a ruptured AAA are summarised in Table 4.1. There were some noticeable differences in the postoperative care required by patients undergoing open and EVAR procedures. Over 80% of patients who had an open procedure required level 3 critical care after the procedure, with a median length of stay of 4 days. There was also a greater proportion of patients who returned to theatre within their hospital admission, and who suffered from respiratory problems. This is likely to reflect differences in the severity of patients' conditions, and is also highlighted in the in-hospital postoperative mortality rates for open and EVAR procedures. These were 41.2% (95% CI 39.1 to 43.4) and 23.2% (95% CI 20.3 to 26.3), respectively.

Table 4.1: Postoperative details of emergency repairs for ruptured AAAs undertaken between January 2014 and December 2016

		Open AAA (n=2,115)	EVAR (n=798)		
*Admitted to	Ward	0.3%		9.4%	
	Level 2	6.6%		41.4%	
	Level 3	86.0%		44.2%	
	Died in theatre	7.1%		5.0%	
		Median	IQR	Median	IQR
*Days in critical care:	Level 2	3	1 to 6	1	0 to 3
	Level 3	4	2 to 9	2	1 to 5
Hospital length of stay (days)		11	4 to 21	8	4 to 16
		Rate	95% CI	Rate	95% CI
In-hospital postoperative mortality		41.2	39.1 to 43.4	23.2	20.3 to 26.3
Defined complications					
	Cardiac	25.5	23.6 to 27.5	15.4	12.9 to 18.1
	Respiratory	33.4	31.4 to 35.6	20.1	17.3 to 23.1
	Haemorrhage	5.3	4.3 to 6.3	2.4	1.4 to 3.7
	Limb ischaemia	10.9	9.6 to 12.3	3.1	2.0 to 4.7
	Renal failure	27.6	25.6 to 29.6	11.2	9.0 to 13.6
	Other	9.7	8.4 to 11.1	4.2	2.9 to 5.9
None of predefined		36.4	34.3 to 38.6	64.3	60.8 to 67.7
*Return to theatre		21.2	19.5 to 23.1	7.7	5.9 to 9.9
*Re-admission within 30 days		6.3	4.9 to 7.9	11.8	9.2 to 15.0

In the last two Annual Reports, the in-hospital postoperative mortality rates for open repair were 40.4% and 41.2%, whilst for EVAR they were 20.7% and 23.2%. This continuation of higher mortality rates may reflect the increased case-ascertainment, with the NVR capturing more of the sickest patients. We note that the in-hospital mortality rate for EVAR procedures is lower than that reported in the IMPROVE trial (30 day mortality for 275 EVAR patients with confirmed rupture was 36.4%), although the rates for open procedures is comparable (30 day mortality for 261 Open repairs was 40.6%) [Powell et al 2014]. This might be due to the NVR reporting in-hospital mortality rather than 30 day mortality rates, and it may also be due to the conservative adoption of EVAR for patients with ruptured AAA.

In recognition of the relatively recent uptake of EVAR for emergency repair of ruptured AAA, we summarise the risk of an endoleak below (Table 4.2). In comparison to the elective EVAR repair of an intact infra-renal AAA, the risk of an endoleak was slightly higher, with 6.9% of patients experiencing a Type 1 complication (compared with 5.5%).

Table 4.2: Rates of endoleak for emergency repair of ruptured AAAs undertaken between January 2014 and December 2016

Endoleak	%Patient with an endoleak	% endoleaks requiring intervention	Endoleak successfully repaired
Type 1	6.9%	81.5%	81.8%
Type 2	7.2%	16.1%	55.6%
Type 3	1.0%	62.5%	100.0%
Type 4	0.6%	60.0%	66.7%
Unclassified	1.2%	25.0%	50.0%

4.2 Postoperative in-hospital mortality for ruptured AAA repair

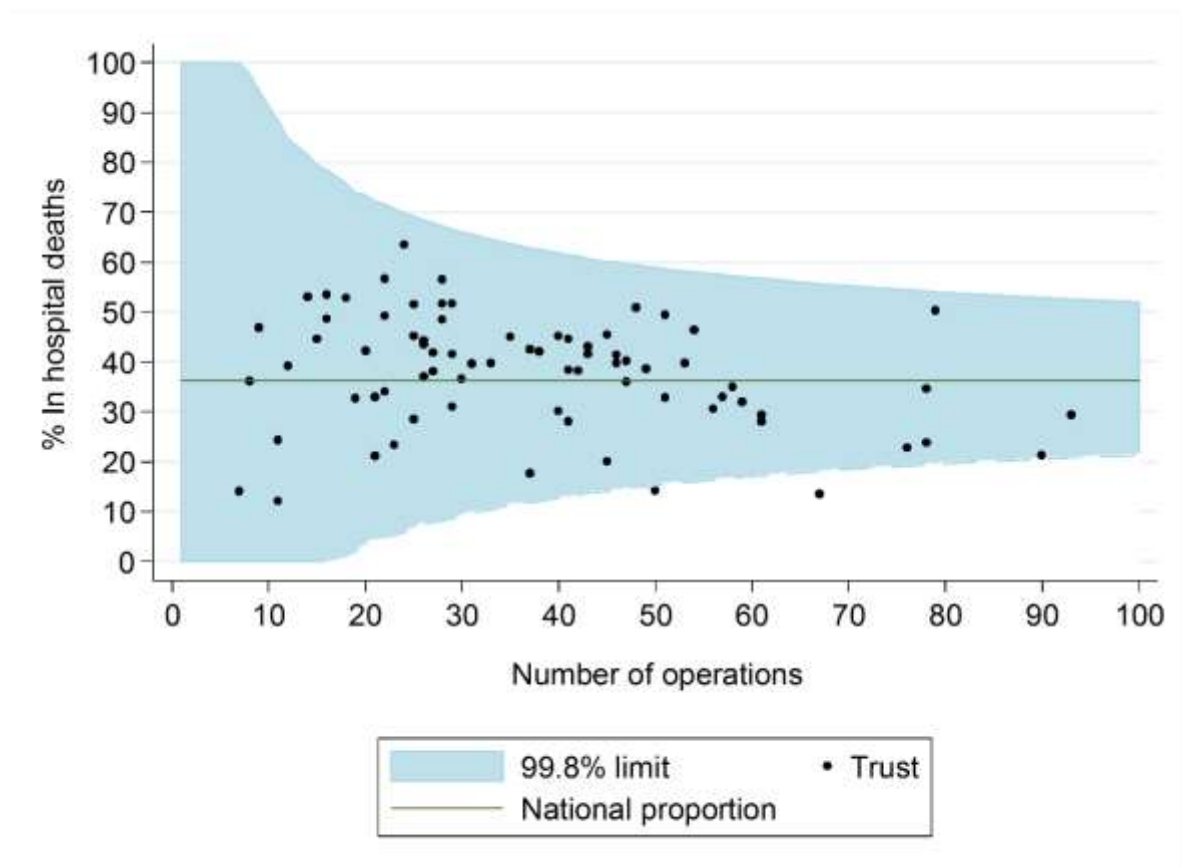
In this section, we report in-hospital mortality for NHS organisations undertaking ruptured AAA repairs during the period from 1 January 2014 to 31 December 2016. This is to make use of the three years of data available in the NVR dataset introduced in January 2014, and in order to undertake better risk-adjustment based on the changes to the NVR.

The risk-adjusted mortality rates for individual NHS trusts are shown using a funnel plot in Figure 4.1. The horizontal axis shows surgical activity with dots further to the right showing the hospitals that performed more operations. The 99.8% control limit defines the region within which the mortality rates would be expected to fall if their outcomes only differed from the national rate because of random variation.

All but two of the NHS trusts had a risk-adjusted rate of in-hospital mortality that fell within the expected range around the national average of 36.3%, given the number of procedures performed. There were two NHS trusts that had mortality rates that were lower than expected.

We note that the rates among the hospitals tended to range from 20-60% but this reflects the relatively low volumes used to calculate these rates. Appendix 6 gives the figures for each NHS trust.

Figure 4.1: Risk-adjusted in-hospital mortality for emergency repairs of ruptured AAAs between January 2014 and December 2016 by NHS trust. Mean mortality was 36.3%.



4.3 Conclusion

These results highlight a number of issues. First, a ruptured AAA remains a very serious condition, with high postoperative mortality and morbidity. This highlights the important role that the screening programme can play in preventing these events.

Second, only 27% of patients undergo an EVAR procedure for a ruptured AAA. There are likely to be various clinical factors resulting in the selection of one technique over the other, including anatomical suitability and the physiological characteristics of patients. Indeed, the comparatively favourable results for EVAR procedures suggest that it is being introduced cautiously in patients for whom it is most clearly appropriate. We emphasise that the results here provide no evidence of the relative merits of the two techniques, and the initial results of the IMPROVE trial showed that the open and EVAR procedures produced equivalent results [Powell et al 2014]. Nonetheless, it is also possible that the use of EVAR reflects limitations in the availability of endovascular facilities and skills in some vascular units. Further work is required to investigate whether pathway factors are influencing the use of EVAR for ruptured AAA patients.

5. Carotid Endarterectomy

5.1 Background

In the UK, around 4,000-5,000 patients undergo a carotid endarterectomy (CEA) each year. The information in this report primarily concerns the carotid procedures performed between 1 January 2016 and 31 December 2016. During this period, data were submitted by 467 surgeons, who were working at 87 NHS trusts and Health Boards in England, Wales, Scotland and Northern Ireland. Data were submitted to the Registry on a total of 4,330 interventions, which covered:

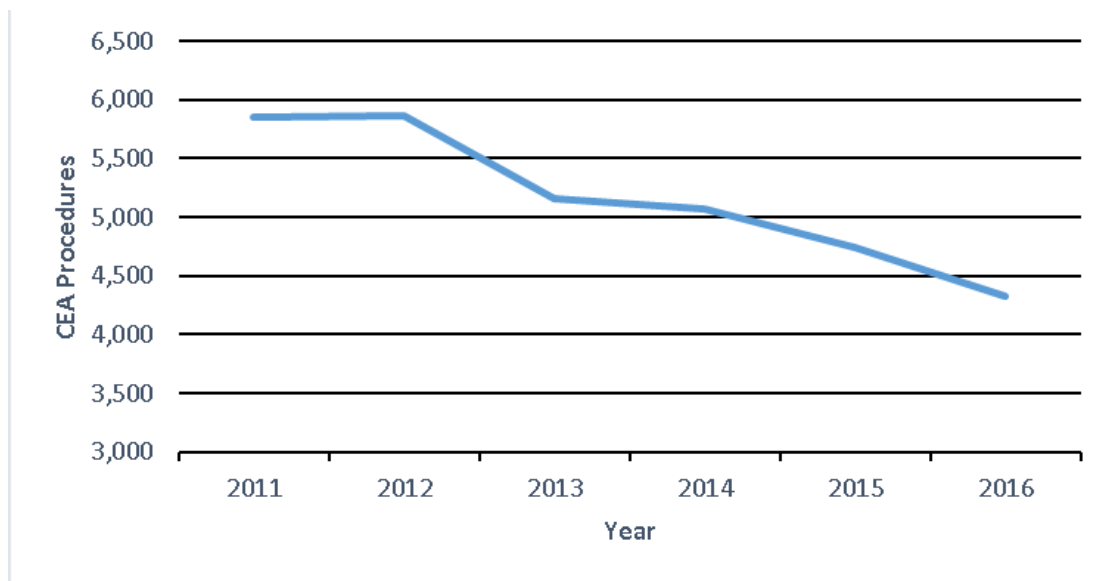
- 4,026 symptomatic patients
- 4,330 cases with complete 30 day survival information
- 3,333 cases for whom information was submitted on a follow-up appointment

The number of carotid endarterectomies reported to the NVR in 2017 was considerably lower than in the previous two years (Figure 5.1). This seems to reflect an overall reduction in the number of procedures being performed (a 15% drop in two years) rather than a drop in case-ascertainment, which has been consistently high for all three years (Table 5.1). The 2016 estimated case-ascertainment figures for the four nations were: 90% for England, 102% for Northern Ireland, 69% for Scotland and 104% for Wales.

Table 5.1: Estimated case-ascertainment of carotid endarterectomy in the UK

	2014	2015	2016	Total
Audit procedures	5,065	4,739	4,330	14,134
Expected procedures	5,568	5,173	4,830	15,571
Estimated case-ascertainment	91%	92%	90%	91%

Figure 5.1: Number of CEAs performed between 2014 and 2016



5.2 Treatment pathways

Despite the reduction in the level of surgical activity over time, the characteristics of the cohort has remained fairly stable (see appendix 3). The mean age of patients was 72 years, and there was no obvious fall in the proportion of older or more comorbid patients being treated. Similarly, the distribution of symptoms and degree of stenosis was relatively unchanged:

- Nearly three-quarters of the patients had at least 70% stenosis in their ipsilateral artery at the time of operation, and 93.0% were symptomatic.
- Among the 4,330 patients with symptomatic disease, TIA was the most common symptom (47.3%) followed by stroke (35.8%). Only 0.7% of patients had a previous ipsilateral treatment.
- Medication for cardiovascular conditions was common among patients prior to surgery. Overall, 93.4% were on antiplatelet medication, while 88.7% were taking statins. ACE inhibitors and beta blockers were being taken by 37.7% and 24.2% of patients, respectively.

Patients may be referred for carotid endarterectomy from various medical practitioners. The stroke physician is the increasingly common source of referral, increasing from 75.8% in 2013 to 81.3% in 2016. The next most common referral sources in 2016 were: neurologists (3.9%), general practitioners (3.5%) and vascular surgeons (3.0%)

The current NICE guideline recommends two weeks as the target time from symptom to operation in order to minimise the chance of a high risk patient developing a stroke [NICE

2008]. In the years from 2009 to 2012, there was a steady decline in the median time from the index symptom to operation for symptomatic patients, falling from 22 days (IQR 10-56) in 2009 to 13 days (IQR 7-28) days in 2012. The proportion of patients who were treated within 14 days rose from 37% to 56%. It has been relatively stable since then, with the median time for symptomatic patients in 2016 being 13 days (IQR 7-27) days and 56% of patients being treated within 14 days.

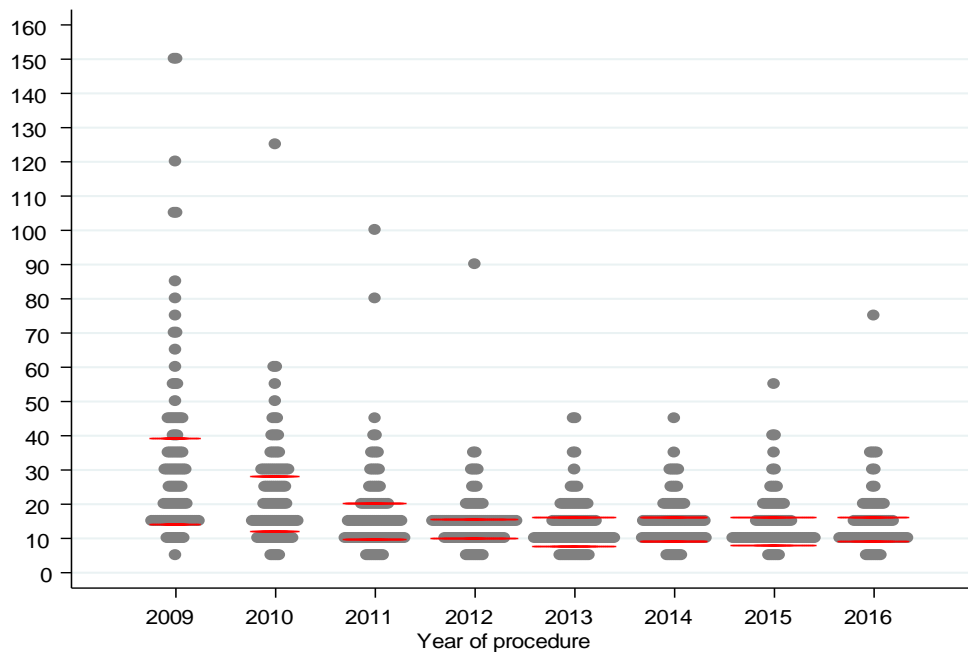
In 2016, the median times along the care pathway were similar for patients with symptoms of stroke or TIA. Patients with amaurosis fugax, where the stroke risk is lower and greater delay acceptable, took comparatively longer to progress from symptom onset to surgery, with the median delay being 19 days (IQR 10 to 42).

The patient pathway from symptom to surgery can be split into three distinct points in times. In 2016, the median time delays for these components were:

- 4 days (IQR 1-11) from symptom to first medical referral
- 1 day (IQR 0-5) from first medical referral to being seen by the vascular team, and
- 5 days (IQR 2-12) from being seen by a vascular surgeon to undergoing CEA.

Figure 5.2 shows the changes over time in median delays from symptom onset to undergoing CEA for every UK NHS hospital performing CEA for the past eight years.

Figure 5.2: The median time from index symptom to carotid surgery for each NHS trusts by year of procedures*



* Two highest values (179 and 207) in 2009 were winzorised to 150 days to reduce their effect on the scale of the vertical axis.

The distribution of symptom to operation times for all NHS trusts is summarised in Figure 5.3. The graph contains figures for all organisations that had 10 or more symptomatic cases with exact symptom and procedure dates. The median time is represented by a black dot. The interquartile ranges (IQRs) are shown by horizontal green lines. Any upper quartile line that is red indicates that the upper quartile value was above 100 days. This typically occurs when the number of patients with exact symptom and procedure dates for the NHS organisation is relatively small. The vertical red line in the graph represents the current NICE Guideline of 14 days from symptom to procedure.

Figure 5.3 shows that there was considerable variation among NHS trusts in the median time to surgery during 2016. The median was 14 days or less for 52 of the 79 organisations, but the median exceeded 20 days for 16 vascular units. The values for the individual organisations can be found in Appendix 7.

Figure 5.4 shows the eight trusts where the symptom to procedure times were the longest. When looking at the patient pathway by the different components, it can be seen that the symptom to referral for the eight trusts are within 10 days. However, for two trusts, the median time from referral to first being seen by the surgical time exceeded 10 days. The time from being seen to the procedure varied greatly from a couple of days to almost 50 days.

Figure 5.3: Median time (and interquartile range) from symptom to procedure by NHS trust for procedures done between January and December 2016

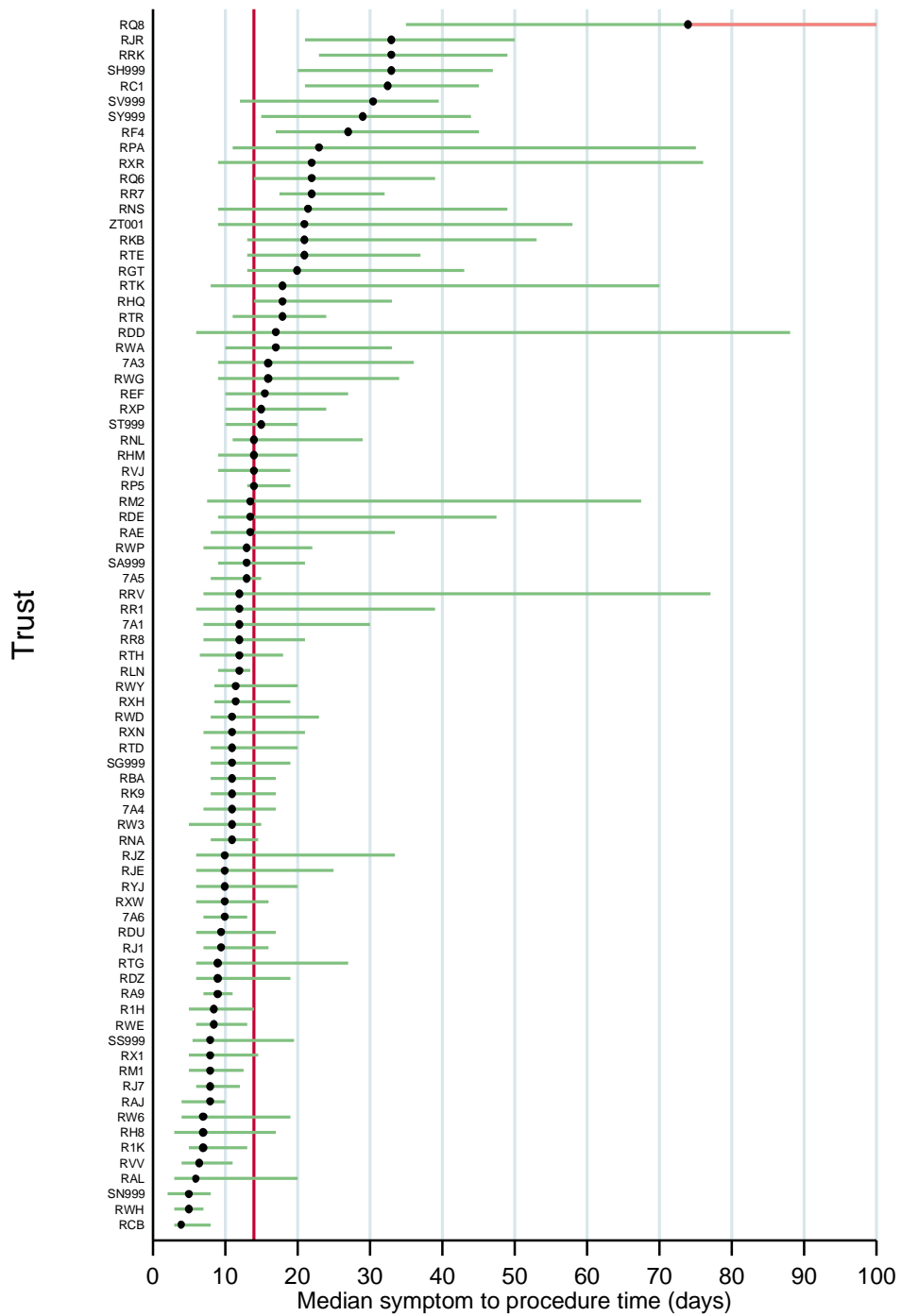
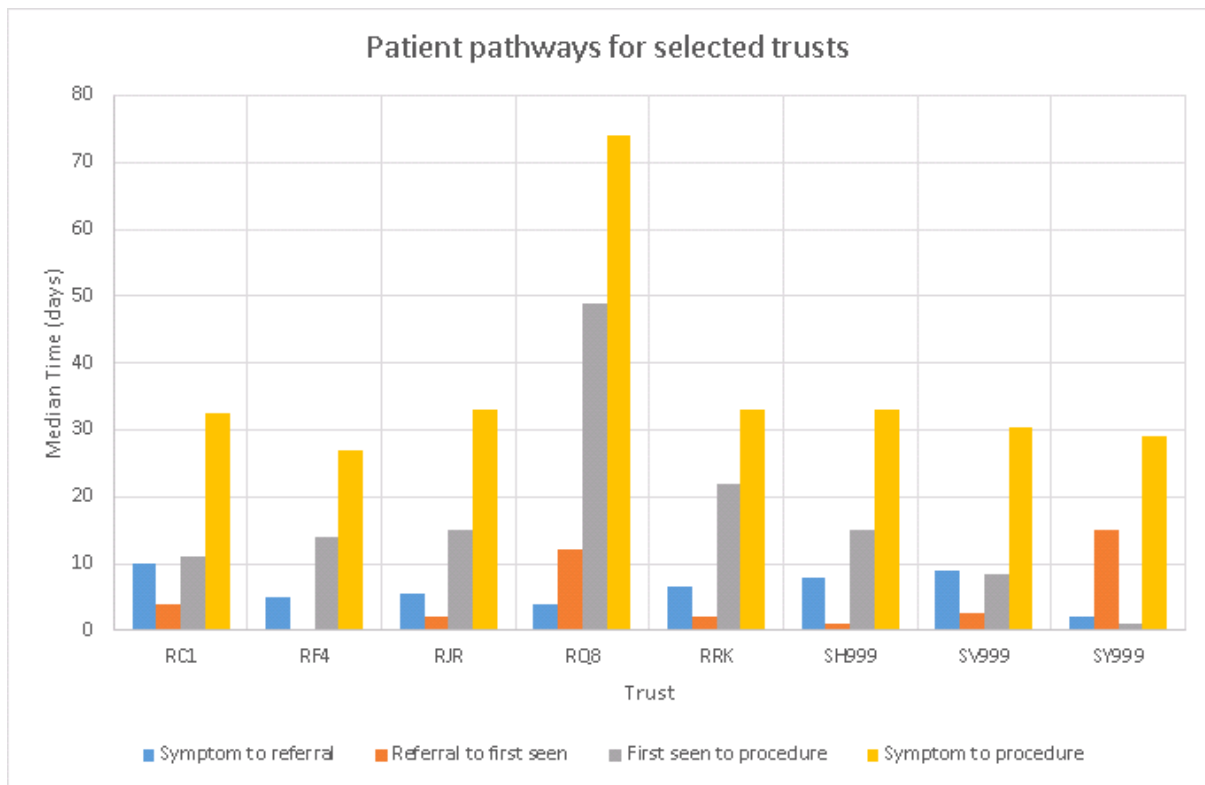


Figure 5.4: Median times for eight trusts with longest symptom to procedure times in 2016.



5.3 Operative details and postoperative surgical outcomes

The majority of carotid interventions that are submitted to the NVR are unilateral endarterectomies. There was only one bilateral procedure. An endovascular carotid stent was used in 1.1% of procedures (see box overleaf).

Most carotid endarterectomy were on patients admitted as elective cases (61.1%) and 99% had their operation start within the hours of 8am and 6pm.

Table 5.2 summarises the operative details of unilateral carotid endarterectomies performed during 2016:

- The most common procedure involved using a carotid patch after a standard endarterectomy.
- Just over half of the procedures were performed under general anaesthetic
- 54.4% of procedures involved the use of a shunt.

Just over half of the patients were admitted to the ward after their operation, with 42.9% of patients being admitted to either level 2 or level 3 critical care wards. The length of stay in critical care was typically short, with the median duration in level 2 and level 3 critical care wards being 1 day (IQR 0 to 1) and 1 days (IQR 1 to 2), respectively. Overall, the median length of stay in hospital was 3 days (IQR 2 to 5).

Table 5.2: Details of unilateral carotid endarterectomies undertaken during 2016

Operation details		Procedures (n=4,329)	(%)
Anaesthetic	General only	2,378	54.9
	Local only	1,073	24.8
	Other	878	20.3
Type of Endarterectomy	Standard	572	13.2
	Standard + patch	3,467	80.1
	Eversion	290	6.7
Carotid shunt used		2,357	54.4
Ipsilateral patency check		2,463	57.9

Information submitted to the NVR on carotid stenting

Carotid stenting is an alternative to carotid endarterectomy for improving the blood flow within carotid arteries that have narrowed due to the build up of plaque. The stent is deployed using an endovascular technique, with a wire guiding the deployment of the stent. The procedure can be performed under general or local anaesthetic.

In the three year period between January 2014 and December 2016, the NVR received information on 161 stent procedures (annually 58, 57 and 46). Only 6 of the 26 NHS trusts that submitted cases performed more the 5 procedures within the three year period. The median number of procedures by NHS trust was 2. Among the 161 procedures, there were 8 patients who had either stroke or died within 30 days of the procedure (4.97%; 95% CI 1.54 to 8.39).

Patients may experience various complications following carotid endarterectomy. The rate of post-operative stroke is of primary concern, but other complications include:

- Bleeding
- Cardiac complications including a myocardial infarction
- Cranial Nerve Injury (CNI), which describes damage to one of the nerves to the face and neck

The risk of these various complications was low. For the nearly 15,000 procedures performed in NHS hospitals between 2014 and 2016, the rates of the different complications tended to be around 2% (see Table 5.3). And, over this 3-year period:

- the rate of return to theatre was 2.6 (95% CI 2.4 to 2.9), and
- the rate of readmission within 30 days was 4.2% (95% CI 3.9 to 4.6).

Table 5.3: Postoperative outcomes following carotid endarterectomy

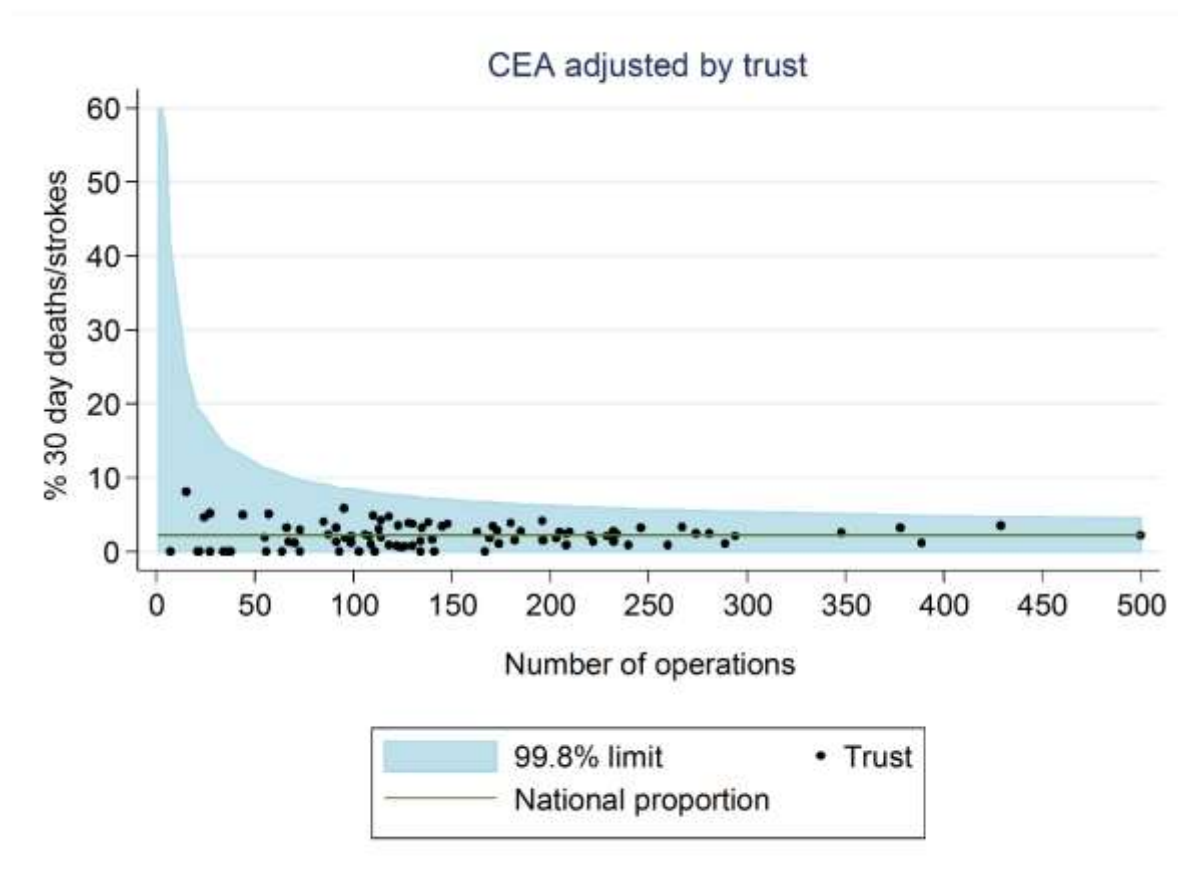
Complication	Procedures in 2014-2016	Complication rate (%)	95% Confidence interval
Bleeding within admission	14,133	2.3	2.1-2.6
Myocardial Infarct within admission	14,133	1.3	1.1-1.5
Stroke within 30 days	14,134	1.8	1.5-2.0
Death and/or stroke within 30 days	14,134	2.2	1.9-2.4
Cranial nerve injury within admission	14,043	1.8	1.6-2.0

5.4 Rates of stroke/death within 30 days among NHS trusts

The primary measure of safety after carotid endarterectomy is widely-accepted to be the rate of death or stroke within 30 days of the procedure. The values for each NHS trust for this outcome are described in this section. To account for differences between the characteristics of patients treated at the various organisations, we calculated risk-adjusted rates using a logistic regression model. This model took into account the patient age, if a patient had cardiac disease or diabetes their preoperative Rankin Scale and ASA grade.

The comparative, risk-adjusted 30 day death/stroke rates for individual NHS trusts are shown in the funnel plot in Figure 5.5 [Spiegelhalter 2005]. The horizontal axis shows surgical activity with dots further to the right showing the organisations that perform more operations. The 99.8% control limit defines the region within which the mortality rates would be expected to fall if the organisations' outcomes only differed from the national rate because of random variation.

Figure 5.5: Funnel plot of risk-adjusted rates of stroke/death within 30 days for NHS trusts, for carotid endarterectomies between January 2014 and December 2016



The overall national average rate of stroke/death within 30 days = 2.2%

The funnel plot shows the risk adjusted rate of death/stroke within 30 days for all NHS organisations are all within the expected distance of the overall national average rate of 2.2% (i.e., they were within the 99.8% control limits). Appendix 7 gives the figures for each organisation.

5.5 Conclusion

A continuation of the data collected on carotid interventions in 2016 was the change in the number of procedures submitted to the NVR compared with the two previous years. As mentioned earlier, this seems to reflect an overall reduction in activity rather than a drop in case-ascertainment. The reasons for this change are unclear, but it might reflect a change in the epidemiology of risk factors for stroke.

Despite this fall in activity, there was little change in the median time from symptom to surgery. This seems to have stabilised around 13 days after the time fell between 2009 and 2012, with 56% of patients having their surgery within the recommended time. The results continue to show considerable variation in the time to intervention across NHS trusts, with 16 having a median above 20 days. The clinical teams and the executives of these organisations need to explore how they can meet the NICE recommendations. High performing centres demonstrate that it is possible to achieve a pathway of care that meets the recommended standard of access for this treatment.

Despite these problems of delay at some organisations, the results show that carotid surgery continues to be performed safely in the NHS, with low rates of stroke and other post-operative complications. Most patients undergo carotid endarterectomy (in one form or another), with few centres adopting carotid stenting. This perhaps reflects the lack of evidence for stenting conferring any advantage to patients.

6. Lower limb angioplasty/stent for peripheral artery disease

6.1 Introduction

Lower limb peripheral artery disease (PAD) is an increasingly serious public health issue. Medical treatments, such as antihypertensive and antiplatelet medications, and lifestyle interventions, such as supervised exercise programmes, are the first line therapies for PAD but when these no longer prove to be effective, endovascular and surgical revascularisation procedures can be used to restore blood flow to the affected limb.

This chapter describes the process and outcomes of care for patients undergoing lower limb endovascular procedures, which either involve angioplasty and/or the insertion of a stent. Endovascular revascularisation has become an increasingly attractive treatment option since its introduction. It is less invasive than bypass surgery and can be undertaken in day-patient units.

The NVR has collected data on endovascular revascularisation since 2014, and for the first time we can provide three full years of data on these procedures, from January 2014 to December 2016. In all, data on 13 886 lower limb angioplasties: 3,474 performed in 2014, 4,471 in 2015 and 5,941 in 2016.

We have estimated the case-ascertainment for these procedures by comparing the numbers in the NVR to those in routinely collected Hospital Episode Statistics (HES) data (Tables 6.1 and 6.2). The overall case-ascertainment has increased over the data collection period, from 15.7% in 2014 to 20.7% in 2015 and 27.5% in 2016, but there is considerable variation between NHS trusts (Figure 6.1) and the case-ascertainment remains far from ideal. Some NHS trusts achieved a case-ascertainment of 90% but there was a disappointingly large number of providers submitting less than 10% of procedures. Case-ascertainment estimates for all NHS trusts actively performing lower limb angioplasties are shown in Appendix 8.

Table 6.1: Estimated case-ascertainment for lower limb angioplasty / stent

	2014	2015	2016	Total
Audit procedures	3,474	4,471	5,941	13,886
Expected procedures	22,152	21,567	21,567	65,286
Estimated case-ascertainment	15.7%	20.7%	27.5%	21.3%

Figure 6.1 Case-ascertainment by NHS Trust between January 2014 and December 2016

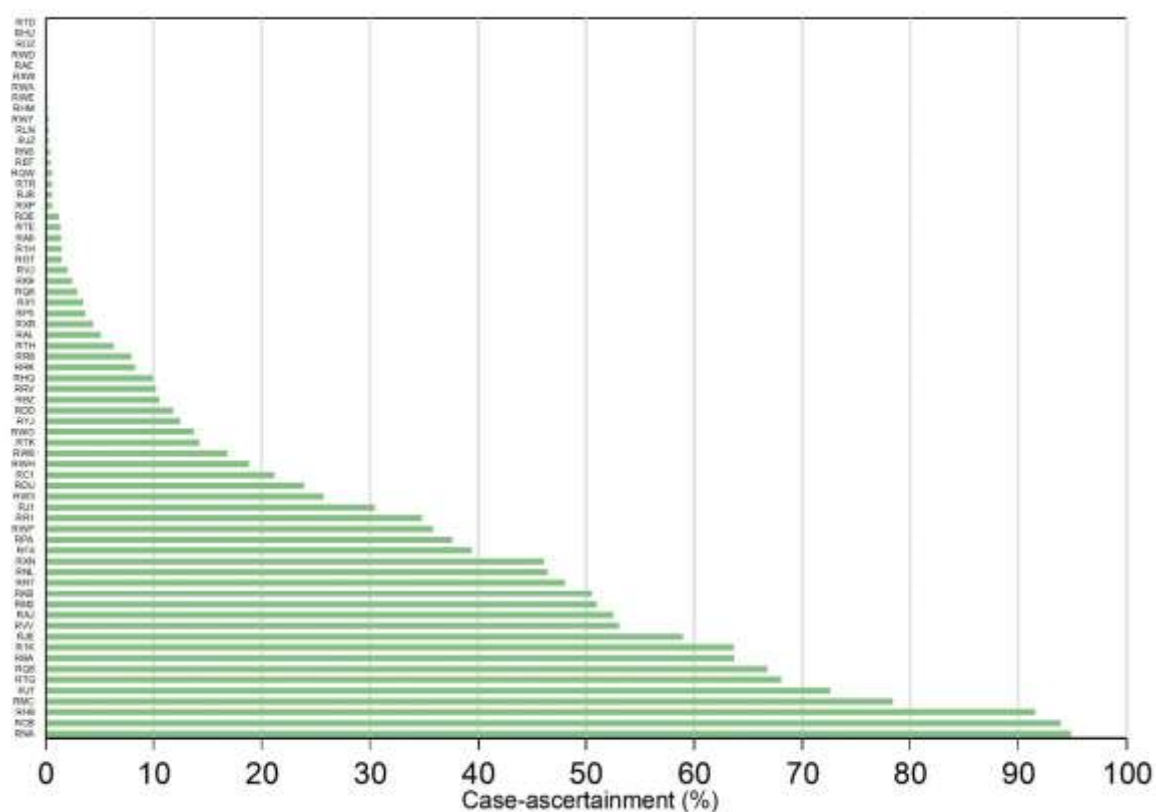


Table 6.2. Distribution of case-ascertainment by arterial centre

Case-ascertainment	Number of centres (%)		
	2014	2015	2016
<1%	18 (29.0)	17 (28.30)	28 (37.8)
1-20%	30 (48.4)	23 (38.3)	17 (23.0)
21-50%	5 (8.1)	5 (8.3)	10 (13.5)
50+ %	9 (14.5)	15 (25.0)	19 (25.7)

Throughout the data collection period, the majority of patients undergoing lower limb angioplasties have been men. About a quarter of patients were aged 80 year or older and just under a third had undergone a previous ipsilateral procedure.

Lower limb angioplasty / stent procedures were used to treat patients with a range of symptoms, with Fontaine scores ranging from asymptomatic to tissue loss. Most procedures were elective but emergency procedures were also performed. Pre-operative risk factors among angioplasty patients are summarised in Appendix 3. The prevalence of ischaemic heart disease, hypertension and diabetes was high and most patients were on antihypertensive or antiplatelet medication.

6.2 Procedure characteristics

Characteristics of lower-limb procedures, by the anatomical location of the procedure, are summarised in Table 6.3. Superficial femoral angioplasty was the most common procedure, accounting for 40% of cases, followed by popliteal and tibial/pedal angioplasties.

Overall, most endovascular procedures were performed under local anaesthetic (12,295 procedures, 88.5%) but general anaesthetic (1,221 procedures, 8.9%) and regional anaesthetic (370 procedures, 2.7%) were also used. In all, stents were used in 1,934 (13.9%) procedures.

The majority of endovascular procedures were recorded as successful by the operator. Many angioplasties were performed as day cases, though with significant variation between Trusts. Among the patients who did stay in hospital overnight, the length of stay was generally short. Only a small proportion of patients were admitted to critical care.

The proportions of successful procedures, by individual NHS trusts, are shown in Figure 6.2. Encouragingly, over half of the procedures were successful in most trusts, but there was a fair amount of variation in many estimates.

The proportions of angioplasties performed as day cases, by NHS trust, are shown in Figure 6.3. These numbers are based on procedures performed between January 2015 and December 2016 (this question was introduced in the NVR data collection system in January 2015). There is wide variation in the proportion of patients done as day cases, but it is unclear whether this represents an accurate picture of practice. It is possible that the data collection process within some NHS trusts means day cases are less likely to be entered.

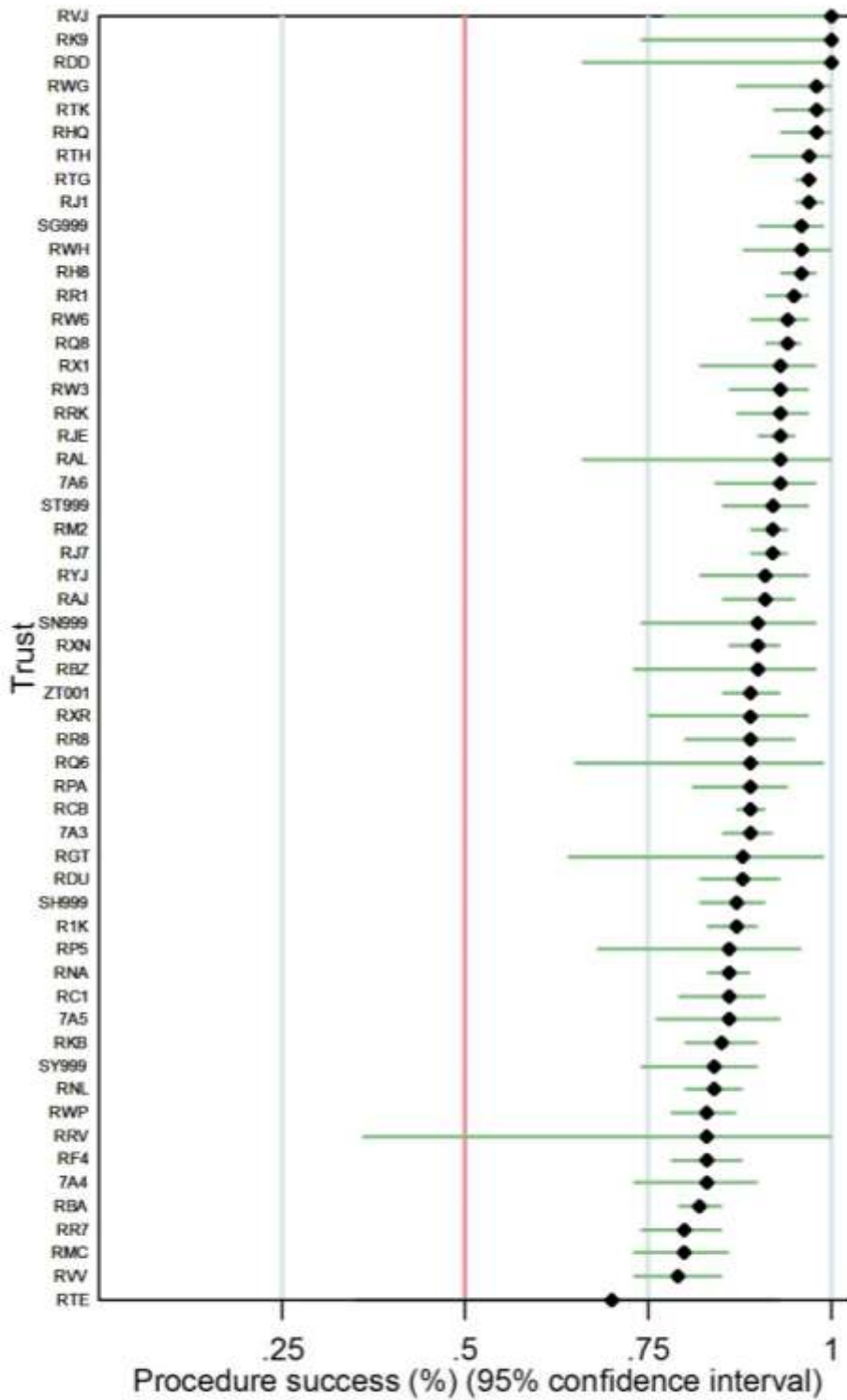
Table 6.3: Characteristics of lower limb endovascular procedures by anatomical location

	Procedure N (%)¹	ASA grade\geq4 (%)	Type of lesion Occlusion (%) Stenosis (%)	Procedure success (%)	Admitted as day cases (%)²	Admitted to critical care (%)	Length of stay among overnight admissions Median (IQR), days
Common iliac	1,472 (10.6)	35 (2.7)	207 (17.7) 961 (82.3)	1,044 (89.4)	327 (29.5)	45 (3.1)	1 (0 to 4)
External iliac	1,552 (11.2)	42 (3.2)	180 (14.7) 1,049 (85.4)	1,140 (92.8)	329 (23.3)	52 (3.4)	1 (0 to 6)
Common iliac & external iliac	466 (3.4)	17 (4.1)	51 (13.9) 317 (86.1)	334 (90.8)	97 (27.3)	16 (3.4)	1 (0 to 5)
Superficial femoral	5,574 (40.1)	187 (4.0)	1,753 (39.3) 2,711 (60.7)	3,913 (87.7)	1,062 (25.7)	114 (2.1)	2 (0 to 11)
Superficial femoral and popliteal	2,051 (14.8)	92 (5.3)	538 (33.7) 1,060 (66.3)	1,423 (89.1)	317 (21.7)	34 (1.7)	3 (1 to 13)
Popliteal	3,460 (24.9)	140 (4.8)	1,042 (38.0) 1,702 (62.0)	2,394 (87.2)	519 (20.5)	67 (1.9)	3 (1 to 13)
Popliteal and tibial/pedal	1,070 (7.7)	70 (7.7)	336 (40.1) 501 (59.9)	712 (85.1)	111 (14.5)	22 (2.1)	6 (1 to 18)
Other	2,937 (21.2)	116 (4.7)	971 (41.1) 1,393 (58.9)	2,256 (95.4)	504 (22.0)	183 (6.2)	2 (1 to 8)

¹These numbers do not add up to the total number of angioplasties in the NVR because they relate to procedures on one leg, and many patients had procedure(s) on both legs.

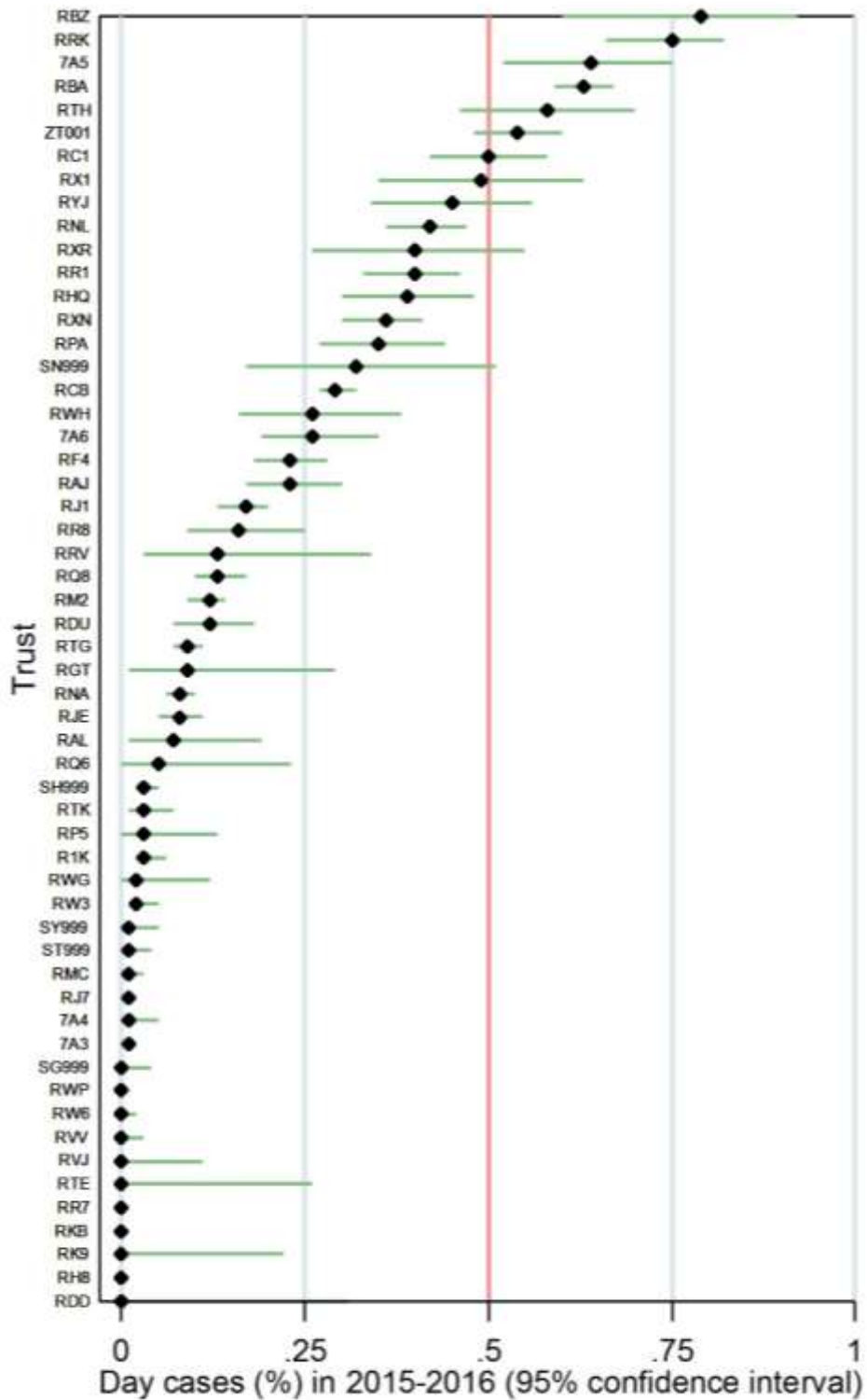
²These numbers refer to years 2015-2016 only, as this was when the relevant question was introduced in the NVR.

Figure 6.2. Success rate (procedure defined as successful by the operator), by NHS trust



Note: These numbers refer to years 2015-2016 only, as this was when the relevant question was introduced in the NVR.

Figure 6.3. Proportion of procedures as day cases, by NHS trust, in 2015-2016



Note to Figure 6.3: The numbers in procedures performed between January 2015 and December 2016 as this was when the relevant question was introduced in the NVR dataset.

6.3 Outcomes of lower limb angioplasty/stents

Overall, only a small number of patients was admitted to critical care and a large majority of patients had no post-procedural complications. However, all outcomes differed by admission status, and patients undergoing emergency angioplasties generally had worse outcomes than those undergoing elective procedures. These are summarised in Table 6.4.

Table 6.4: Postoperative outcomes following endovascular lower limb revascularisation, by mode of admission

		Emergency	%	Elective	%
Total procedures		3,780		10,106	
Admitted to	Ward	3,532	93.4	7,306	72.3
	Level 2	169	4.5	207	2.1
	Level 3	53	1.4	39	0.4
	Day case unit ¹	19	0.7	2,423	31.8
	Died in theatre	<5	<0.1	<5	<0.1
		Median	IQR	Median	IQR
Days in critical care:	Level 2	1	0 to 2	1	0 to 1
	Level 3	2	1 to 4	2	1 to 3
Hospital length of stay (days)		13	7 to 27	0	0 to 2
		Rate	95% CI	Rate	95% CI
In-hospital mortality rate		5.0	4.3 to 5.7	0.4	0.3 to 0.5
Defined complications					
	Cardiac	3.9	3.3 to 4.5	1.6	1.3 to 1.8
	Respiratory	3.7	3.1 to 4.4	0.9	0.7 to 1.0
	Haemorrhage	0.7	0.4 to 1.0	0.4	0.2 to 0.5
	Limb ischaemia	4.0	3.4 to 4.7	0.4	0.3 to 0.5
	Renal failure	1.3	0.9 to 1.7	0.1	0.05 to 1.0
	Cerebral	0.4	0.2 to 0.6	0.04	0.01 to 0.1
None of predefined		88.9	87.8 to 89.9	96.3	96.0 to 96.7
Further unplanned lower limb procedure					
	None	82.7	81.4 to 83.9	95.8	95.4 to 96.2
	Angioplasty without stent	2.3	1.0 to 2.8	1.1	0.9 to 1.3
	Angioplasty with stent	1.6	1.1 to 2.1	0.8	0.7 to 1.0
	Lower limb bypass	3.1	2.6 to 3.8	0.8	0.6 to 1.0
	Amputation at any level	9.3	8.4 to 10.3	0.8	0.6 to 1.0
Re-admission to higher level care		2.7	2.2 to 3.3	0.8	0.6 to 1.0
Readmission within 30 days		15.8	14.6 to 17.2	6.3	5.8 to 6.8

¹ These are based on procedures performed in 2015-2016, due to changes in the dataset on the NVR.

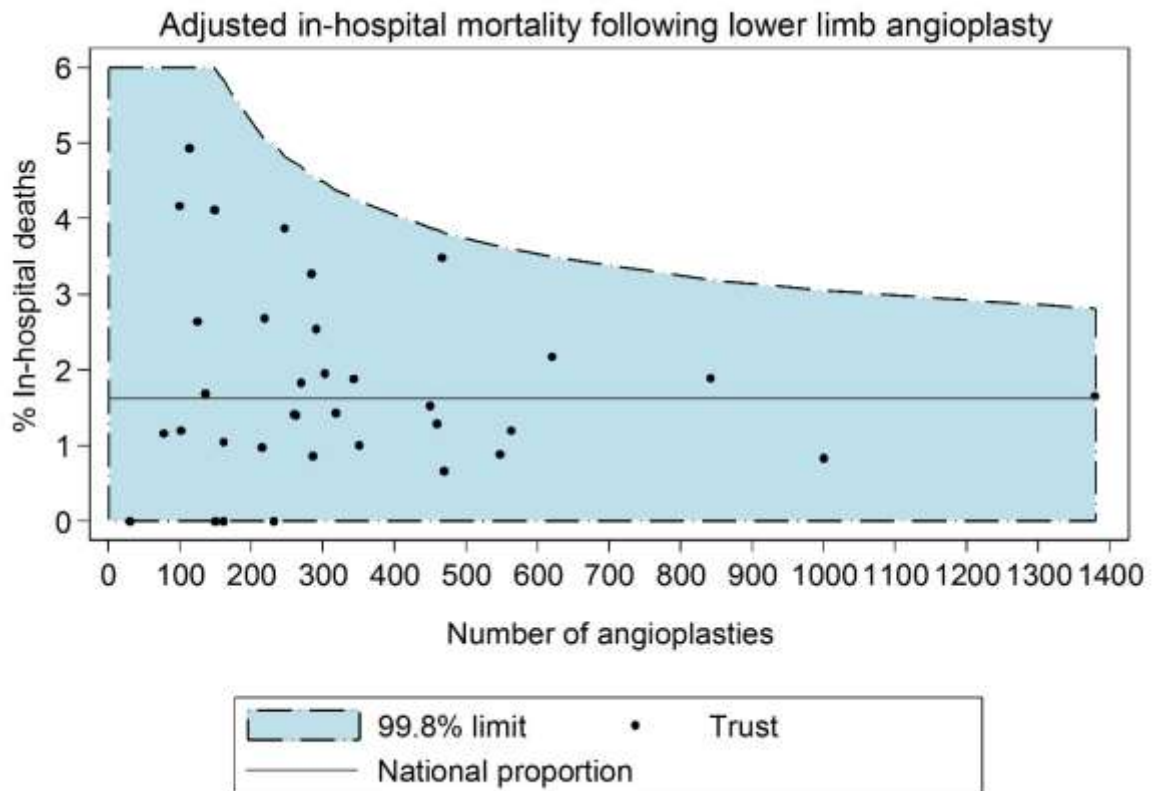
6.4 Risk-adjusted in-hospital deaths

Risk-adjusted rates of in-hospital death for were calculated for each NHS trust. The rates were adjusted to take account of the differences in patient populations within each organisation. Separate risk adjustment models were used for elective and emergency cases due to the different number of observed events. The postoperative mortality rates for emergency cases were adjusted for patient age, Fontaine score at admission, and chronic lung disease and chronic heart failure as comorbidities. The model for elective cases included patient age and chronic heart failure.

Risk-adjusted rates of in-hospital mortality following endovascular lower limb revascularisation are shown, by NHS trust, in Figure 6.4. As the numbers of angioplasties /stents submitted by some organisations were small (and many had low case-ascertainment), the rates are only shown for the NHS trusts with at least 10 procedures and an estimated case-ascertainment of 20% or more.

All NHS Trusts' risk adjusted mortality rates were within 99.8% control limits (Figure 6.4).

Figure 6.4: Risk-adjusted in-hospital deaths following lower limb angioplasty, shown in comparison to the national average of 1.63%



Note: This figure is based on data from Trusts actively performing angioplasties, with at least 10 angioplasties in the NVR and a case-ascertainment of at least 20%.

6.5 Summary of findings and future directions

Case-ascertainment varied between NHS trusts and despite the efforts of the NVR, VSGBI and BSIR to increase this, particular during the past year, the national figures lag behind AAA repair, CEA and lower limb bypass. The NHS Trusts performing lower limb endovascular procedures need to review how they identify / submit cases with the aim of overcoming barriers to recording patients in the NVR.

It is encouraging that, within the limitations of the poor case-ascertainment, NHS trusts had risk-adjusted in-hospital mortality rates that fell within the expected range.

7. Lower limb bypass for PAD

7.1 Introduction

In this chapter, we give results on the processes and outcomes of lower limb bypass procedures. We focus on the data from 17,202 procedures entered into the NVR over the three year period between January 2014 and December 2016. We estimated that the NVR has captured approximately 90% of the procedures performed between 2014 and 2016 in the NHS.

Table 7.1 summarises characteristics of lower limb bypass procedures, the majority of which were performed under general anaesthetic. The most common anatomical location for the bypass procedure was a femoral to above knee (popliteal) procedure (22.1%), followed by femoral to below knee bypass (18.6%). Most graft types were autologous or prosthetic making over 80% of procedures.

Table 7.1: Characteristics of lower limb bypass procedures undertaken between January 2014 and December 2016

	Procedures (n=17,200)	%
Anaesthetic Type		
General	12,648	73.5
Regional	2,308	13.4
GA + regional	1,703	9.9
Other	541	3.1
Bypass location		
Femoral – femoral	1,262	7.3
Femoral – above knee	3,799	22.1
Femoral – below knee	3,196	18.6
Femoral – tibial	2,471	14.4
Other	6,634	38.6
Endarterectomy		
Alone	1,325	7.7
Adjunct to bypass	6,532	38.0
Graft type		
Autologous	7,800	45.3
Vein and prosthetic	575	3.3

Lower limb bypass was recorded as being performed for a full spectrum of peripheral artery disease as measured with the Fontaine scores: asymptomatic, intermittent claudication, critical limb ischemia, although endovascular interventions were more common for patients with less severe symptoms. The prevalence of diabetes, hypertension and coronary heart disease was high, and only a small proportion of patients had no comorbid disease. Not surprisingly, most patients were on some form of cardiovascular/risk modification medication (see appendix 3).

The outcomes of the revascularisation procedures are summarised in Table 7.2. As might be expected, the outcomes show a distinct pattern with regard to mode of admission. The in-hospital postoperative mortality rate for elective patients was 1.2% (95% CI 1.0 to 1.4) and for emergency patients was 5.8% (95% CI 5.2 to 6.4). The length of stay was much greater for emergency patients at 16 days compared with 5 days for elective cases.

Complications were relatively uncommon and 90% of elective patients and 79% of emergency patients did not require further unplanned intervention. The key outcome measure for both endovascular and bypass procedures is amputation free survival. The national rates of unplanned amputation during the same admission was around 1 in 100 elective patients and around 5 in 100 emergency cases.

The outcomes for lower limb bypass are in line with recent literature. However the observed 10% unplanned readmission rate suggests this is an area for improvement. The NVR does not have information on the reasons for readmission but local services should review their local readmission rates to determine the cause of these readmissions.

Table 7.2: Postoperative outcomes for patients undergoing elective and emergency lower limb bypasses between January 2014 and December 2016

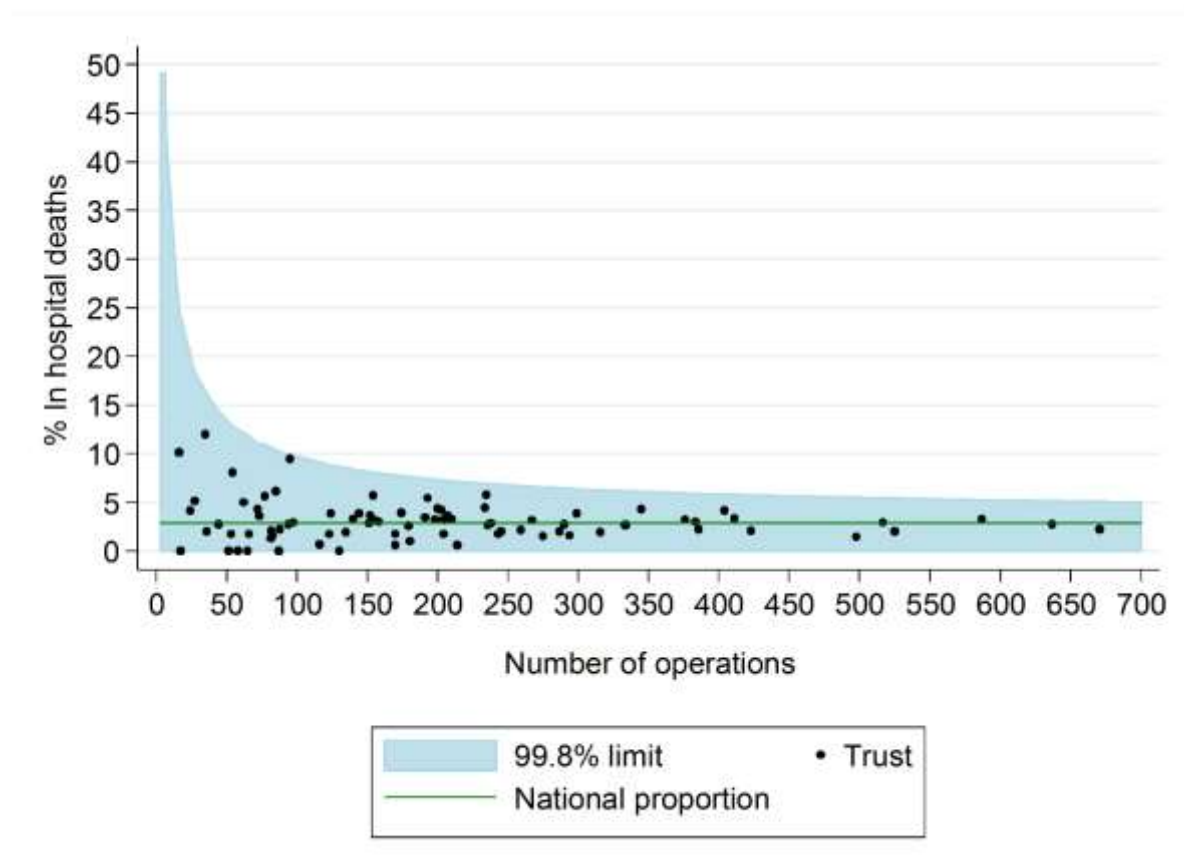
		Elective		Emergency	
		No. of procs	%	No. of procs	%
Total procedures		11,074		6,126	
Admitted to	Ward	8,090	73.1	4,151	67.8
	Level 2	2,422	21.9	1,499	24.5
	Level 3	557	5.0	470	7.7
	Day case unit	0	0.0	<5	0.0
	Died in theatre	<5	0.0	<5	0.1
		Median	IQR	Median	IQR
Days in critical care:	Level 2	1	0 to 2	1	0 to 2
	Level 3	2	1 to 4	3	2 to 4
Hospital length of stay (days)		5	3 to 9	16	9 to 28
		Rate	95% CI	Rate	95% CI
In-hospital mortality rate		1.2	1.0 to 1.4	5.8	5.2 to 6.4
Defined complications					
Cardiac		2.3	2.0 to 2.6	5.8	5.2 to 6.4
Respiratory		3.1	2.8 to 3.4	6.3	5.7 to 7.0
Haemorrhage		1.7	1.5 to 2.0	2.7	2.3 to 3.2
Limb ischaemia		3.2	2.9 to 3.6	8.2	7.5 to 8.9
Renal failure		1.0	0.8 to 1.2	2.6	2.2 to 3.1
Other		0.4	0.3 to 0.5	0.6	0.4 to 0.8
None of predefined		89.9	89.3 to 90.5	79.1	78.0 to 80.1
Further unplanned lower limb procedure					
None		94.7	94.2 to 95.1	85.7	84.8 to 86.5
Angioplasty without stent		0.6	0.4 to 0.7	1.0	0.7 to 1.2
Angioplasty with stent		0.3	0.2 to 0.4	0.5	0.3 to 0.7
Lower limb bypass		2.1	1.9 to 2.4	3.3	2.8 to 3.7
Amputation at any level		0.9	0.7 to 1.1	5.3	4.8 to 5.9
Re-admission to higher level care		1.7	1.5 to 1.9	4.1	3.6 to 4.6
Readmission within 30 days		9.1	8.6 to 9.7	13.8	12.9 to 14.8

7.2 Rates of in-hospital death after lower limb bypass

Risk-adjusted rates of in-hospital death for lower limb bypasses and were calculated for each NHS trust. The rates were adjusted to take account of the differences in the characteristics of patients treated at the various organisations. Risk adjustment model took into account the following characteristics: age, Fontaine score, anatomy of procedure, ASA grade, mode of admission, presence of renal disease and chronic lung disease.

Figure 7.1 shows the funnel plot of risk-adjusted mortality rates for the bypass procedures performed between January 2014 and December 2016. All the NHS trusts had a risk adjusted rate of in-hospital death that fell within the expected range given the number of procedures performed.

Figure 7.1: Funnel plot of risk-adjusted in-hospital deaths of a lower limb bypass for NHS trusts, shown in comparison to the overall average of 2.8% for procedures performed between January 2014 and December 2016



8. Major lower limb amputation

8.1 Introduction

This chapter describes the patterns of care and outcomes for patients undergoing major lower limb amputations during the three-year period from January 2014 to December 2016. We focus on unilateral major amputations due to vascular disease, and for this reason bilateral amputations (n=265, 2.1% of all reported amputations) and amputations due to trauma (n=117, 0.9%) were excluded from the figures reported here. A number of minor amputations (n=2,078, 16.8%) were also recorded in the NVR between 2014 and 2016, but due to low case-ascertainment (these represent an estimated 11% of minor amputations nationally during this period), these procedures were excluded.

Since January 2016, NVR IT system has had a facility to record amputations associated with a bypass and during this year, 193 of these procedures (4.5% of all major amputations recorded in 2016) were recorded. Due to small numbers these procedures were only included in the case-ascertainment estimates and excluded from other calculations.

Over the three-year data collection period, 9,804 major amputation records were entered into the NVR: 3,059 were performed in 2014, 3,441 in 2015 and 3,304 in 2016. Overall, there corresponded to 6,978 (71.2%) below the knee amputations (BKA) and 2,826 (28.8%) above the knee amputations (AKA). Many results in this chapter are presented separately for these two types of procedure.

Yearly case-ascertainment estimates, based on comparisons with routinely collected hospitalisation data, are shown in Table 8.1 and Figure 8.1. The yearly estimates suggest that the overall case-ascertainment improved over the data collection period, from 65.2% in 2014 to 72.5% in 2015 and 69.7% in 2016, which is encouraging. However, the variation shown in Table 8.2 indicates that many NHS trusts are still failing to record large proportions of their amputation cases in the NVR.

Table 8.1: Estimated case-ascertainment for amputation

	2014	2015	2016	Total
Audit procedures	3,059	3,490	3,437	9,804
Expected procedures	4,692	4,743	4,743	14,178
Estimated case-ascertainment	65.2%	73.6%	72.5%	69.1%

Figure 8.1: Estimated case-ascertainment for major lower-limb amputation by NHS trust for procedures between January 2014 and December 2016

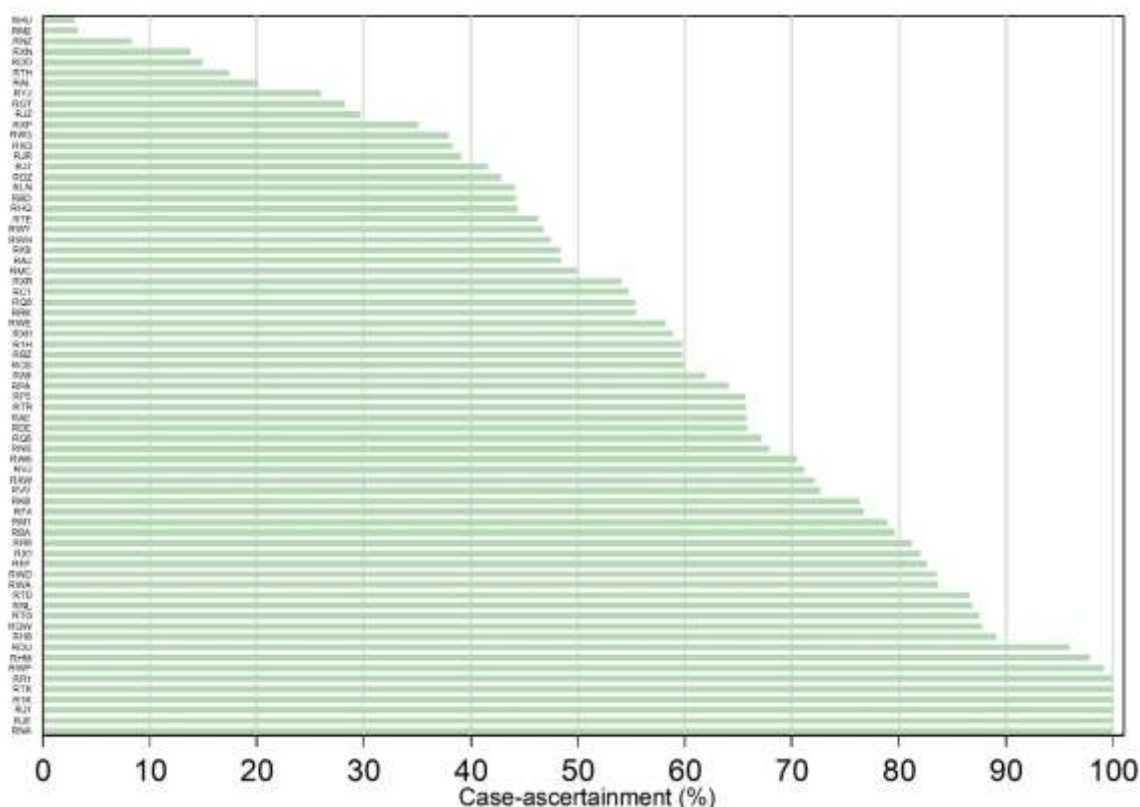


Table 8.2 Case-ascertainment by year and arterial centre

Case-ascertainment	Number of centres (%)		
	2014	2015	2016
Under 1%	15 (18.5)	15 (18.3)	15 (18.5)
1-20%	6 (7.4)	7 (8.5)	5 (6.2)
21-50%	17 (21.0)	14 (17.1)	15 (18.5)
50% or more	43 (53.1)	45 (54.9)	46 (56.8)

Overall, BKAs were more common in patients under 60 years and AKAs more common in patients older than 80 years. Most patients in both amputation groups were men and many were either current or ex-smokers. The most common presenting problem for BKAs as well as AKAs was tissue loss. Among the BKA patients, the second most common presenting problem was uncontrolled infection. For AKA patients, acute or chronic limb ischaemia were also common. Over a half of the patients had undergone a previous ipsilateral limb procedure. This may be because with the more frail, older patients, angioplasty (as a less invasive procedure) has been attempted prior to amputation. However, due to current poor

case-ascertainment for angioplasty (see Chapter 6), this cannot be explored further in the currently available datasets.

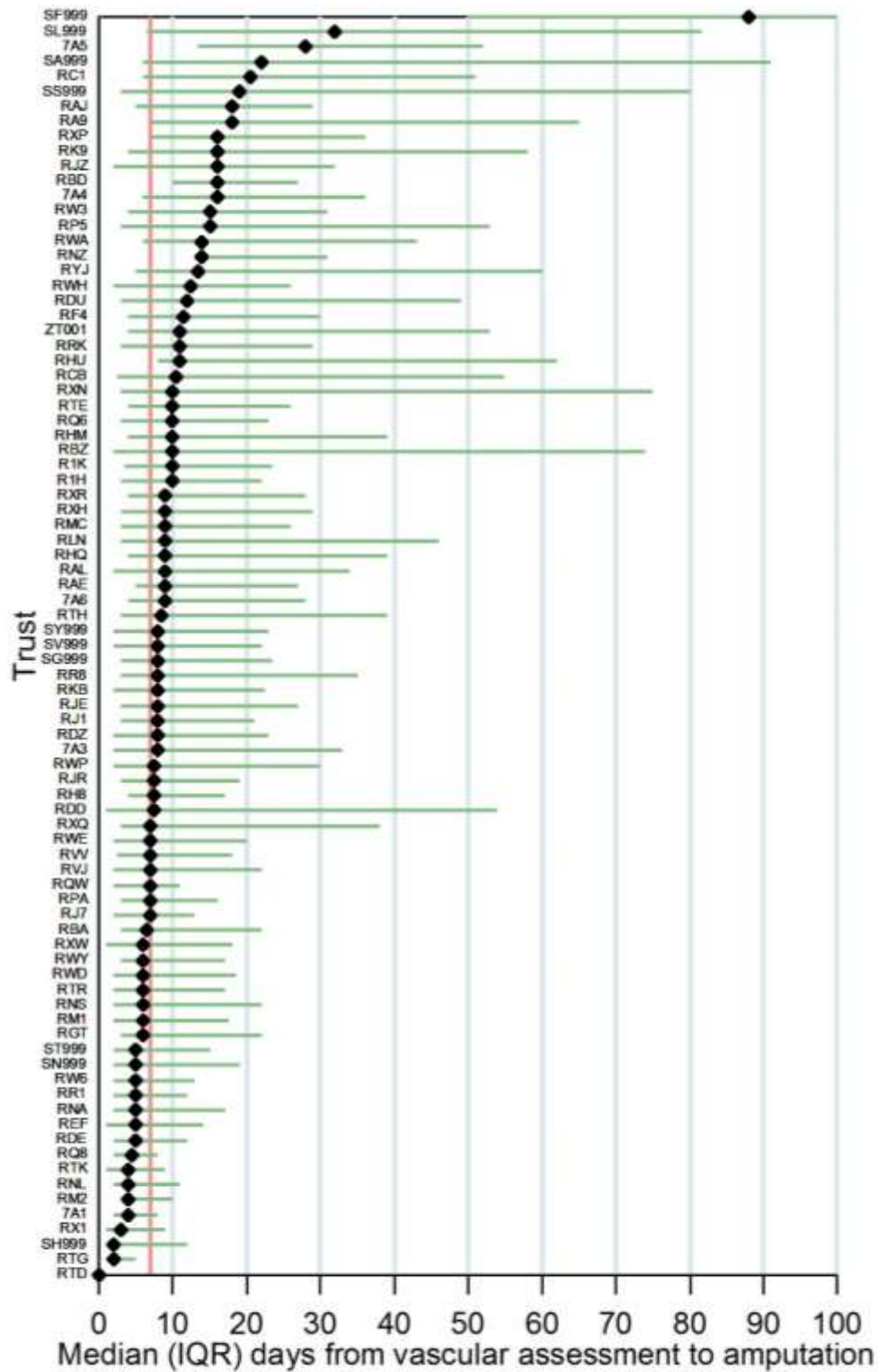
The majority of patients had severe comorbid disease. The most common comorbidities in both BKA and AKA groups were hypertension, diabetes and ischaemic heart disease. A large majority of patients in both groups were taking antiplatelet medication or statins, and about a quarter to a third of the patients were on beta blockers, ACE inhibitors or ARBs.

8.2 Care pathways

National and organisation-level results on time from vascular assessment to amputation are shown in Figure 8.2. The graph is limited to NHS trusts with 10 or more major lower limb amputations submitted to the NVR. The overall median time from assessment to amputation was 7 days (interquartile range: 2 to 24 days). These figures remained nearly unchanged throughout the data entry period. However, there was considerable variation in these timelines across the NHS trusts.

In terms of improving patient outcomes following major lower limb amputation, it is often important to perform the procedures as soon as possible once the decision to operate has been made [NCEPOD, 2014]. Consequently, within the constraints of needing to balance urgency with pre-operative optimisation of patient's condition, vascular units should, as much as possible, attempt to reduce the time patients wait for the operations.

Figure 8.2: Median (IQR) time from vascular assessment to amputation, by NHS trust



Note: The black dots represent NHS trust-specific medians and the horizontal green lines represent interquartile ranges (IQRs). The vertical line shows the national median (7 days).

8.3 Procedure characteristics

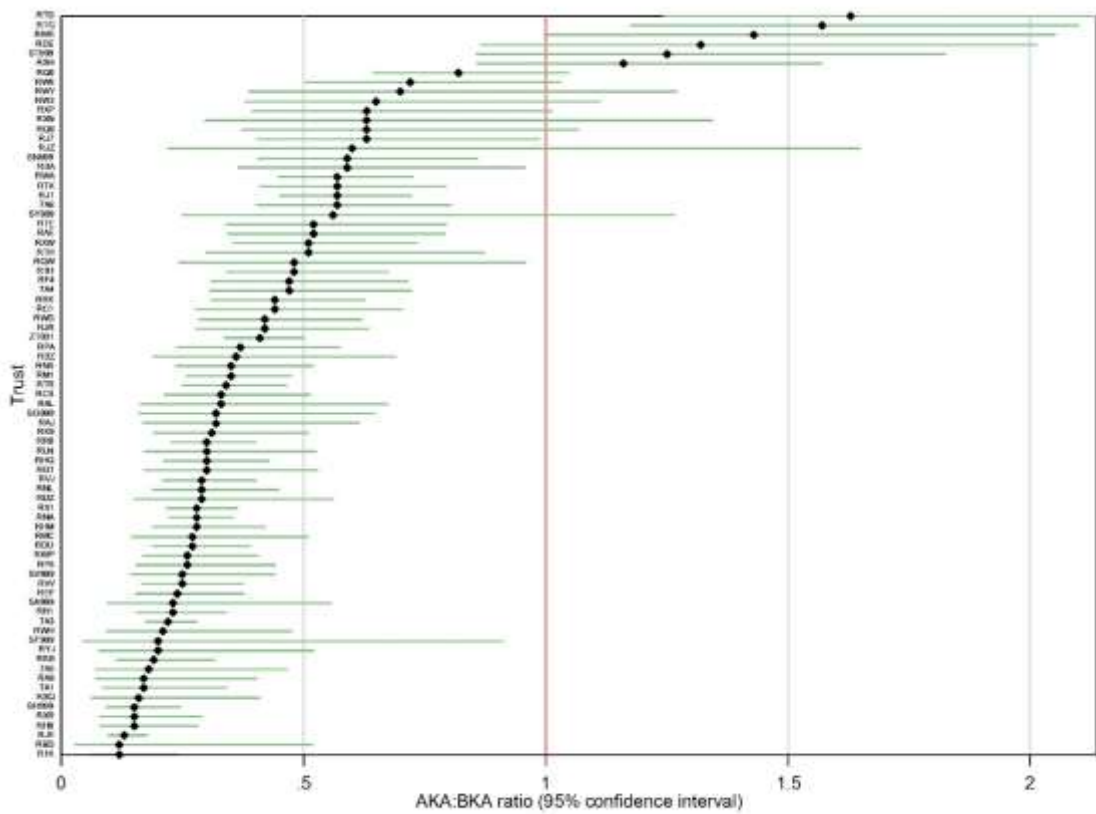
The majority of procedures were undertaken under general anaesthetic (6,757 amputations, 69.0%). Regional (2,909 amputations, 29.6%) and local anaesthetic (133 amputations, 1.4%) was also used.

The most commonly used wound closure method was primary closure (7,473 amputations, 78.5%); skin flat was used in 1,148 amputations (12.1%) and skin graft in 15 procedures (0.2%). In 883 amputations (9.3%), the wound was left open.

National clinical care recommendations outline that below the knee amputation should be undertaken where appropriate and that at each vascular unit, the above the knee to below the knee amputation ratio should ideally be below one [NCEPOD 2014; VSGBI 2016]. The AKA to BKA ratio, nationally and by NHS trust, is shown in Figure 8.3.

Nationally, over the whole data collection period, the AKA:BKA ratio was 0.40. The ratio varied from 0.39 in 2014 to 0.40 in 2015 and 0.42 in 2016. At NHS trust-level, most of the NHS trusts had a ratio less than one, indicating that the recommendation is generally being met.

Figure 8.3: Ratio of above knee to below knee amputations by NHS trust¹



¹These estimates based on data from trusts reporting at least 10 amputations over the study period. For presentation purposes, one trust with a ratio of 3 (RDD) was left out of the figure.

8.4 Perioperative care

Some of the key recommendations for improving perioperative amputation care in NHS hospitals concern the timing of the procedure. In particular, it is recommended that

- major amputations should be undertaken on a planned operating list during normal working hours;
- a consultant surgeon should operate or at least be present in the theatre to supervise a senior trainee (ST4 or above) undertaking the amputation; and
- the patient should have routine antibiotic and DVT prophylaxis according to local policy (VSGBI 2016).

Characteristics of perioperative care for BKA and AKA patients, summarised in Table 8.3, suggest that, by and large, these recommendations are not met. Over 80% of major amputations (both BKAs and AKAs) are performed during the day, and a consultant surgeon was present in approximately three quarters of the procedures. Prophylactic antibiotics and DVT medication were used for only just over 60% of patients, but it is possible that these figures underestimate the actual rate because the data items were only recently introduced into the NVR dataset.

Table 8.3: Perioperative care of patients undergoing lower limb amputation

	Below knee	%	Above knee	%
Procedures	6,978		2,826	
Admission				
Emergency	5,287	75.8	2,312	81.8
Elective	1,691	24.2	514	18.2
Time procedure started				
Day (8am-6pm)	5,924	84.9	2,278	80.7
Evening (6pm-midnight)	886	12.7	447	15.8
Night (midnight-8am)	164	2.4	99	3.5
Consultant present in theatre ¹	2,340	79.8	916	74.1
Prophylactic medication ¹				
Antibiotic prophylaxis	1,850	63.1	713	57.7
DVT prophylaxis	1,860	63.4	725	58.7

¹ These figures are based on amputations performed between 1 October 2015 and December 2016.

return to theatre within the admission were 11.1% for BKA and 8.1% for AKA patients. Overall, the majority of patients were discharged alive, but 6.7% of BKA patients and 12.4% of AKA patients died in hospital.

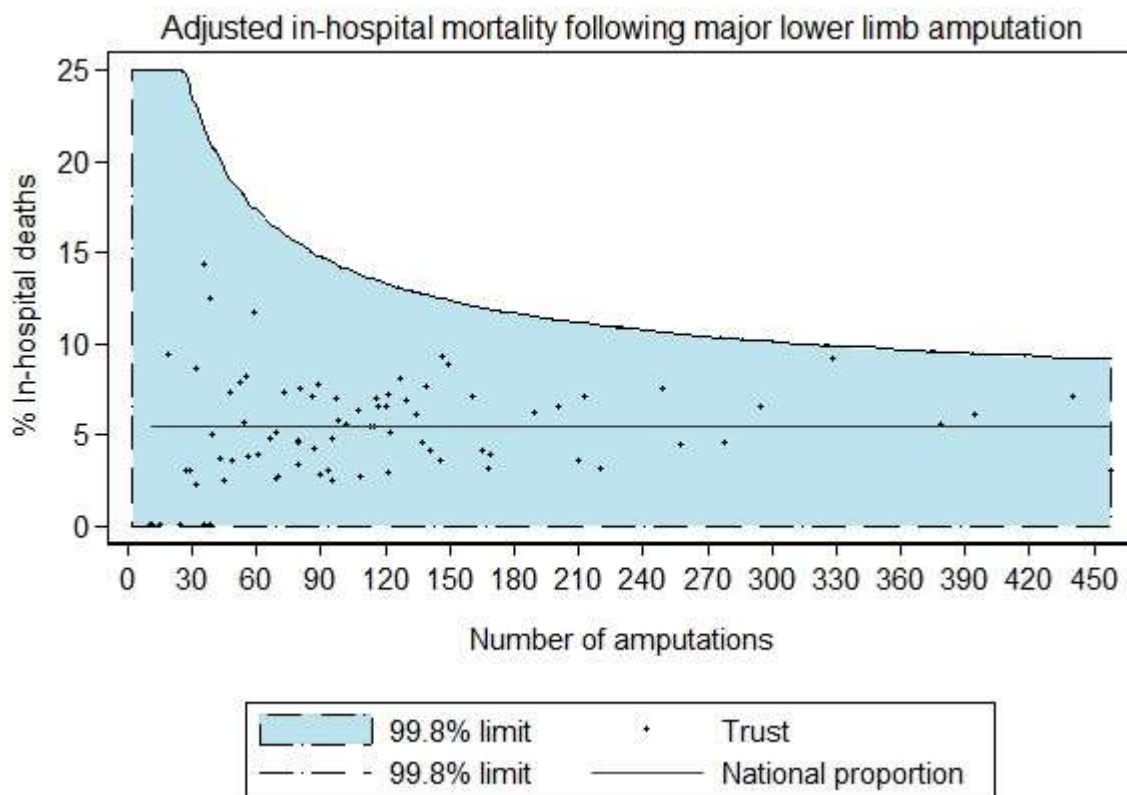
Table 8.4: Patient outcomes following lower limb amputation

	Below knee		Above knee	
Procedures	6,978		2,826	
	N	%	N	%
Destination after procedure				
Ward	6,016	86.2	2,121	75.2
Level 2 unit	691	9.9	466	16.5
Level 3 unit	268	3.8	233	8.3
	Median	IQR	Median	IQR
Days in Level 2 critical care	2	1 to 4	2	1 to 4
Days in Level 3 critical care	3	2 to 7	4	2 to 8
Length of stay (days)	22	13 to 40	22	13 to 39
	Rate	95% CI	Rate	95% CI
In hospital mortality	6.7	6.1 to 7.2	12.4	11.2 to 13.7
Procedure complications				
Cardiac	4.9	4.4 to 5.4	8.6	7.6 to 9.7
Respiratory	7.5	6.9 to 8.1	12.4	11.2 to 13.7
Cerebral	0.7	0.5 to 0.9	1.0	0.6 to 1.5
Haemorrhage	0.7	0.5 to 0.9	0.7	0.4 to 1.0
Limb ischaemia	4.7	4.2 to 5.2	3.8	3.1 to 4.5
Renal failure	3.6	3.2 to 4.0	5.2	4.4 to 6.1
None of predefined	8.3	8.2 to 8.4	7.8	7.6 to 7.9
Return to theatre	11.1	10.5 to 12.0	8.1	7.1 to 9.1
Readmission to higher level care	3.6	3.2 to 4.1	3.6	3.0 to 4.4

Note to Table 8.4: 2 patients died in theatre, one undergoing below the knee and one above the knee amputation.

Adjusted in-hospital mortality following major unilateral lower limb amputation is shown, by NHS trust, in Figure 8.6. The rates were adjusted for age, sex, ASA grade (≥ 4 vs. < 4), amputation level (below or above the knee) and chronic renal failure as a comorbidity, separately for elective and emergency procedures. The overall rate of in-hospital death was 8.3 (95% CI: 7.2 to 8.9). All NHS trusts' adjusted death rates were estimated to be within the 99.8% control limits.

Figure 8.6: Risk-adjusted 30-day in-hospital deaths following major amputation, shown in comparison to the overall average of 8.3%



Note to Figure 8.6: this figure is based on data from Trusts with ≥ 10 amputations.

8.6 Discharge and follow-up

Discharge and follow-up of patients undergoing lower limb amputations, among patients discharged alive, are summarised in Table 8.5. The wounds of just over half of patients had healed by 30 days, and this increased slightly by the time of discharge. About two thirds of all major amputation patients were referred to rehabilitation units or limb fitting centres. Approximately, 1 in 10 patients were readmitted to hospital within 30 days of discharge.

Table 8.5: Discharge and follow-up of patients undergoing lower limb amputations, among patients discharged alive

	Below knee	%	Above knee	%
Procedures	6,513		2,475	
Wound healed at discharge	4,122	65.8	1,732	76.5
Wound healed at 30 days	3,376	78.1	1,192	86.4
Referred to rehabilitation or limb fitting	4,499	71.8	1,576	69.6
Readmission to hospital within 30 days	595	11.2	149	8.1

8.7 Summary of findings

Although the case-ascertainment for lower limb amputations has improved, it is still not high enough to make truly generalisable conclusions from the NVR data. The yearly estimates suggest that although the overall case-ascertainment has improved over the three year data collection period, still only 2/3 of major lower limb amputations, on average, are being recorded in the NVR. Also, the case-ascertainment estimates vary by trust, indicating that many trusts submit data on most if not all of their major amputations yet others are still failing to record large proportions of their amputation cases in the NVR.

The VSGBI Amputation QIF [2016] recommends that below the knee amputation should be undertaken where appropriate and that vascular units should aim to have an above the knee to below the knee amputation ratio below one. Overall, about two thirds of major lower limb amputations recorded in the NVR between 2014 and 2016 were below knee amputations about a third were above knee amputations. At trust-level, most NHS trusts had an AKA to BKA- ratio smaller than one, indicating that the best care recommendation are generally being met. There were some trusts with ratios higher than 1, but the ratio-estimates were not adjusted for case-mix at these trusts, so it is possible that the high ratios relate to more severely ill patients being treated.

Further recommendations outlined in the VSGBI Amputation GIF [VSGBI 2016] are that amputations should be undertaken on a planned operating list during normal working hours and that a Consultant Vascular Surgeon should operate, or be present in the theatre to supervise a senior trainee (ST4 or above) undertaking the amputation. Patient should also have routine antibiotic and DVT prophylaxis according to local policy. The NVR data suggests that a large proportion of amputations are performed during daytime, but many are undertaken as emergency operations. Furthermore, whilst many Trusts are following the recommendations that a consultant should be present in theatre and prophylactic

antibiotics given to all patients, there is variation in practice and not all providers meet these care guidelines.

The overall rate of in-hospital death was 8.3 (95% CI: 7.2 to 8.9). All Trusts have in-hospital death rates were well within the 99.8% confidence limits. However, due to the low case-ascertainment it is difficult to make generalizable conclusions from these findings. Based on the available data, it seems that most trusts have safe practice. At national level, the clinical recommendations outline an aim to reduce the 90-day mortality following major lower limb amputation to 10% or less. The NVR only collects data on in-hospital deaths, but with planned linkage to Hospital Episode Statistics (HES) data, will in the future be able to examine the level to which this recommendation is being met.

Appendix 1: Organisation of the Registry

The NVR is assisted by the Audit and Quality Improvement Committee of the Vascular Society and overseen by a Project Board, which has senior representatives from the participating organisations and the commissioning organisation.

Members of Audit and Quality Improvement Committee of the Vascular Society

Prof I Loftus	Chair	Vascular Society of GB&I
Mr J Boyle		Vascular Society of GB&I
Mr M Clarke		Vascular Society of GB&I
Mr D Harkin		Vascular Society of GB&I
Prof R Fisher		Vascular Society of GB&I
Mr J J Earnshaw		National AAA Screening Programme
Dr C Hammond		British Society of Interventional Radiology
Dr R Mouton		Vascular Anaesthesia Society of GB & I

plus members of the CEU involved in the NVR: Prof David Cromwell, Dr Katriina Heikkila, Dr Amundeeep Johal, and Mr Sam Waton.

Members of Project Board

Prof J van der Meulen, Chair	Royal College of Surgeons of England
Mr K Varty	Vascular Society of GB&I
Dr F Miller	British Society of Interventional Radiology
Mr C Clifford-Jones	Patient Representative
Ms T Strack	HQIP
Ms V Seagrove	HQIP
Ms Caroline Junor	Northgate Public Services (UK) Limited
Mr P Rottier	Northgate Public Services (UK) Limited

Plus members of the project / delivery team: Prof Ian Loftus (Outgoing Lead Clinician), Mr Jon Boyle (Incoming Lead Clinician) Prof David Cromwell, Dr Katriina Heikkila, Dr Amundeeep Johal, and Mr Sam Waton

Appendix 2: NHS organisations that perform vascular surgery

Code	Organisation Name	AAA	CEA	Angio	Bypass	Amp
7A1	Betsi Cadwaladr University Local Health Board	Yes	Yes	Yes	Yes	Yes
7A3	Abertawe Bro Morgannwg University Local Health Board	Yes	Yes	Yes	Yes	Yes
7A4	Cardiff and Vale University Local Health Board	Yes	Yes	Yes	Yes	Yes
7A5	Cwm Taf Local Health Board	Yes	Yes	Yes	Yes	Yes
7A6	Aneurin Bevan Local Health Board	Yes	Yes	Yes	Yes	Yes
R1H	Barts Health NHS Trust	Yes	Yes	Yes	Yes	Yes
R1K	London North West Healthcare NHS Trust	Yes	Yes	Yes	Yes	Yes
RA9	South Devon Healthcare NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RAE	Bradford Teaching Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RAJ	Southend University Hospital NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RAL	Royal Free London NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RBA	Taunton and Somerset NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RBD	Dorset County Hospital NHS Foundation Trust	No	No	Yes	No	No
RBN	St Helens & Knowsley Teaching Hospitals NHS Trust	No	No	Yes	No	No
RBZ	Northern Devon Healthcare NHS Trust	No	No	Yes	Yes	Yes
RC1	Bedford Hospital NHS Trust	Yes	Yes	Yes	Yes	Yes
RCB	York Teaching Hospital NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RDD	Basildon and Thurrock University Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RDE	Colchester Hospital University NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RDU	Frimley Health NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RDZ	Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
REF	Royal Cornwall Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
REM	Aintree University Hospital NHS Foundation Trust	No	No	Yes	No	No
RF4	Barking, Havering And Redbridge University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RGN	Peterborough and Stamford Hospitals NHS Foundation Trust	No	No	Yes	No	No
RGR	West Suffolk NHS Foundation Trust	No	No	Yes	No	No
RGT	Cambridge University Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RH8	Royal Devon and Exeter NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RHM	University Hospital Southampton NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes

Code	Organisation Name	AAA	CEA	Angio	Bypass	Amp
RHQ	Sheffield Teaching Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RHU	Portsmouth Hospitals NHS Trust	No	No	Yes	No	Yes
RHW	Royal Berkshire NHS Foundation Trust	No	No	Yes	No	No
RJ1	Guy's and St Thomas' NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RJ7	St George's Healthcare NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RJE	University Hospital of North Midlands NHS Trust	Yes	Yes	Yes	Yes	Yes
RJR	Countess of Chester Hospital NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RJZ	King's College Hospital NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RK9	Plymouth Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RKB	University Hospitals Coventry and Warwickshire NHS Trust	Yes	Yes	Yes	Yes	Yes
RL4	Royal Wolverhampton Hospitals NHS Trust	No	No	Yes	No	No
RLN	City Hospitals Sunderland NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RM1	Norfolk and Norwich University Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RM2	University Hospital of South Manchester NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RMC	Bolton NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RNA	The Dudley Group NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RNL	North Cumbria University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RNS	Northampton General Hospital NHS Trust	Yes	Yes	Yes	Yes	Yes
RP5	Doncaster and Bassetlaw Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RPA	Medway NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RQ6	Royal Liverpool and Broadgreen University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RQ8	Mid Essex Hospital Services NHS Trust	Yes	Yes	Yes	Yes	Yes
RQQ	Hinchingbrooke Health Care NHS Trust	No	No	Yes	No	No
RQW	Princess Alexandra Hospital NHS Trust	Yes	Yes	Yes	Yes	Yes
RR1	Heart of England NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RR7	Gateshead Health NHS Foundation Trust	No	Yes	Yes	Yes	Yes
RR8	Leeds Teaching Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RRK	University Hospitals Birmingham NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RRV	University College London Hospitals NHS Foundation Trust	No	Yes	Yes	Yes	No
RTD	Newcastle upon Tyne Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RTE	Gloucestershire Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RTG	Derby Teaching Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RTH	Oxford University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RTK	Ashford And St Peter's Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes

Code	Organisation Name	AAA	CEA	Angio	Bypass	Amp
RTR	South Tees Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RVJ	North Bristol NHS Trust	Yes	Yes	Yes	Yes	Yes
RVV	East Kent Hospitals University NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RW3	Central Manchester University Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RW6	Pennine Acute Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RWA	Hull and East Yorkshire Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RWD	United Lincolnshire Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RWE	University Hospitals of Leicester NHS Trust	Yes	Yes	Yes	Yes	Yes
RWG	West Hertfordshire Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RWH	East and North Hertfordshire NHS Trust	Yes	Yes	Yes	Yes	Yes
RWP	Worcestershire Acute Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RWY	Calderdale and Huddersfield NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RX1	Nottingham University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RXF	Mid Yorkshire Hospitals NHS Trust	No	No	Yes	No	No
RXH	Brighton and Sussex University Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RXN	Lancashire Teaching Hospitals NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RXP	County Durham and Darlington NHS Foundation Trust	Yes	Yes	Yes	Yes	Yes
RXR	East Lancashire Hospitals NHS Trust	Yes	Yes	Yes	Yes	Yes
RXW	Shrewsbury and Telford Hospital NHS Trust	Yes	Yes	Yes	Yes	Yes
RYJ	Imperial College Healthcare NHS Trust	Yes	Yes	Yes	Yes	Yes
SA999	NHS Ayrshire & Arran	Yes	Yes	Yes	Yes	Yes
SF999	NHS Fife	No	Yes	Yes	Yes	Yes
SG999	NHS Greater Glasgow and Clyde	Yes	Yes	Yes	Yes	Yes
SH999	NHS Highland	Yes	Yes	Yes	Yes	Yes
SL999	NHS Lanarkshire	Yes	Yes	Yes	Yes	Yes
SN999	NHS Grampian	Yes	Yes	Yes	Yes	Yes
SS999	NHS Lothian	Yes	Yes	Yes	Yes	Yes
ST999	NHS Tayside	Yes	Yes	Yes	Yes	Yes
SV999	NHS Forth Valley	Yes	Yes	Yes	Yes	Yes
SY999	NHS Dumfries and Galloway	No	Yes	Yes	Yes	Yes
ZT001	Belfast Health and Social Care Trust	Yes	Yes	Yes	Yes	Yes

Appendix 1: Summary of procedures and patient characteristics

Abdominal aortic aneurysms

An abdominal aortic aneurysm is the local expansion of the abdominal aorta, a large artery that takes blood from the heart to the abdomen and lower parts of the body. Most aneurysms occur below the kidneys (i.e., are infra-renal), but they can occur around the location where blood vessels branch off from the aorta to the kidneys or even higher up towards the chest.

The condition tends not to produce symptoms until the aneurysm ruptures. A rupture can occur without warning, causing sudden collapse, or the death of the patient. A ruptured AAA requires emergency surgery.

Screening and intervening to treat larger AAAs reduces the risk of rupture. An aneurysm may be detected incidentally when a patient is treated for another condition, and is then kept under surveillance. However, to provide a more comprehensive preventative service, the National Abdominal Aortic Aneurysm Screening Programme (NAAASP) was introduced in 2010. This invites men for AAA screening (a simple ultrasound scan) in the year they turn 65 years old (the condition is much less common in women). Once detected, treatment to repair the aorta before it ruptures can be planned with the patient, and surgery is typically performed as an elective procedure.

Aneurysms may be treated by either open surgery or by an endovascular repair (EVAR). In open surgery, the AAA is repaired through an incision in the abdomen. An EVAR procedure involves the insertion of a stent graft through the groin. Both are major operations. The decision on whether EVAR is preferred over an open repair is made jointly by the patient and the clinical team, taking into account characteristics of the aneurysm as well as the patient's age and fitness.

More information about abdominal aortic aneurysms and their treatment can be found on the Circulation Foundation website at: <https://www.circulationfoundation.org.uk/help-advice/abdominal-aortic-aneurysm>

Elective repair of infra-renal AAAs

The characteristics of patients who underwent an elective repair of an infra-renal AAA during 2016 are summarised in Table A3.1.

Table A3.1: Characteristics of patients who had elective infra-renal AAA repair between January and December 2016. Column percentages

		Open AAA	%	EVAR	%	Total
Total procedures		1,246		2,907		4,153
Age group (years)	Under 66	329	26.5	247	8.5	576
	66 to 75	615	49.5	1,079	37.2	1,694
	76 to 85	288	23.2	1,317	45.5	1,605
	86 and over	11	0.9	254	8.8	265
Male		1,106	88.8	2,596	89.3	3,702
Female		140	11.2	311	10.7	451
Current smoker		329	26.4	536	18.4	865
Previous AAA surgery		103	8.3	294	10.1	397
Indication	Screen detected	468	38.5	797	27.7	1,265
	Non-screen	633	52.0	1,718	59.8	2,351
	Other	116	9.5	359	12.5	475
AAA diameter (cm)	Under 4.5	26	2.1	104	3.6	130
	4.5 to 5.4	79	6.3	161	5.5	240
	5.5 to 6.4	791	63.5	1,889	65.0	2,680
	6.5 to 7.4	182	14.6	461	15.9	643
	7.5 and over	167	13.4	292	10.0	459
ASA fitness grade	1,2	478	38.4	693	23.8	1,171
	3	739	59.3	2,062	70.9	2,801
	4,5	29	2.3	152	5.2	181
Comorbidities	Hypertension	836	67.1	2,092	72.0	2,928
	Ischemic heart disease	396	31.8	1,157	39.8	1,553
	Chronic heart failure	24	1.9	164	5.6	188
	Stroke	63	5.1	197	6.8	260
	Diabetes	133	10.7	457	15.7	590
	Chronic renal failure	117	9.4	416	14.3	533
	Chronic lung disease	240	19.3	835	28.7	1,075

Repair of ruptured abdominal aortic aneurysms

Ruptured abdominal aortic aneurysm is a common vascular emergency. For a long time, the only surgical technique for a ruptured AAA was open repair. Recently, it has been possible to take an endovascular approach, and some observational studies have reported that EVAR procedures might have lower short-term mortality rates than open repairs. However, many patients with ruptured aneurysms are unsuitable for conventional EVAR, and so these results might reflect differences in the patients selected for each technique. Indeed, the results of the IMPROVE trial [Powell et al 2014], which compared the outcomes of EVAR and open repair among patients with ruptured AAAs reported 30 day mortality of 35.4% and 37.4%, respectively. It concluded that endovascular repair was not associated with any significant reduction in short-term mortality. It is likely that some patients will benefit most from open repair, while others could benefit from EVAR, given their anatomical and physiological characteristics.

Compared to patients who had an elective repair of an infra-renal AAA, the patients who had surgery for a ruptured AAA were older on average, with most aged over 76 years at the time of surgery and tended to have a larger diameter of the aneurysm (Table A3.2). In comparison to patients undergoing an open repair, patients having EVAR had a smaller AAA diameter, on average, and a greater proportion had also undergone AAA surgery previously.

Table A3.2: Characteristics of patients who had a repair of a ruptured AAA between January 2014 and December 2016

		Open AAA	%	EVAR	%	Total
Total procedures		2,115		798		2,913
Age group (years)	Under 66	234	11.1	56	7.0	290
	66 to 75	773	36.5	219	27.4	992
	76 to 85	953	45.1	373	46.7	1,326
	86 and over	155	7.3	150	18.8	305
Male		1,748	82.6	691	86.6	2,439
Female		367	17.4	107	13.4	474
Previous AAA surgery		143	6.8	151	18.9	294
AAA diameter (cm)	<4.5	21	1.0	33	4.1	54
	4.5 to 5.4	80	3.8	50	6.3	130
	5.5 to 6.4	357	16.9	160	20.1	517
	6.5 to 7.4	411	19.5	169	21.2	580
	7.5 and over	1,240	58.8	385	48.3	1,625
ASA fitness grade	1 or 2	81	3.8	28	3.5	109
	3	185	8.8	116	14.5	301
	4	1,236	58.5	534	66.9	1,770
	5	611	28.9	120	15.0	731

Carotid endarterectomy

The carotid arteries are the main vessels that supply blood to the brain, head and neck. As people age, these arteries can become narrow because of a build-up of plaque on the arterial wall. The plaque may cause turbulent blood flow and blood clotting. Material breaking off can lodge in the blood vessels of the brain causing either transient symptoms or a stroke. Those with transient symptoms have the highest risk of stroke in the period immediately following the onset of symptoms.

The risk of stroke can be reduced if surgery is performed quickly following the onset of symptoms. An analysis of pooled data from several randomised clinical trials showed that maximum reduction in the risk of stroke was achieved if surgery was performed within 14 days of randomisation [Rothwell et al 2004], a result that is reflected in the NICE guideline for the management of stroke. It recommended that surgery to remove the plaque (carotid endarterectomy) is performed within 2 weeks of an ischaemic cerebrovascular event

(Transient ischaemic attack (TIA) or minor stroke) in symptomatic patients with ipsilateral high- (70-99%) or moderate-degree (50-69%) carotid artery stenosis [NICE 2008]. More information about carotid endarterectomy can be found on the Circulation Foundation website: <https://www.circulationfoundation.org.uk/help-advice/carotid>

Table A3.3: Characteristics of patients who had carotid endarterectomy between 1 Jan 2014 and 31 Dec 2016, compared with characteristics from previous two years

Patient characteristics	No. of procedures	2016 %	2015 %	2014 %
Total procedures	4,330			
Age (years), (n=4,314)				
Under 66	1,147	26.6	25.0	27.2
66 to 75	1,531	35.5	35.3	34.9
76 to 85	1,366	31.7	34.2	31.8
86 and over	270	6.3	5.4	6.0
Male	2,906	67.1	67.8	66.1
Female	1,424	32.9	32.2	33.9
Patients symptomatic for carotid disease				
Index symptom if symptomatic: (n=4,026)				
Stroke	1,442	35.8	34.9	34.1
TIA	1,904	47.3	47.9	48.0
Amaurosis fugax	593	14.7	15.4	15.3
None of the three above	87	2.2	1.8	2.7
Grade of ipsilateral carotid stenosis* (n=4,330)				
<50%	70	1.6	1.5	2.1
50-69%	1,122	25.9	24.4	23.8
70-89%	1,834	42.4	42.9	44.9
90-99%	1,294	29.9	31.1	28.9
Occluded	10	0.2	0.2	0.3
Rankin score prior to surgery (n=4,330)				
0-2	3,977	91.8	92.4	91.1
3	296	6.8	6.4	7.7
4-5	57	1.3	1.2	1.2
Co-morbidities (n=4,330)				
Diagnosed diabetic	976	22.5	23.6	23.2
Current symptoms / treatment	1,370	31.6	34.0	32.7
Ischaemic heart disease				

* level of stenosis recorded at the time of initial imaging.

Peripheral artery disease

Peripheral artery disease (PAD) is a restriction of the blood flow in the lower limb arteries that can severely affect a patient's quality of life [Peach et al 2012]. The disease can affect various sites in the legs, and produces symptoms that vary in their severity from pain in the legs during exercise to persistent ulcers, or gangrene.

Patients with PAD have various treatment options [Peach et al 2012]. Endovascular or open surgical interventions (such as bypass) become options when conservative therapies have proved to be ineffective. The indication for either procedure depends upon the site(s) and length of the diseased arteries as well as vessel size but there is a degree of overlap between the two therapies, and they are increasingly used in combination. More information about peripheral artery disease and its treatment can be found on the Circulation Foundation website at:

<https://www.circulationfoundation.org.uk/help-advice/peripheral-arterial-disease>

Lower limb angioplasty/stenting

The majority of patients undergoing lower limb angioplasties have been men. About a quarter of patients were aged 80 year or older and just under a third had undergone a previous ipsilateral procedure. Lower limb angioplasty were used to treat patients with a range of symptoms, with Fontaine scores ranging from asymptomatic to tissue loss. Most procedures were elective but emergency procedures were also performed.

Table A3.4 Characteristics of patients undergoing endovascular lower limb revascularisation

	No. of procs	%	No. of procs	%
	2014-2015		2016	
Total procedures	7,945		5,941	
Age group (years)				
Under 60	1,245	15.7	981	16.5
60 to 64	912	11.5	685	11.6
65 to 69	1,204	15.2	963	16.2
70 to 74	1,321	16.6	1,023	17.2
75 to 79	1,246	15.7	900	15.2
80 and over	2,017	25.4	1,388	23.4
Men	5,217	65.7	4,032	67.9
Women	2,728	34.3	1,909	32.1
Smoking				
Current smoker	1,991	25.1	1,507	25.4
Ex-smoker	4,519	56.9	3,304	55.6
Never smoked	1,431	18.0	1,130	19.0
Previous ipsilateral limb procedure	2,490	31.3	1,873	31.5
Admitted as an emergency	2,186	27.5	1,594	26.8
Fontaine score				
1 Asymptomatic	271	3.5	248	4.2
2 Intermittent claudication	3,236	41.3	2,569	43.8
3 Nocturnal &/or resting pain	1,652	21.1	1,164	19.9
4 Necrosis &/or gangrene	2,671	34.1	1,879	32.1
Comorbidities				
None	2,044	14.7		
Hypertension	8,544	61.5		
Diabetes	5,643	40.6		
Ischaemic heart disease	4,645	33.5		
Chronic lung disease	2,084	15.0		
Chronic renal disease	1,862	13.4		
Stroke	1,073	7.7		
Chronic heart failure	916	6.9		
Medication				
None	1,081	7.8		
Anti-platelet	10,954	78.9		
Statin	10,516	75.7		
ACE inhibitor/ARB	5,036	36.3		
Beta blocker	3,462	24.9		

Lower limb bypass

Table A3.5 summarise the patient characteristics and risk factors of patients undergoing bypasses. This procedure was used for treating patients with a full range of disease (asymptomatic, intermittent claudication, critical limb ischemia (Fontaine scores 3 and 4)), although endovascular interventions were more common for patients with less severe symptoms. The prevalence of diabetes, hypertension and coronary heart disease was high, and only a small proportion of patients had no comorbid disease. Not surprisingly, most patients were on some form of cardiovascular/risk modification medication.

Table A3.5: Patient characteristics of patients undergoing lower limb bypass between January 2014 and December 2016

	Bypass	
	No. of procs	%
Total procedures	17,200	
Age group (years)		
Under 60	3,461	20.2
60 to 64	2,279	13.3
65 to 69	3,015	17.6
70 to 74	2,900	16.9
75 to 79	2,602	15.2
80 and over	2,884	16.8
Men	12,560	73.0
Women	4,640	27.0
Smoking		
Current smoker	5,854	34.0
Ex-smoker	9,446	54.9
Never smoked	1,893	11.0
Previous ipsilateral limb procedure	6,507	37.8
% Emergency admissions	6,126	35.6
Fontaine score		
1 Asymptomatic	266	1.7
2 Intermittent claudication	4,860	30.4
3 Nocturnal &/or resting pain	5,846	36.6
4 Necrosis &/or gangrene	5,010	31.3
Comorbidities		
None	2,355	13.7
Hypertension	11,617	67.5
Ischaemic heart disease	6,436	37.4
Diabetes	5,482	31.9
Stroke	1,319	7.7
Chronic lung disease	3,674	21.4
Chronic renal disease	1,686	9.8
Chronic heart failure	952	5.5
Medication		
None	662	3.8
Anti-platelet	14,678	85.4
Statin	14,150	82.3
Beta blocker	3,982	23.2
ACE inhibitor/ARB	6,492	37.8

The NVR dataset includes the facility for the collection of the ankle brachial pressure index (ABPI). The collection of this ABPI is recommended for patient assessment by NICE guidance for PAD [NICE 2012], but it is only entered for a minority of bypass (6.8%) procedures. Assuming these samples are representative, we note that the average ABPI for bypass procedures was 0.48, which is just within the range associated for severe disease (under 0.5).

Lower limb major amputation

Characteristics of patients undergoing major unilateral amputations are summarised in Table A3.6, separately for above knee amputations (AKAs) and below knee amputations (BKAs). Overall, BKAs were more common in patients under 60 years and AKAs more common in patients older than 80 years. Most patients in both amputation groups were men and many were either current or ex-smokers.

The most common presenting problem for BKAs as well as AKAs was tissue loss. Among the BKA patients, the second most common presenting problem was uncontrolled infection. For AKA patients, acute or chronic limb ischaemia were also common. Over a half of the patients had undergone a previous ipsilateral limb procedure. This may be because with the most frail, older patients, angioplasty (as a less invasive procedure) has been attempted prior to amputation. However, due to current poor case-ascertainment for angioplasty (see Chapter 6) this cannot be explored further.

Table A3.6: Characteristics of patients undergoing major unilateral lower limb amputation

	Below knee	%	Above knee	%
Procedures	6 978	71.2	2 826	28.8
Age group (years)				
Under 60	1 791	25.7	453	16.0
60 to 64	774	11.1	284	10.1
65 to 69	1 020	14.6	381	13.5
70 to 74	980	14.0	455	16.1
75 to 79	964	13.8	467	16.5
80 and over	1 449	20.8	786	27.8
Men	5 127	73.5	1 895	67.1
Women	1 8551	26.5	931	32.9
Smoking				
Current	1 912	27.5	907	32.3
Ex-	3 460	49.7	1 408	50.1
Never	1 590	22.8	497	17.7
Presenting problem				
Acute limb ischaemia	834	12.0	630	22.3
Chronic limb ischaemia	1 341	19.3	620	22.0
Neuropathy	116	1.7	37	1.3
Tissue loss	2 757	39.6	1 004	35.6
Uncontrolled infection	1 901	27.3	497	17.6
Aneurysm	19	0.3	35	1.2
Previous ipsilateral limb procedure	4 400	63.2	1 660	58.8

Pre-operative risk factors are summarised in Table A3.7. The majority of patients had severe comorbid disease. The most common comorbidities in both BKA and AKA groups were hypertension, diabetes and ischaemic heart disease. A large majority of patients in both groups were taking antiplatelet medication or statins, and about a quarter to a third of the patients were on beta blockers, ACE inhibitors or ARBs.

Table A3.7: Pre-operative risk factors among patients undergoing lower limb amputation

	Below knee	%	Above knee	%
Procedures	6 978	71.2	2 826	28.8
ASA grade				
1 Normal	57	0.8	19	0.7
2 Mild disease	700	10.0	172	6.1
3 Severe, not life-threatening	4 730	67.8	1 699	60.1
4-5 Severe, life-threatening, or moribund patient	1 490	21.3	935	33.1
Comorbidities				
None	608	8.7	304	10.8
Hypertension	4 252	60.9	1 776	62.9
Ischaemic heart disease	2 689	38.5	1 172	41.5
Diabetes	4 369	62.6	1 156	40.9
Stroke	719	10.3	370	13.1
Chronic lung disease	1 224	17.5	690	24.4
Chronic renal disease	1 523	21.8	537	19.0
Chronic heart failure	688	9.9	321	11.4
Medication				
None	538	7.7	259	9.2
Anti-platelet	5 040	72.2	1 964	69.5
Statin	5 025	72.0	1 926	68.2
Beta blocker	1 869	26.8	775	27.4
ACE inhibitor/ARB	2 371	34.0	838	29.7

Appendix 4: Elective infra renal AAA repairs

Appendix 5: Repair of complex AAAs

Appendix 6: Emergency repair of ruptured AAA

Appendix 7: Carotid endarterectomy

Appendix 8: Lower limb angioplasty/stent

Appendix 9: Lower limb bypass

Appendix 10: Major lower limb amputation

Appendix 11: Audit methodology

Method of data collection

The data on these vascular procedures were collected using the National Vascular Registry IT system which is hosted by Northgate Public Services (UK) Limited. The NVR IT system is a secure web-based data collection system used by vascular surgeons and other members of the vascular team to enter clinical data on each patient undergoing a major vascular procedure.

The data used in this report were extracted from the IT system on 1 August 2017. In the preceding months, the Registry had undertaken several rounds of communication with vascular surgical units, asking them to validate the data, ensuring that all eligible patients were entered, and that their data was complete and accurate.

Data collected on patients, their surgery and outcomes

The NVR used datasets that are tailor to each of the various procedures within the scope of the audit, although these share a similar structure and some common data items. In particular, each dataset captures features to captures information about:

- The demographics of a patient (their age, sex, and region of residence),
- Where and when the patient was admitted to hospital.
- The indications for surgery, the severity of a patient's vascular disease, and other co-existing conditions.
- The type and timing of surgery received, and
- The care received after surgery before the patient is discharged from hospital.

For AAA repairs, the NVR uses OPCS codes to describe the type of surgery that a patient has undergone:

- Open repairs are described using OPCS codes L19.4, .5, .6, .8
- EVAR procedures are described using OPCS codes L27.1, .5, .6, .8, .9 and L28.1, .5, .6, .8, .9

For the other procedures, the details of the operation are captured using distinct data items.

Analysis

In this report, we present summary information on patient characteristics and hospital activity, for the NHS as a whole and for individual NHS trusts / Health Boards. Results are typically presented as totals and/or percentages, medians and interquartile ranges (IQR), with numerators and denominators stated where appropriate. In a few instances, the percentages do not add up exactly

to 100%, which is typically due to the rounding up or down of the individual values. Measures of outcome are presented with 95% confidence intervals to describe the level of uncertainty associated with the estimates value. Stata 14 (StataCorp LP, College Station, TX, USA) was used for all statistical calculations.

Where individual NHS trust and Health Board results are given, the denominators are based on the number of cases for which the question was applicable and answered. The number of cases included in each analysis may vary depending on the level of information that has been provided by the contributors and the total number of cases that meet the inclusion criteria for each analysis.

Activity figures from national routine datasets (eg, HES for England, PEDW for Wales) were used to estimate case-ascertainment for the time periods included in the analysis. These were created by identifying the relevant OPCS procedure codes and ICD10 diagnosis codes in the HES procedure fields. Further information on these codes is available from the NVR team.

Multivariable logistic regression was used to derive the unit-level risk-adjusted mortality rates, and take into account differences in the patient case-mix across the NHS organisations. The regression models were used to produce the risk of death for each individual patient. The risk-adjusted mortality rates were then produced by dividing the observed number of deaths at each organisation with the predicted number and multiplying this ratio with the national mortality rate.

Not all patient records contained complete information on these risk factors. Multiple imputation by chained equations was used to address missing values on these case-mix variables when modelling postoperative complication rates for NHS organisations [White et al 2011].

Graphical presentation

A funnel plot was used to assess whether there are systematic differences in mortality rates between NHS organisations. This is a widely used graphical method for comparing the outcomes of surgeons or hospitals [Spiegelhalter, 2005]. In these plots, each dot represents an NHS organisation. The solid horizontal line is the national average. The vertical axis indicates the outcome with dots higher up the axis showing trusts with a higher stroke and/or death rate. The horizontal axis shows NHS trust activity with dots further to the right showing the trusts that perform more operations. The benefit of funnel plot is that it shows whether the outcomes of NHS trusts differ from the national average by more than would be expected from random fluctuations. Random variation will always affect outcome information like mortality rates, and its influence is greater among small samples. This is shown by the funnel-shaped dotted lines. These lines define the region within which we would expect the outcomes of NHS trusts to fall if their outcomes only differed from the national rate because of random variation.

If the risk-adjusted mortality rate fell outside the outer control limits of the funnel plot, the organisation would be flagged as an outlier. If this occurred, there could be a systematic reason for the higher or lower rate, and they would be flagged for further investigation. In this report, outliers are managed according to the outlier policy of the Vascular Society, drawn up using guidance from the Department of Health. This policy can be found on the www.vsqip.org.uk website

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Glossary

Abdominal Aortic Aneurysm (AAA)	This is an abnormal expansion of the aorta. If left untreated, it may enlarge and rupture causing fatal internal bleeding
Amaurosis fugax	Transient loss of vision in one eye due to an interruption of blood flow to the retina.
ACE inhibitors	Angiotensin-converting enzyme inhibitors are medications designed to decrease blood pressure.
ARBs	Angiotensin-receptor blockers are drugs designed to decrease blood pressure. They are similar to ACE inhibitors but work in a different way.
Angiography	Angiography is a type of imaging technique used to examine blood vessels. It may be carried out non-invasively using computerised tomography (CT) and magnetic resonance imaging (MRI).
Asymptomatic Patient	A patient who does not yet show any outward signs or symptoms of plaque.
Cardiopulmonary Exercise Testing (CPET)	Cardiopulmonary Exercise Testing is a non-invasive method of assessing the function of the heart and lungs at rest and during exercise
Carotid Endarterectomy (CEA)	Carotid Endarterectomy is a surgical procedure in which build-up is removed from the carotid artery.
Carotid Stenosis	Abnormal narrowing of the neck artery to the brain.
Complex AAA	A term used to describe aortic aneurysms that are not located below the arteries that branch off to the kidneys. These are categorised into three types: juxta-renal (that occur near the kidney arteries), supra-renal (that occur above the renal arteries) and thoraco-abdominal (more extensive aneurysms involving the thoracic and abdominal aorta.
Cranial Nerve Injury (CNI)	Damage to one of the 12 nerves supplying the head and neck.
Endovascular Aneurysm Repair (EVAR)	A method of repairing an abdominal aortic aneurysm by placing a graft within the aneurysm from a small cut in the groin.
Hospital Episode Statistics (HES)	HES is the national statistical data warehouse for England regarding the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. There are equivalent agencies in Northern Ireland, Scotland and Wales but in this report, the term HES is used generically to describe data that are collected by any of these national agencies.
Infra-renal AAA	An abdominal aneurysm that is located below the point where the arteries branch off the aorta to the kidneys.

Interquartile range (IQR)	Once the data are arranged in ascending order, this is the central 50% of all values and is otherwise known as the 'middle fifty' or IQR.
Hybrid operating theatre	An operating theatre with built-in radiological imaging capabilities. The imaging equipment is able to move and rotate around a patient and multiple monitors provide good visibility around the operating table.
Median	The median is the middle value in the data set; 50% of the values are below this point and 50% are above this point.
Myocardial Infarct (MI)	Otherwise known as a Heart Attack, MI involves the interruption of the blood supply to part of the heart muscle.
Occluded artery	An artery that has become blocked and stops blood flow.
National Abdominal Aortic Aneurysm Screening Programme (NAAASP)	A programme funded by the Department of Health to screen men over the age of 65 years for AAA
NHS	National Health Service
National Vascular Database (NVD)	An on-line database funded by The Vascular Society to collect data on major vascular procedures performed in the National Health Service. This was the predecessor of the National Vascular Registry.
OPCS	Office of Population and Censuses Surveys. A procedural classification list for describing procedures undertaken during episodes of care in the NHS
Peripheral arterial disease (PAD)	Peripheral arterial disease (PAD) is a restriction of the blood flow in the lower-limb arteries. The disease can affect various sites in the legs, and produces symptoms that vary in their severity from pain in the legs during exercise to persistent ulcers or gangrene.
Plaque	Scale in an artery made of fat, cholesterol and other substances. This hard material builds up on the artery wall and can cause narrowing or blockage of an artery or a piece may break off causing a blockage in another part of the arterial circulation.
Stroke	A brain injury caused by a sudden interruption of blood flow with symptoms that last for more than 24 hours.
Symptomatic	A patient showing symptoms is known to be symptomatic.
Transient ischaemic attack (TIA)	A "mini-stroke" where the blood supply to the brain is briefly interrupted and recovers after a short time (eg, within 24 hours).
Trust or Health Board	A public sector corporation that contains a number of hospitals, clinics and health provisions. For example, there were 4 hospitals in the trust and 3 trusts in the SHA.

Vascular Society of
Great Britain and Ireland
(VSGBI)

The VSGBI is a registered charity founded to relieve sickness and to preserve, promote and protect the health of the public by advancing excellence and innovation in vascular health, through education, audit and research. The VSGBI represents and provides professional support for over 600 members and focuses on non-cardiac vascular disease.

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