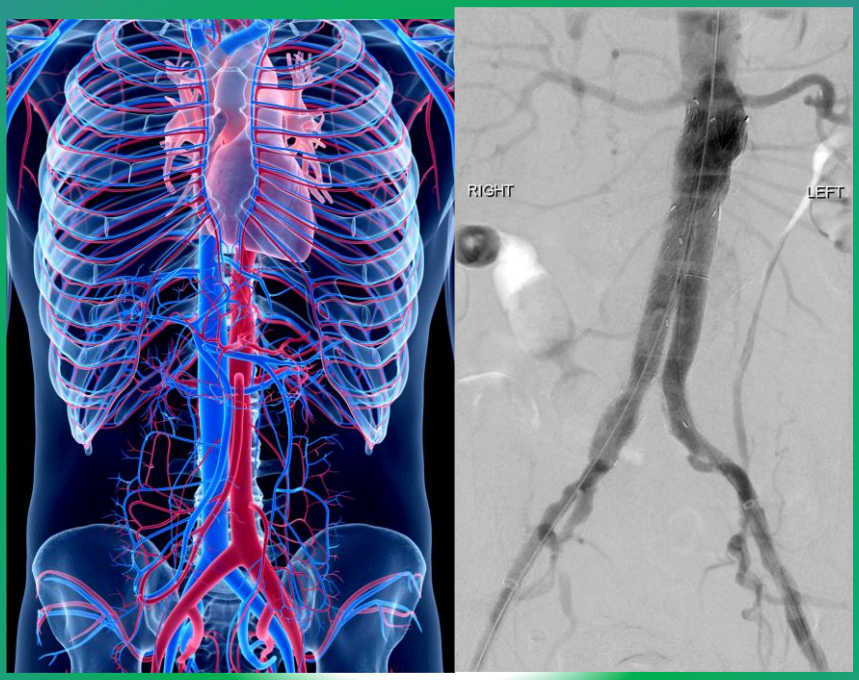
National Vascular Registry: Short Report



Developing and implementing implantable medical device capture for aortic aneurysm repair

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FOREWORD

The management of many vascular patients involves the use of implantable medical devices. These devices enable life and limb saving procedures to be safely performed and reduce the impact of vascular conditions on patients' quality of life, but occasionally problems arise.

The Endovascular Aneurysm Sealing technology (EVAS) device for the repair of abdominal aortic aneurysms (AAA) was an example of a device having worse than expected outcomes [MHRA 2019]. The EVAS devices began to fail 2 to 4 years after implant at a faster rate than expected [Singh 2020, Singh 2021, and Harrison 2018]. At unit level, the occasional failing device may not be recognised as a sign of a more systematic problem with the technology. To be effective in recognising systematic problems requires a national database of all implanted vascular devices.

The National Joint Registry (NJR) has been collecting information on hip replacement implants for many years. The NJR team are world leaders in patient-centred, clinician-led registry device capture and have implemented a highly effective surveillance process. The data collected by the NJR enabled the inferior performance of metal-on-metal hip replacements to be identified earlier than would have been possible without it [Smith 2012].

This report describes the results of a pilot project to implement the capture of implantable medical devices used in procedures to repair aortic aneurysms. Many stakeholders were involved in developing this pilot project, and contributed to its success. The Healthcare Quality Improvement Partnership (HQIP), the Medicines and Healthcare products Regulatory Agency (MHRA) and NHS England and NHS Improvement (NHSEI) have been very supportive from the outset. The Association of British HealthTech Industries (ABHI) and Northgate Public Services also played vital roles.

Whilst we recognise this report only provides early information and that the true value of the dataset additions will be seen in the years to come, it is really encouraging to see how vascular clinicians have engaged in recording both device and re-intervention information within the National Vascular Registry (NVR). Ultimately, this data will drive improved quality and safety for our patients.

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INTRODUCTION

The National Vascular Registry (NVR) was established to measure the quality and outcomes of care for adult patients who undergo major vascular procedures in NHS hospitals, and to support vascular services to improve the quality of care for these patients. All NHS hospitals in England, Wales, Scotland and Northern Ireland are encouraged to participate, so that the Registry can 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.

One of the vascular procedures collected in the NVR is aortic aneurysm repair. An abdominal aortic aneurysm (AAA) is the local expansion of the abdominal aorta. The condition is often asymptomatic until the aneurysm ruptures. Most aneurysms occur below the kidneys (i.e., are infra-renal), but they can also extend higher into the thoracic area of the aorta, up to and including the aortic arch.

An aneurysm can be repaired by either an open or endovascular method, and an implantable medical device is left inside the patient in both procedures. An open repair involves surgically opening the abdomen, clamping the aorta above and below the aneurysm, repairing the aneurysmal section of the aorta and replacing it with a sown-in prosthetic graft. In an endovascular repair (EVAR), a stent graft is fed up into the patient's aorta from smaller incisions into the arteries in the groin. This stent-graft then lines the inside of the aorta, and blood flows through it, thus allowing the aneurysm to shrink around it.

The success of the operation relies on the implanted device continuing to prevent aneurysm rupture for the remainder of the patient's life. Patients who undergo endovascular repair are routinely followed up with regular imaging, and between 20-25% of patients require further intervention [Boyle 2019, Patel 2016, and Singh 2020]. Patients who undergo open surgical repair are not usually followed up because the risk of a patient needing further intervention is very low.

In 2020, the Independent Medicines and Medical Devices Safety Review (IMMDS Review), led by Baroness Cumberlege, published its report entitled "First do no harm" [Cumberlege 2020]. The report focused on how the healthcare system in England responded to reports about harmful side effects from medicines and medical devices. One of the main recommendations of the report was to collect and publish information on implantable medical devices to monitor safety. A number of complementary recommendations were also made by HQIP in its report on the desirability of a medical devices registry, such as to prioritise the collection of implantable medical devices especially in novel procedures [HQIP 2020]. Both reports highlighted a number of significant patient safety and quality issues and noted that no one has immediate and ready access to data that could be used to alert relevant bodies and more importantly, the patient population, about defective devices.

The publication of the IMMDS Review in July 2020 coincided with the National Vascular Registry enabling information on implantable devices used in AAA repairs to be entered in its datasets. This development was the culmination of three years' work by the NVR team and others. The purpose of this short report is to describe our initial experience on recording AAA device information and to make recommendations for how robust data on implantable vascular devices can be captured on an ongoing basis.

INITIAL DEVELOPMENT

Discussions about the feasibility of collecting device information in the NVR started in 2017 among various stakeholders. At a policy level:

- Approval for the initiative was sought from HQIP and NHS England (as commissioners and data controllers of the NVR) in 2018. Discussions also took place with the relevant bodies within Wales, Scotland and Northern Ireland.
- Views on the desirability and feasibility of the work were sought from the Vascular Society of Great Britain & Ireland (VSGBI) and the British Society of Interventional Radiology (BSIR). Both supported the collection of implantable devices within the NVR.
- The NVR team also approached the Medicines and Healthcare products Regulatory Agency (MHRA), Getting it Right First Time (GIRFT), and NHS Improvement. Discussions also took place with Professor Tim Briggs, National Director of Clinical Improvement for the NHS.

It was decided that the initiative would focus initially on collecting implantable device information from one vascular procedure – the repair of aortic aneurysms. This reduced the complexity of the development and would allow lessons to be learnt that could inform the expansion of the NVR IT system to all procedures.

It was recognised that it would be important for devices to be entered as simply as possible on to the NVR IT system, and that the details of devices for inclusion in the data collection system were complete and kept up-to-date. Vascular procedures often included more than one implantable device and it was important to ensure that all could be recorded. The practical and logistical aspects of the project were developed by the NVR team, Northgate Public Services and the Association of British HealthTech Industries (ABHI). Northgate Public Services has built and hosted the NVR IT system since 2013. It also hosts the IT system for the National Joint Registry (NJR), which has been collecting details of implantable devices for a number of years, and their team were able to provide technical expertise and guidance on how implantable devices could be captured within the NVR IT system.

The ABHI acts as the overarching body to represent the companies that manufacturer aortic grafts and stent grafts. The ABHI's vascular group contained many of the manufacturers of aortic devices and a key aspect of the development phase was to ensure each was represented in discussions about the logistics of data capture and type of device performance information that would be important to industry. Working principles were agreed between the ABHI, HQIP and the Royal College of Surgeons of England (on behalf of the National Vascular Registry) that specified the scope of the project and the key outputs from the initial phase of aortic devices data collection. In particular, these provided a framework to manage commercial sensitivity as well as the public interest, and established that:

- Any published information would be based on a minimum number of procedures
- That the device data captured during this phase not be included in any release of NVR data that could be approved by HQIP as part of the standard data access request process.
- The NVR team would cooperate with the MHRA or other regulatory body if a concern was raised regarding the performance of an implant recorded within the NVR during the initial phase. Data from the NVR (including device information) would be provided to MHRA if legally obliged to do so.

The agreement was approved by the following manufacturers: Cook Medical, CryoLife Inc., Medtronic Inc., Terumo Aortic and W.L Gore & Associates Inc. Additionally, device data was subsequently provided by B. Braun Aesculap, Bard/BD, Bentley Innomed, Cordis (A Cardinal Health Company), Endologix Inc., Getinge, and LeMaitre Vascular. This report contains data on patients undergoing aortic procedures containing devices from all of them.

REVISION OF NVR CLINCIAL DATASET

The existing NVR dataset for AAA repairs needed to be modified to support the analysis and reporting of device information. First, changes were required to enable the entry of devices used in the procedure. Second, the dataset needed to be updated to ensure that aortic re-intervention procedures could be captured precisely, as the existing dataset primarily focussed on primary procedures. Re-intervention rates are a key long-term outcome metric of aortic procedures and it will be important for the NVR to differentiate between the various indications for re-intervention and whether they were due to patient or device related factors. The type of re-intervention was also important to collect because some devices are specifically designed for particular procedures.

The datasets were updated in consultation with the VGSBI's Audit & Quality Improvement Committee (which acts as the clinical reference group for the NVR) and the members of the vascular group of the ABHI.

Approval was also gained from the Confidentiality Advisory Group (CAG) for collection of the extra data items in the NVR.

CREATION OF THE NVR DEVICES DATASET

A key topic for the meetings between the NVR, Northgate and the vascular group of the ABHI was the structure of the dataset that stored the information on the implantable devices used in AAA procedures. This had two elements. The first related to various attributes of the devices, such as:

- name of the manufacturer, product name or description, product number and batch number
- the dimensions of the device, the dimensions of the patients' anatomy that could be treated, treatment indications, its material, and location within the artery system that the device could be used.

This information was kept up-to-date by the manufactures providing the NVR team with the dataset for new devices as they entered into the market. Including this dataset within the NVR IT system ensures that the device information is entered in a consistent and accurate way.

The second element of the devices dataset was a classification to differentiate between the types of device and the specific procedures in which each device could be used. The classification would be fundamental for evaluating the performance of comparable devices, and was developed during a series of consultations.

ADAPTATION OF THE NVR IT SYSTEM

The NVR IT system was adapted to provide the following additional functionality for users entering patient information:

- The ability to select "AAA revision" as the procedure type and use the dedicated data items for this situation.
- The option to enter device information on all types of AAA procedure

The IT system was also adapted to allow the NVR team to upload into the 'back-end' of the system the information from device manufacturers about the names of the devices and their attributes.

The NVR IT system was designed to allow users several ways to enter device information:

1. Users could search for devices by selecting the relevant company and entering the product code, or
2. Users could use a USB barcode scanner to scan the barcode or QR code on the label of a device. To ensure this was possible, the Global Trade Item Number (GTIN) or Health Industry Bar Code (HBIC) was included in the dataset for each device.

Enabling the use of barcode scanning was important for speed and accuracy of data entry. Many hospitals already used barcode scanners for stock control purposes and some were also capturing the device used within theatre and patient management systems. If users were unable to use a barcode scanner, the device dataset enabled the IT system to offer a device "look-up facility" for NVR users to search when entering a procedure onto the NVR. The IT system also instructed users who to contact if a device could not be found in the "look-up facility" so that the NVR team could seek the information from the relevant manufacturer.

The changes to the NVR IT system were subject to a period of testing by a select group of registered users. Sample barcodes were requested from each company for testing purposes and to ensure that the format was correctly picked up within the NVR IT system. A demonstration was also provided to the ABHI. The final dataset was deployed in July 2020.

INFORMATION ON THE FIRST DEVICES CAPTURED IN THE NVR

The results in this report are based on an extract of activity taken from the NVR IT system in March 2021, and covered the period from January 2020 to February 2021. Although the ability to enter device information was not activated until July 2020, some hospitals entered data into the NVR IT system on procedures performed before this date. This report has been designed to present basic information, and we expect to be able to expand on this in future publications, once the data becomes more mature and complete.

In total, there were 3,205 AAA procedures entered in NVR from January 2020 to February 2021 and 1,056 (33%) contained device information. The proportion of AAA procedures on the NVR with device data increased throughout 2020 (Table 1). The patterns were explored for both elective and non-elective procedures to see if there was any significant difference, but the pattern was fairly similar (Figure 1). There were 70 EVAR revision procedures (Table 2) and 36 open revision procedures. Among open repair revisions, there were four procedures with a device recorded. These were analysed with the open procedures, as only the type of implanted device was taken into account and not any patient outcomes.

Table 1: Number of AAA procedure records on the NVR containing device information

Month	Number of AAA procedure records with device data	Total AAA procedures submitted on NVR	% of all AAA procedures containing a device
Jan ‘20	22	399	6%
Feb ‘20	25	374	7%
Mar ‘20	36	250	14%
Apr ‘20	14	98	14%
May ‘20	20	122	16%
Jun ‘20	49	227	22%
Jul ‘20	104	254	41%
Aug ‘20	120	236	51%
Sep ‘20	180	319	56%
Oct ‘20	154	296	52%
Nov ‘20	158	299	53%
Dec ‘20	128	228	56%
Jan ‘21	30	68	44%
Feb ‘21	16	35	46%
Total	**1,056**	**3,205**	**33%**

Figure 1: Percentage of AAA procedures with device information between January 2020 and February 2021, by month of operation and mode of admission

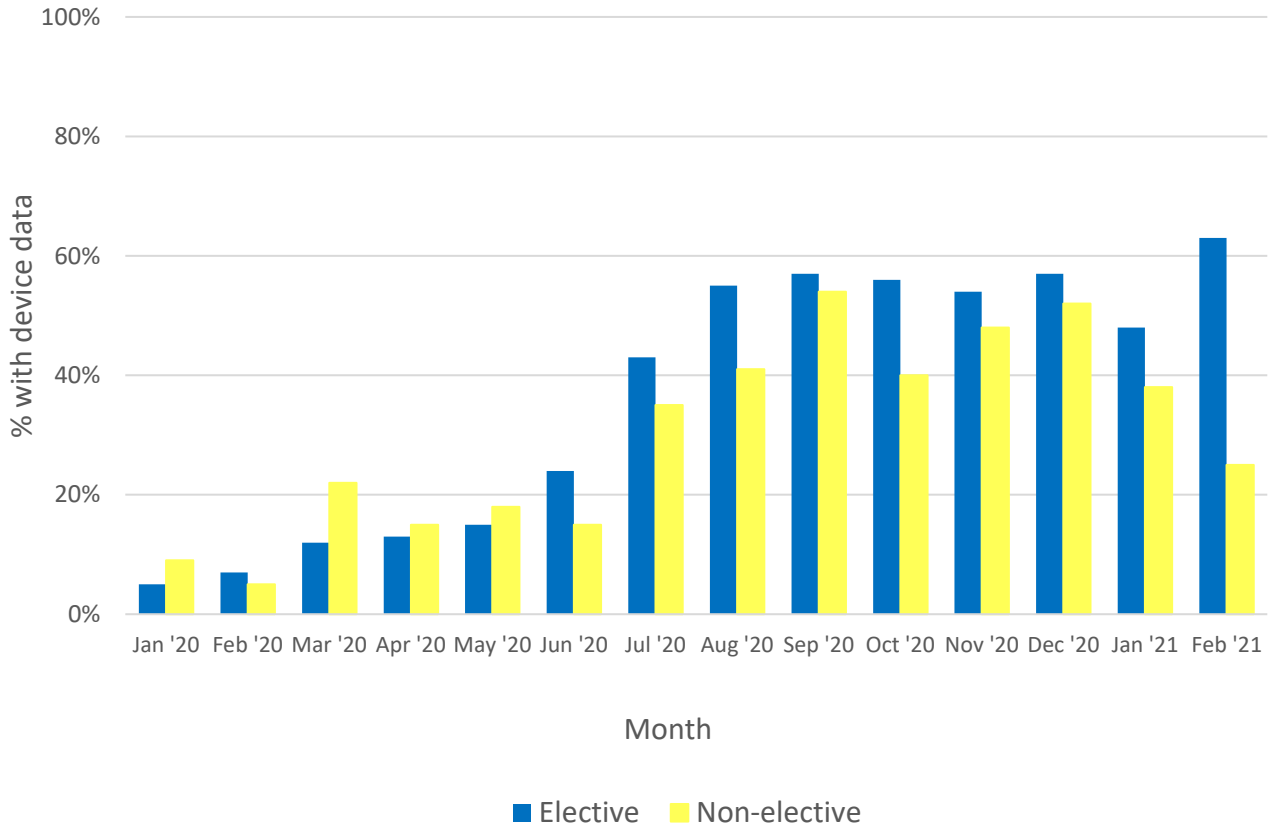


Table 2: Device information available by type of AAA repair

Repair type	Elective	Non-elective	Total	% repair type with device information
Open	145	59	204	18%
EVAR	418	125	543	40%
Complex EVAR	198	41	239	41%
Revision EVAR	45	25	70	49%
Total	806	250	1,056	33%

Note: A revision EVAR is defined as an endovascular procedure on a patient who has had a previous repair (either open or endovascular).

Open procedures

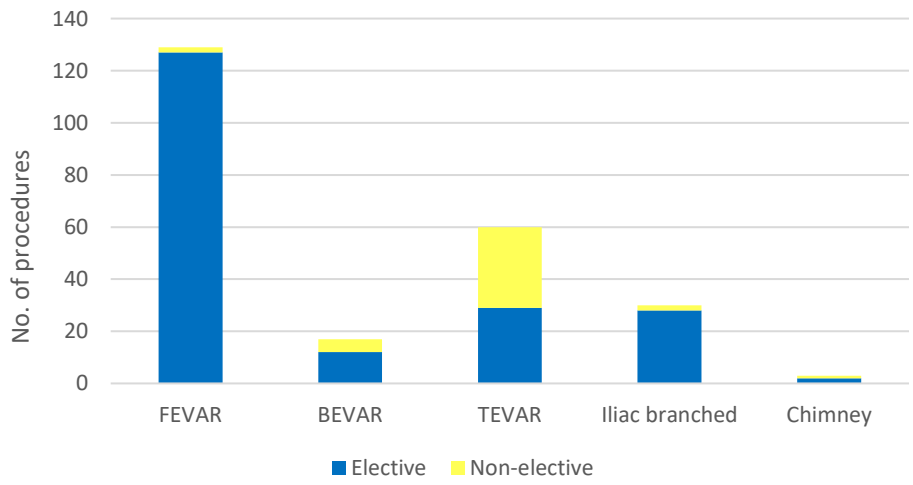
The majority of open repairs entered in the NVR with device information recorded were elective admissions (71%) and involved an infra-renal clamp (n=179, 88%). Most grafts were tube grafts (n=145, 71%), compared to bifurcated (n=59, 29%).

Not all open repair grafts were available in the device dataset for selection on the NVR in July 2020, and so the numbers were lower at the start. The completeness of the dataset for open repairs increased over the data collection period, once the additional grafts were added.

Endovascular procedures

There were 852 endovascular aneurysm repairs where a device was recorded on the NVR. As expected, the vast majority of procedures were standard infra-renal EVARs (Table 2). The most common complex endovascular procedures involved a fenestrated or thoracic device (fig.2).

Figure 2: Complex endovascular procedures with device information, by admission mode

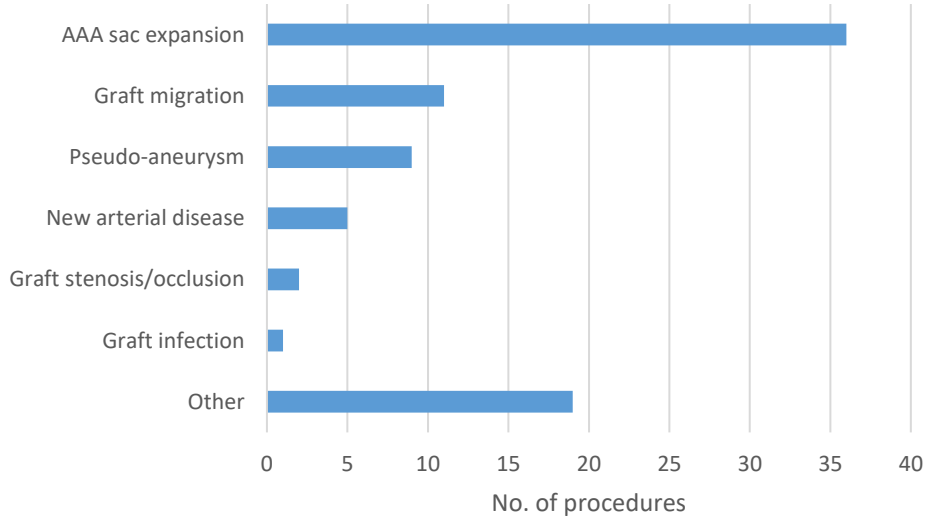


For endovascular aneurysm repairs, information about the angulation, length and diameter of the aneurysm was collected, as the number of stents that might be suitable for a procedure is based on this anatomy and the manufacturer's instructions for use (IFU). Among the records for infrarenal AAA repairs for which device information was available:

- 85% of patients had an aneurysm with a neck angulation of 60 degrees or less
- 59% of patients had an endovascular device with a neck length of more than 20mm, 31% had a neck length of 15-20mm, 8% had a neck length of 10-14mm and 2% of less than 9mm
- 75% of patients had a neck diameter between 18 and 25mm, 19% had a neck diameter of more than 25mm, 3% had a neck diameter of less than 18mm, and 3% had a neck diameter of more than 30mm.

The reasons for re-intervention for revision EVARs are described in Figure 3. For just over half of these patients, the revision EVAR was due to their aneurysm sac expanding.

Figure 3: Number of revision EVAR procedures by indication



Device components

The 1,056 procedure records analysed in this report contained 2,806 devices. The 204 open surgical procedures involved 215 grafts. In contrast, most endovascular aortic procedures required the use of more than one device component. The combination of devices used in the endovascular repairs is summarised in Table 4, with the specific devices being grouped according to the device classification developed by the NVR and manufacturers. Limbs were the most frequently used component (see glossary for an explanation of the different components).

The NVR IT system also asks users to report whether each device component was used as per the manufacturer's instructions for use. The responses received for the entered devices are shown in Table 5. Deviation from the manufacturer's instructions for use was most common among complex AAA repairs, particularly in relation to the use of peripheral stents.

Table 4. Types of devices entered in NVR by type of endovascular repair

Component	Type of endovascular repair							
	EVAR	**FEVAR**	**BEVAR**	**TEVAR**	**Iliac branched**	**Chimney**	**Revision EVAR**	**Total**
Main body	512	134	23	89	20	2	23	803
Limb	1,103	189	17	3	78	6	85	1,481
Peripheral stent	20	142	28	12	13	3	9	227
Extension	16	3	0	2	2	1	8	32
Converter	2	0	0	0	0	0	1	3
Endoanchor	14	0	0	4	4	0	2	24
Coil	6	3	0	0	0	0	12	21
Total	1,673	471	68	110	117	12	140	2,591

Table 5. Devices that followed instructions for use (IFU) by type of endovascular repair

Component	IFU followed							
	EVAR		**Complex EVAR**		**Revision EVAR**		**Total**	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Main body	488	21	246	22	21	2	755	45
Limb	1,077	17	267	26	80	3	1424	46
Peripheral stent	20	0	119	76	9	0	148	76
Extension	16	0	8	0	7	1	31	1
Converter	2	0	0	0	1	0	3	0
Endoanchor	13	1	7	1	2	0	22	2
Coil	6	0	3	0	12	0	21	0
Total	**1,622**	**39**	**650**	**125**	**132**	**6**	**2,404**	**170**

17 components were missing IFU information

Conclusions

The Cumberlege "First do no harm" review recommended collecting key details of the implantation of all devices at the time of operation and the NVR has started to deliver on this recommendation.

The results from the pilot phase of this initiative to collect information on implanted medical devices in vascular procedures are very encouraging. The project involved a number of inter-connected tasks, including:

- approval at policy level
- approval and collaboration with device manufacturers
- acceptance by the medical professionals involved in collecting data on vascular procedures, and
- changes to the NVR datasets and IT system to enable the capture and analysis of device information.

The initial phase required changes to the NVR datasets in relation to the clinical orientation as well as to the devices. A key observation for other work on medical device capture is that simply allowing data on medical devices to be entered within existing IT systems may not result in clinically meaningful results to be generated. Changes to allow the entry of medical device data need to be undertaken alongside a review of (and update to) the collected clinical data items.

The first phase of the initiative demonstrated that it was possible to successfully:

1. capture unique device identifiers at the time of implant, and
2. collect details of re-interventions as an indicator of longer-term device safety and patient outcomes.

Next steps

The NVR team is required to submit a more detailed feasibility proposal to the commissioners and funders of the NVR in order for them to make an informed decision on whether to approve the expansion to collect device information for other vascular procedures.

As part of this feasibility we will recommend:

- to make the device and re-intervention fields within the AAA datasets mandatory
- to work with the ABHI on plans to provide regular feedback reports on AAA repairs to industry on comparative device performance, in keeping with the model successfully developed by the NJR
- to work with the ABHI to develop a MoU for the longer term funding of the devices element of the NVR, potentially via a subscription model
- to develop plans to allow the entry of implanted medical devices for the carotid, angioplasty and lower limb bypass datasets.

The collection of data on medical devices within the NVR is a major step forward, with the potential to provide valuable information for vascular specialists, manufacturers, the MHRA and patients. We would welcome feedback from the users of the NVR on the new datasets with suggestions for additions or improvements. These will contribute to the ongoing work of the NVR and other stakeholders on taking the work further.

References

Boyle JR. Is In Hospital Mortality Following EVAR Still a Valid Outcome Measure? Eur J Vasc Endovasc Surg. 2019 Apr;57(4):520. doi: 10.1016/j.ejvs.2018.10.020. Epub 2018 Dec 13. PMID: 30554837.

British Medical Journal (BMJ). National registry will record patient outcomes from devices implanted during vascular surgery. *BMJ* 2020; 370 doi: https://doi.org/10.1136/bmj.m2981 (Published 24 July 2020) Cite this as: BMJ 2020;370:m2981

Cumberlege "First do no harm" The report of the Independent Medicines and Medical Devices Safety Review July 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Harrison SC, Winterbottom AJ, Coughlin PA, Hayes PD, Boyle JR. Editor's Choice - Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System - a Single Centre Experience. Eur J Vasc Endovasc Surg. 2018 Sep;56(3):342-348. doi: 10.1016/j.ejvs.2018.06.031. PMID: 30190039.

Healthcare Quality Improvement Partnership (HQIP). Proposal for a medical devices registry: HQIP 2020.
https://www.hqip.org.uk/wp-content/uploads/2020/03/Final-HQIP-Proposal-for-a-medical-devices-registry-SHORT-report.pdf

Medicines and Healthcare products Regulatory Agency (MHRA) January 2019.
Nellix Endovascular Aneurysm Sealing (EVAS) System - Device recall and enhanced patient surveillance (MDA/2019/002).
https://www.gov.uk/drug-device-alerts/nellix-endovascular-aneurysm-sealing-evas-system-device-recall-and-enhanced-patient-surveillance

National Institute for Health and Clinical Excellence (NICE). Abdominal aortic aneurysm: diagnosis and management. NICE guideline [NG156] March 2020.
https://www.nice.org.uk/guidance/NG156

Patel R, Sweeting MJ, Powell JT, Greenhalgh RM; EVAR trial investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet. 2016 Nov 12;388(10058):2366-2374. doi: 10.1016/S0140-6736(16)31135-7. Epub 2016 Oct 12. PMID: 27743617.

Smith AJ, Dieppe P, Howard PW, Blom AW; National Joint Registry for England and Wales. Failure rates of metal-on-metal hip resurfacings: analysis of data from the National Joint Registry for England and Wales. Lancet. 2012 Nov 17;380(9855):1759-66. doi: 10.1016/S0140-6736(12)60989-1. Epub 2012 Oct 2. PMID: 23036895.

Singh AA, Benaragama KS, Pope T, Coughlin PA, Winterbottom AP, Harrison SC, Boyle JR. Progressive Device Failure at Long Term Follow Up of the Nellix EndoVascular Aneurysm Sealing (EVAS) System. Eur J Vasc Endovasc Surg. 2021 Feb;61(2):211-218. doi: 10.1016/j.ejvs.2020.11.004. Epub 2020 Dec 7. PMID: 33303312.

Singh AA, Boyle JR. Introduction of New Medical Devices: Lessons Learned From Experience With Endovascular Aneurysm Sealing. J Endovasc Ther. 2020 Feb;27(1):160-162. doi: 10.1177/1526602819886338. Epub 2019 Nov 6. PMID: 31694456.

Singh AA, Boyle JR. Readmission and Re-intervention are Better Measures of EVAR Quality. Eur J Vasc Endovasc Surg. 2020 Oct;60(4):518. doi: 10.1016/j.ejvs.2020.08.011. Epub 2020 Aug 18. PMID: 32826175.

Wanhainen A, Verzini F, Van Herzeele I, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms. Eur J Vasc Endovasc Surg. 2019 Jan;57(1):8-93. doi: 10.1016/j.ejvs.2018.09.020. Epub 2018 Dec 5. Erratum in: Eur J Vasc Endovasc Surg. 2020 Mar;59(3):494. PMID: 30528142.

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.
Association of British HealthTech Industries (ABHI)	The ABHI is the UK's leading industry association for health technology (HealthTech).
Branched EVAR (BEVAR)	A complex endovascular aortic repair in which separate grafts, attached to the main graft, are deployed on each blood vessel from the aorta.
British Society of Interventional Radiology (BSIR)	The BSIR is a charitable foundation founded to promote and develop the practice of Interventional Radiology.
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).
Chimney EVAR (chEVAR)	A complex endovascular aortic repair where covered stents are used in conjunction with an EVAR device to preserve the blood flow to arteries that branch off the aorta, mainly the renal arteries.
Coil	An endovascular device used to block blood flow into an artery or aneurysm.
Converter	A component placed in the aorta or in an existing main stent graft to direct blood to only one iliac artery, blocking the other.
Endoanchor	A small helical "screw" that fixes an endovascular graft to a patient's aorta in order to reduce the chance of it slipping.
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.
Extension	A component used in combination with an EVAR main stent graft to extend it proximally and cover a longer part of the aorta.
Fenestrated EVAR (FEVAR)	A complex endovascular aortic repair that involves the use of a graft that has holes (fenestrations), where smaller peripheral stents are inserted to allow the passage of blood to arteries that branch off the aorta.
Getting It Right First Time (GIRFT)	A national programme designed to improve medical care within the NHS by reducing unwarranted variations.
Global Trade Item Number (GTIN)	An internationally recognised identifying number for products such as medical devices.
Health Industry Bar Code (HIBC)	An internationally recognised identifying number for products in the health industry.
Iliac branched device	A device for endovascular repair that preserves the blood flow to the internal iliac arteries.
Instructions For Use (IFU)	Information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken.

Limb	A component of an endovascular device that is used in the iliac arteries.
Main body	A component of an endovascular device that is used in the aorta.
Medicines and Healthcare products Regulatory Agency (MHRA)	An executive agency of the Department of Health that regulates medicines, medical devices and blood components for transfusion in the UK.
Infra-renal AAA	An abdominal aneurysm that is located below the point where the arteries branch off the aorta to the kidneys.
Open repair	A method of repairing an abdominal aortic aneurysm by surgically opening the abdomen, clamping the aorta above and below the aneurysm, repairing the aneurysmal section of the aorta and replacing it with a sown-in prosthetic graft.
Peripheral stent	A component used in an endovascular repair in conjunction with an EVAR device to preserve the blood flow to arteries that branch off the aorta, mainly the renal arteries.
Thoracic endovascular aortic/aneurysm repair (TEVAR)	A complex endovascular aortic repair that involves the thoracic segment of the aorta higher up in the chest.
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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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. Registered charity no: 1102769

The British Society of Interventional Radiology is the specialist society that represents interventional radiologists. It is one of the key partners leading the audit. Registered charity no: 1084852

Commissioned by

The National Vascular Registry is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). 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 in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering 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 projects, other devolved administrations and crown dependencies. www.hqip.org.uk/national-programmes.
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