Abdominal aortic aneurysm: diagnosis and management

NICE National Institute for Health and Care Excellence

Consultation on draft guideline – deadline for comments 5pm on 29 June 2018 email: AAaneurysm@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the short version and any comments you may have on the evidence presented in the full version. We would also welcome views on the Equality Impact Assessment. We would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**British Society of Endovascular Therapy (BSET)**

Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A
Name of commentator person completing form:	**Miss Rachel Bell MS FRCS, Consultant Vascular Surgeon**
Type	[office use only]

1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.	The impact on the NHS we would predict will be significant. The length of stay is significantly increased with open repair. The National Vascular Registry (NVR) 2017[1] shows 4,153 elective aortic aneurysms were repaired in 2016. Simplistically, with open repair having an average of 8 days stay, five longer than that of EVAR, if even 70% of the EVAR population were deemed "fit" for open surgery an additional 10,000 bed days would be required of vascular services, a significant number of these in HDU or ITU facilities. This will create a burden on ITU and HDU services and hospital wards that is unrealistic at this time. [1] Waton S, Johal A, Heikkila K, Cromwell D, Boyle J, Loftus I. National Vascular Registry: 2017 Annual report. London: The Royal College of Surgeons of England, November 2017. The true picture is most likely worse by a number of factors since the cohort that underwent EVAR are likely to have significant co-morbidity and stay longer for social reasons and have even more complications, further lengthening the stay. There is a significant risk on impacting waiting times for aneurysm repair. It is quite clear that the NHS services are a long way from meeting adequate waiting times. The current situation is that most patients wait 70 days between assessment and aneurysm repair, but in many units, a significant group of patients are waiting 140 days. To dismiss the clear benefits to patient care based on the fact that EVAR ultimately fails in the longer term in a small proportion of patients is a grave error. If this philosophy was extrapolated to other health care arenas, one would then have to question the benefit of chemotherapy for cancer as some patients get recurrences and some die of metastatic disease. The concept of informed patients deciding between the upfront benefits of a more minimally invasive treatment compared with durability benefits of more invasive treatments are enshrined as patient choice considerations in many healthcare arenas. Rather than stop elective EVAR use, we must get better at selecting the patients that will benefit from EVAR, improve our ability to treat some less anatomically favourable cases with open surgery and finesse our ability to detect those patients who will not benefit from treatment by either modality. Recommending a wholesale abandonment of elective EVAR treatment is naive, unevidenced and could not be safely adopted within current UK vascular practice. The likely (perhaps unintended) consequences would be: a. An increase in AAA mortality, after years of improvement. This would be very visible within the NVR and in the public domain. b. An increase in LoS and critical care use at a time when NHS in-patient capacity is at an all-time low. c. An increase in emergency presentations from patients waiting longer for open surgery or from those turned down as 'unfit', but then present as emergencies. d. A lack of ability to treat emergency patients with EVAR as a result of reduced experience, training and consignment stock. e. A probable negative re-evaluation of the benefits of AAA screening. f. The UK being an outlier in global vascular healthcare. The lack of patient choice, potentially being a human rights infringement. g. Increased social care required on discharge for elderly patients recovering from open surgery. There will also be pressure on bed based rehab, community physio and General Practice. These services are already under pressure with no additional capacity to deal with the extra workload.

	In addition, theatre time for open surgery is double that of EVAR and the length of stay is double and this has the potential to increase the waiting time because you will be able to do the maximum of two open surgical patients a day compared to three EVARs, with a high potential for cancellation on the day because of lack of critical care capacity which will have an impact on theatre utilisation. This would make it difficult to achieve the 8 week treatment pathway recommended by GIRFT. This suggestion in the guidelines to remove the practice of elective EVAR is not in line with NHS practices of most other conditions that are seeking a minimally invasive approach and is a removal of a well-established therapy, not a recommendation on a new device. Since over 70% of patients with aneurysms are treated using EVAR in the UK, clearly there is a patient acceptance of this treatment. The impact of removing a treatment option for many patients, on and outside the screening programme cannot be understated, as many patients will be denied treatment of their aneurysm despite having it monitored for many years, expecting endovascular stent placement. There has been a significant change with surgeon level outcome reporting in the UK over the last few years, a change of practice so vivid will impact the mortality figures for most if not all the surgeons and institutions in the UK, with consequences that may well lead to significant adverse publicity, a need to investigate and retrain a number of surgeons and most likely, a reluctance to offer repair in many cases, leading to a significant turn down rate – which will overall decrease the number of patients successfully treated for aneurysm repair. The rest of the world has embraced EVAR almost universally, including in financially deplete developing countries, as they recognise the benefits of EVAR for patients who have associated co-morbidity in the short term and that with developing technology it is likely that there is a significant improvement in the results of trials performed up to 15 years ago. A move to reduce EVAR to a few patients with ruptured abdominal aortic aneurysms has an Important National Health Service reputational impact, with a message of cost saving rather than an innovative, world class service.

	At the BSET Annual Meeting on 21st June, we surveyed the attendees. The questions and responses are below: **Do you think the current NICE proposals on AAA treatment could be safely adopted in your hospital in November 2018?** Yes – 19% No – 74% Don't know – 6% **If adopted, would this lead to an increase or decrease in overall AAA mortality?** Increase – 92% Decrease – 8% **Do you think the AAA screening programme is viable if EVAR is not an option for treatment?** Yes – 50% No – 50% **Do you think patients should have the right to choose (where appropriate and with accurate information) between EVAR and open surgery?** Yes – 92% No – 8% **If you were not routinely performing elective EVAR in your hospital, would you be able to deliver an emergency EVAR service for rAAA as recommended?** Yes – 12% No – 88% **Does your hospital have enough critical care capacity to allow a switch to 100% open AAA surgery?** Yes – 5% No – 85% **Do you believe the data discussed re EVAR for IRAAA can automatically be extrapolated to complex EVAR?** Yes – 2% No – 79% Not sure – 19%

2. Would implementation of any of the draft recommendations have significant cost implications?	Implementation of these draft recommendations could potentially lead to: 1. More ward bed days used because of the use of OSR resulting in a significantly longer length of stay post operatively than EVAR 2. More critical care bed days used as an increasing number of patients will require critical care support because of the need for open surgery in all patients and the need for ventilation and temporary renal replacement therapy support (particularly for those undergoing surgery requiring a suprarenal or supracoeliac clamp). 3. Higher return to theatre rate for open surgery – increased use of emergency theatres 4. Increase cost of blood products as there is a higher blood product requirement for maximally invasive surgery 5. Reduced capacity in theatre because standard OSR takes longer than EVAR and hence decreased theatre and departmental productivity (EVAR has a lower theatre cost per time) 6. Increased cost of rehabilitation, social care and added burden to the GP and community services as open aortic surgery takes longer to recover from than EVAR and often means the patient does not reach baseline and requires ongoing support for activities of daily living for a longer period of time post operatively 7. Potentially increased number of patients presenting with ruptured AAA requiring an increased resource for emergency treatment
3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)	EVAR in 2018 is not the finished article and continues to evolve and improve. Much can be learned from where EVAR has not been so successful and it is recognised that some practice has not resulted in the outcomes hoped for: 1. Using devices outside the Instructions for Use (IFU) in unsuitable anatomy 2. The balance between profile and durability 3. Rapid adoption of sac sealing technology before sufficient evidence 4. Increasing focus on augmenting a proximal seal zone and achieving fixation, when the real problem is continual dilatation of the native neck We accept that there are flaws to current practice and that there is too much work done off IFU for EVAR, a reluctance to turn patients down for surgery and not enough open surgery for younger fitter patients. We feel that a pragmatic approach to this would be to set stricter criteria for endovascular treatment on IFU only. We would propose more stringent guidelines for controlled use of EVAR within IFU for all devices.

Comment number	**Document** (**full** version, **short** version or the **appendices**	**Page number** Or **'general'** for comments on the whole document	**Line number** Or **'general'** for comments on the whole document	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	Short	General	General	Endovascular Aneurysm Repair (EVAR) has been an option for abdominal aortic aneurysm (AAA) treatment for nearly 25 years. Over that time, devices and techniques have evolved to enable treatment in a greater proportion of patients. The research involved and relationship with industry have rightly been labelled as an excellent example of innovation with translational benefits to offer minimally invasive treatment to patients

				and increase efficiency within the wider health service. This has allowed a reduction in length of stay (LoS) and critical care use with a greater proportion of patients being discharged directly to home who then enjoy a much faster return to normality. The adoption of appropriate EVAR use has been partly responsible for a significant reduction in 30 day mortality since 2007 when Vascunet figures revealed a UK mortality of >7% compared with 2% now. This was fundamental in the development of the national AAA screening programme.
2	Short	9	179	The recommendations not to offer infrarenal EVAR are based on a "lack of long-term durability" for EVAR over open repair. Unfortunately, the evidence used to make these recommendations is fatally flawed. The mistake being made here is that the randomised trials on which the recommendations are based were never designed to look at long term durability. All of these trials had a sample size calculations based on comparing all cause mortality between EVAR and open surgery at 30 days and at a maximum 3 years where EVAR was still superior to open repair.[1] This means that longer term comparisons will be statistically dubious at best, but attrition rates were so high in these trials that 5 to 15 year comparisons between EVAR and open surgery based on these data are meaningless.[2] It is on the basis of these comparisons that the NICE committee are suggesting we actively withhold the most common treatment for infrarenal EVAR performed in the UK today.[3] The long-term results of these trials are still actively debated at scientific vascular meetings around the world, and there are strong, valid arguments over flaws in the way the long-term data are being presented and applied to modern practice.[4-6] These include: a lack of long-term complication data in the open AAA group; the fact that EVAR devices have been updated since the devices used in the early 2000's and have significantly lower complication rates;[7] and the huge updates in understanding in anatomical suitability and application of EVAR which was lacking in these trials but has led to better patient selection and therefore outcomes since. All of these are valid arguments against EVAR being inferior to open repair in the long term, but are superseded by the simple fact that these trials were not designed for long terms comparisons between EVAR and open surgery and cannot be used to withhold EVAR as a result. 1. Brown LC, Epstein D, Manca A, Beard JD, Powell JT, Greenhalgh RM. The UK Endovascular Aneurysm Repair (EVAR) trials: design, methodology and progress. Eur J Vasc Endovasc Surg. 2004 Apr;27(4):372-81. 2. 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. 3. https://www.vsqip.org.uk/reports/2017-annual-report/ 4. 1: Dubois L, Mayer D, Rancic Z, Veith FJ, Lachat M. Debate: whether endovascular repair offers a survival advantage over open repair for ruptured abdominal aortic aneurysms. J Vasc Surg. 2015 Feb;61(2):546-55. doi: 10.1016/j.jvs.2014.11.042. PubMed PMID: 25619580. 5. Mayer D, Rancic Z, Veith FJ, Lachat M. Part two: against the motion. EVAR offers no survival benefit over open repair for the treatment of ruptured abdominal aortic aneurysms. Eur J Vasc Endovasc Surg. 2015

				Feb;49(2):119-27. doi: 10.1016/j.ejvs.2014.11.016. PubMed PMID: 25662727. 6. Dubois L. Part one: for the motion. EVAR offers no survival benefit over open repair for the treatment of ruptured abdominal aortic aneurysms. Eur J Vasc Endovasc Surg. 2015 Feb;49(2):116-9. doi: 10.1016/j.ejvs.2014.11.015. PubMed PMID: 25662726. 7. Kent F, Ambler GK, Bosanquet DC, Twine CP; BSET (British Society for Endovascular Therapy). The Safety of Device Registries for Endovascular Abdominal Aortic Aneurysm Repair: Systematic Review and Meta-regression. Eur J Vasc Endovasc Surg. 2018 Feb;55(2):177-183. doi: 10.1016/j.ejvs.2017.11.013.
3	Short	10	183	Clarification is required about technical issues (rather than "anaesthetic risk and medical condition") which may make a patient unsuitable for open repair regardless of fitness - secondary aneurysms, type 1a endoleak, hostile abdomen, inflammatory aneurysms as described in the study used by NICE (and possibly SR/extent IV in most of England). This applies to standard and complex. The term "fit for operation" is important in the NICE document, since this is clearly patient, situation, anatomy and surgeon dependent. One patient who is not "fit" for open elective surgery when the aneurysm is small clearly can be "fit" for operation when the aneurysm is larger and/or tender. An important group will be those refused procedures who later develop symptoms and if EVAR is not the preferred option this group will further impact on the services of the NHS. We require clarification as to how you would assess and determine patients' fitness for surgery.
4	Short	10	189	The NHSE a4 policy document on complex recommends consideration of complex EVAR if hostile abdomen or high anticipated blood loss. Another issue is cost of open complex which appears to be less than open standard. The committee have used a Cochrane RR multiplier of 0.33 for EVAR from NVR data to estimate risk of OR. For complex, there is an error in that 3.6% increases to 10.8% with 0.33 RR multiplier and not 10.1%. The multiplier gives a mortality of 1.2% for standard open repair and 10.8% for complex open but the cost of complex is estimated at about £200 less. If technical complexity is associated with mortality 10-fold higher than infrarenal then risk of complications will be also and this will be significantly more expensive than NICE estimate. This could close the cost gap for JRAAA. For SR/extent IV, it is quite different. An SLR from LHCH in 2012 was £27000 for these which equates to £31000 in 2018. This is less than the published cost from Edinburgh where over 60% of practice is SR/IV. This more accurate assessment of cost would make complex EVAR cost effective for SR/extent IV and perhaps supravisceral clamp for JRAAA (the majority in the Edinburgh series of SR/IV did not require renal bypass/implantation so are technically very similar in terms of physiological insult). **1.5.5 and 1.5.6** Removing the option of endovascular repair would deprive patients with more extensive aneurysms of a treatment that has been found effective in large, contemporary analyses. - The GLOBALSTAR registry (BSET Collab Circulation 2012), collating data on 318 patients from 14 centres in the UK performing FEVAR for juxta renal aneurysms, found a 4% peri-operative mortality rate

				and demonstrated a primary technical success rate of 99%, and intraoperative target vessel loss of just 0.6%. Overall survival was 94%, 91% and 89% 1, 2, and 3 years respectively. - A more recent analysis of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database identified 535 patients who underwent complex (fenestrated) endovascular repair and 1207 who had open elective repair for abdominal aortic aneurysms that affected the visceral segment (Gupta et al. J Vasc Surg 2017). Outcomes for FEVAR were better than open repair with a significantly shorter length of stay (2 vs 7 days, P<0.0001), fewer respiratory complications, lower rate of renal failure requiring dialysis, fewer cardiovascular events, less major transfusion requirements and lower peri-operative mortality. - Analysis of the American College of Surgeons National Surgical Quality Improvement Program Targeted Vascular Module (Ultee et al. J Vasc Surg 2017) demonstrated a lower peri-operative mortality (3.4% vs 6.6%, P<0.05), lower respiratory, cardiac and wound complications, shorter length of ITU (1.0 vs 4.7 days, P<0.001) and hospital (4.1 vs 11.3 days, P<0.001) stays after fenestrated compared with open aneurysm repair. - We acknowledge that certain endovascular techniques proposed for complex aneurysm repair (e.g. Endoanchors, parallel stenting) may have limited follow up to show efficacy but long term data now exist for fenestrated repairs as illustrated by points above and also by superior results related to work in centralised centres of excellence. Haulon et al, for example, recently reported an 82% two year survival rate after FEVAR with a patency rate of 97% associated with renal fenestrations (Martin-Gonzalez et al. Eur J Vasc Endovasc Surg 2016). Emphasis should be placed on further centralising complex endovascular repairs into experienced centres, incorporating multi-disciplinary teams, to optimise outcomes rather than excluding this treatment all together. - The vascular community would not have equipoise to randomise patients to other endovascular or open repair of thoracoabdominal aortic aneurysm. The vast majority of patients would be unsuitable for open repair owing to anaesthetic and/or medical concerns. Representatives from high-volume UK aortic centres used the RAND appropriateness methodology to conclude that there was no clinical equipoise for treatment of suprarenal/extent IV TAAA with consensus in favour of FEVAR for patients who require supra-renal clamping at open repair and those at moderate anaesthetic/medical risk for this open repair (Cross et al Br J Surg 2012).
5	Short	11	204	NICE has not followed their scoping document by failing to provide specific advise on acute symptomatic high-risk for rupture cases which were to be assessed alongside rupture. There is one line to state the committee did not think they were any different from elective cases even though mortality in these acute cases is generally double that for elective as there is no time to assess risk and optimise.

6	Short	General	General	Implications for training the next generation of vascular surgeons That the removal of EVAR would reduce the training opportunities in endovascular skills of trainees significantly. There may be global ramifications of this that are not envisaged in terms of translatable skills from EVAR to other endovascular procedures, most obviously the skills involved in complex endografting which requires a baseline competence in EVAR. Equally there will be a significant effect on the technical skills of the operator and non technical skills of the team, and in the scenario of ruptured AAA we cannot begin to expect the same outcomes as were observed in the improve trial. Lastly there may will be effects on technical and non technical skills in endovascular intervention in other territories such as the lower limb. A potential strategy would be that of skills training on simulators and team training in theatre of fully immersive endovascular suites to maintain skills ready for the ruptured AAA case. Skills training is effective but will add a huge cost burden to the NHS if teams are to be trained regularly. We are aware that the operative skills of trainees have reduced as a result of a number of factors including the European working time directive, patient expectation, and increase in minimally invasive techniques and pressure on operating time. This will have the effect of drawing consultants to operate in pairs or teams in most units in the UK we envisage. The practice of the NVR to list individual consultant mortality figures will only strengthen this desire for dual consultants operating. This comes at a cost which is not calculated in any cost effectiveness model.
7	Short	General	General	Patient & Public Involvement It is not clear from the guidelines how much patient & public engagement has been sought in their preparation. The recommendation to not offer EVAR ignores patient choice (Key principal 4 of the NHS Constitution) and removes a treatment option available in the majority of healthcare system in the developed world. - A number of publications support the notion that patients prefer EVAR (e.g. Winterborn et al. J Vasc Surg 2009; Reise et al. EJVES 2010) - The psychological impact of being turned down for repair and impact over what could be many years of living with an aneurysm are unknown and ignored in these recommendations. The deleterious psychological effects of being diagnosed with an aneurysm are reported (Bath et al. Br J Surg 2018) A recent meeting of the Liverpool Aneurysm PPI group reported the following headlines:

				1) Patients strongly prefer to be informed of all of the treatment techniques and as detailed information as possible regarding supporting evidence. 2) Recommendation or offer of 'one best' treatment based on evidence and / or guidelines was not considered adequate counselling. 3) Patients take different choices under the same circumstances, with the same information. 4) Patients understand the importance to the NHS of treatment costs. 5) Patients expect treatment costs to play no role in selection or offer of treatments.

Insert extra rows as needed

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