NICE National Institute for Health and Care Excellence

Abdominal aortic aneurysm: diagnosis and management

Consultation on draft scope

Stakeholder comments table

25th August – 23rd September 2015

Stakeholder	Page number	Line number	Comments	Developer's response
Association of Ambulance Chief Executives	General	General	Ambulance services were originally asked to participate in the scoping workshop, but then it was cancelled. Also an ambulance/pre hospital representative is not required as part of the guideline development group. We wish to stress that consideration of the pre hospital element of this guideline is very important-see points below	Unfortunately, the stakeholder scoping workshop was cancelled by NICE due to the small numbers registered. It is hoped that stakeholders engaged with the consultation process in its place. With regards the inclusion of an ambulance/pre hospital representative, this was discussed amongst the Development team, the Commissioning team and Committee members that were recruited early to support this work. It was decided that an ambulance/pre-hospital representative would be added to the Committee's constituency.
Association of Ambulance Chief Executives	3 6	84 175 179	We suggest that this is more specific to state how far and within what time frame the patient should arrive at a specific vascular unit, depending on the condition of the patient. Also to be specific about the decision that needs to be made early on about appropriate destination and again depending how critical the patient is, which destination is best.	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under 'Management of ruptured abdominal aortic aneurysms and abdominal aortic aneurysms at high risk of rupture', 'referral and transfer to a specialist vascular unit'.
Association of Ambulance Chief Executives	1	11 13 14	We think that health care professionals (ambulance clinicians) should be specifically mentioned, as ambulance and pre hospital are neither primary or secondary care	Thank you for your comment. The following group has now been added to the 'Who the guideline is for' section of the guideline: "Other healthcare professionals, including ambulance and other prehospital clinicians."
British Society of Interventional Radiology	General	General	No comments on behalf of BSIR	Thank you.

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Department of Health	General	General	Thank you for the opportunity to comment on the draft scope for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you.
Medtronic Limited	General	General	Medtronic support the draft scope of this key clinical guideline and are happy to provide any supporting clinical evidence related to Medtronic technologies where appropriate.	Thank you.
Medtronic Limited	General	General	We support the proposal to supersede and update the TA167 recommendations into this clinical guideline. However we wish it to be noted that we do have concerns that the removal of the mandated TA may impact patient access and politely request that audit measures or quality standards are concurrently developed to ensure patient access is not unduly impacted and objective measures are in place to monitor this access and unmet need.	Thank you for your comment. The update of TA167 is still subject to the Technology Appraisal programme's review process. After consultation with stakeholders, the Technology Appraisal programme will make the final decision with regards this update. To help promote continued patient access should the decision be taken for this guideline to update TA167, this guideline will be used to develop the NICE quality standard for abdominal aortic aneurysm (see Topic section of the scope).
NHS Abdominal Aortic Aneurysm Screening Programme	1	16	vascular technologists are now known as vascular scientists	Thank you for your comment. 'Vascular technologists' has now been amended to 'vascular scientists'.
NHS Abdominal Aortic Aneurysm Screening Programme	2	54	could include as a special group patients with AAA and connective tissue disease	Thank you for your suggestion. It was discussed with the early recruited Committee members and clinical advisors, but they did not feel that connective tissue

				disease was a key comorbidity in people with abdominal aortic aneurysm (it is more associated with thoracic aortic aneurysms). Although it has not been stated in the scope as a key subgroup for whom the diagnosis and management of abdominal aortic aneurysm may vary, this does not preclude the Guideline Committee from specifying this group as a subgroup of interest for certain review questions.
NHS Abdominal Aortic Aneurysm Screening Programme	2	57	A number of colleagues have questioned why patients with isolated iliac aneurysms should be excluded; there will never be another opportunity for guidelines in their management, which could fit with the current work.	Thank you for your comment. Unfortunately, isolated iliac aneurysms do not fall within the remit of the referral made by the Department of Health to NICE.
NHS Abdominal Aortic Aneurysm Screening Programme	5	150	NAAASP has timelines for assessment and treatment (2 weeks to outpatient assessment; 8 weeks to intervention) that are Programme standards endorsed by the VSGBI. The GDG will obviously need to consider whether these targets should be extended to all people with large AAA, not just screen-detected AAA.	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under 'Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and surgical, including perioperative, management'. Those whose aneurysm is not detected by the screening programme will be proposed as subgroup in all relevant reviews.
NHS Abdominal Aortic	5	148	Men in NAAASP are referred for intervention once their	Thank you for this information. This topic is captured

Aneurysm Screening Programme			AAA reaches 5.5cm in diameter (evidence based from the Small Aneurysm Trial). Is this the optimal threshold, or as some are suggesting, can risk be individualised, rather than having an arbitrary size.	in section 1.3, 'Key areas that will be covered', under '*Management of unruptured abdominal aortic aneurysms*', '*planning of surgery, taking into account aneurysm size*, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and surgical, including perioperative, management'.
NHS Abdominal Aortic Aneurysm Screening Programme	12	306	NAAASP is in discussion with the National Screening Committee to change surveillance intervals for small and medium aneurysms.	Thank you for this information.
NHS England	General	General	Thank you for the opportunity to comment on the above Clinical Guideline. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.	Thank you.
Royal College of Emergency Medicine	General	General	We agree with the scope of the guideline. The questions to be answered in relation to care pre-hospital and in Emergency Departments seem sensible.	Thank you.
Royal College of Emergency Medicine	5	133 -158	Unruptured aneurysm – should this include the suggested lead time expected from discovery of an aneurysm (by GP, ED or other clinician) to the time that the patient should be seen by a vascular specialist to then plan surveillance vs operative repair etc?	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under 'Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and surgical, including

				perioperative, management'. However, it should be noted that its final inclusion will be confirmed by Guideline Committee, with whom your comment will be shared.
Royal College of Emergency Medicine	6	159 -187	Most relevant for Emergency Medicine – nothing to add.	Thank you.
Royal College of General Practitioners	3	67	Management of asymptomatic abdominal aortic aneurysm in primary care needs consideration and a review of the recall systems that are available to primary care doctors throughout England. Clinical areas not covered by the quality outcomes framework for a directly enhanced service are difficult to monitor within the practice without a clearly defined audit such as those provided by HQIP for chronic kidney disease. Recall systems primary-care Information Systems are difficult to use effectively and needs further investigation.	Thank you for your comment. With regards the management of asymptomatic abdominal aortic aneurysms, the scope covers the following topics: • the monitoring of aneurysm growth and risk of rupture, • which non-surgical interventions should be used to reduce the rate of aneurysm growth and reduce the risk of rupture, and • the planning of elective surgical intervention. Recall systems will not be covered in the guideline. With regards the production of audit criteria, it is planned that the guideline will also be used to develop the NICE quality standard for abdominal aortic aneurysm. The other issues raised – recall and information systems in primary care – were discussed amongst the Development team, the Commissioning team and the early recruited Committee members, but it was

				felt that these are issues that extend beyond the topic of 'Abdominal aortic aneurysm: diagnosis and management'.
Royal College of General Practitioners	3	87	Whilst post-operative care is in the scope of this consultation there is no consideration for post-operative care within primary care and management of cardiovascular risk factors.	This topic is captured in section 1.3, 'Key areas that will be covered', "Postoperative care' under 'interventions to reduce the risk of postoperative complications in people who have had surgery for an abdominal aortic aneurysm, including antithrombotics."
Royal College of Nursing	General	General	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above draft scope consultation at this time. Thank you for the opportunity. We look forward to participating in the next stage of development.	Thank you.
Royal College of Physicians and Surgeons of Glasgow	General	General	The College supports the scope of this guideline, while noting that it is extensive and will require a considerable amount of work to address all the issues raised. We do not have any further comments or issues.	Thank you.
Vascular Anaesthesia Society of Great Britain & Ireland	General	General	The Vascular Society "Framework for improving the results of elective AAA repair" requires that all elective patients are assessed by an anaesthetist with a vascular anaesthetic practice and that appropriate mechanisms are in place to transmit the outcome of this assessment to the vascular MDT (multidisciplinary team).	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under '*Management of unruptured abdominal aortic aneurysms*', 'planning of surgery, taking into account aneurysm size, *preoperative risk assessment to determine whether surgery is suitable for a person*,

			Arrangements to achieve this vary widely across the UK and include anaesthetic attendance at the MDT, the provision of written reports, and more informal arrangements. The VASGBI suggests that it may be useful to include guidance on this aspect of care.	preoperative imaging, and surgical, including perioperative, management'.
Vascular Anaesthesia Society of Great Britain & Ireland	General	General	There is evidence of an increased incidence of sexual dysfunction in men following AAA repair. NICE may wish to include this amongst the outcomes considered.	Thank you for this information. The 'incidence of adverse events or complications' – a relatively broad groups of outcomes in which postoperative sexual dysfunction would fall – is listed as a key outcome of interest under section 1.6, 'Main outcomes'. It will be discussed with the Guideline Committee when agreeing the review protocols for AAA repair.
Vascular Anaesthesia Society of Great Britain & Ireland	General	General	The Vascular Society "Framework for improving the results of elective AAA repair" requires that patients are managed intraoperatively by an anaesthetist with an established vascular practice. There are observational data to support improved outcomes from vascular surgery when care is delivered by a vascular anaesthetist. NICE may wish to include this aspect of care in their guidance	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under '*Management of unruptured abdominal aortic aneurysms*', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and *surgical, including perioperative, management*'.
Vascular Anaesthesia Society of Great Britain & Ireland	General	General	There is no mention of anaesthetic technique – patient choices between GA and regional and local anaesthetic based on best clinical options should be considered. Data regarding the most appropriate anaesthetic	This is included under the 'Key issues and questions' (section 1.5) for 'Management of ruptured abdominal aortic aneurysms and abdominal aortic aneurysms at high risk of rupture':

			technique for both elective and emergency EVAR are not absolutely conclusive and further studies are in progress. Nevertheless, some units and practitioners have strongly held views on this matter and NICE may wish to include this aspect of care in the guidance.	"What perioperative care (including *anaesthetic management*, or the use of statin therapy or antithrombotic drugs) is effective in improving outcomes during surgical repair of ruptured abdominal aortic aneurysms?" It has now also been included under the 'Key issues and questions' for 'Management of abdominal aortic aneurysms': "What perioperative care (including *anaesthetic management*, or the use of statin therapy or antithrombotic drugs) is effective in improving outcomes during surgery for unruptured abdominal aortic aneurysms?"
Vascular Anaesthesia Society of Great Britain & Ireland	General	General	The VASGBI is aware that the MHRA has published guidance on delivering an endovascular aneurysm repair service (Joint working group to produce guidance on delivering an endovascular aneurysm repair (EVAR) service, 2010) and suggests that of location of endovascular repair should be considered e.g. operating theatres, hybrid suites?	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under: - 'Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and surgical, including perioperative, management'. - 'Management of ruptured abdominal aortic aneurysms and abdominal aortic aneurysms at

				high risk of rupture', 'specialist care, including emergency surgical intervention and perioperative management'
Vascular Anaesthesia Society of Great Britain & Ireland	1	11 -28	Specific inclusion of haematology services and their critical role in judicious provision of advice and blood products during emergency AAA should be included. NICE may wish to consider.	Thank you for this information. This topic is captured in section 1.3, 'Key areas that will be covered', under: - 'Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and surgical, including perioperative, management'. - 'Management of ruptured abdominal aortic aneurysms and abdominal aortic aneurysms at high risk of rupture', 'specialist care, including emergency surgical intervention and perioperative management' There is, however, new NICE guidance (anticipated to be published in February 2016) on the assessment and management of airway, breathing and ventilation, circulation, haemorrhage and temperature control in major trauma which considers, for example, the use of haemostatic agents, therapeutic anticoagulation, and volume resuscitation

				and fluid replacement strategies. If this topic is not explicitly reviewed in the evidence reviews for the AAA guideline, it will fall out of good care principles.
Vascular Anaesthesia Society of Great Britain & Ireland	2	32 -36	With regard to equality, the issue of treatment of screen detected aneurysms in patients over 85 years of age is noted as a concern in the scoping document. As elective AAA repair is a prophylactic procedure to prevent rupture rather than a curative procedure the questions of life expectancy and health adjusted quality of life with and without intervention are thrown into especially sharp relief. The Society suggests that that the guidance should consider the role of tools to inform this calculation (including but not limited to CPET)	'Preoperative risk assessment to determine whether surgery is suitable for a person' is listed as a 'Key area that will be covered' under 'Management of unruptured abdominal aortic aneurysms'. However, it should be noted that the use of CPET for routine preoperative assessment is covered in the update of the NICE preoperative tests guideline. The Guideline Committee will take this into consideration when developing the review protocols for how preoperative risk assessment should be conducted, and when reviewing any appropriate evidence. People over 85 years of age will be considered as a subgroup for this review area.
Vascular Anaesthesia Society of Great Britain & Ireland	5	128	When considering risk assessment for AAA the society consider that the work of [redacted] should be considered. He has written extensively on quantifying specific mortality risk for individual patients with AAA compared with their age related mortality risk derived from Age–Standardised Mortality Rates produced by the UK Office for National Statistics. Specific insights arising	Thank you for this information. The Guideline Committee will appraise and consider any published data that meets the inclusion and exclusion criteria specified for each review, including any reviews conducted on risk factors for AAA, and risk factors for aneurysm growth and risk of rupture. These topics are captured in section 1.3, 'Key areas that will be covered', under:

			from his work include evidence that current data no longer support established treatment thresholds for elective repair of AAA e.g. an aneurysm diameter of 5.5 cm in men. A reanalysis of data from studies of aneurysm management in the light of contemporary risk stratification models suggests that repair of smaller aortic aneurysms may be appropriate in low risk patients.	• "identifying people with abdominal aortic aneurysms", "signs, symptoms and risk factors that might indicate imaging for abdominal aortic aneurysms" • "management of unruptured abdominal aortic aneurysms", "checking for aneurysm growth and risk of rupture" and "planning of surgery, taking into account aneurysm size"
Vascular Anaesthesia Society of Great Britain & Ireland	5 -6	128 153	The role of preoperative physiological testing in the anaesthetic assessment of AAA patients for elective surgery should be considered. Preoperative cardiopulmonary exercise testing (CPET) is used in the preoperative anaesthetic assessment of AAA patients in many centres. Results from CPET tests are used to aid the estimation of both perioperative risk and long-term survival in the absence of AAA rupture.	Thank you for your comment. This topic is captured in section 1.3, 'Key areas that will be covered', 'Management of unruptured abdominal aortic aneurysms' under 'planning of surgery, taking into account aneurysm size, *preoperative risk assessment to determine whether surgery is suitable for a person*, preoperative imaging, and surgical, including perioperative, management'. However, it should be noted that the use of CPET for routine preoperative assessment is covered in the update of the NICE preoperative tests guideline. The Guideline Committee will take this into consideration when developing the review protocols for how preoperative risk assessment should be conducted, and when reviewing any appropriate evidence.
Vascular Anaesthesia	6	182	What type of surgery is most effective: There is no	Thank you for your comment. This topic is captured

Society of Great Britain & Ireland	10	183 254	mention of conservative treatment - When considering treatment options for elective and emergency AAA, the society consider that 'decision not to treat' should also be discussed and be put forward as a reasonable option.	in section 1.3, 'Key areas that will be covered', under 'Management of unruptured abdominal aortic aneurysms', 'non-surgical interventions to reduce the rate of aneurysm growth and reduce the risk of rupture, including drug therapy and risk factor management." It can also be considered an outcome under 'Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, *preoperative risk assessment to determine whether surgery is suitable for a person*, preoperative imaging, and surgical, including perioperative, management." And an option/comparator under "Management of unruptured abdominal aortic aneurysms', 'planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, and *surgical*, including perioperative, management'.
Vascular Anaesthesia Society of Great Britain & Ireland	7	General	There is wide variation in the provision of postoperative care for elective EVAR patients ranging from the use of HDU care for a significant proportion of cases to early experience with day case EVAR in some centers. NICE	Thank you for your comment. This topic is captured in section 1.3, 'Key areas that will be covered', under 'Postoperative care'. However, it should be noted that its final inclusion will be confirmed by Guideline

			may wish to consider this aspect of care in the guidance	Committee, with whom your comment will be shared.
Vascular Anaesthesia Society of Great Britain & Ireland	13	336 -338	Line 336-338 suggests that there is no place for EVAR in ruptured AAA however, the IMPROVE study and clinical experience would suggest otherwise and endovascular repair in this setting is now established practice.	This text is intended to be a summary of current practice as dictated by current guidance. However, the use of EVAR in emergency surgical intervention for ruptured abdominal aortic aneurysms will be reviewed in the proposed guidance.
W.L. Gore and Associates Limited	General	General	Gore has recently introduced two new Endovascular Medical Devices, as part of their abdominal aortic portfolio, GORE(R) EXCLUDER(R) AAA Endoprosthesis featuring C3(R) Delivery System and GORE(R) EXCLUDER(R) Iliac Branch Endoprosthesis for the treatment of abdominal aortic aneurysms, common iliac aneurysms and aorto-iliac anurysms. Gore is able to provide useful data into the process of creating new NICE Clinical and Interventional Procedures, both related to the long term performances of the GORE(R) EXCLUDER(R) AAA Endoprosthesis and to the short and mid term results of the above mentioned newer devices. This comprises of and is not limited to, results of the real-world prospective multicenter registry GREAT (Global Registry for Endovascular Aortic Treatment), US IDE clinical study, single Arm case studies and observational studies.	Thank you for this information. The Guideline Committee will appraise and consider any published data that meets the inclusion and exclusion criteria specified for each review. Specific devices may be mentioned in the evidence reviews but the recommendations will be generic, as is standard practice in NICE guidelines.
W.L. Gore and Associates	2	55	Please could you provide a description of type I, II, III or	Thank you for your comment. Definitions of these

Limited		56 57	V thoracoabdominal aneurysms, thoracic aortic aneurysms, or isolated iliac aneurysms. The description of these aneurysms vary by organisation and it would be good to have a definition provided.	terms will be provided within the glossary of the guideline. Although it was noted that the nomenclature in describing these aneurysms is not always consistent in the evidence, the Development team and the early recruited Committee members did not feel that their definition was sufficiently disputed to cause uncertainty over the anatomical parameters of an abdominal aortic aneurysm in the proposed guidance.

Registered stakeholders: http://www.nice.org.uk/guidance/indevelopment/gid-cgwave0769/documents