NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Abdominal aortic aneurysm: diagnosis and management

Topic

The Department of Health in England has asked NICE to develop a clinical guideline on abdominal aortic aneurysm.

This guideline will also be used to develop the NICE quality standard for abdominal aortic aneurysm.

Who the guideline is for

- People using services, families and carers and the public.
- Healthcare professionals in primary care.
- Healthcare professionals in secondary care, including:
  - vascular specialists, including clinicians, surgeons, nurses and technologists
  - anaesthetists
  - radiologists
  - care of the elderly clinicians
  - generalist clinicians and surgeons
  - emergency care physicians.
- Commissioners and providers of services, including:
  - specialist vascular services
  - surgical services
  - anaesthesia services
  - radiology services
  - emergency departments
  - ambulance services.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment [add hyperlink in final version] during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope, if this was done.

1 What the guideline is about

1.1 Who is the focus?

Groups that will be covered

- People with an increased risk of an abdominal aortic aneurysm (abdominal aortic aneurysm will be defined as infrarenal aortic aneurysms, juxtarenal aortic aneurysms, suprarenal aortic aneurysms and type IV thoracoabdominal aneurysms, as well as aortoiliac aneurysms).
- People with a suspected or confirmed abdominal aortic aneurysm (including ruptured and symptomatic unruptured).
- Specific subgroups for whom the diagnosis and management of abdominal aortic aneurysm may vary and for whom subgroup or separate analyses will be considered. These may include, but are not limited to:
  - women
  - people with comorbidities when the comorbidity (or management of that comorbidity) may affect the diagnosis or management of an abdominal aortic aneurysm, including people with other cardiovascular conditions, people with obesity, people who smoke and people nearing the end of life.

Groups that will not be covered

- People with type I, II, III or V thoracoabdominal aneurysms, thoracic aortic aneurysms, or isolated iliac aneurysms.

1.2 Settings

Settings that will be covered

- All settings in which NHS-funded care is received.

1.3 Activities, services or aspects of care

Key areas that will be covered

1 Identifying people with abdominal aortic aneurysms:
   - signs, symptoms and risk factors that might initiate imaging for abdominal aortic aneurysms
   - imaging of abdominal aortic aneurysms

2 Management of asymptomatic unruptured abdominal aortic aneurysms:
   - checking for aneurysm growth and risk of rupture, including how often this happens and the type of imaging used
   - non-surgical interventions to reduce the rate of aneurysm growth and reduce the risk of rupture, including drug therapy and risk factor management
   - planning of surgery, taking into account aneurysm size, preoperative risk assessment to determine whether surgery is suitable for a person, preoperative imaging, interventions to reduce potential complications and the type of surgery used

3 Management of symptomatic unruptured abdominal aortic aneurysms and ruptured abdominal aortic aneurysms:
   - signs, symptoms and risk factors that could indicate a ruptured abdominal aortic aneurysm
   - prehospital care, including permissive hypotension
   - care and investigations in the emergency department, including imaging
   - referral and transfer to a specialist vascular unit
   - specialist care, including emergency surgical intervention and perioperative management

4 Postoperative care:

- monitoring aneurysm growth or rupture in people who have had surgery for an abdominal aortic aneurysm, including how often this happens and the type of imaging used
- checking for complications in people who have had surgery for an abdominal aortic aneurysm, including how often this happens and the type of imaging used
- interventions to reduce the risk of postoperative complications in people who have had surgery for an abdominal aortic aneurysm, including antithrombotics
- management of postoperative complications

5 Service organisation:

- volume-outcome relationships in the provision of surgery

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Areas that will not be covered

1 Prevention of abdominal aortic aneurysm:

- management of risk factors for abdominal aortic aneurysm in those without a suspected or confirmed abdominal aortic aneurysm

2 Identifying people with abdominal aortic aneurysm:

- population screening for abdominal aortic aneurysm

1.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses. The reference case used will be that for interventions with health outcomes in NHS settings; therefore the preferred unit of effectiveness will be

the quality-adjusted life year (QALY), and costs will be considered from an NHS and personal social services (PSS) perspective.

1.5 Key issues and questions

While writing this scope, we have identified the following key issues, and key questions related to them:

1 Identifying people with abdominal aortic aneurysms:

- Which signs, symptoms and risk factors (or combinations of these) are most accurate in predicting the presence of an abdominal aortic aneurysm?
- What is the effectiveness of available risk assessment tools?
- In addition to ultrasound, or in cases in which the aortic diameter cannot be seen using ultrasound, which imaging techniques are the most useful in confirming the presence of an abdominal aortic aneurysm?

2 Management of unruptured abdominal aortic aneurysms:

- What are the key comorbidities experienced by people with an abdominal aortic aneurysm, and how will this affect the management of their abdominal aortic aneurysm?
- How often should people with an unruptured abdominal aortic aneurysm be monitored?
- Which imaging techniques are most useful when monitoring people with an unruptured abdominal aortic aneurysm? In particular, which are most useful in the assessment of the risk of rupture and the suitability of the aneurysm for surgery?
- What risk factors are associated with abdominal aortic aneurysm growth and rupture?
- Which non-surgical interventions (including drug therapy and risk factor management) are effective in preventing growth and rupture in people with unruptured abdominal aortic aneurysms?
- What is the effectiveness of early surgical intervention compared with a ‘watchful waiting’ approach in people with unruptured abdominal aortic aneurysms?

- Which factors predict poor and good surgical outcomes in people with unruptured abdominal aortic aneurysms?
- What is the effectiveness of available risk assessment tools?
- Which type of surgery is most effective in repairing unruptured abdominal aortic aneurysms?
- What additional interventions (including statin therapy or the use of antithrombotic drugs) are effective in improving outcomes during surgery for unruptured abdominal aortic aneurysms?

3 Management of ruptured abdominal aortic aneurysms:

- Which signs, symptoms and risk factors (or combinations of these) are most accurate in indicating the presence of a ruptured abdominal aortic aneurysm?
- What is the effectiveness of available risk assessment tools?
- What interventions, such as permissive hypotension, can be used before a person with a suspected ruptured abdominal aortic aneurysm reaches the hospital to increase their chance of survival or improve the stability of their condition?
- What interventions can be used once a person with a suspected ruptured abdominal aortic aneurysm reaches the emergency department to increase their chance of survival or improve the stability of their condition?
- What investigations, including imaging, should the emergency department use in a person with a suspected ruptured abdominal aortic aneurysm?
- Which factors predict poor and good outcomes in the transfer of people with ruptured abdominal aortic aneurysms, and therefore indicate which people are stable enough for transfer to a specialist vascular unit?
- What interventions, facilities or staffing improve outcomes in the transfer of people with ruptured abdominal aortic aneurysms to a specialist vascular unit?
- Which type of surgery is most effective in repairing ruptured abdominal aortic aneurysms?

- What perioperative care (including type of anaesthesia, or statin therapy or the use of antithrombotic drugs) is effective in improving outcomes during surgical repair of ruptured abdominal aortic aneurysms?

4 Postoperative care:

- How frequently should people be monitored for postoperative complications, further aneurysm growth and aneurysm rupture after surgical repair of an abdominal aortic aneurysm?
- When checking people after they have had surgical repair of an abdominal aortic aneurysm, which imaging techniques are most useful for detecting postoperative complications, further aneurysm growth and aneurysm rupture?
- What interventions (including statins or antithrombotic drugs) are effective in reducing the risk of complications after surgical repair of an abdominal aortic aneurysm?
- How should complications, including endoleak and stent kinking or migration, be managed if they do arise?

5 Service organisation:

- Do hospitals with a higher volume of surgeries per year have better surgical outcomes?

1.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1 Diagnostic accuracy (sensitivity, specificity, positive and negative predictive values)
2 Mortality
3 Rate of aneurysm growth
4 Incidence of rupture
5 Incidence of adverse events or complications
6 Acceptability of approach to patients
7 Health-related quality of life
8 Resource use and cost

2 Links with other NICE guidance and NICE Pathways

2.1 NICE guidance

NICE guidance that will be updated by this guideline

- Endovascular stent–grafts for the treatment of abdominal aortic aneurysms (2009) NICE technology appraisal guidance 167

  It is proposed that this guideline will update all recommendations from TA167.

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to abdominal aortic aneurysm:

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76
- Surgical site infection: prevention and treatment of surgical site infection (2008) NICE guideline CG74

NICE guidance in development that is closely related to this guideline

NICE is currently developing the following guidance that is closely related to this guideline:

- Endovascular aneurysm sealing (EVAS) for abdominal aortic aneurysm. NICE interventional procedure guidance. Publication date to be confirmed.

2.2 NICE Pathways

NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

When this guideline is published, the recommendations will be added to a new NICE pathway. Other relevant guidance will also be added to the pathway, including:

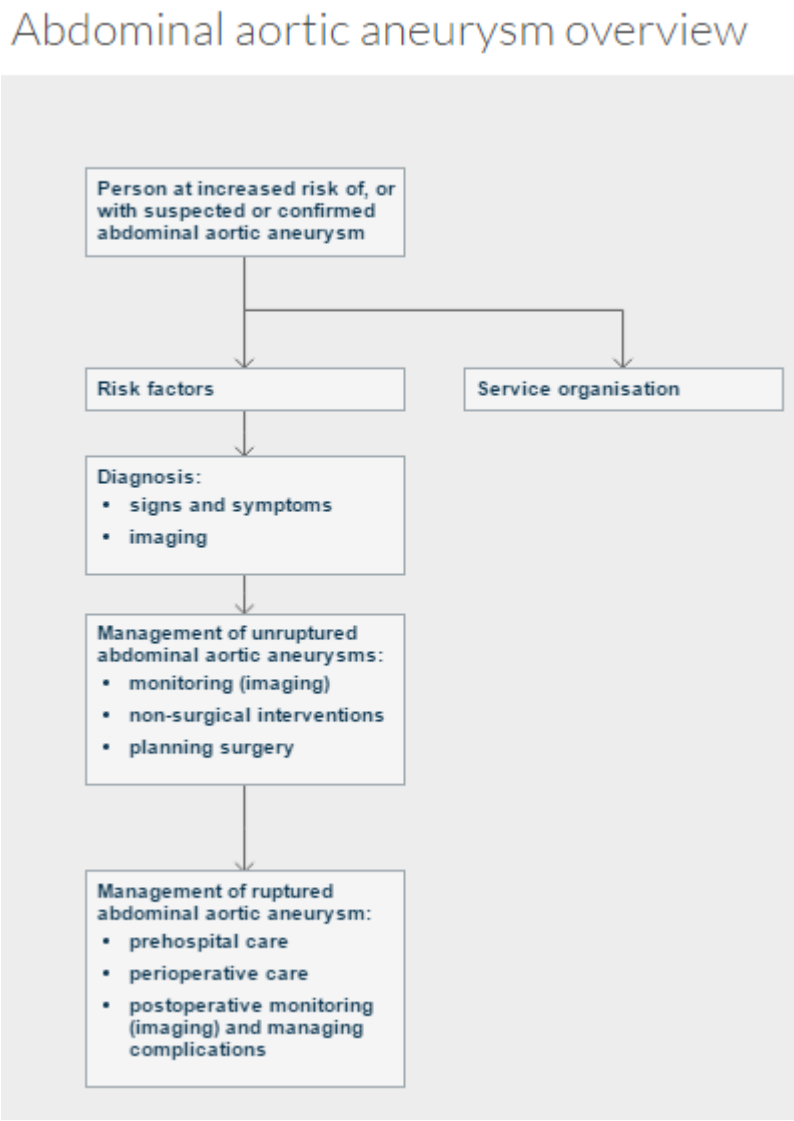
- Endovascular stent–grafts for the treatment of abdominal aortic aneurysms (2009) NICE technology appraisal guidance 167

- Laparoscopic repair of abdominal aortic aneurysm (2007) NICE interventional procedure guidance 229

- Stent-graft placement in abdominal aortic aneurysm (2006) NICE interventional procedure guidance 163

The new pathway will update and replace the existing section on abdominal aortic aneurysms in the pathway on aortic aneurysms.

A draft pathway outline, based on the draft scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.



3 Context

3.1 Key facts and figures

Aortic aneurysms develop when the wall of the aorta weakens, causing it to bulge and form a balloon-like projection. When this weakening and expansion of the aorta occurs in the abdomen and reaches a diameter at least 1.5 times the normal diameter of the aorta, or greater than 3 cm diameter in total, the condition is known as an abdominal aortic aneurysm.

Further stretching of the wall of the aorta and an increase in tension may eventually lead the wall of the aneurysm to rupture. If people with a ruptured aneurysm do not quickly get emergency surgical repair, the subsequent

internal bleeding is fatal in approximately 80% of cases; even when they have emergency surgery, only about half survive beyond 30 days. This compares with a postoperative mortality rate in high-quality vascular services of around 2% following planned surgery.

Before reaching this life-threatening state there is a long period of often subclinical growth in the diameter of the aneurysm, estimated at a mean of 2.3 mm/year in small aneurysms (those between 3.0 and 4.4 mm in diameter). Symptoms that can occur as an aneurysm enlarges include a pulsating sensation in the abdomen, and back and/or abdominal pain, although the majority of abdominal aortic aneurysms are asymptomatic.

Growth and rupture rates increase significantly as the diameter of the aneurysm expands. For each 0.5 cm increase in aneurysm diameter, growth rates increase by about 0.5 mm/year and rupture rates double. The rate of aortal growth may depend on a number of factors, including increasing age, smoking, blood pressure and a family history of aneurysm.

Because most abdominal aortic aneurysms are asymptomatic, it is difficult to estimate their prevalence; however, screening studies in the UK have estimated a prevalence of between 1.3 and 12.7% depending on the age group studied and the definition used. They occur most frequently in men over the age of 65, amongst whom there are around 3000 deaths each year in England and Wales because of rupture. Abdominal aortic aneurysms account for around 1.7% of all deaths in men aged 65 and over.

Although the incidence of abdominal aortic aneurysms is approximately 6 times lower in women, the rate of aneurysm rupture is significantly higher, highlighting the need for careful consideration of this population in the proposed guidance.

3.2 Current practice

Abdominal aortic aneurysms are often asymptomatic. Self-referral for assessment is therefore rare, and most diagnoses occur either through

targeted screening of high-risk individuals or by chance during clinical investigations (for example, ultrasound or X-ray) for other conditions.

In 2009, the National Screening Committee began rollout of the NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) for the detection of abdominal aortic aneurysms in men over the age of 65, inviting them for an ultrasound scan during the year they turn 65. Men over the age of 65 are welcome to self-refer themselves for screening as part of the NAAASP, though do not receive a direct invite to do so by the scheme. Currently, the programme does not offer screening to women or to men younger than 65.

Management of an abdominal aortic aneurysm depends primarily on its size. Under the NAAASP, no further scans are planned following a normal ultrasound (that is, an aortal diameter of less than 3 cm). Small and medium aneurysms (that is, aortal diameters of 3.0 to 4.4 cm and 4.5 to 5.4 cm, respectively) lead to conservative management. This involves regular surveillance scans to check for growth of the aneurysm; for small aneurysms a follow-up will be arranged in 1 year, and for medium aneurysms a follow-up will be arranged in 3 months. Conservative management may also include recommending lifestyle changes (such as stopping smoking, taking regular exercise, losing weight or improving the diet) or medicines (such as statins, aspirin or blood pressure medications) to reduce the chance of the aneurysm expanding or rupturing.

If the aorta reaches a diameter of 5.5 cm (a large aneurysm), a patient will be referred to a vascular surgeon because the risk of the aneurysm rupturing is now considered to be greater than the risk of having it surgically repaired. Conventional (open) surgical repair involves making a large incision in the abdomen, removing the damaged section of the aorta and inserting a prosthetic graft. It can also be performed laparoscopically. Alternatively, endovascular aneurysm repair is a minimally invasive technique in which a stent-graft is inserted through a small incision in the groin, and anchored to the wall of the aorta under X-ray guidance.

In current UK clinical practice, the decision to have surgery and the choice of surgical intervention is based on aneurysm size and morphology, patient age, fitness for surgery, and the short- and long-term benefits, as well as the risks, of the procedures. Potential advantages of endovascular aneurysm repair over open repair include a reduced time under general anaesthesia, elimination of the pain and trauma associated with major abdominal surgery, a reduced length of stay in the hospital and intensive care unit, and reduced blood loss. Potential disadvantages include a greater possibility that additional surgery may be needed because of slipping or dislodging of the stent-graft and the development of endovascular leaks (endoleaks).

Patients with a symptomatic aneurysm need rapid medical intervention as it may be an indicator of imminent rupture. In these cases, and in particular when rupture occurs, emergency surgical repair may be needed. The use of endovascular aneurysm repair is not currently recommended in the treatment of ruptured abdominal aortic aneurysms.

After either elective or emergency surgery, follow-up checks and management - including both lifestyle and medical management - are important in ensuring that further aneurysm growth or risk of rupture is minimised.

3.3 Policy, legislation, regulation and commissioning

NHS Abdominal Aortic Aneurysm Screening Programme (2011) Essential elements in developing an abdominal aortic aneurysm (AAA) screening and surveillance programme

NHS Commissioning Board (2013) Clinical Commissioning Policy: Complex Endovascular Stent Grafts in Abdominal Aortic Aneurysm

NHS England (2013) A04/S/a 2013/14 NHS Standard contract for specialised vascular services (adults)

Public Health England (2013) Cross-border operational protocol: NHS Abdominal Aortic Aneurysm Screening Programme and Wales Abdominal Aortic Aneurysm Screening Programme

Public Health England (2014) Ultrasound equipment quality assurance guidance: guidance for abdominal aortic aneurysm screening providers

Public Health England (2014) Non-visualised aortas: guidance for local AAA screening programmes in the management of non-visualised screening results

Public Health England (2014) NHS Abdominal Aortic Aneurysm Screening Programme: guidance for monitoring of waiting times standards

Public Health England (2014) NHS public health functions agreement 2015-16 Service specification No.23: NHS Abdominal Aortic Aneurysm Screening Programme

Public Health England (2015) Guidance for the validation of annual pathway standards: abdominal aortic aneurysm screening programme

Public Health England (2015) Protocol for reporting deaths: process for AAA screening programmes

Public Health England (2015) Pathway Standards for NHS Abdominal Aortic Aneurysm Screening Programme

Royal College of Radiologists (2012) Best practice guidelines for the management and transfer of patients with a diagnosis of ruptured abdominal aortic aneurysm to a specialist vascular centre

Vascular Society (2011) Framework for improving the results of elective AAA repair

4 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 25 August to 22 September 2015.

The guideline is expected to be published in October 2017.

You can follow progress of the guideline. [Hyperlink ‘guideline’ to its web

page.]

[After consultation, delete the first paragraph above and replace it with 'This is the final scope, incorporating comments from registered stakeholders during consultation'.]

Our website has information about how NICE guidelines are developed.