Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment of abdominal aortic aneurysm (AAA) screening for men

Draft report for public consultation

1 May 2025

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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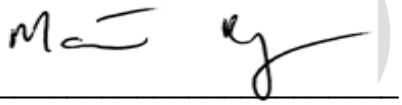
Foreword

The National Screening Advisory Committee (NSAC), established in 2019 by the Minister for Health, serves as an independent advisory body and plays a strategic role in the development and consideration of population-based screening programmes in Ireland. The role of the NSAC is to provide advice to the Minister for Health and the Department of Health on new screening proposals and proposed changes to existing screening programmes. At the request of the Department of Health, the Health Technology Assessment (HTA) directorate within the Health Information and Quality Authority (HIQA) undertakes evidence synthesis and provides evidence-based advice to NSAC on behalf of the Minister for Health.

Abdominal Aortic Aneurysm (AAA) is the abnormal widening and rupture of the abdominal aorta. This condition often develops slowly and without symptoms, making detection difficult. In the absence of screening, AAA is typically diagnosed incidentally or as a medical emergency, following rupture. A ruptured AAA is a life-threatening event, with a high mortality rate, even with emergency surgery. Given the asymptomatic nature of the disease and the severe consequences of rupture, early detection through screening could provide important benefits, namely a reduction in AAA-related morbidity and mortality. Detection of AAA can be carried out using a simple, non-invasive ultrasound scan, which measures the diameter of the abdominal aorta. Once identified, AAAs may be managed through surveillance and or elective surgery.

Work on the HTA was undertaken by an Evaluation Team from the HTA Directorate in HIQA. A multidisciplinary Expert Advisory Group was convened to advise the Evaluation Team during the course of the HTA. HIQA would like to thank the Evaluation Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.



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- Dr Aoife O'Connell, Specialist Registrar in Public Health Medicine.

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The membership of the EAG was as follows:

Ms Mary Barry	Consultant Vascular Surgeon, St Vincent's Hospital (National Clinical Programme for Surgery)
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Conflicts of interest

Consultants and staff from the St. James's Vascular Department, including Mr Prakash Madhavan, were involved in a screening project in 2024 with industry involvement. Medtronic covered the cost of the event facilities, but no direct financial contributions were received.

No other potential conflicts of interest were reported by members of the Expert Advisory Group or HIQA's evaluation team.

List of abbreviations used in this report

AAA	Abdominal aortic aneurysm
BIA	Budget impact analysis
CEA	Cost effectiveness analysis
CHEC-list	Consensus on Health Economics Criteria
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CPD	Continuous professional development
CPI	Consumer price indices
CPRD	Clinical Practice Research Datalink
CSO	Central Statistics office
CT	Computed tomography
CTA	Computed tomography angiography
CUA	Cost utility analysis
DRGs	Diagnosis related groups
DRL	Diagnostic reference levels
EAG	Expert Advisory Group
ESVS	European Society for Vascular Surgery
EU	European Union
EVAR	Endovascular repair of abdominal aneurysm
GASP	Gloucestershire Aneurysm Screening Programme
GBD	Global Burden of Disease
GDPR	General Data Protection Regulation
GP	General practitioner
GPACD	General Practitioner Access to Community Diagnostics
HADS	Hospital Anxiety and Depression Scale
HDL	High-density lipoprotein
HIPE	Hospital InPatient Enquiry
HIQA	Health Information and Quality Authority
HPO	Healthcare pricing office
HR	Hazard ratio
HRQoL	Health-related quality of life
HSE	Health Service Executive
HTA	Health Technology Assessment
ICD-10	International Classification of Diseases 10th Revision
ICER	Incremental cost-effectiveness ratio
ICT	Information and communication technology
ICU	Intensive care unit
IHD	Ischemic heart disease
IIRRT	Irish Institute of Radiography and Radiation Therapy
IQR	Interquartile range

ISPOR	International Society for Pharmacoeconomics and Outcomes Research
ISRCTN	International Standard Randomised Controlled Trial Number
ITI	Inner to inner
KPI	Key performance indicator
LDL	Low-density lipoprotein
LELE	Leading edge to leading edge
LYG	Life year gained
MASS	Multicentre Aneurysm Screening Study
MRI	Magnetic resonance imaging
mSv	Millisieverts
NAAASP	National Health Service AAA Screening Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIPH	Norwegian Institute of Public Health
NSAC	National Screening Advisory Committee
NSS	National Screening Service
NTPF	National Treatment Purchase Fund
OECD	Organisation for Economic Co-operation and Development
OR	Odds ratio
OSR	Open surgical repair
OTO	Outer to outer
OWSA	One-way sensitivity analysis
PICO	Population, intervention, comparator, outcome framework
POCUS	Point-of-care ultrasound
PPI	Patient and public involvement
PPP	Purchasing power parities
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
PRSI	Pay related social insurance
PSA	Probabilistic sensitivity analysis
QA	Quality assurance
QALY	Quality-adjusted life year
QoL	Quality of life
RCT	Randomised controlled trial
RR	Relative risk
SD	Standard deviation
SENSE	St. JamEs and MidlaNds AneurySm ScreEning Project
SES	Socioeconomic status
UK	United Kingdom
US	United States
USPSTF	United States Preventive Services Task Force

VAT	Value added tax
VSGBI	Vascular Society of Great Britain and Ireland
WHO	World Health Organization
WTE	Whole time equivalent
WTP	Willingness-to-pay

Executive summary

A health technology assessment (HTA) is a multidisciplinary process that summarises information about the clinical, economic, and ethical issues related to the use of a health technology and does so in a systematic, transparent, unbiased, and robust manner. A HTA is intended to support evidence-based decision-making regarding the optimal use of resources in healthcare services.

The aim of this HTA was to establish the clinical, economic, resource and ethical considerations associated with the introduction of an abdominal aortic aneurysm (AAA) screening programme in men in Ireland.

Background

Following submissions received by the National Screening Advisory Committee (NSAC) in relation to new population-based screening programmes, the NSAC requested that HIQA undertake a HTA of population-based screening for AAA. Based on preliminary scoping exercises presented to the NSAC in May 2023, it was agreed that the scope of this HTA would be restricted to population-based screening in men.

Methods

This research was carried out in accordance with HIQA's guidelines for the conduct of HTAs. In summary, the following took place:

- The Terms of Reference and deliverables for the HTA were agreed between HIQA and the Chair of the NSAC, on behalf of the NSAC.
- An Expert Advisory Group (EAG) was convened by HIQA comprising representation from relevant stakeholders. These included patient representation from the Irish Heart Foundation, public representation from the Irish Senior Citizens Parliament, the Department of Health, the National Screening Service (NSS), the Faculty of Radiologists and Radiation Oncologists, the National Clinical Programme for Surgery, the National Clinical Programme for Critical Care, Primary Care, and international expertise from the National Health Service (NHS) AAA Screening Programme. An Evaluation Team was appointed comprising HIQA staff.
- The epidemiology and burden of AAA in Ireland and internationally was described.
- The current care pathway for patients with AAA in Ireland, and the proposed care pathway for screening, were described.
- A review of international policy and guidelines on screening for AAA was conducted.

- A systematic review of the clinical effectiveness and safety of screening for AAA in men was conducted.
- A systematic review of the cost effectiveness of screening for AAA in men was conducted.
- The organisational and budgetary implications of introducing a screening programme for AAA in men in the Irish context were described and estimated.
- A description was provided of the ethical, patient and societal considerations that the introduction of a screening programme for AAA for men may have for patients, families, the general public and the healthcare system in Ireland.
- A draft report outlining the findings of this HTA was discussed at a meeting of the EAG and subsequently amended, where appropriate.
- The final draft report was circulated to the EAG for review, and was subsequently published for public consultation.

Epidemiology of AAA

An Abdominal Aortic Aneurysm (AAA) is a bulge or ballooning of the abdominal section of the aorta, the largest blood vessel in the body. Based on aortic diameter, AAA can be sub-classified into small (3.0 cm to 4.4 cm), medium (4.5 cm to 5.4 cm) and large (5.5 cm or more). In most men, the normal diameter of the abdominal aorta is approximately 2.0 cm. An aortic diameter of ≥3.0 cm is generally considered to be aneurysmal.

The most common risk factors for AAA include: male sex, increasing age, family history of AAA, smoking, and cardiovascular risk factors, such as hypertension. Smoking is considered the most important modifiable risk factor for the development of AAA, with smokers being two to three times more likely to develop an AAA, compared to never smokers. Smoking is also associated with an increased AAA growth rate and rupture risk.

Rupture is the main complication of AAA and is associated with life-threatening internal bleeding. In patients with ruptured AAA, the mortality rate is estimated to be approximately 80%. The main independent predictor of rupture is the aortic diameter, with the rupture rate approximately doubling for every 0.5 cm increase in aortic diameter.

The prevalence of AAA is low until approximately 60 years of age and increases steadily thereafter with advancing age. In Ireland, the prevalence of AAA is uncertain due to the lack of recent data and a national vascular registry. In the absence of up-to-date Irish epidemiological data; data from the NHS AAA Screening Programme (NAAASP) in men aged 65 years provides an estimate of the current

burden of disease in Ireland. Between 2023 and 2024, the prevalence of AAA among males aged 65 years participating in screening in England was 0.7%.

International evidence consistently demonstrates a decrease in the prevalence of AAA over time, believed to be primarily due to decreased smoking rates, as well as improvements in cardiovascular risk factor management. Based on current trends, AAA prevalence is expected to continue to decrease.

The prevalence of clinically significant AAA also appears to be decreasing. In Ireland, since 2007, the rate of AAA-related hospitalisation has decreased, coinciding with a decrease in age-specific and age-standardised AAA-related mortality in men over the same time period. These mortality trends align with international patterns. However, these decreases may not necessarily translate into a reduction in the absolute number of AAA-related deaths, given the ageing population. Between 2007 and 2021, AAA-related deaths in men in Ireland averaged 115 annually, with crude mortality rates declining from 6.5 per 100,000 males in 2007 to 3.5 per 100,000 males in 2021 (all ages). In males aged over 65 years, AAA-related mortality accounted for 1.2% of all deaths in 2007, declining to 0.6% in 2020.

If an AAA screening programme is implemented, it is estimated that, on average, approximately 30,000 men aged 65 would be eligible for AAA screening each year from 2026 to 2030. Of these, approximately 165 (<1%) would receive a positive screening test result, among whom approximately 90% would require ongoing surveillance.

Description of technology

Ultrasound is the recommended imaging modality for first-line diagnosis, screening, and surveillance of small AAAs. This is due to its safety, non-invasiveness, affordability and high accuracy. However, there is potential for interobserver variability, and successful imaging can be impacted by the presence of abdominal obesity or bowel gas. Computed Tomography Angiography (CTA) is the recommended imaging modality for diagnosis of suspected AAA rupture, pre-operative therapeutic decision and post-surgical monitoring.

Optimal management of AAA includes early detection and timely elective surgical repair, where indicated. In the absence of an AAA screening programme, asymptomatic patients are typically detected incidentally (during imaging for other indications). After diagnosis, the patient can either be managed through surveillance or elective surgical repair of the AAA, with this choice being primarily dependent on the size of the AAA. Cardiovascular risk factor optimisation, including smoking cessation, blood pressure control, and statin and antiplatelet therapy, is recommended to support cardiovascular risk prevention in patients at risk of adverse cardiovascular outcomes.

Symptomatic AAA is detected either based on presenting with clinical symptoms or with rupture. Symptomatic AAA, especially in those presenting with rupture, follows an expedited care pathway due to its time-sensitive and life-threatening nature.

For both elective and emergency admissions, surgical options include open surgical repair (OSR) or endovascular aneurysm repair (EVAR). EVAR is a minimally invasive technique with better peri-operative outcomes, including lower surgery-related morbidity and mortality, compared with OSR. In order to maintain treatment success, lifelong follow-up, including imaging, is recommended after any type of AAA repair.

There is currently no population-based screening programme for AAA in Ireland. Screening of some high-risk individuals (for example, on the basis of family history of AAA) is in place in some hospitals in Ireland on an ad-hoc basis. Further, access to AAA screening is available through the private healthcare system, where individuals can self-refer to medical ultrasound clinics, or be referred by a GP to private hospitals on the basis of risk factor identification. The number of people accessing screening through these channels is unknown due to the lack of a centralised reporting system. Implementation of a systematic population-based screening programme would standardise the care pathway and improve equity of access.

International guidelines, policy and practice in AAA screening were reviewed across 21 countries, including selected countries in the European Economic Area, the United States, Canada, Australia and New Zealand up to December 2024. European guidelines generally advise AAA screening in men who are 65 years or older. In North American guidelines, AAA screening is primarily suggested for individuals with a history of smoking. Suggested surveillance intervals range from two to three years for small AAAs, and three months to one year for medium AAAs. In all clinical guidelines reviewed, the threshold for consideration for elective surgical repair in men was an aortic diameter greater than or equal to 5.5 cm.

Population-based AAA screening in men aged 65 years has been implemented in Germany, Sweden and the United Kingdom. AAA screening programmes are expected to be piloted in Denmark and the Czech Republic in 2025. A one-time, targeted screening based on smoking status and family history of AAA is in place in the US. Regional screening initiatives have been piloted in nine countries, including Belgium, Italy, Spain, Switzerland, New Zealand, Greece, Norway, Portugal, and Poland. If implemented, an AAA screening care pathway would need to be developed with consideration to international guidelines and practice, previous screening studies conducted in Ireland, and current and planned approaches to delivery of vascular surgery services in Ireland, as outlined in the model of care for vascular surgery published by the National Clinical Programme for Surgery.

Clinical effectiveness and safety of screening

To evaluate the clinical effectiveness and safety of AAA screening in men, a systematic review was conducted to compare the evidence on population-based ultrasound screening versus no systematic screening.

A high-quality systematic review conducted by the US Preventive Services Task Force was identified that provided evidence from randomised controlled trials (RCTs). Based on data from four RCTs within this review invitation to screening was associated with a 35% reduction in AAA-related mortality (OR = 0.65, 95% CI: 0.57 to 0.74, number need to invite to screening: 305 men), a 39% reduction in AAA rupture (OR = 0.61, 95% CI: 0.54 to 0.69, number needed to invite to screening: 239 men), and a 47% reduction in the number of emergency surgeries (OR = 0.53, 95% CI: 0.44 to 0.64), at 13 to 15 years' follow-up in men age 65 years or older.

Data from five RCTs shows that the total number of surgeries was significantly higher in the group invited to screening. While emergency surgeries were reduced, the increase in elective surgeries exceeded the scale of this reduction. Specifically, the net increase in the total number of operations at 13 to 15 years' follow-up equated to 6 additional operations per 1,000 men invited to screening. There was no significant difference, at any time point, between the group invited to screening and the no screening group, in the risk of 30-day postoperative mortality following elective or emergency surgery.

The RCTs investigating the effectiveness of screening for AAA began in the 1980s and 1990s and may therefore be limited in terms of their applicability to the current context. Therefore, a search was conducted to identify more recent data from other study designs including reports from international population-based AAA screening programmes. Twenty-four studies of varying design reported on the clinical effectiveness, safety, and psychosocial harms of AAA screening in men.

Among these 24 additional studies, comparative data were limited; only four of the studies compared clinical outcomes between screened and unscreened populations. Based on limited evidence, screening was associated with a reduction in AAA-related mortality and AAA rupture rates in the screened group relative to the comparator group. There is insufficient evidence from the non-RCT studies identified to estimate the impact of AAA screening on all-cause mortality, rates of surgical intervention, 30-day mortality, or surgery-related adverse events, compared with no screening.

The impact of AAA screening on psychosocial outcomes was investigated in ten of the 24 non-RCT studies. The available evidence suggests that the benefits of an AAA screening programme are partially offset by unintended, but generally unavoidable, harms, which include overdiagnosis and transient psychological distress. Men

managed with surveillance may experience a psychosocial burden related to fear of rupture and poorer health perception.

Across the evidence examined, though limited, the available evidence suggests an overall benefit from a one-time ultrasound screening in reducing AAA-related mortality and rupture rates, compared with no screening. However, these benefits are accompanied by increased elective surgeries, overdiagnosis and potential psychosocial harms.

Cost effectiveness of screening

A systematic review was conducted to examine international literature assessing the cost effectiveness of population-based ultrasound screening for AAA in men compared to no screening.

Twenty studies, including 17 cost utility analyses (CUAs), and three cost-effectiveness analyses (CEAs) were included. Sixteen economic evaluations were specifically undertaken in men aged 65 years, while four were based on a broader age range.

To facilitate comparison, incremental cost-effectiveness ratios (ICERs) were converted to 2023 Irish Euro. Cost effectiveness was interpreted using willingness-to-pay (WTP) thresholds of €20,000 and €45,000 per quality-adjusted life year (QALY). The available evidence suggests that AAA screening in men aged 65 years is cost effective, based on a WTP threshold of €45,000 per QALY, with ICERs in 16 out of 17 studies ranging from €200 to €30,600 per QALY. However, in these studies, modelled estimates of AAA prevalence ranged from 1.3% to 11.5%, which are higher than the expected prevalence in the current Irish context. In one CUA with ICER of €61,956 per QALY, AAA screening was not cost effective.

Eighteen studies investigated the impact of uncertainty on the outcomes through sensitivity analysis or scenario analysis. Ten studies reported the results of one-way sensitivity analysis for AAA prevalence, identifying it as an influential parameter in eight studies. In all studies, decreasing the prevalence of AAA resulted in a higher ICER.

Following critical appraisal, including consideration of methodological quality and transferability, although 18 studies were considered moderate-to-high quality, none were considered directly transferable to the Irish context. Factors such as differences in population characteristics, healthcare systems, AAA prevalence, surgical outcomes, rates of opportunistic detection, and variability in the modelling of the care pathway presented challenges for directly transferring the results to the Irish setting.

In the absence of new clinical data since existing CUAs were completed, and given the lack of robust Irish epidemiological data on AAA, it was determined that a de novo, Irish-specific CUA would not sufficiently resolve uncertainties regarding the cost effectiveness of screening.

Budget impact analysis

A budget impact analysis (BIA) was undertaken to estimate the incremental budget impact associated with the potential introduction of an AAA screening programme for men aged 65 years in Ireland, compared to no screening, over a five-year time horizon. The assumption that men aged 65 years would be eligible for screening was made with consideration to the epidemiology of AAA in men, and the availability of real-world evidence in this age group.

To facilitate planning and capacity building, the BIA model included a two-year pre-implementation phase followed by a phased national rollout from year three (30% of men aged 65 years invited in year three, 60% in year four, and 100% in year five). The pre-implementation phase only included costs relating to setting up the programme, such as information and communications technology (ICT) infrastructure and administrative staff. Phased implementation comprised gradual rollout of screening, with associated follow-up, where indicated.

Over a five-year time horizon the incremental budget impact was estimated at €20.3 million with most of the expenditure being attributable to total staff costs (68%). Together, equipment, consumables, communication, and education and awareness initiatives comprised approximately 7% of the five-year incremental budget impact. Setting up the programme database was estimated to account for 22% of total costs. The incremental cost associated with treatment and management of cases with large AAA referred to vascular surgery comprised less than 2% of the total incremental cost.

Assuming an average AAA prevalence of approximately 0.7% over five years, and a phased implementation strategy, it is estimated that 266 men with small and medium AAAs would be under surveillance by the end of year five. Considering a single cohort of screening participants followed for five years, it is estimated that 22% of those with screen-detected AAA at age 65 would have undergone elective surgical repair by 2030. Screening was estimated to result in a 21% increase in the number of AAA elective surgical repairs (that is, less than 20 additional surgeries) in the modelled population (men aged 65 to 69 years) over the five-year period.

To account for uncertainty and quantify the variability in the parameters, sensitivity analysis and scenario analyses were undertaken. Key uncertainties which could result in a substantial increase in the incremental budget impact include the potential need for increased clinical staff depending on the clinical governance

framework agreed, and potential requirements for construction of additional hybrid surgical theatres to facilitate implementation across all vascular surgery units nationally. A further scenario analysis was performed to investigate the costs associated with an organised targeted screening model (that is, based on risk factors other than age). For the purposes of the analysis, this was assumed to involve sending an information letter to all men aged 65 years inviting them to participate in an AAA screening programme if they smoke or have ever smoked. Compared with no screening, organised targeted screening in this way would be associated with an incremental budget impact of €18.7 million over a five-year time horizon; the reduced cost of targeted screening, relative to the main analysis findings (€30 million) was largely attributable to a reduction in clinical staff costs associated with this model of screening provision.

With consideration to the expected number of participants under surveillance by the end of year five, it is unlikely that recruitment of additional screening staff would be required in the short-term post implementation. Recruitment of additional screening technicians (see Organisational considerations, below) may be necessary in the longer-term to manage follow-up of these cases.

Organisational considerations

It is expected that an AAA screening programme in men aged 65 years would be overseen by the National Screening Service (NSS).

Extending eligibility to self-referred men older than 65 years and those with incidentally-detected small and medium AAA would ensure access to standardised care across all identification routes. Additional investment would be required to support such inclusion of additional populations under the care of the programme.

Aligned with strategic priorities within the healthcare system, a community-based delivery approach could help reduce unnecessary hospital activity and may increase accessibility, and therefore screening uptake. Implementation of a community-based delivery model would be contingent on the identification of ultrasound equipment compatible with this approach. A validation exercise would need to be undertaken to investigate agreement of potential ultrasound systems with required standards; this would include consideration of accuracy, safety, portability, technological specifications, and cost. In selecting the ultrasound systems to be used by the programme, there may be a trade-off between technical specification and portability.

Workforce deficits in key disciplines including radiology, radiography, and vascular surgery present challenges for recruitment, and therefore implementation of a screening programme. Recruitment and training of a dedicated, specialist screening and surveillance workforce operating in the context of a quality-assured screening programme would help to improve standardisation of service delivery and ensure

optimal use of clinical skills. For example, in the UK, a dedicated 'screening technician' role was developed specifically for the purposes of AAA screening. This role does not currently exist in the Irish context.

A staffing model requiring radiology sign-off would be challenging to deliver in the context of staff shortages and would be relatively more costly when compared with staffing models in AAA screening programmes in the UK and Sweden. Alternative staffing models, however, may require revisions to training pathways and regulatory frameworks to ensure test accuracy and patient safety.

In the context of a screening programme, processes for clinical reporting must be undertaken within a clear governance framework that aligns with the proficiency standards set out by relevant governing bodies in Ireland. Further, protocols for imaging would need to be developed to ensure delivery of standardised care and to minimise the potential for incidental findings.

Should a decision be made to implement an AAA screening programme, consideration should be given to the development of a national vascular registry to support quality assurance processes, healthcare service planning in response to epidemiological trends, and monitoring of patient outcomes. This would be in addition to the screening programme database. Ensuring interoperability between both data collection systems would be important to facilitate outcome monitoring. Aligning recorded variables with those used in international registries would facilitate international benchmarking and collaboration.

Ethical, patient and social considerations

AAA is well-suited to screening with evidence suggesting that screening reduces AAA-related morbidity and mortality in men aged 65 and older. Detection of AAA can be reliably achieved through ultrasound imaging, which is non-invasive, painless and well-tolerated, enabling elective surgical repair to happen in a timely manner, where indicated. However, these factors must be weighed against the possible harms of AAA screening, including overdiagnosis, overtreatment, surgery-related complications and potential psychological harms.

Overdiagnosis (that is, when screening identifies an AAA that would not have caused symptoms or death during a patient's lifetime) and overtreatment (that is, medical interventions that may not provide a significant benefit to the patient and could potentially cause harm) are unavoidable consequences of AAA screening. Screening and treatment pathways can, however, be designed to minimise potential harms. For example, the choice of aortic measurement method is a careful balance between minimising overdiagnosis and avoiding missed cases.

For those with a small or medium AAA, the surgical risks generally outweigh the benefits. As a result, elective surgical repair of AAA is not recommended for those with an aortic diameter <5.5 cm. For those with large AAA and a reasonable life expectancy, the lifetime risk of rupture exceeds the risk of surgery-related mortality. However, the risks of surgery-related complications remain; strict referral thresholds and pre-surgical assessments can help to ensure that only those likely to benefit from surgery are offered it.

Accepting self-referrals and including sub-aneurysms in surveillance could improve the overall effectiveness of a screening programme and may be perceived as 'fair'. However, this would increase the risk of overdiagnosis and overtreatment, and may therefore have implications for the benefit-harm balance.

Screening for AAA may also be associated with emotional distress and anxiety for the participants and their families, particularly for men with a positive screening test result. Measures such as the provision of clear information and access to psychological supports (for example, programme nurses) have the potential to reduce risk perception, stress and worry. Screening may also identify incidental findings (unrelated abnormalities in nearby anatomical structures) which may cause psychological distress, particularly when such findings were not anticipated. Robust imaging protocols and staff training can help to minimise the identification of, and ensure consistent management of, incidental findings.

Additionally, equity in screening uptake is important to ensure fair health outcomes across all socioeconomic, geographic, and demographic groups. The prevalence of AAA is estimated to be higher in individuals with lower socioeconomic status, but uptake of screening is typically lower in this group. Strategies such as pre-screening reminders, encouragement by GPs, repeat invitations, and follow-up reminders, can help to increase uptake. Community outreach can also boost awareness and uptake in underserved groups.

Without careful planning, implementing a screening programme would likely exacerbate existing capacity constraints within the healthcare system. Providing accurate diagnosis and timely access to elective surgery, without adversely impacting other care pathways, is a key consideration.

Conclusion

The typically asymptomatic nature of AAA, the high mortality rate associated with AAA rupture, the availability of an accurate test with good acceptability, and the availability of an effective treatment mean that AAA is a suitable candidate for screening. However, changes in the clinical landscape over time, characterised by declining AAA prevalence, improvements in cardiovascular risk factor management, and the increasing use of imaging studies, indicate that the magnitude of the clinical

and economic benefits observed in earlier studies are not directly applicable to the current context. It is likely that the direction of the benefit-harm balance, at present, still favours screening despite these changes in the clinical landscape over time. However, there may be a shift towards the population-based AAA screening no longer being cost effective over the next five to 10 years, as AAA prevalence declines.

Without careful planning, implementing an AAA screening programme may exacerbate existing capacity constraints within the healthcare system. Capacity deficits in radiology and vascular surgery would need to be addressed prior to implementation of an AAA screening programme. The potential to manage staff shortages in clinical radiology, to some extent, through changes in workflows could be explored, in partnership with the appropriate professional bodies. Significant investment in vascular services would be required to support timely access to elective surgical repair and adequate resources for post-operative follow-up.

In light of current healthcare system resource deficits, and the potential for the evolving epidemiological and clinical context to tip the balance in favour of targeted screening, a decision to implement screening (whether population-based or targeted) should be preceded by a capacity-building phase, with particular emphasis on development of surgical capacity and data reporting mechanisms.

1 Introduction

1.1 Background to the request

In 2019, the National Screening Advisory Committee (NSAC) was established by the Minister for Health as an independent advisory committee to play a significant strategic role in the development and consideration of population-based screening programmes in Ireland. At the request of the Department of Health, the Health Technology Assessment (HTA) directorate within the Health Information and Quality Authority (HIQA) undertakes evidence synthesis and provides evidence-based advice to NSAC on behalf of the Minister for Health.

Following submissions received as part of the 2021 and 2022 Calls for Submissions, NSAC requested that HIQA undertake a HTA of population-based screening for AAA.[(1)] Based on preliminary scoping exercises presented to the NSAC in May 2023, it was agreed that the scope of this HTA would be restricted to population-based screening in men.[(2)]

The NSAC outlines 20 criteria for appraising the viability, effectiveness and appropriateness of a screening programme.[(3)] The purpose of this HTA is to systematically synthesis the evidence in relation to population-based ultrasound screening for AAA in men with reference to the NSAC criteria for appraising the viability, effectiveness and appropriateness of a screening programme in order to support decision-making by NSAC.

1.1.1 Decision context

An abdominal aortic aneurysm (also known as 'triple A' or AAA) develops when the wall of the aorta, the largest artery in the body, becomes weak, causing it to bulge.[(4)] Over time, pressure from inside the artery causes the weakened area to expand. As the diameter of the AAA grows, the risk of rupture increases. Unruptured AAAs are often asymptomatic or have nonspecific symptoms.[(4)] Rupture of an AAA is considered a medical emergency and is associated with a very high mortality rate.[(5)]

Abdominal ultrasound can be used to screen for AAA.[(6)] Patients with a positive screening test result may enter a surveillance pathway, or be referred to vascular surgery for evaluation of surgical candidacy, depending on the size of the AAA detected.[(7)] Population-based screening for AAA is currently offered to all men aged 65 in some European countries, including the United Kingdom and Sweden.[(8, 9)] This practice is in line with the 2019 European Society for Vascular Surgery (ESVS) Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms, which recommended population-based ultrasound screening for AAA in men at age 65 years.[(10)] These guidelines did not recommend population-based

screening in women due to evidence of a lower disease prevalence compared with men, and a limited evidence base for AAA screening in women.[10] International guidelines and practice in AAA screening are described in detail in this HTA in Chapter 3. In Ireland, there is currently no population-based screening programme for AAA. With consideration to the evidence of a lower prevalence of AAA in women than men, and the limited evidence base for AAA screening in women, the scope of this assessment was restricted to men.

Numerous factors contribute to uncertainty regarding the potential benefits and harms of an AAA screening programme in men. These include heterogeneity in the natural history of disease, changes in the clinical context over time, the mortality risk associated with elective AAA repair, and the need for high compliance at initial screening and follow-up, where appropriate, in order to realise a potential reduction in AAA-related morbidity and mortality. These and additional factors will be considered in evaluating the risk-benefit balance of an AAA screening programme in men in Ireland as part of this assessment.

1.2 Terms of reference

Based on the available evidence, this HTA will inform the decision-making by, and subsequent recommendation of, NSAC to the Minister for Health. The terms of reference for this HTA, which were agreed between HIQA and the Chair of NSAC, on behalf of the NSAC, are to:

- describe the epidemiology and burden of disease of AAA in Ireland
- describe the current care pathway for patients with AAA in Ireland, and the proposed care pathway for screening
- conduct a review of international policy and guidelines on screening for AAA
- describe the clinical effectiveness and safety of screening for AAA in men
- review the methods and results of published economic evaluations reporting on the cost effectiveness of screening for AAA
- assess the cost effectiveness and budget impact of introducing a screening programme for AAA in men in the context of the Irish public healthcare system
- review the potential resource and organisational implications of introducing an AAA screening programme for men in Ireland

- consider any ethical or societal implications that a screening programme for AAA in men may have for patients, families, the general public or the healthcare system in Ireland.

1.3 Overall approach

A multidisciplinary EAG was convened by HIQA comprising representation from relevant stakeholders. These included patient representation from the Irish Heart Foundation, public representation from the Irish Senior Citizens Parliament, the Department of Health, the National Screening Service (NSS), the Faculty of Radiologists and Radiation Oncologists, the National Clinical Programme for Surgery, the National Clinical Programme for Critical Care, Primary Care, and international expertise from the National Health Service (NHS) AAA Screening Programme.

The role of the EAG is to inform and guide the process, provide expert advice and information, and to provide access to data where appropriate. A full list of the membership of the EAG is available in the acknowledgements section of this report.

The terms of reference of the EAG are to:

- contribute to the provision of high quality research and considered advice by HIQA to NSAC on behalf of the Minister for Health
- contribute to the work of the group by providing expert guidance, as appropriate
- be prepared to provide expert advice on relevant issues outside of group meetings, as requested
- provide advice to HIQA regarding the scope of the analysis.
- review the project plan outline and advise on priorities, as required
- support the Evaluation Team during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- review the draft report from the Evaluation Team and recommend amendments, as appropriate
- contribute to HIQA's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment

- notify the project lead if a nominee can no longer participate or contribute to the process, as non-participation may require alternative EAG membership to be sought.

HIQA appointed an Evaluation Team, comprising staff from the team within the HTA Directorate designated to support NSAC, to carry out the assessment.

The HTA protocol, including the terms of reference of the HTA, was reviewed by the EAG prior to the first meeting. Draft versions of the assessment were circulated to the EAG for review and discussion at three formal meetings of the group, and amendments were made where appropriate. This draft version of the report has been made available for targeted and public consultation. The feedback received during this consultation and HIQA's responses to the issues raised, including any changes made to the report as a result, will be summarised in a Statement of Outcomes report. After the consultation, a final draft of the report, including the advice to NSAC, will be circulated to the EAG for review.

Consistent with standard HIQA governance processes, the final draft of the HTA and associated Statement of Outcomes report arising from the consultation will be submitted to the Board of HIQA for approval. Following its approval, the final HTA will be submitted to NSAC for consideration and published on the HIQA website.

2 Epidemiology

Key points

- The aorta is the largest blood vessel in the body, and, passing through the chest and abdomen, carries blood from the heart to the rest of the body. An abdominal aortic aneurysm (AAA) is typically defined as an aortic diameter of 3.0 cm or more.
    - AAAs can be further sub-classified into three categories based on the diameter of the abdominal aorta: small (3.0 cm to 4.4 cm), medium (4.5 cm to 5.4 cm) or large (5.5 cm or more). The risk of rupture is directly related to the diameter of the AAA.
    - Rupture of an AAA is associated with life-threatening internal bleeding. The mortality rate from a ruptured AAA is approximately 80%.
- The most common risk factors for AAA include male sex, increasing age, smoking, and family history of AAA. Other factors, such as hypertension, can also play a role in the formation and progression of an AAA.
- The prevalence of AAA is low until approximately 60 years of age. Thereafter, the prevalence increases steadily with advancing age.
    - The prevalence of AAA in Ireland is uncertain due to the absence of a national vascular registry or up-to-date epidemiological studies. In the absence of Irish data, data from the NHS population-based AAA screening programme in males aged 65 years provide an indication of the current burden of disease in Ireland. Between 2023 and 2024, the prevalence of AAA among males aged 65 years participating in screening in England was 0.7%.
    - A decrease in the prevalence of AAA has been observed over time. This has been linked to a decrease in cigarette smoking as well as changes in other cardiovascular risk factors.
    - Based on data from the UK NHS AAA Screening Programme, the prevalence of AAA is expected to continue to decline over time, assuming current trends continue.
- In Ireland, since 2007, the rate of AAA-related hospitalisation in men has decreased. This coincides with a decrease in age-specific AAA-related mortality in men over the same time period. This suggests that the prevalence of

clinically significant AAA is decreasing in Ireland, consistent with the international evidence.

- It is estimated that between 2007 and 2021, on average, up to 115 men died from AAA in Ireland each year.
- Globally, the age-standardised AAA-related mortality rate has decreased over time. However, due to the ageing population, decreases in the age-standardised AAA-related mortality rate may not translate into a decrease in the absolute number of AAA-related deaths.
- If an AAA screening programme is implemented, it is estimated that, on average, approximately 30,000 men aged 65 would be eligible for AAA screening each year. Of these, approximately 165 (<1%) would receive a positive screening test result, among whom approximately 90% would require ongoing surveillance to monitor AAA growth.

2.1 Introduction

The purpose of this chapter is to describe the epidemiology of abdominal aortic aneurysm (AAA or 'triple A') in men. The chapter outlines the aetiology of AAA, the disease prevalence in men, and the associated burden of disease, including AAA-related mortality, with particular reference to the Irish context.

The evidence is synthesised with consideration to important epidemiological considerations in the context of screening, as outlined by the National Screening Advisory Committee (NSAC), namely:[3]

- *The condition should be an important health problem. The epidemiology, incidence, prevalence and natural history of the condition should be understood, including development from latent to declared disease and/or there should be robust evidence about the association between the risk or disease marker and serious or treatable disease.*

2.2 Abdominal aortic aneurysm

An aneurysm is an abnormal widening or bulging in the wall of a blood vessel, such as an artery. Aneurysms can occur in any blood vessel throughout the circulatory system, but most commonly develop along the aorta (that is, the largest blood vessel in the body) and the blood vessels in the brain. Untreated aneurysms can burst (rupture), leading to internal bleeding. Depending on the location of the aneurysm, a rupture can be life threatening. This HTA is specifically concerned with AAA in men.

The aorta carries oxygenated blood from the heart to the rest of the body. The most common definition of an AAA is based on the diameter of the abdominal aorta. In most adult men, the abdominal aorta has an approximate diameter of 2.0 cm, with individual variation due to factors such as height, weight and age.[7] At a population level, in men, an abdominal aortic diameter of 3.0 cm or more is generally considered to be aneurysmal.[6] A lower threshold might be more appropriate in women and some ethnic groups. AAA can also be defined as a dilation of the abdominal aorta of at least 50% relative to the diameter of the aorta at the level of the renal arteries, to allow for individual variation.[6] As described in Chapter 3, if detected prior to rupture, the management pathway varies depending on the diameter of the AAA.

2.3 Pathophysiology

The aorta is made up of three layers: the inner layer (tunica intima), the middle layer (tunica media), and the outer layer (tunica adventitia). Aortic aneurysmal disease is recognised as a distinct degenerative process involving all layers of the

vessel wall.[11, 12] The pathophysiology of aortic aneurysmal disease is characterised by infiltration of the vessel wall by white blood cells, destruction of important structural proteins in the aortic wall such as elastin and collagen, loss of smooth muscle cells and thinning of the aortic wall. As this cascade of events is sustained over time, the aortic wall becomes progressively thinner. This makes it more prone to dilation and rupture when the blood pressure within the aorta exceeds the ability of the aortic wall to resist stretching or tearing under pressure.[13] Thinning of the aortic wall, a reduction in elastin fibres and impairment of endothelial function occur naturally with age.[11] However, in addition to age-associated structural and functional alterations in the aortic wall, various risk factors affect the mechanical properties of the aorta, contributing to the development and progression of AAA (section 2.3.1, Risk factors).

The structure of the layers of the aortic wall also changes between the different sections of the aorta (that is, the ascending aorta, the aortic arch, the thoracic or descending aorta, and the abdominal aorta). The middle layer of the aorta, which is the thickest, is formed by elastic fibres and vascular smooth muscle cells.[11] The number of elastic fibres decreases in the abdominal section relative to the thoracic aorta.[11] Such structural differences in the aortic wall contribute to the increased risk of irreversible aortic wall expansion along the abdominal section of the aorta.[11, 13]

2.3.1 Risk factors

AAA is a multifactorial disease influenced by both environmental and genetic factors.[14] Certain risk factors such as gender, age and family history of AAA are not modifiable. However, other risk factors such as smoking and hypertension can be modified.[15, 16] Well-defined risk factors associated with the development of AAA are described below. However, this is not an exhaustive list.

Increasing age and male sex

The link between older age and vascular disease is well documented and persists even after adjusting for other demographic and clinical risk factors.[17] Evidence from a systematic review of the global and regional incidence and prevalence of AAA demonstrates that across all regions, including Western Europe, the prevalence of AAA increased with advancing age.[18] A small-scale screening study conducted in Connolly Hospital, Blanchardstown, in 2006 and 2007 demonstrated that, as expected, among those with screen-detected AAA aged 55 to 75, aortic diameter increased with increasing age.[19]

Furthermore, the prevalence of AAA has been shown to be higher among men than women across all age groups.[18] Evidence from studies investigating gender-specific differences in the epidemiology of AAA indicate that men have five to six times the

odds of developing an AAA compared with women, regardless of the presence of other risk factors.[16, 20, 21] Women tend to present at a later age.[21]

Smoking

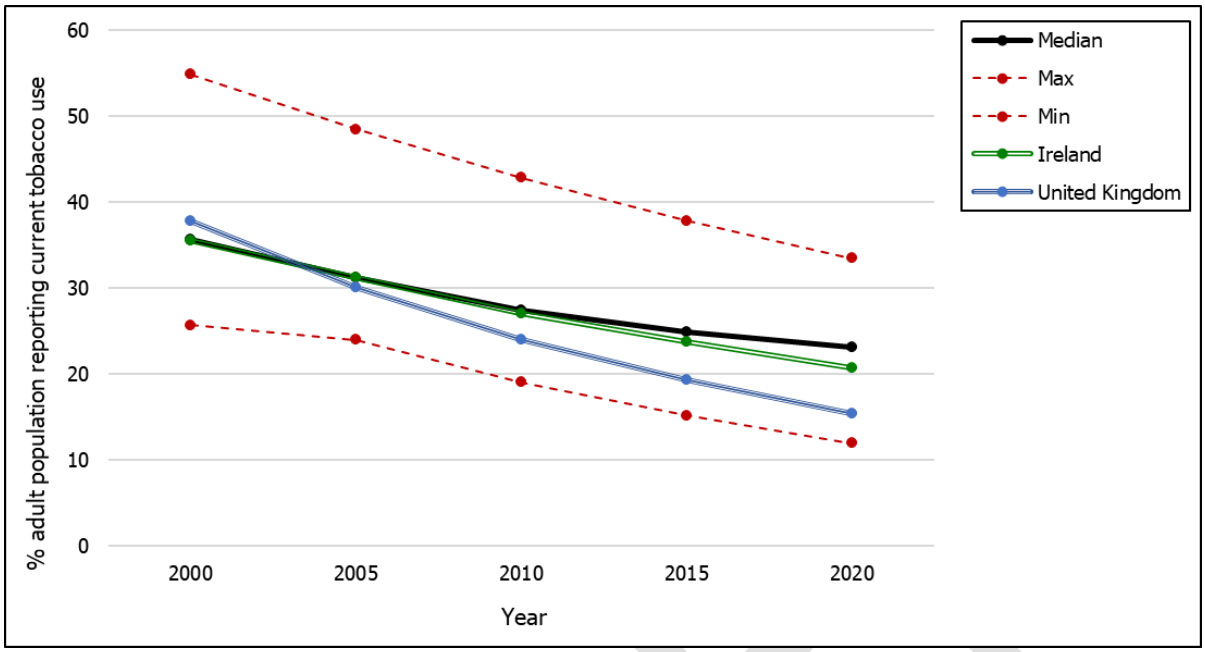
Smoking is considered the most important modifiable risk factor for the development of AAA.[22] Overall, it is estimated that people who have ever smoked are two to three times more likely to develop AAA than those who have never smoked.[16, 20] The relationship between smoking and AAA risk has also been shown to be dose-dependent, that is, both duration and amount of smoking matter.[23] Evidence from a 2018 systematic review indicates that the relative risk of AAA is increased over four-fold in current smokers (RR 4.55, 95% CI: 4.19 to 4.94) and more than two-fold in past smokers (RR 2.43, 95% CI: 2.17 to 2.73) compared with never smokers.[23] Even within these subgroups, the risk attributable to smoking varies over a wide range. Those with relatively low consumption have the lowest risk (less than 0.5 packs per day for ≤10 years: OR 2.61, 95% CI: 2.47 to 2.74), while those who smoke more than one pack per day for over 35 years have the highest risk (OR 12.13, 95% CI: 11.66 to 12.61), relative to non-smokers.[24] Smoking cessation has been associated with a decrease in the risk of developing an AAA. The longer the period since smoking cessation, the lower the risk of an AAA.[25]

Smoking is also associated with AAA expansion and rupture risk. Current smoking is associated with an increased AAA growth rate of approximately 0.35 mm per year compared with past- or never-smokers, and is also associated with twice the risk of rupture, compared with past or never smokers.[26] Although the evidence base is limited, there is evidence to suggest that second-hand smoking is associated with mortality from aortic aneurysm or dissection in a dose-dependent manner.[27]

Evidence from the Swedish AAA screening programme suggests that over 85% of participants with screen-detected AAA had a history of smoking.[28-30] The Highland aortic aneurysm screening programme in Scotland and one AAA screening study from Norway also reported a history of smoking in 85% of all AAA cases.[31, 32]

It should be noted that a decrease in the prevalence of smoking has been observed globally over time,[33] which has the potential to influence the epidemiology of AAA. The prevalence of smoking was historically much higher, estimated to be over 50% in men in the early 1970s.[34, 35] Evidence from the Our World in Data project indicates that the percentage of the adult population in selected European countries who currently smoke any tobacco product decreased from a median of 36% in 2000, to 23% in 2020.[36] A downward trend was observed for the majority of, but not all, included countries. Decreases in smoking have likely contributed to a decrease in the prevalence of AAA (see section 2.6).[22]

Figure 2.1 Percentage of adult population in selected European countries who currently smoke, 2000 to 2020



Includes the population aged 15 years and older who smoke any tobacco product on a daily or occasional basis. Data were not available by age or sex. Data from a sample of European countries were included: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, the United Kingdom.
Data source: World Bank via Our World in Data.[36]

Evidence from the HSE Smoking Prevalence Tracker, a telephone survey, indicates that the prevalence of smoking in Ireland decreased between 2002 and 2023.[37] Based on the 2022 Census and 2023 Healthy Ireland Survey, the current prevalence of smoking is approximately 20% among adult men.[38, 39] Furthermore, results of the 2023 Healthy Ireland Survey show that smoking rates are consistently higher in men than women.[38] Up-to-date estimates of the prevalence of AAA in men in Ireland are lacking (as described in section 2.6.1). However, epidemiological evidence from the UK is likely broadly applicable to the Irish context with consideration to similarities in the distribution of key risk factors for disease development and progression, particularly current and past smoking rates, within the target population (Figure 2.1 and Table 2.1).

Table 2.1 Smoking among adult males in Ireland and the UK

Country	Current smoker†		History of smoking		
	Adult males ≥18 years	Men aged 55 to 64	Adult males ≥18 years	Men aged 55 to 64	Source
Ireland	19.6%	16.9%	26.3%	33.3%	Central Statistics Office (2022)[39]
United Kingdom	14.6%	14.0%	27.6%	31.3%	National Statistics Office (2022)[40]

† For the Irish 2022 Census data, current smoker includes daily or occasional tobacco use. Current smoker was not defined in the UK National Statistics Office data.

Family history of AAA

An incremental increase in the risk of an AAA has been observed according to the degree of familial relationship.[41] Evidence from a systematic review and meta-analysis suggests that people with a first-degree relative who has a history of AAA are approximately 10 times (95% CI: 1.72 to 53.98) more likely to develop an AAA compared with those with no family history.[16] In Ireland, a study conducted between 1990 and 1993 showed that the prevalence of AAA among siblings was 12% overall, and 22% in the subgroup of male siblings.[42] In a study among AAA patients attending a vascular surgery unit for surgical intervention or follow-up in Northern Ireland between 2001 and 2005, the prevalence of AAA among participating siblings aged over 60 years was 5%.[43] Approximately 11% of participating families were found to have two or more members with an AAA.[43]

Other cardiovascular risk factors

Hypertension has been estimated to increase the odds of developing AAA by approximately 1.5 times.[16, 20, 44] The link between hypertension and AAA progression (that is, growth rate and rupture risk) is debated, but there is some evidence of a dose-dependent relationship rupture risk with increasing blood pressure.[45]

Abnormal total cholesterol, triglycerides, and high-density lipoprotein (HDL) and low-density lipoprotein (LDL) levels are major risk factors for atherosclerosis and cardiovascular disease.[46] However, cardiovascular disease and AAA are generally considered distinct disease entities.[45] While high HDL levels have been shown to have a protective effect against AAA development, the link between AAA development or progression and other plasma lipids is less certain.[47, 48]

Due to the considerable overlap in risk factors between AAA and other cardiovascular diseases, people with AAA commonly present with other

cardiovascular comorbidities, such as ischemic heart disease (IHD), as outlined in section 2.4.4.

2.4 Natural history of disease

2.4.1 Clinical presentation

An AAA is typically asymptomatic until it ruptures. However, some patients may present with nonspecific symptoms including abdominal tenderness or back pain.[6] A pulsating abdominal mass on physical examination may indicate the presence of an AAA. However, abdominal palpation is inherently insensitive for detection of AAAs, particularly in patients with abdominal obesity.[6, 49, 50]

Where present, symptoms may be caused by complications such as compression of nearby organs or embolic events (that is, a blockage in an artery caused by a blood clot). As the AAA grows patients may present with distal embolism or other features such as duodenal obstruction, lower limb oedema or ureteral obstruction as nearby structures become compressed.[6]

When an AAA ruptures, patients usually have sudden and severe signs and symptoms including abnormalities in blood pressure and heart rate (also called haemodynamic instability or haemodynamic collapse), pallor, severe abdominal or back pain, and abdominal distension due to massive internal bleeding.[6, 51]

2.4.2 AAA growth

The natural history of AAA is towards progressive expansion. This is driven by multifactorial degeneration of the aortic wall, which may eventually lead to rupture. AAAs can be classified into three categories based on the diameter of the abdominal aorta:[4, 52]

- small (3.0 cm to 4.4 cm)
- medium (4.5 cm to 5.4 cm)
- large (5.5 cm or more).

Baseline aortic diameter is related to growth rate, although the growth rate can vary between individuals. Abdominal aortas ranging from 2.5 cm to 2.9 cm in diameter may be considered subaneurysmal (also called abdominal aortic ectasia). A subaneurysmal aorta is considered to be a precursor to AAA, but not all subaneurysmal aortas will progress to AAA. Evidence from a systematic review and meta-analysis (n = 8,369 patients, almost exclusively males) indicates that 45.0% (95% CI: 28.5 to 61.5) of subaneurysmal aortas reached 3.0 cm within five years of initial detection, 0.3% (95% CI: 0.0 to 0.6) reached 5.5 cm within the first five years and 5.2% (95% CI: 2.2 to 8.2) within 5 to 10 years.[53]

A systematic review and meta-analysis including evidence published up to 2010 was undertaken by the RESCAN collaborators to investigate the relationship between AAA growth and rupture risk as a function of aortic diameter at baseline.[26, 54, 55] Based on meta-analysis of data from 15,475 individuals (89% men) with small to medium AAAs undergoing follow-up, overall, the mean annual growth rate was estimated to be 2.2 mm.[26] AAA growth rate has been shown to vary depending on the diameter of the AAA at baseline. In men, the mean annual growth rate was 1.28 mm (95% CI: 1.03 to 1.53) for an AAA of 3.0 cm, 2.44 mm (95% CI: 2.22 to 2.65) for an AAA of 4.0 cm, and 3.61 mm (95% CI: 3.34 to 3.88) for an AAA of 5.0 cm.[55] For men with a baseline AAA of 3.0 cm, the estimated mean length of time to have a 10% chance of developing an AAA of 5.5 cm (that is, the typical threshold for referral for surgical evaluation) was 7.4 years (95% CI: 6.7 to 8.1).[55] The corresponding estimated mean length of time for an AAA measuring 4.0 cm and 5.0 cm at baseline was 3.2 years (95% CI: 3.0 to 3.4) and 0.7 years (95% CI: 0.6 to 0.8), respectively. However, there was evidence of substantial unexplained between-study heterogeneity for all estimates.

It is plausible that the epidemiology of AAA may have evolved over time, secondary to reductions in smoking and improved cardiovascular risk factor management, and that the growth rate may correspondingly have changed. Given this context, an up-to-date review of AAA growth rates was undertaken to inform the 2024 ESVS guidelines.[56] Based on results from 43 studies published since 2015, including 28,277 patients, the mean AAA growth rate was estimated to be 2.38 mm per year (95% CI: 2.16 to 2.60),[56] similar to the average rate of 2.2 mm estimated by the RESCAN collaborators, above. While subject to some uncertainty, the authors concluded that current population patterns of reduced smoking prevalence, better blood pressure control, and increased rates of statin and anti-platelet treatment for AAA patients have not had a clinically significant impact on AAA growth rates.[56] It is worth noting, however, in the updated review, growth rates were found to be lower when the analysis was limited to RCTs (1.88 mm, 95% CI: 1.69 to 2.06) or to studies at low risk of bias (2.09 mm, 95% CI: 1.87 to 2.32); based on this evidence, the current AAA growth rate may be lower than reported in historical cohorts. However, inclusion of heterogeneous data with different measurement modalities and techniques, and the absence of complete risk factor information, could lead to potential biases.

Rapid AAA growth has been shown to be significantly associated with an increased risk of AAA-related clinical events.[45] As described in Chapter 3, the link between AAA diameter and rupture risk has been used to inform surveillance intervals for patients with an incidentally detected or screen-detected AAA less than 5.5 cm in diameter.

Some subpopulations may have fast-growing aneurysms that may be missed by infrequent monitoring. Factors such as smoking or uncontrolled hypertension have been associated with faster growth rates.[5] Further evidence from a systematic review and meta-analysis undertaken by the RESCAN collaboration demonstrated that among all risk factors examined, smoking was the only risk factor that was independently associated with an increased risk of small AAA growth (defined by the review authors as an AAA 3.0 cm to 5.4 cm in diameter). Among current smokers, on average, AAAs grew 0.35 mm faster per annum when compared with ex-smokers or those with no smoking history.[26] Despite the presence of more severe vascular co-morbidities in diabetes, growth tends to be less rapid in patients with diabetes compared with those without diabetes (-0.25 mm/year; 95% CI: -0.35 to -0.15).[57] The reason behind this paradoxical association is uncertain, but may be related to the use of medications targeting risk factors for AAA or structural changes in the aortic wall in diabetes.[58, 59]

2.4.3 AAA rupture and case-fatality rate

Rupture is the main complication of AAA and is associated with a high mortality rate, particularly when rupture occurs outside the hospital setting. The main independent predictor of rupture is the aortic diameter. Based on the results of a systematic review and meta-analysis by the RESCAN collaborators, the rupture rate approximately doubles (1.91, 95% CI: 1.61 to 2.25) for every 0.5 cm increase in aortic diameter. For an AAA 3.0 cm in diameter, the average time to reach a rupture risk of 1% was 8.5 years (95% CI: 7.0 to 10.5). For an AAA 5.0 cm in diameter, a 1% risk of rupture was reached after approximately 1.4 years (95% CI: 1.2 to 1.8).[55]

A meta-analysis of 24 studies undertaken between 1969 and 2007 found that the pooled total mortality rate among patients with a ruptured AAA was 81% (95% CI: 78% to 83%).[60] Of all patients with a ruptured AAA, the pre-hospital mortality rate was 32% (95% CI: 27% to 37%).[60] Among those who reached hospital, the pooled estimated non-intervention rate (defined as patients who die in hospital without undergoing surgery) was 40% (95% CI: 33% to 47%).[60] Among surgically treated patients, the pooled estimate for perioperative mortality was 53% (95% CI: 48% to 59%).[60] In patients with ruptured AAA, emergency care pathway stage (that is, pre-hospital, in-hospital triage, and emergency intervention) can be considered to reflect time since rupture. Therefore, these data suggest that increasing time since rupture corresponds to increasing risk of mortality. An additional finding of this meta-analysis was that there was evidence of a decline in the pre-hospital mortality rate, the non-intervention rate and in perioperative mortality over the time period examined in the study.[60]

2.4.4 Cardiovascular comorbidities

While AAA rupture is the main direct complication of AAA, given that the risk factors associated with the development of AAA are also linked to a number of other cardiovascular diseases, many patients with AAA have cardiovascular comorbidities including coronary artery disease, peripheral artery disease and cerebrovascular disease.[45] Results of a systematic review of cardiovascular risk in patients with a small AAA (defined by the study authors as an AAA 3.0 cm to 5.4 cm in diameter), indicate a high prevalence of IHD (also called coronary artery disease or coronary heart disease) (44.9%), myocardial infarction (26.8%), stroke (14.0%) and heart failure (4.4%).[61] Data from a retrospective registry-based study of all cases of ruptured AAA in two regions in Finland between 2001 and 2011 also highlighted a high prevalence of IHD (36%) and cerebrovascular disease (18%) among men with ruptured AAA.[62]

Evidence from a meta-analysis indicates that a diagnosis of IHD is a strong predictor of future AAA events (HR = 3.49, 95% CI: 2.56 to 4.76, n = 4 studies).[63] Similarly, evidence from a population-based cross-sectional study conducted in Varese, Northern Italy, demonstrates that among those aged 65 to 75 with previously-diagnosed or screen-detected AAA, the prevalence was higher in those with a previous myocardial infarction (4.9%, 95% CI: 2.0% to 9.9%), compared with the general male population aged 65 to 75 years (1.9%, 95% CI: 1.2% to 2.8%).[64]

2.5 Incidence of AAA

The incidence of AAA overall cannot be known with certainty as for most people an AAA develops slowly over time and is typically asymptomatic. In the absence of screening, cases are identified through incidental diagnosis, GP referral for ultrasound investigation based on risk factors (for example, family history), or presentation at emergency departments with AAA rupture or impending rupture (see chapter 3, section 3.2). Therefore, the number of cases detected per annum represents a subset of all new cases occurring. However, the incidence of clinically-significant AAA based on AAA-related hospitalisations per annum can be measured, as outlined in section 2.7.

2.6 Prevalence

2.6.1 Prevalence of AAA

As noted in section 2.3.1, the prevalence of AAA increases with advancing age. Evidence from a systematic review of epidemiological data and associated modelling analysis indicates that in Western Europe in 2010, the estimated prevalence of AAA among those aged 50 to 54 years was between 0.18% and 0.49%, while in those aged 80 years and older, the prevalence was estimated to be between 2.49% and 9.52%.[18]

Trial data

Population-based randomised controlled trials (RCTs) and outcomes from screening programmes in place internationally (for example, the UK and Swedish AAA screening programmes) offer the best available estimates regarding time trends in the prevalence of AAA. Four RCTs conducted in Denmark, the UK and Western Australia, comparing population-based ultrasound screening for AAA with no screening in older men, began between 1988 and 1996 (see Chapter 4, section 4.3.1). In these RCTs, the prevalence of screen-detected AAA ranged from 3.9% to 7.7%, with a prevalence of at least 4.5% expected in the age range 65 to 73 years.[65, 66] Variation in the overall prevalence of screen-detected AAA across these RCTs was due, in part, to differences in the age ranges, and differences in age distribution within these age ranges.

Observational study data

For the purposes of this assessment, a targeted literature search was conducted to identify observational studies reporting on the prevalence of AAA in high income or European countries. Twenty-four publications reporting on population-based screening programmes and smaller scale prevalence studies internationally were identified; data from these publications indicated a decrease in the prevalence of AAA since seminal RCTs began (Figure 2.2).[8, 32, 67-89] Fourteen studies identified examined the prevalence of AAA in males at age 65 only; in two studies conducted before 2000 the AAA prevalence rates reported were 5.0% and 8.5%, while the AAA prevalence rates reported from studies conducted between 2006 and 2018 ranged from 4.7% to 1.2% (Figure 2.2, panel a).[8, 32, 68-70, 73-75, 77-79, 82, 84, 87] Ten studies looked at the prevalence of AAA in men aged 65 years and older. In four of these studies, between 1990 and 1993, the AAA prevalence rates were higher, ranging from 8.4% to 13.0%, while the remaining studies from 1995 to 2018 reported lower AAA prevalence rates, ranging between 2.1% and 5.0% (Figure 2.2, panel b).[67, 71, 76, 80, 81, 83, 85, 86, 88, 89] As expected, the prevalence of AAA was higher in studies that enrolled men aged 65 years and older (Figure 2.2, panel b), relative to studies that enrolled men at age 65 years only (Figure 2.2, panel a), as a result of increasing prevalence with increasing age. Across different regions, the AAA prevalence estimates did not appear to vary considerably.

Data from the NHS abdominal aortic aneurysm screening programme (NAAASP)

As noted previously, given likely similarities in smoking rates, evidence from the NHS AAA screening programme is likely indicative of the prevalence of AAA in Ireland. In England, prior to the introduction of the national population-based AAA screening programme in 2009, a regional screening programme was in place in Gloucestershire since 1990 for men aged 65 registered with a GP. In total, 52,690 men were

screened during this period. Outcomes of this regional programme indicated that between 1990 and 2009 the prevalence of screen-detected AAA decreased from 4.8% to 1.1%.[75] Since the implementation of the national population-based AAA screening programme in men aged 65 years in England in 2009, the overall prevalence of screen-detected AAA has steadily declined over time.[79, 90] The most recent estimates from the national population-based AAA screening programme in England report a prevalence of 0.74% (April 2023 to March 2024).[91] There was, however, evidence of geographic variation, with regional estimates ranging from 0.42% to 1.42%.[90] In line with evidence from the UK, evidence from the Swedish population-based screening programme in men aged 65 demonstrated a decrease in the prevalence of AAA over time.[8, 87]

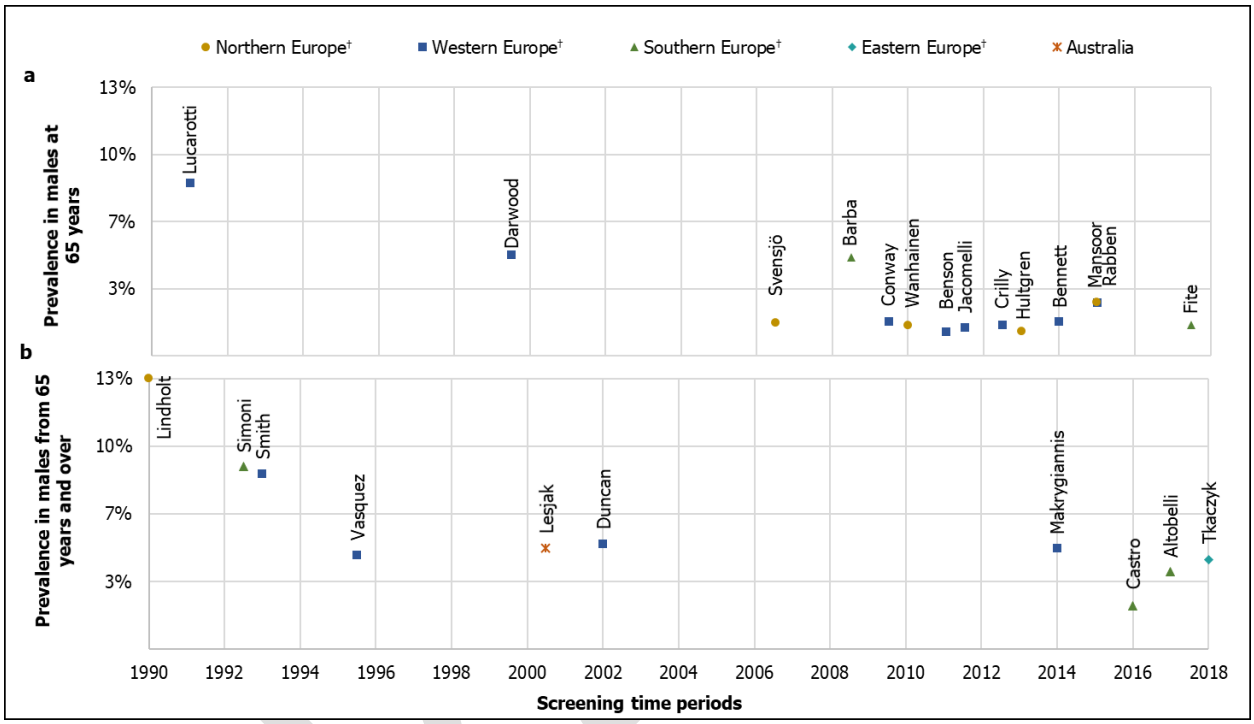
Irish data

In the absence of a national vascular registry or up-to-date local epidemiological data, the prevalence of AAA in men in Ireland is subject to uncertainty. Three Irish studies were identified, which reported on the prevalence of AAA in the mid to late 2000s.[92-94] Among these, two pilot studies undertaken between 2006 and 2008 in Ireland indicate that the prevalence of AAA in older men is broadly consistent with results from UK-based studies undertaken during the same time period, although results of UK-based studies are largely specific to the cohort aged 65 years at the time of screening. Between 2006 and 2007, men aged 55 to 75 years living in the catchment area of Connolly Hospital Blanchardstown were invited to participate in screening (n = 904). The overall prevalence of undiagnosed AAA was 1.9%, with evidence of a statistically significant difference between age groups (55 to 64 years: 0.6%; 65 to 75 years: 4.2%).[92] Similarly, between 2007 and 2008, a pilot study was undertaken as a collaboration between the vascular service at St. James's Hospital and general practices in the midlands. Males aged 63 to 67 years and all adults aged 50 to 74 years with a family history of AAA were invited to participate in screening (n = 746). The overall prevalence of AAA was 1.3%.[93] A third study undertaken in men aged over 60 years (mean 63.9, SD 3.6) attending the Department of Preventative Medicine at the Blackrock Clinic between 2003 and 2006 (n = 481) reported an overall prevalence of AAA of 4.6%.[94] The reason behind the higher prevalence in this study is unclear, but may be related to the smaller sample size, and the fact that participants were male volunteers self-referring for screening, who may be more likely to have signs, symptoms or risk factors than those who do not self-refer.

As noted in section 2.3.1, the prevalence is higher in those with certain risk factors, including a family history of disease and smoking history. In the United States, a retrospective review of a regional Veterans Affairs screening programme found that among veterans aged 65 to 75 years who smoked at least 100 cigarettes during their lifetime, the overall prevalence of AAA was 6.3% between 2007 and 2016,

declining from 7.2% to 5.5% during the 10-year analysis.[95] Of note, the target population (that is, veterans) coupled with the inclusion of a large proportion of patients not meeting the inclusion criteria (18.7%) limits the generalisability of these findings.

Figure 2.2 Prevalence of AAA from epidemiological studies in men aged a) 65 years and b) 65 years and older*

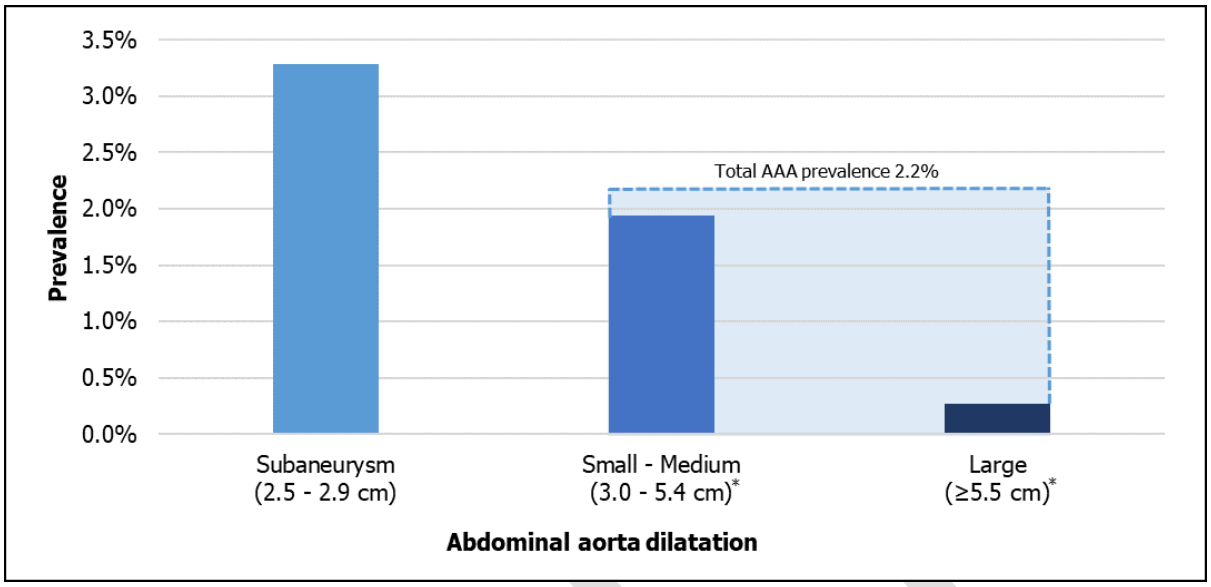


Key: AAA – abdominal aortic aneurysm.
* Panel 'a' includes studies that specifically examined the prevalence in males aged 65 years. Panel 'b' includes studies that investigated the prevalence in males from age 65 years and older (that is, across an age range). The year shown on the x-axis represents the mid-point of the screening period for each included study.
† Northern Europe (Norway, Sweden); Western Europe (Belgium, France, Germany, Ireland, UK); Southern Europe (Italy, Portugal, Spain, Turkey); Eastern Europe (Poland).

2.6.2 Prevalence of sub-aneurysm

A subset of studies identified in the targeted literature search also reported on the prevalence of sub-aneurysm, defined as an abdominal aorta dilatation of 2.5 cm to 2.9 cm in diameter. Seven studies reported on subaneurysm prevalence in males 65 years old. Across these, the average prevalence of sub-aneurysm was 3.3%, ranging from 1.3% to 6.7%;[32, 68, 77, 78, 84, 87, 96] this is 1.5 times higher than the average prevalence of AAA (2.2%, range 0.7% to 4.7%) from the same studies (Figure 2.3).

Figure 2.3 Distribution of sub-aneurysm and AAA in males aged 65 years; average prevalence reported across seven observational studies



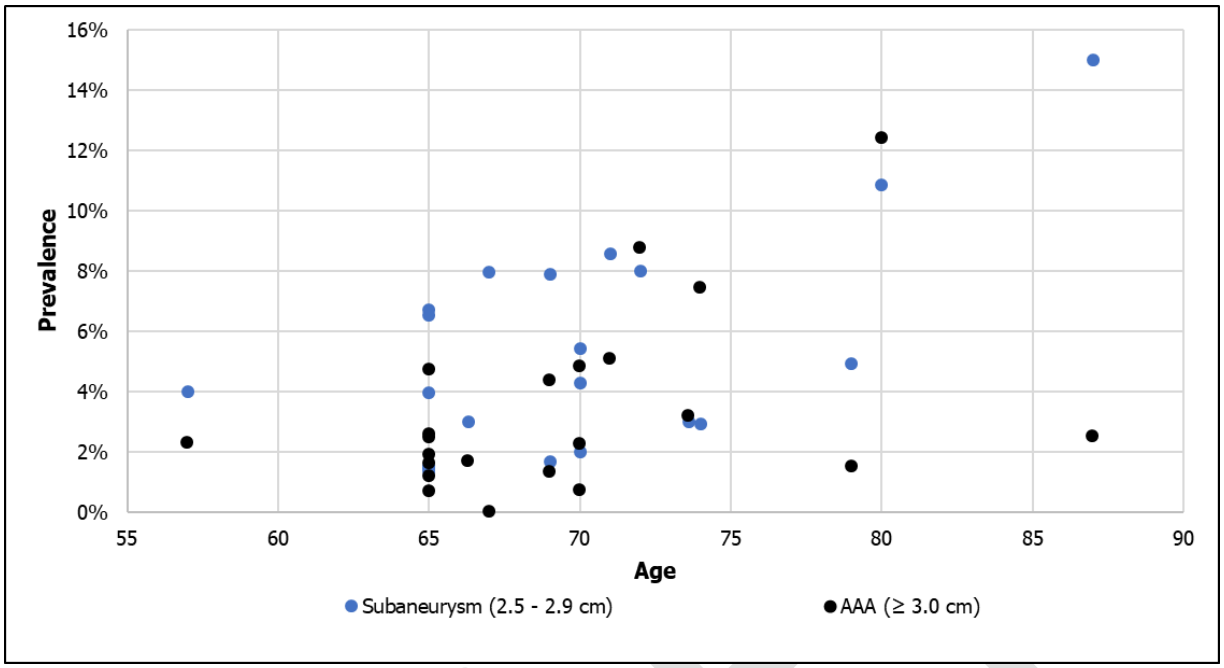
Key: AAA – abdominal aortic aneurysm

Source: Observational studies reporting on the prevalence of AAA and sub-aneurysm in high income or European countries.[32, 68, 77, 78, 84, 87, 96]

* The definition of AAA and sub-categories according to aortic diameter varied between studies. In this analysis, the data were categorised into the following groups, where possible: AAA ≥ 3.0 cm, small to medium AAA from 3.0 to 5.4 cm, and large AAA ≥ 5.5 cm. Where this categorisation was not possible based on the data reported, the data were grouped as follows: AAA ≥ 2.5 cm, small to medium AAA from 3.0 to 4.9 cm, and large AAA ≥ 5.0 cm. Data that did not fit these classifications were excluded.

Sixteen studies reported the prevalence of sub-aneurysm with data presented for various ages. As with AAA, subaneurysm prevalence seemed to increase with advancing age (Figure 2.4).[29, 31, 32, 64, 68, 77, 78, 80, 83-85, 87, 96-99]

Figure 2.4 Prevalence of sub-aneurysm and AAA by age, as reported across 16 observational studies



Key: AAA – abdominal aortic aneurysm
Source: Observational studies reporting on the prevalence of AAA and sub-aneurysm in high-income or European countries.[29, 31, 32, 64, 68, 77, 78, 80, 83-85, 87, 96-99]

2.7 AAA-related hospitalisations

2.7.1 AAA-related hospitalisations in Ireland

In order to understand the volume of AAA-related hospitalisations in Ireland, data from the Hospital In-patient Enquiry (HIPE) database were analysed.[100] These data relate to inpatient cases discharged from public acute hospitals in Ireland with a diagnosis of AAA. The methods and results of this analysis are described in the following sections.

Methods

Hospital inpatient and day cases discharged from public acute hospitals in Ireland are recorded in the HIPE system using the ICD-10-AM coding system (International Classification of Disease, 10th Revision produced by the WHO with the Australian Modification).[101] Diagnoses can be recorded in HIPE as a 'principal' or 'additional' diagnosis. A principal diagnosis is defined as the diagnosis established following admission to be chiefly responsible for a given episode of care. Every HIPE discharge record can capture up to 29 additional diagnoses. Data regarding inpatient admissions with a principal or additional diagnosis of AAA were requested from the HIPE database with the following objectives:

- to estimate the number of inpatient discharges with a principal or additional diagnosis of AAA in men aged 50 years and older, between 2007 and 2022, by:
    - diagnostic subclassification (that is, ruptured versus unruptured)
    - procedure type (that is, open surgical repair (OSR) versus endovascular repair of abdominal aneurysm (EVAR))
- to investigate the potential for changes in surgical intervention patterns over time
- to estimate the rate of in-hospital mortality in men, between 2014 and 2022, by:
    - diagnostic subclassification (ruptured/unruptured)
    - procedure type.

All recorded male cases aged 50 years and older with a principal or additional diagnosis of AAA during the period 01 January 2007 to 31 December 2022 were identified.[100] Diagnosis and procedure codes were identified using the ICD-10-AM/ACHI/ACS as outlined in Appendix 2 Table A1. Cases with a diagnosis of AAA were identified using the following diagnosis codes: I71.3, 171.4 and I71.02. Cases with diagnosis codes relating to post-acute care or rehabilitation were excluded (Z50 Care involving use of rehabilitation procedures, Z48.8 Other specified surgical follow-up care, and Z51.88 Other specified medical care). Diagnosis codes for thoracic aortic aneurysms were excluded. Data could not be presented by age group due to the relatively small number of cases in younger age groups. Data for cases aged less than 50 years were not analysed due to the expected low prevalence of AAA in this age group. Data relating to in-hospital mortality were limited to the time period 01 January 2014 to 31 December 2022 as older mortality data were not considered transferable to the current context due to improvements in operative techniques and care pathways. Mortality estimates are based on cases with a principal diagnosis of AAA screening only. Data beyond 2022 were not available at the time of analysis.

As outlined in Chapter 3, section 3.3.2, AAA can be repaired surgically using OSR or EVAR. EVAR is the less invasive option. In a small number of cases both OSR and EVAR may be recorded in the same episode of care (for example, where EVAR was converted to open surgical repair). The total number of events (admissions or surgical repairs) was expressed per 100,000 male population aged 50 years and over to facilitate comparisons between years. The average population for the years 2007 to 2022 was based on population estimates from the Central Statistics Office.[102]

The HIPE database contains de-identified records for each episode of care and therefore cannot be linked to individual patients. As such, individual patient consent or ethical approval was not required. Event values less than or equal to five are suppressed as part of the healthcare pricing office data protection policy.

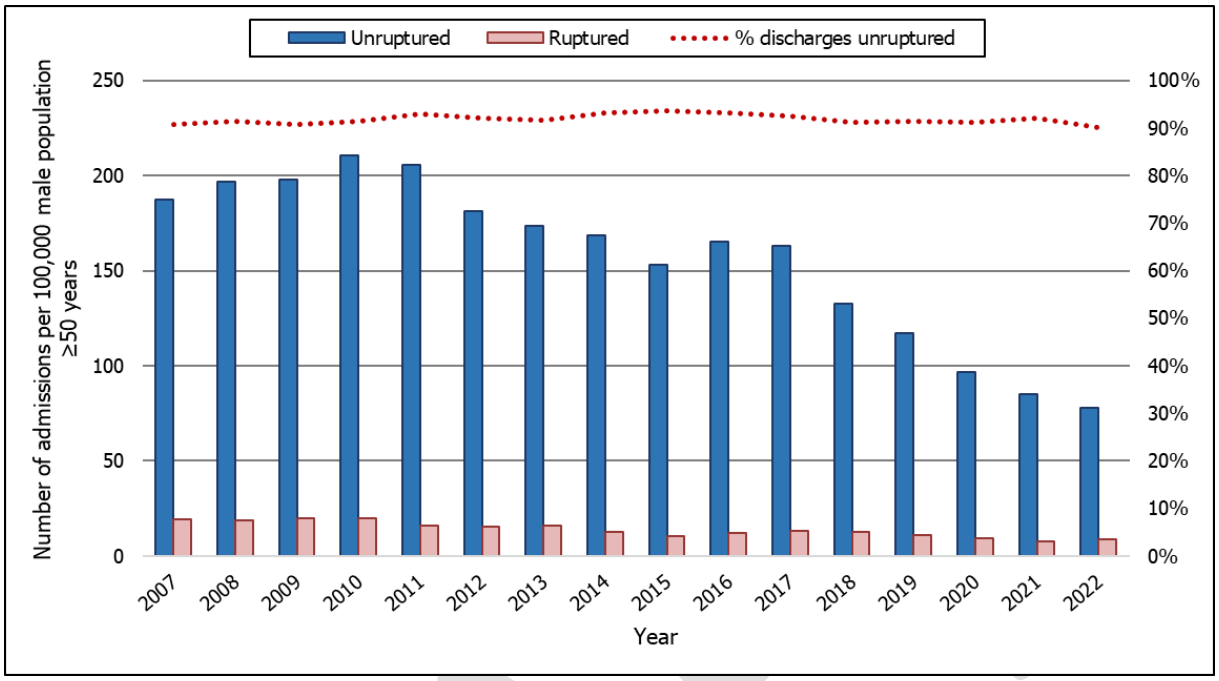
Patients with a diagnosis of AAA below the threshold for surgery may be admitted as day cases for monitoring, including imaging studies. HIPE data is based on hospitalisations which may include multiple admissions for the same patient. As such, day cases were excluded to reduce the potential for duplication of cases. This analysis captures cases that were discharged from public acute hospitals only. HIPE data include private procedures carried out in public hospitals. However, HIPE does not capture activity in private hospitals.

Results

Between 2007 and 2022, the average number of discharges for AAA (ruptured and unruptured AAA) in the public hospital system in Ireland was 1,125 per year, equating to 172 per 100,000 male population aged 50 years and older. There was evidence of a steady reduction in total cases (including aortic dissection) with AAA over time, from 207 per 100,000 in 2007 to 88 per 100,000 in 2022 (Figure 2.5). Relative to 2007, there was a 58% decrease in the discharge rate for cases with unruptured AAA in 2022. The discharge rate for ruptured AAA decreased by 54% during the same time period. On average, there were 90 cases of ruptured AAA per year among men aged 50 years and over between 2007 and 2022, equivalent to a rate of 14 ruptures per 100,000 male population aged over 50 years. It is estimated that each vascular surgery unit in Ireland managed on average nine cases of ruptured AAA per year between 2007 and 2022.

Between 2007 and 2022, on average, 92% of all admissions with a principal or additional diagnosis of AAA were classified as unruptured (Figure 2.5). The relative proportion of cases recorded as unruptured was relatively consistent over time (range 90 to 94%).

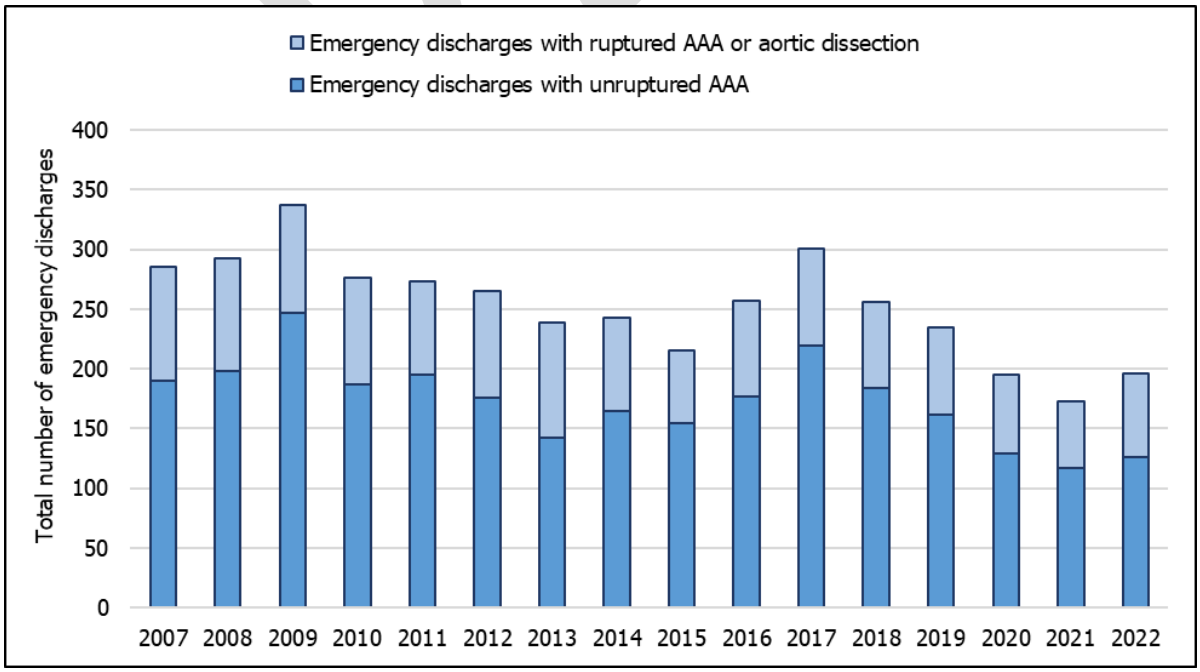
Figure 2.5 Inpatient discharges for ruptured or unruptured abdominal aortic aneurysm in men aged 50 years and older†



Data source: Hospital In-Patient Enquiry (HIPE) System.[100]

On average, between 2007 and 2022, 68% of emergency discharges with a principal diagnosis of AAA presented with an unruptured aneurysm (Figure 2.6).

Figure 2.6 Emergency discharges according to rupture status



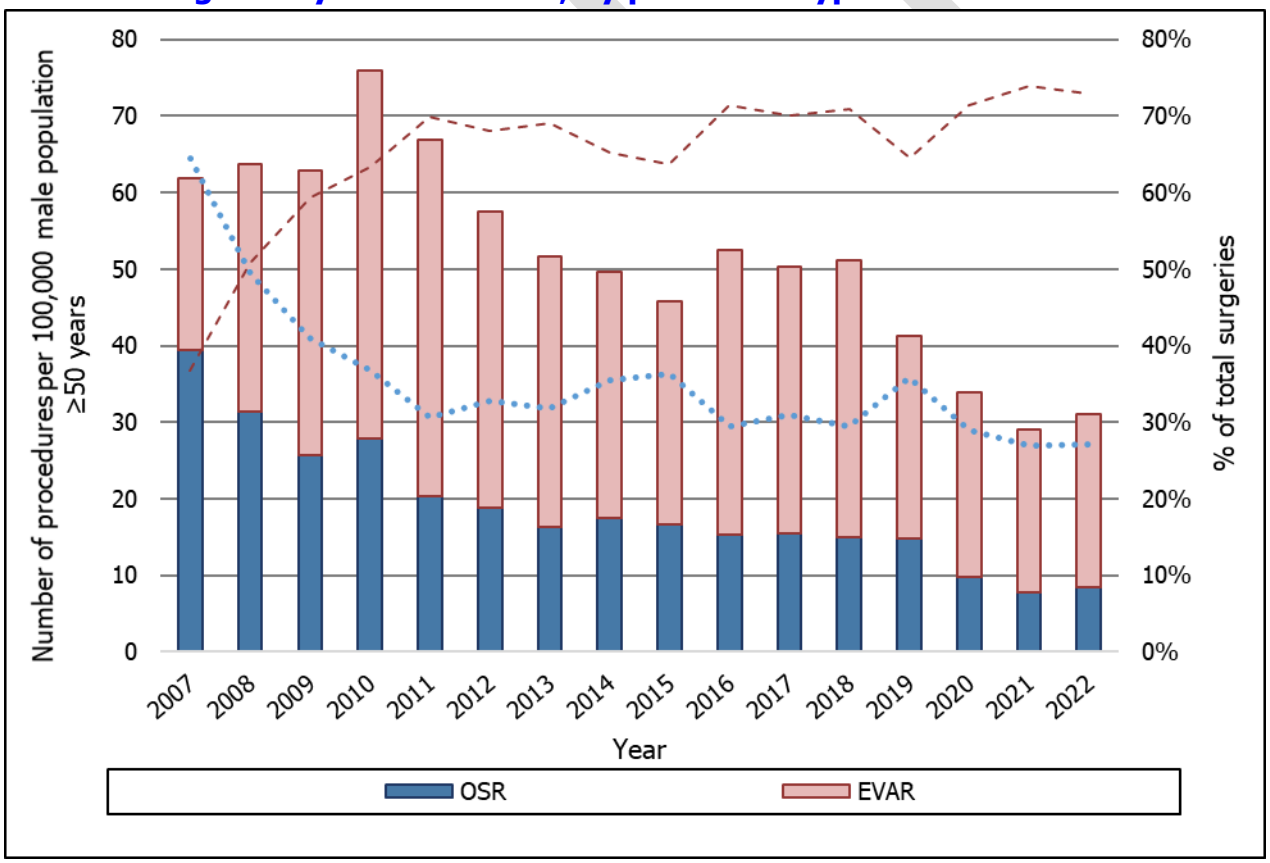
Data source: Hospital In-Patient Enquiry (HIPE) System.[100]

There was evidence of a decrease in the rate of surgical intervention (open and EVAR) over time (Figure 2.7). Relative to 2007, the rate of surgical repair decreased

by 49% in 2022. Over this time period, surgical practice in AAA repair was characterised by an increase in the proportion of surgical repairs that were EVAR, and a concomitant decrease in the proportion of procedures conducted using the open surgical approach.

The rates of EVAR increased substantially between 2007 and 2011, but have remained relatively stable since then. On average, 65% of all surgical repairs of AAA were EVAR, ranging from a minimum of 37% in 2007 to a maximum of 74% in 2021. The rate of open surgical repair decreased in parallel over the same time period. In 2007, an estimated 39 open surgical repairs per 100,000 male population aged 50 years and over were carried out (64% of total surgical repairs in 2007), relative to 8 per 100,000 male population aged 50 years and over in 2022 (27% of total surgical repairs), corresponding to a reduction of 79%.

Figure 2.7 Inpatient discharges for abdominal aortic aneurysm in men aged 50 years and older, by procedure type



Key: EVAR – endovascular aneurysm repair; OSR – open surgical repair.
Source: Hospital In-Patient Enquiry (HIPE) System.[100]

Between 2014 and 2022, among men aged 50 years and over, the in-hospital mortality rate was higher for repair of ruptured AAA, when compared with intact AAA repair. For unruptured cases, the in-hospital mortality rate was estimated to be 60 per 1,000 male cases for open surgical repair, relative to 12 per 1,000 for EVAR. For cases with ruptured AAA, the in-hospital mortality rate was estimated to be 403 per

1,000 male cases for open surgical repair, relative to 212 per 1,000 for EVAR. The estimated in-hospital mortality rate for repair of ruptured AAA includes only cases in whom surgical repair was attempted. This should not be interpreted as the mortality rate for all cases attended by emergency medical services.

2.7.2 International estimates of AAA-related hospitalisation

In general, reductions in the age-standardised incidence of ruptured AAA have been observed over time in countries without an AAA screening programme including Finland,[103] Denmark,[104] New Zealand,[105] and Canada.[106] However, there is considerable variation in the rate of AAA-related hospital admission between countries, which may be related to differences in AAA prevalence, reporting (for example, differences in coding between administrative databases or methods for estimation of event rates), primary and secondary prevention interventions, prehospital transport times, or the timing of studies.

Comparisons between the rate of AAA-related hospitalisations between settings were not considered appropriate as observed variation between studies or settings may be related to methodological differences, such as differences in coding practices between administrative databases, or contextual factors such as the prevalence of AAA, the availability of primary prevention interventions, or the timing of studies. In addition, given that AAA rupture is a time-critical medical emergency, factors such as emergency response times and distance from the nearest hospital may impact the admission rate for ruptured AAA.

2.8 AAA-related mortality

AAA-related mortality rates in Ireland were estimated using data from the Central Statistics Office (CSO).[107] Estimates from the international literature and the Global Burden of Disease (GBD) Study 2019 were used to set national estimates within the broader European and global context.

2.8.1 AAA-related mortality in Ireland

Methods

Data on mortality related to aortic aneurysm and dissection (I71) for the period 2007 to 2021 were obtained from the CSO. Consistent with a previous analysis,[108] deaths in which the following International Classification of Diseases 10th edition (ICD-10) codes were registered as the underlying cause of death were included:

- abdominal aortic aneurysm, ruptured (I71.3),
- abdominal aortic aneurysm, without rupture (I71.4),
- thoracoabdominal aortic aneurysm, ruptured (I71.5),
- thoracoabdominal aortic aneurysm, without rupture (I71.6),

- aortic aneurysm of unspecified site, ruptured (I71.8),
- aortic aneurysm of unspecified site, without rupture (I71.9).

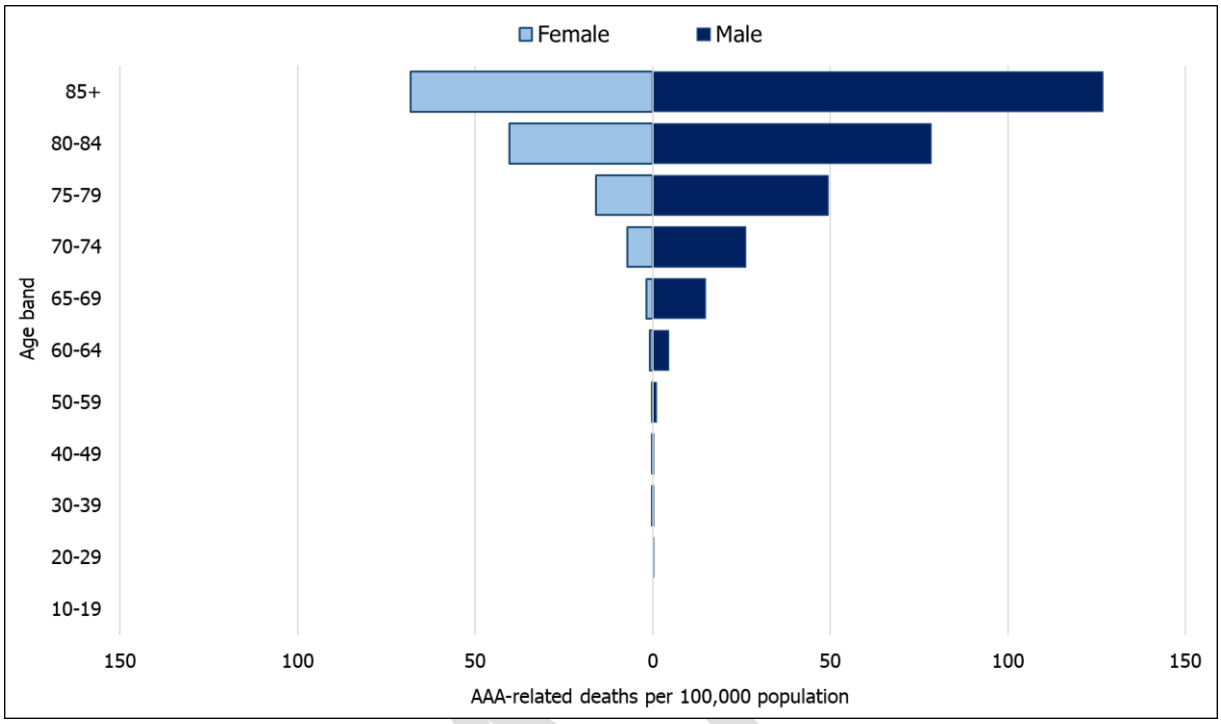
The following codes were excluded: known thoracic aneurysms (thoracic aortic aneurysm, ruptured (I71.1); thoracic aortic aneurysm, without rupture (I71.2)); aortic dissections (dissection of aorta (I71.0)). Although not specific to AAA, thoracoabdominal aneurysms (I71.5 and I71.6) and aortic aneurysms at an unspecified site (I71.8, and I71.9) were included, as it is plausible that these aneurysms may be detected by an AAA screening programme. Results are also presented for the subgroup of cases classified specifically as ruptured and unruptured AAA (I71.3 and I71.4).

The age- and sex-specific mortality rate was calculated using population estimates for males and females for the years 2007 to 2021, which were obtained from the CSO. Data were stratified by gender and age bands for analysis. Additionally, an age-standardised AAA mortality rate was calculated using data for all men aged 10 years and above and based on the European Standard Population (ESP).[109]

Results

The average yearly AAA-related mortality rate over the period 2007 and 2021 was higher in older men, rising sharply in men at 60 to 64 years of age (5 per 100,000), up to a maximum of 127 per 100,000 in men aged 85 and older. In women, AAA-related mortality increased at a later age, reaching 68 per 100,000 in those aged 85 and older between 2007 and 2021. On average, between 2007 and 2021, in men aged 65 to 69, age-specific AAA-related mortality was approximately eight times higher in men (15 per 100,000 population) than in females of the same age group (2 per 100,000 population) (Figure 2.8). Sex-specific differences in the risk of AAA-related mortality between men and women gradually decreased with advancing age. However, the mortality rate was still approximately two times higher in men aged 80 years and older.

Figure 2.8 Average age-specific AAA-related mortality (2007 to 2021) by sex

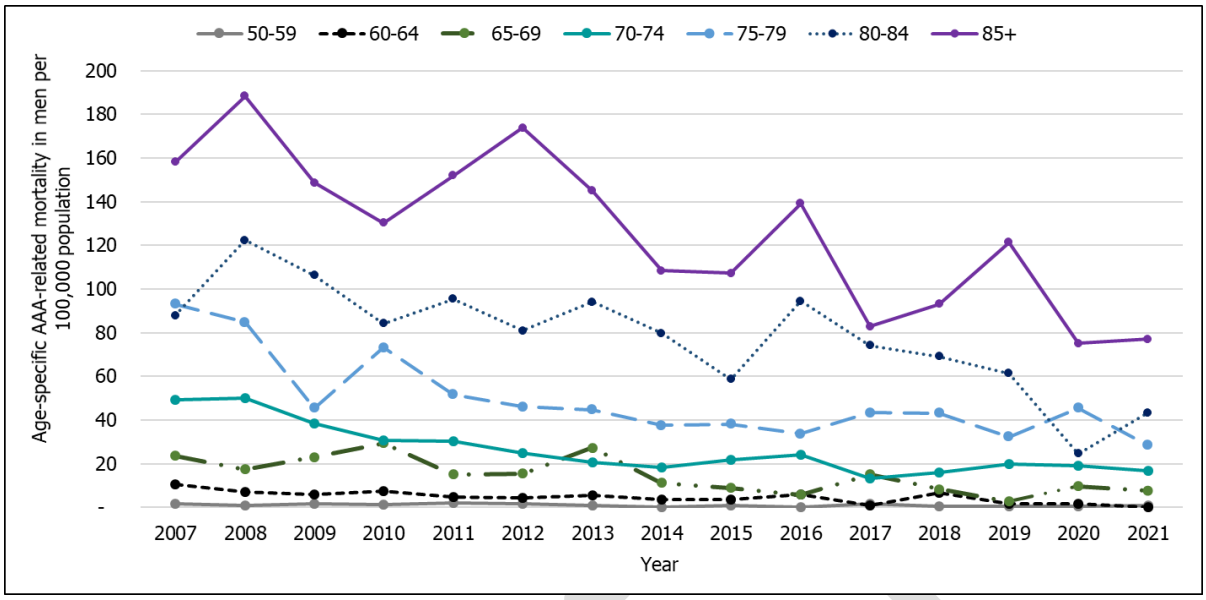


For the purposes of this analysis, AAA-related mortality was defined as International Classification of Diseases 10th edition (ICD-10) codes I71.3 to I71.9, which includes abdominal and thoracoabdominal aortic aneurysms (with or without rupture), and aortic aneurysms of unspecified site. Inclusion of thoracoabdominal aortic aneurysms had a minor impact on estimated AAA-related mortality at all ages due to the low number of deaths in which I71.5 or I71.6 was recorded as the underlying cause of death (less than one death per annum between 2007 and 2021).
Data source: Central Statistics Office (CSO).[107]

Between 2007 and 2021, on average, there were 115 deaths per year from AAA in men. Overall, the crude rate of AAA-related mortality in men decreased from 6.5 per 100,000 to 3.5 per 100,000 male population during this period. As shown in Figure 2.9, age-specific AAA-related mortality in men fluctuated over time, particularly among those aged 80 years and over. However, overall, there was a consistent downward trend in age-specific AAA-related mortality in older age groups. The age-standardised AAA-related mortality in men decreased from 16.1 per 100,000 (95% CI: 13.5 to 18.3) to 6.2 per 100.000 (95% CI: 4.9 to 7.5).

The mortality rate from ruptured AAA (ICD-10 code I71.3 only) decreased from 4.8 per 100,000 male population in 2007 to 2.3 per 100,000 in 2021. The rate of unruptured AAA (ICD-10 code I71.4 only) was approximately 1.0 per 100,000 male population (range: 0.5 to 1.1) between 2007 and 2021. Mortality from ruptured and intact AAA increased with advancing age, although there was variation likely due to the small absolute number of cases (Appendix 2, Figure A2).

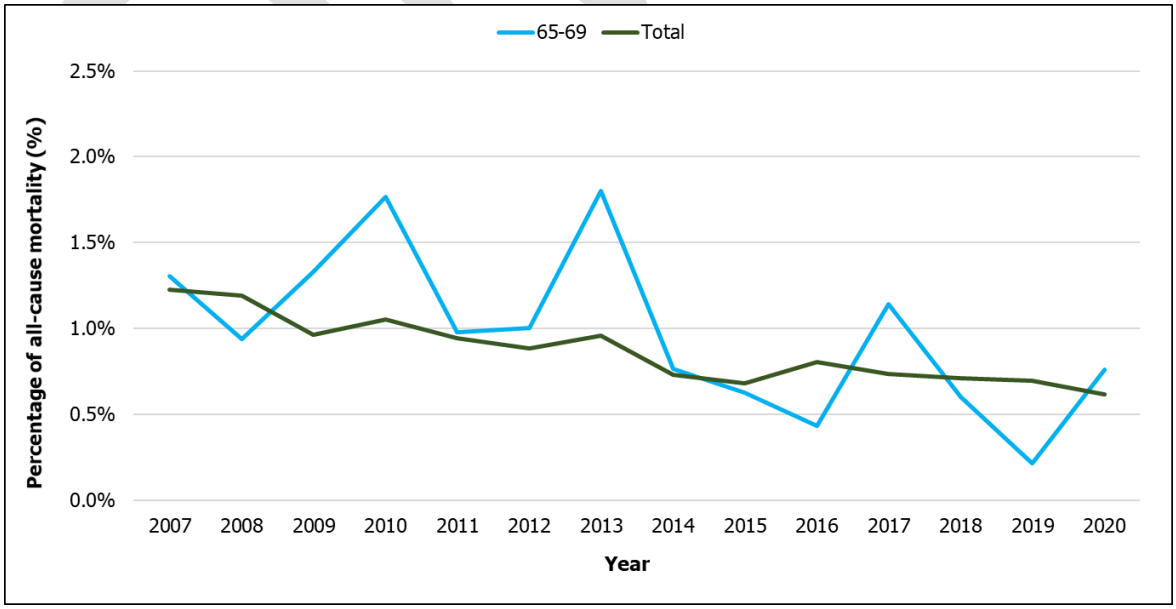
Figure 2.9 Age-specific AAA-related mortality in men (2007 to 2021)



Data source: Central Statistics Office (CSO).[107]

Decreases in AAA-related mortality have occurred alongside reductions in all-cause mortality, although without necessarily the same gradient of decline. During the period from 2007 to 2020, all-cause mortality decreased from 5,009 to 4,265 deaths per 100,000 males over 65 years (Figure A3). In 2007, AAA-related mortality accounted for 1.2% of all deaths, declining to 0.6% in 2020. In males 65 to 69 years, AAA-related mortality accounted for 1.3% of all deaths in 2007, decreasing to 0.8% in 2020, although there was evidence of considerable variation (Figure 2.10).

Figure 2.10 AAA-related mortality as a percentage of all-cause mortality



Data source: Central Statistics Office (CSO).[107]
'Total' refers to all-cause mortality among all men aged 65 years and older.

2.8.2 International estimates of AAA-related mortality

It is difficult to compare international estimates of age-standardised mortality given different approaches taken across studies, for example, with respect to the choice of standard population used and the population subgroups considered within the analysis. There is substantial heterogeneity in published AAA age-standardised mortality rates. However, considering trends, aortic aneurysm related-mortality, including AAA-related mortality, has decreased over time.[110, 111]

Retrospective analyses of regional or national administrative databases specifically reporting on AAA-related mortality are in line with trends reported globally. An analysis of national mortality data in the Netherlands reported a reduction in age-adjusted AAA mortality between 1995 (21 deaths per 100,000) and 2010 (11 deaths per 100.000).[112] In 2015, the incidence of AAA-related mortality in Nova Scotia was estimated to be 8.6 (95% CI: 7.8 to 9.4) per 100,000 men, with evidence of a decrease over time.[106] Prior to the introduction of the NHS AAA screening programme, age-standardised AAA mortality in England and Wales declined from approximately 6 to 4 per 100,000 (men and women) between 2001 and 2009, equivalent to an annual decline of 5%.[113]

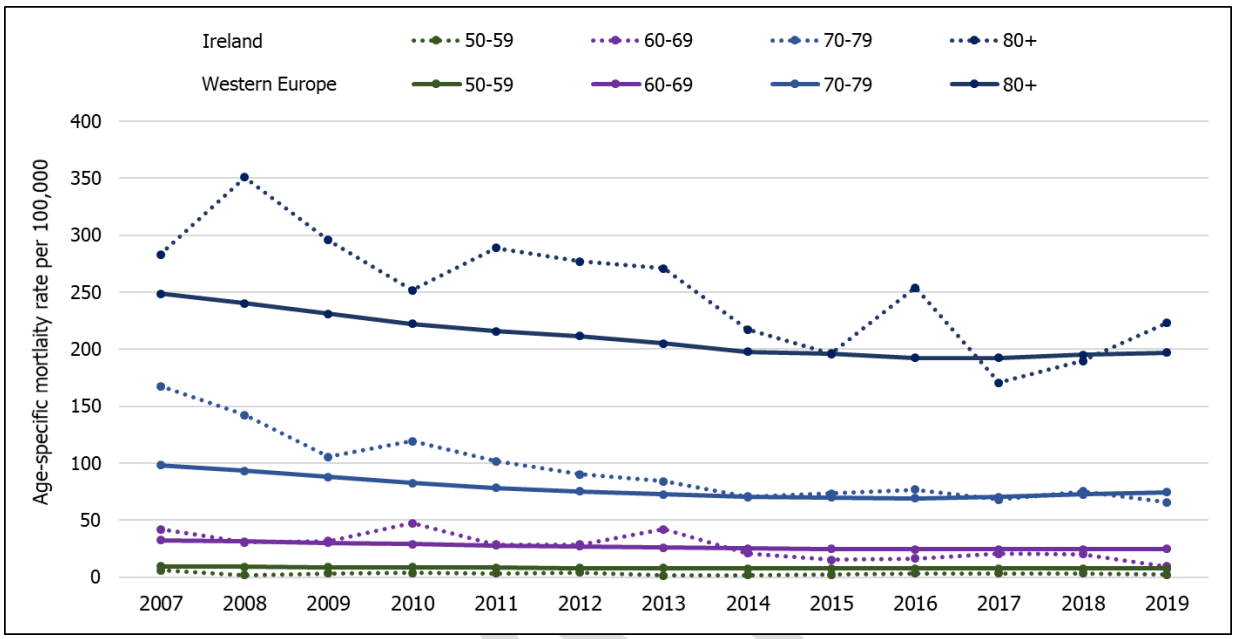
Comparison of aortic aneurysm-related mortality in Western Europe with Ireland

In order to consider AAA-related mortality in Ireland in the context of data for other European countries, aortic aneurysm-related mortality data were obtained from the GBD Study 2019 for the period 2007 to 2019.[114] The subset of Western European countries was adopted, the list of countries for which was predefined within the GBD data visualisation tool. Data were not available by aortic aneurysm site (for example, thoracic or abdominal). Therefore, a proportion of reported deaths include non-abdominal aortic aneurysms. Aortic aneurysm-related mortality data for Western European countries were compared with aortic aneurysm-related mortality data from the CSO (that is, all subcategories of ICD-10 code I71, aortic aneurysm and dissection).

Relative to other Western European countries, age-specific aortic aneurysm-related mortality appears to be lower in Ireland for men aged 50 to 69 years, although absolute differences in case numbers are small (Figure 2.11 and Appendix 2, Figure A1). For those aged above 70 years, age-specific aortic aneurysm-related mortality appears to be higher in Ireland when compared with other European countries as estimated using GBD Study data (Figure 2.11 and Appendix 2, Figure A1). Of note, GBD Study data are based on modelled outputs underpinned by data inputs from a variety of administrative databases, while CSO data are based on annual estimates

of underlying cause of death as reported on death certificates. Therefore, greater variability in estimated aortic aneurysm-related mortality for Ireland is expected.

Figure 2.11 Age-specific aortic aneurysm-related mortality in men in Western Europe and Ireland (2007 to 2019)



Data for the following "Western Europe" countries (as defined by the Global Burden of Disease (GBD) database) were extracted: Andorra, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, the Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, and the United Kingdom. Subgroups according to geographic region were extracted as pre-specified within the GBD data visualisation tool. Data for Ireland included all deaths for which the cause of death was recorded by the CSO as aortic aneurysm and dissection (ICD 10 code: I71).
Data sources: Global Burden of Disease (GBD) Study 2019,[114] and the Central Statistics Office (CSO).[107]

2.9 Projected burden of AAA

2.9.1 Projected prevalence of AAA and AAA subtypes

In the absence of up-to-date national data sources, prevalence estimates from AAA screening programmes in Sweden and the UK are presented to inform estimated trends in the future prevalence of AAA in Ireland. As noted in sections 2.3.1 and 2.6.1, the prevalence of AAA in other European countries, in particular the UK, is likely broadly applicable to the Irish context.

The prevalence of AAA detected as part of NAAASP in the UK between 2013 and 2022 was extracted from AAA annual standards reports.[115] Estimates prior to 2013 were excluded as the NAAASP had not reached full implementation; therefore, available estimates may not be nationally representative. The estimated prevalence of AAA in four local Swedish AAA screening programmes including a total screened

population of 94,835 was extracted from Wanhainen 2024: Uppsala (2006 to 2022), Gävle (2009 to 2022), Dalarna (2008 to 2022), and Västerbotten (2009 to 2022).[116] The line of best fit for these data was estimated using a least squares regression in Excel 2013. The estimated equation of the line was used to approximate data over a short-term time horizon (up to 2029).

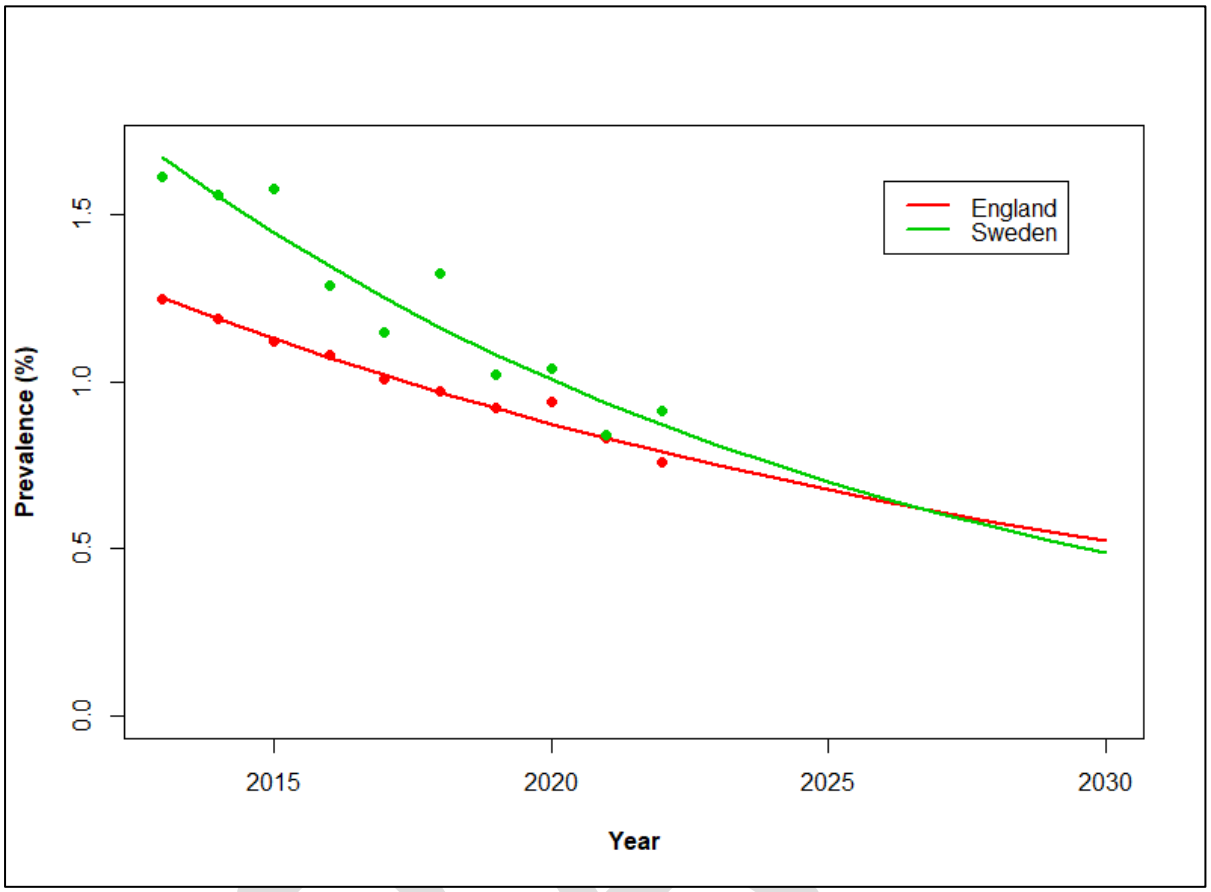
Assuming current trends continue, and all other factors remain constant, the prevalence of AAA is expected to continue to decline over the next five years (Figure 2.12). Changes in the AAA prevalence in the UK are unlikely to be explained by changes in the population attending screening; uptake was consistently above the acceptable performance standard set by the NAAASP (that is, ≥75%) and was broadly consistent over this time period, ranging from a minimum of 77.0% (April 2019 to March 2020) to a maximum of 81.4% (April 2018 to March 2019).

Prevalence estimates from Swedish counties were variable, likely due to the smaller sample size (Figure 2.12). Uptake was noted to be high (85.3%) and stable over time.[116] Similar to outcomes from the UK NAAASP, individual counties showed a significant reduction in prevalence over time, despite variations within and between counties. Between 2018 and 2022, a mean prevalence of 1.0% or lower has been observed in the four counties, with the lowest prevalence of 0.5% observed in Uppsala.[116] The trend in prevalence of AAA was noted to strictly follow smoking trends.[116]

In Sweden, there was evidence of a decline over time in the percentage of men with an AAA ≥5.0 cm, from approximately 35% in 2006 to <10% in 2022.[116] As noted in Chapter 4, in the UK NAAASP the proportion of screen-detected AAAs that are large (≥5.5 cm) has remained relatively consistent over time at approximately 10%. Trends over time may be influenced by differences in the threshold used for reporting purposes (≥5.0 cm versus ≥5.5 cm), differences in the reporting periods, or sampling bias. It appears that, within the Swedish programme, the proportion of men with a large AAA during the first three years post-implementation was relatively high (approximately 15% to 35%). Estimates for 2013 onwards, at which point the UK NAAASP had reached full implementation, are broadly comparable between the two programmes (10 to 15%). Given that Swedish AAA prevalence data are based on a subset of local screening programmes, estimates may not be nationally representative.

Estimation of the longer-term prevalence of AAA is challenging owing to the dependence of AAA prevalence on multiple factors including the prevalence of smoking, patterns of tobacco use among those who smoke (for example, the number of cigarettes consumed per day), and cardiovascular risk factor management.

Figure 2.12 Short-term projection of AAA prevalence in Sweden and England



Key: AAA – Abdominal aortic aneurysm.
The prevalence of screen-detected AAA was estimated using a binomial model based on the observed prevalence in the population attending screening for the period 2013 to 2022. Only the total population attending screening between 2006 and 2022 was reported by Wanhainen et al (n = 94,835); therefore, a constant annual population size was assumed (n = 5,579).
Sources: NAAASP AAA annual standards reports 2013 to 2023; Wanhainen 2024.[116]

2.9.2 Projected burden of AAA-related morbidity and mortality

It is likely that a continued decline in AAA prevalence will translate into relative reductions in AAA-related morbidity and mortality. Such changes however, may not be directly proportional, as the incidence of AAA-related morbidity and mortality are influenced by factors such as cardiovascular risk factor management and access to elective surgery, where indicated.

There are limited robust, population-based data to assess how changes in prescribing patterns for managing cardiovascular risk factors influence AAA development and progression. Anjum et al. investigated several potential reasons behind the change in mortality from ruptured AAA between 1997 and 2009 in the population aged 65 years and older in England and Wales.[117] The increase in elective AAA repairs and the reduction in smoking were estimated to have

contributed equally to the decline in mortality from ruptured AAA between 1997 and 2009, at approximately 11 deaths avoided per 100,000 population.[117] Increased prescription of anti-hypertensive drugs was estimated to have had a small impact on the reduction in AAA-related mortality (0.5 to 1.6 deaths avoided per 100,000 population).[117] The increased use of statins potentially had a larger effect (7.3 to 17.2 deaths avoided per 100,000 population) than either increasing elective surgery or declining smoking prevalence.[117] It is important to note, however, that reliable population estimates were available to inform estimates of deaths avoided by changes for smoking only.[117] Thus, these results should be interpreted with caution. For example, evidence from a meta-analysis found that while there was a possible association between cardioprotective drugs (that is, lipid-lowering drugs, aspirin, beta-blockers, calcium channel blockers or angiotensin-converting enzyme (ACE) inhibitors) and AAA growth rate, the magnitude of effect was considered small.[26]

As described in section 2.4.2, although subject to limitations, the available evidence suggests that AAA growth rates have not changed significantly over time, despite improvements in cardiovascular risk factor management.[26, 56] This may suggest that while the number of men developing an AAA has declined, for those who develop an AAA, the disease progression remains largely unchanged. However, recent evidence from the Swedish AAA screening programme, indicating a significant decrease in the proportion of screen-detected AAAs classified as large, may challenge this theory (section 2.9.1).[116] However, definitive conclusions cannot be drawn due to the limitations of the evidence base. As noted in Chapter 3, section 3.3.2, a specific pharmacological treatment to slow or reverse AAA growth has not been identified.

2.9.3 Life expectancy

Life expectancy in Ireland is among the highest in Europe. Over the past 20 years, life expectancy in Ireland has grown faster than the EU average.[118] At age 65 years, the estimated average number of years of life remaining in 2021 was 19.2 in Ireland, compared with an average of 17.3 years in EU27 countries.[119] The observed increases in life expectancy are reported to be predominantly attributable to consistent reductions in mortality from cardiovascular diseases, including ischaemic heart diseases and stroke.[118] Importantly, men and women aged 65 years and older in Ireland are likely to spend a greater portion of their life without disabilities compared to the EU average.[118]

The potential impact of increases in life expectancy on AAA-related morbidity and mortality is challenging to interpret. Evidence from the Gloucestershire Aneurysm Screening Programme demonstrates that mean aortic diameter has decreased over time in men age 65 years,[75] which may result in an apparent shift in the burden of aortic disease to later in life.[117] It is also worth noting that smoking is negatively

correlated with life expectancy.[120, 121] In the context of declining smoking rates, increases in life expectancy may not necessarily be accompanied by an increase in the burden of aortic disease.

2.9.4 Population age structure

It is estimated that the proportion of the population aged 65 years and older will increase by 54% between 2023 and 2043.[122] Population ageing has major implications for the planning and provision of healthcare services. In the context of an ageing population, decreases in the age-standardised incidence of AAA-related morbidity and mortality rate may not translate into a decrease in the absolute number of people experiencing AAA-related morbidity and mortality.

2.10 Estimation of the population that would be eligible for screening and, subsequently, surveillance

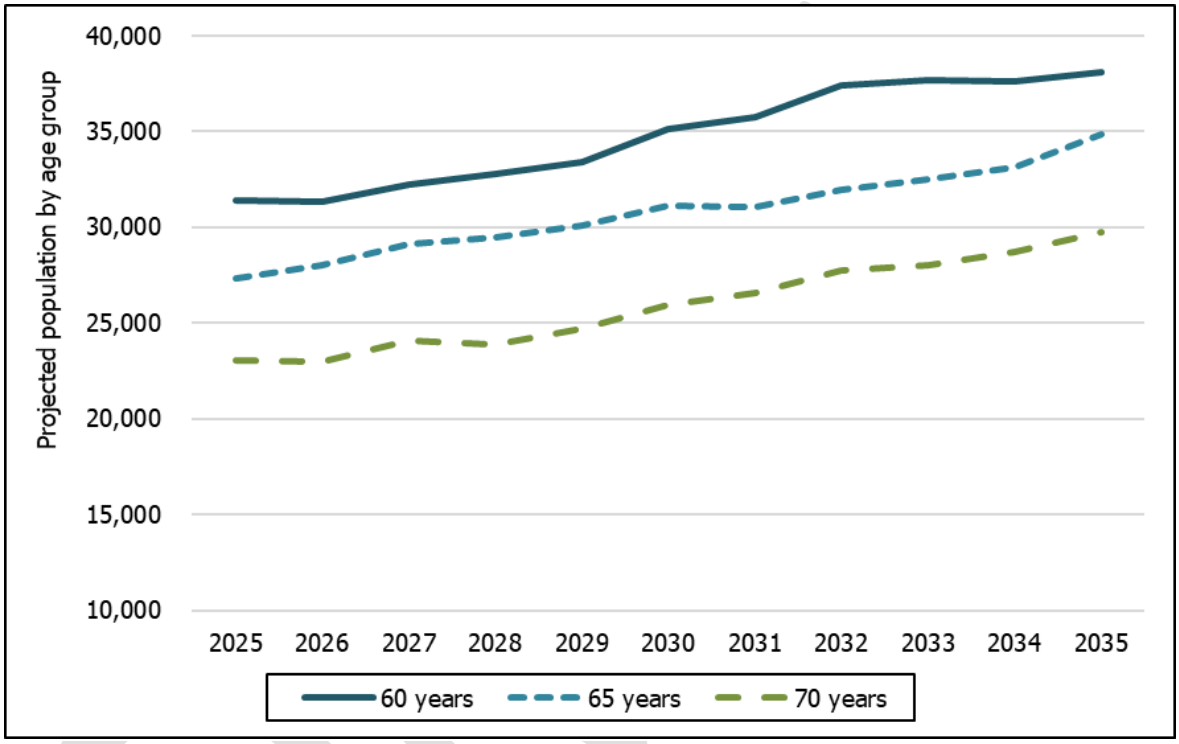
The scope of this assessment is limited to one-time ultrasound screening for AAA in men. The specific age group targeted by screening will be informed by numerous factors including the epidemiology of disease in Ireland, evidence of clinical effectiveness and safety, cost effectiveness, international practice, feasibility and acceptability. Based on evidence from international practice and clinical practice guidelines (see Chapter 3, section 3.4), and evidence of a sharp increase in both the prevalence of AAA and incidence of AAA-related mortality in men over 65 years of age, it is likely that an AAA screening programme targeting men aged 65 would yield greater clinical benefits than a programme targeting a younger population.

Population projections for Ireland indicate that the number of men aged 65 years and over will increase over time. Increases in the population aged 65 years and over would translate into an increase in demand for AAA screening. The impact of the growth in the older population on demand for subsequent surveillance or elective surgical repair would be dependent on the underlying disease prevalence, and the distribution of aortic diameters within the prevalent population.

Figure 2.13 illustrates population projection estimates from the CSO for men aged 60, 65 and 70 for the years 2025 to 2035. Based on these estimates, on average, approximately 30,000 men aged 65 would be eligible for screening each year from 2026 to 2030. Decreasing the target age group to age 60 would result in an increase in the number of men eligible for screening (approximately 33,000 in total per year, Figure 2.13). Relative to 2025, it is estimated that the number of men aged 65 will increase by approximately 14% by 2030, and by approximately 27% by 2035. The number of men aged 65 is projected to continue to increase beyond the time horizon presented.

Based on data from the NHS AAA screening programme (NAAASP), assuming an average prevalence of 0.70% and an uptake rate of approximately 80%, approximately 165 men would receive a positive screening test result each year, of which a considerable proportion (range 80% to 94%, see section 2.6.1) would likely require access to ongoing surveillance to monitor AAA growth.

Figure 2.13 Estimated population projections between 2025 and 2035 according to potential target age groups: all men aged (a) 60 years; (b) 65 years; (c) 70 years



Population projections were based on the 2022 census. Population projections are available for six different population outcomes resulting from the combination of assumptions regarding mortality and international migration. In the base case analysis, as a conservative approach, high net inward migration was assumed (assumption M1 of the CSO).
Source: Central Statistics Office (CSO).[123]

2.11 Discussion

The key findings of this chapter were firstly that, internationally, the prevalence of AAA has decreased steadily over time, believed to be driven largely by decreases in cigarette smoking. Irish-specific up-to-date estimates of the prevalence of AAA are lacking due to the absence of a national vascular registry or recent epidemiological studies. However, estimates from the UK are likely applicable to the Irish context given the strength of the association between smoking and AAA, and similarities in smoking rates. It is important to note that reductions in the prevalence of AAA have the potential to reduce the relative benefits (Chapter 4) and cost effectiveness (Chapters 5 and 6) of an AAA screening programme. Secondly, corresponding decreases in AAA-related hospitalisations and AAA-related mortality rates have been observed in Ireland over time, consistent with the international evidence. It is important to note, however, that the fatality rate associated with AAA rupture has decreased only marginally over time, due to the nature of the acute event, characterised by rapid onset of massive internal bleeding.[60] Given the asymptomatic nature of AAA prior to rupture, and the poor outcomes associated with out-of-hospital rupture, early detection and intervention are of critical importance in reducing AAA-related morbidity and mortality.

Risk factors for AAA include smoking and, to a lesser extent, hypertension. Evidence from international screening programmes suggests that over 85% of cases with screen-detected AAA have a history of smoking.[28, 29, 31, 32] It is plausible that the risk of AAA may also be related to passive smoking exposure in a dose dependent manner, which may explain, at least in part, cases of AAA in non-smokers. People with AAA also have a high prevalence of comorbid cardiovascular disease.[61] Screening for AAA, therefore, provides an opportunity to identify those at risk of cardiovascular morbidity and mortality that may benefit from aggressive cardiovascular risk factor management to reduce AAA growth rates and improve overall cardiovascular health.

There have been considerable changes in public health and healthcare since the 1970s, including a reduction in the prevalence of smoking, more aggressive cardiovascular risk factor management strategies and improved access to healthcare. These changes have likely influenced AAA-related morbidity and mortality.

The tobacco epidemic affected different European countries at different stages. In Northern, Western and Southern Europe, tobacco consumption is said to have peaked between the 1950s and 1970s, followed by a period of stabilisation or reduction.[124, 125] Based on cigarette sales data, as a proxy for cigarette consumption, smoking peaked in Ireland in the mid-1970s which appears to coincide with the peak of smoking rates in the UK.[126, 127] In absolute terms, and as a

proportion of all deaths, smoking-attributable deaths among males peaked between the 1960s and 1990s.[124] It is important to note this reflects the consequences of tobacco consumed two to three decades previously.[124, 128] The burden of AAA-related mortality experienced in the second half of the 20th century has been described as a cohort effect associated with the pattern of tobacco use in the mid-20th century.[128]

Since the 1980s, tobacco control policies in the EU have contributed to reductions in smoking-related mortality and overall improvements in public health.[117, 124] Changes in smoking habits are believed to largely explain the decreasing prevalence of AAA.[28, 128] A further decline in AAA prevalence could be expected over time if the rate of smoking among men continues to decline. Assuming current trends continue, and all other factors remain constant, the prevalence of smoking in Ireland is expected to be 5% by 2037.[129] However, recent trends in smoking prevalence in Ireland suggest that the rate of decline has potentially plateaued or slowed.[38] Even if the rate of decline has slowed, it is also important to consider the dose-response relationship between AAA prevalence and smoking.[23] Policy initiatives such as restrictions on the places in which people can smoke, and tobacco price increases have likely contributed to a reduction in tobacco consumption per person among those who smoke, which in turn translate into relative reductions in AAA-related morbidity and mortality.[130] While declining smoking is believed to be the largest contributor to decreases in AAA prevalence, it is worth noting that changes in the prevalence of smoking may not be independent of other factors such as cardiovascular medication use and lifestyle changes, which may also influence AAA risk.

The reduction in the prevalence of smoking is not the only factor contributing to declines in AAA-related morbidity and mortality. Cardiovascular diseases, including AAA, are multifactorial.[124] Smoking acts alongside other risk factors, such as diet, physical activity and cardiovascular risk factors (such as, hypertension or dyslipidaemia) to influence the risk of AAA development and progression. As outlined in section 2.9.2, evidence from the UK suggests that increases in elective repairs contributed almost equally to the decline in death from AAA rupture as declines in smoking between 1997 and 2010.[117] Based on limited evidence, the increased use of statins potentially had a larger effect than either increasing elective surgery or declining smoking prevalence, although this was subject to considerable uncertainty.[117] Despite uncertainty in the magnitude of the effect size, the available evidence highlights the multifactorial nature of changes in the epidemiology of AAA over time. It is uncertain whether AAA-related morbidity and mortality will continue to decline at the current rate, as this will be dependent on factors such as the continued decline in the prevalence of smoking and successful disease management,

including cardiovascular risk factor modification in the target population and timely access to elective surgical repair.

In the short-term, primary prevention alone is unlikely to be sufficient to prevent AAA-related morbidity and mortality given the potential time lag between changes in lifestyle factors and cardiovascular risk reduction. Observational evidence suggests that the cardiovascular benefits of smoking cessation become apparent within five years. However, heavy smokers continued to be at a significantly increased risk of cardiovascular complications for up to 25 years following smoking cessation.[131]

Furthermore, while certain modifiable risk factors increase the risk of developing an AAA, aortic aneurysmal disease is a degenerative process that occurs naturally with age. Life expectancy in Ireland has increased rapidly and is among the highest in the EU.[118] Ireland has also experienced a demographic shift characterised by an ageing population; the population aged 65 and over has increased by 35% since 2013, approximately double the average rate of increase in the EU.[122] In the context of increasing life expectancy and an ageing population, cardiovascular risk factor management in isolation may be insufficient to reduce the burden of AAA on the healthcare system and society. Moreover, with consideration to the risk-benefit balance associated with elective surgical repair, advanced age at presentation may result in a tendency towards non-operative management, which may support the argument for earlier detection and intervention.

In addition to primary prevention, early detection through screening has the potential to reduce AAA-related morbidity and mortality. It is important to note, however, as the elasticity of the aorta declines slowly with age, the absence of an AAA at a single time point does not preclude development of an AAA later in life. This is an important consideration in the context of increasing life expectancy. Given that a proportion of those with sub-aneurysm in middle age may eventually develop clinically significant AAA in later life, inclusion of this group in an AAA screening programme may be considered. It is estimated that only approximately 5% of sub-aneurysms would reach the threshold for referral to vascular surgery within 5 to 10 years.[53] Inclusion of those with sub-aneurysm would likely be associated with a 2.5-fold increase in the number of men entering the surveillance pathway (Figure 2.3). A decision to undertake surveillance of those with sub-aneurysm at baseline must consider the increased potential for overdiagnosis, as well as the potential resource implications in terms of follow-up capacity.

Consistent with international trends, EVAR as proportion of total surgical repairs has increased over time in Ireland.[105, 132, 133] This practice change has been underpinned by evidence suggesting a short-term survival benefit from EVAR versus open surgical repair, and the potential to offer EVAR to patients who may not have been candidates for open surgery. However, there is ongoing uncertainty regarding

long-term durability of some devices used for EVAR, the risk of repeat rupture in the longer-term, and potential requirements for re-intervention.[6, 133] Thus, although EVAR may be considered the preferred treatment modality for the majority of patients, the open surgical approach may be considered in younger, fitter patients with a long life expectancy. It is plausible that the introduction of an AAA screening programme in men may result in increased use of the open surgical approach in younger men with screen-detected large AAA. However, given it is estimated that only approximately 10% of men would be eligible for referral for surgical evaluation at the time of screening, the impact on surgical trends would likely be minor.

AAA surgical activity data in Ireland were extracted from HIPE. HIPE is an administrative database, designed to record and classify the level and nature of activity in Irish public hospitals in order to inform payment to hospitals. The use of the HIPE data for purposes other than this carries limitations. In some settings, the accuracy of administrative hospital discharge data relative to clinical chart data has been shown to vary.[134-136] Reporting accuracy may be influenced by factors such as the clinical condition under consideration, the type of data (for example, secondary diagnoses may not be recorded where they are not relevant to the admission episode), or the experience and training of clinical coders. However, a 2012 systematic review concluded that reporting accuracy in hospital coding data was sufficiently robust to support the use of such data for research purposes.[137] Nonetheless, administrative data coded using ICD-10 are widely used internationally for healthcare research and planning, given that these data are routinely collected and thus readily available, and the potential for international comparability. In the absence of a national vascular registry, HIPE represents the best available data regarding AAA-related hospitalisations in Ireland. Nonetheless, these data should be interpreted with consideration to the known limitations of the HIPE database, including the inability to track individual patients, and the lack of data from private hospitals.

Secondary to declining prevalence and improvements in surgical practice, globally and in Ireland, AAA-related-mortality has decreased over time. It is important to note, however, that the reliability of the mortality estimates is dependent on the accuracy of the underlying data. For the purposes of this assessment, aortic aneurysm-related mortality in Ireland and Western Europe were based on estimates from the CSO and the GBD Study 2019, respectively. Despite representing the best available evidence in relation to deaths from aortic aneurysm-related mortality, these datasets are subject to limitations. Estimation of AAA-related mortality is largely based on the underlying cause of death as reported on death certificates, which may be misclassified where an autopsy is not performed. In older populations in particular, in which the prevalence of AAA is highest, it is unlikely that an autopsy would be carried out in many cases. Where AAA rupture occurs in old age outside

the hospital setting, death may be attributed to other causes, most likely cardiac, due to the high prevalence of coronary artery disease among those with AAA.[61]

Furthermore, GBD Study data are based on modelling of data from a variety of administrative databases. The completeness of such datasets and data collection practices may vary between countries. It is therefore challenging to determine if observed differences represent true differences in aortic aneurysm-related mortality, or differences in recording of data. The GBD database does not subcategorise aortic aneurysms according to anatomic location, precluding estimation of AAA-related mortality specifically. However, as abdominal aneurysms represent the majority of all aortic aneurysms, the data presented may be considered a reasonable proxy for AAA-related mortality in Western Europe.

It is also important to note that due to population ageing, the number of people living with multimorbidity is increasing. The concept of a single identifiable underlying 'cause of death' is thus becoming increasingly flawed.[138] The possibility of underreporting of AAA-related mortality cannot be eliminated due to the potential for misclassification of cause of death in patients with multimorbidity. However, errors in coding are likely consistent over time, meaning trend analysis is likely reflective of relative changes over the period of analysis. Despite the potential for underreporting, the principal findings of the analysis of AAA-related mortality in Ireland, namely, an increase in the AAA-related mortality rate with advancing age, a higher incidence in males across all age groups, and a trend towards decreasing AAA-related mortality over time, are consistent with the international literature and thus can be considered valid.[139]

The scope of this assessment was limited to men only. The evidence base for AAA screening in women is limited, with only one underpowered RCT showing no significant difference between the screened and unscreened groups in AAA rupture rates among women at 10 years' follow-up, or in AAA-related mortality and all-cause mortality at five years' follow-up.[140] In women compared with men, the prevalence of AAA is lower, operative mortality is higher, and AAA-related morbidity and mortality occurs at an older age.[6] As a result of these and other considerations, population-based screening in women has not been recommended in clinical guidelines to date (see Chapter 3, section 3.4.1). Importantly, women have traditionally been under-represented in epidemiological studies of AAA, resulting in unresolved uncertainties. The available evidence suggests that women have a higher rupture risk than men at the same aortic diameter.[141] Given that mean aortic diameter in women is generally smaller than men, an AAA of the same diameter likely represents more advanced disease in women.[142] This results in uncertainty regarding the appropriate definition of an AAA, and appropriate surveillance intervals and referral thresholds in the context of population-based screening in women, as those derived from male populations may not be applicable. It might be argued that

the lower prevalence of AAA in women is biased by the use of a disease definition based largely on the epidemiology of disease in men. However, prevalence alone is not a useful measure of the overall burden of disease, particularly in the context of AAA where the risk of complications is not definite. The literature consistently demonstrates that AAA-related morbidity and mortality is lower in women than men, and tends to occur at a later age. While age alone does not determine suitability for surgical repair, it is also worth considering that older age at presentation in women may result in a tendency towards non-operative management, and thus reduce the potential benefits of an AAA screening programme in women.[21] Taken together, further investigation of the natural history of disease in women would be needed to inform implementation of a gender-specific AAA screening pathway in women, if shown to be clinically effective and safe.

2.11.1 Conclusion

AAA follows a course of progressive growth with silent development. Given the asymptomatic nature of AAA prior to rupture, and the poor outcomes associated with out-of-hospital rupture, early detection and intervention are of critical importance in reducing AAA-related morbidity and mortality.

It is estimated that 1% (approximately 200) of men aged 65 in Ireland have an AAA and are at risk of AAA rupture leading to life-threatening bleeding. The declining prevalence of AAA is an important consideration in the context of the potential introduction of an AAA screening programme in men. On the other hand, increases in life expectancy and an ageing population in Ireland may translate into an absolute increase in the number of people experiencing AAA-related morbidity and mortality.

3 Description of the technology

Key points

- Ultrasound is the recommended imaging modality for first-line diagnosis, screening, and surveillance of small AAAs; this is due to its safety, non-invasiveness, affordability and high accuracy. Ultrasound is highly sensitive and specific for the detection of an AAA. However, there is potential for interobserver variability, and successful imaging can be impacted by the presence of abdominal obesity or bowel gas.
- Computed tomography angiography (CTA) is the recommended imaging modality for the diagnosis of suspected AAA rupture. In the context of surgical intervention to repair an AAA, CTA is used pre-operatively to inform therapeutic decision-making, and may be used peri-operatively, and for post-surgical monitoring.
- Currently, in the absence of a national AAA screening programme in Ireland, asymptomatic patients with an AAA are usually identified incidentally during imaging for other indications, or through GP referral based on risk factors. Such patients undergo first-line imaging with abdominal ultrasound. Patients presenting with signs such as pallor or abdominal pain follow an expedited care pathway due to the time-critical nature of AAA rupture.
- Where detected prior to rupture, management of an AAA in an asymptomatic patient depends on several factors including the aortic diameter, comorbidities, and patient preference.
    - Risk factor optimisation, in particular smoking cessation, is important to reduce the rate of AAA expansion and rupture risk.
    - There is no international consensus on appropriate surveillance intervals, but, in general, the frequency of surveillance increases with increasing aortic diameter.
    - Generally, an AAA is considered for elective surgical repair once it reaches 5.5 cm in diameter in men. Patients meeting the referral threshold based on abdominal ultrasound are referred to vascular surgery for pre-operative risk assessment. Surgical candidates proceed to pre-operative CTA to inform pre-operative planning.
    - For both elective and emergency admissions, surgical options include open surgical repair (OSR) or endovascular aneurysm repair (EVAR).

EVAR is less invasive, and may be considered the preferred treatment modality for the majority of patients. However, the choice of surgical approach is dependent on the clinical context for a given patient.

- Screening of some individuals with risk factors (for example, family history of AAA) is in place in some hospitals in Ireland on an ad hoc basis. The number of people accessing screening through private healthcare services is unknown. Implementation of a systematic population-based screening programme would standardise the care pathway and improve equity of access.
- International guidelines and practice in AAA screening were reviewed for 21 countries, including selected countries in the European Economic Area, the United States, Canada, Australia and New Zealand.
    - European guidelines generally advise AAA screening in men who are 65 years or older. In North American guidelines, AAA screening is primarily suggested for individuals with a history of smoking.
    - Suggested surveillance intervals range from two to three years for small AAAs, and three months to one year for medium AAAs. In all clinical guidelines, the threshold for performing surgery in men is an aortic diameter greater than or equal to 5.5 cm.
    - Nationwide population-based screening programmes for AAA have been implemented for men of 65 years or older in Germany, Sweden, and the UK. AAA screening programmes are expected to be piloted in Denmark and the Czech Republic in 2025.
- Optimal management of AAA includes early detection and timely elective surgical repair, where indicated. Ultrasound screening is safe and effective for the detection of an AAA. If implemented, an AAA screening care pathway should be developed with consideration to international guidelines and practice, previous screening studies conducted in Ireland, and the model of care for vascular surgery in Ireland published by the National Clinical Programme for Surgery.

3.1 Introduction

As set out by the World Health Organization (WHO), a formal screening programme ideally includes the complete end-to-end care pathway from screening and diagnosis through to long-term follow-up.[143] Screening programmes can be targeted or population-based, with the programme structure influencing effectiveness, cost effectiveness and overall uptake of screening. Population-based screening may be understood as a programme which is offered to a group of people identified from the whole population and defined demographically, such as by age or sex.[144] Targeted screening may be defined as a programme which aims to identify individuals who have a higher risk of developing the disease due to factors other than age or sex (for example, comorbidities, genetic variants or lifestyle factors).[144] In line with the request received from NSAC (see Chapter 1, section 1.1), the focus of this HTA is population-based, one-time ultrasound screening in men.

The evidence in this chapter is synthesised with consideration to the NSAC criteria, in particular:[3]

- *The screening method should be, as far as is practicable, simple, safe, precise reliable, and validated.*
- *The distribution of screening values in the target population should be assessed and suitable cut-off levels/measurements defined and agreed by the applicant.*
- *There should be an agreed policy on the further diagnostic investigation of individuals with a positive screening result and on the choices available to those individuals.*
- *There should be agreed evidence-based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.*

With consideration to the information needs of the NSAC, the aims of this chapter are to:

- describe the current AAA care pathway in Ireland (section 3.2)
- describe AAA detection and management options (section 3.3)
- provide an overview of AAA screening in Ireland, including screening studies and screening in the private healthcare system (section 3.4)
- provide an overview of international policies and guidelines for the screening of AAA (section 3.5).

Following this, an overview of an AAA screening care pathway in Ireland, proposed by the National Clinical Programme for Surgery, is described (section 3.6). The current care pathway for AAA in Ireland contains many of the elements, such as diagnosis and management, which would be included in a formal population-based

screening programme for AAA. In the context of the screening care pathway, only elements of the care pathway that differ from existing clinical practice are described.

3.2 Current AAA care pathway in Ireland

In Ireland, the AAA care pathway which a patient follows may incorporate any, or all of, the following key elements:

- Diagnosis: first-line AAA diagnosis with abdominal ultrasound
- Management:
    - surveillance or referral to vascular surgery to determine surgical candidacy, dependent on the size of the AAA
    - for those meeting the threshold for repair and deemed appropriate surgical candidates, pre-operative assessment of the AAA with Computed Tomography (CT) Angiography (CTA) is undertaken to assist with therapeutic decision making.[6]

The patient's entry point to the care pathway, the speed at which they progress through this care pathway, and management approach, are dependent on a number of factors including admission type (emergency versus elective), clinical characteristics (for example, the presence of contraindications to surgery), and patient preference. The current AAA care pathway in Ireland is described in sections 3.2.1 and 3.2.2 for each of asymptomatic and symptomatic presentation.

3.2.1 Asymptomatic presentation

As outlined in Chapter 2, AAA is often asymptomatic and deemed clinically silent (that is, there are no noticeable clinical signs) until rupture.[6] Identification of an unruptured AAA based on clinical symptoms alone is therefore challenging and unreliable. Currently in Ireland, in the absence of a formal screening programme, asymptomatic, unruptured AAA is typically identified through either incidental diagnosis or healthcare professional referral due to the identification of risk factors. In the case of incidental diagnosis, AAA is often identified during investigation for other pathologies, using imaging techniques such as ultrasound, CT or Magnetic Resonance Imaging (MRI).[4] In the case of risk factor identification, during routine examination or investigation of unrelated symptoms, a healthcare professional may suspect AAA due to the presence of risk factors such as smoking, a family history of AAA, or high blood pressure (see Chapter 2, section 2.3.1 for further information on risk factors), and refer the patient for further imaging in the community (see section 3.2.3) or outpatient setting.(4)

Regardless of care pathway entry point, the patient initially undergoes first-line diagnostic testing with abdominal ultrasound (see section 3.3.1). This ultrasound may be conducted in the community, at hospital bedside (for those already within a

hospital setting), or the patient may be referred for radiological assessment. If an AAA is detected using abdominal ultrasound, depending on the diameter of the AAA detected, the patient either undergoes regular surveillance, or is referred to a vascular surgeon to be considered for surgical repair (see section 3.3.2).

Patients being considered for elective surgical care undergo a CTA scan to provide the vascular surgeon with a complete image of the entire aorta, including the thoracic aorta and access vessels.[6] This allows for surgical intervention planning. Currently there are two accepted methods to repair an AAA: Open Surgical Repair (OSR) and Endovascular Aneurysm Repair (EVAR), both of which are outlined in section 3.3.2.[6, 145, 146] Following surgery the patient undergoes further CTA scans as required for post-operative surveillance, and to guide appropriate patient care.

3.2.2 Symptomatic presentation

In the case of symptomatic presentation, a patient may contact their GP, emergency services, or present to an emergency department with signs including pallor, abdominal and or back pain, or abdominal distension. From here, the clinician conducts a complaint-directed history and physical examination in order to determine the haemodynamic stability of the patient (for example, heart rate and blood pressure are measured to determine whether blood flow in the body is stable).

In a haemodynamically unstable patient, the patient will receive the necessary treatment, such as resuscitation and or a blood transfusion. If some level of stability is achieved, the patient may be brought for CTA to confirm the AAA rupture and assess the anatomic feasibility of the abdominal aorta for an EVAR. If, due to the critical condition of the patient, CTA is not possible, and or EVAR is not feasible, the patient will be brought to the operating room for immediate control of the haemorrhage, resuscitation, and aneurysm repair via OSR.[147]

Where the patient is conscious and haemodynamically stable, a medical history and physical examination is conducted, directed at excluding other pathologies that may explain their symptoms. The patient then undergoes an abdominal ultrasound to diagnose an AAA (if unknown) or to assess the size and growth rate of the AAA, if known. Where an AAA is diagnosed, the patient is then referred to a vascular surgeon. Here, they may be referred back to the surveillance pathway or expedited through the elective surgery pathway, as appropriate.

As with asymptomatic patients, following either elective or emergency surgery, the patient undergoes further CTA scans as required for post-operative surveillance, and to guide appropriate patient care.

Where AAA rupture occurs outside of a healthcare setting, approximately one third of patients die before reaching hospital (see Chapter 2, section 2.4.3).[148] A

ruptured AAA can therefore be a catastrophic event and it is suggested that the timeframe from 'door to intervention' for a known or suspected ruptured AAA should be 90 minutes.[148]

3.2.3 Access to diagnostic imaging

Patients with symptoms suggestive of AAA and or clinical risk factors may be referred for diagnostic imaging for further investigation. However, traditionally, access to publicly-funded diagnostic imaging for patients attending GP practices in Ireland has been extremely limited.[149]

The General Practitioner Access to Community Diagnostics (GPACD) Scheme was introduced in 2021 to support improved access to community diagnostic imaging including MRI, ultrasound, CT, X-ray and dual-energy X-ray absorptiometry (DEXA) for the adult population. In 2023, over 330,000 examinations were undertaken as part of this scheme, with the majority of patients being seen within one month of referral.[150] GPs are reported to be predominantly referring patients for MRI scans, which account for approximately two-thirds of scans organised through the scheme. Results from a mixed-methods study involving 11 GPs reported that the scheme has supported improvements in patient care and reduced outpatient referrals.[149]

Prior to the launch of the GPACD, patients had to be referred to an outpatient appointment with a hospital consultant for radiological assessment or pay to access care privately. Due to the asymptomatic nature of AAA, GPs do not typically refer patients for abdominal ultrasound for AAA; as noted previously, the vast majority of patients are identified incidentally during imaging for other indications. The availability of improved access to community-based diagnostic imaging has the potential to result in increased incidental diagnoses in patients undergoing imaging of the abdominal region for other indications.[151] Although ultrasound is the recommended imaging modality for diagnosis and follow-up of intact AAA, clinically-relevant AAA can likely be sufficiently imaged by other imaging modalities such as CT or MRI.[152] Definitive conclusions regarding the impact of the introduction of the GPACD on AAA diagnoses cannot be drawn due to the novelty of the programme. However, it is plausible that increased access to community diagnostics could reduce the relative benefit of an AAA screening programme.

3.3 AAA detection and management

Different imaging modalities are important at different stages of the AAA care pathway. In general, ultrasound is considered the first-line imaging tool for detection of suspected AAA, and for screening and monitoring of AAA growth rate in those with known small to medium AAAs.[6] Those with AAAs meeting the threshold for surgical repair, based on the results of ultrasound, and considered fit for surgical intervention, undergo CTA to confirm that the threshold for surgical intervention has

been met and to inform pre-operative planning (see section 3.3.2, Surgery). The aim of imaging during long-term follow-up is to predict or detect late complications (see section 3.3.2, Post-operative follow-up). The choice of imaging modality during follow-up is dependent on numerous factors including the choice of surgical approach (that is, endovascular aneurysm repair (EVAR) or open surgical repair), the sensitivity of the imaging modality to detect complications, and patient-related factors (for example, contra-indications to contrast agents, abdominal obesity, life expectancy and symptoms status).[6]

Large unruptured aneurysms may present as a pulsatile abdominal mass which may be detected on physical examination. However, sensitivity and specificity of physical examination have been reported to vary considerably relative to ultrasound.[50, 153-155] The ability of physical examination to detect AAA may be impacted by factors such as the size of the AAA, the experience of the clinician, and a person's anthropometrics.[6, 145, 146] Therefore, physical examination is not considered a reliable tool for AAA diagnosis, but may be used alongside imaging studies as part of preliminary investigations.[6]

3.3.1 Imaging modalities

Ultrasound

Ultrasound is the imaging modality recommended by the European Society for Vascular Surgery (ESVS) 2024 guidelines for first-line detection, screening, and surveillance of small AAAs.[6] This is on the basis that it is non-invasive, relatively inexpensive, easy to implement, does not expose patients to ionising radiation and has high accuracy in the detection of AAA.[140, 156]

Ultrasound is painless and non-invasive, using high-frequency sound waves to visualise the structure of internal organs and tissues, such as blood vessels.[157] During the ultrasound procedure the participant lies on their back, while a gel is applied to the abdomen. The transducer, a handheld device, is then moved gently over the abdomen emitting high-frequency sound waves that bounce off the abdominal organs and walls of the aorta. These sound waves create images of the aorta that are displayed on the monitor, to facilitate measurement of the aorta size, and assessment of blood flow. The procedure typically takes between 10 to 20 minutes.[158]

Types of ultrasound

Doppler ultrasound is a form of ultrasound used to produce images which depict blood flow, and display the speed and direction of blood flow, by bouncing high-frequency sound waves off of red blood cells.[159] However, it is limited by its inability to provide detailed anatomical information. Duplex ultrasound, which

combines traditional ultrasound images with Doppler ultrasound, can be used to measure the width of blood vessels, providing both structural and functional information about blood vessels.[160]

Portable ultrasound refers to compact ultrasound systems that offer imaging capabilities similar to traditional ultrasound machines but are designed for mobility and ease of use. Portable ultrasound systems offer advantages such as real-time imaging, convenience and relatively low cost, but may have limitations in terms of image quality and depth penetration compared with larger systems.[161] Point-of-care ultrasound (POCUS) specifically emphasises the immediate availability and use of ultrasound at the bedside or point of care for rapid diagnostic assessment.[162] While portable ultrasound machines can be used for POCUS, not all portable ultrasound machines are strictly designated for point-of-care use.

Measurement of aortic diameter

For detection, screening or surveillance of AAAs, when measurements are taken in a plane perpendicular to the aortic longitudinal axis, abdominal duplex ultrasound can be used to measure aortic diameter, which is strongly associated with rupture risk (see Chapter 2, section 2.4.3).[163] Several aortic aneurysm diameters can be measured, including antero-posterior (that is, from front to back), transverse (that is side-to-side), or the maximum diameter in any direction.[6] Accurate measurements of the aortic diameter are essential to direct appropriate clinical management of those undergoing abdominal ultrasound for detection, screening or surveillance of AAA. Evidence from a review assessing the reproducibility of various ultrasound measurements of aortic diameter found that intra-observer repeatability (that is, variation in repeated measurements from the same person) for the antero-posterior (that is, from front to back) and transverse diameters varied from 1.6 to 7.5 mm, and 2.8 to 15.4 mm, respectively.[164] The ESVS 2024 guidelines recommend measurement of the antero-posterior aortic diameter for detection, screening and surveillance of AAA. This recommendation is based on the acceptable level of observer variation between aortic diameter ultrasound measurements, specifically 5mm, as suggested by the NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP), and on the greater intra-observer repeatability of measurements obtained in the antero-posterior direction.

Measurement of aortic diameter is accomplished technically by firstly pausing ultrasound images on the monitor screen. Aortic diameter is then measured using callipers on screen in the preferred diameter (for example antero-posterior). There are three principal ways in which the callipers can be placed to measure aortic diameter during abdominal ultrasound examination:[6]

- the inner to inner (ITI) bounds of the aorta (that is, excluding the vessel wall)

- the outer to outer (OTO) bounds of the aorta (that is, including the vessel wall)
- the leading edge to leading edge (LELE) (also known as the outer to inner method; includes the vessel wall on one side only).

Due to a lack of evidence to determine a gold-standard approach, there is a lack of consensus internationally regarding the optimal calliper positioning method, with all three methods in use in different settings. For example, the ITI bounds are used by the NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) (UK), while the LELE method is in use in the Swedish AAA screening programme.[6] While no preferred method is recommended by the ESVS 2024 guidelines, it is recommended that a single method is used consistently. Inherently, these methods are not directly comparable, with the ITI and OTO methods resulting in the smallest and largest diameters respectively, by definition. It is estimated that the OTO method gives aortic diameter measurements that are 3 to 6 mm larger than the ITI method.[165] In the context of screening, the method adopted has implications for the number of positive screening test results and associated follow-up. The risk of overdiagnosis is highest with the OTO method, while the risk of missed cases is greatest with the ITI method. The preferred method should be selected with consideration to the balance between overdiagnosis and potential for missed cases.

Accuracy of ultrasound

Test accuracy refers to how well the test under evaluation discriminates between those who do and do not have the target condition relative to the 'reference standard' used for diagnosis in clinical practice. In the context of an AAA screening programme, the accuracy of abdominal ultrasound must be considered in terms of the goals of ultrasound testing, including:

- AAA detection (that is, the ability of abdominal ultrasound to detect AAA in an asymptomatic population)
- risk classification (small, medium or large AAA) and AAA growth (that is, the ability of abdominal ultrasound to precisely measure aortic diameter at baseline and during long-term follow-up in order to inform patient management)
- post-surgical monitoring (for example, measuring AAA sac shrinkage during follow-up as an indicator of successful exclusion of the AAA).

Ultrasound has gained widespread acceptance as a screening modality for AAA, based on a number of factors including reported sensitivity and specificity close to 100%.[166, 167] However, there is a lack of high-quality evidence looking specifically at the test accuracy of ultrasound in the context of screening.

A Danish study published in 1999 assessed the validity of ultrasound as a screening method for AAA, based on inter-observer variability of aortic measurements.[166] The authors reported estimated diagnostic specificity close to 100%, but noted that the exact sensitivity, specificity and predictive value of ultrasound was not defined based on comparison with a clinical gold standard. In 2002, a study from the UK assessed the accuracy of ultrasound screening for detection of AAA, where the number of false positive scans was determined by comparing, in AAAs greater than 4.5 cm, the infrarenal aortic diameter (that is, the aortic diameter in the abdominal area below the kidneys) between ultrasound and CT measurements.[167] They reported that all 64 patients with an AAA (> 4.5 cm) identified on ultrasound were confirmed with CT. Furthermore, among screened men that died from a ruptured AAA, none were previously classified as having a normal aortic diameter on ultrasound.[167] This suggests that the risk of clinically significant false negatives is low. However, the true number of false negatives cannot be known with certainty due to the absence of long-term follow-up and confirmatory testing.

In a validation study comparing ultrasound and non-contrast-enhanced computed tomography (nCT) for AAA screening, 533 men from the Danish CardioVascular Screening trial underwent screening using both modalities.[156] nCT exhibited higher sensitivity (82.6 to 88.9%) than ultrasound (57.1 to 70.4%) in detecting AAA, with nCT identifying aneurysmal lesions undetected by ultrasound. Ultrasound demonstrated slightly higher specificity (99.2 to 99.6%) compared with nCT (97.7 to 98.4%). An important limitation of this study is the absence of an independent reference standard. However, in the case of conflicting findings between ultrasound and nCT, blinded re-examination of nCT scans was undertaken by two senior consultants. All cases detected by nCT only, and none of the cases detected by ultrasound only, were classified as an AAA by the consultants. Of note, the imaging in this trial was undertaken by medical students. Although the students received training, operator experience may influence test accuracy. While this study suggests that in a screening setting, nCT has improved sensitivity over ultrasound, there is substantial clinical evidence favouring ultrasound as a screening tool, in particular, due to the absence of ionising radiation.

Given that indications for surgical treatment and surveillance intervals of AAA are defined by the aortic diameter and its changes over time, it is important that the approach to measurement of the diameter is reproducible. There is evidence to suggest that abdominal ultrasound for the detection of AAA is highly sensitive and specific when performed in different settings and by different healthcare professionals.[168, 169] Considering the potential impact of setting on the accuracy of ultrasound, a 2013 systematic review of emergency department bedside ultrasound, compared with the reference standard (defined as CT, MRI, aortography, radiologist-performed ultrasound, radiologist-reviewed ultrasound, exploratory laparotomy, or

autopsy results), reported a pooled sensitivity of 99% (95% CI: 95% to 100%) and specificity of 99% (95% CI: 97% to 99%).[170] In terms of operator dependence, a 2014 systematic review compared the accuracy of non-radiologist performed ultrasound with the 'gold standard' of radiologist-performed aortic imaging, (including ultrasound, CT, MRI and angiography), intraoperative findings or post-mortem findings. Across 11 studies, pooled sensitivity and specificity were reported to be 98% (95% CI: 94% to 99%) and 99% (95% CI: 98% to 100%), respectively.[168] Details of training and the level of experience of the non-radiologists were often not reported in the included studies.[168] Rather than the specific healthcare professional performing the scan, the reproducibility of results may be primarily driven by the availability of standardised training and imaging protocols.[171-173]

Clearly specifying the preferred measurement method in imaging protocols would be important to ensure reproducible results. A 2023 review by Bissacco et al. compared the reproducibility of OTO, ITI and LELE calliper placement when measured in the anteroposterior direction for abdominal aortic diameter measurement.[174] Overall, ITI and OTO methods were found to be associated with less variation than the LELE method; inter-observer reproducibility was 2.4 to 2.6 fold smaller (that is, better reproducibility) with ITI and OTO calliper placement than with LELE. However, when considering studies published since 2010 only, the LELE method was the most reproducible. For all analyses, differences between these methods were not considered statistically significant. However, this could be influenced by the small absolute differences between measurements, the limited evidence base, and evidence of methodological and clinical heterogeneity. Observed heterogeneity in terms of the ultrasound system used, measurement protocols, the timing of studies (which may influence ultrasound performance), participant characteristics, observer expertise and training, as well as small sample sizes (range 10 to 215 participants) may contribute to differences in reproducibility across studies. The authors concluded that additional data are needed to underpin robust recommendations regarding the preferred calliper placement approach.[174] In addition to differences in the setting, operator and ultrasound system used, it is worth noting that the prevalence of AAA would be lower in the context of screening. The applicability of studies undertaken in the context of diagnostic imaging is therefore uncertain, given that test accuracy may be influenced by the underlying disease prevalence.[175]

Despite the limitations of the evidence base, ultrasound screening for AAA has been performed in the primary care setting in Ireland as part of the SENSE pilot study (see section 3.4.1) and in international practice (see section 3.5.3). As noted previously, inter-observer variability can be reduced with systematic training and the use of standardised protocols.[171] In the context of an AAA screening programme,

appropriate training and oversight would play an important role in optimising screening performance.

Limitations of ultrasound

Despite the evidence of high sensitivity and specificity, ultrasound imaging for measurement of aortic diameter has limitations. For example, obtaining high-quality images in patients with obesity can be technically challenging, as ultrasound waves are directly attenuated by fat, which limits the image quality.[176] The presence of abdominal obesity or excess bowel gas can make visualisation of the aorta challenging, resulting in non-visualised screens, as has been observed in the results of the SENSE pilot study.[93] For example, in the UK NAAASP approximately 1% of participants were recorded as non-visualised in 2021/2022.[177] Proper dietary preparation, particularly the avoidance of fizzy drinks immediately prior to the appointment, may help enhance scan visibility and reduce the likelihood of non-visualised scans.[178] As described in Chapter 4, section 4.3.2 ('Test accuracy'), false positive results can occur in the context of screening, which may be related to incorrect aortic measurements or challenges in distinguishing between nearby tissues and organs. Such false positives have been reported to be more likely to occur during early implementation of population-based screening programmes.

As noted previously, methodological differences in aortic diameter measurement (that is, the method of diameter measurement and calliper positioning) may result in variation in the aortic measurement obtained. Notably, a review by Long and colleagues in 2012 highlighted the need for standardised methodology for AAA maximum diameter measurement to improve the efficiency of AAA management (including in screening programmes, follow-up and decision for intervention).[179] In the context of screening, a consistent approach in terms of the use of ultrasound imaging for reporting of aortic measurements is important to ensure reliable clinical decision making in the care pathway. These decisions include whether to discharge a patient or enrol them in surveillance, and or whether to refer a patient to vascular surgery.

In addition, the timing of imaging during the cardiac cycle (that is, the period from the beginning of one heartbeat to the next, composed of systole and diastole) may influence aortic diameter measurements. However, the estimated difference in measurement performed in diastole versus systole is 2 mm and therefore would be unlikely to result in failure to identify clinically significant AAA. Some of these limitations, in particular, those related to methodological differences, can be managed with appropriate training and reporting standards.

In the context of surveillance, ultrasound does not fully reflect other aneurysm characteristics known to increase the risk of rupture, such as intraluminal thrombus, plaque ulceration, or surrounding inflammation.[180, 181]

Computed Tomography

Computed Tomography (CT) is a diagnostic imaging procedure that uses X-ray technology (ionising radiation) to create detailed images of any part of the body, including the bones, tissue, muscles and blood vessels.[182] This test, as discussed previously, is not the first line for screening or surveillance of AAA. However, under certain clinical scenarios (for example obesity or poor sonographic window) a CT scan may be consider as an appropriate diagnostic or monitoring alternative.[181]

Computed Tomography Angiography

CT angiography (CTA) combines a CT scan with the injection of a contrast dye via an intravenous line. This allows enhanced visualisation of the blood vessels in order to accurately delineate the size and shape of the abdominal aortic aneurysm and its relationship to branch arteries and the aortic bifurcation (the point at which the abdominal aorta forks into the left and right common iliac arteries).[183] When combined with dedicated post-processing software, CTA enables analysis of the aorta and surrounding area in three perpendicular planes, construction of a centreline, and accurate diameter and length measurement.[6]

For AAAs detected incidentally or through screening, CTA plays a key role, at the point at which the threshold for surgical repair is considered has been reached, in assessing the extent of the aneurysm and in informing therapeutic decision-making. CTA is also the recommended imaging modality for the diagnosis of suspected AAA rupture and may be used for real-time peri-operative guidance[6] and during post-surgical follow-up to predict or detect late complications (see section 3.3.2).[184] While CTA is more accurate for measurement of aortic diameter, due to the risks associated with exposure to ionising radiation, CTA is not recommended for use in the context of first-line screening of asymptomatic populations.

Accuracy of CTA

CTA is regarded as the gold-standard imaging tool for measuring AAA diameter. For the diagnosis of AAA rupture, a 2021 meta-analysis of seven studies outlined pooled specificity of 91.4% and a pooled sensitivity of 93.6% for CTA, when compared with the reference standard of intraoperative diagnosis.[153]

While the intra-observer reproducibility of using CTA for AAA diameter measurement is noted as within a clinically-accepted range in 90% of measurements (±5 mm, as defined by the ESVS 2024 clinical guidelines),[6] the inter-observer reproducibility is low, with 87% comparisons being outside this range.[185] To limit variation across

CTA measurement, the ESVS 2024 clinical guidelines recommend that aortic diameter measurement is performed using dedicated post-processing software analysis in three perpendicular planes, with a consistent calliper placement.[6]

Compared with ultrasound, the ESVS 2024 guidelines noted that there is often poor agreement between ultrasound and CTA measured AAA diameters, particularly as the diameter nears the threshold at which treatment would normally be undertaken.[6] In general, aortic diameter reported from CTA is larger than that reported from ultrasound measurement.[186] It has been reported that the anteroposterior CTA diameter is, on average, 4.2 mm larger than anteroposterior ultrasound diameter.[6] Importantly, in the context of an AAA screening programme, this suggests that the potential for inappropriate referrals to vascular surgery and associated pre-operative CTA (that is, referrals prior to meeting the aortic diameter at which surgical repair is considered) is reduced. It is suggested that this lack of agreement between ultrasound and CTA measurements may be due to poor reporting, and methodological differences in measurement techniques.[6]

CTA and ionising radiation exposure

As noted above, CTA involves exposure to ionising radiation.[6] While the risks are generally considered to be low, all exposures to ionising radiation carry some risk. One of the main risks associated with exposure to ionising radiation in the medical setting is the elevated risk of developing cancer – this risk may occur at low doses and persist for decades but increases as the accumulated radiation dose for any one person exceeds 100 millisieverts (mSv).[187] Alternative imaging methods that use less, or no, ionising radiation should therefore be considered, as appropriate.[188] As a population-based AAA screening programme involves the screening of people, the vast majority of whom will receive a negative screen result (where their aortic diameter does not meet the threshold for an AAA), exposure to ionising radiation via first-line screening using CTA would be inappropriate.

Furthermore, patients deemed suitable for EVAR will have additional ionising radiation exposure, as this procedure requires the use of intra-operative X-ray imaging as well as imaging during long-term follow-up.[189] A systematic review examining the radiation exposure in patients undergoing EVAR found a mean exposure of 20 mSv, which increased proportionally to the complexity of the procedure.[190] Additionally, the radiation exposure at follow-up with CTA scans during the first year was approximately 15 mSv. For reference, the average person receives approximately 3.5 mSv in background radiation exposure per year.[190]

Diagnostic reference levels (DRLs) for radiodiagnostic and interventional procedures have been proposed as a means to enhance radiation safety. DRLs are dose levels set to aid optimisation of diagnostic and interventional medical exposures. They

provide a standard for comparison to help ensure that the radiation dose received by patients for a specific type of medical radiological procedure is optimised.[191] A 2017 study collected radiation dose data from five European centres performing EVAR procedures, located in Ireland and Italy.[192] The findings led to the establishment of local DRLs and an interim European DRL for EVAR, with the goal of improving radiation monitoring and safety. Similarly, national DRLs for various types of EVAR repair (for example, standard branched or thoracic) have been established in the UK and Ireland.[193, 194] In the context of an AAA screening programme, the availability of DRLs in the Irish context is important to ensure the safety of screened participants being evaluated for surgical repair and during long-term monitoring post-surgery.

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 designate HIQA as the competent authority for medical exposure to ionising radiation. One of HIQA's competent authority functions includes the establishment and review of national DRLs in Ireland.[195] It must be noted that the work undertaken in this HTA is separate to HIQA's role as competent authority.

Other limitations of CTA

Further limitations of CTA include adverse events, such as allergic reaction to contrast agents or contrast toxicity, and cost and accessibility (when compared to ultrasound). Allergic reactions to CTA contrast agents can be immediate or delayed.[196] Immediate reactions take place within one hour of contrast agent injection and examples include nausea (mild), shortness of breath (moderate) and or circulatory collapse (severe). The incidence of immediate reactions ranges from severe (0.01% to 0.04%) to mild (3%). Delayed reactions occur weeks after the contrast agent injection and are generally self-limiting. Examples include rash and fever.[196] The most common toxicity caused by contrast agents is contrast-induced nephropathy. This alteration accounts for approximately 10% of all hospital-acquired renal failures and is characterised by a sudden compromise of renal function within 24 to 48 hours of exposure to a contrast agent. In most cases, however, the prognosis of contrast toxicity is benign.[197] Considering operational factors, CTA is more expensive, not as widely available, and more time consuming to administer and complete, than ultrasound.[198] Further limitations of CTA are similar to those for ultrasound imaging, including methodological differences in measurements (including calliper placement and which diameter is measured) and variation of aortic diameters with the cardiac cycle.

Other imaging modalities

Unruptured AAAs may be detected incidentally during imaging studies including X-rays, CT scans or MRIs undertaken for other indications such as back or chest pain, abdominal and genitourinary symptoms. The sensitivity and specificity of imaging modalities other than abdominal ultrasound or CTA are uncertain. Therefore, patients with incidentally-detected AAA are typically referred to vascular surgery for further investigation, including first-line imaging with ultrasound to confirm the presence of an AAA in accordance with agreed methodology for the diagnosis of AAA (for example, the plane of measurement and calliper positioning).

In the UK, there is evidence to suggest that incidentally diagnosed AAAs are not consistently referred to vascular surgery.[199] It is unclear if all cases diagnosed in the Irish context receive appropriate follow-up care. However, in the absence of a systematic programme with a standardised care pathway there is potential for delayed or missed diagnoses.

3.3.2 Management options

AAA management options, and recommendations for those with an identified AAA, depend on several factors including clinical presentation (symptomatic versus asymptomatic), aortic diameter, comorbidities, patient preference and surgical fitness. The distinction between management of a ruptured AAA versus a symptomatic or asymptomatic intact AAA is important (see section 3.2). All those with known AAA are assessed to identify risk factors for disease progression and to treat comorbidities as appropriate.[6, 145, 146] Depending on aortic diameter the person is immediately considered for surgical repair of the AAA or followed up at time intervals determined by the diameter size and growth of the AAA.[6, 145, 146]

Risk factor optimisation and medical management

Risk factor optimisation and medical management are essential components of the AAA care pathway. They can reduce the risk of aneurysm expansion, rupture, and cardiovascular events.[6, 145]

Smoking is the most important modifiable risk factor for AAA development and rupture.[6] Smoking cessation in this population is therefore crucial.[6, 146, 200] The relationship between smoking status and the occurrence of both clinically relevant AAA and asymptomatic AAA was examined in a community-based cohort study that estimated the lifetime risk of these conditions among 15,792 participants over 24 years' follow-up.[201] The study found that, compared to active smokers, those who quit smoking recently had a 29% reduced risk of AAA occurrence. However, their risk was still higher than those who quit smoking earlier or never smoked at all.[201] Moreover, smoking cessation at least 30 days before open AAA repair has been

associated with lower perioperative morbidity and mortality, compared to active smokers.[202]

The impact of managing cardiovascular risk factors, such as hypertension and dyslipidaemia, on aneurysm development and outcomes, remains uncertain. However, these interventions may enhance survival by reducing cardiovascular risks.[5] Long-term statin use after successful AAA surgery is associated with lower overall mortality.[203] The ESVS 2024 clinical practice guidelines therefore recommend that all patients with AAA should receive cardiovascular risk factor management, including smoking cessation, blood pressure control, and statin and antiplatelet therapy.[6] It is suggested that, unless contraindicated, these therapies reduce the risk of cardiovascular complications and improve surgical outcomes, and will therefore benefit patients with AAA.[6, 145, 146] Similarly, other healthy lifestyle strategies applicable for any patient with cardiovascular disease, such as exercise and diet, are advisable. However, the National Institute for Health and Care Excellence (NICE) guidance on AAA diagnosis and management outlined that further research is required before recommendations can be made around the use of exercise programmes to improve surgical outcomes, when used either before or after AAA surgery.[146]

Surveillance

As described in Chapter 2 (section 2.4.3), the risk of AAA rupture increases with increasing aortic diameter. Evidence from a 2019 systematic review conducted by the USPSTF found no significant differences in all-cause or AAA-specific mortality at any follow-up between participants receiving early surgical repair (that is, AAA 3.0 cm to 5.4 cm in diameter) versus those under surveillance across four RCTs.[140] There is international consensus that surgical repair should generally only be considered in those with an aortic diameter of greater than or equal to 5.5 cm (see section 3.5). This is based on evidence to suggest there is increasing rupture risk with increasing aortic diameter, no mortality benefit associated with intervention early in the disease course, and on the risks associated with surgery. Therefore, patients with small to medium AAAs are generally managed with surveillance until the threshold for surgical repair is reached (see section 3.5.1).

Surveillance protocols vary internationally (see Section 3.5), but in general the frequency of surveillance increases with increasing aortic diameter.[66] Currently there is no international consensus regarding appropriate surveillance intervals (that is, the time between follow-up appointments to assess AAA growth) for patients with an AAA.[6] Surveillance intervals have not been studied in RCTs, and therefore surveillance intervals outlined in the literature are based on the modelling and synthesis of large observational datasets including patients with small and medium AAAs.[55, 204]

In their 2024 guideline update, the ESVS outlined that the following sex-specific surveillance intervals should be considered:[6]

- For men, the suggested surveillance intervals are:
  - five years for a sub-aneurysmal aorta diameter of 2.5 cm to 2.9 cm;
  - three years for an AAA diameter of 3.0 cm to 3.9 cm;
  - annual for an AAA diameter of 4.0 cm to 4.9 cm;
  - six months for an AAA diameter of 5.0 cm or greater.
- For women, the suggested surveillance intervals are:
  - five years for a sub-aneurysmal aorta diameter of 2.5 cm to 2.9 cm;
  - three years for an AAA diameter of 3.0 to 3.9 cm;
  - annual for an AAA diameter of 4.0 to 4.4 cm;
  - six months for an AAA diameter of 4.5 cm or greater.

Of note, these sex-specific surveillance intervals outlined in the 2024 guidelines are amended from the 2019 guidelines, where population-based screening for AAA in women was not recommended.[10] The ESVS 2024 clinical guidelines also outline that discontinuation of surveillance should be considered for patients with a small AAA who are not expected to reach the repair threshold, are "unfit" for repair, or who would prefer conservative management.[6] As with diagnosis, the ESVS 2024 clinical guidelines recommend ultrasound as the method of surveillance for small AAAs.[6]

Surveillance intervals recommended in European and North American clinical guidelines are summarised in Table 3.2.

Pre-operative work-up and surgical intervention

Currently there are two accepted methods to repair an unruptured or ruptured AAA. These are open surgical repair (OSR) and Endovascular Aneurysm Repair (EVAR).[6, 145, 146] Historically, OSR was the standard of care for AAA repair.[205, 206] This procedure entails making a substantial incision in the abdomen to allow for direct observation of the aorta. A synthetic tube, known as a graft, is then stitched to the aorta, bridging the two ends of the aneurysm and reinstating normal blood flow.[189] EVAR is a more recent development, with the first successful operation taking place in 1990.[205, 206] EVAR is considered to be minimally invasive as access to the aorta is gained through a small incision in the groin, and the stent graft (that is, a thin metal mesh tube covered in fabric that takes the pressure off the aneurysm) is guided to the site of the AAA using intra-operative X-ray imaging.[189] Routine imaging of the entire aorta, access and femoropopliteal arteries using pre-operative CTA imaging is an important factor in determining the optimal AAA repair strategy (see section 3.3.1). Factors such as the location of major branch vessels or unsuitable access vessel anatomy (for example, tortuosity or narrow vessel diameter), which can be assessed with CTA, may preclude use of the endovascular approach.[207]

EVAR has demonstrated improved health outcomes, such as lower perioperative mortality and morbidity, compared with OSR, due to its minimally invasive approach.[6, 208, 209] The European Society of Cardiology guidelines classify OSR as a high-risk procedure (defined as having a 5% or higher risk of cardiovascular death or myocardial infarction within 30 days), while EVAR is categorised as an intervention with intermediate risk (between 1% and 5%). This is consistent with the findings of a 2014 Cochrane review.[210] However, while there is evidence to suggest a significant short-term survival benefit for EVAR relative to OSR, the longer-term survival rate (after two years or more) does not differ between the two techniques.[208, 209, 211]

Patients who undergo either OSR or EVAR are at risk of post-surgical complications, which may require re-intervention.[212, 213] The risk of re-intervention in long-term follow up (after approximately 8 to 10 years) is increased following EVAR, compared with OSR.[208, 211] Post-surgical aortic rupture is a rare complication that is estimated to occur in 1% to 3% of patients.[213-215] Several risk factors for post-surgical complications following EVAR have been identified including anatomic, patient-related, and stent-related factors;[214] these should be considered when selecting the surgical option. Patients who undergo AAA repair require life-long follow-up, in particular for those with a long life expectancy, due to the ongoing risk of complications.

Overall, the ESVS 2024 clinical guidelines recommend that EVAR should be considered the preferred approach for elective AAA repair in patients with suitable anatomy and reasonable life expectancy. For patients with a life expectancy greater than 10 to 15 years, the ESVS 2024 guidelines recommend that OSR should be considered the preferred treatment modality for elective AAA repair.[6] The choice of surgical approach, however, is dependent on the clinical context for a given patient.

For electively operated patients, the ESVS 2024 clinical guidelines and the German Society of Vascular Surgery and Vascular Medicine guidelines outline that the patient's preference between either OSR or EVAR (elective or emergency) should be considered when selecting the interventional procedure, assuming EVAR is anatomically feasible.[6, 145] This decision should be made after thoroughly explaining the differences between EVAR and OSR, including discussion of aspects such as peri-operative management, post-operative follow-up, and potential surgery-related complications.[6]

In the case of an AAA rupture, systematic reviews of RCTs for AAA rupture have not conclusively shown a short-term or mid-to-long term mortality difference that would favour either OSR or EVAR.[216, 217] However, observational studies seem to indicate a reduction in peri-operative mortality in favour of EVAR.[218] Thus, European guidelines generally recommend EVAR in AAA rupture when anatomically feasible, as

EVAR is not inferior to OSR in terms of mortality and appears to offer better peri-operative recovery.[6, 145]

Surgical repair of AAA carries several risks, including those associated with the procedure itself, potential post-surgery complications and the possibility of re-intervention. Consequently, AAA management requires careful assessment and balancing of the surgical risk versus the risk of aneurysm rupture. Some patients may be deemed unfit for aneurysm repair surgery, for example, due to limited life expectancy or the presence of comorbidities, given the higher risk of surgical complications.[6] Surgical repair would not be recommended for these patients and they would be managed with risk factor optimisation (see section 3.3.2).

Post-operative follow-up

The ESVS 2024 clinical guidelines recommend that all patients undergoing OSR, and high-risk patients undergoing EVAR, should receive early postoperative monitoring in an intensive care or high dependency unit.[6] There is a lack of RCTs assessing the impact of medical management on prognosis after surgical repair.[6] However, given that many patients requiring AAA repair have advanced atherosclerotic disease or other smoking-related comorbidities, the ESVS 2024 clinical guidelines recommend that patients who have undergone surgical repair for AAA should receive post-operative cardiovascular risk management including statin therapy, antiplatelet medication and blood pressure control to improve overall cardiovascular outcomes.[6]

Post-operative imaging is also recommended for patients to monitor for post-surgical complications. The imaging modality and frequency of follow-up vary depending on the surgical intervention. For patients who have undergone OSR, CTA imaging of the entire aorta and peripheral arteries every five years may be beneficial.[6] More regular imaging follow-up is recommended following EVAR due to the risk of graft-related complications and late rupture. The ESVS 2024 guidelines recommend post-operative early imaging within 30 days of EVAR using CTA to assess for the presence of complications such as endoleak (that is, the leaking of blood outside a stent graft into the aneurysm sac that can lead to aneurysm enlargement and rupture) or graft migration. Longer-term imaging follow-up is also recommended following EVAR, to detect late complications and identify potential device failure and disease progression.[6] However, the frequency of long-term follow-up may vary depending on the results of early post-operative imaging. Lifelong follow-up after any type of AAA repair is considered mandatory in order to maintain treatment success.

3.4 Abdominal aortic aneurysm screening in Ireland

There is currently no population-based screening programme for AAA in Ireland. Screening of high-risk patients (for example, on the basis of family history) is in place in some hospitals in Ireland on an ad hoc basis.[148] In the absence of a formal

screening pathway for AAA, access to screening is dependent on awareness among general practitioners and patients, and the available resources within a given vascular centre. Additionally, some people with or without risk factors for the development of AAA may access screening in the private healthcare system (see Section 3.4.2).

Four studies were identified that investigated the feasibility and acceptability of screening for AAA in Ireland, and are described in sections 3.4.1 and 3.4.2.

3.4.1 AAA screening studies in Ireland

Three small-scale AAA screening studies conducted within the public healthcare system were identified. These studies were associated with St. James's Hospital (the St. JamEs and MidlaNds AneurySm ScreEning (SENSE) study),[219] Connolly Hospital,[19] and the Mater Misericordiae University Hospital (MMUH)[220] (see Table 3.1). The three studies differed in some key aspects, including the sample populations, recruitment methods, screening setting, and the surveillance and treatment pathways, all of which could affect study outcomes. In all studies, ultrasound was the imaging modality used for screening.

Two of the studies, the SENSE study[219] and the Connolly Hospital study,[19] were broadly similar in terms of their target populations and recruitment methods. Both of these studies aimed to recruit men from the general population, who were identified from the databases of participating GP practices within a pre-defined catchment area. However, they differed slightly in the age range recruited (see Table 3.1). The SENSE study also offered screening to first-degree relatives (male and female) of patients with screen-detected AAA on request. The setting of ultrasound screening also differed in these two studies. For the SENSE study, screening was performed at participating GP practices by a vascular technologist using a portable ultrasound machine.[219] In the second study, ultrasound screening was conducted in the Vascular Diagnostic Unit in Connolly Hospital as part of a broader cardiovascular risk factor assessment which included screening for hypertension, hypercholesterolemia and type 2 diabetes. The third study, conducted in MMUH, focused on a high-risk population (that is, people referred to a vascular laboratory for non-invasive arterial studies) and included both men and women who underwent abdominal aorta screening using duplex ultrasound. In this study AAA ultrasound screening was performed at the hospital vascular laboratory by a vascular technologist.

Of the three studies, the SENSE study is most relevant to the context of the present HTA,[219] as the study conducted in Connolly Hospital involved combined cardiovascular screening,[19] and the study carried out in MMUH enrolled a high-risk group.[220]

There was also variability between the three studies in terms of the definition of an enlarged aorta, and the surveillance and treatment pathways. In the Connolly Hospital study[19] an enlarged aorta was defined as an aortic diameter greater than 3.0 cm; this threshold was used in the SENSE study[219] for participants over 69 years only. For participants under 69 years, the SENSE study defined an enlarged aorta as an aortic diameter greater than 2.6 cm.[219] The study conducted in MMUH also used an aortic diameter greater than 2.6 cm as the threshold for a positive screening test result.[220] There were some differences in the surveillance intervals and thresholds for surgery across the three studies. The studies conducted in Connolly Hospital[19] and MMUH[220] followed similar surveillance intervals for patients with an aortic diameter between 3.0 and 5.5 cm (see Table 3.1). Additionally, surveillance was recommended every two years for those with sub-aneurysm (aortic diameter 2.6 to 2.9 cm) in the MMUH study. In the SENSE study, yearly surveillance was recommended at an aortic diameter of 3.5 to 3.9 cm, while for those with an aortic diameter of 3.0 to 3.4 cm, surveillance was extended to every two years. Those with screen-detected sub-aneurysm were recalled every three years. The criterion for referral for vascular surgery was an aortic diameter greater than 4.0 cm in the SENSE study;[219] this threshold was lower than that applied in the other two studies, which both used a threshold of aortic diameter greater than 5.5 cm in men. Organisational considerations, including the setting and resource requirements associated with the potential introduction of a national population-based AAA screening programme in men, will be considered in Chapter 7.

Table 3.1. Overview of the characteristics of AAA screening studies in Ireland.

Setting Project Title Timeline	Structure Recruitment Method	Population of interest Sample	Definition of enlarged aorta	Discharge criteria and surveillance pathway	Referral pathway
GP practices Led by St James's Hospital (Dublin) St. JamEs and MidlaNds Aneurysm ScreEning (SENSE) Project[219] January 2007 until approximately 2012 (data presented to April 2008)	▪ Regional screening programme for AAA.† ▪ Recruited via GPs in the midlands region. ▪ Screening performed by vascular technologist using portable ultrasound machine.	▪ Men 65 – 85 years ▪ Men and women 50 - 74 years first-degree relatives of patients with AAA. ▪ n = 549 participants	Aged ≥69 years: AD ≥ 3.0 cm Aged <69 years: AD ≥ 2.6 cm	Criteria for discharge: ▪ AD < 2.6 cm: no follow-up required Enlarged aorta: ▪ Follow-up scan in 12 months. After 12-month follow-up scan: ▪ AD 2.6 - 2.9 cm: recall every 3 years ▪ AD 3.0 - 3.4 cm: recall every 2 years ▪ AD 3.5 - 3.9 cm: recall yearly	Threshold for referral to vascular surgery: AAA > 4.0 cm Timeframe for referral to consultant vascular surgeon: ▪ 4.0 - 4.9 cm: within 12 weeks ▪ 5.0 - 5.4 cm: within 4 weeks ▪ >5.5 cm: within 3 weeks
Vascular unit for AAA and cardiovascular risk factor screening in Connolly Hospital (Dublin)[19] April 2006 to December 2007	▪ Local screening programme for AAA combined with clinical risk assessment. ▪ Recruited via GPs in hospital catchment area.	▪ Men 55 - 75 years ▪ Those with terminal medical conditions or previous diagnosis of AAA were excluded. ▪ n = 904 men	Aortic diameter ≥ 3.0 cm	Criteria for discharge: ▪ AD < 3.0 cm: no follow-up required Surveillance intervals: ▪ AD 3.0 - 4.0 cm: 12-month follow-up scan ▪ AD 4.0 - 4.5 cm: 6-month follow-up scan ▪ AD 4.5 - 5.4 cm: 3-month follow-up scan and surgical consultation	Threshold for referral to vascular surgery: AAA > 5.5 cm Components of care pathway: Men with AD > 3 cm receive a consultation with a vascular surgeon on the day of diagnosis.

Setting Project Title Timeline	Structure Recruitment Method	Population of interest Sample	Definition of enlarged aorta	Discharge criteria and surveillance pathway	Referral pathway
	▪ Ultrasound screening performed by vascular technologist. Measured leading edge to leading edge in transverse and longitudinal section.				
Hospital vascular laboratory in Mater Misericordiae University Hospital (Dublin)[220] January 2010 to December 2016	▪ Targeted screening programme for AAA in a high-risk population. ▪ Patients identified from hospital records. ▪ Ultrasound screening performed by vascular technologist.	▪ Men and women > 60 years attending hospital vascular laboratory for non-invasive arterial studies. ▪ Patients receiving abdominal aorta duplex for reasons other than for AAA screening were excluded. ▪ n = 5,422 participants (n = 3,261 men, n = 2,161 women)	AD ≥ 2.6 cm	<u>Criteria for discharge:</u> ▪ AD ≤ 2.5 cm: no follow-up required. <u>Criteria for entering surveillance pathway:</u> ▪ Men: 2.6 – 5.4 cm ▪ Women: 2.6 – 4.9 cm <u>Surveillance intervals:</u> ▪ AD 2.6 - 2.9 cm: recall every 2 years ▪ AD 3.0 - 3.9 cm: recall yearly ▪ AD 4.0 - 4.5 cm: 6 months follow-up ▪ AD 4.6 - 5.4 cm: 3 months follow-up	<u>Threshold for referral to vascular surgery:</u> ▪ Men: AAA≥ 5.5 cm ▪ Women: AAA ≥ 5.0 cm <u>Components of care pathway:</u> Refer to vascular consultant for risk factor modification and surveillance.

Key: AAA – abdominal aortic aneurysm; AD – aortic diameter.

† Population-based studies are defined as a group of individuals taken from the general population who share common characteristics, such as age, sex, or health conditions. Studies were considered population-based if participants were enrolled based on geographical location (for example, an entire region or country), as opposed to healthcare setting (for example, hospital-based enrolment).

3.4.2 Access to screening in the private healthcare system

Access to AAA screening is available through the private healthcare system where individuals can self-refer to medical ultrasound clinics, or be referred by a GP to private hospitals on the basis of risk factor identification (for example, family history of AAA). Such screening is funded through private health insurance or through out-of-pocket expenses for those without private health insurance.[221] Similar to the procedure in the public healthcare system, patients receive an abdominal ultrasound scan, which measures the diameter of the aorta. In the absence of a standardised care pathway, processes for follow-up care, where indicated, are uncertain.[221, 222] The number of people accessing screening for AAA through the private healthcare system in Ireland is currently unknown, as there is no centralised reporting system for private hospitals operating in Ireland.

A 2008 study, conducted within a private hospital and clinic in Ireland, investigated the feasibility of expanding an AAA ultrasound screening protocol to address all-cause cardiovascular mortality.[94] Study participants were self-referred men aged over 60 years attending for AAA screening as well as a full cardiovascular risk factor assessment.[94] An enlarged aorta was defined as an aortic diameter greater than 3 cm in the anteroposterior diameter, consistent with best practice guidelines (see section 3.5.1).[94] In terms of the care pathway, only those with aortic diameters greater than 5.5 cm were referred onwards. It was noted that those with a history of cardiovascular events would likely already be receiving follow-up care.

3.5 International guidelines and policy

Guidelines outlining recommendations for AAA screening were retrieved from three European[6, 145, 146] and four North American[223-226] medical societies (Table 3.2). Eight HTA reports from health authorities in six countries, namely, Canada, France, Germany, Norway, Spain, and Sweden, were also identified.[227-233] The conclusions are summarised in Table 3.3. Of note, the scope of this HTA is men at age 65 (see Chapter 1, section 1.1). However, where reported, recommendations and practices that included different populations (for example, women or younger males), were also included.

It should be noted that in many countries the advice generated in a HTA is not binding. The time between the publication of a HTA and the subsequent integration of research findings into policy is context dependent and can be highly variable.[234, 235] Therefore, the conclusions of a HTA may not reflect current clinical practice in that country, but can indicate international interest in implementation of AAA screening. Results of the review of international practice, which includes evidence from planned, pilot or implemented screening programmes, are summarised in section 3.5.3.

3.5.1 International guidelines

All of the seven guidelines identified recommend screening in men aged 65 years or older, and apply the same definition of AAA (that is, a diameter of 3.0 cm or more). However, the three US medical societies limit AAA screening to men with smoking history.[223, 224, 226] Across all guidelines, where reported, there was agreement that surgical repair is indicated in men once the AAA reaches a diameter of 5.5 cm or more. The surveillance intervals for AAAs between 3.0 and 5.0 cm in diameter were similar across four guidelines,[6, 145, 223, 226] with the United States Preventive Services Task Force (USPSTF) and NICE guidelines recommending shorter intervals.[146, 224] The threshold for referral for surgical repair was not explicitly stated by the Canadian Society for Vascular Surgery.[225] Three guidelines recommended re-screening after five to ten years in men with a sub-aneurysmal dilation (that is a diameter between 2.5 cm and 2.9 cm) at initial screening.[6, 223, 225] The USPSTF recommendations statement advised that well-conducted cohort studies examining rescreening benefits (including growth rates and health outcomes) are needed for persons who initially screen negative for AAA to determine the benefit and timing of rescreening.[224]

No guidelines recommended a population-based screening approach in women, but rather a targeted approach based on identification of risk factors. All guidelines included recommendations for screening of AAA in women with family history of AAA.[6, 145, 146, 223-226] Of the seven guidelines, six included recommendations for screening in women over 65 with smoking history.[145, 146, 223-226] Four guidelines had lower surgical repair thresholds for women (5.0 cm) than for men (5.5 cm).[6, 145, 223, 226]

Table 3.2 Clinical guidelines on AAA screening

Advising body Country or region	Year Methodology Search date	Population recommended to be screened	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication
SVS[223] **US**	2017 Systematic review Up to Sep 2016	• Men and women 65 - 75 years with smoking history or older if in good health • Men and women 65 - 75 years with family history or older if in good health	≥ 3.0 cm	Considered when sub-aneurysmal dilation† after 10 years.	3.0 - 3.9 cm: Every 3 years 4.0 - 4.9 cm: Every year 5.0 - 5.4 cm: Every 6 months Surgery: Men: ≥ 5.5 cm Women: ≥ 5.0 cm
ESVS[6] **Europe**	2024 Systematic review Up to Aug 2023	• Men at 65 years. • Men at 65 years, former or current smoker • Men and Women ≥ 50 years with first degree relative with AAA. • Men and Women with other peripheral aneurysm or organ transplant.	≥ 3.0 cm	Considered when sub-aneurysmal dilation† after 5 to 10 years.	Men: 3.0 - 3.9 cm: Every 3 years 4.0 - 4.9 cm: Every year ≥5.0 cm: Every 6 months Women: 3.0 - 3.9 cm: Every 3 years 4.0 - 4.4 cm: Every 6 months ≥4.5 cm: Every 6 months Surgery: Men: ≥ 5.5 cm Women: ≥ 5.0 cm
USPSTF[224] **US**	2019 Systematic review Up to Sep 2018	• Men 65 - 75 years with smoking history • Men 65 - 75 years with risk factors‡ different to smoking history • Women 65 - 75 years with smoking history or family history	≥ 3.0 cm	No (insufficient evidence)	3.0 - 3.9 cm: Every year 4.0 - 5.0 Cm: Every 6 months Surgery: ≥ 5.5 cm

Advising body Country or region	Year Methodology Search date	Population recommended to be screened	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication
DGG[145] **Germany**	2019 Systematic review Up to Jan 2017	• Men ≥ 65 years • Women ≥ 65 years with smoking history • Men and women with family history of AAA	≥ 3.0 cm	No recommendation provided.	Men: 3.0 - 3.9 cm: Every 2 years 4.0 - 4.9 cm: Every year 5.0 - 5.4 cm: Every 6 months Women: 3.0 - 3.9 cm: Every 2 to 3 years 4.0 - 4.5 cm: Every 6 months 4.6 - 4.9 cm: Every 3 months Surgery: Men: ≥ 5.5 cm Women: ≥ 5.0 cm
NICE[146] **UK**	2020 Systematic review Up to Dec 2017	• Men ≥ 66 years • Women ≥ 70 years with smoking or family history, or other risk factors[ǂ]	≥ 3.0 cm	No recommendation provided.	3.0 - 4.4 cm: Every year 4.5 - 5.4 cm: Every 3 months Surgery: ≥ 5.5 cm
CSVS[225] **Canada**	2020 Review Not mentioned	• Men 65 to 80 years or older if in good health • Women 65 - 75 years with smoking history or cardiovascular disease • Men and Women ≥ 55 years with first degree relative with AAA.	≥ 3.0 cm	Considered when sub-aneurysmal dilation[†] after 10 years.	No recommendation provided.

Advising body Country or region	Year Methodology Search date	Population recommended to be screened	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication
AHA/ACC[226] **US**	2022 Systematic review Up to Apr 2021	▪ Men ≥ 65 years with smoking history ▪ Women ≥ 65 years with smoking history ▪ Men or Women ≥ 65 years with first-degree relative with AAA	≥ 3.0 cm	In asymptomatic men or women>75 years who have had a negative initial ultrasound screen, repeat screening for detection of AAA is not recommended	Men: 3.0 - 3.9 cm: Every 3 years 4.0 - 4.9 cm: Every year ≥ 5.0 cm: Every 6 months Women: 3.0 - 3.9 cm: Every 3 years 4.0 - 4.4 cm: Every year ≥ 4.5 cm: Every 6 months Surgery: Men: ≥ 5.5 cm Women: ≥ 5.0 cm

Key: AAA - Abdominal Aortic Aneurysm; AHA/ACC - American Heart Association/American College of Cardiology; CSVS - Canadian Society for Vascular Surgery; DGG - German Society for Vascular Surgery and Vascular Medicine; ESVS - European Society for Vascular Surgery; NICE - National Institute for Health and Care Excellence; SVS - Society for Vascular Surgery; USPSTF - US Preventive Services Task Force.

† Abdominal aortic diameter between 2.5 cm to 2.9 cm.

ǂ Chronic obstructive pulmonary disease; Coronary, cerebrovascular or peripheral arterial disease; Hypertension; Hyperlipidaemia.

3.5.2 International assessments

Eleven assessments were identified,[227-233, 236-239] including a European-level assessment conducted by the European Network for Health Technology Assessment (EUnetHTA).[237]

Where reported, surveillance intervals for those with small and medium AAA varied between assessments (see details in Table 3.3). The threshold for referral to vascular surgery among those with large AAA was greater than or equal to 5.5 cm in all assessments, except in those published by HAS in France,[231] and FinOHTA in Finland,[238] which adopted a more conservative threshold of greater than or equal to 5.0 cm.

Overall, six assessments considered re-screening, with four outlining that rescreening men with a sub-aneurysm at baseline should be considered after five years,[228, 231, 233, 236] consistent with international guidelines. Two assessments recommended no further follow-up for cases with an initial aortic diameter less than 3.0 cm.[227, 238] One of these, the Ontario HTA, noted that one-time screening in men is sufficient for a population-based screening programme with regard to initial negative scans and the potential for development of a large AAA.[227] Five assessments did not provide advice in relation to rescreening,[229, 230, 232, 237] or rescreening was beyond the scope of the assessment.[239]

Overall, nine of the 11 identified assessments came to positive conclusions regarding the benefits of a population-based AAA screening in men aged 65 and older.[227-230, 232, 233, 236-238] The HAS assessment recommended the implementation of a one-off opportunistic screening programme targeting males with risk factors, such as smoking or family history of AAA.[231] One assessment from the Netherlands concluded that the estimated effect of an AAA screening programme on AAA-related mortality would not offset the serious harms related to overdiagnosis, overtreatment and false positives.[239] Where investigated, there was said to be insufficient evidence to support population-based screening for AAA in women.[227, 232, 236-238] The AVALIA-T agency's HTA concluded that targeted one-time screening for AAA could be considered for women based on smoking and family history of AAA.[228]

Table 3.3 International assessments on AAA screening

HTA body Country or region	Year Methodology Search date	Population	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication	Conclusions
OHTAS[227] **Ontario, Canada**	2006 Systematic review Up to Aug 2005	▪ Men at 65 years	≥ 3.0 cm	No (one-time screen is sufficient with regard to initial negative scans and potential for development of large AAAs).	Surveillance: Not reported Surgery: ≥ 5.5 cm	There is sufficient evidence to determine that AAA screening using ultrasound is effective and reduces negative health outcomes associated with the condition. Overall, the clinical utility of an invitation to use ultrasound screening to identify AAA in men aged 65 to 74 is effective at reducing AAA-attributable mortality. The benefit of screening women is not yet established. However, Ontario data indicate several areas of concern including population prevalence, detection of AAA in women, and case management of AAA in women in terms of age cut-offs for screening and natural history of disease associated with age of rupture.
AVALIA-T[228] **Galicia, Spain**	2007 Literature review Up to Apr 2006	▪ Men 65 to 75 years or women with smoking history ▪ Men and women with family history of AAA	≥ 3.0 cm	Considered when sub-aneurysmal dilation† with no timeframe specified.	3.0 - 3.9 cm: Every year 4.0 - 5.4 cm: Every 3 to 6 months Surgery: ≥5.5 cm	The available scientific evidence is extensive and of high quality. The results of the studies indicate that one time ultrasound screening for AAA in the male population between 65-75 years of age reduces mortality associated with AAA. Other susceptible groups for screening are women with smoking history and any person over 50 years old with family history of AAA.
SBU[229, 240] **Sweden**	2008 Literature review Up to Jun 2008. Updated Jan 2015.	▪ Men at 65 years	≥ 3.0 cm	Not reported.	Surveillance: Not reported Surgery: ≥ 5.5 cm	Screening for AAA leads to reduced AAA-related mortality in men. The scientific evidence is insufficient regarding the effects of screening for AAA in women. Screening for AAA is ethically defensible provided that the activity is designed so that basic ethical principles are met and that the information provided in connection with initial examination and follow-up is objective and easy to understand.

HTA body Country or region	Year Methodology Search date	Population	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication	Conclusions
AETMIS[230] **Québec, Canada**	2010 Systematic review Up to Sep 2008	▪ Men 65 to 74 years	≥ 3.0 cm	Not reported.	Surveillance: Not reported Surgery: ≥ 5.5 cm	An AAA screening programme would theoretically be effective, since the criteria relating to the disease, the screening test, the treatment and cost-effectiveness are met, particularly for men aged 65 to 74 years. The current state of epidemiological and organisational conditions in Quebec, although not favourable to the immediate implementation of such a programme, suggests several avenues for possible improvement.
HAS[231] **France**	2012 Literature review Up to Jul 2009	▪ Men 65 to 75 years with current or past chronic smoking ▪ Men 50 to 75 years with family history of AAA.	≥ 3.0 cm	Considered when sub-aneurysmal dilation† after 5 years.	3.0 - 3.9 cm: One to 3 years 4.0 - 4.9 cm: 6 months to 1 year Surgery: ≥5.0 cm OR growth ≥ 10 mm/year OR symptoms	HAS recommends the implementation of a single opportunistic targeted screening by Doppler ultrasound in people at risk: men between 65 and 75 years old who smoke or have been smokers as well as to men between 50 and 75 years old with a family history. The practical effectiveness of such a programme, in a real world context, has not been demonstrated
FinOHTA[238] **Finland**	2011 Systematic review Up to Oct 2010	▪ Men and Women at 65 years old	≥ 3.0 cm	No	3.0 - 3.5 cm: Every 2 years 3.6 - 4.5 cm: Every year > 4.5 cm: Every 6 months and referral to vascular surgeon Surgery: ≥ 5.0 cm in women and ≥ 5.5 cm in men OR growth ≥ 10 mm/year.	A single screening for AAA in men aged 65 in Finland would prevent 237 deaths in the cohort, that is among those born in the same year, and 318 deaths in both men and women aged 65. The introduction of screening would require additional resources for the Finnish health system compared to the current situation.

HTA body Country or region	Year Methodology Search date	Population	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication	Conclusions
EUnetHTA[237] **Europe**	2012 Full HTA including systematic review (13 March 2012)	▪ Men and women aged 64 or more	At least 1.5 times the diameter of the aorta measured at the level of the renal arteries. >3.0 cm	Not reported	Identified guidelines recommend surveillance of patients with aneurysms <5.5 cm in diameter, but these recommendations vary in the intensity of follow-up and the cut-off points of the aortic diameter.	Evidence from the literature indicates that AAA screening is beneficial in men over 65 years of age, as it reduces AAA-related mortality by nearly half in the mid- and long-term. In contrast to men, there are no reliable clinical data showing that women benefit from AAA screening. The majority of the available evidence, as well as our present evaluation, suggests that one-time ultrasound screening for AAA of 65-year-old men and women is cost-effective compared with a situation where no AAA screening is offered. Local adaptation of the results would be required.
IQWiG[232] **Germany**	2015 Systematic review Up to Dec 2014	▪ Men ≥ 65 years	≥ 3.0 cm	Not reported.	Surveillance: Not reported Surgery: ≥ 5.5 cm	The present benefit assessment provides evidence of a benefit of ultrasound screening for AAA for men. There is no evidence of a benefit of ultrasound screening for AAA in women.
Gezondheidsraad[239] **Netherlands**	2019 Literature review Not reported	▪ Men 55- to 80- year	≥ 3.0 cm	Not applicable	3.0 - 3.9 cm: Every 2 years 4.0 - 4.9 cm: Every year. 5.0 cm: Every 6 months Surgery: ≥5.5 cm	It is uncertain how much additional health benefit population screening would provide but in all likelihood it would be limited, too limited to offset the significant risks. Instead of establishing a population-based study, the committee recommended exploring whether the current AAA pathway can be optimised to continue the positive trend of increased preventive surgery and reduced AAA mortality.
Folkehelsein-stituttet[233] **Norway**	2020 Systematic review Up to Nov 2019	▪ Men at 65 years	≥ 3.0 cm	Considered when sub-aneurysmal dilation† after 5 years.	3.0 - 4.0 cm: Every 2 years 4.0 - 4.5 Cm: Every year 4.5 – 4.5: Every 6 months Surgery: ≥ 5.5 cm	AAA screening in men aged 65 years can halve mortality caused by aneurysms in both the short and long term. There is no significant reduction in total mortality in the short term, but in the long term AAA screening can reduce total mortality. The number of preventive operations increases by 2-3 times, while the number of emergency operations is halved as a result of AAA screening.

HTA body Country or region	Year Methodology Search date	Population	Definition of AAA	Re-screening	Surveillance intervals and Surgery indication	Conclusions
AQuAS[236] **Catalonia, Spain**	2023 Systematic review Up to Jun 2022	▪ Men ≥ 65 years	≥ 3.0 cm	Considered when sub-aneurysmal dilation† after 5 years.	3.0 - 3.9 cm: Every 3 years 4.0 – 4.9 cm: Every year 5.0 – 5.4 cm: Every 6 months Surgery: ≥5.5 cm	In men older than 65 years, AAA screening could reduce overall mortality and AAA-related mortality, as well as increase AAA detection. The evidence is very uncertain in women over 65 years of age. The candidate population has been defined as men over 65 years of age. The proposed care pathway is based on carrying out screening in primary care centres with subsequent referral to specialised vascular surgery services for follow-up and treatment.

Key: AAA - Abdominal Aortic Aneurysm; AETMIS - Agence d'évaluation des technologies et des modes d'intervention en santé; AQuAS - Agència de Qualitat i Avaluació Sanitàries de Catalunya, AVALIA-T - Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia; FinOHTA – Finnish Office for Health Technology Assessment, HAS - Haute Autorité de Santé, IQWiG - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; OHTAS - Ontario Health Technology Assessment Series; SBU - Swedish Agency for Health Technology Assessment.
† Abdominal aortic diameter between 2.5 cm to 2.9 cm.

3.5.3 International policy and practice

Based on the findings of a scoping review of international policy and practice, only Germany,[241] Sweden[242] and the United Kingdom[9] have implemented nationwide population-based screening programmes for AAA. AAA screening programmes are expected to be piloted in Denmark and the Czech Republic in 2025.[243-245] A one-time, targeted screening programme is in place in the US since 2007. The characteristics of these screening programmes are summarised in Table 3.4. Information regarding the delivery of international screening programmes will be used to guide operational considerations, examined in Chapter 7 of this HTA, for an AAA screening programme in men in Ireland.

The approach to inviting the population to screening varies between regions. In Germany, AAA screening is offered to all eligible men interacting with the healthcare system for another reason (that is, opportunistic screening).[241, 243] In the UK and Sweden, men aged 65 are systematically invited to screening (that is, organised screening).[9, 241] While organised screening generally facilities greater coverage compared with opportunistic approaches,[246] whether or not required standards in terms of coverage and quality assurance can be achieved with an opportunistic approach is dependent on access to primary care within a given healthcare system and a programme's quality assurance frameworks.

It is noted that the absence of systematic invitation process in Germany has resulted in lower uptake compared with other countries, and thus a lower demand for associated resources. The setting of screening also varies between countries, likely reflecting differences in healthcare system structuring. In Sweden, screening is based in hospitals, while in Germany screening appears to be offered by the family doctor at a primary care level. In the UK, screening clinics may operate in health centres or hospitals, depending on the region.

Across the three programmes, an aortic dilation of 3.0 cm or more is classified as an aneurysm. Healthcare in Sweden is implemented at a regional level. In some Swedish counties, participants with sub-aneurysmal aortic diameters are offered surveillance screening after five years.[247] For patients with a screen-detected AAA, management depends on the diameter of the AAA detected. Definitions of small to medium AAA and the associated surveillance intervals vary between programmes. In Germany,[241] patients are monitored every two years for an AAA 3.0 to 3.9 cm in diameter, annually for an AAA 4.0 to 4.9 cm, and every six months for an AAA 5.0 to 5.4 cm. In Sweden,[242] patients are monitored every two years for an AAA 3.0 to 3.9 cm in diameter, annually for an AAA 4.0 to 4.5 cm, every six months for an AAA 4.6 to 5.0 cm, and quarterly for an AAA more than 5.0 cm. In the UK,[9] patients with an AAA of 3.0 to 4.4 cm in diameter are monitored annually, and quarterly for an AAA

4.5–5.4 cm in diameter. In all programmes, surgical repair is considered at an aortic diameter greater than or equal to 5.5 cm, in line with international clinical guidelines.[9, 145, 241, 242]

In the United States a national one-time AAA screening programme was implemented in 2007.[95] However, unlike the programmes in place in some European countries, screening is targeted and only available to Medicare beneficiaries. In the US, those turning 65 are automatically enrolled in Medicare and are eligible to receive social security benefits. The programme specifically targets men aged 65 to 75 who have ever smoked at least 100 cigarettes, and men and women over 50 with a family history of AAA.[95, 248]

According to the Danish Health Authority, an AAA screening programme in men aged 65 years is planned to be introduced.[244] Initially, implementation is planned for a five-year period, with subsequent review of programme outcomes, owing to uncertainty regarding the changing incidence of AAA in Denmark. It is unclear whether this programme would screen for AAA only or if it will be rolled out as part of a combined cardiovascular screening programme.[244] Similarly, the Czech Republic intends to pilot an AAA screening programme for men aged 65 to 67 in 2025, with the possibility of discontinuing the programme if the observed AAA prevalence rate is below 0.5%.[243, 245]

In contrast, in 2019 the Netherlands Health Council recommended against the implementation of an AAA screening programme. This recommendation was on the basis that the risk-based approach and current opportunistic screening practice within the healthcare system was successful in detecting AAA and preventive AAA repair was being performed at a rate twice that in the UK and Sweden.[249] This, in addition to the decreased AAA-related mortality observed in the Netherlands over time, led to the conclusion that the health gain would be limited and unable to compensate for the 'considerable' risks relating to post-operative complications and mortality that would be introduced with the programme.[249] In Finland, as of 2014, the Ministry of Health and Social affairs had recommended against the implementation of an AAA screening programme on account of organisational considerations and concerns about the relative benefits of such a programme.[250] No evidence of a change in this position was identified in our review.

In Ontario, Canada, no formal AAA screening programme has been rolled out. However, physicians may choose to offer publicly-funded screening to any male at age 65, following the recommendations of the Ontario Health Technology Assessment Series (OHTAS).[227, 230] Similarly, while there is no established national AAA screening programme in Australia, medical practitioners may conduct targeted screening for patients based on risk factors, which is covered under Australia's Medicare Benefits Schedule.[251] In France, as noted in section 3.5.2, a HTA report

from HAS recommended targeted screening of males aged 65 to 75 years with current or past heavy smoking history.[231] However, some studies suggest these recommendations have not been widely implemented and uptake is reported to be low.[252, 253]

Regional screening programmes for AAA, with local government support, have been piloted in some countries including Belgium,[83] Italy,[32, 71, 254, 255] Spain,[77] Switzerland,[256] and New Zealand.[257] Regional screening programmes have also been piloted in Greece,[254] Norway,[32] Portugal,[71] and Poland,[255] but it is unclear if government funding was received to support these pilot programmes. No published evidence regarding population-based screening for AAA in Austria was identified. However, The Austrian Association for Vascular Medicine (ÖVG), have called for the introduction of such a programme.[258]

Table 3.4 Countries with national AAA screening policies

Country	Year of initiation Uptake	Population being screened	Definition of positive screening finding	Surveillance intervals and Surgery indication	Re-screening	Structure
Germany (145, 241, 259)	2017 Uptake: unclear	Men: ≥65 years	≥3.0 cm	3.0–3.9 cm: 2 years 4.0–4.9 cm: 1 year 5.0–5.4 cm: 6 months Surgery: ≥5.5 cm	Not offered	• Those with statutory health insurance are entitled to a general health and disease-specific health examinations. AAA screening is offered as part of the general health examination to eligible men since 2018. • Low participation rates have been a challenge due to lack of awareness among eligible men and GPs.
Sweden (8, 242, 260)	2006 Uptake: 84% (2006-2014)	Men: ≥65 years	≥2.5 or ≥3.0 cm*	3.0–3.9 cm: 2 years 4.0–4.5 cm: 1 year 4.6–5.0 cm: 6 months >5.0 cm: every 3 months Surgery: ≥5.5 cm	Not offered	• Centralised hospital-based screening by county. • Invitations are sent to all 65 year old men. • Self-referrals are accepted.
United Kingdom (9, 261)	2009 Uptake: 79% (2014-2022)	Men: ≥65 years	≥3.0 cm	3.0–4.4 cm: 12 months 4.5–5.4 cm: 3 months Surgery: ≥5.5 cm	Not offered	• Offered by AAA screening clinics in GP surgeries and hospitals around the country. • Invitations are sent to all 65 year old men. • Self-referrals are accepted.
United States (95, 248, 262)	2007 Uptake: unclear	Men 65 to 75 years with smoking history† Men or women ≥50 years with family history of AAA	≥3.0 cm	3.0–3.9 cm: 3 years 4.0–4.4 cm: 2 years 4.5–5.4 cm: 1 year Surgery: ≥5.5 cm	Not offered	• Offered only during the Initial Preventive Physical Exam of new Medicare enrolee by physician. • Self-referrals are not accepted. • No systematic invitations are sent.
Czech Republic (243, 245)	To be introduced in 2025 Uptake: NA	Men 65 to 67 years old with a life expectancy longer than one year.	≥3.0 cm	3.0–3.9 cm: 3 years 4.0–4.9 cm: 1 years 5.0–5.4 cm: 3 to 6 months Surgery: ≥5.5 cm	Not offered	• Offered directly by GP during the first office visit after the age of 65 years. • Screening takes place at radiology and angiology departments. • Detected AAAs cases are referred to and managed in a cardiovascular care centre.

Key: AAA – abdominal aortic aneurysm.

* In Sweden, some vascular surgery units offer periodic follow-up to participants with an abdominal aortic diameter of 2.5 to 2.9 cm (sub-aneurysm).

† Smoking history (at least 100 cigarettes in their lifetime).

3.6 Overview of the proposed AAA screening care pathway in the model of care for vascular surgery

As highlighted in Chapter 2, an AAA is typically asymptomatic until it ruptures, which is associated with a high mortality rate. Therefore, screening aims to identify intact AAAs in asymptomatic individuals to facilitate timely access to elective surgery, where indicated, and better patient outcomes. In November 2023, the Irish National Clinical Programme for Surgery published a vascular surgery model of care for Ireland. This document outlines the changes considered necessary to enable optimum delivery of the vascular surgery service over the next five to ten years, and, as part of this, describes a rationale for the introduction of screening for AAA. A potential algorithm for an AAA screening programme is presented, which is reproduced in Figure 3.1 and described below. This screening algorithm is considered here in the context of international guidelines and practice in section 3.6.1.

As part of the pathway outlined within the model of care for vascular surgery, participants with an aortic diameter less than the pre-defined threshold for a positive screening test result (that is, an aortic diameter of 3.0 cm), would be discharged from the programme and no further screening would be necessary. As noted in the vascular surgery model of care, the eligible population plays a key role in determining the resources required to run an AAA screening programme. Discharge of all those with an AAA less than 3.0 cm, including those with sub-aneurysm (that is, an aortic diameter of 2.5 to 2.9 cm), would mean that no further follow-up would be required for those participants.[148]

Within the pathway proposed in the model of care, participants who have a positive screening test result (that is, an aortic diameter equal to or greater than 3.0 cm), but are below the threshold for referral to vascular surgery (that is, an aortic diameter of less than 5.5 cm) would be invited for regular surveillance. Participants with a small AAA (an aortic diameter between 3.0 cm and 4.4 cm) would be called for a follow-up scan in 12 months, and those with a medium AAA (that is, an aortic diameter between 4.5 cm and 5.5 cm) would be recalled in six months.[148]

Lastly, those meeting the threshold for repair as defined by the programme (that is, aortic diameter greater than 5.5 cm) or with an AAA larger than 4.0 cm with a fast growth rate (that is, a growth greater than 1 cm per year) would be referred to vascular surgery, in line with international clinical guidelines and international practice (Figure 3.1). Following referral to vascular surgery, patients would undergo clinical assessment to evaluate suitability for surgery, consistent with processes under the current AAA care pathway in Ireland (see section 3.3).

3.6.1 Further considerations

In addition to the algorithm proposed by the model of care for surgery, a number of further considerations in relation to the structure of an AAA screening programme for men in Ireland require exploration.

Firstly, as outlined in section 3.3.2, as part of a population-based AAA screening programme, it would be important that all individuals with screen-detected AAA have access to risk factor optimisation including behavioural modifications and pharmacological treatment, as appropriate, to reduce the rate of AAA expansion and rupture risk.[6]

As noted in section 3.5.3, one-time, population-based ultrasound screening is offered to men aged 65 years in the UK and Sweden, while men aged 65 years and over are offered ultrasound screening in Germany. If a decision is made to implement a population-based AAA screening programme in men in Ireland, the specific age or age group targeted should be informed by a number of factors including the epidemiology of disease, evidence of clinical effectiveness and safety, cost effectiveness, international practice, feasibility and acceptability. Based on the epidemiology of disease (Chapter 2) and evidence from international practice (section 3.5), it is likely that targeting men aged 65 years would be appropriate. However, potential age-related differences in clinical and cost effectiveness will be considered in Chapters 4 and 5. Furthermore, considerations regarding the potential extension of screening eligibility to self-referred populations and the setting where screening would be delivered are discussed from an organisational perspective in Chapter 8.

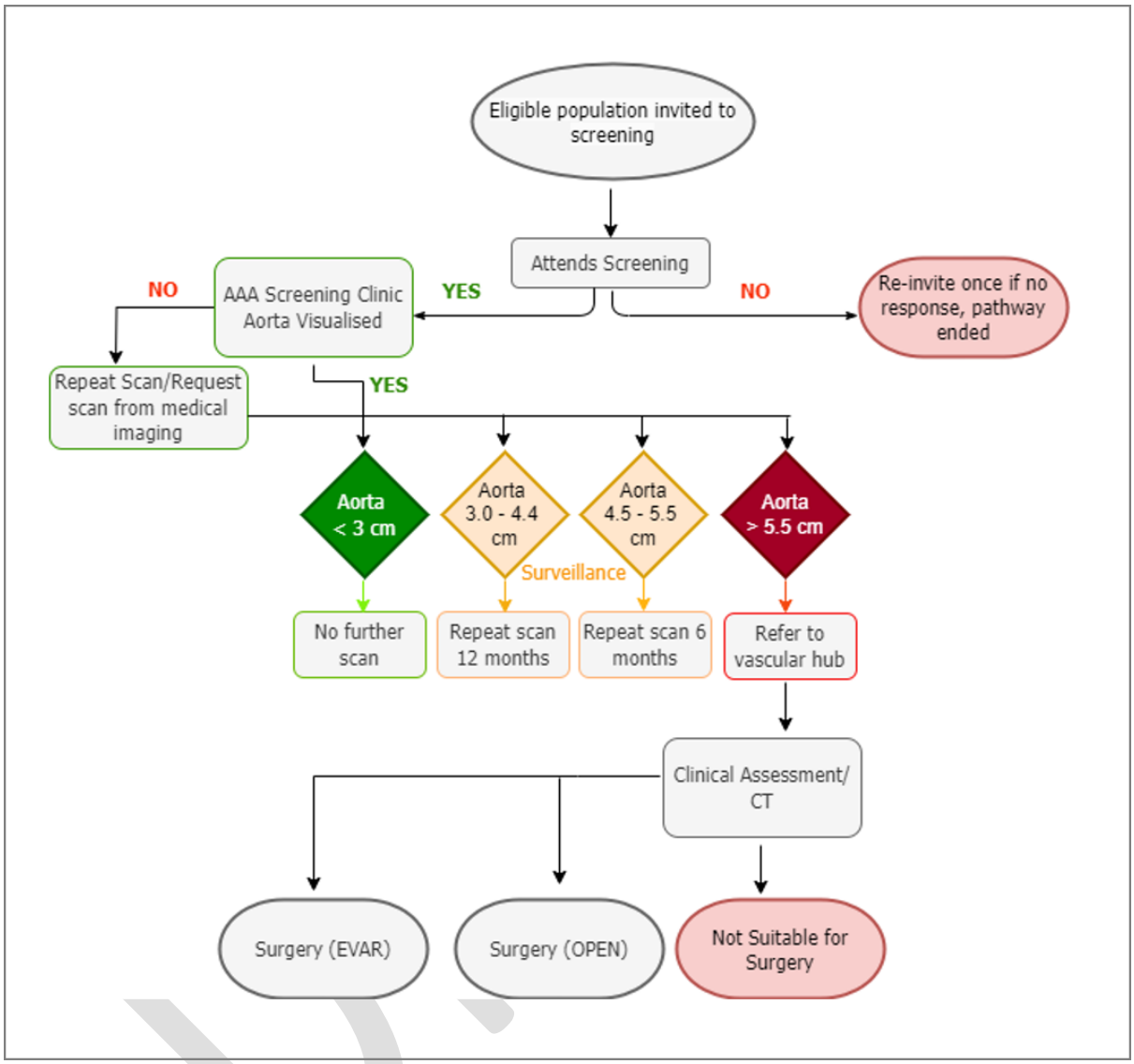
The threshold for a positive screening test result proposed by the model of care for vascular surgery is broadly in line with population-based AAA screening programmes internationally (see section 3.5.3), where men with a sub-aneurysm detected during initial AAA screening generally do not enter a surveillance pathway. However, in some Swedish counties, participants with sub-aneurysms are offered surveillance screening after five years.[263] As outlined in section 3.4.1, some local and regional screening studies conducted in the Irish context have included those with sub-aneurysm during AAA follow-up. The threshold for a positive screening test result would need to be determined with consideration to factors such as the local epidemiology of disease, available resources, and the risk of over diagnosis.

As noted in section 3.5, definitions of small and medium AAA vary internationally, as do the associated surveillance intervals. For example, the surveillance interval proposed for medium AAAs within the proposed pathway proposed in the model of care (6 months),[148] is longer than that used by the NHS AAA screening programme (3 months).[9] However, the NHS AAA screening programme defines a medium AAA as an aortic diameter between 4.5 cm and 5.4 cm. Importantly, when considering

pathway implementation, the definitions of small and medium AAA, and the associated surveillance intervals, would have implications in terms of the capacity needed for ultrasound monitoring, and potentially the clinical effectiveness of an AAA screening programme. Appropriate surveillance intervals should be defined with consideration to best practice guidelines and available resources.

Another important factor to be considered is the setting of the screening service. As outlined in section 3.5.3, in the UK, screening is offered at designated screening clinics based in GP surgeries and hospitals across the country. In Sweden, screening is carried out in the hospital setting. Previous screening studies conducted in the Irish public healthcare system were based in primary care or hospital vascular units (see section 3.4.1). The optimal setting of an AAA screening programme in Ireland would need to be determined based on a range of factors including available capacity, the availability of skilled staff, and the influence of setting on uptake. Operationalisation of screening for AAA will be considered in Chapter 7 (Organisational considerations).

Figure 3.1 Potential pathway for abdominal aortic aneurysm screening, surveillance and treatment, as outlined in the National Clinical Programme for Surgery model of care for vascular surgery



Key: AAA – Abdominal aortic aneurysm; CTA - Computed Tomographic Angiography; Surgery (EVAR) - Endovascular Aneurysm Repair; Surgery (Open) - Open Surgical Repair.
† The frequency of surveillance increases with increasing aortic diameter. A small proportion of patients with evidence of rapid aneurysm growth (for example, aortic diameter of 4.0 cm with growth of more than 1.0 cm per year) or symptoms may be referred for surgical evaluation prior to reaching the population-level threshold for referral to vascular surgery (≥5.5 cm).
Source: Adapted from the National Clinical Programme for Surgery's model of care for vascular surgery.[148]

3.7 Discussion

As outlined in the model of care for vascular surgery, in the absence of an AAA screening programme, almost all electively operated AAAs in Ireland are detected as an incidental finding during routine examination or investigation for unrelated symptoms.[148] Many patients are not detected until they present with rupture in the context of a life-threatening medical emergency. While the care pathway for ruptured AAA is distinct due to the need for emergency surgical consultation, many components of the current care pathway for patients diagnosed prior to rupture would be similar to those for patients diagnosed through screening. There is consistency across international guidelines and practice regarding many aspects of the AAA care pathway including the preferred use of ultrasound as a first-line imaging tool, the definition of a positive screening or diagnostic test result, the need for ongoing surveillance among those with small to medium AAAs, and the threshold for referral to vascular surgery. However, there is variation in the intensity of follow-up for those under AAA surveillance and technical aspects of ultrasound measurement, which would require further consideration if a decision is made to implement an AAA screening programme in men.

While the guidelines are broadly consistent in terms of the AAA care pathway, it is worth noting the changes between the 2019 and 2024 versions of the ESVS clinical guidelines in relation to AAA screening. These changes were driven by the changing epidemiology of AAA and the uncertainty regarding the applicability of available RCT evidence.[6] The 2019 version recommended one-time, population-based ultrasound screening in men aged 65, and recommended against population-based screening in women.[10] However, the most recent update has refrained from recommending a target population for screening. Instead, the 2024 guidelines state that high risk groups should be determined at a local level with consideration to factors such as AAA prevalence, life expectancy and healthcare system factors.[6] Of note, men aged 65 years are still listed among the risk groups that may be considered for screening.[6] Decision-makers should be aware of the changing epidemiology of AAA, in particular, evidence of declining prevalence, as discussed in Chapter 2, when selecting the population to be screened.

Despite clinical guidelines recommendations and positive conclusions of identified assessments regarding AAA screening in men, few countries have implemented a population-based AAA screening programme for men. The reasons behind this disconnect between the conclusions of assessments and practice in some countries is unclear, but it is likely multifactorial, including competing priorities and resource constraints. For example, although the 2010 HTA from AETMIS in Canada concluded that AAA screening is likely clinically effective in men, organisational structures in Quebec including inadequate access to ultrasound imaging were identified as a barrier to implementation.[230] A 2013 review of international practice found that

population-based screening programmes for AAA were in place in the UK and Sweden, while targeted screening was reported to be in place in the US.[247] The findings of the review of international practice undertaken to inform this HTA suggest that changes in the landscape of AAA screening since the 2013 review was completed have been limited. Furthermore, the authors of the 2013 review noted marked variation in surveillance frequency between countries.[247] The findings of our updated review indicate that although the frequency of surveillance consistently increased with increasing aortic diameter, there remains uncertainty regarding the optimal surveillance interval for those with screen-detected AAA. Although current clinical guidelines have recommended screening intervals based on the best available evidence, these are inconsistent with the screening intervals in use in international screening programmes. Variation in practice may be related to factors such as the local epidemiology of disease and resource availability for monitoring at a local level.

A further notable development in terms of the international landscape is the recommendations of the Netherlands Health Council in 2019 not to implement a population-based AAA screening programme. Following an assessment of the risk-benefit balance, the Health Council concluded that the added benefits of a population-based screening programme would be limited. Rates for AAA detection and treatment were reported to be relatively high in the Netherlands as a result of targeted screening and incidental diagnoses. It was also reported that the mortality rate following AAA rupture is lower in the Netherlands (approximately 50%) when compared with the international literature (approximately 80%, see Chapter 2, section 2.4.3). This was attributed, in part, to the relatively low perioperative mortality rate, well-organised ambulance care, and short distances to hospitals in the Netherlands. Instead, the committee recommended strengthening existing care pathways for targeted screening and surveillance.

The risk-benefit balance of a population-based AAA screening programme must be assessed at a local level, with consideration to healthcare system structuring and existing care pathways. In the Irish context, it is noted that the majority of AAAs are detected incidentally, with screening available on an ad hoc basis only.[148] Furthermore, as outlined in Chapter 2, section 2.7.1, approximately 50% of admissions for AAA in Ireland are emergency cases, with no evidence of a trend towards shifting presentation from emergency towards elective. Therefore, the conclusions of the Netherlands Health Council may not be transferable to the Irish context.

Given the high comorbidity profile among patients with AAA (see Chapter 2, section 2.4.4), many of those with AAA may already be engaged with the healthcare system, for management of other comorbidities. However, in the absence of a systematic programme with a standardised care pathway clearly outlining pathways for follow-up care, current practices for linkage to care are uncertain. The ESVS 2024

guidelines noted that in the international literature there is evidence to suggest that many patients identified incidentally do not receive appropriate follow-up care.[6]

The screening algorithm proposed in the vascular surgery model of care provides the initial foundation for a potential AAA screening programme in Ireland.[148] However, numerous factors warrant further consideration, which may influence the benefit-harm balance and capacity requirements. The proposed definitions of small and medium AAA are consistent with those in use in the UK NAAASP, while the surveillance intervals appear to be based on the ESVS 2024 guidelines. While in general, consistency with best practice guidelines is preferred, adoption of the UK NAAASP surveillance intervals may be justified given this pathway has been implemented in practice.[96, 264, 265] It should be noted, however, that extending the screening interval from 3 months to 6 months among those with an AAA of 4.5 to 5.5 cm in diameter may be associated with an increased risk of rupture in this group. A decision to extend the screening interval should be based on a review of the outcomes of the UK screening programme and consideration of their applicability to the Irish context.

In terms of the population being screened, although the optimal age for screening in men has never been formally assessed,[6] it is likely that an AAA screening programme in Ireland would target men aged 65 with consideration to the epidemiology of AAA in men, and international practice. There should also be consideration of whether those with sub-aneurysm are kept under surveillance. There was considerable variation in the target populations included in previous Irish AAA screening studies. Differences in the target populations across these studies may reflect the best available evidence at the time these studies were conducted, convenience sampling or lower capacity requirements in the context of small sample sizes when compared with a national programme. It is noted that the study conducted in Connolly Hospital, Blanchardstown, concluded that screening in the 55 to 64 age group would not be justified based on the prevalence of disease in this group.[92]

As noted in the 2024 ESVS guidelines, there is a lack of evidence formally assessing the optimal age at which to undergo AAA screening in order to maximise clinical and cost effectiveness.[6] Instead, target populations have been selected based on the epidemiological literature, which indicates a sharp increase in AAA-related mortality from approximately age 65 onwards. In the absence of studies formally assessing the optimal age for baseline screening, screening of men aged 65 is likely a reasonable approach with consideration to the epidemiology of disease. In addition to those aged 65, the UK and Swedish AAA screening programmes allow self-referral of men who have not previously been screened. Inclusion of self-referrals, including those with a family history of AAA, may increase the effectiveness of an AAA screening programme, but would be associated with additional capacity

requirements. As discussed in Chapter 2, inclusion of those with subaneurysm would also have implications in terms of follow-up capacity requirements as well as increased potential for overdiagnosis.

Furthermore, if a decision is made to implement AAA screening in men, technical standards would need to be agreed at a national level to ensure appropriate clinical management of programme participants. Calliper placement determines the boundaries for defining the aortic diameter during ultrasound. Three methods are currently in use in different settings: outer to outer, leading edge to leading edge, or inner to inner.[6] The inner to inner wall measurement is currently in use by the UK NAAASP, while the Swedish screening programme uses the leading edge to leading edge method.[6] While the 2022 ACC/AHA guidelines report that the outer-to-outer diameter should be reported,[226] the 2024 ESVS guidelines instead acknowledge that multiple methods are in use, each with advantages and disadvantages.[6]

In the context of an AAA screening programme, the approach adopted would have practical implications for the number of positive screening test results and associated follow-up. Adoption of the inner to inner method would facilitate comparison of programme outcomes with the UK. It is estimated that the inner to inner method gives aortic diameter measurements that are 3 to 6 mm smaller than the outer to outer method.[6] Therefore, adoption of the outer to outer method may result in the threshold for referral to surgery being reached earlier, which may contribute to unnecessary referrals or overtreatment. Furthermore, use of different methods by different operators or screening centres could result in failure to identify fast growing AAAs during surveillance. In the context of an AAA screening programme, the most important aspect is consistent implementation of a single method, with awareness of the potential implications for clinical decision-making. For example, the ESVS 2024 guidelines suggest that where the inner-to-inner method is used by screening programmes, those with sub-aneurysm may require follow-up.[6]

Multicomponent cardiovascular screening (for example, hypertension, cholesterol and AAA screening) was beyond the scope of this assessment with consideration to the request received from the NSAC (see Chapter 1, section 1.1) and the evidence base for such interventions at the time of the HTA. The review of international policy and practice did not identify any multicomponent cardiovascular screening programme, including AAA screening, in place in any of the included countries. Furthermore, while the feasibility of conducting cardiovascular screening alongside AAA screening has been demonstrated in two single-centre studies in Ireland,[19, 94] the feasibility of such a programme at a national level is uncertain. Only one RCT has investigated the clinical effectiveness of combined cardiovascular screening programme including ultrasound screening for AAA, with no significant differences between the screened and unscreened groups for AAA-related or cardiovascular mortality at four year's follow-up.[266] Furthermore, a 2019 Cochrane systematic

review found that regular health checks had no effect on cardiovascular mortality (RR 1.05, 95% CI: 0.94 to 1.16, 9 RCTs, n = 170,227 participants) compared with no health checks.[267] This suggests that screening for additional cardiovascular risk factors such as blood pressure or cholesterol in addition to AAA may not translate into improvements in hard cardiovascular endpoints. Overall, evidence to support combined cardiovascular screening is lacking.

3.7.1 Conclusion

Ultrasound is a sensitive and specific test for the detection of AAA. There is international consensus regarding thresholds for screen positivity and referral to vascular surgery. However, some components of the screening care pathway would require further consideration, such as the potential inclusion of self-referrals, the pathway for those with sub-aneurysm, the intensity of follow-up surveillance, and technical aspects of ultrasound with appropriate consideration to their relative impact on the overall benefit-harm balance of an AAA screening programme.

4 Clinical effectiveness and safety of screening

Key points

- The aim of this chapter is to assess the clinical effectiveness and safety of one-time population-based ultrasound screening for abdominal aortic aneurysm (AAA) in men. To facilitate this, a systematic review was undertaken to identify the best evidence available for the research question.
- A high-quality systematic review conducted by the US Preventive Services Task Force was identified that provided evidence from randomised controlled trials (RCTs) on the clinical effectiveness and safety of screening for AAA. This review included four population-based RCTs with up to 15 years' follow-up comparing one-time population-based screening for AAA with no screening.
    - The prevalence of AAA in men within the RCTs ranged from 3.9% to 7.6% at the time of initial screening (1980s and 1990s).
    - Across the four RCTs, in men age 65 years or older, invitation to screening, compared with no screening, was associated with a 35% reduction in AAA-related mortality (OR = 0.65, 95% CI: 0.57 to 0.74, number need to invite to screening: 305 men), a 39% reduction in AAA rupture (OR = 0.61, 95% CI: 0.54 to 0.69, number needed to invite to screening: 239 men), and a 47% reduction in the number of emergency surgeries (OR = 0.53, 95% CI: 0.44 to 0.64), at 13 to 15 years' follow-up.
    - It is estimated that the increase in elective surgeries would exceed the magnitude of reduction in emergency surgeries. The net increase in the total number of operations at 13 to 15 years' follow-up would equate to 6 operations per 1,000 men invited to screening.
    - There was no significant difference, at any time point, between the group invited to screening and the no screening group, in the risk of 30-day postoperative mortality following either elective or emergency surgery.
- Other forms of evidence identified included 24 studies of varying design reporting on the clinical effectiveness, safety, and psychosocial harms of AAA screening. Of these, 14 studies reported on the clinical effectiveness and safety of AAA screening across six population-based screening programmes. The data

within these 14 studies was collected between 1990 and 2019. Only four of these studies compared outcomes for screened versus unscreened populations.

  - Across five studies, at the time of initial screening, on average, 90% (range 89% to 94%) of men with screen-detected AAA had a small- to medium-sized AAA (that is, 3.0 to 5.4 cm in diameter) and thus entered a surveillance care pathway.

  - Evidence from six studies shows that the prevalence of AAA has decreased over time. Reductions in the prevalence of AAA may result in a less favourable benefit-harm balance. Therefore, the estimates of clinical effectiveness seen in the RCTs are unlikely to be reproducible in the context of the current epidemiology of AAA and associated clinical care pathways.

  - There is insufficient evidence from the studies identified to estimate the impact of AAA screening on all-cause mortality, rates of surgical intervention, 30-day mortality, or surgery-related adverse events, compared with no screening. Based on limited evidence, screening was associated with a reduction in AAA-related mortality and AAA rupture rates in the screened group relative to the comparator group.

- Ten studies investigated the impact of AAA screening on psychosocial outcomes by comparing outcomes for men with screen-detected AAA versus those with a normal aorta at the time of screening, or using a longitudinal study design in men with screen-detected AAA.

  - The benefits of an AAA screening programme are partially offset by unintended, but generally unavoidable, harms including overdiagnosis and transient psychological distress. Men managed with surveillance may experience a psychosocial burden related to fear of rupture and poorer health perception.

- In light of declining AAA prevalence, targeted screening (that is, screening based on risk factors) has been proposed as a potential approach to increase efficiency. Reports of poor uptake in targeted AAA screening programmes internationally suggest that the results of modelling studies may not translate into practice. Due to the absence of studies comparing alternative screening approaches, it is unknown if a clinically important number of men with AAA would be missed by targeted screening.

- An evaluation of the outcomes of the UK NHS AAA Screening Programme (NAAASP) found that, in addition to declining AAA prevalence and

improvements in healthcare, screening contributed to ongoing reductions in AAA-related deaths.

    - Between 2013 and 2023, ruptured AAA surgical repairs decreased by half in men outside the cohort offered screening, and by two thirds in the screened cohort (65 to 74 years).

- Despite uncertainties in the benefit-harm balance related to a decrease in the prevalence of AAA over time, the available evidence suggests an overall benefit from one-time ultrasound screening for AAA in men aged 65 years and older, in terms of reduction in AAA rupture rates and AAA-related mortality. However, the benefit-harm balance warrants careful consideration owing to the potential for overdiagnosis and post-operative mortality.

4.1 Introduction

The aim of this chapter is to describe the clinical effectiveness and safety of population-based one-time ultrasound screening for abdominal aortic aneurysm (AAA), relative to no systematic screening, as assessed using systematic review methodology. The following National Screening Advisory Committee (NSAC) criterion will be considered in interpreting the evidence of clinical effectiveness and safety of screening for AAA:

- *There should be evidence that the screening programme is effective in reducing morbidity or mortality. Where screening is aimed solely at providing information to enable informed choice, there must be evidence from high quality trials that the test accurately measures risk.*
- *The benefit gained by populations and individuals from the screening programme should outweigh the harms.*

As set out by the World Health Organization (WHO), ideally, a screening programme should comprise the complete care pathway including identification of the target population, invitation to screening, testing, diagnosis, and linkage to care with long-term follow-up, where appropriate.[143] Therefore, the effectiveness of an AAA screening programme is dependent on the effective management of identified cases. Current disease management approaches for patients with a diagnosis of AAA are described in Chapter 3.

4.2 Methods

The systematic review described within this chapter is reported according to the criteria of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[268] The protocol for this review was prespecified as part of a wider systematic review, which included a search for studies reporting on the cost effectiveness of screening for AAA, and was registered on the International Prospective Register of Systematic Reviews (PROSPERO registration number: CRD42024501141). Detailed methods are available in the study protocol.

The aim of this review was to assess the clinical effectiveness and safety of population-based ultrasound screening for AAA in men compared with no systematic screening. The specific research question for this review was formulated according to the Population, Intervention, Comparator, Outcome (PICO) framework (Table 4.1).

Table 4.1 Research question

Population	Asymptomatic men
Intervention	One-time population-based ultrasound screening for abdominal aortic aneurysm†
Comparator	▪ No comparator ▪ No systematic screening (that is, clinical presentation, family history or incidental diagnosis only)
Outcomes	▪ Morbidity ○ prevalence of screen-detected AAA ▪ by aortic diameter, if available ○ AAA rupture ○ rate of emergency and elective surgeries ▪ surgical outcome ▪ Mortality ○ AAA-related mortality ○ all-cause mortality ▪ Safety ○ any potential harms (for example, anxiety or psychological distress) ○ operative mortality ○ surgery-related adverse events (for example, infection, re-operation) ▪ Pathway timings (for example, time from diagnosis to follow-up, time to surgical treatment, where indicated).
Study design	▪ Systematic reviews ▪ Randomised or non-randomised controlled trials (nRCT)† or comparative observational studies ▪ Population-based‡ non-comparative observational studies

† As defined by the Cochrane Effective Practice and Organisation of Care (EPOC) group, nRCTs are trials in which participants are allocated to different groups for comparison using a method that is not random (for example, chart number).[269]
‡ Population-based studies are defined as those that report on a group of individuals taken from the general population and who share common characteristics, such as age, sex, or health conditions. Studies will be considered population-based if participants were enrolled based on geographical location (for example, an entire region or country), as opposed to healthcare setting (for example, hospital-based enrolment).

4.2.1 Search strategy

The search strategy was designed to identify studies reporting on the clinical or cost effectiveness of screening for AAA in men. Eligibility screening was conducted for these systematic reviews in parallel. Only studies reporting clinical effectiveness and/or safety outcomes are described in this chapter. Included studies reporting on the cost effectiveness of AAA screening will be described in Chapter 5.

Electronic database searches were conducted on 27 November 2023 in Medline (EBSCO), Embase (OVID) and the Cochrane Library. Databases were searched from inception, and no language restrictions were applied. The complete electronic search strategy for all databases is available on Zenodo.[270] The Medline search strategy was saved on EBSCOhost and re-run monthly (up to 23 July 2024) to monitor for new relevant results.

4.2.2 Study selection

Two reviewers independently screened titles and abstracts, and full texts, in Covidence. Studies were screened for eligibility against the inclusion criteria outlined in Table 4.1. In accordance with the hierarchy of evidence (a classification system used to rank study designs based on the rigour of their research methods),[271] a top-down approach was used to identify the best evidence available for the research question. Firstly, recent, well-conducted systematic reviews were sought. Where evidence from a systematic review addressing all relevant components of the research question (that is, population, intervention, comparator, outcomes and study design) was not identified, levels of evidence lower in the hierarchy were included, in accordance with the pre-specified study designs outlined in Table 4.1.

Clinical effectiveness and safety

For the purposes of this review, a review was considered systematic if the following key characteristics were satisfied:

- clearly defined objectives and eligibility criteria
- explicit, reproducible methodology
- a systematic search that attempts to identify all studies that meet the pre-defined eligibility criteria (including a systematic search of two or more databases)
- an assessment of the validity of the findings of the included studies.
- a systematic presentation and synthesis, of the characteristics and findings of the included studies.[272]

Identified systematic reviews were ordered by search date and relevance to the review question (for example, outcomes considered). For clinical effectiveness outcomes, an overview of reviews was not considered appropriate given that the identified systematic reviews in many cases represented sequential updates of each other, that is, they did not contain mutually exclusive sets of studies (Table A4). As such, the most recent systematic review was selected and quality appraised using the ROBIS tool (section 4.2.5). In the event that this review was found to be of insufficient quality, the next most recent systematic review would then be quality appraised.

In accordance with the methods outlined above, a 2019 review of the benefits and harms of screening for AAA undertaken by the US Preventive Services Task Force (USPSTF), which updated previous iterations of the review published in 2005 and 2014, was selected to evaluate the clinical effectiveness and safety of AAA screening.[140, 273, 274] In the 2019 USPSTF systematic review, the only study design used to evaluate the effectiveness of screening for AAA was randomised clinical trials (RCTs) comparing one-time screening with no screening.[140] Based on the results of the systematic literature search undertaken to inform this HTA (section 4.2.1), no additional RCT evidence comparing population-based screening for AAA with no screening has been published since the 2019 USPSTF systematic review was undertaken. Therefore, an update of this systematic review was not considered necessary. Following formal quality appraisal (section 4.2.5), evidence from the USPSTF systematic review was used to summarise the RCT evidence on the clinical effectiveness and safety of screening. Where data were duplicated across the different iterations of the USPSTF review, outcomes were extracted from the most recent iteration reporting on a given outcome.

As noted above, the USPSTF systematic review did not consider observational evidence in the evaluation of the clinical effectiveness of screening for AAA.[140] Similarly, all other identified systematic reviews also considered population-based RCTs only, or observational evidence was considered only for evaluation of the potential harms of screening (Table A4). Since RCTs investigating the effectiveness of screening for AAA began in the 1980s and 1990s, there is potential for changes in the clinical context (for example, reductions in smoking, and improved cardiovascular risk factor management over time). Thus, it was considered important in the present review to supplement the RCT evidence with more recent evidence from other study designs including clinical outcome data from international population-based AAA screening programmes. In the absence of an up-to-date, high-quality systematic review of observational studies reporting clinical effectiveness and safety outcomes of one-time population-based AAA screening, a de novo synthesis of non-RCT evidence was conducted.

As outlined in the study protocol and Table 4.1, non-comparative studies were excluded if they were not population-based. However, there is no universally accepted and easily implementable definition of a population-based study. For the purpose of this systematic review, population-based studies were only included if they invited all eligible participants in a large, clearly defined geographic region (that is, entire counties, regions or countries internationally) to participate; studies undertaken in a single health centre, hospital, town, or subset of towns within a wider geographic region were not included as the representativeness of the populations in these studies could not be determined.[275]

Population-based screening typically involves the complete care pathway from identification of the eligible population through to long-term follow-up. Given that the focus of this systematic review was to summarise the impact of screening for AAA on patient outcomes (including morbidity, mortality and resource utilisation and potential harms), only population-based studies designed to assess clinical effectiveness and safety outcomes were considered eligible for inclusion. Epidemiological studies using sampling methods to estimate the prevalence of AAA only, without details of linkage to care and subsequent follow-up, were excluded. The estimated prevalence of AAA in the context of the epidemiological literature is described in Chapter 2, section 2.6.

Psychosocial outcomes and/or quality of life

Five systematic reviews (including two updates) were identified that investigated the impact of AAA screening on psychosocial outcomes and/or quality of life.[140, 273, 274, 276, 277] Overlap of primary studies reporting on psychosocial outcomes or quality of life across identified systematic reviews was investigated by developing an evidence matrix (Table A2). The aim of the matrix was to identify unique studies of relevance to the specific research question of this review. No evidence was identified addressing the potential psychosocial harms of screening for AAA for the comparison of interest, that is, screening versus no screening (Table 4.1). Therefore, it was necessary to expand the inclusion criteria for this outcome. Only studies with a comparator group, or that conducted repeat measures in the screened group (for example, pre and post-screening) were included. Psychosocial consequences are a broad concept, with no standardised definition or approach to measurement in the context of screening. For the purposes of this review, eligibility included any study considering aspects such as quality of life, depression, anxiety, or physical or social functioning, in population-based or non-population-based studies, for the following comparisons:

- participants with screen-detected AAA versus screen-negative findings
- participants with screen-detected AAA who underwent surgery versus those managed with surveillance.

4.2.3 Data extraction

Previous systematic reviews

Data from the USPSTF systematic review were extracted by a single reviewer, and cross-checked by a second reviewer. Single extraction was considered appropriate given that data extraction and quality appraisal were undertaken in duplicate by the original systematic review authors. The findings were supplemented and corroborated with data from the underlying RCTs.

Other study designs

For other study designs included in the de novo systematic review (for example, observational studies and stepped wedge design studies), data extraction was carried out independently by two reviewers using a standardised, pre-piloted data extraction form. Disagreements were resolved through discussion or, if necessary, with a third reviewer.

Studies with overlapping populations were grouped as related citations. For a given outcome, data were typically extracted from the most recent publication only, in order to avoid duplication of populations. The related publications reporting on a subset of the participants in the primary study were not included as individual studies, but were reviewed for additional information of relevance.

Where disaggregated data were available, outcomes were extracted according to aortic diameter at baseline. Where reported, outcomes of patients with subaneurysmal aortic diameters (that is, 2.5 to 2.9 cm) were also extracted.

4.2.4 Data synthesis

Previous systematic reviews

Where underlying primary studies were sufficiently homogeneous, meta-analysis was used to generate a pooled effect estimate. Meta-analyses were performed using the meta package (version 4.19-1) in R. Due to the small number of studies available for individual comparisons, the fixed-effects estimate was used as it was considered that there were insufficient data to support reliable estimation of between-study variance. For some outcomes (that is, AAA-related mortality, rupture, and surgical procedures), the Peto method was used to pool odds ratios (ORs) given the rarity of the events and absence of substantial imbalances between treatment and control group sizes.[278] The risks of all-cause mortality and 30-day postoperative mortality were expressed as relative risks (RR).

The impact of the statistical model used was investigated in sensitivity analysis (that is, fixed or random effects). Where the choice of statistical model changed the interpretation of the evidence for an outcome of interest, results of both analyses were reported. Statistical heterogeneity was assessed using the I^2 statistic, in line with Cochrane methodology.[278]

Where reported, outcomes were reported according to age at enrolment. There was insufficient data to pool estimates for age-based subgroups across studies.

Other study designs

Due to the presence of heterogeneity in either clinical aspects (for example, population characteristics or care pathways) or methodological aspects (for example, length of follow-up or outcome definitions), as well the limited number of comparative studies available for individual comparisons, results for other forms of studies (for example, observational study designs) were synthesised narratively. Descriptive statistics were used to summarise data. For the description of AAA prevalence, the percentages of screened-detected cases (i) under surveillance, and (ii) referred to vascular surgery at initial screening, were based on the care pathway as defined by the study authors (see section 4.3.2, Prevalence).

AAA-related mortality was defined as reported by the study authors. AAA-related mortality, AAA rupture and surgeries (emergency and elective) were each expressed as events per participants screened, where possible. However, three studies from the UK provided outcome data for sub-populations (that is, men with small to medium AAA, men with large AAA, or men with more than 10 years' follow-up) as opposed to the whole screened population. For these studies, the data are presented as a percentage of the subpopulation.[75, 264, 265] In addition, data for three studies were reported in person-years, based on the actual time at risk for individual participants, as it was not possible to reliably convert to rates per population based on the data reported.[8, 279, 280] Results were stratified by aortic diameter, where reported. Data were presented graphically, where possible.

For psychosocial outcomes and quality of life, results were synthesised narratively due to heterogeneity across studies in terms of the timing of evaluation, study populations and assessment tools.

4.2.5 Quality appraisal

Systematic reviews

The quality of the 2019 systematic review undertaken by the USPSTF was assessed using the ROBIS tool.[281] The ROBIS tool evaluates the quality of systematic reviews over three phases; assessing relevance, identifying concerns, and judging risk of bias. Given that the methodological approach was broadly consistent across the updates (2005, 2014 and 2019), it was not considered necessary to quality appraise each version of the USPSTF review individually.[140, 273, 274] Quality appraisal was undertaken by one reviewer and checked for accuracy by a second reviewer.

Other study designs

The aim of critical appraisal is to assess the quality, reliability and relevance of the included studies in relation to the specific research question for this review (Table 4.1). While all included studies reported data relevant to the clinical effectiveness

and safety of screening for AAA, the aim of the included studies may differ from the specific aim of this review.

No validated quality appraisal tool tailored specifically to population-based studies of screening interventions was identified. A de novo quality appraisal tool was developed to assess the conduct and reporting of both comparative and non-comparative population-based screening studies. This was developed with consideration to relevant criteria in existing quality appraisal tools and with a view to assessing the reporting of information pertaining to key criteria for an effective screening programme as set out by the World Health Organization (WHO).[143, 282] The domains of interest included: 1) the target population, 2) invitation and information, 3) screening algorithm, 4) referral, 5) diagnosis, 6) treatment and follow-up, 7) reporting and 8) conflict of interests (Table A3). For non-comparative descriptive studies, use of the Risk Of Bias In Non-randomised Studies-of Interventions (ROBINS-I) was not considered appropriate as not all included studies adjusted for potential confounders including demographic characteristics, known risk factors and comorbidities.[283]

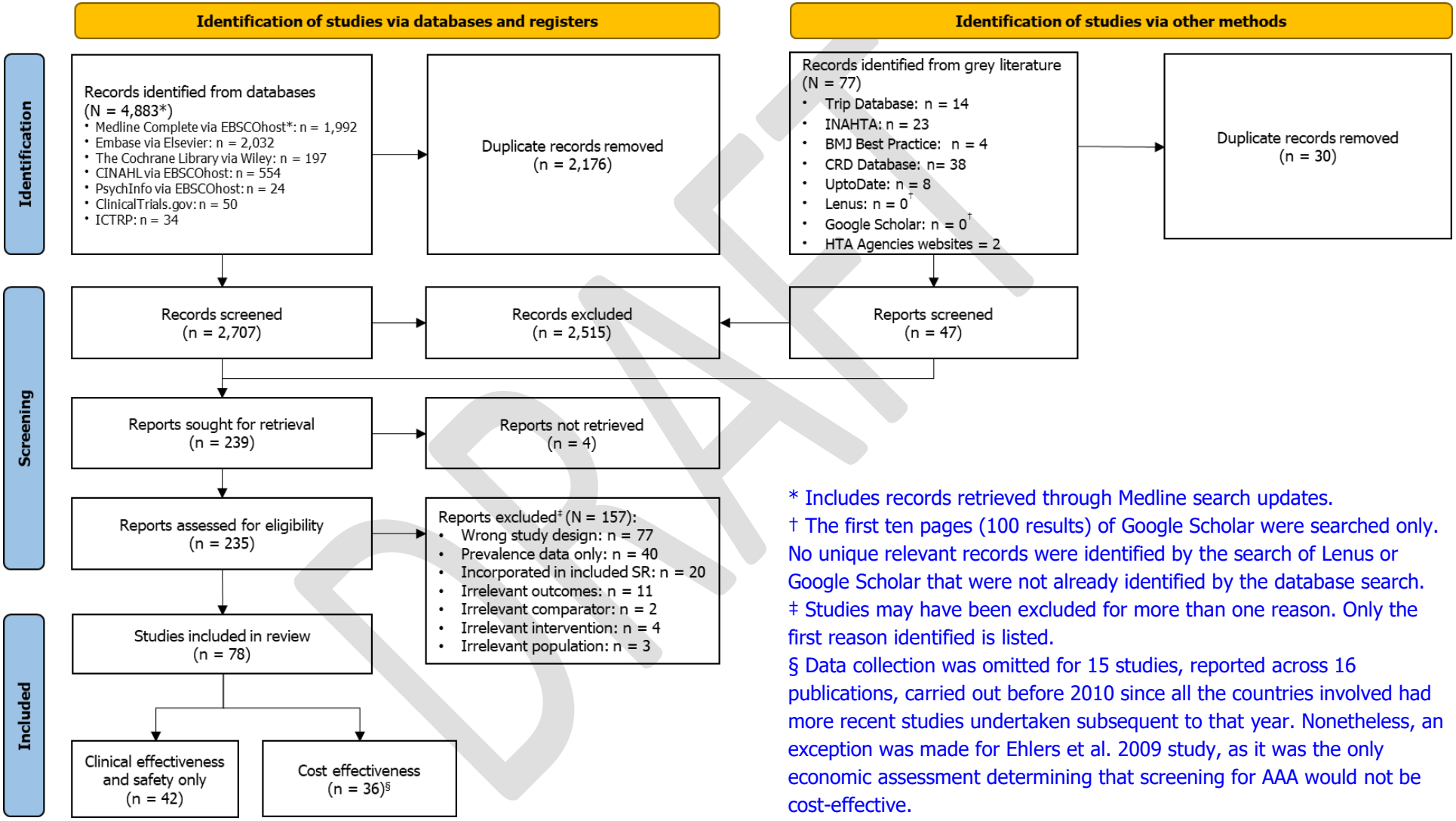
4.3 Results

An overview of the study selection process is provided in Figure 4.1. After removal of duplicates, 2,707 title and abstracts were assessed for eligibility. Following review of 230 full texts, 78 publications met the inclusion criteria, including 42 publications (31 individual studies) reporting on the clinical effectiveness and safety of one-time population-based screening for AAA. The remaining publications (n = 36 including 35 individual studies) considered the cost effectiveness of screening for AAA and will be reviewed in Chapter 5.

Seven systematic reviews reported across 12 publications were identified.[140, 141, 227, 273, 274, 276, 277, 284-288] In accordance with the methods outlined in section 4.2.2, a series of systematic reviews (2005, 2014 and 2019) conducted by the USPSTF reporting on the benefits and harms of one-time screening versus no screening in RCTs were used to evaluate the effectiveness of screening for AAA in RCTs.[140, 141, 273, 274, 286] For other systematic reviews, which reported only on RCTs already included in the USPSTF systematic review, data were not extracted (see Table A4).[227, 277, 284, 287-289]

In the absence of an up-to-date, high-quality systematic review which included non-RCT evidence, a de novo synthesis of additional evidence was conducted; this comprised 18 publications,[8, 31, 75, 76, 78, 79, 82, 84, 87, 96, 264, 265, 279, 280, 290-293] representing 14 individual studies (section 4.3.2).[8, 31, 75, 76, 78, 82, 84, 87, 96, 264, 265, 279, 280, 291] In addition, in order to consider psychosocial outcomes, ten studies reported across 12 publications were identified for review.[266, 294-304]

Figure 4.1 PRISMA flow diagram of study selection process



* Includes records retrieved through Medline search updates.
† The first ten pages (100 results) of Google Scholar were searched only. No unique relevant records were identified by the search of Lenus or Google Scholar that were not already identified by the database search.
‡ Studies may have been excluded for more than one reason. Only the first reason identified is listed.
§ Data collection was omitted for 15 studies, reported across 16 publications, carried out before 2010 since all the countries involved had more recent studies undertaken subsequent to that year. Nonetheless, an exception was made for Ehlers et al. 2009 study, as it was the only economic assessment determining that screening for AAA would not be cost-effective.

4.3.1 Evidence from previous systematic reviews of RCTs

Characteristics of included randomised controlled trials

As noted previously, a series of systematic reviews undertaken by the USPSTF was used to synthesise the evidence of clinical effectiveness of screening for AAA, relative to no screening, from RCTs. These systematic reviews provided evidence on four relevant population-based RCTs. These trials began between 1988 and 1997 and compared one-time ultrasound screening with no systematic screening: the Multicenter Aneurysm Screening Study (**MASS**);[294, 305-307] the **Chichester** screening trial;[308-310] the **Viborg** County screening trial;[311-315] and the **Western Australia** screening trial.[316, 317] The mean or median duration of follow-up ranged from 12.8 to 15.0 years.[308, 316] One additional population-based RCT, the Viborg Vascular (VIVA) trial, compared the efficacy of combined cardiovascular screening (that is, peripheral arterial disease, hypertension and AAA) screening with no systematic screening.[266] This RCT was included by the systematic review authors for estimation of the number of elective or emergency surgeries only. For other outcomes, the effects of AAA screening within the multicomponent screening programme could not be independently assessed.

The Chichester RCT included men and women,[308-310] while the other three RCTs included men only.[294, 305-307, 311-314, 316, 317] For the Chichester RCT, data are presented here for the male subgroup only. The target age group varied between the four RCTs, as did the distributions by individual year of age within the specified age range. The mean (or median) age across included RCTs ranged from 67.5 to 72.6 years.[311, 317] Additional baseline characteristics, such as smoking history, family history of AAA, race/ethnicity or comorbidities, were not reported. Outcomes were reported according to age and sex. Subgroup analysis according to aortic diameter (for example, small, medium or large) was not reported by the underlying studies, likely due to low event rates.

All RCTs defined AAA as an aortic diameter of 3.0 cm or more. However, surveillance protocols and thresholds for referral to a vascular surgeon differed across RCTs. In the MASS RCT, those with aortic diameters measuring 3.0 to 4.4 cm were rescanned annually, those with AAAs measuring 4.5 to 5.4 cm were rescanned at three month intervals, and those with an aortic diameter measuring 5.5 cm or more were referred to a vascular surgeon.[294] In the Viborg trial, individuals with a subaneurysmal aorta (that is, 2.5 to 2.9 cm) were offered a repeat scan at five years, those with an aortic diameter measuring 3.0 to 4.9 cm were offered annual scans, and those with AAAs measuring 5.0 cm or larger were referred to a vascular surgeon.[315] In the Chichester trial, cases with AAAs measuring 3.0 to 4.4 cm were rescanned annually, those with AAAs measuring 4.5 to 5.9 cm were rescanned every three months, and

those with an AAA measuring 6.0 cm or more, or with an increase in diameter of 1 cm or more per year, were referred to a vascular surgeon.[309] There was no standardised surveillance protocol in the Western Australia trial; results of the initial ultrasound scan were sent to the primary care physician for further management.[317]

The primary outcome reported across the four RCTs comparing one-time ultrasound screening with no systematic screening was AAA-related mortality. AAA-related mortality was defined as all AAA deaths, plus all deaths within 30 days of AAA surgical repair. The four RCTs also reported on all-cause mortality, AAA rupture and 30-day mortality. The VIVA trial, which comprised combined cardiovascular screening relative to no screening, was also included in the analysis of the rate of elective and emergency AAA repairs as it was considered plausible that this outcome would be exclusively related to AAA screening, consistent with the approach adopted by the USPSTF systematic review.

Prevalence

The prevalence of AAA at the initial screening for male attendees ranged from 3.3% in the VIVA trial to 7.6% in the Chichester trial (Table 4.2). Differences in the prevalence of AAA were likely related to the age of participants at enrolment, with higher AAA prevalence rates reported in the RCTs with higher mean age at baseline. However, results from the Collaborative Aneurysm Screening Study (CASS) Group, including collaborators from the four population-based RCTs comparing screening for AAA with no screening, demonstrate that a significant difference in the AAA prevalence remained across the four studies after adjusting for age.[65]

The overall prevalence of AAA at baseline ranged from 3.3% to 7.6% in the screened population. All RCTs sub-classified AAA according to diameter at initial screening. Small- to medium-sized AAA (defined as aortic diameter 3.0 to 5.4 cm in four RCTs,[266, 294, 317, 318] and 3.0 to 5.9 cm in one RCT[309]) comprised 87% to 93% of all AAAs detected.[317, 318] The remainder (7% to 13%) were classified as large (defined as ≥5.5 cm in four RCTs,[266, 294, 317, 318] and ≥6.0 cm in one RCT).[309] The overall prevalence of large AAA was 0.3% to 0.7% in the screened population (Table 4.2).[266, 309]

Table 4.2 Prevalence of AAA in the screened population, according to aortic diameter

Study, year	Total prevalence of AAA	Prevalence of AAA classified by aortic diameter (cm)						
		Small		Medium		Large		
		3-3.9	3-4.4	4-4.9	4.5-5.4	5-5.9	≥5.5	6.0+
Chichester 1995[309]†	7.6%	4.6%	-	1.6%	-	0.6%	-	0.7%

MASS 2002[294]	4.9%	-	3.5%	-	0.8%	-	0.6%	-
Western Australia 2004[317]	7.2%	-	5.7%	-	0.9%	-	0.5%	-
Viborg 2005[318]	3.9%	3.4%				-	0.5%	-
VIVA 2017[266]	3.3%	-	2.6%	-	0.4%	-	0.3%	-

Key: AAA – abdominal aortic aneurysm.
† Data on the distribution of aortic diameters among those with screen-detected AAA were extracted using WebPlotDigitizer and may be subject to rounding errors.

Methodological quality

Quality appraisal was undertaken by the USPSTF review authors using the USPSTF criteria, which grade the quality of the evidence on a 3-point scale (that is, good, fair or poor).[319] Overall, the MASS and Viborg RCTs were considered good quality.[273] In the Viborg trial, however, non-attendees were noted to be significantly older than attendees.[273] The Chichester and Western Australian trials were assigned fair quality ratings due to inadequate description of blinding of outcome assessment, lack of reporting of loss to follow-up (Chichester),[309] or lack of detail regarding randomisation methods (Western Australian).[273, 317] Adherence to screening ranged from 63% of those invited to attend screening in the Western Australia trial,[317] to 80% in the MASS trial.[294] All trials appeared to use intention-to-treat analysis, which may increase the applicability of the findings to real-world settings.

There were no concerns raised by the USPSTF review authors regarding the potential for bias in the trials arising from industry-based employment, funding, consultancy and or advisory fees.

Table 4.3 Study and population characteristics of included randomised controlled trials

Study, year(s)	Country	Participants randomised, Acceptance rate in the screened cohort	Follow-up (years)†	Eligible age group; Mean age of participants (years)	Definition of AAA, Prevalence	Care pathway (surveillance protocols and thresholds for referral)	Outcomes assessed	Exclusion criteria	Quality rating as reported by the systematic review authors§
Chichester 1995,[309] 2002,[310] 2007[308]	United Kingdom	N = 15,775 (6,040 men; 9,342 women) Acceptance rate: 68.4%	Men 15.0; Women 10.0 (median)	Eligible age: 65-80 Mean 72.0	> 3.0 cm, 7.6% (men)	*Surveillance* • AAA: 3.0–4.4 cm: rescanned annually • 4.5–5.9 cm: rescanned every 3 months *Threshold for referral* • AAA ≥6.0 cm, an increase in diameter of ≥1 cm per year, or onset of symptoms: referral to vascular surgeon	• AAA-specific mortality • All-cause mortality • AAA rupture • 30-day operative mortality • Emergency and elective surgeries	None reported	Fair
MASS 2002,[294] 2007,[307] 2009[306]	United Kingdom	N = 67,800 men Acceptance rate: 80%	13.1	Eligible age: 65-74 Mean 69.2 (SD 2.9)	> 3.0 cm, 4.9%	*Surveillance* • AAA 3.0–4.4 cm: rescanned yearly • AAA 4.5–5.4 cm: rescanned at 3 month intervals *Threshold for referral* • AAA ≥5.5 cm: Urgent referral to a vascular surgeon	• AAA-specific mortality • All-cause mortality • AAA rupture • 30-day operative mortality • Emergency and elective surgeries • Quality of life	Men who were terminally ill, had other serious health problems, or had a previous AAA repair.	Good
Viborg 2002,[311] 2006,[312] 2007[313] 2010[314]	Denmark	Randomised: 12,658 men Acceptance rate: 76%	13.0	Eligible age: 65-73 Mean 67.5	> 3.0 cm, 3.9%	*Surveillance* • AAA 2.5–2.9 cm: rescreening after 5 years • AAA 3.0–4.9 cm: annual scans *Threshold for referral*	• AAA-specific mortality • All-cause mortality • AAA rupture • 30-day operative mortality	None reported	Good

Study, year(s)	Country	Participants randomised, Acceptance rate in the screened cohort	Follow-up (years)†	Eligible age group; Mean age of participants (years)	Definition of AAA, Prevalence	Care pathway (surveillance protocols and thresholds for referral)	Outcomes assessed	Exclusion criteria	Quality rating as reported by the systematic review authors§
						• AAA ≥5 cm: referred to a vascular surgeon.	• Emergency and elective surgeries • Quality of life		
Western Australia 2004,(317) 2016(316)	Australia	Randomised: 41,000 men Acceptance rate: 63.1%	12.8	Eligible age: 64-83 Mean 72.6 (SD 4.7)	> 3.0 cm, 7.2%	Participants were given a letter detailing the results of their ultrasound scan and a copy for their primary care physician. No further attempts were made to influence any aspect of clinical management after the scan was completed.	• AAA-specific mortality • All-cause mortality • AAA rupture • 30-day operative mortality • Emergency and elective surgeries • Quality of life	None reported	Fair
VIVA 2017(266)	Denmark	Randomised: 50,156 men Acceptance rate: 74.7%	4.4	Eligible age: 65-74 Mean 70.0 (95% CI: 65 to 74)	> 3.0 cm, 3.3% (95% CI: 3.0 to 3.6)	*Surveillance* • AAA <5 cm: annual ultrasound scan. *Threshold for surgery* • AAA ≥ 5 cm: referred for CT scan and assessment by a vascular surgeon.	• Emergency and elective surgeries‡	None reported	Not assessed

Key: AAA – abdominal aortic aneurysm; SD – standard deviation.
† Data represent the mean unless otherwise stated.
‡In the VIVA trial, outcomes assessed included all-cause mortality (primary outcome) cardiovascular mortality, AAA-related mortality, hospital services related to cardiovascular conditions and costs for such services, quality of life, and aneurysmal progression. However, only data relating to emergency and elective surgeries for AAA repair were assessed; this is because the independent contribution of AAA screening within the multicomponent screening programme could not be assessed for other outcomes.
§ The USPSTF quality criteria grades the quality of the evidence on a 3-point scale (good, fair or poor).

Clinical effectiveness

AAA-related mortality

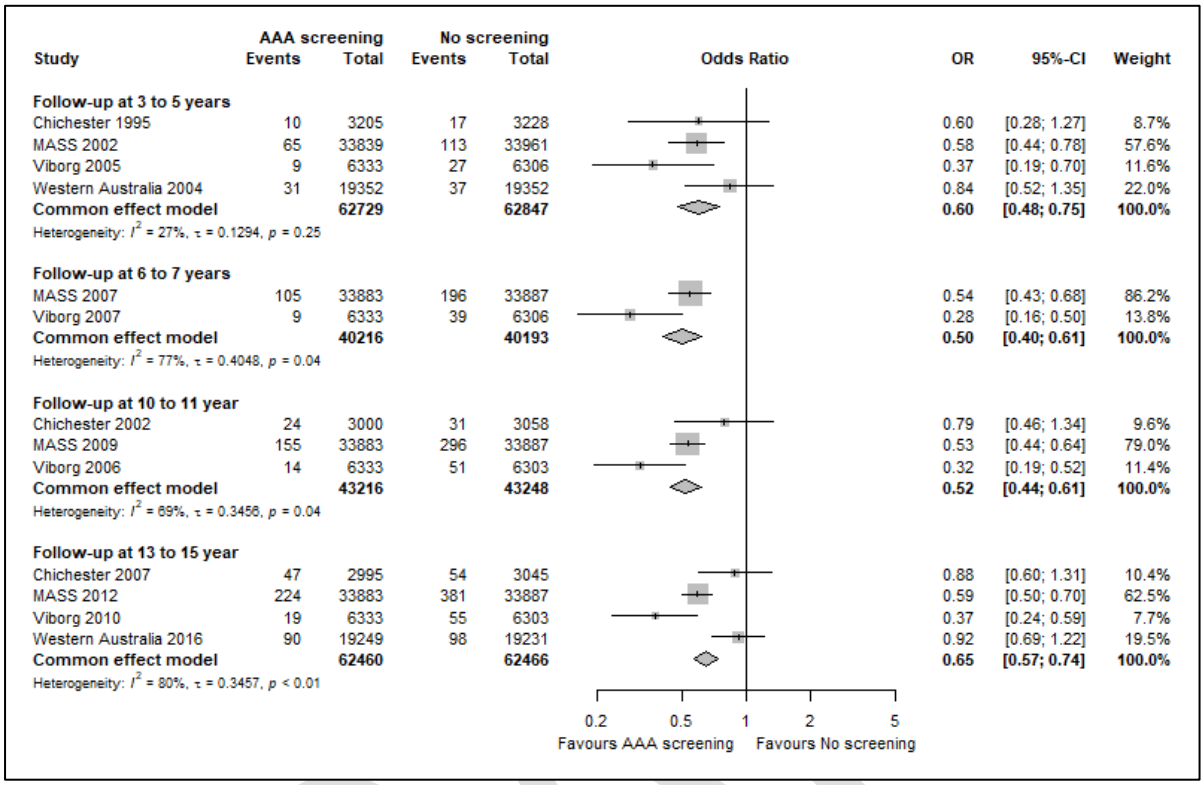
Pooled fixed effects meta-analysis indicated that population-based screening for AAA resulted in a statistically significant reduction in AAA-related mortality at all time points up to 15 years' follow-up, with no evidence of a statistically significant difference over time (test for subgroup differences $p = 0.08$) (Figure 4.2). However, substantial statistical heterogeneity was detected at all time points after three to five years' follow-up (≥69%), that is, there was variability observed in the effect of screening across the studies after this time point.

At 13 to 15 years' follow-up, screening was associated with a 35% reduction in the odds of AAA-related mortality (OR = 0.65, 95% CI: 0.57 to 0.74, I^2 = 80%, n= 4 RCTs), relative to no screening; 305 men (95% CI: 248 to 411) would need to be invited to one-time screening to prevent one AAA-related death (Figure 4.2).[305, 308, 314, 316] Across the four RCTs, results were based on intention-to-treat analysis, with 26.3% to 64.4% of AAA-related deaths in the invited group occurring among non-attendees at 13 to 15 years' follow-up.[314, 316]

The Viborg and Western Australia RCTs were the only two population-based screening trials reporting AAA-related mortality outcomes stratified by age.[314, 316] In both trials, there was no evidence of a difference in the odds of AAA-related mortality by age group, however, trials were not powered to detect differences between subgroups. At 13 years' follow-up in the Viborg trial, there was no evidence of a significant difference between subgroups aged ≤65 years and 65 to 73 years (test for subgroup differences $p = 0.90$, Figure 4.3).[314] In the Western Australia trial at 13 years' follow-up, there was a non-significant reduction in AAA-related mortality in the subgroup invited to screening aged 65 to 74 years (OR = 0.92, 95% CI: 0.62 to 1.36), similar to the findings for the overall trial population (OR = 0.92, 95% CI: 0.69 to 1.22; test for subgroup differences $p = 0.89$, data not shown).[316]

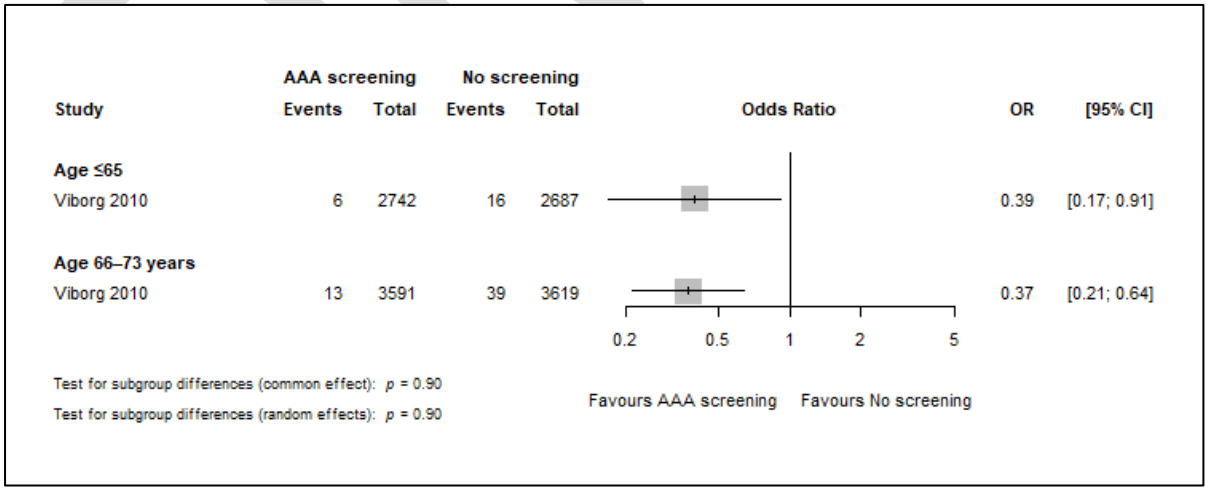
In sensitivity analysis, for pooled estimates, use of the random effects model did not change the interpretation of the evidence.

Figure 4.2 Meta-analysis of AAA-related mortality in men for AAA screening compared with no screening, stratified by length of follow-up



Key: AAA – abdominal aortic aneurysm; CI – confidence interval; OR – odds ratio.

Figure 4.3 Subgroup analysis of AAA-related mortality in men for AAA screening compared with no screening, stratified by age group: Viborg trial at 13 years' follow-up



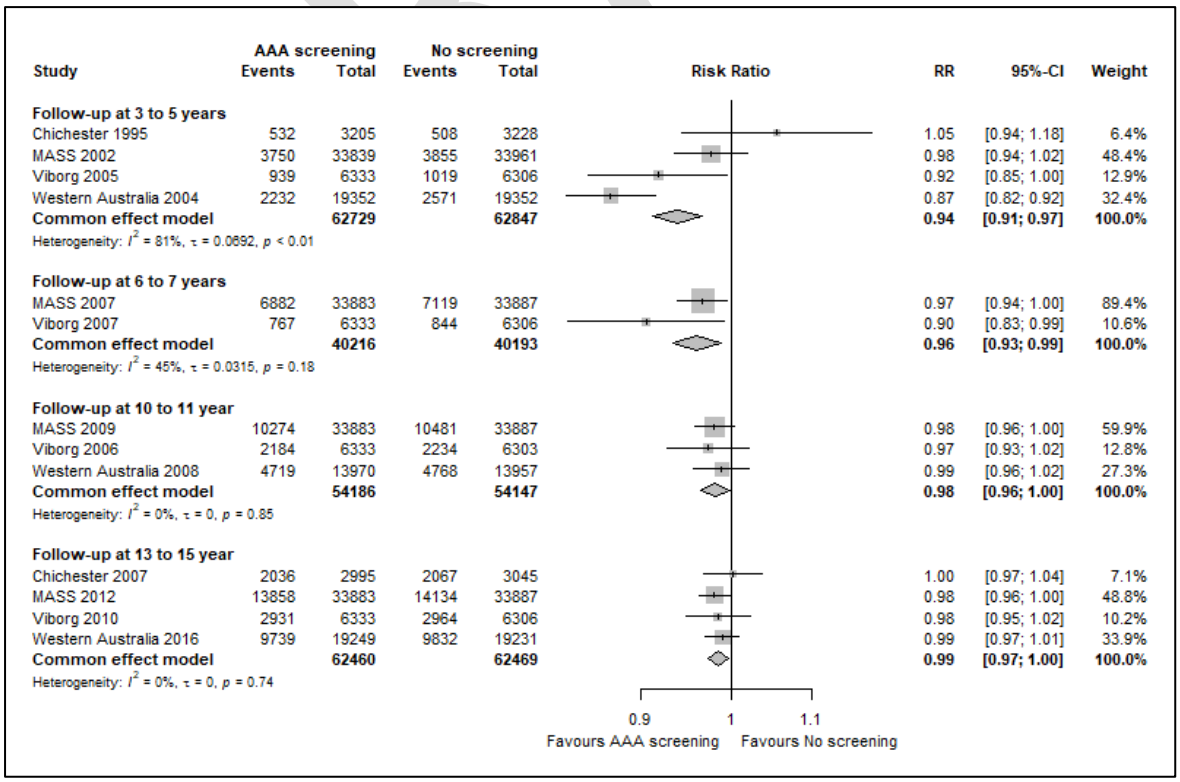
Key: AAA – abdominal aortic aneurysm; CI – confidence interval; OR – odds ratio.

All-cause mortality

Fixed effect meta-analysis of all-cause mortality from the four population-based screening RCTs demonstrated a statistically significant difference between groups at three to five years' follow-up (RR = 0.94, 95% CI: 0.94 to 1.00, I^2 = 81%, n = 4 RCTs),[294, 309, 317, 318] and six to seven year's follow-up (RR = 0.96, 95% CI: 0.93 to 0.99, I^2 = 45%, n = 2 RCTs) (Figure 4.4).[307, 313] However, at both time points there was evidence of moderate to substantial statistical heterogeneity, and the findings were not considered statistically significant using the random effects model (Figure A4). There was no evidence of a statistically significant difference at 10 to 11,[306, 315] or 13 to 15 years' follow-up.[305, 308, 314, 316]

The Viborg and Western Australia RCTs reported all-cause mortality stratified by age. In the Viborg trial, subgroup analysis of men aged 64 to 65 years was conducted to inform the potential generalisability of results to a population-based screening programme in 65 year olds. At 13 years' follow-up there was no evidence of a statistically significant reduction in all-cause mortality in the overall population aged 64 to 73 years (HR = 0.98, 95% CI: 0.93 to 1.03) or in the subgroup aged 64 to 65 years (HR = 0.98, 95% CI: 0.89 to 1.07).[314] Similarly, the Western Australian trial showed no all-cause mortality benefit in the group aged 65 to 74 years (OR = 0.98, 95% CI: 0.94 to 1.03) or those aged 64 to 83 (OR = 0.98, 95% CI: 0.54 to 1.02; test for subgroup differences p = 0.91).[316]

Figure 4.4 Meta-analysis of all-cause mortality in men for AAA screening compared with no screening, stratified by length of follow-up



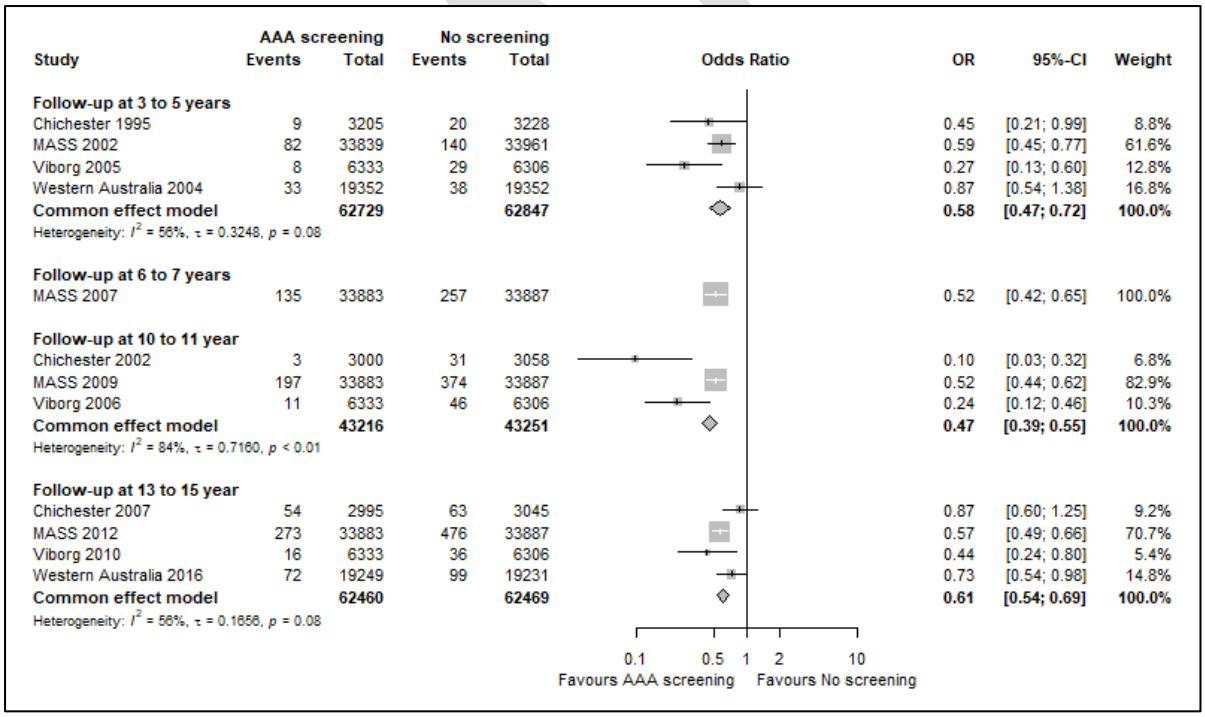
Key: AAA – abdominal aortic aneurysm; CI – confidence interval; RR – risk ratio.

AAA rupture

Results of meta-analysis indicated that population-based screening for AAA resulted in a 42% reduction in AAA rupture at three to five years' follow-up (OR = 0.58, 95% CI: 0.47 to 0.72, I^2 = 56%, n = 4 RCTs) (Figure 4.5).[294, 309, 317, 318] A similar magnitude of effect was observed at six to seven years (OR = 0.52, 95% CI: 0.42 to 0.65, n = 1 RCT),[307] and 10 to 11 years' follow-up (OR = 0.47, 95% CI: 0.39 to 0.55, I^2 = 84%, n = 3 RCTs).[306, 311, 315] At 13 to 15 years' follow-up, invitation to screening for AAA was associated with a 39% reduction in AAA rupture, compared with no screening (OR = 0.61, 95% CI: 0.54 to 0.69, I^2 = 56%, n = 4 RCTs).[305, 308, 314, 316] The estimated number needed to invite to screening to prevent one ruptured AAA was 239 (95% CI: 203 to 301) at 13 to 15 years' follow-up.

Subgroup data were not available for AAA rupture.

Figure 4.5 Meta-analysis of AAA rupture in men for AAA screening compared with no screening, stratified by length of follow-up



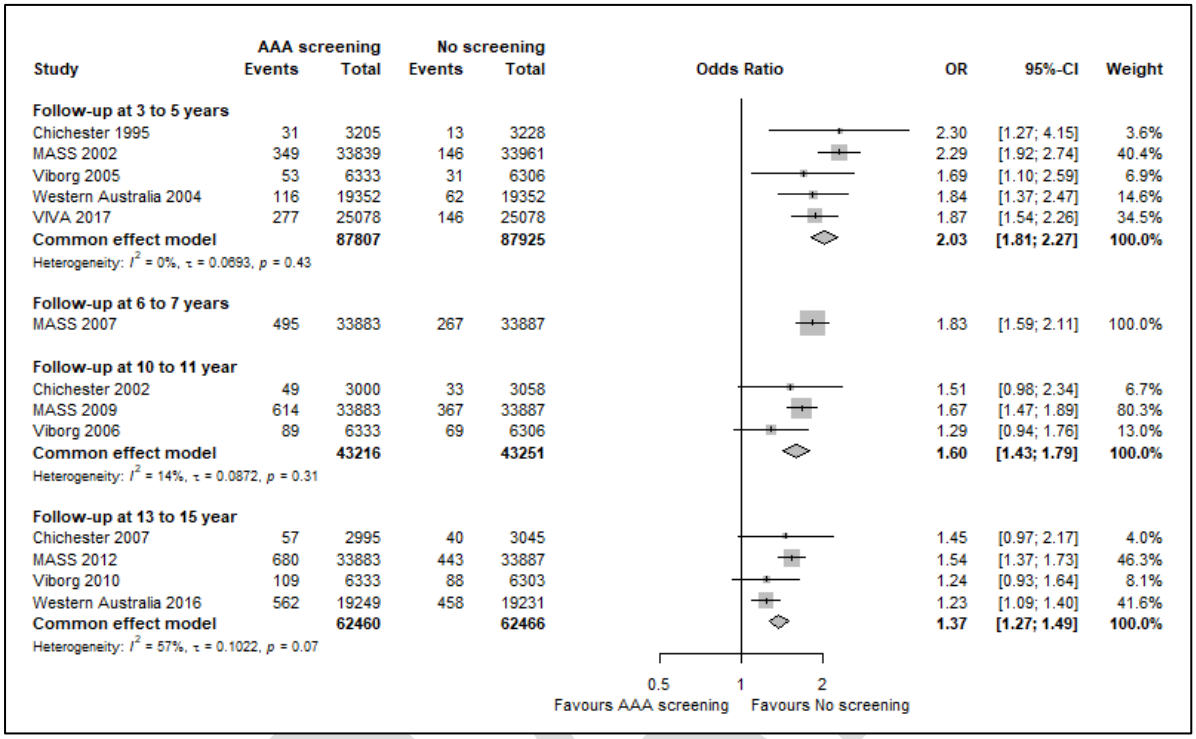
Key: AAA – abdominal aortic aneurysm; CI – confidence interval; OR – odds ratio.

Number of overall surgeries for AAA

Based on data from five RCTs, the odds of undergoing surgery were significantly higher in the group invited to screening, compared with no screening, at all follow-up time points up to 13 to 15 years post-screening (OR = 1.37, 95% CI: 1.26 to 1.48, I^2 = 57%, n = 4 RCTs) (Figure 4.6).[305, 308, 314, 316] This would increase the

total number of operations at 13 to 15 years' follow-up after initial screening by 6 per 1,000 men invited to screening.

Figure 4.6 Meta-analysis of the odds of surgery for AAA for screening relative to no screening, stratified by length of follow-up

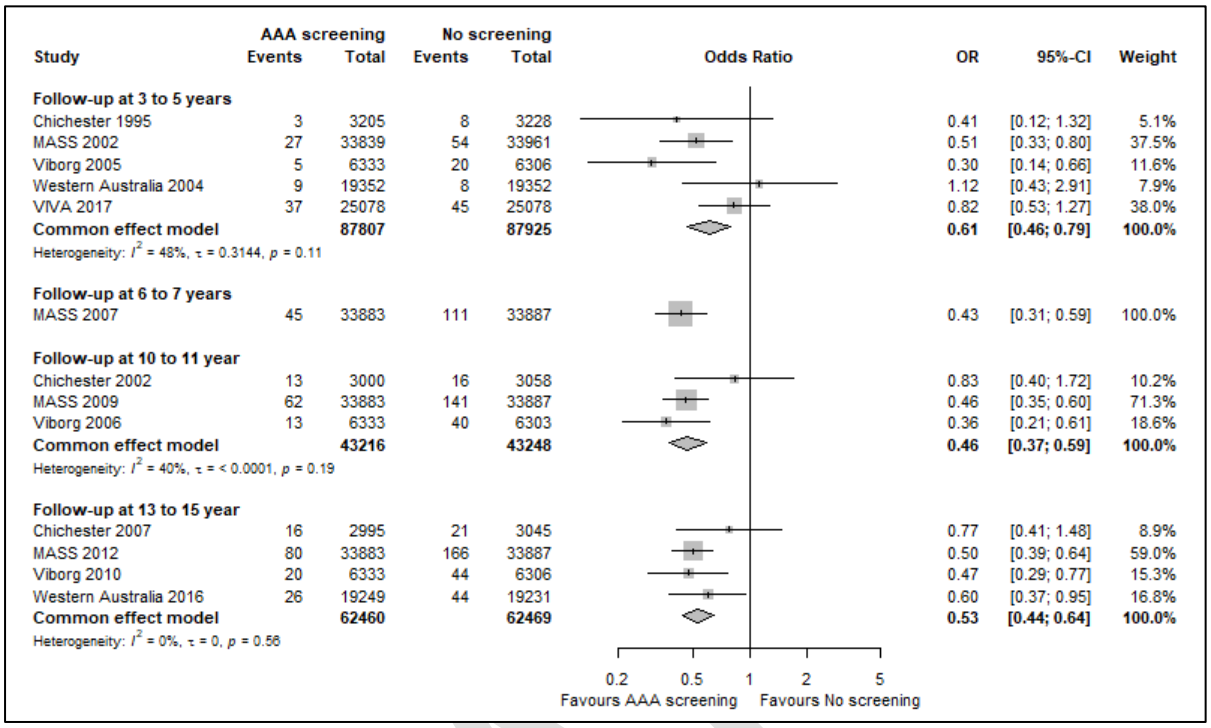


Number of emergency surgeries

For the outcome number of emergency operations, results of individual RCTs varied (Figure 4.7). However, in general, pooled effect estimates suggested that invitation to screening was associated with a reduction in the number of emergency AAA operations, compared with no screening. At three to five years follow-up, invitation to screening was associated with a 39% reduction in the odds of emergency surgery (OR = 0.61, 95% CI: 0.46 to 0.79, I^2 = 48%, n = 5 RCTs) (Figure 4.7).[266, 294, 309, 317, 318] At 13 to 15 years' follow-up results of fixed effects meta-analysis indicated a statistically significant reduction in the odds of emergency surgery for AAA, and there was no evidence of statistical heterogeneity (OR = 0.53, 95% CI 0.44 to 0.64, I^2 = 0%, n = 4 RCTs).[305, 308, 314, 316] Expressed another way, at 13 to 15 year's follow-up screening was estimated to result in a reduction in the number of emergency surgeries of 2 per 1,000 men invited to screening. For pooled estimates, use of the random effects model did not change the interpretation of the evidence.

In the Western Australia trial at 13 years' follow-up, there was no evidence of a significant difference in the odds of emergency surgery between the subgroup aged 65 to 74, and the overall trial population aged 64 to 83 (test for subgroup differences p = 0.76).[316]

Figure 4.7 Meta-analysis of the odds of emergency surgery for AAA, stratified by length of follow-up



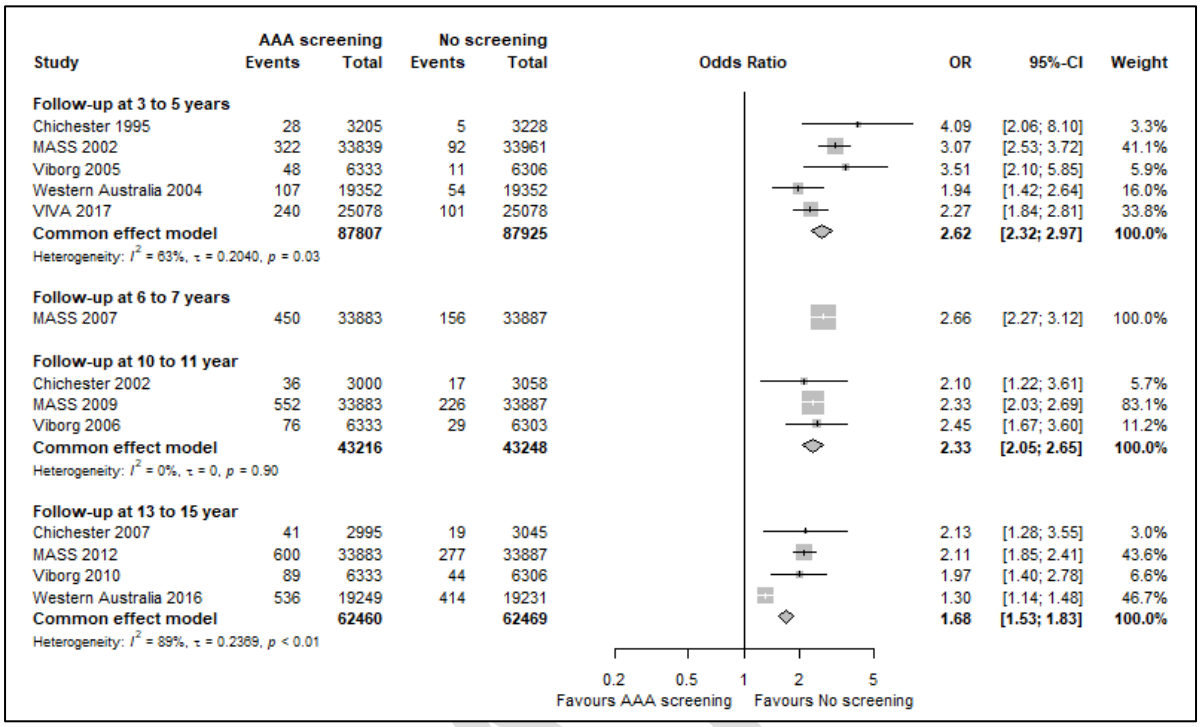
Key: AAA – abdominal aortic aneurysm; CI – confidence interval; OR – odds ratio.

Number of elective surgeries

Across five RCTs, the odds of undergoing elective surgery were significantly higher in the group invited to screening, compared with no screening, at all follow-up time points (Figure 4.8). Pooled estimates ranged from 2.62 (95% CI: 2.32 to 2.97, I^2 = 63%, n = 5 RCTs) at three to five years' follow-up,[266, 294, 309, 310, 317, 318] to 1.68 (95% CI: 1.53 to 1.83, I^2 = 89%, n = 4 RCTs) at 13 to 15 years' follow-up.[305, 308, 314, 316] At 13 to 15 years' follow-up, it is estimated that invitation to screening would result in an increase of 8 elective surgeries per 1,000 men invited to screening. Of note, there was evidence of substantial statistical heterogeneity at short and long-term follow-up. In sensitivity analysis, use of the random effects model did not change the interpretation of the evidence for pooled estimates.

Only one RCT, the Western Australia trial, reported subgroup analysis according to age group for elective surgery. At 13 years' follow-up, there was no evidence of a significant difference between the subgroup aged 65 to 74, and the overall trial population aged 64 to 83 years (test for subgroup differences p = 0.78).[316]

Figure 4.8 Meta-analysis of the odds of elective surgery for AAA, stratified by length of follow-up



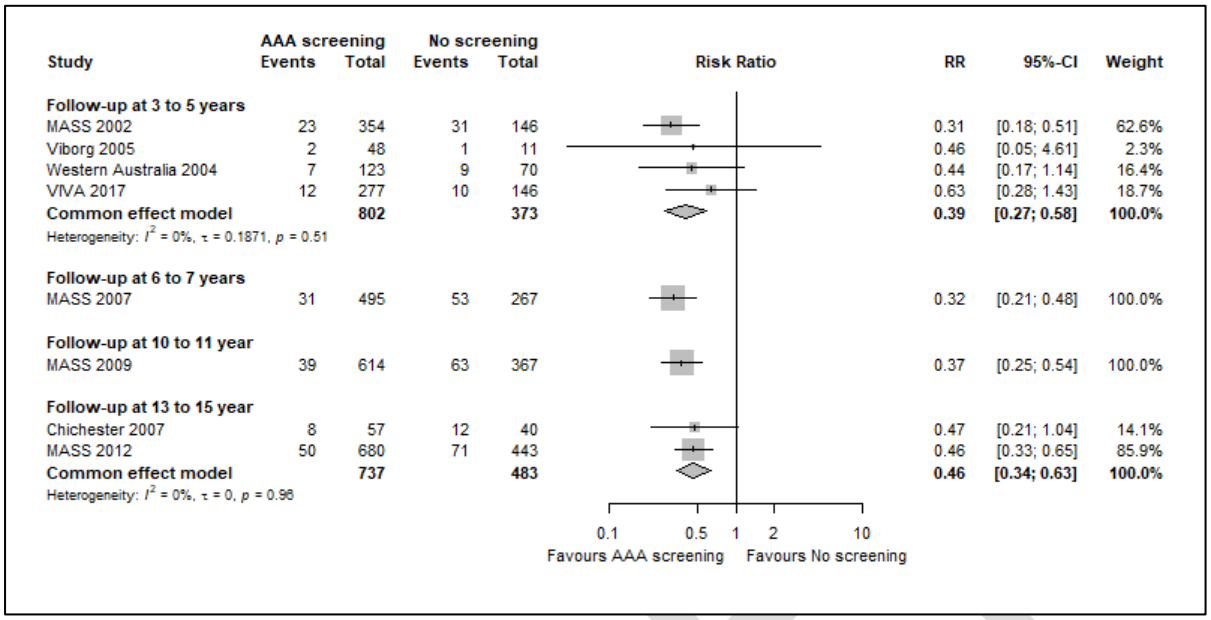
Key: AAA – abdominal aortic aneurysm; CI – confidence interval; OR – odds ratio.

Harms

30-day post-operative mortality for all surgeries

Compared with no screening, invitation to screening was associated with a statistically significant reduction in 30-day postoperative mortality from all AAA operations (emergency and elective) at all time points (Figure 4.9). At 13 to 15 years' follow-up, invitation to screening was associated with a 54% reduction in the risk of post-operative mortality (RR = 0.46, 95% CI: 0.34 to 0.63, I^2 = 0%, n = 2 RCTs) (Figure 4.9).[305, 308] Results between fixed and random effects meta-analysis were consistent.

Figure 4.9 Meta-analysis of 30-day postoperative mortality (emergency and elective) for screening compared with no screening, stratified by length of follow-up

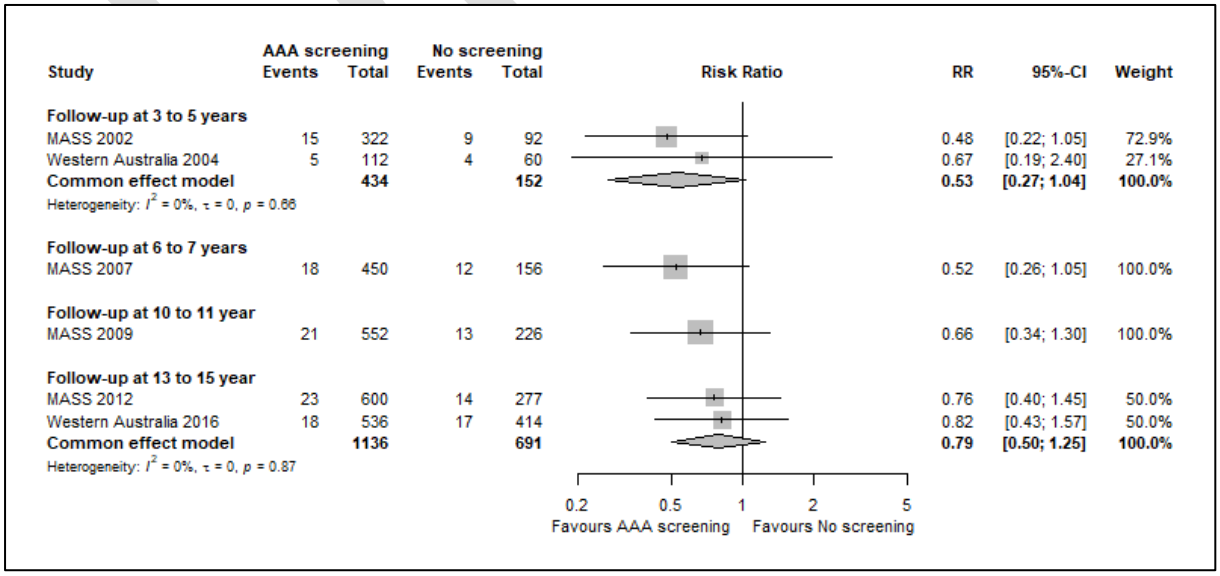


Key: AAA – abdominal aortic aneurysm; CI – confidence interval; RR – risk ratio.

30-day post-operative mortality for elective surgery

There was no significant difference between the group invited to screening and the no screening group in 30-day postoperative mortality following elective surgery at any time point (Figure 4.10).

Figure 4.10 Meta-analysis of 30-day postoperative mortality following elective surgery for screening compared with no screening, stratified by length of follow-up

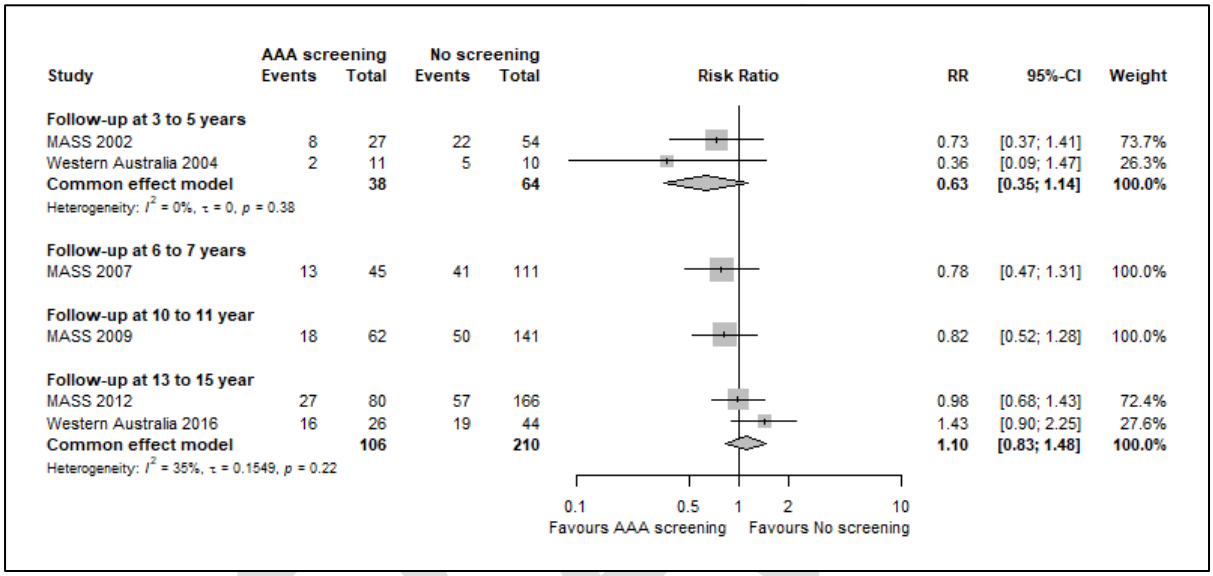


Key: AAA – abdominal aortic aneurysm; CI – confidence interval; RR – risk ratio.

30-day post-operative mortality for emergency surgery

Screening was not associated with a statistically significant reduction in 30-day postoperative mortality following emergency surgery at any time point up to 15 year's follow-up (Figure 4.11). Use of the random effects model did not change the interpretation of the evidence.

Figure 4.11 Meta-analysis of 30-day postoperative mortality following emergency surgery for screening compared with no screening, stratified by length of follow-up



Key: AAA – abdominal aortic aneurysm; CI – confidence interval; RR – risk ratio.

Surgery-related adverse events

Data relating to perioperative complications (for example, infection, re-operation, ICU admission or blood loss) were not reported by the included RCTs.

Overdiagnosis

The widely-accepted definition of overdiagnosis, as applied to the present HTA, is the detection of AAA through screening that otherwise would not have been diagnosed within the person's lifetime.[320, 321] Across the four RCTs, the risk of overdiagnosis was approximated by estimating the number of men that experienced an AAA rupture or underwent elective surgery in the comparator (no screening) arm, relative to the number of men diagnosed with AAA in the screening arm. It was estimated that between 171 and 453 men per 10,000 screened were diagnosed with AAA but would not have experienced AAA rupture or undergone elective surgery in the absence of screening at 13 to 15 years' follow-up. The implications of the concept of overdiagnosis in this context are explored further in the discussion (section 4.4.2).

Table 4.4 Estimated rate of overdiagnosis per 10,000 men invited to screening at 13 to 15 years' follow-up

Trial, year	Intervention			Comparator			Overdiagnosis per 10,000
	AAA diagnoses	Intervention arm	Diagnoses per 10,000	Rupture or elective surgery	Comparator arm	Event rate† per 10,000	
MASS 2012[305]	1,334	33,883	394	753	33,887	222	171
Viborg 2010[314]	191	6,333	302	80	6,303	127	175
Chichester 2007[313]	170	2,995	568	82	3,045	269	298
Western Australia 2016[316]	1,386	19,249	720	513	19,231	267	453

Key: AAA – abdominal aortic aneurysm.
† The event rate in the comparator arm includes AAA ruptures (fatal and non-fatal) plus elective surgeries. The number of AAA ruptures and elective surgeries were assumed to be mutually exclusive. The number of emergency operations were not included due to potential for duplication of data with AAA ruptures.

Quality of life and psychosocial harms

Three RCTs used subsampling approaches to investigate the impact of AAA screening on quality of life among participants. Outcomes of these case-control studies involving a subsample of participants were synthesised separately (see section 4.3.2, Quality of life and psychosocial harms).

Quality appraisal

Quality appraisal of the USPSTF systematic review was conducted using the ROBIS tool.[281] Overall the risk of bias was considered to be low. There were some concerns regarding the study eligibility criteria, and methods for identification and selection of studies. The exclusion criteria included non-English language studies, poor quality studies, studies conducted in settings not considered applicable to primary care populations, and studies not set in very high income countries. These exclusion criteria were not appropriately justified, and have the potential to introduce bias in the selection of studies. However, despite the application of highly restrictive exclusion criteria in the systematic review, no additional RCTs relevant to the research question were identified by our de novo systematic search strategy in which no date or language limits were applied.

For pooled analyses, sensitivity analyses were conducted to investigate the robustness of the pooled estimates by changing effect measure (for example, odds ratio (OR), hazard ratios (HR) or risk ratios (RR)), or the statistical model (that is, fixed versus random effects meta-analysis). No major concerns were identified regarding data collection and study appraisal or synthesis of findings.

4.3.2 Evidence from other study designs

Characteristics of included studies

Study design

A total of 30 publications met our inclusion criteria, comprising 24 original studies. Eighteen publications, comprising 14 individual studies, provided data on clinical outcomes (Table 4.5), and 12 publications, comprising 10 individual studies, reported data on psychological outcomes (Table 4.6). The studies were conducted in three regions: Scandinavia, including Norway, Denmark and Sweden, UK, and Western Australia.

Overall, 20 publications reported results of five formal and one informal screening programmes.[8, 31, 75, 76, 78, 79, 82, 84, 87, 96, 264, 265, 279, 280, 290-293, 295, 302] One study reported results from a Norwegian screening programme piloted from 2011 to 2019.[84] Five studies reported results from the Swedish National AAA Screening Programme, which started AAA ultrasound screening in 2006.[8, 78, 87, 279, 291] The remaining 14 studies included data from past or current UK-based screening programmes, including:

- The Gloucestershire Aneurysm Screening Programme, which started in 1990, and later became part of the National Health Service (NHS) screening programme (NAAASP), which began in 2009[75, 82, 96, 290, 302]
- The Huntingdon Aneurysm Screening Programme, which started in 1991 (later became part of the NAAASP)[280, 292, 293]
- The Highland Aortic Aneurysm Screening Programme, which started in 2001[31, 76]
- The current NHS AAA screening programme, which was implemented on a phased basis between 2009 and 2013.[79, 264, 265, 295]

Eleven comparative studies were reported across 13 publications. [8, 84, 87, 279, 280, 291-293, 295, 298-300, 302] Comparative study designs included six cohort,[84, 87, 279, 291, 295, 298] two case-control,[299, 300, 302] and two stepped wedge studies,[8, 280] reported across four publications.[8, 280, 292, 293] The latter is a form of cluster RCT whereby participants (in clusters, such as, individual GP practices) receive the intervention in 'steps'; for example, in the studies presented here, clusters moved from the control arm to the intervention arm in a phased manner.

Nine descriptive studies were reported across 12 publications.[31, 75, 76, 78, 79, 82, 96, 264, 265, 290, 296, 297] Descriptive study designs included eight population-based non-comparative studies,[31, 75, 76, 78, 79, 96, 264, 265] across 10 publications,[31, 75, 76, 78, 79, 82, 96, 264, 265, 290] and one cross-sectional study,[296] reported across two publications.[296, 297]

Additionally, four studies,[266, 294, 301, 304] comprising five publications, reporting on psychosocial outcomes represented subsamples of RCTs. [266, 294, 301, 303, 304]

Sixteen publications included males aged 65 years old,[8, 75, 78, 79, 82, 84, 87, 96, 264, 265, 279, 291, 295, 296, 298, 302] three studies from the Huntingdon Aneurysm Screening Programme invited all males over 50 years,[280, 292, 293] and 10 studies included males across an age range, all starting at 65 years old up to 83 years old.[31, 76, 266, 290, 294, 299-301, 303, 304] In addition to the invited cohort, the UK NAAASP allowed self-referral of men aged over 65 years at the time of implementation, or those who initially declined screening. The number of participants screened ranged from 2,736 to 1,248,048, depending on the region covered and duration of follow-up.[87, 264] Uptake rates were broadly consistent across studies, at an average of 81% (range 63% to 90%).

Outcome measurement and the care pathway

All studies used ultrasound as the screening technique, to measure the maximum distance, from the front to the back (also called the anteroposterior diameter), of the abdominal aorta below the renal arteries. Across all studies, an AAA was consistently defined as an aortic dilatation greater than 3.0 cm (Table 4.5). However, at its inception, the Gloucestershire Aneurysm Screening Programme adopted an aortic dilatation of 2.5 cm as the cut-off point for offering annual ultrasound surveillance as a conservative approach,[82] a standard that was maintained until 2009 when the NAAASP was implemented across the UK.

Criteria for classification of AAA and thresholds for referral to vascular surgery have evolved over time. Where clearly reported, in most studies the threshold for referral to a vascular surgeon was an aortic dilation equal to or greater than 5.5 cm (Table 4.5). However, in four studies the threshold for referral was lower (4.0 cm,[82] 4.5 cm,[84] 4.6 cm,[293] and one study where the threshold changed from 4.0 cm to 4.5 cm in 2005).[75] Of note, three of these four studies were undertaken in the 1990s and were based on the best available evidence at that time.[75, 82, 293] Where reported, the frequency of surveillance for those with small to medium AAAs varied across studies. However, across all studies, the frequency of surveillance increased as the AAA diameter approached the referral threshold (Table 4.5). Five studies did not report surveillance protocols or thresholds for referral to a vascular surgeon.[8, 280, 290-292]

In general, studies reporting on psychosocial harms used a variety of different instruments to measure quality of life and assessed this at different time points. Seven studies used generic instruments to measure quality of life, anxiety and depression,[266, 294, 299-302, 304] one study used a condition-specific questionnaire,[296] and two studies used a combination of generic instruments and non-validated AAA-

specific questions.[295, 298] Where longitudinal data were collected, reporting was generally limited to very short-term follow-up (for example, one to six months). Three studies reported data at one to two years' post initial screening.[294, 296, 304] In one study, quality of life outcomes were reported ≥37 months post-screening.[295]

Clinical effectiveness and harms

It is important to note that a single screening programme or study may produce multiple publications over time, reporting outcomes for the same population. To avoid duplication of data, only the most recent publication from each screening programme or study that reported a given outcome was included.

In total,

- 15 publications,[8, 31, 75, 78, 79, 82, 84, 87, 264, 265, 279, 280, 290, 292, 293] comprising 10 unique studies,[8, 31, 75, 78, 84, 87, 264, 265, 279, 280] reported AAA-related mortality
- 8 publications,[31, 75, 79, 82, 84, 87, 96, 265] comprising six unique studies,[31, 75, 84, 87, 96, 265] reported on all-cause mortality
- 12 publications,[75, 78, 79, 82, 84, 87, 264, 265, 279, 280, 292, 293] comprising eight unique studies,[75, 78, 84, 87, 264, 265, 279, 280] reported on AAA ruptures
- 16 publications,[8, 75, 76, 78, 79, 82, 84, 87, 96, 264, 265, 279, 280, 290, 292, 293] comprising eleven unique studies,[8, 75, 76, 78, 84, 87, 96, 264, 265, 279, 280] reported on surgical repair
- 12 publications,[8, 75, 78, 79, 82, 84, 87, 264, 290-293] comprising seven unique studies,[8, 75, 78, 84, 87, 264, 291] reported on surgery-related mortality
- 1 study reported on surgery-related adverse events[291]
- 12 publications,[266, 294-304] reported across ten studies,[266, 295, 296, 298-302, 304, 308] investigated the impact of screening for AAA on psychological outcomes for screen-detected AAA, relative to those with no abnormality detected by screening, or by comparing pre and post-screening health status (Table 4.6).

Table 4.5 Characteristics of included studies

Screening programme	Author, Year Study design Region	Screening period Study duration Follow-up (years)†	Eligible age group Population invited Uptake	Number of participants screened	Definition of AAA	Care pathway (surveillance protocols and thresholds for referral)	Outcomes reported	Exclusion criteria
Scandinavia								
Norway	Mansoor 2023[84] Cohort study Oslo	Screening period: May 2011 - Sep 2019 Study duration: May 2011 - Jul 2022 Follow-up: 7.1 years (IQR 3.8)	Males at 65 years old N invited: 19,328 Uptake: 63-78%	13,215	AD > 3.0 cm	*Surveillance* 2.5–4.4 cm: Managed by GPs *Threshold for referral* AAA ≥ 4.5 cm	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair 30-day postoperative mortality	None reported
Swedish National Screening Programme	Hultgren 2020[78] Population based - single arm Stockholm	Screening period: Jul 2010 - Dec 2016 Study duration: Jul 2010 - Dec 2017 Follow-up: 4.6 years (Range 1 - 7.5)	Males at 65 years old N invited: 71,393 Uptake: 78%	55,691	AD > 3.0 cm	*Surveillance* 3.0-3.9 cm: 24 months 4.0-4.5 cm: 12 months 4.6-4.9 cm: 6 months 5.0-5.4 cm: 3 to 6 months *Threshold for referral* AAA ≥ 5.5 cm	AAA-related mortality AAA ruptures AAA surgical repair 30-day postoperative mortality	Men with known AAA were not invited to be screened
	Johansson 2018[279] Cohort study National	Screening period: 2006 - 2009 Study duration: 2006 - 2015 Follow-up: NR	Males at 65 years old N invited: NR Uptake: 85%§	25,265	AD > 3.0 cm	*Surveillance* <5.5 cm: Monitored with ultrasound at regular intervals. *Threshold for referral* AAA ≥ 5.5 cm	AAA-related mortality AAA ruptures AAA surgical repair	Counties where screening was introduced in various age groups simultaneously, or introduced later than 2009, or had not been fully implemented.
	Wanhainen 2016[8] Stepped wedge National	Screening period: 2006 - 2014 Study duration: 2006 - 2014 Follow-up: 4.5 years	Males at 65 years old N invited: 30,2957 Uptake: 84%	253,896	AD > 3.0 cm	NR	AAA-related mortality AAA surgical repair 30-day postoperative mortality	Counties with incomplete records

Screening programme	Author, Year Study design Region	Screening period Study duration Follow-up (years)†	Eligible age group Population invited Uptake	Number of participants screened	Definition of AAA	Care pathway (surveillance protocols and thresholds for referral)	Outcomes reported	Exclusion criteria
	Linne 2014[291] Cohort study National	Screening period: May 2010 - Jan 2013 Study duration: May 2010 - Jan 2013 Follow-up: NR	Males at 65 years old N invited: NR Uptake: NR	NR	NR	NR	30-day postoperative mortality	All women Patients with AD <5.0 cm Patients with "unknown" screening status.
	Svensjo 2013[87] Cohort study Uppsala	Screening period: 2006 - 2007 Study duration: 2006 - 2012 Follow-up: 5 years	Males at 65 years old N invited: 3,268 Uptake: 83.7%	2,736	AD > 3.0 cm	*Surveillance* 2.5-2.9 cm: 5 years 3.0-3.9 cm: 24 months 4.0-4.4 cm: 12 months 4.5-4.9 cm: 6 months ≥5.0 cm: 3 months *Threshold for referral* Individuals with symptomatic or rapidly expanding AAA. AAA ≥ 5.5 cm	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair 30-day postoperative mortality	Patients with history of AAA repair
United Kingdom								
NHS national screening	Meecham 2021[264] Population based - single arm England	Screening period: Apr 2009 - Aug 2016 Study duration: Apr 2009 - Aug 2017 Follow-up: NR	Males at 65 years old N invited: NR Uptake: NR	1,248,048	AD > 3.0 cm	*Surveillance* 3.0-5.4 cm: Invited for nurse assessment to modify medical risk factors. *Threshold for referral* AAA ≥ 5.5 cm	AAA-related mortality AAA ruptures AAA surgical repair 30-day postoperative mortality	Men who refused use of their personal information for research
	Oliver-W 2019[265] Population based - single arm England	Screening period: Apr 2009 - Aug 2016 Study duration: Apr 2009 - Aug 2017 Follow-up: 2.5 years (IQR 1.4 - 3.9)	Males at 65 years old N invited: NR Uptake: NR	NR	AD > 3.0 cm	*Surveillance* 3.0-5.4 cm: Invited to join a surveillance programme.	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair	None reported

Screening programme	Author, Year Study design Region	Screening period Study duration Follow-up (years)†	Eligible age group Population invited Uptake	Number of participants screened	Definition of AAA	Care pathway (surveillance protocols and thresholds for referral)	Outcomes reported	Exclusion criteria
	Jacomelli 2016[79] Population based - single arm England	Screening period: Apr 2009 - Aug 2014 Study duration: Apr 2009 - Aug 2014 Follow-up: NR	Males at 65 years old N invited: 896,287 Uptake: 78.1%	727,421	AD > 3.0 cm	*Surveillance* 3.0-5.4 cm: offered regular ultrasound surveillance. *Threshold for referral* AAA ≥ 5.5 cm	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair 30-day postoperative mortality	Men with known AAA were not invited to be screened
The Gloucestershire Aneurysm Screening Programme (GASP)‡	Oliver-W 2018[96] Population based - single arm Gloucestershire, England	Screening period: 1990 - 2015 Study duration: 1990 - 2015 Follow-up: 5.1 years	Males at 65 years old N invited: 100,574 Uptake: 80.7%	81,150	AD > 3.0 cm	*Surveillance* 2.6-4.4 cm: 12 months 4.5-5.5 cm: 3 months *Threshold for referral* AAA ≥ 5.5 cm	All-cause mortality AAA surgical repair	None reported
	Darwood 2013[75] Population based - single arm Gloucestershire, England	Screening period: 1990 - 2009 Study duration: 1990 - 2009 Follow-up: Unclear	Males at 65 years old N invited: 61,982 Uptake: 84.2%	52,690	AD > 3.0 cm	*Surveillance* After 2005 2.6-4.4 cm: 12 months 4.5-5.5 cm: 6 months Before 2005 2.6-3.9 cm: 12 months 4.0-5.5 cm: 6 months *Threshold for referral* After 2005 AAA ≥ 4.5 cm Before 2005 AAA ≥ 4.0 cm	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair 30-day postoperative mortality	None reported
	Heather 2000[290] Population based - single arm Gloucestershire, England	Screening period: 1990 - 1998 Study duration: 1990 - 1998 Follow-up: NR	Males 65 to 73 years old N invited: 24,479 Uptake: 84%	20,633	AD > 3.0 cm	NR	AAA-related mortality AAA surgical repair 30-day postoperative mortality	None reported

Screening programme	Author, Year Study design Region	Screening period Study duration Follow-up (years)†	Eligible age group Population invited Uptake	Number of participants screened	Definition of AAA	Care pathway (surveillance protocols and thresholds for referral)	Outcomes reported	Exclusion criteria
	Lucarotti 1993[82] Population based - single arm Gloucestershire, England	Screening period: 1990 - 1992 Study duration: 1990 - 1992 Follow-up: 2 years	Males at 65 years old N invited: 5,337 Uptake: 79%	4,232	AD > 2.5 cm	*Surveillance* 2.5-3.9 cm: offered regular ultrasound surveillance. *Threshold for referral* AAA ≥ 4.0 cm	AAA-related mortality AAA ruptures All-cause mortality AAA surgical repair 30-day postoperative mortality	None reported
Highland aortic aneurysm screening programme	Duncan 2012[31] Population based - single arm Highlands, Scotland	Screening period: Apr 2001 - Jan 2004 Study duration: Apr 2001 - Jun 2010 Follow-up: 7.4 years (IQR 6.9 – 8.2)	Males 65 to 74 years old N invited: 9,323 Uptake: 89.6%	8,355	AD > 3.0 cm	*Surveillance* 3.0-4.4 cm: 12 months 4.5-5.4 cm: 3 months *Threshold for referral* AAA ≥ 5.5 cm	AAA-related mortality All-cause mortality	Men not completing the questionnaire and so were unavailable for record linkage.
	Duncan 2005[76] Population based - single arm Highlands, Scotland	Screening period: Feb 2001 - Jan 2004 Study duration: Feb 2001 - Jan 2004 Follow-up: NR	Males 65 to 74 years old N invited: 9,323 Uptake: 89.6%	8,355	AD > 3.0 cm		AAA surgical repair	None reported
The Huntingdon Aneurysm Screening Programme	Wilmink 2006[280] Stepped wedge Huntingdon, England	Screening period: Nov 1991 - Sep 2001 Study duration: Jan 1991 - Dec 2003 Follow-up: NR	Males over 50 years old N invited: 18,548 Uptake: 73.5%	13,634	AD > 3.0 cm	NR	AAA-related mortality AAA ruptures AAA surgical repair	Men deemed not suitable for elective open aneurysm repair.
	Wilmink 2003[292] Stepped wedge Huntingdon, England	Screening period: Nov 1991 - Dec 2000 Study duration: Jan 1991 - Dec 2000 Follow-up: NR	Males over 50 years old N invited: NR Uptake: 74%	NR	AD > 3.0 cm	NR	AAA-related mortality AAA ruptures AAA surgical repair 30-day postoperative mortality	None reported

Screening programme	Author, Year Study design Region	Screening period Study duration Follow-up (years)†	Eligible age group Population invited Uptake	Number of participants screened	Definition of AAA	Care pathway (surveillance protocols and thresholds for referral)	Outcomes reported	Exclusion criteria
	Wilmink 1999[293] Stepped wedge Huntingdon, England	Screening period: Nov 1991 - Dec 1996 Study duration: Jan 1991 - Dec 1996 Follow-up: 0.5 years - 5.1 years	Males over 50 years old N invited: 13,147 Uptake: 74%	9,728	AD > 3.0 cm	*Surveillance* 2.5-2.9 cm: 12 months 3.0-4.5 cm: 6 months *Threshold for referral* AAA ≥ 4.6 cm	AAA-related mortality AAA ruptures AAA surgical repair 30-day postoperative mortality	End-stage carcinoma, end-stage cardiac or respiratory disease, and senile or pre-senile dementia.

Key: AAA – Abdominal aortic aneurysm, AD – Aortic dilatation, GPs – General practitioners, IQR – Interquartile range, NR – Not reported.

† Follow-up mean and range or interquartile range as reported by the authors.

ǂ Before implementation of the national level NHS Abdominal Aortic Aneurysm Screening Programme in 2009, the regional Gloucestershire Aneurysm Screening Programme used an aortic diameter >2.5 for entry into the surveillance pathway.

§ The uptake rate was assumed based on the data reported in a linked publication by Wanhainen & Björck (2011).

Table 4.6 Studies assessing psychological outcomes among patients with and without AAA

RCT or screening programme	Study, year(s)	Setting, Country Study period	Study design	Population Characteristics	Quality of life scale	Timing of assessment	Response rate
Gloucestershire Aneurysm Screening Programme	Lucarotti 1997[302]	Gloucestershire, England. Sept 1990 to Jun 1994.	Case-control	Men aged 65 (N = 161) AAA: n = 61 Normal aorta size: n = 100	28-item General Health Questionnaire (GHQ)	The questionnaire was administered just before screening and 1 month later.	Unclear
NA	Khaira 1998[299]	Good Hope Hospital, England. Unclear.	Case-control	Men aged 66 to 78 Four subgroups: 1. Normal screening result (n = 45) 2. Patients with small AAA attending follow-up (n = 38) 3. Patients with AAA on waiting list for repair (n = 24) Controls (n = 11)	The Hospital Anxiety and Depression Scale (HADS)	Small AAA: 1 month and 6 months post-screening. Other groups: Unclear	Unclear
Viborg trial	Lindholt 2000[301]	Denmark 1994	Case-control (Subsample of Viborg trial)	Men aged 65 to 73 15% of n = 4,404 men received pre-screening questionnaire. 10% received post-screening questionnaire. • AAA: n = 127/149 • Operated on: 29/36 • Controls: n = 231/350 • Non-attendees: n = 168/348 • Attenders before: n = 271/660 • Attenders after: n = 286/440	ScreenQoL (validated)	Pre-screening, 1 month post-screening after and 1 month before annual surveillance, and 3-6 months after operation.	Non-attenders: • Pre 48% Attenders: • Pre 81% • Post 85% Small AAA: Post (1 month) 85% Post (3-6 months) 81% Controls: 66%

RCT or screening programme	Study, year(s)	Setting, Country Study period	Study design	Population Characteristics	Quality of life scale	Timing of assessment	Response rate
NA	Lesjak 2012[300]	Broken Hill, Australia. 2007	Case-control	Men aged 65 to 74 years (N = 183) • AAA: n = 53 Normal aorta: n = 130	• Medical Outcomes Short Form 36 v2 (MOSF36) • HADS	Data were collected at the time of screening (pre-screening) and 6 months later.	AAA: 74% Normal aorta: 74%
MASS trial	Ashton 2002[294]	United Kingdom Jan 1997 - May 1999	Case-control (representative subsample of MASS trial)	Men aged 65 to 74 years *All participants* • Negative screen: n = 631 • Positive screen: n = 599 • Controls n = 726 *Positive screen* • Surveillance: n = 426 • Surgery n = 129	• HADS • short-form state anxiety scale of the Spielberger state-trait anxiety scale • SF-36 • EQ-5D	Pre-screen and 6 weeks after *Subset with positive screen* 3 months and 12 months	Invited: 90% Controls: 77%
	Marteau 2004[303]	United Kingdom Jan 1997 - May 1999	Case-control (representative sub-sample)	AAA: n = 571 Normal aorta: n = 609	• Five items from the SF-36 health survey	Baseline questionnaire and six weeks post-screening	Invited 90%
Western Australia trial	Spencer 2004[304]	Western Australia April 1998	Case-control (subsample of Western Australia trial)	Men aged 65 to 83 years • AAA: n = 120/157 • Normal aorta n = 245/341	• Medical Outcomes Study Short Form (MOSSF-36)	Pre-screen and after 12 months	AAA: 77% Normal aorta: 73%
NA	Ericsson 2017[298]	Skåne University Hospital, Sweden. Unclear.	Cohort study	Men aged 65 years (N = 170) • AAA: n = 52 • without AAA: n = 118	• Short Form 36 Health Survey, • HADS • Sense of coherence (SOC) • 3 study-specific questions about stress • 9 specific non-validated AAA questions (men with AAA only)	Two questionnaires: Within 12 weeks of initial screening 6 months after the first questionnaire	100%*

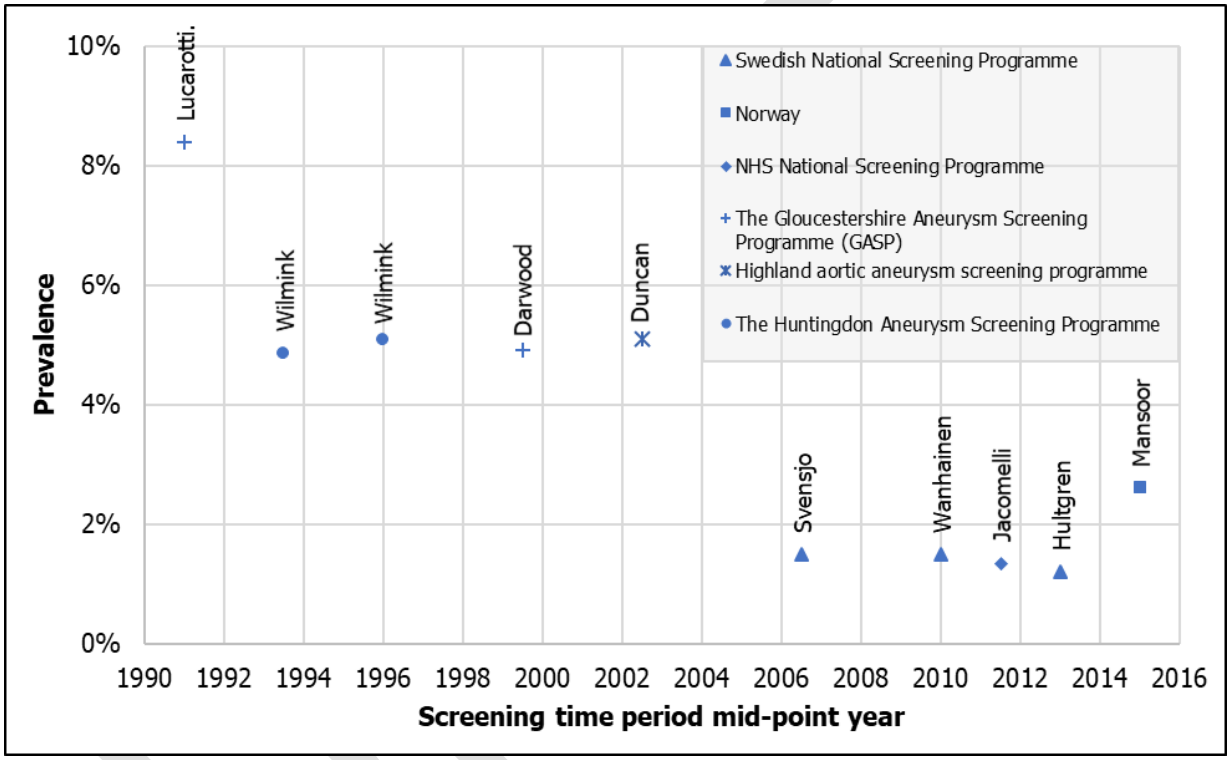
RCT or screening programme	Study, year(s)	Setting, Country Study period	Study design	Population Characteristics	Quality of life scale	Timing of assessment	Response rate
VIVA trial	Lindholt 2017[266]	Central Denmark, Oct 2008 to Jan 2011	RCT (subsample of VIVA trial)	Men aged 65-74 years *Baseline* Screening group: n = 18,245 AAA: n = 591 Non-screening: n = 821 to 828† *Longitudinal* AAA: n = 445	• EuroQol five-dimension three-level instrument. QoL indices were generated using Danish preference weights.	Pre-screening (in the waiting room) and before follow-up 1 year after positive AAA (also in the waiting room).	Screening: 73% No screening: 82% AAA: 64%
Welsh and English screening programmes	Bath 2018[295]	England and Wales Sept 2011 to Jul 2015.	Cohort study	Men aged 65 (N = 5,011) • Normal aorta: n = 4,630 • AAA: n = 381	• 8 questions adapted from the Medical Outcomes Study Short Form 36 questionnaire (SF-8) • AAA-specific questions: How often they thought about their AAA, and the potential for AAA growth in the preceding 4 weeks (Likert scale: 1 = not at all; 5 = all the time).	At the time of screening and annually thereafter (mean 19.0 (9.1) months)	Unclear
NA	Broeren 2023[296]; Damhus 2021[297]	County of Vastra Gotaland, Sweden. January to April 2013.	Cross-sectional	Men aged 65 • AAA: n = 158; • Normal aorta size: n = 275	Consequences of Screening in Abdominal Aortic • Aneurysm (COS-AAA) (34 out of 95 questions)	Cross-sectional survey with 1-24 months of screening	AAA: 63% Normal aorta: 55%

Key: AAA – abdominal aortic aneurysm; HADS - Hospital Anxiety and Depression Scale; NA – not applicable; QoL – Quality of life.
* All men meeting the inclusion criteria (that is, participation within 12 weeks of the screening examination, ability to understand the Swedish language, and to respond to the questionnaire) were reported to be included in the study, representing approximately 56% of cases initially invited to participate.
† For the screening group, the number of respondent varied for general health (n = 821) and anxiety or depression (n = 828).

Prevalence

AAA prevalence was reported in six studies, comprising 10 publications,[8, 75, 76, 78, 79, 82, 84, 87, 280, 292] and ranged from 1.2% to 8.4% across the studies;[78, 82] this variation appears to reflect the timing of the study (Table 4.7). Earlier studies, specifically from regional screening programmes in the UK, reported higher prevalence rates. Recent estimates from studies using data from the UK NAAASP and from AAA screening programmes in Scandinavia suggest that the current prevalence is approximately 1% to 2%.[8, 78, 79, 84, 87]

Figure 4.12 Prevalence of AAA reported by study time periods



Key: AAA – Abdominal aortic aneurysm.
Included studies reported the mean prevalence of AAA over a given time period (for example, 2011 to 2019). The year shown on the x-axis represents the mid-point of the screening period for each included study.

Five studies, across six publications,[8, 75, 76, 79, 84, 87] reported the prevalence of AAA stratified by aortic diameter; the categories of aortic diameter here were 3.0 cm to 5.4 (that is, small- to medium-sized AAA), and greater than or equal to 5.5 cm (that is, large AAA). From these studies, it was estimated that, on average, 90% (range 84% to 94%) of individuals with screen-detected AAA had a small- to medium-sized AAA at the time of initial screening, thus entering the surveillance care pathway.[75, 87] The remaining 10% (range 6% to 16%) were estimated to have a large aneurysm and were consequently referred to a vascular surgeon for potential elective surgical repair.[75, 87]

Table 4.7 Prevalence of AAA in screened population from studies identified in the de novo review, by aortic diameter

Screening Programme	Author Year	Region Study screening period	Total prevalence of AAA†	Prevalence of AAA classified by aortic diameter (cm)							% of people with screened-detected AAA under surveillance‡	% of people with screened-detected AAA referred to vascular surgery §
				SAD	Small		Medium		Large			
				2.5-2.9	3-3.9	3-4.4	4-4.9	4.5-5.4	5-5.4	≥5.5		
Scandinavia												
Norway	Mansoor 2023[84]	Oslo May 2011 - Sep 2019	2.5%	6.5%	2.2%		-	0.1%		0.2%	87.8%	12.1%
Swedish National Screening Programme	Hultgren 2020[78]	Stockholm Jul 2010 - Dec 2016	1.2%	1.3%	0.9%	-	0.2%	-	0.1%		88.2%	11.8%
	Johansson 2018[279]	National 2006 - 2009	-	-	-	-	-	-	-	-	-	-
	Wanhainen 2016[8]	National 2006 - 2014	1.5%	-	1.0%	-	0.3%	-	0.2%	0.1%	92.8%	7.2%
	Linne 2014[291]	National May 2010 - Jan 2013	-	-	-	-	-	-	-	-	-	-
	Svensjo 2013[87]	National 2006 -2007	1.6%	-	0.9%	-	0.4%		-	0.3%	84.0%	16.0%
United Kingdom												
NHS national screening	Meecham 2021[264]	England Apr 2009 - Aug 2016	-	-	-	-	-	-	-	0.1%	-	-
	Oliver-W 2019[265]	England Apr 2009 - Aug 2016	-	-	-	1.1%	-	0.1%	-	-	-	-
	Jacomelli 2016[79]	England Apr 2009 - Aug 2014	1.4%	-	-	1.1%	-	0.2%	-	0.1%	92.3%	7.9%
The Gloucestershire Aneurysm Screening	Oliver-W 2018[96]	Gloucestershire, England 1990 - 2015	-	1.5%	1.9%				-	-	-	-
	Darwood 2013[75]	Gloucestershire, England 1990 - 2009	4.9%	4.6%					-	0.3%	94.2%	5.8%

Screening Programme	Author Year	Region Study screening period	Total prevalence of AAA†	Prevalence of AAA classified by aortic diameter (cm)							% of people with screened-detected AAA under surveillanceδ	% of people with screened-detected AAA referred to vascular surgery §
				SAD	Small		Medium		Large			
				2.5-2.9	3-3.9	3-4.4	4-4.9	4.5-5.4	5-5.4	≥5.5		
Programme (GASP)‡	Heather 2000(290)	Gloucestershire, England 1990 - 1998	-	-	-	-	2.2%				-	-
	M. Lucarotti 1993(82)	Gloucestershire, England 1990 - 1992	8.4%	-	-	-	1.3%				-	14.9%
Highland aortic aneurysm screening programme	Duncan 2012(31)	Highlands, Scotland Apr 2001 - Jun 2004	5.1%	8.2%	-	-	-	-	-	-	-	-
	Duncan 2005(76)	Highlands, Scotland Feb 2001 - Jan 2004	5.1%	-	3.2%	-	1.1%	-	0.3%	0.5%	90.2%	9.8%
The Huntingdon Aneurysm Screening Programme	Wilmink 2006(280)	Huntingdon, England Nov 1991 - Sep 2001	5.1%	-	4.6%				0.5%		89.6%	10.2%
	Wilmink 2003(292)	Huntingdon, England Nov 1991 - Dec 2000	-	-	-	-	-	-	-	-	-	-
	Wilmink 1999(293)	Huntingdon, England Nov 1991 - Dec 1996	5.5%	-	-	4.9%	-	0.6%			89.1%	11.0%

Key: AAA – abdominal aortic aneurysm; SAD - subaneurysm dilatation.
† The total prevalence based on the threshold used by the study. In the GASP, the total prevalence of AAA included aortic diameter >2.5 cm.
‡ GASP used aortic diameter >2.5 cm as the threshold for entry into the surveillance pathway before joining the NHS AAA screening programme in 2009.
§ The proportion of participants with screened-detected AAA referred to vascular surgery at the baseline scan was based on the referral threshold as defined by the study authors (generally ≥5.5 cm). Thresholds for referral to vascular surgery were more conservative in one study from Gloucestershire (4.0 cm), one Norwegian study (≥4.5 cm) and two studies from Huntingdon (≥ 4.6 cm and ≥ 5.0 cm), and it was not possible to estimate the prevalence of AAA ≥ 5.5 cm.

Clinical effectiveness

Overall, six studies, reported across 13 individual publications, provided data on clinical effectiveness or safety (excluding psychosocial harms).[8, 31, 75, 76, 78, 84, 87, 96, 264, 265, 279, 280, 291] The clinical effectiveness results from the 13 publications, including two stepped wedge cluster randomised trials, and three comparative and eight non-comparative descriptive studies, are summarised in the appendix Table A5. Results are expressed per 100,000 men screened throughout, except where otherwise stated. One cohort study did not report absolute numbers, instead data were reported in terms of the absolute difference between the screened and unscreened cohorts only.[279] Therefore, the event rate in the individual groups could not be estimated.

AAA-related mortality

Six studies, comprising 10 publications, reported on AAA-related mortality. These included two stepped wedge cluster randomised trials,[8, 280] three descriptive studies comparing those who participated in screening with non-participants,[78, 87, 279] and five non-comparative studies (see Appendix, Table A5).[31, 75, 84, 264, 265] Few studies explicitly defined AAA-related mortality. In one study, AAA-related mortality was based on AAA ruptures only.[280]

One cohort study and the two stepped wedge studies evaluated the impact of AAA screening on mortality rates.[8, 279, 280] The findings indicated a reduction in AAA-related mortality within the screened groups compared with their unscreened counterparts. Two studies, reporting outcomes from the Swedish National Screening Programme, found absolute reductions in AAA-related mortality of 3.7 and 15.7 deaths per 100,000 person-years, respectively, with evidence of reduced mortality over time.[8, 279] Specifically, Johansson et al. reported that AAA-related mortality had decreased by 30% in the screening cohort relative to the control cohort, or an absolute reduction of 3.7 deaths per 100,000 person-years (95% CI: 1.7 to 9.1) after six years of screening.[279] This corresponds to 20 men avoiding death from AAA per 100,000 men offered screening. In addition, a study from the Huntingdon Aneurysm Screening Programme in the UK estimated a 75% reduction in mortality from ruptured aneurysms (95% CI: 58 to 85%) after 13 years of screening, which is equivalent to an absolute reduction of 42 deaths per 100,000 person-years.[280]

Two studies evaluated the impact of AAA screening on AAA-related mortality, compared with non-attenders.[78, 87] One study reported one AAA-related death in the screened group (n = 55,691) and three deaths among the group of non-attenders (n = 15,702), with a median follow-up of 4.8 years.[78] This represents an absolute reduction of 17.3 deaths per 100,000 in the screened group. Another study from Sweden reporting on outcomes from the region of Uppsala found that there

were no AAA-related deaths in the screened cohort (n = 2,736) after five years, and reported one death (0.19%) in a small control group (n = 532) who were invited but did not attend screening.[87] However, the small sample size in this study limits the ability to draw definitive conclusions.

Five non-comparative descriptive studies also reported on AAA-related mortality in screened cohorts. There is evidence to suggest that the AAA-related mortality rate in screened cohorts has declined over time. A 2023 study by Mansoor et al. investigating outcomes of a regional AAA screening programme in Oslo at 11 years of follow-up (n = 13,215), reported an AAA-related mortality rate of 15 deaths per 100,000 persons screened.[84] They reported no deaths in the sub-aneurysmal group (n = 859). From the Highlands Aortic Aneurysm Screening Programme in Scotland (n = 8,146) Duncan et al. reported an overall abdominal aortic subaneurysm or aneurysm-related mortality rate of 135 per 100,000 persons screened after a median of 7.4 years follow-up.[31] They reported a rate of 110 AAA-related deaths per 100,000 persons screened in the AAA subgroup, and 25 per 100,000 persons screened in the sub-aneurysmal subgroup. From the Gloucestershire Aneurysm Screening Programme in the UK, Darwood et al. reported outcomes for a subgroup of men (n =1,254) who had at least ten years' follow-up and noted that AAA-related mortality increased with increasing aortic size. They found that 2.4% of men with a sub-aneurysm (n=547) had an AAA-related death and 9.6% of men with a small to medium aneurysm (n = 668) had an AAA-related death.[75]

Studies from the UK's NAAASP reported AAA-related mortality from patients with small to medium aneurysms (that is, 3.0 to 5.4 cm in diameter)[265] and from patients with large AAAs (that is greater than 5.4 cm in diameter) over the study period of approximately eight years.[264] In patients with large aneurysms (n = 3,026) who were referred for vascular treatment, the percentage of AAA-related deaths (including ruptures and post-operative deaths) was 1.4%.[264] In this group, 20% of AAA-related deaths occurred among those considered unfit for surgery.[264] In patients with small- to medium-aneurysms (n = 18,652), the percentage of AAA-related deaths was 0.15%.[265]

All-cause mortality

Five studies, comprising six publications, reported all-cause mortality outcomes in screened men.[8, 31, 75, 84, 87, 96, 265] The all-cause mortality rate varied between studies, which is likely to be explained by differences in the populations enrolled. Four studies reported sufficient data to estimate the all-cause mortality per 100,000 population screened at five to ten years' follow-up (see Appendix, Table A5).[31, 84, 87, 96] The all-cause mortality rate was broadly comparable in two studies in which men aged 65 years were screened, ranging from 600 to 1,200 per 100,000 men screened.[75, 84, 96] Of these, Mansoor et al. also reported that all-cause mortality was

significantly higher in the AAA group relative to the subaneurysm group.[84] A third study from the Highlands and Western Isles in Scotland reported considerably higher all-cause mortality of 8,028 per 100,000 men screened but this may be explained by the fact that older men (up to 74 years of age) were invited to screening.[31] A fourth study from Uppsala in Sweden reported an all-cause mortality rate of 5,446 per 100,000 men screened, at five years' follow-up.[84]

One study from the UK NAAASP reported that, of the initial cohort of 18,652 men with a small to medium AAA, 5% died during the study period.[265] Darwood et al. reported the all-cause mortality for a subgroup of men with at least 10 years of follow-up. It was estimated that approximately 40% of men with screen-detected AAA died during the follow-up period.[75]

AAA rupture

Five studies, comprising eight publications, reported on AAA rupture.[75, 78, 84, 87, 264, 265, 279, 280] Two studies compared screened and unscreened populations,[279, 280] two studies compared screened groups with those who declined the invitation to screening[78, 87] and four studies reported on the screened population only (see Appendix, Table A5).[75, 84, 264, 265] Evidence from the two studies comparing screened and unscreened populations suggests that screening is associated with a reduction in AAA ruptures.[279, 280] In one study from the Swedish National Screening Programme the magnitude of the reduction in the screened cohort versus the unscreened cohort was -0.10 percentage points (95% CI: -0.19 to -0.02), equivalent to a reduction of 100 ruptures per 100,000 person-years after six years of screening.[279] Similarly, a stepped wedge study from the Huntingdon Aneurysm Screening Programme reported that the reduction in AAA rupture increased over time. Relative to the comparator group, the reduction in incidence of ruptured AAA in the group invited for screening was 49% (95% CI: 3 to 74%) after the first five years of the screening programme. After 13 years, screening was associated with a 73% (95% CI: 58 to 82%) reduction in the incidence of AAA rupture relative to the comparator group.[280]

One study compared AAA rupture rates among men participating in the Swedish National Screening Programme (n = 55,691) with non-attenders (n = 15,702). They reported decreased rupture rates in the screened group relative to the unscreened group, with an absolute reduction of approximately 92 ruptures per 100,000 persons over a mean follow-up period of four years and eight months (range 1 – 7.5 years).[78] An earlier study from Uppsala in Sweden reported no AAA ruptures in the screened cohort (n = 2,736) after five years, and one rupture (0.19%) in a small control group (n = 532) who were invited but did not attend screening.[87] The small sample size in this study makes interpretation challenging. Of note, it is likely that non-attenders are systematically different from those who elected to participate in the screening programme.

From Norway, Mansoor et al. reported a rupture rate of 30 per 100,000 men screened after approximately seven years of follow up. They also observed that the AAA rupture rate was higher among men with AAA at the initial scan (that is, 22.7 per 100,000 men screened), relative to those with a subaneurysm (that is, 7.6 per 100,000 men screened).[84]

Two studies from the UK NAAASP reported outcomes for each of the subsets of patients with small-to-medium AAAs at the initial scan and with large AAAs identified at initial scan or during surveillance.[264, 265] In the group of men with large aneurysms (n = 3,026) who were referred for treatment, 0.3% had a ruptured aneurysm. Of those referred to vascular surgery who experienced an AAA rupture, 50% of ruptures occurred among those undergoing investigations, 37.5% occurred among men with a scheduled surgery and 12.5% occurred among men considered unfit for surgery.[264] In the group of men with small-to-medium aneurysms (n = 18,652) 0.2% had a ruptured aneurysm.[265] From the Gloucestershire Aneurysm Screening Programme in the UK, Darwood et al. reported that the number of ruptured AAAs treated annually decreased over the course of the 20 year study period. The rupture rate was 9% amongst a subgroup of men with at least 10 years of follow-up.[75]

Rate of overall surgery

Five studies, reported across eight publications, allowed the calculation of the rate of surgical repair.[8, 78, 84, 87, 96, 264, 265, 280] The surgical repair rate ranged from 271 to 946 per 100,000 men screened (see Appendix, Table A5).[78, 280] No study reported the rate of overall surgery for screened relative to unscreened cohorts.

Two studies that compared the rate of overall surgery between screened men and non-attenders reported inconsistent findings.[78, 87] However, results of these studies should be interpreted with caution due to the potential for systematic differences between these groups.

One study from the UK NAAASP, reported across two publications, estimated that 87% of men with large AAAs underwent surgical repair, while 7% of men with small to medium AAAs underwent surgery during the study period.[264, 265]

Rate of elective surgery

Six studies, described across nine publications, reported on the rate of elective surgical repair.[75, 76, 78, 84, 87, 96, 264, 279, 280] Overall the elective surgical repair rate ranged from 268 to 858 per 100,000 men screened (see Appendix, Table A5).[78, 280]

Only one publication compared the rate of elective surgery between screened and unscreened cohorts; this found that the incidence of elective surgery for AAA was higher in the screened relative to the unscreened cohort.[279] The absolute difference

was 36 elective surgeries per 100,000 person-years (95% CI: 21 to 51) after six years of screening, equivalent to 220 additional elective surgeries per 100,000 men offered screening.

Two further publications compared screened males with non-attenders. The rate of elective surgical repair was reported to be higher among screened males, compared with non-attenders (see Appendix, Table A5).[78, 87]

In two publications the elective surgical repair rate was calculated as a percentage of the study-specific sub-population.[75, 264] Darwood et al. only reported the outcomes for a subsample of males with at least 10 years of follow-up, and estimated that 52% of men with a screen-detected AAA had elective surgery.[75] One study from the UK NAAASP reported that 83% of men with a large AAA underwent elective surgical repair.[264]

Rate of emergency surgery

Five studies, described in seven publications, reported on the rate of emergency surgery. [75, 78, 84, 87, 96, 264, 280] Overall the rate of emergency surgical repair ranged from zero to 88 per 100,000 men screened (see Appendix, Table A5).[87, 280] No study reported the rate of emergency surgery for screened relative to unscreened cohorts.

Two studies from Sweden reported lower rates of emergency rupture repair in the screened cohort relative to the group that declined invitation to screening.[78, 87] In two publications the emergency surgical repair rate was calculated as a percentage of the study-specific sub-population.[75, 264] Darwood et al. reported the outcomes for a subsample of males with at least 10 years of follow-up, and estimated that 3% of men with screen-detected AAA underwent emergency surgery.[75] One study from the UK NAAASP reported that 3% of men with a large AAA underwent emergency surgery.[264]

Pathway timings

Six studies provided data on time from initial screening to referral to vascular surgery or surgical treatment, stratified by aortic diameter (Table 4.8). As described in Chapter 2, section 2.4.2, baseline aortic diameter is related to AAA growth rate. Overall, as expected, over time, the percentage of patients reaching the surgical threshold of 5.5 cm and the percentage of patients undergoing surgery, increased with increasing aortic diameter at baseline. On average, approximately 35.1% (range 21% to 53%) of the patients with AAA ≥3.0 cm underwent AAA surgical repair within a mean follow-up ranging from 1.8 to 6.3 years. For subgroupings according to aortic diameter, variation between studies is likely attributable to differences in the length of follow-up across the studies.

Table 4.8 Time from initial screening to referral to surgery and surgical repair, stratified by baseline aortic diameter

Study, year	Mean aortic diameter at baseline (cm)	Follow-up	Percentage of patients undergoing surgery
Sub-aneurysmal AAA			
Svensjo 2013	2.5 to 2.9	At 5 years	0.0%
Mansoor 2023	2.5 to 2.9	Mean 8.2 years	0.6%
Darwood 2012	2.6 to 2.9	Mean 9.4 years	10.4%
Small AAA			
Mansoor 2023	3.0 to 3.9	Mean 1.8 years	5.4%
Hultgren 2020	3.0 to 3.9	Mean 3 years	2.1%
Svensjo 2013	3.0 to 3.9	At 5 years	20.0%
Darwood 2012	3.0 to 3.9	Mean 6.3 years	37.9%
Medium AAA			
Darwood 2012	4.0 to 5.4	21 months	65.7%
Mansoor 2023	4.0 to 5.4	Mean 1.8 years	60.8%
Hultgren 2020	4.0 to 4.9	Mean 3 years	29.6%
Svensjo 2013	4.0 to 5.4	At 5 years	83.3%
Small to medium			
Mansoor 2023	≥3.0 to 5.4	Mean 1.8 years	15.2%
Oliver-Williams 2019	≥3.0 to 5.4	Mean 2.5 years	7.0%
Hultgren 2020	≥3.0 to 4.9	Mean 3 years	7.3%
Svensjo 2013	≥3.0 to 5.4	At 5 years	40.5%
Darwood 2012	≥3.0 to 5.4	Mean 6.3 years	65.7%
Large AAA			
Darwood 2012	≥5.5	Not specified	84.5%
Mansoor 2023	≥5.5	Shortly after surgery†	100.0%
Meecham 2020	≥5.5	Within 8 weeks of diagnosis	86.7%
Svensjo 2013	≥5.5	At 5 years	100.0%
All AAA			
Mansoor 2023	≥3.0	Mean 1.8 years	20.6%
Hultgren 2020	≥3.0	Mean 3 years	22.8%
Wanhainen 2016	≥3.0	Mean 4.5 years	29.0%
Svensjo 2013	≥3.0	At 5 years	50.0%
Darwood 2012	≥3.0	Mean 6.3 years	53.2%

Key: AAA – abdominal aortic aneurysm.
† Time to surgery not reported.

Test accuracy

Four publications, including three unique studies, reported findings on the accuracy of ultrasound in detecting AAA, as defined by the respective authors.

In a Swedish study, eight false positive cases of AAA were reported, accounting for 1.2% of the cases identified during the initial ultrasound screening. The authors noted that most of these false positives occurred during the first year of implementing the screening programme. The underlying issue was a methodological error, specifically related to measuring the aortic diameter above the renal arteries.[78] One study from the UK NAAASP reported a false positive rate of 3.8% for large AAA;[264] 1.4% had an AAA less than 5.5 cm and were redirected to the surveillance pathway, and the remaining 2.4% were diagnosed with other conditions such as iliac aneurysms, bladder diverticulum, or renal cysts. An earlier report from the Gloucestershire Aneurysm Screening Programme, which employed a more conservative aortic diameter threshold of 4.0 cm or more for referral to vascular surgery, stated that all aortas of 4.0 cm diameter detected through screening underwent at least one additional ultrasound scan in a hospital setting, with no false positives identified.[82]

Non-intervention rate

Six studies, reported across seven publications, reported on the non-intervention rate for AAA surgical repair.[75, 76, 78, 79, 84, 87, 264] In the context of AAA screening, the non-intervention rate may be defined as the proportion of patients referred to vascular surgery that were not surgically treated for any reason (for example, patient declined surgery, inappropriate referral, unfit for surgical intervention). A subset of these studies also reported on the true non-intervention rate, that is, the proportion of patients that were declined for medical reasons.[264]

The non-intervention rate varied considerably across five studies. In two studies, the non-intervention rate was 0% (that is, all patients with large AAA underwent surgery).[84, 87] Two studies reported non-intervention rates of 10% and 14%,[76, 264] and in one study the non-intervention rate was 29%.[75] The notably higher non-intervention rate reported by Darwood et al. may be due to the longer period of follow-up relative to the other studies, which may result in a higher likelihood of age-related contraindications to surgery.[75] Additionally EVAR may not have been an option when the study began in 1990, and OSR may have presented challenges for older patients.

Meecham et al. reported that the true non-intervention rate among men with a large AAA referred for elective surgical repair was 8%. Of those, 19% underwent surgery following risk factor optimisation.[264] Svensjo et al. and Mansoor et al. reported that

no patients referred to vascular surgery were considered unfit for surgical intervention (true non-intervention rate 0%).[84, 87]

Additionally, Hultgren et al. reported the proportion of patients that did not enter the surveillance pathway after initial assessment. Approximately 4.5% of those followed up after screening did not undergo further surveillance due to the presence of severe comorbidities or personal preference.[78]

Harms

Eight studies, reported across nine publications, described the 30-day post-operative mortality (Figure 4.13). Of these, three studies presented comparative data for screening relative to no screening.[78, 87, 291] Five studies, reported across six publications, presented 30-day mortality for screened participants only.[8, 31, 75, 76, 84, 264]

30-day mortality for all surgical repairs

Six studies reported on 30-day mortality for all surgical repairs. One study reported no 30-day mortality in a five-year period among those who had been screened. The mortality rate among non-attenders could not be reliably calculated due to the small sample size (n = 2 cases).[87] The second study reported a 30-day mortality rate of 0.7 per 100 repairs in the screened cohort and 4.1 per 100 repairs in the non-participants arm (RR = 0.16, 95% CI: 0.02 to 1.52, p = 0.111).[78] The overall 30-day mortality rate in the screened cohort across six studies ranged from 0.0 to 5.5 per 100 surgical repairs.

30-day mortality for elective surgery

Three studies compared 30-day mortality for elective surgical repair between those with screen-detected AAA, and those who declined participation in screening (Figure 4.13),[78, 87] or those who were not offered screening.[291] In one study, there was no significant difference in 30-day mortality between participants and non-participants in screening (RR = 0.40, 95% CI: 0.08 to 2.05).[291] In the other two studies, sample sizes were too small to generate a reliable estimate of 30-day mortality.[78, 87] The 30-day mortality rate in the screened cohort across seven studies ranged from 0.0 to 3.3 per 100 elective surgical repairs.

30-day mortality for emergency surgery

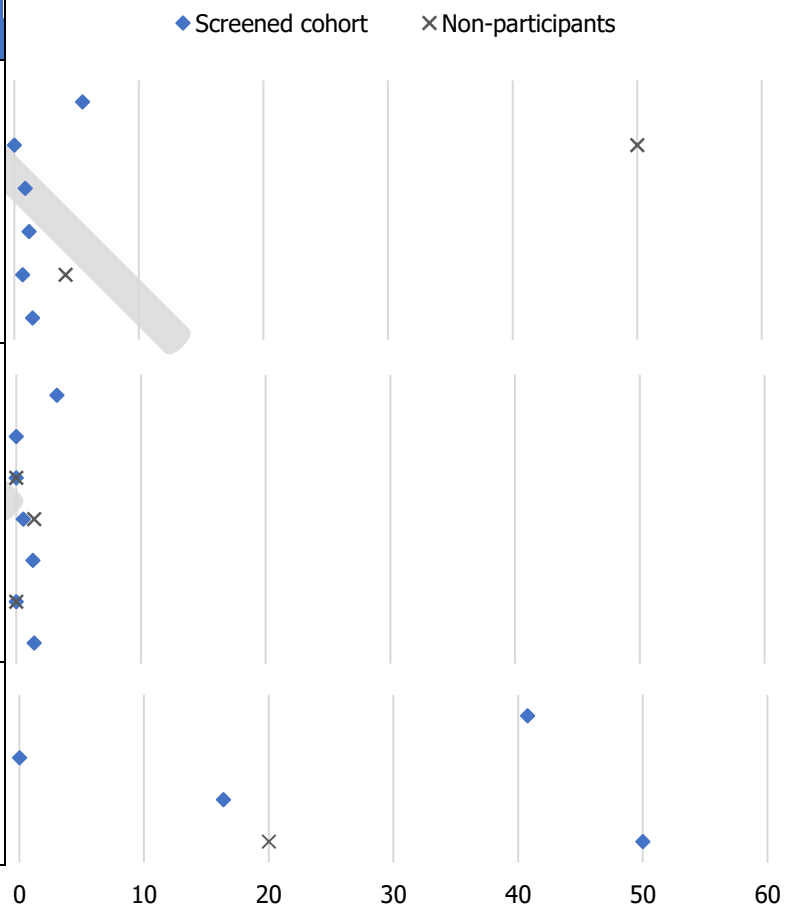
Two studies compared the 30-day mortality between those with screen-detected AAA, and those who declined participation in screening following emergency surgery.[78, 87] However, sample sizes were too small to facilitate a reliable estimation of the 30-day mortality rate.[78, 87] The 30-day mortality rate in the screened cohort

across four studies ranged from 0.0 to 50.0 per 100 elective surgical repairs.[75, 78, 84, 264]

Figure 4.13 Mortality at 30 days following overall surgical repair, elective repair and emergency repair

Study	Mid-year†	Screened cohort Events	Repairs	Rate x100	Non-participants Events	Repairs	Rate x100
Overall surgical repair 30-day mortality rate							
Darwood, R.	2000	25	456	5.5	-	-	
Svensjo, S.	2007	0	22	0.0	1	2	50.0
Wanhainen, A.	2010	6	683	0.9	-	-	
Meecham, L.	2013	30	2532	1.2	-	-	
Hultgren, R.	2013	1	151	0.7ǂ	3	73	4.1ǂ
Mansoor, S.	2015	1	68	1.5	-	-	
Elective repair 30-day mortality rate							
Darwood, R.	2000	14	429	3.3	-	-	
Duncan, J. L.	2003	0	54	0.0	-	-	
Svensjo, S.	2007	0	22	0.0	0	1	0.0
Linne, A.	2012	2	350	0.6ǂ	5	350	1.4ǂ
Meecham, L.	2013	33	2489	1.3	-	-	
Hultgren, R.	2013	0	149	0.0	0	58	0.0
Mansoor, S.	2015	1	70	1.4	-	-	
Emergency repair 30-day mortality rate							
Darwood, R.	2000	11	27	40.7	-	-	
Meecham, L.	2013	17	104	16.3	-	-	
Hultgren, R.	2013	1	2	50.0	3	15	20.0
Mansoor, S.	2015	0	2	0.0	-	-	

† The year shown represents the mid-point of the screening period for each included study.
ǂ No statically significant difference (p > 0.05) between the 30-day mortality rate in the screened cohort compared with non-participants.



Surgery-related adverse events

One cohort study reported surgical outcomes for men with screen-detected AAA, relative to those with AAA detected through usual care pathways (that is, men who could not have undergone population-based screening).[291] There was no significant difference in complication rates for the primary endpoint (defined as a combined endpoint of mortality and major adverse events, including acute myocardial infarction, stroke, amputation, bowel ischemia, and renal failure, within 30 days) or individual endpoints for open surgery or EVAR in screen-detected versus non-screen detected-groups.

Overdiagnosis and overtreatment

One stepped wedge study from the Swedish National Screening Programme reported specifically on overdiagnosis, defined as the excess risk or probability of having an AAA diagnosis in the screening cohort relative to the control cohort at six years' follow-up, and overtreatment, defined as overdiagnosed men who had elective surgery.[279] After six years of follow-up, the odds of having an AAA diagnosis were significantly higher in the screening cohort (n = 25,265) relative to the control cohort (n = 106,087) (OR = 1.52, 95% CI: 1.16 to 1.99), corresponding to an absolute increase of 0.49 percentage points (95% CI: 0.25 to 0.73). The incidence of elective surgery was also reported to be significantly higher in the screening cohort relative to the unscreened cohort (OR = 1.59, 95% CI: 1.20 to 2.10), corresponding to an absolute increase of 0.30 percentage points (95% CI: 0.14 to 0.45). This increase in elective surgeries was not fully offset by a -0.10 percentage points (95% CI: –0.19 to 0.02) decrease in AAA ruptures. They therefore estimated the risk of overtreatment as 0.19 percentage points (95% CI: 0.01 to 0.37), equivalent to 190 potentially avoidable elective surgeries per 100,000 men offered screening.

Quality of life and psychosocial harms

Ten studies, reported across 12 publications, investigated the impact of AAA screening on psychosocial outcomes or quality of life.[266, 294-304] Nine studies, comprising 11 publications, reported outcomes for men with screen-detected AAA versus those with a normal aorta at various time points.[294-304] One study reported on measures of general health and anxiety of depression pre and post-screening in the screen-detected AAA group.[266] Further subsets of these studies reported outcomes for men managed with surveillance versus those on the waiting list for surgery or who underwent surgery,[294, 299, 301] or measured the psychosocial consequences of an AAA diagnosis among men with screen-detected AAA measured with a condition-specific questionnaire.[295, 296, 298]

Results of the VIVA trial demonstrated no significant difference in general health and anxiety or depression scores between baseline and one year of follow-up in those with screen-detected AAA.[266] Of those with screen-detected AAA who completed a quality-of-life questionnaire, 6% reported increased anxiety during the follow-up period.

Two studies, comprising three publications, assessed health status among men with screen-detected AAA, compared with a normal aorta, using generic questionnaires before and up to one year post-screening.[294, 304] In a subsample of participants from the MASS trial at six weeks post screening, there were no differences in measures of anxiety, depression or the EQ-5D weighted health index between the screen-positive and screen-negative groups.[294] Those with screen-detected AAA, however, had significantly lower scores on the physical and mental subscales of the SF-36, and lower self-rated health as measured by the EQ-5D, compared with the screen-negative group. At all time points, anxiety, depression, and health status measures were within the age-matched and sex-matched population norms. A second study from the MASS trial reported no significant difference in the mean decline in self-assessed health between groups at six weeks post screening. Prior to screening, self-assessed health was poorer among men in whom an AAA was later detected, compared with those with a normal aorta.[303] In a subsample of participants from the Western Australian trial,[304] men with (n = 97) and without AAA (n = 189) had non-significant improvements in the mean level of perceived general health from baseline to 12 months' post screening.[304] Of note, consistent with the findings of Ashton et al., the mean age-adjusted score for self-perceived general health before screening was significantly lower in men subsequently found to have an AAA compared with men with a normal aorta.

A further two studies also reported on health status as measured with generic questionnaires. However, results were available up to six months' follow-up only.[300, 302] Results from the Gloucestershire Aneurysm Screening Programme indicated no difference in general health questionnaire scores between the screen-detected (n = 61) and normal aortic diameter (n = 100) groups before and one month after screening. There was a statistically significant decrease in anxiety levels in both groups at one month post screening. Of note, over 90% of men reported that the information sheet was helpful and informative, over 95% had a clear understanding of the reasons for screening and over 95% clearly understood that the screening test may result in referral for surgery.[302] A study based in Broken Hill in Australia found that baseline quality of life, as measured with the Medical Outcomes Study Short Form 36 (MOSF36) and the Hospital Anxiety and Depression scale (HADS), was slightly worse among men with AAA (n = 53), relative to those with a normal aortic diameter (n = 130), however, differences were not statistically significant.[300] The mean difference in the general health score increased in both men with AAA (n

= 33) and those with a normal aorta (n = 81) between baseline and follow-up, indicative of better self-perceived health, although the difference was only statistically significant for the group with an abnormal aorta.[300]

Four studies measured quality of life using generic instruments in those with and without screen-detected AAA at one to two time points post screening only.[295, 296, 298, 301] A single-centre study in Sweden found that men with AAA reported more problems with physical functioning, pain, and general health, compared with men without AAA, within 12 weeks of screening.[298] Six months post-screening, men with AAA reported more problems with physical functioning and significantly higher levels of disease-related stress compared with men without AAA. No differences were observed for other outcome measures.[298] Similarly, in a subsample of participants from the Viborg trial, men with screen-detected AAA showed a lower score as measured with ScreenQL, relative to controls.[301] Conversely, a study based in a single centre in England reported no significant difference in measures of anxiety and depression between patients with screen-detected AAA and normal aortic diameters.[299] A fourth study which included participants from the English and Welsh screening programmes showed that men with AAA experience significantly lower physical health, as measured with the MOSF36 questionnaire, up to 36 months' post-screening. However, differences were not statistically significant at or beyond 37 months post-screening. For the mental health component, scores were significantly lower in the first year post screening only; no significant differences were identified at any other time point at or beyond 37 months.[295]

Three studies asked men participating in the screening programme questions relating to the AAA screening pathway, using validated or non-validated disease-specific questionnaires.[295, 296, 298] Results of a cross-sectional survey undertaken at one to 24 months post screening among men participating in the Swedish AAA screening programme demonstrated that, in general, men with screen-detected AAA reported more negative psychosocial consequences except for the following items: 'regret of the screening examination' and 'feeling terrified'.[296] Of men with and without screen-detected AAA, 96.2% and 99.6%, respectively, did not regret participating in screening.[296] Only 9% of men with AAA reported feeling that they would have been better off not knowing. More than half of men with AAA were anxious about the potential for rupture, in particular during intense physical exercise or sexual activity. Overall, men diagnosed with AAA were significantly more likely to report a desire to change their lifestyle habits, including considering smoking cessation. Among men with AAA diagnosis, approximately 22% had sought knowledge about disease progression. Due to the cross-sectional design of this study, it was not possible to evaluate potential for changes over time.[296] For men diagnosed with AAA as part of the Welsh and English AAA screening programmes, over time there was evidence of a progressive reduction in the frequency with which

men thought about the aneurysm, relative to the first year post-screening.[295] In contrast to this evidence suggesting that any negative psychological consequences of AAA screening may be transient, results from a single-centre study in Sweden demonstrated that among those with a diagnosis of screen-detected AAA, there was a decrease during follow-up in the number of patients reporting to be sufficiently informed about the diagnosis and glad to know they have an AAA.[298]

Three studies investigated the psychosocial impact of the management approach (that is, surgery or surveillance) for patients with screen-detected AAA. Overall, there is evidence to suggest that patients with screen-detected AAA managed with surveillance may experience a greater psychosocial burden, relative to those eligible for surgery. Comparison between screen-detected participants undergoing surgery and surveillance in a subsample of the MASS trial demonstrated initial differences in the mental health component of the SF-36 and EQ-5D self-rating at three months' follow-up.[294] By 12 months' follow-up, there were no differences between patients who underwent surgery and those undergoing surveillance in the SF-36 mental or physical health component, or measures of anxiety or depression. However, the EQ-5D self-rated health measure remained significantly lower in the surveillance group compared with those who had undergone surgery.[294] In a second study, there appeared to be more patients with higher scores for anxiety and depression (indicative of greater severity) in the 'on waiting list for repair' and 'small aneurysm at one month' groups, relative to controls. However, the differences were not statistically significant.[299] A substudy of participants in the Viborg trial showed lower quality of life scores among men with small AAA managed through surveillance compared with controls, which was reported to be attributable to poorer health perception and distress.[301] Scores declined further relative to controls during follow-up, but improved post-operatively for patients who later met the threshold for surgery.[301]

Quality appraisal

Quality appraisal of studies with clinical and safety outcomes

The results of quality appraisal undertaken for this review reflect the ability of included studies to answer the specific research question of this review; the aims of individual studies may differ from the aims of this review. For studies reporting on clinical effectiveness and safety outcomes, 17 studies were considered good quality and one of moderate quality. In general, the weakest areas related to reporting of the diagnostic pathway (7 publications),[76, 82, 84, 96, 279, 290, 291] care pathway and follow-up (4 publications),[8, 82, 279, 291] and conflict of interest (3 publications)(Figure 4.14).[76, 82, 290]

In one study judged to be of moderate quality[279] and three judged to be good quality[8, 84, 291], the criteria for selecting the study population, information about the processes for inviting the eligible population for screening, and some or all aspects of the care pathway (including testing, referral, diagnosis and follow-up) were either missing or incomplete.

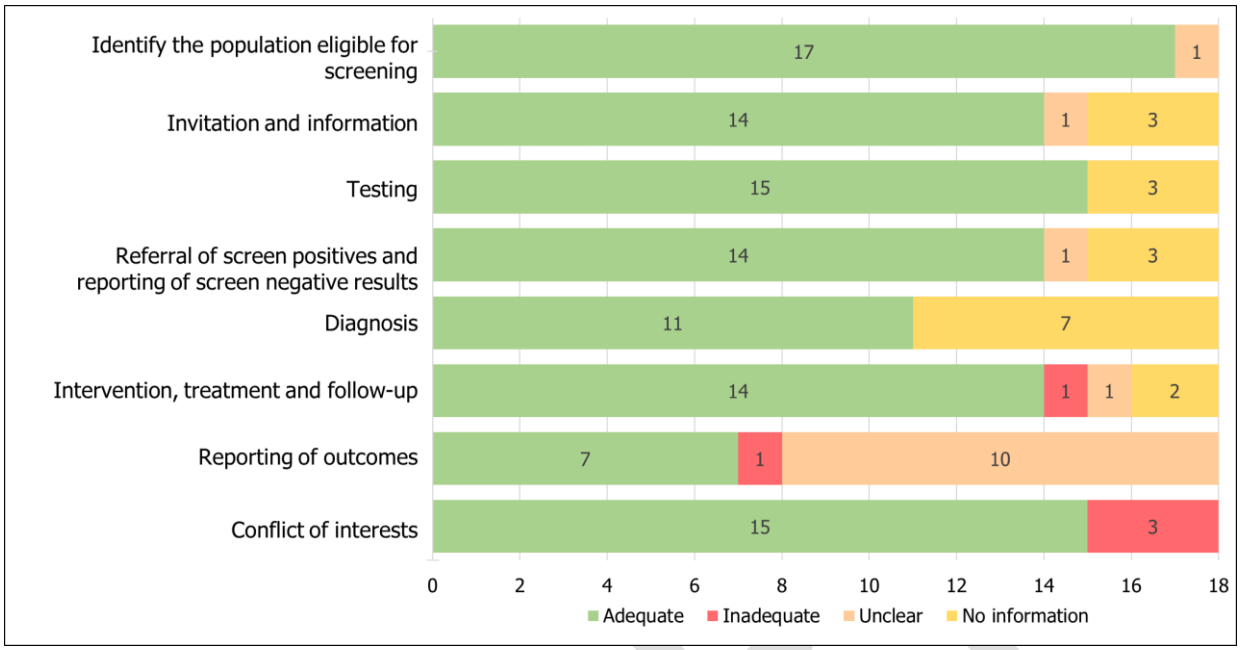
As for the reporting of outcomes, only the three studies from the Huntingdon Aneurysm Screening Programme[280, 292, 293] used an intention-to-treat analysis (that is, based on whether an invitation had been given, rather than on whether screening had taken place) to minimise the potential for volunteer bias. Duration of follow-up was considered reasonable in all studies except for an early study reporting the results from the initial two years of the Gloucestershire Aneurysm Screening Programme only.

For the purpose of our analysis, only three studies clearly defined AAA-related mortality, AAA rupture and-or 30-day mortality.[8, 279, 291] In eleven publications the reporting of outcomes was unclear or inadequate. Issues included lack of reporting of absolute numbers of events,[279] reporting of outcomes for specific subpopulations only (for example, small to medium AAA),[75, 79, 264, 265] lack of clarity around outcome definitions,[31, 75, 76, 79, 264, 265, 280, 292, 293] and incomplete reporting of outcome data including the number of AAA repairs,[8] AAA-related mortality,[8, 280, 292, 293] and AAA ruptures.[31, 76]

Studies reporting on AAA-related mortality and all-cause mortality were associated with limitations due to the nature of these outcomes. Authors relied on national death registries and medical records to identify the cause of death. Only two studies reported systematically checking autopsy reports of those with sudden death, where conducted.[75, 280] Despite the efforts to reliably calculate the AAA-related and all-cause mortality rates, the results might overestimate AAA-related deaths in patients known to have AAA. Conversely, the results may potentially underestimate AAA-related deaths in participants who did not have an AAA at screening, for example, and where such deaths took place outside of hospital and where an autopsy was not conducted.

Only four studies compared outcomes for screened versus unscreened groups,[8, 279, 280, 291] and of these, only two presented an adjusted analysis.[279, 291] For non-randomised studies, the distribution of important risk factors (for example, family history, comorbidities, smoking status, medication use) has the potential to influence outcomes.

Figure 4.14 Quality appraisal of studies reporting on clinical effectiveness and safety outcomes



Quality appraisal of studies with psychological outcomes

For studies reporting on psychological outcomes, one study was considered to be of good quality,[295] four studies study were considered moderate quality,[266, 294, 296, 304] and five studies were considered poor quality (Figure 4.15).[298-302] Key areas of concern related to the validity of quality of life instruments, inadequate reporting of the care pathway, insufficient length of follow-up, and concerns regarding the statistical approach (for example, appropriateness of comparisons and potential for underpowering of studies).

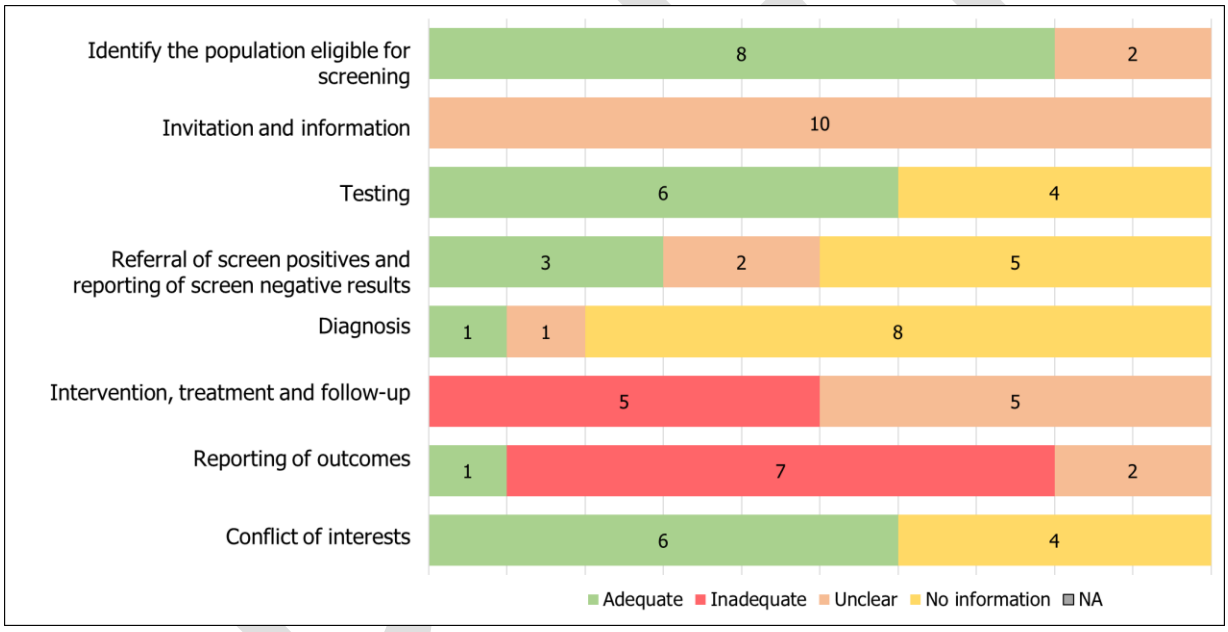
Ideally, psychosocial health outcomes within this population would be explored before, and periodically after, screening. In all studies,[266, 294-296, 298-302, 304] the timing of assessment or duration of follow-up was considered insufficient to assess potential for changes over time. Furthermore, for studies using generic instruments to measure aspects of quality of life (n = 9), the sensitivity of these tools in the context of AAA screening was uncertain. Where disease-specific questionnaires were used (n = 3),[295, 296, 298] the questions used have been shown to have high content validity in one study only.[296]

Concerns regarding the representativeness of participants related to failure to report survey response rates,[295, 299, 302] or lack of clarity surrounding recruitment methods.[298] Four studies explicitly reported that they were likely underpowered to detect differences between groups due to small sample sizes.[298-300, 304] In many of the included studies, investigation of statistical differences between the AAA and normal aorta groups were based on cross-sectional measures at follow-up only, rather than the between-group mean difference between pre-screening and follow-

up. This has the potential to lead to erroneous conclusions given evidence to suggest that those with screen-detected AAA may have lower baseline health status, even in the absence of screening.[300, 301, 303] Furthermore, sample size imbalances between groups may increase the risk of type II error. It is acknowledged, however, that the sample size in the screen-detected AAA group is dependent on the disease prevalence and survey response rate. Therefore, larger sample sizes may not be feasible.

Although participants in three studies were asked about their satisfaction with the information received,[296, 298, 302] details of informed consent processes and post-diagnostic supports were not described in any of the included studies, which presents challenges for interpretation. Furthermore, the care pathway for patients who reported evidence of psychosocial harms was not described in any of the identified studies.

Figure 4.15 Quality appraisal of studies reporting on psychosocial outcomes



4.3.3 Targeted screening

As outlined in Chapter 1, the scope of this assessment was limited to consideration of population-based screening in men aged 65 years relative to no systematic screening. However, given the declining prevalence of AAA (Chapter 2, sections 2.6.1 and 2.9.1) and the potential implications on the benefit-harm balance of population-based screening, a targeted screening approach may nonetheless warrant consideration.

As outlined in Chapter 3, section 3.1, targeted screening may be defined as a programme which aims to identify individuals who are at a higher risk of developing the disease due to factors other than age or sex, including genetic variants, lifestyle

factors or comorbidities.[322] The focus of this section is on risk factors other than age or sex. Risk factors associated with an increase in the relative risk of a disease are typically identified from epidemiological research.

Relevant literature was identified from the USPSTF systematic review that considered the following research question:[141, 273]

- Do the effects of one-time screening for AAA vary among subpopulations (that is, by age, sex, smoking status, family history, or race/ethnicity)?

The USPSTF systematic review included RCTs only. However, due to the scarcity and limitations of the RCT evidence, additional literature was considered in the discussion of the review. All relevant evidence from the USPSTF review is considered in this HTA. A systematic search looking specifically for studies comparing risk-based screening with population-based screening was not undertaken for the purposes of this assessment, as it is considered likely that any new high-quality comparative evidence would have been identified by the search strategy outlined in section 4.2.1, or through additional scoping.

The following clinical trial registries or databases were searched for ongoing studies:

- ClinicalTrials.gov
- ISRCTN Registry
- EU Clinical Trials Register
- The WHO International Clinical Trials Registry Platform (ICTRP).

Clinical effectiveness of AAA screening in subgroups

No population-based screening trials comparing low- and high-risk screening approaches were identified as part of the USPSTF systematic reviews.[141, 273] The Viborg, Western Australia and VIVA trials reported subgroup analyses stratified by comorbidity status, smoking history and family history of AAA, respectively.[313, 316, 323] However, these were subject to considerable limitations, as described below. There is a lack of evidence examining the role of other risk factors in differential screening effectiveness or safety.

No additional studies (other than those in the USPSTF reviews) were identified comparing the clinical effectiveness and safety of population-based and targeted screening approaches.

Comorbidity status

One RCT, the Viborg trial, conducted subgroup analysis comparing high- and low-risk screening approaches based on hospital discharge data.[313] The 'high-risk' group included participants with one or more of the following conditions: hypertension,

myocardial infarction, COPD, ischemic heart disease, peripheral arterial disease, stroke, or transient ischemic attack.[313] Men with none of these risk factors were allocated to the 'low-risk' group.[313] Limiting screening to men at 'high-risk' would have reduced the number of screened individuals by 73%; however, this in turn would have meant that the AAA-related deaths that would be prevented would be 47% of those avoided by population-based screening in men aged 65 years.[313]

It is important to note that comorbidities were determined based on hospital discharge data. Errors in comorbidity reporting and lack of information about smoking habits bias the results towards the null hypothesis. Furthermore, identification of risk based on comorbidity status alone would likely result in underestimation of the risk of AAA-related morbidity and mortality, which would bias the estimated impact of 'high-risk' screening towards a lesser effect.

Smoking status

Only one RCT, the Western Australia trial, reported outcomes by smoking status in the screened group.[316] The results demonstrated that smoking was associated with a higher risk of all-cause mortality (OR 1.59, 95% CI: 1.47 to 1.72) and AAA-related mortality (OR 2.95, 95% CI: 1.04 to 8.43) in the screened group of men ages 64 to 83 years.[316] However, the study was not powered to detect subpopulation differences, a formal test for interaction was not performed, and data in the unscreened group were not reported.

Family history

The VIVA trial was the only RCT identified that estimated the prevalence of familial AAA. In the screened cohort, the prevalence of AAA in men aged 65 to 74 years with at least one first-degree relative with an AAA was double the prevalence of those without a family history (6.7% versus 3.0%).[323] However, familial history was based on the knowledge of participants which may lead to recall bias as those with an AAA may be more likely to remember familial history than those without. This could possibly bias the results towards an increased difference between groups.

Ongoing studies

One ongoing in-silico trial (that is, results are modelled or simulated) of targeted screening compared with population-based screening in men ages 65 was identified.[324] As part of this study, patient-level data for all men invited to AAA screening between 2013 and 2022 (N = 2.5 million) will be linked with data the Clinical Practice Research Datalink (CPRD), a database containing coded and anonymised patient-level data from GP practices in England.[324] The study aims to establish targeted AAA screening criteria through development of a multivariable risk prediction model including demographic and clinical risk factors for AAA.[324] It was

noted that the only significant risk factor for AAA not routinely collected in the CPRD is family history of AAA. The long-term clinical and economic outcomes of targeted screening compared with population-based screening will be estimated using an established discrete event simulation model.

Risk scores

In the absence of robust subgroup analyses, or empirical evidence comparing alternative screening strategies, risk prediction models have been developed in an attempt to more accurately predict an individual's risk of AAA based on a broad range of demographic and clinical risk factors.

Using data from large cohort studies or RCTs, at least five risk scores have been developed between 2000 and 2024 to predict those most of risk of AAA-related morbidity and mortality.[24, 325-328] There is variation in the number of variables used across identified risk scores, with a minimum of eight variables contributing to the overall risk score.[328] The results of these analyses suggest that using a risk prediction tool could be a reasonably effective and relatively efficient (in terms of cases detected per person screened) approach to identification of cases, compared with targeted screening of 'ever smokers', or population-based screening. However, the authors of the USPSTF systematic review concluded that, although promising, external validation of such risk prediction models would be necessary prior to clinical application.[141]

Retrospective analysis of risk factors among men participating in the Swedish AAA screening programme

A retrospective analysis of risk factor data recorded in a health questionnaire among men participating in four local AAA screening programmes in Sweden between 2006 and 2010 suggests that targeted screening could detect most AAAs in the population while screening significantly fewer individuals.[30] A smoking history of ≥30 years and presence of coronary artery disease (defined as history of angina pectoris or myocardial infarction) was considered the optimal approach: 74% of cases would be detected by screening 33% of men aged 65 years.[30] However, given the potential lethal nature of AAA and the safety of ultrasound screening, a lower specificity would be considered reasonable in order to maximise the number of AAA cases detected by a targeted screening programme.[30] Considering duration of smoking as a risk factor only, decreasing the minimum duration of smoking progressively resulted in small gains in sensitivity, compared with a population-based screening approach.[30] A risk-based approach including ≥10 years of smoking, presence of coronary artery disease, or both, would detect 86% of AAAs, by screening 59% of the population.[30] A simplified strategy targeting those with a smoking history of ≥1 year was estimated to detect 85% of all AAAs, by screening 61% of the population.[30]

While the results of this analysis suggest that a targeted screening strategy based on smoking history alone may be a simple and effective approach to maintaining a high AAA detection rate, while reducing resource consumption relative to population-based screening, further studies are needed to evaluate the feasibility and safety of targeted screening.[30] Reports of poor uptake in targeted AAA screening programmes in France and the US suggest that the results of modelling studies may not translate into practice.[30]

Considerations for a risk-based screening approach

In light of declining AAA prevalence, more targeted approaches to AAA screening may increase efficiency and acceptability. Benefits and harms of screening may differ between people with different risk factors. For example, a comorbidity-based approach to AAA screening would likely result in an increased yield in terms of cases detected per person screened.[329-332] However, it is likely that the presence of severe comorbidities may increase the risk of post-surgical complications or compromise a person's ability to attend surveillance appointments.[273, 333] Furthermore, a comorbidity-based targeted screening approach would likely substantially underestimate AAA risk. It is worth noting that in the Irish context, targeted screening in a population previously hospitalised for existing cardiovascular conditions or COPD would largely reflect the population already identified through incidental diagnosis or GP referral. Thus, the additional yield from a systematic, comorbidity-based, targeted screening programme would likely be low.

As outlined in Chapter 2, section 2.3.1, in addition to age and sex, the dominant risk factor for AAA is smoking.[6] The strength of the association between smoking and AAA development has meant that current or past smoking has been used as an additional risk factor to inform more targeted identification of the population for screening in clinical guidelines and international practice (see Chapter 3, section 3.5). It is estimated that a targeted AAA screening programme including 'ever smokers' aged 65 years would likely result in a 40 to 50% reduction in the population eligible for screening,[39, 334] and detect over 85% of cases of AAA, relative to population-based screening approach.[23, 28, 30, 70] While it has been suggested that screening could be further limited to current male smokers at age 65,[335] the risk of missed cases would be increased.

As described in Chapter 3, section 3.5.3, a risk-based AAA screening programme based on smoking status has been implemented in men aged 65 years in the US.[224] However, uptake is reported to be low.[336] No other formal risk-based screening programmes were identified. In France, one-time, opportunistic targeted screening based on smoking history and family history has been recommended by HAS.[231] However, this has not been implemented as a formal screening programme, and uptake is said to be low.[252, 253] Although these contexts are not directly transferable

to the Irish setting, the potential for lower uptake with a targeted screening programme may result in suboptimal clinical outcomes. The potential for the screening strategy (population-based versus targeted) to impact uptake will be considered further in Chapter 7 (Organisational considerations).

Targeting AAA screening towards men with a history of smoking may be more efficient than population-based screening, however, as a single risk factor, 'ever smoking' cannot identify all cases of AAA in men aged 65 years. Due to the absence of studies comparing alternative screening approaches, it is not known if a targeted screening strategy would miss a clinically important number of non-smokers with AAA, and the associated impacts on AAA-related morbidity and mortality. A robust, externally-validated, risk prediction tool to accurately identify those most at risk of AAA-related morbidity and mortality has not yet been developed. Ongoing work to identify a set of risk factors to predict AAA risk by linking the NAAASP and CPRD datasets will be important to identify the optimal set of criteria to inform a risk-based screening programme.[324] However, results of this study are not expected to be available in the short-term, and would likely require further external validation prior to widespread clinical application.

The clinical utility of a risk prediction tool in the context of a national screening programme will be dependent on the nature and number of variables included. While such risk scores may be useful at an individual patient level, at a population level, in the absence of an integrated electronic health record in Ireland, the up-to-date clinical information required to populate such risk scores (for example, high blood pressure, high cholesterol) is unlikely to be readily available for all members of the potentially eligible population. Collection of the necessary risk factor data to inform risk stratification prior to issuing an invitation to screening may negate potential efficiencies associated with the implementation of a risk-based screening approach.

4.3.4 Outcomes of the UK abdominal aortic aneurysm screening programme

The UK NAAASP was introduced on a phased basis from 2009, with the screening programme fully operational across the UK by 2013. A review was recently conducted in the UK to consider whether the NAAASP had been effective in its first decade (April 2013 to March 2023). The aim was to review data collected by the four UK programmes (England, Scotland, Wales and Northern Ireland), in addition to examining national statistics on hospital admissions and deaths related to ruptured AAA, supplemented with vascular registry data. Cost-effectiveness analysis, qualitative quality of life research (literature review) and a quantitative analysis of inequality were also included. The following summarises the findings of this review, as reported by the authors.

Detection rate of AAAs

The prevalence of AAA declined in the UK between 2013 and 2023, from 1.2% to 0.8%, respectively. Most aneurysms detected at the initial screen were small (3.0 to 4.4 cm); about 10% of aneurysms were medium (4.5 to 5.4 cm), and 5 to 10% were large (over 5.5 cm), the latter being referred for assessment of suitability for surgical intervention.

Mortality from ruptured AAA

Based on data from the Office for National Statistics, the review found that the proportion of deaths from AAA rupture in men aged 65 years and over reduced yearly across the UK between 2013 and 2022. In England and Wales, the percentage of deaths from AAA rupture declined from 1.02% in men aged 65 years and over in 2013 to almost half of this (0.55%) in 2023. The reductions in Northern Ireland and Scotland were proportionally lower, but, in all four countries, by 2022, ruptured AAA accounted for approximately 0.60% of deaths in men over 65 years.

Morbidity

Ruptured AAAs

Although rates of ruptured AAA declined generally during this period, the reduction was greater in the cohort offered screening. The number of ruptured aneurysms recorded as treated by UK vascular surgeons fell by more than half from approximately 1,000 in 2013 to just under 500 by 2022. In the screened age group (65 to 74 years), ruptured aneurysms declined from 350 in 2013 to approximately 100 in 2022.

Referral and surgical interventions

As a percentage of total elective AAA repairs in the UK, the percentage of men referred from the AAA screening programme increased over time, from approximately 2% in 2015 to 30% in 2022. In total, of the 7,500 men referred to vascular surgery from AAA screening programmes, 75% were referred from surveillance.

Rate of elective surgery and surgical outcomes

Between 2023 and 2022, a total of 6,253 men underwent elective AAA repair in England. The rate of elective repairs was estimated based on the size of the eligible population and uptake rate reported. In 2013, the rate of elective repairs per 100,000 screened males was 222, which increased to 281 in 2022, peaking at 370 in 2020.

Safety

Short-term post-operative mortality

The risk-adjusted in-hospital mortality rate for elective AAA treatment was found to have remained at around 1.5% since 2012, with elective OSR having a higher mortality rate than elective EVAR (3.0% vs 0.5%). The number of in-hospital deaths after ruptured AAA repair decreased over time from the peak in 2014, reflecting a reduction of approximately 50% in 2022. Overall, the risk of surgery-related mortality for screen-detected AAA was low, and within the target range (<3.5% elective mortality).

Quality of life

Based on a review of the literature performed for the UK report, men under surveillance reported lower health-related quality of life compared to those with negative scans and the general population.[337] The report noted that qualitative studies included in a relevant systematic review found that men experience shock and anxiety despite being under surveillance.[338] Partners of men with screen-detected AAA also reported negative impacts on their wellbeing and day-to-day lives including worry, being reminded of fragility, and managing a changing relationship.[339] The report also referenced a quantitative study in the UK which also showed worse mental health in those diagnosed with AAA compared with those with negative screen results, although this difference disappeared after 12 months.[295] However, a recent systematic review referenced in the report concluded that current evidence did not support a negative impact on quality of life from being in surveillance.[276]

Findings in context

Overall, following the introduction of the AAA screening programme in the UK, the number of AAA ruptures declined, while the rate of elective surgical repair of screen-detected AAAs increased over time. Given that AAA prevalence declined by approximately one third during this period, a corresponding decrease in AAA-related mortality and AAA rupture would be expected. However, the UK review authors concluded that declining AAA prevalence and cardiovascular risk factor reduction were unlikely to have reduced mortality from ruptured AAA by the magnitude observed; AAA screening was considered to have accelerated the existing rate of decline in aortic disease. In Ireland, a decrease in AAA-related mortality has also been observed over time, even in the absence of an AAA screening programme (Chapter 2, section 2.8.1), likely due to improved cardiovascular risk factor management and increasing incidental diagnoses. AAA-related mortality appears to be comparable between Ireland and the UK. As outlined in the UK review, by 2022, ruptured AAA accounted for approximately 0.6% of all UK deaths in men over 65 years. Similarly, data from the CSO in Ireland indicate that by 2020, AAA-related

mortality accounted for 0.6% of all deaths in men in Ireland aged over 65 years (see Chapter 2, Figure 2.10).

As noted in the UK review, at the time of the decision to commence AAA screening in the UK (recommended by the National Screening Committee in 2005), peri-operative outcomes for elective AAA surgery were among the worst in Europe.[340, 341] To support implementation, in 2009 the Vascular Society of Great Britain and Ireland (VSGBI) set standards for treatment of AAA in a quality improvement framework. The review authors concluded that the VSGBI quality improvement framework supported reductions in surgery-related mortality for EVAR and OSR since the introduction of the programme.

The authors recommended that the UK National Screening Committee review the outcomes of the programme again in five to 10 years to ensure continued effectiveness of the programme in the context of declining AAA prevalence. Based on the results of the UK review, quality of life and inequity issues were identified as potential targets for improvement. For countries with similar smoking habits and documented low AAA prevalence and which are considering the introduction of an AAA screening programme in men, the authors recommended that consideration should be given to targeted screening for AAA as an alternative to population screening.

4.4 Discussion

4.4.1 Summary of findings

Based on the evidence from one high-quality systematic review, including four RCTs, invitation to one-time screening for AAA in men contributes to a reduction in AAA rupture rates and AAA-related mortality, relative to the scenario where population-based screening is not in place. Reductions in AAA rupture rates and AAA-related mortality were accompanied by an increase in the number of elective surgeries undertaken, and to a lesser extent, a decrease in the number of emergency surgeries, compared with no screening. In terms of potential harms, evidence from RCTs indicated no significant differences in 30-day postoperative mortality for elective and emergency surgeries, compared with no screening.

For other study designs identified through the de novo review, limited comparative evidence was available (n = 4 studies). Where reported, AAA rupture rates and AAA-related mortality were lower in the screened group, compared with the unscreened group. In one study, there was no significant difference in 30-day mortality or surgery-related complications between those with screen-detected AAA and age-matched controls. For non-comparative studies, there was evidence of significant variation between studies in terms of AAA ruptures, AAA-related mortality, and surgical intervention rates. These differences may be related to factors such as differences in the timing of individual studies, length of follow-up, population characteristics, or methodological differences.

In terms of potential psychosocial harms, observational evidence suggests that screening for AAA may negatively impact psychosocial outcomes in men diagnosed with AAA due to factors such as fear of rupture or concerns regarding engaging in physical activity. While limited longitudinal data are available regarding potential longer-term psychosocial impacts of a diagnosis of screen-detected AAA, the available evidence suggests that negative psychosocial consequences may be transient.

4.4.2 The benefit-harm balance

A fundamental principle of screening is that the overall benefit gained by the population should outweigh any harms.

Although there is evidence to suggest that AAA screening reduces AAA-related morbidity and mortality through a reduction in AAA rupture rates, this must be balanced against the potential harms of AAA screening which include overdiagnosis and its potential psychosocial consequences, and the risks of perioperative mortality associated with elective surgical repair.

Given that the aim of AAA screening is earlier detection and subsequent elective surgery to circumvent rupture, initial increases in the diagnoses of AAA and elective surgical repair are expected. All five screening RCTs reported more AAA-related operations in the screened group than in the unscreened group, corresponding to an estimated increase of 8 per 1,000 men invited to screening at 13 to 15 years' follow-up. The reduction in AAA-related morbidity and mortality in the screened cohort due to preventive surgical intervention may be offset, to some extent, by an increase in operative mortality following elective surgery – a potential harm of screening.

Importantly, however, evidence from RCTs demonstrates that there is no significant difference in 30-day postoperative mortality following elective surgery between the group invited to screening and the no screening group at any time point up to 13 to 15 years' follow-up.[140] It is also plausible that the potential for earlier intervention as a result of screening may be associated with improved fitness for surgery (for example, less frailty, fewer comorbidities or less advanced disease), and a corresponding decrease in surgery-related adverse events. Only one study compared the rate of surgery-related adverse events in screened and unscreened cohorts, finding no significant difference between the groups.[291] However, this study was likely underpowered, and therefore, a conclusive answer regarding differences in the risk of surgical complications between patients with screen-detected and non-screen-detected AAA cannot be drawn.

Many cases with screen-detected AAA would not be eligible for elective surgical repair at the time of diagnosis. Based on the evidence from studies identified from the de novo review, it is estimated that between 89% and 94% of screen-detected AAA cases would not meet the criteria for surgical intervention at the time of diagnosis, and would thus enter a surveillance care pathway. Where reported, data relating the progression through the care pathway suggest that for cases with a small AAA, in particular, a considerable proportion of cases may not reach the threshold for surgical intervention at a time in their life when they would be considered a candidate for elective surgery. In general, surveillance may be considered an appropriate management approach where the risk associated with non-intervention is less than the risk associated with intervention. One study reported AAA-related mortality amongst those with small and medium screen-detected AAAs under surveillance stratified by aortic diameter; the cumulative incidence of rupture was 0.4% and 0.6%, respectively.[265] In screened cohorts, the 30-day mortality rate following elective surgeries ranged from 0% to 3%. Although 30-day mortality estimates for those who meet the threshold for elective surgery cannot be directly applied to those with smaller aneurysms, it is likely that the risk of surgery-related mortality with elective AAA repair exceeds the risk of rupture in those with small-to-medium AAAs.

For men who enter the surveillance pathway, but never reach the threshold for surgery, this could be considered overdiagnosis. If overdiagnosis did not occur, the initial increase in AAA diagnosis would directly correspond with a later reduction in AAA rupture and AAA-related mortality. However, the available evidence, although limited, suggests this is not the case. That said, it is important to recognise that although some patients may not meet the threshold for surgery or may not be surgical candidates, these patients may still benefit from interventions to support cardiovascular risk factor reduction including lifestyle changes, smoking cessation and pharmacotherapy, as appropriate, which, may help to slow or arrest disease progression.[342] Results of a cross-sectional survey of men participating in the AAA screening programme in Western Sweden indicate that approximately half of male smokers diagnosed with AAA considered stopping smoking, suggesting that screening may support positive behaviour change.[296] Furthermore, an analysis of primary care patient records in the UK demonstrated that compliance with recommended medications has been shown to increase survival in patients with AAA.[343] The potential benefits associated with cardiovascular risk factor reduction in this population are not limited to avoidance of AAA rupture, given the high prevalence of cardiovascular comorbidities (Chapter 2, section 2.4.4). Therefore, it would be important that all identified cases have access to interventions to support cardiovascular risk factor reduction so that all cases yield some benefit from a diagnosis of screen-detected AAA.

However, the requirement for ongoing surveillance amongst those with small and medium sized AAAs has the potential to cause psychosocial harms. Consistent with the findings of this review, the results of the 2019 USPSTF review, which included five studies, reported varying results in terms of the impact of AAA screening on quality of life, but in general, there was no evidence of substantial differences between screen-positive and screen-negative participants at up to 12 months' follow-up.[140] While the overall conclusions of a 2020 systematic review suggest that being under surveillance for an AAA does not negatively impact health related quality of life, qualitative evidence documented within that review demonstrated that some men under surveillance reported fear of rupture when going about their day-to-day lives.[276] Meanwhile, a 2017 systematic review concluded that it is possible that being labelled with a diagnosis of AAA causes moderate psychological distress, though there is insufficient evidence to allow precise estimation of the severity and frequency of such distress.[344] Despite evidence of uncertainty, the totality of the available evidence suggests that detection of AAA through screening is unlikely to have durable, clinically significant psychosocial consequences, which may lessen concerns regarding the harms of overdiagnosis.[276] Further, it is also important to note that details of the pre- or post-screening information provided to screening participants were not provided in any of the studies included in this review. It is plausible that the magnitude of the potential psychosocial consequences may be

lessened by the provision of adequate pre- and post-screening information, as well as post-diagnostic educational and psychological supports.

Overtreatment may be associated with clinically significant consequences when considering the risk of perioperative mortality. Only one Swedish registry-based cohort study specifically investigated the potential for overtreatment, concluding that AAA screening in men aged 65 may result in 19 potentially avoidable elective surgeries per 10,000 men offered screening.[279] It is important to note, however, that in this study follow-up was limited to six years' only, and is therefore insufficient to capture the full effect of screening, leading to overestimation of the risk of overtreatment. Although elective surgical repair of AAA is not without risks, restriction of surgical intervention to those at greatest risk of rupture (that is, AAA ≥5.5 cm in diameter or rapid growth) minimises the risk of unnecessary intervention and perioperative mortality.

RCTs comparing screened and unscreened populations found no evidence of a difference between groups in terms of all-cause mortality. However, AAA screening alone would be unlikely to impact all-cause mortality due to the low prevalence of AAA in the screened population. All-cause mortality or cardiovascular mortality may be a suitable endpoint in RCTs of combined cardiovascular screening where the intervention is intended to result in improvements in multiple cardiovascular risk factors, and therefore may impact the development or progression of multiple endpoints.

In a modern AAA screening programme, it is plausible that those with screen-detected AAA may experience a reduction in all-cause or cardiovascular mortality where access to comprehensive cardiovascular risk management is provided. However, in the VIVA trial, combined cardiovascular screening (that is, AAA, peripheral arterial disease and hypertension) and initiation of prophylactic interventions was associated with only a modest reduction in all-cause mortality (HR 0.93; 95% CI: 0.88 to 0.98), and no reductions in the specific causes of death targeted by the intervention (that is, AAA or cardiovascular disease).[266] Therefore, the mechanisms behind the observed difference in all-cause mortality in the VIVA trial are unclear.[345]

It has been suggested that the effectiveness of screening may be reduced in older populations, as the screened population may die from other causes before they can derive a benefit from screening.[346] As age-specific mortality increases with advancing age, the relative impact of any intervention on disease-specific mortality is reduced.[346] A retrospective review of deaths in New Zealand as recorded by administrative health information systems found that 77% of those with the cause of death recorded as AAA had comorbidities that would likely be associated with a reduction in quality and or quantity of life. The authors concluded that this may limit

the potential for these patients to benefit from an AAA screening programme.[347] Thus, it is important to consider that undertaking AAA screening may not always translate into meaningful benefit to patients with screen-detected AAA in terms of quality and or quantity of life.[347] The potential impact of AAA screening on population health in terms of quality-adjusted life years gained is reviewed in Chapter 5.

The implementation strategy adopted by a population-based AAA screening programme has the potential to influence the real-world effectiveness. This review was limited to consideration of the clinical effectiveness and safety of one-time ultrasound screening for AAA as a further review of the clinical effectiveness and safety of repeat screening was considered unlikely to change the conclusions of existing reviews on this topic.[140, 277, 286] No RCTs have been conducted evaluating the clinical effectiveness of one-time or no screening versus repeat screening of those without AAA at the initial scan. Based on evidence from cohort and case-control studies only, previous systematic reviews concluded that there is insufficient evidence to estimate the benefits of repeat screening in a previously screened population.[140, 277]

In light of the potential for development of incident AAA over time in those with a screen-negative result at age 65, and uncertain clinical benefits associated with rescreening, rescreening has been offered after five to ten years to those with a subanuerysm at the initial scan at age 65 years in some Swedish counties.[263] Approximately 30% of subaneurysms were estimated to reach the threshold for repair within 10 years.[263] While such a strategy may effectively identify additional men with AAA that may benefit from elective repair, this would be associated with a further increase in overdiagnoses. In addition, the UK National Aneurysm Screening Programme allows self-referral of cases outside the specific age cohort into the programme, reporting a higher prevalence of disease in the self-referred population, relative to those invited to screening.[79] Of note, however, non-intervention was more common in men who came from surveillance or self-referral, likely related to lower fitness for surgery when compared with those identified at a younger age. Therefore, in older populations, increased AAA diagnoses may not necessarily translate into improved clinical outcomes. As noted in Chapter 3, a previous pilot study in Ireland also offered screening to first-degree relatives of patients with AAA and those with a family history of AAA, in addition to males aged 65 years and over. Lowering the threshold for entry into the surveillance pathway or extension of screening eligibility to self-referred populations may increase the overall effectiveness of an AAA screening programme. However, this must be considered in the context of potential harms associated with overdiagnosis and increased resource demands.

Furthermore, the effectiveness of any screening programme is also dependent on the uptake rate. Clinical effectiveness estimates from RCTs were based on uptake rates of 63% to 80%. Uptake in publications arising from international screening programmes ranged from 74% to 90%. It is worth noting that in included RCTs, a significant proportion of AAA-related deaths in the invited group occurred among non-attendees at long-term follow-up. If implemented, the use of publicity to promote uptake of screening, which was not possible during the course of RCTs,[308] may help to ensure that uptake rates observed in AAA screening programmes internationally can be achieved, thereby maximising effectiveness. While reductions in disease prevalence over time will translate into a reduction in the magnitude of clinical benefit, this could be offset, to some extent, if high uptake could be achieved.

4.4.3 Applicability of the available evidence

Multiple contextual factors preclude direct translation of RCT evidence to contemporary practice. The four population-based RCTs began in the 1980s and 1990s when the prevalence of AAA was 4 to 7% in screened men, and most repairs were done by open surgery. As demonstrated by more recent observational studies, the prevalence of AAA has declined over time from 8% in the early 1990s, broadly in line with RCT evidence, to approximately 1% by the latter part of the 2010s. The changing clinical context, characterised by a decrease in AAA prevalence, improvements in cardiovascular risk factor management, increased life expectancy, and improvements in surgical practice should be taken into account when considering a modern AAA screening programme. Over the past two to three decades, increased surgical experience and training, changes in the procedures performed (for example, the introduction of EVAR) and improved care pathways (for example, the development of best practice guidelines) have contributed to a reduction in the risk of peri-operative mortality after elective surgical repair of AAA; however, late mortality remains high.[348] Given that both the clinical benefits and potential harms have decreased over time, it is possible that the overall benefit-harm balance may remain relatively consistent. However, the exact magnitude of these shifts in the benefit-harm balance cannot easily be quantified in the absence of contemporary comparative evidence.

As described in Chapter 2, the burden of disease related to AAA increases with advancing age. Population-based screening RCTs recruited men across an age range, and subgroup analyses, where reported, were not powered to detect differences between groups.[314, 316] It is therefore uncertain whether or not these findings can be applied to subpopulations, in particular, men at the lower end of the age range of included populations. While the direction of effect observed across included studies was consistent, many of these studies began prior to widespread adoption of aggressive cardiovascular risk factor management strategies, reductions

in smoking, and consequent reductions in the prevalence of AAA, which may alter our understanding of the relative benefit of screening. The magnitude of effect in the current clinical context is subject to uncertainty.

4.4.4 Strengths and limitations of this review

A robust approach to the review process was employed with prospective registration of the study protocol on PROSPERO and adherence to best practice guidelines.[268, 278] Nevertheless, the findings should be interpreted with consideration to limitations relating to both the underlying evidence and the review process.

In contrast to existing systematic reviews on this topic, this review considered other study designs, in addition to evidence from RCTs, reporting on the clinical effectiveness and safety of screening for AAA, given concerns regarding the applicability of the available RCT evidence to the current clinical context. However, despite the application of broad inclusion criteria, limited additional high-quality evidence was retrieved that was of relevance to the specific research question of this review, in particular due to the dearth of comparative studies. Thus, considerable uncertainty remains regarding the applicability of RCT evidence to the current clinical context.

For non-RCTs, there was evidence of significant variation between studies in terms of AAA-related morbidity and mortality, and surgical outcomes. These differences may be related to differences in the timing of individual studies, length of follow-up, population characteristics (for example, age or comorbidities), outcome definitions (for example, AAA-related mortality) recruitment methods (invited versus invited plus self-referred), programme characteristics (for example, surveillance intervals), and adherence to invitation to surveillance among those with screen-detected AAA. Potential for such differences presents challenges for comparisons between studies, but reflects the real-world context.

For the purposes of this review, the rate of overdiagnosis in RCTs was estimated by comparing the rate of AAA-related events in the non-screening arm, relative to AAA diagnoses in the screened arm, consistent with the methods previously described by Johansson et al.[279] However, the approach adopted is subject to limitations, which have the potential to both underestimate and overestimate overdiagnosis. For estimation of overdiagnosis, only cases in the comparator arm that experienced AAA rupture or elective surgery were included. It was assumed that all cases undergoing emergency surgery experienced AAA rupture, due to the potential for duplication of cases between AAA rupture and emergency surgery. However, a proportion of patients undergoing emergency surgery may present with symptomatic but intact AAA, which may contribute to underestimation of the number of AAA-related events in the comparator arm, and thus overestimate the rate of overdiagnosis. Further, the rate of overdiagnosis was based on the available evidence at longest follow-up (13

to 15 years). A proportion of men in the comparator arm would experience AAA rupture or elective surgery beyond the time period for which data were available, which may contribute to overestimation of the rate of overdiagnosis. Finally, the potential for contamination in the comparator arm may lead to a greater number of elective surgeries in the unscreened group, which may underestimate the potential for overdiagnosis when these estimates are applied to settings in which screening is not currently available. Similarly, in the observational literature the risk of overdiagnosis cannot be accurately estimated due to limitations in the recording of mortality data and inadequate length of follow-up

A small number of studies have investigated the impact of AAA screening in men on measures of psychosocial harms, demonstrating varying results. Observed variation in results across these studies may be related to factors such as the timing of assessment, the sensitivity of the instruments used, sample sizes, and differences in the information and support provided to patients. For assessment of psychosocial outcomes, where generic preference-based quality of life tools and mood scales were used, these may lack sufficient sensitivity to detect small, but potentially clinically meaningful, psychosocial consequences specific to screening for AAA. While disease- or condition-specific tools may have greater content validity, for the purposes of decision-making, generic preference-based instruments are preferred as they allow comparison across health conditions and encompass all dimensions of health relevant to patients and society.[349]

In many of the identified studies reporting on the psychosocial consequences of screening, outcomes were compared at a single point in time, or after the intervention only. Longitudinal data are important to examine the potential for changes in health-related quality of life over time given the potential for the impact on psychological health to vary at key time points in the care pathway, and given evidence of potential differences between men with screen-detected AAA versus those with a negative screening test result at baseline.[300, 301, 303] The potential for differences at baseline might be explained by the evidence to suggest that men with AAA have a greater number of comorbidities, which may contribute to impaired health (Chapter 2, section 2.4.4). Therefore, poorer self-assessed health in those with screen-detected AAA may not necessarily be a consequence of screening.

4.4.5 Conclusion

Evidence from four large population-based RCTs demonstrates that one-time ultrasound screening for AAA in asymptomatic men aged 65 years and older reduces AAA ruptures and AAA-related mortality, as a result of increased elective surgical repairs in the screened cohort, relative to the unscreened cohort. Importantly, there was no evidence of a significant difference in 30-day mortality between these groups following elective surgical repair. Due to the promising results obtained in RCTs, AAA

screening programmes have been implemented in the United Kingdom and Sweden. However, limited contemporary comparative data from population-based studies are available. The benefits of an AAA screening programme may be partially offset by unintended, but generally unavoidable, harms including overdiagnosis and transient psychological distress.

5 Cost effectiveness of AAA screening in men

Key points

- This chapter aims to critically assess international literature on the cost effectiveness of screening for abdominal aortic aneurysm (AAA) in men compared with no screening.
- Of 235 publications reviewed in full, 20 studies published after 2009, including 17 cost-utility analyses (CUAs) and three cost-effectiveness analyses (CEAs), were analysed in detail. Sixteen economic evaluations were specifically undertaken in men age 65, while four were based on a broader age range (for example, age 65 to 75).
- Willingness-to-pay (WTP) thresholds of €20,000 and €45,000 per quality-adjusted life year (QALY) were used as reference points to guide interpretation of cost effectiveness.
- The available international evidence suggests that AAA screening in men is cost effective. However, the conditions under which these conclusions were reached may not reflect the current clinical context in Ireland.
    - AAA screening in men aged 65 was considered cost effective in 16 of the 17 CUAs, with incremental cost-effectiveness ratios (ICERs) ranging from €200 to €30,600 per QALY. However, in these studies, modelled estimates of AAA prevalence ranged from 1.3% to 11.5%, which would not be considered transferable to the current Irish context.
    - In one CUA, AAA screening was not considered cost effective (€61,956 per QALY).
    - In the three CEAs, ICERs ranged from €7,500 to €16,100 per life year gained.
- The results were generally robust in sensitivity and scenario analysis. However, uncertainty around parameters such as AAA prevalence, opportunistic detection rates, ultrasound screening costs, rupture rates for large AAAs, and reductions in health-related quality of life (HRQoL) after AAA detection, contributed to variability in the ICERs.
    - AAA prevalence was the most influential parameter in eight out of ten studies that reported this as part of their sensitivity analysis. Lowering AAA prevalence consistently resulted in increased ICERs, affecting the

interpretation of cost effectiveness in four models.

- While 18 of the 20 included CUAs were considered of moderate to high quality, none were directly transferable to the Irish context due to differences in healthcare systems, inadequate reporting of the methodological approach, and limitations of the underlying evidence base, in particular, concerns regarding the applicability of key input parameters.
    - Further, it should be noted that programme-specific administrative, infrastructural and operational costs, such as, staffing, and setting up and maintaining the programme database and quality assurance frameworks, were frequently not reported in included CUAs. This may contribute to underestimation of implementation costs and therefore overestimation of cost effectiveness if the results are transferred to the Irish context.
- In the absence of new clinical data since existing CUAs were completed, and given the lack of robust Irish epidemiological data on AAA, it was determined that a de novo, Irish-specific CUA would not sufficiently resolve uncertainties regarding the cost effectiveness of screening in the current context.
- Uncertainty regarding the long-term cost effectiveness of introducing a population-based AAA screening programme is multifactorial, and is related to declining AAA prevalence, improvements in cardiovascular risk factor mangement over time, and the increasing use of imaging studies as part of usual care.

5.1 Introduction

The National Screening Advisory Committee (NSAC) criteria for appraising the viability, effectiveness and appropriateness of a screening programme specify that:

- *the opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (value for money). Assessment against these criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.*

This HTA therefore considers both cost effectiveness and affordability, with the focus of this chapter on the cost effectiveness of screening for AAA in men. The specific aim of this chapter is to synthesise and critically appraise the international literature on the cost effectiveness of screening for AAA in men, compared with no systematic screening, including an assessment of the applicability of the international evidence to the Irish context.

5.2 Methods

The systematic review described within this chapter is reported according to the criteria of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[238, 268, 350, 351] The protocol for this review was prespecified as part of a wider systematic review, which included a search for studies reporting on the clinical effectiveness and safety of screening for AAA, and was registered on the International Prospective Register of Systematic Reviews (PROSPERO registration number: CRD42024501141). Detailed methods are available in the study protocol.[352]

This review aimed to assess the cost effectiveness of population-based ultrasound screening for AAA in men compared with no systematic screening, where both the methods and results of published cost effectiveness analyses (CEA), expressed as cost per life year gained (LYG), and cost utility analyses (CUA) expressed as cost per quality-adjusted life year (QALY), were critically appraised and synthesised. A secondary aim was to identify factors that influence the cost effectiveness of AAA screening in men aged 65 years. The PICO (Population, Intervention, Comparator, Outcomes) framework used to formulate the research question is presented in Table 5.1. Inclusion and exclusion criteria are described in full in the study protocol.[352]

Table 5.1 PICOS framework for systematic review of cost effectiveness

Population	Asymptomatic men
Intervention	One-time population-based ultrasound screening for abdominal aortic aneurysm
Comparator	▪ No systematic screening (that is, clinical presentation, family history or incidental diagnosis only)
Outcomes	▪ ICER (for example, cost per life-year gained or cost per quality-adjusted life-year) or NMB
Study design	▪ Full economic evaluations: ○ cost-utility analysis ○ cost-effectiveness analysis ○ cost-benefit analysis.

Key: ICER – incremental cost-effectiveness ratio; NMB – net monetary benefit.

5.2.1 Search strategy

The systematic search for this review was nested within a wider systematic search to identify studies relevant to the clinical effectiveness and safety of screening for AAA in men, as described in Chapter 4. Eligibility screening was conducted for the systematic reviews in parallel. Only studies reporting cost effectiveness outcomes are described in this chapter. Information on the electronic search strategy is described in Chapter 4, section 4.2.1.

5.2.2 Study selection, data extraction and quality appraisal

Full text screening, data extraction and critical appraisal were performed independently by two reviewers as outlined in the study protocol. Studies were screened for eligibility against the inclusion criteria outlined in Table 5.1. Any disagreements were resolved through discussion, or if necessary, a third reviewer. Further information on study selection and exclusion criteria are described in the study protocol.[352]

Full data extraction and quality appraisal was confined to studies published from 2009 onwards to ensure that the most recent studies with up-to-date data were included. For individual countries, for all economic evaluations published prior to 2010, a more recent analysis has since been published from that country. One 2009 study was identified which appeared to have conflicting findings to those studies published before and afterwards. Thus, 2009 was chosen as cut-off for full

extraction to allow this review to consider the findings of this study. To facilitate investigation of the relationship between AAA prevalence and cost effectiveness, selected information including the study cost year, AAA prevalence and ICERs (cost per QALY) were extracted from all CUAs (including those published prior to 2009) meeting the inclusion criteria.

Assessment of the methodological quality of included studies was conducted using the Consensus on Health Economics Criteria (CHEC)-list.[353] The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) questionnaire was used to assess the applicability of individual study findings to the Irish setting.[354] Critical appraisal plots (CHEC-list and ISPOR questionnaire) and figures were produced in Excel 2013.

5.2.3 Data synthesis

There is no agreed best practice method for synthesis of economic evidence as the approach depends on the purpose of the review.[355] Given the heterogeneity across studies in terms of methodology, population and healthcare system characteristics, a narrative synthesis was undertaken. In line with ISPOR's best practice recommendations, the results of model-based (that is, parameters are based on multiple sources) and empirical evidence-based (that is, parameters are based on a single study such as a randomised controlled trial) economic evaluations were synthesised separately.[355] Where multiple studies used the same model, which was adapted for their individual country, the model structure was described only once.

To facilitate comparing results across countries and years, where appropriate, costs were adjusted in accordance with national HTA guidelines (under review at the time of analysis).[356] Briefly, costs were adjusted to a common cost year (2023) using country-specific consumer price indices (CPI) for health and purchasing power parities (PPP). For the purposes of this analysis, ICERs were converted to a common cost year and currency and referred to as adjusted ICERs. Unadjusted ICERs, as reported by included studies, and corresponding context-specific willingness-to-pay (WTP) thresholds, are also presented in the supplementary appendix. WTP thresholds of €20,000 and €45,000 per QALY gained were adopted as reference points for guiding interpretation of cost effectiveness as these are commonly employed in Ireland and are consistent with empirically based thresholds used in other high-income countries.[357, 358]

Where studies presented ICERs in terms of both the cost per QALY and the cost per life year gained (LYG), preference was given to the cost per QALY due to its ability to summarise the impact of the intervention on both quality and quantity of life, and the availability of accepted WTP thresholds to facilitate interpretation.

5.3 Results

An overview of the study selection process and PRISMA flow chart is presented in Chapter 4 (see section 4.3). Briefly, following review of 235 full texts, 78 publications met the inclusion criteria. Of these, 35 studies, reported across 36 publications, considered the cost effectiveness of screening for AAA, and 20 of these were published between 2009 and 2024. Full data extraction and quality appraisal was therefore carried out on those 20 studies.[233, 236, 238, 306, 314, 350, 351, 359-371]

5.3.1 Characteristics of included studies

All of the studies reported the costs and consequences associated with screening for AAA in men aged 65 years or older (comprising screening and subsequent surveillance or treatment of identified cases as appropriate), relative to a strategy of no systematic screening, where diagnosis occurs through clinical presentation or opportunistic detection (that is, the incidental detection of an AAA during medical imaging or diagnostic procedures conducted for reasons unrelated to AAA screening).

Of the 20 full text articles that met the inclusion criteria, 18 were model-based and comprised 16 CUAs and two CEAs,[233, 236, 238, 350, 351, 359-371] and two were trial-based, one CEA and one CUA.[306, 314] The trial-based CEA was from 2009, and was based on data from the Multicentre Aneurysm Screening Study (MASS) in the UK.[306] The trial-based CUA was from the Viborg County screening trial in Denmark in 2010.[314]

Of the 18 model-based studies: four were conducted in Sweden,[350, 366-368] two in the UK,[362, 363] and two in Denmark.[351, 370] One study estimated the cost effectiveness of AAA screening relative to no screening in two different countries, Norway and the Netherlands, using context-specific input parameters, where available.[369] The remaining studies considered the cost effectiveness of screening for AAA in each of the following countries: Canada,[359] Estonia,[360] Finland,[238] Iran,[365] Italy,[360] New Zealand,[361] Northern Ireland,[364] Norway,[233] and Spain.[236]

Fourteen of the model-based studies expressed cost effectiveness in terms of both cost per QALY gained and cost per LYG ,[233, 236, 359-364, 366-368, 371] two studies expressed cost effectiveness using cost per LYG only,[238, 369] and two studies reported cost per QALY gained only.[351, 370]

5.3.2 Model characteristics

Model structure

A total of 17 of the 18 model-based studies used a Markov model to simulate screening costs and outcomes.[233, 236, 238, 350, 351, 359-361, 363-371] Of these, 13 adapted or developed a structurally unique Markov model,[236, 238, 351, 359, 360, 363, 364, 366-371] while four directly adopted an existing one.[233, 350, 361, 365] The remaining study used a discrete event simulation (DES) model (see Table 5.2 and Table 5.3).[362]

Table 5.2 Overview of economic evaluation methods

Author, year	Country	Study type	Type of analysis	Model type and cycle length	Perspective	Time horizon	Discount rate (cost/ outcomes)	Outcomes	Model source
Model-based economic evaluations									
Vervoort 2024[359]	Canada	Model-based	CEA, CUA	Markov, 3 months	Healthcare system	Lifetime	1.5%/1.5%	QALY, LYG	New Model
AQUAS 2023[236]	Spain	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	4,10 years, Lifetime	3%/3%	QALY, LYG	New Model
Reile 2020[360]	Estonia	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	35 years	5%/5%	QALY, LYG	New Model
Nair 2019[361]	New Zealand	Model-based	CEA, CUA	Markov, 3 months	Healthcare system	Lifetime (30 years)	3%/3%	QALY, LYG	Adapted from Glover 2014
Glover 2014[363]	UK	Model-based	CEA, CUA	Markov, 3 months	Healthcare system	30 years	3.5%/3.5%	QALY, LYG	Adapted from Kim 2007
Glover 2018[362]	UK	Model-based	CEA, CUA	Discrete event simulation (DES)	Not reported	30 years	3.5%/3.5%	QALY, LYG	New Model
Badger 2011[364]	Northern Ireland	Model-based	CEA, CUA	Markov, NR	Healthcare system	30 years	3.5%/3.5%	QALY, LYG	Adapted from Kim 2007
Daroudi 2021[365]	Iran	Model-based	CEA, CUA	Markov, 3 months	Healthcare system	Lifetime	3%/3%	QALY, LYG	Adapted from Glover 2014 and Zarrouk 2016
Zarrouk 2016[366]	Sweden	Model-based	CEA, CUA	Markov, 1 year	Not reported	35 years	3%/3%	QALY, LYG	New Model
Hager 2017[367]	Sweden	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	Lifetime	3%	QALY, LYG	Adapted from Henrikson 2005
SBU 2015[350]	Sweden	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	13,40 years	3%	QALY, LYG	Adapted from Svensjo 2014
Svensjo 2014[368]	Sweden	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	10,13,40 years	3.5%	QALY, LYG	New Model

Author, year	Country	Study type	Type of analysis	Model type and cycle length	Perspective	Time horizon	Discount rate (cost/ outcomes)	Outcomes	Model source
NIPH 2020[233]	Norway	Model-based	CEA, CUA	Markov, 1 year	Healthcare system	40 years	4%	QALY, LYG	Adapted from Svensjo 2014
Spronk 2011[369]	Netherlands Norway	Model-based	CEA	Markov, 1 year	Societal	Lifetime	Netherlands: 4% (costs) /1.5% (benefits) Norway: 4%	QALY	New Model
Sogaard 2012[372]	Denmark	Model-based	CUA	Markov, 6 months	Healthcare system	Lifetime	3%	LYG	New Model
Ehlers 2009[351]	Denmark	Model-based	CUA	Decision tree with Markov model, 1 year	Healthcare system	Lifetime	3%	LYG	New Model
Mäklin 2011[238]	Finland	Model-based	CEA	Markov, NR	Healthcare system	Lifetime	3%	QALY	Modified Ehlers 2009
Giardina 2011[371]	Italy	Model-based	CEA, CUA	Markov, 6 months	Healthcare system	Lifetime	3%	QALY, LYG	New Model
Trial-based economic evaluations									
Lindholt 2010[314]	Denmark	Trial-based	CEA, CUA	N/A*	Healthcare system	14 years	3%	QALY, LYG	N/A*
Thompson 2009[306]	UK	Trial-based	CEA, CUA	N/A*	Healthcare system	10 years	3.5%	QALY, LYG	N/A*

Key: CEA – cost-effectiveness analysis; CUA – cost-utility analysis; NA – not applicable.

* Trial-based economic evaluations by their nature rely on direct measurements of health outcomes from trial participants, and therefore do not require a model.

Health states

The number of health states included in the Markov models varied between studies, from seven[236, 367] to 15 health states[369] (see Table 5.3 for full details). One CUA did not report any health states.[364]

Eleven models used in 13 studies distinguished between no AAA (< 3.0 cm), small AAA, medium AAA, and large AAA (≥ 5.5 cm) health states.[236, 238, 351, 359-361, 363, 365-367, 369-371] This distinction is important as there is epidemiological evidence showing that the risk of rupture becomes exponentially larger with increasing aneurysm size.[314, 370] One model included two health states for medium AAA (4.0 to 4.9 cm, and 5.0 to 5.4 cm).[236] For large AAAs, one model included additional health states for aneurysm size larger than 5.5 cm (5.5 to 5.9 cm, 6.0 to 6.9 cm, 7.0 to 7.9 cm, ≥8.0 cm). However, within the model these states behaved the same way, thus there were no implications of these states on the model results.[372] In addition, three models also included states for sub-aneurysm (aortic diameter 2.5 to 2.9 cm) in the base case analysis (see Table 5.2).[236, 367, 370] However, the model by Svensjo and colleagues[368] which was used by two other CUAs[233, 350] did not subcategorise AAA according to aortic diameter. This model contained a single health state for AAA and a state for no AAA. The distribution of aortic diameter among screen-detected cases, where reported, ranged from 71%[238, 351] to 79%[359, 361, 363, 365] for small AAA, from 12%[359, 363, 365] to 17%[238, 351] for medium AAA, and from 7%[360, 361] to 12%[238, 351, 369] for large AAA (See Table 5.4).

There was considerable variability in the other health states incorporated in the models. Six models included a state for rupture,[236, 238, 360, 363, 366, 368] while six did not.[351, 359, 367, 369-371] Models adopted different approaches to representing the acute surgical care episode within the model structure; for example, four models included distinct health states for emergency and elective surgical repair,[236, 363, 366, 371] three models included an elective surgery state,[238, 360, 368] and five models did not explicitly include surgical states.[351, 359, 367, 369, 370] All of the models comprised at least one post-surgical state with five models including a single post-surgical state.[236, 360, 363, 367, 370] As noted in Chapter 3, Section 3.3.2, post-operative monitoring protocols and the timing of complications may vary depending on whether a patient undergoes EVAR or OSR. To account for this, three models sub-categorised post-surgical states into post-EVAR and post-OSR.[366, 368, 369] Three models distinguished between post-elective repair and post-emergency repair.[238, 351, 359, 371] One model included four health states to distinguish between post-elective EVAR, post-elective OSR, post-emergency EVAR and post-emergency OSR.[359] Models that distinguish between post-elective and post-emergency surgical repair may represent a more clinically accurate estimate given that there is evidence for significantly higher postoperative mortality rates following emergency versus elective surgery.[372]

Only two models explicitly included states for post-surgical complications or re-intervention.[366, 369] Although not explicitly stated, in other models complication costs may have been accounted for in the post-surgical health states (see 'Important input parameters' below for relevant information on costs).

Finally, four of the models distinguished between AAA-related mortality (typically defined as within 30-days after rupture or surgery) and non AAA-related mortality (that is, death from other causes),[359, 363, 366, 369] whereas the remaining seven models included a single state for all deaths and did not distinguish between AAA-related and all-cause mortality.[236, 351, 360, 367, 368, 370, 371]

Table 5.3 Included health states across 12 structurally unique Markov models

	AQUAS (236)	Ehlers (351)	Giardina (371)	Glover[363] Nair[361]	Hager (367)	Mäklin (238)	Reile (360)	Sogaard (372)	Spronk (369)	Svensjo[368] SBU[350] NIPH[233]	Vervoort (359)	Zarrouk[366] Daroudi[365]
Invitation	-	X	-	-	-	-	-	-	-	-	-	-
Non-attenders	-	X	-	-	-	-	-	-	-	-	-	-
Unknown Small	-	-	X	-	-	-	-	-	-	-	-	-
Unknown Medium	-	-	X	-	-	-	-	-	-	-	-	-
Unknown Large	-	-	X	-	-	-	-	-	-	-	-	-
No invitation	-	X	-	-	-	-	-	-	-	-	-	-
No AAA	X	X	X	X	X	X	X	X	X	X	X	X
Sub-Aneurysms	X	-	-	-	X	-	-	X	-	-	-	-
Re-Scan	-	-	-	-	-	-	-	X	-	-	-	-
AAA	-	-	-	-	-	-	-	-	-	X	-	-
Surveillance	-	-	X	-	-	-	-	X	-	-	-	-
Small	X	X	X	X	X	X	X	X	X	-	X	X
Medium	X	X	X	X	X	X	X	X	X	-	X	X
Large	X	X	X	X	X	X	X	X	X	-	X	X
Pre-surgical assessment	-	-	-	X	-	-	-	-	-	-	-	-
Contraindicated	-	-	X	X	-	-	-	X	X	-	-	-
Surgery pending	-	-	-	X	-	-	-	-	-	-	-	-
Elective surgery	X	-	X	X	-	X	X	-	-	-	-	X
Post-elective surgery	-	X	X	-	-	X	-	-	-	-	-	-
EVAR	-	-	-	-	-	-	-	-	X	X	-	-
Post-elective EVAR	-	-	-	-	-	-	-	-	X	X	X	X
OSR	-	-	-	-	-	-	-	-	X	X	-	-
Post-elective OSR	-	-	-	-	-	-	-	-	X	X	X	X
Rupture	X	-	-	X	-	X	X	-	-	-	-	X
Emergency surgery	X	-	X	X	-	-	-	-	-	-	-	X
Post-emergency surgery	-	X	X	-	-	X	-	-	-	-	-	-
EVAR	-	-	-	-	-	-	-	-	X	X	-	-
Post-emergency EVAR	-	-	-	-	-	-	-	-	X	X	X	X
OSR	-	-	-	-	-	-	-	-	X	X	-	-
Post-emergency OSR	-	-	-	-	-	-	-	-	X	X	X	X

	AQUAS (236)	Ehlers (351)	Giardina (371)	Glover[363] Nair[361]	Hager (367)	Mäklin (238)	Reile (360)	Sogaard (372)	Spronk (369)	Svensjo[368] SBU[350] NIPH[233]	Vervoort (359)	Zarrouk[366] Daroudi[365]
Post-surgery (Any)	X	-	-	X	X	-	X	X	-	-	-	-
Complications	-	-	-	-	-	-	-	-	X	-	-	-
Re-intervention	-	-	-	-	-	-	-	-	-	-	-	X
Death	X	X	X	-	X	X	X	X	-	X	-	-
AAA-related death	-	-	-	X	-	-	-	-	X	-	X	X
Non-AAA-related death	-	-	-	X	-	-	-	-	X	-	X	X

Key: AAA – abdominal aortic aneurysm; EVAR – endovascular aneurysm repair; OSR – open surgical repair.
Notes: Health state labels have been rephrased for consistency and may not directly correspond to the wording used in the original publication.
The model-based CUA by Badger *et al.* (2011) did not report the model health states,[364] and the model-based CUA by Glover *et al.* (2011) used a discrete event simulation (DES) model.[362] Therefore, these studies were excluded from this table.

Time horizon, cycle length and perspective

All of the models adopted a time horizon of at least 30 years.[236, 351, 359, 363, 364, 366-371] Where reported, seven models reported in nine studies used annual cycle lengths,[233, 236, 350, 351, 360, 366-369] two used six-monthly cycles[370, 371] and two used three-monthly cycle lengths.[359, 363]

Of the 18 model-based studies, a total of 15 studies (14 CUAs and one CEA) conducted the analysis from the healthcare system perspective.[233, 236, 238, 350, 351, 359-361, 363-365, 367, 368, 370, 371] In one CEA the analysis was conducted from the societal perspective.[369] Two CUAs did not clearly specify the perspective adopted, but given that only direct costs were included it was assumed that the analysis was conducted from the perspective of the healthcare system.[362, 366]

Population characteristics and care pathway

In terms of the target population, sixteen of the model-based studies modelled one-time ultrasound screening for men aged 65 years,[233, 238, 350, 351, 359-363, 365-371] while two CUAs included men aged 65 to 75 years.[364, 371] In addition, one CUA from Canada performed an alternative base case analysis for men aged 75 years, to align with Canadian guideline recommendations.[359] The two trial-based CEA and CUAs also included a broader age-range; in the Viborg CUA they included men aged between 64 and 73 years, and the trial-based model using data from the MASS trial included men between 65 to 74 years.[306, 314]

In 15 of the model-based studies, the attendance rate modelled was between 73% and 80%.[233, 238, 350, 359-363, 365-371] Lower attendance rates were used in two CUAs, conducted in Northern Ireland (45%)[364] and Italy (62%).[371] One Spanish CUA modelled an attendance rate of 93%; while acknowledging that this rate is high, the authors noted that it was in line with data from a Spanish feasibility study on AAA screening in primary healthcare.[98, 236] In the two trial-based studies, similar attendance rates of 77% and 80% were reported from Denmark and the UK respectively.[306, 314]

The modelled values of AAA prevalence ranged from 1.3%[362] to 11.5%.[369] While the prevalence of AAA is declining, as noted in Chapters 3 and 4, some recent CUAs used relatively high prevalence rates in the base case analysis.[236, 360, 361] The potential impact of declining prevalence on the cost effectiveness of AAA screening is described in section 5.3.3 (sensitivity and scenario analyses). The prevalence of AAA was reported to be 4% in one of the trial-based CUAs.[314]

All studies adopted the definition of an AAA of an aortic diameter > 3.0 cm.[236, 351, 359, 363, 364, 366-371] Twelve of the model-based studies defined the threshold for referral to vascular surgery as an aortic diameter ≥ 5.5 cm,[233, 236, 238, 350, 351, 359, 360,

[364-366, 369, 370] three CUAs defined it as an aortic diameter > 5.4 cm[361, 363, 367] and one CUA from Italy defined it as an aortic diameter > 5.0 cm.[371] Two CUAs did not report the threshold for referral to vascular surgery.[362, 368] One of the trial-based CUAs, from Denmark, also reported a lower threshold of aortic diameter > 5.0 cm,[314] while the MASS CUA reported the more common threshold of an aortic diameter ≥ 5.5 cm.[306]

As noted previously, AAAs were generally categorised as small (3.0 to 4.4 cm), medium (4.5 to 5.4 cm) and large (≥5.5 cm) (Table 5.4). Three CUAs also included a sub-aneurysm category (2.5 to 2.9 cm).[236, 367, 370] As noted in Chapter 4 there is variation across guidelines on recommended surveillance and follow-up protocols; this was reflected in the models where the specified follow-up and treatment regimens of detected aneurysms varied across studies. Eight studies described annual follow-up for smaller aneurysms and biannual or quarterly follow-up for medium-sized aneurysms (see Table 5.4).[362-365, 367, 369-371]

The possibility of incidental detection was acknowledged in 14 model-based studies, however, there was considerable variability in the estimates reported.[233, 359-363, 365-371] Where reported, the rates of opportunistic detection per year ranged from 1%[359] to 12%.[370, 371] Twelve studies reported the probability of incidental detection for all sizes of aneurysm,[233, 350, 359-363, 365-369] while two CUAs reported the probability for large aneurysms only.[370, 371] Three CUAs reported cumulative incidental detection rates between 39%[350] and 42%.[233, 368] Four studies did not report the rate of incidental detection (see Table 5.4).[236, 238, 351, 364]

Table 5.4 Overview of included studies: patient characteristics and care pathway

Author, year	Country	Target population	Threshold for AAA diagnosis	Threshold for surgical referral	Prevalence of AAA	Screening uptake	Surveillance strategy	Opportunistic detection per year	Distribution of AAA sizes
Vervoort 2024[359]	Canada	Men and women 65 and 75 years	AD ≥ 3cm	AD ≥ 5.5cm	1.50%	73.0%	3 years (3.0 to 4.4 cm) 1 year (4.5 to 5.4 cm)	1.0%	Small (3.0 - 4.4 cm): 78.8% Medium (4.5 - 5.4 cm): 12.0% Large (≥5.5 cm): 9.2%
AQUAS 2023[236]	Spain	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	4.70%	93.0%	5 years (2.5 to 2.9 cm) 3 years (3.0 to 3.9 cm) 1 year (4.0 to 4.9 cm) 6 months (5.0 to 5.4 cm)	NR	2.5 - 2.9 cm: 4.0% overall cohort >3.0 cm: 4.7% overall cohort • 3.0 - 3.9 cm: 78.7% • 4.0 - 4.9 cm: 4.3% • 5.0 - 5.4 cm: 14.9% • >5.5 cm: 2.1%
Reile 2020[360]	Estonia	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	2.20%	75.0%	1 year (3.0 to 5.4 cm)	6.0%	Small (3.0 - 4.4 cm): 77.9% Medium (4.5 - 5.4 cm): 14.3% Large (≥5.5 cm): 7.8%
Nair 2019[361]	New Zealand	Men 65 years	AD ≥ 3cm	AD > 5.4cm	2.50%	75.0%	NZ surveillance strategy: 5 years (3.0 to 3.4 cm) 3 years (3.5 to 3.9 cm) 2 years (4.0 to 4.4 cm) 1 year (4.5 to 4.9 cm) 6 months (5.0 to 5.4 cm) Actual model inputs: 3 years and 7 months (3.0 to 4.4 cm) 9 months (4.5 to 5.4 cm)	2.6%	Small (3.0 - 4.4 cm): 78.5% Medium (4.5 - 5.4 cm): 13.7% Large (≥ 5.5 cm): 7.7%
Glover 2014[363]	UK	Men 65 years	AD ≥ 3cm	AD > 5.4cm	1.50%	75.0%	1 year (3.0 to 4.4 cm) 3 months (4.5 to 5.4 cm)	1.1%	Small (3.0 - 4.4 cm): 78.9% Medium (4.5 - 5.4 cm): 11.9% Large (≥5.5 cm): 9.1%

Author, year	Country	Target population	Threshold for AAA diagnosis	Threshold for surgical referral	Prevalence of AAA	Screening uptake	Surveillance strategy	Opportunistic detection per year	Distribution of AAA sizes
Glover 2018[362]	UK	Men 65 years	AD ≥ 3cm	NR	1.34%	75.0%	Current strategy: 1 year (3.0 to 4.4 cm) 3 months (4.5 to 5.4 cm)	4.6%	NR
Badger 2011[364]	Northern Ireland	Men 65-75 years	AD ≥ 3cm	AD ≥ 5.5cm	5.40%	44.5%	1 year (3.0 to 4.4 cm) 3 months (4.5 to 5.4 cm)	NR	Large (≥5.5 cm): 12.0%
Daroudi 2021[365]	Iran	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	3.00%	75.0%	1 year (3.0 to 4.4 cm) 3 months (4.5 to 5.4 cm)	1.1%	Small (3.0 - 4.4 cm): 78.9% Medium (4.5 - 5.4 cm): 12.0% Large (≥5.5 cm): 9.1%
Zarrouk 2016[366]	Sweden	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	1.80%	78.3%	2 years (3.0 to 4.4 cm) 6 months (4.5 to 5.4 cm)	9.7%	Small (3.0 - 4.4 cm): 78.8% Medium (4.5 - 5.4 cm): 12.7% Large (≥5.5 cm): 8.5%
Hager 2017[367]	Sweden	Men 65 years	AD ≥ 3cm	AD > 5.4cm	2.00%	85.7%	1 year (3.0 to 3.9 cm) 6 months (4.0 to 5.4 cm)	3.0%	2.5 - 2.9 cm: 4.2% overall cohort > 3.0 cm: 2.0% overall cohort • 3.0 - 3.9 cm: 65.0% • 4.0 – 5.4 cm: 25.0% • >5.4 cm: 10.0%
SBU 2015[350]	Sweden	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	1.70%	80.0%	NR	39.0%*	NR
Svensjo 2014[368]	Sweden	Men 65 years	AD ≥ 3cm	NR	1.70%	80.0%	NR	42.0%*	NR
NIPH 2020[233]	Norway	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	2.50%	80.0%	2 years (3.0 to 4.0 cm) 1 year (4.0 to 4.5 cm) 6 months (4.5 to 5.5 cm)	42.0%*	NR

Author, year	Country	Target population	Threshold for AAA diagnosis	Threshold for surgical referral	Prevalence of AAA	Screening uptake	Surveillance strategy	Opportunistic detection per year	Distribution of AAA sizes
Spronk 2011[369]	Netherlands Norway	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	11.50%	Netherlands: 83.0% Norway: 77.0%	1 year (3.0 to 4.4 cm) 6 months (4.5 to 4.9 cm) 3 months (5.0 to 5.5 cm)	Netherlands: 5.0% Norway: 7.0%	Small (3.0 - 4.4 cm): 77.3% Medium (4.5 to 5.4 cm): 10.4% Large (≥5.5 cm): 12.1%
Sogaard 2012[372]	Denmark	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	3.30%	75.0%	1 year (3.0 to 4.9 cm) 6 months (5.0 to 5.4 cm)	12.0%†	Small (3.0 - 4.9 cm): 83.4% Medium (5.0 - 5.4 cm): 6.8% Large (≥5.5 cm): 9.8%
Ehlers 2009[351]	Denmark	Men 65 years	AD ≥ 3cm	AD ≥ 5.5cm	4.00%	77.0%	NR	6.0%	Small (3.0 - 4.4 cm): 71.0% Medium (4.5 - 5.4 cm): 17% Large (≥5.5 cm): 12%
Mäklin 2011[238]	Finland	Men and women 65 years	AD ≥ 3cm	AD ≥ 5.5cm	6.00%	80.0%	2 years (3.0 to 3.5 cm) 1 year (3.6 to 4.5 cm) 6 months (>4.5 cm) and referral to vascular unit	NR	Small (3.0 - 4.4 cm): 71.0% Medium (4.5 - 5.4 cm): 17% Large (≥5.5 cm): 12%
Giardina 2011[371]	Italy	Men 65-75 years	AD ≥ 3cm	AD ≥ 5.0cm	2.90%	62.0%	1 year (3.0 to 3.9 cm) 6 months (4.0 to 4.9 cm)	12.0%†	NR
Lindholt 2010[314]	Denmark	Men 64-73 years	AD ≥ 3cm	AD ≥ 5.0cm	4.00%	76.6%	1 year (3.0 to 5.0 cm)	NR	Small to medium (3.0 – 4.9 cm): 87.5% Large (>5 cm): 12.5%
Thompson 2009[306]	UK	Men 65-74 years	AD ≥ 3cm	AD ≥ 5.5cm	4.90%	80.0%	1 year (3.0 to 4.4 cm) 3 months (4.5 to 5.4 cm)	NR	NR

Key: UK – United Kingdom; AD – aortic diameter; NR – not reported.

* The incidental detection rate likely represents the cumulative rate over the time horizon of the analysis.

† Rate reported for large AAAs only.

Important input parameters

Trial-based

In the two trial-based economic evaluations from the UK and Denmark,[306, 314] the cost of the invitation was €3 and €6, respectively. The cost of an ultrasound was €43 in the UK and €34 in Denmark. Surveillance in the UK trial-based CUA had a cost of €105. Elective repair was estimated to cost €15,697 in the UK and €22,097 in Denmark. Emergency repair was costed as €25,392 in the UK, and in the Danish trial, the cost was €39,363 if there was no rupture and €51,189 for ruptured AAA.

Model-based studies

Among the model-based studies, 14 reported an average invitation cost of €8.[233, 236, 238, 350, 351, 360-363, 366-369, 371] In 12 of these studies, the cost ranged from €2 to €12.[366, 369] In two studies, the costs were €21 and €26, due to the inclusion of additional operational costs including administration, monitoring and evaluation.[360, 361]

Across 17 studies, the screening ultrasound price averaged €56, ranging from €14 to €117.[233, 236, 238, 350, 351, 359-363, 365-371] The average cost of follow-up ultrasound scans was €116 in 12 studies,[233, 238, 350, 361-363, 366-371] with a range from €30 to €266.[366, 367]

Across nine studies that reported aggregate costs for emergency and elective repairs, without further breakdown by EVAR or OSR, emergency repairs were on average €10,500 more expensive than elective repairs, with cost differences ranging from €2,000 to €23,200.[233, 306, 314, 351, 361, 363, 366, 367, 371] In five studies that reported the costs of emergency and elective EVAR, emergency EVAR was consistently more expensive by an average of €14,300.[236, 350, 359, 368, 369] Similarly, the cost of emergency OSR was higher than elective OSR in eight studies, with an average difference of €17,100. Among nine studies reporting disaggregated costs for EVAR (elective or emergency) and OSR (elective or emergency),[236, 238, 350, 359, 360, 362, 368-370] six found that both elective and emergency EVAR were more expensive than the OSR.[236, 360, 362, 368-370] In two studies, the costs of elective EVAR and elective OSR were similar,[238, 359] while one study reported that the cost of elective EVAR was less than elective OSR.[350]

The cost of preoperative consultations was reported in seven studies.[236, 359-363, 366] In six of these studies, the cost ranged from €232 to €910,[236, 360-363, 366] while one study reported a relatively low cost of €55.[359] As noted in section 5.3.5, differences in healthcare system costs might reflect variation in healthcare financing methods and the range of medical procedures performed. For example, three models specified that this cost included a confirmatory CT scan.[236, 360, 366] Additionally, one

study reported the cost of €232 for a pre-anaesthetic consultation for patients undergoing elective surgery.[236]

The cost of post-operative follow-up and its reporting varied across six studies.[233, 236, 350, 359, 366, 369] Only two studies disaggregated the cost of long-term follow-up and long-term complications.[367, 369] The Norwegian HTA model estimated a total post-operative cost of €14,911, which decreased to 70% by the second year, 10% by the third year, and continued to decrease gradually, reaching 2% after six years, totalling €29,673 per case after seven years post-repair.[233] Similarly, the Swedish HTA model estimated a total cost per case of €4,738 and €4,964 after an average of 5.4 years of follow-up post-EVAR and OSR, respectively.[350] One study reported a cost of €32,614 for cases requiring reoperation, but no other follow-up costs were identified.[366] Another study, reporting costs for Norway and the Netherlands, indicated an annual post-EVAR imaging cost of €145 and €456, a cost of €6,180 and €5,819 for post-EVAR complications, and a cost of €18,541 and €17,440 for post-EVAR complications.[369] Two models reported the cost of postoperative follow-up: one with a single cost of €108 regardless of the type of surgery,[236] and another with a cost of €49 post-EVAR and €92 for any other procedure.[359] In both studies, the level of resource use was unclear.

5.3.3 Summary of findings

Cost-effectiveness analyses

Three of the 20 included studies expressed the cost effectiveness of population-based AAA screening as the cost per LYG only (that is, CEA).[238, 306, 369] One of these was an RCT-based study from the UK which reported an ICER of €16,095 per LYG.[306] The remaining two were model-based studies, one in the Finnish context,[238] and one simultaneously evaluating the cost-effectiveness in Norway and the Netherlands.[369] In the base case analysis, the ICERs were €7,545 per LYG in the analysis based in Finland, €11,255 per LYG in the Norwegian analysis, and €11,453 per LYG in the Dutch analysis.

Cost-utility analyses

Seventeen of the 20 included studies expressed the cost effectiveness of population-based AAA screening using cost per QALY gained (CUA).[233, 236, 314, 350, 351, 359-368, 370, 371] These included one RCT-based CUA from Denmark, which reported ICERs of €255 per QALY after 13 years of follow-up.[314]

Across 16 model-based studies, 15 studies reported results that indicated the screening programme was likely cost effective; the cost per QALY gained ranged from €206 to €30,645 (See Table 5.5).[233, 236, 350, 359-368, 370, 371] There was variation in the QALYs gained per participant screened between studies, ranging from 0.003

to 0.180. Four studies in particular reported higher QALY gains per participant compared with other CUAs.[236, 314, 359, 370] The reasons for this were unclear; the assumptions regarding AAA prevalence and utility values, for example, appeared to be broadly consistent with other CUAs. An early CUA from Denmark in 2009 was the only one to report that the screening strategy was not cost effective, with an ICER of €61,956, exceeding the Danish WTP threshold (expressed in GBP, £) of £30,000 per QALY (approximately €33,000).[351] As discussed in section 5.4, as more recent data has emerged, it has come to light that this model likely underestimated the cost effectiveness of AAA screening.

Given a WTP threshold of €20,000 per QALY, AAA screening would not be considered cost effective in two studies.[351, 360] However, if a WTP threshold of €45,000 per QALY were used, AAA screening would be deemed not cost effective in one study only.[351] Of note, the interpretation of the adjusted ICERs to an Irish context with WTP thresholds of €20,000 per QALY and €45,000 per QALY did not alter the interpretation of cost effectiveness in the original context (See Appendix, Table A7).

Table 5.5 Adjusted incremental cost-effectiveness ratio for cost-utility analyses

Author, year	Country	Adjusted ICER*	Interpretation in the Irish context† (WTP 20,000)	Interpretation in the Irish context† (WTP 45,000)
Ehlers, 2009[351]	Denmark	€61,956	Not cost effective	Not cost effective
Linholt, 2010[314]	Denmark	€255‡	Cost effective	Cost effective
Giardina, 2011[371]	Italy	€6,050§‡	Cost effective	Cost effective
Badger, 2011[364]	Northern Ireland	€5,036‡	Cost effective	Cost effective
Sogaard, 2012[370]	Denmark	€671	Cost effective	Cost effective
Svensjo, 2013[368]	Sweden	€12,866	Cost effective	Cost effective
Glover, 2014[363]	UK	€11,935	Cost effective	Cost effective
SBU, 2015[350]	Sweden	€6,927	Cost effective	Cost effective
Zarrouk, 2016[366]	Sweden	€13,984	Cost effective	Cost effective
Glover, 2017[362]	UK	€10,286	Cost effective	Cost effective
Hager, 2017[367]	Sweden	€5,599	Cost effective	Cost effective
Nair, 2019[361]	New Zealand	€10,083	Cost effective	Cost effective
Reile, 2020[360]	Estonia	€30,645	Not cost effective	Cost effective
NIPH, 2020[233]	Norway	€18,424	Cost effective	Cost effective
Daroudi, 2021[365]	Iran	€12,794‖	Cost effective	Cost effective
AQuAS, 2023[236]	Spain	€206	Cost effective	Cost effective
Vervoort, 2024[359]	Canada	€1,409	Cost effective	Cost effective

Key: AAA – abdominal aortic aneurysm; ICER – incremental cost-effectiveness ratio; QALY – quality-adjusted life year; UK – United Kingdom; WTP – willingness to pay.
* Costs were adjusted based on national consumer price indices (CPI), unless specified otherwise, and purchasing power parities (PPP) in accordance with national HTA guidelines.

† WTP thresholds of €20,000 and €45,000 per QALY gained, commonly employed in Ireland, were used as reference points to guide interpretation of cost effectiveness.
‡ When the base cost year was not provided, it was estimated by subtracting the median time elapsed between the base cost year and the publication year, as reported in other studies, from the year of publication.
§ National CPI using the same base year since 2000. We used the CPI reported by the OECD.
‖ In the original analysis, all costs were converted from IR Rials to US dollar using 2017 PPP. Due to the unavailability of the CPI and PPP for Iran, a direct conversion and adjustment from IR Rials to Irish Euros was not possible. Therefore, for this analysis, the costs in US dollars were converted and adjusted to Irish Euros using the CPI and PPP for the USA.

Sensitivity and scenario analyses

Results of probabilistic sensitivity analysis (PSA) were reported across 14 CUAs, of which 13 indicated that one-time AAA screening for 65-year-old males is likely to be cost-effective.[233, 236, 238, 359-363, 365, 367, 369-371] In one 2009 Danish CUA, only 30% of simulations were below the WTP threshold of £30,000 per QALY (approximately €33,000 per QALY).[351] As described in section 5.4, this analysis adopted a very conservative approach, likely due to the limited long-term follow-up data available at the time of analysis.

Eighteen studies investigated the impact of uncertainty on the outcomes through sensitivity or scenario analysis. Commonly conducted uncertainty analyses included varying factors such as AAA prevalence, opportunistic detection rates, ultrasound costs, screening uptake, surgery costs, discount rates and reductions in health-related quality of life (HRQoL), among others (See appendix Table A6)

One-way sensitivity analysis (OWSA)

Fifteen studies reported conducting an OWSA to identify influential parameters.[233, 236, 238, 314, 350, 351, 359-361, 365-369, 371] Thirteen of these studies reported detailed results, which are summarised in Appendix, Table A6.[233, 238, 350, 351, 359-361, 365-369, 371] Among these, ten studies reported the results of OWSA for AAA prevalence,[233, 238, 350, 351, 360, 361, 365, 366, 368, 369] with eight studies identifying it as an influential parameter.[233, 351, 360, 361, 365, 366, 368, 369] The relationship between AAA prevalence and the ICER is described further below. Increasing the rate of opportunistic detection,[368, 369, 371] or the cost of ultrasound screening, reduced the cost effectiveness of AAA screening.[361, 365, 368] In contrast, decreasing the rate of rupture for large AAAs[365, 366, 371], or the discount rates, increased the cost effectiveness of screening.[350, 365, 366] In two CUAs,[360, 367] a reduction in HRQoL following AAA detection significantly affected the ICER, making the non-screening strategy dominant in the Estonian CUA. Additionally, in the Estonian CUA a decrease in HRQoL after AAA repair led to screening no longer being considered cost-effective.[360]

Lindholt et al. observed a cost-saving effect when the cost of elective repair and emergency repair was increased by 26% and 62% respectively.[314] The CUA in the Spanish HTA indicated that their model was sensitive to the prevalence of sub-aneurysm, though it was unclear if this affected the cost-effectiveness interpretation.[236] Additionally, this CUA evaluated other parameters, such as the proportion of large AAA, the rupture rate of large AAA, and screening costs. However, these factors were assessed within a very narrow range and did not affect the ICER.

In contrast, in the CUA by Ehlers et al. screening remained not cost effective in all the explored sensitivity analyses.[351] When either AAA prevalence, the rate of pre-hospital death after rupture, or the utility values were reduced, the ICER increased significantly above the WTP threshold used in the original analysis (£30,000 per QALY).[351]

Scenario analysis

Eight studies reported results of scenario analysis.[236, 314, 350, 359, 361, 362, 367, 370] Two studies conducted scenario analyses in which the population eligible for screening or surveillance was changed.[359, 362] Vervoort et al. conducted an alternative scenario analysis for screening individuals aged 75.[359] While screening remained cost effective for this group, it was less so compared to 65-year-old men and women. Glover et al. examined a scenario where males with sub-aneurysms (aortic dilation of 2.5 cm to 2.9 cm) were included in the surveillance pathway, screening remained cost effective in this scenario.[362] Additionally, Vervoort et al. investigated scenarios with a lower uptake of 50%, which did not influence the ICER, and lower rate of pre-hospital death after rupture, which, when decreased, resulted in higher emergency surgery costs in the unscreened groups thus rendering the screening strategy cost-saving.[359]

Two CUAs evaluated the impact of changing the surveillance intervals. Glover et al. reported potential cost reductions when spacing the surveillance intervals every two years for small AAAs and every one year for medium AAAs (that is, equivalent clinical benefits at a lower incremental cost).[362] The CUA conducted as part of a Spanish HTA examined the effect of reducing surveillance intervals from three years to two years for small AAAs, finding no significant difference on the ICER.[236]

Three CUAs conducted scenario analyses to include costs from the societal perspective and reductions in HRQoL after AAA detection and or surgical repair.[350, 367, 370] Only the reduction in HRQoL after AAA detection in the model by Hager et al. resulted in a considerable increase in the ICER.[367] Finally, the RCT-based CUA by Lindholt et al. conducted a scenario analysis in which only a subgroup of men with

cardiovascular comorbidities would be invited for screening, which was cost saving.[314]

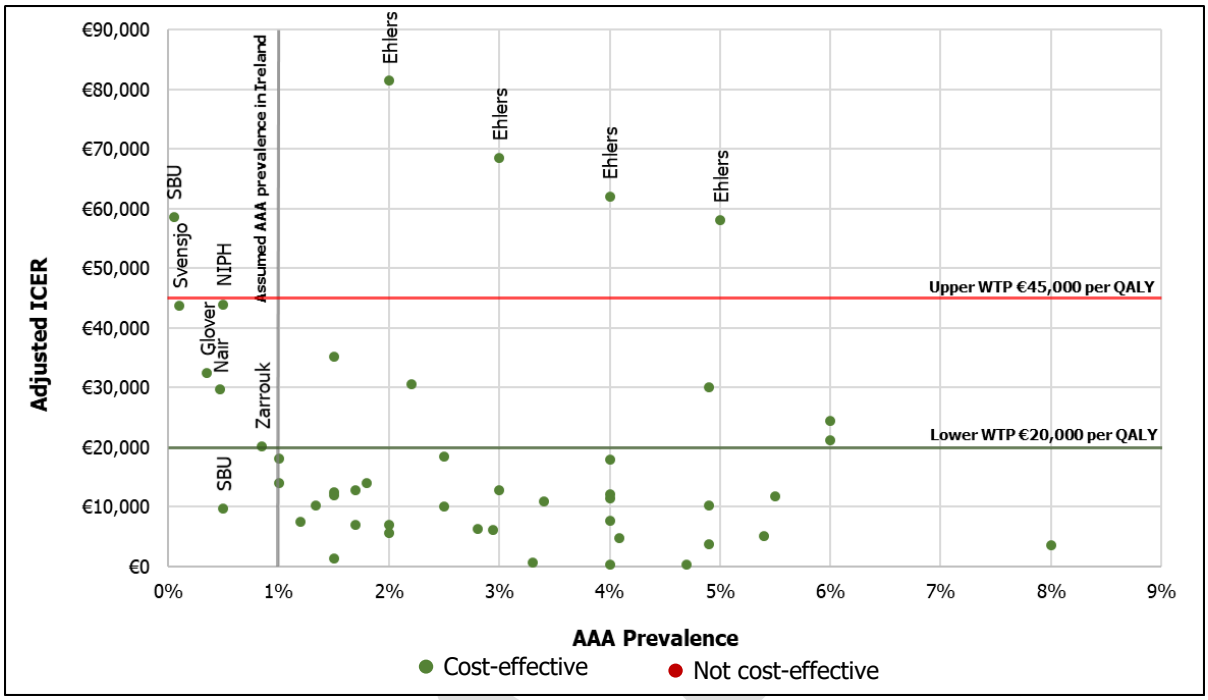
AAA prevalence

As mentioned, AAA prevalence was a key influential parameter explored across 10 studies in OWSA.[233, 238, 350, 351, 360, 361, 365, 366, 368, 369] In all studies, decreasing the prevalence of AAA resulted in a higher ICER, substantially increasing the ICER in eight studies, while rendering screening not cost effective in four studies at an AAA prevalence between 0.1% and 0.85%.[233, 350, 366, 368]

Given the substantial impact of AAA prevalence on the cost effectiveness of AAA screening, this was explored further for all CUAs meeting the inclusion criteria (n = 22). The relationship between adjusted ICERs (cost per QALY in Irish Euro) and corresponding prevalence estimates in base case and sensitivity analyses, is presented with reference to the Irish context in Figure 5.1. Across the 22 CUAs (from 2005 to 2024), 47 ICERs were presented across base case, sensitivity, or threshold analyses. Among these, when an AAA prevalence of equal to or greater than 1% was assumed (n = 40 ICERs), 31 out of 40 (77.5%) of the ICERs were below a WTP threshold of €20,000 per QALY. In contrast, when an AAA prevalence below 1% was assumed (n = 7 ICERs), five out of seven (71%) ICERs fell between the traditionally accepted WTP thresholds of €20,000 and €45,000 per QALY (Figure 5.1). Although data points for lower prevalence estimates were limited, the available evidence suggests that as the prevalence decreases, cost effectiveness also decreases.

Information on the impact of a prevalence below 1.0% was available from six CUAs, one of which (SBU) included two such analyses.[233, 350, 361, 363, 366, 368] Three of these (NIPH, Svensjo and Zarrouk) specifically tested AAA prevalence estimates below 1.0% (0.1%, 0.5%, and 0.85%) in OWSA;[233, 366, 368] in all three, the ICERs obtained were below €45,000 per QALY (range €20,000 to €43,000 per QALY). The remaining three studies (Glover, Nair and SBU) conducted a threshold analysis to establish the prevalence at which AAA screening in men would no longer be considered cost effective.[350, 361, 363] In the CUA by Glover et al.,[363] this threshold was an AAA prevalence of 0.35% at a WTP of £20,000 per QALY (equivalent to approximately €24,000), while in the CUA by Nair et al.,[361] the threshold was <0.48%. In both cases, after adjustment, the ICERs (€32,300 per QALY and €29,600 per QALY) were below €45,000 per QALY. The Swedish HTA CUA (SBU) reported a threshold of 0.1%, which resulted in an adjusted ICER of €58,500 per QALY.[350]

Figure 5.1 ICERs (cost per QALY) by AAA prevalence in included cost utility analyses



Key: AAA – abdominal aortic aneurysm; ICER – incremental cost-effectiveness ratio; NIPH - Norwegian Institute of Public Health; QALY – quality-adjusted life year; SBU – Swedish Agency for Health Technology Assessment and Assessment of Social Services; WTP – willingness to pay.

Note: Only the analyses where the prevalence of AAA was below 1% or the ICER exceeded the traditionally accepted WTP of €45,000 per QALY were labelled; this was to facilitate the readability of the graph.

5.3.4 Quality Appraisal

Economic models are necessarily simplifications of reality, aiming to strike a balance between accuracy and technical complexity. Adequate and clear reporting is therefore fundamental to allow a fair and balanced interpretation of the results obtained.[372]

Following quality appraisal with CHEC-list, four of the 20 studies were considered of high quality,[361, 366, 369, 370] 14 were deemed as moderate quality,[233, 236, 238, 306, 314, 350, 351, 359, 360, 362, 363, 367, 368, 371] and two as poor quality.[364, 365] The summary of the quality appraisal by CHEC-list criteria is shown in Figure 5.2.

Concerns with the model structure were noted for six studies.[233, 238, 350, 361, 364, 368] Three Scandinavian CUAs did not discriminate between small and large aneurysms.[233, 350, 368] This limits their face validity, as it does not accurately reflect the clinical care pathway and associated resource use.[372] The New Zealand CUA used surveillance intervals that do not reflect widely accepted international recommendations.[361] In seven studies, the validity of model inputs was unclear due

to poor reporting of the methodological approach, including the cycle length,[238, 362] base case year for costs,[233, 238, 362, 364, 371] study perspective,[362, 366] key input parameters,[364] and data sources.[365]

A lifetime time horizon (approximately 30 years), adopted in 18 models,[233, 236, 238, 350, 351, 359-371] was considered most appropriate to capture all relevant costs and outcomes in the screened and unscreened cohorts. However, in the context of limited data, projections over longer-term time horizons are subject to considerable uncertainty. In three models, cost effectiveness was estimated over two or more shorter time horizons to deal with this uncertainty.[236, 350, 368]

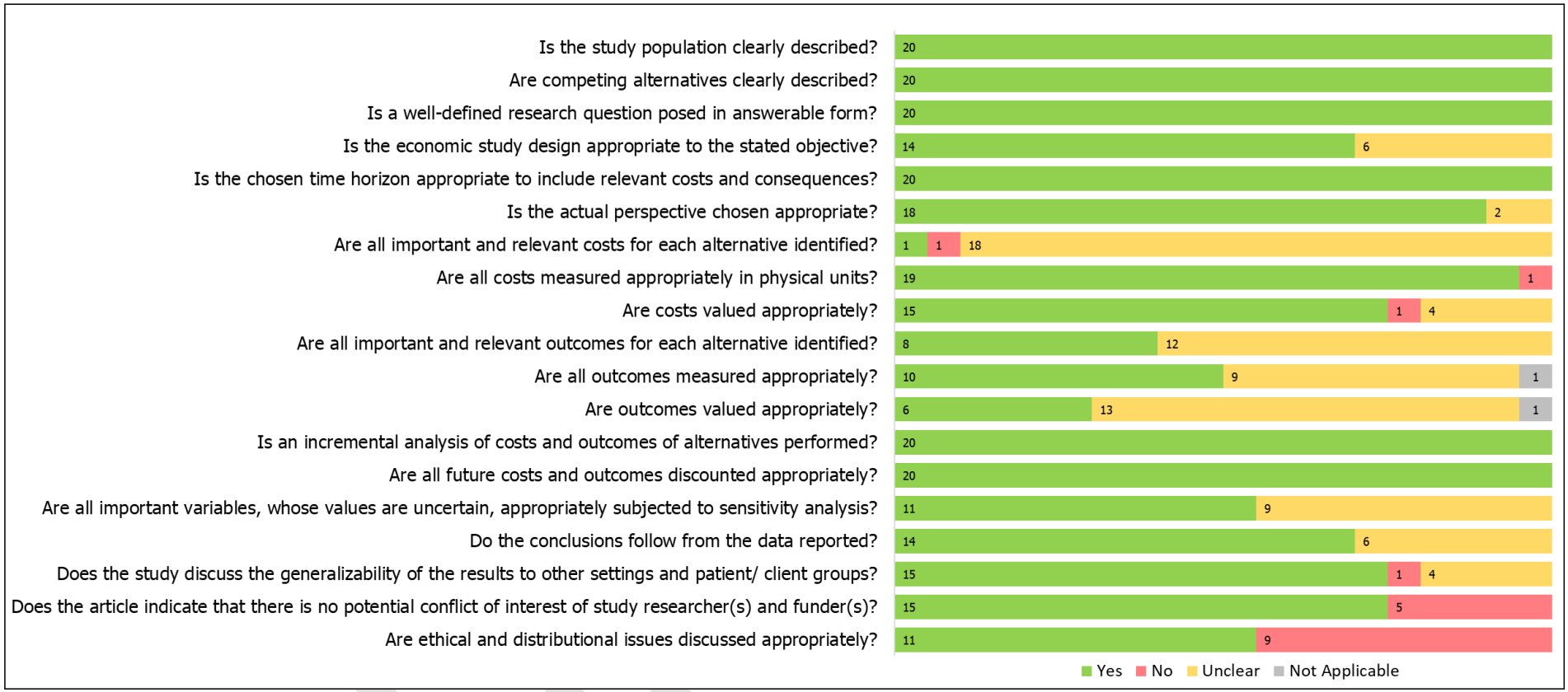
Concerns around the relevant costs were noted for 19 studies.[233, 236, 238, 306, 314, 350, 351, 359-365, 367-371] One of these did not report any cost parameters,[364] while the reminaing studies did not appear to include pre- or post-operative costs.[233, 236, 238, 306, 314, 350, 351, 359-363, 365, 367-371] Of note, two studies attempted to address this limitation by adding a multiplier to the surgery costs (that is, multiplying costs by a factor to increase the original value).[361, 370] Among the models that reported pre- or post-operative unit costs, only three specified the volume of resources consumed per person.[233, 350, 368] Of note, the health states and costs considered may reflect local data availability.

Concerns were noted in the identification, measurement or valuation of all relevant outcomes for 18 studies.[233, 236, 238, 306, 314, 350, 351, 359-365, 367-369, 371] Nine studies did not account for post-operative outcomes.[236, 238, 306, 314, 351, 360, 363, 367, 371] This could potentially bias the cost effectiveness in favour of screening if patients treated by elective surgery have to undergo secondary intervention due to complications. Three studies did not report a clear clinical pathway, limiting the appraisal of the outcomes identified.[350, 364, 368] In fourteen studies, the rationale behind the utility values used was not reported or unclear.[233, 306, 314, 351, 359-365, 367, 369, 371]

Nineteen studies performed sensitivity analysis comprising either OWSA, scenario analysis or both.[236, 351, 359, 363, 366-371] In seven, there were concerns regarding the methodological approach (for example, choice of parameter distribution or validity of reported confidence intervals) and completeness of results.[236, 314, 350, 359, 360, 367, 371] While it is acknowledged that estimates of uncertainty may be challenging to obtain for all parameters, the choice of parameters for sensitivity analysis should be clearly reported.

Finally, five studies did not include a conflict of interest statement.[238, 350, 359, 362, 371] The lack of inclusion of such a statement typically raises concerns regarding potential financial or non-financial conflicts of interest.[373] Nine studies did not discuss ethical and distributional issues in sufficient detail.[306, 314, 350, 362, 363, 367-369, 371]

Figure 5.2 Quality appraisal of economic evaluations studies included.



Note: The quality appraisal of the 20 included studies was conducted following the Consensus on Health Economics Criteria (CHEC)-list.[353]

5.3.5 Transferability assessment

The purpose of this section is to identify potential differences between key parameters used in included studies and those that would be applied in an Irish context, to inform assessment of the transferability of the available cost-effectiveness evidence to the Irish setting. The results of the assessment of applicability of the included studies is illustrated in (Figure 5.3). Overall, 14 studies were considered partially applicable to the Irish context,[233, 236, 306, 314, 350, 351, 359, 361, 363, 366-370] while six studies were not considered applicable.[238, 360, 362, 364, 365, 371]

In four studies, differences in population characteristics,[365] and healthcare system structure and financing,[359, 361] presented challenges for direct transferability of the results of cost-effectiveness analyses. Furthermore, three CUAs and one CEA included populations aged 64 to 75 years, which limits the transferability of their results to the target population of the current HTA.[306, 314, 364, 371] Of note, despite the remaining CUAs reporting a target population of males aged 65 years, some age-specific model inputs (for example, prevalence, surgical outcomes) were not necessarily specific to the cohort under analysis, which also limits the transferability.

The prevalence of AAA is a key parameter that could affect the applicability of the results from included CUAs. In the absence of current Irish data on AAA prevalence, the prevalence of AAA in UK represents the best available evidence (<1.0%),[374, 375] considering the demographic and smoking rate similarities. All the included economic evaluations used an AAA prevalence above 1.0% (see Table 5.4). Seven studies adopted prevalence estimates between 1.0% and 2.0%,[350, 359, 362, 363, 366-368] nine studies between >2.0% and 5.0%,[233, 236, 314, 351, 360, 361, 365, 370, 371] and two studies >5.0%.[238, 364] As noted previously, only six studies presented cost effectiveness findings for AAA prevalence estimates below 1.0% (range: 0.1% to 0.85%), as examined in sensitivity analyses.[233, 350, 361, 363, 366, 368] To address this concern, as part of this HTA, the relationship between AAA prevalence and estimated ICERs was explored further (see Figure 5.1). This analysis suggests that AAA screening may not be cost effective at a threshold of €20,000 when prevalence drops below 1.0%. This should be considered in light of declining trends in prevalence of AAA, as discussed in Chapter 2, Section 2.6.1 and Chapter 4, Section 4.3.2.

As detailed in section 5.3.2, there was variability in the modelling of the care pathway. Models that more accurately reflect the care pathway used in practice are considered more appropriate. Three CUAs adopted a structure that did not account for AAA size distribution.[233, 350, 368] Another notable limitation of seven economic evaluations was the absence or limited use of EVAR.[238, 306, 351, 361, 363, 367, 369] As discussed in Chapter 3, Section 3.3.2, due to the minimally invasive nature of EVAR, men who might otherwise be considered unfit for open surgical repair may be eligible for treatment with EVAR, potentially leading to a lower non-intervention rate.

Further, due to lower post-operative mortality rate but the higher probability of re-intervention in the long term, the extent and timing of post-surgical care costs may differ between EVAR and OSR.

In all studies, the post-operative follow-up pathway was either not reported or not clearly described, likely due to challenges in obtaining reliable data in the absence of surgical registries. However, six studies did include some costing of post-surgical follow-up.[233, 236, 350, 359, 366, 369] It is difficult to establish whether surgical costs are directly comparable with costs in Ireland in the absence of disaggregated Irish cost data by surgical approach or rupture status; however, the cost of AAA surgical repair was considered broadly comparable to the Irish context (based on cost estimates provided by HIPE (See Chapter 6, Table 6.2)) in six studies.[233, 238, 314, 359, 369, 370] The vascular surgery model of care for Ireland produced by the National Clinical Programme in Surgery notes that the cost of emergency repair is higher than the cost of elective repairs.[148] This was reflected in nine studies.[233, 306, 314, 351, 361, 363, 366, 367, 371] Of note, differences in the cost of emergency versus elective repair can only substantially influence cost effectiveness if the number of emergency repairs is relatively high in the unscreened cohort. In Ireland, ruptures are estimated to account for only 10% of all admissions (See Chapter 2, Section 2.7.1), suggesting that the cost of emergency repairs is unlikely to have a substantial impact.

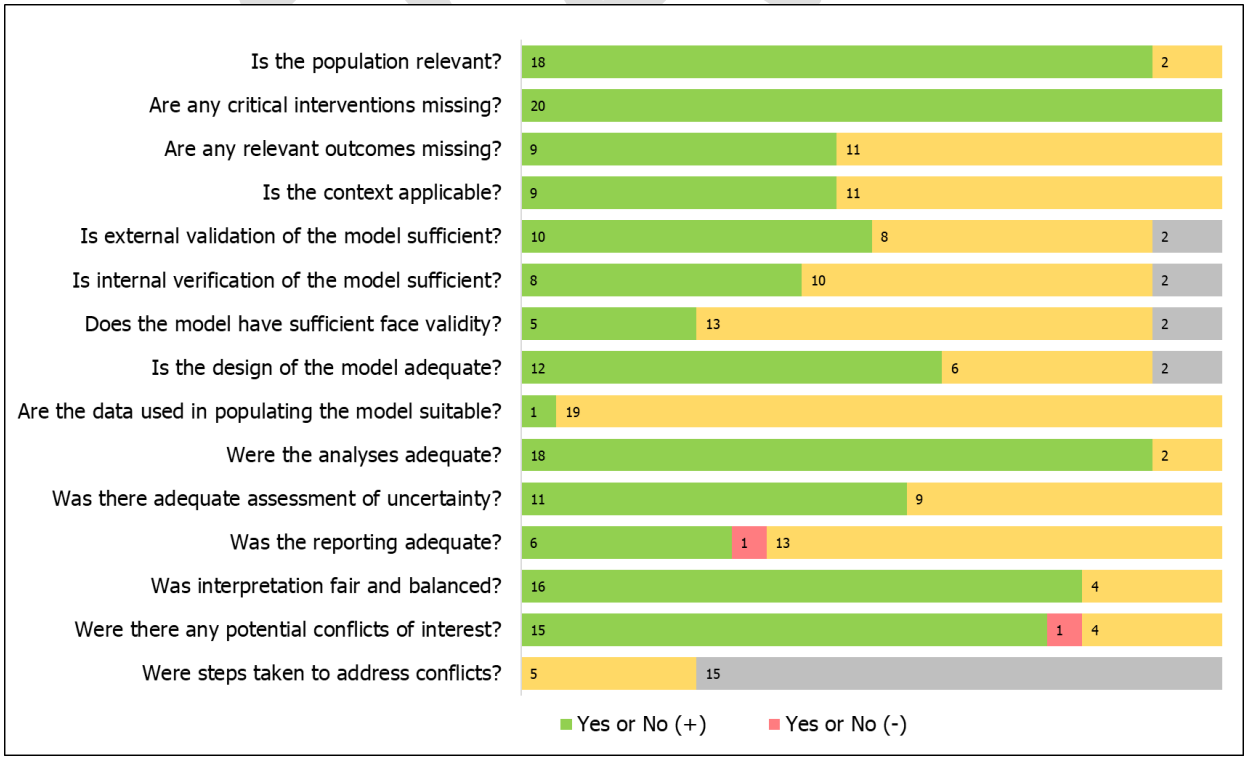
Across 16 economic evaluations reporting on the cost of the invitation per person, three CUAs provided some detail of the sub-costs accounted for, including administrative costs, printing, mailing, advertising, and operating a call centre.[314, 361, 371] However, none explicitly considered other costs related to setting up and running a programme, including the programme database, quality assurance frameworks, governance structures, and monitoring costs. Since the costs related to implementing a screening programme are context-dependent, where these costs are not clearly reported it is challenging to make informed judgements about transferability. Similarly, none of the studies attempted to cost the inclusion of self-referrals or the addition of incidental diagnoses into the surveillance pathway. Such an approach has the potential to result in increased costs, but also improved outcomes for a broader population.

As noted previously, there was considerable variability in the rates of opportunistic detection used in the models and it was often unclear how these rates were estimated. Several studies used estimates from the MASS trial which may no longer be applicable to the current context, given increases in the use of diagnostic imaging over time.[233, 350, 362, 363, 368] One CUA attempted to account for the uncertainty in the incidental diagnosis rate by exploring a range of plausible values (42 to 75%), finding that the cost per QALY increased with increasing rate of opportunistic detection.[350] In Ireland, it is estimated that 90% of AAA surgical repairs are performed electively (See Chapter 2, Section 2.7.1), suggesting a high rate of

incidental diagnosis. However, limited data and the likelihood of a high non-intervention rate in cases with out-of-hospital rupture make it difficult to reliably estimate the incidental diagnosis rate in the Irish context, thus posing challenges for assessment of transferability.

Finally the reporting of internal and external model validation varied across the studies, and was generally not in line with best practice standards.[372, 376] Eight studies described some form of internal validation which included descriptions related to the following: model calibration, testing or debugging.[351, 360-363, 366, 368, 370] In the remaining 10 studies, no information was provided relating to internal model validation.[233, 236, 238, 350, 359, 364, 365, 367, 369, 371] The reporting of external validity was considered appropriate in 10 studies,[350, 351, 359, 361-363, 368-371] and insufficient or unclear in the remaining eight studies.[233, 236, 238, 360, 364-367] Notably, due to limitations in local data availability, these studies relied on RCT evidence or data from international screening programmes for model inputs, which meant that the modelled outputs could not be validated against these sources. Even when suitable data for validation were available, replicating RCT outcomes might not accurately reflect the current clinical context; while the simulated population may mirror the validation population, RCT evidence primarily derived from older men may not be applicable to the population aged 65 years.

Figure 5.3 Transferability assessment of economical evaluations studies included



Note: The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) questionnaire was used to assess the applicability of individual study findings to the Irish setting.[354]

5.4 Discussion

This chapter aimed to critically assess the cost effectiveness of AAA screening in men aged 65 years, applying the NSAC criteria of viability, effectiveness, and economic balance, with a focus on the Irish context. Twenty studies published after 2009 were included, including 17 CUAs and three CEAs. Across 16 CUAs, AAA screening was considered cost effective at a WTP threshold of €45,000 per QALY, with ICERs ranging from €200 to €30,600 per QALY. In one CUA, population-based AAA screening was not considered cost effective (€61,956 per QALY) at a WTP threshold of €45,000 per QALY. In the three CEAs, one of which modelled for two countries, ICERs ranged from €7,500 per LYG to €16,100 per LYG. Overall, the available evidence suggests that the introduction of AAA screening in men aged 65 years would likely result in additional QALYs at an acceptable cost. Economic models employed varying methodological approaches to reach this conclusion.

Although findings were generally consistent across included studies, one CUA from 2009, set in the Danish context, reported an ICER of €62,000, which exceeds the threshold of €45,000 commonly used in the Irish setting. Ehlers et al., the authors of this CUA, noted that their key model outputs were consistent with published data at the time of analysis. They attributed the main difference from previous models to their use of weighted average inputs from the MASS trial for men aged 65 to 74 years, applied to a screening strategy for men aged 65 only. This approach resulted in a lower estimate of cost effectiveness due to the lower prevalence in this subgroup, compared with the broader RCT populations. However, while Ehlers et al. used a prevalence rate of 4%, 14 of the remaining 16 CUAs used a prevalence rate lower than 4%, and still favoured AAA screening. Additionally, in seven of these CUAs, even when performing an OWSA with an AAA prevalence as low as 0.1%, the highest ICER was €43,000 per QALY, which is significantly lower than the ICER reported by Ehlers et al. Therefore, despite the conclusions of the study authors, factors other than prevalence likely contributed to the higher ICER in this study. The conflicting results in this study are challenging to interpret due to the lack of clarity in reporting key methodological aspects, particularly structural assumptions. Recent CUAs conducted in the Danish context found AAA screening in men to be cost effective,[314, 370] suggesting that the CUA by Ehlers et al. may have underestimated the cost effectiveness of AAA screening. Since the literature search informing this review was undertaken, at least one additional CEA has been published.[245] AAA screening in men was reported to be cost effective in this analysis undertaken in the Czech Republic, which estimated a cost per death prevented of €21,583.

Our findings are broadly consistent with the findings of three previous systematic reviews that suggested AAA screening in men is likely cost effective.[372, 377, 378] Since the most recent review was published,[377] seven additional studies have been published, [233, 236, 359-362, 365] all concluding that AAA screening in men is cost

effective. However, given that limited up-to-date epidemiological or comparative clinical effectiveness data has been published in recent years, recent CUAs may not necessarily reflect the current context.

Despite the overall findings supporting the cost effectiveness of AAA screening, the transferability of the results of the included CUAs to the Irish setting is uncertain (see section 5.3.5). Notably, key uncertainties include future trends in AAA prevalence, the rate of incidental diagnosis in Ireland, and the organisation of the proposed screening programme. In the absence of robust Irish data, the cost effectiveness conclusions drawn from international data may not be applicable to the Irish healthcare context. The absence of such local data, however, similarly precludes the development of an accurate Irish-specific cost-utility analysis (CUA). The lack of emergence of new epidemiological or clinical data since existing analyses were completed, as noted above, further means that development of a de novo, Irish-specific CUA would not sufficiently resolve uncertainties regarding the cost effectiveness of screening in the local context.

As noted in the epidemiology and clinical effectiveness chapters, there has been a steady decline in AAA prevalence over time. This trend introduces uncertainty regarding the clinical and cost effectiveness of a population-based AAA screening programme in the longer term. Due to the absence of recent RCTs, many published CUAs used outdated prevalence estimates, or relied on sensitivity analyses to gauge the impact of declining AAA prevalence on the overall cost effectiveness of AAA screening. As anticipated, the findings of this review suggest that the cost effectiveness of AAA screening is highly dependent on AAA prevalence. As shown in Figure 5.1, the ICERs are consistently low when the AAA prevalence is 1.0% or higher, but increase rapidly below this level. Although detailed analyses were not reported, a previous systematic review noted a similar observation.[377] The sensitivity of ICERs to changes in AAA prevalence highlights the need for up-to-date epidemiological data to inform decision-making in Ireland.

The rate of opportunistic detection is another important parameter that could impact the cost effectiveness of a population-based screening programme for AAA in men. Although the current rate of opportunistically detected AAA is unknown in Ireland, it is likely that detection rates have increased over time due the increasing use of diagnostic imaging for other medical evaluations.[350] If a high proportion of AAAs are already being detected incidentally, the incremental clinical benefit of a formal screening programme may be limited, while the implementation costs would remain largely unchanged.

Moreover, in Ireland, context-specific administrative and operational costs, such as setting up a programme database, quality assurance, and programme governance, could affect the cost effectiveness However, these were often not transparently

reported in the included studies. In some jurisdictions, it may be possible to leverage existing resources to support implementation (for example, ICT infrastructure), which may reduce upfront implementation costs. Additional considerations that would likely be part of an AAA screening programme in the Irish setting, such as the inclusion of self-referrals and incidentally diagnosed cases in the surveillance pathway, were also not considered in the included CUAs. Therefore, it is not possible to comment on the impact of changes in the population eligible for screening on cost effectiveness.

These uncertainties are not exclusive to Ireland. The lack of recent RCTs addressing the knowledge gaps, in the context of a changing epidemiology, likely contributes to the low adoption of formal population-based screening programmes internationally (See Chapter 3, section 3.5.3). The international literature suggests that the prevalence of AAA is declining, and that it is expected to continue to do so (see Chapter 2, section 2.6.1). This decline in AAA prevalence has only been captured to a limited extent in published economic evaluations. As a result, the long-term cost effectiveness of a population-based screening programme is uncertain. This has led to debate about whether a switch to targeted screening should be considered.[10] Although targeted screening programmes fall outside the scope of this HTA, it is important to consider the results of studies on the cost effectiveness of target screening programmes and their potential implications within the Irish context.

Three studies were identified that reported on the cost effectiveness of targeted screening for AAA.[379-381] Two studies, one CEA in the Finnish context,[379] and one CUA in the Swedish context,[380] assessed the cost effectiveness of screening first-degree relatives, and siblings of patients with AAA, respectively. Both studies found this strategy to be cost effective, with ICERs lower or similar to those of the population-based screening programme. However, in these studies, targeted screening was not intended to replace population-based screening, but rather to augment existing approaches to capture those who might otherwise not be invited. In the Irish setting, the extent to which relatives considered at elevated risk of AAA are systematically offered targeted screening is uncertain. One CEA study in Sweden also reported that targeted AAA screening for patients referred to the vascular laboratory could be highly cost effective compared with no screening.[381] Similarly, the CUA by Lindholt et al. conducted a scenario analysis in which inviting a subgroup of high-risk men (history of cardiovascular disease, for example, hypertension, previous myocardial infarction) was found to be cost saving compared to inviting all men. An ongoing in-silico trial in the UK by Bown et al. aims to analyse the cost effectiveness of offering targeted screening based on the results from the NHS AAA screening programme from 2013 to 2021.[324] However, the feasibility of such a strategy in practice depends on the availability of databases to identify high-risk individuals, using risk factors such as smoking history or cardiovascular

comorbidities. In Ireland, this may present a challenge, as robust, integrated health databases are not available. Therefore, while targeted screening may be advantageous with consideration to the changing epidemiology of disease and the benefit harm balance, its implementation may require significant improvements to ICT infrastructure and data collection processes.

Another key factor that could influence the cost effectiveness of an AAA screening programme is the spacing of surveillance intervals. Shorter intervals allow for closer monitoring, however, they also demand more healthcare resources, which increases overall costs. Currently, there is no international consensus on optimal surveillance intervals (See Chapter 3, section 3.5.1). For example, the UK's NHS AAA Screening Programme (NAAASP) surveillance intervals of one year for small AAAs and three months for medium AAAs were reflected in the screening care pathway in two UK-based CUAs by Glover et al.,[362, 363] and were also adopted in six other studies, all of which demonstrated cost effectiveness. However, more recent guidelines, including the 2024 update from the ESVS, recommend longer intervals, which has the potential to reduce costs, but may also reduce effectiveness. Two UK-based studies have suggested that lengthening surveillance intervals could lower costs without compromising the effectiveness of the screening programme, compared with the current surveillance intervals.[362, 382] Furthermore, as described in Chapter 3, section 3.5.3, longer intervals between surveillance have been reported to be safe and effective in the Swedish AAA screening programme.[383] Given the uncertainty around AAA prevalence in Ireland and its potential decline, optimising surveillance intervals could maximise resource efficiency, although absolute cost savings are likely to be small. The absence of RCTs comparing surveillance intervals poses a challenge to establishing the optimal surveillance strategy in terms of the benefit-harm balance. Thus, caution would be warranted if extending the surveillance intervals were to be considered.

5.4.1 Strengths and limitations

This review has several key strengths that contribute to its comprehensiveness and relevance for informing consideration of the cost effectiveness of an AAA screening programme in men in the Irish context. Notably, the publication of a protocol promotes transparency in the evidence synthesis process. In a minor deviation from the published protocol, this analysis focussed on a subset of studies published since 2009 to direct the analysis towards the most relevant literature. This approach was considered appropriate in the context of the changing epidemiological and clinical context over time, the strength of the evidence base, the broad range of contexts considered, and the consistency of the findings. Additionally, the absence of language restrictions enabled the consideration of evidence from a range of contexts internationally, while, the inclusion of grey literature, including non-peer-reviewed sources such as HTAs from other jurisdictions, allowed this review to capture

insights of particular relevance to decision-makers including organisational and budgetary factors. A further notable strength of this review is the structured assessment of quality and transferability to determine the validity and relevance of modelled outcomes to the Irish context. Furthermore, this systematic review investigated factors that influence the cost effectiveness of AAA screening, in particular, AAA prevalence.

However, there are also limitations that must be acknowledged. The validity and findings of the studies were presented with respect to the Irish context; however, factors limiting transferability require careful consideration. Differences in healthcare systems, economic conditions, and policy priorities between jurisdictions may affect the applicability of findings. Moreover, as noted above, the omission of programme-specific administrative, infrastructural, and operational costs, such as staffing, database management, and quality assurance frameworks may lead to an underestimation of total implementation costs.

5.4.2 Conclusion

The international evidence consistently suggests that AAA screening in men is cost effective, with reference to WTP thresholds commonly used in Ireland. While the results are generally robust, uncertainty around key parameters, in particular AAA prevalence, contributes to uncertainty regarding the long-term cost effectiveness of population-based AAA screening in men. Further, programme-specific costs including a programme database and staff were often not reported in included studies and would be associated with increased implementation costs in the Irish context. Development of a de-novo CUA in Ireland would primarily depend on international epidemiological and clinical estimates due to the lack of Irish-specific data for key input parameters; as such, conducting an Irish-specific CUA would not sufficiently resolve uncertainties regarding the cost effectiveness of screening in Ireland.

6 Budget impact analysis

Key points

- A budget impact analysis was undertaken to estimate the incremental cost associated with the introduction of an AAA screening programme for men in Ireland, compared with no systematic screening, over a five-year time horizon.
    - It was assumed that men aged 65 years would be eligible for screening; this assumption was based on the epidemiology of AAA in men, and the availability of real-world evidence in this age group.
- To facilitate planning and capacity building, the budget impact model design assumes a two-year pre-implementation phase, followed by phased national rollout (30% of men aged 65 years invited in year three, 60% in year four, and 100% in year five).
- An uptake rate of 80% was assumed, based on evidence from international practice.
- The incremental budget impact associated with implementation of a population-based screening programme in men aged 65 years was estimated at €20.3 million over five years, compared with no systematic screening. Total staff costs comprised 68% of expenditure over the five-year time horizon.
    - Programme staff involved in operations comprised 22% of costs, while clinical posts (including some staff working in both clinical and programme roles) comprised 46% of the total five-year budget impact.
    - Setting up the programme database was estimated to account for 22% of total costs. Collectively, equipment, consumables, communication, and education and awareness initiatives comprised approximately 7% of the five-year incremental budget impact. The incremental cost associated with treatment and management of cases with large AAA referred to vascular surgery comprised less than 3% of total costs.
    - Assuming a phased implementation approach, and declining AAA prevalence (from 0.77% in year one to 0.64% in year five), it was estimated that 266 men with small and medium AAAs would be under surveillance by the end of year five.
    - It was estimated that population-based screening would lead to a 21% increase in the number of AAA elective surgical repairs (that is, less than

20 additional surgeries) in the modelled population (men aged 65 to 69 years) over the five-year period.

- Scenario analysis was undertaken to quantify the variability in the incremental budget impact due to uncertainty associated with key inputs and assumptions.
    - Changes to the incidental diagnosis rate and AAA prevalence within the plausible range of values had a relatively small effect on the incremental budget impact.
    - Compared with no screening, organised targeted screening would be associated with an incremental budget impact of €18.7 million.
- If sub-aneurysmal aortas were included in surveillance, on average, it is anticipated that an additional 250 men would enter the surveillance pathway annually. Additional screening technicians may be required in the longer-term to manage follow-up of these cases.

6.1 Introduction

Finite healthcare budgets require prioritisation of which programmes can be funded. In the absence of appropriate planning, introduction of a new health technology may result in unintentional redirection of resources from existing services or exacerbate existing pressures within the healthcare system. This chapter provides information to inform the feasibility of implementing an AAA screening programme in the context of the broader healthcare system, as outlined in the NSAC criteria:

- *There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is acceptable and can be implemented.*
- *The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (value for money). Assessment against these criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resources.*

The aim of this budget impact analysis (BIA) is to estimate the short-term incremental budget impact associated with the potential introduction of a population-based AAA screening programme for men aged 65 in Ireland from the perspective of the publicly-funded healthcare system.

As outlined in Chapter 5, in light of declining AAA prevalence, the long-term cost-effectiveness of population-based AAA screening for men aged 65 is uncertain. Organised targeted screening based on risk factors has been proposed as a potential approach to improve resource efficiency by concentrating resources on those at highest risk of AAA-related morbidity and mortality.[324] Due to uncertainty regarding the optimal screening approach for men in the context of the changing epidemiology of the disease and the evolving healthcare system landscape in Ireland, an organised targeted screening programme was considered in scenario analysis.

6.2 Methods

For the purpose of the BIA, in the base case, it was assumed that an AAA screening programme would be delivered in community-based healthcare facilities by a dedicated, specialist workforce. The inputs and data sources used in the base case and scenario analyses are outlined in the following sections. The rationale for the key assumptions made in conducting this analysis is summarised in tabular format in the Supplementary Appendix (Table A1). The rationale underpinning the assumptions made, from the point of view of the screening programme delivery model, is explored in detail in Chapter 7. The analysis described in this chapter was

conducted in line with national and international guidelines,[384, 385] and was undertaken in Excel 2013.

6.2.1 Target population

The optimal age of one-time AAA screening in men at which the most lives are saved and at the lowest cost has never been formally assessed.[6] Given that AAA-related mortality begins to increase among men in Ireland at approximately age 65 years (Chapter 2, section 2.8.1), the evidence of slow aneurysm growth over time (Chapter 2, section 2.4.2), and the substantial real-world evidence base for population-based AAA screening for men age 65 years (Chapter 4, section 4.3.2), it was assumed that an AAA screening programme in Ireland would target this age group. High quality evidence to support screening in other age groups is lacking. It was estimated that approximately 30,000 men aged 65 years would be eligible for one-time AAA screening each year based on the population projections for the years 2026 to 2030.[123]

6.2.2 Intervention

The intervention under consideration was a population-based AAA screening programme for men aged 65 years comprising end-to-end care from invitation to screening through to long-term follow-up, where indicated.

6.2.3 Comparator

Currently, there is no systematic screening for AAA in men in Ireland. As outlined in Chapter 3, in the absence of a systematic AAA screening programme in Ireland, current practice is that men with an AAA are typically identified through incidental or opportunistic detection during investigations for other indications. It is estimated that less than 13% of cases aged 65 to 69 years present to emergency services with a ruptured AAA.[100]

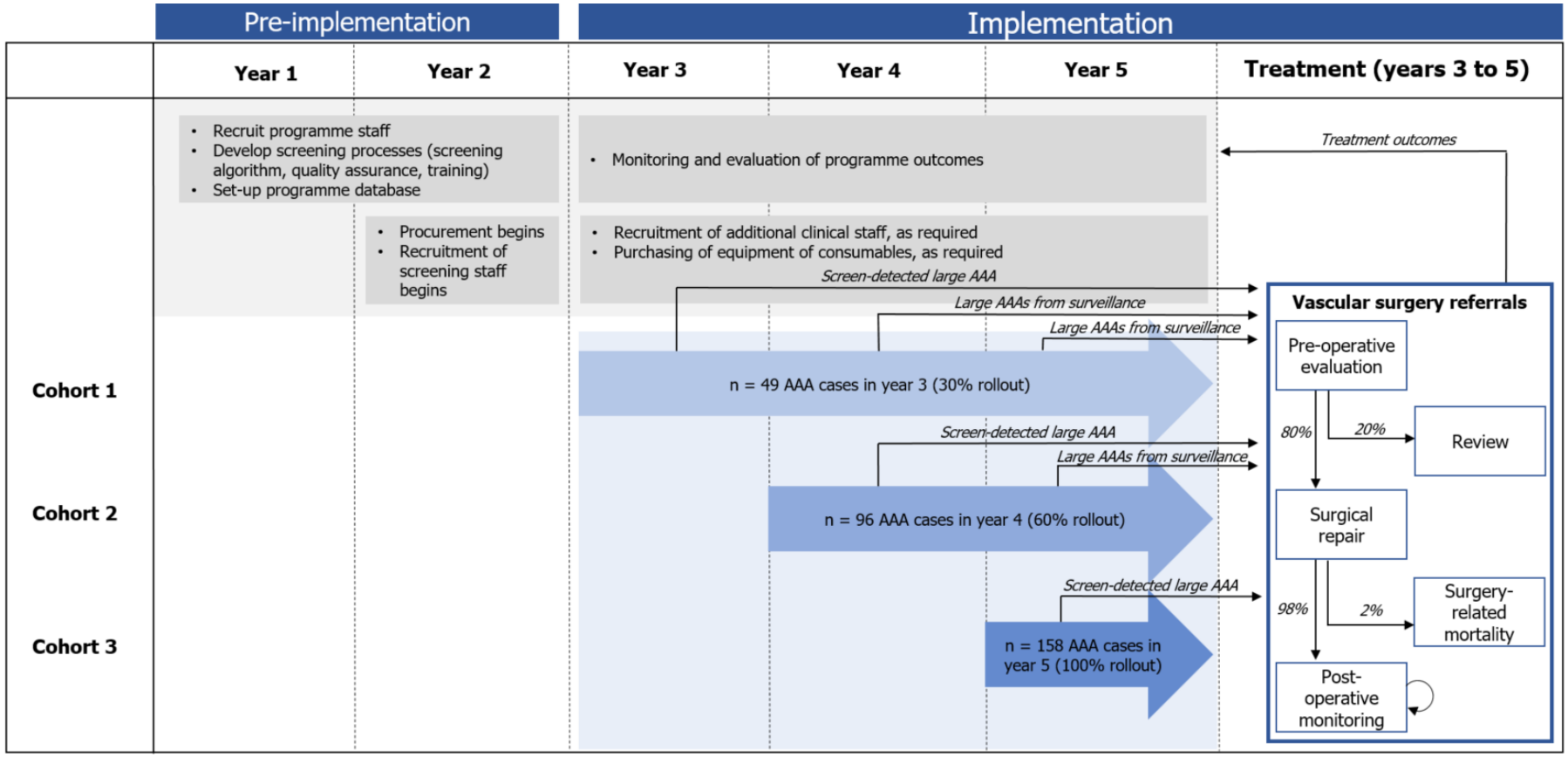
6.2.4 Model structure

The BIA was designed as an open-cohort model where a new cohort of men aged 65 years was invited to participate in screening each year. The model also included ongoing costs related to surveillance and long-term post-operative follow-up of screening participants from previous years. To facilitate comparison between cohorts**,** the unscreened cohort was also structured as an open cohort model starting in men aged 65 years, as opposed to reflecting the cost of treating the entire male population presenting with AAA under current practice.

Implementation of a screening programme requires a lead-in or pre-implementation phase for recruitment and training of staff, development of the screening algorithm and programme standards, and set up and validation of the programme database.

For the purposes of this analysis, it was assumed that the lead-in time or pre-implementation phase would be two years. Accordingly, only programme costs were included for the first two years of the BIA (for example, information and communication technology (ICT) infrastructure and administrative staff). Screening of eligible men was assumed to commence in year three, with phased implementation across screening regions (for example, Eastern, Southern and Western regions) over a three-year period (see Chapter 7, section 7.4.2). It was assumed that the proportion of the eligible population invited to participate in screening would increase incrementally each year, reaching full implementation by year five (that is, 30% of men aged 65 years invited in year three, 60% in year four, and 100% in year five). A simplified schematic of the assumed approach to implementing the screening programme is presented in Figure 6.1. The full clinical care pathway following a positive screening test result, as outlined by the National Clinical Programme for Surgery's model of care (Chapter 3, Figure 3.1), is outlined in section 6.2.6.

Figure 6.1 Simplified schematic of staggered implementation of screening in years 3 and 4, with full implementation in year 5, for men aged 65 years



A two-year pre-implementation phase was assumed, followed by phased national rollout (that is, 30% of men aged 65 invited in year three, 60% invited in year four and 100% invited in year five). Programme staff were assumed to be recruited during the pre-implementation phase to support development of screening processes. Clinical staff were recruited in line with phased roll out. From 2028 (Cohort 1), a new cohort of men aged 65 years were invited to participate in screening each year. It was assumed that only men with an aortic diameter ≥3.0 cm would be followed up. Men with an AAA ≥5.5 cm were referred to vascular surgery. Assumptions regarding the number of AAA cases detected and referrals to vascular surgery (large AAA) were dependent on the phase of programme rollout, the annual projected cohort size, projected AAA prevalence, the mean AAA growth rate and the distribution of aortic diameter at

baseline. The model included ongoing costs related to surveillance and post-operative follow-up of screening participants from previous years. Men not invited to screening during phased roll out (70% in year three and 40% in year four) or who declined to participate in screening (20%) were diagnosed through the usual care pathway.

The estimate of surgery-related mortality presented (2%) reflects a weighted average of mortality from OSR (4.7%) and EVAR (1%), based on 35% of patients undergoing OSR and 65% undergoing EVAR.

6.2.5 Perspective and time horizon

The analysis was conducted from the perspective of the Irish publicly-funded health and social care system, namely the Health Service Executive (HSE). In accordance with national HTA guidelines, only direct medical costs to the HSE were considered.[384] Indirect costs such as productivity losses associated with AAA-related morbidity and mortality, and out-of-pocket expenses incurred by individuals attending healthcare services, were not considered. These factors are considered in Chapter 8.

The base case analysis estimated the incremental budget impact over a five-year time horizon, consistent with national HTA guidelines.[384]

6.2.6 Care pathway

Screening care pathway

For the purposes of this analysis, the screening care pathway was modelled based on the 2023 vascular surgery model of care for Ireland (see Chapter 3, Figure 3.1),[148] international guidelines and policy (see Chapter 3, section 3.5), and the input of the EAG convened to support this assessment. In the base case analysis, participants with an aortic diameter ≥3.0 cm were considered 'screen positive'. Participants with an AAA <3.0 cm in diameter were discharged from the programme and did not undergo further follow-up. Participants with a small AAA (that is, 3.0 cm to 4.4 cm inclusive in diameter) underwent a surveillance scan once per year, and those with a medium AAA (that is, 4.5 cm to 5.5 cm inclusive in diameter) underwent a surveillance scan twice a year.

Those with an aortic diameter ≥5.5 cm (that is, large AAA) were referred to vascular surgery to assess suitability for surgical repair. Based on consultation with clinical experts, it was assumed that these patients would have two outpatient appointments with a multidisciplinary team for pre-operative evaluation. Following pre-operative evaluation, it was estimated that 81.4% of patients would under elective surgical repair,[386] with 65% of these patients undergoing endovascular aneurysm repair (EVAR) and 35% undergoing open surgical repair (OSR).

As outlined in the 2024 ESVS guidelines, lifelong follow-up including imaging after AAA repair is considered mandatory.[6] In clinical practice, the frequency of post-surgical follow-up may vary depending on factors such as post-operative outcomes (for example, evaluation of sac shrinkage, seal zone integrity) and the benefit-harm balance associated with continued post-operative monitoring (for example, fitness for surgery if expansion of the aneurysm sac is detected). It was assumed that patients who underwent OSR (35% of all surgical candidates) would have three post-operative outpatient appointments at six weeks, six months and 12 months

during the first year post-surgery, while patients who underwent EVAR (65%) would attend two post-operative outpatient appointments at six months and 12 months. Thereafter, it was assumed that all patients would require one outpatient appointment in each subsequent year for the duration of the BIA. As a conservative approach, it was assumed that men considered ineligible for surgery following pre-operative evaluation (19%) would have one review appointment annually for the duration of the BIA.

Unscreened care pathway

In the unscreened cohort, patients with an incidentally-detected large AAA were managed according to the same algorithm as the screened cohort; the care pathways differed only in terms of the number of cases detected, the timing of detection, and the proportion of cases presenting with ruptured AAA (13%).[100] Pre-operative outpatient costs were not included for cases with ruptured AAA.

6.2.7 Model input parameters

Where possible, estimates were based on national data sources. In the absence of national data, estimates were derived from the international literature, and were corroborated by expert clinical input.

Screening uptake and satisfactory scans

Traditionally, uptake rates for screening programmes have been similar between the UK and Ireland. In the absence of an AAA screening programme in Ireland, it was assumed that uptake would be similar to the UK NAAASP. Between 2013 and 2023, the average uptake rate for the NAAASP in England was 80% (range 77% to 81%, Table 6.1).[387] It has been estimated that a second postal invitation to AAA screening can increase the uptake by 8% to 10%.[388] Therefore, it was assumed that uptake would be 70% after first round invitations, with 30% receiving a second invitation to screening, increasing overall uptake to 80%. It was assumed that men who accepted the initial invitation to screening would continue to participate in surveillance.

Consistent with the assumptions applied in published cost utility analyses (CUAs) of AAA screening (see Chapter 5), where reported, abdominal ultrasound was assumed to have 100% sensitivity and specificity for the detection of AAA.[238, 359, 360, 367, 369, 371] Based on NAAASP screening outcome data, it was assumed that for approximately 1.65% of men attending screening it would not be possible to image the aorta due to the presence of bowel gas, abdominal obesity or technical errors (Table 6.1).[387] In the Irish context, those for whom the aorta could not be satisfactorily visualised would be invited to attend a hospital appointment for a repeat abdominal ultrasound at a later date. With consideration to the potential

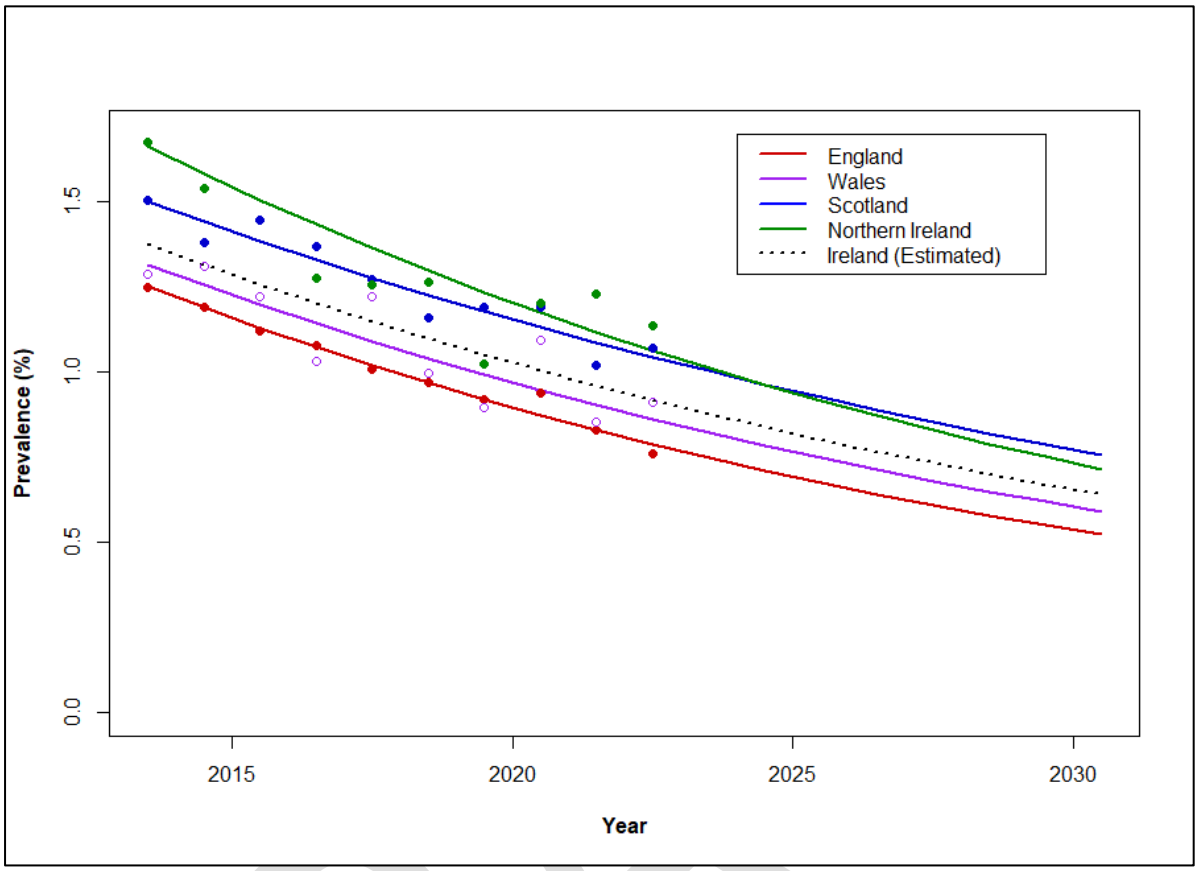
volume of non-visualised screens (estimated 1.65% of attendees) and current waiting lists for hospital-based radiological imaging, it was assumed that follow-up of those with non-visualised aortas could not occur within existing hospital capacity. Repeat imaging of those with non-visualised aortas was therefore costed as one outpatient appointment per non-visualised screen.

Epidemiological and clinical outcomes

AAA prevalence

In the absence of a national vascular registry or up-to-date national epidemiological studies, the prevalence of AAA in Ireland is subject to considerable uncertainty. Epidemiological estimates were based on the international literature, and were corroborated by expert clinical input. The projected prevalence of AAA in each of England, Northern Ireland, Scotland, and Wales was estimated using a binomial model based on screen-detected prevalence rates in each country and their respective annual screening populations (unpublished report). The midpoint of the highest and lowest annual projected prevalence estimates for the period 2026 to 2030 was assumed to be applicable to the Irish context for the purposes of this analysis (Figure 6.2 and Table 6.1). In absolute terms, this represents on average of 165 cases per year between 2026 and 2030, based on the estimated annual cohort size of 30,000 men.

Figure 6.2 Projected prevalence of screen-detected AAA among men aged 65 years based on UK NAAASP outcomes



† Using a binomial model, the projected prevalence of screen-detected AAA was estimated based on the observed prevalence in the population attending screening as part of the NHS Abdominal Aortic Aneurysm Screening Programme for the period 2013 to 2023 (unpublished data). Exact annual screening attendance numbers were used, where reported in annual outcome reports. Where not reported, approximate estimates, informed by available annual reports, were used.

AAA distribution and growth rate

Few studies were identified that reported on the distribution of aortic diameter among men with an AAA.[8, 32, 76, 79, 87, 96] Where reported, methodological aspects such as the timing of data collection, sample size, completeness of the data or application of atypical cut-offs for AAA sub-classification did not directly align with the data requirements of this specific analysis. The available evidence suggests that aortic diameter in men aged 65 years follows a right-skewed distribution. In the BIA, the likely clinical course for men with screen-detected AAA was informed by the distribution of aortic diameter at baseline screening in the Highlands and Islands of Scotland between 2001 and 2004.[76] It was estimated that 9% of screen-detected cases would have a large AAA and would thus be referred to vascular surgery at the time of screening (Table 6.1).[76] The remaining cases with small (76%) and medium (15%) AAA would enter a surveillance pathway, with the frequency of surveillance

dependent on sub-classification as a small or medium AAA (see section 6.2.6).[76] AAA growth rate was estimated using the following equation:[56]

$$\text{AAA growth/year} = \text{AAA max. diameter [mm]} \times 0.08 - 1.09 \text{ mm/year}$$

AAA growth rate was related to baseline AAA diameter. For example, an AAA of 30.0 mm diameter at baseline would be expected to grow to 31.3 mm by year two, while an AAA of 50.0 mm diameter at baseline would reach 52.9 mm by year two.

Incidental diagnosis rate

To estimate the incidental diagnosis rate, the Hospital In-Patient Enquiry (HIPE) database was used to retrieve the number of inpatient discharges among males aged 65 to 69 years who underwent surgical repair for ruptured or unruptured AAA between 2017 and 2023. The previous patterns in inpatient discharges in the target population were used to estimate case numbers for the period 2026 to 2030, accounting for expected decreases in AAA prevalence over time. Comparison between the projected case numbers for the period 2026 to 2030, based on hospital activity, and model predictions regarding the anticipated total number of large AAAs (diagnosed and undiagnosed) between 2026 and 2030, suggested a five-year incidental diagnosis rate of approximately 65%.

A range of alternative values for the incidental diagnosis rate were tested in scenario analysis (50 to 80%; section 6.2.9). The HIPE data indicate that in the 65 to 69 year old age cohort, currently (and in the absence of screening) only 12% of cases presenting for surgical repair of an AAA are in those aged 65 (Table 6.1). Screening would therefore likely result in a shift towards younger age at detection and treatment. As noted in the 2024 ESVS guidelines, a proportion of cases with an AAA detected incidentally during imaging for other indications may not receive systematic follow-up.[6] In the absence of evidence on the number of men aged 65 to 69 years currently under surveillance in Ireland, and to maintain a conservative approach to cost estimation, surveillance costs were not accounted for in the unscreened cohort.

In the cohort invited to screening, at full implementation, the detection rate among those with large AAA was estimated to be 93%. This is based on assumptions that screening has 100% sensitivity for detection of AAA among those that accept an invitation to screening (80% those invited), and that the proportion of men that decline the invitation to screening (remaining 20% of those invited) would be diagnosed through the usual care pathway.

Surgical outcomes

Based on evidence presented in an overview of reviews, it was assumed that the non-intervention rate among men assessed for suitability for intact AAA repair would be 18.6% (95% CI: 13.4 to 25.2),[386] which is consistent with estimates from a

single centre Irish study undertaken in St Vincent's University Hospital (16.6%).[389] Mortality rates for surgical repair of ruptured AAA were higher than intact AAA repair.[390] For those surviving the primary surgery, the type of primary surgery (EVAR versus OSR) may influence requirements for re-intervention. Re-intervention rates for EVAR and OSR have been shown to be similar in the medium term (five years),[391] while EVAR has been associated with a higher re-intervention rate in the longer-term (up to 15 years).[392] For the purposes of this analysis, the re-intervention rate was assumed to be the same for EVAR and OSR, and was based on an analysis of patients undergoing primary EVAR in St Vincent's University Hospital between July 2006 and June 2015 (Table 6.1).[393] It was assumed that the re-intervention rate would be the same in screened and unscreened cohorts.

As described in Chapter 3, a pharmacological treatment to slow or reverse AAA growth has not been identified; surgical repair is the only curative treatment. It was assumed that an AAA screening programme would not impact the risk of small or medium AAA rupture for men under surveillance (that is, there is no difference in rupture risk for those with small or medium AAA between screened and unscreened cohorts). The natural history of screen-detected or undiagnosed large AAA cannot be directly observed from RCTs or observational studies given that the majority of cases with large AAA would undergo surgical repair. The available evidence reporting on the rupture rate for large AAA is largely derived from populations considered unfit for elective repair,[394, 395] which may not be transferable to the overall population with large AAA. In the absence of robust evidence regarding the rate of large AAA rupture in a contemporary screened population, it was assumed that all cases identified through an AAA screening programme that are eligible for surgical repair would undergo elective surgery (see Supplementary Appendix, Table A8).

All-cause mortality was based on national life tables for Ireland in 2022, stratified by age and sex.[396] As a conservative approach, it was assumed that detection through screening would not be associated with a relative reduction in all-cause mortality.

Table 6.1 Epidemiological and clinical parameters

Parameter	Estimate	Source
Percentage of patients with large AAA ineligible for surgery (turn down rate)	18.6%	Ulug 2017[386]
Percentage of AAA repairs that are EVAR	65%	HIPE[100]
Percentage of AAA repairs that are OSR	35%	HIPE[100]
In-hospital mortality, OSR for intact AAA	4.7%	Scali 2021[390]
In-hospital mortality, EVAR for intact AAA	1.0%	
In-hospital mortality, OSR for ruptured AAA	37.2%	

Parameter	Estimate	Source
In-hospital mortality, EVAR for ruptured AAA	23.0%	
Annual probability of post-surgical re-intervention	3.5%	Healy 2017[393]
Screened cohort		
Non-visualised screens	1.65%%†	NAAASP effectiveness review (unpublished data)
Prevalence of AAA in men aged 65 years in 2026	0.77%	Assumption based on projected prevalence of AAA (Figure 6.1)
Prevalence of AAA in men aged 65 years in 2027	0.73%	
Prevalence of AAA in men aged 65 years in 2028	0.70%	
Prevalence of AAA in men aged 65 years in 2029	0.67%	
Prevalence of AAA in men aged 65 years in 2030	0.64%	
Screened men with a small AAA (3.0 to 4.4 cm)	76%	Duncan 2005[76]
Screened men with a medium AAA (4.5 to 5.4 cm)	15%	
Screened men with a large AAA (≥5.5 cm)	9%	
Percentage of the eligible population that are 'ever smokers'	62%	TILDA 2011[334]
Relative increase in AAA prevalence among male 'ever smokers' aged 65 to 69 years, compared with overall male population aged 65 to 69 years	1.4	Soderberg 2024[30]; TILDA 2011[334]†
Unscreened cohort		
Five-year incidental diagnosis rate	65%	Assumption based on HIPE inpatient hospitalisation data
Proportion of cases incidentally diagnosed at age 65 years	0.12	HIPE[100]
Proportion of cases incidentally diagnosed at age 66 years	0.17	
Proportion of cases incidentally diagnosed at age 67 years	0.23	
Proportion of cases incidentally diagnosed at age 68 years	0.23	
Proportion of cases incidentally diagnosed at age 69 years	0.25	
Proportion of cases presenting with unruptured AAA	0.87	
Proportion of cases presenting with ruptured AAA	0.13	

Key: AAA - abdominal aortic aneurysm; EVAR – endovascular aneurysm repair; HIPE – Hospital InPatient Enquiry database; NAAASP – NHS Abdominal Aortic Aneurysm Screening Programme; OSR – open surgical repair; TILDA - The Irish Longitudinal Study on Ageing.
† The percentage of non-visualised screens was based on the average reported percentage of scans resulting in a non-visualised aorta across England, Wales, Scotland and Northern Ireland between 2014 and 2023.

Cost inputs

Where appropriate, costs were adjusted to the latest cost year for which complete data are available (2023) using the consumer price index (CPI) for health and purchasing power parities (PPP), in line with national HTA guidelines for the conduct of budget impact analysis.[384] The cost of goods and services presented is inclusive of value added tax (VAT), at the standard (23%) or reduced (13.5%) rate, as appropriate.

Infrastructure, equipment and consumables

Based on consultation with key stakeholders, physical space constraints may present challenges for implementation of AAA screening at some sites. In the base case, it was assumed that screening would be implemented at sites where existing infrastructure could support it, following a planning phase to determine suitable locations (for example, primary care facilities or regional hospitals). It was assumed that, on average, there would be two screening clinics per county (n = 52), established within existing healthcare facilities. It was anticipated that screening staff, including screening technicians and co-ordinators, would travel between fixed screening clinics, in line with the screening schedule set out by the NSS.

Equipment and consumables required to implement AAA screening are listed in Table 6.2. Under the assumption that implementation of AAA screening would be phased, purchasing of equipment would also be phased, in line with existing HSE procurement contracts. The cost of equipment and consumables would likely be subject to the outcome of a formal tendering process prior to procurement and therefore cannot be estimated with certainty. The estimates provided reflect the knowledge of key stakeholders at the time of the analysis. The number of adjustable examination beds required would be dependent on existing resources at a given screening location. As a conservative approach, it was assumed that two adjustable examination beds would be required at each screening clinic. The annual maintenance fee for ultrasound equipment was estimated to be 10% of the original purchase price and was applied from year two. Maintenance services were subject to VAT at the reduced rate.[397]

For the purpose of the BIA, it was assumed that screening would be implemented at sites where existing connectivity supports efficient and safe data transfer. The availability of secure, highly integrated and efficient methods and structures for

clinical information management would have to be reviewed as part of pre-implementation activities. It was assumed that the cost of laptops and standard ICT equipment is covered by the total staff cost (that is, including 25% for overheads).[384]

Healthcare utilisation

The cost of individual screening and surveillance appointments was not explicitly modelled, but was represented by the cost of new community-based clinical staff required for an AAA screening programme (see 'staff costs'). Therefore, a change in the frequency of surveillance appointments would be reflected by a change in whole time equivalent (WTE) staffing requirements. For men with large AAA referred to vascular surgery, the number and frequency of outpatient appointments during the pre- and post-operative period are outlined in section 6.2.2 (care pathway). Ethical considerations relating to the care of men considered unsuitable for surgery are discussed in Chapter 8.

Diagnosis-related groups (DRGs) are designed to group cases that are clinically similar. There is no DRG code specific to AAA surgical repair. As advised by the Healthcare Pricing Office, the average cost of treating a case admitted with a principal diagnosis of AAA in 2022, across all relevant DRG codes, is presented in Table 6.2 (approximately €26,000).[100] Further breakdown of costs according to rupture status or specific surgical procedure was not possible. As outlined in the model of care for vascular surgery, however, the average hospital cost of treating a ruptured/urgent case is estimated to be considerably greater than that of an elective procedure.[148] In the absence of Irish data, the costs of intact and ruptured AAA repair were estimated based on a combination of available national data,[100] and estimates presented in a UK cost-utility analysis.[363] The cost of elective surgery presented in Table 6.2 reflects a 65/35 split for EVAR versus OSR. It was also assumed that the cost of early post-operative complications was captured by the cost of the index hospital admission. The same cost was applied for the index hospital admission and secondary intervention, where required.

Table 6.2 Estimated costs of equipment, consumables and healthcare service utilisation

Parameter	Units	Unit cost	Timing of incurred cost†	Source
ICT infrastructure				
Programme database	1	€4.5 million	Years 1 and 2	NSS information request[398]
Equipment and consumables				
Invitation to screening or surveillance	Approx. 30,000 per year	€1.86	Annual (years 3, 4 and 5)	NSS information request[398]
Portable ultrasound equipment	14	€50,000	Phased (years 2, 3, 4)	Expert opinion
Adjustable examination beds	52	€2,000	Phased (years 2, 3 and 4)	Assumption/ Expert opinion
Ultrasound gel	Variable†	€8,043‡	Annual (years 3, 4 and 5)	Manufacturer websites (publicly available price)
Resource use				
Outpatient appointment	Dependent on other variables§	€210	Years 1 and 2: No difference between screened and unscreened cohorts (pre-implementation) Year 3 to 5: Scaled increase in costs in the screened cohort	HIPE[100]
Repair of ruptured AAA with EVAR		€32,753		HIPE[100]; Glover 2014[363]
Repair of ruptured AAA with OSR		€32,753		
Repair of unruptured AAA with EVAR		€20,915		
Repair of unruptured AAA with OSR		€20,915		

Key: AAA – Abdominal Aortic Aneurysm; EVAR – endovascular repair; HIPE - Hospital InPatient Enquiry; ICT - information and Communication Technologies; NSS – National Screening Service; OSR - open surgical repair.

† With consideration to existing dynamic purchasing systems within the HSE, equipment would be purchased and delivered when required. It is anticipated that procurement of equipment intended for clinical use would begin in the preceding financial year to allow time for tender, evaluation processes (where required), and training.

‡ Average cost obtained from publicly available information published by medical suppliers.[399-403] Estimated volumes include 20% extra to account for wastage and surveillance scans. It was assumed that 20mL of contact agent would be used per scan.[404]

§ In the screened cohort, treatment-related resource consumption was dependent on AAA prevalence, AAA growth rate and the distribution of aortic diameter. In the unscreened cohort, resource consumption was dependent on the prevalence of AAA and the incidental diagnosis rate for large AAA.

Staff costs

The Department of Health Consolidated Salary Scales applicable at the time of analysis (effective from 1 October 2024) were used to estimate staff costs.[405] In line with updated national HTA guidelines, salary costs were based on the mid-point of the scale and adjusted for employer's pay related social insurance (PRSI), pension and overheads (for example, office space, lighting and heating).[356] Estimated total staff costs and WTEs are presented in Table 6.3.

The roles and responsibilities of staff employed by the programme would be dependent on the operational model agreed and contractual arrangements at the point of service delivery. Input from clinical experts would be required to support administrative staff with operational functions, including development of programme standards, training and quality assurance. It is noted that the categorisation of staff into 'clinical' and 'programme' roles does not fully capture the complexity of roles and responsibilities within a screening programme (Table 6.3).

Clerical and management administration grades were based on programme staffing requirements for existing screening programmes in Ireland (Table 6.3). It was assumed that administrative and management roles would be recruited from year one to support pre-implementation activities. Clinical leads were also assumed to be recruited from year one to inform the development of clinical aspects related to the care pathway.

It was assumed that clinical staff involved in screening, surveillance and quality assurance would be working clinically from year three onwards in line with the phased implementation strategy. For the purposes of this analysis, it was assumed that there would be three screening regions, with clinical oversight from a clinical lead/clinical director, typically a consultant vascular surgeon, costed in accordance with medical consultant salary scales.[405] As a conservative approach, it was assumed that 1.2 WTE clinical leads would be required; at the point of service planning, WTE requirements may be revised depending on roles and responsibilities outlined in the job specification. Based on the ratio of radiographers per eligible population applied in the BreastCheck screening programme, it was assumed 14 WTE 'screening technicians' would be required nationally. It was assumed that recruitment would be phased, with four screening technicians working clinically in year three, four in year four, and six in year five. Each screening clinic would require a screening co-ordinator to oversee day-to-day operational management of the local screening service, with the recruitment strategy aligning with the recruitment of

'screening technicians' (two recruited to begin clinical work in year three, two in year four, and three in year five). Under the assumption that all ultrasound scans require review by a radiologist prior to reporting, it was assumed that 1.2 WTE consultant radiologists would be required for full implementation. Given the anticipated low volume of screen positive cases, one WTE clinical nurse specialist to provide cardiovascular risk factor management support at a national level was assumed. The specific configuration of this post (for example, five x 0.2 WTE/one day per week/remote consultations) would be determined at the point of service planning. For the purpose of the BIA, it was assumed that one WTE senior medical physicist would be required at a national level to quality assure the ultrasound systems, with regional coverage to be determined based on local capacity. A multiplication factor of 1.25 was applied to clinical roles to cover backfill for statutory leave entitlements.

Staff costs may be higher for a community-based screening programme due to additional costs such as mileage and subsistence. Accurately estimating mileage and subsistence costs requires knowledge of the geographic distribution of screening clinics and the base location for screening staff. For the purpose of this assessment, the cost of reimbursing community-based staff was estimated based on average mileage per year in Ireland for goods vehicles, and current motor travel rates.[406] For a mid-range engine size (1,201 to 1,500 cc), the estimated cost of motor travel would be approximately €7,000 per vehicle, or approximately €150,000 annually at full implementation (n = 7 coordinators and n = 14 screening technicians).[407]

It was assumed that informal training of healthcare professionals recruited specifically for an AAA screening programme (for example, information sessions on programme updates, or HSELanD modules) would be delivered as part of continuous professional development (CPD) requirements for the role, and would therefore not incur an additional cost.

As opportunity costs (that is, the cost of the healthcare resources foregone as a result of introducing a new intervention) are not direct expenditures, and therefore do not directly impact the affordability of the intervention, opportunity costs associated with redirection of staff from existing activities to duties relating to an AAA screening programme were excluded from the BIA.

Table 6.3 Staff costs

Parameter	WTE	Unit cost†	Year recruited	Source
Programme manager (general manager)	1.0	€142,767	Year 1+	
Deputy programme manager (clerical grade VIII)	1.0	€134,791	Year 1+	

Parameter	WTE	Unit cost†	Year recruited	Source
Quality assurance coordinator (clerical grade VII)	1.0	€100,354	Year 1+	HSE salary scales[405]
Clinical coordinator (clerical grade VII)	1.0	€100,354	Year 1+	
Business and ICT support (clerical grade VII)	1.0	€100,354	Year 1+	
ICT developer (maintenance phase) (clerical grade VI)	1.0	€95,617	Year 3+	
Administrators (clerical grade VI)	1.0	€95,617	Year 1+	
Assistant staff officer (clerical grade IV/V)	1.0	€76,539	Year 1+	
Software management company	Not quantifiable prior to tender		NA	
Senior medical physicist	1.0	€137,870	Year 3+	
Clinical lead	1.2	€424,135	Year 1+	
Consultant radiologist‡	1.2	€424,135	Year 2.5+§	
Senior radiographer/ senior sonographer/ senior vascular technologist	3.0	€92,523	Year 2.5+§	
Screening co-ordinator (clerical grade IV/V)	7.0	€76,539	Year 2.5+§	
Screening technician (ECG technician grade assumed)††	14.0	€63,194	Year2.5+§	
Clinical nurse specialist	1.0	€99,850	Year 3+	

Key: HSE – Health Service Executive; ICT - information and Communication Technologies; NA – not applicable; WTE – whole time equivalent.
† Salaries are based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads (such as office facilities, general supplies, heating and lighting) as per national HTA guidelines.[384, 405] For posts that may be filled by different professions or grades, the average total staff cost across professions or grades is presented (applicable to senior radiographer/senior sonographer/senior vascular technologists and assistant staff officer roles (grade IV/V)).
‡ As a conservative approach, radiology input was costed at the level of a consultant post. Recruitment of non-consultant hospital doctors (NCHDs) would result in lower costs.
§ It was assumed that clinical staff involved in screening, surveillance and quality assurance would be recruited six months in advance of their clinical duties to accommodate onboarding and training.
†† Similar to the delivery model in the UK, it was assumed that screening and surveillance would be delivered by 'screening technicians'. An equivalent role does not currently exist in the Irish context. For the purpose of the BIA, the total staff cost of an ECG technician was used.

Education, information and public awareness

Implementation of an AAA screening programme would be accompanied by a public awareness campaign aimed at encouraging high and informed uptake of screening. The cost of developing and delivering a public awareness campaign is difficult to quantify, given that it depends on the approach adopted to reach the target audience. The NSS provided approximate cost estimates for the individual components of a typical public awareness campaign based on experience with similar screening programmes in Ireland (Table 6.4).[398] In practice, the cost of a public awareness campaign may vary depending on factors such as programme uptake and the preferred communication channel to reach the target population (for example, radio, TV, social media, newspapers).

Table 6.4 Estimated cost of education, information and awareness

Scenario	Estimate†	Timing of incurred cost	Source
Campaign content research	€14,000	Year 1	NSS information request[398]
Creative development	€70,000	Year 2	NSS information request[398]
Information leaflets (annually)	€3,500	Year 3, 4 and 5	
Posters	€350	Year 3 and 5	
Primary public awareness campaign	€100,000	Year 3	
Ongoing public awareness initiatives	€25,000	Year 5 (bi-annual)	
eLearning module (HSeLanD)	€2,500	Year 2	

Key: NSS – National Screening Service.
† The costs shown include value added tax.

6.2.8 Model outputs

The incremental budget impact, defined as the difference in costs between the screened and unscreened cohorts, was estimated on an annual basis and in total over the five-year timeline.

The cost per additional case of large AAA detected was calculated by dividing the total incremental budget impact by the estimated number of additional cases of large AAA identified through screening.

The number of cases managed with surveillance and treated with surgical repair were projected based on assumptions regarding AAA distribution and growth trajectories (see section 6.2.7)

6.2.9 Assessment and quantification of uncertainty

Guidance from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommends using empirically-derived distributions to investigate uncertainty, where possible.[408] Plausible estimates of uncertainty could not be identified for the majority of resource and cost estimates used in this analysis. It was not considered appropriate to assign arbitrary confidence intervals to these parameters, as the output of the model would reflect the estimates of uncertainty assigned, rather than actual parameter uncertainty. In the absence of plausible estimates of uncertainty for all key input parameters, scenario analysis was used to explore the plausible range of values for key input parameters and assumptions, informed by the international literature, clinical guidelines, and expert opinion.

Scenario analyses were limited to parameters values or assumptions associated with considerable uncertainty, and or expected to have a considerable impact on the incremental budget impact based on the results of the base case analysis. Structural changes were required to investigate the impact of targeted screening and inclusion of sub-aneurysm on the incremental budget impact. In each scenario, model assumptions were changed or a base case parameter value was replaced with an alternative estimate (Table 6.5).

Clinical staff

Estimated programme and clinical staff requirements are subject to uncertainty that cannot easily be quantified prior to pre-implementation planning. For example, the clinical governance framework agreed by the programme, including processes for quality assurance, would influence requirements for radiology input. In the base case analysis, it was assumed that radiology review would comprise one day per week in each of the three screening regions (0.2 x three WTE). In scenario analysis, the potential for three WTE consultant radiology posts nationally (one per region) was considered.

Organised targeted screening

A scenario analysis was conducted comparing an organised targeted screening programme in male 'ever smokers' aged 65 years with no systematic screening. It was assumed that under an organised targeted AAA screening programme, an information letter would be circulated to all men aged 65 years inviting them to participate in an AAA screening programme if they smoke or have ever smoked.

A 35% reduction in community-based screening and surveillance staff (that is, screening technicians and coordinators only) was assumed, given that approximately 62% of men aged 65 years are 'ever smokers', and therefore would be eligible to participate in a targeted screening programme.[334] A corresponding reduction in the volume of equipment and consumables required was assumed for those items where

the quantity is dependent on the number of screening staff or the number of people eligible for screening (ultrasound equipment and ultrasound gel). Equipment requirements were rounded to the nearest whole number. Adopting a conservative approach, all other staffing and ICT requirements were assumed to be the same as a population-based programme (see Table 6.2 to Table 6.4).

The impact of targeted screening on acute services is subject to a high degree of uncertainty, given the dependence on uptake, and in particular, the potential for differential uptake based on factors such as education and income. Due to the relatively minor contribution of treatment and management costs to the overall budget impact in the base case analysis (see Results, Figure 6.3), and considerable uncertainty associated with the uptake rate, the treatment and management costs for those with large AAA were assumed to be the same as in the base case analysis.

Hospital infrastructure

The BIA was limited to costs directly related to the provision of an AAA screening programme as broader healthcare system costs are not within the scope of this analysis. To illustrate the potential scale of the changes and investment required to support implementation of an AAA screening programme, the cost of construction of additional hybrid operating theatres was included in a scenario analysis. Two separate scenarios were considered:

- Hybrid theatres for all vascular surgery units
- Hybrid theatres in centres of excellence or 'hubs' only.

At present, vascular surgery is delivered across ten vascular surgery units nationally.[148] Of these, four do not have access to hybrid operating theatres. Secondly, as outlined in the model of care for vascular surgery, centralisation of vascular services in a 'hub and spoke' model would align with the objectives of Sláintecare, improve patient care, and promote efficient use of physical and staff resources.[148] As indicated in the model of care, it is reasonable to assume that each health region (as defined under Sláintecare) would have one hub.[148] Although centres of excellence have not been designated, based on the information outlined in the model of care, centralisation of services may result in the following vascular surgery services being amalgamated: i) St James's and Tallaght Hospitals ii) Mercy University Hospital and Cork University Hospital iii) The Mater Misericordiae University Hospital and Beaumont Hospital and iv) St Vincent's University Hospital and Waterford University Hospital.

Inclusion of sub-aneurysm in surveillance

A limited scenario analysis was undertaken to explore the potential downstream effects associated with inclusion of sub-aneurysm (that is, aortic diameter 2.5 to 2.9

cm inclusive) which extends beyond the five-year time horizon of this BIA. A plausible estimate of the number of additional screening participants entering the surveillance care pathway is presented. However, the potential cost implications associated with follow-up of those with sub-aneurysm have not been quantified as this falls outside the time horizon of the BIA (that is, five years).

As outlined in the 2024 ESVS guidelines, men with a sub-aneurysmal aorta should be considered for imaging surveillance with ultrasound every five years.[6] As this population has not traditionally been included in screening programmes internationally, the prevalence of sub-aneurysm is subject to considerable uncertainty. For the purpose of this analysis, it was assumed that the prevalence of sub-aneurysm was 1.5 times higher than the prevalence of AAA (see Chapter 2, section 2.6.2, and Table 6.5). The growth rate model outlined in section 6.2.7 reflects the average rate of growth for AAAs (3.0 to 5.4 cm in diameter), and may overestimate the growth rate for sub-aneurysm. Therefore, the rate of sub-aneurysmal growth was based on 25 year follow-up data from men with sub-aneurysm at baseline participating in the Gloucestershire Aneurysm Screening Programme.[96]

Table 6.5 Investigated scenario analyses

Scenario	Parameters	Base case estimate	Scenario estimate	Source
Increased radiology input	WTE consultant radiologists	Year 1: 0 Year 2: 0 Year 3: 0.2 Year 4: 0.4 Year 5: 0.6	Year 1: 0 Year 2: 0 Year 3: 1.0 Year 4: 2.0 Year 5: 3.0	Assumption
Higher AAA prevalence	AAA prevalence	2026: 0.77% 2027: 0.73% 2028: 0.70% 2029: 0.67% 2030: 0.64%	2026: 0.89% 2027: 0.85% 2028: 0.82% 2029: 0.78% 2030: 0.75%	Assumption based on projected prevalence of AAA in Scotland (Figure 6.2)
Incidental diagnosis rate	Five-year incidental diagnosis rate	65%	50% 80%	Assumption
Construction of hybrid theatres	Number of hybrid theatres	Not included	n = 1 to 4[†]	Model of care for vascular surgery[148]
	Cost of a hybrid theatre	Not included	€5 million	Expert opinion
	Percentage of men aged 65 years that are 'ever smokers'	NA	62%	TILDA 2011[334]

Scenario	Parameters	Base case estimate	Scenario estimate	Source
Organised targeted screening	Reduction in number of screening invitations	NA	Not included (0%‡)	Assumption
	Relative reduction in screening staff requirements	NA	35%	Assumption
	Relative reduction in programme costs (operations and staff)	NA	0%	Assumption
	Uptake among male 'ever smokers' aged 65	NA	50%	Assumption (NHS Health Check;[409] Lung cancer screening RCTs[410, 411])
	Relative increase in AAA prevalence among male 'ever smokers' aged 65 to 69, compared with overall male population aged 65 to 69	NA	1.4§	Soderberg 2024[30]; TILDA 2011[334]
Inclusion of sub-aneurysm (aortic diameter 2.5 to 2.9 cm)	Prevalence of sub-aneurysm	Not included	1.5 times the prevalence of AAA	Chapter 2, section 2.6.2
	Annual transition probability sub-aneurysm to small AAA	Not included	0.16	Oliver-Williams 2018[96]

Key: AAA- abdominal aortic aneurysm; TILDA - The Irish Longitudinal Study on Ageing.
† Requirements for hybrid operating theatres would vary depending on the potential reorganisation of vascular services in a hub and spoke model. If access to hybrid operating theatres in all current vascular surgery units is considered necessary, four additional theatres would be required. Centralisation of care would result in a reduction in requirements for hybrid operating theatres, in the context of AAA repair specifically.
‡ In the absence of a national database to identify male smokers aged 65 years an information letter would be sent to all men aged 65 years inviting them to participate in an AAA screening programme if they smoke or have ever smoked.
§ Compared with population-based screening for men aged 65 years, the relative increase in the prevalence of AAA among smokers aged 65 was estimated based on the assumption that approximately 62% of men aged 65 years would need to be screened to find 85% of cases.[30, 334]

6.2.10 Quality assurance

Internal validation was conducted in accordance with HIQA's Quality Assurance Framework. All model inputs, calculations, and model outputs were reviewed by a second member of the evaluation team. Input parameters and assumptions underpinning this BIA were reviewed and endorsed by the EAG.

6.3 Results

6.3.1 Base case analysis

Incremental budget impact

Over a five-year time horizon the incremental budget impact was estimated at approximately €20.3 million (Table 6.6). The annual incremental budget impact increased from €3.5 million in year one (pre-implementation) to €4.8 million in year five (100% rollout). The exception to this was in year two, where the incremental budget impact was higher (€4.2 million), than in year three (€3.3 million), reflecting increased ICT and equipment procurement costs incurred in the year prior to programme launch. The contribution of individual cost categories to the annual incremental budget impact is further detailed in Table 6.7. Treatment costs in both the screened and unscreened cohorts increase incrementally each year as the size of the cohort grows (Table 6.6).

The incremental cost presented in year five reflects the total incremental annual cost of running a fully-resourced AAA screening programme at the point of full implementation. However, in year five, surveillance and long-term post-operative follow-up costs for screening participants in previous years reflect the phased implementation approach (that is, only 30% of the eligible population were invited in year three, and 60% in year four).

Table 6.6 Five-year incremental budget impact

Year	Screening†	Usual care	Incremental budget impact
Year 1 (Pre-implementation)	€3.6 million	€88,175	€3.5 million
Year 2 (Pre-implementation)	€4.4 million	€218,324	€4.2 million
Year 3 (30% rollout)	€3.7 million	€394,560	€3.3 million
Year 4 (60% rollout)	€5.0 million	€573,569	€4.4 million
Year 5 (100% rollout)	€5.6 million	€772,042	€4.8 million
Total	€22.3 million	€2,046,670	**€20.3 million**

† To avoid underestimation of costs, the total cost of the screening cohort includes the cost of usual care for men aged 65 years who were not invited during phased rollout, and those who did not attend screening.

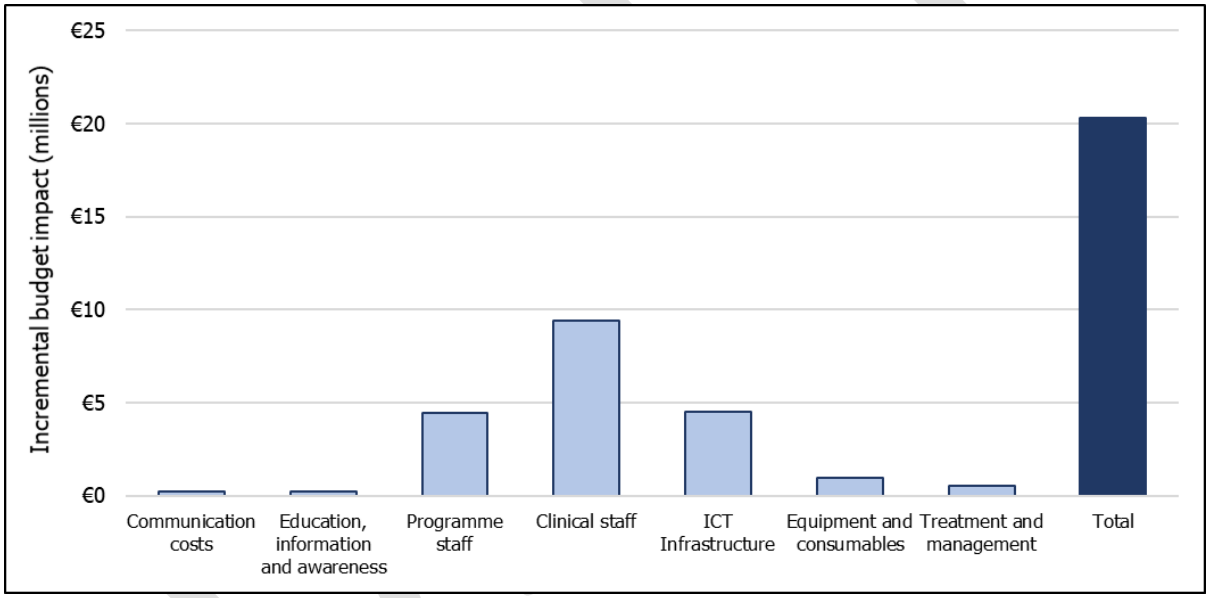
Programme and clinical staff costs comprised a considerable proportion of the total incremental budget impact over five years (68%, see

Figure 6.3). Programme staff involved in operations comprised 22% of the five-year incremental budget impact, while clinical staff comprised 46% of the incremental

costs. Costs related to equipment, consumables, communication (that is, invitations to screening or surveillance, and written confirmation of test results), and education and awareness initiatives, comprised approximately 7% of the five-year incremental budget impact (

Figure 6.3). Setting up the programme database across years one and two accounted for 22% of the incremental budget impact. The incremental cost associated with treatment and management of cases with large AAA referred to vascular surgery was relatively low (<3% or €540,529). This estimate is contingent on key assumptions such as the anticipated rate of disease progression, an incidental diagnosis rate of 65% in the absence of screening, and a two-year pre-implementation planning phase, followed by phased national rollout. Treatment and management costs comprise inpatient and outpatient care for those with large AAA referred to vascular surgery only; clinical staff costs are presented separately.

Figure 6.3 Itemised five-year incremental budget impact



Key: ICT - Information and communication technology.

The analysis assumed implementation on a phased basis to manage the volume of activity and potential implications for healthcare system capacity. In the model, as the programme progressed through phased implementation, the budget allocated to individual cost components shifted accordingly. In the pre-implementation phase, a significant portion of funding was directed towards establishment of foundational programme processes including the programme database (€4.5 million over two years), procurement of equipment (beginning in year two) and administrative capacity building**.** As the programme moved to full implementation, the budget structure transitioned towards expenditures related to day-to-day operations (for example, communication costs) and service delivery. Staff costs increased marginally over time, reflecting phased recruitment of clinical posts in line with phased rollout.

Beyond the time horizon of the BIA, changes in budget allocations should be anticipated, including the potential for marginal year-on-year increases in treatment and management costs as the size of the cohort continues to grow.

Table 6.7 Annual and five-year incremental budget impact

Cost category	*Pre-implementation*		*Post-implementation*			Total
	Year 1	Year 2	Year 3	Year 4	Year 5	
Communication	€0	€0	€34,585	€70,757	€122,178	€227,521
Education and awareness	€14,000	€72,500	€103,850	€3,500	€28,850	€222,700
Programme staff	€750,777	€750,777	€984,265	€984,265	€984,265	€4,454,350
Clinical staff	€508,962	€916,064	€1,855,079	€2,790,903	€3,319,624	€9,390,632
ICT	€2,250,000	€2,250,000	€0	€0	€0	€4,500,000
Equipment and consumables	€0	€232,000	€257,113	€390,226	€87,493	€966,831
Treatment and management	€0	€0	€83,093	€170,060	€287,376	€540,529
Total	€5,523,740	€4,221,341	€3,317,985	€4,409,711	€4,829,787	€20,302,564

Incremental cost per additional case of large AAA detected

It was not possible to estimate the cost of screening for AAA per case of AAA detected due to the absence of nationally representative estimates of the number of men with small or medium AAA under surveillance in the absence of screening.

Assuming a mean AAA prevalence rate of 0.70%, and an incidental diagnosis rate of 65%, the incremental cost per additional case of large AAA detected, specifically, was approximately €989,701 million over the first five years, compared with usual care. This metric estimates the financial investment, over the budget impact timeline of five years, needed for each patient with a large AAA to be identified through screening. However, it should be noted that it is not intended to be used to assess the cost effectiveness of AAA screening in men.

Surveillance volumes

Under a phased implementation strategy for screening, it is estimated that 266 men would be under surveillance by the end of year five. It is anticipated that over 80% of those under surveillance would have a small AAA by the end of year five, reflecting assumptions regarding the proportion of men with small and medium AAA at baseline screening (small AAA: 76%; medium AAA: 15%; see Table 6.1), and AAA growth rate.

Surgical repair rate and surgical volumes

Considering a single cohort of screening participants followed for five years, it is estimated that 22% of those with screen-detected AAA at age 65 would have undergone elective surgical repair by 2030.

Implementation of an AAA screening programme could lead to a 21% increase (that is, less than 20 additional elective surgeries) in the number of elective AAA surgical repairs in the modelled population (men aged 65 to 69 years) over a five year period. This estimate should be interpreted with caution due to its dependence on assumptions regarding the screening uptake and the incidental diagnosis rates.

6.3.2 Scenario analyses

It should be noted that the results of scenario analyses reflect assumptions regarding a two-year pre-implementation stage, followed by a phased implementation approach. Reducing the time to full implementation would result in a greater change to the incremental budget impact for the majority of scenarios considered. However, the infrastructural costs are largely independent of the screening cohort size and therefore the timing of the implementation strategy. Results of scenario analyses are summarised in Figure 6.4.

Clinical staff

As described in section 6.3.1, total staff costs comprise a considerable proportion of the total incremental budget impact (68%). Therefore, changes in assumptions regarding staffing requirements would likely have an important impact on the incremental budget impact.

Recruitment of three WTE consultant radiologists on a phased basis from year three onwards would be associated with an additional €2.4 million over five years compared with the base case analysis, or a total incremental budget impact of €22.7 million (versus €20.3 million).

It was assumed that 14 WTE screening technicians would be needed to screen approximately 30,000 men per year, taking into consideration uncertainty regarding factors such as uptake, clinical contact time, and the number of surveillance scans and self-referrals (see Chapter 7, section 7.4.4). As a crude estimate, an absolute increase in the cohort size of approximately 2,000 would correspond to a requirement for approximately one additional WTE screening technician (estimated annual total staff cost: €63,194). With consideration to the expected number of participants under surveillance by the end of year five, it is unlikely that additional recruitment would be required in the short-term post-implementation. However, aforementioned uncertainties may influence capacity requirements.

Higher AAA prevalence

In the base case analysis, the midpoint of the highest (Scotland) and lowest (England) annual projected prevalence estimates for the period 2026 to 2030 was used (Figure 6.2). In a scenario analysis, the highest plausible estimate of AAA prevalence for the period 2026 to 2030 was assumed, based on AAA prevalence projections for Scotland (Figure 6.2). Adopting a mean prevalence rate of 0.82% over this period resulted in an increase of approximately €66,000 above the base case incremental budget impact (€20.3 million, see section 6.3.1). The incremental cost per additional case of large AAA detected decreased from €989,701 million (base case) to €846,331 million, reflecting relatively constant implementation costs spread across an increased number of cases.

AAA incidental diagnosis rate

Given the absence of empirical evidence for the incidental diagnosis rate in the absence of a screening programme, a pragmatic approach was taken in selecting estimates of the incidental diagnosis rate for scenario analysis. Varying the incidental diagnosis rate between 50% and 80% caused the incremental budget impact to increase or decrease by €60,000, respectively, owing to a relative change in the number of men identified and treated through screening than would be in the absence of screening.

Hospital infrastructure

In the base case analysis, it was assumed that surgical repair of AAAs would be conducted using existing hospital infrastructure. Requirements for additional investment in surgical facilities would vary depending on the approach to delivery of vascular services at the point of implementation. If construction of additional hybrid surgical theatres at all current vascular surgery units was considered necessary to facilitate implementation of an AAA screening programme, it is estimated that this would cost an additional €20 million, or €5 million per theatre (see Chapter 7, section 7.4.2 for additional information). Centralisation of services in a 'hub and spoke' model may require investment in one hybrid operating theatre in HSE Dublin and South East only (€5 million).

The cost associated with establishing hybrid operating theatres would not be specific to AAA surgical repair; hybrid theatres are also used by a number of other disciplines including cardiology, obstetrics and emergency medicine. It is also important to note that additional investment in hub and spoke centres to support vascular service reconfiguration would be required, beyond upgrading or investing in new surgical theatres.

Organised targeted screening in male 'ever smokers' aged 65 years

Compared with no systematic screening, organised targeted screening would be associated with an incremental budget impact of €18.7 million, or approximately a €1.6 million reduction compared with the base case incremental budget impact over a five-year time horizon (see section 6.3.1). This was largely attributable to a reduction in clinical staff costs.

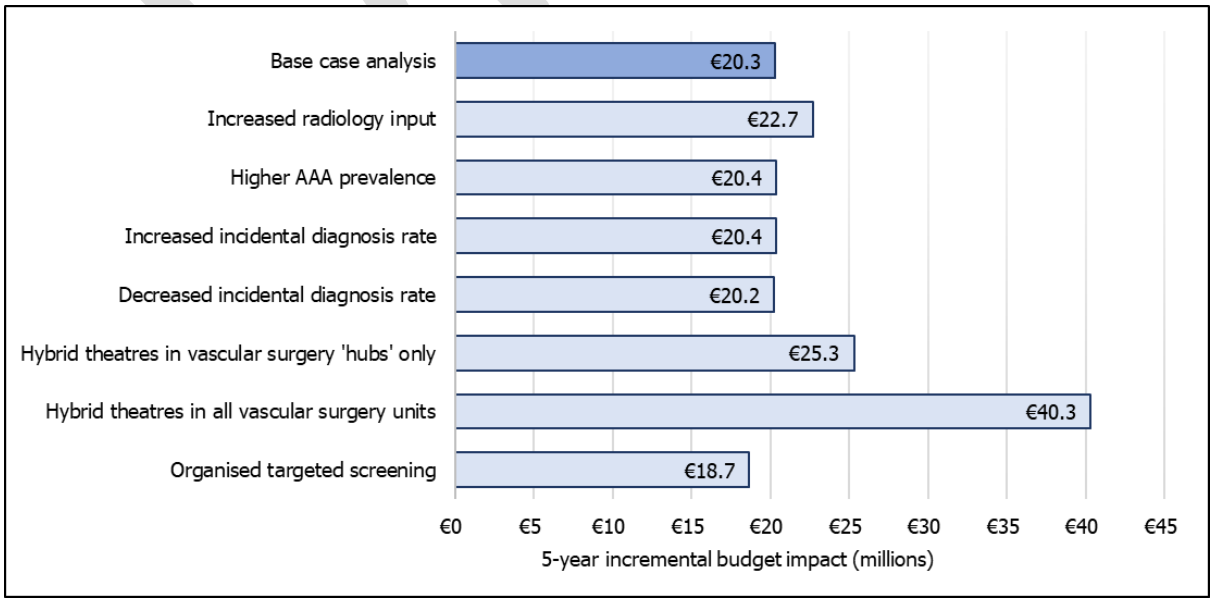
Structural and operational factors can influence screening workforce requirements. For example, if screening technicians work in pairs, as is the case in the UK NAAASP, this increases baseline staffing requirements.[412] Therefore, a decrease in the size of the eligible population under a targeted screening approach may not lead to a proportional reduction in staffing requirements.

Inclusion of sub-aneurysm

If sub-aneurysmal aortas were included in the programme's definition of a 'screen-positive' result, on average, between 2026 and 2030, it is anticipated that an additional 250 men annually would enter the surveillance pathway. Of these, it is estimated that 60% would have developed an AAA at five years' follow-up, and would therefore require more intensive surveillance (that is, once yearly for an AAA measuring 3.0 to 4.5 cm in diameter, see section 6.2.6). At ten years' follow-up, it is estimated that approximately 2% of those with sub-aneurysm at baseline would have developed a large AAA.

The additional costs associated with an increase in the size of the cohort under surveillance by inclusion of sub-aneurysm were not estimated given that these costs would be incurred outside the time horizon of the BIA. Recruitment of additional screening technicians may be necessary in the longer-term to manage follow-up of these cases.

Figure 6.4 Results of scenario analyses



Key: AAA –abdominal aortic aneurysm.
Increased radiology input: staggered recruitment of three whole-time equivalent consultant radiologists (one per screening region), in line with phased implementation.
Higher AAA prevalence: prevalence based on projections from the Scottish NHS AAA Screening Programme outcome data (2026: 0.89%; 2027: 0.85%; 2028: 0.82%; 2029: 0.78%; 2030: 0.75%; see Figure 6.2).
Incidental AAA diagnosis rate in the absence of screening varied between 50% and 80%.
The cost associated with construction of hybrid operating theatres would vary depending on whether or not vascular surgery services are centralised in a hub and spoke model (estimated one to four theatres at €5 million each).
Organised targeted screening of 'ever smokers': 35% reduction in community-based screening and surveillance staff, ultrasound equipment and consumables.

6.4 Discussion

6.4.1 Summary of findings

In the base case analysis, the incremental cost associated with the introduction of an AAA screening programme in men aged 65 years was estimated at €20.3 million over a five-year time horizon, compared with no systematic screening. The majority of the incremental budget impact was associated with clinical and programme staff costs (68%), followed by capital expenditure related to setting up the programme database (22%). Treatment and management costs comprised less than 3% of the incremental budget impact over five years. Implementation of an AAA screening programme could lead to a 21% increase in the number of elective AAA surgical repairs in the modelled population (men aged 65 to 69 years) over a five-year period, based on phased implementation.

In scenario analysis, varying the incidental diagnosis rate (from 50% to 80%) and AAA prevalence (increased from 0.70% to an average of 0.82%) had a marginal effect on the five-year incremental budget impact. A key contributor to cost uncertainty is the potential need for additional investment in hybrid surgical theatres to support rollout across all vascular surgery units. Construction of four hybrid surgical theatres was estimated to cost an additional €20 million.

The expected growth in the size of the surveillance cohort identified through screening by year five would be unlikely to warrant recruitment of additional screening staff in the short-term (that is, at least in the first five years of implementing the programme). However, in the medium- to long-term, modest growth in the cohort size, the potential for longer appointment times for men under surveillance, and in particular, inclusion of men aged 65 years with sub-aneurysm in surveillance, may result in additional requirements for screening staff.

6.4.2 Interpretation

The aim of screening at age 65 is to detect cases of AAA before they become clinically significant. In light of this, it may be expected that treatment and management costs comprise a small proportion of the short-term incremental budget impact. It is plausible that the additional costs associated with treatment and management of men identified through screening would become more pronounced over longer-term time horizons. In some contexts, such as screening for certain types of cancer, earlier detection followed by earlier access to treatment may result in cost shifting or cost avoidance in the longer-term.[413] In the context of AAA screening, the fixed cost of AAA surgical repair generally, coupled with the anticipated increase in patient volumes for elective AAA repair, would likely result in an increase in treatment and management costs, rather than cost avoidance. However, in light of declining AAA prevalence and the available evidence to suggest

a relatively high incidental diagnosis rate, the impact of a relative increase in the rate of elective surgical repairs on total treatment costs is unlikely to be substantial As discussed in Chapter 7, based on input from the Expert Advisory Group convened to support this assessment, any additional surgical activity for elective AAA repair may strain existing healthcare system capacity, regardless of cost, particularly in the long-term as the size of the cohort increases.

Estimating the clinical staff requirements needed to support internal quality assurance of an AAA screening programme is challenging. As explained in Chapter 7, the quality assurance framework would need to be agreed during pre-implementation planning. For the purpose of this assessment, from a quality assurance perspective, it was assumed that there would be one senior radiographer, sonographer or vascular technologist in each of the three screening regions to provide support to screening technicians. In addition, overall, 2.4 WTE consultant posts were costed to provide clinical oversight. The operational model agreed at the point of service planning would inform the allocation of consultant posts in terms of clinical specialty (radiology versus vascular surgery) and associated WTEs. Given that staff were a key contributor to the incremental budget impact in the base case analysis, substantial changes to the estimated clinical staff required to support quality assurance may result in considerably higher costs. In particular, increased clinical input may be required during the pre-implementation and early implementation phases to support development of programme standards, quality assurance processes and training.

In many European countries, a national-level decision on population-based AAA screening has not been made. As outlined in Chapter 3, where reported, the policy debate relates to concerns regarding changes in the clinical context since RCTs were conducted (including decreases in disease prevalence and improvements in cardiovascular risk factor management), and organisational challenges. Approaches to running a national screening programme may differ between countries, with implications for the cost of running the programme. For example, in the UK NAAASP, screening is conducted by trained vascular technicians using ultrasound systems validated specifically for the purpose of AAA screening.[412] On the other hand, a Spanish HTA published in 2023 assumed that ultrasound screening would be conducted in primary care by GPs using existing ultrasound systems, where possible.[414] The recent surge in the use of point-of-care ultrasound devices or 'POCUS' in Spain was cited as a facilitator of such an approach.[414] A GP-based approach may not be considered feasible in the current Irish context with consideration to the absence of free GP access, ongoing GP shortages, and potential challenges for quality assurance where information and invitations are not systematically disseminated by the programme. It is important to note, however, that while substantial investment in dedicated staff and equipment may improve the

quality of care, it does not necessarily lead to proportional improvements in patient outcomes. Beyond a certain point, additional investment may yield only marginal gains.

The incidental diagnosis rate in the absence of screening is subject to considerable uncertainty. Assessments undertaken in Sweden, Norway and the Netherlands have also noted similar challenges.[233, 249, 350] At short-term follow-up (three to five years) in RCTs undertaken in the 1990s and early 2000s, the incidental diagnosis rate was estimated to be approximately 15%.[294, 309, 317, 318] However, given the increasing use of diagnostic imaging over time, these estimates are unlikely to be applicable to the current context. Evidence from screening studies undertaken in Sweden and Portugal indicates that 25% to 64% of participants aged 65 had a known AAA diagnosis prior to attending screening, respectively.[28, 77] While these values reflect a single point in time, and therefore cannot be applied longitudinally, they can be used as an indicator of the lower bound for the incidental diagnosis rate at age 65 in these settings. Evidence from Sweden indicates a relatively modest increase in the rate of intact AAA repair since the introduction of the AAA screening programme; from 2010 to 2014, repair of screen-detected AAAs constituted 18.6% (95% CI: 17.2 to 20.1) of all intact AAA repairs. This suggests that the incidental diagnosis rate among unscreened men is relatively high. Although subject to considerable uncertainty, the incidental diagnosis rate of 65% used in this base case analysis is considered plausible in the context of the available contemporary national and international evidence. Furthermore, in scenario analysis, varying the incidental diagnosis rate had a marginal impact on incremental costs.

6.4.3 Targeted screening

Based on discussion with the NSS, programme costs associated with organised screening, such as ICT infrastructure and quality assurance processes, would be largely independent of the size of the eligible population. Adoption of a targeted screening approach, as opposed to population-based screening, would therefore be unlikely to result in a substantial reduction in costs due to baseline programme requirements. A 35% reduction in clinical staffing requirements was assumed for a targeted screening programme relative to population-based screening. However, due to the influence of structural and operational factors on screening workforce requirements, in practice, a decrease in the size of the eligible population may not lead to a proportional reduction in staffing requirements.

While an opportunistic approach to screening may be associated with lower implementation costs, such an approach was not costed in this analysis due to the evidence suggesting that organised screening is associated with better outcomes than opportunistic screening in terms of participation and equity of access.[246, 415] Meeting widely accepted standards for screening programmes, in particular in

relation to quality assurance, may be challenging in the context of opportunistic screening.[143]

6.4.4 Strengths and limitations

The estimated costs included in this BIA are based on the best available national and international evidence at the time of analysis. Consistent with best practice, a conservative approach was adopted in circumstances where assumptions were necessary. However, depending on the implementation approach adopted, some costs may have been underestimated. Actual resource requirements, and their costs, may differ at the point of service delivery following pre-implementation planning. In the event that suitable existing healthcare facilities cannot be identified during the preparatory phase, additional investment would be required to support structural modifications to existing facilities, in addition to potential investment in mobile screening units. Prior to tender, and given complexities related to ongoing annual costs for mobile units (for example, servicing, haulage and management costs), estimation of these costs was not considered feasible.

Uncertainty associated with treatment and management costs due to the absence of nationally-representative data sources for key input parameters (such as, AAA prevalence and the incidental diagnosis rate) is anticipated to have a relatively minor effect on the incremental budget impact, given that additional staff requirements comprise the majority of incremental costs. It should also be noted that treatment of incidental findings identified as a result of screening was not costed as part of this analysis, as it was not considered feasible to estimate the cost of care for a broad range of potential incidental diagnoses of unclear clinical significance. If measures are taken to minimise the potential for incidental findings during screening, the additional costs would likely be minor (see Chapter 7, section 7.3.5). Costs related to screening, surveillance treatment of self-referred or incidentally diagnosed cases were not captured in this analysis due to considerable uncertainty regarding patient volumes. Inclusion of additional populations under the care of the programme may increase WTE requirements for surveillance scans and therefore costs.

Although subject to limitations, the estimates used in this analysis reflect the best available evidence at the time of analysis. Information on key cost drivers, in particular staff costs, and the range of plausible outcomes depending on different assumptions, provides a solid basis for decision-making.

6.4.5 Conclusion

Implementing an AAA screening programme in men aged 65 years would be estimated to cost €20.3 million over five years, largely driven by programme and clinical staff costs. Key uncertainties which could result in a substantial increase in the incremental budget impact include the potential need for increased clinical staff

depending on the clinical governance framework agreed, and potential requirements for construction of additional hybrid surgical theatres to facilitate implementation across all vascular surgery units nationally.

Since population-based screening represents the most equitable policy option, strong epidemiological, clinical and economic justification would be needed to support implementation of a targeted screening approach in place of a population-based programme. From a cost perspective, organised targeted screening may be unlikely to result in substantial reductions in costs, compared with population-based screening, given baseline programme resource requirements.

7 Organisational considerations

Key points

- A population-based AAA screening programme in men aged 65 years would comprise a complete care pathway from identification of the eligible population through to collection and reporting of programme outcomes. It is expected that the programme would be overseen by the National Screening Service (NSS).
- Extending eligibility to self-referred men older than 65 years and those with incidentally-detected small and medium AAA would ensure access to standardised care across all identification routes. Additional investment would be required to support inclusion of additional populations under the care of the programme.
- A community-based delivery approach would help to reduce unnecessary hospital activity and may maximise uptake, if ultrasound equipment compatible with this approach can be identified.
- A range of ultrasound equipment specifications are available. A validation exercise would be needed to ensure potential ultrasound systems meet the required standards, including consideration of accuracy, portability, technological specifications, and cost, prior to procurement.
- Workforce deficits in key disciplines including radiology, radiography, and vascular surgery present challenges for recruitment, and therefore implementation.
    - In the UK, a dedicated 'screening technician' role was developed specifically for the purposes of AAA screening and requires specialist training. Recruitment and training of a dedicated, specialist screening and surveillance workforce operating in the context of a quality-assured screening programme would help to improve standardisation of service delivery and ensure optimal use of clinical skills. However, such a role does not currently existing in the Irish context.
    - A staffing model requiring radiology sign-off would be challenging to deliver in the context of staff shortages. Alternative staffing models may require revisions to training pathways and regulatory frameworks to ensure test accuracy and patient safety.

- If an AAA screening programme is implemented, processes for clinical reporting must be undertaken within a clear governance framework that aligns with the proficiency standards set out by relevant governing bodies in Ireland, taking feasible staffing models into consideration.
- Ensuring timely access to elective surgical repair of AAA is a significant challenge at present. Implementation of AAA screening would be expected to result in an increase in surgical activity related to elective repair of AAA, which would further strain existing resources.
    - If implemented, vascular surgery units must be adequately resourced to allow timely assessment of referrals and intervention, where indicated, in line with international standards. This would be required to minimise the risk of men experiencing AAA rupture or clinical deterioration while waiting for surgery.
    - Addressing vascular surgery waiting lists effectively would require facilitating protected access to surgical theatre space for patients managed by the programme.
- Robust information and communications technology systems would be required to track screening participants through the care pathway and to capture end-to-end outcome data for quality assurance and programme evaluation.
    - As the number and scale of screening programmes managed by the NSS grows, consolidating individual screening registries becomes increasingly necessary to achieve operational efficiencies.
    - Consideration should be given to the development of a national vascular registry to support quality assurance processes, healthcare service planning in response to epidemiological trends, and monitoring of surgical outcomes.
- It is anticipated that an AAA screening programme would need to be implemented on a phased basis to facilitate development of screening processes, training requirements and capacity building.

7.1 Introduction

The aim of this chapter is to provide an overview of the potential organisational considerations associated with the introduction of AAA screening in men aged 65 in Ireland including aspects related to the clinical care pathway, resource requirements, feasibility and logistical considerations, and quality assurance. The information is presented with consideration to key operational and implementation considerations set out in the NSAC criteria, including:[3]

- *there should be an agreed policy on the further diagnostic investigation of individuals with a positive screening result and on the choices available to those individuals*
- *there should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is acceptable and can be implemented*
- *clinical management of the condition and patient outcomes should be in place before a screening programme is initiated*
- *adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme*
- *all other options for managing the condition should have been considered (such as improving treatment or providing other services), to ensure that no more cost-effective intervention could be introduced, or current interventions increased within the resources available*
- *there should be a plan for managing and monitoring the screening programme against an agreed set of quality assurance standards. This should include monitoring performance against different sub-groupings in the population.*

A budget impact analysis investigating the short-term financial implications associated with the potential introduction of an AAA screening programme in men is presented in Chapter 6. The screening programme modelled was based on the assumption that AAA screening would be delivered in community-based healthcare facilities by a dedicated, specialist workforce. The rationale underpinning the assumptions of the base case analysis, as well as alternative programme delivery approaches, are described in this chapter.

7.2 Healthcare system context

The design of any new screening programmes in Ireland will be shaped by the existing approaches to delivery of healthcare in the Irish context, including screening services, and strategic priorities for the future of healthcare services. Prior to examining the organisational requirements for a potential AAA screening

programme, it is important to consider the current healthcare system context, including existing arrangements for other screening programmes, access to imaging studies that may result in a diagnosis of AAA, hospital waiting lists, and ongoing changes in the approach to healthcare service delivery, which may impact the realisation of the benefits of screening and or the approach to delivery.

7.2.1 The National Screening Service

Currently, the National Screening Service (NSS) manages delivery of four population-based national screening programmes: BreastCheck, CervicalCheck, BowelScreen and Diabetic RetinaScreen. If a decision is made to implement an AAA screening programme in men in Ireland, it is expected that the programme would be overseen by NSS, ensuring consistency with existing and planned processes for delivery of screening services in Ireland.[416]

7.2.2 Access to diagnostic imaging

In the absence of structured AAA screening in Ireland, the increasing use of diagnostic imaging may be contributing to an increased rate of incidentally diagnosed AAA.[151, 417-419] In the US, retrospective reviews have shown that 23% to 48% of men who underwent AAA screening had undergone at least one prior radiological test which may have been sufficient for AAA screening.[419, 420]

In response to a growing demand for radiology services in Ireland, numerous initiatives are in place to support improved access to imaging studies in acute and community settings. The General Practitioner Access to Community Diagnostics (GPACD) Scheme was launched in 2021 to support improved access to community radiology diagnostic scans including MRI, ultrasound, CT, X-ray and DXA for the adult population (see Chapter 3, section 3.2.3).[149, 150] Furthermore, in 2024, the first National Radiology Diagnostic Waiting List Management Protocol was launched by the National Treatment Purchase Fund (NTPF), intended to support waiting list management in radiology diagnostic services in acute hospitals.[421] Given that most AAAs are asymptomatic and detected incidentally, increasing access to diagnostic imaging could lead to an increase in incidentally-detected AAAs. The relative benefit of an AAA screening programme may be reduced in the context of a potential increase in the rate of incidental AAA detection as a result of increased access to diagnostic imaging in community and acute hospital settings.[417, 419]

Separately, prior to the implementation of the GPACD Scheme, data suggest possible avoidable hospital activity among individuals who presented to the emergency department (ED) with a primary diagnosis of unruptured AAA. Ruptured AAA is a medical emergency; however, unruptured AAA would not typically be expected to warrant ED presentation, albeit uncommonly patients may experience symptoms such as pain (Chapter 2, section 2.4.1). However, between 2007 and 2020, a

considerable proportion of discharges with a principal diagnosis of AAA from the emergency setting presented with unruptured AAA (range 59 to 73%; see Chapter 2, section 2.7.1). There was no evidence of a change in the proportion of emergency discharges with unruptured AAA in subsequent years up to 2022, however, interpretation of the data is complicated by the COVID-19 pandemic, and gradual increases in radiology diagnostics delivered through the scheme over time. The available data may include coding errors, and or a proportion of these discharges may represent cases with symptomatic but intact AAA. However, although subject to considerable uncertainty, it is possible that lengthy waiting times for diagnostic or follow-up imaging may be contributing to non-emergency cases presenting to emergency departments.

7.2.3 Hospital waiting lists

Based on consultation with clinical experts, it is presently a significant challenge to ensure timely access to elective AAA repair for patients identified incidentally. Due to capacity constraints across the healthcare system, competition for acute surgical resources, including theatre space and staff, can result in diversion of resources to areas considered to be of particular urgency, for example, oncology and emergency services.

In Ireland, the NTPF receives referrals for patients waiting in excess of three months for a procedure or treatment. Waiting list data published by the NTPF indicate that, as of December 2024, a total of 2,445 public patients were waiting for access to vascular surgery inpatient beds (for example, for treatment of varicose veins), highlighting a significant shortfall in the resourcing of inpatient vascular surgical services. AAA surgical repair is not currently covered by the NTPF.[422] Therefore, for patients without private health insurance, opportunities to expedite access to care are limited.

The scope of this assessment did not extend to examining the capacity of the healthcare service to meet additional demands for vascular surgery services in the context of screening given cross-specialty competition for inpatient beds. Evaluation of cross-specialty capacity constraints would require a review of clinical workflows and available resources at the level of individual hospitals or hospital groups. However, addressing vascular surgery waiting lists effectively is likely to require both immediate interventions (such as temporary increases in bed capacity or staff allocation) and longer-term strategies, such as, increasing training and incentives for desired clinical specialities, expanding existing facilities, and facilitating protected access to surgical theatre space for surgical repair of AAA. Ongoing plans to open six surgical hubs to increase capacity for non-complex procedures may reduce pressure on existing theatre space.[423]

7.2.4 Reform of healthcare service delivery in Ireland

As part of ongoing health services reform, the approach to delivering care in Ireland is changing. Sláintecare is a ten-year programme aiming to transform health and social care services in Ireland by facilitating universal access to timely, quality integrated care at the lowest level of complexity.[424]

Six new geographically-based regional health areas or health regions have been established, with each health region responsible for providing both hospital and community care for people living in the region.[425] Management of chronic disease will primarily be delivered in the community through GP-led primary care (Level 1), supported by community specialist services (Level 2).[426] Specialist ambulatory care hubs (Level 3) will be linked to local acute hospital sites (Level 4) to facilitate access to specialist services for those with more complex care needs.[426] This model of care is intended to support delivery of equitable, accessible care in the community, particularly for those with chronic disease, and to avoid unnecessary hospital activity.

As described in section 7.4.2, an AAA screening programme should be designed and delivered with consideration to the strategic goals of the health service.

7.3 Considerations for the screening care pathway

AAA screening aims to identify and link men with an AAA to appropriate care, thereby reducing AAA-related morbidity and mortality. As outlined by the World Health Organization (WHO), a formal screening programme ideally comprises a structured care pathway from identification of the eligible population through to evaluation of programme outcomes.[143] Key considerations to inform the development of the screening care pathway are outlined below with consideration to the model of care for vascular surgery proposed by the National Clinical Programme in Surgery,[148] relevant clinical guidelines, and international practice (Chapter 3, section 3.5).

For the purposes of this assessment, the term 'surveillance' is used to refer to management of men with a screen-detected AAA measuring <5.5 cm in diameter in line with the agreed surveillance pathway to support early detection and management. In the international literature, the term 'post-operative surveillance' may be used to refer to post-surgical follow-up of men after AAA surgical repair by the vascular surgery unit to detect potential post-surgical complications. To differentiate between pre- and post-referral stages of the care pathway, the term 'post-operative monitoring' will be used in this HTA.

The term *'incidental diagnosis'* is used to refer to an AAA diagnosed as a result of imaging for other indications. This is the most common way in which electively operated AAAs are identified in Ireland.[148] Within this assessment, the term *'incidental findings'* is used to describe unanticipated results unrelated to the

primary purpose of the ultrasound screening test, which may have clinical significance (for example, renal cysts).

7.3.1 Invitation to screening

A screening register would be needed to identify and invite men aged 65 years to screening. Technical aspects related to the screening register are outlined in section 7.5.2.

The effectiveness of a screening programme can be maximised through achieving high uptake (that is, the proportion of the invited population with a satisfactory screening test), particularly in subgroups at increased risk. Re-inviting individuals that do not respond or do not attend their scheduled AAA screening appointment has been shown to increase uptake by up to 10%.[388] As noted in a 2024 evaluation report of the Swedish AAA screening programme, the opportunity to reschedule screening appointments may also increase uptake and reduce resource waste related to non-attendance.[383] Self-registration options can increase population coverage (that is, the proportion of the eligible population who are successfully screened) by helping to ensure that individuals excluded due to migration dynamics (for example, recent changes in address or recent immigration) can participate in screening.

Targeted screening

In light of declining AAA prevalence, and the high prevalence of AAA among male smokers, targeted screening based on risk factors, such as smoking history or family history of AAA, is of increasing interest internationally. As described in Chapter 3, in 2024, the European Society for Vascular Surgery (ESVS) revised their strong recommendation to consider one-time screening for AAA for men age 65 years,[10] instead recommending identification of suitable populations for screening based on factors such as AAA prevalence, life expectancy and the healthcare system context.[6] At present, systematic targeted AAA screening programmes are not in place in any European countries, this may reflect the recency of the revised recommendations. Informal targeted AAA screening based on risk factors such as smoking status or family history is available in France and the US, but uptake is reported to be low.[224, 252, 253, 427-429]

Targeted screening may be organised or opportunistic. In the absence of a database to identify male smokers in Ireland, an organised targeted programme may involve sending an information letter to all men aged 65 years inviting them to participate in an AAA screening programme specifically if they smoke or have ever smoked. Under an opportunistic screening programme, men aged 65 years who smoke or have ever smoked, and interact with the healthcare system for reasons other than screening, would be invited to participate in AAA screening. With this approach, the target population would not be systematically invited and uptake would be dependent on

access to and buy-in from healthcare providers. Therefore, organised screening would likely be associated with higher uptake, more equitable access, increased reproducibility and improved standardisation of screening processes.(430)

7.3.2 Screening

AAA screening involves a simple, painless, ultrasound scan of the abdomen that is targeted to measure the diameter of the aorta below the level of the renal arteries (infrarenal abdominal aorta) and is conducted by an appropriately-qualified healthcare professional. Service delivery should prioritise elements crucial to maintaining quality assurance and a positive participant experience, as well as considerations relating to accessibility (see section 7.4), equity, and informed consent (see Chapter 8).

Due to reliability of ultrasound as a tool for detection of AAA in asymptomatic patients, confirmatory testing is not required as part of an AAA screening pathway. Under the UK NAAASP, if a screening participant with a screen positive result (see below) meets the threshold for referral as defined by the programme (for example, those with a large or fast-growing AAA), a referral is made to a vascular surgeon, who makes the diagnosis of a large AAA.(412)

Screening protocols

The definition of a screen positive result would need to be clearly defined. International screening programmes have generally only included those with an aortic diameter of ≥3.0 cm for follow-up (see Chapter 3, section 3.5.3). However, some local screening programmes in Sweden have included those with sub-aneurysm.(383) The exclusion of those with sub-aneurysm from population-based screening programmes has resulted in a weaker evidence base regarding progression risks.(141) The available evidence from a systematic review suggests that approximately 5.2% of those with sub-aneurysm develop a large AAA within five to ten years.(53) The definition of a screen positive result adopted by the programme should be made with consideration to the trade-off between overdiagnosis and the potential for development of clinically significant AAA in later life among those with sub-aneurysm at age 65. Potential ethical consequences associated with the definition of screen positivity adopted are discussed in Chapter 8, section 8.3.1.

A clear, standardised screening protocol should be developed during the pre-implementation phase, including specification of:

- the direction of measurement (typically anteroposterior)
- the measurement method (for example, inner-to-inner (ITI), outer-to-outer (OTO), leading edge to leading edge (LELE))
- recommended equipment and settings
- processes for image optimisation, measurement and capture

- annotation and image storage requirements
- processes for management of non-visualised aortas, including pathways and governance frameworks
- processes for management of incidental findings.

Each measurement method has distinct advantages and limitations related to accuracy, reproducibility, and the benefit-harm balance. For example, as noted in Chapter 3, section 3.3.1, the ITI method, employed by the UK NAAASP, produces smaller measurements, thus resulting in the lowest number of screen positive results, but potentially increasing the risk of missed cases.[431]

Even with the availability of robust protocols and modern technologies, exact calliper position may still be challenging under some specific circumstances (for example, participants with obesity, the presence of bowel gas, or endoluminal thrombus). The most common reason cited for the non-visualisation of the aorta is the presence of bowel gas.[432] The number of non-visualised screens may be minimised with appropriate staff training, robust imaging protocols (for example, adjusting the image depth and gain to obtain the highest quality image possible) and outlining potential dietary restrictions for participants immediately prior to the scan as part of informed consent processes in advance of arranging the appointment (for example, avoidance of fizzy drinks or a large meal).[178, 433]

Whether or not the results of screening and surveillance scans are communicated to participants at the time of the screening test would be dependent on the internal quality assurance framework set out by the programme (see sections 7.3.4 and 7.7).

Self-referrals

In addition to invited populations, men older than age 65 at the time of implementation could also be offered the opportunity to self-refer for screening, as with the UK NAAASP. Criteria for self-referrals should be developed with consideration to international practice, existing practices in vascular surgery units, and available capacity. If included in the programme, the absolute number of self-referrals that may present to screening services would be highly dependent on awareness regarding the opportunity to avail of screening among men older than 65.[434] Inclusion of self-referred populations may lead to varying levels of demand and may present challenges for estimation of clinical staff requirements, in particular screening staff. International AAA screening programmes have taken measures to manage the number of men self-referring. A recent evaluation of the Swedish AAA screening programme recommended that, first and foremost, there should be sufficient capacity to provide high-quality, end-to-end care to invited populations (that is, men aged 65) prior to considering expansion of local screening programmes.[383] In the UK NAAASP, the number of self-referrals that can be

accepted by the programme each year is limited with consideration to available resources.[434] As outlined in Chapter 8, fairness and ethical standards should be considered in the development of waiting list policies and eligibility criteria. If self-referrals are accepted, promoting self-referrals among men older than 65 with a history of smoking and or cardiovascular comorbidities may yield the greatest clinical benefits.

7.3.3 Surveillance and review

Men with screen-detected AAA would be invited for surveillance imaging with abdominal ultrasound to monitor growth of the aneurysm, in line with the screening algorithm set out by the programme. As noted in Chapter 3, section 3.5, international practice and clinical guidelines vary in the sub-categorisation of AAA according to aortic diameter and surveillance intervals. Surveillance intervals recommended by the ESVS 2024 guidelines were originally based on a systematic review of AAA growth rates and rupture risk undertaken by the RESCAN collaboration in 2013,[6, 55] which are still considered clinically relevant.[56] Different approaches were adopted by screening programmes implemented prior to the publication of this review, including the Swedish and UK programmes. An evaluation of the Swedish AAA screening programme published in 2024 highlighted increasing alignment with ESVS guidelines in local screening programmes, although some inconsistencies remain.[383]

Given the lack of consistency, it would not be possible to align with both international guidelines and international practice for the purposes of international benchmarking. Importantly, surveillance intervals used by AAA screening programmes in Sweden and the UK are generally more conservative than those recommended by the ESVS guidelines, and have been shown to be safe and effective in practice.[265, 383] While adoption of more intensive surveillance intervals may not be an efficient use of resources, it is noted that changes in the number of surveillance appointments would have a relatively minor impact on the incremental budget impact associated with an Irish AAA screening programme, with consideration to the low overall prevalence of AAA and the relatively minor variation in surveillance frequencies in the published literature.

Discharge protocols

Protocols should be implemented to support timely discharge of patients who are unlikely to benefit from continued surveillance, with the use of standardised criteria, where possible.[412, 435, 436] In the context of a national screening programme, it would not be considered feasible to regularly review surgical fitness for all those under surveillance using pre-surgical assessment tools used in the context of

consultant-led pre-operative assessment clinics.[437] However, criteria based on age or progression of AAA over time, for example, may be appropriate.

Such discharge protocols may apply to those with sub-aneurysm(if included) who do not demonstrate evidence of clinically significant disease progression at follow-up scans, or to men with a small AAA in old age. For example, as part of the UK NAAASP, it is considered appropriate to discharge men whose aorta remains less than 4.5 cm in diameter after 15 years of surveillance.[412] As described in Chapter 8, section 8.3.3, discharge decisions should be made as part of shared decision-making between the patient and the multidisciplinary team.

Integration of screening and non-screening care pathways

It would be a fundamental requirement that the implementation of a national AAA screening programme would complement, and not compromise, the existing pathway for patients diagnosed incidentally. The integration of screening and usual care pathways may create operational efficiencies and presents an opportunity to develop a standardised, quality-assured, care pathway regardless of the route through which cases are identified. Such an approach may facilitate redirection of capacity in vascular surgery units for management of patients with more advanced disease. It may also drive quality improvements in the delivery of care to populations outside the scope of the proposed programme. Importantly, the number of patients currently under surveillance in vascular surgery units that may be redirected to the screening programme is unknown due to the absence of a national vascular registry. This presents challenges for capacity planning.

7.3.4 Internal quality assurance

It would be important that screening and surveillance scans are subject to internal quality assurance to ensure accuracy and consistency in programme delivery. The process for quality assurance of AAA screening results may be context dependent with consideration to factors such as risk tolerance levels, staff capacity and skillsets, and the availability of robust protocols to minimise the potential for variation in the delivery of screening and surveillance scans in the first instance.

For example, as part of the UK NAAASP quality assurance process, a sample of images are subject to review by the quality assurance lead, including:[438]

- screen positive results (that is, ≥3.0 cm)
- AAAs that have reached the referral threshold (that is, ≥5.5 cm)
- a monthly random sample (minimum eight scans)
- specific requests made by the screening technician due to technical challenges or incidental findings.

In addition, local programmes can set a threshold for AAAs within a certain range (for example, AAAs ≥2.7 to <3.0 cm) to be automatically selected for review by the local quality assurance lead.[438]

At a minimum, in an Irish AAA screening programme, an appropriately-qualified healthcare professional would need to quality assure all or a portion of ultrasound scans. If review of all ultrasound scans were to be considered necessary to ensure appropriate management of screening participants, this may present challenges for recruitment given current shortages of relevant healthcare professionals (see section 7.5.3). If a review of all scans is not considered feasible or necessary from a clinical perspective, the ability to flag borderline cases for review, similar to the approach adopted by the UK NAAASP, may lessen concerns regarding inappropriate discharge of men from the programme.

7.3.5 Incidental findings

Given the age and comorbidity profile of screening and surveillance participants, the potential for incidental findings of unclear clinical significance may be considerable. Given that incidental findings occur unexpectedly, their frequency and nature are inherently difficult to quantify. The likelihood of incidental findings increases with age.[439] Some studies suggests that approximately 8% to 15% of ultrasound examinations could result in incidental findings, most commonly iliac artery aneurysms and renal masses.[439-441] Other potential incidental findings include enlarged prostate, hepatic steatosis, renal stones, and renal masses. Some potential unexpected findings, such as pathologically confirmed renal cell carcinomas, have the potential to critically change patient management.[419]

In the context of AAA screening, the likelihood of detecting incidental findings largely depends on the expertise of the healthcare professional conducting the screening test. Employing screening technicians trained exclusively to assess the abdominal aorta likely reduces the risk of incidental findings, compared with other healthcare professionals with broader expertise, such as, vascular technologists, radiographers or sonographers.[152] UK NAAASP guidance for screening technicians outlines that technicians are expected to scan within the scope of the screening guidelines only.[442] This is consistent with standards set out by the Faculty of Radiologists and Radiation Oncologists in Ireland in 2012, which notes that ultrasound scanning should be limited to provide the diagnostic information required for the episode of care.[443]

Management of incidental findings would fall outside the scope of the programme, as they cannot be diagnosed and managed as part of the screening care pathway. Where an incidental finding is suspected during screening or surveillance, clear protocols should be in place to link those with incidental findings with appropriate

care. Screening protocols should be designed to minimise the potential for incidental findings, with consideration to the risk-benefit balance.

From a quality assurance perspective, all images should be reported by an observer with appropriate clinical training. Given that the aim of the programme would be to measure aortic diameter only, it would not be considered necessary for screening technicians to have broader clinical training. However, potential incidental findings would likely need to be reviewed by a consultant radiologist.

Incidental findings are most likely to occur during pre-surgical investigations using, for example, CT angiography (see Chapter 3, section 3.3.2). Given similarities in risk factor profiles, pulmonary nodules are commonly detected on high resolution CT among patients with AAA.[444, 445] Where identified, these may require ongoing monitoring given the possibility of cancer development.[446, 447] It is expected that the absolute increase in the number of incidental findings would be small and would therefore not be expected to result in a significant increase in referrals, for example, to pulmonary medicine.

7.3.6 Cardiovascular risk factor management

In the UK NAAASP, men with screen-detected AAA are referred to a vascular nurse at specific points in the care pathway to provide counselling and advice on lifestyle changes, such as smoking cessation.[412] However, AAA surveillance pathways were not specifically developed to deliver cardiovascular risk factor modification.[342] Evidence of very high follow-up with AAA surveillance in the NAAASP presents a major opportunity to offer better cardiovascular prevention to a population at very high risk for cardiovascular events; those with AAA typically have multimorbidity (see Chapter 2, section 2.4.4) and are often socio-economically deprived.[448] Research is currently underway to examine the feasibility of developing a cardiovascular risk reduction intervention to be embedded within the existing NAAASP clinical care pathway.[342] However, pharmacological management of cardiovascular risk factors within the context of a national screening programme would be challenging. Regular medication reviews would be needed, and drug prescriptions may need to be tailored to account for individual patient factors including medical and family history, potential contraindications, and personal factors such as the challenges of managing complex treatment regimens and the potential impacts of polypharmacy on quality of life. Findings from this research may inform the extent to which cardiovascular risk factors can be managed within an AAA screening programme, if implemented.

If cardiovascular risk factor management is considered beyond the scope of an AAA screening programme, implementing processes to inform GPs about the outcome of the screening test, or of clinically significant AAA progression during surveillance, could help to support appropriate management of risk factors for those with a

positive screening test result. However, the absence of universal access to primary care and GP shortages present challenges, as described in Chapter 8, section 8.3.4.

7.3.7 Referral to vascular surgery

Establishing a referral pathway, including clear referral criteria, is critical to the delivery of a safe and effective AAA screening programme. As outlined in Chapter 3, section 3.5, widely accepted referral criteria for evaluation in men for surgical AAA repair include an aortic diameter ≥5.5 cm or evidence of rapid AAA growth (for example, growth of >1.0 cm in one year).

The point at which the programme's remit ends and responsibility is transferred to the vascular surgery unit should be clearly defined. For example, in the UK NAAASP, once a referral is accepted by the vascular surgery unit, the vascular surgery unit assumes responsibility for clinical decision-making and follow-up.[412]

7.3.8 Acute surgical care episode

Implementing an AAA screening programme would impact hospital capacity, requiring careful planning to ensure sufficient resources are available to meet the potential increase in surgical demand and requirements for lifelong follow-up. Patient management protocols during the pre-, peri- and post-operative period should be consistent with best practice recommendations, as outlined in the 2024 ESVS guidelines.[6] The choice between endovascular aneurysm repair (EVAR) and open surgical repair (OSR) should be determined on an individual basis; it requires full aortic evaluation with CTA to assess anatomic suitability for EVAR (for example, excessive aortic tortuosity or a short proximal aortic neck may contra-indicate EVAR), as well as consideration of factors such as patient age and life expectancy, comorbidities, institutional experience and patient preference.[449] In the UK NAAASP, a greater proportion of men with a screen-detected AAA have OSR, due to the younger age profile of the cohort and greater durability of this procedure. Under current practice in Ireland, approximately 65% of AAA repairs are EVARs (see, Chapter 2, section 2.7.1). Potential changes in the types of procedures performed, and associated differences in short- and long-term surgical outcomes between these procedures, may need to be considered in the resourcing of vascular surgery units.

In the context of a national screening programme, robust data collection mechanisms would be required to facilitate monitoring of surgical outcomes against agreed KPIs (see section 7.7.1). Requirements to submit surgical outcome data for screen-detected cases to the AAA screening programme may create an additional administrative burden in vascular surgery units. It is noted that as part of the UK NAAASP, all vascular surgery units accepting referrals from the programme must agree to comply with data reporting requirements.[412]

7.3.9 Long-term monitoring

Long-term post-surgical monitoring protocols should align with the type of surgical repair performed, and may vary depending on the outcome of early post-operative imaging to inform risk stratification. In general, while OSR is associated with increased short-term resource requirements, long-term follow-up requirements and re-intervention rates tend to be higher after EVAR due to the risk of potential late complications (for example, device migration or endoleak) and disease progression (for example, aneurysm sac growth). The ESVS 2024 guidelines suggest that patients who have undergone OSR should have comprehensive imaging studies at five-year intervals.[6] Patients who have undergone EVAR are recommended for long-term imaging follow-up, regardless of initial risk stratification, to monitor for potential late complications.[6] Due to the potential need for individualised follow-up based on clinical need and access to additional imaging modalities and tests,[146] it would not be considered appropriate to discharge men from vascular surgery units back to the screening programme following surgical intervention.

The increasing cohort of patients that would requiring long-term monitoring may pose challenges for healthcare system capacity. Ongoing investment may be required to support access to appropriate long-term follow-up care. As outlined in the 2024 ESVS guidelines, lifelong follow-up is required after any form of AAA repair for maintained treatment success.[6] However, it is noted that the decision to continue with long-term monitoring should also be made with consideration to the fitness of a patient for re-intervention if a late complication is detected.

Efforts to minimise cumulative exposure to ionising radiation should be made for both patients and staff involved in repeated imaging; this is accomplished through implementation of appropriate radiation protection measures, particularly for follow-up of patients post-EVAR.

7.4 Programme structure

7.4.1 Examples from other contexts

As noted in Chapter 3, section 3.5.3, the organisation of AAA screening programmes internationally varies depending on the local healthcare system context and structure. Formal AAA screening programmes are in place in the UK and Sweden. In the UK, screening and surveillance are delivered by dedicated 'screening technicians' with specialist training; screening and surveillance are delivered in community-based healthcare facilities, including primary care centres, community clinics, community hospitals and mobile units, to maximise accessibility.[412, 438] Those with large AAA are referred to vascular surgery units for radiological and clinical evaluation, and cannot be referred back to the programme for monitoring once referred.[412] In Sweden, while there is some regional variation in programme delivery, screening and surveillance appear to be largely delivered in hospitals and by ultrasound technicians

or nurses with specific training in aortic ultrasound.[30, 242] High uptake (>80%) has consistently been achieved in both programmes.[91, 116]

Informal AAA screening programmes are in place in France, Germany and the US. Poor uptake has been reported to be a challenge across each of these programmes, which may be linked to the absence of a systematic delivery approach.[253, 259, 331, 450] In Germany, men 65 years and older are entitled to a free ultrasound examination of the abdominal aorta, with referral of screen positive cases to vascular surgery for surveillance or treatment, as appropriate.[259, 331] While the German healthcare context is not directly transferable to Ireland due to differences in funding mechanisms,[451] it is worth noting that, if high uptake were to be achieved, it may not be considered feasible or necessary to have a delivery approach whereby all screen-detected cases are referred to hospitals for further follow-up (compared with an approach whereby a threshold for referral of screen-detected AAAs is established).

While the reasons behind low uptake in some international screening programmes are likely multifactorial, the available evidence suggests that public and provider information and awareness, systematic invitation, and a structured care pathway, would be central to the success of an AAA screening programme.

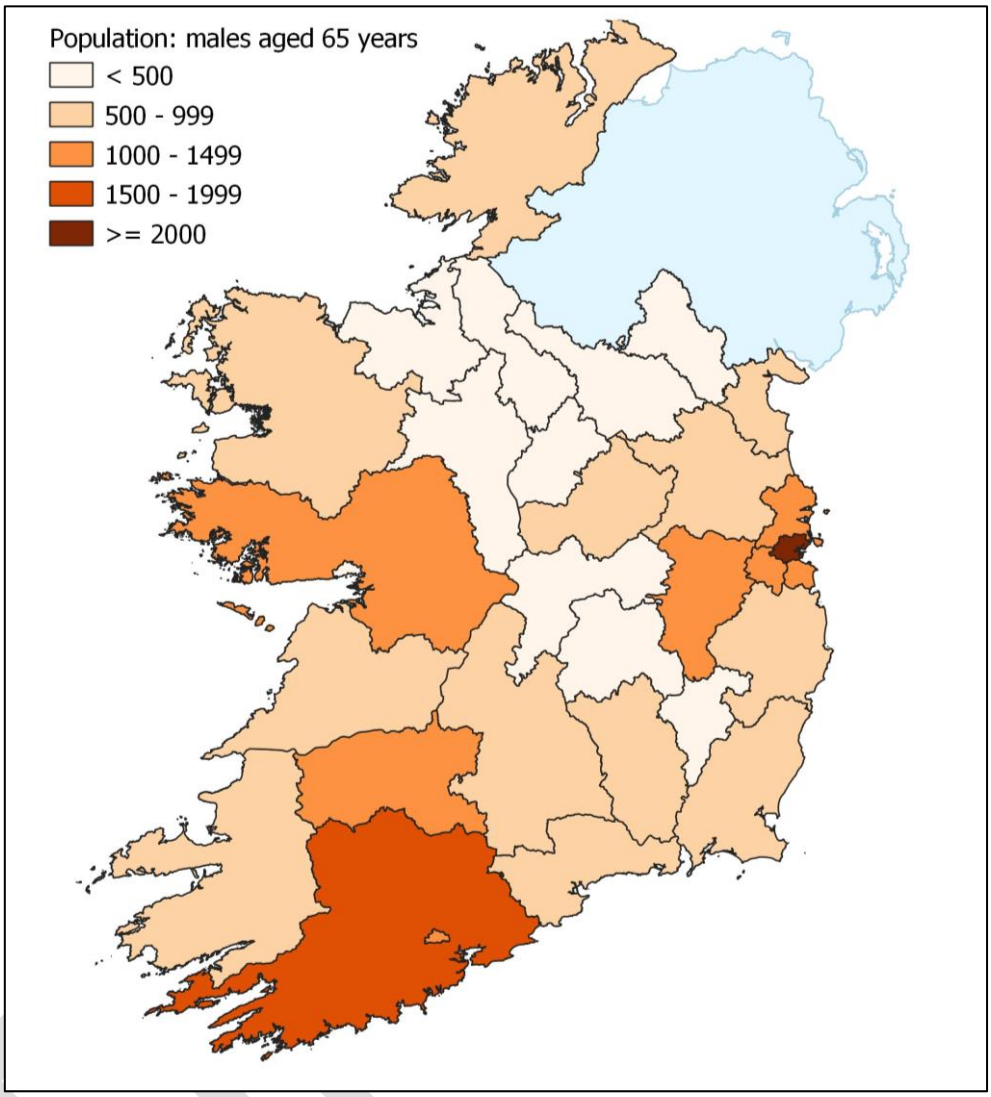
7.4.2 The Irish context

The design of an AAA screening and surveillance programme in Ireland should be developed with consideration of ongoing healthcare system reforms, existing screening programmes in Ireland, the volume and geographic distribution of the target population, and the current clinical context. Given the screening regions outlined in the national breast screening programme, BreastCheck,[452] and existing hospital group configurations in Ireland,[425] an AAA screening programme could be structured into three or four screening regions, each comprising one to two health regions, as follows:

- one to two Eastern screening units (HSE Dublin and North East, and HSE Dublin and Midlands)
- the Western screening unit (HSE West and North West, and HSE Mid-West), and
- the Southern screening unit (HSE South West and HSE Dublin and South East).

Based on population projections from the 2022 census, there are approximately 27,000 men aged 65 years in Ireland, with the highest population density near urban areas (Figure 7.1). The population aged 65 years is expected to increase by approximately 30% by 2035 due to population ageing.

Figure 7.1 Population density of men aged 65 years in Ireland by county and city



Source: Central Statistics Office (CSO).

Setting of screening and surveillance

Whether screening technicians undertake screening only, or screening and surveillance, may influence the potential screening setting and technical specifications of the ultrasound system used by an AAA screening programme. For example, in the SENSE project, an AAA screening study conducted in the midlands and led by St James's Hospital, ultrasound screening was performed in GP practices (see Chapter 3, section 3.4.1). Those with a positive screening test result were referred to vascular surgery for appropriate follow-up, dependent on the size of the AAA detected. An alternative delivery model is implemented in the UK NAAASP. Men with small to medium screen-detected AAA are followed up by the screening programme, unless otherwise advised based on individual patient factors. Only those

with screen-detected AAA meeting the criteria for referral are sent to vascular surgery units for assessment of suitability for elective surgical repair.

From a quality assurance perspective, ensuring implementation of programme policies and standards may be more challenging where large numbers of healthcare professionals working across multiple hospitals are involved in surveillance of small and medium AAAs in addition to their current workloads. Furthermore, ensuring that surveillance appointments for those with small and medium AAA are undertaken in line with agreed programme standards may be a considerable challenge where capacity for surveillance is not ring-fenced. The experience in the UK suggests that the majority of men with small or medium screen-detected AAA can be safely managed with surveillance by a standardised, community-based screening programme using portable ultrasound imaging systems. However, with community-based screening, there is an inevitable reduction in clinical contact time to allow for travel of healthcare professionals and set up. This would need to be reflected in screening staff estimates.

In order to ensure efficient use of hospital-based imaging services, the UK model for surveillance could be followed. However, where surveillance is undertaken by screening technicians in the community, ultrasound systems that facilitate precise measurements of changes in aortic diameter would be necessary to support appropriate clinical decision-making.

Organisational delivery

The organisational design of any screening programme often includes a trade-off between local provision which facilitates higher attendance, and operational efficiencies associated with centralised screening. As noted previously, the optimal programme structure may vary between different healthcare systems with consideration to the organisational structure and healthcare system context at the time of implementation. The following potential organisational models for combined screening and surveillance clinics were considered as part of this HTA:

- purpose-built, community-based, static and mobile screening units
- community-based screening within existing healthcare facilities, such as primary care centres or regional hospitals
- a combination of screening in purpose-built facilities such as mobile units, and screening within existing community-based healthcare facilities
- screening within existing hospital radiology departments
- a combination of community- and hospital-based screening, depending on local or regional factors such as accessibility and available resources.

Each strategy is associated with distinct advantages and disadvantages (Table 7.1). For combined screening and surveillance clinics, under each delivery approach, a

dedicated specialist workforce operating in the context of a standardised, quality-assured programme would likely support improved patient outcomes and satisfaction with the care experience.

Table 7.1 Advantages and disadvantages of potential screening and surveillance delivery models

Delivery model	Advantages	Disadvantages
Combined screening and surveillance clinics		
Community-based in purpose-built facilities	▪ Accessible to the target population, which may result in increased uptake. Use of mobile screening units, where appropriate, maximises accessibility. ▪ Minimises demands on hospital radiology departments.	▪ May be challenging to recruit and retain staff to roles requiring travelling. ▪ Significant investment in infrastructure required. Not suitable for feasibility studies or short-term implementation.
Community-based in existing healthcare facilities	▪ Accessible to the target population, which may result in increased uptake. ▪ Minimises demands on hospital radiology departments. ▪ Lower capital investment costs when compared with purpose-built screening facilities. ▪ May be possible to align service delivery with Sláintecare levels of care.[424, 426] For example, smoking cessation support and counselling/advice could be delivered in specialist ambulatory care hubs.	▪ May be challenging to recruit and retain staff to roles requiring travelling. ▪ Physical space constraints. Structural modification may be required at some sites.
Combination of community-based in purpose-built and existing healthcare facilities	▪ Accessible to the target population, which may result in increased uptake. ▪ Minimises demands on hospital radiology departments. ▪ Mobile units can be used in areas where appropriate facilities cannot be identified.	▪ May be challenging to recruit and retain staff to roles requiring travelling. ▪ Some investment in infrastructure required. Not suitable for feasibility studies or short-term implementation.
Hospital-based	▪ Operational efficiencies. Potential to build on existing infrastructure and expertise.	▪ Less accessible to the target population, which may result in lower uptake. ▪ Physical space constraints. Some structural modification would likely be required.

		▪ Challenging to ring-fence staff time for screening and surveillance. ▪ QA may be challenging where surveillance monitoring is not undertaken by a dedicated, specialist workforce.
Combination of community- and hospital-based	▪ Resources can be tailored to the local context.	▪ May be challenging to ensure consistency in programme delivery. ▪ Physical space constraints. Some structural modification may be required. ▪ Challenging to ring-fence staff time for screening and surveillance in hospital-based screening centres. ▪ QA may be challenging where surveillance monitoring is not undertaken by a dedicated, specialist workforce.
Separate screening and surveillance clinics		
Community-based screening with referral to vascular surgery for follow-up	▪ POC ultrasound systems could be used in the context of screening. ▪ POC ultrasound systems may be shared between screening centres. Capital investment costs may be reduced. ▪ Increasing the number of screening locations would result in increased accessibility, and may facilitate high uptake.	▪ POC ultrasound systems may not be suitable for obtaining precise measurements of aortic diameter over time for cases under surveillance. Referral of screen positive cases to vascular surgery for follow-up may be necessary. ▪ Referral of relatively low risk cases with small and medium AAA may not be an effective use of hospital resources, and may compound existing capacity constraints for imaging studies. ▪ QA may be challenging where surveillance is not undertaken by a dedicated, specialist workforce. ▪ Hospital-based follow-up reduces the accessibility of care to patients, and may result in increased loss to follow-up.

Key: AAA – abdominal aortic aneurysm; KPI – key performance indicator; POC – point of care; QA – quality assurance.

The optimal screening delivery model in the Irish context requires careful consideration of the balance of costs and benefits. Distance to testing facilities and concerns regarding transportation influence a person's decision to attend screening.[453] The requirement to travel may also be unattractive to screening personnel and hinder recruitment.[454] Although not directly applicable to AAA screening due to differences in patient and disease factors, in the context of gestational diabetes screening in the West of Ireland, it has been estimated that the probability of attending screening is reduced by 3.0% (95% CI: 2.0% to 3.9%) for every additional 10 km required to travel to attend screening.[455] The potential influence of distance to screening centres on uptake, and thus the effectiveness of a screening programme, should be considered in the design and delivery of an AAA screening programme, if implemented. A community-based screening programme would facilitate the greatest geographic coverage. However, it would require the most significant investment in infrastructure and staff.

As outlined in section 7.2.2, due to significant demands on hospital-based radiological imaging capacity in Ireland, additional funding has been allocated to improve access to diagnostic imaging, in the form of the GPACD Scheme. In light of current capacity constraints within the hospital setting, implementation of AAA screening and surveillance within existing hospital physical resources is unlikely to be feasible. Furthermore, ring-fencing of staff time would be a considerable challenge.

As noted previously, men with small to medium screen-detected AAA are followed up by the community screening programme in the UK NAAASP. Only those with large or fast-growing AAAs are referred to vascular surgery units for assessment of suitability for elective surgical repair. If a similar delivery model were adopted in the Irish context, in addition to any new cases identified in the screened cohort each year, participants with small to medium screen-detected AAAs in previous cohorts would require ongoing review. Therefore, the total population for screening and surveillance would be expected to increase modestly each year in the short- to medium-term (approximately n = 165 cases per year). Capacity for ongoing monitoring of those with small and medium screen-detected AAA should be factored into estimates of resource requirements of screening and surveillance centres.

In light of declining disease prevalence and uncertainty regarding the optimal delivery model in the Irish context, a local feasibility study may be necessary prior to proceeding with national roll out or implementation of screening on a time-limited basis, as has been suggested in Denmark (see Chapter 3, section 3.5.3). However, substantial investment in new purpose-built facilities or adaptation of existing healthcare facilities may not be considered an effective use of available funding if the intervention is intended for short-term implementation only. Community-based screening within existing healthcare facilities may be more appropriate in circumstances where the longevity of a screening programme is unclear.

Acute surgical care episode and follow-up

There are currently ten vascular surgery centres in Ireland: five in Dublin (Beaumont Hospital, the Mater Misericordiae University Hospital, St James's Hospital, St Vincent's University Hospital, Tallaght University Hospital), two in Cork (Cork University Hospital and Mercy University Hospital) and one each in University Hospital Galway, University Hospital Limerick, and University Hospital Waterford.[148] Almost all arterial surgery is carried out in these vascular surgery units. There are established care pathways within each hospital group for referral of patients to vascular units. Enhanced service integration through Sláintecare has the potential to streamline patient transitions between community- (for example, screening and surveillance) and hospital-based services (for example, pre-operative assessment).

As outlined in the 2023 Model of Care for Vascular Surgery in Ireland, high-quality vascular care is best delivered by integrated vascular networks given evidence of a volume-outcome relationship.[148] Pathways for referral of patients meeting the threshold for surgery from the AAA screening programme to vascular surgery units should be developed with consideration to the present hospital group configuration, which aligns with the six health regions outlined in the Sláintecare strategy.

The success of a hub and spoke model for vascular surgery would be dependent on adequate volumes of surgery per unit to optimise patient outcomes, and appropriate staffing, facilities and equipment in vascular surgery units. Elective surgical repair volumes are challenging to predict in the absence of up-to-date prevalence estimates or a national vascular registry. If the prevalence of AAA continues to decline, it may be necessary to designate national centres of excellence to ensure minimum volume requirements can be maintained. While centralising care has advantages in terms of ensuring adequate surgical volume to optimise outcomes, reliance on a small number of high volume centres may create challenges for accessibility, healthcare system resilience and competition for theatre access. The balance between volume-outcome relationships and the challenges associated with competition for critical resources in large hospitals requires careful consideration during the pre-implementation phase.

Long-term follow-up would be delivered in hospital-based vascular surgery units. Under current practice, after the early post-operative period, patients are typically followed up with imaging studies every one to two years, with potential for discharge of patients who underwent OSR where their condition is stable following multiple follow-up appointments. Capacity for lifelong follow-up and secondary intervention for a proportion of patients should be taken into account in determining appropriate multidisciplinary team staffing levels in vascular surgery units.

7.5 Infrastructure and resources

Healthcare infrastructure refers to the physical and organisational structures, facilities, and systems that collectively support the delivery of healthcare services. The resources required to establish and run an AAA screening programme may depend on factors such as existing healthcare system capacity, the aim of ultrasound imaging (that is, screening versus screening and surveillance), the populations managed by the programme (for example, men aged 65, self-referred cases, surveillance of incidentally-detected AAA) and the setting in which imaging is to be carried out. For the purposes of this HTA, resource requirements were estimated with reference to existing screening programmes in Ireland, international AAA screening programmes, and the estimated number of men in the eligible population.

For the purposes of this assessment, pre-implementation refers to the preparatory period of up to two years from the decision to implement a screening programme until screening of the eligible population commences. A significant pre-implementation phase is required to prepare for the introduction of the programme and would include recruitment of programme and clinical staff, stakeholder engagement activities, development of the care pathway, and agreement on quality assurance frameworks. The operational or post-implementation phase includes all costs and activities associated with running the programme, including clinical activities.

As described in Chapter 2, section 2.4.3, the strongest predictor of AAA rupture risk is aortic diameter. However, not all individuals with an AAA would be identified incidentally or experience AAA rupture during their lifetime in the absence of screening. Therefore, the detection of cases through screening who would not have been picked up under usual care would lead to increased resource consumption associated with surveillance, elective surgical repair and long-term monitoring, which must be considered in capacity planning. The consequences of overdiagnosis and overtreatment from clinical effectiveness and ethical perspectives are considered in Chapter 4, section 4.4.2, and Chapter 8, section 8.3.1, respectively.

7.5.1 Facilities, equipment and resources

Screening and surveillance clinics

Each screening clinic would require the following facilities:

- a waiting area
- changing facilities
- one to two examination rooms, depending on the number of screening technicians per clinic
- a consultation room
- facilities for screening staff breaks
- a storage area for equipment and consumables.

Further, a separate changing area in addition to the examination rooms would be considered advantageous in terms of providing participants with privacy and enhancing participant flow.

Based on consultation with key stakeholders, if a decision is made to implement AAA screening, physical space constraints may present challenges for implementation of AAA screening in some community-based locations. The pre-implementation phase would involve a review of the potential sites (for example, primary care facilities or regional hospitals), including consideration of existing facilities and accessibility for the target population. In the event that suitable facilities cannot be identified, additional investment would be required to support structural modification of existing healthcare facilities, in addition to potential investment in mobile screening units to service underserved areas. This may result in delays to rollout. Additionally, ongoing costs related to servicing, haulage and management of mobile units would need to be taken into account.

The estimated equipment and consumables required to run a screening programme at a national level (for example, portable ultrasound machines, height-adjustable examination beds) were costed as part of the budget impact analysis (Chapter 6, Table 6.2). However, specific resource requirements may vary at a local level.

In the UK NAAASP, two screening technicians are assigned to each clinic to ensure high throughput. In the Irish context, the number of screening technicians, and thus examination rooms and ultrasound systems, needed per screening clinic should be determined with consideration to the eligible population size in the catchment area and minimum staffing requirements.

As noted in section 7.3.6, men with screen-detected AAA may be offered an appointment with a vascular nurse to provide information and advice to support appropriate disease management. The setting of appointments with the vascular nurse may vary depending on local healthcare system structures. In some settings, it may be practical to allocate an additional consultation room at the same site as the screening and surveillance clinic. Alternatively, vascular nurses could be situated in specialist ambulatory care hubs, as planned under Sláintecare.

Ultrasound equipment

A range of ultrasound equipment specifications are available, from relatively inexpensive systems designed for portability and ease of use, to high specification systems typically used in the hospital setting for diagnostic purposes. A 2023 HTA of AAA screening undertaken by the Catalan Agency for Health Information, Assessment and Quality (AQuAS) noted that the use of point-of-care ultrasound systems in primary care has increased substantially in recent years.[236] The potential to leverage existing ultrasound systems already available in primary care centres to

conduct AAA screening was noted in the HTA from a cost containment and feasibility perspective.[236] However, given potential variability in the specification of different ultrasound systems, use of validated, standardised equipment would be important in the context of a formal screening programme.

The populations managed by the programme (be it screening only, or screening and surveillance) and setting of screening (that is, hospital versus community) would influence the specification of ultrasound imaging system required. Based on the information synthesised in section 7.4, in addition to screening men aged 65 years, managing surveillance of small and medium AAA in previously-screened men by the community-based screening programme, as opposed to vascular units, may be considered optimal to promote consistency in service delivery and operational feasibility. Under current diagnostic practice in Ireland, in non-emergency circumstances, high-resolution ultrasound systems are typically used in radiology departments to diagnose AAA. However, these systems are not designed for portability and therefore would not be suitable for use in a community-based screening programme. In selecting the ultrasound system(s) to be used by the programme, there may be a trade-off between technical specifications and portability.

A technical equipment specification outlining the required standards would need to be developed prior to procurement. A validation exercise would then need to be undertaken to investigate agreement of potential ultrasound systems with required standards. Important factors to consider in the evaluation of ultrasound equipment are listed in Table 7.2.

It is estimated that the working life of a new ultrasound system is approximately five years.[443, 456] The replacement rate or maintenance frequency for probes may be higher due to potential for improper handling which may lead to damage. Service and repair agreements should be considered as part of the equipment evaluation process (Table 7.2). Equipment used by the programme would need to be purchased and replaced in line with agreed HSE procurement and replacement frameworks and standards set out by the Faculty of Radiologists and Radiation Oncologists.[443]

It is noted that hardware requirements for data storage depend on the connectivity at a given site and quality assurance processes (for example, whether all images are stored or only a sample for quality assurance purposes, duration of storage etc.); inadequacies in hardware and connectivity negatively impact the efficiency and quality of programme reporting.

Table 7.2 Potential factors to inform selection of ultrasound equipment

	Accuracy (sensitivity, specificity)

Test accuracy	Safety (for example, false negatives)
Test performance	Ease of use
	Inter- and intra-observer reliability/reproducibility/precision
Equipment characteristics and technology	Portability
	Data storage and connectivity (for example, PACS, cloud-based, local/network storage)
	Compatibility with existing systems
Organisational and budgetary factors	Availability (required quantity and timeframe)
	Upfront cost
	Service (for example, recalibration) and repair agreements
	Training and technical support

Based on the NAAASP evaluation report 2019,[456] and existing HSE dynamic purchasing systems.
Key: PACS - picture archiving and communication system.

Vascular surgery units

If screening is implemented, vascular surgery units should be adequately resourced to allow timely assessment of referrals and intervention where indicated, in line with international standards, to minimise the risk of men experiencing AAA rupture or clinical deterioration while waiting for surgery. If expanding surgical capacity to the level required is not considered feasible across all ten vascular surgery units, an alternative approach may involve appointing designated centres that can deliver care in line with the programme's key performance indicators (KPIs). In consultation with individual hospital groups, the number of vascular surgery units receiving referrals from the screening programme would need to be agreed with consideration to factors such as available theatre space, bed capacity, clinical staff, data collection and reporting mechanisms, and competing surgical activity. Such an approach may build expertise in these centres and ensure appropriate volumes to maintain competence. However, maintaining reasonable geographic coverage would be important, taking differences in population densities across the country into consideration. Appropriate access to ICU/HDU would need to be available within each hospital receiving referrals from the programme.

It is noted that reconfiguration of vascular surgery services in a 'hub and spoke' model was recommended by the model of care for vascular surgery published in 2023 to optimise patient outcomes and available resources.[148] The designation and resourcing of spoke centres would be influenced by many factors, including the structure of new health regions, as well as the approach to delivery of emergency medicine and trauma services.[148] If the number of centres carrying out vascular

surgery is reduced, it would be important that remaining centres are adequately resourced to act as a vascular hub with increased surgical volumes. Currently, no vascular surgery unit is resourced to undertake the role of a vascular hub.[148] Without adequate resourcing, competition for theatre space between, for example, trauma and AAA repair cases in centres of excellence could comprise the ability to deliver surgical repair of AAA in line with the programme's KPIs. The potential reconfiguration of vascular surgery services should be considered in the design of an AAA screening programme.

Ideally, each vascular unit would have access to a hybrid theatre; this combines a traditional operating room with an interventional suite.[6, 148, 457, 458] This configuration enables optimal use of radiological imaging through an efficient and coordinated movement of the radiation source and the patient position, thus decreasing the overall time of radiation exposure for the patient and the clinical staff, and requirements for contrast agents.[6] A literature review reporting dose data during EVAR and complex EVAR, reported that the lowest levels of radiation (measured in terms of the dose-area product) were identified in modern hybrid rooms with fixed systems.[459] An additional benefit of hybrid theatres in the context of AAA repair is facilitating seamless transition between endovascular and open procedures (for example, conversion to open surgery after failed EVAR).[457, 460]

In light of these benefits, the 2023 ESVS clinical practice guidelines on radiation safety recommend that preference should be given to fixed imaging systems over mobile systems for endovascular procedures to improve image quality and reduce radiation exposure.[458] At present, hybrid theatres are available in six out of the ten vascular surgery units nationally, including a new digital hybrid operating theatre at Beaumont Hospital in Dublin. The costs and benefits associated with construction of additional hybrid theatres at Mercy University Hospital, St Vincent's University Hospital, Tallaght University Hospital, and University Hospital Waterford would not be specific to surgical repair of AAA, given that they can also be used across a variety of medical disciplines including neurosurgery, emergency medicine and obstetrics.

Hybrid theatres should be risk-assessed and resourced to ensure radiation exposure is kept to as low as reasonably achievable for the safety of patients and staff, in accordance with Irish legislation (SI 256 of 2028, as amended) and the European Directive.[461-463]

7.5.2 Information and communication technology systems

The design of an AAA screening programme database should be aligned with the technical and service delivery requirements of Sláintecare, the Digital Health Framework for Ireland 2024-2030,[464] and governance processes. As set out in the Digital Health Framework, any new collections of patient information must be

compatible with the National Shared Care Record to facilitate consolidation and alignment of patient data, where appropriate.[464] All data management systems in which patient information is stored should comply with relevant data protection legislation, including the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.[465, 466]

The programme database

The programme database is used to identify the eligible population (that is, the population register), operate call and recall systems, monitor programme outcomes against agreed standards, and support quality improvement initiatives.

Approaches to compiling a population register may vary depending on factors such as the characteristics of the population under consideration and existing healthcare information systems. Due to limitations associated with the healthcare information and communications technology systems in Ireland, in particular, the absence of a unique health identifier, existing screening programmes must invest considerable resources in establishing and maintaining the population register for a given screening programme. In the absence of a national screening register, data provided by the Department of Social Protection would be used to identify and invite men to participate in AAA screening in the year they turn 65, consistent with the approach adopted by other national screening programmes in Ireland.[467, 468]

Development of a single screening register serving all NSS screening programmes would be associated with operational efficiencies due to economies of scale. It is planned that a single screening register will be implemented by the end of 2026.[469] With consideration to the complexities associated with development of a large-scale screening register including design and planning, data validation, and pre-launch training, developing a single screening register may exceed the timelines agreed for implementing an AAA screening programme. If so, the potential to leverage existing information systems and registries managed by NSS in the development of an individual AAA screening register, such as the BowelScreen register, could be explored, given that a large proportion of men aged 65 who are ordinarily resident in Ireland would previously have been invited to participate in BowelScreen.

It is noted that the register is only one component of the programme database; a database would still be needed to manage participants under the care of the programme and to monitor programme outcomes.

National vascular registry

As noted previously, there is no national vascular registry in Ireland and this presents challenges for estimating surgical outcome data, epidemiological trends and resource requirements. The ESVS 2024 guidelines recommend that centres

performing aortic surgery record cases in a prospective registry to facilitate monitoring of practice and outcomes.[6] If established, patient characteristics and clinical outcomes should be recorded and reported in line with international practice to facilitate participation in VASCUNET - a collaborative network of vascular surgery registries in Europe and Australasia.[6, 470]

Many vascular surgery registries internationally have established mechanisms for data linkage to other national administrative datasets (for example, death register). If implemented, linking a national vascular registry with the AAA screening database would facilitate monitoring and reporting of programme outcomes. It is noted, however, that data protection restrictions have presented challenges for data linkage between vascular surgery registries and other national databases in some European countries.[470]

Development of a registry involves complexities that extend beyond data capture alone, including important technical, operational, ethical and legal considerations.[471] It would be important that key stakeholders are involved in the development of a national vascular registry to ensure that it reflects the needs of policy-makers, clinicians, patients and researchers. It is important to note that the budget impact analysis presented in chapter 6 was limited to considering the cost of providing an AAA screening programme. Development and maintenance of a national vascular surgery registry would require additional investment, which is beyond the scope of the current assessment.

7.5.3 Staffing requirements

Programme staff

The number and types of staff expected to be required to set up and run an AAA screening programme are outlined in Chapter 6, Table 6.3.

Additional investment in cross-programme NSS activities including, but not limited to, quality assurance and patient safety, finance, HR administration, data analytics, information governance, and customer services (for example, a call centre) will be required, as the number and scale of the screening programmes managed by NSS grows.

Clinical staff

While ultrasound imaging may be typically considered to fall within the scope of clinical radiology, vascular technologists are also clinically trained to conduct vascular ultrasound. Within current practice in Ireland, radiographers or sonographers (that is, specialised ultrasound radiographers) use a range of imaging equipment, including ultrasound, to produce high quality images of the internal human body.[443,

[472] Radiologists, as specialist doctors, then interpret and report on the images generated by radiographers or sonographers in order to direct patient care.[472]

Vascular technologists undertake a wide range of non-invasive tests in the vascular laboratory, including vascular ultrasound, and are largely under the clinical governance of the supervising vascular surgeon.[473] Radiologists, radiographers and vascular technologists may be involved primarily in the screening and surveillance elements of the care pathway. Treatment and follow-up of individuals with a large AAA would require collaboration from multiple disciplines including vascular surgery, clinical radiology, critical care and anaesthesiology.

Clinical workforce shortages

Deficits in key disciplines needed to support implementation of an AAA screening programme, including radiology, radiography, and vascular technology, would likely present challenges for recruitment, and therefore implementation. A 2017 review of the clinical radiology medical workforce in Ireland estimated that in order to align with the European average of 8 consultant radiologists per 100,000 population, Ireland will require a minimum of 150 additional radiologists by 2027.[472] At the time of writing, these staffing levels have not yet been achieved. A more recent report from the UK Royal College of Radiologists suggests that the OECD average is approximately 13 consultant radiologists per 100,000 population,[474] suggesting that previously planned staffing levels may not be sufficient to align with international standards and to support increasing demands for access to imaging in the Irish context, as noted in section 7.2.2.

A survey of 141 radiographers registered with CORU (the state regulatory body for health and social care professions) conducted in 2023 reported significant challenges related to employee retention across public and private healthcare sectors.[418] Among public sector employees, heavy workload was identified as the primary reason for retention issues (78%), followed by staff shortages (76%).[418] Limited career progression opportunities were cited as a contributing factor to retention issues by 49% of public sector employees. The results of this survey suggest that enhanced training programmes and structured career progression may improve job satisfaction and retention in the Irish context.

Internationally and in Ireland, the vascular surgery workforce, including vascular surgeons and vascular technologists, is also experiencing shortages which may compromise delivery of vascular services.[475, 476]

Screening and surveillance

As noted in section 7.4.1, a dedicated 'screening technician' role was developed specifically for the purposes of AAA screening in the UK, and requires specialist

training ('the Level 3 Diploma for Health Screeners') and continuous professional development.[477, 478] However, an equivalent role does not currently exist in the Irish context. Given the limited supply of vascular technologists and radiographers in Ireland, creation of a specialist screening technician role in the Irish context may represent a viable alternative staffing model while maintaining the quality and safety of the service. In the Swedish programme, screening can be undertaken by radiology nurses, doctors, or the following healthcare professionals where they have undertaken ultrasound training: biomedical analysts, nurses, nursing assistants.[383] Similar to conduct in the NAAASP, all men receive verbal confirmation of screening test results at the time of screening.[383, 412]

The number of screening technicians required would be dependent on the size of the population for screening and surveillance, throughput and the extent of additional non-clinical duties necessary for the proper functioning of the programme. Guidance from the Society of Radiographers in the UK suggests that approximately 20 minutes should be allocated for a general abdominal ultrasound scan.[479] However, higher throughput may be achieved in the context of AAA screening due to the targeted nature of the screening test. In the NAAASP, on average, it is estimated that 15 to 18 screening participants can be screened in a three-hour clinic.[412, 479] As noted in a 2010 evaluation of resource use in national cancer screening programmes undertaken by HIQA, while efforts are made to maximise productivity, it is not feasible to achieve a 100% utilisation rate due to factors such as staff training requirements, quality assurance processes, travel between screening centres, non-attendance, variation in appointment times and equipment failure.[157, 480] The potential for longer appointment times for new screening staff, new screening locations, surveillance scans or technical challenges (for example, the presence of abdominal obesity or bowel gas precluding imaging; estimated to be 1 to 2% of those screened) should be taken into consideration. As such, it is estimated that two to three whole time equivalent (WTE) trained vascular technicians per screening unit would be required, or approximately 14 WTE vascular technicians at a national level. The inherent variability of healthcare processes and the need for resilience should be considered in staffing requirements to ensure adequate capacity to deliver high-quality care, particularly if additional populations are included under the care of the programme.

It is noted that in addition to radiographers and vascular technologists, other regulated healthcare professions, such as nursing and midwifery, which are regulated by the Nursing and Midwifery Board of Ireland (NMBI), may undertake additional specialist ultrasound training under current practice. While such an approach may increase the pool of available healthcare professionals who could undertake ultrasound imaging of the aorta and eliminate challenges associated with

establishment of a new profession, it may not address concerns related to relatively high screening staff costs, and optimal use of clinical skills.

Quality assurance

In the UK, the ultrasound workforce predominately comprises sonographers or clinical vascular scientists who report on ultrasound investigations within their scope of practice.[438] This is distinct from practice in some European countries where a radiologist will write the report based on static recorded images. Many local screening services within the NAAASP do not have direct input from a consultant radiologist, although some radiologists may fulfil the role of clinical skills trainer, responsible for quality assurance.[438] The role of the quality assurance lead is intended to be ring-fenced from other clinical duties.[412] Internal quality assurance, comprising a review of a subset of ultrasound scans, occurs *after* the results have already been communicated to the participant.

Differences in clinical reporting structures between Ireland and the UK may mean that quality assurance processes used in the context of the UK AAA screening programme may not be directly transferable to the Irish context. If an AAA screening programme is implemented in Ireland, the staffing model should take into consideration factors such as feasibility and proficiency standards for key healthcare professionals operating in the Irish context. A staffing model requiring radiology sign-off would be relatively more costly when compared with staffing models in AAA screening programmes in the UK and Sweden, and may be challenging to deliver in the context of staff shortages. It is noted that it may be necessary to create split posts (that is, dividing responsibilities between acute and screening services) to overcome logistical and workforce challenges. However, diversification of the scope of quality assurance posts may create challenges for ring-fencing of staff time and timely reporting of results, but would ensure staff maintain competency in broader clinical duties.

The number and qualifications of staff required for internal quality assurance would be dependent on the number of ultrasound scans to be reviewed and the quality assurance framework set out by the programme. Assuming 80% uptake and review of all scans prior to reporting of results to participants, on average, the number of scans to be reviewed would be estimated to range from approximately 100 to 280 per week, depending on the population size in a given screening region, as set out in section 7.4.1.[123, 387]

Acute services

The Vascular Society of Great Britain and Ireland recommends a minimum of 1 vascular surgeon per 100,000 population, although requirements may vary for large centres with complex caseloads.[481, 482] A 2024 review of the surgery medical

workforce in Ireland demonstrated that recommended minimum vascular surgery staffing requirements are not met in five out of the six health regions.[483] It is important to note that vascular service utilisation in Ireland is expected to grow by approximately 2% per year in line with population ageing.[483] Addressing existing workforce deficits, while also planning for increasing demand over time, would be important to ensure that vascular services are adequately resourced to support an AAA screening programme.

Given the expected patient volumes, it is not anticipated that dedicated surgical teams, including vascular surgeons, interventional radiologists, vascular technologists and specialist nurses would be needed for an AAA screening programme, if current understaffing and recruitment challenges in the symptomatic services are addressed. There is a critical shortage of vascular technologists in Ireland.[484] Incentivising and supporting more individuals to train as vascular technologists may also be required to ensure the delivery of safe, effective and sustainable vascular services. Without a national vascular registry that can be linked to an integrated AAA screening programme database, requirements to submit surgical outcome data for screen-detected cases to the programme would create an additional administrative burden in vascular units, which may require additional operational support.

Clinical governance framework

Under current practice, processes for clinical reporting may vary depending on whether an ultrasound scan is provided by the radiology service or the vascular surgery service.

The education and training of healthcare professionals involved in clinical radiology varies across Europe.[485, 486] Understanding the differences in professional scope is essential to designing imaging services that align with national healthcare policies and available resources. In Ireland, a position statement published by the Faculty of Radiologists and Radiation Oncologists noted that sonographers should not practice independently of medical practitioners in the Irish context; ultrasound examinations should be performed or supervised by an appropriately trained medical practitioner, with the final radiologist's report reflecting the radiologist's expertise as a medical imaging specialist and medical practitioner.[443] However, this statement reflects the position of the Faculty as of February 2012 and has not been reviewed or updated since.

A standardised clinical governance framework would need to be agreed in the context of a national screening programme, aligned with the roles and responsibilities of the healthcare professionals involved. It is worth noting that existing clinical governance frameworks in radiology are applied in the context of

diagnosis or screening for radiologically subtle tumours (for example, breast cancer screening using mammography), and were likely not designed with AAA screening in mind. Measurement of the abdominal aorta may be considered a reasonably low complexity scan with minimal risk of clinically significant missed cases, when performed by appropriately-qualified staff using robust imaging protocols.

With consideration to clinical workforce shortages and potential variation in proficiency standards between different healthcare professionals, a clinical governance framework would need to be established, taking feasible staffing models into consideration. Processes for clinical reporting should align with the proficiency standards set out by the relevant professional bodies, including the Faculty of Radiologists and Radiation Oncologists and the Irish Institute of Radiography and Radiation Therapy. Key considerations for healthcare professionals at each stage of the care pathway are outlined in Table 7.3 Potential roles and responsibilities of healthcare professionals involved in the screening care pathway

Table 7.3 Potential roles and responsibilities of healthcare professionals involved in the screening care pathway

Role in the screening care pathway	Responsible healthcare professional	Considerations
Screening and surveillance	Screening technician	• Unlikely to be feasible to appoint radiographers or vascular technologists to screening and surveillance roles due to concerns regarding underutilisation of clinical skills, staff costs, and challenges with and recruitment and retention. • Spilt posts may be required due to logistical challenges. • New 'screening technician' role may need to be created. • n = 2 to 3 per screening centre, or n = 14 nationally.
Quality assurance	Dependent on clinical governance structures: • Sonographer/radiographer • Vascular technologist • Radiologist	• Appointment of radiographers/sonographers or vascular technologists to QA roles may not align with existing clinical governance frameworks in the context of diagnostic imaging. • Review of all ultrasound scans by a radiologist may increase incidental findings. • May not be feasible to fill posts due to staff shortages. • A programme-specific quality assurance framework would need to be established. • Training, reviewing (all or a portion of scans) and monitoring responsibilities, in line with agreed policies.
Incidental findings	Radiologist	• Vascular technologists and radiographers may not be clinically trained to interpret and report on incidental findings.

Reporting	Dependent on clinical governance framework.
	Requirement for radiology review assumed.
		• Responsibility for reporting unclear:
		  ○ Under the current diagnostic pathway, ultrasound scans undertaken by radiographers or sonographers are reviewed and interpreted by a radiologist prior to reporting.
		  ○ In international practice, screening technicians typically communicate results verbally at the time of screening, and the programme follow-up with written confirmation.

Clinical governance	Vascular surgeon	• One clinical lead per screening region (n = 3 to 4)

Key: KPI – key performance indicator; QA – quality assurance.

7.5.4 Approach to implementation

Screening was implemented on a phased basis in the UK (2009 to 2013) and Sweden (2006 to 2015) over five and ten years, respectively.[116, 478] Rollout was not phased in Germany, however, it is noted that systematic invitations to screening are not issued to eligible men in Germany, resulting in lower uptake compared with the UK and Sweden, and thus a lower demand for associated resources. With consideration to implementation strategies internationally and existing healthcare system capacity deficits in Ireland, it is anticipated that an AAA screening programme would need to be implemented on a phased basis to facilitate training requirements, capacity building and development of clinical governance structures.

For the purposes of the BIA, phased introduction across three screening regions (for example, an eastern region, a southern region and a western region) over three years was assumed. In practice, the time required to reach full implementation would be dependent on the scope of the actions required to ensure readiness for change, including infrastructural, staffing and the programme-specific operational considerations. During the pre-implementation phase, a gap analysis would need to be undertaken, including a strategic plan to address capacity deficiencies. Alternative phased implementation approaches may be considered depending on local resource availability. In the event that the surgical capacity deficits identified are addressed, implementation of an AAA screening programme would be not considered feasible.

7.6 Education, information and awareness

7.6.1 Workforce education and training

Measurement error introduced during the acquisition of scans may influence precision and test accuracy. Implementation of robust training and screening processes would therefore be important to support delivery of a quality-assured programme.

The level of education and training required for vascular technicians may vary depending on the prior relevant education and training of the healthcare professional assigned to a given role. Under the assumption that a screening technician role would be created to deliver screening and surveillance, a formal training programme would likely be required to ensure screening and surveillance is standardised. Opportunities to adapt training delivered as part of the UK NAAASP to the Irish context could be explored.[477] Training and accreditation processes would need to be developed and delivered in partnership with relevant higher education institutions and professional bodies in Ireland.

In some circumstances, such as hospital-based follow-up of non-visualised scans ultrasound imaging may be undertaken by radiologists, radiographers, sonographers

or vascular technologists. Given the potential for intra- and inter-observer variability in measurement approaches (see Chapter 3, section 3.3.1), it would be important that all healthcare professionals undertaking screening within the context of the programme receive standardised training and measure aortic diameter in accordance with the programme screening protocol.

7.6.2 Patient and public information and awareness

An information and awareness campaign may include a mix of traditional, digital and community-based media to maximise reach and impact. It would be important that a public awareness campaign is clear, consistent and accessible to everyone in the target population, in line with the HSE Communications Strategy.[487] The information provided should be tailored to the preferred communication channels and health literacy of the target audience. Evidence from surveys and interviews suggests that older adults tend to prefer to receive health-related information from healthcare professionals.[488-490] Community-based healthcare professionals could be supported and encouraged to promote awareness among the eligible population through the use of educational interventions, for example, e-Learning modules.

As described in Chapter 8, section 8.3.4, evidence from international screening programmes suggests that the lowest uptake of screening may be in those at highest risk.[491] In this regard, outreach efforts and educational campaigns should focus on targeting underserved communities to reduce barriers to uptake. The scope of the information and awareness campaign may need to be adjusted over time depending on screening participation rates and feedback from participants, as identified through monitoring and evaluation frameworks (section 7.7.3).

7.7 Quality assurance framework

The four screening programmes currently offered by the National Screening Service in Ireland currently operate under quality assurance standards covering the entire screening pathway, from identifying the eligible population to long-term monitoring.[492] These standards are developed in line with international guidelines and practice to ensure consistency, effectiveness, and evidence-based outcomes.[493] If a decision were made to implement AAA screening programme a quality assurance framework would be required to promote practice consistent with these principles.

7.7.1 Programme standards

The programme remit would need to be agreed and key performance indicators (KPIs) would need to be developed. With consideration to standards set by the UK NAAASP, KPIs could cover areas such as:

- invitation and surveillance uptake

- test performance (for example, non-visualised screens)
- time-to-treatment (for example, time-to-referral, time to surgical intervention)
- treatment outcomes (for example, non-intervention rate or surgery-related mortality).

KPIs outlined by the UK NAAASP specify that patients with screen-detected large AAA should be seen by a vascular surgeon within two weeks, and AAA repair completed within eight weeks for eligible candidates. These timeframes are arbitrary, but were set with consideration to the time-critical nature of intervention for those with a large AAA. As noted in a review of the effectiveness of the NAAASP (unpublished, see Chapter 4, section 4.3.4), vascular units in the UK have found these targets challenging to meet; between 2013 and 2022 inclusive, 43.1% of men with a large screen-detected AAA underwent surgery within eight weeks of their last conclusive ultrasound.

7.7.2 Systems and policies to support quality assurance

Operational policies would be needed to guide adherence to agreed quality assurance standards. This may include developing a standard operating procedure to define programme-specific structures and processes (see section 7.3).

As outlined in section 7.3.2, key aspects to define would include establishing a standardised screening protocol, with consideration of the potential impact on screen positivity, reproducibility, and international benchmarking (see also Chapter 3, section 3.3.1).

7.7.3 Monitoring and evaluation

The structure, processes, and outcomes of the programme should be monitored against programme standards, including KPIs and policies. A QA committee, comprising a multidisciplinary team of experts, may be required to oversee the development of quality assurance processes and standards for the programme, consistent with existing screening programmes run by the NSS.[494, 495]

7.7.4 Quality improvement initiatives

Changes to the programme should be driven by the outcome of monitoring and evaluation processes (for example, uptake rates or proportion of non-visualised screens), identified needs within the Irish healthcare system, and changes in the evidence base. As outlined in the NSS Quality Assurance Policy Framework, the impact of quality improvement activities should be evaluated.[493]

7.8 Discussion

The optimal approach to delivery of an AAA screening programme may vary between different healthcare systems depending on the organisational structures, healthcare workforce roles, and the strategic priorities of the screening programme and broader healthcare system. In Ireland, there is a significant focus on the reform of the health and social care system through the implementation of Sláintecare, aiming to deliver healthcare at the lowest level of complexity possible. Aligned with the objectives of Sláintecare, a community-based delivery model would improve the accessibility of screening, while also minimising potential pressures on hospital imaging capacity compared with a fully hospital-based approach. While a community-based programme likely represents the most appropriate delivery model in the Irish context, it would require the most significant investment in terms of infrastructure and staff. Given the current shortages of clinical staff across essential disciplines, a review of existing practices may be required. This may include exploring the potential to optimise the use of clinical skills across the care pathway through the creation of new roles (that is, 'screening technicians') and the diversification of existing ones (for example, a review of clinical governance frameworks). Should a screening programme be recommended, decision-making regarding the specifics of the implementation model would require careful consideration of stakeholder perspectives regarding the ability to effectively implement the necessary changes in staffing and operations.

In addition to screening and surveillance of men aged 65, extending eligibility to additional populations including incidentally-diagnosed AAA and self-referred men older than 65 years would require additional resources. However, estimating the additional resource required to manage these additional populations is challenging. In the absence of a national vascular database, the number of men aged 65 with small and medium AAAs currently under surveillance by vascular units, and who could potentially transfer to the care of the programme, is unknown. Furthermore, in the absence of a standardised national screening programme, algorithms for follow-up of incidentally-diagnosed enlarged aortas (sub-aneurysm and AAA) may vary between hospitals. In some vascular units, in addition to those with AAA, those with incidentally-diagnosed subaneurysmal aortas may also enter a surveillance pathway, consistent with recommendations of the 2024 ESVS guidelines.[6] Given differences in patient volumes, care pathways that are practical in usual care may not be scalable within the context of a formal screening programme. If usual care and screening care pathways are merged to ensure consistent, high-quality follow-up care irrespective of the route of detection, standardising criteria for entering surveillance in a way that is acceptable and feasible could present challenges.

The number of men self-referring to the programme, if self-referral were enabled, would likely be highly dependent on public awareness. Public information campaigns

aimed at increasing awareness and participation often result in short-term surges in service demand, leading to periods of resource strain. In the UK NAAASP, efforts to manage participant volumes include strategic approaches to public awareness campaigns and application of a cap on referral volumes.[434] While recognising the need to ensure all individuals at risk of AAA-related morbidity and mortality have access to high-quality care, capacity deficits within the healthcare system may mean it is challenging to extend eligibility to self-referred populations. Restricting self-referrals to those at increased risk (for example, 'ever smokers' or those with a family history of AAA) is a potential approach to managing the volume of activity and potential implications for healthcare system capacity, while also maximising the overall effectiveness and equity of the programme.

As noted previously, the populations under the care of the programme and setting of screening would influence the specification of the ultrasound imaging system used by the programme. A trade-off between technical specification and portability of ultrasound imaging systems may be necessary for a community-based screening programme, depending on the programme's priorities. Lower test accuracy may be acceptable in the context of screening, compared with diagnostic imaging. However, ultrasound systems that facilitate precise aortic measurements would be important for accurate clinical decision-making for cases under surveillance and to provide incidentally-detected AAA cases, if redirected to the programme, with access to testing that is comparable to usual care. Whether or not sufficient imaging quality can be achieved using portable systems would be dependent on the outcome of a formal evaluation process. It is also important to consider that factors other than the equipment specification can influence test accuracy, and thus patient outcomes. To support delivery of a high-quality screening programme, it would be important to establish standardised screening protocols, invest in rigorous education and training, and maintain a high volume of scans per screening technician.

Capacity limitations in the healthcare system arise from a combination of factors, including workforce shortages and infrastructural gaps. Staff shortages in clinical radiology are not isolated to Ireland, and affect healthcare systems in many countries, including the UK, Australia, the US, Canada, and across Europe.[474, 496] A combination of strategies including efforts to retain existing staff, increasing training positions, and managing demand for services (for example, reducing unnecessary imaging and leveraging technological innovation) could improve capacity in the medium- to long-term. However, addressing workforce shortages in professions requiring extensive education and training, such as radiology and radiography, in the short-term is challenging. In the context of AAA screening, development of a 'screening technician' role, with focussed, task-specific training, may be necessary to optimise use of clinical skills across the care pathway, and to ensure the availability of screening staff in the short-term.

Internationally, pathways relying on imaging interpretation to direct patient care have adapted by using new strategies to increase efficiency, such as artificial intelligence, and changes to workflows that can offset workforce shortages to some extent.[497] In some contexts, cost pressures and limited workforce availability have resulted in a shift towards imaging interpretation in the absence of radiology input.[498] The clinical implications of changes in practice may vary depending on the complexity of the scan, the availability of robust imaging protocols, and the education and training of other medical imaging specialists.

As noted in section 7.5.3, processes for clinical reporting should take professional, clinical and operational factors into considerations. To ensure efficient allocation of clinical skills, the complexity of imaging studies may be considered in the development of clinical governance frameworks in clinical radiology. While feasible staffing models and optimal use of clinical skills in the context of limited resources must be taken into account, delivery of safe, high-quality care is a priority. Any change from current practice in Ireland would need to be developed in partnership with relevant professional bodies. The professional acceptability and medico-legal implications of radiologists taking responsibility for screening and surveillance scans carried out by other healthcare professionals requires careful consideration.

If AAA prevalence continues to decline, and clinically validated risk factors that may readily identify the subpopulation at greatest risk of AAA are established, a targeted screening programme would become increasingly relevant. A potential change to a targeted strategy from a population-based programme would decrease requirements for screening and surveillance staff; this may warrant consideration in the planning of employment contracts.

Outsourcing in healthcare has become increasingly common in the context of low volume activities, or fluctuations in demand. The basic rationale for outsourcing is to partner with organisations offering specialist expertise and economies of scale to improve efficiency, productivity and quality.[499] However, a decision to outsource services must carefully consider the potential impacts on standards of care.[499] Furthermore, outsourcing of a new service, such as AAA screening, would be challenging, where standards may evolve in response to early monitoring and evaluation outcomes. Effective outsourcing requires that the healthcare system maintains substantive oversight of the performance of the outsourced service, including robust inter-organisational communication and effective mechanisms to safeguard against the potential risks. In the context of AAA screening, regardless of whether healthcare staffing is outsourced, clinical staff would still need to be trained in accordance with required standards. While outsourcing may be a viable long-term solution to address changing demands for staff over time, its impact on current staffing shortages may be limited.

Ensuring timely access to elective surgical repair of AAA is reported to be a significant challenge at present in Irish public hospitals. In the UK NAAASP, the programme standard for time to elective surgical repair is within eight weeks of the last conclusive scan. Although this timeframe is not underpinned by empirical evidence, given the increasing risk of AAA rupture with increasing aortic diameter, it is widely accepted that time to intervention should be kept to a minimum. Furthermore, due to the potential need for repeat pre-operative assessments for patients waiting in excess of three months for surgery,[500] waiting lists longer than three months should be avoided for both resource and patient safety reasons. Although time-to-treatment of eight weeks was considered achievable in the UK, vascular units have struggled to provide access to elective surgical repair within this timeframe. Minimum staffing requirements for vascular surgeons set out by the Vascular Society are currently not met in Ireland or the UK.[482, 483, 501] Therefore, if a decision is made to implement an AAA screening programme, it is likely that vascular surgery units in Ireland would face similar challenges meeting time-to-treatment standards.

Interdisciplinary competition for surgical theatre space also creates significant challenges for timely access to elective AAA repair. Across multiple surgical disciplines in Ireland, including general, cardiothoracic, neuro-, trauma and orthopaedic, and vascular surgery, a high proportion of cases present as emergencies (2017 to 2019: range 27% to 53%), often requiring immediate and complex intervention.[483] The urgent and emergent nature of caseloads across these disciplines creates challenges for managing access to surgical theatre space. Even within vascular units, management of urgent and emergency cases can disrupt scheduled elective surgeries, such as AAA repair.

Delays in accessing surgery, arising from multiple factors, may reduce the potential benefits of a screening programme. Successful implementation of an AAA screening programme would require dedicated operating theatre capacity, including physical and human resources, to ensure timely surgical repair. With consideration to the core requirements of a screening programme as set out in the NSAC criteria, implementation of an AAA screening programme would not be considered appropriate if surgical capacity deficits cannot be addressed.

7.8.1 Conclusion

Community-based delivery of an AAA screening programme with a dedicated, specialist workforce may work best to ensure the programme is accessible to the eligible population, while minimising reliance on hospital capacity, if ultrasound equipment compatible with this approach can be identified.

Numerous barriers to implementation would need to be addressed to support delivery of a standardised, quality-assured AAA screening programme, particularly in

relation to clinical staff shortages. Insufficient clinical workforce capacity may impact the ability of the screening programme to quality assure the testing process, and to provide timely access to AAA repair, where indicated. There is uncertainty regarding whether or not the potential changes in clinical governance frameworks needed to overcome staff shortages in clinical radiology can be implemented, while ensuring the required standards of test accuracy and patient safety are met. These issues contribute to uncertainty regarding the implementability and acceptability of an AAA screening programme in the current Irish context. Lessons from the UK, which faces comparable clinical workforce constraints, suggest that these issues can be managed, but doing so would require changes to existing practice.

8 Ethical, patient and social considerations

Key points

- AAA is well-suited to screening with evidence suggesting that screening reduces AAA-related morbidity and mortality in men aged 65 and older. Detection of AAA can be reliably achieved through ultrasound imaging, which is non-invasive, painless and well-tolerated. This enables elective surgical repair to happen in a timely manner, where indicated. However, this must be balanced against the potential harms of AAA screening.
- Overdiagnosis (that is, when screening identifies an AAA that would not have caused symptoms or death during a patient's lifetime) and overtreatment (that is medical interventions that may not provide a significant benefit to the patient and could potentially cause harm) are unavoidable consequences of AAA screening.
    - Screening and treatment pathways can, however, be designed to minimise potential harms. For example, the choice of aortic measurement method is a careful balance between minimising overdiagnosis and avoiding missed cases.
    - For those with a small or medium AAA, the surgical risks generally outweigh the benefits. As a result, elective surgical repair of AAA is not recommended for those with an aortic diameter <5.5 cm.
    - For those with large AAA and a reasonable life expectancy, the lifetime risk of rupture exceeds the risk of surgery-related mortality. However, the risks of surgery-related complications remain; strict referral thresholds and pre-surgical assessments can help to ensure that only those likely to benefit from surgery are offered it.
    - Accepting self-referrals to screening and including sub-aneurysms in surveillance could improve the overall effectiveness of a screening programme and may be perceived as 'fair'. However, these inclusions increase the risk of overdiagnosis and overtreatment.
- Screening could cause anxiety and emotional distress to participants and their families, particularly men with a positive screening test result. Measures such as the provision of clear information and access to psychological supports (for example, programme nurses) have the potential to reduce risk perception, stress and worry.

- Screening may identify incidental findings (unrelated abnormalities in nearby anatomical structures), potentially leading to anxiety for affected participants and an additional burden on the healthcare system. Robust imaging protocols and staff training can help to minimise the identification of, and ensure consistent management of, incidental findings.
- The prevalence of AAA is higher in individuals with lower socioeconomic status, but uptake of screening is typically lower in this group. Strategies such as pre-screening reminders, encouragement by GPs, repeat invitations, and follow-up reminders, can help to increase uptake. Community outreach can also boost awareness and uptake in underserved groups.
- Without careful planning, implementing a screening programme would likely exacerbate existing capacity constraints within the healthcare system. Ensuring provision of accurate diagnosis and timely access to elective surgery, without adversely impacting other care pathways, is a key consideration.

8.1 Introduction

Ethics refers to the understanding and study of moral principles.[502] The term 'morality' encompasses beliefs, standards of conduct, principles and rules which may guide the behaviour of individuals (for example, the general public) and organisations (for example, the HSE).

Ethical, patient and social factors from the perspectives of patients, the general public and the healthcare system may challenge or support the adoption of a new technology. The value that society places on a given technology is impacted by numerous factors including, political, cultural, legal, religious and economic considerations. The balance of benefits and harms may also be viewed differently over time as a reflection of changing societal attitudes and behaviours. In this way, HTA is an intrinsically complex and value-laden process that aims to capture a range of diverse stakeholder perspectives. The structured ethical analysis presented in this chapter provides a framework to ensure that consideration of such value judgements in decision-making is standardised and transparent. Ethical considerations, however, permeate this HTA as a whole.

Similarly, the NSAC criteria are grounded in the key principles of medical ethics, namely beneficence, non-maleficence, justice and autonomy.[3] The aim of this chapter is thus to describe the key ethical, patient and social considerations associated with the potential introduction of an AAA screening programme for men in Ireland, with reference to the NSAC criteria as a whole.[3] NSAC criteria of particular relevance to this chapter include:

- *ideally there should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an informed choice, there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.*
- *there should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is acceptable and can be implemented.*
- *the benefit gained by populations and individuals from the screening programme should outweigh the harms. The public should be informed of these harms and of their associated undesirable physical and psychological consequences.*
- *the potential benefits and harms of screening, investigation, preventative intervention or treatment, should be made available and explained to the eligible participants to assist them in making an informed choice. There*

should be a clear system of communication incorporated into each screening programme to ensure patients are kept aware of any developments in their case.

8.2 Methods

The content of this chapter was developed broadly in line with the ethical domain of the EUnetHTA HTA Core Model®.[502] The HTA Core Model® is a structured and transparent framework including nine HTA domains intended to guide the assessment of health technologies, with a focus on the information needs of policy-makers.[502]

Ethical, patient and social issues are frequently discussed in articles focusing on other aspects of a technology, which presents challenges for systematic literature searching. Thus, this chapter builds on potential ethical considerations identified throughout the HTA, and offers a reflective ethical analysis of these issues. Patient, social and ethical considerations were discussed at a workshop attended by members of the HIQA's evaluation team and the wider HTA directorate to inform targeted literature searching. Six topics, including 20 sub-questions, were considered, based on the HTA Core Model®:[502]

- benefit-harm balance
- autonomy
- respect for persons
- justice and equity
- legislation
- ethical consequences of the HTA.

The findings of the ethics workshop and literature search were supplemented with input from EAG members, and interpreted in the context of relevant national and international literature including the NSAC criteria,[3] the HSE national healthcare charter,[503] guidance on a human rights-based approach in health and social care services developed by HIQA in conjunction with Safeguarding Ireland,[504] the National Screening Service (NSS) strategic framework for improving equity in screening,[416] and the World Health Organization (WHO) publication 'Screening programmes: a short guide'.[143] Previous HTAs, discussed in Chapter 3, section 3.5.2, were reviewed to identify any additional relevant ethical considerations. Patient and social aspects were discussed under each topic heading, where relevant. No ethical issues specifically related to legislation were identified. However, potential implications for clinical governance frameworks and professional codes of conduct regarding reporting of ultrasound results are considered in Chapter 7.

8.3 Topics

8.3.1 Benefit-harm balance

AAA has been identified as a condition that is well-suited for screening for several reasons. Firstly, as it usually progresses slowly, this allows time for surveillance and surgical intervention, where indicated. Secondly, detection can be reliably achieved through ultrasound imaging, which is non-invasive, painless and well-tolerated. Finally, the natural history of AAA is well documented, enabling development of evidence-based pathways for surveillance and treatment.[505] There is evidence to suggest that AAA screening reduces AAA-related morbidity and mortality, through a reduction in AAA rupture rates as a result of timely elective surgical intervention (see Chapter 4, section 4.3.1). However, this must be balanced against the potential harms of AAA screening including overdiagnosis and its potential psychosocial consequences, and the risks of peri- and post-operative morbidity and mortality associated with elective surgical repair.

Overdiagnosis

The primary benefit of a screening programme for AAA is early detection. Given that AAA is asymptomatic, early detection allows for appropriate treatment to prevent aneurysm rupture, which is often fatal. However, screening for AAA is also associated with potential harms related to identification of asymptomatic individuals.[279, 506] Overdiagnosis, as described in Chapter 4 (section 4.3.1), refers to the detection of an AAA through screening that otherwise would not have been detected within the person's lifetime. However, the concept of overdiagnosis can be complex and context-dependent.[506] For example, individuals with screen-detected AAA may gain access to interventions to support cardiovascular risk factor management, which may reduce the risk of other cardiovascular diseases.[505] While there is inconclusive evidence regarding the benefits of these interventions on AAA-related morbidity and mortality specifically, cardiovascular risk factor reduction in this population could extend beyond preventing AAA rupture to improving overall cardiovascular health in those with a positive screening test result, potentially offsetting concerns about overdiagnosis.[505, 506] Due to the potential benefits of cardiovascular risk factor management on long-term cardiovascular outcomes in men with AAA, the 2024 European Society for Vascular Surgery (ESVS) guidelines recommend that comprehensive care, including lifestyle modifications, smoking cessation, and medical management should be provided to all men with AAA.[6, 146] It would be important to consider this in the design and delivery of a screening programme. For example, the NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) provides nurse-led lifestyle advice for men with screen-detected AAA including guidance on smoking cessation, physical activity and diet.[507]

Evidence from international screening programmes shows that approximately 90% of AAAs detected through screening are small to medium in size at baseline and do not meet the criteria for surgical repair, instead requiring ongoing surveillance (see Chapter 4, section 4.3.2). For these participants, the risks of surgery generally exceed the risk of rupture. While surveillance provides an opportunity to monitor disease progression and intervene, if necessary, it also raises concerns about overdiagnosis.[508]

In the context of an AAA screening programme, the choice of ultrasound imaging protocols could influence rates of overdiagnosis and missed cases. As previously mentioned in Chapter 3 (section 3.3.1), the outer-to-outer (OTO) measurement method is associated with a higher risk of overdiagnosis, while the inner-to-inner (ITI) method increases the risk of missed cases. From an ethical perspective, careful consideration is needed to select a protocol that balances these risks. Ultimately, the choice of method would be a value judgment; if minimising overdiagnosis is considered a key priority for the programme, the ITI may be preferred. However, the potential for missed cases would be increased.

Existing screening programmes for AAA involve once-off screening, which differs from current programmes offered by the National Screening Service where participants are invited for frequent screening (for example, mammography every two to three years). The rationale for once-off screening in AAA is related to epidemiological, clinical and economic considerations. As most AAAs grow slowly over time, a single negative screening test result at the age of 65 is typically sufficient to exclude the risk of AAA-related morbidity and mortality for the remainder of a man's lifetime. Based on five-year follow-up data from the Swedish screening programme, the additional clinical benefit associated with rescreening those with a negative screening test result would likely be minimal.[87] In the context of this once-off intervention, those with a screen negative result may feel a sense of reassurance that they are unlikely to experience AAA-related morbidity or mortality in their lifetime; however, the aim of screening is not to provide reassurance to those without the condition being screened for. There is also a risk of false reassurance following a screening ultrasound scan aimed at specifically identifying AAA, whereby participants may incorrectly assume that the imaging assessment comprehensively evaluated all potential abdominal pathologies. It would be important that participants clearly understand the aims of the screening test, as discussed in section 8.3.2. Furthermore, while the risk of AAA-related morbidity and mortality is very low for men whose aortic diameter is less than 3.0 cm at age 65, one-time ultrasound screening cannot completely rule-out the possibility of experiencing AAA rupture in later life. As discussed under 'Sub-aneurysm', inclusion of those with an aortic diameter of 2.5 to 2.9 cm in surveillance is a potential means

to reduce the risk of men discharged from the programme at age 65 experiencing AAA-related morbidity and mortality in later life.

Overtreatment

Overtreatment arises when those with screen-detected large AAAs undergo elective surgical repair, which may not provide significant benefit and could expose patients to surgery-related risks.[279] As discussed in Chapter 4, evidence from five RCTs indicates that screening groups undergo more AAA-related elective surgeries compared with unscreened groups, with an estimated increase of eight operations per 1,000 men screened over a 13 to 15 year period (see Chapter 4, section 4.3.1). Overtreatment is an unavoidable consequence of AAA screening, though the extent to which this occurs remains uncertain.[279, 505] Implementation of strict thresholds for repair and protocols for pre-surgical assessment would likely minimise the risk of true overtreatment and reduce the likelihood of surgery-related mortality and morbidity.

Balancing the risks and benefits of AAA surgical repair

EVAR and OSR can be associated with clinically significant post-surgical complications, which may require re-intervention, as described in Chapter 3, section 3.3.2.[212, 213] Moreover, surgical repair of AAA is associated with a risk of surgery-related mortality. Data from the international consortium of vascular registries for the period 2010 to 2016 suggest in-hospital mortality rates of 4.7% for OSR and 1.0% for EVAR.[213, 215] The delivery of clinically-appropriate care for patients with an AAA requires balancing operative risks with the likelihood of AAA rupture.

As described in Chapter 2 (section 2.4), AAA rupture risk increases incrementally with increasing aortic diameter. Estimating the risk of AAA rupture among those with small or medium AAA is challenging due to the low event rate.[55] The risk of AAA rupture for AAAs <5.5 cm is estimated to be less than 0.8% per year.[6, 265, 395] Among those with large AAA, the annual rupture risk has been estimated to be 3.5 to 13%.[394, 395] It is noted that the risk of AAA rupture increases gradually along a continuum, rather than in a stepwise manner between subcategories. However, an aortic diameter of ≥5.5 cm is widely acceptable as the threshold for consideration for elective repair (see Chapter 3, section 3.5.1).[6]

While elective AAA repair carries inherent risks, including post-surgical complications and surgery-related mortality as described above, for patients with large AAA and a reasonable life expectancy, the risk of AAA rupture exceeds the risk of surgery-related complications. Thorough pre-operative assessment is crucial to ensure that surgery is performed only on those with large AAA who are expected to benefit from it. For those with a small or medium AAA, however, the surgical risks generally outweigh the potential benefits.

Non-intervention

For some patients, the outcome of pre-surgical assessment is non-intervention, where patients with a large AAA (≥5.5 cm) are considered unfit for elective AAA repair due to factors such as the presence of comorbidities or limited life expectancy, following assessment by a multidisciplinary team. For these patients, the risk of AAA rupture and death needs to be balanced against perioperative risk and expectation of long-term survival.[394] As outlined in Chapter 4, section 4.3.2, evidence from the international literature suggests that up to 29% of patients with large AAA may be considered unfit for surgery, depending on the time since baseline screening.[75, 264, 386, 389] Of these, up to 20% may later experience a rupture, depending on length of follow-up.[389, 394] For those considered unfit for elective AAA repair, in the absence of alternative treatments to slow or arrest disease progression, participation in the screening programme would not have provided a clinical benefit. Further, participation may even be associated with harm due to the potential for an additional emotional and psychological burden on individuals who may already be frail. However, given that those found to be unfit for AAA surgical repair typically have significant comorbidities requiring ongoing care,[264, 389, 509, 510] it is plausible that the majority of screening participants with severe comorbidities precluding surgical intervention would be identified in the absence of screening.

Medical exposure to ionising radiation

Patients with a diagnosis of AAA, and who are candidates for surgical repair, may be exposed to risks associated with ionising radiation exposure. Endovascular Aneurysm Repair (EVAR), in contrast to open surgical repair (OSR), exposes patients and the surgical team to ionising radiation during the index procedure, and has been increasingly used as the preferred repair method. Patients undergoing AAA surgical repair generally are also exposed to ionising radiation during pre-and post-operative CT, when required.[190] Radiation exposure is a risk factor for developing cancer, but is associated with a latency period of between 10 and 20 years.[511] Given that the mean age of patients undergoing EVAR is approximately 75 years, the likelihood of developing radiation-induced malignancies during their remaining lifespan may be relatively low.[511] However, the incidence of malignancy has been reported to be higher in patients who undergo EVAR, compared with OSR.[458, 512, 513] These results should be interpreted in the context of a high incidence of cancer in patients with AAA generally, in particular, lung cancer.[514-516] As outlined in Chapter 3 (section 3.3.1), measures to promote best practice in radiation protection, such as the use of diagnostic reference levels (DRLs),[192] the use of hybrid surgical theatres (that is, a ceiling-mounted interventional imaging system) and adherence to clinical practice guidelines on radiation safety, would be important to keep radiation exposure as low as reasonably achievable for the safety of patients and staff.[190, 517]

Psychological impacts of screening

As described in Chapter 4, AAA screening may be associated with psychological harms including anxiety, fear of rupture, and emotional distress. This may be particularly relevant for individuals who are not immediately eligible for surgical repair but require ongoing surveillance. For some participants, being "labelled" with a potentially life-threatening condition despite being asymptomatic may lead to emotional distress and changes in how individuals perceive their health and quality of life.[344] A 2017 systematic review noted the potential for moderate psychological distress associated with a diagnosis of AAA, though evidence was insufficient to precisely estimate its severity or frequency.[344] It was noted that detection of AAA through screening may cause some men to view themselves as fragile or at constant risk, potentially affecting their mental well-being, lifestyle choices, and engagement in daily activities. Individuals may avoid physical exertion due to perceived risks, despite lack of evidence suggesting that small aneurysms significantly limit activity.[344]

Recent studies conducted in the context of the UK NAAASP highlight that individuals participating in screening and surveillance may experience elevated anxiety levels, where anxiety often stems from fears of rupture, the burden of frequent surveillance, and uncertainty about long-term health outcomes.[518, 519] For men with screen-detected AAA and their families, these concerns can dominate their perception of health, potentially offsetting the clinical benefits of early detection. A cross-sectional survey of staff providing AAA screening services in England noted that men in surveillance may need help managing anxiety.[518] Providing clearer information about the condition, offering access to organised support groups, and increasing contact with the screening service (programme nurses in particular) were identified as potential measures to help mitigate anxiety.[518]

Additionally, it is worth noting that the potential psychosocial harms of screening may extend beyond the screening participants. Some individuals may feel burdened by a need to protect family members from worrying about their condition, making external supports, such as those described above, an important resource for these men.[344] Qualitative evidence suggests that partners of men with a screen-positive diagnosis also experience negative impacts on their wellbeing related to worry and uncertainty.[339] Some may feel a lack of inclusion and understanding about their partner's illness, if they have access only to limited secondary information through their partner. An opportunity for partners to attend screening examinations or discuss concerns with healthcare professionals may reduce negative impacts.[339]

The degree to which AAA affects a partner's life may be influenced by their previous experiences, such as having another affected family member.[339] Given the strong

association between AAA and family history, it is likely that the emotional burden associated with detection of AAA may be clustered within some families, for example, brothers screened over a period of ten years.[41, 42]

There is some evidence to suggest that individuals with a history of smoking may experience additional psychological burden when diagnosed with AAA. Smoking is a major modifiable risk factor for AAA, and awareness of this could lead to feelings of guilt, regret or shame in individuals who smoke or have smoked in the past. Evidence from the Swedish AAA screening programme shows that almost half (45%) of 'ever-smokers' with screen-detected AAA felt guilt related to their smoking history.[296] While most participants (96%) did not regret screening, smokers diagnosed with AAA exhibited heightened psychosocial impacts compared with those with a normal aorta. Counterbalancing these potential psychological harms, a significant proportion of men (78%) expressed interest in smoking cessation following a positive screening test result, suggesting that the screening experience may prompt positive behavioural changes.[296]

While the above-described psychological consequences of screening are relevant to consider, the available evidence synthesised in Chapter 4 suggests that these may be transient; however, limited longitudinal data are available.[140, 276] To minimise potential psychosocial harms among men with screen-detected AAA, if present, organised support groups and improved provision of information may be important.[518] However, high-quality evidence regarding the effectiveness of psychological interventions for adults with chronic health conditions is lacking.[520, 521] In terms of AAA specifically, delivery of an eHealth intervention in a single-centre RCT did not result in an improvement in anxiety scores among 120 patients awaiting AAA surgical repair at up to one year of follow-up.[522, 523] However, qualitative evidence suggests that access to professional follow-up care can be associated with feelings of security among men living with AAA.[524, 525] While high-quality evidence is needed before definitive conclusions can be made, in accordance with the World Health Organization's values to guide decision-making in the context of screening, the precautionary principle advocates for a cautious approach when implementing screening programmes, even in cases where conclusive evidence of harms is lacking. The principle asserts that when there is credible evidence of potential risk, there is an obligation to take preventive measures to safeguard public health. Thus, screening participants might benefit from participant-centred screening support interventions, such as effective informed consent processes and counselling, and personalised information and education about AAA to help minimise the risk of distress, as described in section 8.3.2.

Research is ongoing in the UK to develop a new intervention to help men manage AAA-related anxiety, informed by the characteristics of men under surveillance,

qualitative interviews with men and their partners, and a survey of AAA screening providers.[526] This research could inform the design of a patient-centred psychosocial support framework as part of an Irish AAA screening programme, if implemented.

False screening test results, and non-visualised scans

While any screening test carries the potential for false positives and false negatives, ultrasound has demonstrated high sensitivity and high specificity for detecting AAA when conducted with appropriate training and protocols, making false positives rare (see Chapter 3, section 3.3.1). For false negatives, evidence from the Swedish AAA screening programme indicates that individuals with a negative screening result are highly unlikely to experience AAA rupture.[383]

While ultrasound imaging for AAA screening is highly sensitive and specific, its effectiveness can be limited by certain technical challenges. One notable issue, as outlined in Chapter 3 (section 3.3.1), is the difficulty in obtaining high-quality images in individuals with obesity, as excess abdominal fat attenuates ultrasound beams, reducing image quality.[176] Similarly, the presence of bowel gas can obstruct the visualisation of the aorta. These factors can lead to non-visualised scans, where the imaging fails to provide a definitive assessment of the aortic diameter. From the participant's perspective, non-visualised scans may lead to feelings of embarrassment during the test. Furthermore, the need to attend additional follow-up appointments to complete the screening process may be inconvenient, potentially causing distress or frustration for the participant, and may increase the risk of loss to follow-up. The proportion of non-visualised screens could be minimised, to some extent, through the informed consent process (for example, advising participants to avoid drinking fizzy drinks immediately prior to attending the scan).[527] As noted in Chapter 7, staff training and participant information leaflets outlining potential dietary restrictions prior to the scan may help to mitigate some of these issues.

As obesity rates rise, the proportion of individuals with non-visualised scans may also increase, potentially creating disparities in the effectiveness of screening.[528] A study from Northern Ireland noted that, while fewer men from more deprived areas attended their initial scans, those who did were significantly more likely to have non-visualised scans compared to men from less deprived areas.[69] A socio-economic gradient was observed, with non-visualised scan rates ranging from 1.7% in the least deprived areas to 5.0% in the most deprived areas. The reasons for this disparity remain unclear, but the authors speculated that it may be linked to higher rates of overall and abdominal obesity in more deprived populations.[69]

Incidental findings

Ultrasound screening for AAA could also identify unexpected findings, such as iliac artery aneurysms or renal masses, that could be clinically significant.[152] Incidental findings should be considered within the context of the objectives of the programme and ethical standards. While identification of clinically significant, treatable, incidental findings may generally be considered beneficial, it also raises ethical issues, such as patient distress from unanticipated results, and capacity concerns, including increased demand for follow-up evaluations. Although management of incidental findings would fall outside the scope of the programme, the screening programme would need to ensure that individuals with incidental findings are referred to the appropriate care pathway. From the participant's perspective, the disclosure of incidental health findings may cause psychological distress, particularly when such findings were not anticipated. However, others may feel relieved that such findings were detected early, potentially allowing for timely intervention. Given the lack of certainty regarding availability and effectiveness of treatments for the broad range of potential incidental findings, a cautious approach should be taken when reporting them in the context of screening.[529] Robust imaging protocols and staff training can help to minimise the occurrence and ensure consistent management of incidental findings.[442]

Sub-aneurysms

Structural changes in the aortic wall are a normal part of the ageing process (see Chapter 2, section 2.3). These changes contribute to a gradual increase in aortic diameter over time. However, distinguishing between normal age-related dilation and pathological aneurysmal growth is complex. As previously described in Chapter 2 (section 2.4.2), a sub-aneurysmal aorta (that is, aortic diameter of 2.5 to 2.9 cm) is considered to be a precursor to AAA, but not all sub-aneurysmal aortas will progress to AAA. Pooled estimates across 12 studies including a total of 8,368 patients suggest that within five years of initial detection approximately 45.0% of sub-aneurysmal aortas reach 3.0 cm and 0.3% reach 5.5 cm. It is estimated that 5.2% will exceed 5.5 cm within five to 10 years.[53] While the inclusion of individuals with sub-aneurysm in surveillance could potentially reduce AAA-related mortality by identifying those at risk of progression to a ruptured AAA, this approach introduces concerns about increasing overdiagnosis, overtreatment and potential implications in terms of follow-up capacity requirements.[530] Men with sub-aneurysm share similar risk factors profiles to those with larger aneurysms, including the strong influence of smoking on disease severity and progression.[531]

As described in Chapter 3, the ESVS 2024 clinical guidelines recommend surveillance of sub-aneurysms every five years. Despite these recommendations, this population has not typically been included in international screening programmes (see Chapter 3, section 3.5.2).[6, 9, 223, 225, 227, 228, 231, 233, 236, 238, 241, 247] In 2016, an evidence review

undertaken to support decision-making by the UK National Screening Committee concluded that there was insufficient evidence to support inclusion of sub-aneurysm.[532] In Sweden, there is currently no national-level decision to include sub-aneurysm for follow-up in local screening programmes. However, some local screening programmes include sub-aneurysm in surveillance.[350] Given that follow-up is recommended every five years, the absolute cost associated with follow-up would likely not comprise a substantial proportion of the overall programme budget. However, inclusion of sub-aneurysms in the screening and surveillance programme warrants careful consideration, particularly as it would result in an estimated 2.5-fold increase in the number of men entering the surveillance pathway (see Chapter 2, section 2.11).[32, 68, 77, 78, 84, 87, 96] At an individual level, the potential for psychological distress, despite a relatively low risk of progression, may mean the harms outweigh the benefits. However, educating individuals about disease progression risks may help to optimise the benefit-harm balance. At the societal level, surveillance of a relatively low-risk population may not be considered prudent use of the limited healthcare budget.

8.3.2 Autonomy and communication

As outlined in the HSE national healthcare charter,[503] and the NSS strategic framework,[416] effective communication is important to ensure that members of the eligible population understand the purpose of the screening test and the possible outcomes of screening. It would be important that participants understand that only the abdominal aorta would be imaged, that not everyone with a positive screening test result would require surgery, and that a proportion of patients may not be eligible for elective surgical repair.

When developing a communication strategy, the varying levels of health literacy and preferred modes of communication (for example, social media, radio or newspapers) within the target population need to be considered. In Ireland, approximately 40% of adults have limited health literacy.[533] Surveys assessing AAA health literacy and knowledge in the United States revealed knowledge gaps among study participants.[534, 535] Among 1,008 patients under AAA care pathway across six US institutions, the knowledge of the condition was poor. Additionally, adults over the age of 60 attending an AAA screening event had a significantly lower level of AAA literacy than younger responders.[535] These results indicate potential for improving communication across all stages of the care pathway. Lack of awareness about the programme, difficulty understanding the scope of the programme, and difficulty understanding health information provided during screening can be barriers that hinder participation.[487, 533] For those whose first language is not English, these barriers may be greater.[533] Screening candidates' knowledge of AAA is typically limited prior to receiving an invitation to screening.[535] As such, they may depend on information provided by the programme and medical professionals to inform decision

making. Considering routes to deliver information, older adults commonly rely on their healthcare providers as their most trusted form of health information,[536] therefore, community healthcare practitioners such as pharmacists and GPs could play in important role in promoting awareness and uptake.[537]

Participants should understand how screening could influence their treatment and outcomes. Earlier intervention may circumvent the need for emergency repair of a ruptured AAA, or facilitate timely access to surgery while a patient is still considered fit for surgery. Due to its greater durability, open surgical repair may be preferred in younger screen-detected patients.[6] However, the choice of surgical approach should be made through shared decision-making; participants should understand the differences between procedures in terms of risks, benefits, recovery implications and surgical outcomes (see Chapter 3, section 3.3.2).

As noted previously, an AAA screening programme would be different to population-based screening programmes currently offered by the National Screening Service (NSS), namely BreastCheck, CervicalCheck and BowelScreen, which offer re-screening of participants at regular intervals.[538] Invitees should understand that the AAA screening would be offered at age 65 only, and if their initial screening result is negative, they would be discharged from the programme. It may be important in this context to explain the rationale for the once-off nature, and choice of the age of 65, for screening; for example, the slow growth rate of aneurysms and hence the low likelihood of developing a clinically significant AAA after a screen negative scan at 65, and the evidence base emerging from screening programmes which screen at age 65.[10]

Men appear to be less likely to engage with healthcare services.[539, 540] Barriers to attendance are multifactorial and include individual (for example, fear of diagnosis, minimisation of symptoms) and healthcare system factors (for example, poor availability of services and poor inter-service co-ordination). A survey across waiting rooms in Australian healthcare facilities showed that male-specific literature was under-represented.[541] The potential to leverage existing public health campaigns like the Farmers Have Hearts' cardiovascular health programme[542] and Men's health week[543] could be explored to engage predominantly male audiences.

8.3.3 Respect for persons

With consideration to the HSE Healthcare Charter, respect for persons is a core ethical principle in health service delivery, ensuring that individuals are treated with dignity, compassion, and regard for their autonomy and vulnerabilities.[503]

As outlined in the NSAC criteria, the test and diagnostic procedure should be acceptable and implementable.[3] The screening test, abdominal ultrasound, is non-invasive, accurate, and does not expose participants to ionising radiation (see

Chapter 3, section 3.3.1). However, as described in section 8.3.1, pre-operative work-up and surgical treatment for AAA may involve ionising radiation exposure. Further, abdominal ultrasound is generally well-tolerated, as it is a relatively short, non-invasive and painless procedure. High uptake rates observed in population-based screening programmes, for example in the UK and Sweden, highlight the acceptability and feasibility of ultrasound as a screening tool.[8, 544] Nonetheless, from the perspective of considering 'respect for persons', it is relevant to recognise that the test involves the abdomen being exposed while the participant lies on the examination bed and the ultrasound probe is moved over the abdomen. As noted in section 8.3.1, factors such as obesity or presence of bowel gas may lead to failure to visualise the aorta during the examination, which may in turn lead to feelings of embarrassment. As with other screening programmes, it would be important for providers to be cognisant of the potential for feelings of vulnerability among participants.

Among those participants with screen-detected AAA, surgical intervention or continued surveillance may not be appropriate; this is particularly relevant for participants with significant comorbidities or advanced frailty.[545] As noted in WHO guidance on screening, it is considered unethical for a screening participant to remain in long-term surveillance without a realistic prospect of treatment.[143] Evidence from a retrospective study of 310 individuals with AAA suggests that patients in their 80s and 90s have a low risk of rupture from AAA less than 4 cm.[546] Hence at that age, discontinuing surveillance for small aneurysms may be considered reasonable.[547] In England and Wales, local and national policies suggest that men may be discharged from the programme, or the benefits of continued surveillance evaluated, where there is evidence of limited disease progression over long periods of time (such as, an aorta of less than 4.5 cm after 15 years of surveillance, or patients aged 85 and above with small AAAs).[412, 436] If an AAA screening is implemented, consideration could be given to establishing similar discharge protocols for those unlikely to benefit from continued surveillance.

Respect for persons also extends to ensuring equitable access to screening and surveillance particularly in vulnerable populations. Creating an environment that fosters and prioritises privacy and compassion can significantly enhance the participants' experience. As mentioned in Chapter 7, having a separate changing room may help maintain an individual's privacy and dignity, while also supporting high throughput. Appointment times for an AAA screening ultrasound scan may be shorter than a typical abdominal ultrasound due to the targeted nature of the test; however, it would be important to provide adequate consultation times, to ensure that participants do not feel rushed and have the opportunity to ask questions.

Stakeholder engagement is important to allow incorporation of participants' perspectives into the planning and delivery of care in order to meet the needs and

preferences of participants. For example the AAA screening programme in Northern Ireland incorporates service-users' feedback to ensure that its services are participant-centered.[537]

8.3.4 Justice and equity

Distributive justice

Distributive justice in healthcare involves ensuring equitable access to medical services and fair allocation of resources within a society. Striking the balance between meeting the needs of men at risk of AAA and ensuring that other services are not disproportionately affected through the introduction of a screening programme is a key ethical consideration.

Implementation of a screening and surveillance programme for AAA would likely lead to a rise in elective surgical procedures. Given that there are already delays in accessing surgery for AAA, an increase in elective surgeries would amplify existing pressures. Where there is insufficient capacity to meet demand, delays in accessing surgery could reduce the benefits of early detection.[548] Furthermore, an increase in demand for elective AAA repair and post-surgical monitoring, without investment in additional surgical capacity, could negatively impact other care pathways where access to surgery following screening is given priority. As described in Chapter 7, significant investment may be required to improve surgical capacity, including additional infrastructure and staff resources.[549, 550]

It is also important to note that the cost effectiveness of an AAA screening programme is related to the prevalence of AAA and the incidental diagnosis rate. Given the observed decline in AAA prevalence over time, and increasing use of imaging studies, the long-term cost effectiveness of introducing a population-based AAA screening programme is uncertain. Allocating substantial resources to a programme where long-term cost effectiveness is dependent on an evolving healthcare landscape presents challenges for decision-making.

Equitable access to care

A screening programme should be equally accessible to all population subgroups, regardless of socioeconomic status (SES), geographic location and literacy level, as outlined in the NSS strategic framework.[416] Ensuring high screening uptake is fundamental to the success of a national AAA screening programme, as both its clinical and cost effectiveness rely heavily on widespread participation.[551]

Community-based screening

Evidence from countries with established national AAA screening programmes, such as the UK and Sweden, demonstrates high uptake rates, with approximately 80% of

eligible men attending.[8, 544] Distance from screening centres has been shown to be associated with lower participation rates in different types of screening,[552, 553] including AAA screening.[554, 555] The community-based screening model in the UK has demonstrated that offering services closer to home, including in general practice premises or local facilities, with no cost to access, can support and help maintain high uptake, even in remote rural areas.[76] Equitable access would need to be considered not only for screening and surveillance, but also for access to timely follow-up care as required. For those referred to surgery, a key challenge would be balancing accessibility of treatment centres with achieving adequate surgical volumes in each centre to ensure optimal outcomes.

Vulnerable and underserved populations

The AAA screening programme must also consider reaching underserved populations, including individuals with lower SES and from different ethnic groups. The unequal uptake of screening programmes, described by the inverse equity hypothesis, highlights how health interventions can unintentionally widen disparities by attracting participation from healthier, more educated and well-resourced individuals.[551] Addressing these disparities requires targeted outreach efforts to ensure equitable access to screening for all eligible individuals. Lower SES is associated with increased smoking rates and obesity,[556, 557] which are key risk factors for AAA (see Chapter 2, section 2.3.1). Lower SES is also often associated with lower screening participation rates, suggesting that without targeted efforts to increase uptake in those with lower SES, those most likely to be affected by AAA may have the lowest uptake.[74, 388, 551, 558] Evidence from the MASS trial and other studies demonstrates that social deprivation is linked to poorer participation in screening programmes, with data from Northern Ireland showing uptake rates of 78% in the most deprived areas compared to approximately 89% in the least deprived areas.[537] Measures to increase screening uptake could include strategies such as pre-screening reminders, encouragement from GPs, repeat invitation and follow-up reminders.[383, 388, 559] Community outreach efforts, in particular, may help to promote awareness and uptake in underserved and vulnerable groups.

Financial barriers also disproportionately affect low-income individuals. Even relatively modest expenses, such as travel and indirect costs associated with attending a screening appointment, can place a burden on patients with limited financial resources.[560] Individuals living with comorbidities may face additional financial burdens associated with the cost of managing multi-morbidity, such as medication costs associated with pharmacological management of cardiovascular risk factors, where indicated.[561] These potential direct medical and non-medical costs to participants may limit their ability to adhere to recommended treatments, particularly as the target population (men aged 65 years) would not have access to free GP care until they reach 70 years of age, under existing contractual arrangements between

participating GPs and the HSE.[562] However, aside from potential costs such as transportation, the proposed AAA programme would be free to access, helping to reduce barriers to access and promote equitable participation.

Additional populations

The UK NAAASP allows men over 65 to self-refer for screening at a later date.[434] Adopting a similar approach would allow those aged over 65 at the time of implementation to access screening, potentially increasing the programme's effectiveness.[434] It may be necessary to limit the number of self-referrals over specific time-periods, to ensure feasibility, thereby helping to focus resources on those most in need. It is also important to consider how self-referral might affect equitable access. Self-referral requires a level of awareness and healthcare literacy. A review by the Health Equity Evidence Centre in the UK found that patients with higher levels of education and affluence are more likely to self-refer due to their greater engagement with the healthcare system and better understanding of health information.[563]

As discussed in Chapter 7 (section 7.3.3), it would also be important to ensure that all individuals identified as having an AAA, regardless of how they were detected, receive high-quality care. This may involve including those patients who have an AAA diagnosed through usual care within the screening and surveillance programme.[199] If such patients were not included in the screening programme, there would be a risk that their care would be deprioritised to facilitate timely access to surgery among those with screen-detected AAA, in line with the programme's key performance indicators (KPIs). However, capacity planning in the absence of national estimates of patient volumes and consolidation of screening and usual care pathways may present challenges.

Gender disparities

Generally, the exclusion criteria for a screening programme are determined through evidence-based considerations of the potential for harm versus benefit, cost-effectiveness and feasibility. Exclusion of those with low, but non-zero, risk from screening programmes is not straightforward. As discussed in Chapter 2, (section 2.11), women have generally been excluded from international screening programmes because their risk of developing AAA is considerably lower than that in men, while the risk of surgery-related complications is higher.[6, 140, 224] As outlined in Chapter 3, section 3.5.1, no clinical guidelines recommend population-based screening in women. Overall, clinical, epidemiological and economic evidence to support AAA screening in women is limited.[6, 224] If implemented, the rationale for excluding women from an AAA screening and surveillance programme should be

clearly and transparently reported to ensure the decision is recognised as being evidence-based and to mitigate potential perceptions of inequity.[564]

If the screening and surveillance programme were to include men and women with incidentally-diagnosed AAA, the care pathway would need to be adapted to reflect physiological and anatomical differences by sex, in particular, differences in thresholds for surgical repair, as outlined in the ESVS guidelines (see Chapter 3 section 3.5.1).[6] Furthermore, as discussed in Chapter 2, surveillance intervals and protocols were established from studies conducted in predominantly male populations that have not been validated in female populations. While there is an ethical obligation to ensure that women who are incidentally diagnosed with AAA receive the appropriate treatment, the limited evidence base in women presents challenges for quality assurance of a care pathway.[6, 145, 223, 226]

Access to private healthcare

As outlined in Chapter 3 (section 3.4.2), access to AAA screening is currently available through the private healthcare system where individuals can self-refer to medical ultrasound clinics, or be referred by a GP to private hospitals on the basis of risk factor identification (for example, family history of AAA).[221] If an AAA screening programme is not implemented, those with higher SES would be more likely to be able to access screening privately. In addition, if surgical capacity is not expanded sufficiently to accommodate the increased demand for elective AAA repair, individuals with access to private healthcare may receive more timely access to treatment. Irrespective of whether or not a screening programme is implemented, it is important that all individuals with an AAA have timely access to treatment.

Targeted versus universal screening

The choice between targeted and universal screening for AAA raises important ethical considerations related to equity. A targeted approach, such as screening based on risk factors (for example, smoking or family history) could improve efficiency by detecting a higher proportion of cases per person screened. The reducing prevalence of AAA has led to greater focus on targeted screening approaches in recent years.[28, 79, 116, 265, 565] However, population-based screening offers a more inclusive approach, ensuring more equitable access for all individuals within the population at risk, regardless of their risk profile.

As noted in Chapter 4, section 4.3.3, a targeted programme with 100% uptake could identify approximately 85% of AAA cases by focusing resources on individuals at higher risk.[30] However, uptake for targeted screening is typically lower than population-based programmes, potentially leaving some at-risk individuals undetected.[336] In practical terms, implementing a targeted screening programme in

Ireland would likely require an organised approach coordinated by the NSS where eligible individuals are sent invitation letters. Currently, the infrastructure to support such an approach, such as integrated electronic health records to identify individuals at risk, is lacking. The lack of universal access to primary care also presents challenges, and financial barriers may prevent some individuals from attending a GP. With a view to aiming to identify individuals who are likely to be at higher risk of AAA, the HSE Chronic Disease Management (CDM) Programme provides care for individuals with cardiovascular disease, including heart failure, angina, stroke, and irregular heartbeat, and who are medical card or GP visit card holders. This programme therefore represents a potential opportunity to identify individuals at increased risk of adverse cardiovascular outcomes, including AAA, for screening purposes. However, it is estimated that approximately 55% of the population aged 65 to 69 years do not have a GP visit card or medical card. Therefore a considerable proportion of men aged 65 would not be identified through the CDM Programme.[566-568] Also, the population with clinically significant cardiovascular disease who are engaged with the CDM programme may be likely to be identified through the usual care pathway in the absence of screening. Ultimately, any decision to adopt a targeted or universal screening programme would need to carefully balance consideration of efficiency with ethical obligations to ensure equitable access and prevent disparities in care.

8.3.5 Ethical consequences of the HTA

Scope of the HTA

This HTA considers the implementation of a one-time population-based ultrasound screening programme for AAA among men, compared with no screening. As noted in the protocol, it was considered out of scope to examine rescreening for AAA in an asymptomatic population previously screened for AAA, as no high-quality evidence on the effectiveness of rescreening was identified and existing population-based screening programmes in other countries do not include rescreening as part of their programmes.[352] Combined cardiovascular screening was not considered, as the primary aim was to address AAA. Reasons for this being the primary aim include the evidence base prompting consideration of AAA (as mentioned in Chapter 5, only one RCT provided evidence on combined cardiovascular screening[266]) and that many cardiovascular risk factors, such as cholesterol and blood pressure, can be safely managed in primary care in the absence of screening. Furthermore, increasing the scope of screening would result in a greater risk of overdiagnosis and would have additional resource implications for the screening programme and wider healthcare system.

With respect to inclusion of sub-aneurysm, although those with sub-aneurysm have traditionally not been included in international screening programmes, the

advantages and disadvantages of including those with sub-aneurysm have been considered in this chapter to allow careful consideration of the appropriate cut-off for a screen-positive result. Unlike the robust literature available examining growth rates for AAAs, the evidence base for sub-aneurysms is underdeveloped.[140]

The specific age or age group targeted by AAA screening was not predefined, but was instead guided by the epidemiology of disease, evidence of clinical effectiveness and safety, cost effectiveness, international practice, feasibility, and acceptability. The optimal age of screening has never been formally investigated.[6] The clinical trials comparing AAA screening with no systematic screening were generally undertaken across an age range (65 to 83 years). In international practice, target populations for screening have been selected based on the epidemiological literature, which demonstrates an increase in AAA-related mortality from approximately age 65 onwards. Consequently, the evidence base has been predominantly developed around this age group. However, with population ageing and improved cardiovascular risk factor management, it is possible that there could be an upward shift in the optimal age of screening at which most lives are saved at the lowest cost. Nonetheless, no evidence was identified within this assessment to support an upward shift in the target age group.

As noted in section 8.3.4, the scope of this HTA was limited to population-based screening in men, based on evidence from international guidelines and international practice, and in line with lower prevalence of AAA in women. Although the evidence base for AAA screening in women is limited, it is worth noting that if AAA screening in men is implemented in Ireland, this could lead to a shift in the burden of AAA-related morbidity and mortality to female populations, through avoidance of these events in men. Women are generally underdiagnosed and undertreated for cardiovascular diseases,[569] and tend to experience poorer outcomes after elective AAA repair compared with men.[570] However, as outlined in Chapter 2, section 2.8.1, AAA-related mortality tends to occur later in life in women compared with men. Even in those aged 85 years and older, the majority of cases occur in men. Given that AAA screening primarily aims to reduce premature AAA-related mortality and the benefits of avoiding AAA rupture diminish with advanced age, the associated gains in a female population are likely to be lower.

Choice and measurement of outcomes

A broad range of clinical effectiveness and safety outcomes were included in the assessment of population-based screening for AAA as described in Chapter 4, however, these were often limited by the length of follow-up in the available evidence, particularly for observational studies. Inadequate follow-up periods limit the ability to accurately measure long-term benefits, such as reductions in mortality, potentially leading to an underestimation of the programme's overall impact.

Additionally, accurately measuring rupture rates and AAA-related mortality presents challenges, particularly when autopsies are not performed. The potential over- or under-estimation of these outcomes creates uncertainty regarding the estimated benefits and risks of screening for AAA.

As discussed in Chapter 4, accurately quantifying the psychological harms of AAA screening presents challenges, primarily due to the lack of validated tools specifically designed to measure the psychosocial impact of screening. Generic preference-based quality of life tools and mood scales, while widely used, often lack the sensitivity required to detect subtle but potentially clinically meaningful psychosocial effects specific to screening for AAA. Furthermore, due to the lack of evidence comparing psychological harms between screened and unscreened cohorts, data from studies evaluating psychological impacts on screen-positive versus screen-negative participants were included and assessed. From an ethical perspective, this limitation raises concerns about whether the full extent of the emotional burden on participants is being adequately captured. Without validated tools, there is a risk of underestimating or misrepresenting the true psychological impact.

Availability of evidence

As noted in Chapter 4, the clinical effectiveness of one-time population-based screening for AAA was based primarily on four RCTs, which began in the 1980's and 1990's. The relevance and applicability of these data in light of changes in disease prevalence and treatment options over time is uncertain.[96] While three small-scale AAA screening studies conducted in Ireland were identified, evidence from local studies may not be transferable to a national quality-assured programme. While the best available evidence from existing international screening programmes was evaluated, transferability may be limited. Differences between countries may include variations in healthcare organisation, population characteristics such as socioeconomic status, risk factors (for example, smoking, obesity and hypertension), rates of incidental diagnoses, and screening uptake.

In terms of cost effectiveness, the overall evidence presented in Chapter 5 suggested that screening men aged 65 years is likely to be cost effective compared with no screening. However, the economic evaluations reviewed relied on outdated epidemiological and clinical data and did not account for all costs related to a screening programme, such as operational, staffing and infrastructural costs (see section 5). Additionally, implementation costs can vary significantly between countries due to differences in healthcare system structures and financing. While the most reliable evidence available was used in the budget impact analysis (Chapter 6), there remains a level of uncertainty around the costs associated with implementation of an AAA screening programme in the Irish context, and its long-term sustainability.

Furthermore, as discussed in Chapter 3, currently in Ireland asymptomatic patients are typically identified incidentally during imaging performed for other indications. However, the exact incidental diagnosis rate remains unclear. The lack of reliable data on baseline AAA detection poses a challenge to determining the relative benefits of implementing a population-based screening programme in the Irish context. Furthermore, the absence of Irish-specific AAA prevalence data makes it difficult to accurately predict the clinical and cost effectiveness of population-based screening. Identifying international AAA prevalence estimates applicable to the Irish population, such as those from the UK, has helped to address gaps in local data availability. However, if the actual prevalence of AAA is lower than estimated, or if most cases are already being identified through incidental diagnosis, then the clinical and cost effectiveness of a screening programme may be less than that estimated in this HTA.

Timing of the HTA

If AAA prevalence continues to decline, the potential risks of screening may outweigh the benefits and it may not be cost effective to implement a screening programme.[571] When population-based AAA screening programmes were introduced in countries such as Sweden and the UK, the prevalence of AAA was higher. The value of introducing a screening programme in the current epidemiological and clinical context is uncertain, particularly given that it could be challenging to discontinue the programme at a later stage if the prevalence were to continue to fall.

As noted in Chapter 3, changes in the ESVS 2024 guidelines published in 2024 recommend a more targeted approach to AAA screening.[6] Furthermore, the USPSTF recommends screening in men aged 65 to 74 years who have ever smoked.[224] An ongoing trial from the University of Leicester aims to use linked healthcare datasets, including the NAAASP and primary care data, to determine the clinical and cost effectiveness of targeted screening, compared with population screening.[324] However, the results of this trial were not available at the time of analysis.

Introducing a screening programme for AAA in the context of existing staff shortages, particularly among radiographers and radiologists (as noted in section 8.3.4) could also present challenges.[572] There is an ethical obligation to ensure that the healthcare system can adequately support implementation and sustainability of an AAA screening programme. Therefore, it may not be justifiable to introduce a screening programme for AAA until these staffing challenges are addressed.

8.4 Discussion

The purpose of this chapter was to outline the ethical, patient and social considerations associated with the potential introduction of an AAA screening programme for men in Ireland. The typically asymptomatic nature of AAA, the high mortality rate associated with AAA rupture, the availability of a simple, accurate test with good acceptability, and the availability of an effective treatment (surgical repair), suggest that AAA screening is likely ethically justified. However, screening is also associated with potential harms, including psychological distress, overdiagnosis and overtreatment. Further, declining AAA prevalence, the potential for decreasing cost-effectiveness, and competition for limited healthcare infrastructural and staff resources, complicate decision-making.

An informed assessment of the benefit-harm balance is only possible when all influential factors can be quantified and the approach to managing them is well defined. For example, some potential harms, such as psychological distress, may be managed and mitigated through standard screening processes in place within existing screening programmes internationally and in Ireland, including quality assurance and informed consent. Other factors influencing the benefit-harm balance, however, are challenging to evaluate as they are influenced by downstream decisions, the wider healthcare system context, or are still evolving at the time of decision-making (such as AAA prevalence).

Whether or not sub-aneurysm should be included in surveillance, and the choice of measurement approach for aortic diameter, are subject to debate. As noted in section 8.3.1, the choice of measurement method is based on a balance between the risk of overdiagnosis and the risk of missed cases. Internationally, different screening programmes have adopted different approaches,[6] which may reflect differences in risk tolerance. Given that ITI wall measurements are estimated to be 3 to 6 mm smaller than OTO wall measurements, the approach adopted can have important implications for the number of cases detected through screening, and their frequency of follow-up.[6] In light of this, the 2024 ESVS guidelines suggest that programmes using the ITI method, associated with the lowest risk of overdiagnosis and overtreatment, may need to give careful consideration to inclusion of those with sub-aneurysm in surveillance,[6] given that many of these cases would be identified if a programme were to adopt the OTO measurement method, and a threshold for screen positivity of 3.0 cm. It is important to recognise that the choice of measurement and populations included in the programme's definition of screen positivity are related decisions with ethical, operational and potential clinical consequences.

The acceptability of the screening care pathway may vary along its course, particularly for those with a positive screening test result. As a screening test,

abdominal ultrasound is generally considered acceptable due to its simple, fast and painless nature.[8, 91] Furthermore, a community-based delivery approach would be accessible to the target population which may contribute to higher participation rates. However, for those requiring follow-up, certain aspects of the management or treatment pathway, such as surveillance without guaranteed treatment, surgical eligibility criteria, and the potential for surgical complications, may be less acceptable. Despite potential for reduced acceptability among men with a positive screening test result, a cross-sectional survey of 158 men with screen-detected AAA participating in the Swedish AAA Screening Programme found that 96% of men did not regret their decision to participate in screening.[296] However, as noted in section 8.3.2, surveys and questionnaires assessing health literacy among those participating in AAA screening and those with a diagnosis of AAA revealed some gaps in understanding of disease and screening processes.[436, 534, 535] The potential for knowledge gaps among participants raises questions about the validity of perceived acceptability, as informed decision-making is a key component of true acceptance. If an AAA screening programme is implemented in Ireland, it would be important that individuals invited to screening clearly understand the risks, benefits and uncertainties of screening and surveillance; clear communication is essential to help manage expectations and ensure informed consent.

Considering resource requirements and associated ethical implications, deficits in radiological and surgical capacity could pose challenges to the effective implementation and sustainability of an AAA screening programme in the Irish context. As noted in the WHO publication 'Screening programmes: a short guide', it would be considered unethical to identify people with a disease or condition through screening if access to treatment cannot be guaranteed. Limited surgical capacity is therefore of particular concern, given the importance of providing timely and effective treatment.[548]

8.4.1 Previous assessments

Seven assessments carried out across six countries between 2006 and 2019 considered the ethical and social considerations of AAA screening.[227, 229-231, 233, 238, 249] Of these, five assessments across four countries, namely, Canada, France, Sweden, and the Netherlands, had specific domains that addressed the ethical implications of AAA screening.[227, 229-231, 249] Though HTAs from Finland and Norway also had ethical domains, they were limited in scope.[233, 238]

Of the HTAs that discussed ethical issues, the main topics addressed were broadly consistent with this analysis. The consistency of the topics considered across assessments provides assurance that key ethical issues relevant to the decision-making process have been identified. It is worth noting, however, that the value judgements used to guide screening decisions may vary across different contexts,

which may result in international assessments coming to different conclusions regarding the balance of benefits and harms. For example, the Dutch Health Council undertook an assessment in 2019 to advise on the advantages and disadvantages of an AAA screening programme in the Netherlands, with consideration to the Wilson and Jungner criteria.[249] In their advice, the committee referenced that the principle of subsidiarity was a key factor in the decision-making process – this principle states that there should not be a less invasive way to achieve the same goal.[249] In light of declining AAA prevalence, the high incidental detection rate in the absence of screening in the Netherlands, and potential improvements in cardiovascular risk factor management, the committee concluded that the additional health benefit of a population screening would likely be too limited to offset the significant risks, including post-operative mortality and overdiagnosis.[249] Instead the committee recommended optimising the current AAA care pathway to enable current trends of increasing elective surgeries and reduced AAA-related mortality to continue.[249]

A French HTA, undertaken with reference to 16 screening criteria, concluded that opportunistic screening in men and women with risk factors (current or past smoking and family history of AAA) was most relevant to the French context.[573] Smoking prevalence was noted to be higher in the French population, relative to populations in which RCTs were conducted.[573] It could be argued that in countries with high smoking prevalence**,** a targeted approach would still capture a large number of cases, meaning the potential impact of screening may still be clinically meaningful, even if a proportion of non-smokers with AAA are missed. Such an approach prioritises efficiency over equity, however, given the strong risk factor association, it may be a justifiable balance between impact and feasibility. The findings of previous assessments reinforce the importance of considering local factors in screening decisions.

8.4.2 Strengths and Limitations

A strength of this analysis is the consideration of evidence within the framework of the NSAC criteria, reflecting issues of particular relevance to the Irish context, including capacity and resource constraints, and the lack of universal access to primary healthcare, and the potential impacts on implementation. While a systematic review was not undertaken to inform the ethical analysis, efforts have been made to adopt a structured and transparent approach, in line with the EUnetHTA Core Model®.[502] This approach, although robust, is subject to unavoidable limitations. Ethical considerations are inherently value-based. However, by engaging with key stakeholders on the EAG, including representation from patients, the public, healthcare providers, managers and policy makers, and clinical, public health and methodological experts, this helps to ensure that the value judgements underlying ethical considerations are transparent and reflect the perspectives of a broad range of key stakeholders.

8.4.3 Conclusion

Screening for AAA can be reliably achieved through ultrasound imaging, which is non-invasive, painless and well-tolerated. Yet, all screening interventions involve a trade-off between benefits and harms, at patient and population levels. The potential advantages of AAA screening, such as a reduction in AAA-related morbidity and mortality, are offset by negative consequences including potential psychosocial harms, overdiagnosis (particularly if sub-aneurysms were included in the programme), overtreatment, potential post-surgical complications, and increased strain on healthcare resources. These potential harms could be minimised through thorough informed consent processes, provision of psychological and cardiovascular risk factor management support to those with a screen-positive result, and development of robust quality assurance processes. Nonetheless, uncertainty regarding the current incidental diagnosis rate and evidence of declining disease prevalence complicates the ability to make well-founded, evidence-based judgements regarding the long-term benefits and harms of population-based AAA screening in men aged 65.

9 Discussion

9.1 Introduction

An abdominal aortic aneurysm (AAA or 'triple A') is a pathological dilation of the abdominal aorta that predominantly affects men, with a higher prevalence observed in older age. Unruptured AAAs are typically asymptomatic or have non-specific symptoms. The rupture of an AAA is associated with a high mortality rate, making early detection critical for improving patient outcomes.

This HTA was undertaken to inform decision-making by NSAC regarding the potential introduction of a population-based AAA screening programme for men in Ireland. Drawing on evidence from Chapters 2 to 8, this discussion chapter aims to consider the totality of the evidence in order to inform the conclusions of the HTA.

In the following sections, the results are considered with reference to the NSAC criteria for appraising the viability, effectiveness and appropriateness of a screening programme and the relevant national and international literature (sections 9.2 and 9.3).[3] Key strengths and limitations of the evidence synthesis approach are also noted (section 9.4) followed by the conclusions that can be drawn from the available evidence (section 9.5).

9.2 Interpretation of the evidence

9.2.1 Challenges in assessing clinical and cost-effectiveness due to declining AAA prevalence

Considering the NSAC criteria, the natural history of AAA is well documented and establishes AAA as an important public health issue, although Irish-specific data are limited. AAA is a serious health problem due to the high fatality rate associated with AAA rupture, and can be mitigated through early detection and surgical repair of the aneurysm. These factors, combined with the asymptomatic nature of the disease progression and the possibility for early detection using a relatively simple, painless test (ultrasound), prompt its consideration as a suitable candidate condition for screening. However, changing trends in AAA prevalence and the absence of up-to-date Irish epidemiological estimates mean that it is difficult to assess the relative benefits of introducing an AAA screening programme, and, hence whether such a programme would be cost effective in the Irish context.

The prevalence of AAA has declined steadily over time, influenced by changes in population risk factors such as smoking rates, and improvements in overall cardiovascular risk factor management. Short-term prevalence projections from the UK NAAASP suggest that AAA prevalence may continue to decline up to 2030. Longer-term prevalence estimates are more difficult to estimate due to dependence

on the complex interplay of multiple risk factors, including smoking patterns and cardiovascular risk factor management. Despite declining AAA prevalence, AAA remains an important health concern. Due to the catastrophic nature of a ruptured AAA, marked by rapid onset of massive internal bleeding, the fatality rate associated with AAA rupture has decreased only marginally over time.

Reductions in the prevalence of AAA impact the relative benefits and cost effectiveness of a population-based AAA screening programme, compared with current practice (no systematic screening). Findings from RCTs which began in the 1980s and 1990s indicate that AAA screening was associated with a statistically significant reduction in AAA-related morbidity and mortality at long-term follow-up (13 to 15 years). However, the prevalence of AAA was significantly higher when these RCTs began (prevalence range: 3.9 to 7.6%), compared with the current estimated prevalence of approximately 0.7%, based on data from the UK NAAASP considered likely transferable to Ireland). Therefore, they are likely not applicable to the current population. It is also important to note that the relative benefits of an AAA screening programme may also be impacted by increases in the rate of incidental AAA detection as a result of increased access to diagnostic imaging in community and acute hospital settings.[417, 419] Thus, while there is evidence from high-quality RCTs demonstrating that invitation to AAA screening is effective in reducing AAA-related morbidity and mortality, a core requirement of a screening programme, the applicability of this evidence is increasingly limited.

Beyond RCTs, some data reflecting contemporary care pathways and epidemiological contexts are available, but are primarily observational and non-comparative in nature. The evaluation of the outcomes of the first ten years (2013 to 2023) of the UK NHS AAA Screening Programme (NAAASP) found that the reduction in ruptured AAA surgical repairs was greater in the cohort invited to screening than that observed in the general male population; however, the results are challenging to interpret due to the potential for systematic differences between different age groups.

It is worth noting that the prevalence of screen-detected AAA in international screening programmes is an underestimate of total AAA prevalence among men aged 65 years. This can be explained by the fact that most local screening programmes exclude men with a known AAA, and the prevalence is estimated to be higher in men who decline the invitation to screening.[574] The extent to which the prevalence of screen-detected AAA in the UK is transferable to the Irish context is related to the incidental diagnosis rate in the absence of screening in Ireland; this, as noted previously, is subject to considerable uncertainty.

The cost-effectiveness literature must also be interpreted in light of changing conditions over time. Economic evaluations included in Chapter 5 generally found

that AAA screening in men was cost effective. However, modelled estimates of AAA prevalence estimates ranged from 1.3% to 11.5%,[363, 369] which would not be considered transferable to the current Irish context. Few studies have conducted sensitivity analysis to investigate the impact of declining AAA prevalence, although the available evidence from threshold analyses suggests that AAA screening may no longer be cost effective at prevalence estimates ranging from 0.1% to 0.5% (based on WTP thresholds used in the original analyses).[350, 361, 363] It has been estimated that the population-based AAA screening programme for men aged 65 in the UK may not be considered cost effective within the next five to ten years.[574]

These uncertainties are also reflected in international practice. Sweden and the UK implemented population-based AAA screening programmes for men aged 65 years in 2006 and 2009, respectively.[9, 241] Since then, Finland opted against the implementation of an AAA screening programme in 2014 due to organisational challenges and concerns regarding the relative benefits.[238] In 2019, the Health Council in the Netherlands recommended against the introduction of an AAA screening programme, also citing concerns regarding the benefit-harm balance.[239] More recently, it has been reported that a pilot programme will be launched in the Czech Republic in 2025; however, documentation related to this pilot noted that disinvestment may be considered necessary if AAA prevalence is found to be less than 0.5%.[243, 245]

While long-term projections are subject to uncertainty, the decline in prevalence of AAA to date, coupled with ongoing improvements in cardiovascular risk factor management and increasing incidental diagnoses, mean that the prevalence of AAA is expected to continue to decline. As such, the key question is not whether or not population-based AAA screening will be cost effective in the future, but rather, when this shift will occur. In this context, robust data collection mechanisms to support accurate estimation of AAA prevalence in the Irish context are needed. Furthermore, in light of declining AAA prevalence alternative approaches to identifying those at risk of AAA-related morbidity and mortality may be needed, as described in section 9.2.8.

9.2.2 The ad hoc nature of usual care

As set out in the NSAC criteria, prior to implementing a screening programme, all other options for managing the condition should have been considered, to ensure that a more cost-effective intervention could not be introduced, or current interventions increased within the resources available.[3]

In 2019, in light of declining AAA prevalence, the high incidental detection rate in the absence of screening in the Netherlands, and potential improvements in cardiovascular risk factor management, the Dutch Health Council recommended against the introduction of a population-based AAA screening programme, instead

recommending that the current AAA care pathway should be optimised.[249] In Ireland and internationally, due their asymptomatic nature, AAAs are typically diagnosed incidentally during imaging for other indications. Systematically increasing case detection within a population with traditionally low healthcare service engagement, through a pathway that depends primarily on incidental diagnosis, presents significant challenges. Such an approach may be appropriate where there is robust evidence to support a high incidental diagnosis rate under current practice, as in the Netherlands. In the Irish context, in the absence of a national vascular registry, such information is lacking.

Without a formal screening programme, there may be variation in practice between vascular surgery units in Ireland. In the event that an AAA screening programme is not implemented in Ireland, through additional investment, the existing care pathway should be strengthened to meet international standards set out in the ESVS guidelines, including access to structured follow-up and timely access to elective surgical repair (see section 9.2.7). It is noted, however, that such an approach would not result in increased case detection. While incidental diagnosis plays an important role in the AAA care pathway, incidental diagnosis as a primary method of case detection is unreliable.

9.2.3 Ultrasound as a screening tool for AAA and its application in practice

As outlined in the NSAC criteria, the screening method should be simple, safe, reliable and validated to ensure effective detection of the target condition.[3] Abdominal ultrasound is widely accepted as the first-line imaging tool for detection of asymptomatic AAA as it is easy to use, non-invasive, relatively inexpensive, and is considered highly accurate when appropriate training and governance structures are in place.[156, 167] However, the studies from which estimates of sensitivity and specificity are derived are constrained by their limited applicability to the context of this HTA, which is concerned with the accuracy of ultrasound for the purposes of screening, rather than the accuracy of diagnostic ultrasound used in the context of usual care. As such, there is a lack of direct evidence for the accuracy of ultrasound for screening of AAA. Further, numerous factors including equipment specification, testing protocols, testing volumes, and operator education and training have the potential to influence the accuracy of ultrasound imaging of AAA, as described below.

An important disadvantage of ultrasound as a screening tool is the associated operator dependence and variability.[173] As described in Chapter 2 (section 3.3.1) ultrasound measurements can be carried out using inner-to-inner (ITI), outer-to-outer (OTO) methods or leading-edge-to-leading (LELE) methods. Evidence from a systematic review suggests that the ITI and OTO methods may be more

reproducible than the LELE method, although the strength of the evidence is uncertain.[174] Factors such as operator experience and education may influence these results. In the UK, the ITI method has been favoured based on local data and clinical expertise suggesting greater reproducibility when compared with the OTO method,[173] and the potential to minimise overdiagnoses.[146, 478] It is important to recognise that measurement variability cannot be completely eliminated. In the UK NAAASP, a tolerance of 5 mm is considered acceptable;[146, 164] in practice, a margin of error of 5 mm could mean a man with an aortic diameter of 30 mm could be discharged. Achieving the lowest possible levels of inter- and intra-observer variability through the development and implementation of robust training processes, quality assurance measures and screening protocols would be important.[164, 179] A screening programme would need to consider not just the reproducibility of results, but the practical implications of the method used with regard to the balance between overdiagnosis and risk of missed cases. As noted in Chapters 3 and 8, the OTO measurement method is associated with the highest risk of overdiagnosis, while the ITI method increases the risk of missed cases.

It is not possible to specifically determine the accuracy, reliability and safety of ultrasound for AAA screening in the Irish setting, based on international literature, as these are highly contingent on the delivery model and methodological approach.[575] Based on international experience, delivery of an AAA screening programme involves a delicate balance of optimising accessibility, equipment specification, and clinical expertise. Where screening is undertaken in hospitals or specialised centres, as in Sweden or the Czech Republic (according to plans), access to high-specification imaging equipment is possible. However, standardising practice across multiple centres may present challenges. Delivery of screening by dedicated clinical staff in the community setting, as in the UK, may reduce concerns regarding reproducibility, but a trade-off between equipment portability and specification may be necessary in this context. The potential impact on test accuracy of differences in staffing models between screening programmes is unclear. However, as described in Chapter 3 (section 3.3.1), it is likely that the training of staff, rather than their specific role, has a greater impact on test accuracy. The extent to which high accuracy can be achieved in the Irish context would be dependent on clinical workforce arrangements and the identification of ultrasound systems meeting the required standards.

As noted in the NSAC criteria, the distribution of screening values, suitable cut-offs, and further treatment pathways should be well-defined.[3] Beyond the ultrasound test itself, the safety of an AAA screening programme is dependent on the screening and surveillance algorithm used, including the choice between one-time or repeat screening, the choice of cut-offs, and the frequency of surveillance for those with a positive result. It is important to recognise that degeneration and expansion of the

aorta is a natural part of the ageing process; the cut-off for a pathologically enlarged aorta in the context of screening (typically an aortic diameter ≥3.0 cm), while based on clinical and epidemiological evidence, is somewhat arbitrary.[75, 84, 87, 265, 383] While acknowledging the significant potential for overdiagnosis associated with rescreening, and the lack of high-quality evidence to support it,[140] a negative screening test result at age 65, as a one-time intervention, cannot eliminate the potential for AAA-related morbidity and mortality in old age. As described in section 9.2.4, there is some uncertainty regarding whether the threshold for further follow-up should be an aortic diameter ≥ 2.5 cm or ≥ 3.0 cm, particularly in the context of increasing life expectancy.[6] The choice of cut-off is a value judgment, balancing the risk of overdiagnosis against the potential for missed cases. There is evidence of very low AAA-related morbidity and mortality among those with a negative screening test result at age 65 when a definition of ≥3.0 cm for screen positivity is applied; this suggests that screening performs reasonably well at identifying those with clinically significant AAA.[75, 84, 87, 265, 383] For those with a positive screening test result, surveillance intervals to support timely referral to vascular surgery are available, although some variation across guidelines and practice is noted (Chapter 3, section 3.5.1). Importantly, in the Irish context, the most important factor influencing the safety of an AAA screening programme is likely the extent to which timely access to elective surgical repair can be ensured, as described in section 9.2.7.

9.2.4 Considerations for test positivity criteria and the target population

As noted previously, including those with an aortic diameter of 2.5 to 2.9 cm (that is, sub-aneurysm) in surveillance could reduce the risk of men discharged from the programme at age 65 experiencing AAA-related morbidity and mortality in later life. Evidence from the Gloucestershire Aneurysm Screening Programme and four local AAA screening programmes in Sweden suggests that approximately 30% of men with an aortic diameter 2.5 to 2.9 cm at age 65 years could have a large AAA after 10 to 15 years' follow up.[96, 263] It is worth considering that the non-intervention rate (that is, the rate of ineligibility) for elective surgical repair may be considerable if and when those with sub-aneurysm at baseline reach the referral threshold. While such a strategy (that is, including those with sub-aneursym) may effectively identify additional men with AAA who may benefit from elective repair, this would be associated with an increase in overdiagnosis. As noted in section 9.2.3, evidence of very low AAA-related mortality among those with an aortic diameter <3.0 cm at age 65 years suggests that ≥3.0 cm is an acceptable threshold for follow-up.[75, 84, 87, 265, 383] However, some caution is warranted in the interpretation of these results given that men discharged from screening programmes are not systematically followed; it is possible that deaths may have been misclassified in the absence of autopsy, resulting in under-reporting of AAA-related deaths, as discussed in Chapter 3.

Given increasing life expectancy, an upward shift in the screening age from 65, the age used in the UK and Sweden, could be considered.[6, 478] However, as described in Chapter 8, no evidence was identified within this assessment to support an older target age group for screening. The optimal age at screening in men has never been formally assessed; men older than age 65 have not been systematically invited to AAA screening programmes in place internationally. Therefore, there is an absence of data to support investigation of changes to the target population based on prevalence, clinical effectiveness and cost effectiveness. Plausibly, however, increasing the age at baseline screening to, for example, age 68 or 70, would result in an increase in AAA prevalence at baseline, due to expected age-related degeneration of the aorta. This would in turn lead to an increase in overdiagnosis and overtreatment. Further, this would also have the effect of missing some younger men who would die from AAA rupture prior to age 68 or 70. As previously noted, when men are screened at age 65 the risk of missing cases that later develop an AAA is considered to be low; therefore, it might be argued that the risk of increasing overdiagnosis by shifting the age upwards is not warranted.

9.2.5 The risk-benefit balance in AAA surgical repair: Overtreatment, surgery-related mortality and long-term outcomes

As specified in the NSAC criteria, ensuring that the benefits of the overall screening pathway outweigh the harms is a fundamental principle of screening.[3] In this way, the benefits of elective surgical repair of AAA must be carefully weighed against the possible complications of surgery, which can include surgery-related mortality. An analysis conducted between 2010 and 2016 across 11 countries contributing to the VASCUNET international registry reported an in-hospital mortality rate of 1.0% for EVAR and 4.7% for OSR.[390] Direct comparison of surgical outcomes between EVAR and OSR from registry data may not be appropriate due to potential differences in the characteristics of participants undergoing these procedures.[576, 577] However, evidence from RCTs indicates that, in general, OSR is associated with a higher risk of peri-operative mortality, while re-intervention rates are higher for EVAR in the longer-term.[6]

As described in Chapter 4 (section 4.4.2), for those with small or medium AAA, the risk of surgery-related mortality likely exceeds the risk of AAA rupture, making surveillance the most appropriate management approach. Among men participating in the NAAASP between 2009 and 2017, the cumulative incidence of rupture was 0.4% for those with small AAA and 0.6% for those with medium AAA.[265] Estimating rupture risk amongst those with large AAA is challenging; the inability to study the natural history of large AAA is an unavoidable constraint related to the treatment approach, characterised by timely access to elective surgical repair when a large AAA is detected in a patient considered suitable for surgical intervention. As a result, in

the literature, the estimated rupture rate for large AAA is primarily based on the rupture rate in men identified through screening or incidental diagnosis who were ineligible for surgery and thus managed conservatively. Evidence from systematic reviews suggests that the annual rupture risk for those with large untreated AAA ranges from 5 to 13%.[394, 395] It is important to note that this subpopulation may have a higher burden of disease (for example, comorbidities resulting in surgical contra-indication), and as a result may experience worse health outcomes. Therefore, the rupture risk in this group may not reflect the risk in the population eligible for surgery. Nevertheless, the available evidence suggests that for those with a large AAA, the risk of AAA rupture exceeds the risk of surgery-related mortality.

Aortic diameter is the strongest predictor of AAA rupture risk, but it is not the sole determinant of risk. Aortic wall integrity, comorbidities and genetic factors may also play a role. As a result, it is not possible to precisely identify those with screen-detected AAA who would experience AAA rupture in the absence of screening. As described in Chapter 4, RCT evidence suggests that the total rate of elective surgical repair in the screened group exceeded the combined rate of elective repair and AAA rupture in the unscreened cohort, indicative of overtreatment.[508] Considering the risk of post-operative mortality following elective AAA repair, overtreatment may be associated with clinically significant consequences. It is plausible that a small proportion of patients who would otherwise not have undergone elective AAA repair, may experience post-surgical complications, including surgery-related mortality. Due to an increase in the rate of elective surgical repair in the screened group, even where the surgery-related mortality rate remains constant, there would be an increase in the absolute number of surgery-related deaths. Importantly, however, evidence from RCTs suggests a reduction in AAA-related mortality (all AAA deaths, plus all deaths within 30 days of AAA surgical repair) at all time points up to 15 years' follow-up in the screened group, compared with the unscreened group.[141] While the observed effect size may not be directly transferable to the current context, as noted in section 9.2.1, it is likely that, overall, the benefits of avoiding AAA rupture and its associated high mortality rate outweigh the surgical risks in those with large AAA considered fit for surgical repair.

The advances in vascular surgery over the past two decades, including increased surgical experience and training, changes in the procedures performed, and improved care pathways, including patient selection criteria, have resulted in improved surgical outcomes over time.[578] Iterative learning from long-term follow-up data has been noted to be important in informing surgical judgements in the context of EVAR, in particular.[578] Prior to the introduction of screening, the UK had the highest surgery-related mortality among countries with vascular surgery registries.[341] The current evidence indicating lower surgical mortality compared with the pooled total across registries suggests that quality-assurance processes in place

in the UK, supported by robust data collection mechanisms, have contributed to improved post-surgical outcomes. As described in section 9.2.7, a national vascular database would be important to support monitoring of patient outcomes and development of best practice in Ireland.

Long-term survival

It is unclear if improvements in perioperative surgical outcomes over time have been accompanied by an improvement in long-term prognosis, particularly as these factors may also result in older patients with greater comorbidities being considered eligible for elective AAA repair.[381, 579] Internationally, EVAR has increasingly being used to treat AAA in elderly patients previously considered ineligible for open surgical repair.[580] Such a change in patient selection may not be appropriate if life expectancy does not justify the risks associated with intervention.[6, 580] In the absence of robust patient selection protocols, epidemiological shifts in the burden of aortic disease towards older patients with more comorbidities could have implications for the benefit-harm balance. With consideration to the age and comorbidity profile of the population undergoing surgery, and in particular declining AAA prevalence, meaningful gains in quality and quantity of life at a population level may be increasingly challenging to achieve.

Furthermore, as described in Chapters 2 (section 2.4.4) and 4 (section 4.4.2), many patients with an AAA have a high prevalence of competing comorbidities that would likely be associated with a reduction in quality and or quantity of life.[347] It follows that the reduction in AAA-related mortality as a result of screening may have the effect of exposing patients to other competing mortality risks (for example, malignancy and atherosclerotic disease), and thus potentially mask the effect of elective AAA repair and intensive cardiovascular risk factor management on overall survival.[581, 582] Evidence from retrospective cohort studies suggests that men with a history of AAA repair consistently have poorer long-term survival when compared with the age- and gender-matched population.[579-581, 583] These findings should be interpreted in the context of the NSAC criteria, which set out that intervention at a pre-symptomatic phase should lead to better outcomes for the screened individual compared with usual care.[3] It is worth noting, however, that larger AAA diameter at the time of surgery has been associated with poorer five-year survival, indicating that earlier intervention as a result of screening may be associated with improved outcomes in appropriately-selected patients.[579]

The reasons for persistently compromised life expectancy following AAA repair are unclear. It may imply that opportunities to improve cardiovascular risk factor management are not fully leveraged in this population, or that residual mortality risks in this population cannot be fully addressed with cardiovascular risk factor management, as discussed in section 9.2.6[581, 584]

Shortened survival in those with AAA has cost and quality-of-life implications. CUAs presented in Chapter 5 generally adjusted age-specific background mortality rates to account for higher non-AAA related mortality, such as cardiovascular-related mortality, in the population with AAA.[233, 350, 361, 363, 366-370] However, it is unclear if this sufficiently captures competing mortality risks in the population with AAA, particularly where the relative increase in non-AAA-related mortality appeared to be low,[350, 368, 369] compared with contemporary estimates.[585] This may contribute to an underestimation of the costs related to management of other cardiovascular diseases in the AAA cohort, and overestimation of QALY gains.

The balance of rupture and operative risks should also be considered in the context of alternative treatment options for those with a large AAA. The evidence regarding the role of pharmacotherapy on AAA progression is inconclusive due to a lack of high quality studies.[203, 586-592] The evidence suggests a potentially exponential relationship between aortic diameter and rupture risk at larger diameters. There is also limited evidence regarding effective treatments to slow or arrest AAA growth. Thus, if left untreated, the cumulative incidence risk of AAA rupture would far exceed surgical risks, particularly in the context of technological and medical advancements in AAA surgical repair. Should effective treatments for the non-surgical management of AAA become available in future, this would influence the balance of surgical risks and benefits, potentially leading to revisions in the treatment algorithm.

9.2.6 Cardiovascular risk factors and their impact on AAA development, management, and surgical outcomes

Primary prevention

As noted in the NSAC criteria, all primary prevention options should be attempted, before a decision is made to implement screening.[3] As described in Chapter 2 (section 2.11), despite reductions in smoking and improvements in cardiovascular risk factor management over time, primary prevention alone is unlikely to be sufficient to prevent AAA-related morbidity and mortality in the short-term, given the potential time lag between changes in lifestyle factors and cardiovascular risk reduction.

Secondary prevention

Patients with AAA have a significantly higher risk of cardiovascular disease-related morbidity and mortality.[584, 585, 593] Given that elevated cardiovascular risks are largely driven by modifiable factors including smoking, high blood pressure, and excess weight, proactive cardiovascular risk management among men AAA detected through screening is considered best practice.[6, 342, 594, 595] This may also contribute to improved surgical fitness and surgical outcomes.

Studies undertaken in the UK and the Netherlands demonstrate that there is suboptimal management of cardiovascular risk factors, including under-prescribing of cardiovascular risk-modifying medications, in patients with AAA.[585, 594] A systematic review and meta-analysis of observational studies found that use of statins, aspirin and beta-blockers were significant independent predictors of improved survival following AAA repair.[596] While it is plausible that intensive cardiovascular risk factor management in the population with AAA may contribute to improved surgical outcomes and a decrease in cardiovascular morbidity and mortality, this has not yet been demonstrated in high-quality studies, likely due to challenges associated with the design of such studies. Despite uncertainty, as a secondary prevention measure, risk factor management in the population with AAA is recommended by the ESVS guidelines and other European societies,[6, 145, 146] and has been shown to be effective in the context of other cardiovascular conditions,[595, 597, 598] although evidence for individual drugs may be conflicting.[6, 599]

As described in Chapter 7 (section 7.3.6), prescription of pharmacological agents as a component of a national screening programme would be challenging. Of note, a considerable proportion of those with screen-detected AAA would already be enrolled in the Chronic Disease Management (CDM) Programme due to the high prevalence of other cardiovascular comorbidities covered by the programme in this population (heart failure, angina, stroke and atrial fibrillation), and thereby would have access to structured cardiovascular risk factor management support. As described in Chapter 8, research is underway examining the feasibility of developing an intervention for cardiovascular risk reduction to be embedded within the UK NAAASP.[342] In the Irish context, for those with screen-detected AAA, consideration could be given to leveraging existing initiatives aimed at supporting cardiovascular risk factor reduction in populations at increased cardiovascular risk.

9.2.7 Healthcare system capacity and preparedness

Decision-making regarding the implementation of AAA screening would require careful consideration of the ability to effectively implement the necessary changes in staffing and operations to support an effective, safe, and quality-assured screening programme. As described in Chapter 7, current deficits in surgical capacity and clinical staff shortages represent significant barriers to implementation. With consideration to the core requirements of a screening programme as set out in the NSAC criteria, including the need for appropriate care pathways, staffing, and facilities to be in place prior to implementation,[3] it is likely that a considerable capacity-building phase would be necessary in the Irish context prior to implementation.

Organisation and resourcing of vascular surgery units

In the UK, significant reorganisation of vascular surgery services in a 'hub and spoke' model occurred alongside the implementation of an AAA screening programme.[390] As a result of the centralisation of services, the number of centres performing AAA repair in England decreased from 140 in 2008 to 68 in 2022.[600-602] Remodelling of vascular services in the UK has coincided with a reduction in surgery-related mortality.[133] A number of large retrospective studies have shown that surgery-related mortality following AAA repair is inversely associated with repair volumes.[390, 603, 604]

In a relatively small country such as Ireland, high surgical volumes may be challenging to achieve, particularly in the context of declining AAA prevalence. The 2023 model of care for vascular surgery highlighted the need to deliver vascular surgery services in Ireland through integrated hospital networks within health regions in order to meet suggested volume-threshold levels and to ensure optimal patient outcomes.[148] While centralisation includes the potential to reduce technology and infrastructure costs (such as hybrid theatres), significant investment in broader vascular services would be required across hub and spoke sites, including diagnostic and surgical capacity building in hubs, additional vascular laboratory capacity in both hubs and spokes, and development of image transfer functionality (for example, integration with the National Integrated Medical Imaging System (NIMIS)). The retention and development of vascular services in vascular 'spokes' would be critical to ensure appropriate use of the hub and spoke model and accessibility of services to patients.[148] Organisational shifts would need to take economic, geographic and workforce considerations into account, ensuring emergency cases can be managed appropriately.

Clinical workforce capacity

As noted in the 2023 model of care, significant workforce capacity building in vascular services, particularly with respect to radiographers, clinical nurse specialists, advanced nurse practitioners and vascular technologists, is critical to the delivery of vascular surgery services that meet international standards.[148] However, addressing workforce shortages in professions requiring extensive education and training in the short-term is challenging. Implementation of an AAA screening programme would not be considered appropriate until staff shortages are resolved, both in terms of available positions and the ability to fill them.

As described in Chapter 7, in the UK NAAASP, a 'screening technician' role, with focussed, task-specific training, was developed to optimise use of clinical skills across the care pathway, and to ensure the availability of screening staff in the short-term. Establishing a new accredited healthcare professional course with the relevant regulatory body typically involves multiple stages. These include course design by the relevant higher education institute, a feasibility or pilot study (particularly for

new professions), approval by the Higher Education Authority (HEA), course accreditation in line with the National Framework of Qualifications (NFQ), and, finally, formal submission for professional accreditation. Timelines to deliver this may vary depending on the complexity of the course and the accreditation process. Early consultation with the appropriate regulatory body to ensure the course meets professional practice standards would be important to minimise the potential for delays. It is noted that national recognition and regulation of physician associates in the Irish context, following the introduction of the two-year masters course at the Royal College of Surgeons in Ireland (RCSI) in 2016, has been slow.[605, 606] Processes to identify the appropriate regulatory body for physicians associates are ongoing.[607] In the context of a potential 'screening technician' role, it would be important to consider the scope of the appropriate regulator's existing activities, and their capacity to take on additional responsibilities. Failure to do so could lead to delays in the regulatory process.[605] It is likely that establishment of a new role in Ireland would require an extended period of time, which is important to consider.

As noted in Chapter 8, healthcare practices, including the roles of healthcare professionals, are often context-specific and may not be transferable between countries. In terms of resourcing, some parallels can be drawn between AAA screening and diabetic retinopathy screening. Within the NHS Diabetic Eye Screening Programme, screening staff hold a health screener diploma, similar to that of the screening technicians working within the UK NAAASP.[608] While these degrees are nationally recognised qualifications with formal training requirements, health screeners are not on a regulated professional register.[609] In the Irish context, training and ongoing competency requirements for screeners and graders working within Diabetic RetinaScreen vary depending on the level of clinical or technical grading expertise, with additional requirements for graders who are not also qualified optometrists or ophthalmologists.[610] The feasibility and acceptability of the screening technician role in the Irish context are thus likely contingent on the provision of appropriate training and quality assurance processes. As noted above, the time required to establish such a role may represent the greatest barrier to timely implementation.

Separately, it is likely that changes to clinical governance frameworks would be necessary to address challenges associated with deficits in clinical radiology capacity. Review of all scans by a radiologist would likely not be feasible within existing radiology capacity without compromising existing services, as described in Chapter 7 (section 7.5.3). In the context of resource constraints, revisions to clinical governance frameworks have the potential to positively impact healthcare system capacity by optimising the utilisation of available clinical skills, provided they are implemented alongside appropriate quality assurance processes. As highlighted in Chapter 7, any change from current practice in Ireland would need to be developed

in partnership with relevant professional bodies, including the Faculty of Radiologists and Radiation Oncologists and the Irish Institute of Radiography and Radiation Therapy.

Resource planning, monitoring and evaluation

Uncertainty associated with the incidental diagnosis rate creates challenges for resource planning, given that potential increases in demand for acute surgical services depends, in particular, on the number of men currently detected through usual care. Evidence from countries participating in VASCUNET suggests that between 2010 and 2012, the rate of intact AAA repair ranged from approximately 20 (Hungary) to 120 (Norway) per 100,000 men aged over 59 years.[611] Applied to the Irish context, this suggests that the plausible absolute number of elective surgical repairs in men aged over 59 years would be between 100 and 700 annually. Comparing rates of AAA repair between countries is challenging owing to potential for differences in factors such as AAA prevalence, the non-intervention rate, coding systems, time periods, and population structure. However, for the purposes of resource planning, it is important to consider that capacity for up to 700 AAA repairs nationally per annum may be required if an AAA screening programme is implemented. Alternatively, assuming that the rate of AAA surgery in Sweden and England is the upper bound (approximately 65 per 100,000), this would suggest that the maximum number of AAA repairs among men aged 59 years and older in Ireland annually would be approximately 400. In light of considerable uncertainty, capacity requirements would need to be reassessed during phased implementation to ensure there is sufficient capacity to meet demand when fully implemented. The uncertainty regarding the current rate of AAA repair in Ireland underscores the need for a national vascular database to support monitoring of patient outcomes, epidemiological trends and healthcare system planning.

9.2.8 Navigating decision-making in a changing healthcare landscape

If AAA prevalence continues to decline, and clinically validated risk factors that can readily identify the population at greatest risk of AAA are defined, a targeted screening approach would become increasingly relevant. If a population-based AAA screening programme is implemented in the Irish context, it would therefore be important that it is designed with consideration to the potential need to shift to a targeted screening approach.

There is currently no well-defined or widely-accepted approach to implementing targeted AAA screening. The review of international practice carried out as part of this HTA did not identify any countries in which systematic organised targeted screening is in place. An externally-validated risk prediction tool to accurately identify those most at risk of AAA-related morbidity and mortality has not yet been

developed.[612] Further, the utility of a risk prediction tool for the selection of individuals to be invited for screening would be dependent on access to reliable population-level data (see Chapter 4, section 4.3.3). The digital health infrastructure currently used in the UK facilitates identification of individuals eligible to participate in the NHS Diabetic Eye Screening Programme using primary care records. This suggests that a similar approach could feasibly support the transition to targeted AAA screening in the UK NAAASP, if considered appropriate.[574] However, integrated and up-to-date health databases to support identification of all men based on clinical risk factors are lacking in the Irish context. Comprehensive risk factor data are collected as part of the HSE Chronic Disease Management Programme, but would only be available for a sub-cohort of the target population. Considering a simplified approach, targeting individuals with a history of smoking could, in theory, identify up to 85% of cases (see Chapter 4, Section 4.3.3).[30] However, examples of opportunistic risk-based AAA screening targeted to smokers in France and the US exhibit low uptake. Regardless of the challenges in identifying the target population, and the uncertain real-world effectiveness, it is important to note that in the Irish context formal organised targeted screening would be unlikely to result in substantial reductions in costs, compared with population-based screening, due to baseline resource requirements to establish a screening programme. Therefore, the resultant reduction in case detection would likely not be acceptable from a health economics perspective.

In light of declining AAA prevalence, and evidence to suggest that there is a cohort effect in the epidemiology of AAA (that is, a particular cohort of men are most affected due to patterns of tobacco use in the 20th Century)**,** implementation of screening on a time-limited basis has been considered in some countries, including the Czech Republic and Denmark.[243-245] It is important to note that if a screening programme is likely to be discontinued due to uncertainty regarding the relative benefits, the significant time and financial resources required to establish the programme may not be proportionate to the additional health benefits gained. Furthermore, active disinvestment decisions may not be considered acceptable by the public, particularly where it is perceived to be as a result of financial constraints within the healthcare system.[613, 614] A switch from population-based to targeted screening may be more acceptable than complete withdrawal of services, particularly where supported by outcome data from the programme.

It is important to note that a decision to transition from population-based to targeted screening, particularly in the scenario where population-based screening is no longer deemed cost effective due to declining disease prevalence, differs fundamentally from the decision to initially implement targeted screening. A decision to shift from a population-based to a targeted screening model results in decreased resource utilisation and decreased costs relative to continuing with a population-

based strategy. However, as described in Chapter 6, introduction of targeted screening in the absence of an existing screening programme would involve substantial set up costs.

9.3 Summary of the benefit-harm balance

Deciding the point at which the relative benefits of a screening programme outweigh the harms is a complex decision based on the consideration of multiple factors including the disease epidemiology, clinical effectiveness and safety, resource implications and contextual factors such as stakeholder perspectives. With declining prevalence, the relative benefits of screening may be lower than previously estimated in high-quality RCTs. Even in the absence of screening programmes, the prevalence of AAA and AAA-related mortality has declined internationally, coinciding with a rise in the use of imaging studies to inform patient management approaches. However, for those with a ruptured AAA, high mortality has been sustained over time owing to the catastrophic nature of massive internal bleeding when the aorta ruptures. Early detection and timely elective surgical repair, where indicated, remain the mainstay of AAA management. Early detection is challenging in the absence of screening, given the typically asymptomatic nature of AAA. Early case detection primarily relies on incidental diagnosis, a method that, by definition, cannot be systematically organised. Screening, however, is not a definitive solution. Its effectiveness is constrained by participation and follow-up rates, particularly in high-risk populations. It is also important to consider that one-time screening at age 65 can only have a partial effect on AAA-related rupture in very old age; a small proportion of men without an AAA at age 65 may later develop clinically significant AAA. Inevitably, with or without screening, some cases would be missed.

The available international evidence suggests that AAA screening is a cost effective use of resources. However, the conditions under which these conclusions were reached may not reflect the context of the present assessment. Declining AAA prevalence, the increasing use of imaging studies under usual care, and the resource requirements associated with delivering a national screening programme mean that the long-term cost effectiveness of introducing a population-based AAA screening programme is uncertain. The resource implications associated with introducing an AAA screening programme also need to be considered in the context of the wider healthcare system. Providing access to elective surgery while safeguarding the capacity of other care pathways would be challenging. Furthermore, given that the healthcare budget is finite, allocating resources to a new screening programme would result in a reduction in the funding available for other healthcare services.

The balance between benefit and harm cannot be determined objectively, as it reflects value-based considerations, often involving trade-offs between maximising effectiveness and minimising harms. It is likely that the direction of the benefit-harm

balance, at present, still favours screening despite changes in the clinical landscape over time. However, over time, the benefits may no longer outweigh the harms. While AAA prevalence has declined over time, so too has post-operative mortality following EVAR and OSR. The overall effect may be a minimal change in the balance of benefits and harms. Inclusion of sub-aneurysm, while associated with clinical benefits in terms of additional AAA ruptures avoided, would result in a considerable increase in overdiagnoses. This could have implications for the benefit-harm balance.

9.4 Strengths and limitations

The assessment has a number of strengths relevant to its methodological rigour and contributions to the scientific literature. In terms of strengths, a robust approach to the assessment was employed with publication of a protocol for the HTA, and adherence to national and international best practice guidelines for the conduct and reporting of HTA and systematic review.[268, 352, 502]

Throughout the HTA, the decision problem set out in Chapter 1 was discussed with reference to the NSAC criteria to enhance the utility and relevance of the findings for the purpose of decision-making.[3] Furthermore, a central component of the HTA process is the structured involvement of stakeholders. The EAG convened to support this assessment played a key role in facilitating access to national and international data and ensuring the findings of this assessment accurately reflect the current Irish context. Feedback from additional stakeholder organisations and the general public will be captured by a targeted and public consultation to further increase the acceptability and relevance of the research findings to the local context. A synthesis of the feedback received and the changes arising from this consultation process will be published as a supporting document on the HIQA website.

Although a de novo Ireland-specific economic evaluation would be the preferred approach to inform estimation of the cost effectiveness of an AAA screening programme in men, such an analysis was not considered feasible due to limitations in the clinical and epidemiological evidence base. In general, the structure of existing CUAs was considered sufficient to reflect the natural history of AAA. It is thus plausible that concerns regarding the transferability of cost effectiveness data from other settings to the Irish context could be addressed through parameterisation of an existing model. However, uncertainty regarding the longer-term trajectory of declining AAA prevalence, owing to its dependence on the effectiveness of interventions to support cardiovascular risk factor reduction in the eligible population, and the absence of up-to-date comparative clinical effectiveness data mean that a de novo analysis would not meaningfully reduce decision uncertainty.

The scope of this assessment and the associated advice are limited to considering the appropriateness of implementing an AAA screening programme in Ireland within

a HTA framework. If a decision is made to implement an AAA screening programme, additional work would be needed during the pre-implementation phase to support the development of a national, standardised, quality-assured screening programme. Nevertheless the findings and associated advice represent a roadmap to support implementation, if a decision is made to implement AAA screening. The estimated resources required to establish and deliver an AAA screening programme align with international practice and local stakeholder insights at the time of analysis. However, considerable uncertainty regarding feasible staffing models means that accurate determination of the costs of screening would only emerge during pre-implementation planning.

9.5 Conclusions

The typically asymptomatic nature of AAA, the high mortality rate associated with AAA rupture, the availability of an accurate test with good acceptability, and the availability of an effective treatment mean that AAA is a suitable candidate for screening. However, changes in the clinical landscape over time, characterised by declining AAA prevalence, improvements in cardiovascular risk factor management, and the increasing use of imaging studies, indicate that the magnitude of the clinical and economic benefits observed in earlier studies are not directly applicable to the current context. It is likely that the direction of the benefit-harm balance, at present, still favours screening despite these changes in the clinical landscape over time. However, there may be a shift towards population-based AAA screening no longer being cost effective over the next five to 10 years, as a result of declining AAA prevalence.

Without careful planning, implementing an AAA screening programme may exacerbate existing capacity constraints within the healthcare system. Capacity deficits in radiology and vascular surgery would need to be addressed prior to implementation of an AAA screening programme. The potential to manage staff shortages in clinical radiology, to some extent, through changes in workflows could be explored, in partnership with the appropriate professional bodies. Significant investment in vascular services would be required to support timely access to elective surgical repair and adequate resources for post-operative follow-up.

In light of current healthcare system capacity constraints, and the potential for the evolving epidemiological and clinical context to tip the balance in favour of targeted screening, a decision to implement screening (whether population-based or targeted) should be preceded by a capacity-building phase, with particular emphasis on development of surgical capacity and data reporting mechanisms.

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Supplementary Appendix

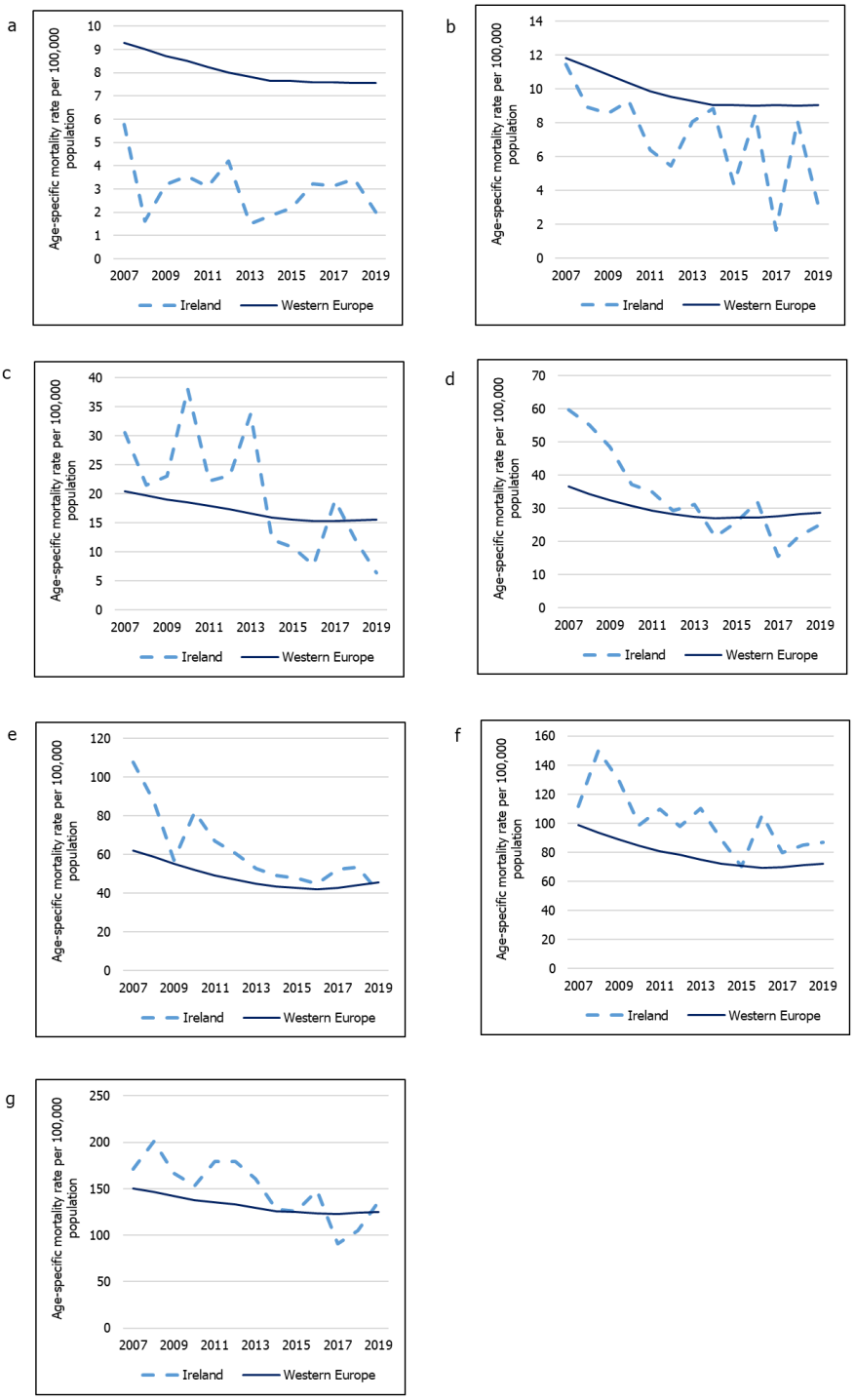
Supplementary Appendix for Chapter 2

Table A1 ICD-10-AM procedure codes for repair of abdominal aortic aneurysm with open surgery or EVAR

Procedure	Procedure code
OPEN SURGERY	
Replacement of suprarenal abdomino-aortic aneurysm with graft	33112-00
Replacement of ruptured suprarenal abdomino-aortic aneurysm with graft	33151-00
Replacement of infrarenal abdomino-aortic aneurysm with tube graft	33115-00
Replacement of ruptured infrarenal abdomino-aortic aneurysm with tube graft	33154-00
Replacement of infrarenal abdomino-aortic aneurysm with bifurcation graft to iliac arteries	33118-00
Replacement of ruptured infrarenal abdomino-aortic aneurysm with bifurcation graft to iliac arteries	33157-00
Replacement of infrarenal abdomino-aortic aneurysm with bifurcation graft to femoral arteries	33121-00
Replacement of ruptured infrarenal abdomino-aortic aneurysm with bifurcation graft to femoral arteries	33160-00
ENDOVASCULAR ANEURYSM REPAIR (EVAR)	
Endovascular repair of aneurysm	33116-00

All discharges are coded using ICD-10-AM/ACHI/ACS. Different versions of ICD-10-AM/ACHI/ACS were in use across the period of this analysis (2005 to 2008: 4th edition; 2009 to 2014: 6th edition, 2015 to 2019: 8th edition; 2020 onwards: 10th edition)
Source: Hospital In-Patient Enquiry (HIPE) System.[100]

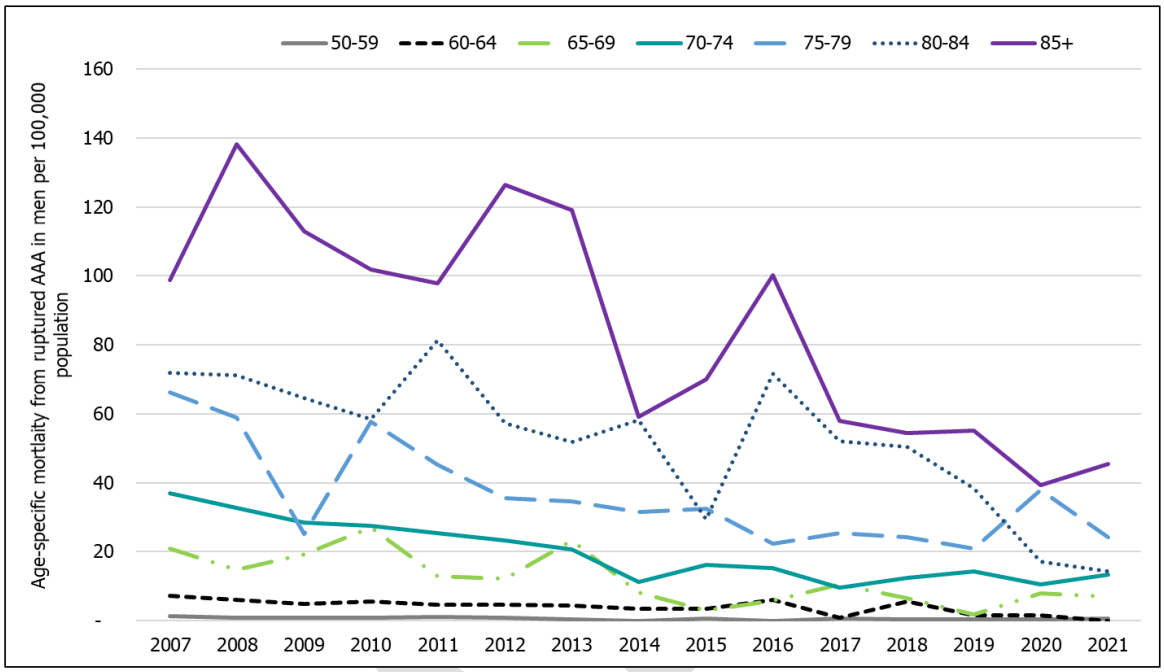
Figure A1 Age-specific aortic aneurysm-related mortality in those aged a) 50-59 b) 60-64 c) 65-69 d) 70-74 e) 75-79 f) 80-84 and g) 85+ years in Ireland and Western Europe



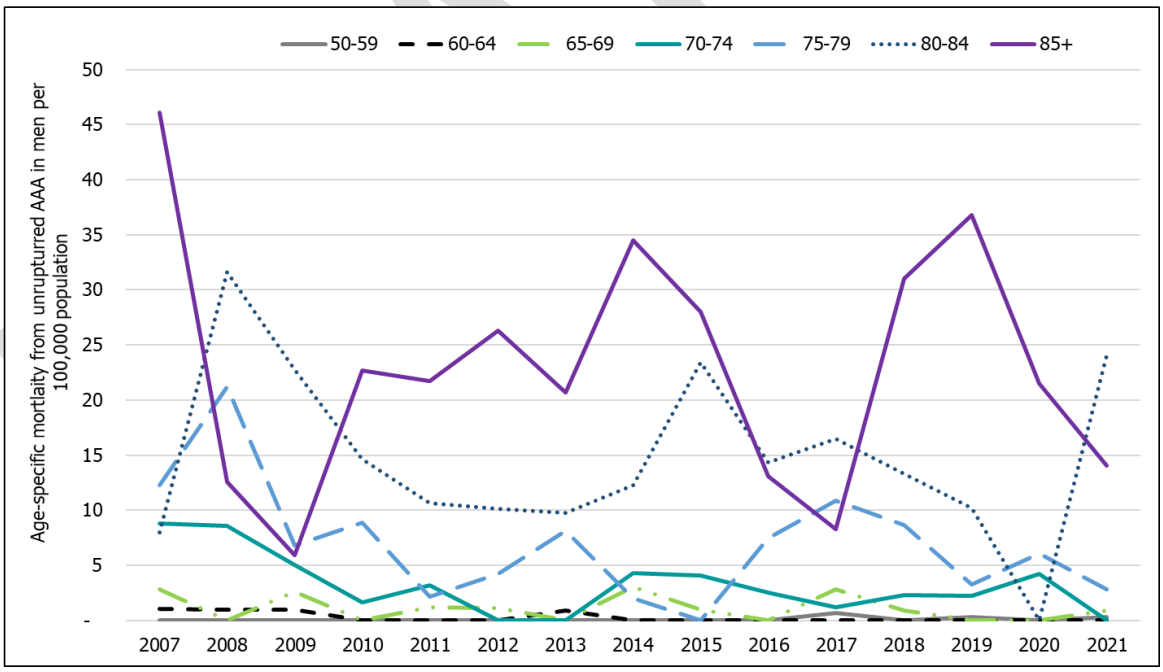
Data for the following Western European countries were extracted from the GBD database: Andorra, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, the Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, and the United Kingdom. Data for Ireland include all deaths for which the cause of death was recorded by the CSO as aortic aneurysm and dissection (ICD-10 code: I71).

Figure A2 Age specific mortality rate from a) ruptured and b) unruptured AAA, 2007 to 2021

a

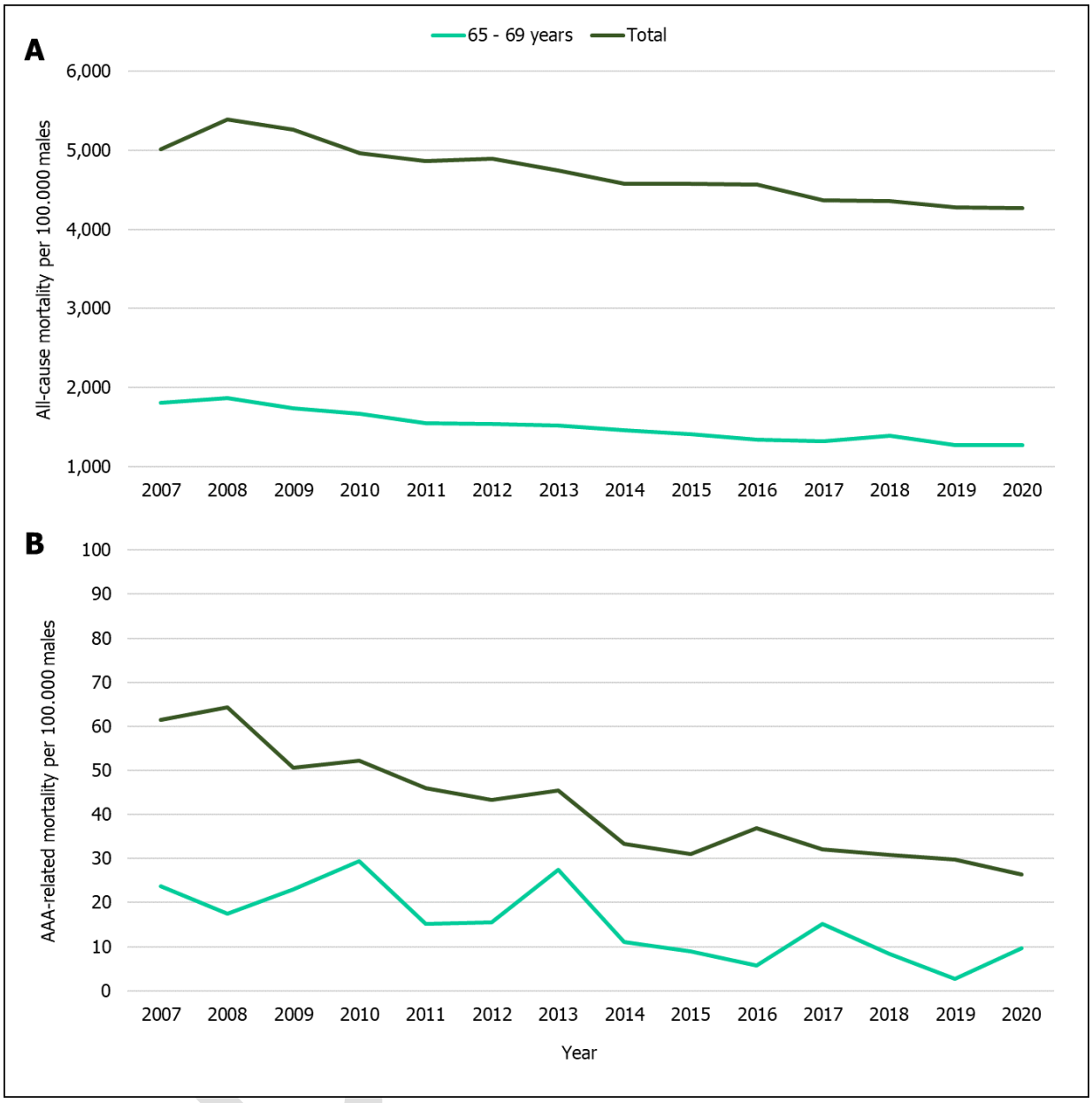


b



Data include all deaths for which the cause of death was recorded by the Central Statistics Office as ruptured or unruptured abdominal aortic aneurysm (ICD-10 codes: I71.3 and I71.4, respectively).

Figure A3 A) All-cause mortality and B) AAA-related mortality per 100,000 males over 65 to 69 years and males 65 years and older.



Key: AAA – Abdominal aortic aneurysm.

Supplementary Appendix for Chapter 4

Appendix A4.1 Methods

Evidence matrix for psychosocial outcomes and quality of life

An evidence matrix was developed to investigate overlap of primary studies across systematic reviews reporting on the impact of AAA screening on psychosocial outcomes and/or quality of life. In total, unique 14 primary publications were identified, comprising 13 individual studies (Table A2). Of these, four primary studies were not considered relevant to the scope of this assessment. In total, 10 publications, reported across nine studies were considered relevant.

Table A2 Evidence matrix of primary studies reporting on quality of life or psychosocial endpoints across identified systematic reviews

Primary study, year	Parent trial†	Systematic review					Included in this review
		USPSTF 2005[274]	USPSTF 2014[273, 286]	USPSTF 2019[140, 141]	Ali 2016[277]	Lyttkens 2020[276]	
Included publications reporting on outcome (n)		3	6	8	4	13	
Marteau, 2004	MASS						Y
Ashton, 2002							Y
Spencer, 2004	Western Australia						Y
Lindholt, 2000	Viborg						Y
Lindholt, 2017	VIVA						Y
Sandstrom, 1996	NA						N‡
Lucarotti, 1997	NA						Y
Khaira, 1998	NA						Y
Wanhainen, 2004	NA						N§
Lesjak, 2012	NA						Y
Hinterseher, 2013	NA						N‡
Scalone, 2013	NA						N††
Ericsson, 2017	NA						Y
Bath, 2018	NA						Y

Key: NA – not applicable; MASS - Multicenter Aneurysm Screening Study; N – No; USPSTF – US preventive Services Task Force; VIVA – Viborg Vascular; Y - Yes.
† Study population includes a subsample of population-based randomised controlled trial.
‡ Included patients through opportunistic detection, not screening.
§ Data were not disaggregated by gender.
†† The screening programme included screening for aneurysms at additional sites (for example, iliac aneurysms).

Quality appraisal of population-based observational studies of screening interventions

- The criteria in Table A3 are intended to guide assessment of the conduct and reporting of studies investigating the effectiveness and safety of population-based screening.
- The criteria are intended to reflect adherence to internationally recognised key components of an effective screening programme, including end-to-end care.[143]
    - The relative importance of each component may vary depending on the condition being screened for and the specific context in a given setting (for example, local epidemiological data and available resources). Therefore, an overall score is not provided.
- The guiding questions were designed to prompt the assessor to ask certain questions about the study to ensure systematic assessment of quality across all studies. However, not all guiding questions will be relevant to every study.
- The conclusion of this assessment may reflect inadequate reporting by the study authors, rather than inadequacies within a given study or programme.

Table A3 Criteria for assessment of the conduct and reporting of population-based screening studies

Screening pathway criteria	Guiding questions	Judgement
1. Identify the population eligible for screening	1. Was an evidence-based approach used to identify the population to be screened? (for example, clinical guideline, local epidemiological data) ○ For comparative studies, was the comparator population representative of the target population? ○ Were the groups similar at baseline on important characteristics that could influence outcomes (for example, age, risk factors, and comorbidities)? Was the comparator group selected from the same time period? 2. Were eligibility/selection criteria for the study population pre-specified and clearly described? 3. Were any exclusion criteria appropriately justified? (for example, terminal illness) 4. Were participants invited using a systematic process? (for example an up-to-date registry) Is there a risk that people in the eligible population were not identified?	▪ Adequate ▪ Inadequate ▪ No information
2. Invitation and information	5. Were all participants in the eligible cohort invited to screening? 6. What was the percentage uptake within the eligible population? 7. Was the eligible population supplied with information tailored appropriately for different groups to enable informed choice to participate? 8. Were processes in place for follow-up of non-responders or non-attenders?	▪ Adequate ▪ Inadequate ▪ No information

	9. Was uptake considered adequate with reference to standards set by the programme and/or international standards? (for example, the WHO suggest the screening programmes should aim for at least 70% uptake)	
3. Screening algorithm	10. Was the screening algorithm clearly described? 11. Was the screening test conducted using agreed, consistent methods? (for example thresholds for a positive result) 12. Was there evidence that healthcare professionals or laboratory staff had the necessary knowledge, skills and resources (for example, equipment and infrastructure) to perform screening? Was tailored training provided? 13. Was the screening test accessible to the target population? (for example, consider setting and geographic distribution of testing centres)	▪ Adequate ▪ Inadequate ▪ No information
4. Referral of screen-positives and reporting of screen-negative results	14. Were all screen-positive results referred to appropriate services? (if individuals decline further participation in the programme, but were offered the appropriate intervention, this criterion can still be considered achieved) 15. Were screen-negative results reported to individuals? (if individuals were informed that negative test results would not be communicated during the informed consent process, this criterion can still be considered achieved) 16. Where appropriate, are individuals invited for rescreening after an appropriate time interval based on epidemiological evidence? 17. Is there evidence that cases were not identified due to deficiencies in the screening pathway?[†] (for example, failure to make follow-up appointments or inadequate reporting systems)	▪ Adequate ▪ Inadequate ▪ No information
5. Diagnosis	18. Was the diagnostic test conducted using agreed and reliable methods? 19. Were diagnostic criteria for reporting of screen-positives agreed prior to implementation? (this criterion can still be considered achieved if diagnostic criteria are revised based on outcomes of screening as part of quality assurance processes)	▪ Adequate ▪ Inadequate ▪ No information
6. Intervention, treatment and follow-up	20. Was the treatment pathway clearly described? 21. Were cases with a positive screening test result offered treatment, where indicated? 22. Were cases with a positive screening test result offered surveillance, where indicated? 23. Was the length of follow-up sufficient?	▪ Adequate ▪ Inadequate ▪ No information
7. Reporting of outcomes	24. Were the data reported complete? Were outcomes of the screening programme collected and analysed for all participants? 25. Were outcomes of the screening programme measured against pre-defined criteria/agreed key performance indicators? 26. Were the data analysed using appropriate statistical methods? 27. Did the authors use an intention-to-treat analysis?	▪ Adequate ▪ Inadequate ▪ No information

	28. Were outcomes reported for any subgroup analysis pre-specified? 29. Was the dropout rate considered reasonable? ○ For comparative studies, was there evidence of differential loss to follow-up?	
8. Conflicts of interest	30. Were there any potential conflicts of interest among study researcher(s) and funder(s)?	▪ Yes ▪ No ▪ No information

Appendix A4.1 Results

Table A4 Systematic reviews reporting on the clinical effectiveness and safety of AAA screening

Organisation	Study year(s)	Search date	Review methods	Research questions or aims of relevance to this review	PICO	Included studies of relevance to this review (follow-up[+])	Author's conclusion
NA	Lyttkens 2020[276]	31 December 2018	De novo systematic search	To investigate current knowledge of impact on HRQoL and patients' experiences of living with a small AAA (30 to 54 mm), while being under surveillance.	NR	N = 21 studies ▪ n = 13 quantitative (n = 9 relevant to this review, see Table A2) ▪ n = 8 qualitative	The current evidence does not support a negative impact on HRQoL from being under surveillance for an AAA. Qualitative data indicate that adequate patient information and professional care have the potential to reduce unnecessary worries and concerns in patients with an AAA.
USPSTF	Guirguis-Blake et al. 2019;[140, 141] Guirguis-Blake et al. 2014;[273, 286] Fleming et al. 2005[274]	26 July 2019	Update of the 2005 and 2014 USPSTF systematic reviews	**RQ1:** AAA-related mortality, all-cause mortality, AAA rupture rate (KQ1 and KQ2) and AAA incidence (KQ2 only). a. Do the effects of 1-time screening for AAA vary among subpopulations (that is, by age, sex, smoking status, family history, or race/ethnicity)? **RQ3:** What are the harms of 1-time and repeated screening for AAA? a. Do the harms of 1-time and repeated screening for AAA vary among subpopulations (that is., by age, sex, smoking status, family history, or race/ethnicity)?	**P:** Asymptomatic adult population **I:** Screening with ultrasound **C:** One-time screening vs. no screening **O:** RQ1: All-cause mortality, aneurysm-related mortality, cardiovascular disease mortality, aneurysm rupture rate, cardiovascular disease events, and quality of life. RQ3: anxiety and downstream procedures related to false-positive results. **S:** RQ1: Randomised, controlled trials RQ3: Randomised, controlled trials; large cohort studies (sample size >1,000)	2019: N = 5 RCTs: ▪ MASS (13.1) ▪ Chichester (15.0) ▪ Viborg (13.0) ▪ Western Australia (12.8) ▪ VIVA (4.4) 2014: n = 4 RCTs: ▪ MASS (13.1) ▪ Chichester (15.0) ▪ Viborg (13.0) ▪ Western Australia (3.6) N = 2 cohort studies (harms only) 2005: n = 4 RCTs: ▪ MASS (4.1) ▪ Chichester (2.5) ▪ Viborg (5.1) ▪ Western Australia (3.6)	One-time AAA screening in men 65 years or older was associated with decreased AAA-related mortality and rupture rates but was not associated with all-cause mortality benefit. Higher rates of elective surgery but no long-term differences in quality of life resulted from screening.
Canadian Task Force on Preventive Health Care	Ali et al. 2018;[284] Ali et al. 2016;[277]	April 2017	Update of the 2014 USPSTF systematic review	**RQ1:** What is the effect of one-time AAA screening using ultrasound scan on health outcomes in asymptomatic adults aged 50 years and older?	**P:** Asymptomatic adults aged 50 years and older **I:** General or targeted screening with ultrasound scan **C:**	2018: N = 4 RCTs: ▪ MASS (NR) ▪ Chichester (NR) ▪ Viborg (NR)	Population-based one-time screening for AAA with ultrasound in asymptomatic men aged 65 years and older remains beneficial during the longer term after screening has ceased, with significant reductions in AAA mortality and

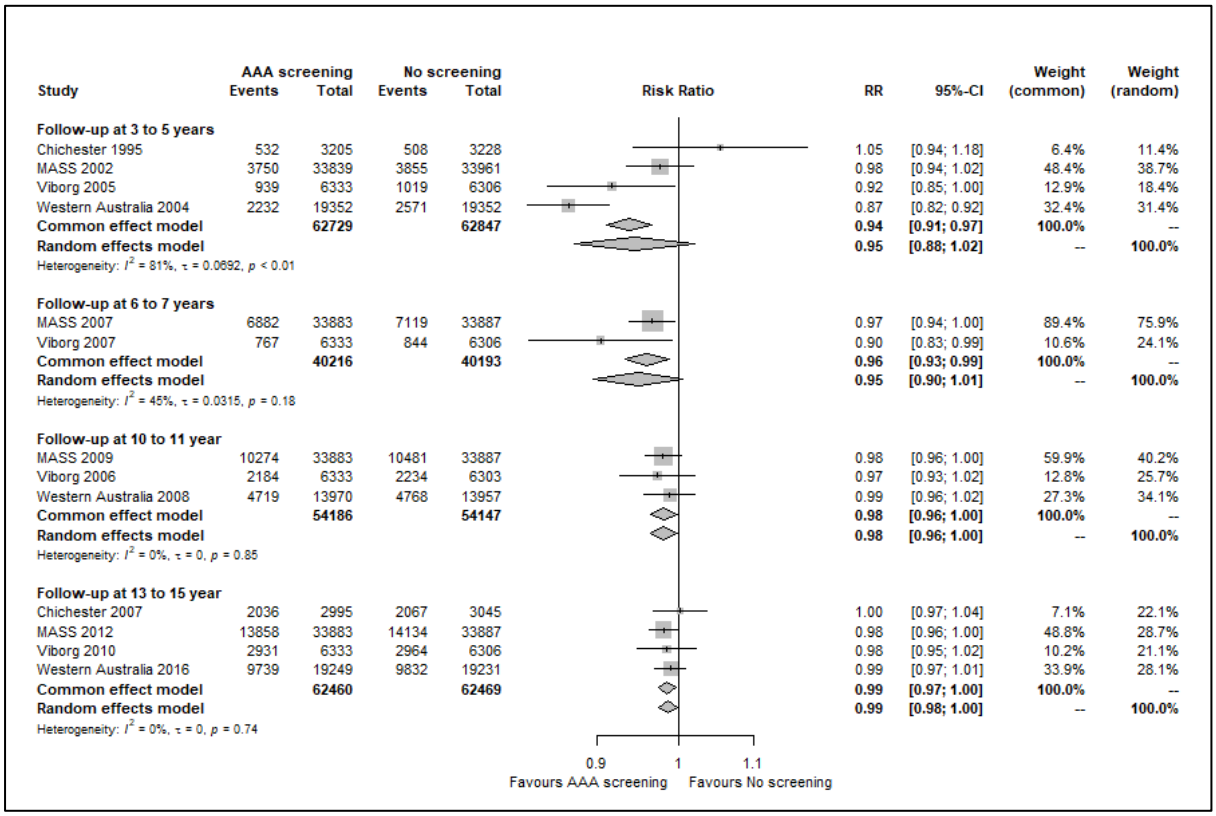
Organisation	Study year(s)	Search date	Review methods	Research questions or aims of relevance to this review	PICO	Included studies of relevance to this review (follow-up†)	Author's conclusion
				a. Does the effect of one-time screening vary between men and women, smokers and non-smokers, older (≥65 years of age) and younger (<65 years of age) adults, adults with and without a family history of AAA, and adults of different races/ethnicities. b. Does the effect of one-time screening vary between different screening approaches (that is, high risk vs low risk status)? **RQ3:** What are the consequences (that is, AAA-related procedures) and harms (that is, mortality because of AAA-related procedures and quality of life) associated with one-time and repeated AAA screening using ultrasound scan?	RQ1: no-screening comparison, or a comparison of different screening approaches (that is, high-risk vs low-risk groups) RQ3: no comparison group was required, however, if a sufficient number of RCTs were found to answer the questions on harms we would not consider uncontrolled studies. O: RQ1: AAA-related mortality, all-cause mortality, and AAA rupture rate RQ3: anxiety from risk labelling, anxiety of mortality, false-positive screening-related procedures, 30-day postoperative mortality, surgical procedures, quality of life, and overdiagnosis-overtreatment.	▪ Western Australia (NR). 2016: N = 4 RCTs: ▪ MASS (NR) ▪ Chichester (NR) ▪ Viborg (NR) ▪ Western Australia (NR). N = 4 observational studies (harms only)	AAA rupture rate, and hence avoids unnecessary AAA-related deaths. The sensitivity analyses also showed that the benefits of AAA screening were more pronounced in men at a mean age of 70 years with a relatively higher prevalence of AAA. Future research should explore the long-term benefits of a targeted AAA screening approach based on risk factors such as age, sex, smoking status, family history, aortic diameter, and baseline risk of rupture.
IQWIG	IQWIG, 2015[287]	1 December 2014	Systematic literature search for systematic reviews. Identification of primary studies from systematic reviews	What is the benefit assessment of screening for AAA using ultrasound examination compared to no screening or another screening strategy with regard to patient-relevant outcomes?	**P:** people who had not previously been diagnosed with AAA **I:** ultrasound screening for AAA **C:** no screening strategy or a different screening strategy (for example other diagnostic procedures) **O:** overall survival, disease-specific survival, morbidity, harm resulting directly and indirectly from screening including consequences of incorrect screening results and	N = 4 SRs n = 4 RCTs ▪ MASS (13.1) ▪ Chichester (15.0) ▪ Viborg (13.0) ▪ Western Australia (3.6).	The present benefit assessment provides evidence of a benefit of ultrasound screening for BAA for men for overall mortality, BAA-related mortality, rupture frequency and number of emergency operations. For those having elective procedures, associated morbidity is an indication of harm from ultrasound screening for men. There is no indication of a benefit of ultrasound screening for BAA for women in terms of overall mortality, rupture frequency, number of emergency operations and number

Organisation	Study year(s)	Search date	Review methods	Research questions or aims of relevance to this review	PICO	Included studies of relevance to this review (follow-up†)	Author's conclusion
					overdiagnosis, health-related quality of life and psychosocial aspects. **S:** RCTs		of elective procedures. No data were available for BAA-related mortality in women. With regard to health-related quality of life and psychosocial aspects, No conclusions could be drawn about the benefits or harms of ultrasound screening for BAA for men or women because the data on health-related quality of life could not be used and there were no data for psychosocial aspects.
NA	Takagi et al. 2010[288]	June 2009	Update of the 2007 Cochrane systematic review	NR	**P:** men **I:** invitation to attend screening for AAA **C:** no invitation to screening for AAA **O:** main outcomes included long-term (≥10 year) mortality **S:** population-based RCTs	N = 4 RCTs ▪ MASS (10) ▪ Chichester (215) ▪ Viborg (14) ▪ Western Australia (11).	The results of our analysis suggest that population-based screening for AAA reduces AAA-related long-term mortality by 4 per 1000 over control in men aged >65 years. Whereas, screening for AAA shows a strong trend toward a significant reduction in all-cause long-term mortality by 5 per 1000, which does not narrowly reach statistical significance.
Cochrane	Cosford et al. 2011[285]	27 July 2007	De novo systematic search	1. To determine the effects of screening asymptomatic people for abdominal aortic aneurysm on their mortality, subsequent treatment for abdominal aortic aneurysm and quality of life. 2. To identify any available information from published data on the cost effectiveness of screening	**P:** people asymptomatic of aortic aneurysm **I:** any screening technique for abdominal aortic aneurysm were eligible, although it was anticipated that trials would focus on ultrasound methods. **C:** No screening **O:** mortality, life expectancy, progression to ruptured aortic aneurysm, complications of surgery including distal embolus, haemorrhage and graft failure, coronary and cerebrovascular events and renal complications, subjective measures including quality of life scores and impact on ability to work, use of resources including hospital stay	N = 4 RCTs ▪ MASS (4.1) ▪ Chichester (2.5) ▪ Viborg (5.1) ▪ Western Australia (3.6).	There is evidence of a significant reduction in mortality from AAA in men aged 65 to 79 years who undergo ultrasound screening. There is insufficient evidence to demonstrate benefit in women. The cost effectiveness may be acceptable, but needs further expert analysis. These findings need careful consideration in judging whether a co-ordinated population-based screening programme should be introduced.

Organisation	Study year(s)	Search date	Review methods	Research questions or aims of relevance to this review	PICO	Included studies of relevance to this review (follow-up†)	Author's conclusion
					and use of intensive care facilities. **S:** Randomised controlled trials		
Health Technology Assessment Ontario	Ontario 2006[227]	August 2005	Update of the 2005 USPSTF systematic review	1. Is population-based AAA screening effective in improving health outcomes in asymptomatic populations? 2. Is AAA screening acceptable to the population? Does this affect the effectiveness the screening programme? 3. What are the harms of screening?	Study designs: ▪ Systematic reviews, RCTs, non-RCTS, or cohort studies that had at least 20 patients. Outcomes of interest: ▪ Effect of screening on AAA rupture incidence ▪ Effect of screening on rates of emergency and elective AAA repair ▪ Effect of screening on AAA-related mortality ▪ Effect of screening on all-cause mortality ▪ Frequency of screening ▪ Case management post-screening related to size of AAA ▪ Risk factors for AAAs and impact on screening ▪ Harms of screening ▪ Quality of life.	N = 1 SR (n = 4 RCTs)	Based on this review, the Medical Advisory Secretariat concluded that there is sufficient evidence to determine that AAA screening using ultrasound is effective and reduces negative health outcomes associated with the condition. Moreover, screening for AAA is cost-effective, comparing favourably for the cost of per life year gained for screening programmes for cervical cancer, hypertension, and breast cancer that are in practice in Ontario, with a high degree of compliance, and can be undertaken with a minimal effort at fewer than 10 minutes to screen each patient. Overall, the clinical utility of an invitation to use ultrasound screening to identify AAA in men aged 65 to 74 is effective at reducing AAA-attributable mortality. The benefit of screening women is not yet established. However, Ontario data indicate several areas of concern including population prevalence, detection of AAA in women, and case management of AAA in women in terms of age cut offs for screening and natural history of disease associated with age of rupture.

Key: AAA – abdominal aortic aneurysm; HRQoL – health-related quality of life; IQWIG – Institute for Quality and Efficiency in Health Care; KQ – key question; MASS – multicentre aneurysm screening study; PICO – Population Intervention Comparator Outcome; RCT – randomised controlled trial; RQ - research question; SR – systematic review; USPSTF - U.S. Preventive Services Task Force
† Follow-up is reported in years.

Figure A4 Fixed and random effects meta-analysis of all-cause mortality in men for AAA screening compared with no screening, stratified by length of follow-up



Key: AAA – abdominal aortic aneurysm; MASS - multicentre aneurysm screening study; RR – risk ratio.

Table A5 Summary of clinical outcomes from de novo review of studies

Screening programme (study)	Publication	Follow-Up (Yrs)	Group	AAA Mortality Rate*	AAA Rupture Rate*	All-cause Mortality*	Elective Surgery Rate*	Emergency Surgery Rate*	30 Day Mortality (%)
Norway	Mansoor (2023)[84]	5-10	Screened (n=13,215)	15	30	1,294	530	15	1.4%
Swedish National Screening Programme	Hultgren (2020)[78]	1-5	Screened (n=55,691)	2	4	NR	268	4	0.7%
			Non-attenders (n=15,702)	19	96	NR	369	96	4.1%
	Johansson (2018)[279]	5-10	Screened (n=25,265)	Absolute difference reported only†	Absolute difference reported only†	NR	Absolute difference reported only†	NR	NR
			Unscreened (n=106,087)			NR		NR	NR
	Wanhainen (2016)[8]	1-5	Screened (n=253,896)	52 (py)	NR	NR	283‡		0.9%
			Unscreened (n=49,061)	67 (py)	NR	NR	NR	NR	NR
	Linne (2014)[291]	NR	Screen detected AAA surgical treatment (n=350)	NR	NR	NR	NR	NR	0.6%
			Non-screen detected AAA surgical treatment (n=350)	NR	NR	NR	NR	NR	1.4%
	Svensjo (2013)[87]	5-10	Screened (n=2,736)	0	0	5,446	804	37	0%

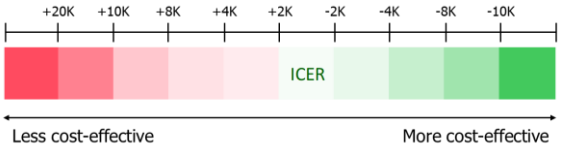
Screening programme (study)	Publication	Follow-Up (Yrs)	Group	AAA Mortality Rate*	AAA Rupture Rate*	All-cause Mortality*	Elective Surgery Rate*	Emergency Surgery Rate*	30 Day Mortality (%)
			Non-attenders (n=532)	188	188	18,045	188	188	50.0%
National AAA Screening Programme, UK	Meecham (2021)[264]*	1-5	Screened Large AAA (n=3,026)	1.4%	0.3%	NR	83.2%	3.5%	1.9%
	Oliver-Williams (2019)[265]§	1-5	Screened small-med AAA (n=18,652)	0.2%	0.2%	5.3%	7.0%		NR
The Gloucestershire Aneurysm Screening Programme, UK	Oliver-Williams (2018)[96]§	5-10	Screened (n=81,150)	NR	NR	604	741	44	NR
	Darwood (2013)[75]§	5-10	Screened (n=52,690)	8.0%	9.0%	42.0%	53.0%	3.0%	5.5%
Highland Aortic Aneurysm Screening Programme. UK	Duncan (2012)[31]	5-10	Screened (n=8,355)	135	NR	8,028	NR	NR	NR
	Duncan (2005)[76]	1-5	Screened (n=8,355)	NR	NR	NR	646	NR	NR
The Huntingdon Aneurysm Screening Programme, UK	Wilmink (2006)[280]	> 10	Screened (n=13,634)	14 (py)	213	NR	858	88	NR
			Unscreened (n=NR)	56 (py)	NR	NR	NR	NR	NR

Key: NR - Not reported; Yrs - Years; py - person-years.
* Results are expressed per 100,000 persons screened throughout, except where otherwise stated.
† Johansson et al. (2018) reported the outcomes in terms of the absolute difference in rates between screened population and unscreened population. Their results are reported narratively in the respective section for each outcome.
‡ Wanhainen et al. (2016) reported total surgeries performed with no distinction between elective and emergency surgery.
§ Meecham et al. (2021) reports data for men with large AAAs only, values are expressed as a percentage of the group with large AAAs. Oliver-Williams et al. (2019) and (2017) reports data for men with small to medium AAAs, values are expressed as a percentage of the group with small to medium AAAs. Darwood et al. (2013) reports data for men with at least 10 years of follow-up, values are expressed as a percentage of the group with screen-detected AAAs with at least 10 years of follow-up.

Supplementary Appendix for Chapter 5

Table A6 Sensitivity and scenarios analysis in included studies.

	Author, Year	Ehlers, 2009	Giardina, 2011	Mäklin, 2011	Spronk, 2011 (NLD)	Spronk, 2011 (NOR)	Svensjo, 2013	SBU, 2015	Zarrouk, 2016	Hager, 2017	Nair, 2019	NIPH, 2020	Reile, 2020	Daroudi, 2021	Vervoort, 2024
AAA prevalence	⬆		-							-					-
	⬇		-							-					-
Proportion of large AAA	⬆		-		-	-	-	-	-	-		-	-	-	-
	⬇		-		-	-	-	-	-	-		-	-	-	-
Screening uptake	⬆				-	-	-	-	-	-		-	-	-	-
	⬇				-	-	-	-	-	-		-	-	-	
Prehospital death	⬆		-		-	-		-	-	-	-	-	-	-	-
	⬇		-		-	-		-	-	-	-	-	-	-	CS
US sensitivity	⬆	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	⬇	-	-	-	-	-	-	-	-	-	-	-	-	-	
Follow-up compliance	⬆	-	-	-			-	-	-	-		-	-	-	-
	⬇	-	-	-			-	-	-	-		-	-	-	
Sub-AAA prevalence	⬆	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	⬇	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Opportunistic detection	⬆							-		-			-		-
	⬇							-		-			-		-
Invitation cost	⬆		-		-	-	-	-	-	-			-	-	-
	⬇		-		-	-	-	-	-	-			-	-	-
US screening cost	⬆	-	-		-	-		-	-	-		-	-		-
	⬇	-	-		-	-		-		-		-	-		-
Cost of EVAR	⬆	-	-		-	-	-	-	-	-	-	-	-		-
	⬇	-	-		-	-	-	-	-	-	-	-	-		-
Cost of emergency repair	⬆		-					-	-	-		-	-	-	-
	⬇		-					-	-	-		-	-	-	-
Cost of elective surgery	⬆		-					-	-	-		-	-	-	-
	⬇		-					-	-	-		-	-	-	-
Rupture rate of large AAA	⬆	-			-	-	-	-		-		-	-		-
	⬇	-			-	-	-	-		-		-	-		-
Post-operative cost	⬆	-	-	-	-	-	-	-	-	-	-		-	-	-
	⬇	-	-	-	-	-	-	-	-	-	-		-	-	-
Disccount rate	⬆						-				-	-	-		-
	⬇						-				-	-	-		-
HRQoL after AAA detection	⬇	-	-	-	-	-	-	-	-		-	-	D	-	-
HRQoL after AAA repair	⬇	-	-	-	-	-	-				-	-		-	-



Key: AAA – abdominal aortic aneurysm; CS – cost-saving; EVAR – endovascular aneurysm repair; HRQoL – health related quality of life; D – dominated; US – ultrasound; ⬆ ⬇ – indicates an increase or decrease of the parameter in relation to the base case analysis.

The colours illustrate the difference in thousands of euros between the adjusted ICER in the base case analysis and the adjusted ICER in the sensitivity analysis. Negative differences (lower ICERs) are represented by increasingly darker shades of green as it moves further away from the base case ICER. Conversely, a positive difference (higher ICERs), are represented by increasingly darker shades of red as it moves further away from the base case ICER.

Table A7 Base case and sensitivity analysis of ICERs in CUAs by AAA prevalence in the original context and the Irish context.

Author, year	Country	AAA prevalence	Original context			Irish Context		
			Unadjusted ICER	WTP threshold	Interpretation	Adjusted ICER*	Interpretation WTP €20,000†	Interpretation WTP €45,000†
Ehlers, 2009	Denmark	4.00%	£ 43,485	£ 30,000	✗ NCE	€ 61,956	✗ NCE	✗ NCE
Linholt, 2010	Denmark	4.00%	€ 179	€ 5,000	✓ CE	€ 255‡	✓ CE	✓ CE
Badger, 2011	UK	5.40%	£ 3,020	NR	✓ CE	€ 5,036‡	✓ CE	✓ CE
Giardina, 2011	Italy	2.94%	€ 5,673	€ 20,000	✓ CE	€ 6,050§‡	✓ CE	✓ CE
Sogaard, 2012	Denmark	3.30%	£ 555	£ 20,000	✓ CE	€ 671	✓ CE	✓ CE
Svensjo, 2013	Sweden	1.70%	€ 14,706	€ 25,000	✓ CE	€ 12,866	✓ CE	✓ CE
Glover, 2014	UK	1.50%	£ 7,370	£ 20,000	✓ CE	€ 11,935	✓ CE	✓ CE
SBU, 2015	Sweden	1.70%	SEK 70,796	SEK 100,000	✓ CE	€ 6,927	✓ CE	✓ CE
Zarrouk, 2016	Sweden	1.80%	€ 15,710	€ 20,000	✓ CE	€ 13,984	✓ CE	✓ CE
Glover, 2017	UK	1.34%	£ 6,352	£ 20,000	✓ CE	€ 10,286	✓ CE	✓ CE
Hager, 2017	Sweden	2.00%	€ 6,325	€ 24,000	✓ CE	€ 5,599	✓ CE	✓ CE
Nair, 2019	New Zealand	2.50%	NZD 15,300	NZD 45,000	✓ CE	€ 10,083	✓ CE	✓ CE
Reile, 2020	Estonia	2.20%	€ 17,303	€ 30,000	✓ CE	€ 30,645	✗ NCE	✓ CE
NIPH, 2020	Norway	2.50%	NOK 154,450	NOK 200,000	✓ CE	€ 18,424	✓ CE	✓ CE
Daroudi, 2021	Iran	3.00%	$ 5,566	$ 6,000	✓ CE	€ 12,794‖	✓ CE	✓ CE
AQuAS, 2023	Spain	4.70%	€ 152	€ 20,000	✓ CE	€ 206	✓ CE	✓ CE
Vervoort, 2024	Canada	1.50%	CAD 2,418	CAD 50,000	✓ CE	€ 1,409	✓ CE	✓ CE

Key: AAA – abdominal aortic aneurysm; CAD – Canadian dollar; CE – cost effective; DKK – Danish Krone; ICER – incremental cost-effectiveness ratio; QALY – quality-adjusted life year; NCE – Not cost effective; NOK – Norwegian Krone; NZD – New Zealand dollar; SEK – Swedish Krone; UK – United Kingdom; USA – United States of America; WTP – willingness to pay.

* Costs were adjusted based on national consumer price indices, unless specified otherwise, and purchasing power parities in accordance with national HTA guidelines.

† WTP thresholds of €20,000 and €45,000 per QALY gained, commonly employed in Ireland, were used as reference points to guide interpretation of cost effectiveness.

‡ When the base cost year was not provided, it was estimated by subtracting the median time elapsed between the base cost year and the publication year, as reported in other studies, from the year of publication.

§ A national consumer price index using the same base year since 2000 was not found. We used the consumer price index reported by the OECD.

‖ No consumer price indices where found for Iran. A decision was made to adjust the cost based on the USA consumer price index.

Supplementary Appendix for Chapter 6

Table A8 Key assumptions

Assumption	Rationale	Source
Men without screen-detected AAA will not experience AAA symptoms or rupture during their lifetime.	Based on the epidemiology of disease, it is unlikely that those with an aortic diameter of less than 2.5 cm at age 65 years would develop clinically significant AAA resulting in AAA rupture during their lifetime. This is consistent with the approach adopted in some CUAs included in Chapter 5.[363, 370]	Chapter 2 (Epidemiology)
Diagnosis of AAA has no impact on non-AAA-related mortality.	Evidence from Chapter 4 suggests that screening for AAA results in a reduction in AAA-related, but not all-cause mortality. It is plausible that aggressive cardiovascular risk factor management in those with screen-detected AAA, as recommended by the ESVS clinical guidelines, may reduce the risk of disease progression. However, no RCTs have been conducted to evaluate the effects of such medications on mortality in AAA patients. As a conservative approach, it was assumed that screening for AAA did not have additional benefits for cardiovascular or all-cause mortality.	Assumption (see Chapter 3, section 3.3.2)
80% of the eligible population would accept the invitation to screening, and would continue to participate in the programme thereafter.	High attendance for baseline screening (≈80%) and small and medium AAA surveillance scans was recorded in the NAAASP for the period 2017 to 2023 (≈95%). As a simplifying assumption, it was assumed that those who accept the initial invitation to screening continue to participate in surveillance.	NAAASP
Among screening participants, all cases of AAA are detected by abdominal ultrasound screening.	The sensitivity and specificity of abdominal ultrasound for AAA was assumed to be 100%, given that abdominal ultrasound is the index test and the reference standard for cases with suspected unruptured AAA. As described in Chapters 3 and 7, numerous factors such as operator education and training, robust screening protocols, screening volumes and equipment specification can influence test performance, and thus test accuracy.	Assumption
The aorta will not be successfully visualised for approximately 1.7% of men participating in screening.	The aorta may not be successfully visualised during screening due to the presence of excess bowel gas or abdominal obesity. Evidence from the NAAASP demonstrates a reduction in the proportion of non-visualised screens over time, possibly attributable to increased experience and training, process improvements, and technological advancements in	NAAASP

Assumption	Rationale	Source
	ultrasound measurement. As a conservative approach, it was assumed that the percentage of non-visualised screens would be the same as the early post-implementation phase in the NAAASP.	
AAA screening has no impact on small and medium AAA rupture.	The rupture risk for small and medium AAA can be observed from surveillance studies as there is no active intervention until the aortic diameter reaches ≥5.5 cm. As a conservative approach it was assumed that there was no difference between small and medium AAA rupture rates between the screened and unscreened cohorts.	Leone 2023;[395] The RESCAN Collaborators 2013[55]
Cases with an AAA <55 mm would not be offered elective surgical repair.	For the purposes of the BIA, it was estimated that AAA growth rate increases linearly with increasing aortic diameter based on evidence from a 2024 systematic review, corresponding to an average growth rate of approximately 2.38 mm/year.[56] A strict threshold for AAA surgical repair was also assumed (that is, aortic diameter ≥55 mm). In clinical practice, a proportion of men may be referred prior to the aortic diameter reaching 55 mm due to evidence of rapid AAA growth (that is, >1 cm per year, or four to five times the average growth rate) or clinical symptoms during surveillance.[148] Definitions of rapid AAA growth vary in the literature. In the absence of an AAA screening programme in Ireland, it is not possible to estimate the proportion of AAAs that are considered fast growing, due to the requirement for systematic follow-up at defined intervals to accurately measure growth rate. Importantly, rapid growth of aortic aneurysms is considered uncommon, and where recorded may be due to differences in measurements techniques or measurement error.[615, 616] Therefore, the practical implications of this simplifying assumption are minimal.	
In the screened cohort, cases with a large AAA undergo elective surgical repair.	The natural history of large AAA cannot be estimated from RCTs or observational studies. Those with a large AAA who are eligible for surgical repair would be treated prior to AAA rupture (that is, the number of ruptures in the absence of screening cannot be known). In an unscreened cohort, the total number of large AAAs is unknown. As a result, in the literature, the estimated large AAA rupture rate is based on the rupture rate in men identified through screening or incidental diagnosis that were ineligible for surgical intervention and managed conservatively.[394, 395] This subpopulation may have a higher burden of disease (for example, comorbidities resulting in surgical contra-indication), and thus experience worse health outcomes. Therefore, the rupture risk in this subpopulation may not reflect the rupture risk in the population eligible for surgery. In a real world setting, as the detection rate increases (through screening or incidental diagnosis), the observed rate of large AAA rupture would likely decrease (that is, they are not independent variables). In a screened population, the large AAA rupture rate is dependent on factors such as the turn-down rate and time to surgical intervention. In the absence of robust evidence regarding the of large AAA rupture in a contemporary screened population, it was assumed that all cases identified through an AAA screening programme that are eligible for surgical repair would	Assumption

Assumption	Rationale	Source
	undergo elective surgery. The available national literature suggests that the majority of patients whose medical comorbidities preclude surgical intervention die from other causes.[389] Thus, with consideration to the high pre-hospital mortality rate associated with out-of-hospital rupture (Chapter 2, section 2.4.3), and the likelihood of death from other causes, costs associated with emergency repair of ruptured AAA in screened men considered ineligible for elective surgical repair would likely be low.	
Uptake is independent of AAA risk.	People who are typically at higher risk of a condition may be less likely to participate in screening, which may reduce screening yield.[617] However, the model does not account for the potential for differential screening uptake according to factors such as socioeconomic status. Modelling interactions between socioeconomic status, disease prevalence, and screening behaviour would require detailed subgroup-specific data, which were not readily available. While differential uptake across socioeconomic groups likely exists, the impact of this variation is likely attenuated when the overall uptake is high. Failure to capture the potential for differential uptake is unlikely to impact the findings of this BIA given that variation in AAA prevalence did not significantly affect the overall incremental budget impact.	

Key: AAA – Abdominal Aortic Aneurysm; BIA – budget impact analysis; CUA – cost utility analysis; NAAAP – NHS Abdominal Aortic Aneurysm Screening Programme.

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