Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Screening for abdominal aortic aneurysm in men: Protocol for a health technology assessment

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About the Health Information and Quality Authority (HIQA)

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 the Minister for Children, Equality, Disability, Integration and Youth, 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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1 Introduction

1.1 Background

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.

1.2 Condition and screening technology

An abdominal aortic aneurysm (AAA) is a pathological condition characterised by the weakening of the entire wall of the abdominal segment of the aorta, the largest artery in the body.[1, 2] This weakening causes permanent and irreversible dilatation (that is, where the artery swells to an abnormal size) of this segment of the aorta. Most patients with an AAA are asymptomatic, posing a life-threatening risk of rupture if not detected. Risk factors strongly associated with the development of an AAA include being aged 65 years and older, male sex, history of smoking, family history of AAA, obesity, and detection of other large vessel aneurysms.[3-7]

In developed countries, AAA affects 1.4% to 3.2% of people aged 65 years and older.[8] The prevalence has been estimated to be three to six times higher in men over 65 years of age than in women of a similar age.[9-12] In Ireland, the prevalence of AAA is unclear due to the absence of a national vascular database. Pilot studies of AAA screening in men aged 55 to 75 years conducted in the Irish context between 2006 and 2008 reported a prevalence of between 1.3% and 4.2%.[13, 14]

The morbidity associated with AAA arises from the growth of the aneurysm, which can lead to compression of nearby structures, causing pain and discomfort.[1, 15] However, the most critical complication is rupture of the aneurysm; this can lead to massive internal bleeding with a fatality rate exceeding 80%.[16] In 2018, the age-standardised AAA-related mortality rate in the UK was approximately 15 and 5 cases per 100,000 population for men and women, respectively.[17]

Due to the relatively high prevalence in older adults and significant mortality rates associated with AAA rupture, screening initiatives aiming to reduce the burden of this condition started to be explored in the 1990s. Abdominal ultrasound is commonly used to diagnose AAA and may also be used in screening; this form of testing uses sound waves to examine blood flow through the aorta. Ultrasound is the

primary screening method according to recommendations from the European Society for Vascular Surgery (ESVS) and the US Preventive Services Task Force (USPSTF) as it is non-invasive, does not involve exposure to ionising radiation, is highly sensitive and is simple to perform.[16, 18] At least four major randomised controlled trials (RCTs) have been conducted to assess the effectiveness of ultrasound screening for AAA compared with no systematic screening,[19-22] with evidence to suggest that screening was associated with decreased AAA-related mortality and rupture rates.[18]

Following on from these findings, in the early 2000s, some countries including the UK and Sweden implemented national population-based one-time ultrasound screening programmes for AAA in men aged 65.[23, 24] Additionally, international organisations such as ESVS,[16] the USPSTF and the American College of Cardiology (ACC) have endorsed the implementation of similar programmes.[25]

However, recent epidemiological studies have indicated a decrease in the prevalence and incidence of AAA since these RCTs were undertaken, due to widespread improvements in the management of cardiovascular risk factors and a reduction in smoking.[3, 8, 26] Thus, the clinical and cost effectiveness of such programmes in today's context is unclear due to the potential for changes in clinical practice and population characteristics over time.[27] Consequently, a detailed analysis of the clinical and cost effectiveness of an AAA screening programme in the Irish context is required to inform decision-making regarding the potential introduction of such a programme.

In response to submissions received as part of the 2021 and 2022 annual calls, at the request of the NSAC, HIQA agreed to undertake a HTA of one-time population-based ultrasound screening for AAA in men. Given the potential significant clinical, budgetary and organisational implications associated with the introduction of population-based one-time ultrasound screening for AAA, a full HTA was considered necessary. The scope of the HTA was agreed with the NSAC following preliminary scoping exercises. With consideration to the evidence of a lower prevalence of AAA in women than men, and the limited evidence base in women, the scope of this assessment will be restricted to men. Although AAA screening programmes elsewhere in Europe invite men aged 65 years, the specific age or age group targeted by screening has not been prespecified. This will 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. In addition, a systematic review published by the USPSTF in 2019 did not identify any high-quality evidence in relation to the effectiveness of rescreening for AAA in a previously screened, asymptomatic population.[28] Preliminary scoping exercises also confirmed that existing population-based screening programmes in place in other European countries do not include rescreening as part of the screening algorithm.[23,

[24] Therefore, it was considered reasonable to limit the scope of this HTA to one-time population-based ultrasound screening in men only. This protocol outlines the methodological approach that will be adopted by HIQA's evaluation team to synthesise the evidence and develop advice to the NSAC on this topic.

2 Evidence synthesis approach

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology. It does so in a systematic, transparent, unbiased and robust manner. HTAs are designed to inform safe and effective health policies that are both patient-focused and achieve the best value.

The HTAs conducted by HIQA are based on the domains outlined within the EUnetHTA Core Model. In this HTA the following domains will be considered:[29]

- epidemiology and burden of disease
- description of the technology
- clinical effectiveness and safety
- costs and economic evaluation
- organisational considerations
- social and ethical implications.

2.1 Aims and objectives

The overarching aim of this HTA is to estimate the clinical effectiveness and cost effectiveness of screening for AAA in men in Ireland. The specific objectives of this HTA are as follows:

- 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
- describe the clinical effectiveness and safety of screening for AAA in men
- review the international literature on cost effectiveness of screening for AAA in men

- 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.

The NSAC outlines 20 criteria for appraising the viability, effectiveness and appropriateness of a screening programme.[30] These criteria will be considered under the relevant HTA domains in order to inform consideration by the NSAC regarding the extent to which ultrasound screening for AAA in men fulfils these criteria.

2.2 Stakeholder engagement

In line with HIQA guidelines for stakeholder engagement, multiple engagement strategies, including convening an expert advisory group (EAG) and engaging in public consultation, will be employed to ensure that the HTA takes into account all relevant and important issues from the perspectives of multiple stakeholders.[31]

2.2.1 Establishment of the expert advisory group

An appropriately represented EAG will be convened as a source of expertise to inform the interpretation of the evidence and development of the advice to the NSAC. This group will comprise nominees from a range of stakeholder organisations, including patient representation, public representation, healthcare providers, and clinical and public health experts.

2.2.2 Public and targeted consultation

A public and targeted consultation will be conducted to provide stakeholders not directly involved in the HTA with an opportunity to give feedback on a draft version of the report. The aim of the consultation will be to obtain feedback on any important issues that may not have been adequately addressed in the draft HTA and, based on the feedback received, to expand coverage of these issues in the final HTA report submitted to the NSAC, where appropriate. The feedback received during the consultation and HIQA's responses to the issues raised, including any changes made to the report as a result, will be published on the HIQA website in a Statement of Outcomes report alongside the final HTA.

3 Epidemiology

The purpose of this chapter within the HTA is to provide an overview of the epidemiology of AAA. The specific aims of this chapter will be to describe:

- the aetiology, classification, symptoms and natural progression of AAA
- the burden of AAA (that is, prevalence, morbidity and mortality).

Where available, national datasets will be used to estimate the burden of AAA in Ireland. Data on the size of the eligible population and AAA-related mortality will be sought from the Central Statistics Office (CSO).

If possible, data from the Hospitalised In-Patient Enquiry (HIPE) system will be used to understand the current level of surgical activity related to elective or emergency surgeries for AAA repair in public hospitals in Ireland. National data will be supplemented with data from the international literature that is considered broadly applicable to the Irish context.

The epidemiological data from this chapter will also be used to inform the inputs to the economic evaluation (section 6) and the estimated resources required (sections 6 and 7) to introduce an ultrasound screening programme for AAA in men in Ireland.

4 Description of the technology

The purpose of this chapter is to provide an overview of a one-time ultrasound screening programme for AAA in men. The specific aims of this chapter will be to describe:

- the current clinical care pathway for diagnosis and management of AAA in Ireland
- the proposed care pathway for an ultrasound screening programme for AAA
- international policy and guidelines in the use of ultrasound screening for AAA (see section 4.1).

As part of the description of the care pathways, a description of AAA detection will be provided, including consideration of the test accuracy of ultrasound.

4.1 Review of international policy and guidelines

An overview of current international screening policies and guidelines, where available, will be provided. The overview will be informed by a search of grey literature sources (for example, national public health organisations, the websites of government departments and relevant agencies), and the peer-reviewed literature using scoping methodology. The specific objectives of this review will be to identify:

1. guidelines from professional societies or organisations in relation to screening for AAA
2. countries or regions in which systematic screening for AAA has been implemented either as a targeted or population-based screening programme.

In relation to the first objective, a search for guidelines, position papers, recommendations and standards from professional societies or organisations reporting on screening for AAA will be conducted. Only guidance or recommendations generated using evidence-based methods (for example, literature reviews, systematic reviews or expert consensus) will be considered. Information of interest will include recommendations on the target population and the care pathway following a positive screening test result (for example, thresholds for intervention). The following exclusion criteria will be applied:

- guidelines that have been replaced by updated guidance (that is, where more than one guidance documented from a professional society is identified, only the most recent document will be included)
- guidelines specific to rescreening for AAA
- guidelines specific to treatment of AAA
- context-specific guidelines (for example, an individual hospital or hospital group)
- guidelines specific to low- and middle-income countries.

In relation to the second objective, the following information will be extracted, where available:

- the status of the screening programme (for example, under consideration, piloting, implemented)
- level of implementation (for example, local, regional, national)
- the population being screened (for example, gender, age and or targeted screening)
- the care pathway following a positive screening test result
- any other relevant characteristics identified during data extraction.

Guidelines intended for use in the European context or considered transferable to the European context will be considered eligible for inclusion. The overview of international practice will focus on the following countries deemed to be of most relevance to Ireland, based on a combination of factors including geographical proximity to Ireland, population size, European Union membership and or availability of documents in English, namely:

EU/EEA

- Austria
- Belgium
- Denmark
- Finland
- France
- Germany
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- Switzerland.

Non-EU

- Australia
- Canada
- New Zealand
- United Kingdom.

5 Clinical effectiveness and safety of screening

Preliminary scoping identified a number of systematic reviews investigating the clinical effectiveness of screening, including a 2019 systematic review from the USPSTF.[28, 32] In line with the hierarchy of evidence, published reviews on the effectiveness of one-time versus no systematic screening for AAA have largely limited their scope in terms of study design to RCT evidence. These RCTs began in the 1980s and 1990s. Thus, these trials may not reflect the current clinical context (for example, reductions in smoking, and improved cardiovascular risk factor management over time). Data from population-based observational studies may provide additional information relevant to the current clinical context.

5.1 Research question

The aim of this review is 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 5.1).

The potential for differences according to age will be investigated in subgroup analyses, if sufficient data are available.

Table 5.1 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	*Comparative and non-comparative studies* ▪ 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), nRCTs are trials in which participants are allocated to different groups for comparison using a method that is not random (for example, chart number).[33]

‡ 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 will be considered population-based if participants were enrolled based on geographical location (e.g., an entire region or country), as opposed to healthcare setting (e.g., hospital-based enrolment).[34]

5.2 Search strategy and study selection

Electronic searches will be conducted in MEDLINE (EBSCOhost), CINAHL (EBSCOhost), PsycINFO (EBSCOhost), Embase (Elsevier), The Cochrane Library, the World Health Organization's (WHO) ICTRP portal and ClinicalTrials.gov supplemented by a grey literature search of national and international electronic sources. The electronic search strategy was developed by a librarian and was peer reviewed by a second librarian using the PRESS tool.[35] The complete electronic search strategy for all databases is available on Zenodo.[36] The structured grey literature search will include the Turning Research into Practice (TRIP) database,

International Network of Agencies for Health Technology Assessment (INAHTA) HTA database, LENUS (the Irish Health Research repository), and websites of HTA agencies. Forward citation searching and searching of the reference lists of included studies will also be undertaken.

Studies will be considered eligible for inclusion in accordance with the hierarchy of evidence. If a high-quality systematic review is identified, it will be used to inform the estimated effectiveness and safety of screening for AAA in men. If new studies or long-term follow-up data have been published since identified reviews were undertaken, an update will be considered. If identified systematic reviews include a subset of study designs of interest only (for example, RCTs), a de novo review of other study designs (for example, non-randomised controlled trials, comparative observational studies or population-based non-comparative studies) may be undertaken to supplement the evidence from identified systematic reviews. Only population-based single-arm observational studies will be considered eligible for inclusion — defined according to geographic region, age and sex.

Exclusion criteria

The following exclusion criteria will be applied:

- studies investigating the effectiveness of opportunistic screening for AAA (that is, screening offered as part of standard care if and when the patient interacts with the healthcare system for an unrelated reason)
- studies investigating the effectiveness of multicomponent cardiovascular screening programmes (for example, hypertension and abdominal aortic aneurysm), unless disaggregated data are available
- studies undertaken in symptomatic populations, populations with known risk factors (that is, targeted screening), or populations with a previous diagnosis of AAA
- studies using or comparing the effectiveness of different screening modalities (for example, physical examination, computed tomography or magnetic resonance imaging)
- studies investigating the effectiveness of rescreening, screening intervals or surveillance intervals
- observational single-arm studies that are not population-based
- letters, editorials, commentaries and conference abstracts
- papers not available in English for which an adequate English translation cannot be obtained.

5.3 Data extraction and quality appraisal

Data will be extracted using a standardised, pre-piloted electronic data extraction form. In addition to the outcomes presented in Table 5.1, the following study and population characteristics will be extracted: coverage/uptake of screening, number of participants and loss to follow-up, inclusion and exclusion criteria, baseline characteristics (for example, comorbidities), care pathway (for example, frequency of surveillance and criteria for surgical intervention).

The appropriate quality appraisal tool will depend on the study designs included, as outlined in Table 5.2. No validated quality appraisal tool tailored specifically to population-based non-comparative observational studies was identified. Unless a more appropriate tool is identified during the conduct of this HTA, key criteria for an effective screening programme set out by the WHO will be used to guide assessment of the conduct and reporting of single-arm population-based screening studies.[37] Adaptation of these criteria to reflect the objectives of this review will be necessary.

Table 5.2 Quality appraisal tools according to study design

Study design	Quality appraisal tool
Systematic review	The Risk Of Bias In Systematic reviews (ROBIS)[38]
Randomised controlled trial	Risk of Bias 2.0[39]
Non-randomised studies of interventions	Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I)[40]
Single-arm observational studies	No formal quality appraisal tool identified

5.4 Data synthesis

Where sufficient data are available, meta-analysis will be used to generate a pooled effect estimate. Results for fixed effects and or random effects models will be presented, as appropriate. Statistical heterogeneity will be assessed using the I^2 statistic, in line with Cochrane methodology.[41]

Where limited or heterogeneous data are available, results will be synthesised narratively.

6 Cost effectiveness and affordability

6.1 Review of cost effectiveness results and methods

Three systematic reviews were identified during preliminary scoping that considered the cost effectiveness of screening for AAA.[42-44] However, published systematic reviews were limited in their scope to reporting only the results, specifically, of

economic evaluations (that is, reporting the incremental cost effectiveness ratio (ICER)), or did not contain the most recent literature.[42] As such, insufficient information was reported by existing systematic reviews relating to the methodology used in included economic evaluations (for example, model structure, assumptions and input parameters) to support interpretation of results and development of a de novo Irish-specific economic model. Furthermore, a number of economic evaluations of screening for AAA in men have been conducted since the previous systematic reviews were published.[45-48] Therefore, a de novo systematic review is warranted.

The aim of this review is to synthesise and critically appraise the i) methods and ii) results of published cost effectiveness analyses (CEA) and cost utility analyses (CUA) reporting on the cost effectiveness of screening for AAA in men (where the comparator is no systematic screening). To facilitate the first objective, the main information of interest to be extracted will include the:

- model structure (for example, health states, time horizon), and
- approach to generation of key model inputs (for example, health state valuation, assumptions regarding resource utilisation).

Of note, all model inputs will not be extracted from included studies. Extraction of specific model inputs will be dependent on their transferability to the Irish context. This will be performed in order to inform the model structure of and inputs to an Irish-specific CUA.

For the second objective, the main outcome of interest will be the ICER (for example, cost per life-year gained or cost per quality-adjusted life-year) or net monetary benefit (NMB). The specific research question is outlined in Table 6.1.

Table 6.1 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.

6.1.1 Search strategy and study selection

Electronic searches will be conducted in MEDLINE (EBSCOhost), CINAHL (EBSSCOhost), PsycINFO (EBSCOhost), Embase (Elsevier), the Cochrane Library, WHO's ICTRP portal and ClinicalTrials.gov. These will be supplemented by a search of grey literature including Google Scholar, national and HTA electronic sources. Reference lists of included studies will be searched for potentially relevant citations.

Economic evaluations can be considered partial (that is, costing studies in which only the cost of healthcare interventions are analysed) or full (that is, studies in which both costs and consequences of two or more alternative strategies are compared).[49] Full economic evaluations are considered the optimal type to inform decision-making. Therefore, only full economic evaluations will be considered eligible for inclusion.

Selection of studies

Articles will be assessed for eligibility according to the criteria outlined in Table 6.1.

The following exclusion criteria will be applied:

- partial economic evaluations
- economic evaluations that investigate the cost effectiveness of rescreening for AAA in a previously screened, asymptomatic population
- economic evaluations that investigate the cost effectiveness of screening for AAA in men and women, unless sex-disaggregated data are available
- economic evaluations that investigate the cost effectiveness of multicomponent screening programmes, unless disaggregated data are available
- commentaries, letters, conference papers and conference abstracts
- papers not available in English for which an adequate English translation cannot be obtained.

6.1.2 Data extraction and critical appraisal

Study characteristics, methods and results will be extracted using a standardised, pre-piloted electronic data extraction form. The preferred cost effectiveness outcome measure will be the cost per quality-adjusted life year (QALY) gained. Where QALYs are not used as the effect measure, other outcomes (for example, cost per life year gained (LYG) or cost per hospitalisation avoided) will be extracted.

Assessment of the methodological quality of economic evaluations will be carried out using the Philips checklist for model-based studies.[50] If any empirical evidence-

based studies are identified (that is, economic evaluations without a modelling component), an alternative tool will be identified, consistent with ISPOR guidance.[49]

6.1.3 Data synthesis

Model characteristics including the structure and approach to generating input data will be synthesised narratively. In line with ISPOR 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 will be synthesised separately.[49] To facilitate comparability of the results across countries and years, costs will be inflated, where appropriate, and converted to Irish Euro in accordance with national HTA guidelines.[51] Willingness-to-pay (WTP) thresholds of €20,000 and €45,000 per QALY gained, commonly employed in Ireland and consistent with empirically-based thresholds in other high income countries,[52, 53] will be adopted as reference points to guide interpretation of cost effectiveness. Unadjusted ICERs as reported by included studies and context-specific WTP will also be reported.

6.2 Economic evaluation

An economic evaluation comprising a CUA and budget impact analysis will be conducted to estimate the cost effectiveness and budget impact of screening for AAA in men compared with no systematic screening from the perspective of the Health Service Executive (HSE). A summary of model characteristics for each of these analyses is presented in Table 6.2.

Epidemiological (section 3) and clinical effectiveness data (section 5) presented in other domains of the HTA will be used to inform inputs to the economic model. Where possible, model inputs will be informed by national data sources. In the absence of robust national data, data from countries considered generalisable to the Irish context may be used. For parameters unsupported by published evidence, input from the EAG will be sought to inform plausible values.

Table 6.2 Model characteristics for economic evaluation

	Cost-utility analysis	Budget impact analysis
Perspective	Publicly-funded health and social care system (HSE)	
Time horizon	Lifetime†	Five years
Discount rate	4% (costs and outcomes)‡ after the first year	N/A
Outcome	ICER (cost per QALY)	Incremental annual and incremental

		five-year budget impact
Sensitivity analysis	Probabilistic and deterministic	Probabilistic and deterministic

Key: HSE – Health Service Executive; ICER – incremental cost-effectiveness ratio; N/A – not applicable.
† The time horizon for the analysis may be dependent on availability of input parameters to support estimates of clinical effectiveness and safety over longer time horizons.
‡ Or the discount rate that applies at the time of analysis.

6.3 Cost-utility analysis

A CUA will be conducted to estimate the cost effectiveness of screening for AAA in men compared with no screening from the perspective of the HSE in a hypothetical patient cohort over a lifetime period. The appropriate time horizon will be dependent on the age of the cohort at baseline. The appropriate model structure will be informed by the results of the systematic review of cost effectiveness (section 6.1). The primary outcome of the CUA will be an incremental cost-effectiveness ratio (ICER) expressed in terms of the mean cost per QALY gained.

As noted previously, there is currently no WTP threshold for non-pharmaceutical technologies in Ireland. However, WTP thresholds of €20,000 per QALY and €45,000 per QALY will be employed to inform interpretation of cost effectiveness. The analysis will be conducted in accordance with national HTA guidelines and current Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting guidelines.[51, 54]

6.4 Budget impact analysis

A budget impact analysis (BIA) will be carried out alongside the CUA, with adaptation of the model structure and inputs, where necessary. The aim of the BIA will be to enable assessment of the affordability of ultrasound screening for AAA in men by policymakers within budget constraints.

The BIA will estimate the incremental direct cost to the HSE associated with the introduction of screening for AAA in men over a five-year time horizon. The analysis will be conducted in accordance with national HTA guidelines for the conduct of budget impact analysis of health technologies.[55]

7 Organisational considerations

Implementation of a new screening programme in Ireland would require consideration of the core principles and elements of a screening programme.[56, 57]

The assessment of necessary organisational changes will be carried out in accordance with the guidance specified in the EUnetHTA Core Model®.[58]

Resource use will be estimated based on the size of the eligible population (section 3), with consideration of estimated screening uptake. Estimated uptake rates will be informed by data reported by previous pilot programmes of AAA screening in Ireland,[13, 14] existing screening programmes in Ireland with similar demographic characteristics (for example, BowelScreen),[59] existing screening programmes internationally (section 4.1) and the input of the EAG.

The analysis will consider the impact of screening for AAA in men on human (that is, staff) and capital resources (such as, equipment and facilities). Depending on the setting of implementation, screening for AAA may have consequences for the availability of other services. Potential challenges associated with managing timely access to surgery and monitoring, where indicated, in the context of existing capacity constraints within the healthcare system will also be considered.

8 Ethical and social issues

Key ethical considerations outlined in the EUnetHTA Core Model will be used to guide the ethical analysis of one-time screening for AAA.[58] Potential ethical issues may include issues related to:

- autonomy and informed consent
- the potential trade-off between the benefits and harms of screening, such as reducing AAA-related mortality and morbidity versus the potential for increasing anxiety, overdiagnosis and overtreatment (including the risk of surgery-related complications and mortality)
- the equity and justice of screening for AAA in men only, such as ensuring fair access and distribution of resources.

9 Anticipated timeline

The final assessment will be submitted to the Board of HIQA for approval. Subject to its approval, the final HTA and associated Statement of Outcomes will be submitted to NSAC for consideration and published on the HIQA website. The anticipated completion date is Q2 2025.

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For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie