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A Core Outcome Set for Intact Abdominal Aortic Aneurysms Under Surveillance

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Background: Current literature on AAA is characterized by selective outcome reporting, while guideline recommendations are frequently based on studies of poor methodological quality. To improve evidence synthesis, standardization of outcome measures through a core outcome set (COS) is advocated, particularly in artificial intelligence (AI) research. A COS consists of essential outcomes for reporting in clinical research based on patient and expert consensus. This study aimed to create a COS for research on patients with AAA under surveillance. This COS will be innovatively applied in AI research focused on cardiovascular disease progression.

Methods: First, a longlist of AAA outcomes was identified through a systematic literature search and focus groups with patients, caregivers, and healthcare professionals. A three-round European Delphi survey was subsequently conducted with patients and healthcare professionals. In an expert consensus meeting with key opinion leaders and patients, the COS was finalized.

Results: The 91-outcome AAA longlist was used in the Delphi study, in which 104 patients and 153 healthcare professionals participated. The highest-rated outcomes from the third Delphi round were discussed in the expert consensus meeting, attended by 23 key opinion leaders, 2 patients, and 1 patient representative from a patient society. Ten core preoperative and

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Data availability: All data supporting the findings of this study are available within the paper and its Supplementary Materials.

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postoperative outcomes were chosen across 6 health domains, with AAA rupture, survival, health-related quality of life, clinical success, and graft infection attaining 100% consensus for inclusion in the COS.
Conclusion: This COS consists of 10 outcomes and should be implemented in clinical and AI research on AAA under surveillance.

INTRODUCTION

Patients with a small abdominal aortic aneurysm (AAA) (diameter 30−55 mm) do not need immediate surgery, but undergo surveillance and may require surgery in the future. These patients are also at increased risk of cardiovascular adverse events.[1,2] Unfortunately, risk of AAA rupture remains difficult to predict, and in many patients, cardiovascular risk factors are inadequately managed. This warrants high-quality research involving patients. However, risk factors for cardiovascular disease and AAA progression are insufficiently understood and current guideline recommendations frequently rely on studies of poor methodological quality.[3] Selective outcome reporting observed in literature further complicates comparison between trials.[4,5]

To enhance evidence synthesis, consistent outcome reporting by use of a core outcome set (COS) is advocated.[6] COS provide a minimum framework for outcome reporting in clinical research on a disease.[7] Different from reporting standards, a COS is endorsed by relevant stakeholders, including healthcare professionals (HCPs) and patients.[8,9] This is important because patient views are rarely acknowledged in research.[4] In addition, COS provide guidance on which outcomes should principally be studied. Previously, a COS has been created for patients undergoing elective AAA repair.[10] However, many patients remain under surveillance several years before they reach the threshold to consider surgery and a substantial subgroup of patients with small AAA never undergo repair at all. The COS on patients undergoing repair is therefore not completely relevant for them. Since no COS yet exists for patients with AAA under surveillance, the current study aimed to create one for these patients. This COS should be overarching and be relevant for all patients with small AAA: those who will never undergo surgery and those who eventually will.

Standardization of outcome measures is especially important in artificial intelligence (AI) research, in which high-quality data should be provided to ensure reliable prediction models.[11] A novel application of COS will be in the VASCUL-AID project: a European collaboration (EU Horizon Grant number 101080947) between vascular surgeons and specialists on medical imaging, AI, and ethics and law.[12] VASCUL-AID aims to create personalized prediction models for cardiovascular disease progression in patients with AAA not (yet) undergoing repair using AI. Use of this COS promotes reliability and validity of the prediction model's measured outcomes, in line with European AI Act (2024) recommendations concerning high-risk AI systems.[13]

METHODS

Study Design

This COS has been developed in accordance with the Core Outcome Measures in Effectiveness Trials (COMET) initiative recommendations and according to the COS-STAR principles.[14,15] The COS was preregistered in the COMET database on October 19th, 2023 (study number 2856). The protocol for this COS development is available online.[16]

The COS was developed in 3 steps. First, a longlist of AAA outcomes was created based on a systematic literature search and outcomes identified from focus groups. Second, a three-round Delphi study was conducted with patients and HCPs across Europe. Third, the final core outcomes were chosen in expert consensus meetings.

Ethical Approval

Ethical and legal experts ensured compliance with relevant privacy, (future) AI legislation, and ethical standards, particularly regarding patient privacy and mitigation of potential biases. The Medical Research Ethics Committee of the Amsterdam University Medical Centers concluded that the current study is not covered by the scope of the Dutch Medical Research Involving Human Subjects Act (WMO). Similarly, institutional approval for patient involvement in the Delphi study was not obtained in Portugal, Serbia, and the U.K. because the Delphi study does not qualify as medical research with human research subjects.

Type of research: Multicentre core outcome set creation using Delphi methodology.

Key findings: 104 patients and 153 healthcare professionals participated in the Delphi study. Twenty-three key opinion leaders, 2 patients and one patient representative chose 10 core outcomes: survival, cerebrovascular accident, aneurysm rupture, endovascular aneurysm repair, health-related quality of life, clinical success, good communication by healthcare professional, adherence to prescribed drugs, and reintervention.

Take home message: Ten core outcomes are essential for reporting in clinical and artificial intelligence research on abdominal aortic aneurysms under surveillance to enhance evidence synthesis.

Stakeholders

Stakeholders were recruited from 8 European countries from the VASCUL-AID consortium[12]: the Netherlands, U.K., Finland, Norway, Serbia, Germany, Portugal, and France. In every participating center, a local coordinator (vascular surgeon) was responsible for participant recruitment. Stakeholders were recruited through purposive sampling to maximize variety of participants. Patients were eligible if they had a diagnosis of AAA with a diameter of $\geq$30 mm or if they had previously been treated for AAA. For the focus groups and Delphi study, a variety of HCPs from the fields of vascular surgery and cardiovascular medicine were invited to participate. Depending on local ethical requirements, informed consent from all participants of the focus groups and Delphi study was obtained in written form or by phone, e-mail, or orally. For the expert meeting, 2 to 4 key opinion leaders (KOLs) from each participating center were invited to participate, in addition to the consortium's AI and legal experts, and patient representatives from relevant European societies.

Focus Groups

Focus groups were conducted to identify additional patient-centered outcomes. They were 60–90 minutes long, followed a semistructured format, and were moderated in participant's native language by vascular surgeons in Serbia or 2 vascular researchers (SZ and LR) in the Netherlands and U.K. The aim was to include between 6 and 10 participants per focus group to allow for free discussion among participants.[17] Guiding questions addressed the following topics: disease progression, quality of life, treatment success, and complications (Supplementary Table I). After 6 participants per stakeholder group per country were recruited, thematic content analysis using an inductive approach was performed.[18] Two vascular researchers (SZ and KM) jointly categorized the transcripts in an analytical framework into themes and subthemes after familiarization with the data. The data was then independently coded into these (sub)themes using MaxQDA software (VERBI Software, 2021) and outcomes subsequently derived from these subthemes.[19,20] Data saturation was reached when the majority of identified subthemes appeared across different countries' focus groups. Newly-identified outcomes were compared to those from the longlist and unique outcomes were added.

AAA Outcome Longlist

The AAA outcome longlist was comprised of all unique outcomes identified from a systematic literature review on AAA outcomes and focus groups with stakeholders.[21] Since this COS should be overarching and relevant for all patients with small AAA (those who will never undergo surgery and those who eventually will), both nonsurgical outcomes, operative outcomes and postoperative outcomes were included in the longlist. From the 264 unique outcomes that were identified, 77 were included in the AAA longlist. These outcomes covered 27 domains from the Dodd taxonomy, a 38-item taxonomy designed for outcome standardization in medical literature.[22] Patient-reported outcomes, as well as those on natural disease progression and interventions were included. The latter were considered relevant, because natural disease progression will in most patients entail operative repair when surgical threshold is reached.

Delphi Study

Patients with AAA that are currently or had been under surveillance from the Netherlands, U.K., Serbia, and Portugal were recruited for participation in the Delphi study, as well as HCPs from all 8 consortium countries. Patients and HCPs that failed to complete a Delphi round were excluded from the following round. Basic demographic information of all participants was collected.

Outcomes and their accompanying plain language description reviewed by a layperson were written in English and Dutch and subsequently translated into Finnish, Portuguese, Serbian, and German with AI-based translation software DeepL and corrected by the local, native-speaking vascular surgeon using the English version as reference.[23] The questionnaires were preferably dispersed through Castor Electronic Data Capture,[24] a web-based data management platform enabling distribution of surveys via e-mail. Alternatively, questionnaires were delivered through post or responses to the questionnaires were collected through interviews with participants (by phone or during a visit).

The number of Delphi rounds was prespecified as 3, considering the length of the longlist. Participants were able to score an outcome on a 9-point Likert scale from 1 (''unimportant'') to 9 (''extremely important''). Consensus definitions per Delphi round were as follows:[25]

- Round 1: > 50% of the respondents in both stakeholder groups scored an outcome 7−9 and < 15% of the respondents scored the same outcome 1−3.
- Round 2: > 70% of the respondents in both stakeholder groups scored an outcome 7−9 and < 15% of the respondents scored the same outcome 1−3.
- Round 3: Twenty outcomes with the highest percentage of 7−9 scores will be discussed in the expert meetings.

Outcomes were presented in the chronological order of the Dodd domains.[22] In Delphi round 2 and 3, participants were shown the previous round's median results of every outcome for both stakeholder groups separately. Participants were able to suggest additional outcomes that they felt were missing during round 1 and 2. Outcomes not meeting the predefined consensus criteria were removed from subsequent rounds. After round 3, the 20 highest-scoring outcomes were distributed to expert meeting participants.

Expert Consensus Meeting

Separate expert meetings were held for patients and for HCP KOL. Both meetings started with an anonymous vote through a web-based voting system on the 20 highest-scored outcomes from the Delphi study.[26] Outcomes that attained 100% consensus were included in the COS without discussion. The 10 highest-scoring outcomes were discussed with the aim of coming to a mutual agreement of which 6 to 8 outcomes to include in the COS. Afterward, both stakeholder groups' core outcomes were combined to form one definitive COS.[25,27]

Statistics

Baseline characteristics were analyzed using descriptive statistics, including mean and median scores and range, using Microsoft Excel.[28] Differences between mean and median scores for stakeholder groups collectively were analyzed using SPSS version 28.[29]

RESULTS

Focus Groups

In total, 19 patients, 11 caregivers, and 18 HCPs participated in the focus groups (Tables I and II). The majority of patients were male ($n = 16$) and most ($n = 14$) were under preoperative surveillance. Eighteen patient-centered outcomes were identified (Supplementary Table S II).

AAA Outcome Longlist

The 18 patient-centered outcomes from focus group analysis and the 77 outcomes obtained from the systematic literature review formed the initial 95-outcome AAA longlist. From this longlist, ''Trauma,'' ''Dementia,'' and ''Cancer'' were removed due to not being AAA-specific; ''In-hospital infection'' was removed because specific infections were already included, and ''Ventilatory assistance'' was filed under ''(Acute) respiratory failure''. ''Return to work'' was combined with another outcome to ''Being able to do (voluntary) work.'' Table III shows the definitive 89-item AAA longlist.

Delphi Study

A total of 99 patients and 149 HCPs participated in the first Delphi round in May 2024 (Fig. 1). Nine additional participants were introduced in round 2, due to delays in receiving informed consent forms ($n = 2$) or invitations to the first round ($n = 7$). In Delphi round 3, previous English and French HCPs were invited to participate again due to low participation rate in these countries. All HCPs filled in the online survey. Eight Dutch patients participated through postal questionnaires. Serbian and Portuguese patients were interviewed by a vascular surgeon, vascular surgery resident, or a medical student.

Most HCPs were vascular surgeons or vascular residents ($n = 108$, 70.6%); Table IV). Most Delphi participants were male (64.1% of HCPs and 88.5%

Table I. Number of focus groups and their participants in the 3 countries that organized focus groups (the Netherlands, United Kingdom, Serbia)

Stakeholder group	Country	Focus group number and date	Number of participants
Patients and partners	The Netherlands	1 December 11th, 2023	5 patients; 4 caregivers
		2[a] February 20th, 2024	1 patient; 1 caregiver
	United Kingdom	1 January 8th, 2024	4 patients; 2 caregivers
		2 January 9th, 2024	2 patients; 4 caregivers
	Serbia	1 December 23rd, 2023	7 patients
Healthcare professionals	The Netherlands	1 February 22nd, 2024	6 healthcare professionals
	United Kingdom	1 January 9th, 2024	6 healthcare professionals
	Serbia	1 December 23rd, 2023	6 healthcare professionals

[a]One focus group turned into an interview because only one patient participated.

Table II. Baseline characteristics of participants of the focus groups in the Netherlands, the United Kingdom, and Serbia

Baseline characteristics	The Netherlands	The United Kingdom	Serbia
Patients - n	*6*	*6*	*7*
Median age - y	73	74	59
Male sex	4	6	6
Undergone intervention for AAA	2	3	0
Healthcare professionals - n	*6*	*6*	*6*
Median age - y	29	35	30
Male sex	2	2	5
Vascular surgeon or resident	1	4	3
Median time of experience - y	4	7	5

Numbers are shown in numbers (%) unless stated otherwise.
AAA, abdominal aortic aneurysm; n, number.

of patients). In total, 98 of 104 patients (94.2%) had undergone routine surveillance, of which 47 (45.2%) were currently under preoperative routine surveillance and 51 (49.0%) had had an intervention (Supplementary Table S III).

The 3 highest rated outcomes were AAA rupture, clinical success, and prolongation of lifespan (Table V). Patients awarded significantly higher mean scores to outcomes than HCPs in the last Delphi round (7.85 vs. 7.11 out of 9; $P < 0.001$).

After the third and last Delphi round, 3 changes to the outcome list were made: ''short-term reintervention'' became the more general ''re-intervention;'' ''symptomatic AAA'' was changed to ''pain from a (symptomatic) AAA'' to distinguish between clinical signs of impending rupture and actual AAA rupture; and ''prolongation of lifespan'' was changed to ''mortality'' to cover both concepts of life extension and mortality.

Expert Consensus Meeting

The expert meetings were held on June 10th, 2024 in Porto, Portugal. In total, 23 KOL, 2 patients, and 1 patient representative from the Dutch Heart Foundation (*Harteraad*), representing 1.7 million Dutch patients with cardiovascular disease, partook in the expert meetings either physically or online via Microsoft Teams (Table VI).[30] Two moderators per meeting facilitated discussion. The spoken language was English. The majority of KOL were vascular surgeons ($n = 13$). Two ethical and legal experts supervised the KOL meeting ensuring compliance with ethical and legal AI regulations.

Final COS

Figure 2 shows the final COS, consisting of 10 outcomes across 6 Dodd domains.[22] Four outcomes are common to both COS: AAA rupture, mortality

Table III. The abdominal aortic aneurysm longlist, categorized according to Dodd taxonomy domain

AAA outcome	Dodd domain Number	Dodd domain
Death	1	Mortality/survival
Prolongation of life span	1	Mortality/survival
Bleeding complications (bleeding, shock, need for blood transfusion)	2	Blood and lymphatic system outcomes
Myocardial infarction (heart attack)	3	Cardiac outcomes
(Congestive) heart failure	3	Cardiac outcomes
Cardiac dysrhythmia	3	Cardiac outcomes
Cardiopulmonary resuscitation (CPR)	3	Cardiac outcomes
Abdominal compartment syndrome	8	Gastrointestinal outcomes
Intestinal ischemia	8	Gastrointestinal outcomes
Intra-abdominal infection (enteritis/peritonitis/abdominal abscess)	8	Gastrointestinal outcomes
Multiple organ failure	9	General outcomes
Decline in overall health	9	General outcomes
Postoperative pain (pain after surgery)	9	General outcomes
Postoperative fatigue (fatigue after surgery)	9	General outcomes
In-hospital infection (Infection during hospitalization)	12	Infection and infestation outcomes
Sepsis	12	Infection and infestation outcomes
Metabolic derangement (dysregulation of metabolism)	14	Metabolism and nutrition outcomes
Cerebrospinal fluid drainage complications	17	Nervous system outcomes
Delirium	17	Nervous system outcomes
Cerebrovascular accident (CVA), including stroke and transient ischemic attack (TIA)	17	Nervous system outcomes
Neurological deficit including spinal cord ischemia	17	Nervous system outcomes
Acute kidney insufficiency/failure	19	Renal and urinary outcomes
Progressive renal insufficiency/ failure	19	Renal and urinary outcomes
Dialysis requirement (temporary/ permanent)	19	Renal and urinary outcomes
Urethral injury	19	Renal and urinary outcomes
Urinary tract infection	19	Renal and urinary outcomes
Erectile dysfunction	20	Reproductive and breast outcomes
Anxiety	21	Psychiatric outcomes
Depression	21	Psychiatric outcomes
Failure to wean (inability to come off the ventilator)	22	Respiratory, thoracic, and mediastinal outcomes
Pneumonia	22	Respiratory, thoracic, and mediastinal outcomes
Pulmonary embolism	22	Respiratory, thoracic, and mediastinal outcomes
(Acute) respiratory failure	22	Respiratory, thoracic, and mediastinal outcomes
Gluteal necrosis	23	Skin and subcutaneous tissue outcomes
Lymphocele/seroma	23	Skin and subcutaneous tissue outcomes

(*Continued*)

Table III. Continued

AAA outcome	Dodd domain Number	Dodd domain
Endovascular abdominal aortic aneurysm treatment	24	Vascular outcomes
Open surgical abdominal aortic aneurysm treatment	24	Vascular outcomes
Abdominal aortic aneurysm growth	24	Vascular outcomes
Rupture of an abdominal aortic aneurysm	24	Vascular outcomes
Regression of the aneurysm sac	24	Vascular outcomes
Amputation	24	Vascular outcomes
Aortic dissection	24	Vascular outcomes
Aortoenteric fistula	24	Vascular outcomes
Thromboembolic complications (blood clot complications)	24	Vascular outcomes
Buttock claudication	24	Vascular outcomes
Graft complications (kink, endograft infection, fracture, etc.)	24	Vascular outcomes
Compartment syndrome of the leg	24	Vascular outcomes
Pseudoaneurysm	24	Vascular outcomes
Symptomatic abdominal aortic aneurysm	24	Vascular outcomes
Endoleak	24	Vascular outcomes
Physical exercise	25	Physical functioning outcomes
Social support	26	Social functioning outcomes
Independence in activities of daily living (functionally independent)	27	Role functioning outcomes
Reassurance	28	Emotional functioning/wellbeing outcomes
Disease acceptance	28	Emotional functioning/wellbeing outcomes
Mental/emotional health	28	Emotional functioning/wellbeing outcomes
Health-related quality of life	30	Global quality of life outcomes
Being able to do (voluntary) work	30	Global quality of life outcomes
Vitality	30	Global quality of life outcomes
Being able to carry out own hobbies	30	Global quality of life outcomes
Maintaining social contact, with family, friends, and others	30	Global quality of life outcomes
Free range of motion	30	Global quality of life outcomes
Clinical success	32	Delivery of care outcomes
Conversion	32	Delivery of care outcomes
Shorter door-to-intervention time (shorter time from symptoms to surgery)	32	Delivery of care outcomes
Primary patency	32	Delivery of care outcomes
Secondary patency	32	Delivery of care outcomes
Technical success	32	Delivery of care outcomes
(Shorter) time to diagnosis	32	Delivery of care outcomes
(Shorter) time to treatment	32	Delivery of care outcomes
Shared decision-making	32	Delivery of care outcomes
Screening of family members	32	Delivery of care outcomes
Smoking cessation	32	Delivery of care outcomes
Stopping alcohol consumption	32	Delivery of care outcomes
Maintaining a healthy diet	32	Delivery of care outcomes
Maintaining a healthy weight	32	Delivery of care outcomes
Adherence to prescribed drugs	32	Delivery of care outcomes
Discharge home	33	Personal circumstance outcomes
Length of hospital stay	35	Hospital outcomes

(*Continued*)

Table III. Continued

AAA outcome	Dodd domain Number	Dodd domain
Length of stay in the intensive care unit (ICU)	35	Hospital outcomes
Readmission	35	Hospital outcomes
Transfer to other hospital	35	Hospital outcomes
The need for hospital monitoring and follow-up appointments	35	Hospital outcomes
Short-term reintervention (during admission)	36	Need for further intervention outcomes
Long-term reintervention	36	Need for further intervention outcomes
Being discharged to a location other than home	37	Societal/carer burden outcomes
Access vessel complications	38	Adverse events/effects outcomes
Surgical wound infections	38	Adverse events/effects outcomes
Surgical wound complications	38	Adverse events/effects outcomes

The outcomes in italics are those that were retrieved from analysis of the focus groups.

(changed to ''Survival'' to ensure patient-centeredness), HRQoL, and cerebrovascular accident. Outcomes that attained 100% consensus were AAA rupture, survival, HRQoL, clinical success, and graft infection.

DISCUSSION

This is the first COS for research on patients with intact AAA under surveillance. In total, 104 AAA patients from 4 European countries and 153 HCPs from 8 European countries participated. Patients and HCPs considered 10 outcomes essential for reporting in research on AAA under surveillance.

Standardization of outcome measures through a COS is imperative to facilitate comparison between trials, enhancing evidence synthesis.[15] Recommendations in current guidelines are frequently based on moderate levels of evidence.[3] Variable disease progression to rupture and the risk of cardiovascular adverse events means patients are subject to often lifelong surveillance of aneurysm diameter and cardiovascular risk management.[3] Several reporting standards have been published in recent years.[8,9] These do not incorporate patient or other stakeholders' perspectives nor acknowledge the significance stakeholders assign to outcomes. The added value of COS lies in facilitating consistent reporting of outcomes considered essential by patients and HCPs, addressing the issue of selective outcome reporting.[15]

An important strength of this study is its patient involvement: focus groups were held with patients to identify additional outcomes for the longlist and 40% of Delphi participants were patients. The longlist was reviewed by a layperson to ensure participants' understanding of terminology. Separate expert meetings were held to ensure that patient-chosen outcomes were included in the final COS. Patient views are rarely acknowledged in trials, although patient-chosen outcomes are clinically relevant.[7,31] In our expert meetings, patients preferred including intervention-related outcomes they wished to avoid, such as ''Graft infection'' and ''Reintervention.'' ''Graft infection,'' associated with high morbidity but relatively low incidence (0.5–5%), reached high degrees of consensus throughout the study.[3] Another patient preference was observed regarding endovascular treatment of AAA, corroborated by literature.[32]

In contrast, KOL-chosen outcomes related more to delivery of care and cardiovascular risk management (''Adherence to prescribed drugs'' and ''Good communication by healthcare worker''). The latter is a newly-identified patient-reported outcome, added to the Delphi study based on a suggestion by an HCP. Good communication by an HCP plays a critical role in shared decision-making, which is especially important since AAA patients are often inadequately informed about treatment options, affecting treatment decisions.[33] Moreover, good communication is necessary to improve disease knowledge among patients with AAA under surveillance.[34] Assessment of whether patients are adequately informed is imperative in increasing disease knowledge as well as facilitating shared decision-making.

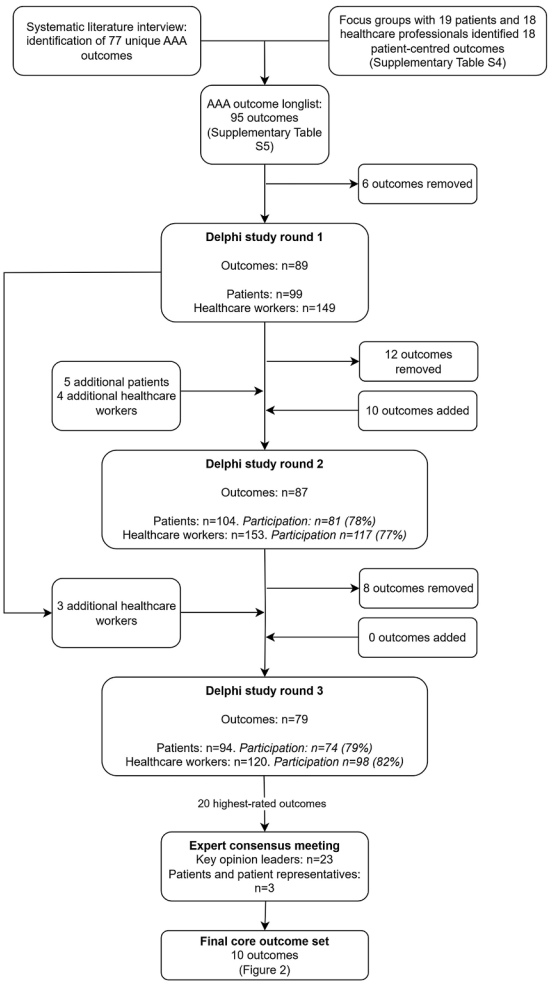


Fig. 1. Overview of the full study design with rates of participation and outcomes added and removed per Delphi round. AAA, abdominal aortic aneurysm.

There are important differences in the final COS on AAA under surveillance and the COS following AAA repair by Machin et al.[10] Seven unique outcomes were identified: cerebrovascular accident, endovascular AAA treatment, clinical success, graft infection, reintervention, good communication by healthcare professional, and adherence to prescribed drugs. Three outcomes (''Mortality,'' ''AAA rupture,'' and ''Quality of life'') are included in both COS. Three outcomes in the COS following AAA repair (''Loss of cognitive function,'' ''Longer-term survival,'' and ''Aneurysm growth after repair'') failed to reach enough consensus for inclusion in the current COS for AAA under surveillance as separate outcomes but are implicitly included in ''Survival'' and ''Reintervention.'' Notably, not included in both the COS on AAA under surveillance and the COS following AAA repair is ''myocardial infarction.'' ''Major adverse cardiovascular events'' (MACE), a composite outcome denoting acute myocardial infarction, cardiovascular death, and stroke, is frequently reported in AAA research.[35] Myocardial infarction may therefore be relevant in specific AAA research but is not recommended to be included in all studies as it is not included in the COS.

The differences between the COS for AAA under surveillance and the COS following AAA repair rely on differences in outcome phrasing, cohort size and characteristics, and their focus on AAA repair. The strength in the COS for AAA under surveillance lies in its applicability in research on mixed patient populations including both those undergoing repair as well as those not undergoing repair. Moreover, as it has included both patients having undergone repair as well as those with AAAs below threshold for operative repair, it may also be applied in research on patients with AAA undergoing repair, balancing both patient populations' outcome preferences.

There is a need for standardization of outcome measures in AI models, for which COS may be employed. AI models rely heavily on the quality of the input data—if outcome measures are not clearly defined and carefully considered by experts, the model may be biased and thus yield inaccurate predictions.[36] COS also enable AI models to align with the Framework for Fair and Trustworthy Use of AI (the ''FUTURE-AI'' guidelines) as it functions as a community-defined standard.[37] To ensure adherence to relevant AI and legal guidelines and regulations, ethical and legal experts were involved in the development of this COS. To our knowledge, this is the first COS that will be applied in AI research and may similarly be used in other cardiovascular prediction models for patients with AAA under surveillance.

To improve the quality of research, COS should be widely adopted. Validation of this COS will occur through use in registries, clinical studies, and AI tools (such as VASCUL-AID),[38] after which it can be further implemented in clinical and AI research. The core outcomes have been defined using community standards (Supplementary Table S IV).[3,9,39–44] As a next step, appropriate measurement scales should be identified or, if missing, created and validated.[45,46] General and disease-specific PROMs already exist to measure HRQoL, such as the Short Form 36 questionnaire and the AneurysmDQoL, respectively.[47,48] For ''Good communication,'' an appropriate patient-reported experience measure will be devised and validated in AAA patients in the context of the VASCUL-AID project.

Table IV. Overview of the participants of the Delphi study per stakeholder group and per country

Stakeholder	NL	RS	PT	UK	DE	FI	FR	NO	Total
Patients									
AAA patient	29	39	30	6					104
Healthcare professionals									
Vascular surgeon	13	17	25		15	7	5		82
Vascular surgery resident	3	18	1	3	1				26
Medical doctor in the (vascular) surgery ward	2			1		1	2		6
Nurse in the (vascular) surgery ward	7	1		1		2			11
Specialized nurse/physician assistant vascular surgery	2			3					5
Vascular (diagnostic) technician	3								3
Perioperative vascular surgery nurse			1						1
(PhD) Researcher vascular surgery	2			1			1		4
Medical student					1				1
Clinical physiotherapist	1								1
Internal medicine specialist	1								1
Radiologist		4							4
Anesthesiology resident				1					1
Perioperative medicine specialist				1					1
Palliative care nurse specialist	1								1
Consultant in Medical Biology							1		1
Professor in medical imaging								1	1
Unknown				1	2				3
Total stakeholder group	64	79	57	18	19	10	9	1	257

Values shown are number of participants per stakeholder group.
NL, the Netherlands; RS, Serbia; PT, Portugal; UK, United Kingdom; FI, Finland; DE, Germany; FR, France; NO, Norway; AAA, abdominal aortic aneurysm.

Notably, 53.8% of the Delphi patients were postoperative, though 91.1% of these patients had previously undergone surveillance and could reflect on their previous surveillance period. Patients (forever) unfit for repair might not benefit from this COS as it was informed by patients with expected operative repair. Furthermore, few patients attended the expert meeting and there was considerable attrition (33.1%) across Delphi rounds, both challenges encountered in other COS developments.[19,49] This was partly mitigated by the involvement of a patient representative in the expert meeting. The extent to which attrition bias has occurred is unknown because no follow-up of dropped-out participants was performed. Though focus groups are a reflection of their participants and its most dominating members, this was minimized through purposive sampling, small group size, and active involvement of less-dominating members. Moreover, focus group analysis may have been biased toward (insider) clinical vascular experiences from vascular researchers and could have benefited from ''outsider'' researchers' analysis. Furthermore, the considerable bias toward Dutch, Serbian, and Portuguese patients may limit generalizability of this COS across Europe. While HCP Delphi participation was higher than intended compared to patients with risk of bias toward HCP opinion, the expert meetings were held separately for patients and HCPs, and their outcome preferences were given equal significance in deciding on the final COS. Lastly, response rates were slightly lower for HCPs than for patients (64.1% vs. 71.2%, respectively), likely due to the high number of outcomes in the Delphi study.[50]

To conclude, this is the first COS for research on intact AAA under surveillance. These core outcomes should be reported as a minimum in all clinical and AI research on AAA under surveillance.

Table V. Overview of the 20 outcomes that attained the highest degree of consensus

Outcome	% Of scores 7−9	Mean healthcare worker score	Mean patient score
AAA rupture	98.8	8.80	8.93
Clinical success after an operation	97.5	8.00	8.62
Prolongation of lifespan	97.5	8.55	8.65
Technical success after an operation	96.3	8.36	8.72
Short-term reintervention	96.3	7.76	8.61
The AAA can be treated through endovascular treatment	95.7	8.25	8.58
The AAA can be treated through open surgical abdominal aortic aneurysm treatment	95.7	8.30	8.63
Aortoenteric fistula after an operation	95.7	7.90	8.48
Graft infection after an operation	95.7	7.87	8.34
Primary patency	95.7	7.75	8.52
Good communication by healthcare worker about diagnosis, secondary prevention, and treatment options and complications	95.7	7.87	8.48
Cerebrovascular accident, including transient ischemic attack	95.1	7.63	8.58
Symptomatic abdominal aortic aneurysm	95.1	7.91	8.56
Health-related quality of life	95.1	7.37	8.41
Adherence to prescribed drugs	95.1	7.76	8.55
Multiple organ failure	94.6	7.84	8.54
Neurologic deficit, incl. spinal cord ischemia	94.5	7.80	8.35
Amputation	94.5	7.64	8.63
Endoleak after endovascular treatment of an AAA	94.4	7.62	8.16
Interdisciplinary healthcare worker collaboration	94.4	7.23	8.12

Shown are the percentage of participants that awarded a score of 7-9 on each outcome and the mean score given to each outcome. AAA, abdominal aortic aneurysm.

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Table VI. Number and specification of key opinion leaders, patients, and patient representative participating in the expert consensus meeting on abdominal aortic aneurysms

Healthcare professional group	Total number	Number per country
Vascular surgeon	13	5 FI, 3 NL, 2 PT, 2 SRB, 1 DE, 1 UK
Vascular nurse practitioner	1	1 UK
Vascular internal medicine specialist	1	1 NL
Vascular surgery resident	2	1 UK, 1 SRB
Surgeon & professor in Serious Gaming, Simulation and Applied Mobile Healthcare	1	1 NL
Professor in Medical Imaging	1	1 NO
Assistant professor in Imaging & Artificial Intelligence	1	1 NL
PhD student Mathematics of Imaging and Artificial Intelligence	1	1 NL
PhD student Artificial Intelligence in Cardiovascular Disease Progression	1	1 NL
Medical Doctor, Chief Medical Information Officer at a company specialized in mobile health	1	1 NL
Patient group	**Total number**	**Number per country**
Patient	2	1 NL, 1 UK
Patient representative	1	1 NL

Number of participants per country are shown.
FI, Finland; NL, the Netherlands; PT, Portugal; SRB, Serbia; DE, Germany; UK, United Kingdom, NO, Norway.

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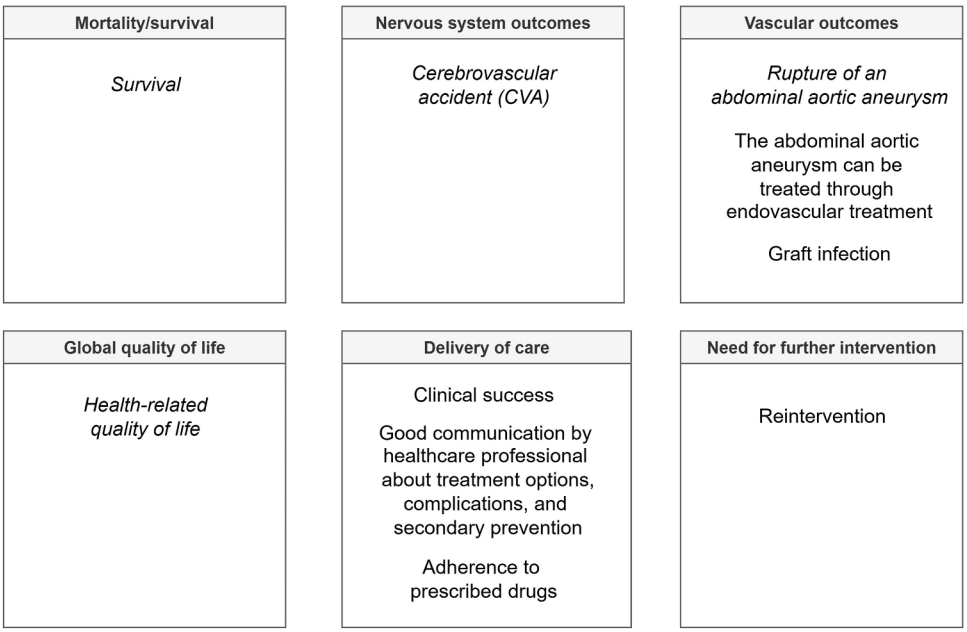


Fig. 2. The stakeholder (patient and healthcare professional) core outcomes that were established during the expert consensus meetings. In italics, the outcomes that are included in both core outcome sets.

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SUPPLEMENTARY DATA

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