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Standards for Abdominal Aortic Aneurysm Repair Quality Improvement Registries: A Delphi Consensus Report From VASCUNET and the International Consortium of Vascular Registries

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WHAT THIS PAPER ADDS

To date, common consensus has been reached on the scope and definition of variables that can be collected by quality improvement registries on abdominal aortic aneurysm (AAA) repair. In this study lead by VASCUNET and the International Consortium of Vascular Registries, an international panel of 49 vascular surgeons representing quality improvement registries in vascular surgery, established a set of 70 variables for AAA registries based on consensus. These variables form a registry standard for AAA repair and will help to harmonise data collection and support international benchmarking of care.

Objective: Outcome registries in vascular surgery are used increasingly to drive quality improvement by vascular societies. The VASCUNET collaboration, within the European Society for Vascular Surgery (ESVS), and the International Consortium of Vascular Registries (ICVR) developed a set of variables for quality improvement registries on abdominal aortic aneurysm (AAA) repair as a registry standard.

Methods: Representatives from international vascular registries within VASCUNET, ICVR, and other nations with established registries were invited to provide the variables. The final variables were developed through a two stage modified Delphi process. Variables from the established registries with at least 60% consensus among all the registries were included for round 1. A five point Likert scale (strongly disagree to fully agree) was used. If the limit of consensual agreement was not reached in round 1, the variable was discussed again in round 2. For round 2, an array question method (yes, no to unsure) was used. Agreement of at least 70% resulted in the variable being included in the final dataset.

Results: A total of 88 of 371 variables extracted from all AAA registries were circulated in the modified Delphi process as they reached the 60% consensus threshold. The questionnaire was circulated to 55 participants (round 1: 49; 89%; round 2: 43; 78%). After two rounds, 70 variables were recommended on consensual agreement. These variables comprised demographics ($n = 4$), pre-operative information ($n = 28$), intra-operative variables ($n = 18$), post-operative variables ($n = 5$), and follow up ($n = 13$).

Conclusion: Based on this modified Delphi process, an international panel of vascular surgeons representing quality improvement registries recommended 70 core variables as standard in AAA repair registries. The inclusion of a core set of variables in AAA vascular registries may help to further harmonise observational research and quality of AAA repair among global healthcare systems.

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INTRODUCTION

Reporting standards for aortic surgery within vascular surgery have been present since 1991.[1] Initially, reporting standards were published on endovascular abdominal aortic aneurysm repair (EVAR) given it was a new technique[2] and, later in 2002, for open surgical repair (OSR), and EVAR.[3] Both of these reports aimed to compare the advantages and disadvantages of the various devices and techniques.[2] Since then, several published studies have attempted to refine the reporting standards,[4,5] focusing primarily on the items of interest for research on aortic surgery.

Increasingly, vascular quality registries are used for evaluating surgical procedures and outcomes.[6,7] For abdominal aortic aneurysm repair (AAA), national registries offer the means to assess outcomes at centre and national level, and to compare treatment strategies and patterns over time. With registries, it is often important to balance the number and granularity of data fields with the practicality of collecting these data, which may require varying amounts of time and effort. To ensure high coverage and compliance by physicians without the risk of data collection fatigue,[8] the number of data fields needs to be pragmatically limited to what is most relevant for quality improvement. To allow for international collaboration and comparisons of registry data, it is desirable that registries across nations have a joint dataset with equal data field definitions that are collected.

VASCUNET, the European Society for Vascular Surgery (ESVS) registry network, analyses international registry data. Its aim is to study contemporary practices, to determine any lacunae in the field, and possibly to improve outcome.[9,10] Since the first VASCUNET meeting in Lisbon in 1997, many countries have joined. Now VASCUNET is composed of more than 40 members from 26 different nations.[11] In the USA, in 2011, the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) was establsihed.[12] The VQI has more than 1 000 participating centres across the USA and Singapore, capturing 14 VQI Registries.[13] Subsequently, the International Consortium of Vascular Registries (ICVR), a co-ordinated registry network within the Medical Device Epidemiology Network, was founded as an amalgamation of VASCUNET and SVS VQI.[9] As a result of the rapid expansion of VASCUNET and ICVR, along with the creation of new vascular registries, opportunities for collaborative studies using harmonised data elements to support high quality observational research studies have naturally evolved during this time.[9] Accordingly, participating members in both organisations have strongly endorsed efforts for standardised data collection to facilitate future quality improvement efforts, fundamental clinical investigations and to foster engagement with industry, regulatory and clinical stakeholders alike.[10,14]

This ongoing process of data harmonisation in VASCUNET and ICVR in recent years has been tackled in various vascular surgery fields, including, but not limited to, peripheral revascularisation,[15] intermittent claudication,[16] and acute limb ischaemia.[17] Over time, VASCUNET has produced a list of variables needed to study AAA outcomes (Supplementary Table S1). Given the expansion of VASCUNET, the inclusion of new vascular registries, and contemporary developments in the field of AAA repair, the need for an updated dataset has become increasingly evident, as highlighted in the recently published ESVS clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms.[18] Hence, the international registry collaboration aimed to develop a core list of important variables dataset for vascular registries on AAA repair. The recently published VASCUNET AAA report on outcomes for patients following intact and ruptured aneurysm repair concluded that harmonisation of data variables would be key in future AAA collaborative projects to align variables such as in hospital *vs*. 30 day mortality rate collected by vascular registries.[7] The importance of updating the harmonisation of variables and validation of international registries was highlighted in the most recent scoping review of vascular registries by the VASCUNET AAA collaborative group.[19]

The aim of the present project was to establish a defined set of variables for quality improvement registries on AAA repair as a registry standard, using a modified Delphi process with clinicians and personnel who have expertise in vascular registries.

MATERIALS AND METHODS

The process for this Delphi consensus followed the recommendations of Waggoner *et al.*[20] who advised on defining the panel of experts participating in the Delphi process. The panel composition was made up of representatives of vascular registries of their respective nations. The representatives were either vascular surgeons with experience in vascular registries management (VASCUNET/ICVR members) or personnel who are the lead, representatives of an established quality improvement registry in vascular surgery, or both. Most of the participants are not only representatives of the registries, but also input data in their respective registry during their day to day work and use registry data for audits and research. The process started during the VASCUNET/ICVR spring meeting in 2021. A core group was formed tasked with performing this project. International vascular registries (within the VASCUNET and ICVR collaboration and beyond) were contacted and provided the variables currently collected in their established AAA registry (Table 1). Representatives were asked to provide an English translation of their variables when possible. Each vascular group was asked to provide one or two contact details of the experts in AAA surgery, vascular registries, or both, as representatives for the modified Delphi process.

Before the start of the Delphi process, the core group of the study agreed *a priori* the format. The modified Delphi process would involve two rounds.[20] Round 1 of the questionnaires had to include variables with at least 60% consensus among all the registries, but also include variables that the core group believed to be important and evidence based in modern clinical AAA management.[21] The participants were asked whether the variables were relevant for a modern AAA data registry, and a Likert scale[22] was to be used for round 1. The participants had to rank each variable from one to five: (1) strongly disagree, i.e., not

Table 1. Registries (nations) that provided the list of variables used for their respective abdominal aortic aneurysm repair registry ($n = 21$).

Australasian Vascular Audit (New Zealand)	Hungary Registry
Bologna AAA Registry (Italy)	Japanese AAA Registry
Brazil AAA Registry	Maltavasc (Malta)
Danish Vascular Registry (Denmark)	Netherlands
Finnish AAA registry (Finland)	Norway (NORKAR)
Romania AAA Registry	Swissvasc (Switzerland)
Serbia Vascular registry	UK National Vascular Registry (United Kingdom)
SVS EVAR registry (USA)	Swedish Vascular Registry (Swedvasc)
VQI Registry (USA)	German AAA Registry
Portuguese Registry (Portugal)	VASCUNET AAA dataset used in previous studies
The Hellenic Vascular Registry (Greece)	

AAA = abdominal aortic aneurysm; EVAR = endovascular aortic aneurysm repair.

relevant; (2) disagree; (3) unsure; (4) agree; and (5) fully agree or very relevant.

Round 1 results were to be analysed according to the following criteria: accept variable if either option 4 or 5 or if the combined sum of chosen options 4 and 5 was 75% or more; reject variable if combined options 1 and 2 amount to 50% or more; question variable in round 2 if option 3 is chosen by 50% or more respondents; question variable in round 2 if option 3 is chosen as much as option 4, 5, or both; and question variable if either option 4 or 5 was chosen by 50% of respondents but combined options 4 and 5 did not reach 75% consensus.

The results from round 1 were discussed among the core group members. For round 2, the core group agreed that an array question method (yes, no, unsure)[23] would be used so that the participants would be more decisive about their choice given it was the final round. A variable would be chosen for inclusion from round 2 if 70% or more of the participants who replied agreed on the inclusion of the variable.

The modified Delphi process (and the minimum dataset identified thereafter) was to avoid subclassification, wherein the level of granularity was to be kept at level one[15] as much as possible, e.g., diabetes mellitus rather than insulin dependent diabetes mellitus, to reduce the burden of data collection on individuals. The level of granularity collected in an individual registry would then be up to each country, registry, or both, to decide.

Participation was via a web based, anonymised electronic questionnaire. Open Source Software (Limesurvey, Hamburg, Germany) (www.limesurvey.org) was used to generate the questionnaires.

RESULTS

The VASCUNET AAA dataset template used in previous studies and 20 international vascular registries provided the variables collected for AAA repair (Table 1). A total of 371 variables were extracted from the AAA registries. Following the review of all the variables by the core group, 88 variables reached the 60% consensus criteria for circulation in round 1 of the modified Delphi process. The questionnaire was circulated to 54 participants, of whom 49 completed round 1 within three reminders to participate. After round 1, 38 variables fulfilled the pre-defined criteria to be selected for inclusion in the minimum dataset for registries. The two COVID related questions were rejected given the burden of COVID 19 infection from the pandemic was beyond us. Some 47 variables fulfilled criteria to be discussed again in round 2 (Supplementary Table S2). Seven additional variables were included in round 2 based on comments provided during the first round. The questionnaire was again circulated to the initial 54 invited participants and 43 completed the questionnaire within three reminders. In all, 32 variables from the 47 variables were chosen to be included in this final dataset from this round (Supplementary Table S3). In total, 70 variables (out of 371) were considered essential to be included in a AAA registry. These variables include four data fields on demographics (Table 2), 28 data fields on pre-operative information (Table 3), 18 data fields on intra-operative variables (Table 4), five variables related to the post-operative period (Table 5), and 13 data fields on follow up (Table 6).

Table 2. Final variables: demographics.

Demographics
Patient identification number
Sex
Date of surgery and date of discharge (date, month and year)
Length of stay in days (comments: registries can choose length of stay *vs.* date of admission and date of discharge)

DISCUSSION

Through this modified Delphi process, a consensus among 43 participants within VASCUNET, ICVR, and other experienced registry personnel was reached on 70 important AAA variables in vascular quality registries. This is somewhat a middle ground between the extensive variables required in reporting AAA outcome by Chaikof *et al.*[24] (2009) and the pragmatic minimum variables as suggested by Boyle *et al.*[4] (2011).

The aim of this consensus project was to develop a set of standard variables for AAA repair in vascular registries with specific definitions, using a Delphi process with clinicians who had expertise in vascular registries. The aim of producing these standard variables is to ensure the safety of the patients treated by either open or endovascular means, and to drive quality improvement. This can be achieved by registries reporting complete population based data and sharing these data. It is of little use to try and share an extensive datasheet in which most of the data are missing, as this leads to information bias.[25]

Table 3. Final variables: pre-operative parameters.
Age of patient on day of surgery
Weight
Date of index operation
Mode of admission
Elective
Urgent
Emergency
Indication for surgery
True aneurysm
Mycotic aneurysm
Pseudoaneurysm
Pre-operative medical condition
Diabetes mellitus
Hypertension
Chronic lung disease
Smoking status
Past history of stroke, transient ischaemic attack, or both
Ischaemic heart disease
Peripheral vascular disease
Chronic kidney disease
Connective tissue disease
Pre-operative functional status
Previous abdominal surgery
Pre-operative parameter (in emergency cases only)*
Pre-operative medications
Antiplatelet (single, dual, or none)
Statins
Antithrombotic medications
Pre-operative aortic morphology
Location of aneurysm
Aneurysm max diameter
Proximal neck diameter
Proximal neck length
Right common iliac diameter
Left common iliac diameter

* Examples for the registry (to be chosen by local registry representatives) include: Pre-operative haemoglobin; loss of consciousness pre-operatively (no vs. yes); cardiac arrest pre-operatively (no vs. yes); lowest pre-intubation systolic blood pressure (mmHg); stable vs. unstable.

Table 4. Final variables: intra-operative parameters.
Endovascular (index) procedure
Endograft used (manufacturer)
Endograft configuration
Endograft used (was this device used on instructions for use basis?)
Percutaneous access (yes or no [bilateral] yes or no [single side] yes or no)
Iliac branch device (none, left, right, or bilateral)
Right iliac limb endograft used (manufacturer)
Left iliac limb endograft used (manufacturer)
Endoleak type at final angiogram on table
Intra-operative adjunctive manoeuvres
Intra-operative vessel coverage
Intra-operative radiation use
Open (index) procedure
Location of aortic clamp (infrarenal clamp, inter-renal clamp, or suprarenal clamp)
Open (index) procedure: type of repair: (1) tubular graft interposition; (2) aorto (bi-) iliac bypass, and (3) aortobifemoral bypass)
Type of graft (synthetic graft, autologous graft, or biological graft)
Clamp time in minutes
Adjunctive procedure
Intra-operative (index) anaesthesia
Type of anaesthesia (general, locoregional, or local)
Blood loss

Some of the results of the Delphi questionnaire were unexpected. An interesting outcome was that the variable "instructions for use (IFU)" was chosen to be included as part of the reporting standards only during round 2. This result is slightly surprising as studies on EVAR follow up have stressed the importance of identifying EVAR on IFU *vs*. outside IFU criteria, as outcomes may be different.[26–28]

EVAR surveillance is deemed important in the ESVS[18] and SVS[24] guidelines, especially when EVAR is carried out outside IFU. The EVAR surveillance variables, however, did not reach consensus in round 1 of the questionnaires but only in round 2. Reasons for this could be multifactorial. Evidence suggests that patients may not be compliant with surveillance,[29] hence participants may have opted to avoid the issue of missing data on EVAR surveillance variables. Debate on ideal follow up intervals is ongoing, hence respondents may have felt that EVAR surveillance is not part of level one data; only upon presenting the question again in round 2 did the respondents choose this. Furthermore, the respondents agreed to choose "any complication at follow up", highlighting the need to keep variables in the registry to a minimum. Finally, registries for the most part only capture information on in hospital, 30 day outcomes, or both, and surveillance is undertaken thereafter.[21]

The inclusion of a core dataset does not limit the error of incorrect data input when transferring data from medical notes to the registry. Systems need to be implemented to reduce human input, such as by avoiding single entries[30] and the use of optical character readers.[31] The UK National Vascular Registry has introduced a barcode reader to read the label off the product code of endografts,[32] whereas some centres in the Vascular Registry of Switzerland (SwissVasc) introduced automatic transfer of data from medical notes to the registry. Similar efforts are ongoing in the SVS Vascular Quality Initiative registries.

Limitations

The authors acknowledge an inherent limitation of the consensus method owing to the lack of input from other

Table 5. Final variables: post-operative parameters.
Discharge status: alive on discharge (yes/no)
Date of discharge or date of death (day, month, year)
Medications on discharge
Antiplatelets
Anticoagulation
Statin

Table 6. Final variables: follow up parameters.
Complications within 30 days of index operation
Hospital re-admission within 30 days of index operation
Was the re-admission for graft or endograft reasons?
Was re-intervention carried out during re-admission episode
Did the patient die within 30 days of the index procedure?
Did the patient die within twelve months of the index procedure
Did the patient suffer from complications within 30 days of the index operation
Date of death
Any issue with the first EVAR surveillance scan (one month)?
AAA maximum diameter on twelve month surveillance scan
Any issue with the twelve month EVAR surveillance scan
Any complication on follow up imaging?
Date of follow up imaging (day, month, year)
Imaging performed (duplex, CTA, or other)

CTA = computerised tomography angiography; EVAR = endovascular aortic aneurysm repairs.

stakeholders (especially patients) in the development of the minimum reporting dataset for AAA repair. The authors acknowledge that future studies will report on patient reported outcome measures.[33]

Only two rounds were carried out for this modified Delphi questionnaire, and only variables that lacked consensus for inclusion were circulated in round 2. Researchers may feel that more than two rounds with the same variables should be circulated for better representation. Given the experience of the respondents in both AAA repair, vascular registries, or both, the VASCUNET/ICVR group did not feel there was a need for more than two rounds of questionnaires. This is consistent with the conclusion of the study by Waggoner *et al.*,[20] who noted that two rounds is an optimal number for a Delphi, and, if a study goes beyond two rounds, reasons for doing so need to be provided.

The compromise between the vast number of variables collected and complete data collection was also discussed in the previous study by Boyle *et al.*[4] The authors noted an "inherent danger in limiting the data because factors that potentially influence outcome are not reported." Some studies, however, reported that this might not be the case in a real world scenario.[34] Therefore, having a list of variables agreed upon by a large international group of participants experienced in AAA repair, international registries, or both, may be a necessary compromise. Furthermore, inclusion of important core variables does not limit respective nations to add, edit variables or both, which they feel are important and conform to the country's acceptable practice. Potential examples include whether the EVAR was carried out by a vascular surgeon, an interventional radiologist, or a mixed team. Another example could be whether the EVAR was carried out in a hybrid operating theatre or a standard vascular theatre with mobile C arm.

Another potential limitation of the study is the lack of conducting a formal pilot study of the Delphi questionnaire to ensure no ambiguous questions, and publication of its results. Whenever VASCUNET/ICVR had official meetings, however, the variables were discussed and an update of the study progress was provided. Furthermore, respondents had the opportunity to ask questions in the comment sections of round 1 to be included in round 2, and round 2 included questions did not have the strong yes or no in round 1. As a result, seven additional variables were included in round 2 based on comments provided during the first round. Moreover, another potential limitation could be that the questions may have been ambiguous to the personnel who input the data during their day to day work. Most of the vascular surgeons who participated in this Delphi process are involved in registry management and input the data themselves at their respective hospital. As a result, it can safely be said that the vascular surgeons who responded to the Delphi questionnaire offer a good representation of the vascular surgeons who input the data in daily practice and, therefore, any ambiguity may have been addressed during the Delphi process.

Conclusion

Overall, 70 of 371 variables were considered suitable to be included as registry standard in quality improvement registries on AAA repair registry. This Delphi consensus, along with others from the VASCUNET and ICVR collaboration, may serve as role model for future harmonisation projects. This will allow contemporary studies to be conducted in a timely manner using comparable data from multinational research and quality improvement programmes, while addressing the need to monitor short and long term outcomes.

CONFLICT OF INTEREST

None.

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None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.12.002.

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