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International Consortium of Vascular Registries Consensus Recommendations for Peripheral Revascularisation Registry Data Collection

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WHAT THIS PAPER ADDS

This paper presents the first international consensus on creation of a minimum and optimum core data set for registries devoted to peripheral arterial revascularisation. A modified Delphi approach with online interaction was used to achieve consensus among international experts from multiple countries. The concept of simple to more complex levels of data capture allows harmonisation at all levels, despite variation among registries. Adoption of a standard variable set by the national registries within the International Consortium of Vascular Registries will provide opportunities for more advanced collaborations, including amalgamation of large scale international data for assessment of outcomes after the introduction of new techniques and devices.

Objective/Background: To achieve consensus on the minimum core data set for evaluation of peripheral arterial revascularisation outcomes and enable collaboration among international registries.

Methods: A modified Delphi approach was used to achieve consensus among international vascular surgeons and registry members of the International Consortium of Vascular Registries (ICVR). Variables, including definitions, from registries covering open and endovascular surgery, representing 14 countries in ICVR, were collected and analysed to define a minimum core data set and to develop an optimum data set for registries. Up to three different levels of variable specification were suggested to allow inclusion of registries with simpler versus more complex data capture, while still allowing for data aggregation based on harmonised core definitions.

Results: Among 31 invited experts, 25 completed five Delphi rounds via internet exchange and face to face discussions. In total, 187 different items from the various registry data forms were identified for potential inclusion in the recommended data set. Ultimately, 79 items were recommended for inclusion in minimum core data sets, including 65 items in the level 1 data set, and an additional 14 items in the more specific level 2 and 3 recommended data sets. Data elements were broadly divided into (i) patient characteristics; (ii) comorbidities; (iii) current medications; (iv) lesion treated; (v) procedure; (vi) bypass; (vii) endarterectomy (viii) catheter based intervention; (ix) complications; and (x) follow up.

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Conclusion: A modified Delphi study allowed 25 international vascular registry experts to achieve a consensus recommendation for a minimum core data set and an optimum data set for peripheral arterial revascularisation registries. Continued global harmonisation of registry infrastructure and definition of items will overcome limitations related to single country investigations and enhance the development of real world evidence.

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INTRODUCTION

Although peripheral arterial disease (PAD) remains an increasing burden for national healthcare systems with >200 million people affected worldwide,[1] many questions regarding treatment of this disease cannot be answered using evidence from trials. Thus, in the absence of such evidence, many recommendations in international practice guidelines are built on expert consensus.[2–4] As there are only a few randomised controlled trials (RCTs) with well known problems of selection bias and limited external validity, with reasonable efforts registries and registry based cohort studies can help to fill the gaps. Registries allow evaluation of treatment practice patterns, medical device evaluation, and can assess convergence of real world and RCT evidence.[5] Although multiple national vascular registries exist, lack of consensus around variables (and their definitions) makes aggregation and comparison of findings difficult.

International collaborations such as the International Consortium of Vascular Registries (ICVR; www.icvr-initiative.org) can help harmonise cross border research. The ICVR is comprised of countries with vascular surgery registries, including the Vascular Quality Initiative (VQI; www.vqi.org) in the USA and the Vascunet Collaboration, consisting of vascular registries from 12 countries in Europe and Australasia (www.vascunet.org). The ICVR was launched in 2014 with the goal of establishing a collaborative platform across registries to share data in order to improve the quality of vascular health care.[6] Contributions regarding abdominal aortic aneurysms (AAA) and carotid artery stenosis were recently published by this collaboration.[6–9] For this project, ICVR members aimed to apply a modified Delphi approach to achieve agreement on a minimum core data set and to create an optimum data set for registries capturing surgical and interventional PAD treatments.

METHODS

The Delphi approach is widely accepted and used to gain consensus among a panel of experts,[10] and has previously been used in various specialties, including vascular surgery.[11–15] Representatives of 14 national vascular registries participating in the ICVR from Australia (Australasian Vascular Audit), Denmark (Karbase), Finland (HUSvasc), Germany (GermanVasc and Aortic Registry of the German Vascular Society), Hungary (Hungarian Vascular Registry), Iceland (Isvasc), Italy (Italian Vascular and Endovascular Registry), New Zealand (Australasian Vascular Audit), Norway (NORKAR), Spain, Sweden (Swedvasc), Switzerland (Swissvasc), and the USA (VQI) submitted their registries' current data sheets and definitions of data elements. An extensive narrative review of the literature was conducted to identify additional items in registry based studies on PAD. All participants in this study agreed to the scope of items identified through the abovementioned process. Members of the ICVR were then invited to participate in web based anonymised electronic questionnaires. Open source software (www.limesurvey.org) was used to generate the questionnaires. The participants could only submit one set of answers in each Delphi round. Following each round, a structured report, including anonymised group responses, mean results with SDs, as well as comments, were forwarded to the participants by email before they were invited to the next round. Each participant was asked to indicate whether they agreed that individual variables should be included in the consensus data set, and each item was scored on a five point Likert scale comprising "strongly agree", "agree", "neutral", "disagree", and "strongly disagree". Additionally, a free text comment could be submitted for each item. Items repeatedly rated with "strongly agree" or "agree" were recommended for the minimum data set. Items repeatedly rated with "strongly disagree" or "disagree" were eliminated from consideration. If consensus was not achieved after three rounds, the remaining items were discussed by the experts in two face to face ICVR meetings and added to the minimum data set if 80% of the experts supported the variable.

During this evaluation, it became apparent that it was important to determine not only which variables to include, but also what level of detail was needed for each variable included. By analysing each current national registry, it was determined that considerable variation existed in the level of detail collected, and in some cases the definition of the variables. In order to allow different levels of detail to be collected by different registries, but still allow harmonisation, three "levels" of variable recording detail but with common core definitions were created. Thus, reporting levels were stratified for data elements as level 1, 2, and 3, ranging from minimum to optimum. Reporting level 1 for variables were considered the minimum information necessary and typically have a simple input (yes, no) or simple numeric range. Level 2 and 3 variables have additional increasing specificity and granularity. For example, reporting the comorbidity of diabetes includes yes/no in reporting level 1. The more specific reporting level 2 includes the type of medical treatment (insulin, oral antidiabetic, etc.), whereas reporting level 3 includes HbA1c level

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