View metadata, citation and similar papers at core.ac.uk
brought to you by CORE
provided by Helsingin yliopiston digitaalinen arkisto

Eur J Vasc Endovasc Surg (2018) 56, 217–237

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

Christian-Alexander Behrendt [a,*], Daniel Bertges [b], Nikolaj Eldrup [c], Adam W. Beck [d], Kevin Mani [e], Maarit Venermo [f], Zoltán Szeberin [g], Gabor Menyhei [h], Ian Thomson [i], Georg Heller [j], Pius Wigger [k], Gudmundur Danielsson [l], Giuseppe Galzerano [m], Cristina Lopez [n], Martin Altreuther [o], Birgitta Sigvant [e], Henrik C. Rieß [a], Art Sedrakyan [p], Barry Beiles [q], Martin Björck [e], Jonathan R. Boyle [r], E. Sebastian Debus [a,†], Jack Cronenwett [s,†]

[a] Department of Vascular Medicine, University Heart Centre Hamburg, University Medical Centre Hamburg-Eppendorf, Hamburg, Germany
[b] Division of Vascular Surgery, University of Vermont Medical Center, Burlington, VT, USA
[c] Department of Cardio-Thoracic and Vascular Surgery, Aarhus University Hospital, Aarhus, Denmark
[d] Division of Vascular Surgery and Endovascular Therapy, University of Alabama at Birmingham, AL, USA
[e] Department of Surgical Sciences, Uppsala University, Uppsala, Sweden
[f] Department of Vascular Surgery, Helsinki University Hospital and University of Helsinki, Helsinki, Finland
[g] Department of Vascular Surgery, Semmelweis University, Budapest, Hungary
[h] Department of Vascular Surgery, Pecs University Medical Centre, Pecs, Hungary
[i] Department of Vascular Surgery, Dunedin School of Medicine, Dunedin Hospital, Dunedin, New Zealand
[j] Department of Vascular Surgery, Kantonsspital St. Gallen, Switzerland
[k] Department of Surgery, Kantonspital, Winterthur, Switzerland
[l] Reykjavik Venous Centre, Domus Medica, Reykjavík, Iceland
[m] Vascular Surgery, Misericordia Hospital of Grosseto, Usl Toscana Sud-Est, Grosseto, Italy
[n] Department of Vascular Surgery, University Hospital of Granada, Spain
[o] Department of Vascular Surgery, St. Olavs Hospital, Trondheim, Norway
[p] Healthcare Policy and Research, Weill Cornell Medical College, New York, NY, USA
[q] Australian and New Zealand Society for Vascular Surgery, Melbourne, Australia
[r] Department of Vascular Surgery, Cambridge University Hospitals NHS Trust, Cambridge, UK
[s] Department of Surgery Dartmouth-Hitchcock Medical Centre, Lebanon, NH, USA

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.

† E.S.D. and J.C. share last authorship.
* Corresponding author.
E-mail address: ch.behrendt@uke.de (Christian-Alexander Behrendt).
1078-5884/© 2018 European Society for Vascular Surgery. Published by Elsevier B.V. All rights reserved.
https://doi.org/10.1016/j.ejvs.2018.04.006

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.
© 2018 European Society for Vascular Surgery. Published by Elsevier B.V. All rights reserved.
Article history: Received 26 January 2018, Accepted 9 April 2018, Available online 30 May 2018
Keywords: Consensus development, Delphi technique, Health services research, Peripheral arterial disease, Registries

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

Table 1. Seventy-nine items in the minimal core and optimal data set for registries evaluating peripheral arterial revascularisation.

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
1) Patient Characteristics	Birth Date	Day (dd), month (mm), and year (yyyy) of birth			Used to calculate age at time of procedure for subsequent analysis and de-identified data sharing. If regulations do not allow date collection, age (years) can be substituted.	
	Sex	Female, Male	Female, Male, Trans female, Trans male		Sex at birth. Trans female has transitioned from female sex to male gender; Trans male has transitioned from male sex to female gender.	
	Weight	Body Weight in kg				
	Height	Body Height in cm				
	Functional Status		Full activity, Light Work, Self Care, Assisted Care, Bedbound	Add disease specific quality of life survey, such as Vascu-Qol-6	A person's level of functioning in terms of their ability to care for them self, daily activity, and physical ability (walking, working etc.).	*Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET,* et al. *Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5(6):649—55.*
						Nordanstig J, Wann-Hansson C, Karlsson J, Lundström M, Petterson M, Morgan MBF. Vascular Quality of Life Questionnaire-6 faciliates health related quality of life assessment in peripheral arterial disease. J VascSurg 2014;59:700-7.
	Ambulation		Fully Ambulatory, Ambulate with Prosthesis, Ambulate with Assistive Device, Wheelchair, Bedbound	Add walking distance survey such as Walking Improvement Questionnaire or GPS monitored walking		
	ASA Grade	Normal healthy patient (1), mild systemic disease (2), severe systemic disease (3), severe systemic disease that is a constant threat to life (4), moribund patient who is not expected to survive without the operation (5), declared brain dead patient				*Owens WD, Felts JA, Spitznagel EL. ASA Physical Status Classifications: A Study of Consistency of Ratings.Anesthesiology 1978;49:239-243. Recent update:* https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
2) Patient Co-morbidities	Diabetes	No, Yes	If Yes: Treated with: Insulin, Oral Antidiabetic, Both, Diet alone, No Treatment	HbA1c in %	Yes = clinical diagnosis documented in medical record based on Fasting $\geq$ 7 mmol/L or post glucose $\geq$ 11.1 mmol/L and/or HbA1c $\geq$ 6.5% and/or antidiabetic medication.	*Stoner MC, Calligaro KD, Chaer RA, Dietzek AM, Farber A, Guzman RJ,* et al. *Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. J Vasc Surg. 2016;64(1):e1-e21.*
						Kumar R, Nandhini LP, Kamalanathan S, Sahoo J, Vivekanadan M. Evidence for current diagnostic criteria of diabetes mellitus. World J Diabetes. 2016;7(17):396—405.
	Current Renal Function	Normal, Abnormal	Serum Creatinine (in µmol/l or mg/dl)	Glomerular filtration rate (GFR) in ml/min (Cockcroft-Gault calculation)	As defined by the National Kidney Foundation::eGFR $<$60 mL/min/1.73 m^2 on two occasions separated by 3 months and that is not associated with a transient, reversible condition such as volume depletion.	*National Kidney F. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2002;39(2 Suppl 1):S1-266.*
	Current Dialysis	No, Yes	Duration of dialysis dependence (years)			
	Tobacco Use	Current Smoker, Former Smoker, Never Smoked	If Former Smoker: Quit Date	If Current or Former Smoker: Pack Years (py) Smoked		*Stoner MC, Calligaro KD, Chaer RA, Dietzek AM, Farber A, Guzman RJ,* et al. *Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. J Vasc Surg. 2016;64(1):e1-e21.*

	Current Ischaemic Heart Disease	No, Yes	If Yes: Asymptomatic, Angina only during Strenuous or Prolonged Physical Activity, Symptoms with Everyday Living Activities, Inability to Perform any Activity Without Angina or Angina at Rest		Yes = current angina or positive stress test indicating ischaemic heart disease	*Lee TH, Marcantonio ER, Mangione CM, Thomas EJ, Polanczyk CA, Cook EF,* et al. *Derivation and prospective validation of a simple index for prediction of cardiac risk of major noncardiac surgery. Circulation. 1999;100(10): 1043—9.*
	Prior Myocardial Infarction	No, Yes	Add Prior Revascularisation: CABG, PCI	Add timing of MI and CABG/PCI: MI $\leq$ 6 Months, $>$ 6 Months; CABG/ PCI $<$ 5 years, CABG/ PCI $>$ 5 years	Yes = clinical history documented in medical record	*Lee TH, Marcantonio ER, Mangione CM, Thomas EJ, Polanczyk CA, Cook EF,* et al. *Derivation and prospective validation of a simple index for prediction of cardiac risk of major noncardiac surgery. Circulation. 1999;100(10): 1043—9.*
	Congestive Heart Failure	Never, Former, Current	If Current: New York Heart Association (NYHA)-Classification for heart failure (Class I to IV)	Current Ejection Fraction in %	Current/former = clinical diagnosis/history documented in medical record, based onPonikowski et al. (2016) andLee et al. (1999): Patient has a history of or current symptoms of congestive heart failure, pulmonary oedema, or paroxysmal nocturnal dyspnea, physical examination showing bilateral rales or S3 gallop, or chest radiograph showing pulmonary vascular redistribution.	*Lee TH, Marcantonio ER, Mangione CM, Thomas EJ, Polanczyk CA, Cook EF,* et al. *Derivation and prospective validation of a simple index for prediction of cardiac risk of major noncardiac surgery. Circulation. 1999;100(10): 1043—9.*

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
						Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JG, CoatsAJ, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. European journal of heart failure. 2016;18(8): 891—975.
	Cardiac Arrhythmia	Never, Former, Current	If Current: Atrial, Ventricular, Previous Ablation, AV-Block with Pacemaker, Defibrillator (ICD), Previous Ablation and Pacemaker or ICD, Other		Yes = clinical diagnosis documented in medical record, including atrial fibrillation, bradycardia, conduction disorders, premature contraction, tachycardia, ventricular fibrillation, other rhythm disorders.	
	Chronic Obstructive Pulmonary Disease	Never, Former, Current	If Current: No Treatment, Medical Treatment, Home Oxygen		Yes = clinical diagnosis documented in medical record of chronic obstructive pulmonary disease or pulmonary medical treatment. As defined byStoner et al. (2016).	*Stoner MC, Calligaro KD, Chaer RA, Dietzek AM, Farber A, Guzman RJ,* et al. *Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. J Vasc Surg. 2016;64(1):e1-e21.*
	Hypertension	Never, Former, Current	If Current: Treated controlled, treated uncontrolled (blood pressure > 140/90 despite treatment)		Blood pressure > 140/90 or medical treatment.	*Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M,* et al. *2013 ESH/ESC Guidelines for the management of arterial hypertension. Eur Heart J. 2013;34:2159-2219.*

	Prior PAD Revascularisation	No, Yes	If Yes: Interventional, Surgical, Both	Location: Inflow, Outflow; Type: Intervention, Bypass, Endarterectomy; Leg: R/L/Aorta		
	Prior Amputation	Minor, Major	If Yes: Level: Toe(s), transmetatarsal, below knee, through knee, above knee, higher of R/L leg			*Conte MS, Geraghty PJ, Bradbury AW, Hevelone ND, Lipsitz SR, Moneta GL,* et al. *Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. J Vasc Surg. 2009;50(6):1462−73 e1-3.*
3) Current Medication	Aspirin	No, Yes	If Yes: $\leq$ 100 mg/d, 101 −320 mg/d, >320 mg/d	Add medication prescribed at discharge.	Medication in effect at time of procedure.	
	Other Platelet Inhibitor	No, Yes	if Yes, medication name	Add medication prescribed at discharge.	Medication in effect at time of procedure.	
	Statin	No, Yes	If Yes: Low Dose, High Dose	Add medication prescribed at discharge.	Medication in effect at time of procedure.	
	Anticoagulant	No, Yes	If Yes: Vitamin K Antagonist, Thrombin Inhibitor, Factor Xa Inhibitor, Other	Add medication prescribed at discharge.	Medication taken chronically before procedure (even if stopped in preparation for procedure).	
4) Lesion treated	Symptoms for Right/Left Leg	Modified Rutherford-Classification: Asymptomatic, Mild Claudication, Moderate Claudication (>200m), Severe Claudication (<200m), Ischaemic Rest Pain, Ulcer/Necrosis, Non-healing Amputation, Both Ulcer/Non-healing Amputation, Acute Ischaemia				will include ref RAPID for the modified Rutherford when published

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
	Foot Infection for Right/Left Leg	No, Yes	Grade 0 None, Grade 1 Mild, Grade 2 Moderate, Grade 3 Severe			*Mills, Joseph L. Sr., MD,* et al. *(2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischaemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp.220-pp.234.e2,* https://doi.org/10.1016/j.jvs.2013.08.003
	Tissue Loss Severity for Right/ Left Leg		None, Grade 1, Shallow, Grade 2, Deep, Grade 3, Extensive			*Mills, Joseph L. Sr., MD,* et al. *(2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischaemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp.220-pp.234.e2,* https://doi.org/10.1016/j.jvs.2013.08.003
	Ankle brachial index for Right/ Left Leg	Highest ABI$\geq$ 1.3, ABI $<$ 1.3 and $\geq$ 0.9, ABI $<$ 0.9 and $\geq$ 0.7, ABI $<$ 0.4, treated leg	ABI exact measurement R/L leg	ABI and TBI exact measurement R/L leg		*Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C,* et al. *Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. Circulation. 2012;126(24):2890—909.*
	Artery vs. Graft	Native Artery, Bypass Graft	Graft Conduit: Vein, Prosthetic; Location: Supra-Inguinal, Infra-Inguinal	Add Graft Origin and Insertion		

	Artery Treated or Bypassed	Aorta, iliac, femoral, popliteal, tibial	Aorta, common Iliac, external iliac, common + external iliac, internal iliac, common femoral, superficial femoral, profunda femoral, popliteal, SFA + popliteal, anterior tibial, posterior tibial, peroneal, tibioperoneal trunk, dorsal pedal, plantar	Add Artery Segment: Prox, Mid, Distal, as in Popliteal P1, P2, P3 segments		
	Side for each Lesion Treated	Right, Left, Aorta				
	Lesion Length	Short (<5cm for aorto-iliac and <25cm for femoropopliteal lesions), Long (≥5cm for aorto-iliac and ≥ 25cm for femoropopliteal lesions)	Length (cm)			*Acin F, de Haro J, Bleda S, Varela C, Esparza L. Primary nitinol stenting in femoropopliteal occlusive disease: a meta-analysis of randomized controlled trials. Journal of endovascular therapy: an official journal of the International Society of Endovascular Specialists. 2012;19(5):585—95.*
						Aboyans V, Ricco J, Bartelink MEL, Björck M, Brodmann M, Cohnert T et al., 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS), European Journal of Vascular and EndovascularSurgery (2017), http://dx.doi.org/10.1016/j.ejvs.2017.07.018
	Most Severe Stenosis		Stenosis, Occlusion	Bollinger Score: Complete occlusion, Stenosis >50% of lumen, Stenosis of 25—50% of lumen, ≤25% stenosis of lumen		*Bollinger A, Breddin K, Hess H, Heystraten FM, Kollath J, Konttila A,* et al. *Semiquantitative assessment of lower limb atherosclerosis from routine angiographic images. Atherosclerosis. 1981;38 (3—4):339—46.*

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
	Outflow from Treated Artery		No outflow, one vessel, two vessels, three vessels	Modified Society for Vascular Surgery (SVS) runoff score: from 0 to 19 points		*Davies MG, Saad WE, Peden EK, Mohiuddin IT, Naoum JJ, Lumsden AB. Impact of runoff on superficial femoral artery endoluminal interventions for rest pain and tissue loss. J Vasc Surg. 2008;48(3):619—25; discussion 25—6.*
5) Procedure	Procedure Date	Day (dd), month (mm), and year (yyyy) of the procedure			Used to calculate length of hospital stay for subsequent analysis and de-identified data sharing. If regulations do not allow date collection, length of stay (days) can be substituted.	
	Living Location		Home, Nursing Care Facility, Homeless			
	Admission Date	Day (dd), month (mm), and year (yyyy) of admission if hospitalised			Used to calculate length of hospital stay for subsequent analysis and de-identified data sharing. If regulations do not allow date collection, length of stay (days) can be substituted.	
	Discharge Date	Day (dd), month (mm), and year (yyyy) of discharge if hospitalised			Used to calculate length of hospital stay for subsequent analysis and de-identified data sharing. If regulations do not allow date collection, length of stay (days) can be substituted.	
	Discharge Destination		Home, Nursing Care Facility, Rehabilitation Facility, Homeless, Other			
	Performance Site		Hospital Outpatient, Hospital Inpatient, Ambulatory Centre, Office			

	Urgency of the Procedure	Elective, Urgent, Emergent			Elective = planned/ scheduled procedure; urgent = surgery within 24 hrs of admission or patient can't be discharged; emergency = surgery within 6 hrs of admission
	Provider Specialty		Angiologist/Vascular Medicine, Cardiologist, Radiologist, Surgeon, Other	Multidisciplinary Team Decision (MTD) achieved prior to the Procedure?	
	Type of Procedure	Surgical Bypass, Endarterectomy, Catheter based Intervention, Hybrid			
6) Bypass	Surgical Bypass Location for Right/Left Leg	Ax-fem, Ax-bifem, Aorto-fem, Aorto-bifem, Fem-fem, fem-ATK popliteal, Fem-BTK popliteal, Fem-tibial, Pop-tibial, Fem/Pop-DP/plantar	Proximal and Distal anastomosis location: Supra-aortic, Thoracic Aorta, Abdominal Aorta, Common Iliac Artery, External Iliac Artery, Internal Iliac Artery, Common Femoral Artery, Deep Femoral Artery, Superficial Femoral Artery, Popliteal Artery Above Knee, Popliteal Artery BelowKnee, Tibioperoneal Trunk, Anterior Tibial Artery, Posterior Tibial Artery, Peroneal Artery, Pedal Artery, Plantar, Other		
	Conduit	Prosthetic, Vein	Prosthetic: Polyester, PTFE, heparin bonded; Cryopreserved allograft; Vein: great saphenous reversed, in situ, translocated; femoral vein; small saphenous; arm vein	Add number of vein segements used or UDI identification of prosthetic graft	
7) Endarterectomy	Endarterectomy Location for Right/Left Leg	Aorta, common iliac, external iliac, common femoral, profunda femoral, superficial femoral, Popliteal			

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
	Patch Used	No, Yes	None, Polyester, PTFE, heparin bonded, Bovine pericardium, Autogenous vein	UDI identification of prosthetic patch		
8) Catheter based Intervention	Access Site(s)		Femoral, Popliteal, Pedal, Arm	Femoral Retrograde, Femoral Antegrade, SFA, Popliteal, Dorsal Pedal, Posterior Tibial, Brachial, Radial, Axillary, Graft, Femoral Retro to Antegrade, Femoral Ante to Retrograde		
	Largest Sheath Size		French size number			
	Intervention Type	Balloon angioplasty, drug coated balloon, bare metal stent, drug eluting stent, covered stent, atherectomy, other	Balloon angioplasty, drug coated balloon, bare metal stent, drug eluting stent, mechanical thrombectomy, covered stent, brachytherapy, atherectomy, laser assisted angioplasty, aspiration, scoring balloon, cutting balloon, cryoplasty, other	GUDID identification of device		
	Planned Adjunct Procedure	No, Yes	None, Thrombolysis Pharmacological, Thrombolysis Mechanical, Suction Thrombectomy, Embolic Protection Device, IVUS, CTO-Device, Bypass, Endarterectomy	GUDID identification of device		
	Closure Device	No, Yes	If Yes: List Device Name	GUDID identification of device		
	Unplanned Procedure for Complication	Bailout Stent, Bailout Stent graft	None, Thrombolysis Pharmacological, Thrombolysis Mechanical, Suction Thrombectomy, Embolic Protection Device, IVUS, CTO-Device, Bypass, Endarterectomy	GUDID identification of device		

	Final Technical Result	Successful (Stenosis $\leq$ 30%), Stenosis $>$ 30% or 10mm Gradient, Target Lesion Occlusion, Failure (unable to cross or deploy device)	Bollinger Score: Complete occlusion (1), Stenosis $>$ 50% of lumen (2), Stenosis of 25—50% of lumen (3), $\leq$ 25% stenosis of lumen (4), Failure (unable to cross or deploy device)		Including only treated region	*Bollinger A, Breddin K, Hess H, Heystraten FM, Kollath J, Konttila A,* et al. *Semiquantitative assessment of lower limb atherosclerosis from routine angiographic images. Atherosclerosis. 1981;38 (3—4):339—46.*
9) Complications	Unplanned Amputation for Right/Left Leg	No, Minor Amputation, Major Amputation	Level: Toe(s), transmetatarsal, below knee, through knee, above knee, higher of R/L leg		Amputation that resulted from a complication or abrupt change in disease severity that was not anticipated at the time of the procedure	
	Site or Graft Thrombosis for Right/Left Leg	No, Yes	If Yes: No Treatment, Medical Treatment, Interventional Treatment, Surgical Treatment			
	Site or Graft Stenosis for Right/Left Leg		No, Yes	If Yes: No Treatment, Medical Treatment, Interventional Treatment, Surgical Treatment	Graft Stenosis is defined as $\geq$ 70% diameter reducing stenosis by Doppler Ultrasonography, CT Angiography, MR Angiography or Fluoroscopy	
	Distal Embolisation for Right/Left Leg	No, Yes	If Yes: No Treatment, Medical Treatment, Interventional Treatment, Surgical Treatment			
	Target Lesion Dissection for Right/Left Leg	No, Yes	If Yes: No Treatment, Medical Treatment, Interventional Treatment, Surgical Treatment			
	Device Failure	No, Yes	If Yes: Failure to Deploy, Fracture, Rupture, Other			
	Bleeding, Hematoma, Pseudoaneurysm	No, Yes	If Yes: Minor, Transfusion, Thrombin Injection, Surgical Treatment			
	Compartment Syndrome	No, Yes	If Yes: Medical, Surgical Treatment			
	Wound Infection	No, Yes	If Yes: Medical, Surgical Treatment			
	Myocardial Infarction	No, Yes	If Yes: Troponin only (NSTEMI), ECG (STEMI) or Clinical Symptoms			

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
	Stroke	No, Yes	If Yes: Minor, Major	Modified Rankin level	As defined byEaston et al. (2009).	*Easton JD, Saver JL, Albers GW, Alberts MJ, Chaturvedi S, Feldmann E,* et al. *Definition and evaluation of transient ischemic attack: a scientific statement for healthcare professionals from the American Heart Association/ American Stroke Association Stroke Council; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Nursing; and the Interdisciplinary Council on Peripheral Vascular Disease. The American Academy of Neurology affirms the value of this statement as an educational tool for neurologists. Stroke; a journal of cerebral circulation. 2009;40(6):2276—93.*
	New Dialysis Required	No, Yes	No, Acute In hospital only, Chronic Dialysis		Any acute renal replacement therapy for acute kidney injury (intermittent/ continuous, haemodiafiltration, haemofiltration, haemodialysis etc.).	
	Death	No, Yes	If Yes: Death caused by procedure?			
10) Follow up	Follow up Date	Day (dd), month (mm), and year (yyyy) of the procedure			Used to calculate duration of follow up for subsequent analysis and de-identified data sharing. If regulations do not allow date collection, follow up duration (months) can be substituted.	
	Death	No, Yes	If Yes: Date of Death	If Yes: Procedure related, Not Procedure related		

	Functional Status		Full activity, Light Work, Self Care, Assisted Care, Bedbound	Add disease specific quality of life survey, such as Vascu-Qol-6	A person's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working etc.).	*Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET,* et al. *Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5(6):649 —55.*
						Nordanstig J, Wann-Hansson C, Karlsson J, Lundström M, Petterson M, Morgan MBF. Vascular Quality of Life Questionnaire-6 faciliates health-related quality of life assessment in peripheral arterial disease. J VascSurg 2014;59: 700-7.
	Ambulation		Fully ambulatory, Ambulate with Prosthesis, Ambulate with Assistive device, Wheelchair, Bedbound	Add walking distance survey such as Walking Improvement Questionnaire or GPS monitored walking		
	Symptoms for Right/Left Leg	Modified Rutherford-Classification: Asymptomatic, Mild Claudication, Moderate Claudication (> 200m), Severe Claudication (< 200m), Ischaemic Rest Pain, Ulcer/Necrosis, Non-healing Amputation, Both Ulcer/Non-healing Amputation, Acute Ischaemia			Level 1 Modified Rutherford	!need to ref RAPID for the modified Rutherford!
	Foot Infection for Right/Left Leg	No, Yes	If Yes: Grade 0 None, Grade 1 Mild, Grade 2 Moderate, Grade 3 Severe			*Mills, Joseph L. Sr., MD,* et al. *(2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp.220-pp.234.e2,* https://doi.org/10.1016/j.jvs.2013.08.003

Continued

Table 1-*continued*

Category	Variable	Reporting Level 1	Reporting Level 2	Reporting Level 3	Comments	*Reference*
	Tissue Loss Severity for Right/ Left Leg		If Yes: None, Grade 1, Shallow, Grade 2, Deep, Grade 3, Extensive			*Mills, Joseph L. Sr., MD,* et al. *(2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp.220-pp.234.e2,* https://doi.org/10.1016/j.jvs.2013.08.003
	Amputation for Right/Left Leg	No, Minor, Major	If Yes: Level: Toe(s), Transmetatarsal, Below Knee, Through Knee, Above Knee, Higher if Right/Left Leg	If Yes: Date of Amputation		
	Graft/Site Patency for Right/Left Leg	No, Yes	Method of Assessment (Clinical Examination, ABI, Ultrasound, MRA, CTA, Fluoroscopy, Other)		Patency of the treated index lesion.	
	Graft/Site Re-Intervention for Right/Left Leg	No, Yes	If Yes: Interventional, Surgical, Both	If Yes: Date of Re-Intervention		
	Major Adverse Cardiac Events (MACE, MACCE)	No, Yes	If Yes: Stroke, MI, CABG, PCI	If Yes: Date of Coronary Procedure or Death	Composite endpoint: Any major adverse cardiac or cerebrovascular event (MACE, MACCE) such as all cause death, myocardial infarction, stroke, or coronary vessel revascularisation.	*Conte MS, Geraghty PJ, Bradbury AW, Hevelone ND, Lipsitz SR, Moneta GL,* et al. *Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. J Vasc Surg. 2009;50(6):1462—73 e1-3. Kip KE, Hollabaugh K, Marroquin OC, Williams DO. The problem with composite end points in cardiovascular studies: the story of major adverse cardiac events and percutaneous coronary intervention. Journal of the American College of Cardiology. 2008;51(7):701—7.*
	Procedure related Re-Admission	No, Yes	If Yes: For infection, Treatment Failure, Systemic Complication	If Yes: Date of Re-Hospitalisation	Any hospital readmission or rehospitalisation after discharge.	

(see Table 1). Some data elements, such as urgency of treatment and type of procedure were judged sufficiently important to always be required (level 1).

Statistical analyses were performed with SPSS Statistics software version 23.0 (IBM, Armonk, NY, USA).

RESULTS

Thirty-one experts were contacted and 25 accepted and completed the first online survey. In total, 187 items were submitted by them and were included in the panel discussion (Table 2). The items were reviewed by the expert panel and subsequently sorted into 11 main topics: (i) patient characteristics; (ii) comorbidities; (iii) current medications; (iv) lesion treated; (v) procedure; (vi) bypass; (vii) endarterectomy; (viii) catheter based intervention; (ix) complications; (x) follow up. The panel comprised vascular surgeons representing their national registry in ICVR, from three continents, 14 countries, and 18 institutions. The final number of data elements was not specified a priori. All panel experts (100%) completed rounds 1—4 and 18 (90%) completed round 5. The Delphi process (Fig. 1) resulted in the ICVR suggested data set for PAD revascularisation registries with different levels of potential detail for each variable (Table 1). After two Delphi rounds, 68 items were designated twice as "agree" or "strongly agree", whereas 60 items were designated twice as "disagree" or "strongly disagree". After five Delphi rounds, a total of 79 items were included in the recommended data set, of which 65 were included in the level 1 version, with an additional 14 included with more data specificity at the level 2 and 3 versions (Table 1). For example interventional device data can be recorded as level 1, which reports devices by class (plain angioplasty, drug coated balloon angioplasty, atherectomy, stent, etc.); level 2, which includes adjuncts such as embolic protection; and level 3, which records the Global Unique Device Identification Database.

It was recommended that all registries create an option to indicate that the state of the variable is "unknown", in order to differentiate omitted from unknown data, and not force users to choose an option when it is unclear. For simplicity, the "unknown" options for each variable have not been included in Table 1.

DISCUSSION

In this modified Delphi study with international experts, consensus was achieved on items to be collected in registries on peripheral arterial revascularisation. Sixty-five items were recommended for a minimum core (level 1) data set with an additional 14 variables with increased specification recommended for the optimum dataset (level 2—3). According to the existing literature and methodological recommendations, the minimum and optimum number for Delphi studies is two rounds. Regarding the panel size, at least 6—11 members are usually recommended to work efficiently. In this Delphi study more experts were included ($n = 25$) and there were more rounds ($n = 5$), emphasizing the rigor of the approach to address the complexity of the

Ankle brachial index for Right/ Left Leg	Highest ABI $\geq$ 1.3, ABI $<$ 1.3 and $\geq$ 0.9, ABI $<$ 0.9 and $\geq$ 0.7, ABI $<$ 0.4, treated leg	ABI exact measurement R/L leg	ABI and TBI exact measurement R/L leg

Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al. Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. Circulation. 2012;126(24):2890—909.

Table 2. 187 items submitted by the expert panel or identified by the literature review.

Date of admission
Date of procedure
Date of discharge
Mode of admission (e.g. emergency vs. elective)/ Urgency of the procedure
Performance site
Intensive care unit LOS
Special discipline responsible for hospital treatment
Hospital capacity/volume/teaching status
Discharge destination
Age (Birth Date)
Sex/Gender
Income
Occupation
Housing
Functional status
Ambulation
Nursing status
Migration background
Race and ethnicity
Education
Health insurance status
Walking distance
Existence of rest pain
Existence of ulcers
Existence of gangrene
Existence of infection
Fontaine classification (symptoms of index leg)
Rutherford classification (symptoms of index leg)
Tissue loss severity (for index leg)
WIfI Score
Texas classification
Wound depth
Angiosome
Acute limb ischaemia (ALI)
Ankle brachial index (ABI)
Toe pressure
Oscillographics
Transcutaneous oxygen measurement (tcp O2)
Duplex ultrasound
Contrast enhanced CT angiography (SCTA)
Contrast enhanced MR angiography (MRA)
Invasive digital subtraction angiography (DSA)
TASC classification
Exact location of treated lesions/artery treated or bypassed
Side for each lesion treated
Exact location of all lesions (even untreated)
Grade of stenosis
Length of stenosis
Inflow quantification
Outflow quantification (from treated artery)
Genuine vessel or graft/artery vs. graft
Pretreatment of lesion
Laboratory findings (e.g. cholesterol, HDL, platelet count, haemoglobin)
Ever smoked/Tobacco use
Current smoking/Tobacco use
Diabetes type 1
Diabetes type 2
Hypertension
Hyperlipidemia
Weight (or Body Mass Index)
Height (or Body Mass Index)
ASA Grade (Risk score: American Society of Anesthesiologists)
Renal function
Dialysis
Chronic obstructive pulmonary disease (COPD)
Myocardial infarction (MI)
Congestive heart failure (CHF)
Atrial fibrillation or flutter (AF)
Cardiac arrhythmia
Pacemaker, defibrillator, orthopedic endoprosthesis or other artificial material
Coronary artery disease (CAD)/Ischaemic heart disease
History of stroke or TIA
History of PAD revascularisation
History of acute limb ischaemia
History of amputation
Open wound or wound infection
History of vascular procedures
Aspirin
P2Y12/Clopidogrel/Other platelet inhibitor
Other platelet inhibitors
Vitamin K antagonists
New oral anticoagulants
Low dose heparin (not procedural)
High dose heparin (not procedural)
Beta blockers
ACE inhibitors or sartans
Statin/Lipid lowering agents
PGE1 infusions
Cilostazol
Naftidrofuryl oxalate
Pentoxifylline
Inositol nicotinate
Special discipline performing the procedure
Level of residency supervision
Pre-treatment of lesion
Side of intervention
Principal anaesthesia technique
Intra-procedural heparin
Additional anaesthesia technique
Operation time
Type of main endovascular procedure
Hybrid procedure
Type of devices used
Instructions for Use (IFU) followed
Detailed device information (includes length and diameter of different devices)
Atherectomy device
PTA device
Stent device
Distal protection device
Embolic protection device
Chronic total occlusion (CTO) device
Access site and approach
Access guidance
Largest sheath size
Use of duplex ultrasound (access)
Information about sheath used
Information about guidewire used
Planned adjunctive procedure

Thrombolysis
Mechanical thrombectomy
Additional approach (e.g. Nitro)
Completion angiography performed
Final technical result (includes technical success)
Dose area product (DAP)/Radiation dosage
Treatment aborted or incomplete
Acute conversion to open surgery
Patency
Closure device
Type of main open procedure
Hybrid procedure
Access site and approach
Diathermia or ligature used for cut down
Existence of infection
Conduit
Type of bypass
Type of prosthetic grafts used
Type and location of vein graft
Instructions for Use (IFU) followed
Type of surgical suture material
Proximal anastomosis
Distal anastomosis
Blood loss
Re-intervention of bypass
Completion angiography performed
Treatment aborted or incomplete
Acute conversion to endovascular procedure
Patency
Dissection
(Pseudo)Aneurysm
Arteriovenous fistula
Distal embolisation
Perforation
Bleeding
Myocardial infarction (MACE)
Death (MACE)
Stroke or TIA (MACE)
Major amputation (MALE)
Minor amputation (MALE)
Re-operation or re-intervention
Transfusion
Acute limb ischaemia/Lower extremity ischaemia
Device fracture or rupture
Compartment syndrome
Nerve injury
Wound infection or graft infection
Lymphoedema
Lymph fistula or seroma
Re-intervention open surgery
Re-intervention endovascular
Pneumonia
Deep venous thrombosis (DVT)
Pulmonary embolism
Acute renal replacement therapy
Delirium
Stent or graft thrombosis
Gastrointestinal complications
MACE
MALE
Patency
Limb salvage
Quality of life
Walking distance
Rehospitalisation
Re-intervention
Infection
Ankle brachial index (ABI)
Destination at discharge/discharge destination

research questions. For example, the additional three rounds resulted in 58 positive or negative recommendations that influenced the final result. An existing and well established international research collaboration of ICVR was used in order to include a high proportion of vascular registry experts. In addition to two face to face meetings, all comments of the panel experts were shared electronically. This innovative approach made the processes rigorous and efficient, considering the fact that international experts from different time zones participated in this Delphi study.

Importantly, the Delphi process resulted in a reduction from 187 items originally included in PAD registries across the ICVR to 79 items in the optimum data set. This is still a large number of variables after the consensus process and may pose a hurdle owing to the burden of data collection. However, considering the complexity of the PAD, and the abundance of medical and surgical treatment alternatives, a more comprehensive data collection is necessary to allow meaningful data analysis. Ultimately, the trade-off between complexity and practicality was challenging and proved to be even more difficult when designing a registry database for PAD than for AAA or carotid artery disease.

The key to collaboration and data sharing among registries is harmonisation of data elements, definitions, and method for similarly recording each variable. While each registry would prefer to register the most detailed data possible, real world practice and current lack of ability to easily extract uniform data from all electronic medical record (EMR) systems makes this impractical. For this reason, it is valuable to recommend not only a minimum core data set (and uniform definitions) that can be used by all registries, but also to recommend more detailed categories (levels) for data recording as registries mature and EMR extraction becomes more feasible. It is important that these higher levels of data collection harmonise with core levels so that all data can be merged at some level. The authors believe that the current proposal of core to optimum data collection “levels” is a novel contribution that could be valuable for other specialties.

It is recognised that the number and selection of data elements is contingent on the intended uses of the registry. A PAD revascularisation registry designed for quality improvement would probably have different elements or fewer granular data than one established for clinical research or device evaluation. In this work there was an attempt to balance the competing interests of inclusiveness with the practicality of data entry. The concept of different levels of modern web based registries with contingent variables already enables efficient data entry, but there is much work to be done. In the future, it is expected that

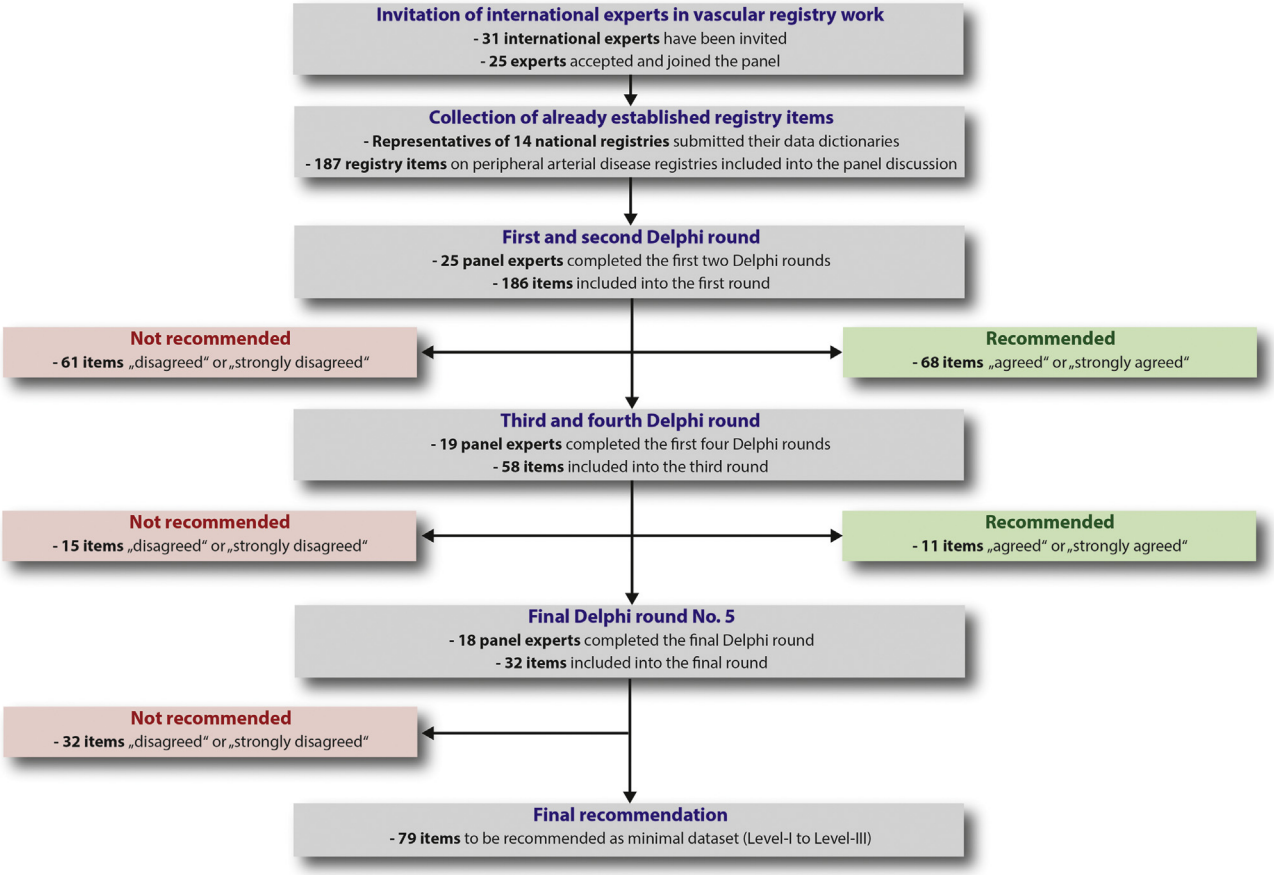

Figure 1. Flow chart of the modified Delphi study.

registries will integrate with EMR systems and claims data to allow more automated data capture to minimise the work of data entry. Clearly, such future developments facing big-data applications will need to meticulously deal with data privacy and safety concerns.[16]

Harmonisation of registries will allow for more meaningful comparisons of practice patterns, medical device performance, and outcomes across countries. Such collaboration will improve our ability to generate real world evidence and design registry based studies of peripheral vascular interventions. In the future, registry based studies may supplement the evidence gained from RCTs and prospective cohort studies. Similar work has been reported by the Registry Assessment of Peripheral Arterial Devices (RAPID) group for multispecialty collaboration within USA.[17,18] The ICVR-recommended data set has many agreements with data elements and definitions in RAPID, which is focused on device evaluation for peripheral vascular intervention in USA. The current ICVR database recommendations extend those of RAPID to encompass both open and endovascular revascularisation and for international studies, while still allowing device evaluation. These efforts provide an important opportunity for global harmonisation of clinical data to improve vascular health care. Existing ICVR registry members are committed to adopting these data elements as the next stage of evolution for ICVR.

CONCLUSIONS

This large scale modified Delphi study among international vascular registry specialists achieved a consensus agreement on a minimum core and optimum data set for registries evaluating peripheral arterial revascularisation. It reduced the overall number of initially suggested variables by nearly half. Global harmonisation of registry infrastructure and definition of items will overcome limitations related to single country investigations and has the potential to speed up and enhance acquisition of real world evidence. National registries in the ICVR plan to incorporate these core data elements into their PAD registries to increase the opportunity for future collaboration.

ACKNOWLEDGEMENTS

The authors thank Thea Schwaneberg (University Medical Centre Hamburg-Eppendorf, Hamburg, Germany) and the IDOMENEO-Consortium (University of Hamburg, Hamburg, Germany) for the valuable comments and editing, which greatly improved the manuscript. The authors also thank Axel Larena-Avellaneda (University Heart Centre Hamburg, Hamburg, Germany), Thomas Troëng (Uppsala, Sweden), Andres Schanzer (University of Massachusetts, Massachusetts, United States), and Reinhart T. Grundmann (Burghausen, Germany) for participating in this survey in addition to the authors of this manuscript.

REFERENCES

1 Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet* 2013;**382**:1329—40.

2 Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Task force on clinical practice guidelines. *J Am Coll Cardiol* 2017;**69**:e71—126.

3 Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg* 2015;**61**:2S—41S.

4 Aboyans V, Ricco JB, Bartelink MEL, Bjorck M, Brodmann M, Cohnert T, et al. Editor's Choice - 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg* 2018;**55**:305—68.

5 Behrendt CA, Heidemann F, Riess HC, Stoberock K, Debus SE. Registry and health insurance claims data in vascular research and quality improvement. *Vasa* 2017;**46**:11—5.

6 Sedrakyan A, Cronenwett JL, Venermo M, Kraiss L, Marinac-Dabic D, Bjorck M. An international vascular registry infrastructure for medical device evaluation and surveillance. *J Vasc Surg* 2017;**65**:1220—2.

7 Beck AW, Sedrakyan A, Mao J, Venermo M, Faizer R, Debus S, et al. Variations in abdominal aortic aneurysm care: a report from the International Consortium of Vascular Registries. *Circulation* 2016;**134**:1948—58.

8 Venermo M, Wang G, Sedrakyan A, Mao J, Eldrup N, DeMartino R, et al. Editor's Choice - carotid stenosis treatment: variation in international practice patterns. *Eur J Vasc Endovasc Surg* 2017;**53**:511—9.

9 Sedrakyan A, Cronenwett JL, Venermo M, Kraiss L, Marinac-Dabic D, Bjorck M. An International vascular registry infrastructure for medical device evaluation and surveillance. *Eur J Vasc Endovasc Surg* 2017;**53**:600—2.

10 Waggoner J, Carline JD, Durning SJ. Is there a consensus on consensus methodology? Descriptions and recommendations for future consensus research. *Acad Med* 2016;**91**:663—8.

11 Eleftheriadou V, Thomas K, van Geel N, Hamzavi I, Lim H, Suzuki T, et al. Developing core outcome set for vitiligo clinical trials: international e-Delphi consensus. *Pigment Cell Melanoma Res* 2015;**28**:363—9.

12 Wallace SJ, Worrall L, Rose T, Le Dorze G. Core outcomes in aphasia treatment research: an e-Delphi consensus study of international aphasia researchers. *Am J Speech Lang Pathol* 2016;**25**:S729—42.

13 Al Wattar BH, Tamilselvan K, Khan R, Kelso A, Sinha A, Pirie AM, et al. Development of a core outcome set for epilepsy in pregnancy (E-CORE): a national multi-stakeholder modified Delphi consensus study. *BJOG* 2017;**124**:661—7.

14 INSITE Collaborators. Diagnosis and management of iliac artery endofibrosis: results of a Delphi consensus study. *Eur J Vasc Endovasc Surg* 2016;**52**:90—8.

15 Golan R, Bernstein A, Sedrakyan A, Daskivich TJ, Du DT, Ehdaie B, et al. Development of a nationally-representative coordinated registry network for prostate ablation technologies. *J Urol* 2018;**199**:1488—93.

16 Behrendt CA, Pridöhl H, Schaar K, Federrath H, Debus ES. Clinical registers in the twenty-first century: balancing act between data protection and feasibility? *Chirurg* 2017;**88**:944—9.

17 Jones WS, Krucoff MW, Morales P, Wilgus RW, Heath AH, Williams MF, et al. Registry Assessment of Peripheral Interventional Devices (RAPID): registry assessment of peripheral interventional devices core data elements. *J Vasc Surg* 2018;**67**:637—44. e30.

18 Jones WS, Krucoff MW, Morales P, Wilgus RW, Heath AH, Williams MF, et al. Registry assessment of peripheral interventional devices (RAPID) — registry assessment of peripheral interventional devices core data elements. *Circ J* 2018;**82**:316—22.