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PUBLICATION STANDARDS FOR THE EJVES

Editor's Choice – European Journal of Vascular and Endovascular Surgery Publication Standards for Reporting Vascular Surgical Research

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Objective: Manuscripts submitted to the European Journal of Vascular and Endovascular Surgery (EJVES) often contain shortcomings in baseline scientific principles and incorrectly applied methodology. Consequently, the editorial team is forced to offer *post hoc* repair in an attempt to support the authors to improve their manuscripts. This repair could theoretically have been prevented by providing more clear definitions and reporting standards to serve researchers when planning studies and eventually writing their manuscripts. Therefore, the general principles for EJVES publication standards are summarised here.

Methods: These publication standards did not follow a systematic approach but reflect the common opinion of the current Senior and Section Editors team. This team decided to only include recommendations regarding the most common pathologies in vascular surgery in this first edition of publication standards, namely carotid artery disease, abdominal aortic aneurysm (AAA), peripheral arterial occlusive disease (PAOD), and chronic venous disease. In future editions, the plan is to expand the areas of research.

Results: Presented are (1) a common set of minimum but required publication standards applicable to *every* report, e.g., patient characteristics, study design, treatment environment, selection criteria, core outcomes of interventions such as 30 day death and morbidity, and measures for completeness of data including outcome information, and (2) a common set of minimum publication standards for four vascular areas.

Conclusion: The editors of the EJVES propose universally accepted definitions and publication standards for carotid artery disease, AAA, PAOD, and chronic venous disease. This will enable the development of a convincing body of evidence to aid future clinical practice guidelines and drive clinical practice in the right direction. These first ever publication and reporting standards for EJVES aim to improve future research published in the journal.

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INTRODUCTION

The most important aim of publication and reporting standards is to improve future research. The editors of the European Journal of Vascular and Endovascular Surgery (EJVES) are generally pleased with the many excellent quality manuscripts being submitted but have also noted that many submitted papers have methodological shortcomings in a way that could have been avoided (internal editorial board communication). Referred to here are both issues in baseline scientific principles as well as incorrectly applied methodology. Either the studied outcome is clinically irrelevant, the applied definitions are not correct, or selection and loss to follow up remain unreported. Very commonly, distinctly different patient groups are merged, often by the incorrect assumption that the larger number of studied patients guarantees a higher quality *per se*. Consequently, the reviewers and editors of the journal often need to repeat themselves in their comments on papers being reviewed in an attempt to support the authors to improve their manuscripts. This *post hoc* repair could

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theoretically have been prevented by providing more clear definitions and reporting standards to the authors at the time of starting to write their paper, or even earlier when designing the study. Therefore, the Senior and Section Editors now summarise the general principles for EJVES reporting standards in the following sections.

The need for defining reporting standards is not novel. Johnston *et al.* published a landmark paper in 1991 in which they defined how clinical research on arterial aneurysms should be reported.[1] Robert Rutherford was the main architect for this process, and it was subsequently extended to peripheral arterial disease and chronic venous disease. The first reporting standards for carotid artery disease were published in 1988.[2] These documents contained several general principles (i.e., population definition, power analysis, etc.) as well as specific parameters defining pathology (i.e., toe pressure measurement in peripheral arterial occlusive disease or definition of transient ischaemic attack in carotid disease), which needed revision over time when new (mostly endovascular) techniques developed.

Different study designs demand different sets of reporting standards. It is not the purpose of this document to repeat the following established recommendations: the CONSORT (CONsolidated Standards Of Reporting Trials) statement: revised recommendations for improving the quality of reports of parallel group randomised trials; the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement; and the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement. These relevant reports are freely available online, are updated on a regular basis, and are of great value for any author.

Instead, this document aims to serve researchers when planning studies and eventually writing their manuscripts. Eventually, this document aims to harmonise the presentation and improve the quality of manuscripts submitted to EJVES. In order to more quickly initiate the process, in this first edition of reporting standards it was decided to only include recommendations regarding the most common pathologies in vascular surgery, namely carotid artery disease, abdominal aortic aneurysm (AAA), peripheral arterial occlusive disease (PAOD), and chronic venous disease. In future editions, it is planned to expand the areas of research. This will enable individual patient data meta-analyses to aid future clinical practice guidelines and drive clinical practice in the right direction.

In a parallel process, international vascular registries for both quality improvement and research purposes, such as VASCUNET, aim to reach international agreement by consensus on common definitions and to define key variables that would facilitate merging data from several countries. VASCUNET has its focus on standardised collection of data, while this current document will focus on standardisation of minimally required reporting parameters and EJVES publication standards. As such, these EJVES and VASCUNET processes go hand in hand and will reinforce each other.

In a third process, the European Society for Vascular Surgery (ESVS) clinical practice guidelines currently cover almost all the important clinical areas, and now also include transcending topics such as the recent guideline for radiation protection and a guideline dedicated to antithrombotic therapy.[3,4] The guidelines writing committees often identify weaknesses in applied definitions[5] and reporting standards[6] in the summarised literature.

Although there are similarities and common issues in the abovementioned three processes, there are also key differences. Quality improvement registries need to define which risk factors, comorbidities, and outcomes are relevant to register in order to allow quality improvement. The clinical practice guidelines have as their main purpose to help clinicians give the currently available best evidence based treatment to each patient. For the EJVES editors it is key to define the publication standards that serve to bring the scientific reports in an optimal and sound manner to the readership.

The overall aim of this document was therefore to define unequivocal criteria, easy to implement, to improve the quality of future vascular surgical research.

Detailed aims of publication standards

No systematic search was applied. Instead, the present publication standards reflect the common opinion of the current team of Senior and Section Editors of the journal. The team reached consensus on the overall content via three online meetings as well as exchange of information via email. The writing team wishes to reaffirm that the publication standards presented are minimum standards, and authors and study statisticians are free to, and should usually aim to, report in more detail than described here.

To date, the lack of a common language with commonly included variables hampers the understanding of outcomes of treatment for a wide spectrum of vascular conditions. The following detailed purposes should be considered: (1) to describe the disease, define pathologies, and anatomical specifications; (2) to define the study population; (3) to define the medical environment; (4) to justify clinical decision making; (5) to describe interventions; and (6) to define early and late outcomes (hard, soft, composite, clinical, economic, quality of life, and patient reported outcome measures [PROMs]) to enable comparability of investigations based on a minimum set of crucial information.

Short term follow up is defined as the first year after the operation or intervention, midterm as follow up of longer than one year but less than five years, and long term follow up as five years or longer. Different vascular areas demand different sets of reporting standards (carotid, AAA, PAOD, venous, etc.). There are three reportable forms of patency following any peripheral vascular intervention and these can be concisely defined as follows: (1) primary patency: no additional procedures at site of initial intervention; (2) primary assisted patency: patency maintained after additional intervention for re-stenosis that was intended to prevent

occlusion; patency is lost in case of thrombosis; and (3) secondary patency: patency lost but restored following re-intervention for occlusion of the treated segment. Patency is lost in case of terminal thrombosis.

Patency rates should be reported by either Kaplan—Meier or life table analysis for freedom from re-stenosis, recurrent symptoms, and amputation. In addition, vessel specific reporting should be performed if more than one vessel has been treated. The Global Limb Anatomic Staging System (GLASS) emphasises limb based patency (LBP) of all treated segments along the target artery pathway (TAP) as a more meaningful reflection of patency after interventions for chronic limb threatening ischaemia (CLTI) (see section on PAOD).

The aim was to develop: (1) a common, absolute minimum set of required publication standards applicable to *every* report (e.g., patient characteristics, study design, treatment environment, selection criteria, core outcomes of interventions such as 30 day death and morbidity, measures for completeness of data including outcome information); and (2) common sets of relative minimum publication standards for each vascular area.

STANDARDS PER DOMAIN AND OR PATHOLOGY SPECIFIC STANDARDS

Carotid artery disease

Carotid interventions aim to lower the long term risk of stroke and stroke related death.[7] The benefit of the procedure results from the balance between the natural course risk and procedure related complications. Major neurological adverse events and complications after carotid intervention nowadays have become less frequent. In order to design future trials, the classic clinical endpoints may need to be replaced or harmonised by surrogate imaging based endpoints.[8] Advances in techniques (endovascular alternatives) and medical treatment (i.e., dual antiplatelet therapy and inflammation inhibitors) as well as the use of post-market registries for conventional *vs.* high risk patients make it imperative to create unequivocal reporting standards that will allow meaningful meta-analyses according to patient diagnostic workup as well as patient, lesion, and procedural characteristics.

Aetiology. Because it may impact both treatment and risk of recurrence, the underlying cause(s) of cerebrovascular symptoms should be defined whenever possible, i.e., cardio- or arterio-embolic, thrombotic (native artery *vs.* prior reconstruction), haemodynamic, dissection, trauma, carotid aneurysm, or hypercoagulable state (acquired or inherited).

Demographics. *Age* at the time of carotid revascularisation is well established as a risk factor for 30 day stroke after carotid endarterectomy (CEA), but especially after carotid artery stenting (CAS). Furthermore, age is recognised as a risk factor for long term stroke free survival. Age should be reported as median and interquartile range.

Sex related outcome differences following conservative treatment, as well as after CEA and CAS, are well recognised.[9] Sex should always be reported in absolute numbers of males and females or as a male to female ratio.

Smoking status should be recorded as current smoker, ex-smoker, or never smoked.

Pharmacological therapy should be reported and should include the following: antithrombotic agents; lipid lowering agents (and dosages); glycaemic control agents; and antihypertensives.

Comorbidities and high risk anatomy. The American Society of Anesthesiologists (ASA) physical status classification is simple to use and is routinely recorded in anaesthetic charts. Contemporary evidence has reported that increasing ASA grade is strongly associated with increased 30 day mortality in vascular patients.[10]

It is recommended that data regarding medical comorbidities include the presence of heart failure and coronary artery disease, recent clinical or biochemical myocardial infarction, and severe lung or kidney disease. Anatomies deemed high risk for CEA have been defined by the SAPPHIRE trial and include post-radiation, very distal internal carotid artery lesions, tandem lesions, post-CEA re-stenosis, and contralateral occlusion. Interestingly, most of these deemed high risk factors do not relate to a high risk of procedural stroke but rather to a high risk of wound healing complications (i.e., post-radiation), a greater need for intraoperative shunting (contralateral occlusion), or a higher rate of temporary instead of permanent cranial nerve palsy.[11]

High risk criteria for CAS such as type III arch, circumferential carotid calcification, and severe tortuosity have been suggested by a Delphi consensus work group[12] but have thus far never been validated. From the CREST trial, plaque length and again type III arch have been related to high risk stent anatomy. In studies on the outcome of transfemoral CAS, it is recommended to always report the type of arch and presence of circumferential calcification.

Diagnostic and imaging workup. Pre-procedural evaluation of patients with carotid disease should include imaging studies to determine the degree of stenosis and to assess morphological characteristics and the location and extent of the carotid lesion. Duplex ultrasound (DUS), magnetic resonance angiography (MRA), computed tomography angiography (CTA) as well as the classic digital subtraction angiography (DSA) can be used to image carotid pathology.

Detailed imaging of the brain is also recommended at baseline, especially in terms of the scoring of new surrogate endpoints related to revascularisation such as magnetic resonance imaging (MRI) based diffusion weighted imaging (DWI) lesions. Reporting of timing of revascularisation is crucial, especially in studies reporting on the carotid brain axis, for example plaque morphology in relation to cerebral infarction.

Degree of stenosis. It is recommended that the degree of stenosis be calculated by the NASCET (North American Symptomatic Carotid Endarterectomy Trial) method applied to either non-invasive imaging (CTA, MRA) inferred from DUS data or applied to DSA and be reported pre- and post-treatment.[7]

Table 1. Baseline clinical evaluation for carotid artery disease.
Asymptomatic
Ipsi- or contralateral ocular symptoms
Ipsi- or contralateral transient ischaemic attack
Ipsi- or contralateral stroke

Indications for intervention. It is mandatory to always differentiate between symptomatic and asymptomatic patients and between primary and redo procedures when reporting indications, workup, and outcome of intervention.

Symptoms. Symptomatic patients must have had a hemispheric transient ischaemic attack (TIA) with distinct focal neurological dysfunction, monocular blindness, or acute retinal ischaemia persisting <24 hours, or a non-disabling stroke with persistence of symptoms for >24 hours within the previous 180 days. It is recommended that symptoms should include cerebral or retinal TIAs, acute retinal ischaemia, or non-disabling stroke within the previous 180 days (Table 1). Preferably, the Rankin score is registered at baseline and at a standardised time point after revascularisation.[7] In symptomatic patients, reporting of the timing of imaging in relation to the index event is warranted.[7,13,14]

Intervention. Reporting on the following is recommended: (1) the anaesthetic technique (general *vs.* cervical block *vs.* local); (2) the surgical technique (eversion *vs.* longitudinal arteriotomy with or without patch angioplasty) (Table 2); (3) the application of any type of peri-operative (neuro) monitoring (pre- *vs.* intra- *vs.* post-operative) or other control measures (Table 3); (4) timing of surgery; and (5) the type of shunting (routine *vs.* selective or no shunting). Specific parameters (Table 4) should be reported for endovascular carotid procedures.

Outcomes. The primary outcome parameter should always include 30 day or in hospital rate of death, any stroke, and ipsilateral stroke (Table 5).

For TIA, it is recommended to always differentiate between hemispheric and ocular events; report the symptomatic side or hemisphere.

Differentiate between in hospital and 30 day events.

For both options, outcome reporting should differentiate between intra- and post-procedural events.[14]

Secondary endpoints should include cranial nerve palsy according to independent neurological post-operative assessment, bleeding complications, and any prolonged stay in hospital (Table 5). Secondary endpoints may include surrogate imaging based brain markers for outcome. There is a strong need for the re-definition of study endpoints and for well defined surrogate markers for ischaemic stroke, both in the semi-acute and late phases.

Table 2. Operative techniques for carotid artery disease.
Longitudinal arteriotomy (closure with a patch or primary closure)
Eversion arteriotomy
Resection with interposition grafting
Hybrid (transcervical carotid revascularisation)
Endovascular

Table 3. Peri-operative monitoring for carotid artery disease.
Electroencephalography
Transcranial Doppler (both micro-embolisation and haemodynamic monitoring)
Near infrared spectroscopy
Angioscopy and or angiography
Intra-operative duplex ultrasound

DWI lesions, silent brain infarcts (SBIs), and white matter lesions (WMLs) are promising and complementary imaging based surrogate markers.[15,16] All three surrogate markers have been associated with increased risk of future cerebrovascular events in patients with carotid artery disease specifically. Both SBIs and WMLs have been associated with increased risk of short term cognitive decline, while the long term effects need to be investigated further.[16]

Standardisation of imaging protocols and reporting of outcomes is required. Differentiating between, and reporting, both *any* and *ipsilateral* lesions is recommended. DWI lesions are most suitable for assessment of peri-procedural outcome, whereas both SBIs and WMLs can be used for long term outcome reporting.[16]

Reporting of follow up and patency. Patency has traditionally been defined as demonstrably patent intervention, bypass, or reconstruction by accepted imaging techniques (DUS, CTA, DSA, MRA). DUS of the site of intervention by an accredited vascular laboratory is the gold standard for follow up and assessment of ongoing patency. The generally accepted long term criterion for anatomic success is freedom from $>50\%$ re-stenosis or occlusion.[17]

Basic science and histological reports. Reports should include information on the sectioning (longitudinal *vs.* transverse), decalcification, and number and staining of histology slides. Reports should include the use of computer image analysis or a similar technique, or manual image scoring.[18]

Table 4. Recommendations for reporting on carotid stent procedures.
Pre-procedural antithrombotic therapy
Access site (transfemoral, transcarotid, transradial, or alternative)
Haemodynamic supportive medication such as atropine
Embolic protection device (occlusive such as flow reversal *vs.* non-occlusive)
Pre-dilatation
Stent type (open *vs.* closed cell design; tapered *vs.* non-tapered)
Post-dilatation
Peri-procedural monitoring and or completion angiography
Simultaneous intra-arterial thrombectomy

Table 5. Primary and secondary clinical outcome parameters for carotid artery disease.

Any death
Primary *vs.* intervention related causes of death
Subclassification of cardiovascular causes of death
Non-cardiovascular deaths and deaths of undetermined cause
Myocardial infarction (clinically manifest)
Silent myocardial infarction
Biochemical myocardial infarction
Unstable angina
Any stroke
Ipsilateral stroke
Any transient ischaemic attack
Ipsilateral transient ischaemic attack
Recurrent events
Bleeding complications

It is recommended that studies of this type report intra- and interobserver reproducibility for the histological assessments as well as those for the imaging technique, and the results of the imaging—pathological comparison should be interpreted in light of these results.

Unless the reasons for reporting selective characteristics are clearly justified, the following well recognised features of unstable plaque should be reported routinely: intraplaque haemorrhage; lipid to fibrous content ratio; intraluminal thrombus; plaque rupture; and minimum cap thickness.[19]

Abdominal aortic aneurysm

Factors that influence outcome for both open surgical repair (OSR) and endovascular aneurysm repair (EVAR) of AAA are well established. It is important that these variables are incorporated during study design and protocol development. While many factors have an important influence on patient outcome irrespective of the type of AAA repair, some variables should be reported for specific outcomes according to the mode of intervention (Table 6).

Aetiology. Risk factors for developing an AAA include family history, smoking, hypertension, (in particular abdominal) obesity and hyperlipidemia. Although connective tissue disorders can predispose patients to abnormal vessel dilatation, it is more commonly seen in the thoracic aorta. Infected or mycotic aneurysms should be identified and reported separately from degenerative AAAs.

Demographics. *Age* is well established as a risk factor for 30 day and in hospital death for both OSR and EVAR. Contemporary international registry data reporting mortality rates for patients aged >80 years were significantly higher for both OSR (9.3% *vs.* 3.3%) and EVAR (1.4% *vs.* 0.4%) compared with younger patients.[20] Furthermore, age is recognised as a risk factor for long term patient and graft related outcomes. See also Carotid artery disease section.

Regarding *sex*, worse outcomes for female patients following both OSR and EVAR are well recognised. International registry

Table 6. Summary of suggested reporting variables, with description of data and units required, for abdominal aortic aneurysm (AAA).

Parameter	Data and units
Demographics	
Age	Year (median/range)
Sex	Number (%) male/female
ASA level	Number (%) ASA grades I–V
Pre-operative renal function	eGFR in mL/min/1.73m^2 (median/range)
Haemoglobin	In g/dL, for ruptured AAAs
Lowest systolic blood pressure	In mmHg, for ruptured AAAs
AAA morphology	
AAA size	Maximum diameter, in mm
Neck length	In mm, and percentage <10 mm
Neck maximum diameter	In mm
Neck angulation	$\alpha > 45^\circ$ or $\beta > 60^\circ$
Common iliac artery maximum diameter	In mm
Type of anaesthetic[9]	
Type of anaesthetic	Number (%) of patients having local, regional, or general anaesthetic
Device type	Tube or bifurcated
	Infrarenal EVAR, aorto-uni-iliac, FEVAR, and manufacturer
	Compliance with manufacturer's instructions for use (percentage)
EVAR proximal fixation	Suprarenal or infrarenal
FEVAR fenestrations or scallops	Number
FEVAR target vessel patency	Percentage (immediate, early, short term, midterm, long term)
FEVAR re-intervention	Percentage (immediate, early, short term, midterm, long term)
Iliac branch device patency	Percentage (immediate, early, short term, midterm, long term)
Iliac branch re-intervention	Percentage (immediate, early, short term, midterm, long term)
Outcomes	
Death	Specify:
	perioperative death (30 day or in hospital)
	all cause mortality rate at specified follow up
	aneurysm related mortality rate
Complications	As per Clavien–Dindo scoring system:
	complications treated conservatively
	complications requiring pharmacological treatment
	complications requiring surgical, endoscopic, or radiological intervention (3a, not under general anaesthetic; 3b, under general anaesthetic)
	life threatening complication requiring ITU management (4a, single organ dysfunction; 4b, multi-organ dysfunction)
	death of patient
Re-interventions	Specify if endovascular, open, or hybrid (immediate, early, short term, midterm, and long term) (percentage)

Continued

Table 6-*continued*

Parameter	Data and units
Indication for re-intervention	Graft infection, pseudoaneurysm, AAA rupture, graft occlusion, endoleak, sac expansion (>5 mm), EVAR graft migration (>5 mm)
Endoleaks	Specify:
	endoleak type I, III (percentage)
	if primary or secondary
Aneurysmal sac size increase	Number (%) of patients with sac size increases, and number (%) requiring intervention
AAA rupture	Yes or no (percentage)
Temporal follow up[*]	
Elective intact AAA repair	
Immediate	In hospital or 30 day
Early	≤ One year
Short term	> One year to < five years
Midterm	≥ Five years to < ten years
Long term	≥ Ten years
Emergency ruptured AAA repair	
Immediate	In hospital or 30 day
Early	≤ One year
Short term	> One year to < two years
Midterm	≥ Two years to < five years
Long term	≥ Five years

ASA = American Society of Anesthesiologists; eGFR = estimated glomerular filtration rate; AAA = abdominal aortic aneurysm; EVAR = endovascular aneurysm repair; FEVAR = fenestrated endovascular aortic repair; ITU = intensive therapy unit.
* Definitions of length of follow up after AAA repair (modified from Boyle *et al.*, 2011[27]).

data recently reported significantly higher AAA mortality rates of 3.0% for women compared with 1.6% for men for all modes of repair.[20] Contemporary data from a meta-analysis reported higher mortality rates for women for both OSR and EVAR (odds ratios 1.49 and 1.86, respectively).[21] Pulmonary complications and bowel ischaemia were more common in women following OSR, and limb ischaemia, arterial injury, and kidney and cardiac complications were more common after EVAR. See also Carotid artery disease section.

Regarding *smoking status*, the rate of AAA growth increases in current smokers.[22] Contemporary evidence suggests that smoking cessation for more than eight weeks prior to AAA surgery reduces the incidence of pulmonary complications.[22] See also Carotid artery disease section.

Comorbidities and high risk anatomy. Reporting the ASA grade physical status classification (see Carotid artery disease section) is recommended.

Contemporary evidence has reported that increasing ASA grade is strongly associated with an increased 30 day mortality rate after vascular surgery.[23] ASA grade is also associated with long term death after AAA repair.[24]

Chronic kidney impairment is an important risk factor linked to poor short and long term outcomes. While creatinine is routinely determined, estimated glomerular filtration rate (eGFR), which can easily be calculated and is often provided by biochemistry laboratories, is a better measure of kidney function.

In addition to the variables described above for elective AAA treatment, it is recommended that lowest systolic blood pressure and haemoglobin level are recorded for all ruptured AAAs as these are surrogate markers for patient instability and are recorded routinely. The most commonly used predictor of AAA rupture is maximum aortic diameter.[25]

Diagnostic and imaging workup. The diagnosis of AAA may be established by clinical examination (although with poor validity), by incidental finding on imaging obtained for other clinical indications, or specifically from AAA screening. Screening uses ultrasound to identify an AAA. The ESVS AAA guidelines recommend considering AAA repair for aneurysms exceeding 5.5 cm in maximum diameter for men and 5.0 cm for women.[26] Smaller aneurysms are surveyed using ultrasound until they reach these thresholds, at which time CTA is performed to assess detailed aortic anatomy and to evaluate options for intervention. In general, AAA repair should only be considered when the risk of rupture is deemed greater than the risk of elective repair.

Indications for intervention. AAA repair may also be considered in small AAAs with rapid growth (> 10 mm per annum), saccular AAAs irrespectively of size, AAAs with a concomitant large (≥ 4 cm) iliac artery aneurysm, and in patients with symptomatic or ruptured AAAs.

Morphology. Whilst AAA morphology is clearly important for the success of EVAR, these anatomical details have not routinely been reported for patients undergoing OSR. However, reporting of important anatomical characteristics for all AAA repairs is encouraged in order to enable comparisons. In particular, neck length and neck diameter, which are not only associated with long term EVAR durability but also with death following OSR or EVAR for ruptured AAA, should be reported.[27,28]

Neck length and diameter, as well as their relationship with the description of an aneurysm as juxtarenal or pararenal, often make it difficult to directly compare patient groups. One way around this is the use of methods recently described in the UK-COMPASS study (UK COMPlex AneurySm Study) where actual neck length of < 10 mm was used as a useful cutoff.[29] Using neck length of < 10 mm or ≥ 10 mm would seem a good way of designating a group at higher risk. Similarly, reporting a neck diameter of < 26 mm or ≥ 26 mm can be used to designate a higher risk group.

Reporting maximum AAA size (median and interquartile range) and maximum iliac artery diameter (on each side) with a diameter of < 16 mm or ≥ 16 mm designating a high risk group is recommended.[30]

Neck angulation is also an important predicter of outcome and should be reported. An α angle > 45° or β angle > 60° impact EVAR outcome. The β angle is more commonly recorded and is a more granular description by severity (< 60°, 60 − 90°, or > 90°).

Symptoms. AAAs do not usually cause symptoms. However, patients may notice a pulsation in their abdomen, and some complain of abdominal and back pain. When reporting AAA outcomes, intact and ruptured AAAs should be reported separately since these are distinct biological entities.

Intervention. AAAs are repaired by either OSR or EVAR. OSR is associated with higher rates of peri-operative death but is more durable than EVAR. Outcomes for OSR and EVAR should be reported separately. Similarly, more complex endovascular repair using fenestrated or branched devices, as well as other endovascular techniques, should be reported as distinct groups.

Factors that influence outcome both for OSR and EVAR are well established. It is important that these variables are incorporated during study design and protocol development. While many factors have an important influence on patient outcome irrespective of the type of AAA repair, other specific variables should be reported according to the mode of intervention.[27]

Outcome reporting. Death in hospital and at 30 days as well as aneurysm related and all cause death at the specified follow up intervals described below should be reported as primary outcome measures following AAA surgery, since the aim of AAA surgery is to prolong life.

Re-intervention or revision and the indication for re-intervention should also be reported.

Follow up. It is important to standardise the length of follow up following AAA surgery. Many authors use short, mid and long term follow up interchangeably without adequately defining these terms. These terms often refer to significantly different periods of time in different studies. This is of increasing importance following EVAR where long term durability is a concern. The definitions first described in 2011 have been modified in Table 6.[27] Follow up is defined as immediate (in hospital or 30 day), early ≤ 1 year, short term > 1 to < 5 years, midterm ≥ 5 to < 10 years, and long term ≥ 10 years for elective AAA repair; and short term > 1 to < 2 years, midterm ≥ 2 to < 5 years, and long term ≥ 5 years for ruptured AAAs.

Implants. Both OSR grafts and EVAR devices used to repair AAAs may require revision or re-intervention during a patient's lifetime to maintain AAA sac exclusion. Contemporary data have highlighted greater rates of iliac limb occlusion with different EVAR devices.[31,32] It is likely that device specific outcomes and comparisons between devices will become more prevalent in the vascular literature and therefore it is vital to include the manufacturer and device type when reporting AAA outcomes in the context of the aneurysm morphology treated. Comparing the outcomes of one device with another should take into account the specific device characteristics and their instructions for use (IFU), so that comparisons are made between similar devices and comparable aortic anatomy. If patients are treated outside of IFU they should be reported as a separate subgroup.

Peripheral arterial occlusive disease

Over the last decade, the diagnosis and management of lower limb ischaemia have become more complex due to the global epidemic of diabetes. In this document, the abbreviation PAOD is used when referring to arterial occlusive disease in the lower limbs. Patients with diabetes often have concomitant PAOD, which may complicate attempts to achieve healing of diabetic foot ulcers and infections. The development and increasing acceptance of newer classification systems is part of a global effort to better understand the impact of various interventions on the natural history of the broad spectrum of PAOD that vascular specialists treat.[33]

Aetiology. These publication standards apply to patients with objectively documented PAOD due to atherosclerosis who present with either claudication or CLTI.

Clinical presentation

Claudication. Intermittent claudication is defined as pain, discomfort, or weakness in the muscles of the leg that is consistently produced by the same amount of walking or exertion and is reliably relieved by rest.[33]

Chronic limb threatening ischaemia. *CLTI* includes patients with objectively documented PAOD and any of the following clinical signs or symptoms: (1) ischaemic rest pain with confirmatory haemodynamic studies; (2) diabetic foot ulcer or any lower limb ulceration present for at least two weeks; and (3) gangrene involving any portion of the lower limb or foot.

Specifically excluded are patients with pure venous ulcers, pure traumatic wounds, acute limb ischaemia (symptoms present for two weeks or less), embolic disease, and non-atherosclerotic chronic vascular conditions of the lower extremity (e.g., vasculitis, Buerger's disease, radiation arteritis).[33]

Demographics. See Carotid artery disease section.

Pharmacological therapy should be reported when applicable and include the following: antiplatelet agents; anticoagulants (standard and novel); lipid lowering agents (statin use and dosages); glycaemic control agents; and antihypertensives. See Carotid artery disease section.

Comorbidities and high risk anatomy. Non-anatomic patient variables that should generally be reported include the following: diabetes mellitus; hypertension; dyslipidaemia; kidney, cardiac, and pulmonary disease; and functional status.

The anatomic characterisation of the lesion(s) treated greatly impacts treatment outcomes and durability. The Bollinger scoring method and Trans-Atlantic Inter-Society Consensus for the management of peripheral arterial disease (TASC II) are the two most generally accepted anatomic classifications for patients with a broad range of PAOD, especially for those with claudication. The Bollinger method is more complex and less widely used but is better than TASC II in discriminating the impact and significance of above knee from below knee disease. Because of the limitations of TASC II, especially in patients with CLTI with

multilevel and below knee disease, a more recent anatomic staging system, the Global Anatomic Staging System (GLASS), is now recommended for classifying infrainguinal disease in patients with CLTI (see below).

Diagnostic and imaging workup. Regarding the diagnosis and longitudinal, non-interventional management of patients with claudication, several common components should be reported. First, the means by which the diagnosis of claudication was made must be specified. A compatible history with objective testing, either resting or post-exercise ankle brachial index, is generally required to confirm the diagnosis of vasculogenic claudication and to exclude patients with other pathology such as spinal stenosis. For large population based studies in which such measurements may not be possible or practical, the use of a validated tool such as the Edinburgh Claudication Questionnaire is suggested.

Indications for intervention. Since the indications for intervention are strong determinants of patency rates and outcomes after intervention, these must be included in all published reports of interventions for PAOD. Patients with claudication should be analysed separately from those with CLTI, and patients with CLTI should be stratified or staged using a limb threat classification system such as the Wound, Ischemia, and foot Infection (WIfI) classification. Finally, patients with diabetes and renal failure should be analysed separately, as these conditions impact outcomes.

Symptoms. PAOD is an extremely broad disease spectrum, ranging from asymptomatic patients (who may have masked lower extremity PAOD), to patients with claudication (exertional pain in the leg muscles relieved by rest), and those presenting with ischaemic ulcers or advanced gangrene of the forefoot, midfoot, or heel.

In order to classify symptom severity, either the Rutherford (1 — 3) or Fontaine (I, IIA, and IIB) classification is required. While these older, well established systems are still useful for patients with asymptomatic disease and claudication, for individuals with CLTI they are insufficiently granular and less applicable to patients with diabetes. Thus, the WIfI classification is recommended in those settings (refer to the discussion below).

Intervention. The options for anaesthetic, open surgical, endovascular, or hybrid techniques should be included in all reports with sufficient detail to adequately characterise and differentiate the wide variety of interventions applied in modern vascular practice (Table 7).

Outcome reporting. The reporting of outcomes is an exceedingly complex issue and has historically been based on clinical improvement, haemodynamic improvement, technical success, patency of the intervention, and, more recently, PROMs. In general, some objective degree of patient improvement, haemodynamic improvement, and patency of the intervention are required components of outcome reporting after peripheral arterial interventions. These are reviewed in more detail below.

Table 7. Interventions for peripheral arterial occlusive disease.

Percutaneous transluminal angioplasty (PTA)
Location of intervention (specific vessel)
Primary *vs.* repeat intervention
Intraluminal or subintimal
Extent or degree of calcification
Length, diameter, and type of balloon
Inflation pressure and time
Standard or drug coated balloon (including the specific agent)
Atherectomy
Type of atherectomy device
Location of treatment (specific vessel)
Treatment time, extent, amount, and length of plaque treated
Adjuncts: PTA and or stent
Embolic protection device use, yes or no
Stents
Location of treatment (specific vessel)
Pre-dilation, yes or no
Vessel preparation, yes or no (atherectomy, intravascular lithotripsy, other)
Length and diameter of stent
Balloon expandable or self expanding
Covered, uncovered, heparin bonded, or drug eluting stent (including the agent)
Final treatment (post-stent dilation)

PTA = percutaneous transluminal angioplasty.

It is also important to report a follow up of at least one year, preferably three to five years, since short term outcomes are not sufficient when evaluating and comparing different treatment options. The follow up index should always be included.[34]

Complications. Reporting standards require a minimum of the following components: (1) all procedure related adverse events should be reported and categorised as procedure or device related; (2) a minimum of 30 days of complications reporting is required; subacute and late complication reporting is suggested; and (3) all cause death.

Reporting of follow up and patency. See Carotid artery disease section for general context. For patients with CLTI specifically, in accordance with the 2019 global CLTI guidelines,[33] primary patency should be based on the target artery pathway (TAP) selected and calculated as limb based patency (LBP). Several published analyses using GLASS, TAP, and LBP suggest that these systems, in patients with CLTI undergoing endovascular therapy, correlate with initial technical success, early patency, and the requirement for re-intervention.[35–37]

Use of target lesion revascularisation should not be considered a primary outcome measure after lower extremity intervention because it is imprecise and not always driven by clinical evidence of symptoms but by a decision (by the patient and the operator) to perform a secondary revascularisation. It is common knowledge that ischaemic ulcers may have healed, and collaterals developed, even when the previously treated lesion has subsequently occluded, making further procedures unnecessary. The improvement in perfusion may have been of sufficient

duration that the wound was able to heal, and repeat intervention would not be needed for re-stenosis or occlusion of the treated segment in the absence of a recurrent wound, rest pain, or other signs or symptoms of ischaemia. Thus, target lesion revascularisation is not an acceptable proxy for patency.

Chronic limb threatening ischaemia

Diagnosis and limb threat severity. This issue has been well covered in detail as part of the global CLTI guidelines.[33] Limb staging in patients with CLTI immediately prior to intervention is mandatory and must include haemodynamic assessment. Limbs affected by CLTI should be staged at initial presentation based on the WIfI classification.[38] In addition, separate analysis of patients with rest pain (W0/I3/fI0) *vs.* those with tissue loss should be performed. Patients with and without diabetes mellitus should also be reported and analysed separately.

Patient risk. Patient risk should be stratified using the criteria and subsequent app developed by Simons *et al.*[39] to predict survival in patients undergoing intervention for CLTI. As part of the global CLTI guidelines document, Simons *et al.*[39] developed an app (https://apps.apple.com/ca/app/calculate-by-qxmd/id361811483) to predict survival based on analysis of 38 470 unique patients with CLTI in the Vascular Quality Initiative (VQI) registry. The survival prediction models differentiated low, medium, and high risk patients; however, the app has not yet been validated. Future studies of open surgical and endovascular management of patients with CLTI are strongly encouraged to use this app, whenever practical, and correlate predicted 30 day and two year mortality rates with the actual rates observed in the reported study population. The observed mortality outcomes could be reported for each of the predicted relative mortality risk groups. Such efforts would serve to validate and or improve the utility of the app in the future and would allow baseline patient risk comparison between different studies. Patients with CLTI are a broad and diverse group, with variable mortality and amputation risks, and without better patient stratification, comparison of outcomes in studies from different centres cannot be performed accurately.

Chronic limb threatening ischaemia anatomic definition. In patients with CLTI who undergo revascularisation, use of the GLASS classification is recommended (including the pedal modifier). For pedal interventions, the Kawarada classification is also acceptable.[40]

Chronic limb threatening ischaemia outcome reporting. Most CLTI endpoints can be broadly divided into four categories: (1) haemodynamic; (2) anatomic; (3) objective clinical (e.g., amputation free survival and major adverse limb events); and (4) subjective clinical patient reported outcomes, including health related quality of life (HRQoL) instruments and PROMs. Haemodynamic and anatomic definitions of success have already been discussed. Recommended outcomes based on the global CLTI guidelines include those related to the patient as well as the treated limb.

Table 8. Definitions of haemodynamic success.

Pressure gradient <10 mmHg across lesion after treatment
Increase in ankle brachial index of ≥0.10 (most commonly used; some have recommended 0.15)
Increase of pulse volume recording amplitude >50%
Venous: complete ablation or abolition of reflux

Complications. The objective performance goals were originally developed and published in 2009 to evaluate catheter based therapy for CLTI and were based on prospective studies of bypass with autogenous vein as an established standard.[33] These outcomes have come to be generally accepted as reasonable endpoints to report in CLTI trials as they capture more of the complexities of care than simply amputation free survival or limb salvage (Table 8).

Quality of life and patient reported outcome measures. There has been increasing interest in, and recognition of, the importance of endpoints and outcomes that reflect more than just technical success, patency rates, and amputation. These focus on the patient's perception of their treatment. Therefore, incorporating HRQoL and PROMs into trials is strongly recommended. PROMs should be disease specific whenever possible. For claudicants, the Walking Impairment Questionnaire (WIQ) and 6 Minute Walk Test (6MWT) are useful and acceptable measures. An additional acceptable quality of life (QoL) metric is the Vascular Quality of Life Questionnaire (VascuQoL). The VascuQoL and EuroQol 5 dimension (EQ-5D) assessments were used in the multicentre BASIL and BEST-CLI trials.[41,42] The EQ-5D and the 36 Item Short Form Health Survey (SF-36) are well validated generic tools to assess health status, but are not disease specific. For patients with CLTI, a disease specific instrument that captures pertinent aspects of the disease from the perspective of the patient and their caregiver(s) is currently lacking.

Quality of life assessments and relief of claudication symptoms are important patient reported outcomes. For large series analysing or comparing outcomes regarding the management of patients with claudication, the use of: (1) at least one baseline functional, general QoL assessment, e.g., EuroQol, 6MWT, Nottingham Health Profile (NHP), etc.; and (2) one validated disease specific QoL measure, WIQ, Claudication Scale (CLAU-S), VascuQoL, Intermittent Claudication Questionnaire (ICQ) is suggested.

Acute limb ischaemia. No widely accepted, validated reporting standards for acute limb ischaemia (ALI) currently exist. The ESVS 2020 clinical practice guidelines on the management of ALI[5] and the update of those guidelines in the light of the COVID-19 (coronavirus disease 2019) pandemic[43] do supply important guidance with respect to definitions and future research.

Limb threat severity at presentation is a major determinant of outcome and therefore it should be categorised or clinically graded by the Rutherford grades of ALI: I, viable, not immediately threatened; IIA, marginally threatened; IIB, immediately threatened; and III, irreversibly ischaemic.[44]

These grades have been in use for more than thirty years and are based on the presence and severity of pain, sensorimotor deficits, and Doppler findings.

Acute limb ischaemia outcome reporting. It is suggested that the precise methods of treatment and major outcomes of importance must be reported. The methods of treatment may include: (1) anticoagulation alone (selective use for high risk patients with low grade ALI); (2) endovascular, catheter directed therapy (thrombolysis and or mechanical or suction thrombectomy); (3) open surgical (thromboembolectomy, bypass with conduit used); or (4) hybrid, i.e., open in combination with adjunctive endovascular procedures (thrombus aspiration, angioplasty, bare metal and covered stenting), often to improve the inflow or outflow.

Major outcomes of importance are related to both the patient and the limb. The following are the minimum outcome measures that should be reported in studies describing the treatment of ALI: (1) major limb amputation (30 days, and one year whenever possible); (2) requirement for fasciotomy; (3) acute kidney injury; (4) major adverse cardiovascular events; (5) major adverse limb events; (6) functional and ambulatory status (from 30 days or discharge to one year); and (7) death (early, 30 days; intermediate, one year; and late, if possible).[45]

In order to improve, harmonise, and standardise registry data, recommendations for variables to be included in registries of patients with ALI have recently been published in this journal.[45]

Device trials. There are a number of key points that should be included in any device trials or endovascular series of peripheral interventions. These are summarised below based on the type of intervention performed (Table 7).

It is also critical that the limb disease severity and class of patients in whom these interventions were performed be clinically delineated in any device report. Patients with claudication and CLTI must be reported separately, and the anatomic classification and limb stage treated must also be clearly defined. Specific devices are used to treat a disease process in a patient population, so the data cannot be understood unless these have been clearly reported. Specific reporting details related to these issues are enumerated below. Intention to treat study design is always preferred.

Chronic venous disease

This document considers only chronic venous disease (CVD).[46,47] Acute venous thrombosis and other venous pathologies are not considered herein.

Aetiology. This can be primary, secondary (intravenous or extravenous), or congenital.[48]

Demographics. Basic patient demographics, such as age and sex, and comorbidities, such as obesity, should be described. For bilateral disease, reports must specify whether both legs were treated, either simultaneously or as a staged approach. History of venous disease complications and treatment details should be recorded. When reporting on epidemiology, risk factors for CVD should include those given in Table 9.[49,50]

Table 9. Risk factors for chronic venous disease.

Heredity
Standing profession
Number of maternal deliveries in women
Previous deep vein thrombosis
Age
Female sex
Ethnicity
Body habitus (increased height and obesity)

Pharmacological therapy. The use of veno-active drugs to ameliorate venous symptoms and improve oedema[51] or to promote healing of venous leg ulcers should be reported, as they may potentially alter outcomes, particularly in open label trials.

Comorbidities and high risk anatomy. Conditions that may alter the decision making process include obesity, obstruction or reflux in the deep venous system, residual obstruction of the superficial axial veins, or aneurysms of the superficial axial veins, particularly in proximity to the deep venous system. Additionally, concomitant incompetence of other superficial veins such as the anterior saphenous vein or the non-saphenous veins.

Diagnostic and imaging workup. Duration of reflux >0.5 or >1.0 seconds and obstruction should be provided for all major veins. The diameter of the great saphenous vein (GSV) should be reported.

Indications for intervention. The location of varicose veins, i.e., thigh, calf, or foot, also in relation to the great or small saphenous veins, or alternatively non-saphenous veins, should be reported. A detailed classification of individual clinical findings, aetiology, anatomical location(s) of the venous abnormality, and pathophysiology (reflux, obstruction, or both) of CVD is provided by the revised Clinical—Etiology—Anatomy—Pathophysiology (CEAP) document[47] (Table 10). It is suggested that specific anatomic location(s) be reported under each P (pathophysiologic) class to identify anatomic location(s) corresponding to P class.[47]

Symptoms. CVD symptoms should be reported as described previously.[52]

Intervention

Conservative treatment. Compression is usually accomplished with graduated elastic compression stockings or tights. Their compression profile, which typically includes the pressure at the ankle level, should be reported, as well as patient compliance. The compression profile of alternative compression forms including elastic bandages and

Table 10. Clinical classes of the 2020 revision of the Clinical–Etiology–Anatomy–Pathophysiology (CEAP) classification.[47]

Clinical (C) class	Description
C_0	No visible or palpable signs of venous disease
C_1	Telangiectasia or reticular veins
C_2	Varicose veins
C_{2r}	Recurrent varicose veins
C_3	Oedema
C_4	Changes in skin and subcutaneous tissue secondary to chronic venous disease
C_{4a}	Pigmentation or eczema
C_{4b}	Lipodermatosclerosis or atrophie blanche
C_{4c}	Corona phlebectatica
C_5	Healed ulcer
C_6	Active venous ulcer
C_{6r}	Recurrent venous ulceration

The presence or absence of symptoms is indicated by a subscript s or a, respectively, e.g., C_{2a} or C_{2s}.

Table 11. Procedural details to be described in endovenous surgery.

Access method
Tumescent technique and anaesthetic agent composition
Distance of the tip of the catheter from the junction with the deep veins
Type of energy delivery, e.g. radial fibre
Power and energy amount
Temperature for radiofrequency ablation
Pull back rate (cm/min)
Treatment duration
Sclerotherapy agent and form of adhesive specifics (non-thermal ablation methods)
Length of treated vein
Type of intra-procedural monitoring (ultrasound)
Time interval between trunk ablation and phlebectomies or sclerotherapy of tributaries (staged procedures)

adjustable compression garments mostly used to treat venous leg ulcers should be provided. Details of post-intervention compression such as type, compression profile, part of the leg that is compressed, adjuvant use of foam pads or other material to accomplish eccentric compression, and duration of compression should be reported.

Open surgical treatment. High ligation of the saphenofemoral junction and stripping of the GSV to the knee level (saphenectomy) is the historical gold standard. The GSV is occasionally stripped to ankle level, but partial or segmental stripping should also be reported. Pre-operative venous mapping and anaesthesia type (e.g., tumescent) should be reported. Isolated varicose veins, often involving a non-saphenous vein, are removed with phlebectomies.

Endovascular treatment. When sclerotherapy is used, the chemical agent, usually polidocanol or sodium tetradecyl sulphate, should be reported. The sclerotherapy agent may be injected in a liquid or foam form, and in various strengths and amounts, which should be described, as well as the methodology to make the foam. Information on the type of vein(s) and their distribution treated with sclerotherapy, i.e., telangiectasias, reticular veins, varicose veins, and the axial GSV and small saphenous vein, should be provided, including use of multiple injection sites along the path of an axial vein or through an intravenous catheter. The compression profile and duration of post-procedural compression should be described.

Describe the thermal (radiofrequency segmental ablation and laser ablation) or non-thermal ablation methods. Laser thermal ablation may be accomplished with a range of laser wavelengths, which should be reported. Procedural details recommended to be reported are given in Table 11.

Outcome reporting. Recurrence of varicose veins, as well as healing and or recurrence of venous leg ulcers, constitute the relevant hard endpoints. Scoring systems, often combining symptoms and signs, which are graded, providing a total score, are recommended. The most commonly used scoring systems are the revised Venous Clinical Severity Score (r-VCSS)[52] and the 3D SYM VEIN symptom assessment tool,[53] while the Villalta scale is specific for post-thrombotic syndrome.[54] Unlike the above scoring systems, PROMs for CVD include the following disease specific tools: the Chronic Venous Insufficiency Questionnaire (CIVIQ);[55] the Aberdeen Varicose Veins Questionnaire (AVVQ);[56] and the Venous Insufficiency Epidemiological and Economic Study quality of life/symptoms (VEINES-QOL/Sym).[57]

It is suggested that clinical success is defined as abolition of all symptoms and signs that are modifiable, such as oedema, lipodermatosclerosis, and venous leg ulcer healing, without any residual symptoms. Time to complete healing and healing rates (cm^2/week or month), as well as length and completeness of follow up should be provided.

Complications include superficial vein thrombosis, venous thromboembolism, and external bleeding. Post-interventions and their complications up to 30 days should also be reported.

Reporting of follow up and patency. Short term follow up after venous interventions is the standard of care primarily to ensure the clinical and, secondly, the anatomical effectiveness of the intervention, to determine any need for secondary interventions, and to detect any complications. Long term follow up performed at regular intervals for research reports should also include a CEAP and REVAS (recurrent varices after surgery)[58] classification; the latter requires examination with DUS. Symptom and disease severity as well as QoL measures should also be reported. For special circumstances related to deep vein intervention (valve repair or iliac vein stenting), selective use of air plethysmography, venography, CT, or magnetic resonance venography are recommended.[59]

REGISTRY BASED RESEARCH

This section relates to all disease entities. Vascular surgery research based on national or regional quality registries is increasingly common. This is reflected by an increasing

number of registries being affiliated to the ESVS VASCUNET collaboration, which is the ESVS network for quality improvement registries in vascular surgery (personal communication). The benefit of registry based research is the possibility for large scale evaluation of treatment patterns and outcomes in routine clinical practice, especially if data are modern and population based. Such studies can supplement randomised trials, which serve as the primary basis for evidence in medicine but are often hampered by limited generalisability due to patient and centre selection.[60,61] Large scale data can also offer a possibility for studies in rare pathologies that are not likely to be studied in randomised trials. International collaboration between national and regional registries offers a unique possibility for big data evaluation in vascular surgery.[62] However, it is important that registry based research takes into consideration the internal and external validity of the registry at hand, as well as uses adequate statistical methodology to correct for inherent biases in the retrospective analysis of prospectively collected data.[63]

Registry data should include variables on the following parameters, as a minimum: (1) patient characteristics and basic comorbidities (with pre-established definitions); (2) indication for surgical intervention (acute or elective, severity of disease); (3) anatomical classification according to established guidelines, when applicable; (4) details of operative procedure performed, including type of procedure, date, and centre; (5) peri-operative outcomes, including complications; (6) in hospital and or 30 day outcomes, including complications, re-interventions, and death; and (7) one year outcome is necessary after many interventions, such as in lower extremity PAOD.

QoL measures and PROMs are considered important when studying interventions focusing on improving QoL, such as for intermittent claudication.

Quality improvement registries may also include data on devices implanted during surgical intervention, enabling evaluation of device specific outcomes. This is of increasing importance in the vascular surgical field, considering the rapid introduction of new techniques and devices. Efforts to integrate electronic patient records in quality improvement registries may facilitate future automated data collection.

Based on the Delphi consensus process, VASCUNET has published a set of variables for peripheral revascularisation and ALI.[45,64] For AAA surgery and carotid intervention, VASCUNET and the International Consortium of Vascular Registries (ICVR) have published reports using a common minimum dataset,[20,65–69] and efforts to present a core registry dataset for standard infrarenal AAA repair and carotid artery stenosis intervention are awaited. For thoracic aortic pathology, an international registry based collaboration report has been published with recommendations regarding a core dataset for thoracic endovascular aortic repair (TEVAR) in quality improvement registries.[9]

DISCUSSION

This document is the first of its kind, summarising recommendations on how to design, perform, and analyse research within multiple fields of vascular surgery. It was decided not to cover all fields in this first edition, but the intention is to add recommendations on vascular access, vascular infections, radiation protection, vascular trauma, etc., in future revisions of the document.

We are also open to include ideas from our peers in future revisions, so please do not hesitate to contact the authors should you have such suggestions. Vascular surgery is a very dynamic field, both clinically and scientifically. To cite the famous rhetoric phrase by Winston Churchill: "This document is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning."

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