Optimal Resources for Vascular Surgery & Interventional Care

2023 Vascular-VP Outpatient Standards
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## VASCULAR-VP OUTPATIENT STANDARDS

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Important Information

These standards are intended solely as qualification criteria for the American College of Surgeons Vascular Verification Program (Vascular-VP). They do not constitute a standard for care and are not intended to replace the medical judgment of the surgeon or healthcare professional in individual circumstances.

In addition to verifying compliance with the standards as written in this manual, the Vascular-VP may consider other factors not stated herein when reviewing an outpatient center for verification and reserves the right to grant or withhold verification based on its judgement of the totality of the program.

This program is intended as a review of the quality infrastructure within an institution. It is intended solely for this purpose and is not designed to cover areas beyond its intended scope, nor is it intended to replace any facility or regulatory accreditation(s). The requesting institution is solely responsible for ensuring compliance with any state, federal, or local guidelines with respect to facilities, services, and regulatory guidelines. Neither the ACS, SVS, nor any associated parties shall be held liable for any areas of review beyond the scope of this manual.
Executive Summary

The American College of Surgeons (ACS) and the Society for Vascular Surgery (SVS) are pleased to present the Vascular Verification Program, a national quality verification program focused on the care and treatment of patients receiving vascular surgical and procedural care.

The diverse range of care required by the vascular patient presented unique opportunities in the design of this program. Vascular procedures can be open or endovascular; arterial, venous, or lymphatic; and can vary greatly in the level of complexity. Given the breadth of scope and complexity of vascular procedures, there has been increased emphasis on the choice of vascular procedures and the outcomes of such selections.

ACS has a long history of establishing quality verification programs which result in improvement in patient care and outcomes in specialties including cancer, trauma, and metabolic/bariatric surgery, among others. Similarly, the SVS has been at the forefront of establishing practice guidelines and education with the aim of achieving ever-better care and outcomes for the vascular patient. Grounded in the four-part framework that is the staple of other ACS accreditation/verification programs, ACS and SVS sought to evaluate and improve the quality of care through (1) program-specific standards; (2) infrastructure needed to meet such standards and deliver high-quality, high-value care; (3) data collection and analysis; and (4) verification site visits to ensure proper implementation and maintenance of components one through three. This program, a collaborative effort between the ACS and SVS over the last five years to leverage the expertise and experience of both organizations in the field of quality improvement, aims to achieve similar growth and outcomes in the field of vascular surgical and procedural care as those demonstrated by other established ACS quality programs.

The Standards contained herein cover a breadth of topics deemed valuable in the provision of vascular outpatient care. Focus areas include institutional commitment, program resources, clinical continuity across the five phases of care, data collection and analysis, and quality improvement activities. Centers participating in this program will be expected to show their commitment across all areas, with the goal of providing feedback to assist all vascular programs on their journey to achieving an ever-higher standard of quality care.

Drawing from background evidence, nationwide pilot site visits, and the expertise of providers and organizations in the field, Optimal Resources for Vascular Surgery and Interventional Care – Outpatient Standards outlines requirements necessary for centers to achieve and maintain verification for their vascular program. Through ongoing participation in this program and compliance with the standards, centers can develop the tools necessary to provide safe, effective, patient-centered, timely, efficient, and equitable care to all vascular patients.
Background on ACS and SVS

About the American College of Surgeons
The American College of Surgeons (ACS) is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and improve the quality of care for all surgical patients. The College is dedicated to the ethical and competent practice of surgery. Its achievements have significantly influenced the course of scientific surgery in America and have established it as an important advocate for all surgical patients. The College has more than 84,000 members and is the largest organization of surgeons in the world. For more information, visit facs.org.

About the Society for Vascular Surgery
The Society for Vascular Surgery® (SVS) seeks to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness. The organization was founded in 1946 and currently has a membership of more than 6,000. SVS membership is recognized in the vascular community as a mark of professional achievement.
Acknowledgments

Clinician Advisors
Anton Sidawy, MD, MPH, FACS, DFSVS, Chair,
   Vascular Verification Program Steering Committee
William Shutze, MD, FACS, DFSVS, Chair,
   Outpatient Work Group
Kellie Brown, MD, FACS, DFSVS
Keith Calligaro, MD, FACS
Eliot Chaikof, MD, PhD, FACS
Michael Conte, MD, FACS, DFSVS
R. Clement Darling, III, MD, FACS, DFSVS
John Eidt, MD, FACS, DFSVS
Patricia Flanagan, MSN, RN, CV-BC, CWCN
Thomas Forbes, MD, FRCSC, FACS
Linda Harris, MD, FACS, DFSVS
Anil Hingorani, MD, FACS
Kim Hodgson, MD, DFSVS
Larry W. Kraiss, MD, FACS, DFSVS
Michael Makaroun, MD, FACS, DFSVS
Daniel McDevitt, MD, FACS, DFSVS
Erica Leith Mitchell, MD, MEd, FACS, DFSVS
Robert G. Molnar, MD, FACS
Marc Passman, MD, FACS
Margaret Tracci, MD, JD, FACS, DFSVS
Gilbert Upchurch Jr., MD, FACS
Omaida Velazquez, MD, FACS, DFSVS

SVS Staff Contributors
Kenneth Slaw, PhD, Executive Director
Jim Wadzinski, Deputy Executive Director
Reva Bhushan, MA, PhD, Director, Clinical Guidelines
   and Quality Practice
Carrie McGraw, MSN, RN, Manager, Quality Improvement
   and Practice
Chantel M. Moore, PhD, Manager, Quality and Practice
Nadine Caputo, Former Quality Director

ACS Staff Contributors
Patricia Turner, MD, MBA, FACS, Executive Director and CEO
Clifford Y. Ko, MD, MS, MSHS, FACS, FASCRS, Director,
   Division of Research and Optimal Patient Care
David B. Hoyt, MD, FACS, Former Executive Director
Sameera Ali, MPH, Administrative Director,
   Division of Research and Optimal Patient Care
Amy Robinson-Gerace, Senior Manager,
   Verification Program Development
Stephanie Mistretta, MA, LCSW, Project Manager,
   Verification Program Development
Tamara Kozyckyj, MPH, Project Manager,
   Verification Program Development
Institutional Administrative Commitment (IAC)
IAC.1 Center Leadership Commitment

Definition and Requirements

Leaders at the outpatient center demonstrate commitment through engaged leadership and financial resources to support the Vascular Program and ensure alignment with the center’s strategic priorities.

There is top-level leadership commitment to quality and safety within the Vascular Program and appropriate allocation of resources through demonstration of the following:

- Resource allocation to and engagement with the Vascular Program
- Center-level leadership has established formal channels for effective communication to align with Vascular Program priorities
- Mechanisms for feedback from ongoing vascular initiatives and quality and safety issues to center-level leadership

Documentation

- Provide a letter from center leadership (for example, CEO, Owner, or equivalent) demonstrating the commitment to the Vascular Program, which includes:
  - A high-level description of the Vascular Program, including program leadership, annual volume, procedure mix, and commitment and organization of multidisciplinary care services for vascular patients
  - Any initiatives involving the Vascular Program in the past 12 months for the purposes of ensuring quality and safety
  - Center leadership’s involvement in the Vascular Program
  - Current and future commitments to and financial investments in the Vascular Program
  - The organization’s commitment to maintaining compliance with verification program standards
- Provide an organizational diagram showing the Vascular Program’s relationships to other departments and internal governing bodies, specifically those that oversee patient safety, quality, and fiscal administration of the Vascular Program, if any

Resource

IAC.2 Culture of Patient Safety and High Reliability

Definition and Requirements

There is an organized effort to create a culture of patient safety and high reliability within the Vascular Program. Exemplary programs will have systems in place to evaluate and continuously improve culture.

A center's culture reflects the aggregate attitude and values of its leaders and members and sets the climate for how patient safety is perceived and reinforced. The culture of a patient care center has been described as a five-step ladder model, including the following five designations:

- **Passive**: Adverse events are expected or considered unavoidable
- **Reactive**: Presence of systems to address sentinel events when they occur, without active surveillance
- **Calculative**: Presence of systems to prevent problems and actively surveil for sentinel events
- **Proactive**: Presence of systems to proactively anticipate both sentinel events and morbidities
- **Generative**: Quality and safety at the core of every aspect of infrastructure

Actively pursuing a generative safety culture is core to the center's mission. This culture, as well as the practice of high-reliability principles, is embedded and identifiable throughout the center. There is safety culture training and regular, formal assessment of safety culture across all vascular care providers. Results drive tailored improvement initiatives and ongoing safety culture education.

This commitment to a culture of patient safety and high reliability is demonstrated by the following:

- Ongoing measurement of safety culture with feedback to frontline staff and demonstrated effort to act on the basis of measured results
- Results of safety culture surveys are communicated to vascular staff
- Training on safety culture as part of onboarding process for new staff and ongoing maintenance of training for existing staff
- Robust mechanisms in place for monitoring and management of safety events, including regular and robust monitoring of event-reporting data, such as the capture of and education on near misses, safety huddles, and broadly distributed safety dashboards
- Continuous effort to improve the safety culture with the goal of creating a generative culture, where quality and safety are at the core of every aspect of the center's infrastructure

Documentation

- Provide reports from safety culture assessments (for example, Safety Attitudes Questionnaire [SAQ]) in which the Vascular Program participated over the previous three years, if any
- Provide most recent quality dashboard with vascular-specific measures, if any
- Provide a listing of recent training/education initiatives for the vascular team on safety culture/safety attitudes, including dates of training (for example, TeamSTEPPS)

Resources


Program Scope and Governance (PSG)
P.1.1 Definition and Scope of a Vascular Program

**Definition and Requirements**

A Vascular Program can be established in a variety of outpatient settings, including freestanding Ambulatory Surgery Centers (ASC) and Office-Based Labs (OBL), and encompasses all vascular care at the center. These standards are designed to address the care provided in all phases of care for the vascular patient regardless of setting.

In the outpatient setting, procedural areas may include any or all of the following:

- Peripheral Arterial (endovascular)
- Arteriovenous Hemodialysis Access (open/endovascular)
- Deep Venous (open/endovascular)
- Superficial Venous (open/endovascular)
- Surgical Thrombectomy (arterial/venous)

The verification level is indicative of a center having the infrastructure and staffing to perform a set of procedures. It does not mandate that a center performs every procedure within the package. The Vascular Program must have a written scope of practice that aligns with the selected verification level and addresses resources and care requirements within the designated setting. All procedures performed by the center will be evaluated within the scope of the program.

The full scope of vascular procedures by designated level and setting (such as inpatient or outpatient) is referenced in Appendix I.

**Documentation**

- Provide the Vascular Physician Roster Pre-Review Questionnaire table
- Provide the Vascular Case Volume Pre-Review Questionnaire table that includes all vascular interventions performed at the center
- Provide the center’s written scope of practice for the Vascular Program
- Provide any policies or protocols detailing criteria for selecting appropriate procedures for the outpatient setting
- Provide any policies or protocols detailing criteria for selecting appropriate patients for the outpatient setting
PSG.2 Vascular Program Medical Director

Definition and Requirements

The Vascular Program Medical Director is a qualified physician leader who has demonstrated appropriate training, experience, authority, and commitment to effectively lead the program. The Medical Director maintains oversight and accountability for clinical care and quality across the Vascular Program, including the following:

1. Reviews mortality and adverse event rates, including subsequent distribution of review findings
2. Addresses clinical practice variation
3. Establishes quality and safety standards and guidelines for use in the Vascular Program
4. Monitors primary clinical outcomes data to identify issues
5. Develops and implements vascular-specific quality improvement initiatives
6. Provides strategic leadership and prioritization of vascular quality initiatives and goals
7. Provides oversight and leadership of the Vascular Program Committee
8. Participates in governance, including approving vascular privileges for surgeons and interventionalists

Documentation

- Provide official job description for the Vascular Program Medical Director position, including percentage of full-time employment specific to this role
- Provide an organizational diagram inclusive of the Medical Director position listed above, as well as all other Vascular Program staff (Standard PSG.3) that illustrates the reporting structure and relationships to center leadership
- Provide the curriculum vitae for the individual serving as the Medical Director
Vascular Program Management Resources

**Definition and Requirements**

Program management, quality improvement, and clinical data abstraction/analysis roles and responsibilities must be established within the Vascular Program. These may be fulfilled by either full- or part-time dedicated employees and can be joined or split depending on the size and organization of the center. Official job descriptions must reflect the responsibilities outlined below and support dedicated time and compensation commensurate to duties assigned.

- **Vascular Program Manager**: An individual, either clinical or nonclinical with appropriate experience, dedicated to managing and coordinating the administrative functions of the program and supporting the Medical Director. The Program Manager role provides oversight of program support, including but not limited to:
  - Establishing and maintaining a collaborative working relationship with the Medical Director to assist with program needs and goals
  - Establishing and maintaining a functional system of collaboration for programmatic, data, and quality improvement (QI) needs
  - Management of administrative functions within the Vascular Program, including supporting committee meetings and ensuring adequate program resources

- **Quality Improvement Support**: There must be dedicated support for vascular-specific quality improvement activities either through an individual or team within the Vascular Program or at the center level. The designated individual/team should have demonstrable and appropriate training, experience, and success in quality improvement methodology and leading data-driven QI initiatives.

- **Clinical Data Abstraction and Analysis**: There must be support for clinical data abstraction and analysis specific to the Vascular Program, either through an individual within the Vascular Program or at the center level, or through a contracted service. There should be demonstrable and appropriate training, experience, and maintenance of necessary certifications and database access to abstract, analyze, and report on data relevant to the program. Clinical data abstraction and quality improvement support functions work closely together to ensure data accuracy and meaningful QI initiatives.

**Documentation**

- Provide official job descriptions for each of the job functions outlined within the standard

**Resources**


Vascular Program Committee

Definition and Requirements

The Vascular Program Committee is comprised of the Vascular Program Medical Director, program manager, quality improvement support representative, clinical data abstraction and analysis representative(s), vascular surgeons and interventionalists, an anesthesiology representative, a non-invasive vascular lab representative, and multidisciplinary care team members that serve vascular patients. The committee provides infrastructure that fosters communication throughout the Vascular Program and within the larger center.

The committee oversees and facilitates quality improvement efforts within the Vascular Program, ensuring that a multidisciplinary perspective guides these activities. The committee meets at minimum quarterly and serves three primary functions:

- Provide program administrative and operational oversight (including protocol review and development)
- Conduct retrospective case review, outcomes data review, and quality improvement activities (see Standards DSS and QI for further details)
- Conduct protected peer review and periodic review of physician-level outcomes to identify individuals needing additional interventions/proctoring. As determined by state and local bylaws, peer review committee members may be a subset of the core Vascular Program Committee members

Documentation

- Provide the Pre-Review Questionnaire table with committee membership roster, dates of meetings, and attendance for the previous 12 months
- Provide meeting minutes for the most recent committee meeting
- Provide an organizational chart showing the Vascular Program Committee's position within the overall center framework
- Provide the Vascular Program Committee charter inclusive of written goals and statement of purpose
Facilities and Equipment Resources (FER)
Center Licensure and Accreditation

Definition and Requirements

The center and its vascular providers meet all local and federal regulatory requirements and maintain a license by the appropriate state licensing authority.

Ambulatory Surgery Centers must also maintain accreditation by The Joint Commission (TJC) or an equivalent nationally recognized healthcare facility accrediting body. Other facilities, such as Office-Based Labs, are recommended to maintain accreditation by an external organization such as American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), or another qualified entity.

Documentation

- Provide recent copies of licensure and accreditation/certification from the various regulatory programs that designate the center, including but not limited to The Joint Commission, AAAASF, AAAHC, or other qualified entities
- Provide current improvement plans to address findings from the most recent accreditation review, if any
- If accreditation is not required at the state level for the center, provide documentation of this statute
FER.2 Dedicated Operating Room or Procedure Suite

**Definition and Requirements**

There must be a dedicated operating room or procedure suite (including catheterization lab, interventional radiology [IR] suite, and/or hybrid room) with the necessary supplies, resources, and knowledgeable perioperative staff for vascular procedures. Operating rooms/procedure suites must be equipped with technology capable of monitoring vital organs and intravascular pressures.

The center must have at minimum digital subtraction angiography (C-arm and/or fixed imaging) with post-processing capabilities and B-mode ultrasound for guidance during vascular access.

**Documentation**

- Provide the center's written policies and procedures for operating room/procedure suite availability, use, and staffing/personnel requirements
FER.3 Appropriate Inventory

Definition and Requirements

Operating rooms/procedure suites must have an appropriate inventory of specialty devices for performing vascular procedures, including but not limited to balloons, stents, covered stents, and thrombectomy devices relevant to the procedures performed.

The center must also have appropriate inventory for managing vascular emergencies and urgent patient care needs in the operating room/procedure suite setting.

Documentation

- Provide a summary of all inventory related to vascular surgical and procedural needs, including but not limited to a selection of sheaths, guidewires, angioplasty balloons, occlusion balloons, stents, stent grafts, thrombectomy catheters and/or devices, embolic protection devices, and vascular closure devices as appropriate to the setting
- Provide a summary of appropriate inventory maintained onsite for managing emergency patient care needs
Post-Procedure Care/Observation Unit

**Definition and Requirements**

There must be a post-procedure care unit available for observation of patients in the immediate postoperative period. This unit must be staffed by dedicated personnel trained to manage and recognize postoperative complications following vascular surgery and interventions.

Minimum requirements include:
- Pulse oximetry monitoring
- Difficult airway cart
- Advanced Cardiovascular Life Support (ACLS) trained staff
- Fully stocked crash cart (with airway equipment, medications, IVs, and oxygen)

**Documentation**

- Provide the center's written policies and procedures for post-procedure care/observation unit availability, use, and staffing/personnel requirements
Accredited Non-Invasive Vascular Lab

Definition and Requirements
The center must be accredited by a nationally recognized accrediting agency to perform and interpret specialized non-invasive vascular lab imaging relevant to the types of procedures performed at the center.

These services must be available when patients are present in the center.

Documentation
- Provide current certificates for the non-invasive vascular lab from all nationally recognized accrediting agencies

Resources

**Definition and Requirements**

The center must have arteriogram and venogram capabilities during business hours.

The center must have the technical capabilities to receive, upload, and view imaging obtained at outside facilities.

**Documentation**

- Provide the center's written policies for capabilities regarding imaging obtained at outside facilities.
Personnel and Services Resources (PSR)
Personnel and Services Resources (PSR)

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**PSR.1 Qualified Surgeon/Interventionalist**

### Definition and Requirements

The center must have at least one actively practicing, credentialed surgeon or interventionalist that has privileges to perform vascular surgery and/or endovascular interventions. Any surgeons or interventionalists performing arteriovenous access and/or peripheral arterial procedures must have active privileges at a local hospital capable of caring for vascular patients in need of a higher level of care.

There must be thorough processes for credentialing and privileging that ensure all vascular surgeons and interventionalists are qualified and able to provide safe and appropriate care. This includes a formal onboarding process with the involvement of the Vascular Program Medical Director in developing and approving privileging criteria. The institution’s credentialing body must adhere to current nationally recognized privileges.

To obtain and maintain active privileges to perform vascular procedures (renewed at least every two years), all physicians performing vascular procedures must fulfill the following requirements:

**Initial Vascular Surgery Privileges:**
- State medical licensure in good standing
- Completion of appropriate vascular surgery-specific training via one of the three pathways (traditional, integrated, or early specialization) outlined in the Society for Vascular Surgery Privileging Guidelines
- Vascular Surgery Certification or board eligibility by the American Board of Surgery or American Osteopathic Board of Surgery (see alternative pathway for foreign-trained and late-career surgeons whose certification lapsed in good standing)
- For board eligible candidates, a letter of completion from the director of a formal vascular surgery fellowship training program
- Privileges to perform open and/or endovascular interventions, as appropriate
- Surgeon demonstrates they are “actively practicing” vascular procedures for which they are privileged as defined by the local Vascular Program Committee
- Active membership in related professional societies and regional/national quality meeting attendance

**Maintenance and Renewal of Vascular Surgery Privileges:**
- The surgeon meets requirements for Continuous Certification by the Vascular Surgery Board of the American Board of Surgery or American Osteopathic Board of Surgery (see alternative pathway for foreign-trained and late-career surgeons whose certification lapsed in good standing)
- The surgeon must demonstrate continued critical assessment of their outcomes
- Verification that surgeon maintains compliance with all aforementioned criteria for initial vascular surgery privileges
- The individual overseeing the credentialing and privileging process must verify that these criteria have been met
- Active membership in related professional societies and regional/national quality meeting attendance

**Endovascular Intervention Privileges:**
- State medical licensure in good standing
- Completion of appropriate vascular intervention-specific training
- Board eligibility or certification in vascular surgery, interventional cardiology, interventional radiology, or vascular medicine
- Letter of completion from the director of a formal vascular interventional fellowship training program or alternative equivalent
- Privileges to perform endovascular interventions
- Demonstrates they are “actively practicing” vascular procedures they are privileged for as defined by the local Vascular Program Committee
- Active membership in related professional societies and regional/national quality meeting attendance

**Maintenance and Renewal of Endovascular Intervention Privileges:**
- Meets requirements for board certification
- Demonstrates continued critical assessment of their outcomes
- Verification of maintained compliance with all aforementioned criteria for initial vascular privileges
- Verification that these criteria have been met
Credentialing, privileging, and core onboarding procedures are specific to the specialty to ensure that all vascular surgeons and interventionalists are qualified and able to provide safe and appropriate surgical care. The Vascular Program Committee (see Standard PSG.4) must offer a pathway for surgeons and interventionalists in the following circumstances:

- New physicians (either recent graduates or new to the center) requesting privileges
- Established physicians renewing existing privileges
- Established physicians requesting new privileges or new technologies
- Established physicians reestablishing privileges following a break in practice
- Safe introduction of innovative procedures and technologies (for example, robotic operations)

The center must demonstrate standardized and systematic pathways for each circumstance noted above, with training requirements that include the following:

- Didactic educational component
- Skills training: inanimate
- Skills training: supervised/proctored
- Incorporation into practice
- Measurement of results

Additionally, the pathway must include a plan for transitioning the surgeon/interventionalist into independent practice that includes monitoring and benchmarking the individual’s outcomes.

**Documentation**

- Provide center privileging criteria for surgeons and interventionalists performing vascular procedures
- Provide written process for safe introduction of new procedures or technologies, including the most recent example of this training process
- Provide documentation of admitting privileges for any surgeons or interventionalists performing arteriovenous access or peripheral arterial procedures

**Resources**


Vascular Team Education

**Definition and Requirements**

Nurses, advanced practice providers, and members of the healthcare team caring for vascular patients must have ongoing vascular-specific training. Team members should be knowledgeable regarding vascular care pathways, order sets, and the signs and symptoms of postoperative complications.

Ongoing training and education may be provided by the center or through external continuing education opportunities, including but not limited to those offered as part of the Certified Vascular Nursing program.

**Documentation**

- Provide documents relating to vascular team education, including specific training on vascular care pathways, vascular order sets, and identification of post-procedure complications

**Resource**

PSR.3 Anesthesia Services

Definition and Requirements

A physician anesthesiologist or certified anesthesia provider under a physician anesthesiologist’s direction within an anesthesia care team model must be readily available to provide anesthesia care whenever needed for vascular patients. Conscious sedation providers must be certified. Consulting agreements with a physician anesthesiologist or hospital anesthesiology department must be in place for high-risk patients.

Documentation

- Provide written policy documentation regarding conscious sedation credentialing to non-physician anesthesia providers at the center as indicated by state regulation, if applicable
- Provide documentation of credentialing for non-physician anesthesia providers performing conscious sedation, if applicable
- Provide the center’s written policy documentation regarding supervision of certified non-physician anesthesia providers and care team model supervision, if applicable

Resource

PSR.4 Surgical and Medical Specialty Services

Definition and Requirements

The center must have an established relationship, including a written transfer agreement and protocol, with a local inpatient hospital capable of providing the full spectrum of surgical and medical specialty services that may be required for the treatment of vascular patients.

Documentation

- Provide transfer agreement documents between the center and local hospital(s)
PSR.5 Patient Support Services

Definition and Requirements

The following patient support services must be made available as needed to all vascular patients, either onsite or via referral system:

- Case Management
- Social Services
- Translation Services
Patient Care: Expectations and Specific Protocols (PC)
**PC.1 Standardized Clinical Pathways and Procedure Selection**

**Definition and Requirements**

The center must have standardized order sets and clinical pathways for vascular patients that are evidence-based and align with nationally recognized guidelines and practice statements, such as those issued by the Society for Vascular Surgery, American College of Surgeons, American Heart Association, American College of Cardiology, and Society for Interventional Radiology.

Standardized, team-based processes must be in place to ensure quality, safety, and reliability in all five phases of care of the primary morbid condition requiring surgery or interventional care. The five phases of care are defined as:

1. Preoperative phase
2. Immediate preoperative phase
3. Intraoperative phase
4. Postoperative phase
5. Post-discharge phase

Standardized processes may include but are not limited to:

- Standardized preoperative evaluation and risk assessment processes
- Preoperative optimization/surgery-readiness protocols for high-risk patients, such as the American College of Surgeons’ Strong for Surgery or centralized perioperative care clinic to assess multimodal patient needs, including nutrition, medication use, smoking cessation, and pain control
- Geriatric-specific protocols
- Intraoperative procedures such as timeouts, handoffs, and debriefs
- Multimodal pathways for Enhanced Recovery After Surgery (ERAS) that include optimization of nutrition; standardized, opioid-sparing analgesic and anesthetic regimens; and early mobilization
- Discharge and post-discharge protocols to ensure safe pain and wound management, appropriate follow-up, and continuity of care

Additionally, the center must have documented, standardized procedure selection protocols that are evidence-based and align with nationally recognized guidelines, such as those issued by the Society for Vascular Surgery, American College of Cardiology, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society for Interventional Radiology, and American College of Surgeons.

Exemplary centers will have standardized processes for patients across all five phases of care and regularly measure compliance with protocols. Additionally, there will be mechanisms in place to ensure appropriate education, review, maintenance, and identification of new opportunities for protocol development and standardization. Such centers will be able to demonstrate compliance with order sets and clinical pathways in the majority of cases and will have reliable methodology for tracking compliance and noting areas of deviation.

**Documentation**

- Provide all available and in-use order sets and clinical pathways for vascular patients with source documentation
- Provide documentation demonstrating compliance rates for order sets and pathways, if any are in use
- Provide any procedure selection protocols currently in use for vascular patients with source documentation

**Resources**


PC.2 Patient Education

Definition and Requirements

The center has documented plans and materials for pre- and postoperative patient education, including but not limited to the areas indicated below.

Preoperative Education
- Indications and contraindications for surgery/procedure
- Various surgical and nonsurgical interventional options provided at the center or at other facilities
- Center/surgeon/interventionalist's procedure volume and outcomes for indicated procedure(s)
- Clear explanation of goals, risks, benefits, and alternatives for indicated procedure(s) as part of the informed consent process
- Operative approach and anesthesia options, if applicable
- Immediate preoperative skin preparation and medication management

Postoperative Education
- Explanation of the expected course of postoperative care, including instructions regarding wound management, diet, medications, pain management, lifestyle, and physical activity modifications
- Signs and symptoms of complications such as tachycardia, fever, shortness of breath, excessive pain, and vomiting, including when and whom to call
- Ongoing involvement in treatment planning and access to care coordination

Documentation
- Provide all educational materials currently in use with vascular patients, including both pre- and postoperative materials
**PC.3 Informed Consent Process**

**Definition and Requirements**

The informed consent process must include a clear explanation of goals, risks, benefits, and alternatives for indicated procedures(s) and must be clearly documented in the medical record for all vascular patients. The center must demonstrate a process for patients that includes discussion and documentation of the following, when appropriate:

- Goals of Care
- Power of Attorney
- Advance Directives
- Patient Consent

For non-urgent/emergent procedures, the informed consent document should be signed by the patient or surrogate prior to arrival in the pre-procedural area.

**Documentation**

- Provide each of the following forms:
  - Goals of Care
  - Power of Attorney
  - Advance Directives
  - Patient Consent
**PC.4 Peripheral Artery Disease Protocol**

**Definition and Requirements**

The center demonstrates adoption of national clinical practice and appropriate use guidelines for the evaluation and management of peripheral artery disease, such as those published by the Society for Vascular Surgery, American College of Surgeons, American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, and Society for Interventional Radiology.

The center must have a written protocol for complex peripheral artery disease management, including:

- **Evaluation and Management of Acute Peripheral Arterial Emergencies**: The center must have a protocol for the initial evaluation, transport, and treatment of acute peripheral arterial emergencies via endovascular, open, or hybrid means.

- **Vascular Surgeon Availability**: A capable and qualified board-certified, board-eligible, or equivalent vascular surgeon must be available 24/7/365 (with a 45-minute response time) either onsite or via transfer agreement for operative and perioperative assistance as needed.

For claudication, there must be a perioperative evaluation protocol that includes medication evaluation, smoking cessation, and exercise therapy or documentation of patient refusal.

The center must demonstrate processes for reviewing compliance with these guidelines for patients that meet protocol criteria. Exemplary centers will be able to demonstrate compliance with the protocol in a majority of cases and will have processes in place to review and update protocols at regular intervals.

**Documentation**

- Provide written protocol for peripheral artery disease management
- Provide documentation of protocol-compliance tracking

**Resources**


Arteriovenous Hemodialysis Access Protocol

Definition and Requirements

The center demonstrates adoption of national clinical practice and appropriate use guidelines for the evaluation and management of arteriovenous hemodialysis (AV) access such as those published by the Society for Vascular Surgery, American College of Surgeons, American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, and Society for Interventional Radiology.

The center must have a written protocol for arteriovenous hemodialysis access, including:

- Preoperative evaluation
- Treatment of complication
- Patient selection
- Medical management
- Closed loop communication postintervention with dialysis center
- Outpatient dialysis evaluation for metabolic stability

The center must demonstrate processes for reviewing compliance with these guidelines for patients that meet protocol criteria. Exemplary centers should be able to demonstrate compliance with the protocol in a majority of cases and will have processes in place to review and update protocols at regular intervals.

Documentation

- Provide written protocol for arteriovenous hemodialysis (AV) access
- Provide documentation of protocol-compliance tracking

Resources


Definition and Requirements

The center demonstrates adoption of national clinical practice and appropriate use guidelines for the evaluation and management of superficial and deep venous disease, such as those published by the Society for Vascular Surgery, American College of Surgeons, American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, and Society for Interventional Radiology.

The center must have a written protocol for superficial and deep venous disease management, including:

- Preoperative evaluation protocol for conservative treatment
- Post-procedure thrombotic event diagnosis and treatment

The center must demonstrate processes for reviewing compliance with these guidelines for patients that meet protocol criteria. Exemplary centers should be able to demonstrate compliance with the protocol in a majority of cases and will have processes in place to review and update protocols at regular intervals.

Documentation

- Provide written protocol for superficial and deep venous disease management
- Provide documentation of protocol-compliance tracking

Resources


PC.7  Geriatric Patient Care Protocols

Definition and Requirements

The center must have protocols specific to the care of older adults that address the unique needs of this population across the five phases of care. These protocols should be integrated into standardized care pathways for vascular patients.

Protocols specific to the care of older adults include but are not limited to the following:
- Identification of vulnerable geriatric or frail patients
- Identification of patients who will benefit from the input of a health care provider with geriatric expertise
- Assessment of frailty
- Prevention, identification, and management of dementia, depression, and delirium
- Process to capture and document what matters to patients, including preferences and goals of care, code status, advanced directives, and identification of a proxy decision maker
- Medication reconciliation and avoidance of inappropriate medications
- Screening for mobility limitations and assurance of early, frequent, and safe mobility
- Implementation of safe transitions to home or other health care facility

Documentation

- Provide any protocols specific to the care of older adults currently in use with vascular patients

Resource

PC.8 Rescue Protocol

Definition and Requirements

The center must have rescue protocols in place for cardiac emergencies (such as myocardial infarction), pulmonary emergencies (such as pulmonary embolism), bleeding emergencies (such as life-threatening hemorrhage), and neurologic emergencies.

Documentation

- Provide all written rescue protocols
Transfer Agreements and Protocols

Definition and Requirements

Centers that provide services through transfer agreements must have written protocols for when, how, and where patients must be transferred if a patient requires a higher level of care or outside service. Written transfer agreements must be in place to support transfer protocols.

Documentation

- Provide all transfer agreements and transfer protocols in place for referral services or instances when patients require a higher level of care.
Data Systems and Surveillance (DSS)
### DSS.1 Data Collection and Registry Participation

#### Definition and Requirements

Data must be available for use specific to vascular quality and safety that span the scope of the vascular practice at the center. Data must be accompanied by sufficient resources for collection, analysis, and generation of reports.

At baseline, the Vascular Program must have a defined process for data capture and review and a list of measures that are monitored continuously. Measures may be maintained across a single or multiple platforms up to and including data registries, administrative data reports, and/or local data tracking. Data must be available for review by the Vascular Program Committee at minimum quarterly. Data must also be abstracted by an individual with appropriate clinical knowledge and expertise to ensure the accuracy of the data.

Where available, the center submits vascular cases to a national, population-based, clinical data registry that offers risk-adjusted benchmarking reports on vascular-specific outcomes measures (such as SVS Vascular Quality Initiative [VQI], ACS NSQIP). Exemplary centers will have registry data available for all procedures within the center’s scope. For centers where 100% case capture is not available, specified sampling criteria regarding capture of vascular cases must be followed.

At minimum, all patients should be followed through the 30-day postoperative period. Exemplary centers will be able to demonstrate follow-up at both 6 months and 12 months postoperatively. The center must provide a written protocol for monitoring data entry and patient follow-up, including a schedule for contact/outreach and a lost-to-follow-up protocol.

Data must be used to monitor and identify potential quality and safety issues and support quality improvement initiatives within the Vascular Program. The Vascular Program must have access to reports on standard core outcome measures to facilitate identification and investigation of outcomes. Exemplary centers will have risk-adjusted, benchmarked data reports available for review at least twice annually. Available data sources should also provide capability for the center to analyze its own data and generate its own unique reports to evaluate its level of care and outcomes. Exemplary centers will have formalized processes to communicate results of data reports throughout the Vascular Program as well as to center leadership.

In addition to required safety measures, adverse events, and clinical outcomes, exemplary centers will have methods and protocols for capture and review of vascular-specific process measures, appropriateness measures, and/or patient-reported outcomes (PROs). Where available, these measures could be available for review by the Vascular Program Committee at set intervals and used to develop quality improvement initiatives.

While it is recognized that not all centers will participate in a formal registry at the time of initial verification, it is expected that exemplary centers will be using clinical, non-administrative data by the time of their next verification site visit (3 years).

#### Documentation

- Provide the most recent (patient de-identified) data reports from each registry or data source monitored for quality improvement purposes, including patient experience data, center-wide event reporting, outcomes data, and all vascular-specific data.
- Provide the Pre-Review Questionnaire Data Collection Table for all procedures not captured in submitted data reports.
- Provide the center’s policy/training on reporting quality and safety events.
- Provide the center’s written protocol for 30-day and long-term (six-month and/or annual) patient follow-up.
- Provide the center’s protocols and methods for developing, tracking, and evaluating process, appropriateness, and patient-reported outcomes measures, if any.

#### Resources


Quality Improvement (QI)
QI.1 Quality Assessment and Improvement

Definition and Requirements

There are dedicated and sufficient resources to support formal quality and process improvement based on high-quality, reliable data specific to the Vascular Program.

The center must demonstrate how it uses data sources to monitor for, identify, and conduct formal quality improvement (QI) activities specific to the Vascular Program. The center must show evidence of established processes for using objective, risk-adjusted, and externally benchmarked data to drive QI efforts led by the Vascular Program Medical Director. Formal quality improvement initiatives must include and document the following:

- Identification of a problem using case review, registry information, or other high-quality data sources
- Propose an intervention using standardized QI methodology and tools (such as LEAN Six Sigma, DMAIC, and/or RCA)
- Implement an intervention using objective data to monitor progress
- Share findings and results of the QI initiative with stakeholders
- Continue active surveillance to sustain improvement

The Vascular Program is expected to continuously engage in QI initiatives. The program should be able to demonstrate at least one QI initiative annually based on a need or issue identified in vascular care.

Documentation

- Provide the Vascular QI Projects Pre-Review Questionnaire table listing all examples of Vascular QI initiatives from the previous three years

Resources


QI.2 Case Review Process

**Definition and Requirements**

There is a standardized, documented process for formal retrospective case review within the Vascular Program to monitor adverse events, assess compliance with protocols, and identify opportunities for improvement and standardization.

The center has established and standardized processes for formal case review that are distinct from a typical morbidity and mortality (M&M) conference and include but are not limited to the following:

1. Establishment of a set of defined, explicit criteria to identify possible cases for review (for example, individual reporting, near misses, reporting system, and registry)
2. Selection of cases for review based on standardized criteria and through periodic random selection
3. Use of a standardized process for case reviews/evaluation and documentation of review and resolution
4. Integration of findings and resolutions with clinical care and quality improvement activities
5. Maintenance of surveillance of identified issues
6. Use of defined criteria to ensure all cases (patient and procedure) are appropriate for the setting in which they are being conducted

The case review process should ensure that the center has standardized processes for identifying problems (such as surveillance mechanisms), reviewing the problems and identifying underlying system-level causes (such as quality conferences), and preventing similar problems in the future (such as feedback and education).

**Documentation**

- Provide diagram/process flow map(s) for any case review processes
- Provide documentation of meeting occurrences and vascular surgeon and interventionalist attendance
- Provide case review template (use of template is suggested, but not required)
- Provide patient charts and case review documentation for a sampling of charts that were identified by the center for review (Chart Review during site visit)

**Resource**

Peer Review Process for the Individual Physician

**Definition and Requirements**

The center has established and standardized processes to monitor and address quality and safety issues with the individual physician through a peer review process that respects the patient, institution, and individual physician. The peer review committee may be organized according to locally defined rules and structures, but must be composed of sufficient membership to ensure clinical knowledge and diversity of specialization relevant to the area of review.

This process aims to ensure that the center has standardized capabilities for identifying and remediating individual physicians who may be experiencing challenges or need support at any point in their tenure.

Exemplary centers will have evidence of a robust review process using data to evaluate individual performance by benchmarking to accepted standards and peer performance. Review should occur on a regular and specified schedule to ensure favorable patient outcomes and compliance with standard protocols and pathways. When an issue with individual performance is identified, there are timely procedures in place to ensure both patient safety and respectful remediation through mentorship, proctoring, and/or additional education.

The center is also recommended to have policies and procedures in place to address the following:

- Physician impairment and safe transitions out of practice
- Management of disruptive physician behavior
- Physician/provider wellness programs
- Second victim support for physicians and other providers who have experienced a sentinel event or other significant events

**Documentation**

- Provide all policies and procedures pertaining to the peer review process
- Provide any policies and processes for addressing issues such as disruptive behavior, physician impairment, and physician wellness programs

**Resource**

QI.4 Quality Improvement Collaborative Participation

**Definition and Requirements**

In involvement in a vascular-specific state-wide, regional, and/or national collaborative is highly recommended. The activities of the collaborative must allow for sharing of center-level data with intention to identify quality improvement areas and improve access to care for vascular patients. Participation should include at a minimum annual attendance in a collaborative meeting.

**Documentation**

- Provide a listing of any state-wide, regional, and/or national collaboratives in which the Vascular Program participates
- Provide collaborative data reports from the previous 12 months used within the Vascular Program, if any
Research: Basic and Clinical Trials (RES)
Definition and Requirements

Patient access to research and clinical trials: Information about the availability of applicable clinical trials is provided to patients through a formal mechanism, such as:

- Pamphlets or brochures in patient packets
- Physician/nurse-led patient education

Documentation

- Provide evidence of current IRB protocols, if any
- Provide a listing of clinical trials and the number of patients accrued in the previous 12 months, if any
- Provide a list of peer-reviewed publications for the previous three years, if any
## Appendix I: Program Scope Table

The table below addresses the breadth of vascular procedural areas evaluated within the Vascular Verification Program. Verification level for each procedural area is indicated as such. The verification level is indicative of a center having the infrastructure and staffing to perform a set of procedures. It does not mandate that a center perform every procedure within the package. The Vascular Program must have a written scope of practice which aligns with the selected verification level and addresses resources and care requirements within the designated setting. All procedures performed by the center will be evaluated within the scope of the program.

<table>
<thead>
<tr>
<th>Anatomical Region</th>
<th>Method</th>
<th>Verification Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Arch and Proximal Brachiocephalic Vessels</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Descending Thoracic Aorta</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Visceral Aorta - Thoracoabdominal</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Visceral Aorta (FEVAR, periscopes, etc.)</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Brachiocephalic Vessels (Innominate, CCA, SCA)</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Descending Thoracic Aorta</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Visceral Vessels (hepatic, splenic, renals, SMA, etc.)</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Visceral Vessels (hepatic, splenic, renals, SMA, etc.)</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Aortoiliac</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Aortoiliac</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
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</tr>
<tr>
<td>Infragenual Arterial</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Upper Extremity Arterial</td>
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</tr>
<tr>
<td>Upper Extremity Arterial</td>
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<td>X</td>
</tr>
<tr>
<td>Carotid-Vertebral</td>
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</tr>
<tr>
<td>Carotid-Vertebral</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Thrombolytic Infusion</td>
<td>Endo</td>
<td>X</td>
</tr>
<tr>
<td>Surgical Thrombectomy (arterial/venous)</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>AV Access</td>
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<td>X</td>
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<tr>
<td>AV Access</td>
<td>Endo</td>
<td>X</td>
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<tr>
<td>Superficial Venous</td>
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<td>X</td>
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<tr>
<td>Superficial Venous</td>
<td>Endo</td>
<td>X</td>
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<tr>
<td>Deep Venous</td>
<td>Open</td>
<td>X</td>
</tr>
<tr>
<td>Deep Venous</td>
<td>Endo</td>
<td>X</td>
</tr>
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</table>