Expanding opportunities to understand quality and outcomes of peripheral vascular interventions: The ACC NCDR PVI Registry

W. Schuyler Jones, MD,[a,*] Kevin F. Kennedy, PhD,[b] Beau M. Hawkins, MD,[c] Robert R. Attaran, MBChB,[d] Eric A. Secemsky, MD, MSc,[e] Faisal Latif, MD,[f] Nicolas W. Shammas, MD, MS,[g] Dmitriy N. Feldman, MD,[h] Herbert D. Aronow, MD, MPH,[i] Bruce Gray, MD,[j] Ehrin J. Armstrong, MD, MSc,[k] P. Michael Grossman, MD,[l] Kalon K. L. Ho, MD, MSc,[m] Anand Prasad, MD,[n] Michael R. Jaff, DO,[o] Kenneth Rosenfield, MD,[p] and Thomas T. Tsai, MD[q]

Durham, NC; Kansas City, MO; Oklahoma City, OK; New Haven, CT; Boston, Newton MA; Davenport, IA; New York, NY; Providence, RI; Greenville, SC; Aurora, CO; Ann Arbor, MI; San Antonio, TX; and Denver, CO

Abstract Lower extremity peripheral artery disease (PAD) and cerebrovascular disease (CeVD) are prevalent conditions in the United States, and both are associated with significant morbidity (eg, stroke, myocardial infarction, and limb loss) and increased mortality. With a growth in invasive procedures for PAD and CeVD, this demands a more clear responsibility and introduces an opportunity to study how patients are treated and evaluate associated outcomes. The American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) Peripheral Vascular Intervention (PVI) Registry is a prospective, independent collection of data elements from individual patients at participating centers, and it is a natural extension of the already robust NCDR infrastructure. As of September 20, 2018, data have been collected on 45,316 lower extremity PVIs, 12,417 carotid artery stenting procedures, and 11,027 carotid endarterectomy procedures at 208 centers in the United States. The purpose of the present report is to describe the patient and procedural characteristics of the overall cohort and the methods used to design and implement the registry. In collecting these data, ACC and ACC PVI Registry have the opportunity to play a pivotal role in scientific evidence generation, medical device surveillance, and creation of best practices for PVI and carotid artery revascularization. (Am Heart J 2019;216:74-81.)

From the [a]Division of Cardiology, Duke University Health System, Durham, NC, [b]Department of Cardiovascular Research, St. Luke's Mid America Heart Institute, Kansas City, MO, [c]University of Oklahoma Health Sciences Center, Oklahoma City, OK, [d]Division of Cardiology, Yale University, New Haven, CT, [e]Division of Cardiology, Beth, Israel, Deaconess Medical Center, Boston, MA; Smith Center for Outcomes Research in Cardiology, Boston MA, [f]University of Oklahoma Health Sciences Center and Veterans' Affairs Medical Center, Oklahoma City, OK, [g]Midwest Cardiovascular Research Foundation, Davenport, IA, [h]Greenberg Division of Cardiology, Weill Cornell Medical College, New York Presbyterian Hospital, New York, NY, [i]Lifespan Cardiovascular Institute/Alpert Medical School at Brown University, Providence, RI, [j]Greenville Health System, Greenville, SC, [k]University of Colorado and Rocky Mountain Regional VA Medical Center, Aurora, CO, [l]University of Michigan and Michigan Medicine Frankel Cardiovascular Center, Ann Arbor, MI, [m]Cardiovascular Division, Beth, Israel Deaconess Medical Center, 330 Brookline Ave, Boston, MA, [n]UT Health San Antonio, San Antonio, TX, [o]Department of Medicine, Newton-Wellesley Hospital, Newton, MA, [p]Division of Cardiology, Massachusetts General Hospital, Boston, MA, and [q]University of Colorado and Institute for Health Research, Kaiser Permanente Colorado, Denver, CO.

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Reprint requests: W. Schuyler Jones, MD, Duke University Medical Center, Box 3330, Durham, NC 27710.

E-mail: schuyler.jones@duke.edu

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Lower extremity (LE) peripheral artery disease (PAD) and cerebrovascular disease (CeVD) are prevalent conditions that affect millions of patients in the United States each year.[1] Despite the growing prevalence, costs, impact on functional status, morbidity (specifically LE amputation and stroke), and mortality associated with PAD and CeVD, these conditions are relatively understudied.[2] Over the past 2 decades, the use of peripheral endovascular intervention (PVI) has surpassed surgical revascularization as the primary treatment modality for patients with claudication refractory to medical therapy or exercise training and critical limb ischemia.[3,4] Surgical carotid endarterectomy (CEA) remains the dominant treatment modality for asymptomatic and symptomatic patients with carotid artery disease; however, carotid artery stenting (CAS) is commonly performed.[5,6]

This article will outline the objectives, structure, discrete data elements, patient characteristics, operator characteristics, and early experience of the American College of Cardiology (ACC) PVI Registry. Furthermore, the rationale and design of the registry will be discussed, as it pertains to the ability to measure and improve clinical care delivery at the site level, patient outcomes, and medical device evaluation and surveillance. Key issues including the rigor of data collection, physician and health system reports of quality of care, and opportunities to collaborate with other ACC NCDR registries will be discussed. Finally, this paper serves as a prelude to future publications about the utilization, quality, and outcomes of PVI and carotid revascularization in the United States.

Registry inception and aims

Along with broad, multispecialty input, the ACC National Cardiovascular Data Registry (NCDR) created the Carotid Artery Revascularization and Endarterectomy (CARE) Registry in 2005 after Centers for Medicare and Medicaid Services mandated the participation in a clinical registry for reimbursement for CAS. Since 2005, multiple scientific reports were generated from the registry to guide the appropriateness and quality of carotid artery revascularization procedures.[7-10] Given the ever-changing landscape of LE PAD, the ACC has launched the ACC NCDR PVI Registry to (*a*) capture and assess the patient and procedural characteristics of patients undergoing endovascular and surgical treatment for LE PAD and carotid disease in the United States and (*b*) measure and improve the quality of care and patient outcomes in contemporary clinical practice. The collection of detailed information on patient, anatomic, and procedural characteristics provides opportunities for systematic evaluation of an already-heterogeneous clinical care landscape (including surveillance of frequencies of use and estimation of effectiveness of available therapeutic options) and assessment of changes in clinical care over time as part of quality improvement efforts.

Registry structure, organization, and governance

In response to the need for more information about the use and clinical outcomes of endovascular and surgical procedures for the treatment of PAD and carotid artery disease, the National Cardiovascular Data Registry launched the PVI Registry in 2014. The registry addresses the transition in cardiovascular care from an open surgical model to an endovascular model for the treatment of PAD and carotid revascularization. Currently, the PVI Registry offers modules for:

- LE endovascular procedures (PVI)
- CAS
- CEA

In updated versions beginning in 2020, the PVI Registry will also offer an additional group of modules. This expansion of the ACC PVI Registry will truly allow NCDR to evaluate the broad procedural outcomes of patients who are treated in the catheterization laboratories, angiography suites, and operating rooms of the participating institutions. The modules will include:

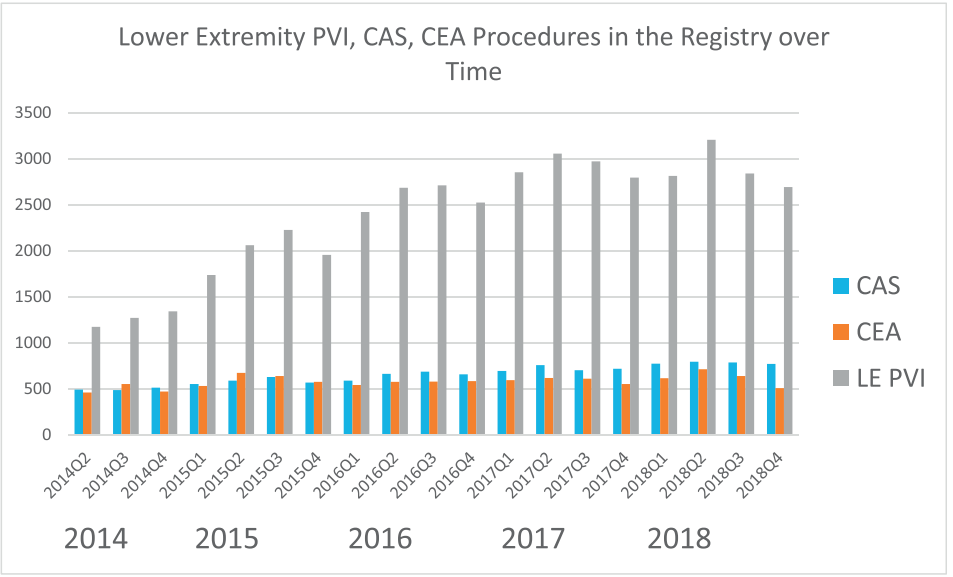
- Open surgical suprainguinal bypass
- Open surgical infrainguinal bypass
- Renal artery intervention
- Mesenteric artery intervention
- Open and endovascular abdominal aortic aneurysm repair
- Pulmonary embolism and deep venous thrombosis intervention, and inferior vena cava filter implantation
- LE venous intervention

The Registry captures patient demographics; operator and facility characteristics; identifiers for high-risk features for carotid artery revascularization; the use of devices including balloons, stents, and embolic protection devices; and complications and adverse event rates. In an attempt to minimize the additional work required for its sites, the ACC PVI Registry convened a multidisciplinary team of cardiologists, vascular surgeons, and interventional radiologists to develop a parsimonious set of core data elements with standard definitions that were aligned with other NCDR registries (ie, registry definitions are consistent) and included disease-specific factors important to patients with PAD and CeVD. The data elements collected were selected and are frequently reviewed by the NCDR Data Governance Committee. In addition to using existing infrastructure and definitions from the NCDR, the ACC PVI Steering Committee and governing bodies report directly to the NCDR Scientific Oversight Committee to maintain consistency and scientific integrity across registries.

Registry data collection

The discrete data elements as listed in the case report form for the Registry are attached as a Supplemental

Figure 1



Distribution of LE PVI, CAS, and CEA over time.Procedures collected by ACC PVI.

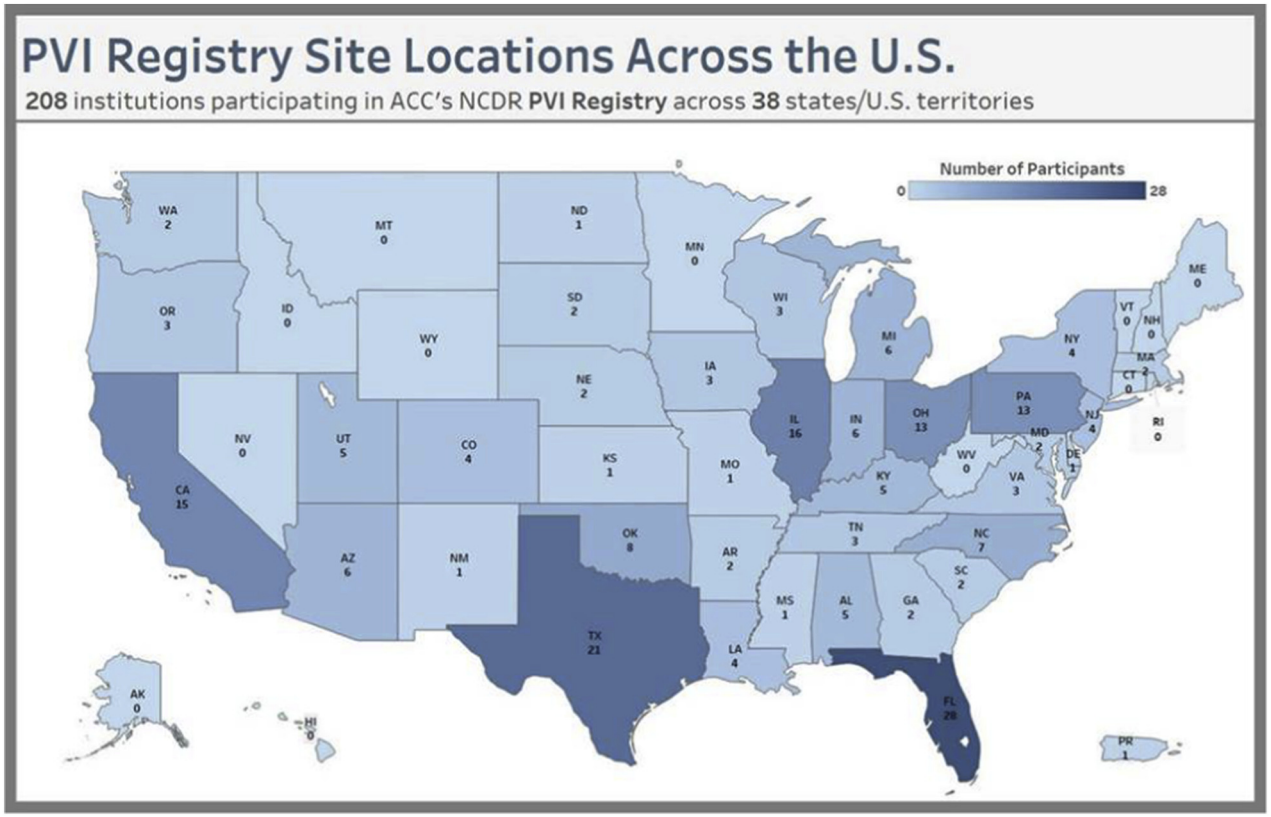
Appendix. Prior to the launch of ACC PVI, upfront efforts were made to harmonize definitions across multiple registries, including Society of Vascular Surgery (SVS) Vascular Quality Initiative (VQI), to permit "apples to apples" comparisons of patients undergoing procedures. Health systems, hospitals, and office-based laboratories that perform diagnostic angiography, PVI, CAS, and CEA voluntarily participate in NCDR's ACC PVI Registry. Onsite data managers facilitate and supervise data collection at each center, and data entry is permitted for procedures from multiple clinical sites within a health system or hospital (eg, cardiac catheterization laboratory, radiology angiography suite, operating room). Participating centers can securely and confidentially submit data to the NCDR central repository using 1 of 2 methods: (1) NCDR-certified software vendors or (2) Web-based data collection tools. When data are received by NCDR, rigorous data quality checks are performed electronically, and a data quality report is available for centers pertaining to whether or not data completeness and quality are sufficient and how centers compare with national averages. Routine external audits are also performed to ensure data completeness, timeliness, and quality. Data collection was designed to be comprehensive enough to support meaningful observational analysis, premarket drug and device studies, and postmarket surveillance studies.

Clinical characteristics

As of January 1, 2019, there were 45,316 LE PVIs, 12,417 CASs, and 11,027 CEA procedures included in the ACC PVI registry. Figure 1 shows the cumulative frequency of data entry into the registry from 2014 Q2 to 2018 Q4. Figure 2 shows the geographic distribution of the 208 sites that enroll patients into ACC PVI. Table I demonstrates the baseline characteristics of patients entered based on the type of procedure performed. Table II shows the procedural indications and procedural data for patients who underwent CAS and CEA. Notably, approximately 44% of patients who underwent CAS were asymptomatic prior to procedure, whereas 60% of patients who underwent CEA were asymptomatic. Table III shows the procedural indications and procedural data for patients who underwent PVI. There is a near-equal proportion of patients with critical limb ischemia and claudication/atypical limb symptoms undergoing LE PVI.

In terms of clinical outcomes, multiple metrics are being collected pre-, intra-, and postprocedure includin: radiation exposure, contrast amount, acute kidney injury, bleeding and need for transfusion, hemodynamic assessments (eg, ankle brachial index, toe pressure), nonfatal myocardial infarction, nonfatal stroke, procedural complications (eg, perforation, dissection, embolism), unplanned amputation, discharge status (eg, alive, deceased) and location (eg, home, skilled nursing facility, rehabilitation), and other adverse events. Although postprocedure outcomes data (including functional status and quality of life) are infrequently collected at the present time (and similar to CathPCI outcomes), future efforts will be made to link the registry with electronic health records, other registry data,

Figure 2



ACC PVI site distribution as of March 7, 2019. Geographical map (by state) of the sites reporting to ACC PVI.

Table I. Baseline characteristics of patients based on type of procedure performed (N = 55,517)**

	CAS (n = 12,417)	CEA (n = 11,027)	LE PVI (n = 45,316)
Age, y	70.3 ± 9.6	71.1 ± 9.0	68.8 ± 11.3
Male sex	7727 (62.2%)	6497 (58.9%)	26,791 (59.1%)
Race, white	11,577 (93.2%)	10,424 (94.5%)	36,940 (81.5%)
Race, black	540 (4.3%)	382 (3.5%)	7065 (15.6%)
Ethnicity, Hispanic	641 (5.2%)	500 (4.5%)	2812 (6.2%)
Medical history			
Hypertension	11,268 (90.8%)	9922 (90.0%)	40,654 (89.8%)
Dyslipidemia	10,674 (86.0%)	9377 (85.1%)	36,881 (81.5%)
Diabetes mellitus	5020 (40.5%)	4092 (37.2%)	24,144 (53.3%)
ESRD (on dialysis)	224 (1.8%)	144 (1.3%)	3233 (7.1%)
Coronary artery disease	6663 (53.7%)	5129 (46.5%)	23,081 (51.0%)
Prior myocardial infarction	2905 (23.4%)	2028 (18.4%)	9942 (22.0%)
Prior PCI	3699 (29.8%)	2473 (22.5%)	12,178 (26.9%)
Prior CABG	2848 (23.0%)	2270 (20.6%)	9528 (21.1%)
Cardiomyopathy or left ventricular systolic dysfunction	1396 (11.3%)	708 (6.4%)	4789 (10.6%)
Atrial fibrillation/flutter	1749 (14.1%)	1415 (12.9%)	*
Tobacco use			
Never	3210 (25.9%)	3170 (28.8%)	10,374 (22.9%)
Former	5478 (44.2%)	4691 (42.6%)	17,958 (39.7%)
Current, everyday	3371 (27.2%)	2840 (25.8%)	15,123 (33.4%)
Prior carotid revascularization	3463 (27.9%)	1614 (14.7%)	*

ESRD, End-stage renal disease; *PCI*, percutaneous coronary intervention; *CABG*, coronary artery bypass grafting.
*Not collected.

Table II. Indications and procedural characteristics for carotid procedures

	CAS (n = 12,417)	CEA (n = 11,027)
Procedure location		
Catheterization laboratory	9074 (73.1%)	82 (0.7%)
Interventional radiology	2295 (18.5%)	8 (0.1%)
Operating room	1046 (8.4%)	10,935 (99.2%)
Procedure status		
Elective	10,123 (81.5%)	9446 (85.7%)
Urgent	1880 (15.1%)	1534 (13.9%)
Emergency	412 (3.3%)	45 (0.4%)
Cerebrovascular presentation		
Asymptomatic	5445 (43.9%)	6622 (60.1%)
TIA ≤60 d	2842 (22.9%)	1873 (17.0%)
TIA >60 d	960 (7.7%)	453 (4.1%)
Ischemic stroke ≤60 d	1621 (13.1%)	1269 (11.5%)
Ischemic stroke >60 d	838 (6.8%)	515 (4.7%)
Acute evolving stroke	626 (5.0%)	227 (2.1%)
Carotid intervention procedure indication		
Asymptomatic	4677 (37.7%)	6517 (59.1%)
Restenosis in target vessel, prior CEA	1019 (8.2%)	70 (0.6%)
Restenosis in target vessel, prior CAS	272 (2.2%)	11 (0.1%)
Urgent cardiac surgery w/in 30 d	107 (0.9%)	122 (1.1%)
Spontaneous carotid artery dissection	114 (0.9%)	14 (0.1%)
Symptomatic lesion w/in 6 m	6221 (50.1%)	4289 (38.9%)
Preprocedure modified Rankin score		
0: No symptoms at all	3071 (59.9%)	1632 (77.3%)
1: No significant disability despite symptoms	1141 (22.5%)	262 (12.4%)
2: Slight disability	381 (8.0%)	95 (4.5%)
3: Moderate disability	235 (4.9%)	58 (2.7%)
4: Moderately severe disability	196 (3.9%)	58 (2.7%)
5: Severe disability	67 (1.2%)	5 (0.2%)
Missing	7326	8917

TIA, transient ischemic attack.

and administrative claims data including Centers for Medicare and Medicaid Services. Following the initial year of data collection for all centers, risk-adjusted measures are available, including risk-adjusted stroke or mortality for CAS and CEA procedures.

Performance improvement and clinical research

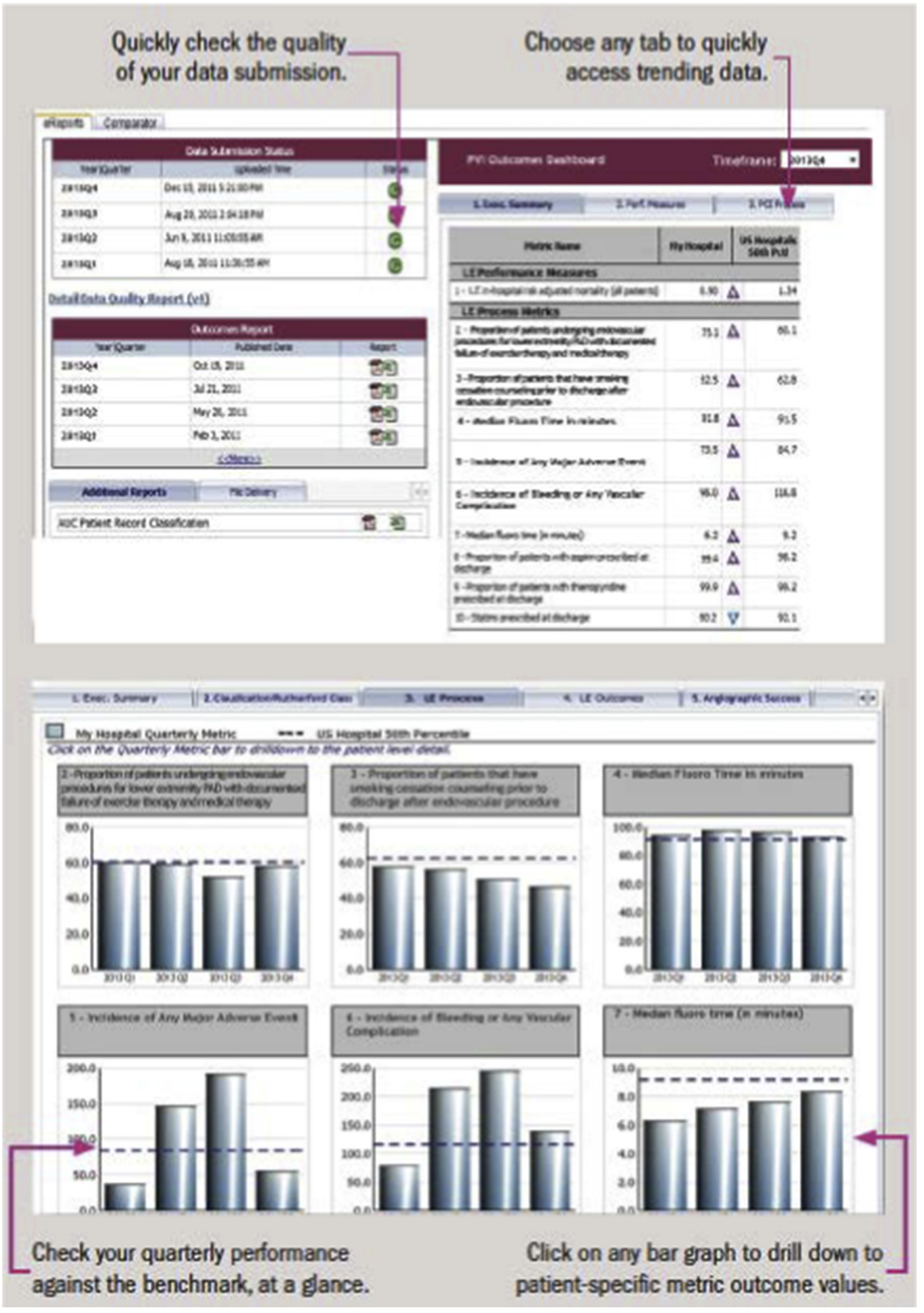
Similar to other ACC registries, the ACC PVI Registry provides clinicians and hospitals with quarterly procedure counts and risk-adjusted statistics (including quality improvement and clinical outcomes) incorporated into a dashboard that allows for detailed comparisons among clinicians and hospitals (Figure 3). Performance measures for LE PAD can be found in the ACC/AHA Task Force for Performance Measures for PAD.[11] Currently, the dashboard provides contemporary data on endovascular LE PVI procedures and carotid procedures, and clinicians and hospitals can assess adequacy of procedure volumes, guideline adherence, and opportunities for performance improvement. Similar to NCDR CathPCI quarterly reports, the ACC PVI statistics have the capability to report on these metrics across a hospital or health system (including combined reports and specific reports for catheterization laboratories, interventional suites, and operating rooms).

The Registry's clinical data are currently available and useful to researchers for comparative effectiveness and safety research, and as such, data governance has been established with oversight facilitated by a Steering Committee. Building on the success and framework of other NCDR registries, the ACC PVI Registry has a data analytic center and administrative support from the ACC. As a goal for clinical research, registry proposals should focus on the evaluation of contemporary practice patterns, dissemination of best clinical practices, and opportunities to improve direct patient care. The data elements (eg, case report forms) can be used as the basis for clinical question development, and the data elements can be found on this link: https://cvquality.acc.org/NCDR-Home/Data-Collection/What-Each-Registry-Collects. The linkage of registry data with longitudinal data sources (eg, Centers for Medicare and Medicaid Services, as described above)

Table III. Indications and procedural characteristics of LE PVI

	LE PVI (n = 45,316)
Admission source	
Elective	34,046 (75.3%)
Emergency department	7698 (17.0%)
Transfer from another acute care facility	1532 (3.4%)
Procedure status	
Elective	34,641 (76.5%)
Urgent	9562 (21.1%)
Emergency	1091 (2.4%)
Procedure location	
Catheterization laboratory	37,003 (81.7%)
Interventional radiology	5452 (12.0%)
Operating room	2831 (6.3%)
Worst presentation	
Asymptomatic	1028 (2.3%)
Atypical claudication	367 (0.8%)
Rutherford 1 (mild claudication)	1052 (2.3%)
Rutherford 2 (moderate claudication)	3045 (6.7%)
Rutherford 3 (severe claudication)	16,599 (36.6%)
Rutherford 4 (ischemic rest pain)	6258 (13.8%)
Rutherford 5 (minor tissue loss)	10,277 (22.7%)
Rutherford 6 (major tissue loss)	3809 (8.4%)
Acute limb ischemia	2760 (6.1%)
Procedure indication	
Typical claudication	20,373 (45.0%)
Atypical claudication	1356 (3.0%)
Maintenance of patency (asymptomatic)	668 (1.5%)
Critical limb ischemia	19,458 (43.0%)
Acute limb ischemia	2821 (6.2%)
Prevention of aneurysm	76 (0.2%)
Treatment of symptomatic aneurysm	128 (0.3%)
Facilitation of other procedure	380 (0.8%)

Figure 3



Example of ACC PVI Data Quality Report and Quarterly Report.Graphical representation of quality improvement reports and quarterly reports for each site/center that participates in ACC PVI.

will occur in late 2019, and this will significantly improve the research readiness and utility of the ACC PVI Registry. Finally, any interested researcher (from any institution) can submit a proposal using the following link: https://cvquality.acc.org/NCDR-Home/Research/Submit-a-Proposal/Steps-for-Submitting-a-Proposal. Research proposals will be evaluated for feasibility by the analytic center's statistician, and the ACC PVI Research and Publications Committee (selected by the American College of Cardiology) will vote on priority, approve proposals to move forward to analysis, and work with authors to complete work. Two manuscripts have recently been published on LE PVI and are available on PubMed.[12,13]

Future opportunities

The growth and maturation of the endovascular and surgical treatment of CeVD and LE PAD have created an exciting opportunity to assess the contemporary use of certain procedures and devices as well as the procedural success, medication use, and complication rates of these procedures. Although regulation has not been as stringent in the PVI space over the past 2 decades, the ability of the ACC PVI Registry to spur process improvement and appropriate use for devices and procedures will allow assessment of the contemporary treatment and variations in treatment and outcomes to be similar to these processes for other cardiovascular procedures (eg, percutaneous coronary intervention, implantable cardioverter defibrillator, transcatheter valve therapies). Examples of collaboration are already evident and include (1) use of ACC PVI data to identify sufficiently trained CAS operators for the Carotid Revascularization Endarterectomy vs. Stenting Trial 2 (CREST 2) and ensure that carotid procedural data and outcomes are synchronized with the SVS VQI data and (2) a public-private collaboration with the US Food and Drug Administration, SVS VQI, and Society of Interventional Radiology registry to harmonize data elements for LE PVI procedures (an MDEpiNet project called Registry Assessment of Peripheral Interventional Devices). The Registry Assessment of Peripheral Interventional Devices initiative has also promoted the collection and reporting of the Unique Device Identifier for interventional devices. Furthermore, the opportunity to create broad postapproval surveillance programs for complex interventional devices whose uses are often based on operator skill/comfort and anatomic severity and burden of disease has the possibility to improve patient safety.

Conclusions

Extending the breadth of registry programs offered by ACC NCDR, the ACC PVI Registry was designed with the intent to support the systematic assessment of contemporary vascular intervention in the United States. As with other registries, the Registry has comprehensive data elements, consistent data collection practices, and broad coverage across more than 200 centers. With expanding capacity of modules; broad partnership with vascular specialists; and dedication to perform quality improvement, device surveillance, and clinical research, the ACC PVI Registry has successfully launched and is uniquely positioned to play a pivotal role in scientific evidence generation, medical device surveillance, and creation of best practices for PVI and carotid artery revascularization.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahj.2019.07.007.

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