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Preliminary Results of the Outpatient Endovascular and Interventional Society National Registry

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Abstract

Purpose: To present a new outcomes-based registry to collect data on outpatient endovascular interventions, a relatively new site of service without adequate historical data to assess best clinical practices. Quality data collection with subsequent outcomes analysis, benchmarking, and direct feedback is necessary to achieve optimal care. **Materials and Methods:** The Outpatient Endovascular and Interventional Society (OEIS) established the OEIS National Registry in 2017 to collect data on safety, efficacy, and quality of care for outpatient endovascular interventions. Since then, it has grown to include a peripheral artery disease (PAD) module with plans to expand to include cardiac, venous, dialysis access, and other procedures in future modules. As a Qualified Clinical Data Registry approved by the Centers for Medicare and Medicaid Services, this application also supports new quality measure development under the Quality Payment Program. All physicians operating in an office-based laboratory or ambulatory surgery center can use the Registry to analyze de-identified data and benchmark performance against national averages. Major adverse events were defined as death, stroke, myocardial infarction, acute onset of limb ischemia, index bypass graft or treated segment thrombosis, and/or need for urgent/emergent vascular surgery. **Results:** Since Registry inception in 2017, 251 participating physicians from 64 centers located in 18 states have participated. The current database includes 18,134 peripheral endovascular interventions performed in 12,403 PAD patients (mean age 72.3±10.2 years; 60.1% men) between January 2017 and January 2020. Cases were performed primarily in an office-based laboratory (85.1%) or ambulatory surgery center setting (10.4%). Most frequently observed procedure indications from 16,086 preprocedure form submissions included claudication (59%), minor tissue loss (16%), rest pain (9%), acute limb ischemia (5%), and maintenance of patency (3%). Planned diagnostic procedures made up 12.2% of cases entered, with the remainder indicated as interventional procedures (87.6%). The hospital transfer rate was 0.62%, with 88 urgent/emergent transfers and 24 elective transfers. The overall complication rate for the Registry was 1.87% (n=338), and the rate of major adverse events was 0.51% (n=92). Thirty-day mortality was 0.03% (n=6). **Conclusion:** This report describes the current structure, methodology, and preliminary results of OEIS National Registry, an outcomes-based registry designed to collect quality performance data with subsequent outcome analysis, benchmarking, and direct feedback to aid clinicians in providing optimal care.

Keywords

ambulatory surgery center, angioplasty, atherectomy, endovascular interventions, office-based procedures, outcome analysis, outpatient laboratory, peripheral artery disease, registry, treatment

Introduction

Outpatient endovascular intervention has grown rapidly into an increasingly prevalent treatment option for vascular disease.[1–4] Advances in pharmacology and technology for endovascular care and the changes in reimbursement by the Centers for Medicare and Medicaid Services (CMS) to shift the cost of care to outpatient sites of service have also led to the growth in outpatient endovascular procedures.[1] Although outpatient and office-based interventional suites have been operational for many years, there has been a

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marked proliferation of these sites nationwide during the past decade.[5] It is estimated, based on informal industry surveys and Medicare claims data, that nearly 750 office-based laboratories currently exist in the United States, and that number continues to grow. Office-based laboratories, also referred to as office-based endovascular suites or outpatient interventional suites, offer distinct advantages for patient care, being more efficient and cost-effective than hospital-based interventions.[5] In addition, patient satisfaction is consistently very high in these centers.[6]

This increased utilization of outpatient and office-based sites of service has raised questions about potential overutilization, adverse patient outcomes, and the overall quality of care provided in this environment.[7–9] Though published reports from individual centers have shown excellent clinical results with very low morbidity and mortality,[4,6,10] there is little statewide or national data available for analysis and comparison. Similarly, there are no established guidelines or metrics from which to assess best clinical practices. Broad-based patient and procedural data collection with associated outcome analysis, benchmarking, and clinician feedback is necessary to achieve optimal care. Outcomes-based registries can serve this purpose.[11]

Over the past 2 decades, physician and professional societies' voluntary clinical registries, such as the Society of Thoracic Surgeons (STS) National Database, American College of Surgeons National Surgical Quality Improvement Program (NSQIP), Society for Vascular Surgery Vascular Quality Initiative (VQI), and the American College of Cardiology National Cardiovascular Data Registry (NCDR), have demonstrated the value of such initiatives in changing physician behavior and improving patient outcomes.[12–32] These established registries have focused primarily either on inpatient outcomes (NSQIP), specialty-specific procedures (STS), or a combination of both (VQI and NCDR).

None, however, has been directed at a multispecialty set of procedures performed by vascular surgeons, interventional cardiologists, and interventional radiologists in an office outpatient environment, and thus they do not meet the unique needs of outpatient endovascular providers. Existing quality outcome measures generally tend to be geared toward medical and inpatient hospital interventions rather than outpatient procedures.[33] Measured surgical outcomes focus primarily on open procedures rather than minimally invasive interventions. In addition, NSQIP requires follow-up data collected at 30 days.[20] Therefore, this does not allow for long-term outcome research or analysis to determine best treatment. Although the VQI requires follow-up at 1 year and allows further follow-up data to be entered up to 5 years, this national registry is costly and requires a full-time on-site data entry manager.[25] Participation in existing registries often requires hospital financial support and are cost prohibitive to most private practice or office-based endovascular centers. Thus, there is a need to develop a patient-centered, physician-friendly, cost-effective registry specifically for outpatient endovascular procedures.

The Outpatient Endovascular and Interventional Society (OEIS) is a multispecialty society composed primarily of vascular surgeons, interventional cardiologists, and interventional radiologists. It was established in 2013 with a mission to address the unique needs of patients and physicians working in the outpatient environment; to enhance the safety, quality, and efficacy of outpatient endovascular procedures; and to improve health care quality by creating and adhering to professional quality standards. Such quality standards are summarized and referred to as SCOCAP: Safety, Credentialing, Outcomes Measures, Compliance, Appropriateness, and Peer Review. These guidelines promote excellence in outcomes through procedure selection, clinical appropriateness, and safety.

To achieve these aims, OEIS in 2017 established a national registry of office-based and outpatient procedures to collect data on safety, efficacy, and quality of care for outpatient endovascular interventions for PAD. As a CMS-approved Qualified Clinical Data Registry (QCDR), it also supports new quality measures development under the Quality Payment Program.[34] The Registry consists of de-identified clinical and procedural data entered at the time of treatment and follow-up office visits from physicians operating in an office-based laboratory or ambulatory surgery center. This report provides an overview of the structure and methodology of the OEIS National Registry and also describes preliminary results.

Materials and Methods

Registry Design

Site Enrollment. The OEIS National Registry collects data related to endovascular interventions performed specifically in an outpatient setting. Centers operating as office-based laboratories or ambulatory surgery centers performing eligible procedures are able to enroll as participating sites. Each site contracts with OEIS for services and safeguarding protected health information in compliance with HIPAA (Health Insurance Portability and Accountability Act) while allowing the Registry to analyze and report on de-identified, cumulative clinical data. Registry participants must agree to enter required data for all eligible cases, not just selected procedures, and comply with regular internal audit guidelines and requests for source documentation. Physicians of all specialties who perform endovascular procedures may participate. Table 1 shows a summary of key features.

PAD Module. The first module developed focuses on peripheral arterial diagnostic and interventional procedures,

Table 1. Summary of Key Registry Features.

OEIS National Registry Features
Collects detailed data specifically for endovascular outpatient interventions
Multispecialty/multidisciplinary physician participation
Secure, web-based data entry system
Regular audits to maintain data completeness and accuracy
Dynamic clinical reports with performance metrics available online anytime to participants
Regular quarterly quality measure performance reports benchmarked to national averages
CMS-approved Qualified Clinical Data Registry with unique measures tailored to the outpatient environment

Abbreviations: CMS, Centers for Medicare and Medicaid Services; OEIS, Outpatient Endovascular and Interventional Society.

including diagnostic angiography, balloon angioplasty, stent placement, and atherectomy in patients with lower extremity arterial disease. Data elements and definitions were developed utilizing established data standards.[35] The electronic data system (EDS) was structured to capture what are defined as data essential fields, which include all minimum data entry requirements, as well as a more expansive set of optional enhanced data fields. Data fields used to calculate supported Merit-Based Incentive Payment System (MIPS) and QCDR measures were included according to CMS standards.

QCDR-MIPS. The Registry has been a CMS-approved QCDR for the MIPS since 2017. QCDRs are one of several methods available for participation in MIPS, which can collect clinical data on behalf of participating physicians for submission to CMS to improve the quality of patient care and establish physician reimbursement adjustment levels. QCDRs enable collection of patient data regardless of patient insurance coverage, not just Medicare beneficiaries. Unlike other submission methods, a QCDR is uniquely able to develop custom quality measures that are subject to annual review and approval by CMS. This process allows QCDRs to create patient-relevant quality measures tailored to provide more meaningful feedback that participants can apply directly in their practices.

The OEIS National Registry is the first and only QCDR to focus solely on detailed outcomes within outpatient interventional suites. For 2020, CMS approved 3 QCDR measures submitted by OEIS: QM OEIS6, appropriate noninvasive arterial testing for patients with intermittent claudication who are undergoing a lower extremity peripheral vascular intervention; QM OEIS7, structured walking program prior to intervention for claudication; and QM OEIS8, use of ultrasound guidance for vascular access.

Data Collection and Transmission. Detailed data are collected at the time of initial treatment and during subsequent follow-up office visits. Variables were selected to provide robust information regarding patient demographics, clinical history, diagnostic testing, procedure indication, Rutherford category, procedural details, complications, and clinical follow-up (Supplementary Figure 1; available in the online version of the article). Data are submitted using a cloud-based EDS system (Syncrony; Syntactx Technologies, New York, NY, USA). OEIS contracted to develop and maintain the registry data entry system and database using this customizable and fully secure system.[36]

Registry users can log into the EDS through a secure web page using any device or computer with web access. Once the procedural data are submitted, the Registry receives de-identified data for analysis. The data are regularly aggregated, and users can access reports with summary statistics, benchmarking, and quality measure feedback via the web portal.

Database Structure and Analytics. The registry utilizes an enterprise-grade, cloud-based NoSQL database architecture (MongoDB Atlas/Enterprise; MongoDB, New York, NY, USA) as the database engine and back end. Data points collected through the EDS are formatted, stored, and analyzed from the database platform. The current data architecture is optimized to add additional future modules.

Currently, analytics are performed and the results are published to dashboards contained within the EDS as described above. These reports are accessible to registry participants. Additional graphical and statistical reports are separately made available to the Registry Committee and OEIS Board of Directors. Individual sites have access to their own data as well as de-identified aggregate measures from the Registry as a whole (Figure 1). The reports include a multitude of clinically relevant metrics and information, basic and advanced demographics, and the individual site/physician performance on supported Quality Measures as well as summary comparative benchmarking data compared to national averages.

Regulatory Oversight

Organization Oversight. The Registry is organizationally administered and directed in a layered and complementary fashion. The structure consists of 3 supervisory layers: a Medical Director, a Technical Director, and the Registry Committee. The OEIS Board of Directors appoints and

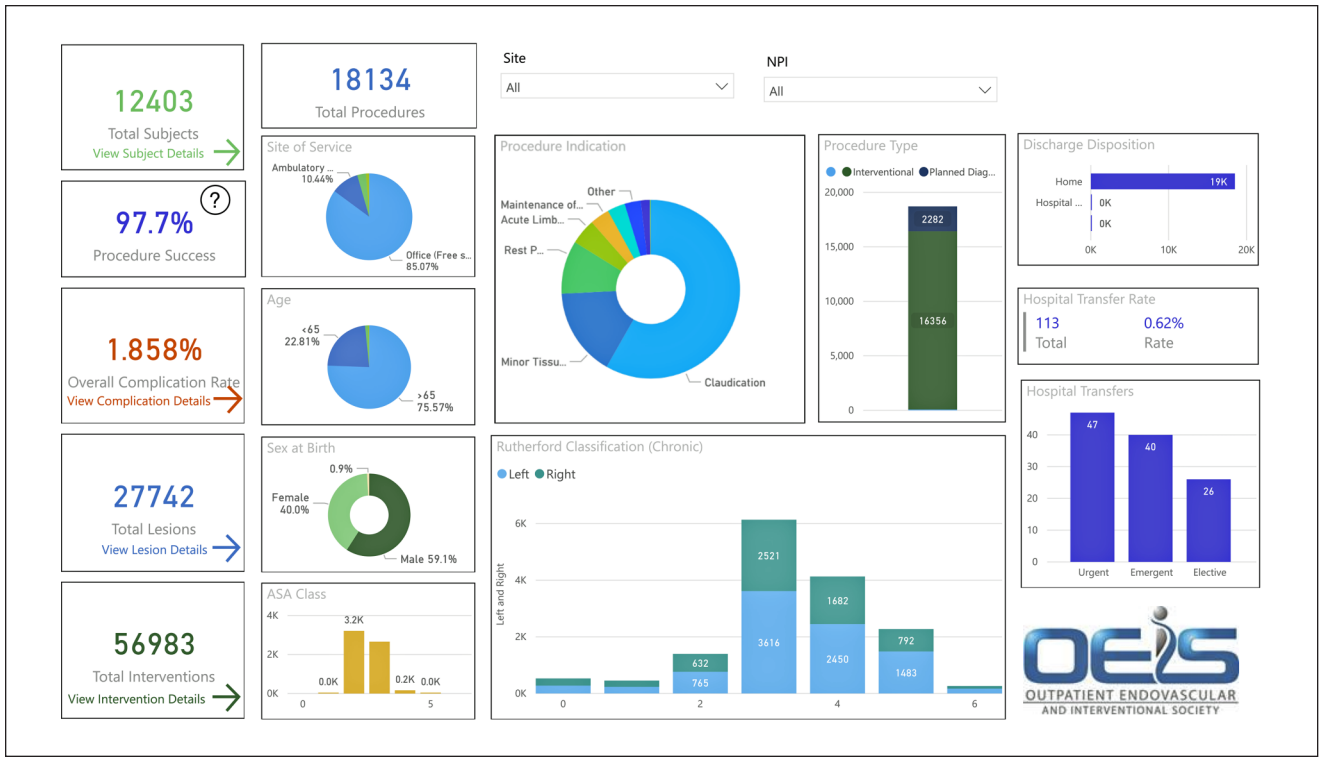

Figure 1. Sample Registry report view showing clinical summary data available to participating sites.

approves both the Medical and Technical Directors and all members of the Registry Committee.

Roles of the Supervisory Agents. The Medical Director and Technical Director provide direction and clinical and administrative oversight and are responsible for Registry operations. Both positions are currently filled by OEIS member physicians and function in an overlapping but complementary fashion. The Medical Director is charged with providing overall direction, strategic vision and goals, global medical oversight, and advocacy/negotiation functions. These duties include interfacing with existing and potential registry sites/participants, interested physician(s), physician groups, health care organizations, other health industry entities, CMS and regulatory bodies, and other professional societies and related registries.

The Technical Director is charged with the day-to-day operation of the Registry and with the maintenance, upgrading, and development of the underlying IT interfaces, including the web interfaces and back end data structure. Primary responsibilities also include direct interaction and technical/medical direction to the Registry Manager; interaction, direction, and negotiations with technical vendors; quality measures; and QCDR functionality. The Medical and Technical Directors receive input and feedback from the Registry Committee with additional direct reporting to the OEIS Board of Directors.

The Registry Committee is composed of physician members of OEIS appointed by the OEIS President. The role of the committee is to oversee and give input regarding the strategic direction of the registry, provide medical expertise in the development and evolution of both existing and future modules, QCDR quality measure development, internal quality measures and adjudication, and feedback to the Medical and Technical Directors. The chairperson reports on committee function and registry activities to the OEIS Board of Directors.

Data Standards and Validation. Data management is conducted internally and in conjunction with the Syntactx Ltd (New York, NY, USA) contract research organization. The web-based EDS database is used to record and manage data and also provides an audit trail. The EDS data can be exported to various file formats for statistical analysis.

Data integrity is achieved through several avenues, including data entry staff training, clinical feedback, and data entry system edit checks and help functions. The Registry EDS is designed to prevent error during entry using indicators of required field completion, detailed help text and definitions, and accepted value limits on data fields. All Registry users who access the database, including physicians, nurses, and/or administrative support staff designated by the individual site to enter data, are required to complete web-based training on Registry protocol, data

collection methods, and data entry standards to ensure accuracy and consistency. Existing users also receive regular updates and access to individual assistance and additional training when needed. Participating sites also receive real-time online feedback reports containing a summary of commonly observed errors, such as missing or out of range dates resulting from human error that they can then use to review their data independently and make corrections.

Internal audits are conducted on an annual basis to ensure data completeness and accuracy. During this process, a 25% sample of records (5–50 cases) entered into the Registry database from a 3% random selection of individual providers [10–50 Taxpayer Identification Number/National Provider Identifier (TIN/NPI) combinations] are reviewed to ensure that data accurately reflects the contents of the subject's medical record, operative notes, and/or other source documentation maintained by the submitting practice. [The internal audit for the previous year identified errors in 1.7% of the sampling.] Complication and hospital transfer logs are also reviewed for any site selected for routine audit and for any site with a complication rate significantly lower than the Registry average to verify complete and accurate entry of these events into the Registry database. Error detection triggers a subsequent additional action to determine the scope and source of the error. Once identified, centers receive improvement feedback, additional training, and/or corrective action, as appropriate.

Participating Site Reporting. Participants can obtain immediately usable data in real time through structured reports provided via the Registry web portal. The Registry reports offer detailed clinical and quality performance feedback reflecting both individual site-level data and aggregated national averages for comparison (Figure 1). Reports can be customized and filtered by date range, individual physician, and site name (available for large groups with multiple practices). Dynamic interactive functionality allows for cross filtering to explore trends in the data. The tabular reports consist of page views showing a clinical summary overview plus detailed views of patient population, lesion, intervention, and complication data. The MIPS quality measure performance dashboard offers a summary view with functionality allowing participants to drill down and granularly review their data. The Registry national benchmarking reports closely reflect the content and structure of the individual center reports and facilitate comparison between physicians within one center, centers within a group, and anonymously between physicians/centers versus national averages.

Cost

The cost to participate in the Registry as of 2019 is $295 per month charged to each participating site, defined as operating under a unique taxpayer identification number, regardless of procedure volume or number of enrolled physicians. Sites where all enrolled physicians are current members of OEIS, however, are eligible for a discounted monthly rate of $175 per month for Registry participation. This fee covers access to the registry database, web-based services, and reporting.

Enrolled providers and groups may also elect for OEIS National Registry QCDR MIPS data submission services once annually for $399 per each physician NPI number. These annual costs are substantially lower than those for other large US registries, especially considering there is no initial setup cost associated with new site enrollment, and centers are responsible only for the nominal monthly fee for registry participation.

Results

Current Status

In just 3 years, the Registry has recruited 251 participating physicians from 64 centers located in 18 states. The most common physician specialties contributing data include interventional cardiology, vascular surgery, and interventional radiology (Figure 2). The Association of American Medical Colleges Physician Specialty Data Report for 2017 showed an almost equal distribution of providers specializing in interventional cardiology (n=3847), vascular surgery (3688), and interventional radiology (n=3416).[37]

Preliminary Results

The current database includes 18,134 peripheral endovascular interventions performed in 12,403 patients with PAD between January 2017 and January 2020. The patient cohort is 39.9% female with an average age of 72.3 ± 10.2 years. Common comorbidities include diabetes (48.1%), hypertension (89.5%), chronic kidney disease (20.8%). History of tobacco use (current and former) was recorded in 65.1% of subjects.

Cases were performed primarily in an office-based laboratory (85.1%) or ambulatory surgery center (10.4%) setting. Most frequently observed procedure indications from 16,086 preprocedure form submissions included claudication (59%), minor tissue loss (16%), rest pain (9%), acute limb ischemia (5%), and maintenance of patency (3%). Planned diagnostic procedures made up 12.2% of cases entered, with the remainder indicated as interventional procedures (87.6%). The hospital transfer rate was 0.62% with 88 urgent/emergent transfers and 24 elective transfers. The overall complication rate for the Registry was 1.87% (n=338), and the rate of major adverse events (defined as death, stroke, myocardial infarction, acute onset of limb ischemia, index bypass graft or treated segment thrombosis,

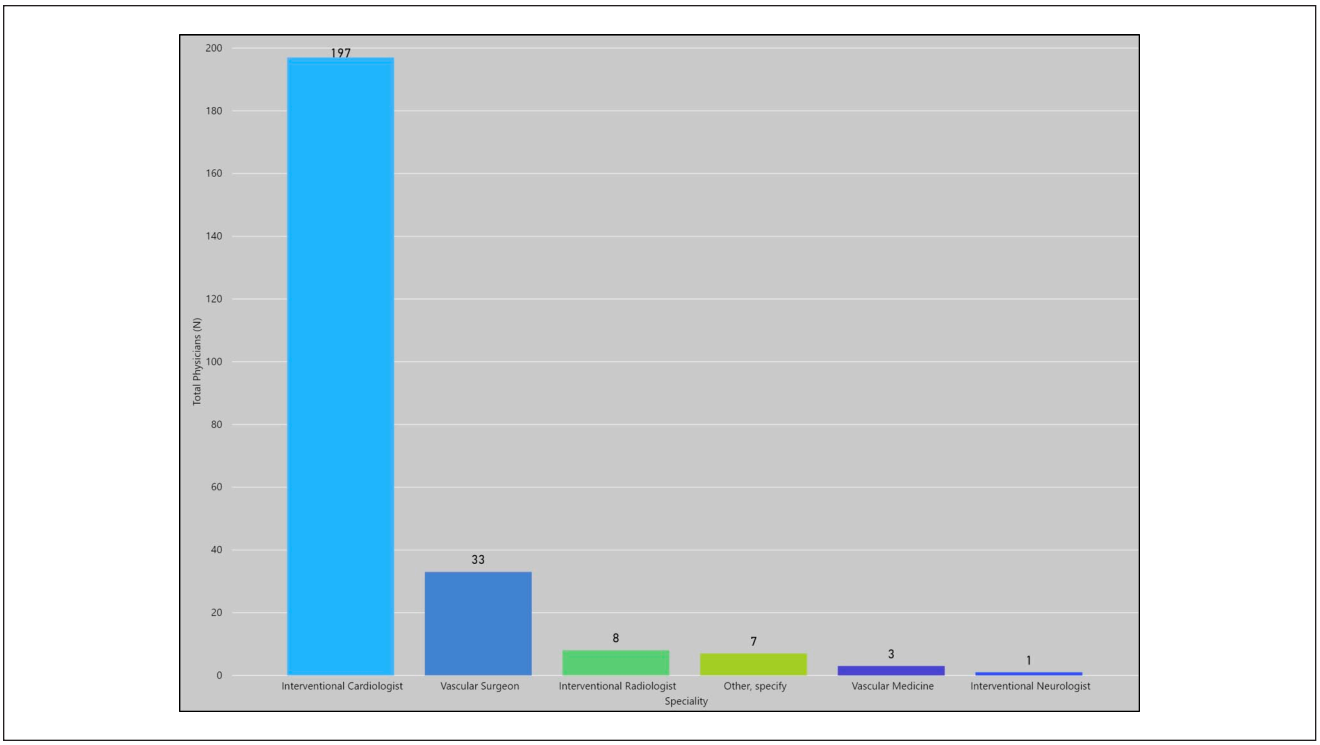

Figure 2. Physician specialty breakdown of registry participants.

and/or need for urgent/emergent vascular surgery) was 0.51% (n=92). Thirty-day mortality was 0.03% (n=6).

Discussion

Additional Module Development

The current PAD module was designed and developed to act as a framework on which future additional modules can be constructed. Near-future plans include expansion to add modules supporting cardiac (coronary interventions and rhythm management procedures, including device implantation), venous (deep and superficial venous system procedures, including inferior vena cava filter management, deep vein thrombosis management, and superficial ablative procedures), and dialysis interventions (including arteriovenous fistula/arteriovenous graft formations and interventions and catheter management). The cardiac module is next in development and will focus on same-day interventions in the outpatient setting.

QCDR Measures

As the registry database grows, new opportunities arise for QCDR quality measure development based on historical data demonstrating gaps in care. The CMS reevaluates measures for inclusion in MIPS on an annual basis. Measures with average performance rates that are too high to demonstrate a gap in care are typically rejected and are not eligible for the topped-out measure timeline as it applies to MIPS measures, so there is a more urgent interest in developing new concepts as high-performing measures are phased out. New measure development is an ongoing process and is an opportunity for the OEIS to help lead the way in advancing value-based care.

Electronic Medical Record Integration

The current process for manual data entry does require some time and resource allocation. Most Registry participating sites also utilize electronic medical record (EMR) systems to collect clinical data. Developing avenues for electronic integration to reduce the need for redundant manual entry would ease the workflow strain associated with clinical registry participation.

Direct integration with existing EMR systems, however, can be difficult to implement due to the variation in EMR vendor platforms, the individual centers' custom configurations, and lack of data uniformity. For example, data stored in unstructured clinical notes is not readily parsed by direct automated extraction without developing advanced natural language processing algorithms. This approach, however, does not work consistently due to differences in terminology and/or definitions between participating physician and subspecialties. Therefore, the Registry is working with select vendors to develop custom EMR forms based on

registry specifications. This would allow centers using these forms to capture all required data into their existing EMR simultaneously with entry into the Registry thus significantly lowering participation cost and reducing error associated with manual data abstraction and entry.

Research Opportunities

The Registry's large sample sizes, routine review for data completeness and accuracy, and detailed dataset all create excellent opportunities for directed clinical research with the potential for improved patient care protocols. Future topics will include short- and long-term safety and efficacy, device usage, and appropriateness. The preliminary data shows safe results, which supports and validates previous single-center results.[4,6] These results will continue to be analyzed and reported in future publications.

Conclusion

The OEIS National Registry is now the standard for quality and outcomes analysis related to outpatient endovascular interventions. Registry data can provide new insights into the safety and efficacy of outpatient endovascular interventions. Opportunities abound for investigators to utilize Registry resources to develop quality standards for best practice in an outpatient setting and provide operator and site-level feedback to drive quality improvement and positive patient outcomes.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Samuel S. Ahn is the Founder and Chief Executive Officer of Vascular Management Associates. Lauren Jones is an employee of the Outpatient Endovascular and Interventional Society.

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Supplementary Material

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