

SEVSG Fall 2020 Meeting Minutes

September 25, 2020

10:00 – 12:30

Remote Meeting

Participation Award Credit – only available if attendee signed in correctly!

Agenda

10:00 - 10:05 am

Welcome and SEVSG Update – Charles Ross, MD

10:05 – 11:15 am

Regional Report Findings - Charles Ross, MD

- including Length of Stay following Carotid Endarterectomy for Stroke – Young Erben, MD

11:15 – 11:25

SEVSG Regional QI project – LTFU rate

11:25 – 11:35

VQI and Patient reported Outcome Measures – Yazan Duwayri, MD

11:35 -11:45 am

Arterial Quality Council Update – Adam Beck, MD

11:45 – 11:50 Arterial RAC Update – Emily Spengler, MD

11:50 -11:55 am

Venous Quality Council Update - Olamide Alabi, MD

11:55-12:00 - Venous RAC Update – Jaime Bennorach-Gample MD

12:00 – 12:15

Spotlight on Recent VQI Publications – J. Middleton Chang, MD

12:15 – 12:30 pm

Closing Remarks: SEVSG Future Directions & Action Items – Charles Ross, MD

Disclosures: Relevant to the content of this educational activity the presenters have no conflict(s) with commercial interest companies to disclose.

Welcome and introductions: Charles Ross, MD

Dr. Ross welcomed participants and reported there are 86 sites in our region, with 7 new sites as of this meeting.

Regional Data Review (see slide deck): Charles Ross, MD

Dashboard Comments:

- **Long term follow-up:** Region continues to struggle with the metric. The percentage dropped from 66% with spring reporting to 56%. Region is next to the last of all regions.

- **Discharge medications:** Region is the worst performing group in VQI with a 79% composite score compared to 85% VQI score. Caroline Morgan shared resources and tools that include sample letters to both patients and referring physicians on the SVS VQI members login page.
- **TFEM CAS ASYMP: Stroke/Death:** Nationally there has been a decrease in these procedures with increase in TCAR procedures. No volume reported for this metric.
- **TCAR ASYMP: Stroke/Death:** Region is performing well with rates that are below the expected rate and better than the overall VQI rate.
- **TCAR SYMP: Stroke/Death:** Region is outperforming the VQI and well below the expected rate.
- **CEA ASYMP: Stroke/Death:** Region is outperforming the VQI and well below the expected rate.
- **CEA SYMP: Stroke/Death:** Region is performing below the expected rate and better than the VQI rate.
- **CEA ASYMP & SYMP: Postop LOS > 1 day:** Regions observed rate is higher than the expected rate and trending upwards for both cohorts. There are some sites with longer LOS than the group and encouraged to review their site-specific data. Region's LOS is higher than the VQI aggregate. Dr. Young Erben shared her review VQI data of the length of hospitalization for the symptomatic patient with CEA. She concluded that symptomatic patients skew the LOS to prolonged hospitalization. In her review, the symptomatic patients with debilitating strokes, modified Rankin Score (mRS) 4-5, drove the longer LOS. There was a significant delay from admission to procedure in the mRS 4-5 patients, and postop stays were significantly longer in these patients. In the multivariable regression analysis, there was some correlation between the prolonged time to admission to the procedure and patient race and also a correlation between prolonged hospitalization and patient race, smoking, hypertension and diabetes. Her review is undergoing further analysis at this time.
- **EVAR: Post op LOS > 2 days:** Region's observed rate is higher than the expected rate and performance is trending up. Sites were encouraged to review their data to determine any opportunities for improvement.
- **EVAR: Sac Diameter Reporting:** Region is below the VQI aggregate. There were no updates from the national level. This continues to be a challenge. Sites were reminded this is a VQI national initiative.
- **EVAR: SVS Sac Size Guideline:** Region is performing slightly below the VQI aggregate.
- **TEVAR: Sac Diameter Reporting:** Results are similar in the TEVAR cohort as the EVAR. Region is underperforming in comparison to the VQI.
- **OAAA: In-hospital Mortality:** Region is performing slightly better than the overall VQI.
- **OAAA: SVS Cell Saver Guideline:** Region is outperforming overall VQI.
- **OAA: SVS Iliac Inflow Guideline:** Region is minimally underperforming in comparison to VQI.
- **PVI: ABI/Toe Pressure:** This metric was discussed at the spring meeting. Issues with this metric are unchanged. Region is significantly underperforming in comparison to the VQI and is the worst region. Dr. Shafi reported they have created a hard stop in their EMR with ties to AUC. This was modeled after their PCI protocol.
- **INFRA & SUPRA: Major Complications:** Performance in both of these metrics is better than VQI.
- **LEAMP: Postop Complications:** Outperforming all regions in VQI.

- **AVACCESS: Primary AVF vs Graft:** Underperforming in comparison to the VQI. Question was raised if this metric will continue with the changed in some of the guidelines. Metric will probably be edited over time.
- **Regional Improvement Projects:** Charles Ross, MD
Kathie Shemwell, RN
Michelle Glanville, RN
- **LTFU:** The region held the data manager “kick off” meeting on August 12, 2020. Charter development, VQI webtools and the Long term follow completion rate report provided in the M2S application was reviewed. SEVSG goal shared with the attendees was to improve the current rate 66% (reported at the spring meeting) to the 50th percentile of 73% for the 2018 procedures LTFU. Some guidance on goals for site performance was also discussed with those sites at ≥ 90% to strive to maintain, those sites at ≤ 60% strive to set a goal of 73% and those sites participating at 73% - 88% strive to increase between 3% - 5% above the 2017 performance. It was noted the region’s performance has dropped from the 66% to 56% with this report. Lead physicians and data managers were encouraged to review their performance and participate and submit charters to Cheryl Jackson at the VQI. Kathie and Michelle offered any assistance to the data managers.

National VQI Update: Caroline Morgan, SVS PSO

Vascular Medicine Consult Registry

Collaboration with Society for Vascular Surgery, American Heart Association, and Society for Vascular Medicine

Inclusion Criteria:

This registry only includes New Outpatient Consults who are being treated medically for:

Lower Extremity peripheral arterial disease due to atherosclerosis

Atherosclerotic carotid artery occlusive disease

Abdominal aortic aneurysm

Exclusion Criteria:

Evaluation/diagnosis of pseudo or neurogenic claudication, peripheral arterial disease due to trauma, popliteal entrapment, medial adventitious cystic disease, chronic compartment syndrome

Carotid disease due to dissection, infection, aneurysm, tumor, isolated common carotid lesion not thought to involve the bifurcation, disease of the carotid bifurcation due solely to vasculitis, and Moyamoya disease, and fibromuscular dysplasia

Isolated aortic dissection without aneurysm

Thoracic, thoraco-abdominal, and mycotic aneurysms

Vascular Medicine Consult Registry

Data Collection:

Registry to focus on non-operative medical management of these conditions

Medication details and dosages, along with lifestyle modifications and counseling will be the emphasis of this registry

Opportunities

Identify patterns/variation of treatment and pre-intervention management

Identify QI initiatives

Opportunities in comparative effectiveness research

First site signed and entering data! Many more in the contracting phase!

Webpage link: <https://www.vqi.org/directory/new-vascular-medicine-consult-registry/>

Recorded webinars: <https://www.vqi.org/vascular-medicine-consult-registry-webinar-recordings-available/>

For more information please contact:

VQI@M2S.com

VQI OnLine Highlights:

- VQI OnLine hosted 12 sessions over 6 weeks
- Attendance ranged from 300 – 125 live users
- PSO thanks all the Speakers and Moderators
- Feedback has largely been positive.
- Need a better registration and invite process
- Will incorporate virtual sessions even as we return to a live event
- Replays can be found on the VQI Members Only website.
- <https://www.vqi.org/wp-content/uploads/VQI-ONLINE-latest-schedule-6.9.2020.pdf>

VQI OnLine:

After the successful completion of our first VQI ONLINE event series, we have posted the video content on the Members Only area

If you wish to view any of the video sessions, please log in to the VQI Members Only area on the website. (If you do not have credentials for Members Only, please contact Nancy Heatley to set up your access. This is only available for registered VQI members.)

VQI Members Only – <https://www.vqi.org/members-login/>

Full recordings of each event are available at no cost to VQI members through Members Only.

Contact Nancy Heatley Nheatley@svspsso.org if you need assistance!

ACC, SVS Join Forces on Single Vascular Registry

The American College of Cardiology and Society for Vascular Surgery are collaborating on a single vascular registry to harness the strengths of both organizations in improving care and outcomes of patients with vascular disease.

<https://www.vqi.org/acc-svs-join-forces-on-single-vascular-registry/>

COVID-19 Variables: See slides

PAD Patient Reported Outcomes (PROs)

My Peripheral Arterial Disease: a VQI Pilot of Patient Reported Outcomes for PAD

The Society for Vascular Surgery Vascular Quality Initiative is seeking practices to participate in My PAD, a pilot program for the collection of patient reported outcomes (PRO) on patients undergoing endovascular treatment for peripheral arterial disease (PAD).

The VQI recognizes that traditional outcomes such as patency and reintervention may not fully capture the quality of care or the experience of PAD patients. There is a long overdue need to learn and measure the patient's perspective.

Must be in the PVI registry and have greater than 80% follow up!

PAD Patient Reported Outcomes (PROs): Yazan Duwaryi, MD

Highlights

- Outpatient peripheral vascular interventions (PVI) for claudication or chronic limb threatening ischemia
- Collect VasculQoL-6 and EuroQoL 5D-5L (estimated completion time 10-15 minutes)
- Collection at three time points: pre-procedure, one month and one year postoperatively
- PRO data entry options include paper forms, computer, tablet and smart phone
- Educational materials for direct from patient data entry
- PRO feedback to participating physicians

Reporting Highlights and Questions:

Changes to Perioperative Dashboards

New On-line LTFU reports

Suggestions for "other reports"?

Perioperative

Dashboard Remodel

Overall Modifications

Change explanation language- confusing

Note also that percentages are computed only among cases with non-missing data for each outcome, so it is possible to have rates for some outcomes but "No cases" for others.

Better to say??: Only cases with complete data have been analyzed.

Reorder sequence

Combine CAS and CEA under "All carotid interventions"- give % of type

All Carotid; then all Aortic (TEVAR/EVAR/OAAA/Supra); then all LE (PVI/LEB/Amp); then all Vein (VV/IVC/AVF); then Medical

Eliminate null entry of registry data

Inefficient and visual fatigue- leave blank and provide no entry; should not require major reprogramming

Develop common metric for complications

Return to OR (RTOR) should be common to all with 'BTR': bleeding/thrombosis/revision and then use registry specific complications in separate row or with BTR

Provide One year and 3 year comparators

Since Dashboard is quarterly, a rapid look at 1Y and 3Y trend data will be very useful and can be provided via linkage

Include Category under each registry of excluded 'N's

Reorganize sequence: Carotid→Aortic→LE→Vein→Medical

Rolling quarter concept to allow for statistical merit on low volume procedures such as OAAA, etc. to achieve $N > \sim 15$. This would also be carried over to LTFU regional reports comparison

Add LTFU metric to category dashboard→Hyperlink option

Replace 25th /50th /75th percentile with whisker plot: 90-10thtile which shows median of VQI and arrow locating center level %tile

Carotid

Combine into all carotid interventions for total of procedures in center

Asymptomatic definition changed to 180 days

Breakout into % CAS vs CEA as well as %TCAR vs TFCAS

Under each category above: % Age \geq 80 and % CMS High Risk Criteria

MACE reported separated for Total CAS (TCAR + TFCAS) and CEA

List BTR separately from Cranial Nerve Injury

% Protamine reversal included in CEA report

Continue with 'Case data'; 'DC meds'; 'Discharge'; 'IV meds for BP' and Dysrhythmia treatment

Combined totals used when statistics do not support separating outcomes and in 'Home' disposition

Homeless and other hospital eliminated from Disposition

Carotid Stenting and Endarterectomy

New On-Line LTFU Reports

InSights EVAR LTFU Report

Select sites scheduled to test Mid October 2020

To be rolled out to all sites soon

Over time LTFU reports to be created for all registries (CEA/CAS next)

*A toggle will be provided at the top of the report to show or hide the (n/m) values

Ability to drill down to the patient PRIMPROCID

Ability to filter on Elective, Ruptured, Symptomatic

Report Suggestions/Ideas?

Regional Bylaw Changes: Charles Ross, MD

Quorum:

All voting for nominations and election of officers will be conducted electronically, even during in-person regional meetings. In order to conduct business, a quorum of the regional Executive Committee (EC) is considered a majority vote of all regional members of the EC that participate in the voting process. Centers are eligible to vote as of the date of the signed contract. No waiting period is required. The regional EC is entitled to one vote per center.

An email notification to the region will be forwarded one week prior to the opening of officer nominations. A region will be permitted a collection period of one week to nominate individuals for the respective office and subsequently the regional EC will be given three weeks to vote for their member of choice.

A regional EC member may designate a proxy for the purposes of voting provided that the VQI is notified in writing, by replying to the voting communication, prior to the end of the voting period. For voting that takes place without SVS PSO involvement, the Regional Medical Director will manage and conduct the voting process in accordance with the regional Bylaws' rules of voting, meeting a quorum. The Regional Medical Director will give prior notification to the regional EC, by means of an agenda, if a vote will be conducted during an upcoming EC meeting or regional meeting.

Medical Director Qualifications:

The Medical Director is a VQI participating physician selected for a three-year renewable term by a majority vote, as defined in the regional Bylaws, of the Executive Committee (EC). The Regional

Medical Director chairs the EC, prepares the agenda for meetings, prepares an annual budget and is responsible for the overall operations of the region between meetings of the EC. The Regional Medical Director will represent the region on the SVS PSO National Governing Council, unless the EC decides to elect someone else in the region.

Associate Medical Director:

The Regional Associate Medical Director (AMD) is a VQI participating physician that will be nominated by the regional Executive Committee (EC) with a final vote based on the regional bylaw policies. This position will report directly to the Regional Medical Director. The Regional AMD will support the Regional Medical Director in managing the region with the application of regional guidelines. Tasks include, but are not limited to, assisting with agenda preparation, budgeting, regional meeting planning and the overall operations of the region. This role is a three-year renewable term, with an automatic succession into the Regional Medical Director's role unless the SVS PSO receives written objection(s) from member(s) of the regional EC. A final vote of the regional EC is required to sanction the transition from Regional AMD to Regional Medical Director. Dr. Ross declared the nomination period open and to forward any nominations to either Dr. Ross or Kathie Shemwell. (Later, after meeting, it was learned that the election for the Associate Medical Directors for all regions will be conducted next Spring.)

CME/CE CREDIT FOR REGIONAL MEETINGS

FALL 2020

Participation Award Changes

We are aware that COVID-19 placed a significant strain on staff and resources

Formal announcement sent out April 9, 2020

Personnel may have been reassigned making the performance of usual operations difficult if not impossible

Many patients have had their follow-up office visits delayed. This may result in patients being seen outside of the prescribed time period (9-21 months) which is beyond anyone's control.

Workflow disruptions may have caused delays in data entry and follow-up

The Participation Committee will assess the 2020 Participation Award criteria to assure that temporary workflow disruptions will not have a negative impact on participation awards.

Updates will be provided via December QI webinar, newsletter, and email blast.

Quality Improvement Update

Fall 2020

Quality Improvement Webinars:

- ▶ 2020 Quarterly Webinars
 - ▶ March 2020
 - ▶ "Starting a QI project"
 - ▶ June 2020
 - ▶ Deferred for Online VQI
 - ▶ September 2020
 - ▶ Featuring Northern California Vascular Study Group and their processes for two regional projects
 - ▶ November/December 2020

- ▶ 2020 Participation Award Information, 2021 Changes and Wrapping up a QI Project

2020 Quality Improvement

Fourteen charters submitted

*LTFU – 5

D/C Medications – 4

Clinical – 2 (LOS – EVAR, LE)

**Documentation – 1 (AAA size compliance)

*2 regions finalizing details for LTFU QI project

** Multi-regional project - finalizing details for AAA size compliance QI project

Focused phone calls are well attended

Recap of 2019/2020 QI Projects

Putting VQI Data into Action

See what your colleagues are doing with QI

Twenty-eight poster abstracts were submitted and accepted for presentation at the 2020 VQI Annual meeting that was scheduled for Toronto

Five abstracts were featured in the Online QI session

Seven abstracts were featured in the Online RAC session

Great feedback received for all presentations!

Thanks to all who presented and attended the Online VQI sessions!

Quality Improvement Details: Charter Information

Charters

- ▶ Charter participants become part of focused group calls
 - ▶ Interactive discussion sharing barriers and successes
 - ▶ Sharing of charters
 - ▶ Networking
 - ▶ Checking in – where are you in the process
 - ▶ Celebrating success

One on one calls, if requested

Newsletters

- ▶ The VQI News
 - ▶ Distributed every other month
 - ▶ Provides updates on regulatory issues, technical updates, and crossover news from the SVS and SVN
- ▶ VQI Quality Improvement Newsletter
 - ▶ Distributed every other month
 - ▶ Focusing on QI processes, tools, and definitions

National QI project details

Submit Project Charters and supporting documentation for presentations and posters to

QI@SVSPSO.ORG or cjackson@svspsso.org.

Visit the VQI Members Only Website for sample charters, webinars, and presentations on VQI Quality Improvement Projects. www.vqi.org

AQC Update – Adam Beck, MD

Randy DeMartino, MD (Mayo Clinic Rochester) is the new Chair of the AQC

AQC Update:

Current projects:

Common variable help text updates

OAAA registry revisions

SVS guidelines collaboration

COVID variables

Patient reported outcome variables

VQC Update – Olamide Alabi, MD

Marc Passman, MD (UAB) new chair of the VQC taking over for Jose Almeida, MD

1-3 year goals

Dedicated podium time for VQI at AVF

Update Varicose Vein and IVC quarterly interoperative dashboards

Create Venous Stent dashboard

Work on LTFU dashboards for all 3 venous procedures

Continue work C2 disease and appropriateness of care

Continue work with United Healthcare

IVC retrieval rate is 30% nationally, need to make this a national quality initiative

Create COPI (Center Opportunity for Process Improvement) reports for venous registries

Arterial RAC Update – Emily Spangler, MD

Adam Beck, MD (Univ of Alabama), is the chair of Arterial RAC as of 9/25

Arterial RAC and Venous RAC alternate months for submissions:

<https://www.vqi.org/data-analysis/national-arterial-and-venous-rac-schedules/>

Proposal Process:

1. Review list of projects approved to avoid duplication

<https://www.vqi.org/data-analysis/rac-approved-project-search/>

2. Submit proposal on line:

<http://abstracts123.com/svs1/meetinglogin>

Venous RAC Update – Jaime Bennorach-Gamble, MD

Nicholas Osborne, MD (Univ of Michigan), is the Chair of the Venous RAC

Dr. Bennorach-Gamble discussed evolving work submitted to the Venous RAC

GC Update – Charles Ross, MD

Appointments of Vice-Chairs to the VQC and VRAC

Dr. Mark Iafrati has been nominated to serve as Vice Chair of the Venous Quality Council

Dr. Fedor Lurie has been nominated to serve as Vice Chair of the Venous RAC

Unblinding EVAR Imaging LTFU: Needs to be voted on by each region

Dr. Goodney presented VISION reporting on EVAR Survival, Reintervention, and Surveillance

The GC discussed the impact to moving to virtual regional meetings and ways to make calls more interactive.

Dr. Beck is the new Vice-Chair of the Executive Committee
The PSO will be appointing 2 new at-large members to the PSO Executive Committee

M2S Updates - Fall 2020 - Regional Group Meetings

VQI Technology Updates

Barcode scanning feature for PVI device capture

Released on 2/26/2020

This new feature can be used to enter device information for all treatment types where the Product Number or DI is required (i.e., excludes plain balloons).

Hemodialysis Access (HemoDA) minor revision

Released on 3/26/2020

Demographics tab:

GFR (eGFR): The GFR numeric field will not allow decimal values. If a decimal value is entered, the value will be automatically rounded to the nearest whole number.

PAD: "None" has been added to options.

HTN: Updated help text and criteria.

History tab:

Central Venous Dialysis Catheter Chest: "None" has been added to options.

Procedure tab:

Intraoperative Target Artery Diameter: Field updates to retire drop-down options and require numeric entry. One decimal value allowed, the value will be automatically rounded to the nearest tenth.

Min/max range values are dependent on the selected Inflow Artery.

Hemodialysis Access (HemoDA) minor revision (continued)

Procedure tab:

Intraoperative Target Vein Diameter: Field updates to retire drop-down options and require numeric entry. One decimal value allowed, the value will be automatically rounded to the nearest tenth.

Min/max range values are dependent on the selected Inflow Artery.

Post-Op tab:

Periop Antibiotics: 3 new antibiotic fields have been added ("1st 2nd Gen Cephalosporin", "Start <1hr Pre-op" and "Stop <24hr Post-op").

Across-registry revision Q2 2020

Released on 4/9/2020

Hypertension Harmonization

The Hypertension field (in the Demographics tab) was updated to align with current clinical guidelines.

Help text and select options are being updated in the CAS, CEA, EVAR, IVC, Infra, LEA, Open AAA, PVI, Supra, TEVAR, VMC, and VUR registries as follows:

New Help Text: "Hypertension = documented in History or recorded blood pressure \geq 130/80 (elevation of either systolic or diastolic) on 3 or more occasions. No = no hypertension Yes, controlled = HTN treated with medication, but BP < 130/80 deemed in control; Yes, uncontrolled = HTN not adequately controlled, typically \geq 130/80 (elevation of either systolic or diastolic) on two occasions."

New select options are: “No”, “Yes, controlled”, or “Yes, uncontrolled.” The former option “Yes (>=140/90 or history) was retired.

Across-registry revision Q2 2020 (continued)

Antibiotics Harmonization

Data fields to collect Peri-op antibiotics in the Post-Op tab for the CEA, EVAR, Infra, Open AAA, Supra and TEVAR registries were retired and replaced with new data fields as described below. Peri-op antibiotics were not previously captured in the LEA registry, but the new set of fields were also added to the Post-op section of the amputation registry. Please review new help text associated with these fields. The new subset of data fields are as follows:

“1st 2nd Gen Cephalosporin”

“Start <1hr Pre-op” (Displayed only if 1st 2nd Gen Cephalosporin is Yes.)

“Stop <24hr Post-op” (Displayed only if 1st 2nd Gen Cephalosporin is Yes.)

Across-registry revision Q2 2020 (continued)

Free text fields to capture details of “Other” Devices:

The VQI updated several registries to add free text fields, labeled as “Please Specify Other Device(s)”, to capture specific device details when “Other” is selected in device lists.

CEA: to capture “other” Patch Manufacturer in Procedure tab

CAS: to capture “other” EPD Type and “other” Flow Reversal Type in Procedure tab for lesions 1 and 2

EVAR: to capture “other” Anchors Used in Procedure and Re-Tx tab and on Follow-up Re-Tx 1, Re-Tx 2, and Re-Tx 3 tabs

IVC Filter: to capture “other” Device Manufacturer and “other” Filter Type in Procedure tab.

TEVAR: to capture “other” Anchor Type in Aortic Devices and Re-Tx tab and on Follow-up Re-Tx 1 and Re-Tx 2 tabs

TEVAR Revision Q2 2020

Released on 4/29/2020

Procedure Tab:

Sheath size and closure device information will now be captured for right, left or bilateral access. The new fields appear once an “Access” type other than “None” has been selected.

Largest Sheath Size (Fr) - The largest French sheath size used by side. There is a Min/Max range of 16-30. (A table with sheath sizes is included in the help text)

Number of Closure Devices - The number of closure devices used by side (0 to >5).

Closure Device Type – The brand name of the closure device(s) used at the access site. This field will appear if “Number of Closure Devices” is greater than zero.

Specify Other - If “Other” is selected as the “Closure Device Type” this field will appear. Please enter manufacturer and device details by free-text.

TEVAR Revision Q2 2020 (continued)

Post-Op Tab:

Several fields were updated or retired and replaced with new access side-specific data fields and options.

Complications section: These new fields will only display for right and/or left access once an access type other than “None” has been selected for the given side on the procedure tab.

Access Site Hematoma / Pseudoaneurysm – The most extensive treatment of hematoma or pseudoaneurysm by side.

Access Site Occlusion – The most extensive treatment for the occlusion by side.

Access Site Infection – The depth and involvement of infection by side.

The new fields above replaced the following, which were retired:

Puncture Site Hematoma

Access Site Occlusion

Surgical Site infection

TEVAR Revision Q2 2020 (continued)

Post-Op Tab:

Re-intervention section:

Indication (Re-Tx) – The “Access Related” option was retired and new options to indicate “Right access related” and “Left access related” were added.

PVI revision in Q2 2020

Released on 6/29/2020

Demographics Tab:

The “Ambulation” field will no longer appear if the “Bed bound” option is chosen for the “Functional Status” field. Previously the “Ambulation” field displayed and defaulted to “Bedridden”. This change was applied to both the Demographics tab in the procedure form, as well as in the Long Term Follow-up form. The existing select option of “Bedridden” for the “Ambulation” field no longer appears on the form with this new dependency.

Procedure Tab:

Closure Device fields: The following fields were added for both access sites, in both the Basic and Comprehensive PVI forms:

“Number of Closure Devices”, with the options: “1, 2, 3, and >3”.

“Closure Outcome”, with the options: “Closure device successful; Closure device failed; Closure device failed, intervention; and Closure device failed, surgery”.

The “Closure Device Successful” field was retired, and appears in the Data Download files preceded with “R-” (R- Closure Device Successful).

PVI revision in Q2 2020 (continued)

Post-Procedure Tab:

“Hematoma” field: The select options for the existing Hematoma fields (for access site 1 and 2 as applicable) were expanded for greater accuracy.

The following Hematoma options were maintained: “No, Minor, Transfusion and Thrombin injection”.

The prior “Surgical Rx” option was re-named “Surgical Re-Tx (intra-op or post-op)”

One new option was added: “Interventional Re-Tx (intra-op or post-op)”.

The “Right/Left Amputation Level” fields no longer appear if the “No” option is chosen for the “Amputation During Admission” field. The existing select option of “No” for the “Right and Left Amputation Level” fields no longer appear on the form with this new dependency.

Add PVI Procedure Context variables to Follow-up data download file

Released on 6/29/2020

In response to member feedback, the VQI added two new columns to the PVI Follow-up data download file to identify the specific arteries and sides treated as selected on the procedure form and displayed in the PATHWAYS follow-up form.

The new columns appear before the “Current Patency” fields in the PVI Long Term Follow-up Data Download file. Follow-Up Data Download file additional columns:

“Arteries Treated”

“Side”

The columns appear in groups by field: “Artery Treated 1, Artery Treated 2, Artery Treated 3, Artery Treated 4.., then Side 1, Side 2, Side 3, ..., then Current Patency 1, Current Patency 2”, etc.

VSR diameter unit change mm2 -> mm and related help text updates

Released on 7/15/2020

The units associated with the “Minimal Diameter Within Stenosis” and “Minimal Diameter at Reference Location” fields were changed from “mm2” to “mm”.

Hemodialysis Access (HemoDA) revision for tapered graft

Released on 7/29/2020

Three new fields were added to the HDA registry to capture “Tapered Devices”. A new “Tapered Device” field was added to the Procedure tab in the Conduit Details section. If “Yes” is selected for the “Tapered Graft” field, then two new diameter fields display: “Tapered Graft Minimum Diameter” and “Tapered Graft Maximum Diameter”.

Revised COVID-19 message for Follow-up Mandatory Fields

Released on 7/29/2020

The VQI added a temporary message about the impact of COVID-19 on LTFU completion rate calculations. The following message is displayed when submitting a LTFU that is missing any mandatory variable:

“IMPORTANT: The PSO understands that routine follow up visits may not be possible due to COVID-19 state mandates. Special considerations will be part of our LTFU calculation for 2020, please collect all of the required fields that are possible during this time.”

As a reminder, the VQI allows phone and telehealth appointments to be used for LTFU when Face-to-Face visits are not feasible.

“Was this helpful?” feature for Help Text

Released on 7/29/2020

This new feature is to provide feedback regarding the current help text. For each help text field, users will have the option to indicate if the help text provided was useful or not. This information will help the VQI to identify data fields that may be unclear to members.

The “Was this helpful?” vote up/down button displays in the bottom right corner of the help text box:

Across-registry revision to add COVID-19 variables

TEVAR Revision to align with SVS/STS guidelines

Vascular Ultrasound Registry (VUR) major revision

Varicose Vein Registry (VVR) revision for New CEAP Clinical Classification

Venous Stent Registry (VSR) revision for New CEAP Clinical Classification

Vascular Medicine Consult (VMC) registry revision to add new drug category and update CAD

VQI PRO collection for PVI

Registry Projects

- These projects are conducted within the SVS PSO and only non-identifiable data (removal of patient, center and physician information) will be provided to Medtronic/BARD/Cook/Gore or the FDA. Only standard of care practice is being evaluated. For such PSO activities, patient informed consent and Institutional Review Board review are not required.
- Sites must follow their institutional guidelines

0 of the 180 required patients enrolled (5 potential cases in process)

Retrospective enrollment allowed- All eligible cases from December 31, 2018 (protocol FDA approval date)

12 of 40 sites enrolled (11 more in contracting)

This project is conducted within the SVS PSO and only non-identifiable data (removal of patient, center and physician information) will be provided to Medtronic or the FDA. Only standard of care practice is being evaluated. For such PSO activities, patient informed consent and Institutional Review Board review are not required.

PVI Post-Market Surveillance Projects

Medtronic IN.PACT® Admiral® DCB ISR Project

The Bard® LifeStent® Popliteal Artery Stent Project

Enrollment Complete

74 of the 74 required patients enrolled

Retrospective enrollment allowed- All eligible cases from 10/1/2016 (protocol FDA approval date)

29 of 30 sites enrolled

This project is conducted within the SVS PSO and only non-identifiable data (removal of patient, center and physician information) will be provided to Bard or the FDA. Only standard of care practice is being evaluated. For such PSO activities, patient informed consent and Institutional Review Board review are not required.

Medtronic IN.PACT® Admiral® DCB ISR

The Medtronic IN.PACT® Admiral® DCB ISR Project Post-market registry surveillance of the clinical use of the Medtronic IN.PACT® Admiral® Paclitaxel-Coated PTA Balloon.

Objective: To assess the long-term safety and performance of the IN.PACT® Admiral® DCB in a U.S. population for the treatment of ISR lesions in the superficial femoral and popliteal arteries.

Patients will be followed at 12, 24 and 36 months

Total reimbursement of **\$1,950 per patient** for a patient followed annually for 3 years

1 additional field added:

Check box to indicate that patient is eligible to enroll project based on the inclusion and exclusion criteria.

Enrollment Complete

300 of the 300 required patients enrolled

Retrospective enrollment allowed- All eligible cases from December 6, 2016 (protocol FDA approval date)

50 of 50 sites enrolled

This project is conducted within the SVS PSO and only non-identifiable data (removal of patient, center and physician information) will be provided to Medtronic or the FDA. Only standard of care practice is being evaluated. For such PSO activities, patient informed consent and Institutional Review Board review are not required.

For More Information Contact:

Medtronic IN.PACT® Admiral® DCB ISR Project

Anita Duxbury

MedtronicAdmiralDCB@m2s.com

The Bard® LifeStent® Popliteal Artery Stent Project

Charlotte Stirewalt

BardLifeStent@m2s.com

PATHWAYS Support

PATHWAYS Communication

We understand that some members do not always receive mass emails from M2S, due to firewall and spam filter configurations at their centers. In an effort to ensure that all members are aware of important registry updates, we've taken the following steps:

Meeting Evaluation: Complete the attendance attestation and meeting evaluation for the CME/CE credits within 7 days of the meeting.

Next Meeting: Submits recommendations for the spring 2021 meeting to either Dr. Ross or Kathie Shemwell.