

Mid Atlantic Regional Vascular Study Group Region Name

Date September 10, 2020

Time 8:00 a.m. – 10:00 a.m. eastern time

Remote- Virtual Ring Central

Respectfully submitted – Vanessa Cambria-Mengel, MSN, RN, CCRN-K

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

Agenda (Copy and paste agenda)

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

Welcome and introductions: Dr. Faisal Aziz, MD

Regional Data Review: Dr. Faisal Aziz, MD

Dashboard Comments: Brief overview below – Slides will be shared on website

- Vascular surgeon participation – across the country 45% - our region 60%
- LTFU – July 2017 – June 2018 – multiple modules
- Goal of increase 1 year follow up – 2016 - 70% - 2018 74% - 2019 82%
- Reason to celebrate – our region is showing Leadership in LTFU
- Impressive AV access – usually poor follow up but we are doing well in this module
LTFU – high 3rd highest in the country – striving to be better – there may be geographic reasons –
- Centers of the region – more than 90% F/U but we also have some centers that are not as good – maybe something to look at –
- Discharge Medications
 - Antiplatelets & Statins – we are relatively low
 - Open forum – no comments
 - Just keep in mind if a prescription is given to the patient it is captured
 - Question – whether surgeons are waiting for PCP to prescribe statins – due to extensive additional studies to follow –
 - Looking to hear from Centers on how they are addressing
- CAS – asymptomatic /symptomatic has led to 4 separate reports
 - Transfemoral Asymptomatic –
 - Transfemoral Symptomatic
 - TCAR asymptomatic
 - TCAR symptomatic
 - Extended from 120 days – 180 days to align with CREST 2 data
 - This data includes ALL strokes – exclude vertebrobasilar
 - Transfemoral stenting – not applicable to our center due to reduced #'s in our region – possible due to more TCARs being done and embraced
 - Not all patients are a candidate
 - Additional slides represent further CAS – our region was too low for #'s to the nation
 - Asymptomatic for TCAR – country 3500 – our region 280
 - Overall for stroke was 1% - our region was over 2% -
 - **Could be a Quality Improvement Project for our Region**

- 2nd highest in the country for asymptomatic Carotid – 2 centers – 1 specific has a risk of 9% for stroke and death post TCAR
 - 1 center that is driving our region to the 2.5% - other centers are ranging to the 2.5% - closer to the 1% or less for the nation
 - Room for improvement for that one center
 - Center Level reports were distributed – please review and see what improvement changes can be implemented
- Symptomatic for carotid TCAR – Stroke and Death
 - Our is higher 3.% overall lower in average VQI
 - Once again – there are 3 centers – 1 being almost 10 % over national average
- Carotid Disease – asymptomatic and Endarterectomies
 - Our risk of stroke 1.4% as compared to .9%
 - Trends overall a bit high
 - Centers across the region – there are few centers that are driving the higher number
- Carotid Disease – symptomatic
 - Our region – our risk 3.5% as compared to 1.7%
 - Our #'s have increased over the past year
 - One center at 14% driving our #'s higher
 - Please look at your cases and see if anything can improve those #'s and patient outcomes
 - Overall numbers were not as large – so is it the impact of COVID that has lessened volume which therefore drives #'s up if only 1 or 2 strokes or deaths occur – something to review
- CEA – Asymptomatic – LOS >1 day
 - Overall doing better
 - Invited one of the Centers to present – Beebe Medical Center – Michele Seiler
 - Brief overview of their process
 - Success factors- tight order sets for BP parameters – NP greet patients in PACU and follow to unit
 - Late day OR starts does this impact LOS – Beebe does not see many late day cases due to Block time in OR in A.M.
 - Foley usage? are they being used – Michelle will review and f/u with Carrie
 - Share order sets – also our Mid Atlantic Vascular Regional Study Group website – is a platform to share best practices
 - <https://www.vqi.org/regional-groups/current-regional-quality-groups/mid-atlantic-vascular-study-group/>
- LOS after EVAR – more than 2 days – poor
 - 14% across the country – we have improved our regional #'s – better than previous years
 - Slide set will be shared for visuals of graphs and statistics
- EVAR Sac diameter recording –
 - LTFU – may include phone call but sac diameter is necessary for inclusion

- U/S or CT Scan -
 - 62% - 9-21 months – as compared to other centers across the country
 - Overall Canadian system is better in regards to F/U – 70% being the best
 - Dictation should include sac diameter not just subjective terms –
- TEVAR sac diameter reporting
 - 54% as compared to 56%
- OAAA mortality
 - # of opened is less –
 - 5.6% our region as compared to Nation of 4.2%
 - Details essentially driven by one center in our region that has a mortality rate of 15%
 - We are the worst in comparison to other regions
 - Again, something to review and analyze
 - Cell saver guidelines –
 - Guidelines SVS – iliac in flow – our #'s are good
 - Procedure that had AVI's and PVI's overall better
 - How will the numbers change when we have more cardiologist join the VQI
- Open bypass for infra inguinal
 - 3.7% compared to 4.1 %
- Supra inguinal – not enough #'s
- Lower extremity amputation – UPENN participates – simply because they chose to belong to all at the time
 - Does it help in lower extremity amputation data – does allow for application of grants etc..
- Dialysis access
 - AV fistula v Grafts
 - 78% for our region
- Filter retrieval reporting – another change in reporting IVC filter
 - Our region does not have enough
 - This report is reporting retrievals in those that had F/u – rather than just retrievals
 - window for f/u 9-21 months

Regional Improvement Projects: Dr. Grace Wang, MD

- **Stroke rate – for CAS**
- **Filter – not enough are participating from the region**
- **Stroke rate after symptomatic CEA**
- **Comparative work between regions – do the bylaws allow for this to occur**

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@svspso.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)

Highlights

- Outpatient peripheral vascular interventions (PVI) for claudication or chronic limb threatening ischemia
- Collect VascuQoL-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 whiskerplot: 90-10%tile 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 ≥ 80 and % CMS High Risk Criteria
MACE reported separated for Total CAS (TCAR + TFCAS) and CEA
Contralat/Ipsi CVA reported for each procedure type
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

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.

Regional Bylaw Changes

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.

Regional Bylaw Changes

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.

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 – Dr. Grace Wang, 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 – Dr. Grace Wang, 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

RAC Update – Dr. Grace Wang, MD

Nicholas Osborne, MD (Univ of Michigan) FIRST chair of the new Venous RAC

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>

GC Update – Dr. Grace Wang, MD

Appointments of Vice-Chairs to the VQC and VRAC

Dr. Mark Iafrazi 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 (\geq 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:

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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

Next Meeting TBD – whether virtual or in person – doodle poll to be sent out to members