



## **Southern Vascular Outcomes Network**

Friday, November 6, 2020

12:00-2:00

Remote

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

### **Agenda**

Regional Data Review

Dennis Gable, MD, Regional Medical Director, SoVONet

Learning Objectives:

- Use the VQI regional reports to establish quality improvement goals for the vascular patients (outcomes) and for their center (process).
- Interpret and compare each centers' VQI results to regional and national benchmarked data.
- Learn, through group discussion the VQI regional results to improve the quality of vascular health care by monitoring measurable performance indicators, SVS PSO evidence-based research, and outcomes.
- Identify high performing regional vascular centers to discuss variations in care and clinical practice patterns to improve outcomes and prompt quality improvement recommendations for vascular care patients. Sharing of best practices/pathways of care.

Regional QI Proposal

Dennis Gable, MD, Regional Medical Director, SoVONet

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National VQI Update

Cheryl Jackson, DNP, MS, RN, CNOR, CPHQ, Quality Director, PSO

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AQC Update – Mark Davies, MD

VQC Update – Sheila Coogan, MD

RAC Update – William Shutze, MD

Governing Council Update – Dennis Gable, MD

Open Discussion/Next Meeting/Meeting Evaluation

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

**Welcome and introductions:** Dennis Gable, MD

**Regional Data Review:** Dennis Gable, MD

**Dashboard Comments:**

**Volume**

SoVONet is in the middle for volume but we have centers that have just started and have not yet had a chance to enter many cases

**LTFU**

SoVONet chose several years ago to unblind long term follow-up results

There is still time to increase LTFU – Deadline is December 31<sup>st</sup>.

It is important to get at least 80% compliance to have viable data for research and quality improvement projects

18 centers are over 80% compliance

If a center goes for a period of time without adequate follow-up there is a chance that center can be put on probation and will not be able to request any data for research

SoVONet as a region is at 60% and Dennis Gable, MD has challenge each center to get at least 70% compliant with their follow-up to increase the region

**Discharge Medication**

It has been proven to improve patient outcomes

SoVONet is over 80% which is right in line with the nation

Reach out to another site if you need help increasing discharge medication compliance

**Carotid Artery Stent /CEA**

Transfemoral and Trans carotid have been separated out in reports

Lengthy discussion on reducing stroke rate and LOS stay

**EVAR LOS**

A few sites that could reduce their LOS by 15% and it would be a huge cost savings to the center  
EVAR Sac Diameter reporting

Region sits at 46% and a specialty that should be higher

All patients should be getting imaging during follow-up

It may be a process improvement where the data manager needs to get more involved. It could be that the diameter is not being dictated or measured and this just needs to be communicated to radiology or their physician champion.

### **EVAR SVS Sac Guidelines**

It is hard to know if data is skewed because reasons why repairs on small aneurysms are not being documented

A hashtag project is starting up and more information will be revealed

### **Infra-inguinal major complications**

8% complication rate

For the centers that have high rates may need to look at cases to find the reasoning

Could be how the leg is being prepped

### **IVC Filter**

This registry allows you to set up reminders to remove filters

SoVONet is the lowest region for submission of projects

Even private practices can submit projects

Centers can work together on a project

Dennis Gable is requesting each center turn in a project **idea** by the end of the year

### **National VQI Update:** Cheryl Jackson, 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](mailto: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](mailto: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**

This will hopefully help us see the impact COVID-19 had on postponing surgeries or how it will even impact the outcomes of patients with COVID

### **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 VasuQoL-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 25<sup>th</sup> /50<sup>th</sup> /75<sup>th</sup> 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  $\geq$  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:**

Quorum bylaws have changed to be the same across all region. 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. There is no waiting period for an EC to vote. There is a list of the EC for each hospital in the PowerPoint. Only 1 vote per center. If there are co-leaders the center will need to decide who the voter is.

#### **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. Nominations will be taken for the new SoVONet Medical Director. Current Medical Director Dennis Gable, MD will be transitioning out of his position and he mentioned that the new Medical Director will need to bring on their own Regional Data Manager. In the transition Rosha Nodine will no longer be the SoVONet Regional Data Manager.

### **CME/CE CREDIT FOR REGIONAL MEETINGS**

Online form must be completed with in 7 days

Cannot be from reading the notes, you must be present

The link to the form was given in the meeting

### **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](mailto:QI@SVSPSO.ORG) or [cjackson@svspsso.org](mailto:cjackson@svspsso.org).  
Visit the VQI Members Only Website for sample charters, webinars, and presentations on VQI Quality Improvement Projects. [www.vqi.org](http://www.vqi.org)

**AQC Update – Dennis Gable MD**

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

**AQC Update:**

Current projects:

Common variable help text updates are ongoing  
OAAA registry revisions are in process  
SVS guidelines collaboration  
COVID variables have been added are live  
Patient reported outcome variables are in process

**VQC Update – Shelia Coogan, 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 – William Shutze, MD**

Nicholas Osborne, MD (Univ of Michigan) FIRST chair of the new Venous RAC  
Arterial and Venous are completely different research committees and submissions must be turned in accordingly

Process is the same for both committees

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 – Dennis Gable, 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

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##### **The Bard® LifeStent® Popliteal Artery Stent Project**

Charlotte Stirewalt

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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**