PATHWAYS Updates

Fall Regional Group Meeting
Technology Update
Technology Released in Q1 2018

- Audit/Site Query tool
  - Released on 2/28/2018
  - Allows functionality for the SVS PSO to create audit projects which users complete in this new tool within PATHWAYS
• Patient/procedure search by primprocID
  — Released on **5/31/2018**
• CAS Revision I
  — Released on 3/26/2018
  — Added 2 new "Pre-dilate Before Stent" variables

Lesions Treated
Distinct Lesions Treated 2

Lesion 1

  Lesion Type: Restenosis graft
  Lesion Length: 20 mm
  Lesion Side: Right
  Lesion Stenosis: 70%
  Protection Device Used: Yes, successful
  Pre-dilate Before Protection Device: No
  Pre-dilate Lesion: Yes
  Number Stents: 1

• Flag bounced email addresses
  — Released on 5/16/2018
• Mandatory Fields for LTFU Forms
  – Scheduled to be released in **Sep. 2018**
  – For each registry, a core set of variables on follow-up forms will be made mandatory
  – Mandatory fields will be color-coded so that they can be easily identified on the form
  – A webinar for this functionality is scheduled for September 11, a recording of this webinar will be available within the PATHWAYS Resources tab.

• Enhancing functionality of CEA, IVC Filter, OPEN, LE AMP, INFRA, and SUPRA
  – Scheduled to be released in **Sep. 2018**
  – Remove “Heart Rate” fields
  – New functionalities available
    • Tab completion indicator
    • Text-based data download
    • Save follow-up forms as incomplete
• 30-day Follow-up Form
  — Scheduled to be released in **Q4 2018**
  — Available for 9 registries, CEA, EVAR, INFRA, TEVAR, LE AMP, PVI, CAS, OPEN, SUPRA
  — Will include new “Procedures/treatments Missing 30-day Follow-up” report

• Update to follow-up reports:
  — Scheduled to be released in **Q4 2018**
  — Update logic and calculations for “Procedure Requiring Follow-up” report, “LTF Completion Rate by Procedure” report, and “LTF PSO Benchmark” bar graph report

• PVI Revision
  — Scheduled to be released in **Q4 2018**
  — Changes of Treatment Type and Balloon Type
  — PVI Basic Form and PVI Comprehensive Form
Other Development Projects

Other Development Projects to be prioritized

- Hemodialysis Access Registry revision
- Adding MBI as a patient identifier for patient creation
- Add GUDID for balloons and atherectomy (for PVI comprehensive form)
- New Venous Stent registry
- Implement Concomitant Procedure Feature
- Add Shockwave Lithotripsy Balloon for Iliac Access in EVAR and TEVAR Registries
- Update PVI Closure Device Type Right/Left
- Implement feature to gather feedback on help text in PATHWAYS
- Data Audit Tool Bulk Update with audited values
- New Vascular Medicine registry
- Help Text Revisions (all registries)
Registry Projects
FDA 21st Century Cures Act
‘A Path Forward for Medical Innovation’

- Moving Past Adequate and Well Controlled
- Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real world data (e.g., not traditional clinical trials).
- “Real World Evidence”= Use of Registry Data
- SVS PSO, industry partners and FDA design protocols
The SVS Vascular Quality Initiative® (VQI) Registry database is designed to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.

The SVS PSO is approved by the Agency for Healthcare Research and Quality (AHRQ) to oversee the data sharing partnerships and patient safety initiatives of the Vascular Quality Initiative (VQI).

Physician oversight of these projects is provided by the SVS PSO Steering Committee.
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 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
# VQI Registry Projects

<table>
<thead>
<tr>
<th>Title</th>
<th>Registry</th>
<th>Enrolling</th>
<th>Targets</th>
<th>Follow-Up</th>
<th>Typical $ Per Patient</th>
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<tbody>
<tr>
<td>TCAR Surveillance Project</td>
<td>CAS</td>
<td>Yes</td>
<td>-</td>
<td>1 yr</td>
<td>NCD</td>
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<tr>
<td>Bard® LifeStent® Popliteal Artery Stent Project</td>
<td>PVI</td>
<td>Yes</td>
<td>74 pts 30 sites</td>
<td>1, 2 yr</td>
<td>$1400</td>
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<tr>
<td>Medtronic IN.PACT® Admiral® DCB ISR Project</td>
<td>PVI</td>
<td>Yes</td>
<td>300 pts 50 sites</td>
<td>1, 2, 3 yr</td>
<td>$1950</td>
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<tr>
<td>CREST 2 Registry</td>
<td>CAS</td>
<td>Yes</td>
<td>-</td>
<td>1 yr</td>
<td>-</td>
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<tr>
<td>TEVAR Dissection Surveillance Project</td>
<td>TEVAR</td>
<td>No*</td>
<td>600 pts 50 sites</td>
<td>30 day</td>
<td>$4000</td>
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<tr>
<td>Lombard Aorfix Surveillance Project</td>
<td>EVAR</td>
<td>No</td>
<td>234 pts 50 sites</td>
<td>30 day</td>
<td>$4000</td>
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</tbody>
</table>

*Expect enrollment to re-open in late 2018

For more information, contact PATHWAYSsupport@m2s.com
PVI Post-market Surveillance Projects

Medtronic IN.PACT® Admiral® DCB ISR Project

The Bard® LifeStent® Popliteal Artery Stent Project

Objective: To conduct long term post-market surveillance of the safety and effectiveness of the Bard® LifeStent® Vascular Stent Systems for the treatment of symptomatic de novo or restenotic lesions in the popliteal artery.

Patients will have 12 month and a 24 month follow up visits.

Total reimbursement of $1,400 per patient for a patient followed annually for 2 years

2 additional fields added:

- Check box to indicate that patient is eligible to enroll project based on the inclusion and exclusion criteria.
- Post-procedure – site will be asked if the patient has had a stroke.
- Angios performed at re-intervention and sent to M2S.
Enrollment

- 26 of the 74 required patients enrolled
  - Retrospective enrollment allowed- All eligible cases from 10/1/2016 (protocol FDA approval date)
- 23 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.
The Medtronic IN.PACT® Admiral® DCB ISR Project is a 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

• 123 of the 300 required patients enrolled
  – Retrospective enrollment allowed- All eligible cases from December 6, 2016 (protocol FDA approval date)
• 46 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
Elizabeth Schwendler or Anita Duxbury
MedtronicAdmiralDCB@m2s.com

The Bard® LifeStent® Popliteal Artery Stent Project
Kathryn Coughlin or Charlotte Stirewalt
BardLifeStent@m2s.com
VQI QCDR
2018 VQI QCDR

- MIPS Quality Component is 50% of the total MIPS score
- VQI QCDR offers 25 measures
- An invitation to enroll for 2018 was sent from PATHWAYS Support in Q1. Enrollment is ongoing.
  - Reminder:
    - Physicians must enroll with M2S annually
- More information:
  - PATHWAYSSupport@m2s.com
  - www.M2S.com
PATHWAYS Support
Ticketing System
• PATHWAYS Support Ticketing System will be rolled out soon pending final testing
  – Currently in BETA testing
• Benefits to VQI members
  – Automated Feedback
  – Prioritization
  – Efficient Routing