FTI Clinical Passport™

2015 PRODUCT TRENDS IN CARDIOVASCULAR & ENDOVASCULAR CARE

Over the next several months, the FTI Consulting Cardiovascular Clinical Passport™ Team will bring you a series of articles on Cardiovascular and Endovascular Care. This first article looks at what is trending in 2015 in the Cardiology, CVOR and Endovascular spaces. Our goal is to help CFOs, supply chain executives and clinical leaders better prepare financially for the introductions of new technology in the days ahead.

Trends in Cardiac Diagnostics

1. **Wearable, Portable Heart Monitoring Devices.** In October 2014, Medtronic launched an external, wire-free heart monitor that can be used for up to 30 days by patients who have been experiencing irregular heartbeats. The SEEQ MCT System's suggested clinical applications are for patients who experience irregular heartbeats with associated syncope (fainting), lightheadedness, vertigo, palpitations or shortness of breath, and whose symptoms had not been previously detected through use of 24-hour Holter monitoring. Healthcare supply chain executives and cardiac services directors should be prepared to address the introduction of these products as part of their value analysis processes.
2. **Left Atrial Appendage Occluder (LAA) Devices.** In March 2015, Boston Scientific's Watchman™ Left Atrial Appendage Occluder (LAA) – currently commercially available in 55 countries for the treatment of patients with non-valvular atrial fibrillation – was cleared by the FDA for distribution in the United States. The Watchman™ device has been successfully implanted in over 7000 patients worldwide experiencing recurring non-heart valve related atrial fibrillation. Patients with non-valvular atrial fibrillation are at higher risk for blood clots breaking loose and settling in the brain, heart or lungs causing strokes, coronary myocardial infarctions or pulmonary emboli. Boston Scientific's The WATCHMAN™ is a three-part system consisting of a transceptal access sheath, a delivery catheter, and a self-expanding nitrol framed device with fixation barbs and permeable polyester fabric covering the atrial facing surface of the device. The WATCHMAN™ could provide US physicians alternative treatment regimes to current long-term anticoagulation therapy and provide new revenue and atrial fibrillation treatment offerings for hospitals.
3. **Insertable Cardiac Monitors (ICMs).** Externally worn Holter monitoring devices, historically the physician-preferred method by physicians for detecting occasional difficult-to-identify cardiac arrhythmia events, seem to be falling by the wayside in favor of new insertable cardiac monitoring devices or ICMs. Medtronic's product line of REVEAL DX™, REVEAL XT™ and REVEAL LINQ™ are the latest products hitting hospital shelves and wreaking havoc to cardiovascular service line directors' budgets. Not much larger than a thumb-drive, ICMs can be inserted quickly and safely just under the skin in the cath lab to deliver clinical ECG readings for extended periods of time – up to three years.

Trends in Structural Heart

1. **Transcatheter Mitral Valve Replacement (TMVR).** With transcatheter aortic valve replacement (TAVR) rapidly establishing itself as the preferred option for treatment of aortic stenosis, the next frontier in interventional structural heart program development likely will be transcatheter mitral valve repair (TMVR). Currently two companies – Edwards Lifesciences, LLC. and Neovasc, Inc. reported human implantations of TMVRs in 2014. With a price-tag of up to $32,500 each for Edwards' SAPIEN XT Transcatheter Heart Valve, supply chain and CVOR service line leaders need to strategically plan how to approach TMVR when the time comes.
2. **Transcatheter Pulmonary Valve Replacement (TPV).** In early 2015, the U.S. Food and Drug Administration (FDA) granted Medtronic a premarket approval

application (PMA) for the Melody® Transcatheter Pulmonary Valve (TPV) and its Ensemble™ Transcatheter Valve Delivery System. Under the PMA, Medtronic was granted wider use of the valve in patients born with congenital heart defects that often require multiple open-heart surgeries as the children grow and mature to continuously correct heart problems created by their original defects. Children's hospitals and other acute care hospitals caring for patients with congenital heart abnormalities will be target sales markets for these new devices.

Trends in Interventional Cardiology & Endovascular Care

1. **Bioreabsorbable Stents**. Two bioresorbable stents have now been cleared for clinical use in Europe. Abbott Vascular is the first vendor to be involved in the U.S. Food and Drug Administration's (FDA) clinical trials for its ABSORB BVS product within the US. While many interventional practitioners are still cautious about making wide-sweeping endorsements, clinical service line directors and supply chain executives should be on the watch to see what happens to patients undergoing the ABSORB BVS clinical trials as indications of when these products may be commercialized within the US market and project accordingly.

2. **Vascular Closure Devices (VCDs).** As transcatheter aortic valve repair (TAVR), Transcatheter Mitral Valve Replacement (TMVR) and percutaneous endovascular aneurysm repair become more commonplace in cardiovascular treatment, healthcare systems and supply chain executives will likely see movement within the vascular closure device (VCD) space. The need for large-caliber femoral arteriotomy suture-mediated closure devices is already becoming more prevalent due to TAVR and will likely continue once TMVR joins TAVR procedures as standards of care. One of the challenges service line directors and supply chain executives could face as a result is balancing the product-mix of VCDs. Most of FTI Consulting's field research indicates hospitals rarely standardize VCDs to a single-sourced vendor. Because the cath lab may use radial closure devices, the IR lab collagen plugs and the CVOR suture-mediated devices or a myriad of combinations. These multi-vendor, multi-product mixes generally serve hospital budgets well since some products are lower in cost than others, so mixing up product usage and selection is not only advantageous financially it generally fits clinically, as well. Each suture-mediated device today can cost from $100.00- $300.00. If the dominant type of VCD sways more toward suture-mediated VCDs, the price uptick or change in product mix usage patterns might be the tipping point to dramatically inflating already tight clinical service line budgets.

3. **Drug-eluting Balloons**. In January 2015 the U.S. Food and Drug Administration cleared Medtronic's IN.PACT Admiral™ drug-coated balloon (DCB) for the interventional treatment of peripheral artery disease (PAD). The IN.PACT Admiral™ was the second drug-eluting balloon (DEB) to be cleared by the FDA within six months. The first DEB, cleared in November 2014, was C. R. Bard's Lutonix® 035 announced in February, 2015 to be distributed by Boston Scientific in the U.S.

About the Author

Pamela Froneberger is a Director in the Healthcare Solutions group of FTI Consulting and is based in Charlotte, NC. Ms. Froneberger has more than 30 years of healthcare clinical and management experience supply chain performance improvement, cardiovascular medical devices, group purchasing strategic sourcing and cardiovascular service-line leadership.

Pamela Froneberger
+1 704 254 4248
Pam.froneberger@fticonsulting.com

Deborah Roy
+1 910 200 4986
Deborah.roy@fticonsulting.com