Vizient Tech Vatch Medical Device | Volume 1, 2021

The future of virtual care delivery

Spine program evolution in the wake of COVID-19

2020 Innovative Technology recipients



Technology advancements offer a bright spot in the new year

s a result of COVID-19 and the obstacles experienced during 2020, most Americans eagerly looked forward to the new year. Although optimism abounds about the potential for change in 2021, only time will tell what this year will bring — and whether the health care industry will emerge more resilient and better prepared to handle ongoing and unforeseen challenges.

Considering the enormous changes the health care arena has experienced, it is more important than ever to provide our members with timely updates about key medical device categories. The complexities and innovations in this space require consistent focus and attention, especially those occurring in cardiovascular and orthopedic care.

Last year, demand for virtual care and telemedicine surged, even as patients returned to traditional care settings. In response, providers and suppliers have accelerated their programs and continue to seek ways to layer technology into the care continuum. Our telehealth article provides expert insights into the market forces at play and makes predictions about how virtual care will continue to evolve.

In the cardiovascular space, we explore new pulmonary embolism technologies, and provide an update on the evolving transcatheter aortic valve replacement market. We've also included statistics and trends to consider when creating a comprehensive spine program and best practices for integrating neuromodulation into your facility's service lines.

In addition, we are proud to showcase the great success achieved by Health Future and St. Charles Hospital. Together with the Vizient[®] consulting team, these organizations tackled a category that was failing to generate revenue and reduced the total cost of care through a recent implant engagement. Finally, we announce the Vizient Innovative Technology Recipients in the clinical preference space for 2020. This designation is achieved through a thorough clinically vetted process, and distinguishes a product or service as a new or improved technology with known or expected incremental clinical or business benefits compared to other products available for sale in the U.S.

In addition to *Tech Watch*, our integrated clinical preference solution team will continue to host frequently scheduled webinars that dig deeper into hot topics for both health care executives and supply chain leaders. We hope this publication and our webinars deliver timely and relevant information to keep your organization at the forefront of our rapidly evolving industry.

Watch our recent webinars covering performance improvement strategies for physician preference items, as well as cardiac and orthopedic service lines:

- Remote Monitoring for Cardiovascular Patients
- Planning for Impact From Shifts in Orthopedic and Spine Care
- Aligning Physicians, Suppliers and Executive Leaders to Sustainably Reduce the Total Cost of Care
- Optimizing Physician Engagement and Supplier Partnerships to Sustainably Reduce the Total Cost of Care



Contents

4 Telehealth's effect on virtually everyone

Cardiology

- 9 Novel strategies for managing patients with pulmonary embolism
- 12 Considerations for transcatheter aortic valve replacement device selection

Orthopedics

- 16 Evolution of a spine program: common trends with a few uncommon threads
- 21 Chief financial officer leads team approach to implementing a new joint initiative
- 23 Developing a neuromodulation program in a changing market

Innovation

27 Vizient 2020 Innovative Technology recipients



Telehealth's effect on virtually everyone

rom shifting sites of care, to patient expectations, to continuity of care, top organizations are examining their delivery models and evaluating how changes could impact revenue, patient acquisition and clinicians. In addition, they're reconfiguring care delivery as they continue to manage the challenges associated with COVID-19. As organizations move forward, their strategies and adoption of various telehealth capabilities will affect and solidify — how society approaches and receives care. Smart technology adoption will be critical to their longterm success.

What is telehealth?

Telehealth uses information and communication technology in the delivery of care and can be implemented in a synchronous (real-time/live) or asynchronous (patient portal) environment. Virtual visits and remote monitoring are considered components of telehealth, which offers the following benefits:

- · Provides both synchronous and asynchronous options
- Ensures health care is accessible to people who live in rural or isolated locations
- Reduces exposure to infectious diseases
- Ensures services are more convenient for people with limited mobility, time or transportation options
- · Improves access to medical specialists
- Improves communication between health care team and patient

Remote monitoring is a component of telehealth that uses implantable and wearable devices to collect patient health data, which is then electronically transmitted to health care providers (Figure 1). Advantages of remote patient monitoring include:

- Patient data is gathered outside of hospital and clinical settings
- Physiologic and subjective feedback is provided
- Implantable and wearable devices increase accuracy and availability of care
- · Patient protocols enable early intervention
- Chronic diseases can be treated using medication management
- Web-based apps wirelessly transmit data

Remote monitoring offers value to both patients and clinicians as the technologies available evolve and integration plans are successfully deployed. Several white papers have confirmed a reduction in hospitalizations and improved outcomes in addition to lower costs associated with a remote monitoring system. Recently, Vizient explored how remote monitoring can be integrated into an organization's strategy in its Developing and Deploying Effective Remote Patient Monitoring Programs webinar. In addition, Vizient has been working closely with strategic suppliers such as Medtronic to offer remote patient monitoring solutions in the wake of COVID-19.

According to Rob Kowal, MD, PhD, Medtronic's chief medical officer for cardiac rhythm business, "Throughout the pandemic, we have seen continued adoption of remote monitoring for patients with Medtronic devices, including our newest smartphone-connected portfolios of pacemakers, implanted defibrillators, cardiac resynchronization therapy devices and insertable loop recorders. Remote monitoring has reduced both patient and staff exposure, without jeopardizing or delaying care. Additionally, remote monitoring delivers timely and actionable data that is improving outcomes and reducing inefficiencies."

Figure 1. Remote patient monitoring pathway



The impact of patient and payer forces on virtual care

Many organizations reported astronomical increases in virtual care appointments during the last year, fueled by reduced regulatory burdens and relaxed payment policies as a result of COVID-19. For example, prior to the pandemic, Stanford Medicine had been slowly building its capacity to provide additional virtual appointment options, particularly for cardiovascular health, but the outbreak led to a spike in telehealth visits that was 50 times greater than prior months.¹

Additional forces have increased the appeal of virtual care, including better technology, high patient acceptance, improved outcomes, reduced hospitalizations, operational efficiencies, a decreased need for exam rooms and liberalized reimbursements.

Five changes made by the Centers for Medicare & Medicaid Services that have increased telehealth adoption²

- Medicare pays physicians the same rate for telehealth services and in-person visits for all diagnoses
- Patients can receive telehealth services in their home or any other setting
- Patients do not need to have an existing relationship with the physician providing telehealth assistance
- Physicians are allowed to waive or reduce costsharing for telehealth visits
- Physicians licensed in one state are allowed to see patients in a different state

In October 2020, an additional 11 telehealth services were added to Medicare coverage including certain neurostimulation and cardiac rehabilitation services — bringing the cumulative total to 144 services that can be performed via telehealth.³

Increased volume ... and revenue

In 2020, nearly a quarter of all health care visits in the U.S. were virtual, compared to less than 10% in 2019.⁴ With reimbursement levels the same for both in-person and virtual visits, as well as the additional factors listed above, telemedicine may be here to stay. Many organizations are reporting that while their percentage of virtual visits has declined since the peak of the pandemic last spring, actual volume has not substantially diminished (Figure 2). As in-person visit volumes return that ratio may shift, but virtual visits remain consistent.

Pre-pandemic telehealth revenue for major industry players totaled around \$3 billion annually, and experts expect growth rates of anywhere from \$185 billion to \$250 billion in health care spending over the next few years.⁵ In fact, nearly 20% of all office, outpatient and home health spending could permanently shift to the virtual arena.⁶ The growth rate may be slower for smaller organizations and those under greater financial strain, as adoption requires both an economic and operational investment. Finding a strategic partner to help deploy a virtual care plan may enable these organizations to find opportunities to add telehealth to their offered services.

Figure 2. Percentage of virtual visits, February to October 2020^a

The percentage of all visits via telemedicine visits is slowly declining from its April peak. But it continues to be well above the prepandemic baseline of very few telemedicine visits.



Data are presented as a percentage: the number of telemedicine visits in a given week is the numerator, while the number of visits in the baseline week (March 1-7) is the denominator. Telemedicine includes both telephone and video visits.

^a Data derived from Phreesia. Source: Mehrotra et al.⁷

Areas of opportunity

Virtual health remains an opportunity for many providers. As of October 2020, one-third of organizations had yet to adopt telemedicine and only 9% reported increased use compared to 2019 (Figure 3).⁷ Many hospitals are beginning to seek outlets to integrate telehealth, including looking at different patient populations and determining whether their medical conditions can be treated remotely, rather than in a traditional clinical setting.

Figure 3. Telemedicine use, April to September 2020^a

Telemedicine use across provider organizations varies. Approximately one-third of organizations never adopted telemedicine at all. From April to September, many organizations shifted from heavy or moderate use of telemedicine to minimal use.



^a Data derived from Phreesia. Source: Mehrotra et al.⁷

Behavioral health

The behavioral health arena is particularly well-suited to virtual care, as the need for mental health support continues to grow. Telemedicine visits in this category have remained over 40%, even as more health care facilities opened their doors in the summer and fall (Figure 4).⁷ Prior to COVID-19, 48% of behavioral health visits were conducted using secure video or phone. Just one year later, those numbers shifted drastically, with 85% of visits conducted using those methods.⁸ The pandemic has contributed to this growth, with higher rates of depression due to social isolation, job loss and financial insecurity, resulting in a greater need for behavioral health intervention. Telehealth has played an invaluable role in delivering that required care.

Figure 4. Behavioral health telemedicine visits, October 2020^a

The most recent data — the week of October 4 — show striking variation among medical specialties in the percentage of visits that are conducted via telemedicine. Telemedicine use in many surgical specialties is very low, but in other specialites, especially behavioral health, its use remains robust.



Data are for the selected specialties shown. Data are presented as a percentage: the number of telemedicine visits in a given week is the numerator, while the number of visits in the baseline week (March 1-7) is the denominator. Telemedicine includes both telephone and video visits. ^a Data derived from Phreesia. Source: Mehrotra et al.⁷

Orthopedics and cardiology

The rate of virtual visits for orthopedics and cardiology overall were both under 5% as of fall 2020; however, virtual visits and telehealth can still be successfully integrated in these categories, breaking through long-standing barriers.⁷ Many organizations are successfully using virtual health to support the surgical pathway (Figure 5).

Figure 5. Where can virtual health support the surgical pathway?

Teleradiology and telerehab are now accepted in both cardiology and orthopedics, and Sg2 predicts that orthopedic and spine evaluation and management visits will be 34% by 2029. Telerehab, including internet-based exercise guidance and monitoring, enables patients to actively participate in physical and occupational therapy, and can also be considered a hybrid approach to inperson care. In response to the growing demand for virtual solutions, suppliers are rapidly advancing clinically supported resources for hospitals to leverage as a part of their virtual strategy.

One such resource is mymobility with Apple Watch, by Zimmer Biomet. This virtual care management platform provides orthopedic and spine patients with access to remote physical therapy, and delivers continual data and patient-reported feedback to help facilitate care. Preliminary data from a recent clinical study found that this platform demonstrated similar early outcomes to traditional care models, while requiring fewer physical therapy visits for primary knee arthroplasty.⁹

Sg2 forecast for 2029 **34%** Orthopedic and spine E&M virtual visits

According to study results presented at the American Heart Association Scientific Sessions 2020 held in November, virtual and remote telehealth cardiac rehabilitation programs implemented during the pandemic were found to maintain levels of patient acceptance, adherence and referrals when compared to in-person outpatient rehabilitation programs.¹⁰

Which patients should be treated virtually?

It may be overwhelming to determine at what point in the continuum virtual care can be most effective, as well as

which patients would most benefit from these types of visits. While the federal government has released several resources for providers to help encourage the use of



Source: Sg2.

Abbreviations: MRI = magnetic resonance imaging; PT = physical therapy.

telemedicine, executing those strategies in a constrained environment may be difficult but necessary to remain competitive and to deliver the best care.¹¹

Virtual visits are ideal for existing patients and those with chronic health conditions who require medication management. Two-thirds of all health care costs are related to treating chronic diseases. As such, implementing virtual care into these patients' health management plan can provide both clinical and financial benefits. Significant demand for improved chronic care management, combined with reimbursement opportunities in this space, make it an obvious area of prioritization.

While only 28% of Americans surveyed in the 2020 State of Telemedicine Report feel that telehealth is comparable to an in-person visit, that percentage increases to 53% for those with chronic conditions due to more frequent visits and an existing rapport with physicians. And while it may not be seen as fully comparable to an in-person visit, more than 80% of patients say they can envision incorporating telehealth into their regular health care plan.⁴ In general, patients who have established relationships with physicians are more receptive to virtual care.

Best practices for virtual visits¹²

- Have a phone number available in case the video connection is lost.
- Have a medical assistant start the visit and ensure all video and audio components are functioning prior to initiating the evaluation.
- Ensure identification badges and professional attire are visible, which add to the credibility and authenticity of the virtual evaluation.
- Explore which patients and situations will receive the greatest benefit from a virtual encounter. For example, a post-discharge evaluation for hospital patients two to three days after being sent home can ensure a proper transition and has proven to increase patient satisfaction and safety while reducing readmissions.

Conclusion

Recognizing that the increase in virtual visits was born out of necessity but has the potential to be sustained will help organizations stay ahead of the curve in the future. Although looming questions regarding Centers for Medicare & Medicaid Services' reimbursement policies remain — especially once the public health emergency is over — we believe the benefits to patients and the industry at large will sustain a growing dependence on telehealth. As time goes on, will private payers be more amicable to extending this offering in a similar fashion? If so, will we see an opportunity to leverage telehealth to a greater extent in markets with a larger private payer mix? Developing and deploying your virtual care strategy now will help ensure your success in the future.

References

- 1 Erickson M. Stanford Medicine increases use of televisits to help prevent spread of coronavirus. Stanford Medicine. March 30, 2020. Accessed December 10, 2020. https://med.stanford.edu/news/all-news/2020/03/ stanford-increases-use-of-telemedicine
- 2 Zarefsky M. 5 huge ways the pandemic has changed telemedicine. American Medical Association. August 26, 2020. Accessed December 3, 2020. https:// www.ama-assn.org/practice-management/5-huge-ways-pandemic-has changed-telemedicine
- 3 CMS adds 11 new telehealth services to Medicare coverage. The Journal of Healthcare Contracting. October 15, 2020. Accessed December 9, 2020. https://www.jhconline.com/cms-adds-11-new-telehealth-services-tomedicare-coverage.html
- 4 Podsada J. The doctor will see you now on your computer or smartphone. HeraldNet. November 11, 2020. Accessed December 3, 2020. https://www. heraldnet.com/business/the-doctor-will-see-you-now-on-your-computeror-smartphone
- 5 Telemedicine market to flourish at 23.5% CAGR and hit USD 185.66 billion by 2026; rising demand for better access to advanced healthcare to aid growth says Fortune Business Insights. News release. Globe Newswire. October 19, 2020. Accessed December 3, 2020. https://www.globenewswire.com/ news-release/2020/10/19/2110170/0en/Telemedicine-Market-to-Flourish-at-23-5-CAGR-and-Hit-USD-185-66-Billion-by-2026-Rising-Demand-for-Better-Access-to-Advanced-Healthcare-to-Aid-Growth-Says-Fortune-Business-Insights.html
- 6 Mulvaney C. Telehealth could replace 7% of healthcare spend if COVID-19 catalyzes broader adoption. Healthcare Financial Management Association. June 12, 2020. Accessed December 3, 2020. https://www.hfma.org/topics/ finance-and-business-strategy/article/telehealth-could-replace-7--ofhealthcare-spend-if-covid-19-cata.html
- 7 Mehrotra A, Chernew M, Linetsky D, Hatch H, Cutler D, Schneider EC. The impact of the COVID-19 pandemic on outpatient care: visits return to prepandemic levels, but not for all providers and patients. The Commonwealth Fund. October 15, 2020. Accessed December 3, 2020. https://www.commonwealthfund.org/publications/2020/oct/impact-covid-19-pandemic-outpatient-care-visits-return-prepandemic-levels
- 8 Zanjani A, Giebink B, Woods K, McMurray K. White paper: Telemental health and the COVID-19 behavioral health crisis. HDR. August 2020. Accessed December 16, 2020. https://www.hdrinc.com/sites/default/files/inline-files/ telehealth-telemental-health-covid-19-behavioral-health-crisis.pdf
- 9 Zimmer Biomet announces preliminary results from mymobility® clinical study at 2020 AAHKS annual meeting. News release. Zimmer Biomet Holdings, Inc. November 5, 2020. Accessed December 28, 2020. https://www. prnewswire.com/news-releases/zimmer-biomet-announces-preliminaryresults-from-mymobility-clinical-study-at-2020-aahks-annualmeeting-301167455.html
- 10 May B. Assessing a virtual cardiac rehabilitation program implemented during the COVID-19 pandemic. Cardiology Advisor. November 10, 2020. Accessed December 3, 2020. https://www.thecardiologyadvisor.com/home/ conference-highlights/aha-2020/assessing-a-virtual-cardiac-rehabilitationprogram-implemented-during-the-covid-19-pandemic/
- 11 Getting started. Telehealth.hhs.gov. Updated November 2, 2020. Accessed December 3, 2020. https://www.telehealth.hhs.gov/providers/gettingstarted/#integrating-telehealth-practices
- 12 Berg S. 6 best practices to sharpen physicians' use of telehealth. American Medical Association. October 19, 2020. Accessed December 28, 2020. https://www.ama-assn.org/practice-management/digital/6-best-practicessharpen-physicians-use-telehealth

Novel strategies for managing patients with pulmonary embolism

pulmonary embolism (PE) occurs when an artery in the lungs becomes blocked. Blockage can result from a number of medical causes, including blood clots, fat agglomeration, gas bubbles, tumors and foreign materials. Blood clots that form in the deep veins — often in the legs — are the most common cause. When an artery is blocked, blood is unable to pass and the lung infarcts. Depending on the size and location of the obstruction in the lung, PE can be fatal. PE is not a disease entity in and of itself; however, it is a manifestation of other underlying conditions.



PE is a common medical condition in the U.S., with an estimated 650,000 episodes per year. It is the third most common cardiovascular disorder, trailing only myocardial infarction and stroke, and affects up to 5% of the population during their lifetime.¹ It is estimated that it causes between 100,000 to 200,000 deaths annually and is the most preventable cause of death in hospitalized patients in the U.S.² Mortality estimates are broad since PE can be difficult to diagnose and clinical presentation is often asymptomatic.

Patients with acute PE experience symptoms such as shortness of breath, chest or pleuritic pain, and hypoxia. With large PE, some patients may experience catastrophic hemodynamic collapse, while others may notice progressive shortness of breath.



Classification of PE severity

PE severity is stratified into three distinct categories (Figure 1):

- Massive: causes hemodynamic compromise
- Submassive: causes right ventricular dysfunction
- Nonmassive: no evidence of right ventricular dysfunction or hemodynamic compromise

Figure 1. Classification of PE

Massive PESubmassive PELow risk(accounts for 5%-10% of cases)(accounts for 20%- 25% of patients)(constitutes about 70%-75% of cases)• Dyspnea• RV dysfunction (right heart failure) despite• Hypotension• parmel sustemis			
(accounts for 5%-10% of cases)(accounts for 20%- 25% of patients)(constitutes about 70%-75% of cases)• Dyspnea• RV dysfunction (right heart failure) despite• Hypotension	Massive PE	Submassive PE	Low risk
 Dyspnea RV dysfunction (right heart failure) despite 	(accounts for 5%-10% of cases)	(accounts for 20%- 25% of patients)	(constitutes about 70%-75% of cases)
Cyanosis arterial pressure	 Dyspnea Syncope Hypotension Cyanosis 	 RV dysfunction (right heart failure) despite normal systemic arterial pressure 	

Source: Slideshare.³

Abbreviations: PE = pulmonary embolism; RV = right ventricle.

The category of PE severity is directly associated with 90-day mortality: An individual experiencing a massive PE has a 90-day mortality rate of 58.3%, while submassive PE has a mortality rate of 15.1% over the same time period.⁴ Approximately 60% of patients who die unexpectedly in the hospital had a massive PE.⁵

Unique approaches for managing PE

The critical nature of this condition has many organizations seeking comprehensive and unique solutions to both identify and treat PEs. Prompt recognition and treatment are essential to improving outcomes and can be achieved by integrating proven strategies into your process and delivering customized care based on each patient's individual situation.

For example, a coalition of physicians at Massachusetts General Hospital developed a noteworthy approach by establishing a Pulmonary Embolism Response Team (PERT). This multidisciplinary group works together to determine an optimal plan of care for critically ill patients, promote rapid risk detection and mobilize the resources necessary to provide the best possible care — all of which reduce both morbidity and mortality in this patient population.⁶

Additionally, there are many promising novel strategies to treat massive and submassive PEs. With a wide range of interventions — including anticoagulation, systemic thrombolysis, catheter-directed thrombolysis, catheter embolectomy, surgical embolectomy and mechanical circulatory support — it is imperative to bring thought leaders together to obtain the best clinical outcomes.

Interventional therapy

Interventional therapy for PEs is an emerging space and can bring additional value to patients, especially those with high bleeding risks. Intervention on an occluded artery can enable more complete and earlier recanalization to restore blood flow to the lungs. Interventional therapy improves lung and body oxygenation, reduces pulmonary vascular resistance and decreases overall cardiac burden. Interventionalists can deploy a variety of technologies in emergency situations, such as catheter-directed fibrinolysis (CDF) and ultrasound-assisted catheterdirected thrombolysis (USAT):

- CDF: There has been increased interest in local delivery of lytic agents, as systemic lytic therapy shunts blood away from the occluded pulmonary artery, making it much less effective. By delivering right to the occluded vessel, lytic therapy is able to work directly on the clot.⁷
- USAT: This technology combines low-frequency ultrasound with a lumen able to deliver local thrombolytic therapy. The low-energy ultrasound dissociates fibrin strands, improving the binding ability of the pharmacology agent. This technology enables direct infusion of lytic agents for 12-24 hours.⁸

PE risk factors

Although anyone can develop blood clots and associated PE, the following factors are associated with a higher risk:

- Surgical procedures
- Family history of blood clots/PE
- Cardiovascular disease, especially heart failure
- Brain, ovary, pancreas, colon, stomach, lung and kidney cancers, and cancers that have spread; undergoing chemotherapy further increases risk
- Inherited blood disorders that affect clotting
- Prolonged bedrest due to surgery or immobility
- Confinement in a plane or car for a long period of time
- Smoking
- Obesity
- Supplemental estrogen
- Pregnancy
- COVID-19 diagnosis

It is estimated that 50% of venous thromboembolism events are associated with temporary risk factors such as recent surgery or a hospital admission for a medical illness. Another 20% are associated with cancer, while the remaining 30% stem from various minor risk factors — or none at all — and are thus deemed unprovoked.⁹

Mechanical thrombectomy

While the multidisciplinary team approach and other novel solutions mentioned above have benefited a large portion of the PE population, some patients with massive and submassive PE have had very few options for lifesaving treatments in the past. This need has led to the development of an emerging technology called mechanical thrombectomy (MT).

MT is used to treat massive and submassive PE that causes cardiac collapse, right ventricular failure or shock. MT involves the use of catheters, suction devices, or other tools to remove or decrease the clot burden. It can be used in stand-alone therapy for patients with contraindications to lytic therapy or used in conjunction with other treatments. Although it is a relatively new treatment option, hospitals are rapidly adopting the technology with strong physician advocacy and support — giving hope to patients.

Indigo Aspiration System

The Indigo thrombectomy device is a new MT option recently brought to market by Penumbra. The device catheter is introduced through vascular access into the clot, where it is directly aspirated. Through the use of a thin "separator" at the end of the catheter tip, the device continuously breaks up the clot and maintains patency during aspiration.¹⁰



Source: Penumbra. Used with permission.

The Evaluating the Safety and Efficacy of the Indigo Aspiration System in Acute Pulmonary Embolism (EXTRACT-PE) trial successfully demonstrated the safety and efficacy of the Indigo Aspiration System in patients with acute PE. These findings prompted new American Heart Association guidelines, which state that catheterbased embolectomy can play an important role in treating PE.¹¹

Conclusion

Many advancements have been made in the treatment of PE. New tools for MT have resulted in early positive results for cases involving massive and submassive clots, with continuous aspiration MT proven to be a feasible and effective treatment. Some patients — such as those with a large residual clot — may benefit from dual therapy involving additional, local, low-dose thrombolytic therapy. By adopting emerging technology and creating multidisciplinary teams such as PERT, hospitals can mobilize staff to rapidly diagnose and treat this life-threatening condition, ultimately improving patient outcomes.

References

- 1 Stein PD, Matta F. Epidemiology and incidence: the scope of the problem and risk factors for development of venous thromboembolism. *Clin Chest Med.* 2010;31(4):611-628.
- 2 Office of the Surgeon General (US); National Heart, Lung, and Blood Institute (US). The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. Office of the Surgeon General (US); 2008.
- 3 Pulmonary embolism -the great masquerader. Slideshare. July 13, 2017. Accessed December 17, 2020. https://www.slideshare.net/E_neutron/ pulmonary-embolism-77825110
- 4 Goldhaber SZ, Buring JE, Lipnick RJ, Hennekens CH. Pooled analysis of randomized trials of streptokinase and heparin in phlebographically documented acute deep venous thrombosis. *Am J Med.* 1984;76(3):393-397.
- 5 Ouellette DR, Harrington A, Kamangar N. Pulmonary embolism (PE). Medscape. Updated September 18, 2020. Accessed December 17, 2020. https://emedicine.medscape.com/article/300901-overview
- 6 Our story. PERT Consortium. Accessed December 17, 2020. https:// pertconsortium.org/about/
- 7 Diamond SL, Anand S. Inner clot diffusion and permeation during fibrinolysis. *Biophys J.* 1993;65(6):2622-2643.
- 8 Braaten JV, Goss RA, Francis CW. Ultrasound reversibly disaggregates fibrin fibers. *Thromb Haemost.* 1997;78(3):1063-1068.
- 9 Wendelboe AM, Raskob GE. Global burden of thrombosis: epidemiologic aspects. Circ Res. 2016;118(9):1340-1347.
- 10 Al-Hakim R, Bhatt A, Benenati JF. Continuous aspiration mechanical thrombectomy for the management of submassive pulmonary embolism: a single-center experience. *J Vasc Interv Radiol.* 2017;28(10):1348-1352.
- 11 Penumbra Indigo® Aspiration System IDE trial for acute pulmonary embolism meets primary safety and efficacy endpoints. Bloomberg. November 6, 2019. Accessed December 17, 2020. https://www.bloomberg. com/press-releases/2019-11-06/penumbra-indigo-aspiration-system-idetrial-for-acute-pulmonary-embolism-meets-primary-safety-and-efficacyendpoints





Considerations for transcatheter aortic valve replacement device selection he transcatheter aortic valve replacement (TAVR) market continues to evolve due to expanded indications — shifting from exclusively high-risk patients in 2012 to including low-risk patients by 2019 — and a growing number of individuals with heart valve disease.

An upward trend

The U.S. heart valve market is the world's largest and continues to rise with a compounded annual growth rate of 6%; spend in this market is estimated to grow from approximately \$4 billion in 2020 to over \$7 billion by 2027.¹

Steady growth has been seen in both the number of sites performing TAVR and the number of procedures performed since 2011, with the 2019 volume per site averaging 110 cases with a median of 89 (Figure 1).² However, many sites have a relatively low volume of cases, highlighting the great variability by location and causing concerns about sustainability.





Source: Carroll et al.²

Abbreviations: CMS = Centers for Medicare & Medicaid Services; TAVR = transcatheter aortic valve replacement.

Device selection in a diverse market

As a result of expanded indications in a multibilliondollar volume industry, a larger pool of patients is eligible for TAVR in the U.S. As shown in Table 1, multiple manufacturers have introduced balloon-expandable (BE) and self-expanding (SE) device designs, such as Edward Lifesciences, Medtronic and Boston Scientific. The competitive market for TAVR has produced high-quality devices that have shown positive long-term efficacy and durability, and they will continue to dominate the surgical valve space.

Key manufacturers

Edwards Lifesciences has historically been the market leader in the heart valve replacement space, with a device market share of approximately 65%. Its latest iteration, Sapien 3 Ultra, is available in both U.S. and European markets. Medtronic has also driven growth in the market; based on its analyst report published in October, its device market share is approximately 28% to 29%. Medtronic is initiating the Small Annuli Randomized to Evolut or Sapien (SMART) trial of its Evolut Pro and Pro+ against Edwards' Sapien 3 Ultra in 700 patients with small native anulus and surgical valve failure, comparing one-year co-primary endpoints of noninferiority, all-use mortality, disabling stroke, repeat rehospitalization and hemodynamic superiority.

Boston Scientific's Lotus valve, which could be repositioned after initial deployment, was abruptly withdrawn from the market on Nov. 17, 2020, with the manufacturer citing complexities in keeping up with device design updates. Boston's latest transcatheter valve, Acurate neo, which it acquired in 2017 when it purchased Symetis, uses a SE platform but was unable to demonstrate noninferiority compared to competitors in the Safety and Efficacy Comparison of Two TAVI Systems in a Prospective Randomized Evaluation (SCOPE) trials. It is estimated that the Acurate neo2 device will be approved by the U.S. Food & Drug Administration (FDA) in 2024, with an updated design that adds a new annular sealing technology to conform to irregular, calcified anatomies to minimize paravalvular prosthetic leak. However, to gain FDA approval Boston may need to add patients to the trial and increase the length of follow-up.

Evolut Pro System



Source: Medtronic. Used with permission.

Table 1. TAVR device manufacturers, considerations and launch dates

Manufacturer	Brand name	Expansion	Considerations	Launch date
Edwards	Cribier-Edwards	BE	First in-man procedure performed	2002
Sadra	Lotus	ME	No rapid pacing requirement	2007
Boston Scientific	Lotus	ME	Acquired Sadra	2010
Edwards Lifesciences	Sapien	BE	Inoperable/high-risk approval	2011
Medtronic	CoreValve	SE	May reduce annular disruption; risk of PVL	2014
Edwards Lifesciences	Sapien XT/3	XT - stented (BE)	Intermediate risk	2016
Edwards Lifesciences	Sapien 3	BE	Aortic and mitral indication	2017
Medtronic	Evolut R/Pro	SE	May reduce annular disruption; risk of PVL; intermediate risk	2017
Boston Scientific	Acurate neo	SE	Boston Scientific purchased Symetis, acquiring Acurate neo	2017
Boston Scientific	Lotus	ME	Withdrawn from market due to problem with delivery system locking mechanism	2019
Boston Scientific	Sentinel	Cerebral embolic protection	Acquired (Claret) embolic protection device	2018
All vendors			Low-risk approval	2019
Boston Scientific	Lotus	ME	Repositionable; lowest risk of PVL; low LVOT trauma; may be preferred for bicuspid valves	2019
Boston Scientific	Lotus portfolio	ME	Withdrawn in November 2020	2019
Boston Scientific	Acurate neo/neo2	SE	Undergoing clinical trials	2020

Abbreviations: BE = balloon-expandable; LVOT = left ventricular outflow tract; ME = mechanically-expandable; PVL = paravalvular prosthetic leak; SE = self-expanding.

Clinical considerations

Features unique to each transcatheter valve offer the opportunity to improve the prosthesis-patient match. With BE, SE and ME devices, the right device can be customized depending on specific patient anatomy. For example, the SE device may work better for select patients due to its relatively higher profile, while BE devices may offer greater coronary protection. One should consider the potential for annular rupture in a specific patient trading this for higher gradients, based on the Comparison of Transcatheter Heart Valves in High-Risk Patients With Severe Aortic Stenosis (CHOICE) trial data.

Anatomical factors should also be considered when selecting a device, including annular size, coronary location, calcific burden, left ventricular outflow tract involvement and aortic root angulation. Hemodynamics, longevity and cost-effectiveness should also be taken into account due to the expanded indications and available features of each valve. Because there are risks associated with the TAVR procedure — including vascular access issues, the need for a pacemaker post-procedure, paravalvular leak and stroke — experienced operators will carefully weigh the risks and benefits of each device when making a decision.

Financial considerations

While TAVR devices vary in size and features, their pricing and rebate structures are similar across both vendors and regions. Many organizations seeking to streamline purchases may attempt to identify which device manufacturer delivers the best value, but for this particular procedure it's best to prioritize clinical factors and allow them to drive device selection, as long as pricing and outcomes remain consistent. While no discernible differences in the occurrence of stroke, durability or costeffectiveness have been revealed in clinical trials to date, the design and construct of each device has the potential to impact patient outcomes.

As demand and volume increase and new suppliers enter the market, it will be critical to maintain visibility into changing device prices or new clinical evidence within this category. For example, Boston Scientific is expected to launch the Acurate neo2 valve in Europe in 2024, but will continue to market its Sentinel embolic protection device until then. Other vendors are benefiting from expanded use in the U.S. after several other devices were discontinued.

Trend data from the Society of Thoracic Surgeons and the American College of Cardiology Foundation

In 2019 the number of TAVRs surpassed the number of surgical aortic valve replacements (SAVRs), including isolated and combination procedures (Figure 2); SAVRs are usually performed when patients have additional requirements, such as those requiring a coronary artery bypass graft.

Figure 2. Annual TAVR and SAVR volumes, 2012 to 2019



Source: Carroll et al.²

Abbreviations: SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

Types of aortic valve disease that may require treatment

Valvular stenosis — or hardening by calcification of the leaflets — affects all four heart valves, but the aortic valve is usually the most severely impacted. Calcific disease is the most common form of valvular disease. Valvular insufficiency occurs when a valve does not completely close due to the back pressure of cardiac contraction — also known as regurgitation while acquired valvular disease is a result of various viral and bacterial infections. Bicuspid aortic valves are congenital defects, in which an individual has two rather than three leaflets. More information can be found in volume 1 2020 of our Tech Watch: Medical Device.

Although TAVR procedure volume has increased every year, length of stay has decreased (Figure 3). In addition, since 2011, the 30-day mortality rate has decreased from 7.2% to 2.5% and stroke has started to decrease from 2.75% to 2.3%, but the pacemaker device category has seen little to no innovation and remains relatively unchanged (10.9% to 10.8%).

Figure 3. Length of hospital stay for TAVR procedures, 2013 to 2019



Source: Carroll et al.² Abbreviation: TAVR = transcatheter aortic valve replacement.

The future of TAVR

While many signs point favorably toward the growth and success of TAVR procedures, patient selection criteria will need to be monitored to sustain optimal results for both patients and organizations. Beyond structural selection criteria, more attention is being given to evaluating procedures' experiential or symptom reduction benefit now that risk indications are lower. Studies will continue to drive both the direction of the development of the TAVR market as well as patient selection, since gains in symptom status are not universal.³ Refining both patient and device selection may prove to be key to the future success of TAVR programs.

References

- 1 Bracciodieta EJ. *Medtech 360: Heart Valve Devices Market Analysis, US, 2019.* Toronto, Ontario: Millennium Research Group; 2018.
- 2 Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT registry of transcatheter aortic valve replacement. J Am Coll Cardiol. 2020;76(21):2492-2516.
- 3 Neale T. NT-proBNP level helps ID patients who won't benefit from TAVR. tctMD. Published November 30, 2020. Accessed December 7, 2020. https:// www.tctmd.com/news/nt-probnp-level-helps-id-patients-who-wontbenefit-tavr?utm_source=TCTMD&utm_medium=email&utm_

Evolution of a spine program: common trends with a few uncommon threads

Spinal procedures mimic a similar recovery pattern as cardiology and orthopedics, but with unique differentiators



In our fall 2020 edition of Tech Watch: Medical Device, we explored the projected impact of shifting sites of care in cardiovascular and orthopedic procedures. Both segments are experiencing and preparing for greater volumes of patients transitioning to ambulatory care centers. Due to dynamic market conditions, spinal procedures are expected to follow a similar path over the next 10 years, slowly recovering and transitioning to outpatient facilities (Figure 1).

Similar to cardiology and orthopedics, the number of spinal procedures initially declined due to the COVID-19 pandemic in 2020. While some procedures are rebounding faster than others, inpatient spine discharges continue to fall as physician, payer and consumer pressures — combined with advances in pain management — drive surgery to outpatient and ambulatory surgery centers. These forces are compounded by pandemic recovery efforts, which are accelerating the shift in sites of care as programs double down their efforts to optimize patient safety and efficiency.

Looking to the future

Spine volumes will take time to recover following COVID-19 shutdowns, but in the long term, high obesity rates and other lifestyle factors will drive an increase in total demand for spine services.

Figure 1. Projected demand for inpatient and outpatient spinal procedures



Source: Sg2 Impact of Change 2020.

In the outpatient setting, total growth has been heavily influenced by rehabilitation services. Physical and occupational therapy (PT/OT) evaluations are expected to nearly double the population-based forecasts as conservative approaches continue to gain traction and therapists play an increasingly important role in the evaluation, triage and conservative management of back pain. Meanwhile, consumer price sensitivity will sustain declining per-person PT use rates, tempering growth in PT/ OT follow-up visits. The adoption of virtual rehabilitation and remote monitoring/wearable technologies will also facilitate patient treatment in fewer visits per therapy episode (Figures 2 and 3).

Imaging will see a sharp decline that will never fully be restored to pre–COVID-19 levels, as care redesign efforts, improvements in patient navigation platforms and

Figure 2. Projected outpatient spine volumes for select services, 2019-2024

regulatory requirements curtail unnecessary use in the early diagnosis of spinal conditions. Payers are also aggressively shifting imaging to lower-cost sites of care, such as freestanding imaging centers, in many markets. Similarly, a reduction in unnecessary emergency department visits in favor of lower-acuity services has been accelerated by COVID-19 and will continue in the long term.

Finally, the pandemic has aggravated an already complex pain management landscape and is likely to drive additional demand for services. While procedures to alleviate pain continue to face payer scrutiny, the evolving opioid epidemic has motivated providers and patients to reconsider targeted interventions — such as injections and spinal cord stimulators — over opioids for pain management, adding another layer of complexity in spine care programs with the associated societal costs.



Figure 3. Projected outpatient spine volumes for select services, 2019-2029



Population-Based Forecast Sg2 Outpatient Forecast

Source: Sg2 Impact of Change 2020.

Abbreviations: E&M = evaluation and management; PT/OT = physical and occupational therapy; RF = radiofrequency.

Top trends for spine surgery

The downstream effects of COVID-19, such as an amplified focus on length of stay/exposure risk reduction, efficiency and cost pressure plus weakened consumer confidence, bolster several trends affecting growth in spine surgery (Figure 4):

- A continued outpatient shift of the majority of cervical fusions, spinal decompressions and laminectomies, as well as an increasing outpatient shift of less complex lumbar fusion procedures
- Improvements in minimally invasive techniques and pain management as well as broadening reimbursement (e.g., removal of lumbar fusion from the inpatient-only list in 2020) that will support the outpatient shift
- Scrutiny of surgical procedures, particularly lumbar fusion, as payers continue to implement initiatives to reduce overutilization of spinal surgeries
- Reductions in or loss of coverage as economic challenges persist and price sensitivity increases

Demand will ultimately grow; however, the shifting landscape will shift spine services utilization and require adoption of truly comprehensive models. Organizations focused on long-term performance will need to evolve to meet rising stakeholder demands.

Spine program challenges

- Outpatient shift and surgery avoidance Payer, provider and consumer pressures have merged to yield additional outpatient shifts of surgical cases, and add pressure to justify recommendations for surgical intervention.
- Outcomes Payers continue to search for value, intensifying incentives to demonstrate improved outcomes with operative and nonoperative care
- Care coordination and opioid stewardship Continued challenges with pain management in the complex spine patient, combined with the ongoing opioid crisis, have driven the creation of alternative approaches and collaborative models.
- Access and workforce Provider shortages and burnout have required innovative solutions and capital investment to keep pace with everchanging technological advances, which in turn have introduced additional resource allocation challenges.



Figure 4. Inpatient and outpatient spine surgical procedure forecast, 2019-2029

 Sg2 Inpatient/Outpatient Forecast 🛛 🔳 Population-Based Forecast

Source: Sg2 Impact of Change 2020.



Successful spine care requires more than just "checking the boxes" across services

Attractive margins and a high commercial payer mix make for a competitive spine surgery environment. However, as with all areas of health care, COVID-19 has amplified preexisting pressures, requiring an evolution to a more comprehensive spine model to capture market share and remain operationally efficient (Figure 5).



Figure 5. U.S. inpatient and outpatient commercial payer mix by volume, 2019

Note: Analysis includes both inpatient and outpatient procedures and excludes 0–17 age group. Sources: Impact of Change®, 2019; HCUP National Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP) 2016. Agency for Healthcare Research and Quality, Rockville, MD; OptumInsight, 2017; The following 2017 CMS Limited Data Sets (LDS): Carrier, Denominator, Home Health Agency, Hospice, Outpatient, Skilled Nursing Facility; Claritas Pop-Facts®, 2019; Sg2 Analysis, 2019.

Abbreviation: CV = cardiovascular.

Successful spine programs will connect the dots for patients as they traverse the continuum. While there is no "one-size-fits-all" model and integrated, comprehensive care takes time to develop, several critical elements common to successful programs should be considered:

Multidisciplinary team engagement across operative and nonoperative services

Spine care spans multiple specialties, sites of care and services, all of which will be increasingly necessary to navigate mounting market pressures and shifting demand. Further, despite the emphasis on surgical care, the vast majority of spine service volumes are nonoperative, as seen in Figure 6. Incorporating services and program models that foster true collaboration between operative and nonoperative providers is paramount to delivering high-value care, particularly as employers and payers challenge spine programs to demonstrate both surgical and nonsurgical outcomes.

Identifying an effective team leader is essential for program success when coordinating a multispecialty team. The leader must serve as a neutral, unbiased captain to steer the team effectively. While the orthopedic-neurological divide is legendary, progressive

Figure 6. U.S. inpatient and outpatient spine volumes, 2019



Note: Analysis includes both inpatient and outpatient procedures and excludes 0–17 age group. Minor procedures include injections and arthrocentesis. Chiropractic visits include chiropractic/osteopathic manipulation. Rehab includes outpatient rehab services (eg, physical and occupational therapy). Sources: Impact of Change®, 2019; HCUP National Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP) 2016. Agency for Healthcare Research and Quality, Rockville, MD; OptumInsight, 2017; The following 2017 CMS Limited Data Sets (LDS): Carrier, Denominator, Home Health Agency, Hospice, Outpatient, Skilled Nursing Facility; Claritas Pop-Facts®, 2019; Sg2 Analysis, 2019.

Abbreviations: ED = emergency department; E&M = evaluation and management; OP = outpatient.

organizations have overcome deep-rooted relationship and structural barriers in a variety of ways (e.g., shared resources, transparent data and development of a distinct spine department). In addition, payment evolution — a catalyst to change — is a common thread strong enough to bridge this gap.

Deliberate channel management and a focus on network integrity

Spine surgery is largely a consumer-driven, elective service. Achieving a positive return on investment hinges on the ability to attract and retain patients. It is imperative to evaluate upstream channels and stakeholder needs — such as primary care physicians, employers and consumers — and develop access points and care pathways with a diverse set of providers. Local primary care physicians and patient focus groups can be excellent sources of intelligence needed to build on multidisciplinary team insights about existing gaps in a community's spine continuum.

Navigation and access strategies that direct patients to effective and efficient care

Expediting initial access and ensuring subsequent streamlined transitions across the continuum improves patient and provider satisfaction and supports network integrity. Increasingly, programs are implementing clear triage protocols involving a multidisciplinary team to expedite evaluation and treatment. Tracking results of these processes can encourage physician buy-in as efficiencies are gained (e.g., via improved surgical conversion rates) and demonstrate value to payers.

Care coordinators can also be used to ensure adherence to preestablished pathways and to reduce referral leakage. Patient navigators and appropriately linked information systems that address patient education, provider communication and outcomes data collection can be critical, particularly for programs that are not co-located.

Opioid stewardship and care coordination for complex spine patients

The ongoing opioid crisis has elevated the focus on pain management, including preoperative and postoperative pain, prevention, the ability to identify patients at risk for long-term postoperative opioid use and many other issues.

While traditional opioid stewardship programs often incorporate provider and patient education as well as prescription monitoring, progressive organizations are partnering with providers to implement three high-impact strategies specifically designed for surgical patients:

- · Long-term postoperative opioid use risk identification
- Preoperative pain tolerance and mitigation strategies
- Multimodal analgesia techniques and postoperative prescription guidelines

These components not only help address the opioid crisis but also produce dividends for value-focused hospitals and health systems, including improved quality (fewer complications and readmissions), reduced total cost of care, and efficient patient and provider care coordination.

Conclusion

Amid evolving market dynamics and heightened pressures as a result of the COVID-19 pandemic, it is increasingly important — although difficult — to prioritize and focus on the strategic initiatives that will have the greatest impact on service line performance. A thorough programmatic, competitor and market assessment may be a necessary first step in developing a model that balances internal needs and capabilities with external realities. While there is no one-size-fits-all model, organizations that can demonstrate value across stakeholders (e.g., payers, employers, physicians and patients) with a comprehensive spine program will be best positioned to succeed. Collecting longitudinal patient-reported outcomes will be helpful in identifying process optimization opportunities and demonstrating the value of transformative spine care models.





Chief financial officer leads team approach to implementing a new joint initiative eadquartered in southern Oregon, Health Future is a health care consortium of hospitals and health systems that focuses on quality improvement, margin enhancement and cost reduction. A group composed of executive leaders, physicians and supply chain professionals joined together to tackle a category that was failing to generate revenue at Health Future's member organizations, and to identify best practices that could be used with future initiatives.

Jenn Welander, chief financial officer for St. Charles Hospital, led the team that implemented the new total joint initiative. Reflecting on the recent implant engagement as well as accomplishments of the team, she shared her perspective on the three key differentiators that made the endeavor successful: data, alignment and transparency.

Data

"The number one differentiator was data," explained Welander. "Comprehensive data was really important. We had to be able to show the economics of a case at a detail level, such as the cost of the exact implant used with a specific patient. Then we could look at the actual margin achieved in a procedure."

With so many data sources available, it was challenging to identify the right type of information and determine how to best apply it to a cost reduction initiative. Cindy Jones, principal for Vizient, works with members like Health Future to aggregate data that can help facilitate and champion change. Her recent article, Five Data Sources to Engage Physicians in Evaluating Preference Items, explores key components such as item cost, variable costs and quality measures, all of which can lead to significant savings and improved quality when accurately analyzed.

Alignment

The second key differentiator for Health Future and St. Charles Hospital was aligning teams around a shared strategy and timeline for deployment. Ensuring that the total joint initiative delivered both savings and sustainability required partnership and consensus from the physician team. Due to the close working relationships that surgeons have with their vendor representatives, the executive team felt it was important to clearly communicate the initiative's strategy and goals with staff prior to sending out the request for proposal.

"Creating alignment within our organization and ensuring a shared understanding of the multiple variables at play, such as joint ownership of our ambulatory surgery center, our market share and obtaining agreement before launching the initiative, was important," continued Welander. "With executive and physician leadership aligned, it established a collective vision and mutual accountability for the success of the engagement."

Transparency

From start to finish, Welander was diligent about prioritizing open communication and transparency.

"We were transparent with our physician partners, with stakeholders inside our organization and with suppliers," said Welander. "We had a respectful understanding of where the hospital was and where the suppliers were. The efforts that resulted were productive, and they were fair."

"When you combine and prioritize data, alignment and transparency, you will see greater success. Ultimately it's about respect between all parties and patient safety. If we can agree on that, the initiatives will be successful," concluded Welander.

For more information about the implant strategy deployed by St. Charles Hospital, Health Future and Vizient consulting services, read the full case study and watch the webinar recording of a recent roundtable discussion.

A member poll conducted on Dec. 8 explored different levels of physician alignment currently being achieved at organizations that participated in the webinar. Results are shown below.

- Active physician involvement in VAT process and/or service line or initiative committees
- Informal discussions with physicians
- Formal gainsharing agreement with physicians
- Formal co-management agreement with physicians
- No physician alignment



Developing a neuromodulation program in a changing market

esigning, developing and evaluating your neuromodulation service line is resource intensive and requires deliberate and careful analysis, planning and implementation over time to achieve clinical and business goals. Whether leading an established neuromodulation service, contemplating new development or expanding services, professionals need to attend not only to the numerous technologies but also the fundamentals of program development.

Neuromodulation is a broad clinical category that encompasses treatments that affect the nervous system and involve externally placed or internally implanted devices. These devices target the brain, peripheral nervous system, spine and other nerve centers that control body function.

Using these devices, electrical impulses can be modulated to achieve interference with and reduction of pain responses, redirection of neural activity and amplification of desirable processes to improve both health and quality of life for patients with chronic pain as a result of back injuries, strokes, cancer and multiple sclerosis. The treatment of chronic pain is one of the primary applications for neuromodulation, creating high demand for this therapy.

The broad continuum of neuromodulation professionals may include neurosurgeons, anesthesiologists, physiatrists and others. A multitude of specialists may refer patients for neuromodulation treatment, including spine specialists, cardiologists, pain management, neurologists, psychiatrists, urologists, gastroenterologists, primary care physicians, pulmonologists and others.

Multiple treatment modalities are creating a growing market

Neuromodulation for pain management has risen in importance due to the concurrent focus on reducing opioid use and increased pressure — from both patients and payers — to offer nonpharmaceutical interventions. Multiple stimulation treatment modalities are in use, and target structures such as the spinal cord, deep brain, sacral nerve, brain and peripheral nerves. Drug delivery is another modality; implanted pumps can deliver medication directly to a targeted site, typically the brain or spinal cord, with dosages that are smaller, more effective and often with fewer side effects.

While established applications currently exist, virtually every manufacturer is actively researching novel applications of currently approved devices and developing additional therapies. The number of new device entrants is continually growing, both in current clinical indications as well as new treatments (Table 1).

Shifting sites of care and the impact of the pandemic

COVID-19 brought about profound disruption and lasting change to health care, particularly for procedures that are largely elective, such as neuromodulation. While there was a dramatic decrease in procedures early in 2020, analysts are predicting strong growth over the next several years in the neuromodulation market as restrictions ease on elective procedures and patients return to treatment. The domestic and global market for neuromodulation devices and treatments is also predicted to grow due to the increasing prevalence of age-related disorders, consumer knowledge, expanded indications and favorable clinical outcomes.

Taking advantage of the anticipated growth will partially depend on an organization's ability to accurately understand its markets and stay ahead of the competition — particularly when it comes to shifting sites of care. As is true for many procedures, the pandemic accelerated the movement of select neuromodulation cases — when safe from traditional inpatient settings to ambulatory settings. Increasing reimbursement parity between inpatient and outpatient settings compounds this shift, although there are some exceptions, including deep brain stimulation, which typically requires inpatient-based support services.

Many hospitals and health systems are ill-prepared to capitalize on the ambulatory opportunity in general due to the lack of owned ambulatory settings or partnerships with them. If they have not committed to proactively

Table 1. Agreements added to Innovative Technology contracts in 2020

Therapy category	Current indications	Active suppliers
Spinal cord stimulation	Chronic pain	Abbott
	Congestive heart failure	Medtronic
		Nevro Corp.
		Nuvectra
		Stimwave
Deep brain stimulation	Parkinson's disease	Abbott
	Essential tremor	Beijing PINS Medical Co.
	Epilepsy	Boston Scientific
	Dystonia	Medtronic
	Obsessive compulsive disorder	
Sacral nerve stimulation	Urinary incontinence	Axonics Modulation Technologies
	Fecal incontinence	Cogentix Medical
		Medtronic
		Nuvectra
Vagal nerve stimulation	Epilepsy	BioControl
	Major depressive disorder	electroCore
	Obesity	LivaNova PLC
	Congestive heart failure	Innovative Health Solutions
		Parasym Ltd.
		tVNS Techologies GmbH
Gastric electrical stimulation	Weight management	IntraPace
	Gastroparesis	MetaCure
Peripheral nerve stimulation	Chronic pain	Bioness
	Congestive heart failure	Nalu Medical
		SPR Therapeutics
		Stimwave
Hypoglossal nerve stimulation	Sleep apnea	Inspire Medical
		LivaNova PLC

Sources: Decision Resources Group, Vizient and Sg2.¹⁻³

adjusting their business model, they are at risk of losing market share and cases to competitive ambulatory settings. Vendors and health systems alike should be devoting strategic and tactical resources to prepare for the market reality and avoid lagging behind competitors.

Neuromodulation program development

While neuromodulation is rich in technology and treatments, both current and in development, technology and continual innovation are not enough to ensure success. Product selection and technology acquisition will be determined by prevalent indications, alternative therapies and your organization's pricing strategy. However, technology adoption is only part of the challenge and opportunity.

Several foundational elements should be addressed to complement neuromodulation technologies and devices to create a comprehensive, successful program. Assessment, planning and development are essential adjuncts; as with many specialty services, if these considerations are not fully addressed, success will be limited and poor clinical, operational and financial performance may result. These core elements are described at right.

Core elements of a successful neuromodulation program



Align stakeholders. As a complex discipline with multiple stakeholders, organizations will need to align internally to ensure participation and long-term success. When establishing and evaluating your neuromodulation program, the following stakeholders need to be consulted and aligned:

- Executive operations
- Finance
- Medical staff
- Strategy and planning
- Supply chain
- · Program leadership and staff
- Quality assurance

Assess current services. A commitment to development should be preceded by a thorough assessment of current and prospective services. Key activities include inventorying and understanding scope, function, staffing and competencies, and identifying gaps. This assessment process forms a baseline understanding upon which to refine and further develop neuromodulation services. For both first-time initiatives as well as expansion of services, it is critical to make a business case, considering that budgets are limited, and hospitals and health systems must be strategic in how they invest.

Engage staff and physician leaders. In many health systems, neuromodulation will often reside under a neurosciences umbrella with direct connections to orthopedics, neurosurgery, anesthesiology, physiatry and other specialties. While having a multidisciplinary structure is ideal, establishing a dedicated and defined neuromodulation leadership team will help ensure proper development and integration among constituent services and will lead to more effective execution.

Evaluate market opportunity. It is not uncommon that specialty program development, and the related focus and resources, are heavily influenced by the advocacy of physician specialists that believe an opportunity exists.

While that may prove to be true, this approach does pose potential risks, as it does not always validate the full market conditions. Additional indicators that should be considered include:

- A sizable population base with favorable demographic factors
- · Evidence of demand from referral sources
- · Lack of access due to limited capacity
- · Opportunity to differentiate from competitors
- · Favorable reimbursement environment

Partner with strategic suppliers. To move beyond a transactional relationship to total value, health care organizations must have strategic partnerships with their suppliers that encompass more than just price. Strategic supply partner evaluation imperatives include the following:

- Product portfolio
- Proven technologies with clinical efficacy for target indications
- · Value-added programs and incentives
- Other partnering opportunities such as research opportunities, trial sites and center of excellence codevelopment
- Return on investment potential
- Enhancement of hospital and program market positioning

Substantiate quality and outcomes. Commit to a quality plan featuring functional outcomes collection and reporting. Hospitals typically collect operational and clinical data such as length of stay, infection rates and so forth. Furthermore, top specialty programs measure their quality through standardized and specialty instruments and report these data to key audiences — internally for quality assurance and improvement and externally to reinforce and promote referral patterns.

Additionally, operational and clinical data can be coupled with functional outcomes and patient satisfaction data. Functional outcomes data focuses on patient response to treatment not only medically but across activity levels, work and personal life, and quality of life measures.

Inform consumers. Regardless of what a hospital, health system or physician chooses to call their promotion of services — marketing, community relations or education — it is an essential element of a neuromodulation program. Defining neuromodulation can be highly technical depending on your audience and may require translation, particularly for consumers.

With growing public awareness of neuromodulation specialty care, it is necessary to articulate the types of services, programmatic competence, competitive differentiators and calls to action.

The Institute of Medicine estimates that chronic pain affects more than 100 million American adults — more than the total affected by heart disease, cancer and diabetes combined.⁴

Conclusion

The future of neuromodulation is bright with robust technologies and growing indications, but will require providers to strategically rethink traditional business practices with a greater emphasis on collaboration and a more intimate understanding of the respective products, services and goals for patients, providers, physicians and suppliers. An overemphasis on compelling technologies, perhaps the most common strategic flaw, can weaken your neuromodulation program and impede sustainability. By integrating market opportunity and ensuring a comprehensive program is developed alongside technology adoption (Figure 1), remarkable clinical, financial and operational results can be realized. The global neurostimulation devices market is estimated to reach \$10.2 billion by 2024, with a compound annual growth rate of 12.7% from 2016 to 2024.⁵

Figure 1. Integrating core elements helps to achieve successful clinical and financial outcomes



References

- 1 Market Insights. Neurostimulation Devices. Decision Resources Group, part of Clarivate; 2020.
- 2 Vizient. *Technology Watch: Spine and Neuromodulation Technologies*. Volume 2, 2018.
- 3 Sg2. Advances in functional neurosurgery technology. 2019.
- 4 10 things to know about neuromodulation. North American Neuromodulation Society. Accessed December 18, 2020. https://neuromodulation.org/LinkClick. aspx?fileticket=4QF5qkX74Q0%3D&portalid=0
- 5 Neurostimulation devices market is estimated to reach \$10.2 billion by 2024; growing at a CAGR of 12.7% from 2020 to 2024. News release. MarketWatch. November 28, 2020. Accessed December 18, 2020. https:// www.marketwatch.com/press-release/neurostimulation-devices-market-isestimated-to-reach-102-billion-by-2024-growing-at-a-cagr-of-127-from-2020-to-2024-2020-11-28?siteid=bigcharts&dist=bigcharts&tesla=y



Vizient 2020 Innovative Technology recipients



he move to value-based care requires transformation in both our health care provider and supplier communities. However, it can be challenging to keep up with the rapid pace at which new technologies are developed and deployed. In addition, it can be difficult to vet these devices while remaining focused on delivering the highest level of care for your communities. This is particularly true this year as hospitals battle the COVID-19 pandemic.

To aid members in this endeavor, the Vizient Innovative Technology Program identifies solutions that can improve patient care or reduce the risk of harm to patients or providers, while simultaneously raising the standard of patient care and safety. The program also accepts submissions for products that contribute to overall improvement in a member's business model, not just those used in the direct care of a patient. Member resources include the Innovative Technology Online Forum; the Innovative Technology Exchange; a list of Innovative Technology contracts (available through the Vizient Catalog); and the Innovative Technology seal, a visual representation of innovative technology determination by member councils.

Member resources

Innovative Technology Online Forum

Our Innovative Technology

Online Forum, located on the Vizient public website, enables suppliers and providers to engage with each other and exchange information on the latest technologies. Products and services submitted are listed on the Innovative Technology Forum for six months. This service is available to any supplier.





Innovative Technology Exchange

Our annual Innovative Technology Exchange brings supplier and health care innovators together and offers an exclusive opportunity for deep conversations and powerful connections. Applications are taken annually for this event, which is focused on showcasing innovative products that address crucial needs. Following the Exchange, some supplier's products will be taken to member councils for new contract consideration. Existing suppliers may earn an Innovative Technology designation for technologies exhibited.

Innovative Technology contracts

Vizient uses a rigorous Innovative Technology review process to identify breakthrough innovations and offer contract opportunities, where appropriate. The review involves a thorough analysis by a council of member experts.

A product or service is deemed innovative when council members view it as a new or improved technology with known or expected incremental clinical or business benefits compared to other products available for sale in the U.S. A list of agreements added in 2020 to the Vizient Innovative Technology contracts in clinical preference item categories is shown in Table 1.



Results confirm Invia Liberty maintains set pressure at the wound bed and more efficiently manages fluid, and therefore innovates current standard of care.

Micro-Tech

Endoscopy USA

Source: Medela. Used with permission.

Surgical products

Contract number **Contract name** Effective date Category Supplier Kerecis MS8600 Kerecis Regenerative Biologic Medicine Feb. 1, 2020 Orthopedic products MS8610 Medela Negative Pressure Medical products Medela Feb. 1, 2020 Wound Therapy MS8790 **Cardinal Feeding Tubes & Sets** March 1, 2020 Medical products Cardinal Health 200 XR0620 **Bionix Radiation Therapy Tattoo** March 1, 2020 Operational **Bionix Development** support services Corporation XR0630 Bloxr Solutions Radiation Safety/ **Bloxr Solutions** March 1, 2020 **Diagnostic imaging Personal Protection** MS7889 Cleanis Patient Care Plastics and March 15, 2020 Medical products Cleanis Steel Products CE2829 Fujifilm Endoscopy Surgical products **Fujifilm Medical** April 1, 2020 Systems, U.S.A XR0444 Sheathing Technologies Ultrasound Aug. 15, 2020 **Diagnostic imaging** Sheathing Technologies

Nov. 1, 2020

Table 1. Agreements added to Innovative Technology contracts in 2020

Micro-Tech USA Ureteral Stone

Probe Covers

Management

MS3445

As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver highvalue care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

Contributors

Doug Beinborn, Associate Principal, Strategic Supplier Partnerships Olya Carter, Senior Compliance Clinical Manager Will Dordal, Senior Portfolio Executive Chad Giese, Associate Principal, Intelligence, Sg2 Cindy Jones, Principal Sherri Mason, Consulting Director Michael Meals, Associate Principal, Strategic Supplier Partnerships Chris Pagano, Consulting Director, Intelligence, Sg2 Melanie Stewart, Consultant Ryota Terada, Consulting Director, Intelligence, Sg2 Patrick Vega, Consulting Director Kate Zentner, Consulting Director, Intelligence, Sg2





vizient

290 E. John Carpenter Freeway Irving, TX 75062 vizientinc.com

© 2021 Vizient, Inc. All rights reserved.

The reproduction or use of this document in any form or in any information storage and retrieval system is forbidden without the express, written permission of Vizient.