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QUALITY IMPROVEMENT TOOL KIT FOR CONGENITAL CARDIOLOGISTS: BE READY FOR THE TRANSITION TO A VALUE-BASED HEALTHCARE ENVIRONMENT

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The field of Quality Improvement (QI) involves devising and tracking the impact of targeted interventions designed to improve healthcare services.[1] Occasionally, the term performance improvement is used interchangeably with QI; however, this term is used more frequently in managerial or administrative systems.[2] Over the past two to three decades, the QI field has evolved through four major stages.[3]

In the first stage, passive diffusion, there was an assumption that clinicians would take actionable information directly from the latest clinical research. In the second stage, there was the publication of guidelines and systematic reviews to effect behavior change among clinicians. In reality, it has been demonstrated that adults receive only about half the amount of recommended care.[4] There are likely several barriers to implementation, but because medicine is still perceived as an art (vs. a science), many clinicians continue to practice with limited reference to guidelines. In the third stage, there was the introduction of a more proactive-style total quality management from well-established industries. Several common QI methodologies were popularized during this stage including plan-do-study-act (PDSA) cycles, Lean and Six-Sigma.[5] Stage four focuses on systems re-engineering to design safer and more effective healthcare delivery systems, e.g., electronic health records or computerized physician order entry. There continues to be further QI evolution, which has taken lessons from other industries to develop high-reliability organizations, e.g., aviation.[6] Clinical decision support modules fall in the realm of systems re-engineering. The debut of the Watson Supercomputer by IBM, Inc., which processes structured and unstructured data fields using natural language processing, is an example of a large-scale artificial intelligence clinical decision support.[7]

Quality in healthcare is often described using Donabedian's conceptual model: structure, process, and outcome.[8] Structure refers to the attributes of the setting where care occurs and may include material or human resources, e.g., the proportion of registered nurses in a unit. Process denotes what is done to the patient. Process measures are straightforward to obtain (no risk-adjustment) and often used as surrogates for outcome measures, e.g., Beta-blocker use post-myocardial infarction. However, process measures must be reliable, valid, lack systematic bias, and most importantly, linked to outcomes. Validating process measures is a lengthy systematic exercise that is very resource intensive. Outcomes, i.e., what happened to the patient, represent clinical or patient-reported outcomes. Outcomes analysis requires robust risk-adjustment because of potential confounders, e.g., commonly used 30-day readmission rate. The context may affect all three components of this conceptual model.

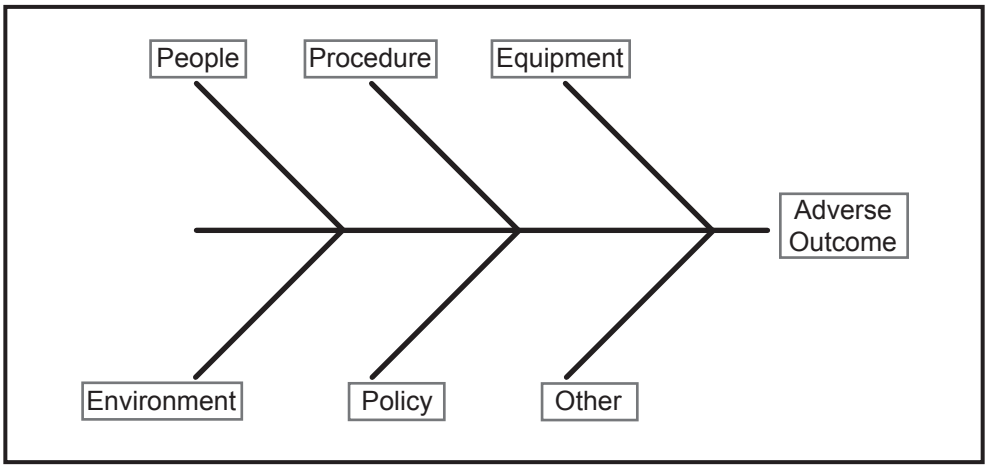

FIGURE 1 *Ishikawa Cause-and-Effect Diagram*[12]

Patient safety is a closely related concept of quality. Likewise, safety culture plays an important role in quality.[9] In some cases, it can be challenging to know where patient safety ends and quality begins. In general, adverse events or failure to adhere to recommended evidence-based therapies represent

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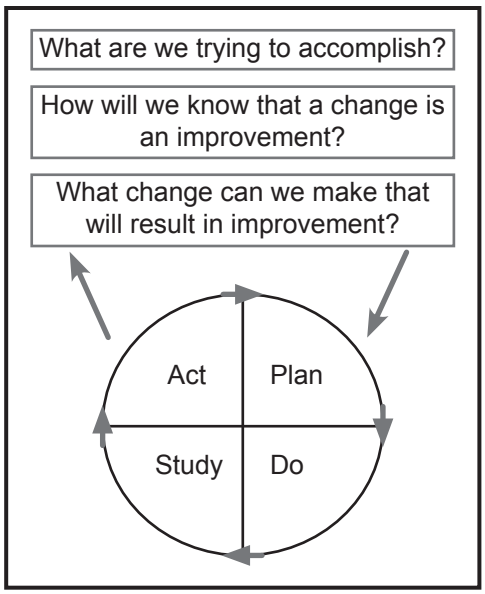

FIGURE 2 *PDSA Cycle also known as The Model for Improvement*[17]

patient safety issues.[10] With a focus on pediatric safety and eliminating harm, the Children's Hospitals' Solutions for Patient Safety Network applies high reliability concepts to more than 135 participating institutions.[11]

QI is proactive and prospective, while quality assurance (QA) is reactive and retrospective. A common application of QA is a review by an external organization, e.g., The Joint Commission. A root cause analysis is another example of a resource-intensive QA method to detect underlying system issues for a sentinel event. Use of an Ishikawa Cause-and-Effect diagram, also known as the Fishbone diagram (Figure 1), is a helpful tool to categorize specific factors, which may contribute to an adverse outcome.[12] Action plans can be prioritized to address specific failures according to the Ishikawa diagram.

QI effectiveness is based on sound interventions; however, it is the implementation plan that often distinguishes successful from failed interventions. For example, pulse oximetry screening for Critical Congenital Heart Disease is the *intervention*, while strategies for successful *implementation* include training of nursing staff, provider/parent education, and other key elements.[13] In general, barriers to the successful implementation of a QI initiative may include:[14]

1. Organizational factors: leadership, safety culture with a qualified staff, information systems, financial resources
2. Clinician factors: knowledge, skepticism, attitudes
3. Social context: patient attitudes, colleague behaviors, leader opinions
4. Economic/legal context: competing interests, reimbursements, regulations

In many cases, routine (practical) QI is a small-scale project (with no risks to patients) performed at the local level to improve the reliability of healthcare delivery. These simple pre/post intervention projects are not typically designed to be scientifically rigorous, e.g., to detect causation or generalizable beyond the local level. More advanced QI projects may involve several centers, data sharing, protocols, and may be conducted to test generalizability. Thus, as research projects, there is potentially some degree of risk to patients (usually limited to loss of confidentiality). These projects are more scientifically rigorous and may contribute to knowledge in the field. Formal QI research, which generally requires institutional review board approval, is often multi-center and may include randomization and/or increasing risks to patients. Formal QI research may make a causal inference and contribute to generalizable knowledge in the field.

The most common QI methodologies are rapid cycle PDSA, Six-Sigma and Lean.[5] The origin of the PDSA model evolved from Walter Shewhart (of Bell Telephone Laboratories) and later from W. Deming's work in industry.[15] The Institute for Healthcare Improvement promoted the use of rapid cycle PDSA as an effective tool for healthcare QI that is readily understandable by everyday practitioners.[16] This practical, efficient technique is an iterative process that applies small-scale interventions with rapid feedback and minimal resources. The steps are illustrated in Figure 2.

Data are often presented in a statistical process control (SPC) chart plotted with control limits (plus or minus three standard deviations of the mean). Figure 3 demonstrates an SPC chart looking at improved teamwork in the pediatric cardiac operating room following TeamSTEPPS (Team Strategies & Tools to Enhance Performance and Patient Safety) training using a TENTS (Team Events Assessment Non-Technical Skill) score.[18] Conventional statistical tools can be applied to determine the level of significance.

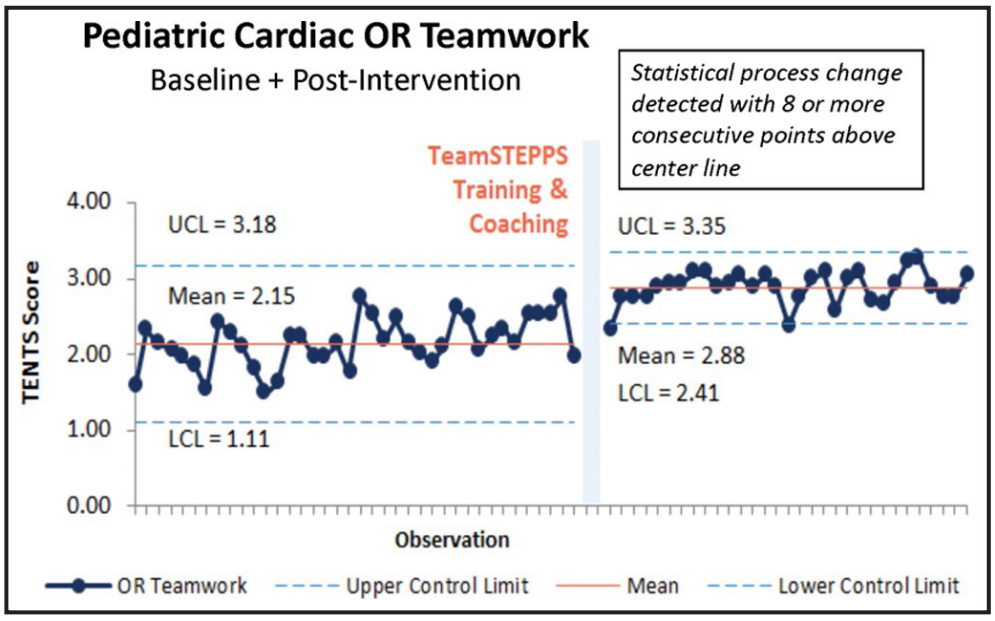

FIGURE 3 *Statistical Process Control Chart*[18]

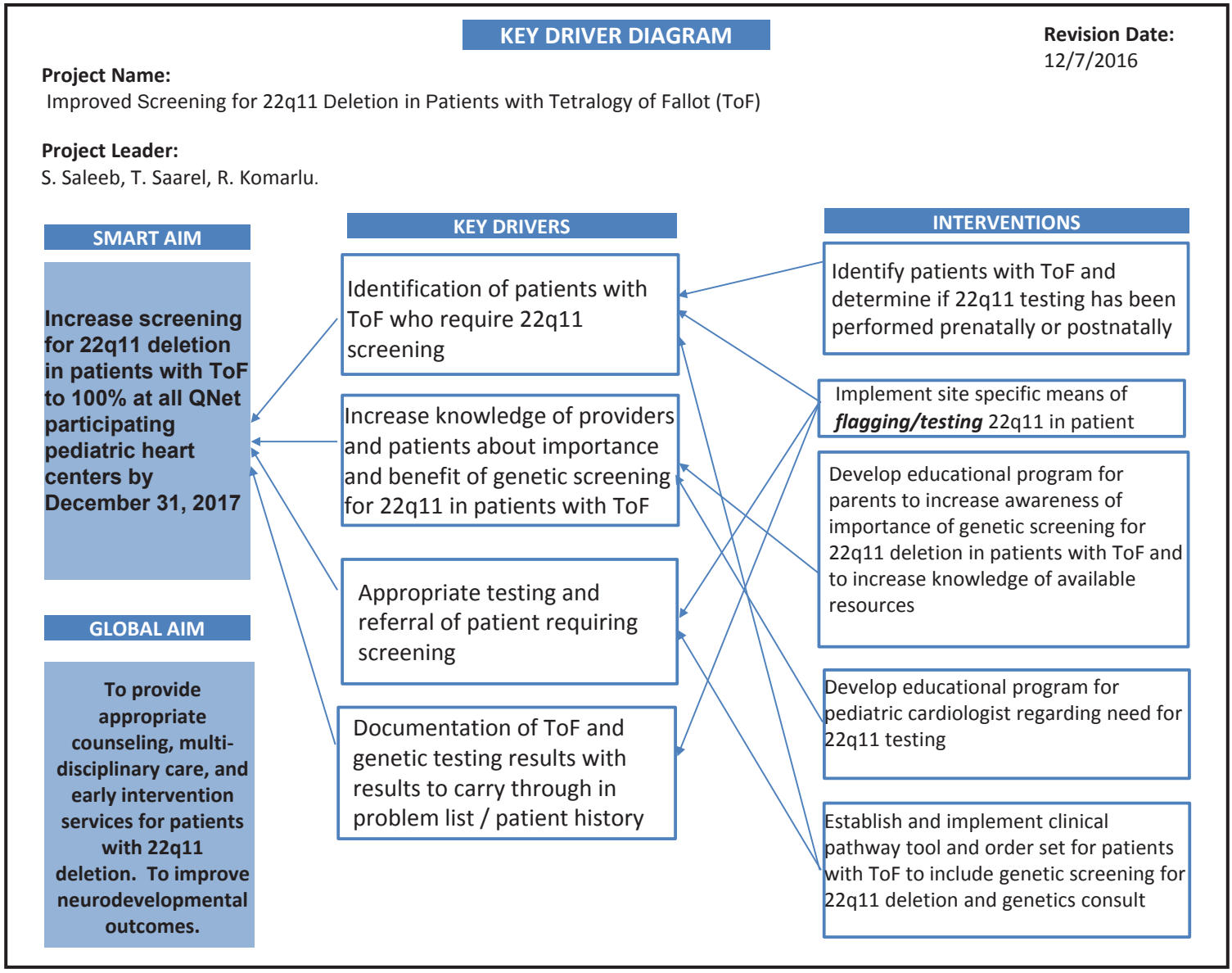

FIGURE 4 *Key Driver Diagram*[20]

A Key Driver Diagram (KDD) is an important tool used in conjunction with the Model for Improvement.[19] This visual tool helps to organize the key drivers which affect the desired outcome. Key drivers may be further refined into secondary drivers. Utilizing an Ishikawa diagram in the planning stage is a helpful way to explore potential drivers. Change initiatives are listed in relation to the drivers. In complex systems, each change initiative may affect more than one driver. The goal of the project is indicated by the use of SMART and global aim statements. A SMART aim is traditionally defined as specific, measurable, achievable, realistic, and timely. An example of a KDD to improve screening for chromosome 22q11 microdeletion in Tetralogy of Fallot is presented in Figure 4.[20]

Six-Sigma, introduced by Motorola, Inc., in the 1980s, is a systematic data-driven improvement methodology used to decrease process variation.[21] A multistep process (Define, Measure, Analyze, Improve, Control) is employed to identify defects to achieve an error rate of only 3.4 defects per million opportunities, i.e., Six-Sigma.[5] Using this framework prevents premature conclusions for complex processes that may have a variety of inputs. A thorough quality control process audits the system to ensure that the defect occurrence rate meets the desired frequency.

Another popular methodology, Lean, originated with Toyota, Inc., in the 1950s.[22] Lean, which means the opposite of waste, strives to eliminate non-value-added (i.e., unnecessary) activities in seven areas, Table 1. An eighth category, human potential, is sometimes included, e.g., underutilizing an employee's skills or talents.

Listing the basic elements in a systematic framework, e.g., suppliers, inputs, process, outputs, customer, outlines the scope of the project.[24] With this information, the current system is diagrammed on a value stream map (VSM). An example of a

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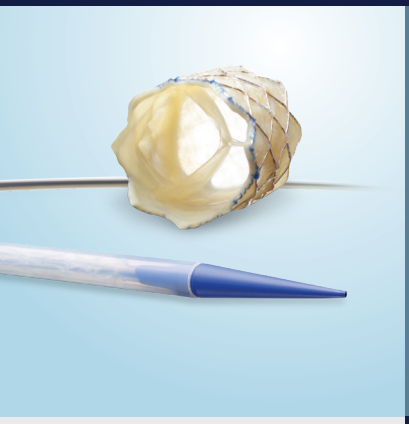

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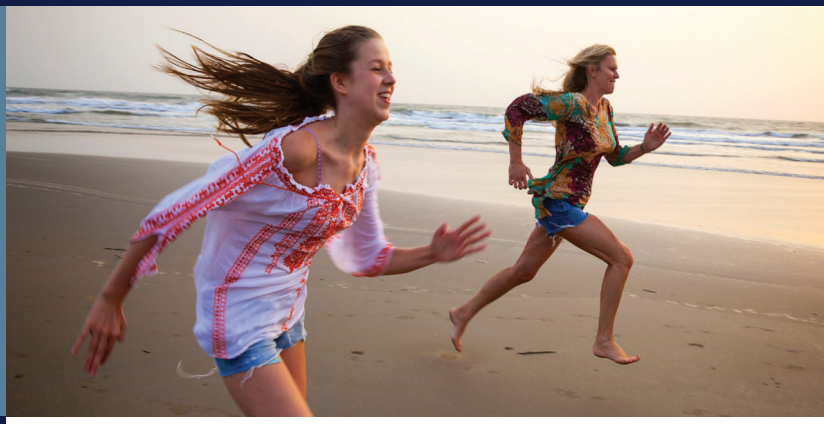

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Category	Example
Overproduction	Using more medications than required
Motion	Unnecessary motion of staff
Transportation	Uneconomical movement of patients, medications, labs or supplies
Delay	Waiting time for patients, physicians, and staff
Inventory	Inefficient inventory practices, e.g., cardiac catheterization lab supplies
Overprocessing	Redundant practices or procedures
Defects	Having to call the family to repeat a lab test because the order was incorrect

TABLE 1 *Non-Value-Added Activities in Healthcare*[23]

perioperative VSM for a cardiac implant electronic device is illustrated in Figure 5. Cycle time (CT) indicates the length of time it takes for each step to be completed. Wait time is shown in between process steps (the upper aspect of the timeline). Option indicates the percentage of time a step is required. Inventory build-up is shown in between process steps. Each process step includes varying degrees of value-added activities.

Activities are categorized from the customer perspective (i.e., patient) as non-value-added, e.g., provider time with the electronic medical record, necessary non-value-added, e.g., multiple patient identification rechecks or value-added, e.g., provider time with the patient. The proposed changes are then charted on a VSM as targets for process improvement. As complementary tools, Lean and Six-Sigma are often used simultaneously for process improvement.[24] Management should emphasize process improvement rather than merely pushing staff for better performance. Lean principles have been applied to various healthcare settings for process improvement.[25]

TRANSITION TO VALUE IN HEALTHCARE

For more than a decade, increasing value for patients (health outcome achieved per dollar spent) remains a central theme of health care reform.[26, 27] Numerous provisions within the Affordable Care Act target this goal.[28] These include a transition to value-based purchasing, improved quality measurement/reporting and innovative healthcare delivery models, e.g., patient-centered medical home (PCMH) and accountable care organizations (ACO). These innovative payment models shift some financial risks to providers to control costs and, in effect, retain some features of managed care.[29]

In 2015, the Department of Health and Human Services (DHHS) set a goal that stated that by 2018, 90% of all Medicare fee-for-service payments be tied to quality or value.[30] Accordingly, the Centers for Medicaid and Medicare Services (CMS), the dominant payer for healthcare services in the United States, has developed a strategy to reward providers for quality outcomes over volume.[31] With an emphasis on value, the Medicare Access and Children's Health Insurance Program Reauthorization Act (MACRA) was passed in a bipartisan fashion in 2015.[32] MACRA eliminated the sustainable growth rate Medicare payment formula and is not contingent on any specific payor system, e.g., government or commercial, nor is it specialty specific.

MACRA introduced a new physician payment system called the Quality Payment Program (QPP) which effectively ties reimbursement to participation in either a merit-based incentive payment system (MIPS) or other alternative payment models (APM).[33] The QPP will be phased in over more than a decade, allowing participating providers to avoid up to a 9% downside financial risk and to earn additional incentive payments. Merit-based incentive payments will be based on composite weighting in various areas such as reporting quality measures in a National Cardiovascular Data Registry (NCDR®), clinical practice improvement activities, advancing care information (formerly known as "meaningful use with an electronic health record") and cost-saving. CMS started to modify future payments in 2019. Nearly all eligible physicians participating in MIPS scored above the target threshold and received a bonus based on their performance in 2018.[34]

As pediatric specialists, Medicare does not typically cover our patients except for end-stage renal disease or kidney transplants; however, commercial payers often calculate rates based on Medicare tables. The DHHS has also recommended state Medicaid and commercial payers adopt value-based purchasing arrangements.[35] In 2012, Comprehensive Primary Care Plus, a CMS national advanced primary medical home model, launched an APM involving commercial payers and Medicaid.[36] Participation in any APM such as an ACO, PCMH, or bundled payment requires quality metric reporting. Coordinated efforts in pediatric quality measurement continue to evolve, but significant challenges remain, which include a lack of evidence-based guidelines, limited funding for quality metric development, and various state reporting practices.[35] The American College of Cardiology Adult Congenital and Pediatric Cardiology

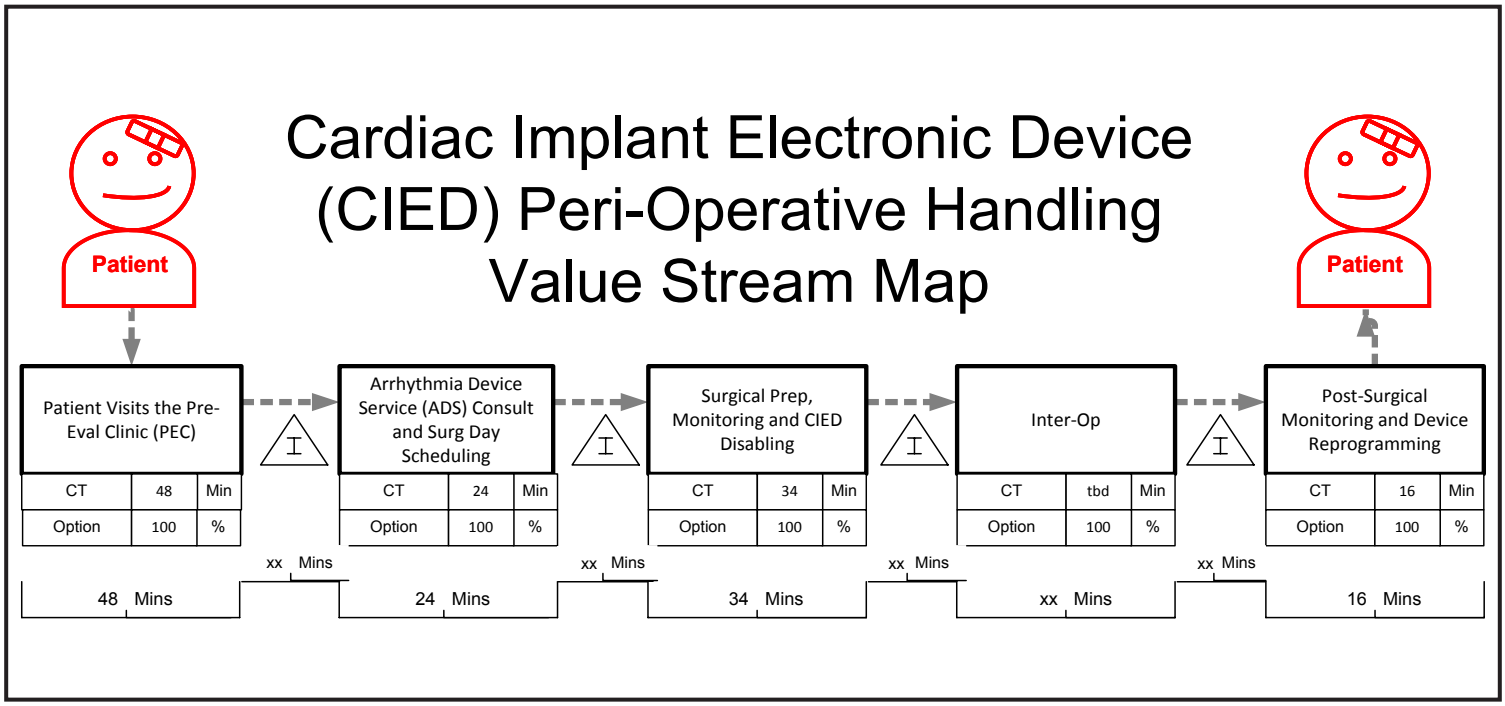

FIGURE 5 *Value Stream Map (Courtesy of Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality, Baltimore, MD).*

I = *Inventory* CT = *Cycle Time*

Quality Network has made significant advances in our field to include performance measures in Ambulatory Pediatric Cardiology.[37] Currently, children's hospitals and pediatricians may qualify for incentive payments by adopting Stage 2 and 3 Meaningful Use as defined by the Health Information Technology for Economic and Clinical Health Act.

In adult coronary artery bypass graft (CABG) surgery, initial experience with bundled payment, a type of risk-sharing APM, has been gathered.[38] In 2016, CMS announced that bundled payments for patients with acute myocardial infarction (AMI) treated with percutaneous coronary intervention or CABG surgery are in effect.[39] Hospitals will be at greater financial risk if their readmission rate following AMI is higher than average. Advanced imaging, e.g., stress myocardial perfusion imaging for Coronary Artery Disease, will require providers to use clinical decision support to consult appropriate use criteria in order to be reimbursed.[40]

The transition to value-based health care represents a fundamental shift where payors demand transparency, accountability, and increased efficiency from providers. Adoption of alternative payment models in pediatrics has been slow in part due to varied state Medicaid management.[41] With the fragmented nature of public and private payors in pediatric care, there is a lack of coordinated policy in this area.[42] Pediatric specialists need to be familiar with the broader transition to value-based health care. MACRA provides a roadmap to help various stakeholders navigate the value-based healthcare landscape. Familiarity with standard QI tools will become essential in a value-based healthcare environment.[43]

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REFERENCES

1. Agency for Healthcare Research and Quality. Uses of Quality Measurement. https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/chtoolbx/uses/index.html#quality. Published 2018. Accessed April 15, 2019.
2. Devers K. The state of quality improvement science in health: What do we know about how to provide better care. Urban Institute. Quick Strike Series Web site. https://www.rwjf.org/en/library/research/2011/11/the-state-of-quality-improvement-science-in-health.html. Published 2011. Accessed April 29, 2019.
3. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Aff (Millwood). 2005;24(1):138-150.
4. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. N Engl J Med. 2003;348(26):2635-2645.
5. Varkey P, Reller MK, Resar RK. Basics of quality improvement in health care. Mayo Clin Proc. 2007;82(6):735-739.
6. Chassin MR, Loeb JM. The ongoing quality improvement journey: next stop, high reliability. Health Affairs. 2011;30(4):559-568.

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7. Castaneda C, Nalley K, Mannion C, et al. Clinical decision support systems for improving diagnostic accuracy and achieving precision medicine. J Clin Bioinforma. 2015;5:4.
8. Donabedian A. The quality of care. How can it be assessed? JAMA. 1988;260(12):1743-1748.
9. Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a culture of safety as a patient safety strategy: a systematic review. Annals of Internal Medicine. 2013;158(5_Part_2):369-374.
10. Institute of Medicine (US) Commmittee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC): National Academies Press (US); 2001.
11. Children's Hospitals' Solutions for Patient Safety. Children's Hospitals' Solutions for Patient Safety. https://www.solutionsforpatientsafety.org/. Published 2019. Accessed September 3, 2019.
12. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign). Rockville (MD)2008.
13. Kemper AR, Mahle WT, Martin GR, et al. Strategies for implementing screening for critical congenital heart disease. Pediatrics. 2011;128(5):e1259-1267.
14. Grol R, Wensing M. Effective implementation of change in healthcare: a systematic approach. In: Improving Patient Care: The implementation of change in health care.2013:40-63.
15. Deming WE. Out of the crisis. Cambridge, Mass.: Massachusetts Institute of Technology, Center for Advanced Engineering Study; 1986.
16. Berwick DM. Developing and testing changes in delivery of care. Ann Intern Med. 1998;128(8):651-656.
17. Langley GJ. The improvement guide : a practical approach to enhancing organizational performance. 2nd ed. San Francisco: Jossey-Bass; 2009.
18. Willis TS, Yip T, Brown K, Buck S, Mill M. Improved Teamwork and Implementation of Clinical Pathways in a Congenital Heart Surgery Program. Pediatr Qual Saf. 2019;4(1):e126.
19. Institute for Healthcare Improvement. Driver Diagram. Tools Web site. http://www.ihi.org/resources/Pages/Tools/Driver-Diagram.aspx. Accessed September 3, 2019.
20. American College of Cardiology National Cardiovascular Data Registry. ToF Project Key Driver Diagram. Quality Improvement for Institutions Web site. https://cvquality.acc.org/docs/default-source/ACPC/key-driver-diagram-acc-tof_12-7-16.pdf?sfvrsn=224a8dbf_0. Published 2016. Accessed September 3, 2019.
21. Chassin MR. Is health care ready for Six Sigma quality? The Milbank Quarterly. 1998;76(4):565-591.
22. Womack JP, Jones DT, Roos D. The Machine That Changed the World: The Story of Lean Production. 1st Harper Perennial Ed ed1991.
23. Zidel TG. A Lean toolbox: Using Lean principles and techniques in healthcare. J Healthc Qual. 2006;28(1):W1-7.
24. George ML. The lean Six Sigma pocket toolbook : a quick reference guide to nearly 100 tools for improving process quality, speed, and complexity. New York ; London: McGraw-Hill; 2005.
25. Mazzocato P, Savage C, Brommels M, Aronsson H, Thor J. Lean thinking in healthcare: a realist review of the literature. Qual Saf Health Care. 2010;19(5):376-382.
26. Porter ME. A strategy for health care reform--toward a value-based system. N Engl J Med. 2009;361(2):109-112.
27. Porter ME, Teisberg EO. Redefining health care: creating value-based competition on results. Harvard Business Press; 2006.
28. Patient Protection and Affordable Care Act. Pub L. No. 111-148, HR 3590. In. 111th Congress (March 23, 2010). Vol 124.
29. Kaiser Family Foundation. Summary of the Affordable Care Act. https://www.kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/. Published 2019. Accessed April 15, 2019.
30. Burwell SM. Setting value-based payment goals—HHS efforts to improve US health care. N Engl J Med. 2015;372(10):897-899.
31. Burd C, Brown NC, Puri P, Sanghavi D. A Centers for Medicare & Medicaid Services Lens Toward Value-Based Preventive Care and Population Health. Public Health Rep. 2017;132(1):6-10.
32. CHIP Reauthorization Act of 2015, Pub L(2015).
33. Centers for Medicaid and Medicare Services. Quality Payment Program. https://qpp.cms.gov/. Published 2019. Accessed April 15, 2019.
34. Verma S. Quality Payment Program Releases 2017 Physician Compare Data and Sees Increases in Clinician Participation Rates and Success for 2018. Centers for Medicare & Medicaid Services. https://www.cms.gov/blog/quality-payment-program-releases-2017-physician-compare-data-and-sees-increases-clinician. Published 2019. Accessed September 30, 2019.
35. Adirim T, Meade K, Mistry K, et al. A New Era in Quality Measurement: The Development and Application of Quality Measures. Pediatrics. 2017;139(1).
36. Centers for Medicaid and Medicare Services. Comprehensive Primary Care Initiative. https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus. Published 2019. Accessed September 3, 2019.
37. Chowdhury D, Gurvitz M, Marelli A, et al. Development of Quality Metrics in Ambulatory Pediatric Cardiology. J Am Coll Cardiol. 2017;69(5):541-555.
38. Engelman DT. Surgical economics: MACRA, MIPS, and bundles-Lessons learned in the first 3 years of a coronary artery bypass grafting alternative payment model. J Thorac Cardiovasc Surg. 2017;153(2):381-384.
39. Advisory Board. CMS launches three new mandatory bundled payment models. https://www.advisory.com/daily-briefing/2016/12/21/cms-launches-two-new-mandatory-bundled-payment-models. Published 2016. Accessed April 15, 2019.
40. Advisory Board. What the FY 2017 MPFS final rule tells us about imaging CDS. https://www.advisory.com/

research/imaging-performance-partnership/the-reading-room/2016/11/cds-medicare-recent-rule. Published 2016. Accessed April 15, 2019.
41. Perrin JM, Zimmerman E, Hertz A, Johnson T, Merrill T, Smith D. Pediatric Accountable Care Organizations: Insight From Early Adopters. Pediatrics. 2017;139(2).
42. Pasquali SK, Dimick JB, Ohye RG. Time for a More Unified Approach to Pediatric Health Care Policy?: The Case of Congenital Heart Care. JAMA. 2015;314(16):1689-1690.
43. Adusumalli S, Fiorilli PN, Saybolt MD. Educating the MACRA-Ready Cardiologist: Developing Competencies in Value-Based Cardiovascular Medicine. J Am Coll Cardiol. 2017;70(5):680-683.

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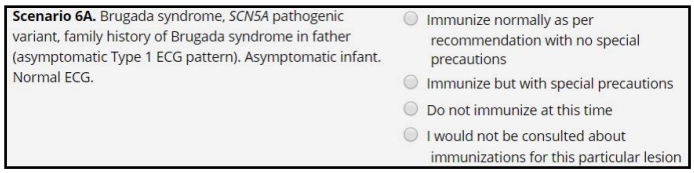
Survey On Childhood Immunization Recommendations In Congenital Heart Disease

WHO Medical professionals (nurses, doctors) who work in pediatric cardiology
WHAT 5 minute survey - respond only once
WHY Conducting a survey to understand the advice that medical professionals give regarding immunizations in pediatric cardiology patients

Sample Question



Standard immunizations are generally scheduled for the first 6-8 weeks of life, a time when some congenital heart patients may present with symptoms. We aim to survey a large group of medical professionals (nurses, doctors) who work in pediatric cardiology about their practice to understand the current practice.

In order to gain a better understanding of the assessment of the risk of immunizations with certain lesions by pediatric cardiology medical professionals, we are studying the approach to hypothetical scenarios which present commonly and may impact the decision to proceed with the first scheduled immunization.

If you would ordinarily be consulted for immunization advice in pediatric patients with structural and/or genetic heart disease that present in infancy (eg LVOT obstruction, cardiomyopathy, VSD), we would be grateful if you would complete our short survey.

Share the Survey

https://rc.bcchr.ca/redcap/surveys/?s=YMFH9R7AKK

Thank you,

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University of British Columbia
Vancouver, CANADA

STATE OF THE HEART BY HAIDER WARRAICH

WRITTEN BY
Virginia Dematatis

"The entire medical team was convinced he didn't have long to live, maybe a few months at best. Everyone nodded in agreement one final time, like a football team about to take the field or a group of paratroopers about to leap from the side of a plane. As we filed into his room and after the customary introduction ...I started talking slowly."

"You have recovered well from your infection, the one thing we cannot help you recover from is your heart failure." "Wait—what—I have heart failure?" he asked abruptly. Startled, he looked to his wife, who started crying. "He has heart failure? No one told us he has heart failure! What is heart failure?" she wailed.

In the first few pages of his book, *State of the Heart*, Haider Warraich recounts his shock and surprise at meeting a new patient that had been living with heart failure for almost two decades while under the care of a cardiologist, with little knowledge of his true condition. By writing this book, Warraich sets out to answer the questions posed to him that day. But, he also does so much more! He draws us into the intriguing world of heart disease by exploring its history, politics and future.

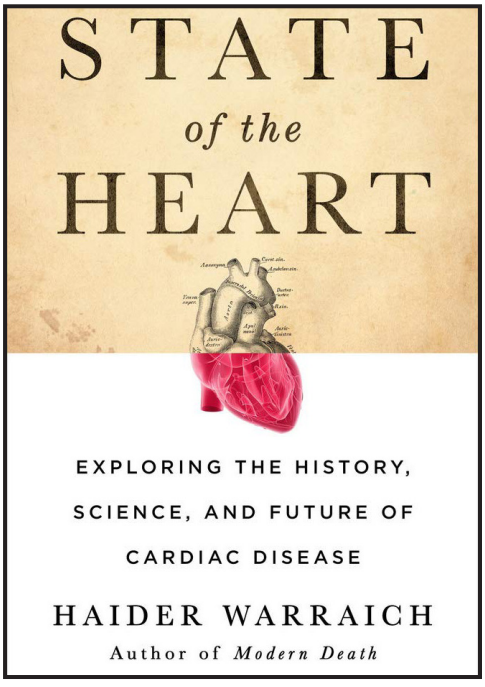
Early in the book, Warraich gives the reader a captivating description of the history of cardiac disease. He writes that the ancient Egyptians were ahead of many other civilizations in understanding the "centrality of the heart in human circulation". They thought it circulated blood, as well as air, bile, feces, semen, and "the spirits and the soul". Ancient papyrus inscriptions detailed symptoms of an early death for those patients with illness of the "cardia" by pointing to: pain in the arms, chest and side of the cardia (angina), the weakening or "kneeling of the heart" (heart failure) and episodes where, "... the heart trembles, has little power and sinks" (symptoms of ventricular fibrillation). But, since these ancient texts were either discounted or hidden from the view of early Western Civilization, other theories about the heart were more widely accepted.

Galen, a Greek physician and a disciple of Hippocrates, promoted the notion that an imbalance of the four humors—black bile, blood, yellow bile and phlegm—explained all disease and it was this theory that gained a widespread acceptance that persisted for centuries. Not until an English physician, William Harvey, appeared on the scene in the seventeenth century, did it die out. Using dissection and experimentation, Harvey proved that all the blood in the body was traveling constantly in a loop over and over again being "driven by the heart, the captain of this crazy train".

After giving the reader some historical perspective on cardiac disease, Warraich launches into a truly ambitious discussion of the science and future of heart disease. He details the myriad of factors that cause and impact the development of cardiac disease, such as: the role of inflammation in the development of arterial plaque, high blood pressure, diabetes and obesity – not to mention the role of smoking, high cholesterol, and stress. He also discusses the fascinating story of how modern day treatments such as the use of statins, balloons, stents, pacemakers, Left Ventricular Assist Devices, mechanical pumps and heart transplants came to be.

While describing the development and use of these treatments, he also occasionally peppers in human interest stories, describing both patient encounters and the rivalry between Michael DeBakey and Denton Cooley, whereby "... in cahoots with one of Denton's assistants, Cooley "commandeered" one of the artificial hearts from DeBakey's lab", transplanted it into a patient and took credit as the pioneer

Haider Warraich, MD, author of State of the Heart and Modern Death: How Medicine Changed the End of Life



of the artificial heart transplant operation. Research rivalries are another subject of Warraich's focus. He explores not only the politics of how research dollars are spent, whether on drugs versus devices, but also on the patients who have been included or excluded from studies. For example, early cardiac studies were focused on men and very little was known about heart disease in women until the National Institutes of Health adopted a policy to increase enrollment of women in clinical trials in 1986. The list of topics the author explores goes on and on and his fascination with his subject matter is more than evident. He covers such a broad range of topics that sometimes the reader is a bit overwhelmed. However, he writes so beautifully, that it is hard to put the book down and there is always more to learn in the next chapter!

For instance, besides exploring the history, science and future of cardiac disease, Warraich discusses the role of the physician in treating cardiac disease. He offers salient advice about how physicians can help patients learn to accept, live with and die of heart disease. In contrast to the lack of information given the patient with heart failure in the opening scene of the book, he encourages cardiologists to be completely honest with patients about their condition and their options. He suggests it is the role of the cardiologist to help patients gain a sense of control by referring to their acceptance of cardiac disease and their subsequent need for self-care (diet, exercise, etc.) as an "unwanted job" that they must now perform. He also promotes the idea that patients should be given choices and control in the progression of their treatment for heart disease. For instance, he thinks they should be told that near the end of life, they can choose to have their defibrillators deactivated or ask their physician to turn off the heart pump that sustains them. By treating patients as partners in the treatment of cardiac disease, he believes patients can find, if not hope, a sense of power as they confront their formidable adversary.

Finally, one of the most captivating aspects of the book is that it provides an important lesson for readers about the history of scientific revolutions. Using cardiac disease as his focus, he explains how new ideas are developed, shared, ignored, accepted or rejected, refined and adopted, then finally discarded as false, in favor of new theories. He also discusses the role of politics, the drug industry, the media and the growing anti-intellectualism that pervades American society and how all these factors impact the direction of the current treatment and research efforts to combat heart disease. Ultimately, Warraich predicts, "... perhaps half of this book will one day be proven false." Until that time, *State of the Heart*, is a book not to be missed!

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MEDICAL NEWS

COMPILED BY
Kate Baldwin
Tony Carlson

MEDTRONIC EVOLUT TAVR SYSTEM RECEIVES EXPANDED INDICATION APPROVAL TO TREAT SYMPTOMATIC SEVERE AORTIC STENOSIS PATIENTS AT LOW RISK FOR SURGICAL MORTALITY

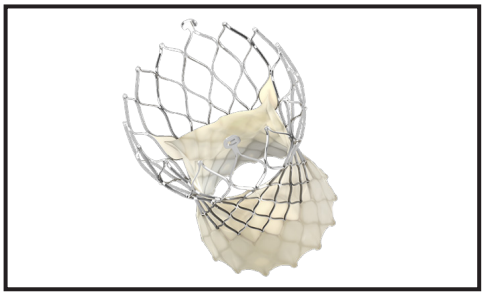
Expanded TAVR Indication Appraisal of Younger, More Active Patients Signals Groundbreaking Shift in the Future Treatment of Heart Valve Disease

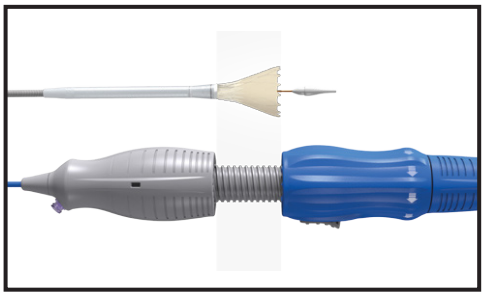
GLOBE NEWSWIRE - Medtronic plc (NYSE:MDT) announced *US Food and Drug Administration (FDA)* approval of the Evolut™ Transcatheter Aortic Valve Replacement (TAVR) system for patients with symptomatic severe native aortic stenosis who are at a low risk of surgical mortality. The low-risk patient population is the final surgical risk category to be approved for this minimally invasive alternative to open-heart surgical valve replacement (SAVR) and includes patients who may be younger and more active than higher-risk patients.

The expanded indication approval is based on randomized clinical data from the global, prospective, multi-center Evolut Low Risk Trial, which evaluated three valve generations (CoreValve™, Evolut™ R, and Evolut™ PRO valves) in more than 1,400 patients. The data showed TAVR to have an excellent safety profile and be an effective treatment option in low-risk patients with shorter hospitals stays and improved quality-of-life scores compared to SAVR. In addition to a significantly lower rate of the composite of all-cause death or disabling stroke with TAVR at 30 days, the Evolut TAVR system demonstrated superior hemodynamic (blood flow) performance with significantly lower mean aortic valve gradients and larger EOAs (effective orifice area) compared to surgery – important factors for more active patients. The rate of new pacemaker implantation and residual aortic regurgitation was higher in the TAVR group.

"The majority of my patients want a replacement valve that's going to minimize the risk of death, stroke, and other cardiovascular events during the procedure and allow them to leave the hospital faster and recover sooner. In patients appropriate for a biologic valve, that option is going to be TAVR," said Michael Reardon, MD, Cardiothoracic Surgeon at Houston Methodist DeBakey Heart & Vascular Center, Principal Investigator and Senior Author of the Evolut Low Risk Trial. "With the low-risk approval, risk stratification for TAVR treatment is becoming obsolete and heart teams will likely need to assess treatment options based on anatomical characteristics, concomitant risk factors, and also patient preference."

The Evolut TAVR System, with its industry-leading hemodynamics, allows for improved heart function that helps many patients resume their pre-aortic stenosis activity levels. The valve is engineered with a self-expanding nitinol frame that conforms the replacement valve to the native annulus with consistent radial force and includes an external tissue wrap that increases surface area contact with native anatomy for enhanced valve sealing. The CoreValve Evolut TAVR platform leads the industry in longer-term data, reporting durability data out to eight years with the Italian Registry.





"Low-risk patients were younger and healthier than those patients enrolled in our prior studies, and were better able to weigh the risks and benefits of surgery or TAVR based on their value preferences," said Jeffrey J. Popma, MD, Director of Interventional Cardiology at Beth Israel Deaconess Medical Center in Boston, and Co-Principal Investigator in the Evolut Low Risk Trial. "It is our impression that patients will now be able to make a choice of the method of aortic valve replacement based on an informed risk-benefit discussion with their heart team."

Severe aortic stenosis affects approximately 165,000 low-risk patients per year in the US, Western Europe and Japan, occurring when the aortic valve becomes diseased (stenotic). The valve leaflets become stiff and thickened and have difficulty opening and closing, making the heart work harder to pump blood to the rest of the body and, therefore, impacting an individual's daily activities. If left untreated, patients with severe aortic stenosis can die from heart failure in as little as two years.

"This expanded indication means that physicians and patients will have more freedom to choose the right aortic valve replacement procedure based on each patient's health and quality-of-life goals, which may vary based on their age, frailty and anticipated daily activity," said Pieter Kappetein, MD, PhD, Vice President and Chief Medical Officer for the Structural Heart and Cardiac Surgery businesses, which are part of the Cardiac and Vascular Group at Medtronic. "This is an exciting time for patients and the clinical community alike as we now have an aortic valve replacement technology clinically demonstrated to be well-suited for the thousands of new patients who seek a less invasive treatment option that helps them get back to active living."

With the approval, the Evolut TAVR platform is now indicated in the US for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low).

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

For more information visit www.medtronic.com.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

ACHA ANNOUNCES FUNDING OF ORGANIZATION'S INAUGURAL RESEARCH GRANTS

The Six Projects Focus on Important Topics Surrounding Adult Congenital Heart Disease

The *Adult Congenital Heart Association (ACHA)* has funded six research grants to advance the science of Congenital Heart Disease (CHD) in adults. With the advent of this new ACHA program, the organization aims to improve the lives of CHD patients and future generations in partnership with medical professionals.

"If it were not for medical research and innovation, Adult Congenital Heart Disease (ACHD) would not exist as a field," says Jamil Aboulhosn, MD, FACC, FSCAI, ACHA Medical Advisory Board Chair, noting that in the textbooks of the early 20th century, there was barely a mention of CHD. "There are so many questions that are still unasked and unanswered in this field and it is imperative that we do our part to move things forward, and that can only happen through research and innovation."

ACHA is the only nonprofit in the country dedicated solely to the unique needs of the 1.4 million adults born with heart defects, the most common birth defect in the United States, diagnosed in one in 100 births. These adults are living longer today with one of the many varying types of congenital heart defects that range among simple, moderate, and complex—which was not a reality 20 years ago.

"ACHA funding research grants is a watershed moment for our organization," says ACHA President & CEO Mark Roeder. "A key goal of our Vision 2025 plan for the future was moving into direct research funding. We are thrilled that with the help of our Medical Advisory Board, we were able to move forward in this direction and to announce our six research grants. We look forward to momentum building in ACHA's research program and awarding an increasing number of grants in the years ahead."

And as a parent of an adult CHD patient told ACHA, "Research is so important because it has improved and lengthened the lives of many CHD patients in the past and can continue to do even more into the future."

The following two-year ACHD provider grants, jointly funded by ACHA and the Meil Family Foundation, were funded at $32,500 per year:

- Patient-Centered Research Models to Diagnose and Treat Anxiety Disorders in Adult Congenital Heart Disease: A Pilot Pragmatic Clinical Trial, Matthew Lewis, MD, MPH, Schneeweiss Congenital Heart Program, Columbia University Medical Center, New York, NY
- Peer Coaching Adaptive Self-Management Interventions for Young Adults with Congenital Heart Disease (CHASM IN ACHD), Richard A. Krasuski, MD, Adult Congenital Heart Disease Center, Duke University, Durham, NC
- Improving Pregnancy Outcomes in Women with Tetralogy of Fallot, Valeria E. Duarte, MD, Boston Adult Congenital Heart Disease Program, Boston Children's Hospital

In addition, jointly funded by ACHA and Project Heart, the following three fellows received one-year grants of $10,000 each:

- Strategies for the Successful Adaption of the PRISM (Promoting Resilience in Stress Management) Intervention to Promote Resilience for Patients with Adult Congenital Heart Disease, Jill M. Steiner, MD, MS, Division of Cardiology, University of Washington, Seattle
- Cognitive Impairments in Adult CHD Patients, Carla P. Rodriguez-Monserrate, MD, Boston Adult Congenital Heart Disease Program, Boston Children's Hospital
- Serial C-Reactive Protein Measurements to Predict Clinical Events in Adults with Congenital Heart Disease, Nael Aldweib, MD, Boston Adult Congenital Heart Disease Program, Boston Children's Hospital

These first projects started July 1, 2019, and ACHA is eager to report on progress and outcomes, as well as continue to fund grants annually after this inaugural round.

"The ACHA research program will provide reliable funding for ACHD investigator and trainee initiated studies," says Arwa Saidi, MB, BCh, MEd, ACHA Medical Advisory Board Vice Chair. "These studies can produce the early data needed to design future large multi-center studies and subsequently guide and improve ACHD patient care."

MEETING CALENDAR

MARCH

23–25

HANDS-ON CARDIAC MORPHOLOGY

London, United Kingdom
https://www.rbht.nhs.uk/for-healthcare-professionals/education-and-training-0/royal-brompton-cardiac-morphology/hands-cardiac-morphology-course

25–28

PICS-AICS ISTANBUL

Istanbul, Turkey
http://picsistanbul.com/

28–30

ACC.20 TOGETHER WITH WORLD CONGRESS OF CARDIOLOGY

Chicago, IL, USA
https://accscientificsession.acc.org/Information-Pages/future-meetings

APRIL

16–18

EPIC-SEC

Atlanta, GA, USA
https://www.epicsec.org/

03–MAY 02

5TH NORTH AMERICAN ECHOCARDIOGRAPHY COURSE ON CONGENITAL HEART DISEASE

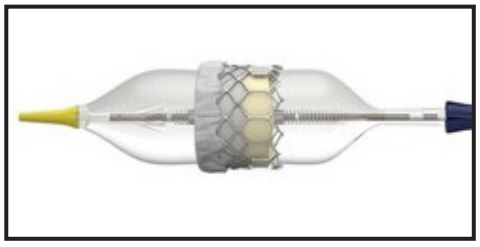
Palo Alto, CA, USA
https://stanford.cloud-cme.com/default.aspx?P=5&EID=34450

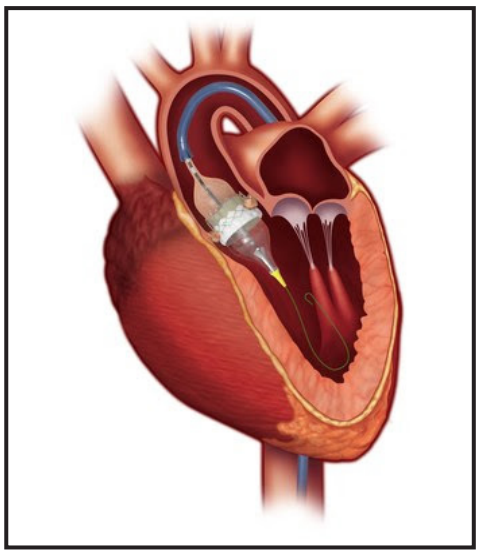
EDWARDS SAPIEN 3 TAVR RECEIVES FDA APPROVAL FOR LOW-RISK PATIENTS

Superior TAVR Valve Available for All Patients Diagnosed with Severe, Symptomatic Aortic Stenosis

PRNewswire-Edwards Lifesciences Corporation (NYSE:EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, announced *US Food and Drug Administration (FDA)* approval to expand use of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve systems to the treatment of severe, symptomatic aortic stenosis (AS) patients who are determined to be at low risk of open-heart surgery.

"The PARTNER 3 Trial demonstrated that low-risk patients treated with the SAPIEN 3 TAVR experienced extraordinary outcomes with 1% rates of death or disabling stroke at one year, a short length of stay and 96% discharged to home or self-care. SAPIEN 3 is the only valve to achieve superiority over surgery based on the prespecified primary endpoint," said Martin B. Leon, MD, Director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian/Columbia University Medical Center and Professor of Medicine at the Columbia University College of Physicians and Surgeons. "... FDA approval of SAPIEN 3 TAVR will expand access to this proven therapy, which should be considered the preferred treatment for the majority of low-risk severe AS patients." Leon is the national Co-Principal Investigator of the PARTNER 3 Trial.





The SAPIEN 3 TAVR's low-risk approval was based on data from the landmark PARTNER 3 Trial, an independently evaluated, randomized clinical trial comparing outcomes between TAVR and open-heart surgery. TAVR with the SAPIEN 3 system achieved superiority, with a 46% reduction in the event rate for the primary endpoint of the trial, which was a composite of all-cause mortality, all stroke and rehospitalization at one year. The data was presented at the American College of Cardiology's 68th Annual Scientific Session and simultaneously published in the New England Journal of Medicine.

"Severe AS is a debilitating disease that often goes undiagnosed and is undertreated," said Larry L. Wood, Edwards' Corporate Vice President, transcatheter aortic valve replacement. "This approval is a significant milestone and will allow all patients diagnosed with severe AS to be considered for TAVR based on their individual preferences and anatomical considerations versus traditional risk scoring."

The SAPIEN family of transcatheter heart valves have treated hundreds of thousands of patients worldwide since 2007, when the SAPIEN valve was first commercially approved in Europe. The SAPIEN 3 TAVR system builds on Edwards' decades of experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves. This low-risk approval covers the SAPIEN 3 and SAPIEN 3 Ultra valves in all sizes.

For more information, visit www.Edwards.com and follow us on Twitter @EdwardsLifesci.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements include, but are not limited to, statements by Dr. Leon and Mr. Wood and statements regarding expected product benefits and procedural outcomes, as well as increased patient access and treatment. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement.

Forward-looking statements involve risks and uncertainties that could cause results to

differ materially from those expressed or implied by the forward-looking statements based on a number of factors including but not limited to unexpected outcomes after more expanded clinical experience, unexpected changes or delays related to product supply, potentials for unexpected regulatory or quality developments, competitive dynamics, or unexpected delays or changes in patient access, litigation or clinician acceptance. These factors are detailed in the company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2018.

WEARABLE HEART MONITORS POSITIONED TO DETECT CARDIAC ANOMALIES IN ATHLETES

Currently Available Wearable Heart Rate Monitors Can Detect Possible Cardiac Issues Where a Life-Threatening Arrhythmia May Occur. InfoBionic Eyes Considers Their Technology as a Tool to Preemptively Diagnose Potential Life-Threatening Arrhythmias' in Athletes.

Sudden cardiac arrest (SCA) remains the leading cause of death in athletes, with recent studies showing the condition occurs more frequently than historical estimates.[1] Currently, there are more than 350,000 SCA-related deaths each year.[2] Stuart Long, CEO of InfoBionic, a digital health company that created the MoMe® Kardia Platform, confirms that remote cardiac monitoring that is FDA cleared for diagnosis of arrhythmias is the next logical step after an alert from an athletes' consumer wearable if confirmed by a physician.

According to a recent study by the University of Toronto, health screenings only identify young athletes who are at risk for cardiac arrest. However, more than 80% of cardiac cases are not discovered through systematic screening, researchers say. In fact, a significant problem with current screenings is that they exclude people whom are perceived healthy enough to safely engage in sports.[3]

A separate study sponsored by the National Institute for Health of 2,640 competitive soccer players featured data collected from 1974 until April 2004. From this population, there were 62 reported cardiac arrests; 24 were sudden death events; and 38 were resuscitated from cardiac arrest.[4] SCA is responsible for as many as 20% of all deaths in the US, according to the study, and "50% of sudden cardiac deaths are first cardiac events, meaning the patient did not know they had heart disease," said Dr. Robert J. Myerburg, a professor at the University of Miami, FL and a cardiologist.[5]

In the US, on average, one young competitive athlete dies suddenly every three days. Young athletes are twice as likely to experience SCA than young non-athletes. Exacerbating the issue is that no two heart conditions are the same, as demonstrated by several young professional athletes who have suffered in-competition cardiac events.[6,7]

Consumer wearable devices can detect worrisome irregular heartbeat in many cases. However, the perceived lack of accuracy is leading to skepticism around false positives. For example, devices that employ electrocardiogram-like technology can be hindered when an athlete's skin is wet, limiting or impairing the device's readout, especially impacted by artifact or noise during intense activity. Wearers who receive an alert through the watch's technology are instructed to consult a physician who can provide further diagnostics.[8]

A growing group of wearables such as watches are educational tools that help raise awareness but are non-medical grade devices and the findings are not qualified for use in the clinical setting. They show promise for early detection of health risks, including arrhythmia, though, meaning the potential of the technology is enormous even if they contain no medically valid data.[8]

"Available FDA-cleared technology for remote cardiac monitoring can provide valuable information almost immediately to the team physician, cardiologist or a first responder should a cardiac event occur on the field of play," Long said. "The devices are enabled to send detailed heartbeat data to the cloud, making it available on a doctors' mobile device. This technological advance can enable rapid diagnosis and intervention for patients experiencing cardiac events." These remote "full disclosure" monitors provide entire waveforms that include the onset and offset of an event, with a system capturing and analyzing the data 24/7 while making 100% of the data available to the physician on demand.

Advances in cardiac monitoring technology benefit the entire population, Long says. "As consumer-based technology continues to improve and mature they will become a solution for clinical use," Long said, "and further automate cardiac detection and streamline diagnosis in real time, unlike traditional monitors." For more information visit www.infobionic.com.

REFERENCES

1. David M. Siebert and Jonathan A. Drezner; "Sudden cardiac arrest on the field of play: turning tragedy into a survivable event"; Netherlands Heart Journal; Mar. 26, 2018; Web.
2. Young Athletes & Sudden Cardiac Arrest (SCA)"; Boston Scientific; May 11, 2019; Web.
3. Maureen McFadden; "Preventing sudden cardiac death in young athletes"; WNDU News; Apr. 13, 2018; Web.
4. Staff; "The Intriguing Problem of Arrhythmias in Competitive Athletes"; Science 2.0; Jan. 31, 2007; Web.
5. Wasfy, Hutter and Weiner. "Sudden cardiac death in athletes," NCBI. nlm. April 2016; Web.
6. K.C. Johnson; "Bulls and Lauri Markkanen are doing the right thing — and the smart thing — by taking a break"; Chicago Tribune; Mar. 28, 2019; Web.
7. Gabriel Baumgaertner; "Why Isn't Kenley Jansen Pitching This Weekend? An Amateur's Guide to the 'Irregular Heartbeat'"; Sports Illustrated; Sept. 7, 2018; Web.
8. Neergaard, Lauran. "Apple Watch May Spot Heart Problem, But More Research Needed." USA Today. 17 March 2019; Web.

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