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Endovascular TODAY

BUILDING A COMPREHENSIVE AORTIC CENTER

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BUILDING A COMPREHENSIVE AORTIC CENTER

A LETTER FROM FRANK R. ARKO III, MD

Dear physicians, health professionals, and hospital administrators,

Building a comprehensive aortic center presents a unique set of challenges to the delivery of cardiovascular care. Improving that quality of care should be the main goal of any comprehensive aortic program. Developing your institution's capabilities and reach is possible with a commitment to more efficient processes, improved data tracking and measurement, and training more effective teams.

Our field is resplendent with existing technologies and emerging innovations, the accumulated efforts of many professionals' commitment to patient care, deep wisdom, and hard work. But have we maximized the synergy between these innovations at all levels of health care delivery? Physician leaders, nurse leaders, and hospital administrators share the responsibility to organize, consolidate, and employ these advancements in a coordinated fashion.

To date, there has been little formal discussion of what best constitutes an aortic center program. To advance this discussion, a day-long summit of aortic program leaders and key members of the aortic team—seasoned aortic center physicians, nurses, and administrators—convened in San Francisco on February 28, 2015, to share their own program's learnings. This special issue of *Endovascular Today* captures key insights from that discussion, featuring decision points pivotal for any institution and successes implementing greater institutional capabilities. Participants included physicians, advanced care providers, nurses, and administrators from the following institutions:

- Aurora St. Luke's Medical Center (Milwaukee, Wisconsin)
- Intermountain Medical Center (Salt Lake City, Utah)
- PinnacleHealth Hospital (Harrisburg, Pennsylvania)
- Sanger Heart & Vascular Institute (Carolinas HealthCare System, Charlotte, North Carolina)
- Stony Brook University Medical Center (Stony Brook, New York)
- The Heart Hospital Baylor (Plano, Texas)

We explore challenges in implementing an aortic center at the institutional and individual levels. We recognize that challenges confronting one institution might not be a problem to another and that each institution's journey will likely be unique. But there are also common threads of success detailed in this issue:

- Taking an honest inventory of one's institutional capabilities and weaknesses is essential to turn them into strengths
- A focus on interdisciplinary collaboration and relationship- and team-building
- Training and education must be continuous and formative to improve the skill of all team members and identify future educational needs
- Outreach and marketing requires forethought, active planning, and timely execution
- Investments in process efficiencies are just as important as investments in tangible resources and supplies

We are privileged to belong to a vibrantly engaged part of medicine with an opportunity to embrace innovation and work closely with other specialties to take your institution to the next level. Developing an aortic center is certainly a worthwhile endeavor that can yield much for your health care team, your institution, your patients, and community at large.

Whether your institution is early in this process or fine-tuning an already robust program, I hope this supplement serves as a useful framework from which you can continue to build.

Sincerely,

Frank R. Arko III, MD
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WHY BUILD AN AORTIC CENTER?

BY FRANK R. ARKO III, MD, AND DENNIS R. GABLE, MD, RVT

The goal of developing an aortic center is to optimize patient outcomes by providing the highest-quality care possible, ensuring the right patient gets the right care in the right place at the right time. However, advancing an entire institution toward this goal can be a significant undertaking. It requires a team commitment to the shared vision of an aortic center, leadership, and a concerted effort in relationship building among all team members and stakeholders. Internally, achieving buy-in with administration and other team members is essential, allowing team planning and personnel training to be orchestrated. The circumspect financing and sage deployment of resources is equally important to a burgeoning aortic center and its community. Overall, improving patient care and satisfaction should be the overriding motivation for developing an aortic center, but there are other benefits to consider.

BENEFITS OF ESTABLISHING AN AORTIC CENTER

Developing an aortic center can strengthen an institution's ability to diagnose and treat all types of aortic pathology and to provide expert care in a system-based, collaborative, multidisciplinary team fashion (Table 1). This can position the center—and its health care system—as a regional leader and an attractive vehicle of high-quality health services for the patient community, referring physicians, employers, and payers. As an aortic center evolves, it can expect measurable improvements in the organization, resource allocation, utilization, and efficiency of delivering care. Improved capabilities and quality will organically grow the aortic center's reputation, with increased referrals as a result. As its reputation grows in the community and region, an aortic center should expect to attract more patients, resulting in increased income and financial performance.

In time, the program should attract additional talent to the center—including leading physicians, researchers, nurses, and administrators. Although initial capital investment is necessary, a center can realize a long-term goal of increased cost savings from quality improvement measures. An enhanced reputation would also bring opportunities to participate in industry- or system-sponsored clinical trials, enabling an aortic center to make valuable contributions to the field, advance best practices, and serve as a host to emerging innovations. These and other benefits would build on the institution's strengths and sharpen its competitive advantage in the marketplace.

Center of Excellence Designation

The phrase "Center of Excellence" has been used across many industries with and without sanctioning designation of the phrase from a governing body. In health care, it could mean that a given center's providers are capable of providing specialized, above-standard care in an environment with dedicated resources for that area of expertise. A "Center of Excellence" should be adequately equipped and staffed to not only provide the highest-level quality of patient care, but also capable of advancing research, informing the development of innovative techniques, and contributing to the standardization of care and what may be considered to be "best practice" in the field. An early example of such a health care program was the National Cancer Institute's (NCI) war on cancer initiative propelled by the National Cancer Act of 1971. This sweeping federal law more than tripled appropriations for the NCI in a 4-year period, particularly for its grants program,[1] fueling the creation of officially recognized regional cancer centers dedicated to research and quality clinical care.[2-4] In 2005, Birkmeyer and colleagues analyzed the national Medicare database from 1994 to 1999, finding in four of six procedures, there were significantly lower mortality rates among the 51 NCI-designated hospitals versus 51 nondesignated hospitals.[2] Although a government-funded designation, the NCI initiative has nonetheless demonstrated that criteria for centers of excellence could help standardize and advance a particular practice, having a positive impact on cost, outcomes, and care quality.

Quality Care Improvement

A contemporary glimpse of what might distinguish a center of excellence and inform development of an aortic center was reported in a 2006 Centers for Disease Control–supported study that evaluated outcomes of ruptured abdominal aortic aneurysms (rAAAs) in 210 "designated" trauma centers versus 675 "nondesignated" hospitals.

TABLE 1. POTENTIAL BENEFITS OF DEVELOPING A COMPREHENSIVE AORTIC CENTER

Domains of Improvement	**Process** *Development Investments*	**Desired Outcomes** *Desired Benefits of Investments*
Overall Capabilities *Big Picture*	Informed expansion of health service capabilities in infrastructure, personnel, technologies, and overall organization	• Improved patient outcomes (eg, survival, reduced complications, and improved risk management) • Patients will receive screening and offered comprehensive treatment for all or a vast majority of types of aortic disease available, not limited to partial services or need for referral • Formation/optimization of outpatient aortic center clinic to provide patients with easier access to initial care, reception point for many referrals/transfers, and follow-up care; will also allow for care coordination among specialists and more standardized pre- and post-procedure surveillance • Improved patient satisfaction of overall care experience • Improved work satisfaction of physician, administrator, nurse, staff, and allied health partners
Subdomain	**Process**	**Desired Outcomes**
Technology	Adoption of innovative technologies to diagnose and treat aortic disease	• Patients will receive cutting-edge care in screening, diagnosis, and treatment, minimizing complications and improving care • Patients and providers alike will have a larger range of therapeutic options to choose from • Formative assessment of technologies to further advance innovation
Research	Investments in research capability (including research database development and standardization, investigator expertise, and dedicated on-the-ground research staff	• Greater involvement in clinical trials (including new device trials) and registries • Expert-authored publications shared with the field to share aortic center experience and voice in advancing best practices • Grow expert and organization reputation and demonstrate willingness to collaborate
Quality care improvement/ planning	Identify need, plan for, and inculcate aortic disease-specific quality care initiatives	• Identify opportunities to further optimize protocols to treat and streamline aortic disease diagnosis and treatment • Creation of or refinements to existing institutional policies and protocols • Optimize reimbursement of aortic disease interventions (eg, pay for performance with CMS and relationships with managed care) • Identify opportunity
Team integration	Invest in the multidisciplinary team (obtain buy-in to aortic center vision, build and sustain relationships with other departments (intra-organizational) and allied health partnerships (outside organization)	• Improve patient's quality of care and outcomes by allowing the expertise of each respective health specialist to do their part at any given point of the care continuum • Optimize reimbursement of aortic disease interventions (eg, CMS pay for performance)
Team training	Devotion of resources to training of physicians and personnel, including use of simulators and relationships with third parties	• Improved provider skill of techniques to improve health outcomes and minimize complications
Planning	Perform organizational inventory and market research to identify gaps in care; consider all stakeholder perspectives; identify aortic center strengths, weaknesses, and opportunities	• Prepare a strategic business plan based on needs identified to plan investments and tactics needed for organizational growth and scale up
Outreach	Market aortic center and identify/establish/renew relationships with referrers and patients	• Raise aortic center visibility, increase referrals, and become the go-to aortic center in the region

A "Center of Excellence" should be adequately equipped and staffed to not only provide the highest-level quality of patient care, but also capable of advancing research, informing the development of innovative techniques, and contributing to the standardization of care and what may considered to be "best practice" in the field.

Predischarge in-hospital mortality was 41.4% at designated centers compared with 45.2% at nondesignated centers (unadjusted odds ratio [OR], 0.85; 95% confidence interval [CI], 0.71–1.02; Figure 1). After adjusting for the presence of a vascular surgery fellowship, hospital beds, annual admissions, comorbidities, and other covariates, the mortality rate was still lower in the designated centers (OR, 0.72; 95% CI, 0.55–0.93; Figure 2). The authors described this as a so-called halo effect due to the ability of the designated centers to systematically mobilize resources, as well as their greater commitment to surgical procedures and intensive care.[5]

Other studies have correlated increases in physician and hospital volume with improved patient outcomes.[6-8] In 2009, McPhee and colleagues used the Healthcare Cost and Utilization Project's (HCUP) Nationwide Inpatient Sample to assess outcomes of patients with rAAAs treated with endovascular aneurysm repair (EVAR) versus open surgical repair. The authors reported lower mortality in patients treated with EVAR compared with open surgical repair (31.7% vs 40.7%; $P < .0001$). Most importantly, the survival advantage with EVAR was independently associated with high-volume centers and teaching institutions.[9] In 2011, the same authors reported that the primary determinant for decreased in-hospital mortality after open elective AAA surgery was higher surgeon volume rather than institution volume. With elective EVAR, however, there was no difference in mortality rate between surgeon or institution volume, both universally low at ≤ 2%.[10]

The results of these two studies emphasize that, for different procedures, both institution volume and surgeon volume can be important predictors of successful outcomes that support regionalization and potential development of high-volume aortic centers. Innovations in surgical safety have prompted the question of whether there is still a survival benefit based on volume or whether it has diminished. However, a 2014 mortality analysis of Medicare claims data from more than 3.2 million patients undergoing gastrointestinal, cardiac, or vascular surgery showed

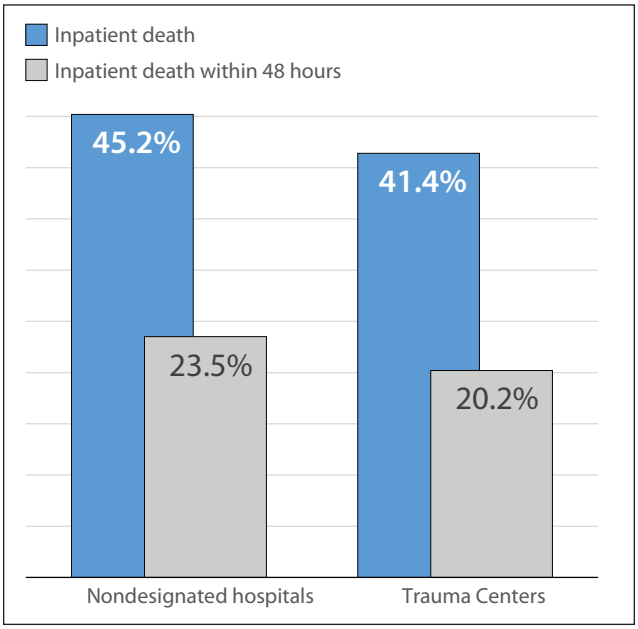

Figure 1. Predischarge in-hospital mortality, nondesignated centers versus designated trauma centers (unadjusted odds of inpatient death: OR, 0.85; 95% CI, 0.71–1.02; unadjusted odds of inpatient death within 48 hours: OR, 0.81; 95% CI, 0.64–1.02; adjusted odds of inpatient death: OR, 0.95; 95% CI, 0.77–1.17; adjusted odds of inpatient death within 48 hours: OR, 0.86; 95% CI, 0.66–1.12).

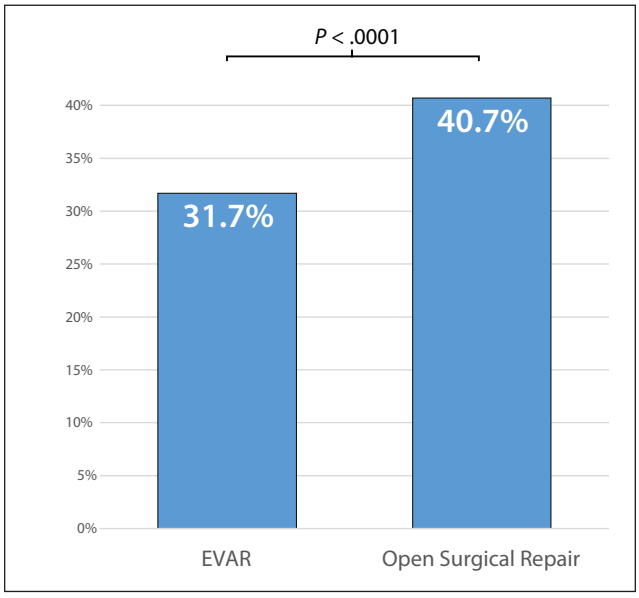

Figure 2. Overall in-hospital mortality for rAAAs by type of procedure. EVAR was independently associated with high-volume centers and teaching institutions.

TABLE 2. PROFILES OF SELECT HEALTH SYSTEMS WITH AORTIC CENTER INSTITUTIONS

Health System	System Characteristics	Type	Delivery Characteristics
Carolinas HealthCare System Charlotte, North Carolina	• 900 care locations, including Sanger Heart & Vascular Institute • 7,460 licensed beds • Budget of $7.7 billion	Multispecialty medical groups and physician-hospital organizations (PHOs)	• Alliance between a physician group/network and one or more hospitals, that sell services to managed care providers • PHO organization contracts for physician and hospital services • Physicians employed by hospitals
Baylor Scott and White Health Dallas, Texas	• 42 hospitals • 600 care locations • 3,781 licensed beds • $5.9 billion in total assets • 3,392 active physicians • 22,000 employees • 127,693 inpatient admissions	Managed independent practice associations (IPAs)	• Association of independent physicians in private practice and physicians who are part of a PHO (physician group/hospital alliance) • Provides services to managed care organizations • Provides clinical education and training to future and current physicians and other medical professionals • Often have research programs
Intermountain Healthcare Salt Lake City, Utah	• Three operating groups with 22 hospitals and > 185 clinics • > 34,000 employees • Serves Utah and Idaho	Hybrid PHO/IPA	• Care is provided by a collaboration of physicians who are a part of an IPA (association of independent physicians in private practice) and physicians who are part of a PHO (physician group/hospital alliance contracts services to managed care providers)
Stony Brook Medicine Stony Brook, New York	• Seven hospitals and institutes • Five health sciences schools • > 50 community-based health care settings • 603 beds • 1,095 physicians • 5,777 employees • 31,964 inpatients (excluding newborns)	Academic/teaching hospital/institution	• Provides clinical education and training to future and current physicians and other medical professionals • Affiliated with medical schools or universities • Often have research programs • Physician employees of academic institution
Kaiser Permanente Oakland, California	• 38 hospitals • 618 medical offices • Revenue $56.4 billion • 9.6 million members • 17,000 physicians • 174,415 employees • Serves eight states and Washington, DC	Organized/integrated delivery systems (IDSs)[23]	• Organized, coordinated, collaborative network linking various health care providers • Provide coordinated, vertical continuum of services to a specific patient population • Clinically and fiscally responsible for clinical outcomes and health status of population served • Systems in place to manage and improve outcomes

that the inverse relationship between mortality and institutional volume remains strong across surgery types.[11]

In 2001, the Leapfrog Group, a national nonprofit advocacy group for employers proposed standards including volume in high-risk surgical procedures, computerized order entry, and fully staffed intensive care units. These recommendations were based on the Institute of Medicine health care safety report, data from the Nationwide Inpatient Sample, and other sources. Although controversial,[12-14] the Leapfrog Group's analysis found a correlation between mortality and higher-volume centers in five procedures, resulting in an estimated 2,581 lives saved. Lives

The health care system is in a state of crisis, currently undergoing a transformation to a value-based insurance design (VBID) payment system driven by the Affordable Care Act.

saved in each procedure were estimated to be 1,486 for coronary artery bypass graft, 464 for AAA repair, 345 for coronary angioplasty, 168 for esophagectomy, and 118 for carotid endarterectomy.[15] These results have been repeated in recent years, with evidence supporting the notion that fewer complications may be a factor in high-volume center success.[16] However, another analysis failed to find a similar correlation.[14]

But volume is likely only part of the equation. The Centers for Medicare and Medicaid Services (CMS) has taken action to promote a value-based system predicated on quality, not quantity. The CMS national imperative has set three overall goals for this paradigm: better health, better care, and lower costs. To this end, CMS and the National Quality Strategy of the US Department of Health and Human Services have outlined six measures of quality for improving outcomes for its beneficiaries. An aortic center should be proactive in striving to improve in all these areas, and its collaborative, multidisciplinary environment offers ample opportunity to implement changes to improve the quality of patient care.

- Safety
- Patient- and caregiver-centered experience and outcomes
- Care coordination
- Clinical care
- Population or community health
- Efficiency and cost reduction

Incentives for Reimbursement

The health care system is in a state of crisis,[17] currently undergoing a transformation to a value-based insurance design (VBID) payment system[18-20] driven by the Affordable Care Act.[21] Such a transition cannot be ignored, especially since Medicare payments for health services will be tied to productivity in the economy. It is a crucial reality for hospital systems, because many receive more than 70% of their reimbursement from Medicare and Medicaid. CMS has proposed a set of rules for voluntary "Accountable Care Organizations" (ACOs), designed to reward systems that put the patient first. This model will incentivize care of an individual patient across multiple settings and health care providers (HCPs). CMS is also rewarding the reduction of unnecessary readmissions attributable to infection (one source of complication in aortic procedures), preventive services, and use of electronic health records (EHRs), all of which should also be criteria for aortic centers. Organizations can obtain program details directly from CMS. An important point regarding such details is that CMS hospital incentives can be attained by relative improvement over a system's own baseline or reaching a CMS-established benchmark and that no low-performing system would be "left to sink or swim."[19]

Several institutions have undertaken the upscaling of their aortic programs, but few have reported on the vision and strategy that formed the foundation of their programs. In 2015, Schanzer and colleagues at the University of Massachusetts[22] reported on the feasibility and practicality of developing an aortic center program. The study team cited several key elements that fueled the growth of its aortic center:

- On-site formal training at already-established centers of excellence
- Industry partnerships to improve access to innovative devices
- A fully integrated team approach, with the referring surgeon included throughout the course of care
- The prospective collection of clinical outcomes data approved by its Institutional Review Board, and
- The testing of new physician-modified devices to advance the field

The authors were keen to emphasize that administrative buy-in was a must and acknowledged that every institution has difference strengths, weaknesses, and opportunities. Strengthening weaknesses and building upon existing strengths unique to their organization reportedly provided direction early in the strategic planning process, then helped them to identify and seize opportunities.

SUMMARY

The field of interventional vascular care is positively rippling with innovation and change. In an evolving, multifaceted health care delivery system, many centers have yet to realize the benefits of continual innovation of diagnostic and interventional devices to meet patient needs. Institutions and teams play a key role in leveraging these technologies to improve the timeliness and quality of patient care. It is the responsibility of all health care team members to translate advances in health intelligence via personal, professional, and institutional commitment to improving patient care. Harnessing these advances is a challenge because of the barriers at the system, team, and individual level. A strong institutional commitment to develop an aortic center should acknowledge, anticipate,

and address these barriers. This level of anticipatory planning, dedication of resources, and organizational focus can help build and support the multidisciplinary team. This collaborative, collective synergy of expertise may then optimally deploy a range of diagnostic and device innovations to meet the needs of patients, improving health care delivery and outcome. ■

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Indications
The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is intended for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy, including:
- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42mm (fusiform and saccular aneurysms/penetrating ulcers), 18 mm to 44 mm (blunt traumatic aortic injuries), or 20 mm to 44 mm (dissections); and
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20mm (fusiform and saccular aneurysms/penetrating ulcers), landing zone ≥20 mm proximal to the primary entry tear (blunt traumatic aortic injuries, dissections). The proximal extent of the landing zone must not be dissected.

Contraindications
The Valiant Thoracic Stent Graft with the Captivia Delivery System is contraindicated in:
- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

Warnings and Precautions
The long-term safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm, endoleaks, migration, inadequate seal zone, or continued flow into the false lumen in the case of a dissection) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*. The Valiant Thoracic Stent Graft with the Captivia Delivery System is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures as described in the *Instructions for Use*. Strict adherence to the Valiant Thoracic Stent Graft sizing guidelines as described in the *Instructions for Use* is expected when selecting the device size. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear. As cautioned in the *Instructions for Use*, a balloon should never be used when treating a dissection. The safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

MRI Safety and Compatibility
Non-clinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems under specific conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events
Potential adverse events include, but are not limited to access failure, access site complications (e.g. spasm, trauma, bleeding, rupture, dissection), adynamic ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anaesthetic complications, aortic expansion (e.g. aneurysm, false lumen), aneurysm rupture, angina, arrhythmia, arterial stenosis, atelectasis, blindness, bowel ischemia/infarction, bowel necrosis, bowel obstruction, branch vessel occlusion, buttock claudication, cardiac tamponade, catheter breakage, cerebrovascular accident (CVA) / stroke, change in mental status, coagulopathy, congestive heart failure, contrast toxicity, conversion to surgical repair, death, deployment difficulties / failures, dissection / perforation / rupture of the aortic vessel and/or surrounding vasculature, embolism, endoleak(s), excessive or inappropriate radiation exposure, extrusion / erosion, failure to deliver stent graft, femoral neuropathy, fistula (including aortobronchial, aortoenteric, aortoesophageal, arteriovenous, and lymph), gastrointestinal bleeding /complications, genitourinary complications, hematoma, hemorrhage / bleeding, hypotension / hypertension, infection or fever, insertion or removal difficulties, intercostal pain, intramural hematoma, leg /foot edema, lymphocele, myocardial infarction, neuropathy, occlusion – venous or arterial, pain / reaction at catheter insertion site, paralysis, paraparesis, paraplegia, paresthesia, perfusion of the false lumen, peripheral ischemia, peripheral nerve injury, pneumonia, post-implant syndrome, procedural / post-procedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysm, pulmonary edema, pulmonary embolism, reaction to anaesthesia, renal failure, renal insufficiency, reoperation, respiratory depression / failure, sepsis, seroma, shock, spinal neurological deficit, stent graft material failure (including breakage of metal portion of device) / migration / misplacement / occlusion / twisting / kinking, transient ischemic attack (TIA), thrombosis, tissue necrosis, vascular ischemia, vascular trauma, wound dehiscence, wound healing complications, wound infection.

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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*Data on file at Medtronic
Source: Valiant Captivia *IFU*

Innovating for life.

MEET THE CHALLENGE: AORTIC CENTER STRATEGIC PLANNING, INVESTMENTS, AND TACTICS

BY JOHN R. DOTY, MD; BRAD KRUGER, MBA; ERIC S. WEISS, MD, MPH; MARK W. MEWISSEN, MD; CHANTAY COULTER, RN; AND TOM DRAPER, MBA

The development of a comprehensive aortic center should start with a thorough planning process that first collects information. Both a market analysis and institutional analysis that identifies strengths, weaknesses, and opportunities are a good starting point, informing an aortic center's vision and steering its direction before making capital requests and team investments. It is important to know the characteristics of your market—patient demographics as well as referrer demographics to understand established referral patterns. This understanding can serve to guide institution-specific strategies to establish or renew existing relationships with primary care physicians and to offer aortic screening to the community.[1] It is important to be aware of all long-term clinics in the area and the transport flow among them, including which facilities care for acute aortic syndrome, for example. A market analysis should reveal epidemiologic trends of aortic disease in the targeted population, the degree of awareness and diagnosis of aortic conditions, and estimates of patients who would benefit from the expertise of the aortic center.

Performing an institutional inventory and assessment can help an institution anticipate barriers, clarify community and peer perceptions, and seize opportunities for building collaborative teams internally and externally. SWOT analysis can be useful because it asks important questions that are self-reflective of the institution and its allies and can be used to identify strengths and weaknesses internally, many of which can point to both internal and external opportunities and threats (Figure 1). All institutions have system and team challenges and recognizing them is critical to doing the important work of patient care.

A SWOT analysis can be especially useful in exploring human factors in any health care organization.

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Unfortunately, medical errors can and do occur,[2,3] the majority of which occur in high-intensity care areas, such as in surgery and intensive care.[4] Medical errors may be the result of mistakes at the team and individual level. For instance, a 2015 study reported that medical errors were associated with nursing staff bullying.[5] There are a variety of technologic innovations to reduce errors that are system- or provider-based electronic or human process measures. Radiofrequency identification tagging has emerged as a method to monitor patient location,[6-8] and automatic drug devices and handoff programs have been used to combat errors in drug and transfusion delivery.[9,10] However, barriers exist that prevent these same innovations from being adopted.[11] Human factors should therefore be anticipated and planned for in the process of developing a comprehensive aortic center, and these system or team weaknesses can be identified in a SWOT analysis.

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tic center consists of stakeholders representing multiple disciplines, it is important to meet with all stakeholders in the SWOT process, which could perhaps be arranged at opportune times, such as protocol and order set review or in individual or group interviews.[12] Traditional SWOT analyses can benefit from integrating stakeholder expectations with current or projected institutional resources needed to meet those expectations.[13] This can open the door to planning an aortic center in a deeper, more meaningful way, answering questions like: "What are stakeholder expectations for an aortic center?" "Can the organization deploy resources (people, finances, capabilities) to meet these stakeholder expectations? Can it be sustainable?" "What factors influence expectations and resources?"

COLLABORATION: PATIENTS, TEAMS, AND SYSTEMS

Collaboration enables individuals to work together to achieve a shared goal. One key type of collaboration is the interaction of a health care team member with a patient and his or her family, a relationship all others are based on in the health system. Patient buy-in is critical since patients perceive risk differently, each interpreting words like "high" or "low" risk differently given that they bring their own insight, education, values, and inclinations to every interaction.[14] The aortic team's interaction with the patient should always be based on respect and cultural sensitivity,[15] engaging the patient to encourage his or her active participation, and should transcend perceived professional hierarchies and boundaries.[16]

Respectful interaction can help avoid antagonistic interactions that could escalate to a liability.[17] The communication of risk should not be overgeneralized or glossed over, but instead tactfully geared toward the values and needs of the individual patient. Patients may be uninformed, confused, and/or conflicted on which procedure to choose and the weighing of benefits and harms. A 2014 systematic review reported "high-quality evidence" that decision aids (vs usual care) can be helpful in assuaging this decisional conflict when patients face treatment or screening.[18] Thus, it is critical to be receptive to patients and listen, understand with empathy, educate persuasively, and pres-

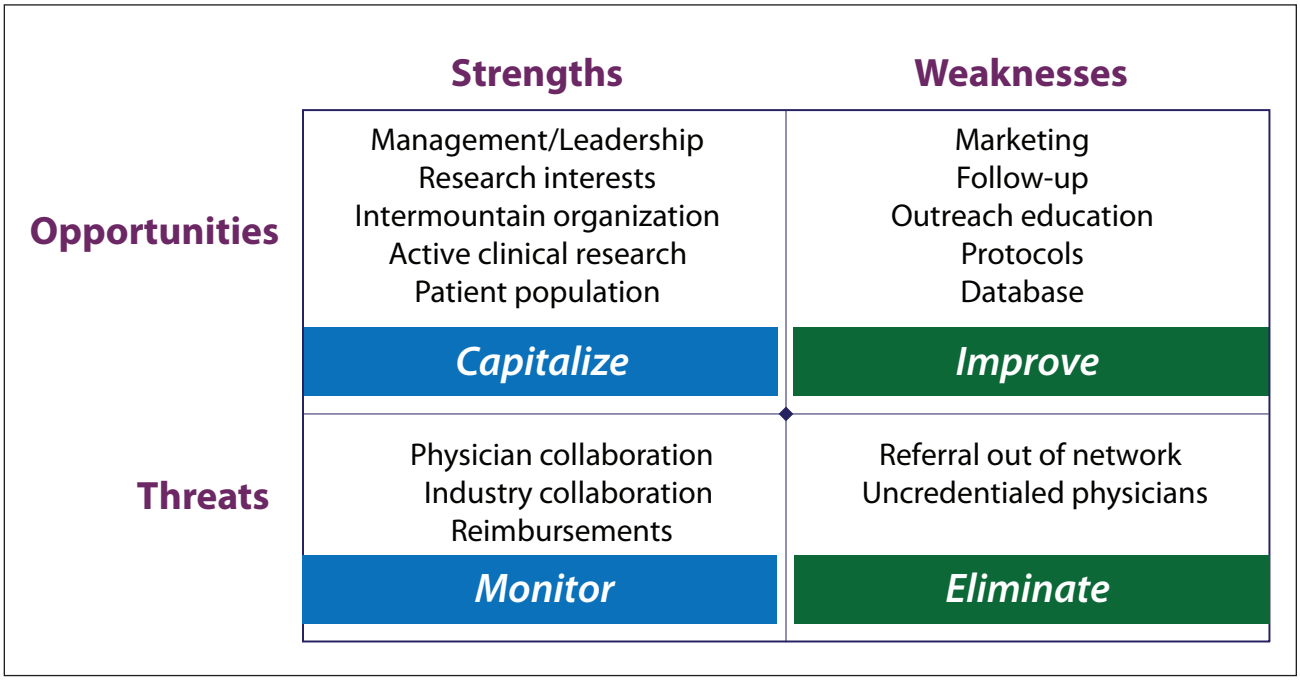

Figure 1. Sample SWOT analysis for a developing aortic center. This analysis highlights areas of opportunity to capitalize on existing strengths and monitor external threats to the hospital system's business model, while improving upon known weaknesses and eliminating threats where possible.

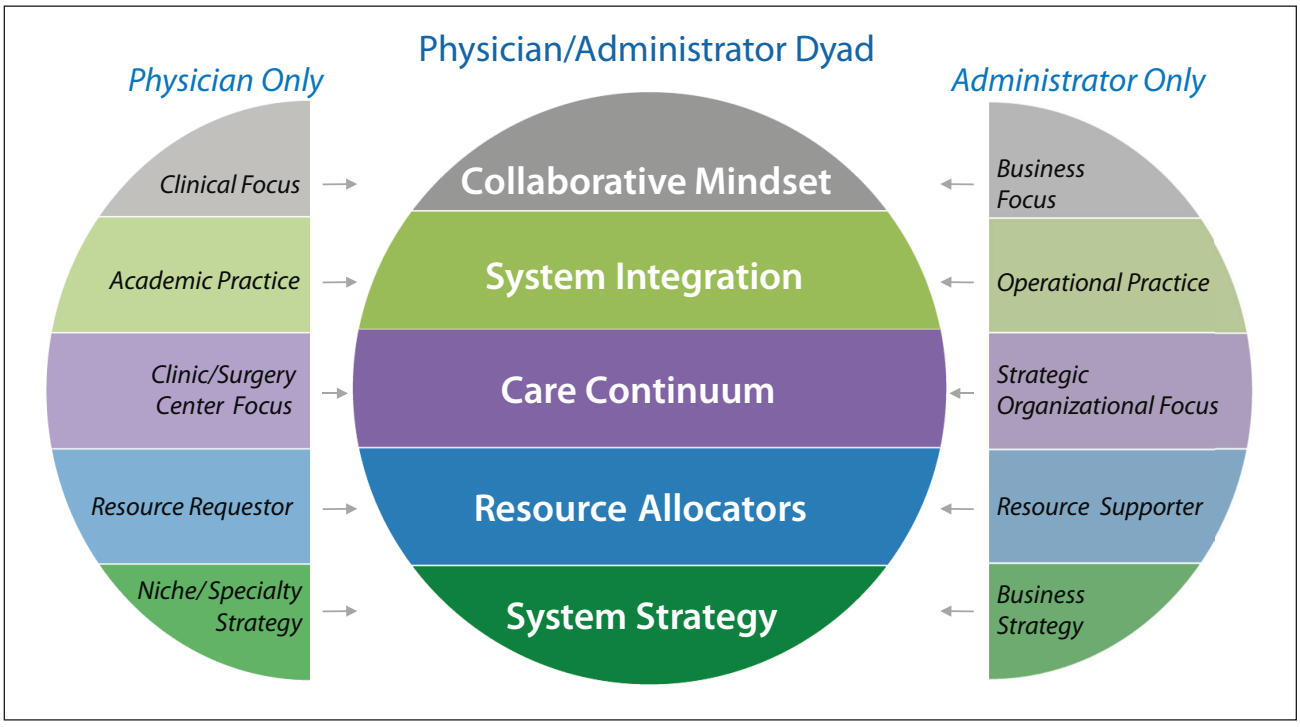

Figure 2. The physician-administrator dyad—collaboration based on core strengths.

ent decision aids to reinforce patients with confidence. Teaching institutions developing an aortic program should also be prepared in this regard to patient interaction. Although patients generally have favorable perceptions of teaching hospitals and usually welcome interaction with surgical residents and fellows, all patients still need to be oriented to the aortic team and informed by the aortic team to maintain confidence and trust.[19]

Collaboration may be inter- and intraorganizational in nature. One example of interorganizational (system-level) collaboration is the experience of a consortium of several hospitals in northern Ohio that collaborated with two large hospital systems and local emergency medical services.[20] They adopted a trauma protocol and 2 years later compared mortality rates with those from 2 years before the policy was implemented. Mortality was reduced as much as 40%. Another example of either intra- or interorganizational collaboration is the linking of redundant electronic medical record (EMR) systems among partnering organizations to pool data resources and backup systems to prevent data loss, which can allow health services to continue in case of unplanned shutdowns.[21]

One of the most important intraorganizational interactions is that of the physician and administrator. Physicians have a responsibility to understand the mind-set of administrators, who are typically data and goal driven, business and strategically oriented, driven by the system's strategic direction, and who may not initially be aware or convinced of the clinical benefits of what they may consider a niche program. Administrators likewise have a responsibility to understand the role and goals of the physician, including their clinical, surgical, and academic/research expertise, as well as their resource needs. The confluence of strengths and focus between these two roles is illustrated as a dyad schema of leadership (Figure 2), in which common goals of a collaborative mind-set, system integration, continuum of care, and appropriate resource allocation are achieved for the benefit of advancing the aortic program's vision to support the health system's strategy. This dyad-based leadership should be established as early as possible in aortic center development to (1) identify needs specific to the aortic center vision (ie, reviewing its current and future state via SWOT, consider patient impact and clinical benefits, and identify operational efficiencies); (2) determine the planning/design team (ie, using a multidisciplinary approach by identifying team members and aligning to strategy with operational resources and throughout implementation process); and (3) actually plan the aortic center with the creation of a business proposal, a financial pro forma, and to map the care delivery model.

The multispecialty team is one of the most critical components of a comprehensive aortic center. In addition to surgical expertise in both cardiac and vascular surgery, other clinical specialists such as cardiologists, radiologists,

and geneticists are important to a successful center. Each specialty provides a clinical perspective and service that allows the center to manage and treat the most complex patients. Successful aortic centers must foster opportunities for this multispecialty team to collaborate and manage as a team.

Regardless of whether multiple organizations are involved, multidisciplinary meetings can be very helpful to get buy-in from all stakeholders and reach agreement on key questions, guide best practices, and make recommendations. However, attendance to multidisciplinary meetings focusing on integration of care has been notoriously underfinanced in chronic care models.[12] These meetings should be a higher organization priority, since they can provide a structured, organized forum for sharing important perspectives of roles from each department, present cases and examples highlighting unmet clinical needs, and the critical sharing of ideas and perspectives to advance an aortic center.

Meetings should take place frequently to adapt to the working needs of all represented stakeholders, and a clear agenda should be prepared, but allow for open discussion. Other discussions may include refining logistics; mobilizing the team and team assignments; health technology requirements, including data entry expectations; procedure and room preparation and equipment requirements; guided treatment decisions; and other resource-related questions. Important team members may include physicians (radiology, surgery, cardiology, interventional), ancillary staff (physician extenders, schedulers, coordinators), research personnel (who help orchestrate potential trial candidates), fellows, residents, and students—any professional who has a role and stake in the outcome of improving patient care.

BARRIERS TO COLLABORATION

There are known barriers to collaborative team interaction, particularly in the context of a rapidly evolving patient system centered on the patient medical home. A 2013 systematic review of 44 studies reported barriers to interprofessional collaboration. Although team members may buy into the need to collaborate to improve patient care, this is not enough to produce effective collaboration. Significant barriers were reported across studies, including challenges to roles and definitions, undermining team building and professional training, breaches in confidentiality, and inadequate information sharing and willingness to take responsibility.[16] Several barriers to the adoption of surgical quality programs were reported in a 2015 article by key members of a multidisciplinary perioperative care team (n = 55; 19 general surgeons, 18 anesthesiologists, 18 nurses). The majority of the team reported that while they supported the Enhanced Recovery after Surgery (ERAS) program at several University of Toronto-affiliated hospitals,[22] there were several barriers to optimal team function, including: (1) a lack of manpower, (2) suboptimal team interaction, (3) disagreement with the program's goals, by what may be characterized by an "old-school" recalcitrance or resistance to change, and (4) patient factors. The authors suggested that barriers could be anticipated proactively by better clarifying best practices and supporting guidelines, clarifying protocols and order sets, and improving team and patient education.[22]

The need for highly skilled aortic operators has increased dramatically over the past 2 decades as endovascular techniques and devices have been increasingly used and preferred in a number of clinical scenarios and pathologies. Acquiring skills should be a priority for all physicians, not just residents and fellows.

Although patient satisfaction is an important qualitative metric for any aortic center, the importance of employee work satisfaction may not be as appreciated as a factor in the total equation of care quality. Work satisfaction is the result of dynamic interpersonal and interdisciplinary interactions every day an employee comes to work. There may be several barriers along these lines that affect work satisfaction and, perhaps to some degree, work effectiveness. A 2012 survey of surgeons (n = 32) in Canada identified barriers to and facilitators of surgeon work satisfaction.[23] Primary barriers reported were lack of access to resources and a perceived disconnect with hospital administrators regarding practice priorities that hampered patient care.

On the other hand, positive, supportive aspects of work satisfaction were also reported. The greatest source of surgeon satisfaction was the effective and timely resolution of patient problems. Another important source of career satisfaction came from professional interaction with colleagues and patients who were supportive of their role. Work satisfaction may therefore impact the delivery of high-quality patient care, with key barriers being lack of professional engagement or being "out of touch" with patients and colleagues. Turnover may also potentially disrupt the formation of a well-functioning care team, the continuum of patient care, and the institution's advancement toward its goals.

TABLE 1. TEN CONSIDERATIONS IN HYBRID SUITE DEVELOPMENT AND MANAGEMENT

Consideration	Factors to Evaluate, Choose, or Implement
Create an environment of care	• The physical space: functional relationship to adjacent surroundings, including the preoperative and postoperative/postanesthesia unit, other ORs, waste disposal and restrooms, and storage • Equipment: Diagnostic, procedural, and safety equipment; electrical support and backup; and information technology integration • Personnel: Trained and knowledgeable in technologies and procedures
Design logically	• Locate suite in area contiguous to both OR and interventional suites for improved access in case of complicating events • Locate away from noise and artifact generating • Temperature, humidity, air-exchange requirements • Larger room size to accommodate for access and movement of the patient and multidisciplinary personnel • Lighting capabilities • Imaging: 10-ft floor-to-ceiling height to accommodate imaging equipment; decide on floor- or ceiling-mounted imaging
Retrofit an existing OR	• 1,000 sq ft and 1,200 sq ft needed • Design separate control room to minimize unnecessary radiation • Increase wall lead lining from 0.5 mm (standard in ORs) to 2 mm to 3 mm, depending on state regulation
Decide on equipment/instruments	• Determine if equipment systems should be floor-mounted or ceiling-mounted (eg, most hybrid OR suite planners opt for mounted fluoroscopy systems over mobile fluoroscopy) • Bed considerations include manual operation or controller only if cord is damaged or malfunctions; does fluoroscopy/angiography require mobile or stationary bed?; Rails or arm board-capable bed for open surgical conversion?
Build a hybrid OR team	• Knowledge and expertise in vascular surgery, interventional radiology, and cardiology (all personnel, including nursing and medical personnel, internists, and generalists) • All members to agree to multidisciplinary approach to standard operating procedures • Staffing requires cross-training of skills needed from both surgery and interventional radiology • Continuing education and annual competencies should address standards of care, organizational and regulatory changes, and new technologies; quality management program needed
Select an anesthetic agent	• General vs regional anesthesia
Emphasize the preoperative assessment	• Preoperative assessment to anticipate complications (eg, renal dysfunction, allergies to contrast media, thrombolytic agent use)
Emphasize the perioperative nurse's role in procedural care	• RN circulator responsible to assess, plan, implement, and evaluate patient care; surgical counting, including instruments and monitoring contrast used
Adhere to guidelines for radiation protection	• Avoid pulsing by using multiple still images • Refer to last image (last image hold) • Confine x-ray beam to smallest area (collimation)
Identify financial considerations	• Anticipate startup costs; first-year estimates typically show a loss • Cost for retrofitting existing OR • Cost justification dependent upon patient population, estimated volume • Cost of fixed vs mobile systems; fixed system cost may be clinically justified if other specialties require it • Cost of sterility maintenance

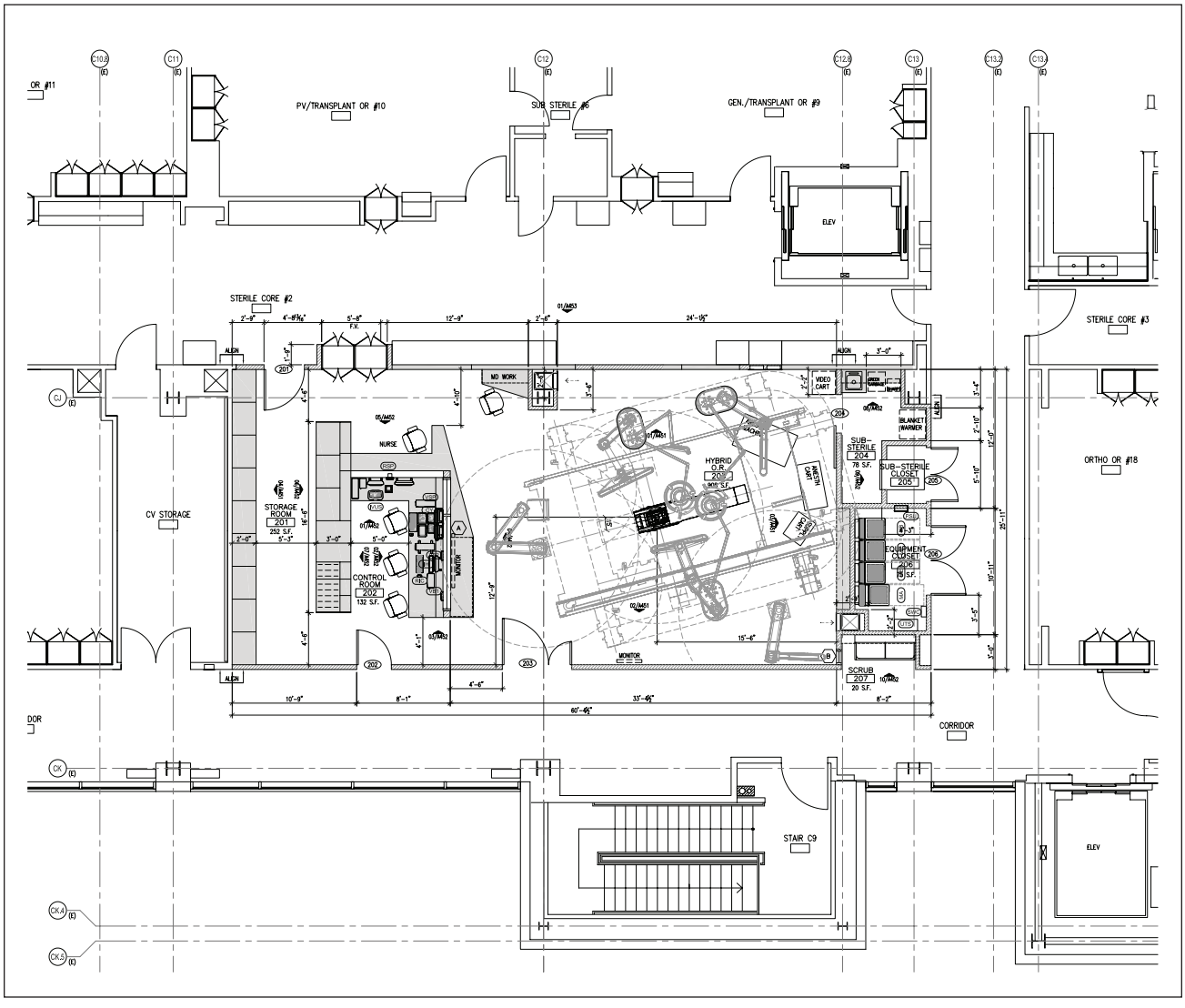

Figure 3. Floor plans of Intermountain Healthcare's dedicated endovascular/OR hybrid suite (Intermountain Medical Center, Murray, Utah). Construction began February 21, 2015, and scheduled completion is mid-August 2015. The blueprint shows the retrofit conversion of two OR spaces creating a single, longer workspace. Diagonal configuration of the patient bed was a creative solution given this suite's spatial dimensions, accommodating all necessary equipment while optimizing flow of personnel and patient traffic. Retrofit construction included increased shielding reinforcement and integration of load-bearing structural elements. This blueprint also highlights the suite's adjacent proximity to other ORs (general/transplant, top), the separate control room for procedure monitoring (left interior), storage (left of control room), and the location of the sub-sterile and equipment closets (right).

Good communication practices among health care professionals can address or even prempt these issues. These practices include open, bidirectional communication, in which colleagues and patients clearly understand roles in the delivery of care privacy laws. Raising colleague and patient awareness of current or potential problems allows those problems to be resolved openly, collaboratively, and inclusively—as long as participants are pursuing and/or inventing "options for mutual gain."[24] A leader can champion these facilitating factors to counteract barriers, such as uncertainty of roles and fragmented or interrupted team communication, ultimately preventing disagreements and tension.[25]

Identifying organizational weaknesses at the interpersonal level can be difficult, particularly when addressing interpersonal skirmishes or breakdowns. Identifying areas where health care professionals—whether they are physicians, nurses, or administrators—can improve their job effective-

TABLE 2. LIST OF PROCEDURES PERFORMED IN HYBRID OPERATING ROOM[28]

- Endovascular abdominal aneurysm repair
- Endovascular thoracic aneurysm repair
- Hybrid arch reconstruction
- Transfemoral aortic valve replacement
- Transsubclavian aortic valve replacement
- Transapical aortic valve replacement
- Endovascular mitral valve repair
- Transpulmonary valve replacement
- Transapical neochord replacement for mitral valve repair
- Hybrid Maze procedure
- Atrial septal defect with septal occluder
- Ventricular septal defect with septal occluder
- Endovascular repair of coarctation of the thoracic aorta
- Hybrid coronary revascularization with coronary angiogram
- Atrial fibrillation/flutter ablation
- Carotid artery stenting/carotid endarterectomy
- Peripheral vascular stenting
- CABG procedures
- Minimal invasive aortic valve/mitral valve procedures
- Hybrid therapies for congenital heart diseases
- Pacemaker/automatic implantable cardioverter defibrillator implantation
- Neurovascular interventions
- Interventional bronchoscopy
- Endoleak coiling
- Diagnostic angiography
- Intravascular ultrasound

ness and competency of care may be just as challenging. Finding the "teachable moment" is one potential strategy for both managers and employees and can appeal to each professional's commitment to self-education. A 2014 survey reported that when 74 licensed clinical instructors were asked about teachable moments,[26] two distinctive types were provided: flexible and inflexible. Recognizing these moments and whether or not intervention would yield a positive outcome may be an instructive organizational tact.

SURGICAL SIMULATION TRAINING FOR PHYSICIANS AND THE TEAM

The need for highly skilled aortic operators has increased dramatically over the past 2 decades as endovascular techniques and devices have been increasingly used and preferred in a number of clinical scenarios and pathologies. Acquiring skills should be a priority for all physicians, not just residents and fellows. But continuing education can be challenging, as it may require time away from work and involve complicated logistics of setting up on-site proctorship visits. Fortunately, a number of simulators are available that can help in the initial steps of developing procedure competency before performing a live procedure.

Simulators can approach realistic surgical conditions in a safe way without impact on a patient. They keep the focus of the activity on the learner, and simulations can be repeated as many times as necessary to achieve competency. They can be useful for centers and training programs to provide feedback allowing trainers to objectively assess trainee surgical skills and competence. Simulators can record metrics to be monitored over repeated sessions. Amount of contrast, number of devices selected, and duration of procedure and other recorded measures allows trainees to set goals for improvement in repeated tests and become proficient in multiple surgical scenarios.

Simulations can also be very effective for teams training to work together more efficiently. It has been posited that procedure simulators may in the future be used for board examination and certification and as part of the physician credentialing process.[27] Specialty boards require a number of cases to be performed every year. If a physician is up for recredentialing and has five cases fewer than what is required, perhaps the remainder could be satisfied with simulator tests.

Industry has played an important role in the development of simulators, based on the need to facilitate training for their own devices. For example, Medtronic's program simulates several of its products for endovascular aneurysm repair (EVAR), thoracic endovascular aneurysm repair (TEVAR), or peripheral vascular applications. Medtronic's simulation program uses the Compass™ (Compass is a trademark of MSC) and Simbionix Module systems, both of which have been featured at international conferences. These systems are also transportable to institutions for training. Residents and fellows can enter the program and debrief individually or as a team with their attending physician. Learning is progressive, and repeated simulations can yield dramatic reductions in duration of cases.

RESOURCE INVESTMENT FOR THE LONG TERM

The Hybrid Suite as a Dedicated Endovascular Environment

The hybrid operating room (OR) suite concept—the combination of an angiography suite and a traditional OR with high-field imaging and anesthetic support—has gained traction in recent years as a model of innovation.

The concept of a fully automated med pod is still the musings of science fiction, but the idea of consolidating modern surgical techniques into one centralized interventional arena has become a reality. Although these types of operating suites have been used for several years, they are only now coming into more mainstream use as they are increasingly viewed as a necessary component of an aortic center rather than a mere luxury. An aortic center should strive to provide all available diagnostic and treatment options for each patient in an efficient and dedicated manner, and constructing a hybrid suite is a significant step to achieving that goal. There are several considerations in planning for and implementing a hybrid suite (Table 1). A hybrid OR retrofit project currently underway at Intermountain Medical Center (Murray, Utah) highlights several aspects of these planning elements to bring to fruition a creative hybrid suite solution specific to the facility's needs by combining two conventional OR suites (Figure 3).

A significant advantage of hybrid suites is that they can combine several aspects of multidisciplinary interventional care in a single operating theater, allowing both traditional open surgery and minimally invasive endovascular procedures on the same patient and at the same time and place, minimizing lost time and reducing risk of other complications like infections. They can be equipped to more efficiently treat a number of vascular conditions including blunt thoracic aortic injury, aneurysm rupture, infrarenal aortic aneurysms, thoracic aortic aneurysms, type A and B thoracic aortic dissections, iliac aneurysms, and other peripheral pathologies. Multiple procedures can take place in the suite with greater efficiency than in separate specialized OR suites. This "OR of the future"[28] can accommodate a wide range of procedures (Table 2). CABG can also be performed. Institutions with hybrid suites can attract clinical studies because new procedures are preferentially performed there, such as percutaneous heart valve replacement, carotid artery stenting, and lower extremity revascularization.

Cost can range from $1.2 million to $5 million depending on the capabilities and technologies installed.[28] A less expensive suite could be installed, but this may limit some capabilities or future software/hardware upgrades and additions. The construction of hybrid suites requires shielding of doors and walls and a control room. Having all or most interventional tools in a single operating theater may have significant advantages in health outcomes, including shortened procedure times, less use of nuclear imaging radiation, faster recovery times, reduced time in the intensive care unit, and shorter hospital stays.[28-31] The accurate visualization of pathology is one of the required tools to navigate vessels, great and small. The ability to recognize and landmark anatomic challenges is the key to guiding stents, catheters, and guidewires to prevent or minimize complications. The full range of imaging needed to support minimally invasive vascular techniques can be integrated into a hybrid operating theater: radiography, angiography, computed tomography (CT), and magnetic resonance imaging. CT fusion capability may also allow for decreased radiation exposure and need for contrast in complex aortic cases. Same-room imaging studies decreases the need for in-hospital transport, which presents additional risks due to the time needed to transport and risk of infection exposure. All of these advantages may lead to improved outcomes and lower costs per case.

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In 2009, Field and colleagues suggested that a hybrid suite's most meaningful advantage may be in the confluence of interdisciplinary efforts.[29] Highly specialized expertise can be found not only under the same roof, but in the same room where physicians can collaborate to direct benefits to patients. Hybrid suites are also suitable for emergency procedures in tandem with multidisciplinary cardiology, radiology, and surgical teams. The hybrid suite may therefore act as one of the centerpieces of collaboration for an aortic center, with all team members aligned for the patient's best interest. ■

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Indications
The Endurant® II/Endurant® IIs bifurcated stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. The Endurant II aorto-uni-iliac (AUI) stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients whose anatomy does not allow the use of a bifurcated stent graft. The Endurant II/Endurant IIs stent graft system is indicated for use in patients with the following characteristics:
- Adequate iliac/femoral access that is compatible with vascular access techniques, devices and/or accessories
- Proximal neck length of ≥10 mm
- Infrarenal neck angulation of ≤60°
- Aortic neck diameters with a range of 19 to 32 mm
- Distal fixation length(s) of ≥15 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

Contraindications
The Endurant II/Endurant IIs Stent Graft System is contraindicated in:
- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

Warnings and Precautions
- The long-term safety and effectiveness of the Endurant II/Endurant IIs Stent Graft System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and the performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleaks may be required to undergo secondary interventions or surgical procedures.
- The Endurant II/Endurant IIs Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use*.
- Renal complications may occur: 1) From an excess use of contrast agents. 2) As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
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Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

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THE AORTIC CENTER TOOL KIT: PATHWAY FOR INSTITUTIONAL GROWTH

BY DAVID LORAN, MD; APOSTOLOS K. TASSIOPOULOS, MD; CHANTAY COULTER, RN; AND OLYMPIA CHRISTOFORATOS, RN, MS

Value in health care has been defined as "the health outcomes achieved per dollar spent."[1] Value should "always be" customer focused.[2] Thus, initial stages of aortic center planning and development should be grounded in altruism and its mission centered on the beneficiaries of that value: patients, their families, and communities. Operations should also reflect a core set of institutional qualities, often referred to as "pillars" or "values," based upon that core mission. Efficiency is an important function of the value equation, which represents cost relative to outcomes. Michael E. Porter, PhD, asserts that when organizations fail to prioritize value improvement in their own delivery of health services, they also fail to measure that value, and innovation slows.[1]

Efficiency is an important function of the value equation, which represents cost relative to outcomes … when organizations fail to prioritize value improvement in their own delivery of health services, they also fail to measure that value, and innovation slows.

DEFINING A COMPREHENSIVE AORTIC CENTER IN THEORY, DESIGN, AND FUNCTION

Aortic pathology is complex and requires complex solutions and clever technologic strategies to treat it. The modern era of aortic care has been propelled by advancements over many years, not least of which is the pioneering endovascular abdominal aortic aneurysm (AAA) technique created by Juan Parodi, MD, in 1991.[3] Aortic surgery may be simply defined as any aortic procedures falling within the purview of the best-trained cardiovascular and vascular surgeons. Advanced aortic surgery may be defined as aortic procedures falling outside the scope of standard cardiovascular or vascular surgery training. These procedures are generally performed in small numbers at a limited number of centers by personnel with focused expertise. Aortic services need to be comprehensive to treat the full spectrum of that pathology via either best medical therapy, endovascular repair, or open surgical repair, as well as perioperative care. A comprehensive aortic center should therefore be capable of and prepared to deliver a full range of aortic services.

The decision of whether to develop an aortic center should not be made solely on the basis of geography or projected patient volume. Rather, an institution should consider whether it can keep the patient engaged and offer needed services at the appropriate time. The patient should be engaged at multiple time points, from first contact, assessment, diagnosis, and clinical care, throughout any required intervention, recovery, and follow-up surveillance. An institution should also consider its ability to provide comprehensive vascular medicine evaluation and management as well as any required genetics evaluation. Tracking total costs and outcomes across a patient's care continuum can more comprehensively measure value delivered, so targeting cost reduction measures in this framework can better guide practices.

The benefit of establishing relationships with primary care referrers, engaging in provider and patient outreach,

Aortic surgery may be simply defined as any aortic procedures falling within the purview of the best-trained cardiovascular and vascular surgeons. Advanced aortic surgery may be defined as aortic procedures falling outside the scope of standard cardiovascular or vascular surgery training.

establishing an efficient outpatient aortic center, and using well-equipped operating suites is to serve a patient across the entire care cycle. This provides opportunity to screen, diagnose, intervene, and follow up to maximize the chances for a good outcome. An aortic outpatient clinic can provide a venue for the referral of patients with nonemergent aortic conditions and for preoperative planning and postoperative follow-up surveillance. An outpatient aortic clinic can also allow for community screening and, with outreach efforts, educate clinicians in referral clinics.

Availability may also be defined as a readiness or preparation of the health care team and patient to interact at the care initiation or throughout continuation of care. The hallmark of this interaction should be characterized by an allied focus on achieving desired outcomes and the proactive engagement of both patient and provider.[4] In 2015, Gibson et al asserted that patients can increase their likelihood of improving or maintaining their health if they are engaged in the coordination of their care.[4] Thus, individuals who are self-directed, informed by their health care provider (HCP), and are active participants in their own care are more likely to be aware of and open to evidence-based, innovative, high-value treatments. Likewise, it is important that HCPs are engaged not only for their patient's health outcomes and care experience, but also for their own health outcomes[5] and career satisfaction.[6]

Research has long shown the importance of the physician-patient alliance in a patient's readiness to engage in care.[4] Ideally, physician-patient communication should be bidirectional, timely, truthful, accurate, reliable, lawful, but also sensitive to a patient's emotions.[7-10] HCPs in both primary care and surgery have ample room for improvement in the area of empathy, as it has been reported that providers routinely miss opportunities to adequately acknowledge patient concerns, potentially undermining the care alliance.[11] A breach of trust may lead to increased risk of liability[12] and a decrease in patient compliance with medical care. HCPs should take an engaging, educational approach, be prepared to identify cues of patient unease, and be ready to educate and address their concerns.[12]

Interpretation and translation services should be available, if appropriate, for community demographics. Genuine, sustained efforts to interact and educate with cultural sensitivity can further strengthen this relationship, because differences in self-care behaviors have been recognized in patients of non-Western European origin.[13] Interaction with families and friends can also make a difference in coordinating or mediating a patient's care and can reinforce patient self-care. Preventing complications may hinge upon a piece of vital information such as an allergy to contrast or symptoms (eg, pain and claudication). Furthermore, coordination of care is planned and implemented by clear communication, face-to-face interaction, prompt telephone calls, and electronic communication, which could include spending time to reply to a patient's email with questions they forgot to ask during their preoperative visit. Patients and their family members are usually quite inquisitive, presenting opportunities to fulfill the critical need of HCPs to fully understand a patient's needs.

A physician's leadership is a championing effort, rallying the entire aortic team with energy and enthusiasm around the vision of improving patient outcomes.

TEAM DEVELOPMENT AND CORE ROLES

There are typically several different members of the health care team across a range of specialties, but the core aortic center team comprises physicians, nurses, and administrators. Achieving excellence in an aortic center requires the commitment of individual employees,

regardless of role or rank. Engagement is a universally valuable virtue in the workplace, characterized by commitment, vigor, dedication, and absorption.[4]

Physician Champions

Physicians are the core clinical decision makers in any aortic center, with a clinical, surgical, and academic focus. Physicians serve an essential leadership role in directing the health care team, interacting with consulting and referring physicians, and interfacing with administration. In this light, a physician's leadership is a championing effort, rallying the entire aortic team with energy and enthusiasm around the vision of improving patient outcomes. Physicians in the aortic center may be experienced cardiac and vascular surgeons, cardiologists, or radiologists involved in the training of residents and fellows, all of whom may interact together in a team approach to meet patient needs. Physician champions should collaborate effectively with all members of the health care team, including patients, their families, and caregivers. Administrative duties go hand in hand with patient care. Physicians should be able to plan, formulate, communicate, and support the clinical aspects of their hospital system, as well as articulating the aortic center's vision. They are resource architects, often requesting equipment, schedule modifications, additional labor, resources, or capital. They should be able to lead and facilitate communication among administration, with whom they share many leadership traits. Like administrators, physicians should be able to drive consensus, educate, and inspire others on the vision for the aortic center, acting as a liaison between the medical staff and hospital administrator. Interfacing with industry partners aids physicians in equipping their facility and team with devices and training. Physicians should also be able to participate in community service/outreach initiatives to educate patients and referral physicians.

Team Coordinator/Nurse Navigators

Nurses, physician assistants, or team coordinators are pivotal "navigators" in the aortic center and in shaping a positive health care setting. They play a leadership role in managing practical aspects of an aortic center and are often the primary liaison between the patient and the physician provider. They interface with physicians, administrators, other staff, patients, and families, and are instrumental in navigating the clinical and operational nuances of patient care. Nurse navigators will typically have at least 2 years of experience in the operating room (OR) or intensive care unit and 2 years of floor experience and are thus adept at coordinating clinical care and supervising others. They are experienced in program development, familiar with research and requirements of clinical trials, and should have compassion and motivation to lower complication rates. It is important that nurses and coordinators are duly recognized for their important contributions to quality patient care and improving outcomes, as this can promote leadership development, team building, and nurse navigator/coordinator work satisfaction.[14]

Administrators can perform a unifying role in the planning and implementation of an aortic center. Administrator leadership provides oversight of program development and the use of research and planning tools … this oversight also carries the responsibility to engage all stakeholders, and so administrators should be adept in engaging all departments and professionals individually and also facilitating interprofessional collaboration.

Hospital Administrators

Hospital administrators are critical team members instrumental in achieving the vision of a comprehensive aortic center. They should enable and support the cardiovascular service line. The skill set of administrators is often rooted in business and strategic management and can provide a focus on facilitating operational and organizational efficiencies. Administrators perform a critical job behind the scenes, supporting their hospital system's delivery of care and tracking financial outcomes and other metrics in the hospital system, including labor, scheduling, operational expenses, and any other factors that may impact the cost of care. Informed administrators will have a good understanding of their system's patient population, common conditions, and clinical services and staff required, ready to use that knowledge in rolling out programs and initiatives. This requires that they are seasoned program planners with prior experience in health management, quality assurance, and/or even health policy.

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Administrators can perform a unifying role in the planning and implementation of an aortic center. Administrator leadership provides oversight of program development and the use of research and planning tools, including market research, SWOT, and the aortic center tool kit to build their program. This oversight also carries the responsibility to engage all stakeholders, and so administrators should be adept in engaging all departments and professionals individually, and also facilitating interprofessional collaboration. They can also be instrumental in identifying barriers to the realization of an aortic center's vision, capable of effectively formulating and communicating for the aortic center together with physician champions and able to represent the aortic center to administrative leadership and external stakeholders.

Multidisciplinary Team Collaboration

The benefits of a multidisciplinary team approach have been lauded across virtually all health care specialties. In aortic disease, several studies report value in the multidisciplinary model of care. For instance, multidisciplinary teams have been shown to safely perform endovascular aneurysm repair of thoracoabdominal aortic aneurysms[15] and improve recovery, reduce morbidity, and reduce length of stay for minimally invasive AAA surgery.[16] Various cardiovascular surgeries, such as cardiac resynchronization and ventricular assist device interventions, have reported advantages in clinical outcomes[17] and reductions in cost.[18] The approach has also been reported advantageous in critical limb ischemia[19] and, most recently, for patients requiring endovascular carotid revascularization.[20] It has been reported as an important, if not essential, approach in the prevention of spinal cord ischemia after thoracic endovascular aortic repair.[15,21]

High-volume multidisciplinary thoracic aortic surgery teams have been reported as effective in treating type A aortic dissections.[22] For any acute aortic dissection, a standardization of the multidisciplinary approach in regional aortic centers can shorten time to treatment and represent a "new paradigm" for one of the most common types of aortic catastrophes.[23] The multidisciplinary approach is thought to improve survival even in smaller patient populations, such as Marfan syndrome.[24]

A multidisciplinary team comprises a cross-functional group of people focused on the outcome and overall well-being of the patient before, during, and after any clinical or surgical assessment or intervention. The surgeon or interventionist often acts as the team leader and directs the planning of patient care, working closely and collaboratively with the facility transfer system to facilitate safe and expeditious patient transfers.

Before the patient arrives, the physician leader directs the staff in preparing the facility, receiving the patient, and taking the steps required after arrival. If the physician leader suspects that operative intervention may be needed, then he or she prepares the department and assembles the needed staff. After the patient arrives, the physician leader and nursing staff should continue to work collaboratively with laboratory and radiology personnel and physicians to obtain the required hematologic and radiologic results and/or to upload any images already obtained at the transferring facility to the institution's picture archiving and communication system (PACS). The nurse navigator and clergy serve an important role in interacting with family members, updating them and offering support until further clinical information is available. Working in the background are the administrative team members, who should ensure that all team members are readily available and the equipment needed to perform the required procedures/interventions is on standby and in good working condition.

Developmental Costs and Capital Equipment

Initial capital investment is a prerequisite to having a well-equipped, functional team to plan and implement treatment in a comprehensive aortic center. There are notable operational costs associated with transfer management, requiring round-the-clock employee teams and labor in aortic centers, emergency departments, and radiology and laboratory departments. But these systems are usually already in place in most institutions, as is 24-hour OR staff. Nonstandard expenses may include some of

the higher-cost equipment, including high-resolution computed tomography scanners and a current hybrid suite. Multiple interventional specialties[25] are increasingly relying on hybrid suites as a necessity, particularly for advanced aortic procedures[26] and for minimizing risk, increasing safety for personnel and patients.[27] Costs of a hybrid suite (see supplement p 18 for brief discussion) can also be a sizable investment. The cost of constructing the suite with good-resolution systems can range from $1.3 million to $2.1 million, not including the cost of support equipment, such as a contrast injector, an IVUS system, and associated support wires, catheters, and stocking of a thoracic, abdominal, and peripheral stent inventory. A shelf stock of thoracic and infrarenal aortic endografts is also needed for emergent cases. These items add up to a significant initial investment, but are necessary to treat various aortic pathologies. To cover these costs, a strong business plan—including marketing outreach and operational plans—should be developed and implemented upon the launch of the aortic center.

Protocols Streamline Patient Access and Care

Protocols can guide the multidisciplinary team throughout an expected care continuum and treatment pathway and act as a checklist of essential actions the institution has standardized as a best practice.[28] Emergency medical services (EMS; eg, field emergency medical technicians, paramedics, and flight nurses) is responsible for transport to a transfer center.[29] Reimerink et al reported that 83% of EMS workers followed a ruptured AAA (rAAA) protocol, posing a risk of harm to some patients by delaying fluid resuscitation (controlled hypotension).[30] It is important to train EMS personnel in relevant aortic protocols and include EMS leaders when developing protocols. The EMS team delivers patients to emergency nurses and physicians, who may then send the patient to the aortic center and OR/hybrid suite team. Intensive care unit teams would then be needed with blood bank support and other staff to streamline the patient flow throughout each step.[31]

Obtaining buy-in from all team members and administration is necessary before developing and standardizing protocols.[32] This may not always be an easy process, but defining roles and establishing a cohesive team ready to respond to emergent and nonemergent cases can streamline patient care. Transfer protocols may help with streamlining interfacility patient transfers. A 2010 single-center study by Starnes et al at Harborview Medical Center (Seattle, Washington) reported significantly improved rAAA outcomes after implementing a protocol coordinating transfer and care.[33] These transfer protocols are not well developed in other parts of the United States, and national standards do not exist. A 2015 survey of 85 physician members of the Western Vascular Society found that the majority of respondents (60%) did not have a formal rAAA protocol at their institution, and > 70% reported that they did not use a transfer protocol.[34] The authors concluded that the development of national guidelines could potentially reduce inefficiencies and adverse outcomes of interfacility rAAA transfers.[34] Aortic centers can likely contribute significantly to a standardization process because most have already developed these protocols. Standardized protocols have been reported to facilitate earlier recognition of stroke symptoms and earlier treatment of carotid stenosis.[35]

Access to an aortic center should be planned and provided for throughout all phases of patient care, including anticipated and unanticipated touch points with the patient, in person or electronically. This element is a core feature of the perioperative surgical home model, as advocated by the American Society of Anesthesiologists.[36,37] General phases of patient care include preoperative, intraoperative, postoperative, and follow-up time frames. The aortic center must be accessible to nonemergent patients and must make it easy to connect with and enroll patients who simply require medical therapy and regular follow-up in the clinic. With such a diverse group of professionals delivering care, it is important for all team members to collaborate regionally to develop care protocols.[29] Some electronic health record (EHR) systems are capable of integrating computer-based protocols that can further streamline the care delivery process, with automatic alerts and prompted next steps.[38] Imaging protocols are also needed to standardize language and scanning practices to maximize safety and facilitate rapid diagnostic response.[39] Barriers to rapid response protocols reported in the literature are predominantly sociocultural in nature and can be addressed with repeated training and reinforcement of an institution's commitment to the vision of the center and the integrity of the rapid response system.[40]

There are three major classes of protocols: elective care protocols, emergency care protocols, and functional care protocols. Protocols are useful in mapping out a care pathway, as well as serving as a framework for monitoring outcomes data. Protocols can be broad or individualized for the condition. For instance, rAAAs can be planned for with the development of a protocol that calls for the earliest activation of the aortic team. This response can be streamlined if handled by a dedicated nurse on staff or at the transfer center who activates "code aorta" and immediately prepares the operating suite and facility for the emergent case. The institutions and physicians should agree on the transfer protocol, with orders for care speci-

TABLE 1. "GUILT BY ASSOCIATION" THORACIC AORTIC ANEURYSM (TAA) SCREENING INDICATORS FOR PATIENTS AND FAMILY MEMBERS[41]

	Indicator	Recommendation
Patients	AAA Intracranial aneurysm Bicuspid aortic valve Coarctation of the aorta Bovine aortic arch Origin of left vertebral artery directly from aortic arch Polycystic kidney disease Intra-abdominal simple cysts (kidney or liver) Temporal arteritis Autoimmune syndromes (eg, Behçet syndrome, Reiter syndrome, ankylosing spondylitis, early onset osteoarthritis)	**Imaging for TAA**
Family/genetic	**Syndromic** Patient affected by TAA (Marfan syndrome, Ehler-Danlos syndrome, Loeys-Dietz syndrome)	**Imaging and genotyping for TAA** Image/genotype all first-order family members (echocardiogram ± CT scan)
	Nonsyndromic Patient affected by TAA	**Imaging for TAA** Image all first-order family members (echocardiogram ± CT scan)
	Patient affected by bicuspid aortic valve	**Imaging for TAA** Image all first-order family members for bicuspid valve, TAA

fied before and during transfer, including acute blood/fluid management, blood pressure management, and rapid imaging as needed. In the past, physicians themselves would have to assemble the team to get them in rapidly. With a nurse handling the coordination, this frees up the physician to take care of the patient.

Research Trials, Databases, and Collaboration

An aortic center should have the institutional capacity for research trials to further the collective knowledge in treating disease. The ability to work closely with regulatory monitors and device manufacturers can be beneficial because most devices have unique characteristics. Manufacturer representatives can offer support with technical questions and provide some advice on equipment and devices needed to accommodate the aortic center's needs. For every condition, patient tracking capabilities are essential to build institutional knowledge of outcomes. For instance, a 2015 study emphasized the importance of mortality data tracking for rAAAs and symptomatic abdominal aortic aneurysms (sAAAs), concluding that analyzing these data is essential to identify areas of opportunity that may lead to improved survival in the "complex patient population" served by Exempla Saint Joseph Hospital (ESJH) in Denver, Colorado.[31] The authors analyzed rates of abdominal compartment syn-

drome and transfusion and identified future transfusion needs through a case debriefing process. ESJH developed the protocol database as a standardized means of tracking these patients by participating in the standardized Vascular Quality Initiative, a collaborative of regional groups governed by the Society for Vascular Surgery that collects, analyzes, and shares data to improve patient care. Participation in consortia like this has other perks, such as satisfying institutional data benchmarking and physician-specific certification requirements. It can also satisfy a physician's requirements to maintain certification by the American Board of Surgery.

Marketing, Education, and Screening

Marketing the debut and operation of an aortic center to the community plays an integral role in the development and success of the program. An active outreach plan can offer large dividends in increased patient referrals, as well as elevating the program's visibility in the local community and region. Publishing and reporting improved outcomes and anticipated improved mortality rates associated with a center will also support the continued success of the program. Accomplishing these items requires some capital investment for developing and implementing a marketing plan, as well as an investment of time by the physician and administrative leaders.

Personal visits to outlying emergency physicians and referral physicians are an important way to put a human face with the physician's name and aortic program. Having a brochure as a leave-behind allows further review of the program by referring physicians after the meeting. It is also an easy way to leave contact information for transfers from the outlying institution. Educational seminars and continuing medication education dinners are another tactic to market the program to the local and regional HCP community, as well as to provide a platform for local experts to further educate referral physicians in initial screening and action needed for a range of aortic pathologies. For instance, for silent thoracic aneurysms, Elefteriades and colleagues proposed adopting an approach that considers a host of factors and conditions that may point to its detection in a "guilt by association" fashion (Table 1).[41] This approach can effectively expand the multidisciplinary team's reach to positively affect the community, establish a good working relationship with allied HCPs, effectively present the center's expertise and capabilities, and build goodwill for a sustainable community partnership. Each of these measures require time, effort, and financing, but they can reap dividends to the aortic center as well as patients in offering a more rapid diagnosis, treatment, and expeditious transfer to the appropriate destination facility. These measures are aligned with the vision of an aortic center that can potentially yield benefits in decreasing morbidity and mortality. No matter how small these benefits are, they should not be ignored. ■

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Indications
The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is intended for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy, including:
- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42mm (fusiform and saccular aneurysms/penetrating ulcers), 18 mm to 44 mm (blunt traumatic aortic injuries), or 20 mm to 44 mm (dissections); and
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20mm (fusiform and saccular aneurysms/penetrating ulcers), landing zone ≥20 mm proximal to the primary entry tear (blunt traumatic aortic injuries, dissections). The proximal extent of the landing zone must not be dissected.

Contraindications
The Valiant Thoracic Stent Graft with the Captivia Delivery System is contraindicated in:
- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

Warnings and Precautions
The long-term safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm, endoleaks, migration, inadequate seal zone, or continued flow into the false lumen in the case of a dissection) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*. The Valiant Thoracic Stent Graft with the Captivia Delivery System is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures as described in the *Instructions for Use*. Strict adherence to the Valiant Thoracic Stent Graft sizing guidelines as described in the *Instructions for Use* is expected when selecting the device size. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear. As cautioned in the *Instructions for Use*, a balloon should never be used when treating a dissection. The safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

MRI Safety and Compatibility
Non-clinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems under specific conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events
Potential adverse events include, but are not limited to access failure, access site complications (e.g. spasm, trauma, bleeding, rupture, dissection), adynamic ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anaesthetic complications, aortic expansion (e.g. aneurysm, false lumen), aneurysm rupture, angina, arrhythmia, arterial stenosis, atelectasis, blindness, bowel ischemia/infarction, bowel necrosis, bowel obstruction, branch vessel occlusion, buttock claudication, cardiac tamponade, catheter breakage, cerebrovascular accident (CVA) / stroke, change in mental status, coagulopathy, congestive heart failure, contrast toxicity, conversion to surgical repair, death, deployment difficulties / failures, dissection / perforation / rupture of the aortic vessel and/or surrounding vasculature, embolism, endoleak(s), excessive or inappropriate radiation exposure, extrusion / erosion, failure to deliver stent graft, femoral neuropathy, fistula (including aortobronchial, aortoenteric, aortoesophageal, arteriovenous, and lymph), gastrointestinal bleeding /complications, genitourinary complications, hematoma, hemorrhage / bleeding, hypotension / hypertension, infection or fever, insertion or removal difficulties, intercostal pain, intramural hematoma, leg /foot edema, lymphocele, myocardial infarction, neuropathy, occlusion – venous or arterial, pain / reaction at catheter insertion site, paralysis, paraparesis, paraplegia, paresthesia, perfusion of the false lumen, peripheral ischemia, peripheral nerve injury, pneumonia, post-implant syndrome, procedural / post-procedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysm, pulmonary edema, pulmonary embolism, reaction to anaesthesia, renal failure, renal insufficiency, reoperation, respiratory depression / failure, sepsis, seroma, shock, spinal neurological deficit, stent graft material failure (including breakage of metal portion of device) / migration / misplacement / occlusion / twisting / kinking, transient ischemic attack (TIA), thrombosis, tissue necrosis, vascular ischemia, vascular trauma, wound dehiscence, wound healing complications, wound infection.

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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