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TAVR Economics in a Community Program

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innacleHealth CardioVascular Institute is the formal cardiac and cardiothoracic service line for PinnacleHealth System, a multicounty system of five hospitals surrounding Harrisburg, Pennsylvania. It was founded in 2011 and is a hospital-contracted body, formed by the merger of two large private practice groups. The Institute consists of more than 75 providers and averages more than 100,000 office and hospital visits per year. The payer mix is based on half Medicare and half private insurance. A unique facet of the program is the substantial effort placed on clinical research, much in the field of structural heart disease, involving the application of various transcatheter aortic valve replacement (TAVR) platforms in lower-risk surgical populations. The Institute's involvement in TAVR trials dates back to 2011 with initiation of the U.S. Pivotal trials for Medtronic CoreValve. The recent growth in the program has been due to robust commercial volume that has developed from expanding indications for TAVR use in populations of acceptable surgical risk.

THE CURRENT STATE OF TAVR ECONOMICS IN A COMMUNITY PROGRAM

TAVR is a transformative, less-invasive therapy for patients with severe aortic stenosis. These procedures are now performed with percutaneous transfemoral approaches, emphasizing quick return to a heightened quality of life with outstanding clinical benefit. Despite the impressive clinical growth of TAVR with rollout to low-risk populations, the perceived cost difference of the TAVR device compared to a surgical valve bioprosthesis often takes center stage in any economics discussion, despite the fact that overall costs for the procedures are not substantially different. Because of this perception, TAVR programs often must focus on developing operational efficiencies in a way previously not usually encountered in medicine. As clinical data substantiate at least noninferiority for TAVR as compared to surgical aortic valve replacement (SAVR), a critical determinant of the success of a TAVR program in the community will be the economic barriers to entry. The financial

viability of a community TAVR program depends on a critical analysis of all aspects of resource utilization in the pre-, peri- and postprocedural settings, and adopting practices that break from the typical postoperative cardiothoracic patient while still ensuring the highest-quality clinical outcomes.

Understanding the impact of TAVR on a community program and its cost-effectiveness involves a departure from classic, payer-based methods of economic analysis, which analyze the societal perspective and costs for a therapy, including quality of life. Practical economic valuation is not based on societal parameters and thus the focus of health care administration in a community program usually does not prioritize their consideration. Instead, the administration must turn their focus to larger budget impact and cost accounting analyses.

REIMBURSEMENT PER PROCEDURE

At its base, reimbursement determinations for Medicare and, to a significant degree, non-Medicare payers, involve an operating base payment rate that incorporates an evaluation of geographic wages. This is then adjusted for case mix based on the severity of the patient and their cost to the hospital via the assignment of a Medicare Severity-Diagnosis Related Group (MS-DRG) for inpatient procedures. MS-DRGs are primarily defined by the principal diagnosis and procedure, and secondary assignment is assigned based on the severity of the patient's illness and intensity of the services required (and resultant cost to the hospital) via any secondary diagnoses that may qualify as major complication or comorbidities (MCCs). For TAVR, the MS-DRGs are 266 and 267, which were established as specific to TAVR in fiscal year 2015. These MS-DRGs specify reimbursement for TAVR with and without MCCs. MCCs primarily include severe acute diseases, an acute exacerbation of a chronic condition, and end-stage renal disease, a rare qualifying chronic condition. Certain complications that may arise during the course of the patient's procedure or periprocedural course also qualify as MCCs. Approximately 3,200 diagnoses qualify

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as MCCs when reported as a secondary diagnosis. Presence of an MCC results in increased cost to the hospital for the additional care required for the secondary condition(s), which then results in an increased reimbursement. On average, in fiscal year 2015, PinnacleHealth was reimbursed \$58,588 for MS-DRG 266 versus \$44,182 for MS-DRG 267. Teaching hospitals will receive an additional payment for each MS-DRG entitled indirect medical education to assist in covering the additional cost of the teaching program. Contrasting the reimbursement for PinnacleHealth, a nonteaching institution, the Hospital of the University of Pennsylvania, an academic institution, was reimbursed \$83,627 for MS-DRG 266 versus \$63,159 for MS-DRG 267.

There are other factors that impact MS-DRGs, including cost of living for an institution's location, volume of indigent patients and uncompensated care, and credits or penalties for value-based purchasing measures. Current hospital reimbursement for TAVR envelops this fee-for-service approach and thus revenue is based on an individual episode of care. This should be contrasted from an alternate payment model, which may involve bundling of episodes, and provide reimbursement based on multiple episodes of care. This will be the future reimbursement landscape for many cardiovascular endeavors, but there are many operational efficiencies, as subsequently detailed, that will lead to economic success regardless of reimbursement model.

POSTACUTE CARE TRANSFER POLICY

One distinguishing feature of a fee-for-service model adjudicating TAVR reimbursement is the current Medicare postacute care transfer policy (PACT). For some MS-DRGs, such as those for TAVR, special rules have been created for patients who are discharged immediately after their hospitalization to a rehabilitation hospital, skilled nursing facility, a long-term care hospital, or with home health care. This incorporates the geometric median length of stay for a particular MS-DRG. If the patient is discharged prior to this "short stay threshold" with use of the ancillary facilities or resources described previously, Medicare will appropriate a per-diem penalty. This is basically a per-day allocation of reimbursement from the hospital to the posthospital facility or resource in order to avoid double payment for the care provided. This per-diem payment is calculated from the total reimbursement for a given DRG divided by the geometric median length of stay. Current short stay thresholds for MS-DRGs 266 and 267 are 5 days and 2 days, respectively.

If home health services are present prior to the TAVR procedure, these can be resumed upon discharge with-

out incurring PACT, provided that there is adequate documentation attesting to the necessity of these preexisting services as unrelated to the TAVR episode of care.

UNDERSTANDING AND MODIFYING COST PER PROCEDURE

The cost of a TAVR program is more complicated than simply looking at the cost of transcatheter valves. In fact, an analysis that limits itself to merely comparing implant costs and reimbursement totals will miss other major contributing factors to the total cost of valve replacement procedures.

In an analysis of PARTNER data, Arnold and colleagues described that 24% of nonimplant-related costs are related to complications, such as major cerebrovascular accident, major bleeding, renal failure, arrhythmia with need for pacemaker implantation, and need for a repeat procedure. Avoidance of complications and maintenance of clinical excellence is key for the viability of a TAVR program in a community hospital. Outside of proficient technical skill and a methodologic approach in the procedure to avoid unnecessary complications, costs to the hospital are dependent on patient selection, peri- and postprocedural resource use, and resultant length of stay.

Ensuring the most appropriate length of stay for the best clinical outcome will allow a facility to use its resources and reimbursement for the most important areas for the patient's care. This involves a concerted effort to medically optimize patients prior to their procedure and even performing balloon aortic valvuloplasty as a bridge to TAVR when clinically indicated. By reducing length of stay prior to the procedure, there is significant cost containment.

With the safety of the transfemoral approach, operational efficiencies could be found in using the cardiac catheterization laboratory, instead of the operating room and its associated resources, and elimination of the routine setup of perfusion. Costs associated with the procedure itself, including use of expensive sheath, wire, and pacing technologies, can also slim margins significantly. A dedicated economic analysis of cost and benefit for each facet of the TAVR procedure is critical for the success of a community program. This analysis can start with listing the supplies used for a typical case and examining lowercost alternatives, or perhaps eliminating the use of an expensive supply altogether. For example, use of one closure device (vs the conventional use of two) for the "preclosure" technique for percutaneous transfemoral closure, in addition to protamine administration and manual pressure, would reduce cost related to the procedure by several hundred dollars. This approach has been shown not to compromise safety related to the procedure.²

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A "fast track" pathway avoids the intensive care unit for lower-risk patients with straightforward procedures. As an institution, aligning providers and nursing staff on appropriate postprocedure care protocols will help develop best practices for subsets of patients. Uncomplicated percutaneous transfemoral procedures, especially those avoiding general anesthesia, may not merit the highest levels of monitoring and postprocedure care. Community institutions may benefit from development of institutional guidelines that would direct the care of appropriate patients in this manner. Such pathways would ideally focus on early ambulation and resumption of outpatient oral medications, to facilitate safe and expedient disposition. The ancillary costs incurred by laboratory and pharmacy use would also be minimized by avoidance of intensive care units.

IMPROVING THE BOTTOM LINE: CHANGING CULTURE

In reviewing the factors related to TAVR in a community program, there is understanding of the uniqueness of all aspects of this procedure when compared to SAVR. However, most community programs maintain the same care pathway for TAVR patients as their postoperative SAVR population. This could lend to wasteful use of resources directed to specific patient care that does not merit such extravagances. Physicians, nursing, as well as ancillary services, such as physical/occupational therapy, social work, case management, and nutrition, must be aware of the differences in the care of an uncomplicated TAVR patient and should adjust their assessments accordingly. There should be strong partnership with health care administration to review the outcomes of efforts dedicated to appropriate resource consumption, as this recognition can help justify the existence and growth of a TAVR program. It is equally important for patients and their families to understand the most likely disposition for a patient who is home after TAVR, without the use of any additional postdischarge resources. This conversation should occur far in advance of the procedure, to aid the patient and their family in preparing for the procedure. In the current fee-for-service paradigm, physicians should be willing to set up immediate postdischarge outpatient visits in order to ensure patients thrive after the procedure and provide patients and their families the reassurance of continuity of care.

The Heart Team approach is absolutely necessary to aid in screening patients for TAVR and prepare patients medically and physically for the procedure. Proper documentation of acuity is essential in accurate medical records and claims submissions, and there should be consistent communication between billing/coding personnel and the providers to ensure this level of detail is achieved in charting. Knowledge of the Medicare PACT policy may also help the Heart Team appropriately plan postprocedure care.

CONCLUSION: DON'T BE INTIMIDATED

TAVR in the United States is expensive, but it is the best therapy for many patients, and should be readily available in community hospitals with strong SAVR programs. It is up to the provider and the administration to make it work for the institution. Comprehending the constructs underpinning costs is essential for the economic viability of a community program. Transitioning from fee-for-service to alternate payment models may require some different approaches in order to achieve economic success, but the culture of a TAVR program must be separated from standard surgical practice in order to navigate pathways of care.

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