The transcatheter aortic valve replacement (TAVR) program at the Hospital of the University of Pennsylvania (HUP) in Philadelphia, PA, was one of the first in the country. It started in 2007 as part of the Food and Drug Administration clinical trial program. Here, we find out how this early program has grown and implemented pioneering TAVR procedures.

Can you share how your TAVR program has evolved over the past four-and-a-half years?

In January 2007, we held our first strategic planning session, which included the core heart team, administration and the clinical trial sponsor to identify what would be needed to develop a TAVR program.

The core heart team included two cardiac surgeons, two interventional cardiologists, a lead anesthesiologist, the surgery team, the cath lab team, a lead echocardiologist, a neurologist, an administrative assistant, and a lead research nurse as the valve coordinator for the program and trial. Our hybrid room had already been built, but modifications were made to accommodate the new technology. The hospital’s administration approved the project, and by November 2007, we had implanted our first valve.

Until November 2011, TAVR therapy was available only as part of an FDA clinical trial called the PARTNER Trial. Over the past four-and-a-half years, HUP has been part of this clinical trial that eventually led to the Food and Drug Administration’s approval of TAVR for the inoperable patient. We have greatly expanded our core team to better serve our patients, and we now offer TAVR at our main campus as well as at our sister location, Penn Presbyterian Medical Center. Many staff members are now trained to expedite and facilitate patient evaluation and care.

How have you educated your referring physicians?

In the early days, our TAVR team spent time meeting with our referring physicians to discuss the trial, device, procedure, and for whom it is appropriate. We invited many colleagues to observe cases so they could better understand the procedure. We made sure our referring physicians had our contact information — including cell phones and email. We also directed them to clinicaltrials.gov, the government website for all clinical trials. We sent educational videos available on the Edwards Lifesciences website that depict the procedure, along with contact information and screening worksheets.

Today, TAVR is much more widely known. Physicians often send patients with full workups for TAVR, and patients and families better understand the device and procedure.
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What tests are done during patient evaluation?
We encourage our referring physicians to do much of the patient testing and send us the information before their visits. This lets our team review the data to determine a plan for when we see the patients. Otherwise, we have to spend clinic time doing a complete work-up for testing. Our heart team requests the following data on all patients:

- Right and left cardiac catheterization with lower-extremity aortogram [Note: if a patient has had previous coronary artery bypass graft surgery (CABG) with either a left or right internal mammary artery (LIMA or a RIMA), we ask for a lateral shot to note the location of the graft in relationship to the sternum];
- Echocardiogram, with attention to aortic valve area (AVA), aortic valve gradients, degree of aortic insufficiency, mitral regurgitation and ejection fraction;
- Computed tomography angiography (CTA) of chest/abdomen and pelvis, 2 mm slices with and without contrast (if renal function is impaired, a non-contrast CT scan can be done);
- Pulmonary-function studies (full set, including lung volumes, spirometry and a room air arterial blood gas);
- Carotid duplex;
- Comprehensive metabolic panel and hematology lab studies;
- Dental clearance

We have been inclusive of our referring physicians, educating them to play active roles in screening and evaluating their patients. We provide tools and education so, if they choose, they can provide the testing required for their patients’ evaluations.

What kind of resources and support were required to get your program off the ground?
Most of the financial support and staffing for the PARTNER trial participation came from our cardiac surgery research program. However we did need support from our administration. While renovations to upgrade the hybrid suite in our OR were underway, negotiations for valve pricing and the clinical research budget took place. While administration had committed capital to the construction, we needed to cost-justify the valve clinic.

HUP has always prided itself on offering cutting-edge technology to patients. In today’s healthcare economy, we needed to help administration understand how this technology would change practice by bringing a life-saving treatment to an underserved population.

What were the challenges of setting up your program?
We needed to shift our clinic so cardiac surgeons and interventional cardiologists could be located where they both could see a patient, if appropriate. We needed to look at all our clinical trials and reallocate responsibilities. We set up weekly meetings to discuss the program’s progress and review potential patients. We also continually examined team members’ roles to ensure efficiency and quality of care were best served.

About one year into the program, we realized we needed to better analyze our program to understand the financial impact on the institution and resources needed to build the program. From day one, we kept a patient log to track referred patients and their outcomes. The log also let us examine the trickle-down effects of TAVR and the cost structure; helped us develop a system for shared revenues; acted as a way to look at cost-billing appropriateness, the impact on ancillary services required for patient evaluation, and the volume of patients who came to HUP because of this new technology, and who ended up with either TAVR or traditional surgical AVR; and finally, supported the need for new resources to allow for growth.

How is your TAVR program structured today, in terms of heart team members’ roles and responsibilities, and the co-existence of clinical and commercial programs?
In addition to having more physicians and nurse practitioners, we have expanded training to our OR and cath lab teams and practitioners system wide. This team approach has greatly eased the transition to the commercial program from the clinical trial.

Our core heart team today is similar to how it was originally developed. The team of physicians, nurse practitioners, and research team members meet weekly to review data of patients being considered for this therapy. A PowerPoint of each patient’s data, including history, Society of Thoracic Surgery (STS) score, why the patient is being considered for the commercial or trial program, test results and imaging, is presented to ensure each patient is an appropriate candidate for the procedure. The team then decides on a treatment plan.

Our program intermingles the research and clinical teams. The nurse practitioner and I review patient data. An administrative assistant schedules patients, collects information, and works with the hospital billing department to obtain insurance clearance for studies ordered and to schedule implants. The research team then compiles the data in PowerPoint format to present to the team. The interventional
cardiologist reviews all the catheterization films and sends images to be formatted in PowerPoint. I initially review all CTA images and 3D images of each patient’s aorta and access; these are put in each presentation. I also review echo loops, adding images that depict annulus, left ventricular outflow tract measurements, and echo gradients.

I would suggest that new sites look at what is special and unique about their institutions, and who or what would complement their programs. Some sites have gerontology and/or renal physicians as part of their teams; others have pulmonologists or rehabilitation medicine join their teams. It is important to understand your referral patterns and access to your system, and to understand what resources may be available.

Since the program evolved from a research project, I looked at other, low-cost resources that were available to help support research needs. HUP is a large academic institution where students are readily available to take part in research projects. One of our TAVR program’s missions was to include students, and we used them to aid the administrative organization. It is important to understand your institution so that the plan of action fits your environment.

What is your background and what led you to your role in the heart team?

The evolution of TAVR at HUP started with our clinical research program. My experience at that time focused on managing multiple clinical trials through to commercial approval. I started my nursing career in the intensive care unit, gaining surgical and medical background at an outside hospital. I joined HUP in 1998 as a surgical critical care nurse in the intensive care unit. From there, I worked five years with our outpatient heart failure team and, in 2004, joined the research team of Joseph Bavaria, MD. Before becoming a nurse, I owned and operated a business while raising my family.

The role of a research clinical nurse has been a good transition for me, because I have juggled many roles over the years, and enjoy challenges and problem-solving. Being a research nurse requires strong organizational skills and attention to detail. I derive great satisfaction from being involved in a project that will affect so many patients’ lives. Over the course of this project, I have worn many hats: patient advocate, negotiator, politician, researcher, and educator. I see myself as the link between the team, patients, referring physicians, and sponsor. Communication is key to ensuring good patient care and good outcomes. Another important component is to sharing your knowledge: program growth can be achieved only by teaching others.

If a hospital is looking to select or hire a TAVR coordinator, what are the most important skills and qualities this person should have?

The candidate should have a good understanding of the aortic stenosis disease process and the elderly heart failure population; possess strong leadership, communication and organizational skills; and be an energetic, independent worker and a self-propelled learner. It may be helpful for the person to shadow other team members so they can fully understand the team’s expectations and whether they are a good fit for the job.

Patient identification is often one of the most challenging aspects of starting a TAVR program. How do you identify potential TAVR patients?

In the beginning, potential TAVR candidates were primarily identified in our outpatient clinics or at the time of admission. As awareness of the technology grew among our referring community, we began to see patients referred specifically for this treatment. The volume of patients can make appropriate patient identification difficult, so to keep myself organized, I created a database that includes the following information:

- Patient name;
- Medical record number;
- Date seen;
- Referring physician;
- Comments about the specific patient;
- Treatment plan;
- Outcome.

I also enlisted the help of patients, their families, and referring physicians to help track patients throughout the process. By sharing the accountability with these groups, all parties are invested in the care process.

Can you share more about how you work with your referral network to identify patients who may be able to benefit from this therapy?

We developed a bullet-point worksheet that outlines the information necessary to help referring physicians decide whether TAVR might be an appropriate treatment for their patients. We also invite referring physicians to observe our patient care process, including observing actual procedures and the outcomes of patients post-procedure. We understand this technology is costly; however, we believe the benefit justifies the cost — and that the best way for everyone to understand is to experience what it is like to care for these patients.

Our primary referring physicians are cardiologists, but we are seeing patients from primary caregivers and other specialists who deal with high-risk patient populations. TAVR opens the door to a treatment option that did not exist for some patients. When we started, we could not have imagined how many patients this disease affected. We theorize that the number has increased because many patients were never referred to specialists for treatment of aortic stenosis, because they were deemed too high risk for open-heart valve replacement.

Was there a protocol or process implemented to identify patients within the hospital system who were being overlooked previously?

Our heart team introduced our program using a grassroots approach. We started by educating our hospital and internal referring physicians about the program. Our team accomplished this through grand rounds and meet-and-greet sessions. Our physicians spoke to their colleagues at invited talks. The nurses presented to their counterparts. We offered inservices to the nurses and caregivers in the various units in which patients would be admitted throughout their stays.

Throughout the program’s development, we kept staff and administration aware of progress and outcomes. We identified benefits for TAVR, such as being able to treat patients who
otherwise did not have any options. We educated our hospital on this new technology, so everyone could better understand how we would help an underserved population and that the trickle-down effects would be able to support the program.

Our lead echocardiologist has worked with the team from the beginning of the program and has educated his colleagues regarding the specific data needed for TAVR evaluation. It is common for our echocardiologist to contact the ordering physician with a preliminary finding. The echocardiologist also is readily available for consult on an echo perhaps done at an outside facility or if there is a question with the study. The echocardiologist is important part of the team and can be great resource for identifying appropriate candidates for the TAVR procedure.

How are patients tracked through the process?
Depending on your resources and volume, you will need to decide who will maintain this database. To ensure patients are not lost in the system, I would suggest that a follow-up visit be scheduled at the time of the initial visit(s).
At HUP, we have an electronic charting system. If you have one, contact the team that manages the system to see if identifiers can be added to help audit patient volumes. Now that TAVR is available commercially, new procedure codes can be used to track the patients. Sites with research patients will already have a tracking system through the research databases.
The databases have helped us analyze patient outcomes, identify challenges, and better understand the financial impact of TAVR on the institution. Regularly reviewing patient outcomes at our team meetings lets us look for areas in which we can improve, and helps us develop personalized treatment plans for each patient. Over time, this practice has helped us to develop screening tools to better determine who is right for TAVR, who is high-risk operable, and who is inoperable.

What is your process for patient screening and evaluation?
Screening starts with referral. We request all patient records, including reports of any studies, along with films of catheterizations, CTA films, or echocardiograms. We provide specific data that we require if the referring physician wants to complete the testing before the patient visit. Once we have received the patient information, we review the data. Again, if the patient has had a completed workup, we will schedule them to meet the heart team in our TAVR clinic. If testing is incomplete, we contact the referring physician and patient to see if testing can be completed before the visit. Patients who still require testing are scheduled with our nurse practitioner for an initial evaluation and ordering of additional testing.
During weekly team meetings, we review the data of patients coming in that week for a recommendation. During those visits, evaluation for operability is done. For patients who are direct admits to the hospital, we try to complete all testing and a meeting with the heart team while they are in-house. Some patients will be treated at the time of their admission; however, many patients are discharged so that an elective procedure can be scheduled. This lets patients recover from their acute events and come to the OR in better condition. Some patients have factors that contribute to their symptoms, and it can be challenging to determine whether TAVR will be the answer.

Who participates in your multidisciplinary TAVR conference?
During the weekly patient data review — attended by surgeons, interventional cardiologists, the nurse practitioner, the research team and the administrative assistant — the team determines a treatment recommendation. Our team communicates throughout the week if changes occur with the patient or something new is discovered, so the plan can be modified if needed.

What kind of pre-procedure care do you provide for TAVR patients that is unique or different than for surgical heart valve patients?
TAVR patients have multiple risk factors and challenges that should be considered when developing a plan of care. We found, in the PARTNER I trial, that the average patient age was approximately 82 years. Many of the patients have other disease processes that need to be managed, such as coronary artery disease, renal disease, lung disease, neurological impairment, diabetes, and arthritis, and other diseases that add risk. Some of these diseases can greatly affect the recovery period, because of challenges with ambulation, anesthesia risks and rehabilitation. For some patients who present as very ill, we have used balloon valvuloplasty to help bridge them so they will be in better condition at the time of valve replacement.

There are also social issues that should be addressed. Many patients are hard of hearing, and so will require patience and more visual aids, along with good interaction with their support systems. For example, assess whether someone will provide care at home and whether there are transportation challenges.
It is important during the screening process to manage the expectations of the patient, the patient’s family, and the referring physician’s expectations. The team should review the patient data to identify challenges that the patient may have and address them in the care plan. A review of your process should be discussed with the patient, family and referring physician so that they understand the required testing and how a treatment plan is formulated.

It is important to be clear with all parties that TAVR therapy is not necessarily an option for every patient. The team may recommend traditional open-heart therapy or continued medical management.

How do you handle post-procedure care?
All patients are transferred to the surgical intensive care unit from the OR. Our ICU is managed by cardiac anesthesia and cardiac surgical nurse practitioners. Protocols have been established for the peri-operative period and post-operative care.
If it is deemed appropriate, patients are extubated in the OR. If not, the team quickly weans and extubates the patients. All femoral lines and Swan-Ganz catheters are removed as early as possible. Discontinuation of temporary pacemakers may be delayed in patients with increased risk of arrhythmias. Standard post-operative procedures include comprehensive lab work, ECG and chest x-ray. On post-operative day one, most patients are transferred to our surgical floor. There, the core team of surgical nurse practitioners cares for our TAVR patients. Patients soon start physical and occupational therapy. Patients, families, and/or caregivers
meet with a social worker to begin discharge planning. Patients are scheduled for a 30-day post-operative visit in our clinic. After that visit, patients are followed up long-term in our nurse practitioner clinic.

**What impact has your TAVR program had at HUP?**

TAVR therapy has greatly affected our institution. We have developed a heart team approach to structural heart disease, engaging multiple disciplines to evaluate and treat patients with aortic stenosis. The collaboration of experts lets us formulate the best care plan for the patient.

The addition of patients being evaluated for this new technology has increased overall valve volume. Some of these patients have gone on to receive TAVR, others have had high-risk open AVR, others were followed until ready for treatment, and others, ultimately, were not TAVR candidates. This volume increase has prompted HUP to better understand the program’s financial impact, to audit the program regularly, and to analyze the resources needed for growth and success.

We seek to offer care to the public through advances in science, research, discovery, knowledge, and education. TAVR continues our mission.

**What general advice do you have for hospitals just starting programs or that hope to start programs?**

1. Pick a heart team and identify specialties that can compliment your team.
2. Understand the resources needed to make the program successful. Reach out to other heart teams for advice.
3. Have a dedicated valve nurse.
4. Understand the patient population's special needs. Many of these patients want to improve quality of life, and not just extend their lives.
5. Set up a database to track patients and outcomes.
6. Audit your program's finances, case volumes, billing compliance and follow-up compliance regularly. Identify challenges and outcomes for quality assurance.
7. Set up a mock OR before your first case and hold regular mock sessions to ensure staff understands their roles during the procedure.
8. Involve administration from the start.
9. The core heart team should perform the first 50 cases, then training of new staff can begin.

**What have you found to be the most rewarding aspect of your TAVR program?**

The most rewarding part of this experience has been helping to bring treatment to patients who previously had no good options. Over the years, I have had the pleasure of getting to know my patients and their stories — they talk of being able to attend life events such as weddings, births, graduations, and anniversaries. The patients want to feel better and improve quality of life, and their families want to find a way to help relieve their loved ones’ suffering.

When patients come back to see us in the clinic and express such gratitude, or families write to thank the team for helping their loved ones, it makes all the hard work and time spent worth the effort. I have received letters from families of patients who have passed away, thanking our team giving their loved ones a chance to have a little more time or the opportunity to experience one more special moment in their lives.

It is humbling to hear stories from these patients and families who appreciate life. As I look at my career as a nurse, I feel privileged that I have been part of something that has helped so many patients and that has truly effected change. TAVR and heart teams make a difference.