STREAMLINING THE PROCESS FOR TAVR PROCEDURES

How St. Francis Hospital, one of New York state’s largest heart and vascular centers, improved the efficiency of TAVR procedure days
As a Leader in Cardiovascular Care, and a TAVR Pioneer, St. Francis is Focused on Expanding Access to TAVR Therapy

Transcatheter aortic valve replacement (TAVR) is a rapidly growing therapy for the treatment of severe Aortic Stenosis (AS).

TAVR employs a multidisciplinary team to evaluate and treat AS patients who are eligible for the therapy. This provides an excellent level of patient care, but also adds operational complexity which needs to be addressed and managed to ensure that the growing number of eligible patients have access to the therapy.

St. Francis Hospital in Roslyn, New York is a leader in cardiovascular care and a TAVR pioneer. They have experienced rapid growth in their TAVR program over the past several years. As the demand for TAVR continues to grow, St. Francis decided they needed to proactively examine every aspect of their TAVR operation and seek ways to further streamline the process to expand their ability to treat more patients.

The first step in this process was the creation of a multidisciplinary performance improvement team dedicated to analyzing their entire TAVR procedure. They ensured that the members of the team were actively involved in the everyday work of TAVR procedures to help guarantee that solutions were driven by the staff closest to the process.

This team’s goal was to identify ways to leverage Lean Sigma and change management methods to optimize TAVR cases so that more patients could be treated on the two days each week that their highly specialized Hybrid OR and Cath Lab Teams came together to perform TAVR procedures. Normally, these two teams function separately, so St. Francis needed an approach to optimize the TAVR procedure workflow when these two teams were blended.

At-A-Glance
- Based in Roslyn, NY (Long Island)
- Service line leaders for Catholic Health Services
- New York State’s only specialty designated cardiac center
- In 2014:
  - 1,129 open-heart surgeries
  - 3,781 cardiac arrhythmia procedures: electrophysiology studies including ablations, pacemakers, and AICDs
  - 10,233 cardiac catheterizations, including all diagnostic, interventional, and peripheral vascular procedures
- In 2015, St. Francis opened a new Heart Valve Center
- More than 590 TAVR procedures as of October 2015
Project Facilitation
Support from Medtronic

The St. Francis team worked with the PRO\CV® Service from Medtronic, which specializes in redesigning and optimizing patient processes in cardiovascular organizations. Together with Medtronic, the St. Francis team created an effective structure and process to thoroughly review the dynamics of their TAVR procedure.

Consultants from the Medtronic PRO\CV Service facilitated a formal performance improvement project with St. Francis that followed a well-defined method for solving problems. The goal of this method was to break down barriers, identify and prioritize opportunities for continuous improvement, and ultimately expand St. Francis’s capability to treat more patients. The PRO\CV approach emphasizes the use of data analysis for improving, optimizing, and stabilizing complex patient workflows.

The multidisciplinary process improvement team at St. Francis was comprised of the following members (in alphabetical order):
- Administration
- Anesthesia
- Cardiothoracic Surgeon
- Cath Lab team
- Hybrid OR team
- ICU
- Interventional Cardiologist
- PACU
- Perfusion
- Radiology
- Surgical Nursing

Medtronic PRO\CV Master Black Belt consultants coordinated data gathering and facilitated several team meetings with the St. Francis process improvement team. They met many times to review operational data and brainstorm innovative approaches to streamline their TAVR procedure. The St. Francis team met regularly with leadership to ensure critical timelines and outputs were being met.

What is Lean Sigma?

Lean Sigma is a methodology used to streamline work processes and remove unnecessary or wasteful steps. This approach was first developed to improve manufacturing, but has been applied successfully to improve many work processes in hospitals and clinics.
Assessing their Current State and Value Stream

One of the first deliverables for the Medtronic PRO|CV and St. Francis team was an analysis called a Current State Assessment. This simply means observing a process or workflow to identify areas for improvement or streamlining. A Current State Assessment helped set a baseline against which to measure improvements. It also gave the team measurable data and shared understanding of the combined Hybrid OR/Cath Lab process during T AVR days.

Another output of the Current State Assessment was a Value Stream Map which essentially broke down the TAVR day process into its critical, value-added elements. For St. Francis, that meant observing and documenting the separate procedural steps for their TAVR patient process and then measuring process times and variability across 19 consecutive TAVR patients.

Medtronic PRO|CV Service

Medtronic PRO|CV stands for Process Redesign and Optimization for CardioVascular services.

It is a fee-based service focused on designing and implementing organizational efficiency solutions that increase access to care, improve patient quality of care, and drive operational and clinical effectiveness.

What is a Current State Assessment?

A Current State Assessment is an activity that helps organizations understand their current workflow in a way that helps them design procedures that are more efficient and productive. One of the outputs of a Current State Assessment is a Value Stream Map that outlines the steps in a workflow.
Value Stream Steps of TAVR Procedures

The graphic below illustrates the average TAVR patient flow at St. Francis on their TAVR procedure day at the beginning of the project, and the discrete steps — or value stream of activities on that day.

![Value Stream Map](image)

Focus Areas for Increased Efficiency

Based on the insights gleaned from the Current State Assessment and Value Stream Map, the St. Francis team analyzed and brainstormed ways to improve efficiency. They prioritized 3 key focus areas for the project as an output of that effort:

1. Optimizing staff time
2. Minimizing patient wait times
3. Streamlining clinical processes and protocols

After a prioritization process, the St. Francis team implemented the following changes to address the needs of their growing TAVR program:
1. Optimizing Staff Time

- Added a second anesthesiologist for faster case starts between the Hybrid OR and Cath Lab
- Implemented a cross-training plan to maximize staff capability during and between procedures
- Implemented a team lead to coordinate between physicians and other departments during TAVR procedures
- Held after-procedure team huddles to improve procedural communication
- Set up more formal patient handoff communication between pre-op/intra-op/post-op activities

2. Minimizing Patient Wait Times

- Standardized processes for admitting patients to the holding room, including:
  - A new TAVR hand-off check list
  - Only one holding area for TAVR patients vs. two
  - Patient consents completed the day before the case

3. Streamlining Clinical Processes and Protocols

- Examined all clinical protocols, and optimized/streamlined a number of them, including:
  - Standardized order sets and checklists
  - Optimized use of Swan-Ganz catheter
  - Assessed for alternatives to general anesthesia
  - Earlier confirmation of access site prior to case
  - Standardized medication orders (aspirin, Plavix)
  - Simplified OR table set up
  - Improved staging of subsequent cases
The Results*

Through the efforts of the project team, and by streamlining the efficiency of their entire end-to-end procedural workflow, St. Francis made significant improvements in its TAVR procedural process which have led to:

- 10% reduction in median time in the TAVR patient process
- 38% to 54% reduction in number of staff needed during the TAVR procedure
- 15% reduction in patient waiting time in PACU holding area
- 50% to 100% increase in number of TAVR cases completed per day
- 2-4 additional TAVR patients were treated on average per week
- Forecasted potential annual savings of over $150,000 as a result of cross-training of staff

The St. Francis team was also able to lower the overall variability of the entire time a patient spent during a TAVR cases by about 1 hour. The team reports that on most TAVR days, they can complete 4 relatively uncomplicated TAVR cases in about the same time it used to take them to do 2 cases. And by adding another hour at the beginning and end of their TAVR days, St. Francis is confident they will eventually be able to complete 10 relatively uncomplicated TAVR procedures each week vs. 4 at baseline.

*Operational, Clinical and Financial impact calculations provided by St. Francis Hospital. Results may vary and depend on site implementation of recommendations.

An Eye on Continuous Improvement

As outlined in this case study, the approach and methods facilitated by the Medtronic PRO|CV Service consultants with St. Francis Hospital can lead to efficiency improvements and cost savings for TAVR programs. As a leader in cardiovascular care, St. Francis is committed to continuous improvement of their TAVR procedure by using all methods at their disposal, including the Lean Sigma problem-solving and improvement approaches facilitated by the Medtronic PRO|CV consultants.

The hospital’s process improvement team holds regular meetings to analyze the data they continue to measure, and look at ways to continue streamlining their TAVR procedures so that more patients can benefit more quickly from TAVR therapy.

The project at St. Francis also created staff development improvements that continue to generate benefits. Because they use a blended Hybrid OR/Cath Lab for their TAVR procedures, they saw the benefit of formalizing a cross-training approach to increase the productivity and flexibility of their staff, including new hires, so that people can shift seamlessly from one role to another as needed on TAVR days.

Finally, St. Francis says that their newly re-designed TAVR procedure can scale up as needed to meet the needs of their AS patients. With newer technologies and therapies on the horizon for these patients, St. Francis is confident that their new TAVR procedure process gives them a template that can be adapted and expanded to other therapies and technologies that demand a multidisciplinary approach.

*Operational, Clinical and Financial impact calculations provided by St. Francis Hospital. Results may vary and depend on site implementation of recommendations.
Valve lesion which does not meet the criteria for severe aortic stenosis (aortic valve area ≤1.0 cm²) has been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for the entire system (bioprosthesis, catheter, and CLS). Do not use a catheter with a damaged capsule. If a capsule becomes damaged during loading or the capsule fails to close, replace it. Prolonged or repeated exposure to the vapors. Damage may result from forceful handling. Prior to Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Repositioning of a deployed valve may cause aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device failure), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve a bioprosthesis if any one of the outflow struts is protruding from the capsule. If any one of the outflow struts has been deployed, the bioprosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter removal. If increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and/or harm to the patient. If the device has not been reprocessed or corrected and the bioprosthesis is used as a single unit over the guidewire, inspect the catheter and confirm that it is complete. The bioprosthesis may improve valve function and sealing. To ensure patient safety, valve size and anatomy must be considered before implantation of the second CoreValve bioprosthesis to ensure proper sizing of the device is maintained after dilation. Data on File.

POTENTIAL ADVERSE EVENTS
Potential risks associated with the implantation of the Medtronic CoreValve transcatheter aortic valve may include, but are not limited to, the following: death; cardiac arrest; coronary occlusion, obstruction, or vessel spasm (including acute coronary closure); emergent surgery (e.g., coronary artery bypass, heart valve replacement, valve explant); multi-organ failure; heart failure; myocardial infarction; cardiogenic shock; respiratory insufficiency or respiratory failure; cardiovascular injury (including rupture, perforation, or dissection of vessels, ventricle, myocardium, or valvular structures that may require intervention); ascending aorta trauma; cardiac tamponade; cardiac failure or low cardiac output; prosthetic valve dysfunction including, but not limited to, friction, bending (out-of-round configuration) of the valve frame; under-expansion of the valve frame; calcification; paravalvular leak; leaflet tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis–patient mismatch); malposition (either too high or too low); malapposition; regurgitation; stenosis; thrombosis/embolus (including valve thrombosis); valve migration/valve embolization/ancillary device embolization (including coronary occlusion); emergent coronary intervention; perforation; other valve defects; permanent disability; renal insufficiency or renal failure (including acute kidney injury); mitral valve regurgitation or injury; tissue erosion; vascular access related complications (e.g., dissection, pseudoaneurysm, arteriovenous fistula); compartment syndrome; arteriovenous fistula, stenosis; conduction system disturbances (e.g., atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker. Please review the CoreValve Instructions for Use for more information regarding indications, warnings, precautions and potential adverse events.

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