Strategies for an Effective Structural Heart Program: Current and Future Considerations

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Interventional Cardiology

Murray Kwon, MD
Cardiac Surgery
Disclosures:

- **Disclaimer:**

  Please Note: The information provided is the experience of UCLA Medical Center, and Edwards Lifesciences has not independently evaluated these data. Outcomes are dependent upon a number of facility and surgeon factors which are outside Edwards’ control. These data should not be considered promises or guarantees by Edwards that the outcomes presented here will be achieved by an individual facility.

- Dr. Suh and Dr. Kwon are paid consultants to Edwards Lifesciences
Why build a SHD infrastructure?

- Identifying Market Demands
  - Patients/Referring Physicians will always desire a minimally invasive option

- Critical to unify resources to efficiently and effectively meet the needs of the various programs under a common institutional mission statement.

- SHD program is critical to:
  - Eliminate redundancies in resource utilization across programs
  - Achieve “Economies of Scale”
  - Maximize efficient and cost effective delivery of care
  - Derive best patient outcomes
  - Develop resources that will enable future application to emerging technologies

  - Growth Begets Growth!
Why build a SHD infrastructure?
Case in Point:

Launched TAVR August 2012 total to date # 366

Launched MitraClip Dec 2015 total to date # 23

Launched Watchman July 2017 total to date #5
TAVR Only One Piece of the Puzzle

Structural Heart Centers Encompassing a Range of Services

**Foundational Services**

- Surgical valve replacement, repair
- Valvuloplasty
- Medication management

**Emerging Technologies**

- TAVR
- Transcatheter mitral valve repair
- Left atrial appendage closure
- Transcatheter pulmonary valve replacement
- Transcatheter mitral valve replacement\(^1\)

Access the [CV Clinical Technology Compendium](#) for more information on structural heart services and considerations for adoption.

TAVR, the entry point for an array of advanced structural heart technologies, clinical research.

\(^1\) In clinical trials.
Other areas of growth: Clinical Trials

**TAVR**
PARTNER 3 Trial
Enrolled first patient December 2016

Aortic valve in valve registry

**UNLOAD trial**
awaiting IRB

**PULMONIC**
COMPASSION Trial

**MITRAL**
CARILLON Trial
What is SHD infrastructure and staffing?

- Cardiology
  - Interventional
  - Non invasive
  - ACNP
- Cardiac Surgery
  - Surgeons
  - ACNP
- Anesthesia
- Nursing
- Administration/Research/Database
Heart Team

- Multidisciplinary approach to patient care
  - Cardiac surgery, interventional cardiology, cardiac imaging, anesthesia all bring their expertise to the table

- Not all patients are suitable for TAVR. Surgical aortic valve replacement is still the gold standard for low risk patients
  - PARTNER 3 Trial

- The patient gains the most benefit. Therapy is tailored to what is best treatment for the patient.
A Program, Not a Procedure

High-Value Care Requires a Strong Structural Heart Foundation

You can’t think of TAVR as just a procedure you offer, and it’s not just about the physicians performing the procedure either. You have to view TAVR as part of a holistic structural heart program, spanning disciplines, services across the hospital, and the continuum. **It’s a program, not a procedure.**

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**Pillars of a Comprehensive Structural Heart Disease Center**

- **Multidisciplinary**
  Engaging appropriate specialists, related services, to ensure appropriate treatment and care plan decisions

- **Patient-Centered**
  Personalizing care decisions for each patient to select most appropriate treatment and ensure ability to thrive

- **Cross-Continuum**
  Encompassing all providers involved in structural heart patient care to ensure coordinated, high-value approach

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*Co-Medical Director of Structural Heart Center, Hospital in the East*
What is leadership’s/your vision for SHD now and in the future?
### Volume Change in Select Structural Heart Disease Procedures

*All-Payer, 2010 to 2015*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2010 Volume</th>
<th>2015 Volume</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>991 (2011)</td>
<td>25,958</td>
<td>2,520%</td>
</tr>
<tr>
<td>SAVR</td>
<td>73,768</td>
<td>75,546</td>
<td>2%</td>
</tr>
<tr>
<td>Surgical Mitral Valve Repair</td>
<td>17,608</td>
<td>17,852</td>
<td>1%</td>
</tr>
<tr>
<td>Surgical Mitral Valve Replacement</td>
<td>19,995</td>
<td>22,054</td>
<td>10%</td>
</tr>
<tr>
<td>Valvuloplasty</td>
<td>4,441</td>
<td>6,159</td>
<td>39%</td>
</tr>
<tr>
<td>ASD/PFO² Procedures</td>
<td>14,564</td>
<td>12,705</td>
<td>-13%</td>
</tr>
<tr>
<td>VSD³ Procedures</td>
<td>2,185</td>
<td>2,563</td>
<td>17%</td>
</tr>
<tr>
<td>LAA⁴ Procedures</td>
<td>239</td>
<td>1,664</td>
<td>596%</td>
</tr>
</tbody>
</table>

1) TAVR not FDA-approved until fall 2011.
2) Atrial septal defect/patent foramen ovale.
3) Ventricular septal defect.
4) Left atrial appendage.

Source: Cardiovascular Roundtable research and analysis.
Which SHD procedures did you prioritize?

- Started with TAVR
  - Combination of market demand, available technologies, institutional commitment
How is your SHD program planning for the current and future market opportunity?

- Pushing the frontier in emerging technologies and being prepared for expanding indications

- Identify your loco-regional competition and look for ways to differentiate
  - Conscious sedation program
  - “Boutique experience” seeing Doctors vs. NPs
  - Make sure process is streamlined for patients in vertically integrated model
  - Make sure that there is a coordinator to put a face to the program
Appealing to the New Consumer Demands

Patients, Referring Physicians Have Similar Expectations of CV

Patient and Referrer Expectations

Convenient Access
- Expanded capacity
- Convenient sites
- Geographic reach
- Timely availability for appointments

Long-Term Quality
- High-quality care
- Cross-continuum coordination
- Exceptional longitudinal outcomes

Positive Experience
- Information continuity
- Care coordination
- Personalization
- Patient experience
- Referring physician communication

High Value
- Competitive unit prices for upstream services
- Total cost management

Source: Cardiovascular Roundtable research and analysis
How has your SHD program structure benefited patients and your program?

- Outstanding patient outcomes
  - QOL
  - Survival

- Redefined the management of critical AS across the range of risk profiles
  - Low risk patients can consider entry into Trial. High risk patients now have options other than Hospice Care

- TAVR is now profitable

- Institutional Reputation due to leading the West Coast on minimalist TAVR
UCLA Transapical Valve Replacement Registry TAVR Program
We Increased Volume & Decreased Complications

Mortality CY 2013-2016

Select a Dimension For Comparison

Discharges

Complication Rate

Operative Mortality Rate

Select Measure

Mean

Admit to Discharge Average LOS (Days)

Procedure to Discharge Average LOS (Days)

Average ICU Hours

Volume Up

Mortality Down
A Program Must Evolve!

- Moderate Sedation vs General Anesthesia
- Pre Admit
  - Decrease Length of stay days preop and postop
- Improved Device & Access apical vs femoral
  - Pump Stand by as needed
  - Transfer to Stepdown vs CTICU decrease cost
- Working with coders for appropriate medical coding
- Working with nurses for appropriate medical documentation
- PACT Policy: Post-Acute Care Transfer

<table>
<thead>
<tr>
<th>FY2017 TAVR MS-DRG Short Stay Threshold:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MS-DRG</strong></td>
</tr>
<tr>
<td>266</td>
</tr>
<tr>
<td>267</td>
</tr>
</tbody>
</table>
People in the Room
2 cardiac surgeons
2 Inv cardiologists
Echo attending/fellow
Anesthesia attending/resident
Cath lab nurses and tech
OR scrub and circulating
Surgery NP
Cath lab NP
Perfusionist
TAVR rep

Total 20 people
TAVR 2016 – Much less crowded

People in the Room
1-2 cardiac surgeons
2 Inv cardiologists
Echo
Anesthesia
Cath lab nurses and tech
Valve crimper
TAVR rep

Total ~10 people
Thank you to UofNebraska ❤️ Team for attending our inaugural #TAVR #Optimentals course! Learning #Minimalist. @unmc @UCLAHealth
How have you secured a competitive advantage through program differentiation?

RESEARCH ARTICLE

Improved costs and outcomes with conscious sedation vs general anesthesia in TAVR patients: Time to wake up?

William Toppen¹, Daniel Johansen², Sohail Sareh², Josue Fernandez², Nancy Satou², Komal D. Patel³, Murray Kwon², William Suh⁴, Olcay Aksoy⁴, Richard J. Shemin², Peyman Benharash²*

¹ UCLA Department of Medicine, Los Angeles, California, United States of America, ² UCLA Division of Cardiac Surgery, Los Angeles, California, United States of America, ³ UCLA Department of Anesthesia and Preoperative Medicine, Los Angeles, California, United States of America, ⁴ UCLA Division of Cardiology, Los Angeles, California, United States of America
Table 3. Conscious sedation cost outcomes, all matched patients.

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>% of GA Control Cost</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct Cost</td>
<td>71.5%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>ICU Direct Cost</td>
<td>45.3%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Anesthesia Direct Cost</td>
<td>47.1%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>OR Recovery Direct Cost</td>
<td>42.6%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Pharmacy Direct Cost</td>
<td>42.1%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Room Direct Cost</td>
<td>45.5%</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

ICU, intensive care unit; OR, operating room
* = statistically significant

https://doi.org/10.1371/journal.pone.0173777.t003

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0173777
### Table 6. Clinical outcomes, excluding Sapien 1 valves.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Total, n = 139</th>
<th>General, n = 90</th>
<th>Sedation, n = 49</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NA</td>
</tr>
<tr>
<td>1+ Major Adverse Event</td>
<td>49 (35%)</td>
<td>33 (37%)</td>
<td>16 (33%)</td>
<td>0.64</td>
</tr>
<tr>
<td>MI</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NA</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Major Vascular Event</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Ischemic Stroke</td>
<td>3 (2%)</td>
<td>1 (1%)</td>
<td>1 (4%)</td>
<td>0.34</td>
</tr>
<tr>
<td>TIA</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td>0.32</td>
</tr>
<tr>
<td>New Dialysis</td>
<td>3 (2%)</td>
<td>3 (2%)</td>
<td>0 (0%)</td>
<td>0.68</td>
</tr>
<tr>
<td>GI Bleed</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Guinea</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NA</td>
</tr>
<tr>
<td>Other Bleeding Event</td>
<td>2 (1.4%)</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Annular Dissection</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Hematoma @ site</td>
<td>2 (1.4%)</td>
<td>1 (1%)</td>
<td>1 (2%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Bleeding @ site</td>
<td>5 (4.3%)</td>
<td>4 (4.4%)</td>
<td>2 (4.1%)</td>
<td>0.92</td>
</tr>
<tr>
<td>Unplanned surgery</td>
<td>2 (1.4%)</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Left Pacemaker</td>
<td>24 (17.3%)</td>
<td>16 (17.8%)</td>
<td>8 (16.3%)</td>
<td>0.83</td>
</tr>
<tr>
<td>New onset afb</td>
<td>16 (11.8%)</td>
<td>13 (14.4%)</td>
<td>3 (6.1%)</td>
<td>0.10</td>
</tr>
<tr>
<td>ICU Hours</td>
<td>81 ± 67</td>
<td>78 ± 71</td>
<td>30 ± 31</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length of Stay (days)</td>
<td>5.1 ± 6.7</td>
<td>3.6 ± 10.1</td>
<td>4.9 ± 4.0</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>26 (18.7%)</td>
<td>10 (20%)</td>
<td>0 (0%)</td>
<td>0.59</td>
</tr>
<tr>
<td>LVEF @ 1 month**</td>
<td>58 ± 12</td>
<td>58 ± 13</td>
<td>58 ± 12</td>
<td>0.74</td>
</tr>
<tr>
<td>Change from prep</td>
<td>5 ± 11</td>
<td>5 ± 11</td>
<td>+3 ± 10</td>
<td>0.33</td>
</tr>
<tr>
<td>KCCQ @ 1 month***</td>
<td>83 ± 19</td>
<td>79 ± 22</td>
<td>96 ± 11</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Change from prep</td>
<td>+33 ± 28</td>
<td>+36 ± 29</td>
<td>+40 ± 25</td>
<td>0.637*</td>
</tr>
</tbody>
</table>

Mi, myocardial infarction; TIA, transient ischemic attack; GI, gastrointestinal; GU, genitourinary; Afib, atrial fibrillation; ICU, intensive care unit; LVEF, left ventricular ejection fraction; KCCQ, Kansas City Cardiomyopathy Questionnaire

* = statistically significant

**LVEF @ 1 month available for 130 patients (86 GA, 44 CS)
***KCCQ @ 1 month available for 126 patients (83 G, 43 CS)

https://doi.org/10.1371/journal.pone.0173777.006


http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0173777
What were the critical elements of success for you?

Heart Team!
What if anything would you do differently? If I knew what I know now, I would have_____?

▪ Begins and ends with Heart Team
  ▪ Initially keep things focused
    ▪ Avoid temptation to open to multiple members. There will be pressure and cries of “foul”
    ▪ Only consider opening team once program has reached a very mature stage in your own institution.

▪ Be honest and open with your program’s metrics
  ▪ Review M&Ms regularly
  ▪ Apply quality measures in an organized fashion
  ▪ Be mindful of denominator when assessing risks. Programmatic considerations are important as well

▪ Know the pros and cons of having competing platforms
  ▪ Decide if there is advantage to having multiple platforms
  ▪ Weigh this against developing familiarity with one platform
  ▪ In general competition is good
What is the Surgeon’s Role in the Process?

- **Class I Recommendation:**
  - For patients in whom TAVR or high-risk surgical AVR is being considered, a Heart Valve Team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in VHD, cardiac imaging, interventional cardiology, cardiac anesthesia, and cardiac surgery should collaborate to provide optimal patient care. *(Level of Evidence: C)*

  - 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease
  - *JACC, Volume 63, Issue 22, June 2014*
The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

A.

TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA approved indication and when all of the following conditions are met:

1.

The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system’s FDA approved indication.

2.

Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient’s suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

3.

The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.
## Vascular Complication Rates in Pre-SAPIEN 3 Valve vs SAPIEN 3 Valve Era

<table>
<thead>
<tr>
<th></th>
<th>Pre-SAPIEN 3 Valve Era n=121</th>
<th>SAPIEN 3 Valve Era n=154</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular Comp</td>
<td>19 (16%)</td>
<td>21 (14%)</td>
<td>0.63</td>
</tr>
<tr>
<td>Mortality</td>
<td>5 (4%)</td>
<td>0 (0%)</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Reasons to Hang on

- Many studies show increasing SAVR in TAVR vs. Non-TAVR hospitals

- Our recent data showing ongoing vascular injuries during SAPIEN 3 valve era limited by the ongoing usage of TA
  - 15% TA usage in S3 era vs 45% pre-S3

- Patients benefit
How were you successful with TAVR addressing Administration concerns and needs?

- Recognizing importance of being responsible stewards of a very expensive technology
- Adhere to guidelines without exception
- Recognizing implications of bottom line
- Asked for resources in graded fashion
  - NP request came after documented profitability and volume
- Maintained strict quality control with stable Heart Team
- Ultimately patient care if paramount
How did you use data to drive the program?

- STS and ACC registry data
  - Utilized for internal metrics
    - Cost/Outcomes
    - Utilized for peer reviewed journal submissions

- Request additional resource allocations as appropriate
  - Dedicated NP
  - Patient education materials
  - Loco-regional marketing
    - Know the limitations of marketing
So Why Have a Structural Heart Program?

- Ultimately, it’s all about providing the best care to our patients and making a true difference in their lives.

TRANSFORMING THE LIVES OF patients
INSPIRED BY patients
Patients ARE OUR FOCUS
DOING NOW WHAT patients NEED NEXT
PUTTING THE patient FIRST
TO MAKE A DIFFERENCE IN THE LIFE OF patients
WE PASSIONATELY WORK TO HELP OUR patients
Post Operative Day #2 – picking out new grips for his golf clubs!

After TAVR, patients return to normal life faster.
Thank You!

Wooden on Leadership

Pyramid of Success

Competitive Greatness
“Perform at your best when your best is required. Your best is required.”

Confidence
“The strongest steel is welded strongest when it is earned, not given.”

Skill
“What a leader learns after he’s learned it all are the most of all.”

Team Spirit
“The sum of the parts is the total. The sum of the team is the total.”

Alertness
“Clarity of vision and planning. Always seek to know where you are and where you are going.”

Initiative
“Make the decision. When thwarted try against它, creative, and overcome its obstacles.”

Intentness
“Tell the courage. When thwarted try against it, creative, and overcome its obstacles.”

Friendship
“Do it to yourself. Be true to yourself and the team.”

Loyalty
“Never let yourself be alienated by the lies.”

Cooperation
“Do what you can for which you are right, right then who’s right.”

Enthusiasm
“True energy and enthusiasm, drive and conviction will stimulate and propel others.”

Self-Control
“Control your organization begins with control of yourself. Be disciplined.”

Condition
“Ability may get you to the top, but character will keep you there: mental, moral, and physical.”

Pose
“Be yourself. Don’t be known all by manner whether good or bad.”

12 Lessons in Leadership

1. Good Values Attract Good People
2. Love Is the Most Powerful Four-Letter Word
3. Call Yourself A Teacher
4. Emotion Is Your Enemy
5. It Takes 10 Hands To Make A Basket
6. Little Things Make Big Things Happen
7. Make Each Day Your Masterpiece
8. The Carrot Is Mightier Than A Stick
9. Make Greatness Attainable By All
10. Seek Significant Change
11. Don’t Look At The Scoreboard
12. Adversity Is Your Asset

www.CoachJohnWooden.com

“Success is peace of mind which is a direct result of self-satisfaction in knowing you made the effort to become the best of which you are capable.”

John Wooden, Head Coach
Please see the important safety information at the speaker podium

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