

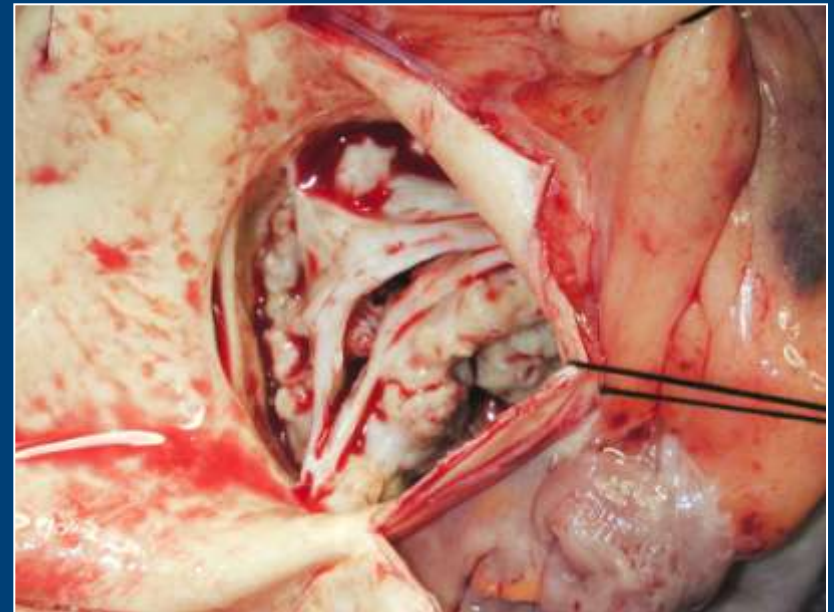
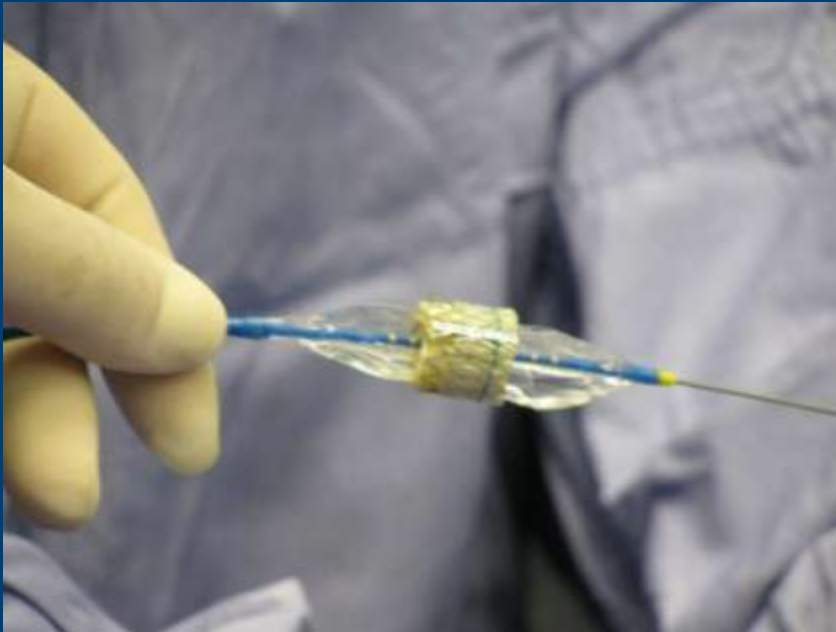
THE FUNDAMENTALS OF A TRANSCATHETER VALVE PROGRAM

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No Disclosures

The Fundamentals of A Transcatheter Valve Program



Penn Medicine Owned Hospitals

HUP

Adult Beds – 782
Admissions – 80,739
CV Surgery – 1,498



PPMC

Adult Beds – 331
Admissions – 17,069
CV Surgery – 590

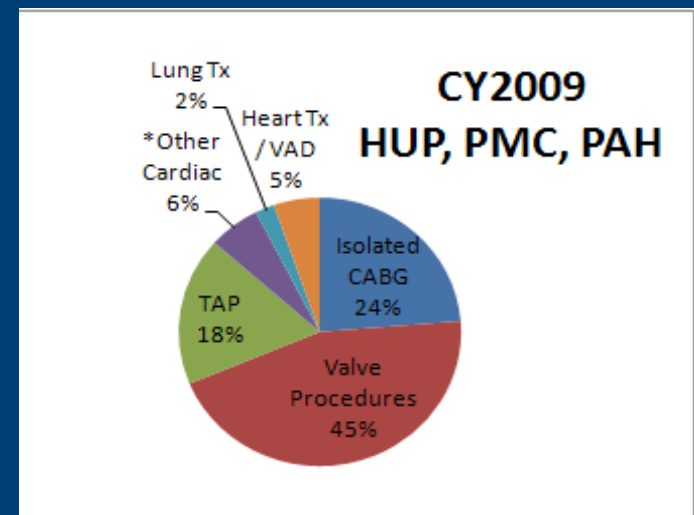
PAH

Adult Beds – 519
Admissions – 23,924
CV Surgery – 166



PENN: Why develop a Transcatheter Valve Program?

- ❖ Lead the World in the treatment of complex diseases
- ❖ Bring New Technology that will change practice through Research and clinical application
- ❖ Hold a competitive place in the Market with continual growth



Transcatheter Valves in Development



Heart Leaflet



Jena Valve



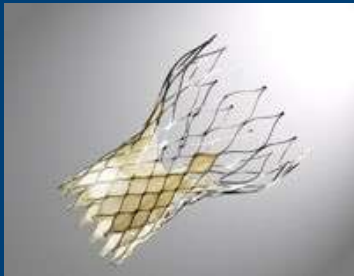
Edwards SAPIEN



ATS/3F Enable



ATS/3F Entrata



CoreValve



Direct Flow

Edwards SAPIEN™
transcatheter heart
valve or Edwards
SAPIEN™ THV



Sadra Lotus

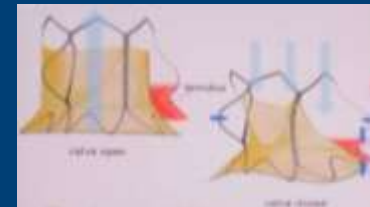


ABPS PercValve



Lutter Valve

Caution: Investigatio
nal device. Limited
by Federal (USA) law
to investigational use



Sorin Perceval



AorTx PAVR

Evolution of TAVR

2011

11/15/2007 1st Implant at HUP



2007



Over 16,000 valves (Sapien and XT) implanted world wide

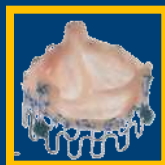
2004



2002



1989



1988



Concept

1st in Animal

1st in Man, TF

1st TA

Feasibility Trial

Partner Sapien Trial in US

Partner XT Trial in US

PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

Total = 1,057 patients

2 Parallel Trials:
Individually Powered

N = 699

High Risk

ASSESSMENT:
Transfemoral
Access

Yes

No

Transfemoral (TF)

Transapical (TA)

1:1 Randomization

1:1 Randomization

N = 244

N = 248

N = 104

N = 103

TF TAVR

AVR

VS

TA TAVR

AVR

VS

Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)

N = 358

Inoperable

ASSESSMENT:
Transfemoral
Access

Yes

No

1:1 Randomization

Not In Study

N = 179

N = 179

TF TAVR

Standard
Therapy

VS

Primary Endpoint: All-Cause Mortality
Over Length of Trial (Superiority)
Co-Primary Endpoint: Composite of All-Cause Mortality
and Repeat Hospitalization (Superiority)

Historical Development of the Penn Transcatheter Valve Program

- ▶ Planning took approximately one year prior to implanting the first valve (with a hybrid OR available)!
- January 2007- Brainstorming meeting for future transcatheter (TAVR) program
- March 2007 – 1st executive meeting with key players from the institution and sponsor
- June 2007 – Contract negotiations with Sponsor, IRB submission
- August 2007 – Hybrid OR upgrades approved
- October 2007 – IRB Approval
- November 2007 – CMS Approval
- November 2007 – 1st Transcatheter Implant



A Collaborative Effort



How to get started

- Capital Investments Required
- Build a Core Team: CVS, IC, Nursing, OR, Cath Lab, Research Team
- Development of a Program
- Education: Patients, Staff, Administration, Referrings
 - Patient Profile
 - In-services, screening tools, Mock OR, protocol development
 - Tracking: what happens to patients that do not go to TAVR?
- Outpatient Clinic

Partner Conference

- Weekly review of pending cases
 - ✓ Discuss clinical issues
 - ✓ Review access and cohort assignment
 - ✓ Decide and schedule tests
- Multi-disciplinary
 - ✓ Surgery
 - ✓ Cardiology
 - ✓ Nurse practitioners
 - ✓ Research coordinators
 - ✓ Echocardiographer
 - ✓ Radiologist



How to manage the patient flow: A Multi-discipline Approach

- Anticipating the patient referrals
- Team approach
- Integrating Specialties
- Sharing Revenue
- Bridging the gap between delivering New Technology in the convex of a clinical trial and remaining fiscally sound

Patient Flow Processes

Process
takes about
6 weeks

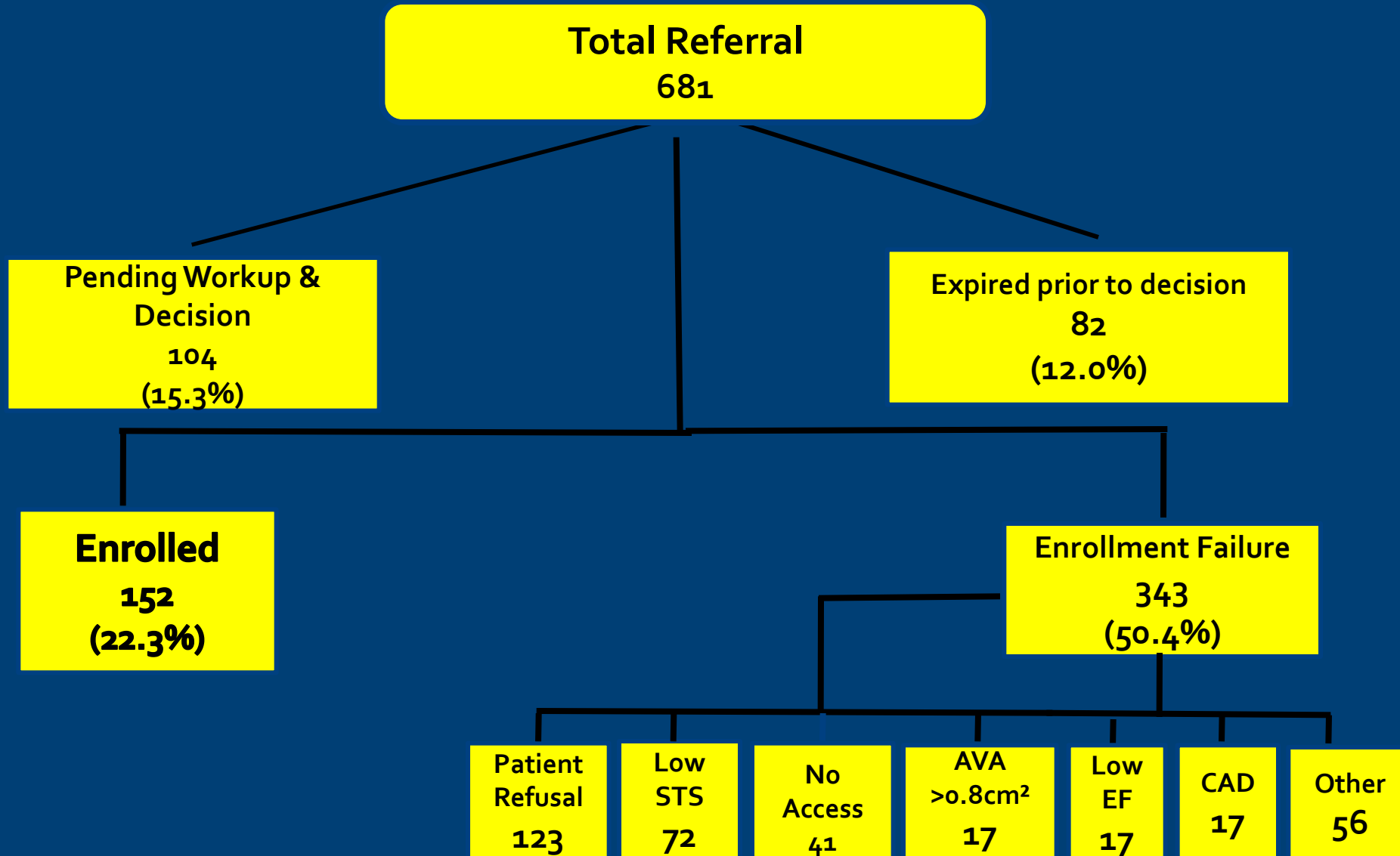
- Education of referring physicians
 - Community outreach
- Requirements for evaluation include multiple tests and data review
 - CTA imaging
 - Cardiac catheterization
 - Pulmonary evaluation
 - Other pre-operative testing as required
- Multiple office visits
- Weekly team meetings of the multidisciplinary team for patient selection
- Development of treatment plan

What is the patient profile?

- ▶ Sick and elderly High Risk patient population
 - Deficits that present challenges
 - Physical
 - Limitations in mobility and ambulation
 - Incontinence
 - Communication
 - Mild dementia
 - Hearing loss
 - Neurological deficits
 - Psycho-Social
 - Comprehension of complexities of being in a clinical trial
 - Support system of the elderly patient is also of advanced age
 - Financial
 - Limitations in reimbursement and benefits



What happens to the patients screened? Not all end up with TAVR.



All cases performed in the hybrid OR



Why a Hybrid Room:

Ability to perform multiple procedures and most importantly address all emergencies which may require surgical intervention



Valve Embolism



Vascular Injury



Staffing

- Clinical
 - Physicians
 - Cardiovascular Surgeons
 - Interventional Cardiologists
 - Anesthesiologists
 - Neurologists
 - Echocardiologists
 - Gerontologists
 - Nurse Practitioners (IP and OP)
- Research - If involved in a pivotal trial
 - Research nurse – 25 patients/nurse
 - Screening takes 8 hours/patient
 - Research assistant
- Administrative Support
 - Scheduling
 - Precertification

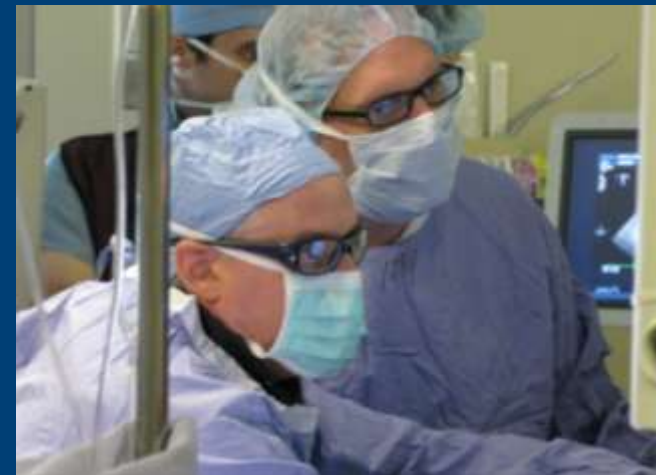
Challenges

- Can we afford this technology?
- Required additional resources....
 - Clinical Staff
 - Physician time
 - Space: Hybrid Rooms and clinic area
 - Administrative support
 - Scheduling
 - Precertification
 - Insurance approvals
- Obtaining approval from CMS

Opportunities

- ▶ Be a part of practice changing technology
- ▶ Collaboration among multidisciplinary providers/teams
- ▶ Agreement to perform procedures in the Hybrid OR
- ▶ Shared outpatient practice
- ▶ Developed a model to share professional revenue
- ▶ Exploring concept of a “transcatheter valve service”
 - Specialty unit with team to follow patient throughout stay
- ▶ Strategies to improve reimbursement.
- ▶ Be a leader in the treatment of Complex Cardiac Diseases

A Team Approach = Excellence in Patient Care



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Thank you

