Evolution of the Multidisciplinary Heart Valve Team – Where are we going?

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Cardiovascular Surgery – Cardiology Teams (The Heart Team) WHY??

- More Procedures require both skill sets (TAVI and TMVI example but there are more)
- Conflicting and Evolving Data regarding Heart Valve Treatment and Outcomes: Heart team and COI therefore patient comes first
- Better Results, Better Decisions, (??), Better perspective
- More resources/power: Financial and Infrastructure within the Hospital/Health System Domain
  - HVC Concept getting stronger
- Academic productivity/Resident Education/

So, at our Penn CV Surgery Faculty Meeting 8 years ago, when I said we ought to "Strategically" prepare to PARTNER with CARDIOLOGY for both Trans-Apical and Transfemoral TAVI ……

What Happened and How do we do it at Penn?

Cardiovascular Surgery – Cardiology (The Heart Team) Founding Concepts

- Financial: All money would be shared equally
  - Clinic, Procedural, create a "New" entity different from Depts Surgery/Medicine Norm. Direct, independent link to CFO
- All cases done in Hybrid OR with equivalent scheduling priority and ownership
- Shared Inpatient care. (Evolved very positively)
- No case could be done without going through Monday morning 90 minute multi-disciplinary conference (protocols for emergencies)
  - Resources for efficient presentations
- No trial would ever be done without total team involvement
- All data would be shared. Protocol development would be shared

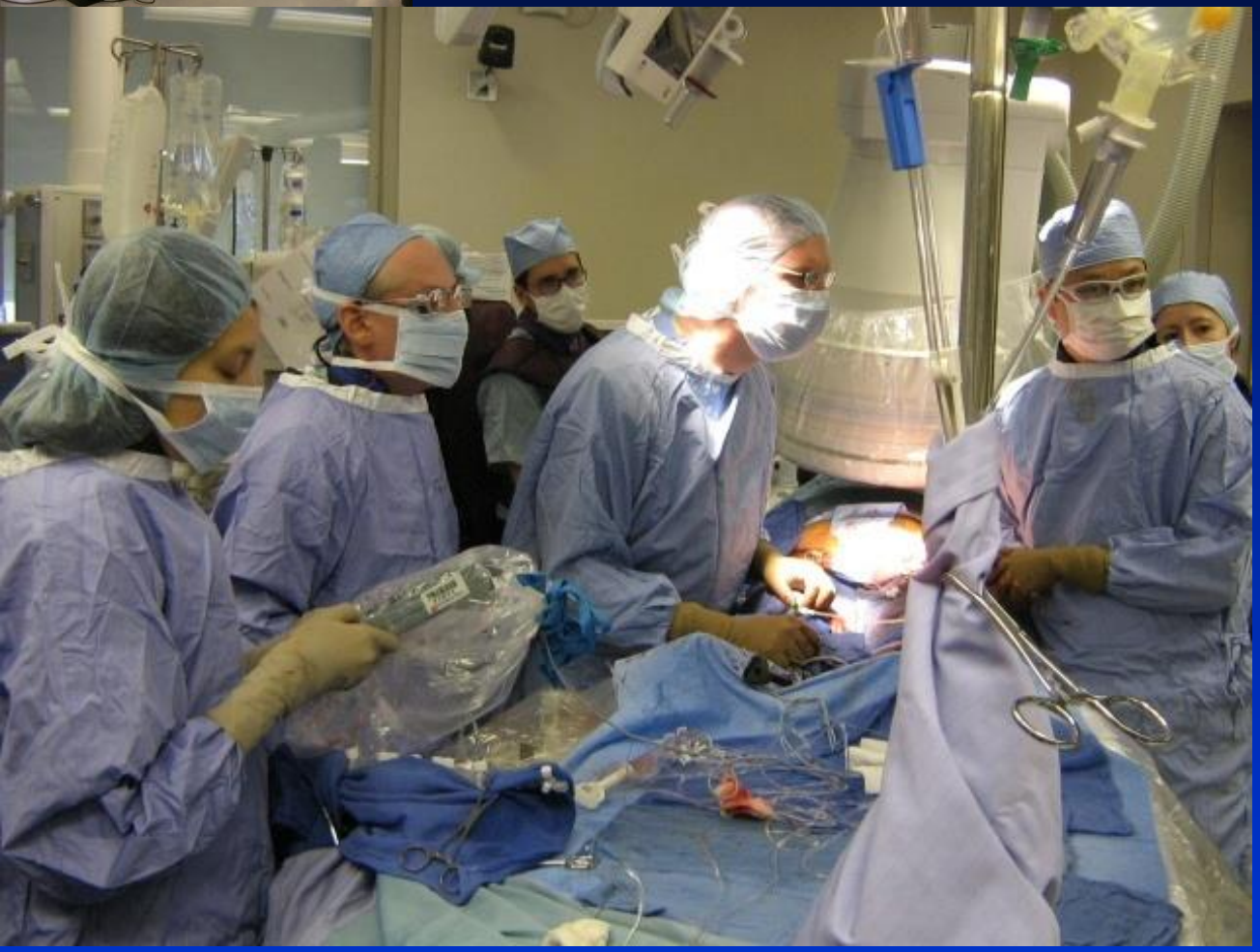
Cardiovascular Surgery – Cardiology Teams (The Heart Team) Initially 2007

- Started with Two Surgeons
- Two Interventional Cardiologists
- Echo/Image Cardiologist
- Nurse
- Research Coordinators
- Neurology (… dotted line)

The OR and Cath Lab Joined Together: A Show of Solidarity

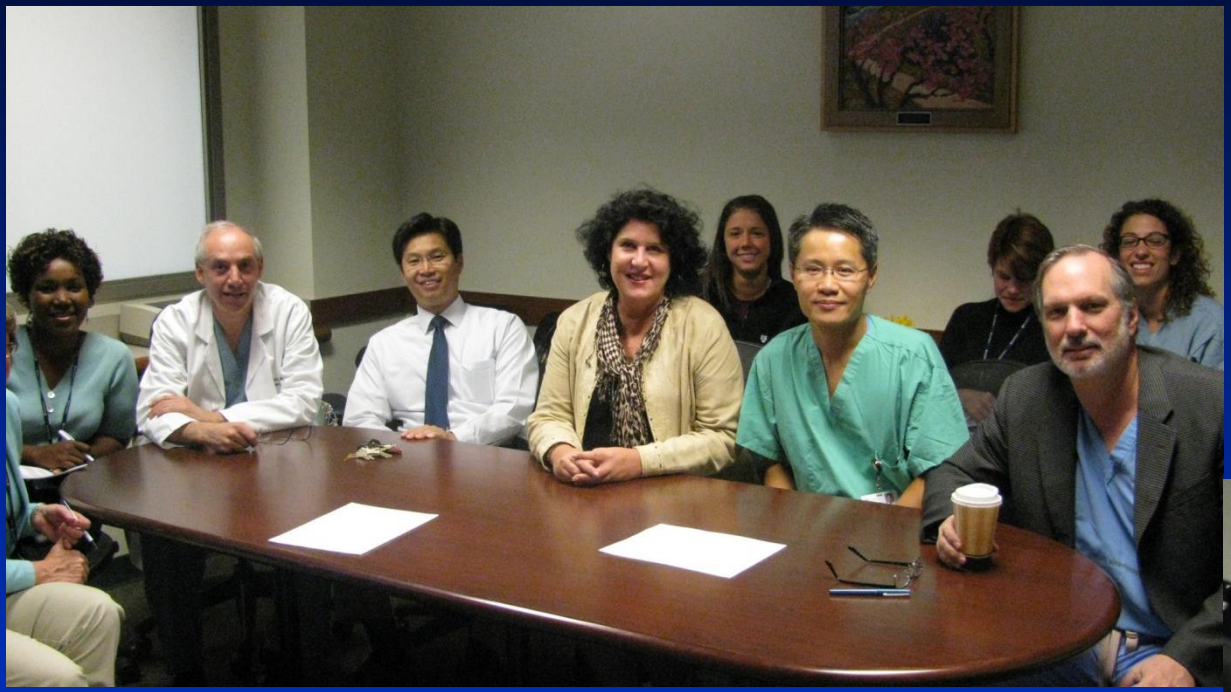
Multi-Disciplinary TEAM Approach

Hybrid OR and The PARTNER Trial




Anesthesia

Early Monday Morning Team Meetings: 2010-2011



National, International, and Governmental Committment to the Heart Valve Team

The Heart Team - Collaboration

SPECIAL REPORT FROM THE SOCIETY OF THORACIC SURGEONS

Transcatheter Valve Therapy: A Professional Society Overview from the American College of Cardiology Foundation and The Society of Thoracic Surgeons

Writing Committee Members: David R. Holmes, Jr, MD, FACC, ACCF President, Michael J. Mack, MD, FACC, STS President

Preamble

The evolution of transcatheter valve therapy raises important questions for practitioners, patients, and government agencies on the appropriate treatment strategy for patients who could be eligible for this procedure. The American College of Cardiology Foundation (ACCF) and The Society for Thoracic Surgeons (STS) joined together to write this paper to set the stage for a series of documents, to be joined by other professional societies, to address the issues critical to successful integration of this new procedure into medical practice in the United States. Final review and approval of the document was provided by the ACCF Board of Trustees and the STS Board of Directors. The ACCF and STS believe this document will be helpful to frame the discussion of key issues and questions for consideration as this new technology unfolds. Our organizations remain committed to providing guidance on key clinical issues.

1. Introduction

niques in surgery, vaccines to cure polio, penicillin and sulfa drugs for infectious diseases, and cortisone. These therapies have each been developed in concert by physicians, scientists, and industry partners.

Catheter-based therapies present new and potentially transformational technology for valvular and structural heart disease (2). The associated issues are complex, with multiple stakeholders: first and foremost, the patients receiving this therapy, but also including clinicians, inventors, industry, regulatory agencies, government and private payers, and professional societies. The purpose of this document is to capture all the core elements proportionally with the overarching goal of aligning the interests of all expert physicians including cardiologists; proceduralists; heart valve, heart failure, and imaging specialists; and imaging experts with other relevant stakeholders (regulators, payers, professional societies) in delivering the best possible patient-centered care. The role of societies is to realize this goal through ongoing development of expert consensus statements, guidelines, credentialing criteria, and training paradigms, thereby ensuring responsible diffusion of this technology.

"the Heart Team has become an integral part of the practice of modern cardiovascular care"

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STATE-OF-THE-ART PAPER

The Heart Team of Cardiovascular Care

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Rochester, Minnesota; Norfolk, Virginia; and Houston and Dallas, Texas

The management of complex cardiovascular disease has changed markedly with the development of new strategies of care, an increasing amount of scientific evidence-based data and appropriate use criteria. Applying this plethora of information and synthesizing it for presentation and recommendations to the patient and family have assumed central importance. To facilitate this process of patient centric evidence-based care multidisciplinary Heart Teams have become identified as cornerstones. While specific strategies for implementation of these teams will vary, this broad approach will become the standard of cardiovascular care. (J Am Coll Cardiol 2013;61:903–7) © 2013 by the American College of Cardiology Foundation

The concept of a Heart Team has become the subject of increasing interest in treating cardiovascular disease. While a team-based approach has been part of the practice in other

hierarchical endpoint composed of various components such as death, myocardial infarction, stroke (either major or minor), need for repeated procedures, or quality of life.

TAVI - Recommendations

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

- TF-/ TA- AVI: Feasibility proven
- **no randomized** Studies (yet), no long term results
- Indication in **high risk patients**
- **Team** approach

Alec V[illegible], Jeroen Bax[4], Bertrand Cormier[5], Alain Cribier[6], Peter De Jaegere[7], Gerard Fournial[8], Arie Pieter Kappetein[7], Jan Kovac[9], Susanne Ludgate[10], Franc[illegible]esco Maisano[2], Neil Moat[11], Jean Nataf[1], Luc Piérard[13], José Luis Pomar[14], Joachim Schofer[15], Pilar Tornos[16], Murat Tuzcu[17], Ben van Hout[18], Ludwig K. Von Segesser[19], and Thomas Walther[12]

Vahanian A Eur Heart J 2008

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Washington DC, 20037

Valve Centers Training/Credentialing Multidisciplinary Heart Team National TVT Registry

September 22, 2011

Louis Jacques, M.D., Director
Coverage & Analysis Group, OCSQ
Centers for Medicare and Medicaid Servic
7500 Security Boulevard, C1-14-15
Baltimore, Maryland 21244

FORMAL REQUEST FOR A MEDICARE NATIONAL COVERAGE DETERMINATION (NCD)
Transcatheter Aortic Valve Replacement (TAVR) Procedures

Sincerely,

Michael J. Mack, M.D.
President
The Society of Thoracic Surgeons

David R. Holmes, Jr., M.D., F.A.C.C.
President
American College of Cardiology

- TAVR approved under “coverage with evidence development”
- Approved for treatment of severe symptomatic aortic stenosis
- FDA approved indication and with an FDA approved device
- Two cardiac surgeons approve
- Performed in facility with
- >50surgical AVR’/year (~400)
- >1000 caths/400PCI/year
- >20TAVR/year
- Mortality<15%
- 1 year running survival of >60%
- Stroke <15%
- Multidisciplinary Heart Team
- Mandatory National TVT Registry participation

Primary Role of "THE HEART TEAM"

Heart, Lung and Circulation (2015) 24, 219–223
1443-9506/04/$36.00
http://dx.doi.org/10.1016/j.hlc.2014.09.009

POSITION STATEMENT

Position Statement for the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) Program

Darren L. Walters [a*], Mark Webster [b], Sanjeevan Pasupati [c], Antony Walton [d], David Muller [e], Jim Stewart [b], Michael Williams [f], Andrew MacIsaac [g], Greg Scalia [a,h], Michael Wilson [i], Adam El Gamel [c], Andrew Clarke [j], Jayme Bennetts [k], Paul Bannon [i]

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"A Heart Team is defined as a multi-disciplinary team of professionals who are charged with the governance of, and accountability for, the decision making and outcomes of the TAVI program within an institution. "

Heart Team to National Registry

- Participation in a National Registry
- Complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56
- Consecutively enrolls TAVR patients
- Registry must be auditable
- All manufactured devices
- Follows the patients for 1 year
- Follows:
  - KCCQ, 30 day and 1 year follow up, MACE AEs

Cardiovascular Surgery – Cardiology (The Heart Team)
Present Structure and Reality

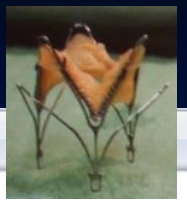
- Financial: Our own Cost/Revenue center
  - CFO: 7 FTE full time
- All cases done in Hybrid OR with equivalent scheduling priority and ownership (N=350/year)
- TAVI (Structural Heart) Service. Joint
- Monday Morning Conference has twice the participants and is video-conferenced (two sites)
  - Four combined operational teams
- Shared Clinic Space for entire team (Two days a week/ Pairs)
  - Referral logistics
- All data shared. Multiple Protocols developed
  - Fast Track, Conscious Sedation,
- Mitral on the way ….. A Navy SEALS approach to life

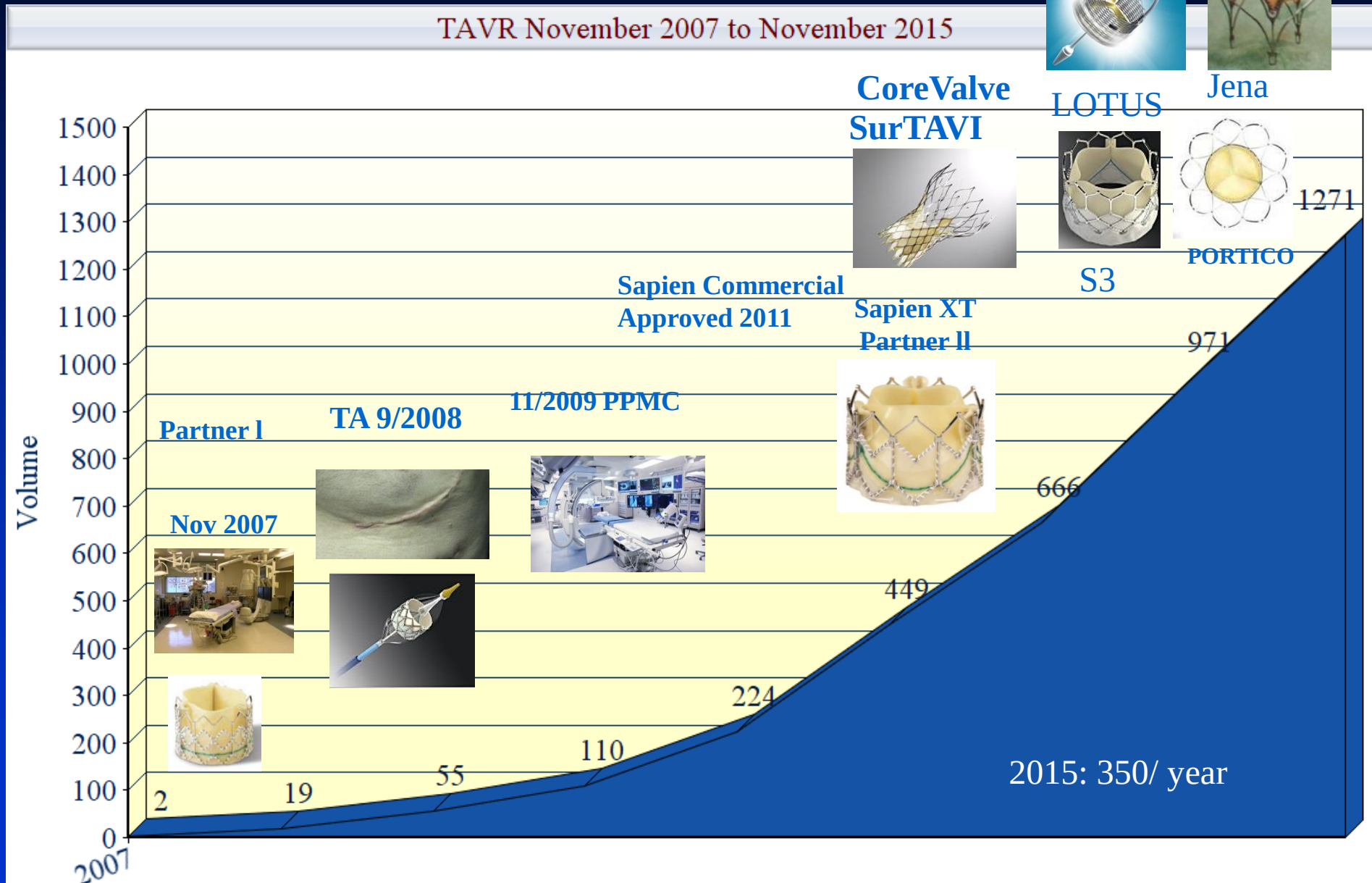
TAVI Team Nurses and Coordinators

Team in 2014:

Future Challenges for the Heart Team?

A Look Back Over the Beginning of TAVR at UPHS
How to Deal with Growth???? Heart Team Challenge



Future Challenges for the Heart Team?

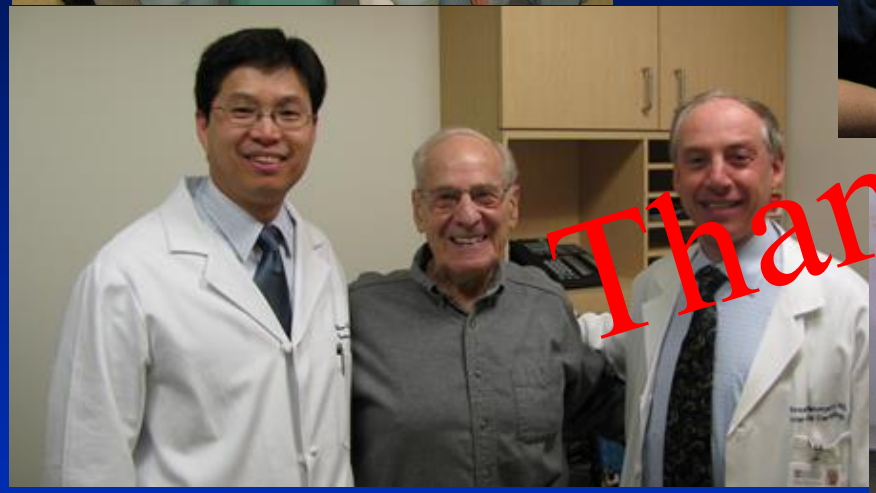
Referral ownership
Mitral
Growth (too big)
Allocation and Efficient use of Time
Departmental Silos
Resources

CEO in the Hybrid OR watching TAVI TA!!

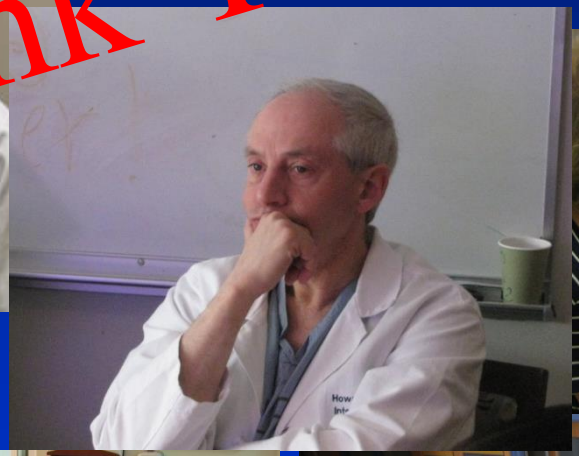
Cardiovascular Surgery – Cardiology (The Heart Team) The Glue

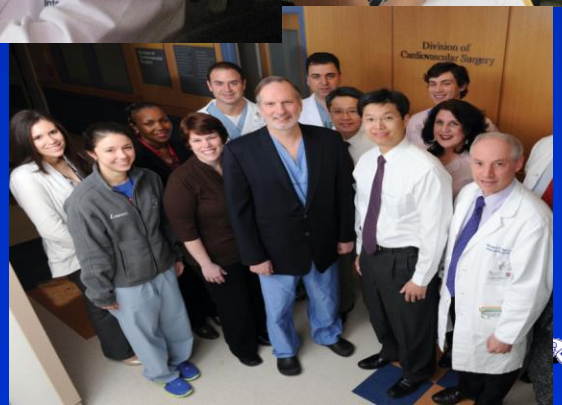
- The ONLY time all are together is the 90 Minute Heart Team Monday morning meeting
  - CaseReview and decision
  - Inpatient Review
  - Case and Outcome Discussion
  - Protocol Development and discussion
  - Trial Policy and Administrative discussion
  - Quarterly review of program
  - Absract and Paper review (Scholarship/Academics)

- Rotate Procedural Teams (up to a point)
- The Clinic



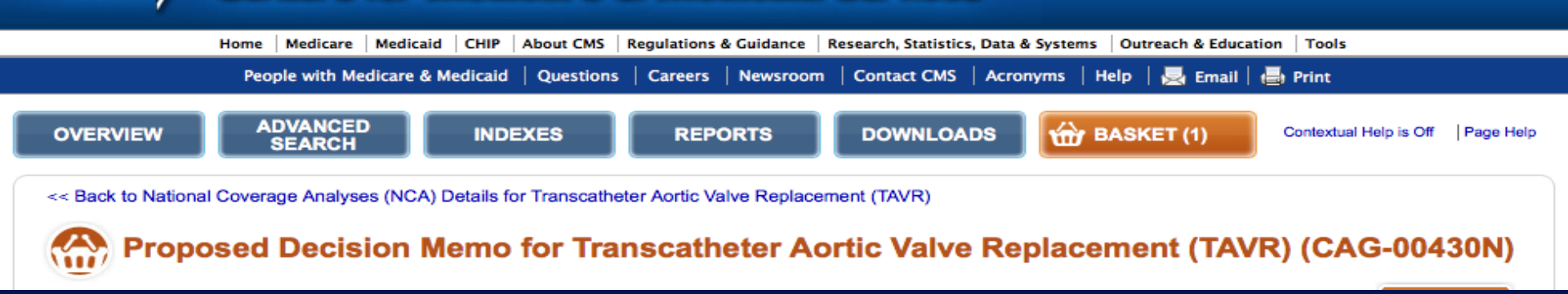
Thank You




Division of
Cardiovascular Surgery


LEGES
SINE MORIBUS
VANE

Penn Heart Valve Team



- **TAVR Program Quality Parameters**
  - 30 day All-Cause mortality < 15%
  - 30 day All-Cause Neuro events (including TIA) < 15%
  - 30 day Major Vascular Complication Rate < 15%
  - > 90% Institutional follow-up in database
  - 60% 1 year survival rate for Non-op (cohort B/Extreme Risk)
    - After program up for 2 years …. Running 2-yr average
  - Maintain EITHER 20 TAVR procedures per year OR 40 over 2 years
  - National TVT database

Weekly Penn Aortic Valve and TAVI Conference: Choosing the RIGHT and Proper Therapy for the Patient

Syntax …. No different