MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH)
OPEN HEART SURGERY
STANDARD ADVISORY COMMITTEE (OHSSAC) MEETING

Thursday May 10, 2012

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order

Chairperson Sell called the meeting to order @ 9:33 a.m.

A. Members Present:
Kourash Baghelai, M.D. Lakeland Healthcare
Craig Banasiak, Chrysler Group
Kevin Birchmeier, Covenant Healthcare
Alonso Collar, M.D. Sparrow Hospital arrived @ 9:36 a.m.
Alphonse Delucia III, M.D.Bronson Methodist Hospital
Duane DiFranco, M.D. BCBSM
John Fox, M.D. Priority Health
Ali Kafi, M.D. The Detroit Medical Center
Jan Penney, MidMichigan Medical Center
Gaetano Paone, M.D. Henry Ford HS
Richard Prager, M.D. University of Michigan arrived @ 10:15 a.m.
Dagmar Raica, **Vice-Chairperson**, Marquette General HS
Timothy Sell, M.D. **Chairperson**, Oakwood Healthcare

B. Members Absent:

Francis Shannon, M.D. Beaumont Health System
Charlie Heckman, AFSCME Local 999

C. Michigan Department of Community Health Staff present:

Scott Blakeney
Tulika Bhattacharya
Sallie Flanders
Natalie Kellogg
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Dr. Paone and seconded by Dr. Kafi to approve the modified agenda. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes from April 17, 2012

Motion by Mr. Birchmeier, seconded by Mr. Fox, to accept the minutes as presented. Motion carried.

V. General Discussion of Charges

Chairperson Sell gave an overview on how charges 1, 3, and 5 will be added to future discussions.

VI. Charge 2 Subcommittee Report

Dr. Paone gave a brief introductory summary report.

Discussion followed.

A. Quality Measures Power Point Presentation

Melissa Cupp, Wiener Associates, Bob Meeker, Spectrum Health, and Donna Long, Allegiance Health gave a brief presentation on quality measures recommended by the Coalition of Hospitals (see Attachment A).

Discussion followed.

B. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM) (Attachment B)

Break @ 11:02 a.m. - 11:22 a.m.

VII. Charge 4 Subcommittee Update

Dr. Delucia gave a brief summary of the publication "Transcatheter Valve Therapy: A Professional Society Overview from the American College of Cardiology Foundation and the Society of Thoracic Surgeons" and the Centers

for Medicare & Medicaid Services (CMS) coverage of transcatheter aortic valve replacement (TAVR) (see Attachments C and D).

Discussion followed.

Motion by Dr. Delucia, and seconded by Dr. Collar, for the SAC to decline to adopt quality or volume standards for Transcutaneous Heart Valve Replacement (TAVR) because:

1. STS/ACC/ACAI/AATS have already established institutional criteria for TAVR as well as a longitudinal registry, and
2. Major payers, including the Centers for Medicare and Medicaid Services, have established standards of institutional competence and coverage, and
3. Establishment of standards for a single, rapidly evolving technology could unintentionally constrain innovation and would be ill-advised.

Motion carried in a vote of 11- Yes, 2- No, and 0- Abstained.

VIII. Public Comment

Dennis McCafferty, EAM
Melissa Cupp, Weiner Associates
Robert Meeker, Spectrum Health

IX. Next Steps and Future Agenda Items

Chairperson Dr. Sell stated that the next agenda will include: initiation and maintenance volumes of Open Heart programs, continued discussion of Hybrid Operating Rooms, and quality measures approach.

X. Future Meeting Dates

A. June 7, 2012
B. July 12, 2012
C. August 7, 2012
D. September 6, 2012
E. October 2, 2012

XI. Adjournment

Motion by Mr. Birchmeier, seconded by Dr. Prager, to adjourn the meeting at 12:33 p.m. Motion Carried.

Coalition of Hospitals

Allegiance HEALTH

Henry Ford HEALTH SYSTEM

CRITTENTON Get Better Here™

SPECTRUM HEALTH

Beaumont® | HEALTH SYSTEM

MidMichigan Health

DMC DETROIT MEDICAL CENTER

Sparrow

ST JOHN PROVIDENCE HEALTH SYSTEM®

Purpose of the Coalition

- Improve CON standards by identifying quality measures
- Provide a draft recommendation to the SAC as a starting point

Process

- Assembled planners, program leaders, data managers, and surgeons
- Researched STS database, quality measures and oversight
- Used National Quality Foundation's 21 measures as base and narrowed down to the 6 most important
- Debated merits of composite score, percentiles, national averages, and other ways of defining quality
- Recognized the importance of selected measures such as mortality
- Looked for a mechanism that was easily understood and implemented, but also distinguished between programs
- Worked with experts within our respective organizations to validate the recommendations

Certificate of Need (CON) Overview

- CON is a state regulatory program intended to balance healthcare:
  - Cost: prevent oversupply of services and facilities to maintain affordability
  - Quality: promote quality services with standards developed by health experts
  - Access: promote access to all residents within a reasonable geographic proximity, particularly in rural areas and medically indigent

- CON statute provides MDCH with wide discretion on how it handles non-compliant programs including:
  - Revoke or suspend CON
  - Reduce level of service
  - Civil fine not to exceed total billings
  - Require notification to all payers of noncompliance
  - Require repayment of all billed amounts
  - Other remedies deemed appropriate

History

- **Open heart volume requirements changed overtime**
  - Pre-1979: no volume requirements (1 per year)
  - 1979 - 1993: > 200 procedures per year
  - 1993 - 2008: > 300 procedures per year
  - 2008 – present: > 300 cases per year
- **Different volume requirements, approved at different times, complicate MDCH's compliance review**
  - Programs move in and out of compliance over time
- **In 2007, SAC attempted to address quality for open heart surgery**
  - Non-compliant programs should share quality data with MDCH
  - MDCH should work with MSTCVS to define quality
  - New programs should submit quality data in their 3-year review
  - Evaluation of program outcomes should include quality
- **Today's standards continue to use volume as a proxy for quality**

Rationale

- Quality measures becoming commonplace in healthcare
- Clinical quality metrics exist for open heart surgery and are utilized today
- Society of Thoracic Surgeons (STS) has created a national database to monitor and improve the quality and safety of cardiothoracic surgery
- Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) utilizes STS data in their quality collaborative that works to continuously improve quality of Michigan's open heart surgery programs.
- Payer requirements
  - Blue Cross Blue Shield requires participation in two quality improvement projects every year as part of the MSTCVS quality collaborative
- Improve Implementation of Michigan CON
  - An additional tool for evaluating program compliance
  - Sets precedent for assessing quality in other CON services

Proposed Quality Measures

- For hospital programs that are not meeting the volume requirements under the standards that they were approved, they are required to submit their STS Composite Quality Rating report (Note: **Data will be Isolated Coronary Artery Bypass (CAB) only**) as well as the portion of their report which includes Blood Product Use for Isolated CAB.

- In order to have a significant sample size of cases, hospital programs must submit enough years of reports to include at least 200 cases but no fewer than the most recent 2 years.

Proposed Quality Measures

Six priority measures

- Need to perform at or above the **NATIONAL 50th percentile in Mortality Avoidance**

  AND

- Need to perform at or above the **NATIONAL 50th percentile in 4 out of the remaining 6 measures (see next slide)**

Programs failing to meet these guidelines should be given the opportunity to show improvement.

Proposed Quality Measures
Isolated CAB Only

"Must Have" Measure	STS Range	National 50th %tile
Mortality Avoidance	94.7 – 99.4%	98.1%

AND

4 out of 6 Measures	STS Range	National 50th %tile
Renal Failure	0.31 – 6.28%	0.97%
Stroke (CVA)	0.55 – 2.49%	0.96%
Deep Sternal Wound Infection	0.26 – 12.93%	0.77%
Prolonged Ventilation	0.27 – 8.12%	0.98%
Intraop/Postop Blood Products Used*	53.9% (mean)	56.4%
Internal Mammary Artery (IMA) Use	64.5% – 99.6%	95.9%

Data Source: STS report ending 12/31/10 (2011 Harvest Report 1)
* Not included in composite score

STS Composite Score Quality Measures
Option A

Process:

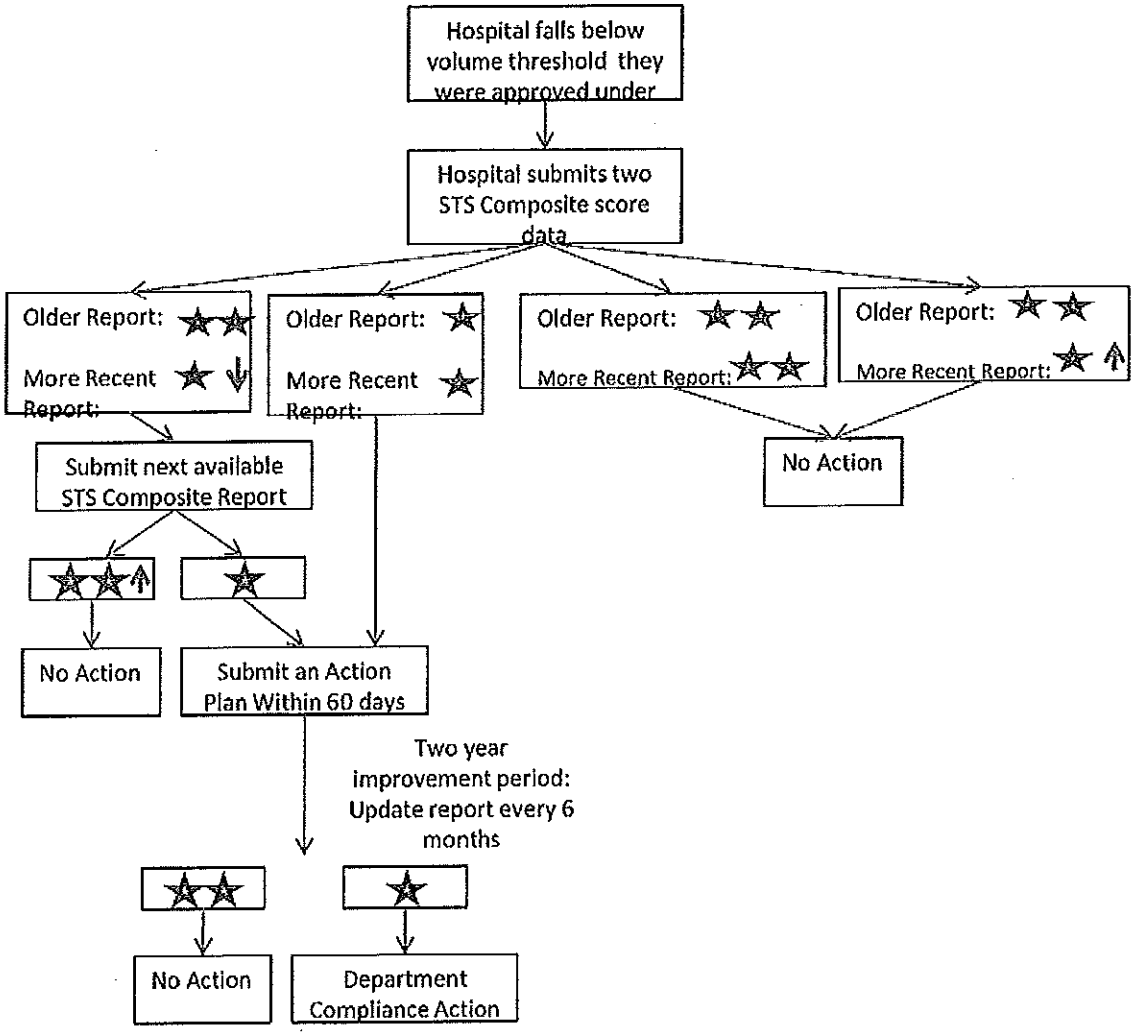
1. For hospital programs that are not meeting the volume requirements in the standards that they were approved under they are required to submit the two most recent 12-month rolling STS Composite Quality Rating reports (covers a total of 18 months of data). Using the overall star rating:
    a. Both reports are at or above a two star rating
        i. No action required
    b. The older report is at one star and the more recent report is at two stars or above (shows positive improvement)
        i. No action required
    c. The older report is at two star and the more recent report is a one star
        i. A third report must be submitted 6 months later.
        ii. If the third report is a two star, no action required.
        iii. If the third report is a one star, an improvement plan needs to be submitted to the Department within 60 days of the Department's notice letter.

Improvement Plan and Period:

- The health system has two years from the date the improvement plan was submitted (the improvement period) to improve. The hospital is required to submit an update report from the STS Composite Quality Rating report every 6 months.
- Improvement is defined as reaching a two star or above overall composite rating by the end of the improvement period.
    - As soon as a 6 month update report shows a two star or above rating no further action will be required.
    - By the end of the improvement period if the composite score is still at one star the Department can proceed to choose a compliance action within their authority.

*Note about data cycles: If an improvement plan is required, the next STS report will most likely remain at 1 star due to the 6 month data overlap. It will take 2 cycles of reports to begin to see improvement.

Option A


Hospital falls below volume threshold they were approved under
Hospital submits two STS Composite score data
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Submit next available STS Composite Report
No Action
No Action
Submit an Action Plan Within 60 days
Two year improvement period: Update report every 6 months
No Action
Department Compliance Action

STS Composite Score Quality Measures
Option B

Process:

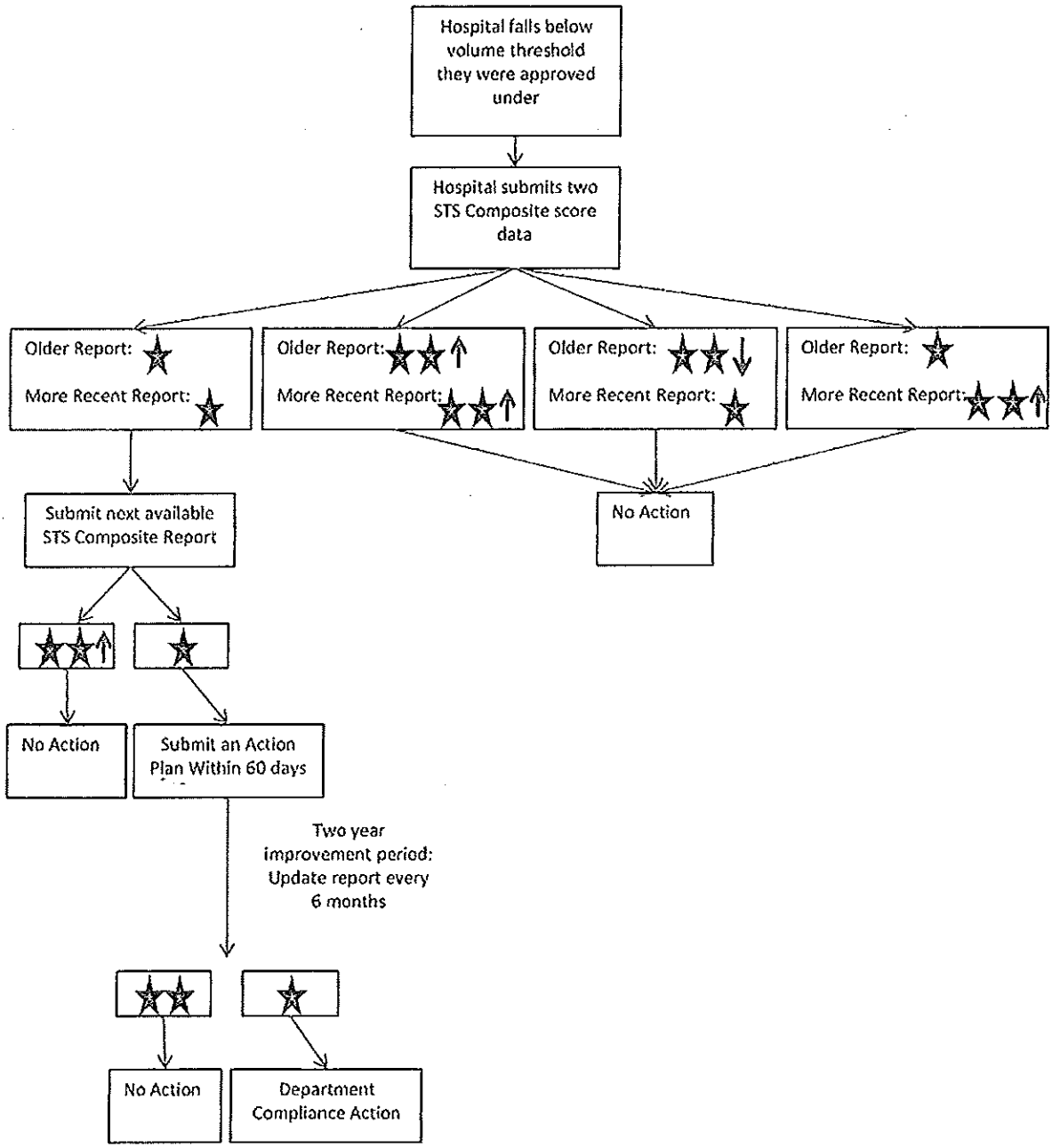
2. For hospital programs that are not meeting the volume requirements in the standards that they were approved under they are required to submit the two most recent 12-month rolling STS Composite Quality Rating reports (covers a total of 18 months of data). Using the overall star rating:
    a. Both reports are at or above a two star rating
        i. No action required
    b. One report is at one star and the other report is at two stars or above
        i. No action required
    c. Both reports are a one star
        i. An improvement plan needs to be submitted to the Department within 60 days of the Department's notice letter.

Improvement Plan and Period:

- The health system has two years from the date the improvement plan was submitted (the improvement period) to improve. The hospital is required to submit an update report from the STS Composite Quality Rating report every 6 months.
- Improvement is defined as reaching a two star or above overall composite rating by the end of the improvement period.
    - As soon as a 6 month update report shows a two star or above rating no further action will be required.
    - By the end of the improvement period if the composite score is still at one star the Department can proceed to choose a compliance action within their authority.

*Note about data cycles: If an improvement plan is required, the next STS report will most likely remain at 1 star due to the 6 month data overlap. It will take 2 cycles of reports to begin to see improvement.

Option B


Hospital falls below volume threshold they were approved under
Hospital submits two STS Composite score data
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Older Report:
More Recent Report:
Submit next available STS Composite Report
No Action
No Action
Submit an Action Plan Within 60 days
Two year improvement period: Update report every 6 months
No Action
Department Compliance Action

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.
       TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

        a. On-site heart valve surgery program,
        b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
        c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
        d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
        e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
        f. Appropriate volume requirements per the applicable qualifications below.

       There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams *without* previous TAVR experience and the second set is for those *with* TAVR experience.
       Qualifications to begin a TAVR program for hospitals *without* TAVR experience:
       The hospital program must have the following:

        a. ≥ 50 total AVRs in the previous year prior to TAVR, including ≥ 10 high-risk patients, and;
        b. ≥ 2 physicians with cardiac surgery privileges, and;
        c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

       Qualifications to begin a TAVR program for heart teams *without* TAVR experience:
       The heart team must include:

Cardiovascular surgeon with:

i. ≥ 100 career AVRs including 10 high-risk patients; or

ii. ≥ 25 AVRs in one year; or
iii. ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and

Interventional cardiologist with:

Professional experience with 100 structural heart disease procedures lifetime; or;
30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and
Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and
Device-specific training as required by the manufacturer.

Qualifications for hospital programs *with* TAVR experience:
The hospital program must maintain the following:

≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and
≥ 2 physicians with cardiac surgery privileges; and
≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

Qualifications for heart teams *with* TAVR experience:
The heart team must include:

A cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:

≥ 20 TAVR procedures in the prior year, or;
≥ 40 TAVR procedures in the prior 2 years; and
Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

   i. Stroke;
   ii. All cause mortality;
   iii. Transient Ischemic Attacks (TIAs);
   iv. Major vascular events;
   v. Acute kidney injury;

vi. Repeat aortic valve procedures;
vii. Quality of Life (QoL).

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
- What is the long term (≥ 5 year) durability of the device?
- What are the long term (≥ 5 year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. TAVR is covered for uses that are not expressly listed as an FDA approved indication when performed within a clinical study that fulfills all of the following.
   1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
   2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:
      - What is the incidence of stroke?
      - What is the rate of all cause mortality?
      - What is the incidence of transient ischemic attacks (TIAs)?
      - What is the incidence of major vascular events?
      - What is the incidence of acute kidney injury?
      - What is the incidence of repeat aortic valve procedures?
   3. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

      a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
      b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
      c. The research study does not unjustifiably duplicate existing studies.
      d. The research study design is appropriate to answer the research question being asked in the study.
      e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
      f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is

regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56. In particular, the informed consent includes a straightforward explanation of the reported increased risks of stroke and vascular complications that have been published for TAVR.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed as Medicare coverage requirements.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

2. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact

information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Re: TAVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

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

David R. Holmes, Jr, and Michael J. Mack

J. Am. Coll. Cardiol. 2011;58;445-455; originally published online Jun 27, 2011;
doi:10.1016/j.jacc.2011.05.007

This information is current as of February 23, 2012

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://content.onlinejacc.org/cgi/content/full/58/4/445

JACC
JOURNAL *of the* AMERICAN COLLEGE *of* CARDIOLOGY

Downloaded from content.onlinejacc.org by on February 23, 2012

Journal of the American College of Cardiology
Vol. 58, No. 4, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.05.007
© 2011 by the American College of Cardiology Foundation and the Society of Thoracic Surgeons
Published by Elsevier Inc.

EXPERT CONSENSUS DOCUMENT

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*

TABLE OF CONTENTS

Preamble 445

1. Introduction 446

1.1. Components of New Valve Technology Introduction 446

2. Heart Valve Surgery and Transcatheter Valve Therapy 446

2.1. The Professional Multidisciplinary Heart Team 447
2.1.1. The Role of the Primary Cardiologist 447
2.1.2. Imaging Specialists 447
2.1.3. Heart Failure Specialists 448

2.2. Specialized Experienced Facilities 448
2.2.1. Regional Heart Centers 448
2.2.2. Procedure Setting: Modified Catheterization Laboratory and Hybrid Operating Room 448

3. Scientific Literature 449

3.1. Results of Clinical Trials 449

4. Technological Improvement 450

5. Operator Training 450

6. Protocols for Care 451

7. Assessment of Outcomes 451

8. Summary 452

Appendix 1. Author Relationships With Industry and Other Entities (Relevant) 453

Appendix 2. Reviewer Relationships With Industry and Other Entities (Relevant) 453

References 454

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. In accordance with the ACCF's policy on relationships with industry and other entities (RWI), *relevant* author disclosures are included in Appendix 1 of this document. In the spirit of full disclosure, authors' *comprehensive* RWI information, which includes RWI not relevant to this document, is available online as a data supplement to this document. RWI restrictions are not applicable for participation in the external peer review process for clinical documents in order to ensure that a variety of constituencies/views inform the final document; however, all *relevant* reviewer RWI is published in Appendix 2 for the purpose of full transparency. In addition, reviewer affiliations for the 26 physicians who participated in this formal peer review process are recorded in Appendix 2. Final review and approval of the document was provided by the ACCF Board of Trustees and the STS Board of Directors.

This document was approved by the American College of Cardiology Foundation (ACCF) Board of Trustees and the Society of Thoracic Surgeons (STS) Board of Directors in 2011. For the purpose of complete transparency, disclosure information for the ACCF Board of Trustees, the board of the convening organization of this document, is available at: http://www.cardiosource.org/ACC/About-ACC/Leadership/Officers-and-Trustees.aspx. ACCF board members who have relationships with industry and other entities that are relevant to the document may review and comment on the document but may not vote on approval.

The American College of Cardiology Foundation requests that this document be cited as follows: Holmes DR, Jr., Mack MJ. Transcatheter valve therapy: a professional society overview from the American College of Cardiology Foundation and the Society of Thoracic Surgeons. J Am Coll Cardiol 2011;58:445–55.

This article is copublished in the July issue of *Annals of Thoracic Surgery*.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (www.cardiosource.org). For copies of this document, please contact Elsevier Inc. Reprint Department, fax 212-633-3820, e-mail reprints@elsevier.com.

Permissions: Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the American College of Cardiology. Please contact healthpermissions@elsevier.com.

Downloaded from content.onlinejacc.org by on February 23, 2012

JACC Vol. 58, No. 4, 2011
July 19, 2011:445–55

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

Transformational technology is defined as one that when introduced radically changes markets, creates wholly new markets, or could even eliminate existing markets for older technology (1). The field of medicine is replete with examples of such therapies that have radically altered the treatment of disease, including sterile techniques 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.

1.1. Components of New Valve Technology Introduction

Several issues emerge with the introduction of this new technology.

1. How will this technology be regulated and by whom?
2. Will the technology be available in all centers by all physicians or only in selected regional centers; if the latter, how will those centers be selected?
3. How will training of physicians and centers be accomplished? What will the training paradigms be and what experience is necessary for credentialing to be deemed proficient? Will the training be the same for cardiologists and surgeons?
4. Will clinical databases be linked to administrative databases facilitating long-term outcome assessment, comparative effectiveness research, and cost-effectiveness analysis? Will data collection be required using standardized definitions in harmonized national clinical and administrative databases and registries, and if so, from where will the resources come to accomplish this? Can these standardized registries be used worldwide?
5. What will be the rational diffusion of the new technology to other patient groups not originally studied in randomized clinical trials?
6. How will this new technology be reimbursed? How will patient cohorts be identified that will benefit the most and provide the most cost-effective and clinically effective treatment?

These complexities are compounded by the multiple constituents involved—patients, competing physicians and practice centers, payers, and industry—each of which may have different goals. The intent of this document is to provide a platform of issues to be solved and provide some direction as to how this may be accomplished.

2. Heart Valve Surgery and Transcatheter Valve Therapy

Traditional aortic and mitral surgery has been the mainstay of treatment for valvular heart disease; prior to surgical techniques for valve replacement and repair, there were no effective therapies for patients with severe disease. In selected patients at experienced centers with expert surgeons, the results have generally been excellent with improved morbidity and mortality compared with medical therapy but at a cost of significant invasiveness and recovery time for the patient. Since the introduction of minimally invasive and catheter-based therapies, patients have wanted less invasive options for all types of medical procedures including general surgical, orthopedic, spine, and urologic operations with the goal of decreasing morbidity and mortality and shortening recovery time (3).

Other issues with traditional aortic and mitral valve surgery include the fact that patients may not even be offered operation; in multiple series from different centers and in different countries, up to 40% of patients with severe aortic stenosis are treated medically (4–6). Some of these patients may be too sick because of associated medical comorbidities, and some may be considered too old to be offered surgery. Finally, some who may benefit the most from an operation may decline surgery even though they develop irreversible damage from the valve lesion that could have been treated.

These factors have led to the continuous development of less invasive strategies in an attempt to preserve the well-documented, long-term efficacy of standard procedures with lower mortality, lower morbidity, and less invasiveness. Such an improved risk-benefit ratio would result in a therapy that could be applied to more patients, as well as earlier in the course of their specific disease process. A critical question is whether there is a change in the risk-benefit ratio with these new therapies that is key to the multiple stakeholders—most importantly, patients and their families.

Downloaded from content.onlinejacc.org by on February 23, 2012

Table 1. Necessary Components for the Successful Introduction of Transcatheter Heart Valve Therapy

1. Specialized heart centers with experienced multidisciplinary physicians and paramedical personnel
2. The professional multidisciplinary heart team
   a. Primary cardiologists
   b. Cardiac surgeons
   c. Interventional cardiologists
   d. Echocardiographers and imaging specialists
   e. Heart failure specialists
3. Proper procedure and facilities
   a. Modified conventional cardiac laboratory
   b. Hybrid operating room
4. Development of and participation in clinical databases and registries to evaluate practice patterns, treatment outcomes, and comparative effectiveness
5. Scientific literature—knowledge of and evaluation of evidence-based medical literature concerning patient selection, procedural performance, and complication management
6. Specific standardized protocols for management strategies, procedural performance, problem solving, and complication management
7. Appropriate ongoing personnel training

For these less invasive approaches to work and to be introduced in a rational, balanced, and least disruptive manner, a number of critical elements must be brought together (Table 1). Successful implementation of these principles and practices will, in our opinion, maximize the chances for the successful introduction of this new technology and treatment paradigms, ensuring greatest patient benefit.

2.1. The Professional Multidisciplinary Heart Team

The concept of a multidisciplinary professional heart team has received increasing interest, beginning particularly with the SYNTAX (SYNTAX Study: TAXUS Drug-Eluting Stent Versus Coronary Artery Bypass Surgery for the Treatment of Narrowed Arteries) trial of patients with advanced coronary artery disease (7). Following angiography, the interventional cardiologist and cardiovascular surgeon reviewed the angiographic films together in the context of the clinical setting. If the patient was deemed to be an acceptable candidate for either procedure, both physician and surgeon—ideally together—would interview both patient and family to formulate an optimal plan. This "heart team" concept has been endorsed and recommended in the recent European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines on Myocardial Revascularization and should become the standard of care (8).

This heart team concept has been extended to valvular heart disease. In PARTNER (Placement of AoRTic TraNscathetER Valve Trial), the pivotal U.S. trial of a new device for transcatheter aortic valve replacement (TAVR), patients are routinely evaluated by "partners" of cardiologists and surgeons together to determine patient eligibility and optimal treatment strategy (9). This requires pre-procedural evaluation in valvular heart disease clinics, multidisciplinary team conferences, and joint performance of the procedure, as well as postoperative care. This same heart team principle has also proven to be extremely successful in centers participating in the U.S. pivotal trial of the first catheter-based approach for the treatment of mitral valve disease, EVEREST II (Pivotal Study of a Percutaneous Mitral Valve Repair System) (10). Such a heart team will be even more critical as the issues with structural heart disease become more complex, as the treatment expands to more centers, and as new technology is applied outside of the constraints of randomized clinical trials. The success of this team concept has been demonstrated in heart transplant centers in which patient treatment decisions and care are managed by heart failure cardiologists, transplant and ventricular assist device surgeons, experts in immunosuppression, as well as specialists in echocardiography and in anesthesia; all collaborate as a multidisciplinary team. Key members of the multidisciplinary team for structural heart valve disease management include primary cardiologists, interventional cardiologists, cardiac surgeons, noninvasive and heart failure cardiologists, echocardiographers and cardiac imaging specialists, cardiac anesthesiologists, nurse practitioners, physician assistants, research coordinators, administrators, dietary and rehabilitation specialists, and social workers. Each component will need to develop and implement specific protocols depending on the individual patient and specific technical procedure.

2.1.1. The Role of the Primary Cardiologist

Typically, patients who are candidates for these procedures have been seen longitudinally in the course of their disease by primary cardiologists who have a unique perspective of patient and family dynamics. These physicians coordinate care, ensure complete evaluation, order and evaluate diagnostic studies, implement medical care, and ensure involvement of patients and families in the decision-making process. These primary cardiologists also resume care of the patient after the procedure and need to be cognizant of the follow-up needs and protocols; accordingly, these individuals are an essential component of the heart team to enhance patient-centered care. Primary cardiologists in concert with the surgeons and interventional cardiology teams will be central in applying scoring systems to evaluate risk-benefit profiles in this diverse group of patients (11,12). The patient's values and goals need to be central in benefit-risk assessment and treatment decisions.

2.1.2. Imaging Specialists

Mandatory imaging modalities necessary for a structural heart disease program include 2- and 3-dimensional transthoracic and transesophageal echocardiography, vascular computerized tomography with 3-dimensional reconstruction, cardiac magnetic resonance imaging, diffusion-weighted magnetic resonance imaging of the brain, and transcranial Doppler imaging.

Downloaded from content.onlinejacc.org by on February 23, 2012

ATTACHMENT D
JACC Vol. 58, No. 4, 2011
July 19, 2011:445–55

Echocardiography will be critical, with collection of standardized definition sets. Such data will be best defined by large-scale registries such as the STS National Adult Cardiac Database and the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). The Valve Academic Research Consortium (VARC) Consensus Report, which established standardized endpoint definitions for transcatheter aortic valve therapy, is the first step in this direction (13). The American Society of Echocardiography (ASE) has developed specific definitions of severity of valvular lesions that could benefit from transcatheter valve therapy that will need to be incorporated in registry reporting (14,15).

An important screening component involves 3-dimensional reconstruction of the aortoiliac vasculature using multislice computerized tomography (MSCT). The current aortic transvalvular device delivery sheaths are large, ranging from 18- to 24-Fr in diameter. Although they are becoming smaller in diameter, access remains an issue. Accordingly, it is essential to identify absolute arterial diameters and specific abnormalities such as severe calcification or tortuosity of the aortoiliac vascular tree that may dictate an alternative access route.

2.1.3. Heart Failure Specialists

An increasing number of patients with advanced valvular heart disease have a component of left ventricular dysfunction. For patients with aortic stenosis, left ventricular dysfunction may render the assessment of the severity of the aortic stenosis difficult, thus complicating decision making about the need for or performance of a procedure. In addition, heart failure specialists will need to help assess the potential for reversibility of left ventricular dysfunction following TAVR. This will also be of particular importance for the treatment of mitral valve disease. Identification of appropriate patients with mitral insufficiency and heart failure who may benefit from a catheter-based approach is best accomplished by consultation with heart failure specialists.

2.2. Specialized Experienced Facilities

2.2.1. Regional Heart Centers

The concept of regional heart centers will be extremely important. Because of the myriad of specialists, imaging equipment, procedural facilities, and support infrastructure necessary to build a valve center, it is unlikely that accessibility to new transcatheter valve technology will be universal and immediate. In the United States, many cardiac surgical centers and catheterization laboratories have a very low volume of structural heart disease cases. In these centers, for example in patients with mitral regurgitation, mitral valve replacement is more frequently performed than is mitral valve repair, which is the preferred strategy (16). Outcomes for patients undergoing surgery for valvular heart disease have clearly been demonstrated to be related to center procedural volume (17). In England, Centers of Excellence with specific volume criteria for treatment of mitral valve disease have been proposed by the National Institutes for Health and Clinical Excellence (NICE) (18). The complexities of the management of valvular heart disease will require the infrastructure available only in regional referral centers with appreciable patient volume in valvular heart disease. The development of specialized regional centers will be controversial; a tenet of modern cardiovascular practice has been that each hospital that has experienced personnel should be able to do any and all indicated procedures. However, in the case of percutaneous valve repair/replacement, the specialized expertise, experience, imaging equipment, and facilities that will be required to optimize outcomes are not available in all programs. The analogy to regional transplant referral centers is apropos. Although access to care should not be as limited as it is with cardiac transplantation, patient populations will not be best served being treated in multiple institutions with relatively low volumes in the same geographic region. It must be remembered that the initial results of the first randomized trial of TAVR were achieved by a heart team of experienced surgeons and structural interventional cardiologists working together in high-volume tertiary care centers. We believe that the criteria for regulatory approval and reimbursement by the appropriate federal agencies should initially be based on similar criteria in terms of expertise and high valve procedure volumes in new, approved centers.

In order for this approach of specialized regional centers to be implemented, detailed lists of facilities and personnel experience in addition to pre- and post-procedural care protocols, as well as complication management strategies, must be developed and then implemented. An analogy to this approach may be the New York State Department of Health program for performance of primary percutaneous coronary intervention centers without onsite surgery that has set up specific requirements with physician oversight, periodic review, and feedback (19). Key to this program, all data must use standardized forms and be sent to a central data registry for reporting. A similar national central data repository needs to be constructed for valve therapy.

2.2.2. Procedure Setting: Modified Catheterization Laboratory and Hybrid Operating Room

Two major approaches have been developed, both with specific advantages and specific proponents. The core tenet of both is that superior imaging is mandatory. In addition, sterility is of paramount importance.

2.2.2.1. MODIFIED CONVENTIONAL CARDIAC LABORATORY

This approach can utilize a conventional cardiac catheterization laboratory with some modifications. A specific drawback is the size of the conventional catheterization room, which is typically 600 square feet. Such a room can support conventional angiography and percutaneous coronary intervention. In addition, for treatment of some types of structural heart disease, these conventional rooms can also be used as such for closure of a patent foramen ovale, a

Downloaded from content.onlinejacc.org by on February 23, 2012

paravalvular leak, and a left atrial appendage occlusion, although for each of these procedures, the rooms typically need to have biplane imaging equipment and be integrated with real-time echocardiography procedural guidance. A modified room of this design can also be used for hybrid surgical procedures where the left internal mammary artery is placed to the left anterior descending, and the remaining stenoses are treated percutaneously. For transcatheter valve therapy, the room needs to be large enough to accommodate anesthesia equipment, echocardiography machines, intra-aortic balloon pumps, and cardiopulmonary bypass machines. If a conventional cardiac catheterization laboratory is to be used, adaptation to meet surgical sterility standards including airflow exchanges is essential.

2.2.2.2. HYBRID OPERATING ROOM

Another type of surgical "hybrid" room has attracted great interest. These are rooms that are focused on newer procedures such as percutaneous aortic and pulmonary valve implantation, hybrid percutaneous/surgical coronary and valve/coronary procedures, and some composite hybrid aortic arch and descending thoracic and abdominal aortic approaches with aortic stent grafts. These rooms are typically larger (800 to 900 square feet) than hybrid coronary angiographic rooms. Catheterization laboratory–quality X-ray imaging is a requisite but is supplemented by a variety of alternative imaging modalities, particularly transesophageal echocardiography and 3-dimensional intravascular ultrasound images. In addition, other technologies, such as rotational angiography, computed tomography (CT), or at the very least, real-time interactive access to magnetic resonance imaging and CT images, need to be available because these newer imaging modalities are expected to play a larger role in the field with real-time 3-dimensional reconstruction of CT images and "road-mapping" of important structures.

An important, yet unresolved issue is the location of these new-generation hybrid rooms. Placement of the new hybrid rooms in an operating room suite environment affords accessibility to the operating suite infrastructure and personnel, whereas placement in the catheterization laboratory provides wider availability to catheterization laboratory personnel and catheter-based equipment. These are important issues because hybrid teams may have very different skill sets if they come from the background of surgery, whereas a hybrid team with a background of interventional cardiology may not have the same skill set. Maintenance of separate teams may not be efficient. Alternatively, cross-training 1 team may dilute the experience. Current procedural teams function best with both disciplines involved and with both catheterization laboratory and operating room personnel participating. No matter where the procedural room is located—catheterization laboratory or operating suites—equal access by both specialties is required.

The location of patient care post-procedure is of considerable importance. Coronary care units are very experienced with hemodynamic assessment but are not accustomed to dealing with very large-bore catheter- and sheath-vessel access issues nor surgical incisions and chest drainage tubes. In addition, surgical units are most accustomed to dealing with the rapidly changing hemodynamics occurring after aortic valve replacement. This part of the field will continue to evolve as the technology becomes smaller with percutaneous vascular access closure devices. It will be important to centralize the immediate post-procedural care of these patients in 1 location on a single clinical service at the individual center to maximize expertise, team training, and the development of clinical protocols.

3. Scientific Literature

3.1. Results of Clinical Trials

A robust knowledge of the current scientific literature is mandatory to place this technology in perspective. Data from multiple single-center series, and national and commercial registries are available for both transcatheter aortic and mitral procedures. Randomized clinical trials represent the highest form of evidence-based medicine and form the backbone of regulatory approval and instructions for use. The results of 1 pivotal trial of transcatheter aortic valves and 1 of transcatheter mitral valves have been published. A complete review of the increasingly large dataset is beyond the scope of this work, but a committee of the societies involved will subsequently convene and publish an expert consensus statement in 2011. Evaluation of some of the data from these 2 randomized trials is important as it affects the process of development and implementation of these technologies.

The pivotal PARTNER trial has received a great deal of interest. Specific details about patient selection, protocols used, endpoints, and statistical evaluation are crucial.

The PARTNER trial was basically 2 parallel trials that enrolled the highest-risk patients ever seen in any cardiovascular trial by virtue of their age and severity of comorbid conditions: 1) PARTNER Cohort A, which randomized high-risk surgical patients to either traditional aortic valve replacement or to TAVR by either a transfemoral or transapical approach; and 2) PARTNER Cohort B in which patients who were inoperable were randomized to either a TAVR by a transfemoral approach or to conventional medical therapy, which typically consisted of balloon aortic valvuloplasty. Screening required an evaluation by 2 experienced cardiac surgeons to agree on the surgical risk using the STS Predicted Risk of Mortality score (20) and was rigorous, with approximately one quarter to one third of screened patients subsequently enrolled. The primary endpoint was death from any cause at 1 year.

The results of PARTNER Cohort B have recently been published (9) and included 358 patients deemed unsuitable for conventional aortic valve replacement because of predicted probability of ≥50% mortality or at risk for a serious

Downloaded from content.onlinejacc.org by on February 23, 2012

ATTACHMENT D
JACC Vol. 58, No. 4, 2011
July 19, 2011:445–55

irreversible complication by 30 days. At 1 year, all-cause mortality with TAVR was 30.7% versus 50.7% with medical therapy (hazard ratio: 0.55, 95% confidence interval: 0.40 to 0.74). Despite the marked improvement in survival and event-free survival, there were some significant safety hazards, particularly a higher incidence of major strokes (5.0% versus 1.1%) as well as increased major vascular complications (16.2% versus 1.1%) with TAVR, both of which may impact early and longer-term outcome adversely. Longer-term outcomes will be required.

These results were received enthusiastically; however, they have important implications. First, they can be applied only in patients similar to those in the study (i.e., those patients deemed to be inoperable). Second, they are the result of treatment by very experienced operators working as a heart team in a hybrid operating room or similar facility with a specific device and do not necessarily apply to other devices.

The preliminary results of the PARTNER Cohort A trial were presented and, when published, will also have important implications. The primary endpoint of the trial was met, with TAVR found to be noninferior to aortic valve replacement for all-cause mortality at 1 year (TAVR versus aortic valve replacement, 24.2% versus 26.8%, respectively, $p=0.001$ for noninferiority). Death at 30 days was lower than expected in both arms of the trial: TAVR mortality (3.4%) was the lowest reported in any series, despite an early generation device and limited previous operator experience. Aortic valve replacement mortality (6.5%) was lower than the expected operative mortality (11.8%). Furthermore, both TAVR and aortic valve replacement were associated with important but different peri-procedural hazards: major strokes at 30 days (3.8% versus 2.1%, $p=0.20$) and 1 year (5.1% versus 2.4%, $p=0.07$), and major vascular complications were more frequent with TAVR (11.0% versus 3.2%, $p<0.001$). Major bleeding (9.3% versus 19.5%, $p<0.001$) and new onset atrial fibrillation (8.6% versus 16.0%, $p<0.001$) were more frequent with aortic valve replacement.

The trial investigators also concluded that "a multidisciplinary valve team approach benefits patients and is recommended for all future valve centers." These results cannot be extrapolated to evaluate the outcome of this procedure in patients who are excellent candidates for conventional aortic valve replacement. For this to occur, more randomized controlled studies will need to be performed.

The 30-day mortality in PARTNER Cohort A (3.4%) and PARTNER Cohort B (5.2%) is better than published European registry mortality (8.5%) (21–23). This raises questions about the "generalizability" of these trial results after commercialization in the United States. Responsible diffusion of this technology with close monitoring of outcomes after commercialization will be critical to maintain these results. The incidence of neurologic events (5.5% at 30 days, 8.3% at 1 year) and major vascular complications (11%) that occur in patients undergoing TAVR also needs to be addressed. The role of embolic protection, smaller delivery systems, and post-procedure anticoagulation remains to be determined.

The other completed pivotal randomized trial is the EVEREST II trial of the MitraClip, which randomized patients with severe mitral regurgitation to surgery or a catheter-based approach. The MitraClip was used to perform an "Alfieri-type" approximation of the free edges of the mitral leaflets for the treatment of either functional mitral regurgitation due to annular dilation or structural mitral regurgitation due to mitral leaflet abnormalities (10). Although less effective at reducing mitral regurgitation, percutaneous repair was associated with superior safety and comparable improvements in clinical outcomes at 12 months compared with mitral valve surgery (10).

4. Technological Improvement

The field of percutaneous structural heart disease therapies continues to advance rapidly. There now are approximately 10 different companies involved in the development of TAVR and even a greater number of companies involved with the development of transcatheter mitral approaches. Although only a few of these technologies have been subjected to randomized clinical trials, it is important to remember that each specific technology may have unique complication patterns, such as the frequency of stroke, vascular complications, and complete heart block, that may require different deployment strategies (24). Other issues will undoubtedly evolve as devices—which can be recaptured and replaced—will be developed and tested. But each device will have its own unique safety and efficacy profile.

The situation is even more complex for the transcatheter mitral valve approaches. Some of these will involve using percutaneous technology to create the equivalent of an Alfieri stitch to treat structural mitral regurgitation. Others will involve manipulation of catheters to deliver energy to shrink the mitral annulus or to deliver a variety of bands to decrease the diameter, as well as other approaches that will be combined. Again, each of these approaches will have specific device deployment issues and considerations. Some of these new technologies and deployment approaches will be aimed at expanding either the number or types of valves that can be treated successfully; some of these will make the procedure easier. The number of new devices, however, will contribute to the growing complexity of the field.

5. Operator Training

Operator training is a crucial component for treating structural heart disease. A number of training programs are already training physicians involved in very complex structural heart disease, but interventional cardiologists and cardiac surgeons who are already in practice may not have the time or the opportunity to train in these programs. For physicians and surgeons in practice, therefore, these issues will be much more

Downloaded from content.onlinejacc.org by on February 23, 2012

problematic. Components of the training program may vary, for example, in the use of simulators or in vivo animal laboratory experience. Construction of a training curriculum is essential. Initial work in developing a curriculum has recently been set forth (25). In the past, with some new technology, for example, carotid stenting, the specific company involved with a particular proprietary device prepared the material to be mastered. It is our opinion that this approach is not adequate; instead, the professional societies should develop the materials, outline the metrics of evaluation, and then certify performance in the training module. How this interfaces with industry training with specific devices as mandated by the U.S. Food and Drug Administration approval process will need to be determined. In addition, the costs of designing and implementing the training programs need to be established. Combined committees of the ACCF and the STS, along with other societies, are currently being formed to address these issues.

The creation of clinical fellowships for training in transcatheter valves is also quite problematic at the current time. Since there is not commercial approval for any aortic or mitral device in the United States, the potential for training exists only in current trial centers. There are only 30 to 40 centers currently with experience in transcatheter aortic valves and approximately 20 centers with transcatheter mitral valves. The procedure volume at each of these centers is currently limited by the constraints of trial enrollment, and experience at the senior staff level is limited, which further constrains fellowship training. The most advantaged individuals for transcatheter valve training are those who are currently fellows in programs that are trial centers. The training of other individuals, especially those who have completed their fellowships and are currently in practice, is also currently being addressed by our societies. The questions being asked include: What is the requisite experience to gain the necessary expertise to be proficient in the procedures? What is the length of training necessary to gain proficiency? Are 3-month fellowships sufficient, or do they need to be 6 months or 1 year? How are these fellowships to be funded? Is 1 common training pathway sufficient for cardiologists and surgeons alike, or are there different fellowships with some commonality? Should cardiologists and surgeons interested in being trained in valvular heart disease be trained as teams?

In our opinion, the professional societies should assume the leading role in establishing the minimal performance criteria and helping to build the infrastructure for these fellowships. Abrogating the responsibility for training to commercial sponsors who have a regulatory responsibility for training in their devices is not sufficient. The establishment of these criteria is beyond the scope of this document; however, the appropriate committees in the professional societies are currently establishing operator and institutional requirements for transcatheter valve performance.

6. Protocols for Care

Specialized heart centers, staffed by trained primary cardiologists, interventional cardiologists, and cardiac surgeons, should have specific protocols for care related to preprocedure assessment and screening. These protocols optimally should be implemented and executed jointly by the multidisciplinary heart team. These protocols will involve screening for the presence, degree, and severity of comorbidities; issues related to the aortic, mitral, or right ventricular outflow tract pathology that may affect outcome; and detailed evaluation of the etiology, severity, and functional impairment of the specific lesion under consideration. In this process, there needs to be full exploration of the patient and family expectations. These protocols should then include obligatory consultations with the heart team to identify optimal strategies and then identify other procedures that may be required (e.g., the treatment of coronary obstructive lesions prior to the placement of a percutaneous TAVR). Such protocols and procedures should be mandated as a patient-care pathway. This will do much to prevent inappropriate use of these devices, as well as misinterpretation of the data required for optimal device utilization.

7. Assessment of Outcomes

Both the STS and ACC maintain large clinical databases that collect and analyze outcomes of surgical and catheter-based procedures. These clinical databases, however, are currently limited by the lack of modules to adequately collect data on transcatheter valves and are further limited to clinical follow-up for only 30 days after the procedure. An initial pilot project, ASCERT: the ACCF/STS Collaboration on the Comparative Effectiveness of Revascularization Strategies, linking the 2 clinical databases to administrative databases including the Social Security Death Master File (SSDMF) and Centers for Medicare & Medicaid Services Medicare Provider and Analysis Review (MedPAR) data in patients with coronary artery disease is currently under way (24,26). Another pilot project highlighting successful linkage of the STS database to the SSDMF and reporting 1-year survival after cardiac surgery was published in 2010 (27). A similar linking of clinical and administrative databases to perform post-market surveillance, assess long-term patient-centered outcomes research, and perform comparative effectiveness research and cost effectiveness for all patients with valvular heart disease is crucial. This linkage needs to involve shared modules to avoid duplicate data entry. One model currently being utilized for tracking outcomes of patients receiving left ventricular assist devices—the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry—should be considered for transcatheter valves (28). This is potentially a huge undertaking for which financial support does not

Downloaded from content.onlinejacc.org by on February 23, 2012

ATTACHMENT D
JACC Vol. 58, No. 4, 2011
July 19, 2011:445–55

currently exist. However, construction of these linked outcome databases is critical to adequately assess the impact of transcatheter valves on the clinical outcomes of patients with valvular heart disease and can overcome the shortcomings traditionally associated with registry outcome data. It is important to also consider the use of common data forms, definitions, and reporting processes in different countries. Initial discussions are under way to determine the feasibility of linking various national registries together to establish a truly global database. Transcatheter and surgical valve therapy provide an optimal initial platform to foster this linkage. This will facilitate evaluation and interpretation of the results of ongoing and future planned studies. It will additionally facilitate regulatory trials for the U.S. Food and Drug Administration by being able to better utilize global data when considering new device trial submissions and will enhance payer understanding of the best decision making for application of these technologies. This will require that the different international societies become more fully engaged and integrated.

8. Summary

Transcatheter valve therapy is a transformational technology with the potential to significantly impact the clinical management of patients with valvular heart disease in a less invasive manner. Although the initial experience is positive, evidence exists from only 1 randomized clinical trial in patients with aortic stenosis and 1 in patients with mitral insufficiency. Adoption of these techniques to populations beyond those studied in these randomized trials, therefore, is not appropriate at the current time. However, in view of the promising results obtained in these limited population subsets, conduct of further randomized trials in other patient groups is strongly encouraged.

In order to address the challenges ahead for the responsible diffusion of this innovative transformational technology, it is critical that the professional societies, industry, payers, and regulatory agencies work together. The leadership of the ACCF and STS in consultation with multiple leaders within the primary and interventional cardiology and cardiac surgical communities, regulators, and payers make the following recommendations (Table 2).

1. Establishment of regional centers of excellence for heart valve diseases. Criteria for centers performing interventional therapy in valvular and structural heart disease should be established, and the availability of devices and reimbursement for those procedures should be limited to those centers meeting those criteria.
2. Formation of multidisciplinary heart teams within these centers led by primary cardiologists, cardiac surgeons, and interventional cardiologists. Performance of isolated procedures without construction of a dedicated valve therapy program to encompass all aspects of care including pre-procedural assessment in common clinics, joint procedure performance, and common patient care pathways is not recommended.
3. Establishment of a national registry of valvular heart disease to perform post-market surveillance, long-term outcome measurement, and comparative effectiveness research. This could be accomplished by linking the ACC-NCDR and STS clinical databases to the Social Security Death Masterfile and Centers for Medicare & Medicaid Services administrative databases in a national "research engine." This will, in effect, create a national registry of valvular heart disease similar to those that exist in Great Britain and Germany. Funding for this initiative will be a concern, but it is our position that this linkage of databases is a key element of quality patient care, outcomes analysis, and comparative effectiveness.
4. Establishment of training and credentialing criteria for practitioners in this field. Formation of criteria for the formation of fellowship programs as well as postgraduate training with appropriate experience for adequate patient care leading to guidelines for credentialing is currently under way by multiple professional societies working together.
5. Interpretation of the current evidence by expert consensus documents and appropriate use criteria is necessary and will be forthcoming.

Table 2. Critical Areas for Implementation

1. Development of multidisciplinary structural heart disease teams and institutions
2. Development of standardized protocols of care
3. Engagement of multiple stakeholder societies in generating procedural, credentialing, and training documents and specific site standards
4. Standardized definitions, data reporting, and post-market surveillance strategies for outcome assessment
5. Robust strategy for comparative effectiveness studies

The ACCF and STS are committed as professional societies to work with the U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services to address all issues that are crucial to the safe and efficacious introduction of transcatheter valve therapy into clinical practice. Forthcoming will be multisocietal guidelines for training and credentialing, an expert consensus document, and grant proposals for creation of a national registry. This is an exciting time with the introduction of new technology and techniques to care for our patients with valvular heart disease. With society leadership, multidisciplinary partnerships, and cooperation, a reasoned, balanced introduction of this new therapy can be accomplished.

Downloaded from content.onlinejacc.org by on February 23, 2012

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—TRANSCATHETER VALVE THERAPY: A PROFESSIONAL SOCIETY OVERVIEW FROM THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION AND THE SOCIETY OF THORACIC SURGEONS

Committee Member	Employment	Consultant	Speakers' Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
David R. Holmes, Jr.	Mayo Clinic—Consultant, Cardiovascular Diseases	None	None	None	None	None	None
Michael Mack	The Heart Hospital, Baylor Plano—Director	None	None	None	• Edwards Lifesciences*	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

*No financial benefit.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—TRANSCATHETER VALVE THERAPY: A PROFESSIONAL SOCIETY OVERVIEW FROM THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION AND THE SOCIETY OF THORACIC SURGEONS

Peer Reviewer	Representation	Consultant	Speakers' Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Ralph Brindis	Official Reviewer—ACCF Board of Trustees	None	None	None	None	None	None
Richard Feins	Official Reviewer—STS	None	None	None	None	None	None
Greg Fontana	Official Reviewer—STS	• Edwards Lifesciences • St. Jude Medical* • Sorin Medical	None		None	• Edwards Lifesciences	None
Sid Levitsky	Official Reviewer—STS	• On-X Valve Company*	None	None	None	None	None
Fred Mohr	Official Reviewer—STS	None	None	None	None	None	None
Mark Turco	Official Reviewer—ACCF Board of Governors	• Boston Scientific • Medtronic Vascular	• Medtronic	None	• Boston Scientific • Medtronic	None	None
Emmanouil Brilakis	Content Reviewer—ACCF Interventional Scientific Council	• St. Jude*	None	None	None	• Medtronic*	None
James Burke	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Fred Edwards	Content Reviewer—ACCF Surgeon Council	None	None	None	None	None	None
T. Bruce Ferguson	Content Reviewer—ACCF Surgeon Council	None	None	None	None	None	None
Fred Grover	Content Reviewer—ACCF Surgeon Council	None	None	None	None	None	None
Robert Guyton	Content Reviewer—ACCF Surgeon Council	None	None	None	• Edwards Lifesciences†	None	None
Robert Harrington	Content Reviewer—ACCF TF CECD	• Baxter	None	None	• Baxter	None	None

Downloaded from content.onlinejacc.org by on February 23, 2012

ATTACHMENT D
JACC Vol. 58, No. 4, 2011
July 19, 2011:445–55

Peer Reviewer	Representation	Consultant	Speakers' Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Joerg Herrmann	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Alice Jacobs	Content Reviewer—ACCF TF CECD	None	None	None	None	None	None
Sanjay Kaul	Official Reviewer—ACCF TF CECD Lead Reviewer	None	None	None	None	None	None
Lloyd Klein	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Bruce Lytle	Content Reviewer—ACCF Surgical Council	None	None	None	None	None	None
Isaam Moussa	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Richard Murphy	Content Reviewer—ACCF Board of Governors	None	None	None	None	None	None
Srihari Naidu	Content Reviewer—ACCF Interventional Scientific Council	• Cordis • Medtronic Vascular	None	None	None	None	None
Catherine Otto	Content Reviewer—Individual	None	None	None	None	None	None
Stephen Ramee	Content Reviewer—ACCF Board of Governors	None	None	• Boston Scientific* • Medtronic	• Boston Scientific† • Edwards Lifesciences† • Medtronic†	None	None
Sunil Rao	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Pasala Ravichandran	Content Reviewer—ACCF Surgeon Council	None	None	None	None	None	None
Richard Shemin	Content Reviewer—STS	• Edwards Lifesciences*	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

*Significant relationship. †No financial benefit.

ACCF = American College of Cardiology Foundation; STS = Society of Thoracic Surgeons; and TF CECD = Task Force on Clinical Expert Consensus Documents.

REFERENCES

1. Christensen CM. The Innovator's Dilemma: When New Technologies Cause Great Firms to Fail. Boston, MA: Harvard Business School Press, 1997.
2. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation 2002;106:3006–8.
3. Mihaljevic T, Cohn LH, Unic D, Aranki SF, Couper GS, Byrne JG. One thousand minimally invasive valve operations: early and late results. Ann Surg 2004;240:529–34.
4. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: the Euro Heart Survey on Valvular Heart Disease. Eur Heart J 2003;24:1231–43.
5. Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J 2005;26:2714–20.
6. Pai RG, Kapoor N, Bansal RC, Varadarajan P. Malignant natural history of asymptomatic severe aortic stenosis: benefit of aortic valve replacement. Ann Thorac Surg 2006;82:2116–22.
7. Serruys PW, Morice MC, Kappetein AP, et al. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. N Engl J Med 2009;360:961–72.
8. Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization: the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J 2010;31:2501–55.
9. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607.
10. Feldman T, Foster E, Glower DG, et al. Percutaneous repair or surgery for mitral regurgitation. N Engl J Med 2011;364:1395–406.
11. Dewey TM, Brown D, Ryan WH, Herbert MA, Prince SL, Mack MJ. Reliability of risk algorithms in predicting early and late operative outcomes in high-risk patients undergoing aortic valve replacement. J Thorac Cardiovasc Surg 2008;135:180–7.
12. Wendt D, Osswald BR, Kayser K, et al. Society of Thoracic Surgeons score is superior to the EuroSCORE determining mortality in high risk patients undergoing isolated aortic valve replacement. Ann Thorac Surg 2009;88:468–74.

Downloaded from content.onlinejacc.org by on February 23, 2012

13. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium. J Am Coll Cardiol 2011;57:253–69.
14. Baumgartner H, Hung J, Bermejo J, et al. Echocardiographic assessment of valve stenosis: EAE/ASE recommendations for clinical practice. J Am Soc Echocardiogr 2009;22:1–23.
15. Zoghbi WA, Chambers JB, Dumesnil JG, et al. Recommendations for evaluation of prosthetic valves with echocardiography and Doppler ultrasound: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Task Force on Prosthetic Valves. J Am Soc Echocardiogr 2009;22:975–1014.
16. Bolling SF, Li S, O'Brien SM, Brennan JM, Prager RL, Gammie JS. Predictors of mitral valve repair: clinical and surgeon factors. Ann Thorac Surg 2010;90:1904–11.
17. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med 2003;349:2117–27.
18. Bridgewater B, Hooper T, Munsch C, et al. Mitral repair best practice: proposed standards. Heart 2006;92:939–44.
19. Hannan EL, Zhong Y, Racz M, et al. Outcomes for patients with ST-elevation myocardial infarction in hospitals with and without onsite coronary artery bypass graft surgery: the New York State experience. Circ Cardiovasc Interv 2009;2:519–27.
20. O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2—isolated valve surgery. Ann Thorac Surg 2009;88:S23–42.
21. Thomas M, Schymik G, Walther T, et al. Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) Registry: a European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation 2010;122:62–9.
22. Eltchaninoff H, Prat A, Gilard M, et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J 2011;32:191–7.
23. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J 2011;32:198–204.
24. Webb JG. TAVI in Canada and Europe: the changing spectrum of management of aortic stenosis—what it means for the United States. Presented at: the Society of Thoracic Surgeons 4th Annual Meeting; January 31, 2011; San Diego, CA. Available at: http://www.sts.org/sites/default/files/documents/pdf/annmtg/2011AM/STS47AM_MonJan31.pdf. Accessed May 13, 2011.
25. Ruiz CE, Feldman TE, Hijazi ZM, et al. Interventional fellowship in structural and congenital heart disease for adults. J Am Coll Cardiol Intv 2010;3:e1–15.
26. Weintraub WS, Edwards FH. Introducing ASCERT: the American College of Cardiology-The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies (abstr). J Am Coll Cardiol 2010;55:A129.E1207.
27. Jacobs JP, Edwards FH, Shahian DM, et al. Successful linking of the Society of Thoracic Surgeons adult cardiac surgery database to Centers for Medicare and Medicaid Services Medicare data. Ann Thorac Surg 2010;90:1150–6.
28. Interagency Registry for Mechanically Assisted Circulatory Support. Available at: http://www.intermacs.org. Accessed April 27, 2011.

Key Words: ACCF/STS Expert Consensus Document ■ heart surgery ■ heart valve diseases ■ transcatheter valve therapy.

Downloaded from content.onlinejacc.org by on February 23, 2012

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

David R. Holmes, Jr, and Michael J. Mack

J. Am. Coll. Cardiol. 2011;58;445-455; originally published online Jun 27, 2011;
doi:10.1016/j.jacc.2011.05.007

This information is current as of February 23, 2012

Updated Information & Services	including high-resolution figures, can be found at: http://content.onlinejacc.org/cgi/content/full/58/4/445
Supplementary Material	Supplementary material can be found at: http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.05.007/DC1
References	This article cites 25 articles, 17 of which you can access for free at: http://content.onlinejacc.org/cgi/content/full/58/4/445#BIBL
Citations	This article has been cited by 2 HighWire-hosted articles: http://content.onlinejacc.org/cgi/content/full/58/4/445#otherarticles
Subspecialty Collections	This article, along with others on similar topics, appears in the following collection(s): **Expert Consensus Documents** http://content.onlinejacc.org/cgi/collection/expert_consensus
Rights & Permissions	Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at: http://content.onlinejacc.org/misc/permissions.dtl
Reprints	Information about ordering reprints can be found online: http://content.onlinejacc.org/misc/reprints.dtl

Downloaded from content.onlinejacc.org by on February 23, 2012