



Standards and Best Practices For Mitral Valve Repair Reference Centers

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Introduction

The Mitral Foundation has created the Standards and Best Practices for Mitral Valve Repair Reference Centers ("Standards and Best Practices") to recognize hospital-based centers throughout the United States which have the facilities, personnel and other specialized resources to successfully perform mitral valve repair surgery.¹

The objectives underlying the Standards and Best Practices include:

- To identify cardiac surgery programs in the United States which have experienced cardiothoracic surgeons, structural heart cardiologists, facilities and support services to perform mitral valve repair procedures.
- To recognize those mitral valve repair centers which have a demonstrated record of superior clinical outcomes and an ongoing commitment to reporting and measuring such outcomes.
- To promote the availability of such mitral valve repair centers to improve geographic access for patients across the entire United States.

The Standards and Best Practices as set forth herein include:

- Mitral Valve Repair Center Standards
- Mitral Valve Heart Team Standards
- Mitral Valve Repair Volume Standards
- Mitral Valve Repair Outcome Standards
- Mitral Valve Repair Process Standards
- Mitral Valve Repair Data Standards
- Mitral Valve Repair Best Practices

The Standards and Best Practices have been developed by the Mitral Foundation in close consultation with its Scientific Advisory Board. The Scientific Advisory Board consists of well-regarded cardiothoracic surgeons, cardiologists, and quality and outcome specialists who have a strong interest in the treatment of mitral valve disease and related mitral valve repair surgery.

¹ Refer to the Glossary for definitions of specific terms throughout the Standards and Best Practices.

Mitral Valve Repair Reference Center Standards and Best Practices

1.0 Mitral Valve Repair Reference Center Standards

- 1.1 The Center must identify as part of a Designated Hospital that provides the physical facilities, resources and structure necessary to support a specialized Mitral Valve Heart Team.²
- 1.2 The Designated Hospital must have all of the following services available 24/7:
 - a. A sufficient number of operating rooms
 - b. Blood bank
 - c. ICU facility and personnel experienced in post-operative cardiac surgery care
 - d. On-site laboratory services for clinically appropriate testing
- 1.3 The Center must have facilities for state-of-the-art imaging, including transesophageal echocardiography, three-dimensional echocardiography, exercise echocardiography, and cardiovascular CT and MRI imaging.
- 1.4 The Center must have the ability to perform intraoperative and peri-operative transesophageal echocardiography on demand with access to immediate and high-quality interpretation critical for valve surgery.
- 1.5 The Center must have facilities for advanced circulatory management, including long and short-term mechanical circulatory assist device capability.
- 1.6 The Center must have a designated electrophysiology program.
- 1.7 The Designated Hospital associated with a Center must be U.S. based (including academic medical centers and community hospitals).
- 1.8 The Center must have a qualified Mitral Valve Heart Team which meets the Standards set forth herein.

² Recognition status is conferred on a Center, not a specific Mitral Valve Reference Surgeon.

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2.0 Mitral Valve Heart Team Standards

2.1 The Center's Mitral Valve Heart Team must include the following:

- a. At least one designated Mitral Valve Reference Surgeon³ who meets the educational, training and volume requirements as set forth in the Standards.
- b. At least one designated Structural Heart Cardiologist with demonstrated interest and experience in valvular heart disease.
- c. One or both of the designated Mitral Valve Reference Surgeon and the designated Structural Heart Cardiologist must be the Leader or Co-Leaders of the Mitral Valve Heart Team.
- d. At least one designated Interventional Practitioner⁴ with experience in transcatheter mitral technologies.
- e. Anesthesiologists, surgeons, or cardiologists with Level III echocardiography certification.
- f. Electrophysiology, Heart Failure, and Imaging.
- g. 24/7 coverage by members of the Mitral Valve Heart Team.

2.2 The Center's designated Mitral Valve Reference Surgeon(s) must have demonstrated ability to perform complex mitral valve repairs.

³ Also referred to as a Reference Surgeon.

⁴ Who may also serve as the designated Reference Surgeon.

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3.0 Volume Standards

- 3.1 The Center must have performed a minimum of 50 Index Mitral Valve Procedures that are repairs in the preceding calendar year.
- 3.2 The minimum volume criterion for a Center may be met by including all procedures performed by both the Reference Surgeons and the Participating Mitral Valve Surgeons⁵ at the Center's Designated Hospital.
- 3.3 Each designated Mitral Valve Reference Surgeon⁶ must have performed a minimum of either (a) 25 Index Mitral Valve Procedures that are repairs in the preceding calendar year or (b) 50 Index Mitral Valve Procedures that are repairs in the preceding two calendar years. For each procedure submitted, the Reference Surgeon must be the surgeon of record, the co-surgeon, or the first assistant surgeon for the procedure. Only one Reference Surgeon may include the procedure when determining procedure volume.
- 3.4 In order to be listed as a Center's Participating Mitral Valve Surgeon⁷ (as opposed to a Reference Surgeon), a surgeon must have participated in at least 25 Index Mitral Valve Procedures that are repairs in the preceding two calendar years. For each procedure submitted, the Participating Surgeon must be the surgeon of record or the co-surgeon or the first assistant surgeon to a Reference Surgeon.
- 3.5 The minimum Volume Standard for a Reference Surgeon or a Participating Surgeon may be met through multiple facilities where the surgeon operates.
- 3.6 Re-repairs of the Reference Surgeon's or the Participating Surgeon's own patients cannot be included in any of the procedure counts used to meet the Volume Standards.

⁵ Also referred to as a Participating Surgeon

⁶ The Center may have more than one Reference Surgeon.

⁷ The Center may have more than one Participating Surgeon.

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4.0 Outcome Standards (Surgeon)

- 4.1 The designated Mitral Valve Reference Surgeon must have an individual repair rate for Index Mitral Valve Procedures which exceeds 95% for the preceding two calendar years.⁸
- 4.2 The designated Mitral Valve Reference Surgeon must have a 90 day post-operative freedom from moderate or greater mitral regurgitation or re-intervention (open or transcatheter) rate of 95% for Index Mitral Valve Procedures that are repairs for the preceding two calendar years⁹ as documented by a post-repair transthoracic echocardiogram.

⁸ The surgeon may report for 2 calendar years; the most recent calendar year if over 100 index mitral valve procedures that are repairs; or the most recent consecutive 100 index mitral valve procedures that are repairs plus replacements within the same time period.

⁹ The surgeon may report for 2 calendar years; the most recent calendar year if over 100 index mitral valve procedures that are repairs; or the most recent consecutive 100 index mitral valve procedures that are repairs.

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5.0 Outcome Standards (Center)

- 5.1 The Center must track and report the following complications for all Index Mitral Valve Procedures that occur within a period of 30 days post-op or from hospital discharge, whichever is longer:
- a. Operative Death
 - b. Postoperative Stroke
 - c. Postoperative Renal Failure
 - d. Deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention within 30 days postoperatively
 - e. Prolonged ventilation > 24 hours
 - f. Surgical re-exploration or transcatheter interventions for patients who require a return to the operating room for bleeding with or without tamponade, graft occlusion, valve dysfunction or other cardiac reason
 - g. 4 or more red blood cell (RBC) transfusions
- 5.2 The Center's Non-Risk Adjusted 30-Day Operative Mortality Rate (for deaths related to the mitral valve repair procedure) for all Index Mitral Valve Procedures that are repairs for the preceding three calendar years¹⁰ must be less than 1%.
- 5.3 The Center's repair rate for Index Mitral Valve Procedures must be greater than 95% for the preceding three calendar years^{11, 12}.

¹⁰ The Center may report for 3 calendar years; the most recent calendar year if over 150 index mitral valve procedures that are repairs; or the most recent consecutive 150 index mitral valve procedures that are repairs.

¹¹ The Center may report for 3 calendar years; the most recent calendar year if over 150 index mitral valve procedures that are repairs; or the most recent consecutive 150 index mitral valve procedures that are repairs plus replacements within the same time period.

¹² Clinical Guideline Recommendations or Other Evidence Supporting the Measure
Nishimura, R. A., Otto, C. M., Bonow, R. O., Carabello, B. A., Erwin, J. P., Fleisher, L. A., ...
Thompson, A. (2017). 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for
the Management of Patients With Valvular Heart Disease: A Report of the American College
of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.
Circulation, 135(25). doi: 10.1161/cir.0000000000000503

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6.0 Process Standards

- 6.1 The Center must have a 100% intraoperative post-repair transesophageal echocardiography rate following weaning from bypass for Index Mitral Valve Procedures that are repairs over the preceding calendar year¹³. Procedures where there is a contraindication to this study are excluded.
- 6.2 The Center must have a 95% post-operative transthoracic echocardiogram rate within 90 days of repair (which may be performed in the Designated Hospital or in any other location as determined by the Center, the patient or the referring physician) for every Index Mitral Valve Procedure that is a repair performed in the preceding calendar year¹³. This discharge echocardiogram may be used when submitting procedure counts.

¹³ The Center may report for the most recent calendar year if over 150 index mitral valve procedures that are repairs; or the most recent consecutive 150 index mitral valve procedures that are repairs.

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7.0 Data / Document Submission Requirements

- 7.1 The Center must participate in the STS database (or equivalent national registry approved by the Foundation). The Center must provide copies of the two (2) most recent STS quarterly reports (or equivalent approved national registry) to the Mitral Foundation. The Center must comply with the STS public reporting program (or the equivalent for other databases approved by the Foundation).
- 7.2 The Center must submit supplemental data or documents as requested by the Mitral Foundation as needed to compute all of the outcome measures.
- 7.3 The reported Index Mitral Valve Procedures that are repairs must be classified as either Simple or Complex Mitral Valve Repairs¹⁴.
 - a. "Simple" degenerative disease is defined as: "Isolated P2 prolapse with limited myxomatous changes and ruptured/elongated chordal support; Predominant annular dilatation with minimal prolapse of any leaflet segment (is repairable by annuloplasty alone)."
 - b. "Complex" degenerative disease is defined as: "All other procedures that are not categorized as "Simple"."
- 7.4 All data submitted by the Center is subject to review for accuracy, completeness and relevance by the Foundation's peer review process.

¹⁴ From **A Complexity Scoring System for Degenerative Mitral Valve Repair**. Anyanwu AC, et al. J Thoracic Cardiovasc Surg 2016 Jun;151(6):1661-70. doi: 10.1016/j.jtcvs.2016.01.033.

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8.0 Mitral Valve Repair Reference Center Best Practices

- 8.1 The Center's designated Mitral Valve Reference Surgeon should be certified by the American Board of Thoracic Surgery or a foreign-equivalent board.
- 8.2 The Center's Structural Heart Cardiologist should be certified by the American Board of Internal Medicine in Cardiovascular Disease or a foreign-equivalent board.
- 8.3 The Center's designated Interventional Practitioner should be certified by the American Board of Internal Medicine in Cardiovascular Disease or the American Board of Thoracic Surgery or a foreign-equivalent board.
- 8.4 The Center's Mitral Valve Heart Team should be familiar with the ACC, AHA and other applicable guidelines that address mitral valve disease, and be able to demonstrate application of those guidelines in daily practice.
- 8.5 The Center should have documented protocols for patient screening, protocols for clinical decision making, and how metrics are reviewed for patient experience that are approved by the Mitral Valve Heart Team.¹⁵
- 8.6 Each surgeon at the Center (including Reference Surgeons and Participating Surgeons) should confirm severity of regurgitation and ascertain the level of complexity of disease prior to the operation.
- 8.7 Patients should not be taken to the operating room based solely on an echocardiogram report without surgical review of the video images. If satisfactory video images are not available, then repeat echocardiography should be performed, and the images should be reviewed by the surgical team before a patient is taken for surgery.
- 8.8 Patients with "Complex" degenerative disease should be treated with the involvement of a Mitral Valve Reference Surgeon.
- 8.9 Surgery for asymptomatic patients without hemodynamic or arrhythmogenic triggers should involve the participation of a Mitral Valve Reference Surgeon, regardless of level of complexity.

¹⁵ This Standard does not require that every patient must be seen by the Mitral Valve Heart Team's cardiologist.

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8.10 In stable patients with moderate (or greater) residual regurgitation after weaning from bypass, valve re-exploration and further reparative measures should be considered.

8.11 A Mitral Valve Heart Team member should review all post-operative transthoracic echocardiograms.

8.12 The Center should have documented protocols to monitor and review (i) the individual repair rate for Index Mitral Valve Procedures and (ii) the post-operative freedom from moderate or greater mitral regurgitation rate for Index Mitral Valve Procedures that are repairs for each Participating Surgeon.

8.13 A process of continued evaluation of early patient outcomes and an established quality assessment program should be in place by Centers undertaking mitral valve repair.

8.14 The Center should demonstrate that it maintains appropriate systems and procedures to provide accurate and timely data as required under the Standards.

Glossary

ACC: American College of Cardiology

AHA: American Heart Association

Center: A unit of a U.S.-based hospital that provides the physical facilities, resources and structure necessary to support a specialized Mitral Valve Heart Team. The Mitral Valve Heart Team, including the designated Mitral Valve Reference Surgeon and the Participating Mitral Valve Surgeons, operate at the Designated Hospital.

Complexity of Mitral Valve Repairs¹⁶: "Simple" is defined as isolated P2 prolapse with limited myxomatous changes and ruptured/elongated chordal support; Predominant annular dilatation with minimal prolapse of any leaflet segment (is repairable by annuloplasty alone). "Complex" is defined as all other procedures that are not categorized as "Simple".

Designated Hospital: Each Center must have a Designated Hospital. The Designated Hospital must have a qualifying Mitral Valve Heart Team as defined in the *Standards and Best Practices*. The Designated Hospital must have the physical facilities, resources and structure as defined in the *Standards and Best Practices*. The Designated Hospital must be a licensed hospital or health system located in the United States. While a Reference Surgeon or Participating Surgeon may operate at multiple hospitals, only one hospital can be named as the Designated Hospital and recognized as the Mitral Valve Repair Reference Center.

Heart Team Roles:

- **Mitral Valve Reference Surgeon¹⁷:** The Center must designate at least one Mitral Valve Reference Surgeon who meets the criteria for training, surgical volume, and outcomes as defined in the Standards. The Reference Surgeon's procedure volume follows a Reference Surgeon between hospitals, but Recognition status is maintained by the Center and is not transferrable.
- **Participating Mitral Valve Surgeon¹⁸:** The Center may designate Participating Mitral Valve Surgeons who meet the criteria for training and surgical volume as defined in the Standards. Participating Mitral Valve Surgeons are different than Reference Surgeons. For example, Participating Surgeons have lower volume

¹⁶ From *A Complexity Scoring System for Degenerative Mitral Valve Repair*. Anyanwu AC, et al. J Thoracic Cardiovasc Surg 2016 Jun;151(6):1661-70. doi: 10.1016/j.jtcvs.2016.01.033.

¹⁷ Also referred to as a Reference Surgeon.

¹⁸ Also referred to as a Participating Surgeon.

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requirements and may not yet be primary surgeons on Index Mitral Valve Procedures. Similar to Reference Surgeons, Participating Mitral Valve Surgeons' procedure volume follows the individual Participating Mitral Valve Surgeon between hospitals.

- **Interventional Practitioner:** The Center must designate an Interventional Practitioner who meets the criteria for training and experience as defined in the Standards.
- **Structural Heart Cardiologist:** The Center must designate a Structural Heart Cardiologist who meets the criteria for training and experience as defined in the Standards.

Index Mitral Valve Procedures: Operations (repair or replacement) for primary (degenerative) mitral valve disease with or without concomitant operations.

- 1) Procedure Type
 - a) Include only elective procedures
 - b) Include only first-time cardiac surgery (any)
 - c) Exclude patients with previous transcatheter mitral procedures
 - d) Include only open heart procedures; excludes transcatheter procedures
 - e) Include both complex and simple mitral valve repair procedures¹⁹
- 2) Disease Type
 - a) Primary (degenerative) with prolapse
 - b) Exclude severe mitral annular calcification (MAC) and leaflet calcification

Procedures should be counted in the following manner, and documentation must be available to demonstrate the following criteria have been met when counting procedures:

- 1) Center:
 - a. The procedure counts as one procedure for the Center.
- 2) Reference Surgeon:
 - a. Surgeon of record
 - b. Counts as 1st Assistant or co-surgeon
 - c. Only one Reference surgeon can count any one case on their list
- 3) Participating Surgeon:
 - a. Surgeon of record
 - b. 1st Assistant or co-surgeon for a case done by a surgeon meeting the Reference Surgeon criteria

¹⁹ *Standards and Best Practices* Data Standard 7.3 for Simple v. Complex definition

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Isolated Mitral Valve Procedure: An operation on the mitral valve with or without a tricuspid valve procedure, an arrhythmia procedure, or closure of a patent foramen ovale (PFO). Operations with CABG, aortic procedures, aortic or pulmonary valves, etc. are excluded.

Operative Mortality Rate: The percentage of patients aged 18 years and older undergoing mitral valve repair who die, including both (i) all deaths related to the mitral valve repair procedure occurring during the hospitalization in which the procedure was performed, even if after 30 days, and (ii) those deaths related to the mitral valve repair procedure occurring after discharge from the hospital, but within 30 days of the procedure.

Postoperative Renal Failure: Serum creatinine of 4 mg/dl or greater or new dialysis postoperatively.

Postoperative Stroke: Any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain that does not resolve within 24 hours.

Reference Center Best Practices: Recommendations for a Center to follow when treating patients with mitral valve disease.

Recognition Standards: Criteria that a Center must meet or exceed in order to be recognized as a Mitral Valve Repair Reference Center. The Standards define the resources, processes, and outcomes that a Center must meet or exceed. Criteria are defined for a Mitral Valve Repair Center, Mitral Valve Heart Team, Procedure Volume, Surgeon Outcomes, Center Outcomes, Center Processes, and Data Submission.

Severe MAC: Severe mitral annulus calcification as documented in preoperative imaging or the operative report.

STS: Society of Thoracic Surgeons.

STS Reports: Data Analyses of the Society of Thoracic Surgeons National Adult Cardiac Surgery Database.

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