

ADVANCED AORTIC TRANS CATHETER VALVE PLACEMENT CLINICAL PRIVILEGES

Delineation of Clinical Privileges

Criteria for granting privileges: Maintain clinical privileges at the facility in an appropriate specialty. Participate in the structured MHMH TAVR program.

Applicants will be requested to provide documentation of practice and current clinical competence as defined on the attached competency grid. Applicants have the burden of producing information deemed adequate by the hospital for a proper evaluation of current clinical competence and other qualifications and for resolving any doubts.

Current Clinical Competence - MLH

In addition to the required education, experience and/or training specified on each DOP (Delineation of Privilege) form, documentation of current clinical competence is required. Current clinical competence is described as having “performed the privilege recently and performed it well”.

Current clinical competence is assessed prior to granting privileges initially and is reassessed when renewing privileges at reappointment – for maintenance of privileges. Current Clinical Competence (CCC) may be location specific (acute hospital care, surgery center) and/or age specific (adult, pediatric, neonatal).

This should not be confused with Focused Professional Practice Evaluation (FPPE)

- FPPE: an evaluation of clinical competence of all new privileges as performed at the specific licensed MLH facility (MHMH, MHOBH) for which they have been initially granted. This applies to privileges for all new applicants as well as to new/additional privileges for current members.

Both FPPE and current clinical competence assessments are privilege-specific. FPPE is conducted during the period after granting new/additional privileges. FPPE must occur at the MLH facility(ies) where privileges/membership are held. Current clinical competence may be evaluated from case logs provided by non-MLH facilities.

Current Clinical Competence: Requirements for New Applicants

- If applying directly from training, or based on the training received in a formal training program, provider should submit case* logs from the program authenticated by the program director along with their recommendation attesting to the comparable training, experience and qualifications relative to the criteria for the clinical privileges requested.
- If applying more than 1 year after training completion, submit the following:
 - Aggregate data from acute care or surgery center facility for the previous 12 month time period, identifying the top 10 diagnosis codes and the number of patients per code. Any complications/poor outcomes should be delineated and accompanied by an explanation.
 - Procedure list from acute care or surgery center facility for the previous 12 month time period, identifying the top 10 CPT/ICD codes and the number of procedures per code. Any complications/poor outcomes should be delineated and accompanied by an explanation.
 - Case logs (see specifications below) for any special privileges requested that meet the criteria specific for the number of procedures defined for current clinical competence.

Current Clinical Competence: Maintenance of Privileges for Current Members

- **For active staff members:** MLH source data will be aggregated to review cases and procedures performed. If this does not meet the minimum requirement for core and/or special privileges, the practitioner will be required to submit additional case logs from other facilities.
- **For courtesy staff members with low activity and for certain active staff with activity that has diminished and is now low:** Department chair recommendation should be obtained from their primary facility; and the practitioner should submit the following:
 - Aggregate data from acute care or surgery center facility for the previous 12 month time period, identifying the top 10 diagnosis codes and the number of patients per code. Any complications/poor outcomes should be delineated and accompanied by an explanation.
 - Procedure list from acute care or surgery center facility for the previous 12 month time period, identifying the top 10 CPT/ICD codes and the number of procedures per code. Any complications/poor outcomes should be delineated and accompanied by an explanation.
 - Case logs (see specifications below) for any special privileges requested that meet the specific number of procedures defined for current clinical competence.

Case Logs

All required case logs and/or procedure lists must contain the following information at a minimum: Date, patient identifier, CPT/ICD procedure code, diagnosis, complications, and disposition, and the facility name, name/title of the person authenticating the log, signature, date signed, and contact information. If the information requested is not available, please provide an explanation.

*A “case” is defined as an episode of care – either cognitive or procedural. For interpretive care, “case” is interpretation of one diagnostic study.

Ongoing Professional Performance Evaluation (OPPE)

OPPE is evaluated periodically (more frequently than annually) in the facility where membership/privileges are held.

To assure OPPE requirements are satisfied, the practitioner must periodically exercise the privileges in the MLH facility(ies) where he/she has membership. OPPE must occur regularly on patient encounters in the MLH facility(ies) where privileges/membership are held.

Advanced Aortic Trans Catheter Valve Placement Privileges

Indications for Use:

- Severe, symptomatic aortic stenosis
- >20% operative mortality risk
- Severe ascending aorta calcification (porcelain aorta) that prevents aortic cannulation or cross-clamping
- Severe radiation damage to the chest or other severe chest deformities that would preclude a sternotomy (transcatheter approach used because radiation damage may also prevent a transapical approach)
- Patients' willingness to comply with follow-up evaluations to assist with ongoing development of this new technology and ethics boards that approve studies with these valves

Contraindications for transcatheter and transapical aortic valve replacement:

- Previously untreated coronary disease (the valve may prevent access for percutaneous coronary interventions although successful stent placement after implantation of a transcatheter valve has been reported)
- No concomitant coronary artery bypass surgery with transapical aortic valve replacement because the exposure would be inadequate
- Infective endocarditis or intracardiac tumor (excision on bypass is the only accepted treatment for intracardiac tumor)
- Estimated life span of less than 1 year (would limit follow-up of investigational valves)
- Recent active gastrointestinal bleeding that would prohibit use of heparin or antiplatelet therapies such as aspirin or clopidogrel
- Patients with a contraindication to transesophageal echocardiography (used preoperatively to assess aortic annulus size and to position the valve)
- Aortic annulus size not amenable to use with the currently available valve sizes (valve sizing is critical to avoid paravalvular regurgitation)
- Anomalous coronary ostia (valve could potentially interfere with flow into anomalous coronary ostia) or an unusually bulky coronary leaflet
- Renal failure with creatinine clearance <20 mL/min
- For transcatheter aortic valve replacement only: severely calcified, diseased, small or tortuous iliac vessels that preclude passage of the delivery catheter or previous aortobifemoral grafting (these patients would qualify for transapical aortic valve replacement) or aortic aneurysm
- For transapical aortic valve replacement only: left apical clot, aneurysm, or scar (these patients would qualify for transcatheter aortic valve replacement); left ventricular clot could be a contraindication for transcatheter
- Patient offered conventional aortic valve replacement but refused surgery

Specialty/Procedure Delineation of Privilege Form	Education/Training Documentation for Initial Granting	Initial Application (Proof of current clinical competence)	FPPE – Validation of competence after appointment and/or granting of a new or additional privilege (To be completed within one year)	Maintenance Requirements
Advanced Aortic Trans Catheter Valve Placement Privileges	Maintain current clinical privileges at facility in either Cardio Thoracic Surgery or Interventional Cardiology, CME including successful completion of didactic training in Advanced Aortic Trans Catheter Valve Placement as part of the structured TAVR training program and documented by a Certificate of Completion from Edwards LifeSciences	Participation in the structured TAVR program at MHMH	First 3 cases	Case log documenting the performance of procedures annually over the reappointment cycle sufficient to maintain current clinical competence and participation in the structured TAVR program at MHMH, and adherence to established patient selection criteria.

Advanced Aortic Trans Catheter Valve Placement Clinical Privileges

Check below the particular privileges desired for each facility:

Please check (✓) applicable age categories for each privilege requested.

Privilege Description	Methodist Healthcare – Memphis Hospitals (MHMH) Germantown, Le Bonheur Medical Center, North, South & University, Outpatient Clinics & Diagnostic Facilities				
	Neonates (0-28 days)	Infants (29 days–2 Years)	Children & Adolescents (2-18 years)	Adults & Adolescents (13 & Above)	Adults (18 & Above)
Advanced Aortic Trans Catheter Valve Placement					
Limitations	Clinical privileges are granted only to the extent privileges are available at each facility.				
Darkly shaded areas represent privileges not available to any practitioner due to the privilege not being offered by the facility.					

Acknowledgement of practitioner

I have requested only those privileges for which by education, training, current experience and demonstrated performance I am qualified to perform and for which I wish to exercise at the facilities indicated above to the extent services are available at each facility; and I understand that:

(a) in exercising any clinical privileges granted, I am constrained by facility and medical staff policies and rules applicable generally and any applicable to the particular situation

(b) any restriction on the clinical privileges granted to me is waived in an emergency situation and in such situation my actions are governed by the applicable section of the medical staff bylaws or related documents

Physician's Signature

Date

Printed Name