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CURRENT OPINION
Valvular heart disease

Standards defining a 'Heart Valve Centre': ESC Working Group on Valvular Heart Disease and European Association for Cardiothoracic Surgery Viewpoint

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Introduction

The increasing number of patients with heart valve disease and the wider range of therapeutic options now available, demands the standardization of organizational structures.[1,2] The 'heart valve clinic' is already established as a specialist outpatient clinic[3,4] linked with multidisciplinary inpatient care as well as education and training. Recent international guidelines extend this specialist concept to a 'Heart Valve Centre of Excellence'[1] or 'Heart Valve Centre'.[2] These centres were proposed in order that durable mitral valve repair could be virtually guaranteed at close to zero risk in patients with asymptomatic severe mitral regurgitation caused by prolapse. The intention was that invasive valve interventions should not occur outside Heart Valve Centres. The standards defining such a centre have not previously been described and this is the purpose of this document. A Heart Valve Centre includes a heart valve clinic, but also multidisciplinary heart teams for the care of patients with mitral valve disease, tricuspid valve disease, diseases of the aorta and aortic valve and infective endocarditis (*Table 1*).

Requirements for a Heart Valve Centre

Heart valve clinic

A heart valve clinic is a dedicated and structured outpatient clinic.[3,4] The cardiologist(s) running the clinic should have competencies in treating patients with heart valve disease (ideally including imaging). Some heart valve clinics may include interventional cardiologists or surgeons allowing immediate case-discussions in patients suitable for intervention.

According to local structures and regulations some roles can be delegated to clinical scientists or specialist nurses within a multidisciplinary service,[9,10] which is safe and cost-effective.[11,12] In the UK, follow-up of patients with native valve disease or biological replacement valves requiring echocardiography is increasingly performed by clinical scientists.[9] Patients after valve replacement who do not require echocardiography may be followed up by a senior cardiac nurse,[9] allowing the cardiologist to focus on new or complex cases.

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Table 1 Requirements of a comprehensive heart valve centre

Minimum	Additional at selected centres
Specialist valve clinic[3,4]	
Imaging	
Echocardiography: 2D/3D, stress, transoesophageal, intraoperative[5,6]	
CMR, cardiac CT, CT-PET[7]	
Departments and individual imagers accredited by recognized national or international systems[8]	
Procedures available	
Surgical: Replacement of all valves, mitral valve repair, tricuspid valve repair, surgery for aortic root and ascending aorta, atrial fibrillation ablation	Surgical: Ross procedure, aortic valve repair, robotic mitral valve repair, heart transplant
Percutaneous: TAVI, Mitral edge to edge procedures (e.g., MitraClip)	Percutaneous: Balloon mitral valvotomy, closure of paraprosthetic regurgitation, developing mitral and tricuspid valve interventions
Links with hospitals offering superspecialist techniques	
Collaborative services	
Other specialist cardiac services including heart failure, and electrophysiology	Percutaneous extraction of electronic devices
Intensive care (dedicated beds, ExtraCorporeal Membrane Oxygenation)	
Extracardiac specialties: vascular surgery, general surgery, neurology, renal, stroke and elderly care medicine, psychology, genetics and dental surgery	
Processes	
Organization into multidisciplinary teams including endocarditis	Research programmes
24 h, 7 day cover allowing for annual leave and sickness	
Culture of safety (e.g. World Health Organisation checklist, review of complications)	
Training	
Job-planning to include valve related sessions including continuing education	
Data review	
Internal audit processes including rates of repair and haemodynamic results, complications, durability of repair and rates of reoperation assessed annually and summarized at 5 and 10 years	
Involvement in national databases with mandatory external review	

CMR, cardiac magnetic resonance; CT, computed tomography; PET, positron emission tomography; TAVI, transcatheter aortic valve implantation.

Echocardiographic and clinical protocols with thresholds for alerting the supervising cardiologist must be established and approximately 10–15% of cases seen by the scientist or nurse need cross-referral to the cardiologist.

The main functions of the heart valve clinic are to confirm and refine the diagnosis of heart valve disease, follow patients and determine the correct timing of referral to the appropriate Heart Team. The activities of the heart valve clinic extend to inpatient care, and to training doctors and educating patients.[3,4] Education of patients is vital for the early identification of symptoms and to allow fully informed decision-making about the type of intervention and its timing. Active patient involvement is essential when requested by the patient and has been shown to improve quality of life after surgery.[13,14] It is also important for the early recognition of infective endocarditis.

A heart valve specialist can be characterized[15] by: (1) a record of training within a Heart Valve Centre; (2) valve-related programmed activity, e.g. valve clinics, inpatient care, involvement with Heart Team meetings, specialization in imaging of valve disease, research; (3) continuous medical education (CME) in valve disease by attendance at scientific meetings of professional societies (e.g. the European Society of Cardiology Working Group on Valvular Heart Disease, ESC, EACVI or EAPCI, European Association for Cardiothoracic Surgery or National Society Working Groups on Valve Disease).

Expert imaging

Echocardiography is the cornerstone for the detection and assessment of valve disease. However, other modalities such as cardiac magnetic resonance (CMR) and computed tomography (CT) provide additional information and help in risk assessment in some patients.[16–18]

Echocardiographic operators need to be certified nationally and preferably accredited by an international organization.[8] Echocardiography skills can only be maintained by continued education and practical involvement. 3D transthoracic and transoesophageal echocardiography and stress echocardiography are mandatory. Surgeons performing valve repair and interventional cardiologists performing transcatheter procedures are likely to develop the ability to interpret echocardiograms and CT scans. However, they will require continued collaboration with cardiologists or clinical scientists who have relevant imaging expertise. Echocardiography should be available 24/7.

Cardiac CT and CMR need to be performed by cardiologists or by radiologists with expertise in cardiovascular disease. CT should be

available 24/7. Software to analyse images and plan structural valve interventions must be available. Positron emission tomography (PET) should also be available since the 2015 European Society of Cardiology modified criteria include PET evidence as a major criterion in the diagnosis of prosthetic valve endocarditis.[19]

Multidisciplinary Heart Teams

A multidisciplinary approach is recommended for all types of valve disease and infective endocarditis.[19–23]

Individuals with areas of expertise (e.g. mitral valve repair, TAVI) should be named. The expertise required for mitral, aortic valve and tricuspid valve disease and endocarditis differs but also overlaps. It is therefore likely that individuals may be members of more than one team, for example a surgeon with expertise in mitral valve repair is likely also to be a member of the endocarditis team. Nurses and case-managers depending on local arrangements are also involved in the multidisciplinary team. Assessment by relevant non-cardiac specialists (elderly care physician, pulmonologist etc.) should be available for patients with significant comorbidities. There should be regular Heart Team meetings to discuss the indications for and timing of intervention together with necessary procedural details. In most high volume centres it will be logistically easiest for separate multidisciplinary meetings to occur for mitral, aortic and endocarditis cases. However it is reasonable to have combined meetings at smaller centres depending on patient volumes and the individuals constituting the teams. This meeting can also be used for case debriefing. Meetings should take place weekly or at a frequency depending on annual hospital volumes. For emergent treatment, *ad hoc* multidisciplinary consultation should be possible.

The wishes of the patient will inform the discussion of treatment options at multidisciplinary meetings. The consensus of the meeting will be communicated to the patient and if desired will inform further discussion about the timing and nature of surgery. It may on occasion be appropriate to invite a patient to a discussion about his or her case.

The details of multidisciplinary teams are discussed in 'Mitral valve multidisciplinary heart teams', 'Aortic valve multidisciplinary heart teams', and 'Endocarditis multidisciplinary team approach' sections.

Collaborative services

In a comprehensive valve service it should be possible to consult cardiologists with complementary expertise, including adult congenital disease, inherited cardiac diseases, heart failure and electrophysiology. Collaboration with members of a heart failure service and electrophysiology specialists is needed in patients with secondary mitral regurgitation to ensure that medical therapy (and cardiac resynchronization if indicated) has been optimized before considering surgical or transcatheter intervention. Patients with heart failure and valve disease may be better cared for in a heart failure clinic (rather than a heart valve clinic) if no invasive intervention is planned. Collaboration with heart transplant centres is also necessary for these patients.

The Heart Valve Centre must have a dedicated cardiac surgical department including cardiac anesthesia,[24] intensive care and step-down unit. The option to use devices such as intra-aortic balloon pump and extracorporeal membrane oxygenation should be available. The following services should also be available: vascular surgery, general surgery, neurology, nephrology, microbiology and infection, stroke and elderly care medicine, and care of psychiatric illness.

Processes and services

The procedures available at a Heart Valve Centre must be: replacement of valves in all four positions; mitral and tricuspid valve repair; atrial fibrillation ablation; transcatheter aortic valve implantation; and surgery for the aortic root and ascending aorta. Transcatheter mitral and tricuspid procedures including mitral edge-to-edge repair should rarely be performed outside a Heart Valve Centre. Aortic valve repair and percutaneous repair of paravalvular regurgitation are infrequently performed and technically challenging and not available at all Heart Valve Centres. Valve disease as part of complex congenital heart disease should be managed by a centre specializing in paediatric and adult congenital disease and relevant expertise will not be available at every Heart Valve Centre. In some countries, percutaneous balloon mitral valvotomy may also not be available at every Heart Valve Centre. Therefore there should be service level agreements in place to allow transfer to centres, which perform highly specialized procedures so that these are not restricted by geography if required for an individual patient. Knowledge of which centres offer these highly specialized procedures should be easily available.

Coverage of the service by an appropriate number of physicians should be organized in order to allow for leave and sickness. There should be sufficient beds to allow uninterrupted transfer of patients from peripheral hospitals and sufficient intensive therapy unit capacity to allow urgent surgery when clinically indicated. Operating schedules should allow urgent or emergent operations. There should be a safety checklist at the start of all procedures and a debriefing at the end.[24]

Mitral valve multidisciplinary heart teams

The team must include at minimum a surgeon with special expertise in mitral and tricuspid valve repair, a cardiologist with specialist expertise in valve disease, a specialist in echocardiography (who may also be the cardiologist), a specialist in other imaging modalities (CT, cardiac MR). An interventional cardiologist is also essential.

Assignment for mitral valve repair

The imaging and clinical data of each patient should be reviewed by the expert Heart Team to determine whether the mitral valve is amenable to repair. Repairable primary disease should be operated on by surgeons with special expertise in valve repair[22,25] and results according to basic data collection (*Table 2*) at least as good as the targets in *Table 3*. Multidisciplinary Heart Team discussions must also take place for patients being considered for transcatheter mitral edge-to-edge repair.[21]

Surgeon and hospital volumes

The relationship between case volume and outcomes of surgery and transcatheter interventions is complex although volume recommendations already exist (or are being discussed) for percutaneous coronary intervention,[32] vascular surgery,[33] and percutaneous valve techniques.[20,21] What constitutes sufficiently high individual surgeon or

Table 2 Data for collection in repair and replacement for primary mitral or aortic valve disease

Preoperative
Demographic data, comorbidities
Grading of valve lesion
Preoperative risk assessment and stratification using validated multivariate scores
Early clinical results
Operative mortality and morbidity at 30 days including stroke, mediastinitis, myocardial infarction, acute kidney injury[26,27]
Repair rates based on preoperative multidisciplinary team classification for repair as 'likely', 'unlikely' or 'not feasible'
Time on Intensive Therapy Unit
In hospital haemodynamic function[28]
Transvalve velocity and mean gradient (all positions) and effective orifice area (aortic position) of replacement or transcatheter valves
Presence and grade of paraprosthetic regurgitation
Residual regurgitation and new obstruction after surgical or transcatheter repair or systolic anterior motion of the anterior mitral leaflet
Follow-up
Complications: infection, valve thrombosis
Mortality: At 1 and 5 years
Durability of repairs based on routine annual echocardiography (more frequent if significant regurgitation present). Proportion per year developing moderate or worse regurgitation
Incidence and timing of structural valve degeneration and non-structural valve degeneration
Rates of redo procedure per year

Table 3 Example targets for surgical outcomes in repair of mitral valve prolapse

	Rate
Mortality	<1%[25,29]
Major complication	<2%[29]
Repair rate for when judged 'likely' repairable by an MDT	>90% (95% for P2 prolapse)
Significant residual mitral regurgitation	≤5% at 5 years[25]
Reoperation rate	
Posterior leaflet repair	<1% per year[30]
Anterior leaflet repair	<2% per year[30,31]

hospital volumes to maintain good results for repair of mitral valve prolapse is controversial. For this reason, the ability to demonstrate good results is more important than mandating volume targets. It is also likely that external audit of results will encourage good outcomes.

Retrospective analyses show that higher annual surgeon volume and institutional experience are associated with higher rates of mitral repair and lower mortality.[34,35] However, a high hospital volume partly reflects high individual surgeon volumes[17] and may also be a surrogate for excellent facilities and processes. Annual thresholds of >20–40 mitral valve repair procedures for individual surgeons[28,34–37] have been suggested by expert consensus[28] or retrospective analyses.[34–37] Hospital mitral surgery volumes of >50 procedures/year have been suggested by expert consensus,[28] although retrospective analyses suggest higher thresholds.[35,37] An analysis[37] of 13 614 operations for mitral regurgitation at 577 US centres showed a surgical mortality of 3.1% in centres performing 1–35 mitral procedures/year compared with 2.0% for those performing 71–140 procedures and 1.1% for those performing >140 procedures/year. Repair rates were 47.7% in the lowest quartile and 77.4% in the 27 high volume centres performing >140 procedures/year. A further retrospective analysis[35] of 50 152 patients undergoing surgery for mitral regurgitation found an inflection point of >95 procedures/year for hospital volume and >21 procedures for individual surgeons. For mitral valve replacement, no individual surgeon thresholds have been identified. However lower mortality rates are demonstrated in higher volume centres, defined as >199 aortic and mitral valve replacement procedures per year[38] or >80 per year for mitral repair and replacement combined.[39] This reduced mortality in high volume centres is shown for both high- and low-risk patient groups.[40] For minimal access mitral surgery a learning set of 75–125 operations has been suggested[41] with an average of at least one operation per week to maintain adequate results although higher volumes are associated with better results.[37] The technique is challenging for the surgeon and the entire theatre team, and is not part of minimum standard procedures.

These are retrospective studies and control for the expertise of individual surgeons and valve and patient characteristics is difficult since repair rates were not matched with the pre-operative likelihood of repair. Some low-volume surgeons had high repair rates and some high volume surgeons had relatively low repair rates.[34,37] Furthermore, these studies did not record non-fatal complications such as stroke and bleeding, rates of residual mitral regurgitation or need for re-do surgery. In view of these limitations, the ability to demonstrate good results (*Table 3*) is a more important standard than volume targets. However, it is likely these will not be attained without high individual surgeon and centre volumes.

Aortic valve multidisciplinary heart teams

Multidisciplinary meetings are needed because decisions concerning the advisability of intervention and its timing, the type of intervention

required (surgery vs. TAVI or biological vs. mechanical valve replacement) may not be straightforward. For example, the role of intervention in low gradient aortic stenosis often requires careful consideration. Comorbidities may both contribute to symptoms and increase operative risk so that the benefit of intervention is often uncertain. Decisions about surgery for coexistent mitral regurgitation or the advisability of replacing an aortic valve with mild or moderate stenosis at the time of coronary bypass grafting may also be difficult. Surgery of the aortic root and ascending aorta including replacement and conservative techniques are within the scope of practice of all aortic valve surgeons. However there should be strong collaborative links with vascular surgeons to manage patients with more generalized aortic pathology. There should also be close links with adult congenital heart disease specialists and clinical geneticists because of the strong genetic contribution in many patients with aortic pathology. The decision to undertake surgery is complex and depends on the aetiology[42] but also risk factors, including systemic hypertension or family history and by the presence and grade of the associated valve disease. Decisions about the timing of surgery should be discussed in a multidisciplinary Heart Team meeting.

Standard aortic valve replacement is a routine cardiac surgical procedure. However, as for the mitral position, new designs of valves requiring different implantation techniques should be introduced with the help of a proctor to minimize the learning curve. The Ross procedure is another example of a complex operation that must be learnt at a centre with large experience. Repair techniques are feasible in bicuspid or prolapsing aortic valves but long-term outcome data are awaited for complex repairs. Approximately 60% of regurgitant aortic valves may be repaired at a specialist referral centre[43,44] and aortic root remodelling may be a component of these repair procedures.[45] Experience and expertise is needed for the whole team since careful pre-operative assessment and intra-operative imaging are essential.[46]

Volumes

Lower early mortality rates for aortic valve replacement have been demonstrated for surgeons who undertake ≥22[38] or ≥25 procedures/year.[47] Similarly, high volume hospitals have lower mortality rates than low volume hospitals[40] with a suggested hinge point of 100 operations/year.[47] For aortic or combined aortic valve and root procedures, one study[50] found that mortality increased exponentially in hospitals performing fewer than 40 procedures per annum. For TAVI, better results (including early mortality and rates of readmission) have been shown for hospitals that undertake >20 procedures/year.[48,49] However, as for mitral surgery all these studies are retrospective. Furthermore registry data suggest that this threshold may be too low in current practice and annual centre volumes >50 TAVI are recommended in France and the UK (and >75 in Holland).

As discussed for mitral repair and replacement, individual surgeon and hospital volumes are unlikely to be perfect surrogates for outcome data and the ability to demonstrate good results is more important than working to volume targets. However, large prospective registries from Heart Valve Centres are expected to inform future guidance on minimum volumes for standard and complex procedures (as well as for new percutaneous approaches).

Endocarditis multidisciplinary team approach

A multidisciplinary team approach is essential for optimal treatment of patients with endocarditis[19,51,52] and has been shown to reduce 1-year mortality from 18.5 to 8.2%.[53] The team should include cardiologists with specialist competencies in valve disease, multimodality cardiac imaging, surgeons with expertise in complex valve surgery, and specialists in infection and/or medical microbiology (depending on the local model of service delivery). Other experts must be available: a specialist in spinal conditions (orthopaedic surgeon or rheumatologist depending on national practice); an electrophysiologist specialized in extraction of implanted electrical devices;[54] a neurologist and neurosurgeon to advise on the management of cerebral complications; and a renal physician.

Inpatient surgery is performed in at least 50% of cases[55] and its timing requires careful Heart Team discussion. Therefore, a means of communication should be established between the Heart Valve Centre and all hospitals without on-site cardiac surgery so that all cases of possible endocarditis can be discussed and potentially transferred depending on clinical need and national arrangements for care. At the Heart Valve Centre there must be communication between the endocarditis team and the microbiology and echocardiography laboratories where many cases will be first detected. All cases should be discussed immediately on identification or transfer by the specialist cardiologist, the infection specialist and cardiac surgeon. If surgery appears likely, the cardiac surgeon must be actively involved to discuss timing and scheduling of the operation. There should be regular Heart Team meetings to follow the progress of inpatients and referrals. However, the need for a formal discussion should never delay emergency surgery and operating schedules should allow for urgent or emergent surgery in patients with endocarditis

Most aortic and mitral valve endocarditis surgery should be within the remit of an appropriately trained surgeon. However, additional expertise is necessary in certain situations such as aortic root abscess or when valve repair is possible. The relative merit of immediate surgery (with a lower chance of repair) as against elective surgery (usually with a higher chance of repair[56] but also of heart failure and irreversible myocardial damage) requires fine judgement. Joint operating by appropriately trained surgeons should be considered for challenging cases.

Data review

There must be robust internal audit processes.[24] Regular outcome or 'morbidity and mortality' meetings are mandatory and reporting of 'near-misses' as a means of avoiding 'never-events' should be established. Rates of repair, pre-discharge results including residual regurgitation or stenosis, hospital mortality, and complications[20,21,26,27] must be evaluated and reported. The centre should report at least 30-day, and 1 and 5 year mortality rates and the information provided in *Table 2*. Echocardiographic follow-up[28] and clinical results must be available for internal and external review. It is recommended that these results, externally audited by national societies, are presented on the Heart Valve Centre website and made available to patients and referring clinicians. Universal recording of all valve procedures in an international or

national database is essential where these exist.[20,21] Commonly used risk scores (e.g. STS score or Euroscore II) including frailty scores for transcatheter valve procedures should be available to interpret outcome data at the level of individual patient risk despite their limitations. Data collection is a guide to early failure of new designs of replacement valve or repair techniques as well as identifying potential problems at an individual centre.

Training

Training is an essential role of a Heart Valve Centre and should be established, coordinated and monitored by national cardiovascular professional societies with provision for surgeons, cardiologists, anaesthesiologists, and other disciplines during their initial professional accreditation.

Thereafter, training should be provided for clinicians seeking to gain specialized experience to minimize the effects of the 'learning curve' on adverse results.[28,35,41] New products increasingly require novel implantation procedures and regulatory bodies have insisted that manufacturers implement training and accreditation programmes where this is necessary to reduce procedural risk. The International Standard for transcatheter valves[57] requires manufacturers to 'establish a structured training program for the physician and staff who will be involved in the peri-procedural care of the patient'. This principle should be the rule rather than the exception. Effective training can occur via training fellowships, collaborative working within units, visits to other units, or by inviting external experts.

All members of the multidisciplinary Heart Team including physicians, surgeons, and nurses need to be involved in continuing education appropriate to their roles. National societies should organize valve-related training and teaching sessions. There is an expectation of involvement in clinical innovation and research.

Future directions

The standards described here are based largely on expert consensus and retrospective studies. Large prospective registries incorporating all important outcome measures indexed to pre-operative valve pathology and surgical risk are sorely needed. These will help guide future recommendations for staffing levels and minimum centre and individual operator volume for surgery and percutaneous approaches, and facilitate multicentre research projects.[58]

Although we recognize that there is wide variability in practice and services related to heart valve disease, this document is meant to provide guidance on how best to develop specialized Heart Valve Centres for the future. Due to the ageing of the population, the prevalence of valvular heart disease will continue to increase while surgical and transcatheter valve interventions will assume an increasing role. Therefore, concerted efforts aiming at the highest standards in diagnosis and treatment are desirable while delivering cost-effective and efficient care. These goals can be best achieved in multidisciplinary care teams established within a network of care for a given region.

It would be difficult to legally mandate the standards discussed here. However we expect that patients, referring clinicians, insurance companies and commissioning bodies will select centres who comply with these standards and are able to demonstrate excellent results.

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