

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Guideline scope

### Heart valve disease presenting in adults: investigation and management

The Department of Health and Social Care in England has asked NICE to develop a clinical guideline on investigating and managing heart valve disease presenting in adults.

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

This guideline will also be used to develop the NICE quality standard for heart valve disease in adults.

## 1 Why the guideline is needed

### Key facts and figures

The heart has 4 valves (aortic, mitral, tricuspid and pulmonary) that control blood flow.

In heart valve disease, valve function can be impaired by:

- stenosis, a narrowing or stiffening of the valve, which restricts its opening and obstructs the forward flow of blood
- regurgitation, failure of the valve to close completely, which allows blood to flow backward.

There can be stenosis and regurgitation of the same valve (mixed valve disease) or disease may affect more than one valve (multiple valve disease). Disease can be primary or secondary. Primary disease affects the valve structure, whereas secondary disease results from enlargement or dysfunction of the heart chambers (atria or ventricles) with otherwise normal mitral or tricuspid valve structure.

Primary disease can be congenital or acquired. Acquired valve degeneration is currently the main cause of heart valve disease, leading to the most common types of calcific aortic stenosis and myxomatous or calcific degeneration of the mitral valve.

Secondary heart valve disease can be classified as:

- ventricular with secondary mitral regurgitation
- ventricular with secondary tricuspid regurgitation
- atrial with secondary regurgitation through the mitral and tricuspid valves.

Among people aged 65 years or over the prevalence of asymptomatic heart valve disease may be more than 50%, while the prevalence of clinically significant heart valve disease is around 11%. It is predicted that for people over 65, the prevalence of heart valve disease will increase from 1.5 million people currently, to more than 3 million in 2046.

People with heart valve disease may have no symptoms or may have symptoms that can depend on the affected valve. Associated heart rhythm problems, such as atrial fibrillation or heart block, may cause palpitations and breathlessness, or dizziness and light-headedness, respectively. Untreated severe disease can lead to valvular heart failure, with symptoms including breathlessness, reduced exercise capacity, tiredness and swollen ankles. Heart valves stiffen as part of the ageing process, making dysfunction more likely in older people. We hope that this guideline will raise awareness of heart valve disease and improve diagnosis and management.

### **Current practice**

- Heart valve disease can be detected from clinical features, with the diagnosis usually confirmed by an echocardiogram. Further investigations may be needed as part of the management plan. GPs often detect heart murmurs when listening to the chest for other reasons, but not all murmurs indicate a problem. This can make it difficult to determine when to refer someone to secondary care. Valve disease usually worsens over time.

- Treatment may include medicines to improve symptoms, such as angiotensin-converting enzyme (ACE) inhibitors and anti-arrhythmics. In cases of severe heart valve disease with symptoms, repair or replacement of the valve may be needed. This can be by either surgery<sup>1</sup> or transcatheter intervention. The timing of any intervention is important to avoid irreversible valvular heart failure, but also unnecessary early intervention. Anticoagulants are prescribed as prophylaxis after surgery or transcatheter intervention, and to reduce the risk of thrombosis associated with comorbidities. Monitoring is continued after intervention for repair or replacement, but there is currently variation in practice.
- There are areas of uncertainty in the indications for intervention, and in the most appropriate medicines for medical management.

## 2 Who the guideline is for

This guideline is for:

- healthcare professionals in all NHS settings
- commissioners and providers of services
- people using services, their families and carers.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#).

### ***Equality considerations***

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating in particular to:

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<sup>1</sup> Surgery refers to both standard and minimally invasive surgery throughout.

- access to echocardiography and specialist assessment by geographic location
- people who use intravenous drugs
- age
- people with dementia
- people with a learning disability.

### **3 What the guideline will cover**

#### **3.1 *Who is the focus?***

##### **Groups that will be covered**

- Adults (18 and over) with suspected heart valve disease.
- Adults (18 and over) with diagnosed heart valve disease (aortic [including bicuspid] stenosis and regurgitation, mitral stenosis and regurgitation, tricuspid regurgitation).

Specific consideration will be given to:

- pregnant women and women considering pregnancy
- people with bicuspid aortic valve disease
- people at higher risk from interventions, for example, people with multiple comorbidities (including cardiac comorbidities) or frailty, or both.

##### **Groups that will not be covered**

- People with congenital heart valve disease, except bicuspid aortic valve disease.
- Children and young people 17 years and under.

#### **3.2 *Settings***

##### **Settings that will be covered**

- All settings where NHS healthcare is provided or commissioned.

### **3.3      *Activities, services or aspects of care***

#### **Key areas that will be covered**

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

- 1      Assessment and diagnosis, including cardiac auscultation, echocardiography, stress testing, cardiac magnetic resonance and cardiac CT.
- 2      Medical management of aortic regurgitation, aortic stenosis, mitral regurgitation, mitral stenosis and tricuspid regurgitation.
- 3      Indications for interventions (surgery and transcatheter intervention) for aortic regurgitation, aortic stenosis, mitral regurgitation, mitral stenosis and tricuspid regurgitation.
- 4      Interventions
  - Approach (surgery or transcatheter intervention)
  - Repair or replacement
  - Type of prosthesis (mechanical or biological)
  - Interventions for prosthetic valve degeneration.
- 5      Anticoagulation and antiplatelet therapy after intervention.
- 6      Monitoring – frequency and type of tests where there are no current indications for intervention, and after intervention.
- 7      Information and support.

#### **Areas that will not be covered**

- 1      Diagnosis and management of pulmonary valve disease and tricuspid stenosis.
- 2      Prophylaxis for infective endocarditis and management of infective endocarditis.

- 3 Prophylaxis for rheumatic valve disease.
- 4 Management of heart failure, unless there are specific considerations for heart valve disease.
- 5 Anticoagulation for atrial fibrillation.
- 6 Congenital heart valve disease, except bicuspid aortic valve disease.

## Related NICE guidance

### *Published*

- [Intrapartum care for women with existing medical conditions or obstetric complications and their babies](#) (2019) NICE guideline NG121
- [Chronic heart failure in adults: diagnosis and management](#) (2018) NICE guideline NG106
- [Sutureless aortic valve replacement for aortic stenosis](#) (2018) NICE interventional procedures guidance IPG624
- [Aortic valve reconstruction with processed bovine pericardium](#) (2018) NICE interventional procedures guidance IPG604
- [Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point of care coagulometers \(the CoaguCheck XA system\)](#) (2017) NICE diagnostics guidance DG14
- [Transcatheter aortic valve implantation for aortic stenosis](#) (2017) NICE interventional procedures guidance IPG586
- [Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures](#) (2016) NICE guideline CG64
- [Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis](#) (2015) NICE interventional procedures guidance IPG541
- [Acute heart failure: diagnosis and management](#) (2014) NICE guideline CG187
- [Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction](#) (2014) NICE interventional procedures guidance IPG504
- [Atrial fibrillation: management](#) (2014) NICE guideline CG180 (currently being updated, publication expected September 2020)

- [Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction](#) (2013) NICE interventional procedures guidance IPG436
- [Transient loss of consciousness \('blackouts'\) in over 16s](#) (2010) NICE guideline CG109
- [Percutaneous mitral valve annuloplasty](#) (2010) NICE interventional procedures guidance IPG352
- [Percutaneous mitral valve leaflet repair for mitral regurgitation](#) (2009) NICE interventional procedures guidance IPG309
- [Endoaortic balloon occlusion for cardiac surgery](#) (2008) NICE interventional procedures guidance IPG261
- [Thoracoscopically assisted mitral valve surgery](#) (2007) NICE interventional procedures guidance IPG245
- [Radiofrequency valvotomy for pulmonary atresia](#) (2004) NICE interventional procedures guidance IPG95
- [Balloon valvuloplasty for aortic valve stenosis in adults and children](#) (2004) NICE interventional procedures guidance IPG78
- [Balloon dilatation of pulmonary valve stenosis](#) (2004) NICE interventional procedures guidance IPG67

### ***In development***

- [Perioperative care in adults](#). NICE guideline. Publication date May 2020

### ***NICE guidance about the experience of people using NHS services***

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to investigation and management of heart valve disease in adults:

- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Medicines adherence](#) (2009) NICE guideline CG76

### **3.4 *Economic aspects***

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective, as appropriate.

### **3.5 *Key issues and draft questions***

- 1 Assessment and diagnosis
  - 1.1 In people with suspected heart valve disease, what symptoms and signs indicate referral (for example, from primary care) for echocardiography?
  - 1.2 In people with suspected heart valve disease, what symptoms and signs indicate direct referral (for example, from primary care) to a specialist?
  - 1.3 In people who have had echocardiography, what are the indications for referral to a specialist?
  - 1.4 In people with heart valve disease, what is the predictive accuracy and cost effectiveness of stress testing and stress echocardiography to determine the need for intervention?
  - 1.5 In people with heart valve disease what is the predictive accuracy and cost effectiveness of cardiac MRI and cardiac CT to determine the need for intervention?
- 2 Medical management
  - 2.1 In people with heart failure and heart valve disease, what is the clinical and cost effectiveness of using angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), beta-blockers, calcium channel blockers, digoxin, diuretics and nitrates to improve the clinical outcome?
- 3 Indications for interventions



- 3.1 What are the indications that interventions should be offered to people with symptomatic and asymptomatic heart valve disease?
- 4 Interventions for valve repair or replacement
  - 4.1 What is the clinical and cost effectiveness of transcatheter intervention, surgery (with mechanical or biological valves) and conservative management compared with each other for people with heart valve disease?
  - 4.2 What is the clinical and cost effectiveness of repeat transcatheter or surgical valve intervention for prosthetic biological valve degeneration following initial transcatheter or surgical intervention?
- 5 Anticoagulation and antiplatelet therapy after intervention
  - 5.1 What is the clinical and cost effectiveness of anticoagulant and antiplatelet therapy for people with transcatheter or surgically placed biological prosthetic valves?
- 6 Monitoring
  - 6.1 Where there is no current indication for intervention, what is the most clinically and cost-effective type of test (for example, BNP or NT-proBNP) and frequency of monitoring in people with heart valve disease?
  - 6.2 What is the most clinically and cost-effective frequency of monitoring with echocardiography in people with repaired or replaced heart valves?
- 7 Information and support
  - 7.1 What information and advice should people with heart valve disease and their family and carers receive?

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

### **3.6 Main outcomes**

The main outcomes that may be considered when searching for and assessing the evidence are:

- 1 mortality
- 2 health-related quality of life

- 3 hospitalisation
- 4 reintervention
- 5 heart failure
- 6 arrhythmias, for example, atrial fibrillation
- 7 thromboembolic events.

## **4 NICE quality standards and NICE Pathways**

### **4.1 NICE quality standards**

**NICE quality standards that will use this guideline as an evidence source when they are being developed**

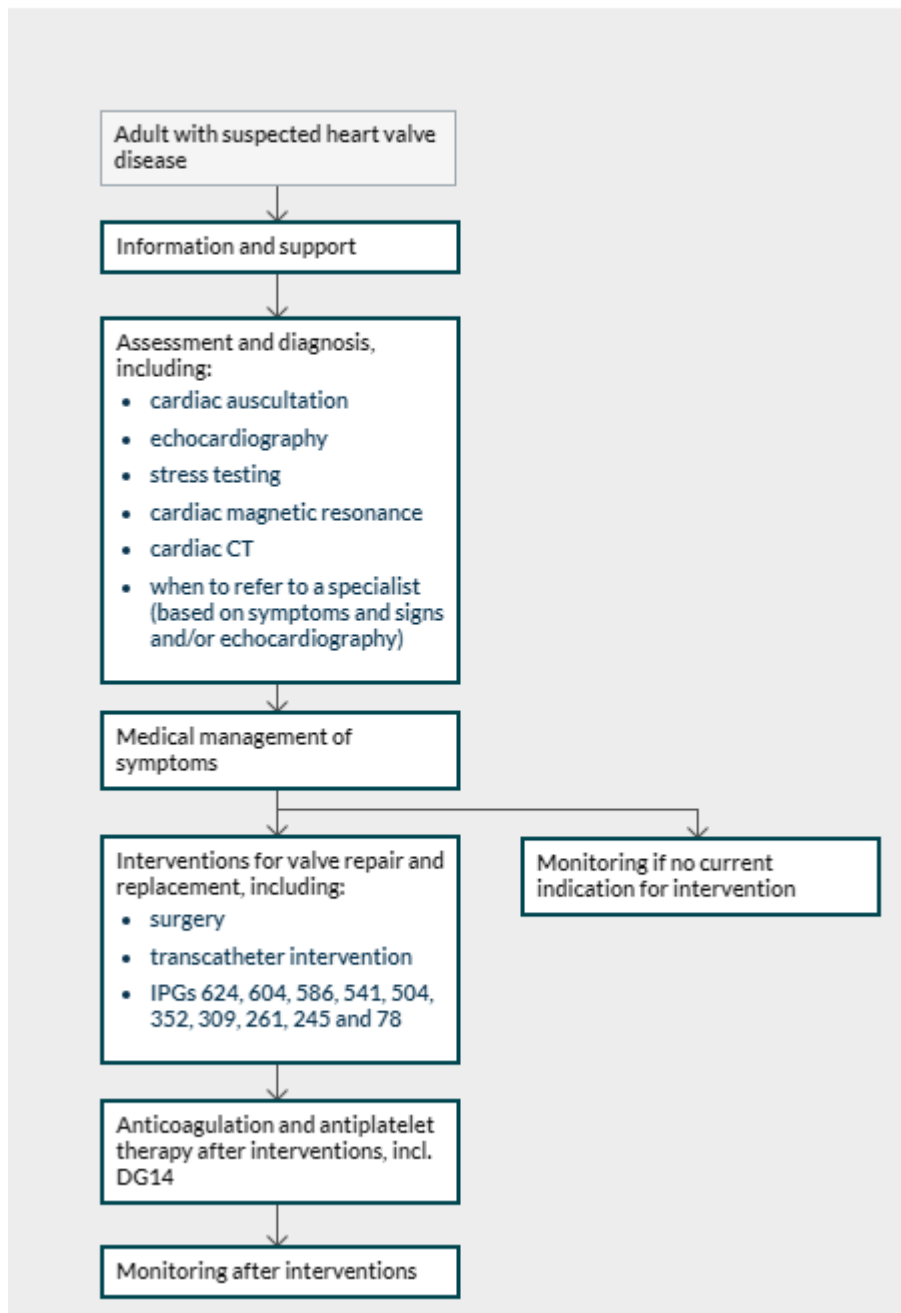
- Heart valve disease in adults. NICE quality standard. Publication date to be confirmed.

### **4.2 NICE Pathways**

[NICE Pathways](#) bring together everything we have said on a topic in an interactive flowchart. When this guideline is published, the recommendations will be included in the NICE Pathway on heart valve disease (in development).

An outline based on this scope is included below. It will be adapted and more detail added as the recommendations are written during guideline development.

## Heart valve disease overview



## 5 Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in May 2021.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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