| 1 2 | NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE |
|----------------------------------|--|
| 3 | Guideline scope |
| 4 5 | Heart valve disease in adults: investigation and management |
| 6 7 8 | The Department of Health and Social Care in England has asked NICE to develop a clinical guideline on investigating and managing heart valve disease in adults. |
| 9 10 | The guideline will be developed using the methods and processes outlined in developing NICE guidelines: the manual. |
| 11 12 | This guideline will also be used to develop the NICE quality standard for heart valve disease in adults. |
| 13 | 1 Why the guideline is needed |
| 14 | Key facts and figures |
| 15 16 | The heart has 4 valves (aortic, mitral, tricuspid and pulmonary) that control blood flow. |
| 17 | In heart valve disease, valve function can be impaired by: |
| 18 19 20 21 | stenosis, a narrowing or stiffening of the valve that restricts its opening and obstructs the forward flow of blood regurgitation, failure of the valve to close completely, which allows blood to flow backward. |
| 22 23 24 25 26 27 | 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 normal mitral or tricuspid valve function. |

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- 1 Primary disease can be congenital or acquired. Acquired valve degeneration
- 2 is currently the main cause of heart valve disease, leading to the most
- 3 common types of calcific aortic stenosis and myxomatous or calcific
- 4 degeneration of the mitral valve.
- 5 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
- 9 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 reported that for people
- over the age of 65, the prevalence of heart valve disease will increase from
- 13 1.5 million people currently, to double that in 2046.
- 14 People with heart valve disease may have no symptoms or may have
- symptoms specific for the affected valve. Associated heart rhythm problems,
- such as atrial fibrillation or heart block, may cause palpitations and
- 17 breathlessness, or dizziness and light-headedness, respectively. Untreated
- severe disease can lead to valvular heart failure, with symptoms including
- breathlessness, tiredness and swollen ankles. In the older population heart
- valves stiffen as part of the ageing process, making dysfunction more likely.
- 21 We hope that this guideline will raise awareness of heart valve disease and
- 22 improve diagnosis and management.

Current practice

23

- Heart valve disease can be detected from clinical features, with the
- diagnosis usually confirmed by an echocardiogram. Further investigations
- 26 may be needed as part of the management plan. GPs often detect heart
- 27 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 control symptoms, such as
- 2 angiotensin-converting enzyme (ACE) inhibitors, anti-arrhythmics and
- anticoagulants. In cases of severe heart valve disease with symptoms,
- 4 surgery to repair or replace the valve may be needed. This can be either
- 5 conventional surgery or transcatheter intervention. The timing of any
- 6 intervention is important to avoid irreversible valvular heart failure but also
- 7 unnecessary early intervention. Monitoring is continued after heart valve
- 8 intervention, but there is currently variation in practice.
- There are areas of uncertainty in the indications for intervention, and in the
- 10 most appropriate medicines for medical management.

2 Who the guideline is for

12 This guideline is for:

11

- 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,
- 18 <u>Scottish Government, and Northern Ireland Executive.</u>

19 **Equality considerations**

- 20 NICE has carried out an equality impact assessment during scoping. The
- 21 assessment:
- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.
- 24 The guideline will look at inequalities relating to:
- geographical location for those who do not live close to a valve clinic
- people who use intravenous drugs
- 27 age
- 28 people with dementia

people with a learning disability.

2 **3** What the guideline will cover

3 3.1 Who is the focus?

4 Groups that will be covered

- Adults (18 and over) with suspected heart valve disease.
- Adults (18 and over) with diagnosed heart valve disease (aortic, mitral,
- 7 bicuspid and tricuspid).
- 8 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.

13 Groups that will not be covered

- People with congenital heart valve disease, except bicuspid aortic valve
- 15 disease.

16 3.2 Settings

17 Settings that will be covered

• All settings where NHS healthcare is provided or commissioned.

19 3.3 Activities, services or aspects of care

20 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
- 24 licensed indications; exceptionally, and only if clearly supported by evidence,
- use outside a licensed indication may be recommended. The guideline will

| 1 | assume tha | t prescribers | will use: | a medicine's | summary of | f product |
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- 2 characteristics to inform decisions made with individual patients.
- 3 1 Assessment and diagnosis, including cardiac auscultation,
- 4 echocardiography, stress testing, cardiac magnetic resonance and
- 5 cardiac CT
- 6 2 Medical management of a rtic regurgitation, a ortic stenosis, mitral
- 7 regurgitation, mitral stenosis and tricuspid regurgitation
- 8 3 Indications for and timing of interventions (conventional surgery and
- 9 transcatheter intervention) for aortic regurgitation, aortic stenosis, mitral
- regurgitation, mitral stenosis and tricuspid regurgitation
- 11 4 Interventions
- 12 Approach (conventional surgery versus transcatheter intervention)
- Repair or replacement
- 14 Type of prosthesis (mechanical or biological)
- 15 Interventions for prosthetic valve degeneration
- 16 5 Anticoagulation and antiplatelet therapy after intervention
- 17 6 Monitoring frequency and type of test before and after intervention
- 18 7 Information and support

19 Areas that will not be covered

- 20 1 Diagnosis and management of pulmonary valve disease and tricuspid
- 21 stenosis.
- 22 Prophylaxis for infective endocarditis and management of infective
- 23 endocarditis.
- 24 3 Prophylaxis for rheumatic valve disease.
- 25 4 Management of heart failure, unless there are specific considerations for
- heart valve disease.
- 27 5 Anticoagulation for atrial fibrillation.
- 28 6 Congenital heart valve disease, except bicuspid aortic valve disease.

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1 Related NICE guidance

| 2 | Published |
|---|-----------|
|---|-----------|

- Chronic heart failure in adults: diagnosis and management (2018) NICE
- 4 guideline NG106
- Sutureless aortic valve replacement for aortic stenosis (2018) NICE
- 6 interventional procedures guidance IPG624
- Aortic valve reconstruction with processed bovine pericardium (2018) NICE
- 8 interventional procedures guidance IPG604
- Atrial fibrillation and heart valve disease: self-monitoring coagulation status
- using point of care coagulometers (the CoaguCheck XA system) (2017)
- 11 NICE diagnostics guidance DG14
- Transcatheter aortic valve implantation for aortic stenosis (2017) NICE
- interventional procedures guidance IPG586
- Prophylaxis against infective endocarditis: antimicrobial prophylaxis against
- 15 <u>infective endocarditis in adults and children undergoing interventional</u>
- 16 <u>procedures</u> (2016) NICE guideline CG64
- Transapical transcatheter mitral valve-in-valve implantation for a failed
- 18 <u>surgically implanted mitral valve bioprosthesis</u> (2015) NICE interventional
- 19 procedures guidance IPG541
- Acute heart failure: diagnosis and management (2014) NICE guideline
- 21 CG187
- Transcatheter valve-in-valve implantation for aortic bioprosthetic valve
- 23 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
- 29 guideline CG109
- Percutaneous mitral valve annuloplasty (2010) NICE interventional
- 31 procedures guidance IPG352

- Percutaneous mitral valve leaflet repair for mitral regurgitation (2009) NICE
- 2 interventional procedures guidance IPG309
- Endoaortic balloon occlusion for cardiac surgery (2008) NICE interventional
- 4 procedures guidance IPG261
- 5 Thoracoscopically assisted mitral valve surgery (2007) NICE interventional
- 6 procedures guidance IPG245
- Radiofrequency valvotomy for pulmonary atresia (2004) NICE
- 8 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
- 12 procedures guidance IPG67

13 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
- 16 topics unless there are specific issues related to investigation and
- 17 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

21 **3.4 Economic aspects**

- We will take economic aspects into account when making recommendations.
- 23 We will develop an economic plan that states for each review question (or key
- 24 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
- 27 analyses, using an NHS and personal social services (PSS) perspective, as
- appropriate.

29

3.5 Key issues and draft questions

30 1 Assessment and diagnosis

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| 1 | | 1.1 In people with suspected heart valve disease, what are the |
|----|---|--|
| 2 | | indications for referral for echocardiography? |
| 3 | | 1.2 In people with suspected heart valve disease, what symptoms and |
| 4 | | signs indicate direct referral to a specialist? |
| 5 | | 1.3 In people who have had echocardiography, what are the indications |
| 6 | | for referral to a specialist? |
| 7 | | 1.4 In people with heart valve disease, what is the diagnostic accuracy |
| 8 | | and cost effectiveness of stress testing and stress echocardiography? |
| 9 | | 1.5 What is the clinical and cost effectiveness of cardiac magnetic |
| 10 | | resonance and cardiac CT for assessing known heart valve disease? |
| 11 | 2 | Medical management |
| 12 | | 2.1 In people with heart failure and heart valve disease, what is the |
| 13 | | clinical and cost effectiveness of using angiotensin-converting enzyme |
| 14 | | (ACE) inhibitors, angiotensin II receptor blockers (ARBs), beta-blockers, |
| 15 | | calcium channel blockers, digoxin and diuretics to improve the |
| 16 | | symptoms of heart valve disease? |
| 17 | 3 | Indications for and timing of interventions |
| 18 | | 3.1 What symptoms, signs and findings indicate interventions for people |
| 19 | | with aortic regurgitation, aortic stenosis, mitral regurgitation, mitral |
| 20 | | stenosis and tricuspid regurgitation? |
| 21 | 4 | Interventions for valve repair or replacement |
| 22 | | 4.1 What is the clinical and cost effectiveness of transcatheter |
| 23 | | intervention or surgery ¹ (with mechanical or biological valves) compared |
| 24 | | with conservative management for people with aortic stenosis, aortic |
| 25 | | regurgitation, mitral stenosis, mitral regurgitation, isolated tricuspid |
| 26 | | regurgitation or tricuspid regurgitation with other heart valve disease? |
| 27 | | 4.2 What is the clinical and cost effectiveness of repeat valve |
| 28 | | replacement compared with transcatheter intervention for prosthetic |
| 29 | | valve degeneration? |
| 30 | 5 | Anticoagulation and antiplatelet therapy after intervention |

¹ Surgery refers to both standard and minimally invasive surgery throughout.

| 1 | | 5.1 What is the clinical and cost effectiveness of antithrombotic and |
|----|------|---|
| 2 | | antiplatelet therapy for people with prosthetic valves following |
| 3 | | transcatheter intervention or surgery (mechanical or biological valve)? |
| 4 | | 5.2 What is the clinical and cost effectiveness of bridging agents for |
| 5 | | people who need to temporarily stop their anticoagulation? |
| 6 | 6 | Monitoring |
| 7 | | 6.1 Where there is no current indication for intervention, what is the most |
| 8 | | clinically and cost-effective type (for example BNP, or NT-proBNP) and |
| 9 | | frequency of test for monitoring in people with heart valve disease? |
| 10 | | 6.2 What is the most clinically and cost-effective type and frequency of |
| 11 | | test for monitoring in people with repaired or replaced heart valves? |
| 12 | 7 | Information and support |
| 13 | | 7.1 What information and advice should people with heart valve disease |
| 14 | | and their family and carers receive? |
| 15 | | |
| 16 | The | key issues and draft questions will be used to develop more detailed |
| 17 | revi | ew questions, which guide the systematic review of the literature. |
| 18 | 3.6 | Main outcomes |
| 19 | The | main outcomes that may be considered when searching for and |
| 20 | asse | essing the evidence are: |
| 21 | 1 | mortality |
| 22 | 2 | health-related quality of life |
| 23 | 3 | hospitalisation |
| 24 | 4 | reintervention |
| 25 | 5 | heart failure |
| 26 | 6 | arrhythmias, for example, atrial fibrillation |
| 27 | 7 | thromboembolic events |

4 NICE quality standards and NICE Pathways

2 4.1 NICE quality standards

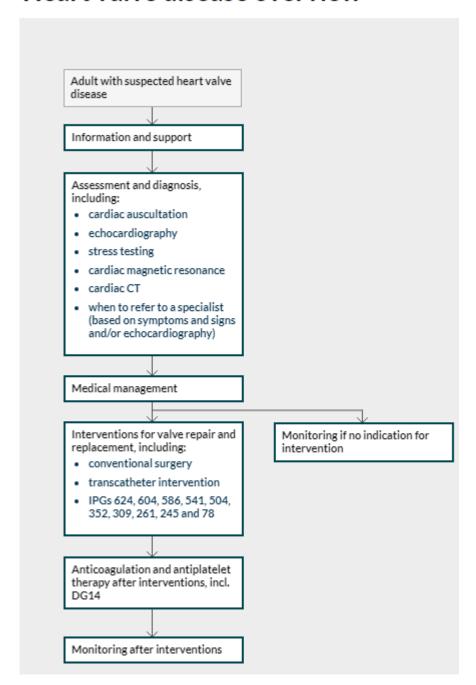
- 3 NICE quality standards that will use this guideline as an evidence source
- 4 when they are being developed
- Heart valve disease in adults. NICE quality standard. Publication date to be
- 6 confirmed.

1

7 4.2 NICE Pathways

- 8 NICE Pathways bring together everything we have said on a topic in an
- 9 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
- 13 development.

Heart valve disease overview



5 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 18 February to 18 March 2019.

The guideline is expected to be published in May 2021.

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You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.

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