

J.1 Asymptomatic mild or moderate heart valve disease

J.1.1 Research recommendation

What is the most clinically and cost-effective monitoring (type and frequency of test) for adults with asymptomatic mild or moderate heart valve disease (aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation and tricuspid regurgitation) and no current need for intervention?

J.1.2 Why this is important

We do not have good data on how people with mild or moderate valve disease progress over time. Because we are unable to identify who is likely to progress, and over what time frame, many patients are followed up routinely every 12 months, in order to 'capture' those that progress more quickly and need closer monitoring. For some this may be too frequent (especially those with mild disease, for whom some may not need follow-up at all). For others, this may not be frequent enough. If we had good data on optimal monitoring periods for patients with mild and moderate valve disease, we could be much more efficient with follow-up approaches, targeting patients who need this most, while avoiding frequent follow-up in those who do not need it or need it less often.

J.1.3 Rationale for research recommendation

Importance to 'patients' or the population	If we could determine how frequently patients need to be followed up, we could reduce the frequency of follow up for some patients, while maintaining an appropriate frequency of follow up to avoid missing important changes in others. In addition, if we could understand the best type of follow-up required - clinical review, echocardiography, blood tests or a combination - that would greatly facilitate optimal follow-up.
Relevance to NICE guidance	No evidence was found on people with mild to moderate heart valve disease. Research would support recommendations to be made on the type and frequency of monitoring.
Relevance to the NHS	Research in this area would inform NICE recommendations on the frequency and type of follow-up required for patients. If reduced follow-up frequency for some patients was shown to be as effective as more frequent follow-up, this would provide major advantages in resource use for the NHS (for example 2 yearly instead of annual follow up would halve the number of follow-up appointments needed). This would also free up resources for those who

	needed urgent assessment or more frequent follow-up.
National priorities	None known
Current evidence base	No relevant studies were identified mild valve disease and moderate valve disease. Monitoring of this group is crucial to treatment because it enables identification of those patients for whom surgery is most timely, leading to improved survival and quality of life.
Equality considerations	The frequency of follow-up impacts particularly on those who are working (generally younger ages, <65 years), and those with reduced mobility or poor access to transport, in whom less frequent follow-up is especially advantageous. In addition, for older patients if regular follow-up was shown to make no difference to outcomes (as they were unlikely to progress within their lifetime), this could result in no follow-up (discharge from clinic) for selected patients.

J.1.4 Modified PICO table

Population	<p><u>Inclusion</u></p> <p>Adults aged 18 years and over with mild to moderate diagnosed heart valve disease and no current indication for intervention</p> <p>Severity assessed by echo and rated as per The British Society of Echocardiography</p> <p><u>Exclusion</u></p> <ul style="list-style-type: none"> • Children aged less than 18 years. • Adults with congenital heart disease (apart from bicuspid aortic valves, which are included). • Tricuspid stenosis and pulmonary valve disease. • People who have had prior heart valve repair or replacement (transcatheter or surgical).
Intervention	<p>Any of the following assessment strategies used for monitoring purposes, followed by appropriate valve intervention, in the specified population:</p> <p>Biomarkers (alone or in combination with echo):</p> <ul style="list-style-type: none"> • BNP (B-type natriuretic peptide) • NT-proBNP (N-terminal prohormone brain natriuretic peptide) <p>Imaging:</p> <ul style="list-style-type: none"> • Echocardiography • CT (alone or in combination with echo)

	<ul style="list-style-type: none"> • CMR (cardiovascular magnetic resonance; alone or in combination with echo) <p>Patient reported outcome measures (PROMS; alone or in combination with echo), including:</p> <ul style="list-style-type: none"> • EuroQol • Minnesota Living With Heart Failure Questionnaire (MLHFQ) • Veterans Specific Activity Questionnaire <p>Other methods:</p> <ul style="list-style-type: none"> • Electrocardiogram (ECG) (alone or in combination with echo) • Clinical review only (no specific tests performed, as defined by the study authors) • Exercise testing (for example Bruce protocol; alone or in combination with echo)
Comparator	<p>Other active comparator listed above</p> <p>No monitoring (for example, tests only performed if new symptoms emerge/symptoms worsen)</p>
Outcome	<p>Primary outcomes</p> <p>All-cause mortality; Cardiac mortality; Health-related quality of life (any validated measure) and Hospitalisation for heart failure or other cardiac reason (e.g., for syncope in severe AS)</p> <p>Secondary outcomes</p> <p>New-onset atrial fibrillation</p>
Study design	Adequately powered randomised controlled trial (ideally)
Timeframe	Long term
Additional information	None