J.3 Asymptomatic severe heart valve disease

J.3.1 Research recommendation

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

J.3.2 Why this is important

Asymptomatic severe disease can progress to become symptomatic, or for reduced cardiac function to develop, indicating decompensation from the previously stable situation. This is associated with reduced prognosis, and these would be indications for surgery. There is divided opinion on how frequently and what type of monitoring would best capture patients soon after decompensation occurs, in order to avoid patients presenting late after decompensation (which can result in irreversible cardiac damage), while also avoiding inappropriately frequent follow-up.

J.3.3 Rationale for research recommendation

Importance to 'patients' or the population	If the optimal frequency and type of follow-up could be determined, this could result in timely surgery/intervention and would potentially avoid some patients developing irreversible cardiac dysfunction, while also avoiding unnecessarily frequent follow-up.
Relevance to NICE guidance	The evidence available was very limited to be able to inform recommendations. The committee noted the limitations associated with the single study identified, including the lack of definition of the guideline non-adherent group and the fact that monitoring frequency varied between patients in the guideline adherent group. In addition, the committee also highlighted that this

	study was performed in the USA, where medical insurance is required to cover costs of medical care. Evidence is needed on people with asymptomatic severe aortic regurgitation, mitral stenosis, mitral regurgitation or tricuspid regurgitation, as well as further evidence for the asymptomatic severe aortic stenosis population, and no current indication for intervention in order that stronger recommendations can be made.
Relevance to the NHS	Research in this area would inform NICE recommendations on the frequency and type of follow-up required for patients. If more frequent or a different type of follow-up was shown to reduce the number of people presenting with late decompensated heart failure, this could improve the long term outcome for patients, by avoid irreversible cardiac damage. 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. This would also free up resources for those who needed urgent assessment or more frequent follow-up.
National priorities	None known
Current evidence base	A single, retrospective study, which consisted of a review of medical records, was included in this review and covered the severe valve disease group, consisting of people with severe asymptomatic aortic stenosis. This study compared outcomes between a group that adhered to existing guidelines and a group that did not. This study was limited as there was no definition of the level of the monitoring that the non-adherent group actually received and it was unclear whether they were followed up less often, more often or were followed up at the same frequency as the adherent group but the methods used for monitoring did not meet the criteria specified in the guidelines. Further research is needed to determine the most clinically and cost effective type and frequency of monitoring.
Equality considerations	None known

J.3.4 Modified PICO table

Population	Inclusion Adults aged 18 years and over with diagnosed heart valve disease and no current indication for intervention with asymptomatic severe aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation or tricuspid regurgitation

	Severity assessed by echo and rated as per The British Society of Echocardiography Exclusion • Children aged less than 18 years. • Adults with congenital heart disease (excluding bicuspid aortic valves). • Tricuspid stenosis and pulmonary valve disease. • People who have had prior heart valve repair or replacement (transcatheter or surgical).
Intervention	Any of the following assessment strategies used for monitoring purposes, followed by appropriate valve intervention, in the specified population: Biomarkers (alone or in combination with echo): • BNP (B-type natriuretic peptide) • NT-proBNP (N-terminal prohormone brain natriuretic peptide) Imaging: • Echocardiography • CT (alone or in combination with echo) • CMR (cardiovascular magnetic resonance; alone or in combination with echo) Patient reported outcome measures (PROMS; alone or in combination with echo), including: • EuroQol • Minnesota Living With Heart Failure Questionnaire (MLHFQ) • Veterans Specific Activity Questionnaire Other methods: • 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	Other active comparator listed above No monitoring (for example, tests only performed if new symptoms emerge/symptoms worsen)
Outcome	Primary outcomes 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) Secondary outcomes New-onset atrial fibrillation

Study design	Adequately powered randomised controlled trial (ideally)
Timeframe	Long term
Additional information	None