NICE National Institute for Health and Care Excellence

IP2039 Transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation

IPAC date: 11/12/2025

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 1 Company Edwards Lifesciences	General	Edwards Lifesciences welcomes this topic as a subject for the IPG process. It is important to recognise, as captured in the description, that the various devices in question have different routes of anatomical access and consequently a markedly different safety profile. One of the stated goals of the IPG is to determine which patients will get the best outcomes and have the lowest safety risk. It is within the scope of the IPG to clearly identify where the relative risks lie, according to the devices used and the method of implanting them in the heart.	Thank you for your comment. A committee comment has been added to section 3, noting that there are different devices with different access routes.
2.	Consultee 1 Company Edwards Lifesciences	3.6 The evidence	It is important to recognise that, as captured in the description, the various devices in question have different routes of surgical access and markedly different safety profiles. One of the stated goals of the IPG is to determine which patients will get the best outcomes and have the lowest safety risk. It is within the scope of the IPG to clearly identify where the relative risks lie, according to the devices used and the method of implanting them in the heart	Thank you for your comment. A committee comment has been added to section 3, noting that there are different devices with different access routes.
3.	Consultee 1 Company	Overview – page 60	PVL rates and severity varies greatly between devices. This should be made clear in the final draft as the PVL observed	Thank you for your comment.

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	Edwards Lifesciences	(paravalvular leak)	and reported for the EVOQUE device have required no further intervention, other than in one patient in the "first in human" reports. The recent STS/ACC TVT registry presentation of 1,024 real-world cases did not have one report of consequential PVL	A committee comment has been added to section 3, noting that there are different devices with different access routes which may affect safety and efficacy outcomes. A summary of the STS/ACC registry data was considered by the committee during the third committee meeting and the committee acknowledged the data aligned with the published evidence. As the data showed short term follow up only, the committee agreed that paraventricular leak should remain as an outcome in section 3.6 of the guidance. The data has not been added to the overview because the unpublished data aligns with the published evidence, so is additional rather than new information. This is in accordance with the process described in the programme manual that was in place when this guidance production began, before July 2025. This states: 'Efficacy data that are unpublished or not peer reviewed are not normally selected for presentation to the

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				Committee. This includes conference abstracts, which are not normally considered adequate to support decisions on efficacy.'
4.	Consultee 1 Company Edwards Lifesciences	2.1 Information about the procedure	Within the Overview, clinical data is provided which involves a mini-thoracotomy and this data should be excluded from the analysis of those which are transcatheter devices delivered via a large blood vessel as defined in the description "This is done through a tube (transcatheter) inserted into a large blood vessel (vein) in the leg or neck". Furthermore, the clinical performance and safety profiles of devices which are implanted via transfemoral and trans jugular approaches are markedly different. This should be highlighted in future versions of the guidance.	Thank you for your comment. The committee discussed this comment but concluded that devices inserted through a mini-thoracotomy were within remit of this guidance. The lay description has been amended to clarify that access is usually through a vein in the leg or neck.
5.	Consultee 1 Company Edwards Lifesciences	2.1 Information about the procedure	Care needs to be taken here as those devices delivered by a thoracotomy are by definition, not a transcatheter device delivered via a large blood vessel. Their clinical results should not be associated with those transcatheter valves which are transcatheter devices delivered via a large blood vessel.	Thank you for your comment. The committee discussed this comment but concluded that devices inserted through a mini-thoracotomy were within remit of this guidance. The lay description has been amended to clarify that access is usually through a vein in the leg or neck.

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6.	Consultee 1 Company Edwards Lifesciences	Overview (study 2)	The Bugan paper includes data on the LuX-Valve (n=93); delivered through a minimally invasive right thoracotomy and transatrial approach. This data does not relate to transcatheter tricuspid valve replacement delivered using a transfemoral or transjugular approach as described in the draft. Therefore, it should not be included in the assessment.	Thank you for your comment. The committee discussed this comment but concluded that devices inserted through a mini-thoracotomy were within remit of this guidance. The lay description has been amended to clarify that access is usually through a vein in the leg or neck.
7.	Consultee 1 Company Edwards Lifesciences	What evidence generation and research is needed	There needs to be careful assessment of the data supporting the various devices in the scope of the IPG and their routes of access to the heart. There are markedly different results seen and this can help to address the question of patient selection and likely safety outcomes.	Thank you for your comment. The device and technique used have been added to the list for further research.
8.	Consultee 1 Company Edwards Lifesciences	What evidence generation and research is needed	Consideration should be given to the various valve types and anatomical approaches as these are associated with markedly different safety profiles. The pacemaker rates vary by valve type. For the EVOQUE device, Angellotti D, 2025 shows a rate of 19% and the TVT registry of 1,017 implanted cases reports 14.9% in pacemaker naïve cases and 9.9% overall.	Thank you for your comment. A committee comment has been added to section 3, noting that there are different devices with different access routes which may affect safety and efficacy outcomes. The device and technique used have been added to the list for further research.

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9.	Consultee 1 Company Edwards Lifesciences	Lay description	A more accurate statement would be to say that "The aim is to reduce the level of blood regurgitation, which will ultimately reduce symptoms, improve quality of life and reduce hospitalisation."	Thank you for your comment. The lay box currently says 'The aim is to reduce symptoms and improve quality of life.' The consultee's wording is more detailed than needed for a lay description.
10	Consultee 1 Company Edwards Lifesciences	1.1	It should be made clear that this is the decision of a multi-disciplinary heart team, as there is no routinely used surgical risk score to assess these patients.	Thank you for your comment. The draft guidance states that 'Patient selection should be done by a multidisciplinary team' for everyone having the procedure. The committee discussed this comment and decided that no change was needed to the guidance.
11	Consultee 1 Company Edwards Lifesciences	1.2	It should be made clear that this is the decision of a multi-disciplinary heart team, as there is no routinely used surgical risk score to assess these patients.	Thank you for your comment. The draft guidance states that 'Patient selection should be done by a multidisciplinary team' for everyone having the procedure. The committee discussed this comment and decided that no change was needed to the guidance.

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12	Consultee 2	1.1	Re: 1.1. “Transcatheter tricuspid valve implantation can be used in the NHS during the evidence generation period as an option to treat symptomatic severe tricuspid regurgitation when…….transcatheter tricuspid valve repair is unsuitable.” • We would recommend inclusion of a statement on the importance of a dedicated structural MDT. This is pertinent because determining the technical suitability for tricuspid TEER is made after a careful review of the imaging and is not always a clearcut binary decision (there is a spectrum which is also impacted upon by the level of operator experience). We would also recommend a statement that decisions on patient management are made in an MDT in a centre where all available treatment options can be offered i.e. open surgical replacement, transcatheter TV replacement as well as tricuspid TEER.	Thank you for your comment. The draft guidance states that ‘Patient selection should be done by a multidisciplinary team’ for everyone having the procedure. The committee discussed this comment and decided that no change was needed to the guidance regarding the MDT. The guidance has been amended to ‘This procedure should only be done in centres specialised in medical and interventional management of tricuspid regurgitation, **where all available treatment options can be offered**.’
13	Consultee 1 Company Edwards Lifesciences	What evidence generation and	Recent data suggests, in the case of the transfemoral approach using the EVOQUE device, that the adverse event rates are lower (Angelotti et al. JACC Cardiovasc Interv . 2025 Aug 11;18(15):1896-19092025), this is reiterated in	Thank you for your comment. The cited study (Angelotti, 2025) is included in table 2 of the overview.

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		research is needed	real-world TTVR experience from the STS/ACC TVT Registry, October 2025.	A summary of the STS/ACC registry data was considered by the committee during the meeting. The data has not been added to the overview in accordance with the process described in the programme manual that was in place when this guidance production began, before July 2025. This states: 'Efficacy data that are unpublished or not peer reviewed are not normally selected for presentation to the Committee. This includes conference abstracts, which are not normally considered adequate to support decisions on efficacy.'
14	Consultee 1 Company Edwards Lifesciences	What evidence generation and research is needed	For the EVOQUE system, from recent publications and post-implantation registries, we are not aware of any clinically significant paravalvular leak (PVL) which has required additional intervention. The real-world TTVR experience from the STS/ACC TVT Registry, published in October 2025 reports on 1,024 implantations of the EVOQUE device and there is no recorded significant PVL. It is fair to say that mild or lower PVL has been observed in 20% of cases after EVOQUE, but this is of no additional consequence to the outcome of the procedure or to patient safety.	Thank you for your comment. The committee discussed this comment but concluded that paravalvular leak is a key outcome for this procedure (which can be done using more than one device), so the guidance has not been changed.

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			Severe PVL has been identified in the trans-jugular approach (ref So, KC et al . https://www.jacc.org/doi/epdf/10.1016/j.jacasi.2025.07.009)	
15	Consultee 1 Company Edwards Lifesciences	Why the committee made these recommendations	The adverse events reported in the Overview and the draft guidance are based on initial experience with the devices. Recent data suggests, in the case of the transfemoral approach using the EVOQUE device, that the adverse event rates are lower than those reported in the draft (Angelotti et al. JACC Cardiovasc Interv . 2025 Aug 11;18(15):1896-19092025). Please also see the real-world TTVR experience from the STS/ACC TVT Registry, published in October 2025, which records life-threatening/major bleeding rates of 1.3% and pacemaker rates of 14.9%, lower than those seen in early clinical studies. The improved safety results for EVOQUE in more recent publications are largely a reflection of differences in case mix, antithrombotic protocols, and maturation of imaging-guided implantation techniques.	Thank you for your comment. The overview states 'Most of the studies reflected early experience with the procedure.' The committee discussed this comment but decided not to change the guidance. A summary of the STS/ACC registry data was considered by the committee during the meeting. The data has not been added to the overview in accordance with the process described in the programme manual that was in place when this guidance production began, before July 2025. This states: 'Efficacy data that are unpublished or not peer reviewed are not normally selected for presentation to the Committee. This includes conference abstracts, which are not normally considered adequate to support decisions on efficacy.'

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16	Consultee 1 Company Edwards Lifesciences	2.2 Information about the procedure	The devices also differ by anatomical access	Thank you for your comment. Some text has been added to section 2.2, noting that there are different access routes.
17	Consultee 1 Company Edwards Lifesciences	3.1 The condition	Tricuspid regurgitation (TR) can occur due to pulmonary hypertension causing right ventricular pressure load and dilatation. TR itself does not cause pulmonary hypertension.	Thank you for your comment. Section 3.1 has been changed to: 'Tricuspid regurgitation is when blood flows backwards through the tricuspid valve because it does not close properly during systole (when the heart contracts). It can be caused by a problem with the valve itself, but more commonly is a result of an underlying cardiac problem **or pulmonary hypertension** that has caused the heart to become dilated.'
18	Consultee 1 Company Edwards Lifesciences	3.2 Current practice	The drugs used in TR are either loop diuretics or mineralocorticoid receptor antagonists. Specific drugs to vasodilate the pulmonary vascular bed such as endothelin antagonists of PDE type V inhibitors are not a routine part of severe TR management.	Thank you for your comment. Section 3.2 has been changed to 'Treatment options for symptomatic severe tricuspid regurgitation include medicines, **such as loop diuretics.**'

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19	Consultee 1 Company Edwards Lifesciences	3.2 Current practice	Certain annuloplasty devices such as Cardioband are no longer available and Carillion is not used in the UK.	Thank you for your comment. Section 3.2 states 'There are also transcatheter techniques for repairing the tricuspid valve, including leaflet repair and annuloplasty.'
20	Consultee 1 Company Edwards Lifesciences	3.3 Unmet need	Please consider adding "increased risk of mortality"	Thank you for your comment. Section 3.3 has been amended to 'Symptomatic severe tricuspid regurgitation can be debilitating and lead to poor quality of life **and increased risk of mortality**.'
21	Consultee 1 Company Edwards Lifesciences	What evidence generation and research is needed	Please refer to Lurz, P et al. This study provides clinical and quality-of-life outcomes at 1 year, with Kaplan-Meier estimates for all-cause mortality and heart failure (HF) hospitalisation assessed at 18 months.	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence. This study (TRISCEND 2) is already included in table 2 (Hahn 2025). Lurz (2025) includes longer term outcomes and stratification by baseline TR severity.
22	Consultee 1 Company Edwards Lifesciences	3.4 The evidence	The recent publication, Lurz et al, was not included in the clinical data reported in the Overview. It contains valuable information on clinical and quality-of-life outcomes at 1 year,	Thank you for your comment.

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			with Kaplan-Meier estimates for all-cause mortality and heart failure (HF) hospitalisation assessed at 18 months. Lurz P, et al Tricuspid valve replacement outcomes by baseline tricuspid regurgitation severity: the TRISCEND II trial. Eur Heart J. 2025 Aug 29:ehaf676. doi: 10.1093/eurheartj/ehaf676.	Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
23	Consultee 1 Company Edwards Lifesciences	3.5 The evidence	The sub-analysis presented in Lurz P et al, 2025, shows a reduction in heart failure hospitalisation in the severe / torrential regurgitation patient group.	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
24	Consultee 1 Company Edwards Lifesciences	Overview – evidence summary	One recent publication is missing (Lurz et al. 2025) showing sub-group analysis of TRISCEND II trial stratified per baseline TR severity (severe TR vs massive and torrential TR). This publication shows that for the most severe patients (massive/torrential TR group), TTVR is associated with a significant reduction in the composite endpoint of all-cause mortality with HF hospitalisation but also significantly reduces the overall HF hospitalisation rate. For every 7 patients treated with TTVR, 1 HF hospitalisation is avoided (NNT).	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.

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			Lurz P et al. Tricuspid valve replacement outcomes by baseline tricuspid regurgitation severity: the TRISCEND II trial. Eur Heart J. 2025 Aug 29:ehaf676. doi: 10.1093/eurheartj/ehaf676. Epub ahead of print. PMID: 40878717.	
25	Consultee 1 Company Edwards Lifesciences	Overview – evidence summary	There should also be sub-group analysis from Lurz et al. 2025 added to this summary. This recent publication adds useful information which helps to address some of the committee considerations / questions particularly with regard to longer term outcomes	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
26	Consultee 1 Company Edwards Lifesciences	Overview	Please include the Lurz et al 2025 study as this gives longer term outcome data	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
27	Consultee 1 Company Edwards Lifesciences	Overview – page 50 (hospitalisation for heart failure)	Please include the Lurz et al, 2025 outcomes	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
28	Consultee 1 Company	Overview – validity and	Lurz et al. 2025 showed a significant difference in HF hospitalization in the sub-group analysis. Please include this additional reference as it adds useful data to this IPG	Thank you for your comment.

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	Edwards Lifesciences	generalisability		Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
29	Consultee 1 Company Edwards Lifesciences	Overview – validity and generalisability	Hard-endpoint benefit has been shown in the TRISCEND II sub-group analysis by Lurz et al. 2025	Thank you for your comment. Lurz (2025) was identified in the updated literature search and has been added to the key evidence.
30	Consultee 1 Company Edwards Lifesciences	3.5 The evidence	These should be two separate bullet points as they are distinctly different and assessed in different ways	Thank you for your comment. The bullet point in 3.5 that states 'improved quality of life, reduced hospital admissions related to heart failure' has been split into 2 separate bullet points.
31	Consultee 1 Company Edwards Lifesciences	3.6 The evidence	PVL which requires further intervention (>= moderate PVL) is only associated with certain devices. Mild PVL does not require intervention. Moderate PVL was only found in 1 patient treated with EVOQUE in the early experience report and was not found in the real-world TTVR experience from the STS/ACC TVT Registry of 1,024 implanted cases	Thank you for your comment. The committee discussed this comment but decided not to change the guidance. A summary of the STS/ACC registry data was considered by the committee during the meeting. As the data showed short term follow up only, the committee agreed that paraventricular leak should remain as an outcome in section 3.6 of the guidance.

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				The data has not been added to the overview in accordance with the process described in the programme manual that was in place when this guidance production began, before July 2025. This states: 'Efficacy data that are unpublished or not peer reviewed are not normally selected for presentation to the Committee. This includes conference abstracts, which are not normally considered adequate to support decisions on efficacy.'
32	Consultee 1 Company Edwards Lifesciences	3.6 The evidence	Patient input should be actively sought via recognised charities. It is imperative that their voice contributes to the guidance	Thank you for your comment. Patient commentary was sought through the usual process but no responses were received.
33	Consultee 1 Company Edwards Lifesciences	3.8 Committee comments	All patients need to be anti-coagulated after the procedure, according to standard regimens	Thank you for your comment. Section 3.8 has been changed to: 'People need anticoagulation after the procedure and regimens for this are being developed.'

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34	Consultee 1 Company Edwards Lifesciences	3.9 Committee comments	The pacemaker rate varies by valve type. For the EVOQUE device, Angellotti D, 2025 shows a rate of 19% and the real-world TTVR experience from the STS/ACC TVT Registry of 1,024 implanted cases reports 14.9% in pacemaker naiive cases and 9.9% overall.	Thank you for your comment. Section 3.9 has been amended to '**Some** people who do not already have a pacemaker may need one after this procedure.' A committee comment has been added, stating 'There are different types of device and different access routes used for implantation, which may affect safety and efficacy outcomes.'
35	Consultee 1 Company Edwards Lifesciences	3.11 Committee comments	All of the valves under consideration are made from animal tissue	Thank you for your comment. Section 3.11 has been amended to 'All the valves considered in the current evidence are made from 5 tissue'.
36	Consultee 1 Company Edwards Lifesciences	3.12 Equality considerations	Edwards Lifesciences are pleased to see that this procedure is recognised as a way of reducing inequalities of care	Thank you for your comment.
37	Consultee 1 Company Edwards Lifesciences	Overview – table 1 (abbreviations)	Should this be "Transcatheter tricuspid valve replacement" to be consistent with the TTVR abbreviation?	Thank you for your comment. TTVR has been used as an abbreviation for transcatheter tricuspid valve implantation, which is the term used in the title of the guidance. The table in the

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				overview has been amended to clarify that it is also an abbreviation of transcatheter tricuspid valve replacement.
38	Consultee 1 Company Edwards Lifesciences	Overview – page 3	EuroSCORE 2 has not been validated for isolated TR surgery	Thank you for your comment. The overview states 'EuroSCORE 2 is a validated and commonly used risk model for assessing the perioperative risk of mortality after major cardiac surgery.' The committee discussed this comment and decided no change was needed.
39	Consultee 1 Company Edwards Lifesciences	Overview – page 4	STS Score has not been validated for isolated TR surgery	Thank you for your comment. The overview states 'The STS score is a risk stratification model, composed of up to 30 variables that predict short- and long-term mortality and morbidity after cardiac surgery.' The committee discussed this comment and decided no change was needed.
40	Consultee 1 Company Edwards Lifesciences	Overview – page 4 (outcome measures)	In addition to those stated, a reduction in Heart Failure hospitalisation should also be considered as a relevant outcome measure	Thank you for your comment. Reduction in heart failure hospitalisation has been added to the list of main outcomes in the overview.

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41	Consultee 1 Company Edwards Lifesciences	Overview – table 2 (study 1)	This should read 75.5%	Thank you for your comment. The proportion of females in Hahn (2025) was reported as 74.9% in the table of the publication and 75.5% in the text. This has been changed to 75% in the overview.
42	Consultee 1 Company Edwards Lifesciences	Overview – table 3 (Bugan 2022)	Although stated in the source document, it is unclear as to how this is derived and does not bear resemblance to other published data. PVL levels observed in all except one published case for the EVOQUE device has been of no consequence	Thank you for your comment. The outcomes are reported as they are in the source paper.
43	Consultee 1 Company Edwards Lifesciences	Overview – page 49 (procedure technique)	They also differ in terms of anatomical access	Thank you for your comment. This has been added to the overview.
44	Consultee 2	General	General comments on the consultation document Overall, we think the NICE recommendation is reasonable. All of the relevant evidence has been taken into account and the summaries offer comprehensive, reasonable interpretations of the available evidence. The recommendations are sound and offer a suitable basis for guidance to the NHS.	Thank you for your comment. Consultee agrees with main recommendation.

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			We need to be mindful of ensuring equality in access to these procedures across the country.	
45	Consultee 2	1.1	The 1.1. statement is also now at odds with the now outdated NICE 2022 recommendation on tricuspid TEER. The 2022 document advised that “more research is needed on transcatheter tricuspid valve implantation to treat symptomatic severe tricuspid regurgitation before it can be used in the NHS when open surgical tricuspid valve repair or replacement is not high risk, or transcatheter tricuspid valve repair is suitable.” This statement is now at odds with the NICE 2022 guidance for tricuspid TEER which commented: “Evidence on the efficacy of transcatheter tricuspid valve leaflet repair is limited in quantity and quality. Evidence on its safety shows there are serious but well-recognised complications. Therefore, for these people, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”	Thank you for your comment. IPG731 Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation (2022) recommends that the procedure can be done with special arrangements for people with severe and symptomatic tricuspid regurgitation and research only for people with mild or moderate tricuspid regurgitation. The committee discussed this comment and decided no change was needed to this guidance on transcatheter tricuspid valve implantation as transcatheter tricuspid valve leaflet repair can be used in people with severe symptomatic tricuspid regurgitation provided it is done with further evidence generation (special arrangements).
46	Consultee 2	General	While the recommended grading of TR for patients being considered for structural tricuspid valve intervention separates severe TR into 3 further categories (severe,	Thank you for your comment.

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			massive and torrential), the data supporting any bearing on symptoms or prognosis for these 3 categories are limited. This deserves acknowledgment.	A committee comment has been added, noting that evidence suggests the procedure may have a greater benefit in people with more severe tricuspid regurgitation but there may also be a higher proportion of adverse outcomes.
47	Consultee 2	General	There is uncertainty around how best to quantify RV function and its importance in deciding which form of TV intervention if any is better ie. TTVR (EVOQUE) vs tricuspid TEER. Following TTVR most patients suffer a reduction in RV function (whether assessed by TAPSE or FAC) but this does not appear to translate into worse clinical outcomes. This uncertainty deserves a comment - we do not know for example, if there a pre-procedure FAC cut-off below which TTVR should not be performed?	Thank you for your comment. The committee discussed this comment and decided no change was needed.
48	Consultee 2	General	We would suggest a comment on need to assess and consider the individual patient's risk of bleeding before making a decision between TTVR vs TEER?	Thank you for your comment. The committee discussed this comment and decided this would be part of the patient selection process by the multidisciplinary team, so no change was needed.
49	Consultee 2	General	There is a notable absence of any reference to the importance of right heart catheterisation - opinion varies on this across UK centres; some centres perform this in all	Thank you for your comment.

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			patients while other centres rarely perform it ahead of TEER or TTVR to guide decision making. This is an area that warrants further research.	The committee discussed this comment and decided not to change the guidance.
50	Consultee 2	General	There is no reference to the recently updated ESC 2025 valve guidelines and its recommendations.	Thank you for your comment. The relevant recommendations from this publication have been added to the overview.
51	Consultee 2	General	We think it is important to emphasise to readers that that only one randomised controlled study is available for this latest technology (Hahn 2025) – and in this study there was no effective blinding of patients.	Thank you for your comment. The guidance lists the type of studies in section 3.4. Hahn 2025 compared TTVR to medical therapy and so blinding would not be feasible.

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