NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1848 Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

Your information

Name:	Martin Arnold, MD
Job title:	Senior Cardiologist
Organisation:	University Hospital Erlangen, Germany, Department of Cardiology
Email address:	martin.arnold@uk-erlangen.de
Professional organisation or society membership/affiliation:	ESC, EAPCI, EHRA, ACC, DGK, DGIM, DGIIN
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Bavarian board of physicians ID 020046380

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	The University Hospital Erlangen is one of the institutions with the largest experience regarding transcatheter tricuspid valve annuloplasty for tricuspid regurgitation worldwide. The program was started in 2018. Since then I have performed more than 50 procedures. I am involved in training new operators, in the ongoing development of the system and in several publications investigating the clinical outcome of transcatheter tricuspid valve annuloplasty.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	I am using this technique routinely. This procedure is about to be introduced to NHS. The procedure is mainly used by cardiologists, but is also performed by cardiac surgeons with interventional background. Patient selection and diagnostics for tricuspid regurgitation is the domain of Cardiology. Besides the interventional treatment of such patients the selection is part of my routine.

	indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The system for transcatheter tricuspid valve annuloplasty for tricuspid regurgitation is commercially available in the EU and an investigational product in the US. The current standard care is either medical treatment or surgical. Therefore it is a completely new concept compared to the standard therapy. It is a new class of procedure but has been investigated in the clinical arena and is already becoming established in several centers as part of the clinical routine. Established practice and no longer new. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	The initial clinical data show that patients who are no good candidates for surgical treatment can benefit from the procedure with regard to their heart failure symptoms. Randomized trials comparing this new method to surgical treatment or medical treatment are not available (yet). Procedural mortality in the published literature is lower compared to registries evaluating tricuspid valve surgery. The new procedure has the potential to replace the indication for medical therapy alone in a certain patient population with tricuspid regurgitation and may also be an alternative to surgical tricuspid valve annuloplasty.

Current management

5	Please describe the current standard of care that is used in the NHS.	Baseline therapy for patients with tricuspid regurgitation is the treatment of any causative conditions (e.g. aortic or mitral valve disease) and symptomatic diuretic medication. Patients with severe tricuspid regurgitation who are candidates for open heart surgery are treated by surgical tricuspid valve annuloplasty or valve replacement.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Another interventional technique to treat tricuspid regurgitation is the so called “edge to edge” technique. Catheterbased devices attach the tips/edges of the tricuspid leaflets together, thus reducing the mobility of the leaflets and therefore reducing the degree of regurgitation. This technique directly addresses the regurgitation whereas transcatheter tricuspid valve annuloplasty reduces the dimensions of the tricuspid annulus (and thereby reduces the degree of regurgitation) and reverses the annular dilatation which is the pathophysiological case of secondary tricuspid regurgitation.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	The procedure is less invasive compared to surgical techniques and is probably more potent than medical therapy.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who are currently seen as inoperable or considered high risk for surgery. Patients with a remaining severe tricuspid regurgitation after other cardiac surgical procedures or patients who need other cardiac surgical procedures and the concomitant treatment of the tricuspid valve would make the overall procedure to long or to complex.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The procedure has the potential to change the pathway of patient care in a way that interventions are available for a larger patient population. The new technique may be more effeicent than medical therapy and an alternative to surgical treatment. More efficient treatment of patients with tricuspid regurgitation may results in reduced hospital admissions for heart failure, transcatheter treatment is less invasive compared to open heart surgery.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Acute device costs may be higher but possible reduction of hospital admissions and less need for intensified heart failure management after successful intervention may compensate for it.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The device costs are likely to be higher.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure can be performed in a standard cath lab. Transesophageal echocardiography is required for procedure guidance. Patients are usually under general anesthesia. There a anesthesia workplace in the cath lab is required. Patients are usually monitored at an intensive care unit until the next day but monitoring at a recovery room until the patient is fully awake

		and clinically stable is also possible.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The procedure requires thorough training of the operator and the echocardiographer.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Access sites complications (6%), perforation/obstruction of the right coronary artery (6-10%), pericardial effusion (1%), (partial) detachment of the annuloplasty band (anecdotal), perforation of right atrium or ventricle (anecdotal), worsening of right heart failure, esophageal injury (anecdotal), kidney injury (3%), conduction disturbance (1-3%), bleeding (10-13%), VT (anecdotal), stroke (anecdotal), mortality (1-3%).
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction of degree of tricuspid regurgitation, improvement in NYHA functional class, improvement in 6 minute walk test.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As no randomized trials have been conducted efficacy is only based on reports of case series, the safety of the procedure was already reported in larger numbers of treated patients
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Kuwata S, Taramasso M, Nietlispach F, Maisano F. Transcatheter tricuspid valve repair toward a surgical standard: first-in-man report of direct annuloplasty with a cardioband device to treat severe functional tricuspid regurgitation. European Heart Journal. 2017;38(16):1261. Nickenig G, Weber M, Schueler R, Hausleiter J, Näbauer M, von Bardeleben RS, Sotiriou E, Schäfer U, Deuschl F, Kuck KH, Kreidel F, Juliard JM, Brochet E, Latib A, Agricola E, Baldus S, Friedrichs K, Vandrangi P, Verta P, Hahn RT, Maisano F. 6-Month outcomes of tricuspid valve reconstruction for patients with severe tricuspid regurgitation. J Am Coll Cardiol. 2019;73(15):1905–15. Davidson CJ, Lim DS, Smith RL, Kodali SK, Kipperman RM, Eleid MF, Reisman M, Whisenant B, Puthumana J, Abramson S, Fowler D, Grayburn P, Hahn RT, Koulogiannis K, Pislaru SV, Zwink T, Minder M, Dahou A, Deo SH, Vandrangi P, Deuschl F, Feldman TE, Gray WA, Cardioband TR EFS Investigators Early feasibility study of cardioband tricuspid system for functional tricuspid regurgitation: 30-day outcomes. JACC Cardiovasc Interv. 2021;14(1):41–50. doi: 10.1016/j.jcin.2020.10.017. Körber MI, Landendinger M, Gerçek M, Beuthner BE, Friedrichs KP, Puls M, et al. Transcatheter treatment of secondary tricuspid regurgitation with direct annuloplasty – results from a multicenter real-world study. Circulation: Cardiovascular Interventions. Circ Cardiovasc Interv. 2021 Aug;14(8):e010019.doi:10.1161/CIRCINTERVENTIONS. 120.010019. Epub 2021 Jul 3 Gerçek M, Rudolph V, Arnold A, Beuthner BE, Pfister R, Landendinger M, et al. Transient acute right coronary artery deformation during transcatheter interventional tricuspid repair with The Cardioband Tricuspid System. EuroIntervention. 2020:EIJ-D-20-00305
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	TriBAND study NCT03779490

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the	Up to 99% of patients with severe tricuspid regurgitation are seen as not eligible for surgical therapy and are currently mainly treated medically.

	target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The procedure can be performed in every standard cath lab with anesthesia support. Echocardiophic imaging is demanding and need a high level of expertise. Operators undergo a significant learning curve.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Randamized trials need to be conducted to provide the evidence with regard to the current standard therapy
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Short term: reduction of degree of regurgitation, NYHA-class, 6 minute walk test, QOL. Long term: persistence of reduction of degree of regurgitation, right heart function (dimensions, TAPSE); NYHA-class, 6 minute walk test, QOL. Adverse outcome measures: Mortality, procedural complications, hospital admission. Hospital admission, at discharge from hospital, 30 days, 6 month, 1 year, and yearly therafter.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Fees for lectures, consulting and training activities for Edwards Lifesciences	**2018**	**ongoing**
Direct - financial	Fees for lectures, consulting and training activities for Abbott Medical	**2015**	**ongoing**
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Martin Arnold**
Dated:	**07.12.2021**