

## Heart valve disease Committee meeting 13

**Date:** 3/11/2020

**Location:** Virtual meeting via Zoom

**Minutes:** Confirmed

<b>Committee members present:</b>		
Norman Briffa (NB)		(Present for notes 1 – 6)
Joy Ellery (JE)		(Present for notes 1 – 6)
Madalina Garbi (MG)		(Present for notes 1 – 6)
Marjan Jahangiri (MJ)		(Present for notes 1 – 6)
Muhammad Murad Khan (MMK)		(Present for notes 1 – 6)
Rajesh Kharbanda (RKK)		(Present for notes 1 – 6)
Saul Myerson (SM)		(Present for notes 1 – 6)
Denise Parkin (DP)		(Present for notes 1 – 6)
Suzannah Power (SP)		(Present for notes 1 – 6)
Phil Smith (PS) (Chair)		(Present for notes 1 – 6)
<b>Expert witness:</b>		
Cathy Head (CH)		(Present for notes 1 – 4.2)

<b>In attendance:</b>		
Victoria Axe (VA)	Guideline Commissioning Manager, NICE	(Present for notes 1 – 6)
Shama Mahammed (SMa)	Health Economist, NGC	(Present for notes 1 – 6)
Alfredo Mariani (AM)	Health Economist, NGC	(Present for notes 1 – 6)
Eleanor Samarasekera (ES)	Senior Research Fellow, NGC	(Present for notes 1 – 6)
Sharon Swain (SS)	Guideline Lead, NGC	(Present for notes 1 – 6)
Katie Tuddenham (KT)	Project Manager, NGC	(Present for notes 1 – 6)

<b>Apologies:</b>		
Nicole Downes	Systematic Reviewer, NGC	
David Wonderling (DW)	Head of Health Economics, NGC	

## 1. Welcome and objectives for the meeting

PS welcomed the Committee members and attendees to the thirteenth meeting of the Heart Valve Disease guideline. The Committee members and attendees introduced themselves.

PS informed the Committee that no apologies had been received.

PS outlined the objectives of the meeting.

## 2. Confirmation of matter under discussion, and declarations of interest

The DOI register was made available to PS. PS reviewed the DOI register and deemed that no committee members had DOIs that were in conflict with the agenda topics under discussion at this meeting:

PS also asked everyone to verbally declare any interests that have arisen since the last meeting. The following new interests were received for this committee meeting:

### Committee Declarations of Interest

N.B. The Committee members were recruited to this guideline using NICE DOI policy published April 2018.

Insert initials	Declaration	Classification (as per the NICE DOI policy wording*)	Chair's action
CH	President UK maternal cardiology society. The UK maternal cardiology society (UKMCS) is a professional body set up to advance the diagnosis and management of cardiac disease in pregnancy through awareness, education and research, and thereby to support the delivery of high quality, safe and equitable maternal cardiology care nationally and internationally. UKMCS is an affiliated society of the British Cardiovascular Society (BCS) Ordinary membership is open to all healthcare professionals actively involved in the care of women with cardiac disease in pregnancy or research in this field.	Direct non-financial	Specific  No action other than the process of declaration
	Member British Society of Haematology writing group for guideline on anticoagulation for mechanical heart valves in pregnancy	Direct non-financial	Specific  No action other than the process of open declaration (topic not covered by this guideline)

RK	<p>I am Chief Investigator of a randomized clinical trial testing the efficacy of routine cerebral embolic protection to reduce stroke in transcatheter aortic valve implantation (TAVI). The BHF Protect TAVI is funded by the British Heart Foundation and Boston Scientific, through an independent investigator initiated grant for provision of devices.</p> <p>Aortic stenosis is treated by transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (AVR). TAVI is less invasive, has less morbidity and allows faster recovery than surgical AVR. However, a major risk of TAVI is stroke, which occurs in about 3% of TAVI patients, and is associated with prolonged hospital stay, disability and earlier death. Most strokes occur at the time of TAVI due to embolism of debris released from the native valve and surrounding anatomy into the cerebral circulation. It is thought that cerebral embolic protection (CEP) devices could reduce the chances of debris reaching the brain and that these devices may reduce stroke. The BHF PROTECT-TAVI trial will investigate whether CEP devices reduce the likelihood of stroke during TAVI. 7730 people having transfemoral TAVI for aortic stenosis will be recruited from across the UK. Half of the participants will be randomised to have TAVI performed with CEP. The control group will have standard of care for TAVI without CEP. The primary outcome will be clinical stroke at 72 hours. BHF PROTECT-TAVI will define the clinical effectiveness of CEP to reduce stroke. A cost-effectiveness analysis to inform NHS decision-making will also be undertaken.</p> <p>The funding for this trial is from the British Heart Foundation and from an investigator initiated grant from Boston Scientific.</p> <p>The funding from both sources is administered by the University of Oxford.</p>	Indirect financial	<p>Specific</p> <p>No action other than the process of open declaration</p> <p>The role of TAVI in cerebral embolic protection is not being covered by this guideline.</p>
SP	CVD COVID UK approvals and oversight board run by British Heart Foundation data science centre and	Direct non-financial	<p>Non-specific</p> <p>No action other than the process of open declaration</p>

	Health Data Research UK.		
<p>NICE DOI policy classifications are:</p> <ul style="list-style-type: none"> <li>• Direct financial specific</li> <li>• Direct financial non-specific</li> <li>• Direct non-financial specific</li> <li>• Direct non-financial non-specific</li> <li>• Indirect financial specific</li> <li>• Indirect financial non-specific</li> </ul>			
<p><b>3. Minutes of the last meeting</b></p>			
<p>The Committee agreed that the minutes were a true and accurate account of the meeting.</p> <p>The Chair confirmed that all matters arising had been completed or were in hand.</p> <p>RK noted the following, which is not relevant to the guideline topics and not considered a declaration but is minuted here for completeness:</p> <p>I was involved in an investigation conducted by the University of Oxford into research misconduct and retracted two publications on which I was an author. The decision to retract the paper followed the conclusion of an investigation under the University of Oxford's ("the University's") Code of Practice and Procedure on Academic Integrity in Research ("the Code"). The Registrar of the University convened a Panel under the Code. The Panel considered a number of issues. The Panel concluded that the first author, Dr Alexander Liu, was responsible for misconduct in research. The Panel's findings with regards to misconduct were limited to the actions of the first author. No other co-author was found to be involved in the misconduct. It is understood that the first author disagrees with the Panel's findings. The first author has raised a complaint with the Office of the Independent Adjudicator for Higher Education (OIA) (The OIA reviews complaints from students about their higher education provider).The Panel's view was that the papers would likely need to be retracted from the literature as they had major irregularities and the conclusions were unsafe.</p>			
<p><b>4. Presentation and Discussion</b></p>			
<p>4.1 CH gave an expert witness testimony on pregnant women and women considering pregnancy with heart valve disease.</p> <p>4.2 The committee discussed draft recommendations.</p>			
<p><b>5. Presentation and Discussion</b></p> <p>5.1 ES gave a presentation on the clinical evidence for the patient information and advice review question.</p>			

5.2 The committee discussed draft recommendations

**6. Any other business**

The group discussed next steps and agreed action points.

**Date of next meeting:** 20/11/2020