

**National Institute for Health and Clinical Excellence**

**286/2 – Transcatheter endovascular closure of perimembranous ventricular septal defect**

**Consultation Comments table**

**IPAC date: Thursday 14<sup>th</sup> January 2010**

<b>Com. no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b> Please respond to all comments
1	Consultee 1 Specialist Adviser	1	The 2nd paragraph above outlining the technique needs to be expanded further in order to make the procedure clearer. The current evidence in the literature does not wholeheartedly support the use of this procedure but the overall view is that the procedure has a role but longer term follow up and evaluation is needed. There are several studies (including one multicentre study from Europe) that has expressed concern about the incidence of heart block after closure of perimembranous VSDs with devices. There the recommendations need to be guarded. For all of these patients undergoing the procedure, surgical facilities should be on site rather than have access to them. Otherwise the procedure may be performed in a unit without surgical cover on-site and that would be dangerous. I use many of the devices made by AGA company for many other congenital heart defects.	Thank you for your comment. Section 2.2 of the guidance is intended to be a summary of the procedure and will not be changed. The incidence of heart block is referred to in sections 2.4 and 2.5.1 of the guidance. Incidence is not normally referred to in section 1 of the guidance, which contains the recommendations. Section 1.3 of the guidance will be changed in relation to access to surgical facilities for patients undergoing the procedure.
2	On behalf of BCIS (British cardiovascular Intervention Society Consultee 2	1	BCIS suggest that in view of the risks involved, section 1.3 should be amended as follows: "When carried out on children, this procedure should only be undertaken in specialist paediatric cardiology units. For patients of all ages, this procedure should only be undertaken by cardiologists trained in the technique including the management of complications. There should be access to on-site emergency cardiac surgery by a surgeon experienced in the treatment of congenital heart disease".	Thank you for your comment. Section 1.3 of the guidance will be changed in relation to access to surgical facilities for patients undergoing the procedure.

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3	Consultee 3 NHS Professional	1	Agree with all these.	Thank you for your comment.
4	Consultee 1 Specialist Adviser	2.1	The indications should state clearly the indications for closure of such defects should be similar to surgery in the modern era. Otherwise there will be uncontrolled closure of these defects as is happening in some parts of the world. The indications have to be more clear, particularly because the incidence of complete heart block after surgery is much lower than after device closure. This is even more important to express caution as surgery is usually carried out in much smaller sized babies compared with catheter closure and so the incidence of heart block may be even lower if the same population is compared.	Thank you for your comment. Section 1.2 of the guidance emphasizes the importance of patient selection, section 1.5 specifies research outcomes and 2.5.1 expresses concerns about the evidence on the incidence of heart block. Section 2.1 will be changed to include symptoms of untreated VSD.
5	Consultee 3 NHS Professional	2.1	Significant VSDs require closure in infancy and this is surgical. The remainder are usually very small and no treatment is necessary. There are a very few who fall between these categories with a restrictive defect but some enlargement of the left ventricle. These are the types considered for transcatheter closure and this is not mentioned in the indications. There is no evidence that mild left ventricular enlargement (2SD) due to a VSD is harmful in the longer term and these defects retain the ability to become smaller with time into the third decade.	Thank you for your comment. Section 2.1.1 of the guidance will be changed.
6	Consultee 1 Specialist Adviser	2.2	Very occasionally the procedure may have to be performed from the arterial approach rather than from the venous approach from the right side of the heart.	Thank you for your comment. Section 2.2.1 of the guidance will be changed.
7	Consultee 3 NHS Professional	2.2	Agree.	Thank you for your comment.
8	Consultee 3 NHS Professional	2.3	Agree.	Thank you for your comment.

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9	On behalf of BCIS (British cardiovascular Intervention Society Consultee 2	2.4	The risks of VSD closure are significant and higher than for ASD/PFO closure (see review by Wahl and Meier Heart 2009 95: 70-82). Because of the occasional need for immediate cardiac surgery to treat a serious complication we suggest in Section 1.3 that the procedure requires on site surgical cover by a surgeon experienced in congenital heart disease. Arrangements for distant surgical cover are in our view inadequate.	Thank you for your comment. Section 1.3 of the guidance will be changed in relation to access to surgical facilities for patients undergoing the procedure.
10	Consultee 3 NHS Professional	2.4	The main issue with transcatheter closure of perimembraneous is AV block which can occur late. This is not surprising in view of the proximity of the conducting system. In our audited experience of 12 patients there has been one who developed late bifascicular block with prolonged PR interval. We have also seen aortic regurgitation occur in one patient.	Thank you for your comment. The incidence of heart block is referred to in sections 2.4 and 2.5.1 of the guidance.
11	Consultee 1 Specialist Adviser	2.5	There is no randomised study comparing heart block incidence between surgery and device closure. However, there are papers which deal with the incidence after surgery in a similar age group to the ones undergoing catheter closure and the incidence is lower after surgery. More information and evidence is needed.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
12	Consultee 3 NHS Professional	2.5	This is because you are trying to compare to different things. Surgery is usually performed in infants to treat heart failure and prevent pulmonary vascular disease. Transcatheter closure is performed in older patients and often the indications are not clear. The development of heart block with the risk of sudden death or need for pacemaker implantation (with multiple revisions over a lifetime) is an unacceptable price to pay in this population. In addition the occurrence of heart block after VSD surgery in infancy is now extremely low.	Thank you for your comment. Section 1.3 of the guidance will be changed to differentiate arrangements for the procedure in children and adults.

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