National Institute for Health and Care Excellence

IP237/2 – Percutaneous closure of patent foramen ovale to prevent recurrent cerebral embolic events

Consultation Comments table

IPAC date: 11 October 2013

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Other Healthcare	**1**	We welcome the proposed change from 'special arrangements' to 'normal arrangements' and agree that this is consistent with the published evidence.	Thank you for your comment.
2	Consultee 2 NHS Professional	**1**	The intention of 1.2 is unclear. Most practitioners involved in this field consider that PFO should only be carried out at centres with on-site cardiac surgery. The recommendation could be interpreted to mean the PFO closure can be done at a hospital without on-site surgery provided that arrangements are in place to transfer the patient in the event of a complication requiring surgery. Is that what is intended?	Thank you for your comment. Section 1.2 of the guidance will be changed.

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3	Consultee 3 Specialist Adviser	**1.2**	1.2 is much too woolly. "Arrangements for cardiac surgical support" could mean an agreement with a hospital 100 miles away. It would be much clearer and more readily understood as "should only be performed in units where there is on-site cardiac surgical support in the event of complications". There are several reasons for the importance of this distinction: 1. Using the current wording, any hospital in the country could undertake PFO closure. This is presumably not the intention. 2. Complications requiring urgent surgery do occur, though rarely. 3. Procedural numbers are limited. Within any Region, it is therefore sensible to concentrate expertise in one unit. Considerations such as availability of surgical and cardiac anaesthetic support, echocardiographic expertise, range of equipment, expertise with snare retrieval devices etc. all militate against this Regional unit being other than the Regional Cardiothoracic Unit.	Thank you for your comment. Section 1.2 of the guidance will be changed.
4	Consultee 4 NHS Professional	**1.2**	1.2 Â Suggest should only be performed in units with on-site cardiac surgery	Thank you for your comment. Section 1.2 of the guidance will be changed.
5	Consultee 1 Other Healthcare	**2**	The Central Cardiac Audit Database records that between approximately 800 and 1,100 percutaneous PFO closures have been performed each year in the UK, in the years 2007 to 2011. Â Percutaneous PFO closure is therefore an established procedure and it would be reasonable to list it under section 2 as a current treatment.	Thank you for your comment. Section 2 is intended to describe current treatments other than the procedure under review.
6	Consultee 4 NHS Professional	**2**	BCIS agree	Thank you for your comment.

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7	Consultee 2 NHS Professional	**2**	Has this reference been considered: JAMA 2009;302(3):290-297	Thank you for your comment. The reference cited is: Krasuski RA, Hart SA, Allen D et al. (2009) Prevalence and Repair of Intraoperatively Diagnosed Patent Foramen Ovale and Association With Perioperative Outcomes and Long-term Survival. JAMA 302: 290–7. This was not included in the overview because it describes patients who were incidentally diagnosed with PFO during cardiothoracic surgery. In this study the patients with PFO were not treated by percutaneous closure.
8	Consultee 2 NHS Professional	**3**	The trials of PFO closure compared PFO closure and medical therapy versus medical therapy alone in patients with cryptogenic stroke and PFO. I am unclear why this section refers to failed medical management as an indication for PFO closure. Failed medical management suggests that the person may have had a second episode of embolism. Also, many patients with PFO are treated with anti-platelet therapy rather than anticoagulation - would contraindication to anti-thrombotic medication be a better term? Should penultimate line refer to echocardiography?	Thank you for your comment. Section 3.1 of the guidance will be changed. The third sentence in section 3.2 of the guidance should refer to 'echocardiograph**y**' and will be changed.
9	Consultee 4 NHS Professional	**3**	BCIS agree	Thank you for your comment.
10	Consultee 1 Other Healthcare	**3.1**	Percutaneous PFO closure is considered as an alternative to medical management in patients who have had a first paradoxical cerebral embolic event. Â Failure of medical management (ie a second event whilst the patient was on medication) need not have occurred for percutaneous PFO closure to be considered.	Thank you for your comment. Section 3.1 of the guidance will be changed.

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11	Consultee 1 Other Healthcare	**3.2**	Intracardiac echocardiography is also used for imaging guidance of percutaneous PFO closure.	Thank you for your comment. Section 3.2 of the guidance will be changed.
12	Consultee 4 NHS Professional	**4**	BCIS agree	Thank you for your comment.
13	Consultee 1 Other Healthcare	**4.1**	Previous discussions at Committee recognised that the interpretation of the results of the intention-to-treat analysis of the 980-patient RESPECT trial were complicated by the occurrence of end point events in the PFO closure arm before the device was implanted and an unequal duration of exposure to the risk of recurrence between the two arms. Â The ‘as treated’ (AT) and ‘per-protocol’ (PP) results were also included in the publication and it may be useful to note in the guidance that these results did show statistical significance in favour of percutaneous PFO closure. Â Addition to the guidance could read: “In the same trial, additional analyses conducted on the As Treated (AT) and Per Protocol (PP) cohorts reported statistically significant stroke risk reduction of 72.7% and 63.4%, respectively, when compared to medical management alone (p= 0.0067, p=0.032).”	Thank you for your comment. The 'as-treated' and 'per protocol' analyses will be biased in favour of the intervention, so will not be included in the guidance. For example, if a patient is randomised to closure on day 10 following randomisation, but has an event on day 9, they will not receive the procedure. If such poor prognosis patients were to be excluded from the analysis in the closure arm but not in the control arm (they would not be excluded from the control arm since they would still have complied with their allocation to no closure), this will introduce an obvious bias. Furthermore, if such patients were to be included in the no closure arm on as 'as-treated' basis, the bias would be even larger.
14	Consultee 1 Other Healthcare	**5**	Previous Committee discussions referenced survival data for patients undergoing percutaneous PFO closure in routine clinical practice and entered into the Central Cardiac Audit Database, which seemed very relevant to safety. Â Could these data be included in the guidance?	Thank you for your comment. Section 4 of the guidance will be changed.

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15	Consultee 4 NHS Professional	**5**	no change suggested	Thank you for your comment.
16	Consultee 2 NHS Professional	**6**	It is perhaps surprising that there is no mention of a multidisciplinary approach to patient selection - this is increasingly accepted as appropriate, although evidence is lacking.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
17	Consultee 4 NHS Professional	**6**	no change suggested	Thank you for your comment.