National Institute for Health and Clinical Excellence

812/1 – Percutaneous closure of patent foramen ovale for recurrent migraine
Consultation Comments table

IPAC date: Thursday 15 October 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	A well designed RCT did not show any benefit. How can NICE conclude that "Clinicians wishing to undertake percutaneous closure of PFO..." can get funding for this?	Thank you for your comment. The guidance sets out the conditions under which the procedure should be used.
2	Consultee 2 BCIS advisor	**1**	PFO closure should only be undertaken in units with ON-SITE cardiothoracic surgery. This is also the view of the joint BCIS/BCCA/BCS working group document due to be published later this year.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
3	Consultee 3 NHS Professional	**1**	It may be worth stipulating that patients with refractory migraine are assessed by a neurologist with a special interest in migraine before they are referred to an interventional cardiologist for consideration of PFO closure. Sometimes the cardiologist appears to be asked to see patients with complicated symptoms before there is clarity about the neurological diagnosis.	Thank you for your comment. Section 1.3 of the guidance will be changed.

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4	Consultee 4 Healthcare Other	**1**	AGA Medical is conducting two randomized clinical trials to evaluate PFO Closure in patients with confirmed PFO and chronic migraine headaches: The PREMIUM Trial (Prospective Randomized investigation to Evaluate incidence of headache reduction in subjects with Migraine and PFO Using the AMPLATZER PFO Occluder compared to Medical Management) is a prospective, multi-center (U.S.) randomized, double-blind study to evaluate whether percutaneous PFO closure is effective in reducing the incidence of disabling migraine headaches (headache days) Â in subjects who are refractory to medical treatment. Â Up to 230 patients will be enrolled in this study enrollment is ongoing at this time. The PRIMA Trial (Percutaneous Closure of Patent Foramen Ovale In Migraine with Aura) is a prospective, randomized, multi-center clinical study designed to evaluate the reduction in migraine headache days in patients who undergo closure of the PFO versus patients who remain on standard medical management. Â At least 144 patients will be randomized within approximately 20 institutions in Europe and Canada enrollment is ongoing at this time.	Thank you for your comments. Information on ongoing trials was included in the overview. Section 1.7 of the guidance states that “NICE may review this procedure on publication of further evidence.”
5	Consultee 5 BUPA	**1**	Bupa agrees, especially with 1.7. The association of FPO with migraine is not well established. [Consultee suffers from recurrent migraine]	Thank you for your comment.
6	Consultee 6 BCIS lead for NICE	**1**	BCIS suggest Â 1.5 Â ...arrangements for on site emergency cardiac surgical support.... Â Transfer to remote surgical centres is associated with adverse outcomes	Thank you for your comment. Please see response to comment 2
7	Consultee 6 BCIS lead for NICE		BCIS no change	Thank you for your comment.

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8	Consultee 5 BUPA	**2.1.2**	2.1.2 Is there any evidence that acupuncture is effective for migraine? If not, it seems inappropriate to mention it.	Thank you for your comment. The guidance and overview state that this is sometimes used. The guidance does not evaluate the efficacy of current other treatment options that may be offered to patients.
9	Consultee 5 BUPA	**2.2**	No comment, thank you.	Thank you for your comment.
10	Consultee 6 BCIS lead for NICE	**2.2**	BCIS no change	Thank you for your comment.
11	Consultee 1 NHS Professional	**2.3**	The RCT was well designed and did not show any benefit.	See response to comment 1.
12	Consultee 3 NHS Professional	**2.3**	Perhaps more weight should be given to the MIST study as the only randomised trial of PFO closure. It is difficult to have confidence in non randomised studies in this field.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
13	Consultee 5 BUPA	**2.3.5**	2.3.5 The primary outcome is frequency and severity of migraine - complete closure is a technical, secondary outcome	Thank you for your comment. Section 2.3.5 is the opinion of the Specialist Advisers and will not be changed.
14	Consultee 6 BCIS lead for NICE	**2.3**	BCIS no change	Thank you for your comment.
15	Consultee 1 NHS Professional	**2.4**	in an RCT of 660 patients - which study was that?	Thank you for your comment. The consultee is referring to Taafe et al (2008) which randomised 220 patients each to Amplatzer, CardioSEAL-STARFlex or Helex Occluder (reference 5 in the overview).
16	Consultee 7 Patient	**2.4**	As a patient on the trial - I suffered a severe peritineal bleed post op and was off work for six weeks post procedure but that said do not regret the procedure	Thank you for your comment.
17	Consultee 5 BUPA	**2.4**	No comment, thank you.	Thank you for your comment.

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18	Consultee 6 BCIS lead for NICE	**2.4**	BCIS comment: Â The procedure for PFO closure for all indications (stroke, migraine, embolism in divers) is the same. Â Thus the safety issues and complications arising from the procedure are not likely to be different. Any differences in trial safety outcomes and complications are likely to be due to play of chance. This section should be uniform across the indications for PFO closure.	Thank you for your comment. The Committee considered this comment and decided to change the guidance. The safety sections for each piece of guidance listed by the consultee will be similar.
19	Consultee 1 NHS Professional	**general**	A well designed RCT did not show any benefit - how can the recommendations be so weak? There is no proven benefit of this procedure as far as I view the data.	Thank you for your comment. See response to comment 1.
20	Consultee 2 BCIS advisor	**general**	PFO closure should in my view only be undertaken in centres where there is ON-SITE cardiothoracic surgery. This is also the position of the BCIS/BCCA/BCS consultation document on the same topic which is due to be published later this year	Thank you for your comment. See response to comment 2.

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21	Consultee 7 Patient	**general**	As a patient who undertook this trial and has benefited enormously, I would like to provide details of my experience. Prior to the closure of my PFO i frequently lost two to three days work and was often very ill with pain and vomiting with migraine with aura. Family Events/holidays were often marred by sudden and frequent onset of Migraine with the most horrific Aura, causing me to lose signt in one eye for hours on end and loss of sensation in one side of my face for a few days after an attack.Despite having a retroperitneal bleed post surgery, my life has been changed. I have not been fully cured as I still Â have the occasional migraine, but with no aura, and these are easily managed by my triptan medication, (which had little effect on my migraine with aura). Â I am very pleased that I undertook the procedure and cannot praise the care pf Dr Mullens team at the Royal Brompton highly enough, his follow up care was efficent and thorough. Dr Dowson at Guildford Migraine was excellent, in monitoring the trial and followed me up appropriately.	Thank you for your comment.