

## National Institute for Health and Clinical Excellence

### 853/1 – Percutaneous closure of patent foramen ovale for the secondary prevention of recurrent paradoxical embolism in divers Consultation Comments table

IPAC date: Thursday 15 October 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	1	NICE should prepare a one page summary for patients on this topic	Please respond to all comments Thank you for your comment. NICE is preparing a document for patients called 'Understanding NICE Guidance' which will be published alongside the guidance.
2	Consultee 2 BCIS lead for NICE	1.3	1.3 Â BCIS suggests ... clinicians with expertise in adverse medical effects of diving...	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
3	Consultee 2 BCIS lead for NICE	1.3	1.4 Â ...arrangments for on site cardiac surgical cover.... Â Transfer to remote surgical centres is associated with adverse outcomes	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
4	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	2.1	good	Thank you for your comment.

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5	Consultee 3 Specialist Adviser Health and Safety Executive on cardiological aspects of diving, Treasurer of the UK Sport Diving Medical Committee, Past Consultant to NASA advising on the role of PFO in subatmospheric decompression sickness in astronauts	<b>2.1</b>	Incorrect to state that paradoxical gas embolism in divers only occurs when a diver surfaces too rapidly. Venous bubbles are liberated after many innocuous dives. So decompression illness as a result of paradoxical embolism usually occurs after dives which are considered unprovocative. Typically divers who have decompression illness by this mechanism have performed safe dives, as I first reported in 1986 and has been shown in many subsequent publications in hundreds of divers. The pathophysiology is well understood. Divers who do not have a PFO (or other right to left shunt) get neurological decompression illness either as a result of pulmonary barotrauma causing alveolar gas to invade the pulmonary vein to cause arterial gas embolism, because they have lung disease or make a rapid ascent. The remainder have done an unsafe dive which liberated so many venous bubbles that the alveolar capillary filter was overwhelmed.	Thank you for your comment. Sections 2.1.2 and 2.1.3 of the guidance will be changed.
6	Consultee 2 BCIS lead for NICE	<b>2.1</b>	BCIS no change	Thank you for your comment.
7	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	<b>2.2</b>	good	Thank you for your comment.
8	Consultee 2 BCIS lead for NICE	<b>2.2</b>	BCIS no change	Thank you for your comment.
9	Consultee 2 BCIS lead for NICE	<b>2.3</b>	BCIS no change	Thank you for your comment.
10	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	<b>2.3.3</b>	Section 2.3.3 should come before 2.3.2. Need to include details of the outcome for those divers who continued diving with a PFO	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.

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11	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	<b>2.4</b>	Unbalanced: need to comment on safety of doing nothing. This is like presenting risks of appendicectomy without presenting risk of not operating in appendicitis.	Thank you for your comment. Unfortunately, we are unable to present this data as comparative data were not presented in the literature. The Committee has alluded to the option of doing nothing in section 1.2: "alternative options which may include modifying their diving practice to reduce the risk of gas bubble formation".
12	Consultee 2 BCIS lead for NICE	<b>2.4</b>	BCIS comment: The procedure for PFO closure for all indications (stroke, migraine, embolism in divers) is the same. 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.
13	Consultee 1 Association of British Neurologists Honorary Secretary Consultant neurologist	<b>2.5</b>	Vague. Need more information	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
14	Consultee 2 BCIS lead for NICE	<b>2.5</b>	BCIS no change	Thank you for your comment.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*