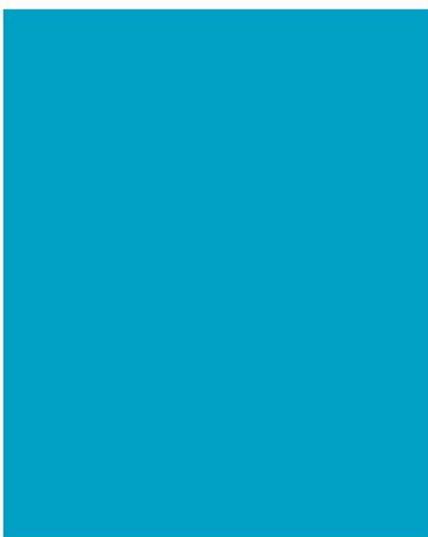


**Clinical Commissioning
Policy Statement: Patent
Foramen Ovale (PFO) Closure**

April 2013

Reference: NHSCB/A09/PS/a



NHS Commissioning Board Clinical Commissioning Policy Statement: Patent Foramen Ovale (PFO) Closure

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POLICY STATEMENT: Patent Foramen Ovale (PFO) Closure	Policy Ref: NHSCB/ A09/PS/a
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Treatment:	Percutaneous Device Closure for Patent Foramen Ovale
For:	The prevention of recurrent stroke
Background:	<p>Closure of patent foramen ovale (PFO closure) is a procedure which involves closing a hole, or potential hole, between the two upper (atrial) chambers of the heart with the aim of preventing recurrent cryptogenic stroke (stroke occurring in the absence of other known causes such as cardiac, pulmonary, vascular or neurological causes).</p> <p>The aim of PFO closure is to prevent recurrent strokes, improve survival and quality of life.</p> <p>The foramen ovale is a channel between the atria of the foetal heart allowing oxygenated blood to bypass the non functioning lungs and flow from the right to the left atrium. This channel is essential during foetal development. When the lungs become functional at birth, the channel usually closes. However, the communication fails to close in a significant minority (15-25%) of adults resulting in a patent (open) foramen ovale (PFO). Some studies have shown that individuals who have a PFO have a higher incidence of arterial emboli, most commonly transient ischaemic attack or stroke, than individuals who do not have a PFO. The causative mechanism for these events is postulated to be the passage of substances (termed emboli, e.g. gas bubbles or blood clots) crossing from the venous circulation or right side of the heart into the left side of the heart through the PFO, and from there into the arterial circulation where they block blood vessels and damage the organ supplied. The most common serious event is a stroke caused by occlusion of one of the arteries supplying the brain.</p> <p>Closure of a PFO is an elective procedure undertaken by a cardiologist on the beating heart. The closure device is inserted via a percutaneous catheter-based delivery system</p>

containing the device in a collapsed state. The delivery catheter is advanced over a guide wire which is introduced via the femoral vein through the inferior vena cava to the right atrium and across the PFO. The closure device is then advanced through the catheter until it reaches the PFO. The device is then deployed across the PFO and the catheter removed. The aim is to reduce the chances of emboli crossing the PFO and causing serious vascular events such as stroke.

The procedure is performed in the catheter laboratory under x-ray guidance and usually takes less than an hour. Patients can be discharged the same day. Over the following months tissue grows into the device to completely seal the PFO.

There are a number of devices that have received a CE mark.

The US FDA has recently removed the Humanitarian Device Exemptions (HDEs) for two Patent Foramen Ovale (PFO) Occluders as they no longer met the essential criteria that the target population for use of the devices be 4,000 or fewer individuals annually.¹

There has been debate about whether or not PFO closure services should be aligned with adult congenital heart disease (ACHD) services but this has been clarified in a recent consultation and review. "Adults living with congenital heart disease" 2012. The paper accompanying the review on the proposed model of care², stated,

1. *The ACHD Advisory Group has advised that closure of patent foramen ovale (PFO) should no longer be considered a part of the spectrum of conditions covered by the term ACHD and the management of PFOs is therefore not covered by this model.*

and

2. *"ACHD INTERMEDIATE CENTRE - LEVEL 2*

Initially likely to apply to de-designated specialist centres.

Network leads would be able to develop further Intermediate Centres (ICs) over time. ... (Intermediate Centres) .will not perform any surgical procedures or catheter interventions. (Closure of PFO is not considered an ACHD procedure and may be delivered in this setting)."

PFO closure may also be carried out if concomitant surgery is being undertaken but there is limited evidence of any benefit

	<p><i>for a specific surgical intervention in trying to prevent recurrent stroke by PFO closure.</i></p> <p>Therefore this policy does not address surgical PFO closure.</p> <p>This policy does not apply to PFO closure for migraine where there is limited evidence of any benefit from the intervention.³</p> <p>Similarly, it does not address percutaneous PFO for the secondary prevention of recurrent paradoxical embolism in divers where the evidence is inadequate in quality and quantity, and the evidence on safety shows that there is a possibility of serious complications.⁴</p>
Commissioning position:	<p>The NHS Commissioning Board will not routinely fund Percutaneous Patent Foramen Ovale (PFO) Closure for the prevention of stroke.</p> <p>There is a current lack of evidence of a suitable quality or statistical significance to demonstrate that percutaneous PFO closure for recurrent stroke shows sufficient benefit for patients. The evidence is not yet of sufficient quality to make a long term judgment regarding whether or not the benefits of percutaneous PFO closure outweigh the risks or that it is good value in the context of the provision of NHS services.</p>
Effective from:	1 April 2013
Evidence Summary:	<p>The prevalence of a PFO in the general population is common with studies suggesting that around 25% of adults (range 15 – 32%) have a PFO. A recent autopsy study found that PFO incidence was similar in men and women, and declined with age. The majority of PFOs were small with a diameter of 5 mm or less.</p> <p>The data from observational studies suggest that this common cardiac anomaly is more prevalent in young (<55 years old) stroke patients in whom nearly 40% of strokes can be described as cryptogenic (stroke with no identified cardioembolic or large vessel source).</p> <p>The British Cardiovascular Intervention Society's (BCIS) analysis of the 2010 audit from the CCAD registry (slides 193 and 194)⁵ shows that 37 units registered 974 PFO closure cases, which was 9.7% more than the number in 2009. This gave an average of 26 cases per unit with a maximum of 96 cases in one year at one unit. 16 centres carried out more than 25 PFO closures in 2010 whilst 15 centres did fewer than 15 and 7 centres performed less than 5 cases per year.</p> <p>NICE IPG 109⁶ states</p> <p><i>Current evidence suggests that there are no major safety</i></p>

	<p><i>concerns and that percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke is efficacious in achieving closure of the foramen. However, its efficacy in preventing future strokes has not been clearly shown.</i></p> <p>A review has been carried out in 2010 but to date the IPG has not been revised.</p> <p>Currently, one published randomised control trial⁷ has tested the clinical efficacy of percutaneous PFO closure compared with standard treatment to prevent recurrent stroke. This recent randomised controlled trial (RCT) did not show evidence of benefit from routine PFO closure in the study population. However, there remains the possibility of clinical benefit from percutaneous PFO closure in selected cases.⁸ Other evidence available to assess the efficacy and safety of PFO closure to prevent recurrent stroke comes from observational studies. Generally the evidence is of limited quality and does not provide clear cut evidence of benefit.</p> <p>There is a clinical expert view that PFO closure is likely to be beneficial in carefully selected individuals and that the RCT might have failed to demonstrate benefit because patient enrolment criteria were not strict enough.</p> <p>The single RCT so far does not demonstrate clinical benefit from the routine closure of PFOs in patients with prior stroke. The trial, however, had low statistical power to detect a difference between the two treatment groups and the results do not exclude a benefit from PFO closure. Recruitment into the trial was slow and there were larger numbers of PFO closures occurring outside of the trial.⁵ It would be beneficial to try to demonstrate clearly if PFO closure in selected patients is worth funding in the long term. Any short term funding should be with a view to support learning from appropriate trials and patient registries.</p> <p>There are trials yet to report (RESPECT, MIST I and MIST II) that may provide further evidence in due course.</p>
<p>Equality Impact:</p>	<p>The NHS Commissioning Board (NHS CB) has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, disability(including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of different protected equality groups in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all the activities for which they are responsible, including policy development, review and implementation.</p>

Responsible CRG:	Complex Interventional Cardiology CRG
Date approved by NHSCB Board:	1 April 2013
Policy review date:	For review during 2013/14
Version:	1

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