SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION CRITERIA FOR CLINICAL COMMISSIONING POLICY PROPOSITION

URN: 1770
TITLE: Percutaneous patent foramen ovale closure

CRG: Cardiac Services
NPOC: Internal Medicine
Lead: Dr Mark Turner
Date: 21 November 2018

This policy is being considered for:	For routine commissioning	X	Not for routine commissioning	
Is the population described in the policy similar to that in the evidence reviewed, including subgroups?	Evidence that PFO closure offers a significant net benefit is limited to younger patients and appears to decline in older patients. PFO closure should be considered very carefully in patients in later middle age as the balance of benefit and risk is increasingly uncertain and the use of anticoagulation may be of equivalent (or greater effectiveness) depending upon the underlying cause of the stroke. There are a number of factors that lead to this conclusion including that: causes of stroke other than PFO are increasingly likely in older patients, and that the disbenefits of long-term anticoagulation use are less in patients initiating therapy at older ages. The evidence and clinical consensus are that PFO closure should only be offered to patients up to the age of 60 years. PFO closure should not be offered to patients 60 years and older due to lack of evidence of net clinical benefit.			
Is the intervention described in the policy similar to the intervention for which evidence is presented in the evidence review?	Yes.			
Are the comparators in the evidence reviewed plausible clinical alternatives within the NHS and are they suitable for informing policy development?	There is evidence that compared to medical therapy (which includes both antiplatelet and anticoagulation therapy) PFO closure in appropriate patients may reduce the absolute risk of stroke by about 1% a year. There is some evidence that anticoagulation may be of similar effectiveness to PFO closure but is associated with a risk of bleeding and that that cumulative risk when used over many years is significant.			

Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	There are risks associated with the procedure. New atrial fibrillation is probably amongst the most significant risks though there are small risks of stroke and other complications. There appear to have been a higher proposition of harms in the CtE compared with the published studies. Efforts to understand why this might be have not produced a clear conclusion. However, these may relate to reversible and minor adverse effects, but it is possible that there could also be a relationship with relative inexperience in PFO closure in some providers.
Are the clinical harms described in the evidence review likely to apply to the eligible and /or ineligible population and/or subgroups in the policy?	Yes.
The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover: • Balance between benefits and harms • Quality and uncertainty in the evidence base • Challenges in the clinical interpretation and applicability of policy in clinical practice • Challenges in ensuring policy is applied appropriately • Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.	Careful patient selection is required. The policy criteria must be amended to eligibility only in patients up to the age of 60 years as this reflects the evidence base and clinical consensus (although Panel recognise that there is a range of clinical opinion). The statement in section 3 '*Such patients tend to be young and consequently the effects of recurrent stroke are more damaging to working and family life*' must be removed as this implies that stroke in older patients may be less damaging and Panel did not think that this was necessarily the case. Stroke can be devastating at any age. The policy proposition helpfully includes audit requirements. This section should be amended to state that these annual audits will be made available to commissioners and should also include the correct procedure code and a requirement that all PFO closure procedures are recorded under one of these codes. Complications rates to be measured by all providers and made available to commissioners. Remove 'adults' from the title and amend to 'up to the age of 60 years'.

Overall conclusion	This is a proposition for routine commissioning and	Should proceed for routine commissioning	X
		Should be reversed and proceed as not for routine commissioning	
	This is a proposition for not routine commissioning and	Should proceed for not routine commissioning	
		Should be reconsidered by the PWG	

Report approved by:

David Black
Deputy Medical Director Specialised Services
07 December 2018

Post Meeting Update

The policy criteria were amended to reflect eligibility only in adult patients aged 60 years or below as this reflects the evidence base.
The statement in section 3 '*Such patients ….*' was removed.

The policy requirements were amended to state annual audits will be made available to commissioners and includes the procedure code and a requirement that all PFO closure procedures are recorded under this code and complications rates to be measured by all providers and made available to commissioners.