Clinical Commissioning Policy: Percutaneous patent foraman ovale closure for the prevention of recurrent cerebral embolic stroke in adults (around the age 60 years and under)

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Contents

Policy Statement

NHS England will commission percutaneous patent foraman ovale closure for the prevention of recurrent cerebral embolic stroke in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain Language Summary

About: Patent Foramen Ovale (PFO) closure for the prevention of recurrent cerebral embolic stroke

The foramen ovale is a small natural channel which allows blood to flow between the two upper chambers of the foetal heart (the left and right atria). In the majority of people this channel closes shortly after birth but in approximately 25% it remains open or ‘patent’ and is referred to as a Patent Foramen Ovale or PFO.

In most adults, a PFO never causes any problems at all. However, in a small minority the channel could be large enough to allow a blood clot which has formed in the veins that return blood to the heart to bypass the lungs (which normally filter such clots out) and instead pass directly into the left side of the heart. From here a clot could travel along the blood vessels to different parts of the body and may cause a blockage. An ischaemic stroke may occur if the blockage happens in a vessel in the brain. If the blockage here is only temporary a brief stroke-like episode called a transient ischaemic attack (TIA) is the result.

About current treatments

Most adults who have had an ischaemic stroke or TIA because of a PFO take regular medications to reduce the clotting tendency of the blood to reduce the chance of another event. These medications are usually anti-platelet drugs such as aspirin or clopidogrel or anti-coagulants such as warfarin or an equivalent.

About the new treatment

An alternative approach to preventing recurrent ischaemic strokes is to block off the PFO using a small closure device. This device is passed through the skin (i.e. percutaneously) into a large vein in the groin and then threaded up into the heart. The device is then positioned across the PFO and deployed so that both ends of the channel are blocked.

What we have decided

NHS England has carefully reviewed the evidence to treat patent foramen ovale with percutaneous PFO closure in those adults who have had a previous ischaemic

stroke. We have concluded that there is enough evidence to make the treatment available.

1 Introduction

Percutaneous PFO closure refers to a minimally-invasive procedure to close a foramen ovale which is a defect in the atrial septum, the structure that separates the two upper chambers of the heart. The foramen ovale normally closes at birth but remains open (patent or persistent) in some people. In those who have an ischaemic stroke of undetermined cause (often referred to as a cryptogenic stroke), there is a greater likelihood that the foramen ovale is patent and its closure may reduce the probability of a further ischaemic stroke.

Percutaneous closure is achieved using an occluder device that is placed under ultrasound and X-ray guidance in a cardiac catheterisation laboratory by a cardiology team with appropriate expertise. During the procedure patients may be sedated or given a general anaesthetic to facilitate transoesophageal echocardiography (TOE).

Percutaneous PFO closure is normally undertaken in adults who have already had an embolic stroke for which no other cause can be identified despite extensive investigations referred to as a cryptogenic stroke. The most likely mechanism by which PFO causes ischaemic stroke is paradoxical embolism: that is the passage of a small venous thrombus from the right side of the heart to the left side being carried in the blood that by-passes the filtering action of the lungs. Once in the arterial system the thrombus may lodge in an artery in the brain and cause an ischaemic stroke.

Adults would normally only be considered for percutaneous PFO closure if they had been proven to have an ischaemic stroke or TIA by brain imaging, have no other evidence of other causes of ischaemic stroke and been shown to have a PFO with appropriate characteristics to make it the most likely explanation of ischaemic stroke.

The clinical problem is that some adults with PFO associated cryptogenic stroke can go on to have further ischaemic strokes despite anti-thrombotic medication. Exposure to the risk of recurrent stroke due to paradoxical embolism may continue over several decades.

The National Institute for Health and Care Excellence (NICE) IPG 472 (2013) reported the optimal treatment for people with PFO who have had a thromboembolic event remains undefined. However, the evidence on the safety of PFO to prevent recurrent cerebral embolic events shows serious but infrequent complications. Evidence on its efficacy is adequate. Therefore NICE considered this procedure may be used with normal arrangements for clinical governance, consent and audit and only be performed in units with appropriate arrangements for urgent cardiac surgical support in the event of complications and details about all people undergoing PFO for this indication should be entered on the UK Central Cardiac Audit Database. NHS England has given due regard to the evidence available when formulating this policy.

2 Definitions

Patent Foramen Ovale (PFO)

The foramen ovale is a small natural channel which allows blood to flow between the Atrial fibrillation (AF)

two upper chambers of the foetal heart (the left and right atria). In the majority of people this channel closes shortly after birth but in approximately 25% it remains open or ‘patent’ and is referred to as a Patent Foramen Ovale or PFO.

A heart condition that causes an irregular heartbeat. It results from loss of co-ordinated contraction of the two atria (the upper receiving chambers of the heart). Non-valvular AF is AF which occurs in the absence of rheumatic mitral valve disease or due to a metallic mitral prosthesis.

Commissioning through Evaluation (CtE): An NHS England evaluation programme whereby a limited number of patients undergo treatments that are not routinely funded by the NHS but have been shown to have potential significant benefit. Treatment is offered within a limited timeframe so that clinical and patient experience data can be collected within this formal evaluation programme to inform NHS England funding decisions.

PFO closure

The use of a device to close a PFO to prevent the flow of blood between the upper chambers of the heart.

Occluder

A medical device designed to close a hole in the heart.

Stroke

A focal area of brain injury due to a disruption in its blood supply.

Ischaemic stroke

A stroke due to blockage of an artery that supplies blood to part of the brain.

Cardio-embolic stroke

A cardio-embolic stroke is one that results from debris or clot in the heart moving into the circulation and blocking a blood vessel supplying brain tissue.

Cryptogenic stroke

A cerebral ischemia of obscure or unknown origin. The cause of cryptogenic stroke remains undetermined because the event is transitory or reversible, investigations did not look for all possible causes, or because some causes truly remain unknown. In the context of younger patients this is where the cause of the stroke remains unknown despite extensive investigations to exclude cardiac and large and small artery sources of thrombo-embolism and pro-thrombotic states or events.

Transient ischaemic attack (TIA)

An episode of focal neurological dysfunction due to a transient interruption in blood supply with symptoms lasting less than 24 hours and without evidence of infarction on brain imaging.

Transoesophageal echocardiography (TOE)

A transoesophageal echocardiogram is an alternative way to perform an echocardiogram. A specialised probe containing an ultrasound transducer at its tip is passed into the patient's oesophagus.

Paradoxical embolus/embolism

A clot which passes from a vein to an artery.

Anti-thrombotic medication

There are two classes of anti-thrombotic drugs: anticoagulants and antiplatelet drugs. Anticoagulants slow down clotting, thereby reducing fibrin formation and preventing clots from forming and growing. Antiplatelet agents prevent platelets from clumping and also prevent clots from forming and growing.

3 Aims and Objectives

This policy considered: the clinical criteria under which NHS England will routinely commission percutaneous PFO closure for the prevention of recurrent stroke.

The objectives were to:

- Determine the clinical effectiveness and safety of percutaneous PFO closure in the prevention of recurrent stroke
- Determine the patient eligibility criteria for percutaneous PFO closure, ensuring the best clinical and cost-effective use and taking account of patient risk stratification
- Ensure robust monitoring and follow up arrangements to enable audit of stroke/other thromboembolic event rate and procedure/device related complications

4 Epidemiology and Needs Assessment

In the UK, there are over 100,000 strokes each year, of which 85% are ischaemic (Stroke Association, 2018). 15-20% occur in people under the age of 60 years.

PFO is the most common association (40-50%) of cryptogenic stroke in adults younger than 55 years (Gonzalez-Alujas et al., 2011; Tobis et al., 2005). The lack of patient modifiable risk factors for cryptogenic stroke leads clinicians and patients to seek to modify risk factors such as PFO in order to reduce the risk of recurrence, in particular for adults who are unable to reduce their overall risk of stroke themselves (Li et al., 2015).

PFO is far more common among cryptogenic cases than in explained cases (OR 6.0 (95%CI 3.7 to 9.7)) (Overell et al., 2000).

However, prospective studies of people with PFO have provided inconsistent findings about stroke risk (Mas et al., 2001; Almekhlafi, 2009).

The recent publication of long term outcomes from randomised controlled trials now provides a much firmer basis for the evaluation of potential treatment benefits.

5 Evidence Base

NHS England has concluded that there is sufficient evidence to support a policy for the routine commissioning of this treatment for the indication.

In coming to this view NHS England has considered the findings of both:

a) a review of the research literature, and

b) an observational registry study commissioned from NICE of adults undergoing PFO closure in NHS England's Commissioning through Evaluation scheme.

   The recently published RCTs, and the systematic reviews and meta-analyses of the pooled outcomes from these RCTs, indicates that for a period of up to median 5.9 years, there is a reduction in risk of up to 3.3% for recurrent stroke for adults with cryptogenic stroke who received a PFO closure device compared with medical therapy alone (MTA) (Shah et al 2018). This compares with a baseline risk of recurrent stroke for adults on MTA of between 4.1% (De Rosa et al 2018) and 4.6% (Shah et al 2018).

Seven studies were included in this review (Shah et al 2018, De Rosa et al 2018, Piccolo et al 2018, Lee et al 2018, Rigatelli et al 2017, Rigatelli et al 2016, Tirschwell et al 2018).

- Two systematic reviews and meta-analyses (SRMAs) (Shah et al 2018, De Rosa et al 2018) and one meta-analysis (Piccolo et al 2018) which compared percutaneous PFO closure (n=1382) and medical therapy alone (MTA) (n=1149) for the prevention of recurrent stroke in people who had had cryptogenic stroke were suitable for inclusion in this review. They all included the same four randomised controlled trials (RCTs) (PC-TRIAL), RESPECT, CLOSE and REDUCE studies). Shah et al (2018) published an update of their SRMA on 25th June 2018, including some amended results, which have been included in the updated Evidence Review.
- De Rosa et al (2018) included the shorter-term outcomes (mean follow up 2.6 years) of the RESPECT RCT published by Carroll et al (2013), whereas Shah et al (2018) and Piccolo et al (2018) included the longer term outcomes (median follow up 5.9 years) of the extended RESPECT RCT (Saver et al 2017), in which there was 27% loss to follow-up. The Shah et al (2018) SRMA was updated on 25 June 2018, and the amended results for all outcomes (recurrent stroke, TIA, major bleeding, atrial fibrillation) are reported in this review.
- In addition, the DEFENSE-PFO RCT (Lee et al 2018) was selected for inclusion as it met the PICO criteria and was not included in any of the SRMAs.
- In addition, two publications from one prospective, non-comparative study of 1000 consecutive people in Italy (Rigatelli et al 2017, Rigatelli et al 2016) reported median 10.5 year outcomes, longer than were available from the SRMAs or any of the individual RCTs.
- One recent cost-effectiveness study which is relevant to the UK was selected for inclusion (Tirschwell et al 2018).

Clinical Effectiveness

- A 3.3% lower absolute risk of recurrent stroke was found in people who had PFO closure (RD: -0.033 (95%CI: -0.062- to -0.004), p=0.037) compared to those who were treated with MTA (Shah et al 2018). This is consistent with the 3.1% lower absolute risk of stroke reported in the SRMA by De Rosa et al (2018). It is likely that there is no reduction in the risk of TIA alone following

PFO closure (Shah et al 2018), although the result reported in the June 2018 update of this paper is not accurate.

- No statistically significant difference was found between groups in any study for all-cause mortality (De Rosa et al 2018); this outcome was not reported in the Shah et al (2018) meta-analysis due to the low number of events.

Safety

- There was no significant difference in the risk of serious adverse events (SAEs) for patients who had PFO closure compared with MTA [25% vs 24% (RD: -0.006(95%CI: -0.036 to -0.048)), p=0.781, I2=31%], with SAEs occurring in about a quarter of patients in both groups (De Rosa et al 2018). SAEs were not clearly defined.
- There was no significant difference in the incidence of major bleeding in patients who had PFO closure compared with MTA [p=0.24 (Shah et al 2018) and p=0.605 (De Rosa et al 2018)].
- Shah et al (2018) concluded that although there was an increased risk of new onset atrial fibrillation (AF), this could not be quantified due to high levels of heterogeneity (I2=81.98%) among the 4 RCTs. The risk difference ranged from 0.006 in the extended RESPECT RCT (PFO closure vs MTA: 7 events/499 patients vs 4/481) to 0.061 in the REDUCE RCT (PFO closure vs MTA: 29 events/441 patients vs 1/223). However, a 3.3% greater absolute risk of new onset AF or atrial flutter for patients who had PFO closure compared with MTA was reported by De Rosa et al (2018) (PFO closure vs MTA: 4.4% vs 1.0% (RD: 0.033(95%CI: 0.012 to 0.054), p=0.002, I2=66%). The proportion of new onset AF which required ongoing treatment or was permanent was not reported in either SRMA.
- In the prospective study of 1000 patients receiving a PFO device, immediate procedural success within 30 days was 99.8%. The PFO device was removed intra-procedurally in two patients (Rigatelli et al 2016, 2017).
- Twenty-six (2.6%) of 1000 PFO device recipients experienced non-electrical complications within 30 days of the procedure, the most common of which was groin haematoma (n=10, 1.0%). Fifty-nine (5.9%) PFO device recipients experienced electrical complications, 49 of which resolved within the

procedure. Permanent AF and permanent atrioventricular block (AVB) were reported in one and three patients respectively and four out of six patients with supraventricular arrhythmia required pharmacological cardioversion (Rigatelli et al 2016, 2017).

- At median 10.5 year follow up, non-electrical complications occurred in 22 (2.2%) out of 1000 patients. The most common were non-cardiac related death (n=13, 1.3%), recurrent stroke (n=8) and device thrombus (n=5). The long term electrical complication rate was 14/1000 (1.4%) which included permanent AF (n=5), paroxysmal AF (n=4) and supraventricular arrhythmia (n=4) (Rigatelli et al 2016, 2017). The proportion of AF which was permanent is lower in this study than the proportion of new onset AF reported in the SRMA by De Rosa et al (2018), suggesting that the majority of AF is temporary or successfully treated.
- The death of one patient (0.1%) was considered device related although no autopsy was performed to confirm this (Rigatelli et al 2016, 2017).

Higher complication rates after PFO closure were observed for some device recipients both within the first 30 days after implantation and longer term (Rigatelli et al 2016, 2017):

- Women were more than twice as likely to have either electrophysiological [OR 2.3 (95%CI 0.5 to 5.1), p<0.001] or acute non-electrophysiological complications [OR 2.1 (95%CI 0.5 to 4.6), p<0.001] within the first 30 days.
- Patients who required a device disk larger than 30mm were between four and five times more likely to experience electrophysiological [OR 5.0 (95%CI 1.2 to 7.2), p<0.001] or acute non-electrophysiological complications within the first 30 days [OR 4.0 (95%CI 0.8 to 6.1), p<0.00].
- Patients who had a large atrial septal aneurysm (ASA) had higher risk of both electrophysiological complications (HR 2.2 (95%CI 0.4 to 3.9), p<0.001) and non-electrophysiological complications (OR 2.9 (95%CI 0.4 to 4.3), p<0.001) at median 10.5 year follow up.
- An increased risk for electrophysiological [HR 2.61(95%CI 0.3 to 4.1), p<0.001] and other complications [OR 3.1(95%CI 0.3 to 5.2), p<0.001] was

also observed for patients whose implant had a mean device size: septum length ratio greater than 0.8.

- A proportion of patients in the RCTs also had an ASA. However, outcomes for PFO closure in patients with concomitant ASA were not reported separately.
- There was heterogeneity among and within the studies for the interventions used (PFO closure devices and medication), the severity of the index stroke or TIA, the proportion of study participants with a moderate or large PFO size and/or a large ASA, and the proportion who had known risk factors for stroke (e.g. hypertension, diabetes, smoking, obesity and oral contraception). This introduces uncertainty about whether all preceding strokes were cryptogenic and associated with the PFO (Shah et al 2018, De Rosa et al 2018, Piccolo et al 2018, Rigatelli et al 2016, 2017).

Cost Effectiveness

- The only PFO closure device included in the cost-effectiveness study by Tirschwell et al 2018 was the Amplatzer device, which is used in current practice. For an undefined sub-population of patients who were recruited to the RESPECT RCT (Saver et al 2017) in the UK, PFO closure reached a cost-effectiveness threshold lower than the NICE threshold of £20,000 after 4.2 years (no confidence interval reported) post treatment.
- Compared to MTA, the incremental cost-effectiveness ratios (ICERs) for PFO closure at 4 year,10 year and 20 year time horizons after the procedure were £20,951, £6887 and £2158 respectively. This was based on incremental costs per patient for PFO closure at 4, 10 and 20 year time horizons after the procedure of +£6071, +£4858 and +2848 respectively.
- The costs are all recent UK costs and NHS costs which means that it is highly likely that the results are reliable and generalisable as long as the patient selection criteria are identical to those used in this UK sub-population (which however was not clearly defined). In addition, indirect costs were not included. This means that the cost effectiveness estimates did not take into account the non-NHS costs of stroke care (social care, personal productivity such as employment etc). Inclusion of these wider costs might increase the estimated cost-effectiveness of PFO closure for this subgroup further.

Commissioning through Evaluation study (CtE)

To clarify the potential benefits of this treatment in NHS settings, 940 adults with PFO were recruited from 19 centres across England, 901 of whom underwent closure through NHS England's CtE scheme. Patients in this scheme were followed up for up to two years.

At the time of reporting to NHS England, analysis was available for the third (notional 1 year) follow up; data were available on 417 (59%) of the 702 eligible adults who had reached this assessment. The adverse events experienced by these patients during a median follow up of 212 days (approx. 7 months) were:

2.2 neurological events per 100 patient years, (95% confidence interval 1.2 to 3.6 events)

2.6 neurological events or deaths per 100 patient years, (95% confidence interval 1.5 to 2.4 events.

In contrast all recent trials, bar one, report that patients undergoing PFO closure experience less than one adverse event per 100 patient years. This suggests that adverse outcomes following PFO closure are more common among procedures undertaken as part of the evaluation scheme than among patients undergoing PFO closure in recently published RCTs. The outcomes of patients within the evaluation scheme appear more comparable with patients in the control (MTA) arms of trials, where the estimated adverse event rates range from 1.3 to 3.4 per 100 patient years albeit that the trial follow up periods (for both MTA and PFO closure groups) are considerably longer (2 to 6 years), giving longer for cumulative adverse events. Comparisons between the NHS CtE study and published RCTs provides some insight into the likelihood of gains in routine practice. Interpretation is not straightforward, not least because patients entering trials are carefully selected and different methods are used for follow up, assessment of outcome and for analysis.

The CtE investigators were unable to identify a UK based model that would assist the economic assessment of CtE; they therefore developed their own Markov model, using clinical data from the RESPECT trial. This analysis concluded that for every

1,000 patients undergoing PFO closure there could be 275 fewer strokes over a lifetime (45-year time horizon). The cost-consequences model indicates that each PFO procedure would cost the NHS £5,360 more per patient undergoing the procedure than MTA (over these 45 years); this after taking account of the costs of treatment, the likelihood of sustaining a stroke and the costs of treatment and care for such events. The additional cost above MTA reduced to £3,733 per patient undergoing PFO when taking into account the societal costs of stroke. This analysis did not however attempt to value the quality of life losses attributable to sustaining a stroke.

6 Criteria for Commissioning

PFO closure will be commissioned for adults around aged 60 years and under, who have suffered ischaemic stroke or TIA with brain imaging abnormalities confirming ischaemic damage, due to paradoxical embolus (where a venous clot has passed through a PFO and caused a stroke).

The age ranges of patient cohorts studied in the RCTs were between 16 and 60 years. The evidence confirms that age is a very good predictor of atherosclerotic disease, which dominates the risk of recurrent stroke in the general population. The impact of a PFO on recurrent stroke risk is clearly discernible in a 50-year-old but far more difficult to establish in patients over 60 where risk of atherosclerotic disease is increasing as is the risk of stroke from other causes. The policy therefore references the age criteria used for trial entry of 60 years or below. If a PFO closure for secondary prevention of stroke is proposed in people under the age of 18 years, they should be referred to a Children's Cardiac Surgical Centre and considered by the relevant MDT. It is recognised that some young people over 16 years of age may also be referred as a new patient to an adult cardiac centre.

The diagnosis of ischaemic stroke or TIA will be supported by clinical assessment and brain imaging. However, it is acknowledged that there are sometimes clear-cut TIA events, particularly in younger people who do not have an MR foot print for very legitimate reasons and these can be referred where there is no explanation for the event other than a PFO. Patients will also have undergone comprehensive

evaluation for the presence of usual stroke risk factors such as hypertension, vascular disease, atrial fibrillation and smoking.

Assessment of PFO

All adults will be discussed at an MDT and the final decision regarding intervention will be taken there.

Stroke or TIA patients where there is a suspicion of PFO should undergo bubble contrast transthoracic echocardiography, including provocative manoeuvres to open a PFO that has no right to left shunt at rest. Transoesophageal bubble contrast echocardiography may be used as an alternative and bubble contrast transcranial Doppler may be used to exclude a PFO. Clinically significant PFOs and those associated with atrial septal aneurysm are more likely to have caused an ischaemic stroke.

Criteria for PFO closure

1. Stroke or TIA with clinical and imaging evidence to support diagnosis (modified Rankin Scale 3 or less).
2. Presence of a PFO with clinically significant shunt or atrial septal aneurysm.
3. Absence of significant atrial fibrillation that warrants anticoagulation. (Patients with other indications for long term anticoagulation, such as previous DVT or PE are less likely to be candidates for PFO closure).
4. Full investigation to identify other explanations for stroke, such as vascular disease (including dissection), hypertension or other risk factors.
5. MDT including stroke clinician and interventional cardiologist consider paradoxical embolus to be the most likely cause of stroke, and do not consider that there are other likely causes.
6. Around age 60 years or under as per the clinical trial criteria.

PFO closure procedure

The PFO closure procedure should be undertaken, following fully informed consent, by a cardiologist experienced in percutaneous procedures on the atrial septum, such as PFO and ASD closure. They should also be trained in managing potential complications of the procedure, such as percutaneous device retrieval and

pericardial drainage (even though these are very rare complications). Ultrasound guidance should be used to access the femoral vein and transoesophageal echocardiography or intracardiac echocardiography coupled with X-ray fluoroscopy should be used to guide the positioning of the PFO occluder. Centres should comply with previous Adult Congenital Heart Disease Guidelines which were supported by British Cardiac Society, British Cardiac Intervention Society and British Congenital Cardiac Association.

The procedure should be performed with arrangements for cardiac surgical back up, even though complications requiring this are extremely rare.

Transthoracic echocardiography should be performed prior to patient discharge to exclude any complications of the procedure.

Anti-platelet, or in some people, anti-coagulant drugs will usually be continued for 6 months post procedure. Long term aspirin is often indicated.

Procedural Complications

Serious complications are very rare. Vascular damage occurred in 0.8% of patients in the RESPECT study but can be reduced by vascular ultrasound to guide the venous puncture. Device embolisation is rare with current devices but follow up echocardiography is required to confirm device position. Atrial arrhythmia is the most common complication but is usually self-limiting and occurs in the first few weeks after the procedure. It remains unclear if there is any excess atrial arrhythmia in the very long term; in the longest and largest study (RESPECT) at mean 2.5 years follow up there was no difference in atrial arrhythmia. There was a slight excess of atrial arrhythmia at mean 5.9 years follow up but this was not statistically significant ($p=0.3$).

Follow up after PFO closure

Follow up may include management of other stroke risk factors if present such as smoking, hypertension and elevated serum cholesterol, as clinically appropriate. Repeat transthoracic bubble contrast echocardiogram, usually after 6 to 12 months or transoesophageal echocardiogram if considered necessary by the cardiology team, should be performed.

7 Patient Pathway

Adults with ischaemic stroke or TIA will be assessed by a neurologist or stroke specialist who will confirm the diagnosis by clinical evaluation and appropriate imaging. Common cause of stroke will be sought but when none can be found, and the pattern of stroke disease is consistent with an embolic mechanism, transthoracic bubble contrast echocardiography should be considered or transoesophageal echocardiography if felt to be indicated.

Adults with a PFO with features suggesting that it may be the cause of ischaemic stroke should be considered by an MDT consisting of a stroke specialist and an interventional cardiologist with expertise in the management of PFO patients. Eligibility for PFO closure should be considered based on the patient selection criteria discussed in section 8.

Follow up will likely be undertaken in the centre in which the procedure was carried out and patients will be seen at least once, including a repeat transthoracic bubble contrast echocardiogram 6 to 12 months after device implantation. Transoesophageal echocardiogram may be appropriate if there is clinical suspicion of device malposition, thrombosis or other complication.

8 Governance Arrangements

It is a requirement that sites will produce information leaflets (clinical indications, clinical benefits, complications, need for follow up, current evidence base and its limitations) for adults about percutaneous PFO closure. Alternatively, implanting sites will have information available via their website.

The use of a Percutaneous PFO occlusion device will subject to the NHS England prior approval system.

A suspected problem (‘adverse incident’) with the medical device should be reported using the Yellow Card Scheme as soon as possible at the following link: https://www.gov.uk/report-problem-medicine-medical-device

9 Mechanism for Funding

The device is excluded from the national tariff and will be funded as a High Cost Tariff Excluded Device to be ordered through NHS Supplychain with reimbursement to Trusts being made against usage by NHS England.

The procedure is included in tariff and will be funded through the routine contract procedures. A specific code exists for percutaneous PFO closure (K16.5 Percutaneous transluminal closure of patent ovale foramen with prosthesis) and maps to HRGs EY22, EC12, EC13 and EC14. All activity must be recorded using these codes.

10 Audit Requirements

Centres must undertake an annual audit of their percutaneous PFO closure programme, reporting efficacy and safety outcomes within the clinical governance structure of their hospital and network. They should contribute to and benchmark themselves against existing and developing regional, national and international data. These audits should include the appropriate procedure code. The audits and their findings should be made available to commissioners.

11 Documents which have informed this Policy

This document updates and replaces Clinical Commissioning Policy Statement: Patent Foramen Ovale (PFO) Closure April 2013 (Reference: NHSCB/A09/PS/a).

For all other indications percutaneous PFO closure is not routinely commissioned.

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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