

**SPECIALISED COMMISSIONING – RESPONSE TO AMENDMENTS REQUESTED TO EVIDENCE REVIEW DURING ENGAGEMENT OR CONSULTATION**

<b>URN</b>	1770
<b>POLICY TITLE</b>	Percutaneous patent foramen ovale closure for the prevention of recurrent cerebral embolic stroke (adults aged 60 years and under)
<b>CRG:</b>	Cardiac
<b>NPOC:</b>	Internal Medicine
<b>Date:</b>	11 April 19

<b>Description of comments during consultation</b>	<p>Papers were submitted during consultation. These were:</p> <ol style="list-style-type: none"> <li>1. Evaluating the cost-effectiveness of percutaneous closure of a patent foramen ovale versus medical management in patients with a cryptogenic stroke: from the UK payer perspective. Hildick-Smith D, Turner M, Shaw L, Nakum M, Hartaigh BÓ, Evans RM, Rhodes JF, Sondergaard L, Kasner SE. J Med Econ. 2019 Feb;22(2):131-139.</li> <li>- Published after preparation of the evidence review. Although this economic appraisal was based on the REDUCE trial cohort, its results were notable by the similarity to those found by Tirschwell et al 2018 based on the RESPECT trial cohort, which is already included in the evidence review. This further study does not therefore materially affect the conclusions of the existing evidence review or affect the guidance within the policy proposition.</li> </ol>
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	<p>2. European position paper on the management of patients with patent foramen ovale. General approach and left circulation thromboembolism. Pristipino C, Sievert H, D'Ascenzo F, Louis Mas J, Meier B, Scacciatella P, Hildick-Smith D, Gaita F, Toni D, Kyrle P, Thomson J, Derumeaux G, Onorato E, Sibbing D, Germonpré P, Berti S, Chessa M, Bedogni F, Dudek D, Hornung M, Zamorano J; Evidence Synthesis Team; Eapci Scientific Documents and Initiatives Committee; International Experts Eur Heart J. 2018 (Oct 25) 00, 1–14</p> <ul style="list-style-type: none"><li>- This position paper is founded on well-conducted systematic literature reviews, came to very similar conclusions to those in the NHS England evidence review, but the position paper was published after preparation of the evidence review. However, the relevant systematic review and meta-analysis (Question 10, Supplementary Appendix 5 available in the supplementary online material to the paper) does not materially affect the conclusions of the existing evidence review or affect the guidance within the policy for people with patent foramen ovale to have access to any PFO device following cryptogenic stroke.</li></ul> <p>3. Cryptogenic Stroke and Patent Foramen Ovale. Mojadidi MK, Zaman MO, Elgendy IY, Mahmoud AN, Patel NK, Agarwal N, Tobis JM, Meier B. J Am Coll Cardiol. 2018 Mar 6;71(9):1035-1043.</p> <ul style="list-style-type: none"><li>- Non-systematic review that presents results from trials already included within the systematic review reported in the evidence review.</li></ul> <p>4. Patent Foramen Ovale after Cryptogenic Stroke - Assessing the Evidence for Closure. Farb A, Ibrahim NG, Zuckerman BD. N Engl J Med. 2017 Sep 14;377(11):1006-1009.</p> <ul style="list-style-type: none"><li>- Editorial that does not present any new evidence.</li></ul> <p>5. Patent foramen ovale closure with GORE HELEX or CARDIOFORM Septal Occluder vs.</p>
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	<p>antiplatelet therapy for reduction of recurrent stroke or new brain infarct in patients with prior cryptogenic stroke: Design of the randomized Gore REDUCE Clinical Study. Kasner SE, Thomassen L, Søndergaard L, Rhodes JF, Larsen CC, Jacobson J. Int J Stroke. 2017 Dec;12(9):998-1004</p> <ul style="list-style-type: none"> <li>- Study protocol for REDUCE trial that does not present any results.</li> </ul> <p>6. close: Closure of patent foramen ovale, oral anticoagulants or antiplatelet therapy to prevent stroke recurrence: Study design. Mas JL, Derumeaux G, Amarenco P, Arquizan C, Aubry P, Barthelet M, Bertrand B, Brochet E, Cabanes L, Donal E, Dubois-Randé JL, Durand-Zaleski I, Ernande L, Finet G, Fraisse A, Giroud M, Guérin P, Habib G, Juliard JM, Leys D, Lièvre M, Lussan JR, Marcon F, Michel P, Moulin T, Mounier-Vehier F, Pierard L, Piot C, Rey C, Rodier G, Roudaut R, Schleich JM, Teiger E, Turc G, Vuillier F, Weimar C, Woimant F, Chatellier G; CLOSE investigators. Int J Stroke. 2016</p> <ul style="list-style-type: none"> <li>- Study protocol for CLOSE trial that does not present any results.</li> </ul>
<p><b>Action taken by Public Health lead</b></p>	<p>Suggested references were checked against the evidence review and read in full text for relevance to the PICO document and methodology.</p>
<p><b>Outcome</b></p>	<p><b><u>New evidence identified by stakeholders that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review</u></b></p>