Consultation Report

Topic details

Title of policy or policy statement:	Percutaneous Patent Foramen Ovale (PFO) Closure for the Prevention of Recurrent Cerebral Embolic Stroke (adults aged around 60 years and under)
Programme of Care:	Internal Medicine
Clinical Reference Group:	Cardiac
URN:	1770

1. Summary

This report summarises the outcome of the public consultation that was undertaken to test the policy proposition. A total of 75 responses were submitted to the public consultation from different organisations or individuals. These came from 14 patients, 5 relatives or friends of a patient, 10 hospitals, 38 clinicians, 1 from industry, 2 from a professional body, 3 non-profit organisations and 2 other individuals.

All of the comments submitted in the public consultation were considered by the Policy Working Group and then by the Internal Medicine National Programme of Care Board.

The following themes related to the policy proposition emerged:

A majority of respondents supported the policy proposition

Of those that did comment, the following themes emerged:

- There was a considerable number of responses regarding the cut off at age 60 in the policy proposition. While the Policy Working Group recognises that paradoxical stroke may occur in patients over the age of 60, the policy proposition reflects the available data from RCTs where patients were aged up to 60 which confirm that age is a very good predictor of atherosclerotic disease, which dominates the risk of recurrent stroke in the general population. Once over 60, the risk of atherosclerotic disease increases, as does the risk of stroke from other causes. The Policy Working Group feels that further research on medical (antiplatelet vs anticoagulation) vs closure therapy in this older age group is required to reduce this uncertainty.

- There were several responses about clarifying the definitions of stroke vs Transient Ischaemic Attacks (TIA), and the use of brain imaging. The Policy Working Group acknowledges 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 this will be clarified in the policy proposition.

- There were several comments regarding the wording about the size of the PFO/shunt and this was clarified in the policy proposition.

- Some other published evidence was identified that had either been included in the updated evidence review document (August 2018) or had not been previously considered as it was published after completion of the evidence review. These papers were considered by the Public Health lead and the conclusions are captured in two Additional Evidence Reports. The evidence section of the policy proposal was updated and reviewed by the Policy Working Group. The PHE assessment of the material papers is that they are supportive of the policy proposition rather than supporting a different position.

2. Background

The Foramen Ovale is a small natural channel which allows blood to flow between the two upper chambers of the foetal heart. In most people this channel closes shortly after birth but in approximately 25% it remains open and is referred to as a Patent Foramen Ovale (PFO). In a small minority of people, the channel could be large enough to allow a blood clot, to travel along the blood vessels and may cause a blockage. A stroke may occur if the blockage happens in a vessel in the brain.

Most people who have had a stroke because of a PFO take regular medications to reduce the clotting tendency of the blood to reduce the chance of another event. An alternative approach to preventing recurrent strokes is to close 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 closed off.

3. Publication of consultation

The policy was published and sign-posted on the NHS England website and was open to consultation feedback for a period of 30 days from 25 February to 27 March 2019. Consultation comments were then shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been considered?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document and why?

4. Results of consultation

There was a total of 75 responses to the public consultation from different organisations or individuals: coming from 14 patients, five relatives or friends of a patient, ten provider organisations, 38 clinicians, one from industry, two from a professional body, three non-profit organisations and two other individuals. Within these there were 138 separate comments that were considered.

- **Has all the relevant evidence been considered?**
  Most of the respondents considered that all the evidence had been considered (64/75).
  Some of those who said 'no' did not give a specific comment (8/75) and three respondents noted more recent evidence from the DEFENSE-PFO study and the cost effectiveness paper from Hildick-Smith et al.
  The Policy Working Group noted that the DEFENSE-PFO and Tirschwell paper were included in an updated evidence review undertaken in August 2018 so had already been considered. The final Evidence Review (August 2018) and the 2 additional evidence reports were shared with the Policy Working Group, Cardiac Clinical Reference Group and the CRG stakeholders to confirm all the evidence considered and the conclusions reached, and which confirm the findings of the main Evidence Review.

- **Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?**
  Most respondents (56/75) felt that the impact assessment had fairly reflected the likely activity, budget and service impact although it was noted that there was some uncertainty as not all the elements had been finalised before public consultation (4/75).

  Of those that answered 'no' the main comment was that it was likely that patients were already in the system as contrary to the commissioning position some hospitals had established waiting lists so although the overall numbers were considered reasonable it may be that initial activity may be higher than anticipated. Conversely there were also comments that it would take time to establish or re-establish referral pathways and networks.

- **Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?**
  The majority of respondents felt that the policy proposition accurately described the current pathway (68/75) but it was noted that that pathway was limited to medical management.

- **Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise because of the proposed changes that have been described?**
  Generally, the responses were indicative of the view that this policy proposition would improve equality and reduce health inequalities.

  The main themes that are identified from responses are:

- There was a considerable number of responses regarding the cut off at age 60 in the policy proposition. While the Policy Working Group recognises that paradoxical stroke may occur in patients over the age of 60, the policy proposition reflects the available data from RCTs where patients were aged up to 60 which confirm that age is a very good predictor of atherosclerotic disease, which dominates the risk of recurrent stroke in the general population. Once over 60 the risk of atherosclerotic disease increases as does the risk of stroke from other causes. The Policy Working Group feels that further research on medical (antiplatelet vs anticoagulation) vs closure therapy in this age group is required to reduce this uncertainty.
- There were a number of responses about clarifying the definitions of stroke vs TIA and the use of brain imaging. The Policy Working Group acknowledges 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 this will be clarified in the policy proposition.
- There were a number of comments regarding the wording about the size of the PFO/shunt and this will be clarified in the policy proposition.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories Level 1 to 4.

- Level 1: There were 15 comments incorporated into the draft document immediately to improve accuracy or clarity.

- Level 2: There were 109 comments / issues that had already been considered by the PWG and CRG in the policy development process and therefore the draft document required no further change.

- Level 3: There were no level 3 comments resulting in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document.

- Level 4: There were four level 4 responses that fall outside of the scope of the policy and NHS England's direct commissioning responsibility.

6. Has anything been changed in the policy as a result of the consultation?

Amendments were made to the policy proposition to clarify the definitions of stroke vs Transient Ischaemic Attack and the use of brain imaging and the size of the PFO/shunt.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

There are no concerns outstanding following the consultation relating to the policy proposition as these have been resolved in the final version. It was noted that research in PFO of patients over 60 years of age would be desirable.