# Consultation Report

## Topic details

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| **Title of policy or policy statement:** | Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation in adults |
| **Programme of Care:** | Internal Medicine |
| **Clinical Reference Group:** | Cardiac |
| **URN:** | 1714 |

## 1. Summary

This report summarises the outcome of the public consultation that was undertaken to test the policy proposal for a one month period. There was a total of 14 responses submitted to the public consultation from different organisations or individuals. These came from one provider, seven clinicians, two from industry, one from a professional body and three other individuals.

All of the comments submitted to the public consultation were considered by the Policy Working Group (PWG) and the Internal Medicine National Programme of Care Board. The following themes related to the policy proposition were:

- A majority of respondents supported the policy proposition
- Of those that did comment the following themes emerged:
    - That given the publication in 2018 of data from the COAPT and MITRA-FR trials in the use of percutaneous mitral valve repair for secondary or functional mitral regurgitation (FMR), there was a view that the policy should also include patients with FMR.
    - The need for a process for centre selection to balance expertise and patient access to ensure safe, sustainable services and equitable access for these very sick patients.

## 2. Background

Primary or degenerative mitral regurgitation (DMR) describes pathology causing structural abnormality of the valve. Whilst there may be an indication for mitral valve surgery in the presence of symptomatic, severe DMR, a significant proportion of patients do not undergo surgery due to advanced age, frailty and co-morbidities. These patients have an increased risk of complications, prolonged intensive care unit stay and mortality which may make a surgical option high risk or inappropriate. Progressive worsening mitral regurgitation however risks decline into a heart failure syndrome whereby the left ventricle struggles to maintain its function.

The percutaneous mitral valve edge-to-edge leaflet repair system offers an alternative approach to treating patients with DMR who may be inoperable or at high surgical risk but would benefit from intervention.

## 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 taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is considered to be 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 14 responses to the public consultation from different organisations or individuals: comprising one provider hospital, seven clinicians, two from industry, one from a professional body and three other individuals.

- **Has all the relevant evidence been taken into account?**
  Nine responses to this question stated that all the relevant evidence had been taken into account.

  Those that did not agree (n=5), did however agree that the evidence for DMR had been accurately described but highlighted the new evidence from the COAPT and MITRA-FR trials in patient cohort with functional MR (FMR). The Policy Working Group was aware of these additional data however a decision was taken to focus on the DMR population based on the strength of the evidence in this cohort. The PWG recognise that, based on these new data, patients with FMR are a different population group with secondary mitral regurgitation, which may benefit from this intervention, albeit with differing pathologies and implications for patient selection and therefore submission of a new policy proposition will be discussed with the Cardiac Services CRG. The additional papers were reviewed by the Public Health lead and an additional evidence form was completed.

- **Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?**

Ten responses to this question agreed that the impact assessment fairly reflected the likely activity, budget and service impact with 3 respondents disagreeing. One respondent agreed with the estimate with regards to the DMR population but felt that the FMR population should also be included. One response felt the numbers were appropriate but that the good geographic coverage is important.
Two respondents felt that although the estimated numbers were appropriate initially, it was likely that numbers would grow more quickly as awareness increased and the referral pathways matured.

The PWG recognise this concern as there was a paucity of data about need; the numbers are a best estimate based on both available epidemiological evidence and also the intention to introduce this therapy in a safe and controlled manner. It was felt that this would enable a managed, stepwise approach through which outcomes and numbers would be closely monitored and further development could be considered if appropriate.

The Commissioning through Evaluation programme selected 3 centres to undertake the procedure for the purpose of collecting data for further evaluation of outcomes. As such, the procedure was not routinely commissioned and therefore not designed to assure equitable geographic access. This also meant referral pathways are necessarily immature. It is intended that if the therapy is commissioned, the aim would be to obtain reasonable geographical coverage and that centres would develop local networks to facilitate access.

One respondent noted that “mitraclip” is one particular brand of device and others are available. The policy title and documents were amended to reflect there is now more than one device available.

- **Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?**
  All respondents to this question agreed that the policy proposition accurately described the current patient pathway.

  Additionally, there was one comment about the importance of both the number and geographic location of commissioned centres given the lack of current referral pathways.

- **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?**
  Overall the responses to this question were indicative of the view that this policy proposition would improve equality and reduce health inequalities as currently there are no active treatment options for this cohort of mainly elderly patients.

There were three main themes from the responses to this question:

- The importance of centre selection to ensure equitable geographic access and good communication around this so referral pathways support access for eligible patients (five responses)
- That the number of procedures and therefore the number of centres commissioned was important in ensuring high quality care (four responses)
- That FMR patients should also be included in the policy proposition (two responses)

## 5. How have consultation responses been considered?

Responses to the specific questions and all comments received have been carefully considered and noted in line with the following categories:

- Level 1: There were no comments incorporated into the draft document immediately to improve accuracy or clarity.
- Level 2: There were 33 comments / issues relating to clinical points and evidence 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 no 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?

No

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

The issue of proposing a new policy for FMR will be raised with the Cardiac CRG. One respondent also asked for other repair approaches and devices to be considered in future, not only this specific approach. This will be raised with the Cardiac CRG and Device Working Groups.