Consultation Report

Topic details

Title of policy or policy statement:	Lung volume reduction by surgery or endobronchial valve for severe emphysema in adults
Programme of Care:	Internal Medicine
Clinical Reference Group:	A01 Specialised Respiratory
URN:	1622

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition for lung volume reduction by surgery or endobronchial valve for severe emphysema in adults. It includes a later stakeholder exercise with an updated Equality and Health Inequalities Impact Assessment following the introduction of a revised process by NHS England.

2. Background

Lung volume reduction (LVR) is an approach which removes the worst affected areas of the diseased lung so that the healthier parts can work better. By removing the enlarged lung air spaces that occur in emphysema less air is trapped so that breathing is more efficient and comfortable. There are two approaches to LVR. One involves surgery to cut out part of the diseased lung; the other is to insert a valve or valves into the airways to stop air from getting into the diseased parts of the lungs.

This policy proposition was originally proposed by the Thoracic Surgery Clinical Reference Group (CRG). When the CRG became part of the Cancer Surgery CRG it was agreed that the Specialised Respiratory CRG would continue the policy work. The purpose of the proposal was to improve equity of access to a service that was already being contracted in parts of England but not all. It was also felt important to describe the central role of an LVR Multi-Disciplinary Team in performing the assessment of a patient as suitable for lung volume reduction and in deciding which approach to use. Subsequently Clinical Panel asked for a single policy to cover the two modalities of lung volume reduction (surgery and endobronchial valve placement).

Stakeholder engagement was carried out and included the Cancer Surgery CRG, the Society of Cardiothoracic Surgery, the manufacturer of the endobronchial valves as well as registered stakeholders of the Specialised Respiratory CRG. Minor amendments were made to the policy proposition and associated papers prior to Public Consultation.

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 28th February 2019 to 27th March 2019. Consultation comments have then been shared with the Policy Working Group (PWG) to enable full consideration of feedback and to support a decision on whether any changes to the policy proposition 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 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

Eleven responses were received as a result of public consultation. These responses came from a patient, a patient organisation, clinicians, professional societies, provider hospitals and a device manufacturer.

- **Has all the relevant evidence been taken into account?**

  Ten respondents considered relevant evidence had been considered. One response from a device manufacturer highlighted five papers which they felt needed to be considered and submitted these to the consultation. The PWG Public Health member has subsequently completed an additional evidence report. Of the papers considered on the umbrella valve it was noted one was a well-constructed trial but overall did not materially change the conclusions of the evidence review and noted most of the published evidence considered the duck bill valve type.

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

  Ten respondents to this question agreed that the impact assessment did fairly reflect the likely activity, budget and service impact. The response submitted by a device manufacturer did not agree as they commented that the policy did not include umbrella- type valves. The PWG felt that as valves are not a high-cost tariff excluded device different types would make no difference to the impact assessment. As they did not feel that the evidence submitted was strong enough to require a change to the policy no amendments to the impact assessment was felt to be required.

- **Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?**

  Six Respondents considered the current pathway was accurately described. Three respondents, including a patient stated that most patients with severe emphysema were not aware of the treatment and did not have access to treatment or had difficulty accessing treatment. Two respondents noted that the NICE COPD Guideline also referenced LVR assessment and treatment. The PWG agreed that the aim in developing the policy is to improve access to the treatment and it is consistent with the NICE COPD Guideline. One respondent described the current pathway within their service and suggested more flexibility within the criteria for selection. The PWG felt it was important to ensure that patients received the most appropriate treatment according to the published evidence for their condition and that the policy proposition treatment criteria should not therefore be amended.

- **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?**

  There were four responses to this question on the promotion of equality and reduction of health inequalities.

  1. One response highlighted that patients were unaware of the treatment being available at some hospitals.
  2. One response identified significant geographical variation.
  3. One response identified that the proposed changes to lung volume reduction procedures would have a positive impact on health inequalities, by equalising access and improving quality of life for all people with emphysema. This was again related to geographical variation. The response highlighted that more men suffer from emphysema than women, and that there are considerable health inequalities related to emphysema (COPD), including socio-economic status, geography, age, gender and occupation. The same response stated that COPD prevalence is around 2.5 times greater in the most deprived 20% of the population.
  4. One response stated that to ensure that the patient has access to all available treatments and does not encounter inequalities the proposal should consider umbrella-type valves as well as duckbill valves. This point does not directly relate to equality but to a type of valve not recommended in the policy proposition.

Subsequently an updated Equality and Health Inequalities Impact Assessment (EHIA) was undertaken and shared with stakeholders of the Specialised Respiratory CRG for thirty days on the 13th April 2020. Three responses were received.

1. One response highlighted that the intervention of LVR was referred to as palliative and did not include any of the evidence relating to significant physical and mental health benefits. The response also highlighted the impact upon people living in remote, rural and island locations.

2. One response submitted a paper which was a re-analysis of NETT data using longitudinal data methods showing sustained improvements to relief of dyspnoea and many other lung function parameters that were not reported in the original trial. This was reviewed by the Public Health Consultant member of the LVR PWG.
3. One response contained observations relating to the impact upon different groups of people either with protected characteristics or groups particularly facing health inequalities.

The PWG revised the EHIA in the light of feedback received from stakeholders.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result 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: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

One response was Level 1. All other PWG responses were Level 2 in nature.

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

In the policy document the sentence relating to emerging technologies in LVR remaining in the research setting now includes a reference to umbrella type valves. All other PWG responses were Level 2 in nature.

The EHIA report was amended following the stakeholder exercise in March 2020 as a number of groups identified as facing health inequalities suffer a higher prevalence of Chronic Obstructive Pulmonary Disease and severe emphysema. These included

- older people
- people from a BAME, Roma and Traveller background
- men, LGBT+ people
- homeless people
- people involved in the criminal justice system
- people with addictions and/or substance misuse issues
- people on a low income
- people with poor literacy or health literacy
- people living in deprived areas
- people living in remote, rural and island locations
- refugees, asylum seekers or those experiencing modern slavery

The findings of the EHIA are that this proposal will contribute to reducing health inequalities as it will improve access to a treatment that is beneficial to a number of groups of people who are both affected by severe emphysema and face health inequalities currently.

Advice from centres with a service is that groups of patients who may face health inequalities have improved access to this treatment, so adoption of this policy will reduce heath inequalities.

The EHIA concluded that the Policy Working Group has identified that the clinical evidence relating to Lung Volume Reduction does not address the issues of health inequalities. However, there is significant evidence relating to COPD and emphysema. The PWG also noted that the Respiratory programme within the NHS Long Term Plan is developing a specific programme of activities to address health inequalities in groups affected by lung disease, so LVR services will need to ensure that this work is used to guide local activities.

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

A patient made the comment that more should be done to make patients aware of the policy consultation process. It was noted the policy development Methods had been followed but this comment about process will be discussed with the Clinical Effectiveness Team.