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Development and implementation of the lung volume reduction pulmonary rehabilitation tool to identify eligibility for lung volume reduction in people with chronic obstructive pulmonary disease during pulmonary rehabilitation

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Abstract

Background: Completion of pulmonary rehabilitation is recognised in chronic obstructive pulmonary disease (COPD) guidelines as a key opportunity to consider systematically whether a respiratory review to assess potential suitability for a lung volume reduction (LVR) procedure might be appropriate. We describe the development of a simple decision-support tool (the LVR-PR tool) to aid clinicians working in pulmonary rehabilitation, to operationalise this process.

Methods: We took an iterative mixed methods approach, which was partnership-based and involved an initial consensus survey, focus groups and an observational study cohort at multiple pulmonary rehabilitation centres.

Results: Diagnosis (97%), exercise capacity (84%), breathlessness (78%) and co-morbidities (76%) were acknowledged to be essential items for assessing basic LVR eligibility. Collating prior investigations and assessing patient understanding were considered useful but not essential. Clinician concerns included; streamlining the tool; access to clinical information and investigations; and care needed around introducing LVR therapies to patients in a PR setting. Access to clearer information about LVR procedures, the clinician's role in considering eligibility and how educational resources should be delivered were identified as important themes from patient group discussions. The LVR-PR tool was considered to be feasible and valid for implementation in a variety of PR services across the UK subject to the provision of appropriate health professional

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training. Clinicians working in specialist LVR centres across the UK who were not otherwise involved in the development process confirmed the tool's validity using the content validity index (CVI).

Interpretation: The LVR-PR tool appears to be an acceptable tool that can be feasibly implemented in PR services subject to good quality educational resources for both patients and healthcare professionals.

Keywords
Lung volume reduction, chronic obstructive pulmonary disease, pulmonary rehabilitation, patient pathway, service imporvement

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Introduction

Lung volume reduction (LVR) procedures have been shown in clinical trials to produce substantial benefits for people with chronic obstructive pulmonary disease (COPD), improving lung function, breathlessness, exercise capacity, quality of life and prognosis.[1–4] However current LVR patient pathways are fragmented and unsystematic.[5] Referrals are often made too late and patients report having to 'fight for a referral', while clinicians describe a lack of clarity about who, when and how to refer.[6]

To address this, the UK National Institute for Health and Care Excellence (NICE) 2019 COPD Guideline Update recommends a three step process; (i) systematically identifying people with COPD who have severe airflow obstruction and limiting breathlessness, but whose exercise capacity is not so limited that LVR cannot be undertaken safely, where the possibility of an LVR procedure should be raised (ii) a respiratory review of these individuals to establish the presence of hyperinflation and emphysema as well as the absence of comorbidities, together with a discussion about patient understanding and preferences. This should lead, where appropriate, to (iii) LVR multidisciplinary team (MDT)* referral to assess technical suitability for lung volume reduction surgery and/or endobronchial valve placement (Figure 1).[7]

This paper focusses on step one of this process, the point where people with COPD complete a pulmonary rehabilitation (PR) programme.[7] At this stage, both medical care and management should have been optimised. If patients continue to experience limiting breathlessness LVR interventions need to be considered systematically. Previous research shows that depending on the breathlessness and exercise capacity criteria used, at this stage between 4.9% and 18.7% of COPD patients completing a PR programme could be considered eligible for onward referral for a respiratory review.[8]

In order to operationalise this guidance, we aimed to develop a decision-support LVR-PR tool reflecting NICE recommendations, that could be adopted by PR services across the UK to facilitate the routine and systematic consideration of all COPD patients accessing a programme, for respiratory review. This should help to address the mismatch between the number who may be eligible and those who are actually referred in a timely way, or at all, for consideration of LVR. Implementing guidelines into clinical practice has been associated with a number of barriers and suggested strategies to address these include decision support systems, education, training and dissemination.[9] Our work uses these strategies to identify and address barriers to NICE LVR guideline[7] implementation.

The tool would include collection of necessary information to support a recommendation that a respiratory review for LVR should be considered or not, as well as the necessary standard text to communicate this, while being usable by PR practitioners who do not have an expert knowledge of LVR.

Methods

We employed an iterative mixed-methods approach to develop the scoring system for the decision-making tool, utilising a 'modified Delphi' methodology[10] as used in other clinical tool development studies.[11–13] This methodology uses elements of a nominal group technique[14] for consensus development. The steps involved included the following: step 1: initial tool development via individual surveys; step 2: stakeholder consultation group interviews and analysis; step 3: assessing external and content validity; step 4: piloting the tool. The development process followed a partnership-based approach whereby the design and improvement stages were collaborative between the research team, those who would use the tool in clinical practice and other key stakeholders,[15,16] and was consistent with the 6SQuID development framework.[17] This provides six essential Steps for Quality Intervention Development in the context of healthcare interventions and was used to identify and plan each stage of this project. A purposive sampling of stakeholders was used for this study.

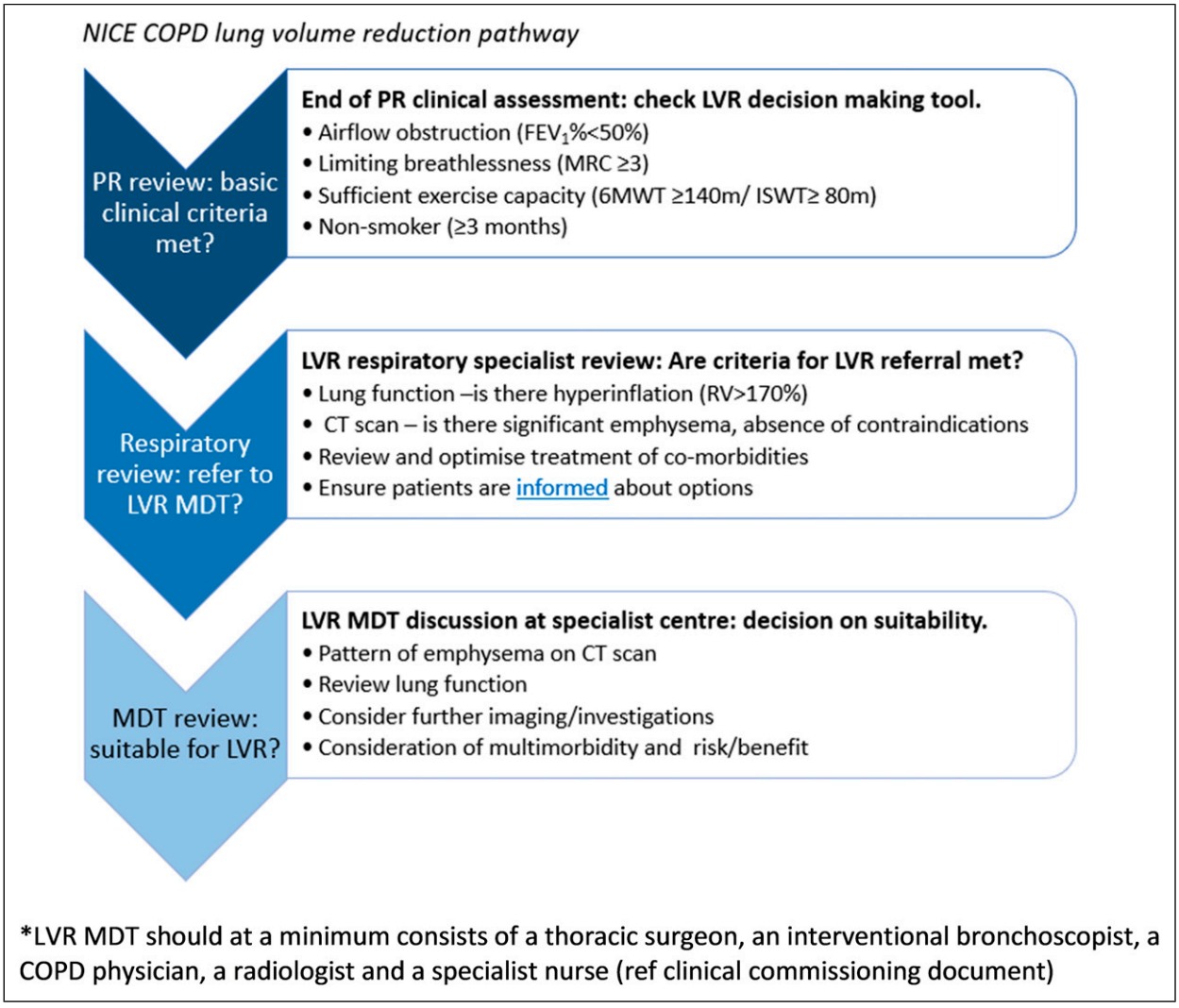


Figure 1. NICE COPD lung volume reduction pathway.

Patient and public involvement statement

Patients who had volunteered to be members of a PPIE group were involved in a consultation group to discuss the development of an LVR-PR decision-making tool.

Step 1: expert survey. We conducted an online survey (Appendix 1) hosted by SurveyMonkey (Momentive Inc, San Mateo, California, USA), of clinical stakeholders from across the UK, including respiratory physicians, thoracic surgeons, interventionists, specialist respiratory physiotherapists, specialist nurses and exercise practitioners. Clinicians were recruited if they had been involved in the Comparative Effectiveness of Lung volume reduction surgery for Emphysema and Bronchoscopic lung volume reduction with valve placement (CELEB) trial,[18] if they were part of a clinical service participating in the King's Health Partners transformation project, or if they were known to the research team as a clinical stakeholder in either an LVR or PR service. The survey was designed based on a scoping review of the literature and guidelines that exist around lung volume reduction pathways. The survey asked about professional identity, current confidence in identifying patients for LVR, involvement in an MDT and/or PR, and views on the necessity of certain measures being included in this decision-making tool. Those invited to take part in the survey were contacted via email explaining why they had been chosen, the current problem and the purpose of the survey. The objective of developing a decision-making tool was also outlined.

Quantitative analysis of closed ended questions converted responses into numerical values (*n* %) to allow trends to be identified. A narrative commentary and visual representation will be used to present these results. The final

question of the survey which was open and allowed free text was analysed by two researchers (SB and NSH) independently, and each comment was considered on an individual basis and used to inform the initial development of the tool.

The results of the survey were used to develop a preliminary working outline of the LVR-PR tool which would then be presented to clinicians, asking those who would be using the tool for further feedback on feasibility and usability, as well as to identify any barriers or extra training that they felt might be required.

Step 2: stakeholder consultation

Clinical specialists. The first stakeholder consultation, conducted in a clinical group including people who would either be responsible for completing the tool at the end of a course of PR or would at least need to be familiar with it. The aim of this focus group was to develop the information gathered from the survey responses and discuss in more detail issues raised, in addition to gaining more insight into the feasibility of implementing the tool and collecting the necessary data, within busy PR programmes.

The meeting was chaired by SB (research physiotherapist) and paraphrased note taking, and transcription was carried out by PW (clinical academic), both experienced in qualitative research and running focus groups. The clinician group one was moderated by NSH (professor of respiratory medicine), an expert clinician in this field with experience in qualitative research methods including conducting focus groups. Further details on interviewer/facilitator characteristics can be found in the online supplement.

Paraphrased transcription of recorded meetings was carried out immediately after, and recordings were then destroyed.

Patient and public involvement. The second group was a patient and public involvement and engagement (PPIE) event consisting of people with COPD. This group was conducted with the aim of examining issues raised in the clinical focus group, particularly relating to how to introduce and educate patients about LVR procedures, and within what environment. Members of the public involved in the PPIE group were shown the online written and video resources that have been developed by Asthma + Lung UK. A+LUK patient information is subject to a formal review process involving clinical experts and patient reviewers every 2 years or more frequently as required. During the PPIE group the moderator role was fulfilled by LB (postgraduate researcher), an expert in PPIE with specialist interests in online PPIE forums. We did not record these meetings, but paraphrased notes were taken during this meeting and used to facilitate future discussion.

The development process for this tool was done as part of a service development programme and the members of the public were part of an already existing Pulmonary Rehabilitation Public Involvement Group. We asked for individuals' opinions about the questionnaire, not for their own experiences and as such ethical approval was not required, as per National Institute of Health Research guidance.[19]

All those involved in the stakeholder consultations were briefed on the purpose of the group, topics that would be discussed, prior to the meetings, and were sent a copy of the proposed LVR-PR tool to review to allow time to formulate relevant questions or thoughts. Participants agreed on ground rules for the running of the meetings and verbally consented to participate. Reimbursement for time was available for individuals taking part in the PPIE event. There were no established relationships between those running the PPIE group and those involved in this group. However, some of those in the clinician focus group had professional relationships with the group facilitators. The outline and aim of the meetings including questions used for discussion in consultation group 1 and 2 are presented as online supplementary material (Appendix 2), and online educational resources which can be accessed here (https://www.asthmaandlung.org.uk/conditions/copd-chronic-obstructive-pulmonary-disease/lung-volume-reduction-procedures).

Results from the stakeholder groups were analysed using a thematic analysis framework based on content analysis, first collecting data, then after familiarisation of the data through individual study and group discussion, themes were drawn. Data from this step are presented in tabular form for the clinician group and from the PPIE event are reported according to the Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF). No direct quotes from the PPIE group are used here as explicit consent was not obtained for this. The meeting was set up and analysed around informal discussion.[20]

Following the stakeholder consultations, the tool was redrafted to reflect findings from qualitative data synthesis.

Step 3: assessing validity. This step involved two strategies to test validity (face and content). First, the tool was sent to members of four PR services within London (Royal Brompton Hospital, Harefield Hospital, Kings College Hospital and Guys and St Thomas' Hospital). Clinicians involved in these services were asked for further comment on the tool, and comments were collected via either a virtual meeting with the PR healthcare professional and research team (SB and PW) or provided over email if this was more convenient. All comments were considered by both SB and PW and then discussed and analysed in a meeting between SB, PW and NSH/LB. The second part involved presenting the tool to PR teams across the UK at 2 specially set up meetings, to gain qualitative feedback. Finally, discussion at a regional specialist LVR meeting was used for further

feedback. These steps were intended to ensure the utility of the tool within variable settings. No consent was taken at these meetings and therefore key points from discussion have been presented, rather than direct quotes. A list of PR centres that were consulted during this process can be found in the online supplement (Appendix 4). Finally, two clinicians from each centre who had been involved in using the tool but were not involved in the focus groups or development of the tool were asked to rate its content validity using the CVI questionnaire. This tool has been previously used in the development of a clinical tool by Corner et al[11] and is the most widely used index when evaluating a tool using a quantitative method.[21] Raters were asked to score each individual item using a four-point scale (not relevant, item needs some revision, relevant, very relevant) and scoring was to be done individually without group deliberation or discussion. The scores would be used to calculate an I-CVI score (validity of each individual item included in the tool) and an S-CVI score (an overall scale validity score). An I-CIV score of ≥0.78 is considered indicative of agreement that the individual item is valid for inclusion and a S-CVI of ≥0.80 suggests that the tool under assessment can be deemed valid and all items are relevant for inclusion.[22]

Step 4: pilot implementation of the LVR-PR tool. Step 4 involved piloting the tool between December 2021 and December 2022 at the 4 hospitals in London (Royal Brompton Hospital, Harefield Hospital, Kings College Hospital and Guys and St Thomas' Hospital) that were involved in the development process to review its feasibility. We asked the PR programme lead at these centres to consider every patient at discharge from PR, against the basic criteria on the final version of the LVR tool. No patient data were collected during this step, only comments on the clinician's opinion and experience of using the tool. As with other steps all comments were considered on an individual basis by the project team (SB, PW and NSH) and used to inform change where indicated. Educational resources that had been developed in line with the consultation group findings, for both practitioners and patients were also sent out to the piloting sites.

Results

37 of 40 clinicians (92.5%) responded to the online survey; 13 consultant physicians, 9 consultant surgeons, 1 speciality trainee, 12 specialist physiotherapists and 2 specialist nurses. 51.4% of respondents were female and 73% within the 35–54 years age bracket (13 (35% 35–44 years and 14 (38% 45–54 years). 60% reported being involved in an LVR MDT, 51.4% were directly involved in a PR programme, and 37.8% were involved in the PR referral process. The remaining 10.8% represented those clinicians that would receive LVR-PR outcome referrals. When asked how confident responders felt in identifying patients who might be suitable for LVR (0 = not confident at all. 10 = very confident) the mean response was 6.2. Figure 2 shows the perceived importance of six key components suggested by literature/guidelines in LVR assessment rated by the survey respondents. All components were voted 'essential' by between 54.1% and 97.3% of respondents with only collating prior investigations and patient understanding being voted 'unnecessary' by 5.4% and 2.7% respectively. The comments collected from the initial survey are summarised and presented in Table 1 and highlight common concern raised by clinicians around the upskilling of PR healthcare professionals in LVR education and some issues relating to implementation of the tool in clinical practice including '*increased referrals to secondary care'* and '*increasing workload for PR services'*.

At this stage, addressing the comments provided involved developing a tool that was sufficient to meet NICE guidance but required the minimum amount of information and specialist knowledge by PR practitioners.

Stakeholder consultation groups

Focus group one was attended by 12 clinical stakeholders working in PR programmes and part of the King's Health Partners Transformation programme. These included 5 band 8 and 2 band 7 physiotherapists, 2 exercise practitioners, 1 band 7 clinical nurse specialist, 1 reader in rehabilitation and 1 professor of respiratory medicine. The main take away points for further development of the tool and in preparing for the second, patient focus group were; streamlining the tool; access to clinical information, investigations and issues around introducing LVR therapies to patients in a PR setting (Table S1) (Appendix 3).

Consultation group two was attended by 10 patients (5 female/5 male), all members of a Pulmonary Rehabilitation Public Involvement Group. All members of the public were retired and had been through at least one course of PR with two attendees completing more than one course. Two of the group members had been considered for an LVR procedure and one had undergone it. The key points that arose from this meeting were the need for clearer information on LVR procedures for patients, the clinician's role in considering eligibility, and how educational resources should be delivered. Comments from this group were used in conjunction with focus group one to understand the importance of how information is delivered and will be used to further develop current educational resources.

Difference in opinion between the two stakeholder groups on how LVR patient discussions are addressed within a PR environment was used to inform the 'patient' domain of the tool. It was decided that clinicians should not be involved in in-depth conversations or decisions around

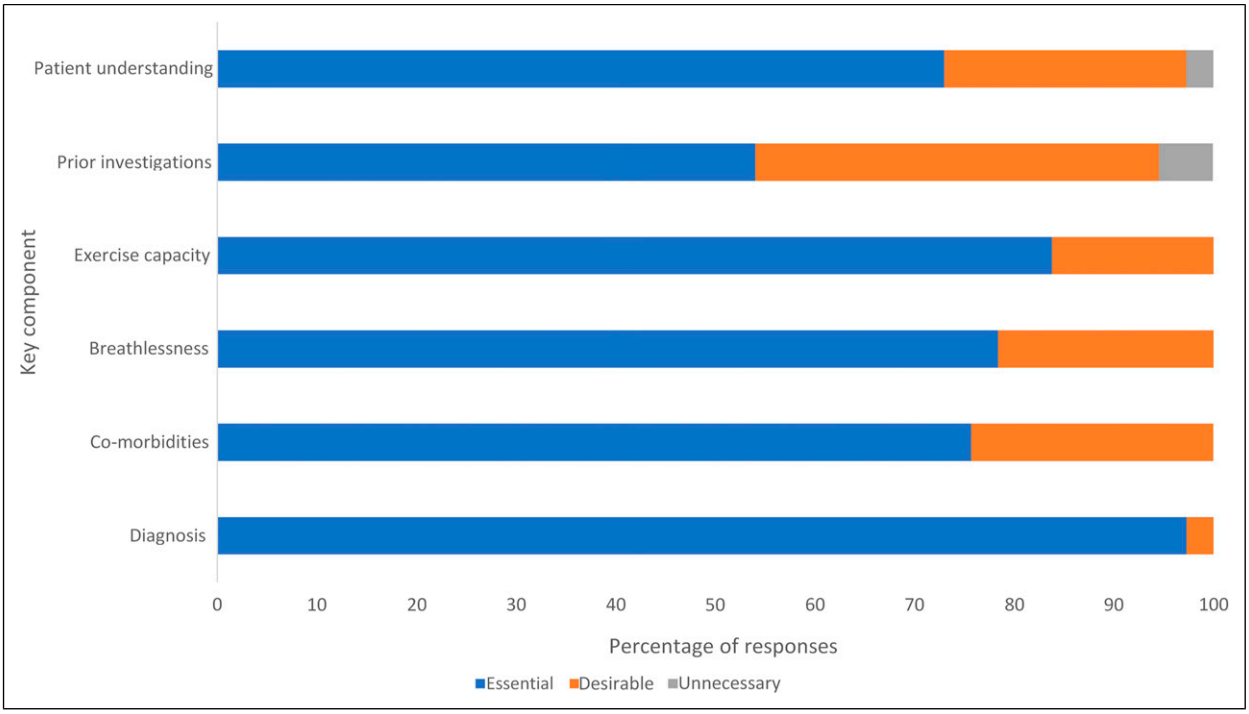


Figure 2. Six key components of an LVR decision making tool.

Table 1. Comments from open-ended survey questions.

Domain	Responder feedback
Further suggestions for inclusion in an LVR decision making tool	Exacerbation frequency/sputum; optimisation of management; smoking history/smoking status/smoking cessation; BMI; substance misuse; lung volumes; previous interventions; patient motivation; oxygen saturations/ABG's; up to date CT scan
Agreement on need for a tool	'If there are clear criteria it seems like a sensible approach' 'Should be routine part of discharge assessment' 'This is how we initially wanted to target patients when starting our MDT.'
Concern over increased referrals to secondary care	'Need to be clear pathways to a specialist clinic for investigation, discussion and selection. A good tool I think therefore would be expected to screen out those clearly unsuitable, and the screening out should be reliable. Those screened in will include a significant number of people ultimately not suitable for LVRS after further testing.' 'Need to ensure that the capacity for timely review in secondary care exists right from the initiation of any tool, otherwise engagement in the process will be low' 'It may well create unprecedented demand!'
Concern over increased workload for PR services	'The work needs to be easy for the rehab team itself and easy to encompass as part of final assessment process, but is likely to create workload for selection clinics, in excess of the increased procedures'
Concern over raising sensitive topics with patients	'Advanced procedures are emotive for patients- potential for a quick and potentially life changing 'fix'. However, as we know benefit depends on accurate patient selection. The initial conversation is key to manage expectations and to be clear that teams do procedures that are likely to benefit patients' 'Change of focus, from self-management to interventions'
Need for further training/educational resources	'Never had any training or information on this so would need some!' 'Little plain English summaries of available LVR procedures exist for HCPs and/or patients' 'If the tool was virtual, perhaps a video explanation may be of great value.'

patient preferences. Instead, they could provide a very brief introduction to patients, requiring only a baseline knowledge of the interventions, and then direct them to additional written or online resources. For this to be effective, it was agreed that quality information would need to be available to signpost patients to and therefore patient resources were refined and included as part of this tool (Table S1).

Assessing feasibility and content validity of the tool

Of the 14 centres that were asked for comment on the tool, all felt that it could feasibly be implemented into their service and the information that was needed to complete the tool was already routinely collected as part of their assessment process. Consensus was gained on the prior investigations component of the tool, but it was agreed that more clarification was needed around which investigations and what timelines. Professionals generally felt comfortable to introduce the tool to patients as part of their educational programme and signpost them to additional educational online resources or provide them with an Asthma + Lung UK leaflet. Clinician educational resources from Asthma + Lung UK were welcomed by those who lacked confidence in their baseline LVR knowledge. Although comments collected were generally supportive of the tool's feasibility, further suggestions collected at this point have been collated in Appendix 6 along with additional comments collected at stage 4.

The LVR decision making tool was found to have an S-CVI score of 0.95 and each individual item achieved a score of 0.78 or greater, suggesting that the tool can be considered valid and no items need deleting or revising (Appendix 5).

Piloting of the tool

The tool was piloted at 4 centres across London who were all part of a King's Health Partners transformation project (Royal Brompton Hospital, Harefield Hospital, Kings College Hospital and Guys and St Thomas' Hospital), over a period of 12 months. Alongside the tool a summary output for clinicians to add to PR discharge summaries was provided (Table 3). Qualitative comments suggested that the tool appeared to be simple to use and feasible to implement in a PR setting. Most suggestions were focussed on the clarity of individual domains of the tool, largely the interpretation of defining significant comorbidities, reliability of patient reported investigations, and when outcomes should be collected/recorded. Changes were made to the final tool to reflect these suggestions (online supplement Appendix 6). There were challenges in collecting quantitative data at this step due to individual site capacity issues.

The development process for this tool began in June 2020 when the first survey was sent out. A final version was drafted in December 2022 and is presented in Table 2. The output summary for use alongside the tool is presented in Table 3. The final version of the tool was shown to three expert clinicians (two physiotherapists and one respiratory physician) that had been involved in different stages of the development process and were from different PR services (one London based service and one North East England service). No further suggestions were proposed at this point.

Discussion

The LVR-PR tool described in this paper has been developed to operationalise NICE recommendations for the systematic assessment of all COPD patients taking part in PR programmes across the UK.[7] This requires considering their eligibility for onward referral within the LVR pathway for an initial respiratory review, with subsequent consideration by a specialist LVR MDT if appropriate. The mixed-methods approach we adopted, following a 'modified Delphi' method and utilising an interventional development framework[17] with wide stakeholder input allowed concerns around implementation to be met. The LVR-PR tool that we present here is not too burdensome for clinicians or patients and should promote the identification of people with COPD eligible for one of these interventions in a timely manner.

We found a broad consensus on which items should be included in a decision-support tool – diagnosis, exercise capacity, comorbidities and breathlessness. For the LVR-PR tool to be useful it would need to be not too burdensome given under-resourced, oversubscribed and time-constrained services.[23] Prior investigations and patient understanding were initially identified as useful but not essential. This was explored further in focus group discussion which revealed that clinicians felt patients were unlikely to be able to provide necessary detail of prior investigations and that searching for such records could be time-consuming, making the tool more burdensome. As multimorbidity is the norm rather than the exception in COPD, the need for clarity around how comorbidity might be considered, and eligibility criteria based on exercise capacity led to small changes to the final tool to make these domains clearer. It was decided that both comorbidity and prior investigations domains would be categorised as desirable rather than essential to ensure the feasibility of PR services adopting the tool.

Patient understanding as a domain in this context was considered of less relevance. Clinicians felt that this should not be explored as part of the initial post-PR eligibility assessment, but instead once a respiratory review had identified whether LVR options might actually be available (NICE step 2/3, Figure 1). This would allow patient decisions and preferences to be meaningful, representing informed choice. There is limited literature on this in the context of LVR, but it has been researched in a lung cancer setting.[24,25] Findings suggest that patient preferences were only selectively taken into consideration and while recommendations were made

Table 2. The lung volume reduction pulmonary rehabilitation tool (final version).

	Referral consideration	When	notes
Diagnosis:	Do they have COPD?		
	Is FEV_1 ≤50% predicted	Assess at beginning or obtain data.	**FEV_1(l):** **FEV_1 % pred:**
	Smoking status	Assess at beginning (and end)	
Breathlessness	MRC dyspnoea score	Assess at end**Consider criteria to flag as possible at baseline? MRC 4 or 5*	**MRC score:**
Exercise capacity	Walking distance	Assess at end **Consider criteria to flag as possible at baseline <300m?*	**ISWT:** **6MWT:**
Patient	Has the patient been introduced to LVR? □ Asthma+Lung UK resource/leaflet provided	Ask at baseline **Consider criteria to flag as possible at baseline?*	
Comorbidities	Do they have a condition that limits survival or ability to benefit from LVR?	Assess at beginning or during programme	**Malignancy** **Frailty** **Severe heart failure**
Prior investigations (only if available)	Have they had a CT scan? (ask patient)	When and where was it performed?	
	Have they had detailed lung function? (ask patient)	When and where was it performed?	
	Have they had an echo? (ask patient)	When and where was it performed?	

Please tick or copy and paste one statement from below into your discharge summary and attach any relevant notes.
Green = essential consideration criteria, Red = desirable consideration criteria.

for more joint decision making, some patients preferred a more directed approach from a professional with in depth knowledge to help weigh up the risks and benefits involved. However, this work largely focusses on different types of treatments rather than if a patient chose to undergo a treatment or not. Studies such as the CELEB trial, comparing the efficacy of LVRS to endobronchial valves[18] will help to facilitate these discussions and assist joint decision making. For the purpose of this tool, it was settled that the clinician should briefly introduce LVR and crucially, provide educational resources, but discussion around patient understanding and also preference should be addressed further down the line with a specialist respiratory physician following review of necessary investigations showing that LVR criteria have been met.

Overall, clinicians who used the LVR-PR tool found it to be feasible to implement in their service. Potential barriers to implementation were raised early in the consensus process which included concerns over professional knowledge in delivering LVR information/education to potential candidates and answering difficult questions, as well as sensitivity around introducing therapies to individuals who may later discover that they are ineligible. To address this education and training resources were developed (healthcare provider and patient) for use alongside the tool, and suggestions for clinicians to provide a very brief introduction to LVR therapies and signpost patients to educational resources were well received. Brief patient education interventions have been used in other areas of COPD management[26] and findings suggest that when

Table 3. The lung volume reduction pulmonary rehabilitation (LVR-PR) text.

☐This person has completed PR – based on NICE criteria they are sufficiently limited by breathlessness to be considered for a respiratory review to see whether a lung volume reduction procedure might be beneficial
- Formal diagnosis of COPD
- FEV_1 <50%
- MRC ≥3
- 6MWD >140 m or ISWT >80 m
- Not a current smoker
- They do not fall outside the established safety criteria and do not appear to have any major co-morbidities that would mean that they are not likely to be suitable
- LVR therapies have been discussed with the patient in broad terms and they have been given the BLF leaflet Lung volume reduction procedures for emphysema
- They report they have had a CT scan of their chest previously Y/N/DK
  - If Y when and where or NK
- They report they have had lung volumes measured (body box) previously Y/N/DK
  - If Y when and where or NK
- They report they have had an echo previously Y/N/DK
  - If Y when and where or NK

☐This person has not completed PR but may be suitable for LVR referral based on baseline assessment- based on NICE criteria they are sufficiently limited by breathlessness to be considered for a respiratory review to see whether a lung volume reduction procedure might be beneficial
- Formal diagnosis of COPD
- FEV_1 <50%
- MRC ≥3
- They do not fall outside the established safety criteria and do not appear to have any major co-morbidities that would mean that they are not likely to be suitable
- Not a current smoker
- LVR therapies have/have not been discussed with the patient
- They report they have had a CT scan of their chest previously Y/N/DK
  - If Y when and where or NK
- They report they have had lung volumes measured (body box) previously Y/N/DK
  - If Y when and where or NK
- They report they have had an echo previously Y/N/DK
  - If Y when and where or NK

☐This person does not meet the criteria to be considered for a respiratory review to see whether a lung volume reduction procedure might be beneficial (tick all that apply)
- No formal diagnosis of COPD
- FEV_1 >50%
- MRC <3
- Their exercise capacity is too limited for a procedure to be undertaken safely
- They are a current smoker

delivered optimally can be effective in improving self-efficacy and reducing burden on healthcare services.[26]

Of note, in the patient PPIE group, which involved presenting the LVR decision making tool and educational resources to people with COPD, there seemed to be less concern among the patient group over the sensitivity of introducing these therapies to those who may not be suitable. Instead, members were more concerned in improving the volume, quality and accessibility of educational resources that are available to them. Comments suggested that they would prefer to be introduced to all existing therapies early in the disease process, to feel educated and allow them to explore all options potentially available to them. This attitude aligns with the self-management and patient empowerment concept that is well documented in COPD care.[27,28] It was suggested that information presented in a group PR setting should provide a broad overview that then signposts patients to more specific educational resources detailing individual therapies, that can be accessed by those who are interested, or are identified as potential candidates. This should facilitate informed patient choice following patient-clinician discussion at a later stage in the LVR pathway. Figure 1 highlights that the LVR referral pathway is a stepwise process and the review of basic criteria within the PR setting is just one step in this process, to identify people who should have a respiratory review as the second step on the LVR eligibility pathway.

A modified Delphi method was used in this study to gain consensus around the use of a decision-making tool within a PR setting, for identifying patients who may be suitable for onward referral for LVR consideration. Consensus methods have been recognised as an important practice for identifying and addressing uncertainly in healthcare settings as well as evaluating validity.[13,21,29] Collecting the views of many stakeholders, including service providers and users through many stages of consensus, enhances the credibility of the development process for this tool. However, the Delphi process can also be associated with limitations that were evident in this project. For example, the opposing views at different stages of development. This required interpretation by the research team which may have introduced bias based on the researcher's baseline knowledge and beliefs. Including a researcher who was not involved in inception of the project would reduce this bias but was unfortunately not used at every step. Additionally, the only stage of development that was anonymous was the expert survey. The importance of anonymity in the Delphi process is well documented and lack of this, coupled with the methods of feedback to participants used may have affected further responses and discouraged honest feedback.[30,31] Although, both the clinician focus group and PPIE group might have been subject to this, the responses appeared to reflect actual beliefs.

Sampling of the stakeholder groups which was purposive, was somewhat limited to those hospitals that were involved in the transformation project and were all London based hospitals with good links to LVR services. However, by presenting the tool at regional meetings and asking for comment we addressed the generalisability of tool acceptability. Introducing a PPIE group in the development process is suggested as a means of improving the relevance and quality of research[20,32,33] and a further strength of this project was including a sample of patients that had all accessed a PR programme and therefore could reflect on prior experience.

Difficulties in collecting outcomes were apparent at some centres due to the COVID pandemic, with one centre being unable to assess against the exercise capacity criteria, due to walk tests not being carried out as part of the assessment process. Although an exercise capacity test is indicated as part of a PR assessment for safety precautions and exercise prescription, for a variety of reasons this may not be achieved.[34] For the purpose of the LVR-PR tool, a future research question remains whether alternative tests of exercise capacity, such as a sit to stand test could be used to identify people in whom LVR may be unacceptably risky. As this work provides only exploratory findings from a service improvement project, research is indicated to evaluate its utility.

The basis of the tool is supported by NICE best practice guidelines and this version is intended as a means of operationalising them. Future work should focus on confirming the reliability and validity of the tool. The development of a digital version of the LVR-PR tool may also help to streamline pathways.

Conclusion

The LVR-PR tool provides a simple mechanism to facilitate the consideration of people with COPD for LVR referral in a systematic manner, within busy PR services. This tool appears to be valid and feasible to implement. However, continuing work will be needed to ensure that educational resources are kept up to date and fit for purpose, to ensure clinicians feel supported in delivering LVR information in a group setting.

Declaration of conflicting interests

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Contributor statement

SB (Bsc Hons) and NSH (MD, PhD) developed the idea for the study with conceptual advice from RAL. SB and PJW (Msc) facilitated stakeholder groups and NSH and LJB (Phd) acted as moderators. LH, KI, MK, MM, LMD, BM, VR were involved in all steps of the development process. CB, AD, GC, HL, LP, and OP were involved in step 3 and 4 of the development process. Qualitative data analysis was carried out by SB and PJW with input from NSH and LJB. Quantitative analysis was carried out by SB. The first draft of the manuscript was written by SB with contribution from NSH. All authors reviewed and agreed on the final version of the manuscript.

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Supplemental Material

Supplemental material for this article is available online.

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