Dear Editor,

The bronchoscopic lung volume reduction treatment using endobronchial valves (EBV) for patients with severe emphysema went through several developmental stages, starting in 2003 [1], with recently positive randomized controlled trials being published [2], leading to the implementation of this therapy in the 2017 COPD (chronic obstructive pulmonary disease) GOLD [3] and National Institute for Health and Care Excellence (NICE) recommendations as well as FDA approval in 2018. Consequently, this treatment is becoming routine care in an increasing number of countries. Since the treatment is only suitable for a carefully selected group of severe emphysema patients, requires significant logistics, costs, and expert skills to perform and to handle its complications [4], its introduction and implementation on a national level should, in our opinion, be carefully guided to fully optimize outcomes and protect patients and physicians from failures. The question rises how to introduce and monitor such a new, promising intervention for a selected and vulnerable group of patients in clinical practice. In this perspective paper, we review the literature regarding the implementation of new interventions and conclude with recommendations from the literature and our clinical experience.

In the literature, no real guidance is given for the implementation of new interventions. The Dutch National Health Care Institute developed a guideline for the introduction of new interventions [5], advising a database development for the purpose of risk analyses, evaluation, and, if necessary, adjustment of processes after implementation. NICE has developed a guideline for the introduction of the EBV treatment in the Netherlands [6], advising a multidisciplinary team (MDT) for patient selection, and clinical outcomes in the short and long term. Currently, a lot of countries have setup registries for the EBV treatment, such as the LIVE study in Germany (NCT01580215), the BreathGroup registry in Italy [9], and an UK registry (ISRCTN16371361). Perhaps, in the future, all could also be combined into one international registry to be able to monitor the treatment at a more global level.

Patient Selection by MDT

Very careful patient selection is key in EBV treatment success. Therefore, besides our local MDT, we started a bi-weekly MDT meeting by videoconferencing with all (experienced and starting) centers in the Netherlands and 1 in Belgium to discuss patient selection, treatment challenges, and complications. These meetings include knowledge of COPD/emphysema, interventional pulmonology, radiology, surgery, rehabilitation, noninvasive ventilation, and transplantation. A nice example of a MDT structure for EBV treatment is described by Chew and Mahadeva [10].

In conclusion, we believe it is crucial to set up a registry to monitor EBV treatment outcomes in routine clinical practice, and to act accordingly. In the Netherlands, we started the BREATH registry (NCT02815683) for this purpose. This registration has a monitoring purpose, can be used for risk analyses, the evaluation of results in clinical practice, and, if necessary, adjustment of processes. This will further optimize the treatment in terms of complications, patient selection, and clinical outcomes in the short and long term. Currently, a lot of countries have setup registries for the EBV treatment, such as the LIVE study in Germany (NCT01580215), the BreathGroup registry in Italy [9], and an UK registry (ISRCTN16371361). Perhaps, in the future, all could also be combined into one international registry to be able to monitor the treatment at a more global level.

Registration Database

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In conclusion, we believe that new treatments reaching the market is not an endpoint but an important starting point. Therefore, it is important to guide the introduction of a new intervention, especially when it is only applicable to a selected group of patients and has known related treatment risks. According to the literature and our experience, important factors in this process are: education, specialized high-volume treatment centers, a mandatory registry, and the use of a MDT and multicenter meetings for patient selection.

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References