

Introduction

Lung Clearance Index (LCI) derived from Multiple Breath Washout (MBW) is a robust measure of ventilation distribution and is an exploratory endpoint in iBEST-1 (1).

Acquisition of good quality MBW data can be influenced by operator training, competence and experience in testing and reporting of the data. MBW set up for clinical trial requires staff training, certification and central "over-reading" for data quality control. Belfast LCI facility performed these functions in the iBest trial.

We have previously reported that training significantly improved knowledge and confidence in MBW testing (2) however further evaluation of training and over-reading processes is essential to inform the inclusion of LCI in future BE studies.

Objective

To summarise the time duration between MBW training & certification and the proportion of tests excluded after over-reading in iBEST-1 .

Methods

Twenty-seven European sites are participating in the LCI sub-study of the in iBEST-1 trial. MBW training was a 1 day face to face session, eLearning tool and mentoring support developed through expert steering group consultation and pilot as part of a Knowledge Exchange programme (PHA HSC R&D).

The programme consisted of 2 hours theory presentation and 5.5 hours hands on calibration and testing. The eLearning tool (Figure 1) provided an interactive platform and a variety of media (slideshow presentations, animation, videos demonstrations) for learning, as well as a point of contact and social media platform for communication.



Figure 1: eLearning tool

The certification process involved the collection of 10 MBW tests per site (5 per operator), including 4 tests from healthy people and 6 people with respiratory disease. 8/10 valid tests were required to complete certification.

Once certified, sites submitted trial MBW data for assessment by a trained "over-reader" using pre-defined criteria (3). Tests were over read by trained personnel at the Belfast centre using SOPs from international expert groups for consistency of scoring.

Site characteristics and the time duration between MBW training & certification are described. The proportion of tests excluded after over-reading are summarised.

Results

A series of 1 day training programmes were delivered by ≥1 clinical researcher certified and experienced in MBW testing using the Exhalyzer® D.

Training

Twenty of the 27 sites participating in the LCI sub-study completed training (Figure 2). Six had previously completed training & certification. One site was unable to participate due to a language barrier.



Figure 2: Location of 20 sites who participated in training

Of the 20 sites that completed training, 12/20 (60%) were MBW naive. 13/20 (65%) completed certification with a mean (range) time since training of 6 (4-14) months. Certification for 5/20 sites is on-going with a mean (range) time since training of 15 (9-24) months. Two sites dropped out (1 no longer had equipment space, 1 no longer had time to participate in LCI sub study).

Over-reading

To date, 205 tests from 10 sites have been submitted. 68/205 (33%) tests were excluded, most commonly due to leak, irregular breathing pattern and technical issues.

Conclusions

- Sites engaged in MBW certification require a mean of 6 months to train and certify in MBW testing for BE trials.
- Study is on-going to reduce time to certification and to determine the support necessary to minimise test exclusion.

Funding: Support received from EU/EFPIA IMI-JU iABC grant n° 115721.

References: 1. O'Neill et al Lung clearance index in children and adults; Chest 2016. 2. . O'Neill et al Training in Multiple Breath Washout (MBW) testing for bronchiectasis (BE) clinical trials; ERS congress 2017. 3. Jensen et al; A Systematic Approach to Multiple Breath Nitrogen Washout Test Quality; PLOS ONE 2016.