Appendix 5

Over-reading training

To certify as an over-reader, as a prerequisite operators were required to have successfully completed their MBW testing certification and have > 1 year experience in testing. Operators completed a 1-day training which involved reviewing the North American MBW Training Centre quality control protocol (http://lab.research.sickkids.ca/ratjen/mbw-centre/), quality control slideshow content, MBW test quality control data collection excel tool and MBW test results collection excel tool. Thereafter, operators completed a full analysis on 20 tests (provided by the North American MBW Training Centre). The outcomes were analysed and compared by against a reference by RJ. Certification in over reading required at least 80% agreement in test outcome. Troubleshooting teleconferences between over-readers in Belfast and the ECFS MBW Central Training and Over-Reading Centre were convened monthly during the studies to discuss and compare over-reading practice in accordance with criteria.

Over-reading

A minimum of 2 technically valid and repeatable tests which represented tidal breathing were required for a valid test in accordance with the consensus statement for MBW[5]. Tests that did not meet the pre-defined criteria were excluded.

Data cleaning

100% of data in both the i-Best-1 and the Cinimetrics study underwent a data-cleaning step to check all data were transcribed correctly. This involved an administrative member of staff (Northern Ireland Clinical Research Network (Respiratory Health)) checking the data entered into excel against the data in the spiroware software of the Ecomedics software. Any transcription errors were logged and highlighted to the original over-reader (KON, KF, DC), who then reviewed and corrected where necessary.

Double over-reading

The double over-reading process involved a second independent over-reader completing full analysis of each testing session and checking inter-rater agreement. The second independent over-reader completed a quality control data collection and results excel tool indicating whether the testing session was accepted or rejected for each testing session. Results from the original over-reader and the second over-reader were compared by an independent checker (JB). Any testing sessions with conflict on whether the tests was accepted or rejected were extracted and meetings were convened to discuss and to reach inter-rater agreement.

The proportion of data double over-read was planned for both studies a-priori. A target of 80% agreement on data was sought (based on 80% agreement required for over-reading qualification).

In the i-Best-1 study the second independent over-readers included KF and DC (75%) and CS and CS (25%). 100% of data in the i-Best study underwent a double over-reading process (funding available). 20/236 (8.5%) testing sessions had conflict on whether the test was accepted or rejected post double over-reading. A further 46/236 (19.5%) tests had differences in mean LCI result calculated (mean difference 0.10 turnovers).

In the clinimetrics study the second independent over-readers included KF, DC and KON (10% of randomly selected data). An initial ~10% of data (n=62 randomly selected) in the clinimetrics study underwent a double over-reading process. On assessment of outcome, no further double over-reading was deemed necessary. 5/62 (8%) testing sessions had conflict on

whether the test was accepted or rejected post double over-reading process. A further 7/62 (11%) tests had differences in mean LCI result calculated (mean difference 0.23 turnovers).

Time and staff capacity required

Researcher delivering the training, certification and quality control/over-reading: The 1 day (8 hours) training was carried out by 1-2 researchers. Re-fresher training and follow up support via telephone, email and webinar was estimated at 1 day (8 hours) per site. Assessment of the MBW data for certification was estimated at 3 days (24 hours, considering 1.5 hours per test x 10 tests plus time for potential repeat tests, collation of results, feedback to the site). To complete quality control of the MBW tests during the trial, 1.5 hours per testing session was estimated (allowing for analysis of the test, completion of the quality control and results excel tool and communication with the site). Double over-reading requires the same amount of time. Operator completing the training and certification: Each operator was required to complete a 1 day (8 hour) training programme. Time for operator certification was estimated at 3 days (taking into account familiarisation with the equipment at site, identification of volunteers for testing, completion of 10 testing sessions, submission of the data and receipt of feedback).