

<b>Institution: Coventry University</b>
<b>Unit of Assessment: 3</b>
<b>Title of case study: Improving outcome measurement in pulmonary and cardiac rehabilitation</b>
<p><b>1. Summary of the impact</b></p> <p>It is important that valid outcome measures are used to assess clinical services and interventions to demonstrate that services are effective. Additionally, outcomes of interventions need to be meaningful to the patients reporting them, as this adds value to the outcome of trials over and above the statistically significant difference derived mathematically. <b>Singh</b> and colleagues explored the minimum clinically important difference of the incremental shuttle walking test for individuals with chronic respiratory disease. As a result of <b>Singh's</b> research, this threshold is now included in international guidelines for pulmonary rehabilitation and has also been introduced into research and practice among people attending cardiac rehabilitation over the last 5 years.</p>
<p><b>2. Underpinning research</b></p> <p>Sally <b>Singh</b> is a Professor of Pulmonary and Cardiac Rehabilitation at Coventry University and is also Head of a busy clinical service.</p> <p>Improving exercise performance is an important therapeutic goal for patients with Chronic Obstructive Pulmonary Disease (COPD) and other chronic respiratory diseases. Both nationally and internationally, <b>Singh</b> is recognised to be a leader in the field of pulmonary rehabilitation. In the early 1990s, <b>Singh</b> et al developed the incremental shuttle walking test (ISWT) as a method of assessing exercise capacity in patients with chronic airways obstruction. The test was found to provide an objective measurement of disability and allowed direct comparison of patients' performance. Further research showed that the results of the ISWT is improved by getting the patients to carry out an initial "practise" walk before commencing the actual test [1]. The ISWT research was extended and found to be suitable for patients with pacemakers and heart failure.</p> <p>In 2008, <b>Singh</b> extended her research on the incremental shuttle walking test and defined a minimum clinically important difference (MCID) [2] in the context of pulmonary rehabilitation. The concept of the minimal clinically important difference was developed to demonstrate the threshold of change that has some meaning for the patient. In the context of a therapeutic trial, laboratory or field exercise, tests are generally used as a proxy outcome that may reflect domestic functional performance. Any positive changes in exercise performance must therefore be perceived as beneficial by the patient. However, the small, statistically significant improvements reported in trials may not necessarily translate into useful recognised benefit to the patients. The MCID overcame this issue and defined the change as required in order to have meaning for the patient. The research monitored the performance of 372 patients in an incremental shuttle walking test before and after a 7-week outpatient pulmonary rehabilitation programme. After completing the course, subjects were asked to identify, from a 5-point Likert scale, the perceived change in their exercise performance immediately upon completion of the incremental shuttle walking test. Two levels of improvement were identified: the minimum clinically important improvement for the incremental shuttle walking test was found to be 47.5m (5 whole shuttle lengths); and in addition patients were able to distinguish an additional benefit at 78.7m (8 whole shuttle lengths).</p> <p>Following the successful implementation of the MCID for the incremental shuttle walking test, <b>Singh</b> collaborated with clinical researchers from Canada to describe the minimum clinically important difference for the complementary endurance shuttle walking test (ESWT) under two different circumstances, pulmonary rehabilitation and pharmacotherapy (bronchodilator) [3].</p> <p><b>Singh</b> also collaborated with researchers in Brazil to determine reference values for the incremental shuttle walking test. The research aimed to determine which anthropometric and demographic variables influence the walking distance achieved in the ISWT in healthy subjects with a broad age range and to establish a reference equation for predicting ISWT for that</p>

population [4].

Further studies by **Singh** and her clinical colleagues provided the evidence for use of the incremental shuttle walking test as the primary outcome measure for low risk cardiac rehabilitation patients [5]. Within cardiac rehabilitation there had been a reliance on laboratory-based measures of exercise capacity. However, the addition of home- and community-based programmes as options for cardiac rehabilitation meant that there was a need for a reproducible and safe measure of exercise outcome that could be used within research and audit of cardiac rehabilitation. ISWT was found to be a suitable outcome measure in this circumstance.

More recently, **Singh** and clinical colleagues evaluated the incorporation of the incremental shuttle walking test as alternative measure of exercise capacity within the BODE index (a tool used by health care professionals to help predict COPD mortality). The incorporation of the ISWT within the BODE index (named the i-BODE) was found to be an independent predictor of mortality in COPD, even when other strong predictors, such as age and smoking history, were adjusted for [6].

### 3. References to the research

1. Jolly, K., Taylor, R.S., Lip, G.Y.H., & **Singh**, S. on behalf of the BRUM Steering Committee. (2008). Reproducibility and safety of the incremental shuttle walking test for cardiac rehabilitation. *International Journal of Cardiology*, 125(1): 144-145 (IF = 5.509; Citations = 8)
2. **Singh**, S.J., Jones, P.W., Evans, R., & Morgan, M.D.L (2008). Minimum clinically important improvement for the incremental shuttle walking test. *Thorax*, 63(9): 775-777 IF 6.525, Journal rank 2/46 Respiratory system. (IF = 8.376; Citations 64)
3. Pepin, V., Laviolette, L., Brouillard, C., Sewell, L., **Singh**, S.J., Revill, S.M., Lacasse, Y., & Maltais, F. (2011). Significance of changes in endurance shuttle walking performance. *Thorax*, 66(2):115-120 (IF = 8.376; Citations 21)
4. Probst, V.S., Hernandes, N.A., Teixeira, D.C., Felcar, J.M., Mesquita, R.B., Gonçalves, C.G., Hayashi, D., **Singh**, S., & Pitta, F. (2012). Reference values for the incremental shuttle walking test. *Respiratory Medicine*, 106(2): 243-248. (IF = 2.585; Citations 8)
5. Robinson, H.J., Samani, N.J., & **Singh**, S.J. (2011). Can low risk cardiac patients be 'fast tracked' to Phase IV community exercise schemes for cardiac rehabilitation? A randomised controlled trial. *International Journal of Cardiology*, 146 (2): 159-163. (IF = 5.509; Citations 3)
6. Williams, J.E.A., Green, R.H., Warrington, V., Steiner, M.C., Morgan, M.D.L., & **Singh**, S.J. (2012). Development of the i-BODE: Validation of the incremental shuttle walking test within the BODE index. *Respiratory Medicine*, 106 (3), 390-396. (IF = 2.585; Citations 5)

#### Key Research Grants:

- Treatments for idiopathic pulmonary fibrosis: a systematic review and economic evaluation Health Technology Assessment £145,064 Co-applicant (awarded May 2012)
- Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) NIHR Programme Grants for Applied Research £1,920,793 Co-applicant (awarded October 2012)
- Effects of continuous Electrical Muscle Stimulation on exercise capacity, physical activity and quality of life in Advanced Chronic Heart Failure patients: a pilot study £158,411 NIHR RfPB. Co-applicant. (awarded Dec 2012)

### 4. Details of the impact

#### Impact on health and welfare (international and UK)

The research of **Singh** and colleagues on the incremental shuttle walking test is cited in the American Thoracic Society and European Thoracic Society Statement for Pulmonary Rehabilitation [a] as well as the British Thoracic Society Guidelines on pulmonary rehabilitation [b]. The importance of the incremental shuttle walking test and associated features of the test, including the minimum clinically important difference will be central to a second statement from the American Thoracic Society and European Thoracic Society examining the use of field exercise tests in chronic respiratory disease (**Singh** - co-chair, anticipated publication date early 2014). In addition,

## Impact case study (REF3b)

the test and the minimum clinically important difference will feature in a third statement that is supported by the European Thoracic Society describing the use of 'functional outcome measures for respiratory disease' (**Singh** - task force member, publication date 2014).

The value of defining a minimum clinically important difference allows clinicians to evaluate the impact of the intervention and assess the clinical effectiveness. Defining the effectiveness of a service is also important to commissioners within the newly formed Clinical Commissioning Groups. To guide the commissioning of pulmonary rehabilitation, the IMPRESS website (a collaboration between the British Thoracic Society and Primary Care Respiratory Group) contains detailed information about the test, the importance of measuring exercise capacity, and the anticipated improvement [c]. Between March 2012 and March 2013 there have been 3582 downloads of the pulmonary rehabilitation guideline from the IMPRESS website. The guideline states -

**Functional exercise capacity:** *of those entering the programme, 1 in 2 should have an improvement above the minimally clinical important difference in their exercise tolerance using a functional exercise test. (ref **Singh** 2008).*

The incremental shuttle walking test is also cited in the 2012 NHS Specification for Pulmonary Rehabilitation, indicating that it is viewed as an important outcome measurement in service development and evaluation [d].

### Impact on practitioners and services (international and UK)

The incremental shuttle walking test has been pivotal to the development and delivery of pulmonary rehabilitation in the UK. The definition of the minimum clinically important difference has supported the delivery of a quality assured service and this has now been extended to the delivery of cardiac rehabilitation programmes. In addition, the incremental shuttle walking test is used to assess the need for oxygen therapy in patients with chronic respiratory disease. The usefulness of the test was described by Sandland et al [e]. Hogg et al give an example of a service using the minimum clinically important difference of the incremental shuttle walking test to demonstrate the effectiveness of their pulmonary rehabilitation programme [f].

The incremental shuttle walking test and its minimum clinically important difference has been taken up internationally and they are now recommended for the measurement of exercise capacity in the Pulmonary Rehabilitation Toolkit of the Australian Lung Foundation [g].

Data from the incremental shuttle walking test has been included in the National Audit of Cardiac Rehabilitation (NACR), into which 75% of the 375 cardiac rehabilitation programmes within England, Wales and Northern Ireland report. The minimum clinically important difference is now being used to evaluate the relative merits of cardiac rehabilitation across the UK. The incremental walking shuttle test has also been validated in other clinical populations (including low back pain [h] and a modified version described for the assessment of cystic fibrosis), extending the scope of practice for many health care professionals to evaluate their interventions objectively. The incremental shuttle walking test has been deployed as a primary outcome measure for a number of research studies, particularly in chronic respiratory disease, and is used to define responders to rehabilitation and foster the development of enhanced rehabilitation services for patients with chronic respiratory disease.

The minimum clinically important difference is valuable to researchers and allows studies to be powered adequately. This has included therapy trials [i,j] and pharmaceutical trials. This is important as conventionally pharmacological trials for patients with respiratory disease have relied on primary outcomes that are of little relevance to individuals. Exercise performance is an important patient reported outcome and the incremental shuttle walking test is increasingly being used in the context of pharmaceutical trials [k]. The test has also been employed by large pharmaceutical companies in phase 3 trials (including, GSK, AstraZeneca, Merck, and Boehringer-Ingelheim). Through engagement with industry and the use of the test in clinical trials, 350 people have been trained to use the test for two of the major pharmaceutical companies (150 at GSK and 200 at Boehringer Ingelheim).

**Practitioner training (UK)**

The incremental shuttle walking test is integrated into the curriculum of a number of physiotherapy degree courses across the UK and Ireland (including Trinity College Dublin, Oxford Brookes, Sheffield Hallam). The test is also presented within MSc modules for advanced respiratory care or specifically pulmonary rehabilitation modules and post graduate courses (University College London – MSc Advanced Cardio-respiratory physiotherapy course, University Hospitals of Leicester NHS Trust post graduate course on pulmonary rehabilitation). The test is therefore introduced to practitioners as part of an advanced curriculum.

**Conclusion**

**Singh** and colleagues have explored the minimum clinically important difference of the incremental shuttle walking test for individuals with chronic respiratory disease. Their research has had impact on the health and welfare of individuals, on practitioners and services, and on practitioner training. As a result of **Singh's** research, this threshold is now included in international guidelines for pulmonary rehabilitation and has also been introduced into research and practice among people attending cardiac rehabilitation over the last 5 years.

**5. Sources to corroborate the impact**

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- c. [http://www.impressresp.com/index.php?option=com\\_content&view=article&id=38&Itemid=325](http://www.impressresp.com/index.php?option=com_content&view=article&id=38&Itemid=325)
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