# Preliminary Testing of the Idiopathic Pulmonary Fibrosis Patient Reported Outcome Measure (IPF PRoM)

A. Russell[1], M. Wickremasinghe[2], L. Saketkoo[3], Z. Borril[4], S. Fletcher[5], H. I. Adamali[6], A. U. Wells[7], T. M. Maher[8], E. A. Renzoni[9], S. Fleming[10], P. Cullinan[8]; [1]National Heart and Lung Instituite, Imperial College & Royal Brompton Hospital, London, United Kingdom, [2]Imperial College NHS Trust, London, United Kingdom, [3]Tulane Univiersity, New Orleans, LA, United States, [4]The Pennine Acute Hospitals Trust, Manchester, United Kingdom, [5]Southampton University Hospitals NHS Trust, Southampton, United Kingdom, [6]North Bristol Lung Center, Bristol Interstitial Lung Disease Service, Bristol, United Kingdom, [7]Respiratory, Royal Brompton Hospital, London, United Kingdom, [8]Imperial College, London, United Kingdom, [9]Interstitial Lung Disease Unit, Royal Brompton Hospital/Imperial College, London, United Kingdom, [10]Royal Brompton Hospital, London, United Kingdom.

**Corresponding author's email: amrussell20@gmail.com**

Introduction The Idiopathic Pulmonary Fibrosis (IPF) Patient Reported Outcome Measure (PRoM) was developed to be concordant with the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) criteria [1] and the UK National Institute of Healthcare Excellence (NICE) guidelines [2]. The 12- item questionnaire has four domains with 3 items and 4 response options. The maximum possible score is 12 per domain. An additional global health score has 5 options. Higher scores are associated with worse health status. The IPF PROM is undergoing longitudinal validation in a UK population. Methodology: The development of the IPF-PROM was robust, using mixed methods embedded in patient-centred design. To test the reliability of this new instrument 85 patients recruited form 5 UK NHS centres completed the 12-item IPF-PRoM at time points (TP) two - four weeks apart. The domains record physical experience of breathlessness; psychological experience of breathlessness; emotional well-being and energy level. 85 patients continued into the validation study completing the MRC breathlessness scale; EQ5-D generic health measure; IPF-PROM and FVC at baseline. All questionnaires were completed at three monthly intervals with FVC recorded six monthly. Twenty patients are completing weekly FVC measurements using hand-held spirometer with telephone support. Results The IPF-PROM has good test-retest reliability between TP1-TP2. See table one. The mean timeframe was 20.69 days. Validation study baseline characteristics: 85 participants; male n= 68 (80%); mean MMRC breathlessness score 1.95 (±1.18). EQ5D domains: mobility 2.43 (±1.21); self-care 1.75 (±1.07); usual activities 1.57 (±1.18); discomfort/pain 2.19 (±1.13); anxiety/discomfort 1.98 (±1.04); VAS score of health today 56.18 (±25.78). FVC 2.58 (±0.65) FVC %predicted 63.38 (±31.77); DLCo 3.62 (±2.03); DLCo %predicted 30.55 (±16.3). The mean global health score for the IPF PROM was 2.84 (±0.81); domain1 7.47 (±2.27); domain2 7.66 (±2.70); domain3 6.49 (± 2.37) domain 4 7.42 (±2.30) and total scores 29.05 (±8.61). Total scores for the IPF-PROM correlated strongly with MMRC (Rˢ0.701 p=0.00001); and with the EQ-5D Self-care domain (Rˢ0.299 p=0.005). Discussion The IPF-PROM is a short easy to use questionnaire that is acceptable to patients. Reporting on longitudinal data will continue to add to the field. This work is supported by

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| Domain | t-statistic | p-value | ICC |
|---|---|---|---|
| 1 | -1.272 | 0.209 | 0.835 |
| 2 | 1.458 | 0.15 | 0.895 |
| 3 | 0.273 | 0.786 | 0.813 |
| 4 | 0.305 | 0.761 | 0.863 |
| Total | 0.275 | 0.784 | 9.24 |

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