Abstract M264 Table 1 Characteristics of the patients at baseline

	Pirfenidone N=96
Age – years (range)	67.1+/-8.1 (47–83)
Male sex - no (%)	71 (73)
BMI (range)	28+/-7.9 (14.4–43.4)
Former Smokers - no (%)	64 (66%)
Duration of Treatment – months (range)	9.3+/-8.3 (0–32)
FVC% Predicted (range)	72.9+/-23.1 (46–146)
FVC 51–80% Predicted - no (%)	69(72%)
FVC >80% Predicted – no (%)	20 (20%)
DLCO% Predicted (range)	43.6+/-19.9 (14–87)
DLCO <25% Predicted or unable – no (%)	12 (12)
DLCO 26–35% Predicted – no (%)	24 (25)
DLCO 36–65% Predicted – no (%)	45 (47)
DLCO >66% Predicted – no (%)	7 (7)
Use of supplementary oxygen - no (%)	22 (23)
Use of prednisolone – no (%)	26 (27)
Use of N-acetylcysteine – no (%)	22 (22)

Based on an annual unit cost of £22, 245.96 for pirfenidone (without undisclosed discount). To date 96 patients have been treated for a total of 876 months at a total cost of £1,623,955 in two and a half years.

Conclusion This study highlights both the health and economic impacts of pirfenidone over a two and a half year period of prescribing.

REFERENCES

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M265 DAILY ACTIVITY MONITORING IN IDIOPATHIC PULMONARY FIBROSIS

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Introduction Idiopathic pulmonary fibrosis (IPF) is an incurable chronic progressive lung disease with a poor prognosis. Decline in forced vital capacity (FVC) is the primary outcome measure in most clinical trials. However, slowing lung function decline does not translate into patients feeling better. We investigated the acceptability of activity monitoring as a patient centred outcome measure in IPF and correlated results with lung function and quality of life (QoL) measures.

Methods IPF Subjects underwent activity monitoring 23 h a day for a minimum of 8 days using the SenseWear armband (Bodymedia, Philadelphia). Monitoring data from the first and last monitored days were discarded to prevent clinic visits impacting the results. Participants completed the St George's Respiratory Questionnaire (SGRQ) as a QoL measure. Lung function measurements performed within 3 months were collected and correlations assessed using Pearsons correlation coefficient. Data are presented as mean±SD.

Results 17 IPF subjects (Age 76 ± 6.3, 82% males, FVC%predicted 82.3 ± 16.1%, TLCO% predicted 48.3 ± 13.3%) were monitored. There was excellent compliance – armbands were worn for an average of 23 h and 9 min per day (range: 22 h and 10 min to 24 h) for 6.2 ± 0.6 complete days. Activity levels measured in METs were 1.25 ± 0.2 with a daily step count of 3364 ± 2504. IPF subjects were physically active (METs >3) for 83.8 ± 57.4 min per day. Mean daily METs inversely correlated with SGRQ score (r=-0.64, p = <0.01). Mean daily METs correlated with FVC (% predicted) (r = 0.50, p = 0.04) but there was no correlation with TLCO (% predicted) (r = 0.39, p = 0.13). Conversely TLCO inversely correlated with SGRQ score (r=-0.55, p = 0.03) but FVC did not (r=-0.29, p = 0.26).

Conclusion Activity monitoring is an acceptable, well tolerated means of measuring functional status in IPF patients. Mean daily activity level correlates well with QoL measures and FVC. Neither individual lung function measurement performed as well in terms of correlation with QoL and activity level. A larger longitudinal study is required to further evaluate the role of activity monitoring in IPF and identify its utility in prognostication.

M266 DEVELOPMENT OF AN IDIOPATHIC PULMONARY FIBROSIS (IPF) PATIENT REPORTED OUTCOME MEASURE (PROM): AN ITERATIVE APPROACH TO ITEM GENERATION

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Introduction Patients diagnosed with IPF experience debilitating symptoms which impact upon quality of life. To date there is no curative treatment and the tolerability andefficacy of existing andemergent therapies require further evaluation. We are developing a new concise IPF-PRoM (according to FDA criteria[1]) for use as a primary endpoint in studies exploring treatments of symptoms associated with IPF andas a secondary endpoint in clinical/therapeutic trials. Robust item generation is fundamental to the development of the IPF-PRoM reflecting what is important to patients and ensuring saturation is reached.

Methodology

- Domains and items were identified in existing symptom and quality of life measures used in IPF studies reported in the literature
- 5 focus groups were held at one of 3 UK centres. 28 patients (18 male) stratified for disease severity according to Composite Physiological Index (CPI) participated. Transcripts underwent inductive analysis and data was coded using NVIVO 10 ©QSR software
- Expert Opinion was sought from 10 ILD physicians utilising the Nominal Group technique. The importance of each descriptor identified in the literature was rated and then ranked according to overall importance. The top 5 were noted anddiscussed. Descriptors defined by focus group participants (n = 9) were added and the process repeated
- A multidisciplinary Research Support Group including patient and carer representatives contribute to the analysis at each stage and have the authority to mandate for the inclusion of 'grey' items.

Interim results A validation list applied to existing measures identified 208 items for inclusion. Systematic coding and recoding within NViVo reduced 28 categories initially identified to 10. Fatigue is identified as a dominant theme in patients with CPI ≥ 45 andmedication availability/impacts has emerged as a significant category in all groups. ILD experts place importance upon breathlessness and emotional and mental well-being (Table 1).