Method Nineteen patients were recruited in two waves from May 2012–January 2013. Key selection criteria included for group 1 FEV₁ < 50% predicted and for group 2 FEV₁ < 75% predicted.

Semi-structured interviews were scheduled for one month and three months after recruitment and were focused around experiences of the programme, benefits and self-management behaviours.

Qualitative data were imported into NVivo 10 and analysed through thematic content analysis. Two researchers discussed the themes and subthemes to ensure non-redundant categorization.

Results Fifteen patients were interviewed. Key benefits: increased motivation for self-management, use of self-management skills, increased access to resources and enhanced understanding of lifestyle risk factors. Benefits were facilitated by use of action plans within TPP, nurse coach support to on-going motivation and completion of a health risk assessment by those with little awareness of lifestyle risks. Barriers to gaining benefit included preference for one-to-one contact, insufficient tailoring of website content and difficulties with website navigation. Patients most likely to benefit were those who: wanted to change but had no behavioural strategy; had little previous disease education; had an autonomous sense of self-determination.

Conclusions The programme provided good support for the action phase of behaviour change, but less so for the motivational phase. Patients who were ready to change but did not have knowledge, skills or strategies benefited the most. When implementing a behaviour change programme providers should identify whether it addresses motivation and/or behaviour and assess potential participants accordingly. People who are not ready or able to change may derive little benefit from a behavioural programme.

IPF: education, information and health status

M263 A QUARTER OF IPF PATIENTS NOT ELIGIBLE FOR PIRFENIDONE TREATMENT DUE TO THE NICE CRITERIA SIGNIFICANTLY DECLINE OVER TIME

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Introduction Pirfenidone has NICE approval and is recommended for patients with IPF if the FVC is 50–80%. We hypothesised that this would disadvantage a significant cohort of IPF patients who have moderate reduction in transfer factor despite preserved FVC.

Methods We present longitudinal data capturing 38 IPF patients who had FVC greater than 80% and not eligible for pirfenidone treatment.

Results Since NICE approval in July 2013, 43 patients were eligible for pirfenidone as per the NICE criteria and 38 (47%) patients were outside the NICE criteria. Of those outside the NICE criteria, the average FVC was 98% (81–145) and average DLCO was 58% (21–88). Sixteen (42%) patients had a DLCO < 55%, nine (24%) had DLCO of 56–70% and nine (24%) with DLCO above 70%. Only nine (24%) had CT evidence of emphysema. We had one or more serial lung function results for 17 (49%) patients. A total of 9/38 (24%) patients demonstrated an absolute decline in FVC of over 10% and one patient had an absolute DLCO decline of over 15%. Only one of these patients became eligible for pirfenidone treatment.

This retrospective data demonstrates that the sole use of FVC in the NICE criteria for treating IPF disadvantages patients who demonstrate a significant reduction in transfer factor despite FVC greater than 80%. In this study this reduced transfer factor and preserved FVC can only be attributed to the presence of coexisting emphysema in 9/38 (24%) of patients. Ten (26%) IPF patients not treated with pirfenidone because they did not meet the NICE criteria demonstrate a clinically significant decline in their lung function. Despite this the majority are still not eligible for treatment with pirfenidone.

We would therefore advocate following our European partner countries and using both FVC and DLCO as per the CAPACITY criteria when assessing patient suitability for pirfenidone treatment for IPF, as the use of FVC alone with an upper limit of 80% excludes a substantial cohort of IPF patients who have preserved FVC, moderately reduced DLCO with or without the presence of coexisting emphysema and over time a quarter of these patients demonstrate lung function decline.

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M264 HEALTH AND ECONOMIC IMPACT OF PRESCRIBING PIRFENIDONE

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Introduction Pirfenidone is the only licensed drug in Europe for Idiopathic Pulmonary Fibrosis (IPF). Clinical trials (1) have demonstrated efficacy in reducing decline in forced vital capacity (FVC), improving progression free survival and reducing mortality. The translation of clinical trial results to clinical practice is a focus of interest.

Methods We describe our experiences in prescribing pirfenidone in a single centre observational study of 96 patients from September 2011 to April 2014.

Results This is an extension of our published work (2). Prior to NICE approval we recruited 49 patients in twenty months. NICE approval resulted in a 140% increase in pirfenidone prescribing. Patient demographics at baseline are shown in Table 1. 54 (56%) patients continued treatment, 19 (20%) discontinued treatments due to adverse effects (AEs), there were 17 (17%) deaths and 4 (4%) patients were transplanted. Patients that died had lower diffusing capacity (DLCO) at baseline compared to those that continued treatment (32.9 vs 47.7 p < 0.0001). Patients that discontinued treatment due to AEs did so within six months and had lower body mass index (25.1 vs 29 p = 0.002) and DLCO (38.8 vs 47.7 p = 0.007).

There were a total of 206 AEs in 77 (79%) patients. The majority were gastrointestinal in nature. Of these adverse effects the majority were self-limiting and resolved with simple measures. 44 (21%) resulted in a dose reduction, 23 (11%) resulted in a temporary discontinuation, in 101 (45%) AEs treatment was unchanged and 38 (19%) AEs resulted in drug discontinuation.

In selected patients we had one or more lung function results before (34%) and after (50%) pirfenidone treatment. Eighteen months prior to pirfenidone treatment there was an observed reduction in mean% predicted FVC over time. Accepting limitations of missing data, this decline appeared to stabilise over twelve months after commencement of pirfenidone.

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.

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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 (Body-media, 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 Pearson's correlation coefficient. Data are presented as mean ± SD.

Results 17 IPF subjects (Age 76 ± 6.3, 82% males, FVC% predicted 82.3 ± 16.1%, TLC0% 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 TLC0 (% predicted) ($r = 0.39$, $p = 0.13$). Conversely TLC0 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 and efficacy of existing and emergent therapies require further evaluation. We are developing a new concise IPF-PROM (according to FDA criteria¹) for use as a primary endpoint in studies exploring treatments of symptoms associated with IPF and as 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 and discussed. 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 and medication 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).