Introduction Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive and irreversible disease that requires long-term management. The objective of this study was to assess the long-term safety of pirfenidone from a pooled analysis of 4 clinical studies.

Methods All patients who received pirfenidone (2403 mg/d) in the Phase 3 studies (ASCEND/CAPACITY) and/or the long-term extension study (RECAP) were included in this analysis. Safety outcomes were assessed during the period from the first dose until 28 days after the last dose of pirfenidone in either study. Analyses included the final data from the Phase 3 studies and RECAP (data cut, June 30, 2015).

Results The pooled population included 1216 patients with a cumulative total exposure of 3366 patient-exposure years. Median pirfenidone exposure was 25.9 months (range, 0–105 months), with a mean dose of 2306 mg/d. 99% of patients reported ≥ 1 treatment-emergent adverse event (TEAE). 57% of patients reported a serious TEAE (0.51 per patient-exposure year [PPEY]), the most common being IPF (21.5%) and pneumonia (9.3%; Table). TEAEs led to discontinuation in 45% of patients (0.17 PPEY), the most common being IPF (15.9%), rash (1.6%) and nausea (1.6%). Median survival on treatment (or ≤ 28 days after discontinuation of pirfenidone) was 82.6 months.

Conclusions The safety findings from this pooled analysis are consistent with the known safety profile of pirfenidone and the underlying disease of IPF.

Abstract P169 Table 1 Summary of TEAEs^a

Preferred Term	No. of Patients With an Event	Patient	Adjusted Rate ^{b,c}	
		Incidence (n = 1058)	No. of Events	Rate per Patient- Exposure Year
Most Frequent TEAEs (incidence in ≥20% of patients)				
Cough	477	39.2%	716	0.213
Nausea	471	38.7%	798	0.237
IPF	424	34.9%	669	0.199
Dyspnea	415	34.1%	573	0.170
Upper RTI	405	33.3%	789	0.234
Diarrhea	374	30.8%	657	0.195
Fatigue	359	29.5%	505	0.150
Rash	331	27.2%	540	0.160
Bronchitis	325	26.7%	624	0.185
Headache	281	23.1%	478	0.142
Nasopharyngitis	280	23.0%	536	0.159
Dizziness	276	22.7%	409	0.122
Dyspepsia	243	20.0%	306	0.091
Most Frequent Serious TEAEs (incidence in ≥5% of patients)				
IPF	262	21.5%	320	0.095
Pneumonia	113	9.3%	130	0.039
TEAEs With Outcome of Death (incidence in ≥1% of patients)				
Deaths	273	22.5%	273	0.081
IPF	148	12.2%	148	0.044
Respiratory failure	26	2.1%	26	0.008
Pneumonia	13	1.1%	13	0.004

IPF, idiopathic pulmonary fibrosis; RTI, respiratory tract infection; TEAE, treatment-emergent adverse event.

^a TEAEs are any events that occurred between the first dose and 28 days after the last dose.

^b 3366 total exposure years.

^c Adjusted rate = total number of events/total exposure years.

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SINGLE CENTRE EXPERIENCE ON IDIOPATHIC PULMONARY FIBROSIS PATIENT TOLERANCE OF PIRFENIDONE; IMPACT ON NURSE-LED ILD HELPLINE USAGE

A Rathnapala, C Ruggiero, A Fries, LP Ho, RK Hoyle. Oxford Centre for Respiratory Medicine, Oxford, UK

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Introduction Idiopathic pulmonary fibrosis (IPF) is a progressively scarring lung disease with a poor prognosis. The anti-fibrotic agent Pirfenidone slows FVC decline and reduces mortality. Side-effect management is critical to help patients remain on treatment.

Objectives To examine tolerance to Pirfenidone in our specialist ILD centre: to identify the prevalence, nature and management of adverse effects, and the impact on the ILD nurse-led helpline.

Methods In this retrospective study, all patients with an ILD MDT diagnosis (ATS/ERS) of IPF treated with Pirfenidone for >3 months were included. Data was derived from the patient records and nurse-led ILD helpline logs.

Results 100 patients were treated with Pirfenidone Feb 2012–July 2016. 16 patients were excluded (<3 months' treatment (n = 7), death <1 month (n = 2), other (n = 7), 84 remained in the study; Definite: Probable IPF 47:37, male: female 68:16, average age 73.7 (40–88).

72 (85.7%) experienced at least one adverse effect; appetite/weight loss (n = 39, 34.5%), nausea (n = 26, 23%), diarrhoea (n = 17, 15%), fatigue (n = 11, 9.7%), photosensitivity (n = 11, 9.7%), skin rash (n = 9, 8%). No patients required side-effect-related hospital admission.

Management: treatment pause (n = 36, 50%), dose reduction alone (n = 15, 20.8%), initial reduction and subsequent pause (n = 4, 5.6%). n = 17 (23.6%) with mild side-effects were managed with advice alone (dose unchanged).

Of those with dose reductions/pause (n = 55), 21 (38%) were gradually re-escalated to full dose, 1 (2%) continued on reduced dose. Pirfenidone was discontinued and offered symptom-based management in n = 17 (31%), (unable to switch to Nintedanib due to FVC $< 50\%$ (7), not preferred (3), bleeding risk (2), other (5)), while n = 16 (29%) were able to switch to Nintedanib.

Impact on the nurse-led helpline was assessed in n = 45 (unselected subset); $> 82\%$ used the helpline, often initiated due to side-effects; patients with deteriorating symptoms or end-stage disease engaged most frequently.

Conclusions In this real-life study, we found a higher prevalence of side effects than previously described. Nurse-led helpline use was often initiated by side effect concerns, but usage broadened into more holistic support as the nurse patient relationship developed. In response, the Oxford ILD Service has initiated a side-effect management protocol with more cautious (than standard) initial escalation and re-challenging regime.

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HEALTH INEQUALITY EXISTS IN PIRFENIDONE PRESCRIPTION FOR IDIOPATHIC PULMONARY FIBROSIS IN THE ENGLISH MIDLANDS ACCORDING TO PATIENT LOCATION

¹FA Woodhead, ²S Townsend, ²D Desai. ¹Institute for Lung Health, Glenfield Hospital, Leicester, UK; ²University Hospitals of Coventry and Warwickshire, Coventry, UK

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