356* Use of patient monitoring systems in clinical trials to generate objective information on patients' drug adherence of inhaled medications

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Cystic fibrosis (CF) patients have to spend a lot of time on inhalation every day. Regular and complete treatments are needed to gain optimal results. Patient adherence to inhaled drugs is an important factor for the outcome of clinical trials and interpretation of their results. Consumption of drug vials and diary entries are commonly used to verify adherence.

Investigational eFlow nebulizer systems with monitoring function are tested on 35 CF patients (16 female, 19 male) between 9 and 41 years old for assessing patient adherence over 24 weeks. For each inhalation the treatment start time and duration are recorded and stored on a chip card that needs to be inserted into the nebulizer for operation.

The chip card is replaced with each clinic visit (week 4, 12 and 24) and downloaded onto a computer using the PARI Pharma Patient Monitoring Software. This software stores all data in a database and offers several reports. Adherence is calculated as the ratio of actual to scheduled inhalations and is shown graphically per study day and as cumulative adherence from the start of the study onwards. This provides immediate information about the patient's adherence to the study protocol.

First results within a clinical trial have shown that adherence to the study protocol measured by the device varies between patients and over duration of the study. The results also showed differences between drug accountability and data on adherence recorded by the patient monitoring system. These results help to evaluate therapy outcomes.

357 A 10 year retrospective audit of clinical psychology referrals within a paediatric cystic fibrosis (CF) team

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Objective: This retrospective audit was undertaken to explore the nature of referrals made by the paediatric CF team to the Clinical Psychologist over a period of 10 years. The aim of the audit was to identify patterns or trends related to difficulties referred by the team.

Methods: A database consisting of all referrals received over a ten year period from 2001–2010 was created. A coding template was then created by KR and AC, which allowed for the categorisation of referrals into three main themes: *Mood disturbance; CF related events; and non-CF related events.* The same coding template was used to categorise referrals to the adult CF service. Descriptive statistics were used to interpret the data.

Results: Over the ten year period, 106 young people with CF were referred to psychology, representing 266 referrals. On average, a referral was made every two weeks. The most common reason for referral was for CF related events (i.e. adherence, living everyday life with CF). Referrals were found to increase with age. Both genders were equally likely to be referred, with females being re-referred most frequently, indicating increased psychological morbidity. The majority of referrals (79%) were repeat referrals, indicating that psychology input is focused upon a small number of young people but over a period of time. In a typical year (09–10), only 16% of all young people with CF were able to access psychology services.

Conclusion: This audit identified patterns related to inequality of access, gender differences, and the identification of common concerns across age groups. The audit also highlighted areas where early intervention and training efforts could be targeted.

358 A ten year audit of clinical psychology referrals in the regional adult cystic fibrosis unit in Northern Ireland

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Objectives: A retrospective audit was conducted into Clinical Psychology referrals made by the adult cystic fibrosis (CF) team from 2001–2010. The aim was to examine the psychological difficulties referred to Clinical Psychology and identify any trends.

Methods: A database of all referrals received over a ten year period was created. A coding template was created which categorised referrals into three main themes: Mood disturbance, CF related events and non-CF related events. The same coding template was used to categorise referrals to the children's CF service. Descriptive statistics were used to analyse the data.

Results: In 2009/10, 11% of the adult CF population were referred to Clinical Psychology. In the past 10 years there were 200 referrals and 105 adults who accessed Psychology services. The majority of referrals (67%) were re-referrals (range 2–7 times). More females were referred and they were also more likely to be referred repeatedly. The main reason for referral was anxiety. Depression, adherence and end of life/transplant issues also accounted for a large proportion of referrals. A small proportion of referrals were due to non CF related events. There were age and gender differences in the reasons for referral.

Conclusion: A minority of CF patients attending the regional unit were referred to Clinical Psychology. Those who accessed the services appear to be at increased risk of psychological morbidity as re-referral rates are high. The gender difference in referral and re-referral rates may reflect a difference in psychological morbidity or males not accessing services.

359 Anxiety and depression in Belgian patients with cystic fibrosis (CF) and their parents: a major national epidemiological study

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Background: Anxiety and depression in patients with CF have received more attention over the past years. Epidemiological studies are crucial to understand the dynamics between psychological well-being and CF.

Aim: To assess prevalence and correlates of anxiety and depression in a large proportion of patients and their parents.

Method: The Hospital Anxiety and Depression scale (HADS) was administered during outpatient clinics in 2010. Medical and demographic parameters were included for analyses.

Results: 626 patients from 6/7 CF centers were included (with 348 parents, mean patient age 18.1 years, SD = 11.4, range 1–69) representing 65% of the total national population.

Lung function – elevated HADS scores (%)

N = 774	FEV1% pred mean (SD, range)	Elevated anxiety %	Elevated depression %
Adolescents (102)	90 (18, 32–132)	20.8	6.9
Adults (324)	67 (24, 17–139)	37.3	18.0
Mothers (242)	na	58.1	24.3
Fathers (106)	na	48.1	24.5

For patients, anxiety was associated with gender (> for females, $p < .05$) and age ($p < .001$). Depression was associated with age ($p < .01$). For parents, mothers reported more symptoms of anxiety than fathers ($p < .01$). 167 participants rated themselves 'poorer than others', and reported significantly more symptoms of anxiety and depression than patients (n = 565) who rated themselves equally rich or richer ($p < .001$).

Conclusion: Many patients and parents reported elevated symptoms of anxiety and depression. Contrary to previous reports lung function was not associated with anxiety or depression, but self-reported SES was. Despite well organized Belgian CF care the present results indicate that psychological monitoring/follow-up of patients and families is essential.