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#### 11. Epidemiology/Registry

### 427 Choice of spirometry values in epidemiological research

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Spirometry values are used in epidemiologic and registry CF research, and generally considered valid parameters for standards of care, morbidity and prognosis.

However, pitfalls exist when collecting and interpreting such values, especially when comparing treatment regimens, centers or countries.

**Methods:** We analysed spirometry values (FEV-1 and FEF<sub>25–75</sub>) from CF center Skejby during a 3 year period. The data were obtained prospectively in the daily clinical setting following the ERS/ATS recommendations for spirometry. Analyses performed included coefficient of variation, comparison of mean and max values, and various calculations of slope.

**Results:** For FEV-1 56% of patients varied more than the normal CF inter-test variation over a 12 month period. For FEF<sub>25-75</sub> the number was as high as 86%. For comparison of mean vs max values on a center level we found a visible, but not significant difference. For FEV-1 there was a 6% difference using the two methods (p=0.052) and for FEF<sub>25-75</sub> a 12% difference (p=0.067). 4 different ways of calculating decline of lung function were performed. Though the results varied slightly there was no significant difference. Decline was steepest in patients with FEV-1 of >100% or between 40 and 59%.

**Conclusion:** One single value of FEV-1 may be used a valid marker of that patient's lung function, whereas  $\text{FEF}_{25-75}$  varies too much. Comparing mean to max values on a center basis may grant seemingly large differences. Consensus on method must be reached. Calculation of slope can be done in various ways with little difference in results.

### 428 Comparing the 'best' spirometry values of the year with values obtained at the 'last' consultation in cystic fibrosis patients in Belgium using the CF Registry data

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**Objectives:** To compare the best % of predicted  $FEV_1$  and FVC with values obtained at the last consultation among CF patients.

**Methods:** The calculations of the % of predicted FEV<sub>1</sub> and FVC were done for patients 6 years and above excluding transplants. Means ( $\pm$ SD) and medians (Interquartile range) were calculated for the overall population, by gender and age groups. The Wang (6–17 years) and Hankinson (18 and above) prediction equations were used.

**Results:** The overall means for the best % of predicted FEV<sub>1</sub> and FVC of the year were 80.9 % (±24.3) and 94.8 % (±19.7) respectively while the last values were 76.6 % (±25.2) and 90.9 % (±21.0). The mean best versus last % of predicted FEV<sub>1</sub> was 82.6 % (±24.6) and 78.3 % (±25.7) respectively in males, and 79.0 % (±23.7) and 74.7 % (±24.5) in females. The overall mean differences between the best and the last FEV<sub>1</sub> and FVC values were 4.3 % (±7.5) and 3.8 % (±7.3) respectively, all p-values <0.0001.

**Conclusions:** The results show an overall significant statistical difference between the best and the last % of predicted FEV<sub>1</sub> and FVC of about 4 %, even by gender and across most age groups with the greatest difference in the age group 18–24 years. The difference obtained was not within a clinically relevant margin of 5%. This means values reported by the Belgian CF registry and other registries that use the last values of the year are on average 4% lower than those used for benchmarking by European Cystic Fibrosis Registry. These registries can still report these values without fear of being seen as having worse patients compared to other registries and thus maintain continuity of the data recording in their registries.

#### 429 Trends in the incidence of acute kidney injury in UK cystic fibrosis patients

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Acute kidney injury (AKI) is a recognised complication of treatment with aminoglycosides (AG). Recent reports have established the increased risk of AKI in patients with CF. Once daily dosing of AG is associated with less nephrotoxicity, whereas intravenous (IV) gentamicin (though not tobramycin) use is associated with AKI. We studied the rates of AKI in two time periods through a national survey and the UK PortCF database and conducted a national survey of prescribing practice, to assess AG usage and its association with AKI.

From 1997–2004, 55 cases of AKI were reported. In a subgroup of 24 in whom AKI was confirmed by inspection of the case notes, 13 cases (54%) required dialysis. An estimate of the total number of cases of AKI requiring dialysis in this period is 27.50 (3.44 cases/year). From 2006–2009, 3.75 cases/year of AKI requiring dialysis were reported via PortCF.

We undertook a questionnaire survey of prescribing practice in UK CF centres in 2006. We found that 12 (35%) of centres had changed to od dosing, 1 (3%) had changed from gentamicin to tobramycin, and 8 (23%) of centres were still using gentamicin.

Our pragmatic survey using all available data suggests that the incidence of AKI may not have changed in the period 2006–09 compared to 1997–2004. In 2009 the UK CF Trust recommended that IV gentamicin should not be used in CF. We plan to re-survey UK CF centres to see if gentamicin use has changed since the 2006 survey and to record the incidence of cases of AKI through PortCF in order to ascertain if the recommendation to avoid IV gentamicin is associated with fewer cases of AKI in the future.

# 430 The disease burden associated with transmissible *Pseudomonas aeruginosa* strains in adult CF

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Although chronic infection with transmissible *Pseudomonas aeruginosa* (Psa) strains confers a poor prognosis in CF patients, the disease burden this places on such individuals has not been studied. To investigate this further, using logistic regression, we matched (for age, sex, BMI, FEV1, and time since diagnosis) 47 adult CF patients chronically infected with the commonest UK transmissible Psa strain (the Liverpool Epidemic Strain, LES) with 47 infected with unique Psa strains and compared the impact of the CF disease on their lives in terms of the use of routine medication, use of home IV therapy, outpatient attendances, and episodes of hospitalisation over a 5 year period.

Fisher's exact test and Mann-Whitney's U test were used to analyse the data.

Although there was no difference in routine medication use or home IV therapy, those infected with LES had more hospital admissions (median 8 [IQ range 3–12] v 2 [1–6]; p < 0.001), more inpatient days (median 90 [ IQ 33–144] v 20 [0–60]; p < 0.001), more outpatient attendances (median 34 [IQ range 18–49] v 21 [10–34]; p=0.002), required more home oral antibiotics (median 3 [IQ 2–4] v 2 [1–3]; p=0.002), and were more likely to receive treatment for CF related diabetes and undergo TIVAD insertion (both 19 v 9, p=0.03), than those chronically infected with unique Psa strains, respectively.

This study shows that patients chronically infected with epidemic Psa strains have a high disease burden compared to other adult CF patients, and confirms the need to prevent cross-infection with these organisms whenever possible. We are conducting a study to assess the impact of these strains on quality of life in the adult CF population.