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Title: Use of an electronic monitoring system to generate objective information on patients' adherence to taking treatments of a novel inhaled tobramycin solution

Prof. Dr Dorota 11714 Sands dorotasands@onet.eu MD , Dr. Ewa 11715 Sapiejka e.sapiejka@wp.pl MD , Prof. Dr Henryk 11716 Mazurek igrabka@wp.pl MD and Dr. Grzegorz 11717 Gaszczyk gaszczyk1602@gmail.com MD . ¹ CF Centre, Instytut Matki I Dziecka, Warsaw, Poland, 01-211 ; ² CF Centre, SZOZ Nad Matka I Dzieckiem, Gdansk, Poland ; ³ CF Centre, IGiCHP, Rabka, Poland and ⁴ Pulmonology, Pulmonology and Allergology Centre, Karpacz, Poland .

Body: Objective: Patient adherence to inhaled medications is important to interpret study results. Self-reported diaries have a high potential for manipulation. To provide a reliable tool to assess patient adherence to treatment, a monitoring feature was developed and incorporated into a specific eFlow technology nebulizer. TIS I (VANTOBRA/Tolero) was compared in a randomised study in cystic fibrosis patients with TIS II (TOBI/PARI LC PLUS). Methods: The configuration's key feature is an electronic chip card recording date, time and duration of each nebulization session and cause for termination. The nebulizer operates only by insertion of a valid chip card. Recorded data were processed using PARI's Patient Monitoring Software. Adherence is calculated as the ratio of actual/planned inhalations and shown graphically per study day or cumulatively. Results: Data of 54/58 patients were analysed. Mean adherence was 99% for all evaluable patients, 98% in patients > 13 years and 99% in patients of 7-13 years of age. The adherence rate was comparable in all treatment cycles, independent whether the patient was randomized to receive TIS I as the first or second treatment cycle. As per patient diary, the compliance in the TIS II group was 99%. Mean time/inhalation was 4.4 min (TIS I) and 24.3 min (TIS II). Conclusion: The eFlow technology nebulizer with patient monitoring function provides objective adherence data. The monitoring feature offers the potential to distinguish whether an observed treatment failure is based on lack of drug efficacy or non-adherence to the prescribed treatment regimen.