G.21 Psychological assessment

Review question: What strategies are effective at identifying people with cystic fibrosis for the presence of a psychological and/or behavioural problem?

Study details	Number of participants and participant characteristics	Test characteristics	Results	Comments
Full citation Daniels, T., Goodacre, L., Sutton, C., Pollard, K., Conway, S., Peckham, D., Accurate assessment of adherence: self-report and clinician report vs electronic monitoring of nebulizers, Chest, 140, 425-32, 2011 Ref Id 362988 Country/ies where the study was carried out UK Aim of the study To assess the agreement between rates of adherence to prescribed nebulizer treatments when measured by self-report, clinician report, and electronic monitoring. Study dates Not reported Source of funding	Sample size N=78 (81 participants started the study: 1 did not gave consent, 1 patient data could not be downloaded) Characteristics Adults with CF on nebulizer therapy Median (IQR) number of daily nebulizer doses: 3 (32 to 3) Median age (IQR): 26 (21 to 31) years Gender: 55.1% male (n=43) Median (IQR) FEV1 % predicted: 69.5 (54 to 86) Inclusion criteria Not reported Exclusion criteria Not reported	Details Sample selection Participants were asked to participate in the study at a routine clinic visit at the Leeds regional CF unit. Data collection A cross-sectional comparison of 3 approaches to measuring adherence: self-report, clinician report and electronic monitoring through the I-Neb Demographic and clinical data taken from patient's electronic medical record Adherence measured as % of prescribed regimen Participants: they were asked to identify their prescribed nebulizer regimen by medication, dose and frequency, and then asked about their adherence using 2 questions, in order to capture different ways of expressing adherence ((1) “On an average week, how often do you take your…” (each medication the	Results Adherence rates Adherence according to self-report: Median (IQR) = 80% (57.5% to 95%) of treatment prescribed Adherence according to electronic monitoring: Median (IQR) = 36% (5% to 84.8%) of treatment prescribed Reliability Clinician agreement: ICC = 0.95 (95% CI 0.44 to 0.66) Agreement between clinician report and electronic monitoring: ICC dietitian = 0.36 (95% CI 0.11 to 0.55) ICC liaison/ home nurse = 0.36 (95% CI 0.15 to 0.54)	Limitations The methodological limitations were assessed using a critical appraisal of outcome measures checklist (Jerosch-Herold,2005): 1. Is the purpose of the study clearly defined and focused on examining one or more measurement properties? Yes 2. Is the instrument described and is there a standardised protocol for administration and scoring which is described fully? Yes 3. Are the observers/testers appropriately trained or certified? Not relevant (important to note the observers were blinded to EM results) 4. Were the data collected on an appropriate sample which is representative of the population to whom the measure will apply? Yes 5. Is the sample size adequate? Yes (power was calculated) 6. Does the measure make intrinsic sense? Yes 7. Does the measure sample the content/domain adequately? Yes 8. Is there evidence of the test’s construct validity? Not relevant 9. What is the test-retest reliability? Not relevant

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This work involves an honorarium payment and began prior to this study.		patient identifi ed was questioned separately) and (2) "Overall, what percentage of your nebulizers do you think you have taken over the last 3 months?") Clinicians: they were asked to complete a questionnaire assessing adherence for each participant over the preceding 3 months. Clinicians were blinded to data from I-Neb and to all other reports of adherence. Electronic monitoring: I-Neb: chosen as it provides accurate and detailed adherence data. Currently for use in the UK. Adherence to a dose was defined as a complete dose taken at any time during the day. Statistical analysis Data analysis using SPSS Assumption was made that I-Neb had no systematic error Agreement was measured using ICC, with 95% CI	ICC physician = 0.42 (95% CI 0.21 to 0.59) ICC ward nurse = 0.34 (95% CI 0.11 to 0.54) ICC pharmacist = 0.28 (95% CI 0.07 to 0.47) ICC physiotherapist = 0.54 (95% CI 0.36 to 0.68) Validity Not reported Diagnostic accuracy data Not reported	10. What is the intertester reliability? Yes 11. Does the instrument capture clinical change? Not relevant Overall quality: moderate Other information Conflict of interest: Financial/non-financial disclosures: The authors reported the following COI: Ms Daniels provides advice as a consultant to Philips regarding nebulizer and associated technology development, to Novartis Pharmaceuticals Corporation and Pharmaxis regarding inhaled therapies, and to Air products regarding home oxygen delivery. These posts were all commenced following the completion of the present work. Ms Pollard has received assistance with travel and accommodation for a meeting from Novartis Pharmaceuticals Corporation. Dr Conway is a member of an advisory board that provides advice to Philips regarding nebulizer development. This board also has provided advice to Medic-Aid Limited and Respironics who developed AAD technology prior to being taken over by Philips. Drs Goodacre, Sutton, and Peckham have reported that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article. The authors noted that providing information about the study before asking them the

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				questions could have influenced the answers Complete data for 68 participants Extreme inaccuracy was observed for individual patients by clinicians and self-report adherence.
Full citation Shearer, J. E., Bryon, M., The nature and prevalence of eating disorders and eating disturbance in adolescents with cystic fibrosis, Journal of the Royal Society of Medicine, 97 Suppl 44, 36-42, 2004 Ref Id 330063 Country/ies where the study was carried out UK Aim of the study To improve previous research by using a semi-structured interview designed to assess and diagnose eating disorders in adolescent population. Study dates Not reported	Sample size N=55 children and young people with CF not undergoing psychological therapy Characteristics mean age (SD), range: centre 1: 14.2 (1.55); 11 to 16.6 centre 2: 14.14 (2.15); 11 to 17.3 gender: centre 1: 51.5% female centre 2: 45.5% female mean BMI (Sd), range centre 1: 18.1 (2.35); 14.5 to 23.4 centre 2: 18.6 (2.86) ; 13.2 to 24.1 Inclusion criteria	Details Test characteristics The Child Version of the Eating Disorder Examination (CEDE is adapted from the adult version of the Eating Disorder Examination (EDE) (considered the 'gold standard' for assessing eating disorders) It adopts the form of a semi-structured, investigator-based interview schedule designed to assess and diagnose the specific psychopathology of eating disorders in children and adolescents from 8 years of age. It produces information concerning the previous 4 weeks leading up to the interview. However, some of the questions ask about the previous 3 months, so that sufficient information can be gained to satisfy DSM-IV criteria.	Results Reliability Inter-rater reliability = 0.69 to 1 Validity Not reported	Limitations The methodological limitations were assessed using a critical appraisal of outcome measures checklist (Jerosch-Herold,2005): 1. Is the purpose of the study clearly defined and focused on examining one or more measurement properties? Yes 2. Is the instrument described and is there a standardised protocol for administration and scoring which is described fully? Yes 3. Are the observers/testers appropriately trained or certified? Unknown (it is not indicated in the study) 4. Were the data collected on an appropriate sample which is representative of the population to whom the measure will apply? Yes 5. Is the sample size adequate? Yes (power was calculated) 6. Does the measure make intrinsic sense? (Yes 7. Does the measure sample the content/domain adequately? (Yes) 8. Is there evidence of the test's construct validity? Yes (not reported in the study, but it

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Source of funding Not reported	A diagnosis of CF and registration on the UK CF database Age 11–17 years Ability to speak English sufficiently to complete the questionnaire and interview without assistance Exclusion criteria Experience of bereavement less than 1 year prior to the study Undergoing psychological therapy or being treated for problems associated with mood	The CEDE provides either frequency or severity ratings for key behavioural and attitudinal aspects related to eating disorders. On both frequency and severity ratings, scores range from 0 to 6. The questions pertinent to a formal diagnosis are termed 'The Diagnostic sub-scale' and scores of 4–6 meet diagnostic criteria. In terms of frequency a rating of 4–6 equates with the presence of features between 16 and 30 days per month. In terms of severity a rating of 4–6 equates with moderate to supreme severity. Scores of 2–3 reveal 'eating disturbance' as the individual shows symptomatology but not to the standard required for a diagnosis. Such scores have been termed 'sub-threshold' scores. In terms of frequency a rating of 2–3 equates with the presence of features between 6 and 15 days per month. In terms of severity a rating of 2–3 equates with mild to moderate severity. Scores of 0–1 reflect concerns within the 'normal' range. Sample selection		the validity of this tool has been already established) 9. What is the test-retest reliability? No 10. What is the intertester reliability? Yes (ICC 0.69 to 1) 11. Does the instrument capture clinical change? Not reported Overall quality: moderate Other information Conflict of interest: not reported

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		Participants were recruited from two paediatric CF centres. Four weeks prior to their appointment, potential participants who met the inclusion criteria and their parents/legal guardians were sent an introductory letter and an invitation to participate This procedure was repeated over a 6-month period, until a minimum sample of 55 had been obtained. Power Calculator was calculated for a range of plausible values of the correlation from 0.3. This suggested that a sample size of between 24 and 68 was required. Data collection Demographic and clinical information was collected from participants' medical notes. More specific clinical information including BMI ranges (kg/m2) were categorized as follows: 17.5 or less Anorectic BMI range (AN BMI range); 17.6–18.9 Under weight; 19.0–24.9 Desirable BMI range; 25.0–29.9 Overweight; 30 or more Obese Data analysis		

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		The inter-rater reliability of the use of the CEDE was assessed by carrying out Pearson's bivariate correlations between the researcher and a second, trained rater who listened to tapes of 20 interviews which had been randomly selected. The correlations ranged from 0.69 to 1, which is satisfactory for the purpose of quantitative analyses.		
Full citation Siracusa, C., Clancy, J. P., Drotar, D., Electronic monitoring reveals highly variable adherence patterns in patients prescribed ivacaftor, Pediatric Pulmonology, 49, 440, 2014 Ref Id 437623 Country/ies where the study was carried out USA Aim of the study To assess self-report adherence, compared to	Sample size N=12 children, young people and adults with CF previously prescribed Ivacaftor Characteristics Mean age (SD); range: 20.8 (9.9) years (6 to 48 years) Weeks on Ivacaftor prior to the study (SD), range: 55.3 924.6); 11.9 to 89.6 Inclusion criteria Confirmed diagnosis of CF with the CFTR-G551D mutation (the only approved	Details Test characteristics Self-report adherence data was obtained using The Self-Reported Treatment Adherence & Barriers Assessment Prescription refill data were obtained from each patient's pharmacy over the study period. Electronic monitoring: the Medication Event Monitoring System (MEMS®; AARDEX Ltd. Zug, Switzerland) was used. MEMS® mimics a traditional pill bottle in both appearance and utility, and tracks the date and time of each bottle opening. Graphic	Results Adherence rates according to (mean, SD, range): self-report: 100% (14% to 100%) pharmacy refill history: 84% (31) (13% to 124% electronic monitoring: 61% (28) (4% to 99%) Electronic monitoring versus self-report rs=0.40; p=0.22 ICC=0.14; p=0.23	Limitations The methodological limitations were assessed using a critical appraisal of outcome measures checklist (Jerosch-Herold,2005): 1. Is the purpose of the study clearly defined and focused on examining one or more measurement properties? Yes 2. Is the instrument described and is there a standardised protocol for administration and scoring which is described fully? the 3 ways of assessing adherence are described, and standardised 3. Are the observers/testers appropriately trained or certified? Not applicable 4. Were the data collected on an appropriate sample which is representative of the population to whom the measure will apply? Yes

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Study details	Number of participants and participant characteristics	Test characteristics	Results	Comments
pharmacy refill and electronic monitoring. Study dates Not reported Source of funding This work was supported under a training grant funded by the National Institutes of Health [Grant 5T32HD068223-02].	mutation at the time of the study) Age 6 years and older Had been prescribed ivacaftor for at least one month Exclusion criteria Patients were excluded if: there was a provider-initiated reason for them not to take their ivacafto; there was a developmental disability that prevented them from effectively monitoring their adherence or completing surveys.	feedback is provided in the form of calendars and time plots at each data download. The number of bottle openings per day are indicated in the calendar feedback, while the frequency of time points for bottle openings are indicated in time plots. Sample selection Patients were recruited from two accredited CF centers, one pediatric (250 total patients) and one adult (140 total patients). Only 16 patients met the criteria. Eligible patients were approached by trained research staff during routine CF clinic visits. Data collection Demographic and clinical data was extracted from medical charts. Self-report measures of medication adherence were completed at time of enrollment and 3-4 months later during a routine CF clinic visit. Prescription refill data: adherence rates were calculated using the medication possession ratio (MPR), a	Electronic monitoring versus pharmacy refill history rs=0.26; p=0.42 ICC-=0.26; p=0.14	5. Is the sample size adequate? No (this is a serious issue, as the study in underpowered) 6. Does the measure make intrinsic sense? Yes (It is not explicitelly indicated, but it makes sense) 7. Does the measure sample the content/domain adequately? Yes (it is not explicitely indicated, but the measures have extensively used before) 8. Is there evidence of the test's construct validity? Not applicable 9. What is the test-retest reliability? Not applicable 10. What is the intertester reliability? Not applicable 11. Does the instrument capture clinical change? Not applicable Overall quality: low Other information Conflict of interest: Dr. Clancy and Cincinnati Children's Hospital Medical Center has obtained research contract funding from Vertex Pharmaceuticals to conduct clinical trials in CF patients, that were not directly related to this present study. All other authors had no conflicts of interest to disclose. Individuals demonstrated wide variability in regards to the different measures of adherence.

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		widely used measurement of pharmacy-obtained adherence data. The MPR is calculated by dividing the total amount of medication obtained by the patient by the total amount of prescribed medication. Pharmacy data were measured from the fill date immediately prior to enrollment to the fill date immediately prior to the end of the study. Electronic monitoring: patients were given an electronic monitoring (EM) device and instructed to use the device to dispense their ivacaftor for the duration of the study. Data from the EM device were downloaded, and patients received feedback on their adherence data. EM data were used to calculate overall adherence rates, weekly adherence rates, and mean duration between doses. Duration between doses was also obtained. Data analysis Mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables and		

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		frequency/percentage for categorical variables. The primary analysis of this study modeled the trajectory pattern of the EM-derived adherence over time. The level of agreement between EM-derived adherence and MPR and self-reported adherence were evaluated using Spearman correlation coefficient (rs) and intraclass correlation coefficient (ICC). SAS 9.3 (Cary, NC, USA) and R 3.1.0 (R Core Team, 2014) were used for all the analyses.		
Full citation White, H., Denman, S., Shaw, N., Pollard, K., Peckham, D., Do longitudinal measures of clinical variation correlate with adherence in cystic fibrosis, Pediatric Pulmonology, 49, 437, 2014 Ref Id 437684 Country/ies where the study was carried out UK	Sample size N=250 young people and adults with CF pharmacy collection data available for 106 patients (42%) Characteristics Mean (SD) age: 29.7 (9.2) Gender: 58.6% males Inclusion criteria Not reported Exclusion criteria Not reported	Details Sample selection Patients attending an adult regional CF centre Data collection Patients: patients were asked to complete an adherence questionnaire (CFQ-R) Pharmacy collection: consent from patients to access pharmacy records Data analysis Correlations (Pearson)	Results Correlation between pharmacy script collection and self-report: Aerosol to open air: r=0.34; p<0.005 Aerosol to thin mucus: r=0.51; p<0.001 Inhaler: r=0.51; p<0.001 PERT: r=0.45; p<0.001 Oral nutritional supplements: r=0.51; p<0.001	Limitations The methodological limitations were assessed using a critical appraisal of outcome measures checklist (Jerosch-Herold,2005): 1. Is the purpose of the study clearly defined and focused on examining one or more measurement properties? Yes 2. Is the instrument described and is there a standardised protocol for administration and scoring which is described fully? 3. Are the observers/testers appropriately trained or certified? 4. Were the data collected on an appropriate sample which is representative of the population to whom the measure will apply?

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Aim of the study To determine the accuracy of self-report adherence and its relationship with clinical variation. Study dates 2007 Source of funding Supported by a grant from Gilead Sciences			Oral antibiotics: r=0.46; p<0.001 Nebulised antibiotics: r=0.55; p<0.001 Total: r=0.61; p<0.001	5. Is the sample size adequate? 6. Does the measure make intrinsic sense? 7. Does the measure sample the content/domain adequately? 8. Is there evidence of the test's construct validity? 9. What is the test-retest reliability? 10. What is the intertester reliability? 11. Does the instrument capture clinical change? Other information Abstract only Conflict of interest: not reported

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