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**Implementing the International Committee on Mental Health in Cystic Fibrosis (ICMH) Guidelines:**

**Screening accuracy and referral-treatment pathways**

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## **ABSTRACT**

**Background:** The International Committee on Mental Health (ICMH) published screening guidelines in Cystic Fibrosis (CF). This work 1) evaluated the sensitivity of the recommended screening tools against the 'gold standard' clinical psychological assessment and 2) investigated referral and treatment pathways.

**Methods:** Ninety-six participants (79 caregivers; 17 adolescents with CF) completed the screening tools prior to formal assessment. Agreement between screening data and psychological assessment was evaluated, sensitivity analyses performed and referral pathways tracked.

**Results:** All participants with an elevated screen (moderate/severe range) were subsequently assessed as requiring treatment for major depression/anxiety disorders. However, many were referred for treatment without elevated scores. Hence, sensitivity was poor with the recommended threshold score of 10, but with a threshold of 5 the sensitivity was 76% for adults and 46% for adolescents. The area under the ROC curve (diagnostic test ability) was 0.89 for caregivers but lower at 0.68 for adolescents.

**Conclusion:** Mental health screening is complex, particularly in adolescents. Nonetheless, it is a first valuable step to improve mental health care in CF. The need for psychological support is greater than anticipated by the TIDES study.

## HIGHLIGHTS

1. Mental health screening is complex, but a first valuable step to improve mental health outcomes in CF.
2. Screening identified those with the most severe psychopathology including all those with suicide ideation.
3. Those who screened in the mild range may warrant further investigation given that many were referred for treatment following psychological assessment.
4. The need for psychological support is greater than anticipated by The International Depression and anxiety Epidemiological Study (CF-TIDES).

## **INTRODUCTION**

Cystic Fibrosis (CF) has a prevalence of about 1500 patients in the Netherlands, of which more than 40% are children [1]. Recent advances in healthcare have increased the median age of death to 42 years [1], however, the progressive nature of CF disease and the demanding treatment burden have the potential to encroach on family wellbeing [2]. Compared to community samples, the symptoms of anxiety and depression have been shown to be 2-3 times more frequent in pediatric CF patients and their primary caregivers [3,4], with associated negative health outcomes, worse treatment adherence and greater healthcare utilization [5-9].

The International Committee on Mental Health in Cystic Fibrosis (ICMH) set up recommendation statements to be implemented in CF Centers internationally [10]. An annual mental health screening program is recommended to assess the levels of depression and anxiety symptoms in adults and adolescents, and at least one primary caregiver of children under 18 years. According to the guidelines, adolescents, adult patients and primary caregivers should receive ongoing preventative psychological education and those with elevated depression and/or anxiety screening scores (moderate / severe range) should receive formal psychological assessment for diagnostic confirmation prior to receiving evidence-based psychological and/or psychopharmacological intervention. Figure 1 provides the procedure for screening and treatment of depression and anxiety [10], still, little is known about the implementation of these recommendation statements in clinical practice.

Brief screening tools can be valuable where time is limited. The screening tools recommended by the ICMH, the Patient Health Questionnaire 9 (PHQ-9) and the Generalized Anxiety Disorder Scale (GAD-7), have been shown to be suitable in general populations [11-14]. The screening characteristics of sensitivity and specificity for these tools have yet to be evaluated in CF.

The CF-team of the VU University Medical Center in Amsterdam (VUmc) has implemented these guidelines for one year. The aims of this work were to evaluate 1) the sensitivity and specificity of the screening tools when compared against the 'gold standard' formal clinical assessment, and 2) the subsequent referral and treatment pathways.

## **METHODS**

### **Study Design**

A cross-sectional screening study, with subsequent formal clinical psychological assessment, in a single CF pediatric center in the Netherlands was undertaken. The medical ethics committee of the VUmc approved the study.

### **Participants and Procedure**

From September 2015 to October 2016, all pediatric CF patients from the VUmc and their caregivers were invited to participate in the mental health screening program. Parent caregivers and children aged 12 years and older (adolescents) provided written consent. Demographic, clinical and mental health screening data were collected during the annual clinical visit. The MH screening timeline was in two phases as follows:

#### *Phase 1 (attendance for annual checkup with all clinical examinations/tests)*

1. The CF nurse administered the screening tools (GAD-7 and PHQ-9 questionnaires) to patients aged 12 years and older and their caregivers for independent completion.
2. The PHQ-9 was immediately checked for suicide ideation endorsement and urgent referral made where necessary.
3. The screening tools were fully scored within one week by the psychologist.

#### *Phase 2 (return 10 days later to discuss results of tests with all disciplines)*

4. The CF psychologist or social worker conducted a formal clinical psychological assessment: the final part discussed the results of the PHQ-9 and GAD-7 (See online supplement 1a and 1b).

5. Any treatment referral plan was discussed with the participant.

It was routine practice at this center to complete comprehensive psychological assessments (semi-structured face-to-face interviews) on all caregivers and patients aged 12-18 years, independently, at annual review. This deviates from the ICMH Guidelines as all patients and parent caregivers (not just those with elevated scores) underwent psychological assessment. This protocol allowed for the evaluation of the sensitivity of the screening tools in CF: Comparison of the screening tools against the 'gold standard' psychological assessment.

## **Measures**

### ***Demographic and clinical variables***

Age, gender and the type of CFTR mutation were obtained from patients and/or their caregivers and verified by medical notes. Forced expiratory volume in one second [15] and Body Mass Index (BMI) with corresponding Z-scores were obtained.

### ***Mental health screening***

#### ***Patient Health Questionnaire 9 (PHQ-9, Dutch version)***

The PHQ-9 measures depressive symptoms, reflecting the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for minor and major depression and has been shown to be a valid instrument [11-13]. Each of the nine items of the PHQ-9 is scored as 0 (not at all), 1 (several days), 2 (more than half of the days), or 3 (nearly every day). Total scores range from 0-4 (minimal), 5-9 (mild), 10-14 (moderate), 15-19 (moderately severe) and 20+ (severe). The PHQ-9 has been shown to be a valid instrument, with strong criterion and construct validity [12]. It has been shown to have an 88% sensitivity and 88% specificity for major depression (total score 10+) in a general medical population [12].

### *Generalized Anxiety Disorder Scale (GAD-7, Dutch version)*

The GAD-7 assesses anxiety symptoms. Participants answer seven questions on a 4-point Likert-scale: (0 not at all), 1 (several days), 2 (more than half of the days), or 3 (nearly every day). Total scores range from 0-4 (minimal), 5-9 (mild), 10-14 (moderate) and 15+ (severe). The GAD-7 has been shown to be a valid instrument, with strong criterion and construct validity [14]. With a threshold of 10, the GAD-7 total score has been reported to have a specificity of 89% and a specificity of 82% in a general population [16].

### ***Clinical Psychological Assessment***

The assessment utilized a 45 minute semi-structured, face-to-face interview [17], with mostly open ended questions to allow probing and encourage the reporting and discussion of detailed information. Adolescents were individually assessed by the psychologist, and caregivers by the psychologist or social worker. Topics addressed included: mental and physical health, psychological impact of the disease in daily life, self-management and adherence, work/school/life/leisure balance, and social/family support. Finally, their self-reported GAD-7 and PHQ-9 scores, and the reasons for the scores, were discussed with participants prior to a decision on referral/treatment options where appropriate (see online supplement 1a and 1b).

### **Data management and statistical analyses**

Analyses were performed using IBM SPSS for Windows version 24. Total scores for depression and anxiety were calculated for mothers, fathers and adolescent patients. A score of 10 or more (on either scale) was considered to be in the elevated range (in accordance with the ICMH recommendation statements); 'moderate and severe' categories on the GAD-7 and 'moderate, moderately severe and severe' categories on the PHQ-9. Pearson correlation coefficients were computed to evaluate family dyad relationships.



### ***Referral and treatment pathways***

Based on the joint screening data and clinical psychological assessment, referral and treatment pathways were provided. Participants were categorized as:

- 1) No treatment advised - ongoing supportive education, as no elevated scores on GAD-7 and/or PHQ-9 and didn't report problems during assessment;
- 2) No treatment advised based on screening results (scores < 10) but advised following assessment and provided;
- 3) Treatment advised (based on elevated screening and confirmation from assessment) and accepted (including continuation of current mental health care);
- 4) Treatment advised (based on elevated screening and confirmation from assessment) but refused.

### ***Sensitivity analyses***

A threshold value for the GAD-7 and PHQ-9 scores was successively selected starting with a threshold of 0+ and moving to the highest possible. For each threshold value in turn, the adolescent patients and all caregivers were divided into 4 groups:

- (1) Those whose scores exceeded the threshold value (tested positive) and were referred for treatment following the clinical assessment (anxiety/depression present), total = A;
- (2) Those whose scores failed to meet the threshold value (tested negative) but who were referred for treatment following the clinical assessment (anxiety/depression present), total = B;
- (3) Those whose scores exceeded the threshold value (tested positive) but were not referred for treatment following the clinical assessment (anxiety/depression absent), total = C;
- (4) Those whose scores failed to meet the threshold value (tested negative) and who were not referred for treatment following the clinical assessment (anxiety/depression absent), total = D.

The diagnostic parameters were then calculated as sensitivity =  $A/(A+B)$  and the specificity was calculated as specificity =  $D/(C+D)$ . Thus a sensitivity and specificity were calculated for all thresholds including the ICMH guideline threshold of 10+. The receiver operator characteristic curve (ROC curve) was plotted as the sensitivity against 1-specificity and the area under the ROC curve was computed as a measure of diagnostic ability of the GAD-7 and PHQ-9 for detecting anxiety/depression in the whole group together with 95% confidence intervals. This analysis was repeated for caregivers and adolescents with CF separately.

## **RESULTS**

### **Participants, demographics and clinical characteristics**

Two CF patients and their caregivers did not provide written consent and were excluded from the study. This resulted in 50 patients (17 were adolescents and therefore screened) and 79 parent caregivers (33 fathers, 46 mothers). There were 31 'families' with both parents responding, 16 mother-adolescent dyads and 10 father-adolescent dyads. No significant associations were noted between mother-father dyads, mother-adolescent dyads or father-adolescent dyads on the GAD7, or for mother-adolescent dyads and father-adolescent dyads on the PHQ9. The correlation coefficient for the mother-father dyads on the PHQ9 was 0.33 ( $p < 0.06$ ) indicating a weak association.

Demographics and clinical characteristics of participants are presented in Table 1. The sample was representative of the national average based on CFTR mutation and lung function, with median Z-score for BMI slightly less than the national CF population but similar to healthy peers [1]. The mean depression (PHQ-9) and anxiety (GAD-7) scores were typically reported within the minimal and mild range. The number of participants who scored in the minimal, mild, or elevated range is shown in Figure 2.

### **Agreement between screening and psychological assessment, and subsequent referral pathways**

Figure 2 illustrates the screening outcomes and treatment referral pathways. All participants with an elevated screen on either or both screening tools were formally assessed as requiring treatment for major depression or anxiety disorders. The screening tools also identified all four cases of suicide ideation. However, many were assessed as requiring treatment without elevated scores on the PHQ-9 and/or GAD-7. In practice, deviation from the ICMH Guidelines occurred given that treatment was provided for 41 participants (9 adolescents with CF, 21 mothers and 11 fathers) who did not score in the elevated range on either the PHQ-9 or GAD-7. Specifically, of the 9 adolescents (5 scored in the minimal range and 4 in the mild range), all 9 were referred for treatment for anxiety and/or depression. Of the 11 fathers, 3 (1 scored in the minimal range and 2 in the mild range) were prescribed treatment for anxiety and/or depression (of the remainder, 6 were referred for stress/burn-out, 2 for relationship difficulties). Of the 21 mothers, 15 (6 scored in the minimal range, 9 scored in the mild range) were deemed to require treatment referral for anxiety and/or depression (of the remainder, 3 were referred for stress/burn-out, 3 for relationship difficulties). Of 96 participants, a total of 52 were referred for psychological intervention based on information gained from both screening and clinical assessment. Thirteen reported that they had previously/were receiving psychological support: 7 had screening scores in the elevated range (5 internal, 2 external support; included those with suicide ideation, except one adolescent who refused treatment) and a further six participants of whom three screened in the minimal range and three in the mild range (4 internal, 2 external support).

Participants reported more and different types of problems during face-to-face conversation with the psychologist than they reported with the screening tools. Several reasons emerged for receiving treatment without elevated GAD-7 and PHQ-9 scores:

- (1) Some participants underreported their problems when completing the screening tools but reported more accurately in the face-to-face assessment;

- (2) Some participants reported other difficulties e.g. concerning their relationship, work problems, and bereavement.
- (3) Some couples received treatment together, but only one of them scored in the elevated range. The external family coach always provided treatment for both parent caregivers together;
- (4) The screening tools refer to the 'last two weeks' and participants may not report difficulties in this timeframe, but have problems that fluctuate over time;
- (5) Despite explanation, two parents completed the questionnaire regarding their child's health rather than their own, and their own difficulties emerged during the assessment (data removed from sensitivity analysis but retained in Figure 2 as this was the actual reality encountered in MH screening).

Most participants received internal treatment. Adolescent patients received treatment by the psychologist (predominantly, Cognitive Behaviour Therapy) and caregivers mainly received counselling by the social worker (see Figure 2). In general, a 6-8 weekly or biweekly 45-minutes CBT-program was offered by the psychologist. Counselling had a lower contact frequency (once in 3 or 4 weeks). Mostly caregivers and social worker maintained counselling over one year (See online supplement 2 for detailed content). Four participants refused treatment mainly due to time and cost constraints. One person believed that a mental health care worker 'can't remove the burden of disease'.

### **Sensitivity analyses**

Table 2 shows that the sensitivity of using a threshold of 10+ (ICMH recommendation) was poor for all participants taken together and for parent caregivers and adolescents with CF separately. A threshold of 5+ considerably increased the sensitivity but reduced the specificity somewhat. Of the caregivers who reported psychosocial problems during assessment that required treatment referral, 75.8% scored 5+ on either the GAD-7 or PHQ-9. Of the caregivers who subsequently did not require treatment

89.1% scored less than 5. The area under the ROC curve (diagnostic test ability) was 0.89. Using a threshold of 5+, the sensitivity remained poor for adolescents with CF (sensitivity 46.2%, specificity 75.0%, and diagnostic test ability 0.68). However, the sample size was small for adolescents and this is reflected in the wide 95% confidence intervals for this group. Figure 3 displays the ROC curve for parent caregivers, for adolescents with CF and for all participants together.

## **DISCUSSION**

This is the first evaluation of the ICMH recommendation statements in clinical practice and demonstrates the practical complexities of managing mental health care in a CF Center. Screening identified those with the most severe psychopathology, and identified all those who endorsed the suicide ideation screening item. As three of the four 'suicide cases' were already in external mental health care, the psychologist received permission to contact the external psychologists, and in two cases the general practitioner. In the other case, an adolescent boy underwent a psychiatric examination/suicide risk evaluation with an internal psychiatrist on the day of screening. In all cases, suicidal ideation was picked up in the interview.

Following the psychological assessment, it was clear that those who screen in the minimal and mild range may also require treatment. A score of 5 or more on either the PHQ-9 (self-report of mild depression) or GAD-7 (self-report of mild anxiety) may warrant further investigation, particularly for adolescents with CF, as issues are picked up in face-to-face assessment not disclosed by screening. Screening is the first step in all populations to identify the presence of depression or anxiety. However, sensitivity of the screening tools was a little less in CF than in a general medical population. CF has multiple clinical, psychological and social impacts and living with 'everything that CF throws at you' is often the 'adjusted norm' for parents and caregivers and adjustment of the cut-off score to allow more attention to be paid to those who score in the mild range, may be warranted. Self-Report bias and the underreporting of depressive symptoms is not uncommon [18]. In interview some participants were

clear about their deliberate under-reporting on the PHQ-9 in an attempt to reduce their symptoms via positive thinking [19], just attributing symptoms to 'everyday life stress' (18) or they view the questions as intrusive, fearing that disclosure may have negative consequences and therefore present themselves more favorably [20,21]. If centers have a psychologist within the team, psychological review on an annual basis is likely to be the norm and false negatives on screening are likely to be picked up. Previous qualitative work suggests that the PHQ-9 is not exhaustive or straightforward to complete (as items are likely to capture a wide range of thoughts, feelings and behaviors), and may miss meaningful symptoms and underestimate symptom intensity [18]. However, this is an insufficient rationale to jettison these screening tools as they are a first step in assisting, rather than determining, a diagnosis. There was the potential for unconscious bias in the referral decisions at clinical assessment, especially for those scoring elevated at screening. It was not possible to undertake a blind assessment as all of these participants had previously, or were currently, receiving psychological interventions.

A few participants were not open to treatment by a mental health specialist suggesting that there are barriers to receiving psychosocial support. Little is known about such barriers in patients with CF and their caregivers. Barriers have previously been investigated in other populations with cost, limited access to healthcare and concerns about 'what others might think' associated with reluctance to receive psychological treatment [22,23]. Future studies should identify patient and parent barriers to receiving psychological treatment in CF and evaluate the outcomes of those who accept and those who refuse treatment. The fact that there were few refusals could be due to the embedding of mental health care in this CF-team. Mental health care is part of the annual check-up and the 45 minute assessments by the psychologist/social worker are scheduled in combination with medical appointments. Therefore, there was already a 'treatment relationship' and the first step of talking to a psychologist/social worker had already been taken.

This is a single pediatric center evaluation with limitations, nonetheless, the dual assessment of screening and formal psychological interview yields useful empirical data and highlights the practical

complexities of implementing the ICMH guidelines in clinical practice. The necessity for psychological help amongst adolescents with CF and their parent caregivers is much greater than anticipated by The International Depression and anxiety Epidemiology Study (TIDES) [4]. If resources are available, annual interview assessment for all participants would be the ideal. This is not possible in many centers but the screening tools are easy to administer, and providing referral pathways are available, they can be administered by any member of the CF team. The screening tools and further information are available on the ECFS website (<https://www.ecfs.eu/mental-health-in-CF>). The Mental Health Guidelines provide a valuable first step in recognizing, addressing and improving the mental health of CF families.

### **Acknowledgements**

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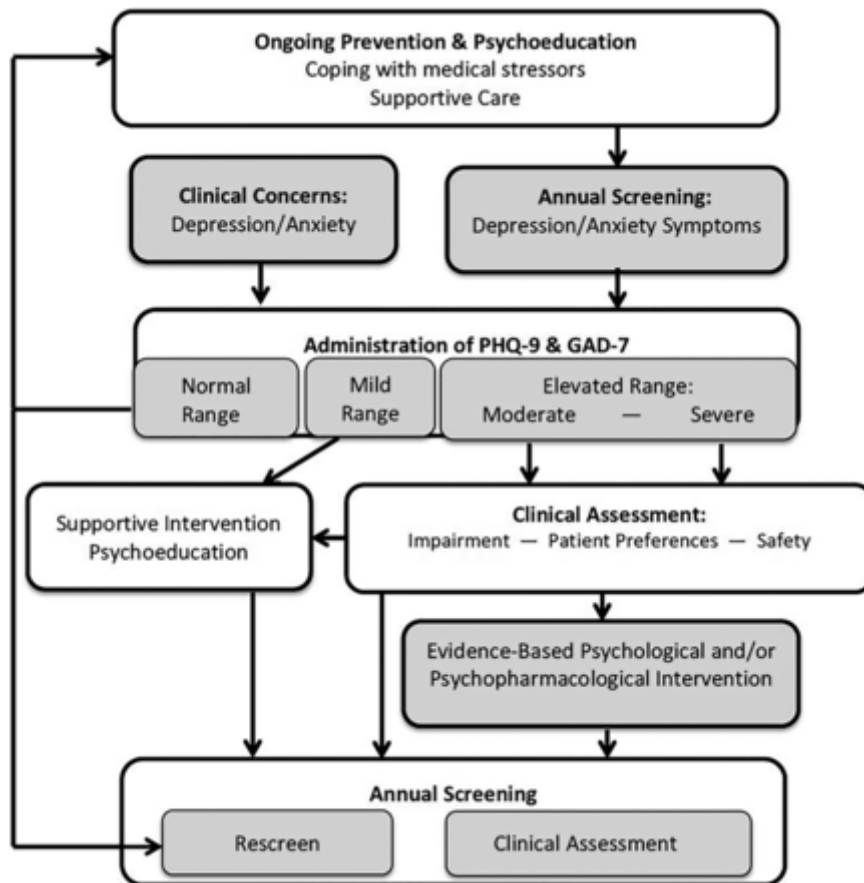
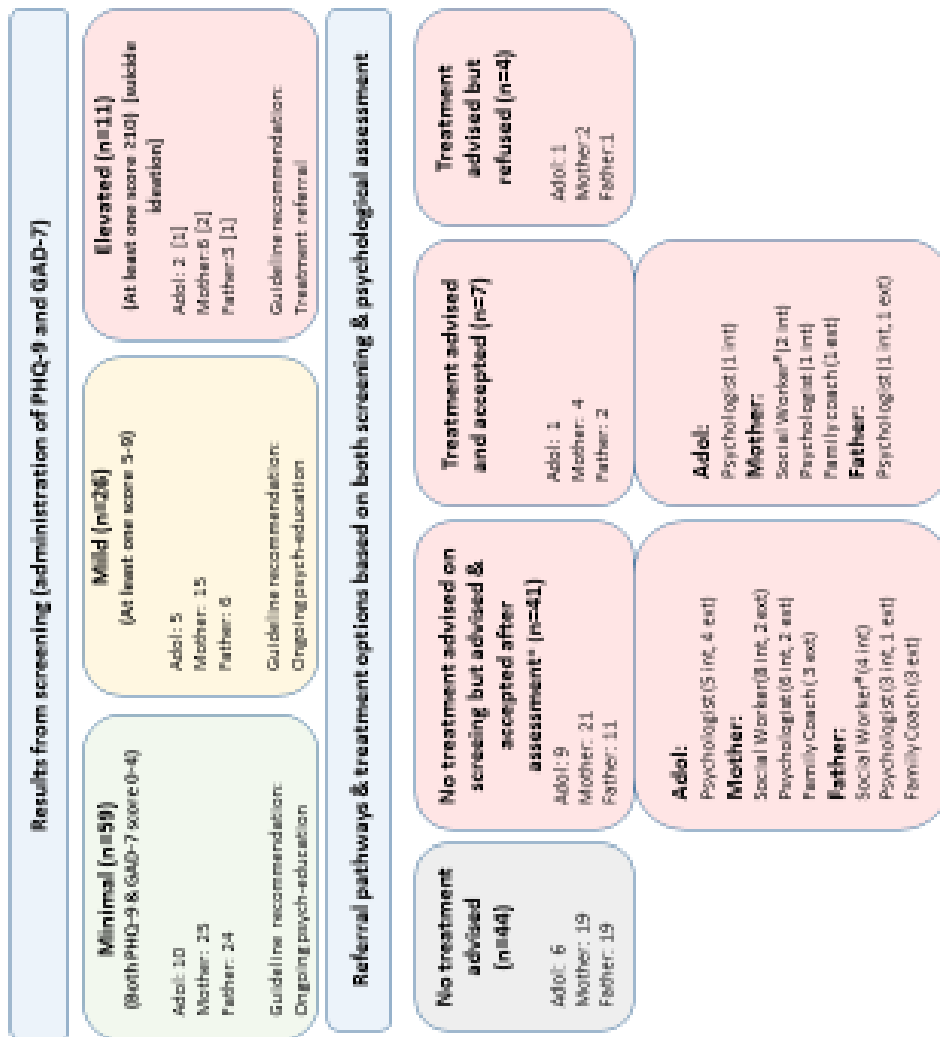


Figure 1: A flexible, stepped-care model for assessing and treating depression and anxiety [10]



**Figure 2. Screening outcomes and treatment referral pathways**  
\* Not all for anxiety and depression (see text) \* 4 mothers & 2 fathers seen by SW were also seen by a psychologist or family coach

<b>Table 1. Demographic and clinical characteristic of participants</b>	
Children/adolescents (n= 33/17; 54% female] Mean age (SD)	8.3 (5.4)
Mothers (n=46) Mean age (SD) (years)	40 (6.6)
Fathers (n=33) Mean age (SD) (years)	42(7.5)
CF Mutation (n)	
F508del/F508del	32
F508del/other	12
Other/other	6
FEV <sub>1</sub> Mean (SD)	82 (23.7)
BMI Mean (SD)	16.7 (2.3)
Depression mean score (SD)	
Adolescents with CF	5 (5.0)
Mothers of adolescent patients	6 (5.2)
Fathers of adolescent patients	7 (7.8)
Mothers of children 0-11	3 (2.8)
Fathers of children 0-11	2 (1.2)
Anxiety mean score (SD)	
Adolescents with CF	4 (3.9)
Mothers of adolescent patients	5 (5.4)
Fathers of adolescent patients	7 (7.4)
Mothers of children 0-11	4 (3.4)
Fathers of children 0-11	2 (2.1)

**Table 2. Estimated sensitivities and specificities for varying threshold levels used to identify anxiety/depression in CF with the GAD-7 and the PHQ-9.**

Threshold	Sensitivity (%)	Approximate 95%CI		Specificity (%)	Approximate 95%CI	
		Lower	Upper		Lower	Upper
<b>Caregivers(n=79)</b>						
5+	75.8	57.7	88.9	89.1	76.4	96.4
10+	27.3	13.3	45.5	100.0	93.7	100.0
	<b>AUROC<sup>1</sup> = 0.89</b>	<b>0.81</b>	<b>0.97</b>			
<b>Adolescents (n=17)</b>						
5+	46.2	19.2	74.9	75.0	19.4	99.4
10+	15.4	1.9	45.4	100.0	47.3	100.0
	<b>AUROC<sup>1</sup> = 0.68</b>	<b>0.37</b>	<b>0.99</b>			
<b>All (n=96)</b>						
5+	67.4	52.0	80.5	88.0	75.7	95.5
10+	23.9	12.6	38.8	100.0	95.2	100.0
	<b>AUROC<sup>1</sup> = 0.86</b>	<b>0.78</b>	<b>0.93</b>			

<sup>1</sup>Area under the ROC curve

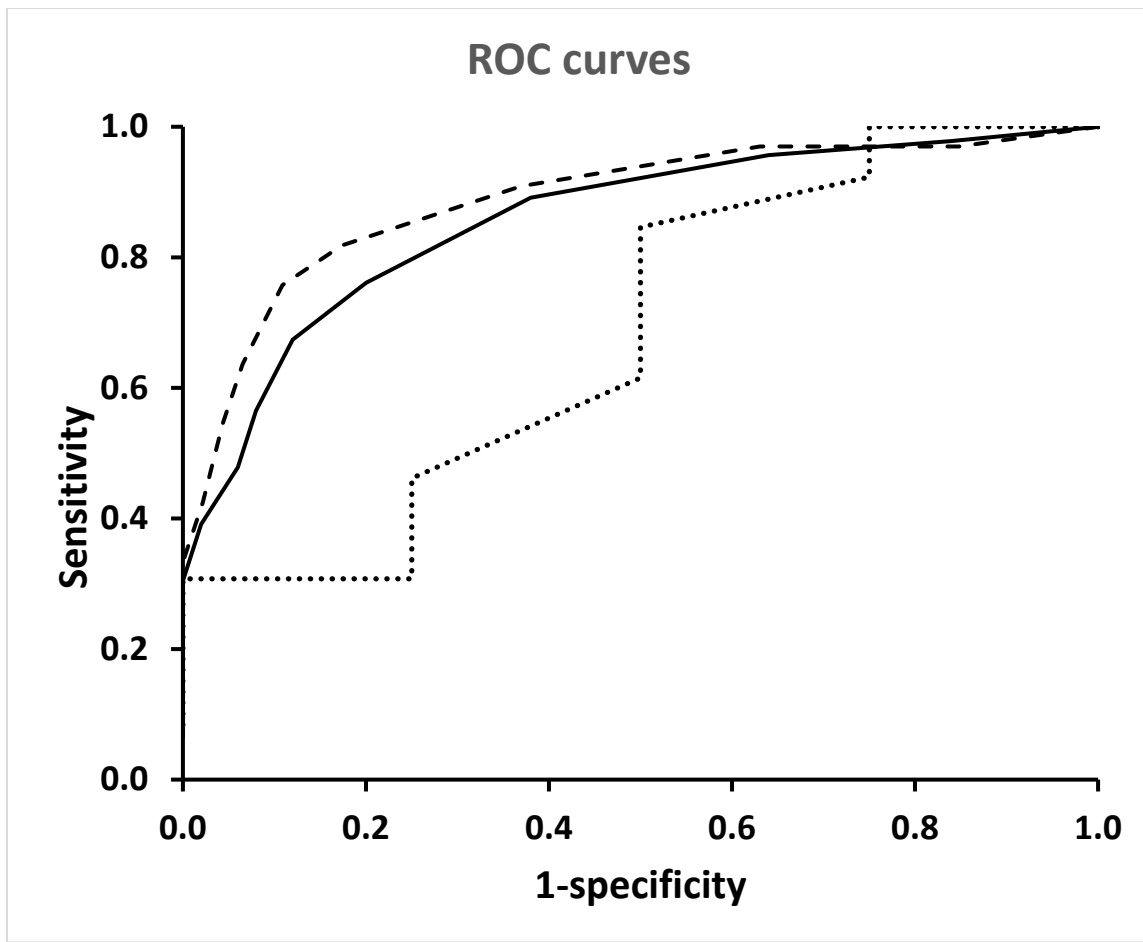


Figure 3. The ROC curve for parent caregivers (dashed line), for adolescents (dotted line) and for all participants (solid line).