

CFF/ECFS Guidelines Committee on Mental Health in Cystic Fibrosis:
Depression and Anxiety Guidelines
8-27-14

Clinical Practice Guidelines for Depression and Anxiety in Cystic Fibrosis prepared by the
CFF/ECFS I Guidelines Committee on Mental Health in Cystic Fibrosis (GCMH)

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TABLE 1: Recommendation Statements

Recommendation Statement	Consensus Vote
Prevention	
1. For all individuals with CF and caregivers, the CFF/ECFS Guidelines Committee on Mental Health in CF (GCMH), recommends that ongoing education and preventative, supportive interventions, such as training in stress management and development of coping skills aligned with appropriate developmental stages and life disease events, be offered.	100%
2. For all individuals with CF undergoing medical procedures, the GCMH recommends that behavioral approaches be used to reduce the risk of distress.	100%
Screening	
3. The GCMH recommends that children with CF ages 7-11 be clinically evaluated for depression and anxiety when caregiver depression or anxiety scores are evaluated, or when significant symptoms of depression or anxiety in the child are reported or observed by patients, caregivers, or members of the CF multidisciplinary team.	100%
4. The GCMH recommends annual screening for depression and anxiety with the PHQ-9 and GAD-7 for adolescents and adults with CF (ages 12-adulthood).	100%
5. The GCMH recommends offering annual screening for depression and anxiety to at least one primary caregiver of children and adolescents with CF (ages 0-17) using one of the following approaches listed below, depending on staffing and resources: <ul style="list-style-type: none"> • Screening with the PHQ-9 and GAD-7 • Screening with the PHQ-8 and GAD-7 • Screening with the PHQ-2 and GAD-2 	100%
Clinical Assessment	
6. The GCMH recommends that any treatment for depression and anxiety in individuals with CF and caregivers be based on clinical diagnosis. <ul style="list-style-type: none"> • A health care provider with appropriate training and expertise should evaluate the clinical significance of elevated screening scores and presenting symptoms to perform a differential diagnosis before initiating treatment. 	100%
7. For caregivers of individuals with CF who have clinically significant symptoms of depression/anxiety, the GCMH recommends referral for treatment to primary care or mental health services as indicated after initial assessment with CF team.	100%

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Intervention	
8. For all individuals with CF and symptoms of depression/anxiety, the GCMH recommends a flexible, stepped care model for clinical intervention developed and implemented in close collaboration with patients and caregivers, the multidisciplinary CF team, and other treatment providers or consultants, such as primary care or mental health specialists. <ul style="list-style-type: none"> • CF teams must identify who will be responsible to initiate and coordinate care, and monitor treatment effects. 	100%
9. The GCMH recommends that, in children with CF ages 7-11, who have clinically significant depression or anxiety, evidence-based psychological interventions are recommended as the first line treatment.	100%
10. For individuals with CF ages 12- adulthood and mild depression or anxiety symptoms, the GCMH recommends education about depression/anxiety, preventive or supportive interventions, and rescreening at the next clinical visit.	100%
11. For individuals with CF ages 12-adulthood and moderate depression or anxiety, the GCMH recommends offering or providing a referral for evidence-based psychological interventions including CBT or IPT. <ul style="list-style-type: none"> • When psychological intervention is unavailable, declined or not fully effective, antidepressant treatment should be considered. 	100%
12. For individuals with CF ages 12-adulthood and severe depression, the GCMH recommends use of combined evidence-based psychological interventions and antidepressant pharmacotherapy.	100%
13. For individuals with CF ages 12-adulthood and severe anxiety, the GCMH recommends offering exposure-based CBT. <ul style="list-style-type: none"> • When exposure-based CBT is unavailable, declined, or not fully effective, antidepressant medications can be considered. 	100%
14. The GCMH recommends that the SSRIs citalopram, escitalopram, sertraline, or fluoxetine are appropriate first-line antidepressants for most individuals with CF, ages 12-adulthood, requiring pharmacotherapy. <ul style="list-style-type: none"> • In selecting an antidepressant and adjusting its dosage, close monitoring of therapeutic effects, adverse effects, drug-drug interactions, and medical comorbidities is recommended. 	100%
15. The GCMH recommends that lorazepam be considered for short-term use for individuals with CF with moderate to severe anxiety symptoms, associated with medical procedures, that have not responded to behavioral approaches.	100%

Abbreviations:

PHQ Patient Health Questionnaire

GAD Generalized Anxiety Disorder Questionnaire

CBT Cognitive Behavioral Therapy

IPT Interpersonal Therapy

SSRI Selective Serotonin Reuptake Inhibitor

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Introduction:

In 2013, the Cystic Fibrosis Foundation (CF Foundation) and the European Cystic Fibrosis Society (ECFS) convened an expert committee, the Guidelines Committee on Mental Health (GCMH), to develop clinical care recommendations for anxiety and depression in individuals with cystic fibrosis (CF) and parent caregivers.

Meta-analyses and systematic reviews indicate that children and adults with chronic diseases, as well as parent caregivers, are at increased risk for depression and anxiety. Studies evaluating depression and anxiety in patients with CF have generally found a high prevalence of psychological distress. Rates of depression in children and adolescents have ranged from 9-29%, using different methods of assessment (ICD-9 diagnoses, Children's Depression Inventory). For adults with CF, rates of depression have ranged from 13-30% and rates of anxiety from 30% to 33%. Among parent caregivers, elevations in psychological distress have also been found, with depression ranging from 20-35%. Overall, psychological symptoms are higher in this population than community samples (Quittner et al., under review); however, small sample sizes and different screening or diagnostic tools make interpretation of the results difficult. Further, the majority of studies have only assessed symptoms of depression, but not anxiety.

The TIDES study (The International Depression Epidemiological Study) was conducted in Europe and the USA over a 3-year period. Two brief screening measures, the HADS (Depression and Anxiety) and the CES-D (Center for Epidemiological Studies-Depression) were administered to individuals with CF, ages 12 and older, and caregivers of children with CF, birth to 18. Measures were completed during a stable, routine clinic visit; demographic and health information were collected and verified via chart review.

Psychological screening measures were completed by 6,088 individuals with CF and 4,102 parents. Elevated symptoms of depression were found in 10% of adolescents, 19% of adults, 37% of mothers, and 31% of fathers. Elevations in anxiety were found in 22% of adolescents, 32% of adults, 48% of mothers and 36% of fathers. Overall, elevations were 2-3 times the rates reported in community samples (Quittner et al., under review).

Analyses of comorbid symptoms indicated that adolescents reporting depression were 14.97 times more likely to report anxiety; adults elevated on depression were 13.64 times more likely to report anxiety; mothers with elevated depression were 15.52 times more likely to report anxiety; fathers with elevated depression were 9.20 times more likely to report elevated anxiety. Significant differences were found by patient age (depression: adolescents 19% vs. adults 29%; anxiety: adolescents 22% vs adults 32%). Mothers reported more symptoms of depression and anxiety than fathers, respectively (depression 37% vs. 31%; anxiety 48% vs. 36%). Concordance between 1,122 parent-teen dyads indicated that adolescents were 2.32

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42 and 2.22 times more likely to be elevated on depression and anxiety, respectively, if a parent
43 was elevated.

44
45 To better understand the context of mental health care delivery, the GCMH sought the views of
46 the international CF community. The GCMH distributed an on-line survey to approximately
47 4,000 CF Health Professionals. In the US, the survey was distributed to approximately 2,500
48 individuals: all CF Center Directors and Affiliate Directors and to email listservs, which included
49 social workers, psychologists, and psychiatrists. In Europe, the ECFS removed duplicates from
50 their databases (those who received the survey from the US) and distributed the survey to an
51 additional 1,500 people across 33 European countries. The survey was available for completion
52 from 3rd November 2013 to 28th February 2014.

53
54 There were 1,454 respondents (response rate of 36%). A similar percentage of the sample came
55 from the US (45%) and Europe (49%). Almost 4% of the sample was located in Canada,
56 Australia, New Zealand, South Africa and Russia. The largest professional categories of
57 respondents were physicians, physiotherapists, and nurses. Only 7% of the sample comprised
58 psychologists or psychiatrists.

59
60 In the US, responsibility for mental health issues was predominantly undertaken by social
61 workers, whereas in Europe, psychologists handled this responsibility. However, the majority
62 did not have a colleague *trained* to manage mental health issues and over 20% of respondents
63 had no one on their team whose primary role was mental health. Thirty percent of
64 respondents were unable/unsure if they could refer to mental health clinicians in their hospital
65 and half did not have up-to-date lists of mental health resources and referrals.

66
67 Seventy-three percent of respondents did not have any experience of screening for anxiety and
68 depression. For those who did, there was a great deal of variability in the screening measures
69 that were used, with the most common measures being the Hospital Anxiety and Depression
70 Scale (HADS: predominantly used in Europe), the Patient Health Questionnaire – 9 (PHQ-9:
71 predominantly used in the US) and the Beck Depression Inventory (BDI). Perceived barriers to
72 screening included problems with referrals and in-house capacity for intervention, a lack of
73 trained personnel to administer the measure, and clinic flow disruption. Resources requested
74 by CF Centers included funds to support a mental health professional, access to mental health
75 resources and referrals, training in mental health screening, access to electronic tools for
76 administration and access to a mental health ‘hotline’ for guidance.

77
78 **Methods:**

79
80 The CF Foundation and ECFS invited 22 experts to develop clinical care recommendations.
81 Committee members included psychiatrists, psychologists, pharmacologists, nurses, social
82 workers, physicians, parent caregivers, and an individual with CF. Convening in May 2013, the
83 committee divided into four sub-groups, each responsible for a topic: Screening, Treatment-
84 Pharmacology, Treatment-Psychology, and Dissemination and Implementation. Topic-specific

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85 questions using the PICO format (Population, Intervention, Comparison, Outcome) were
86 outlined and approved by the entire committee to guide a subsequent literature review. A scan
87 of existing guidelines and systematic reviews about screening, treating, and managing
88 symptoms of depression and anxiety in individuals with chronic illnesses was conducted. Each
89 sub-group also conducted searches in PubMed and ABDATA databases and reviewed CF-specific
90 guidelines and Cochrane reviews, guidelines targeted to general and chronically ill populations.
91 These were supplemented by systematic reviews, standard texts, and targeted literature
92 reviews addressing specific topics requiring further study. Searches were limited to the English
93 language and ranged from 1960 to 2014.

94
95 In April 2014, the committee convened to finalize draft recommendation statements. A priori,
96 the committee agreed to set an 80% agreement threshold for acceptance of a recommendation
97 statement. Sub-groups leaders presented the recommendation statements and rationale.
98 Following discussion, members were instructed to vote anonymously in support of each
99 statement. For statements that did not reach 80% consensus, the committee discussed
100 revisions and re-voted. At the conclusion of the meeting, the final recommendation statements
101 were sent to the committee members who were unable to attend in person. The committee
102 chairs reviewed the results of these votes, and revised one statement that was sent out for a
103 subsequent round of voting.

104
105 A draft of the recommendation statements was presented at the 2014 ECFS Conference and is
106 being distributed via an on-line survey for public comment in both Europe and the United
107 States. The committee will consider all comments and revise the recommendations as
108 appropriate.

109
110 **Results**

111
112 Initially, several thousand abstracts were reviewed. Next, 100 to 400 empirical articles and 30-
113 64 guidelines articles were reviewed by each subcommittee. Articles were excluded if they
114 were not in English or did not address the PICO questions. Between 75 and 100 articles were
115 included in this review by each subcommittee to support the recommendation statements.

116
117 **Prevention:**

118 In the course of routine CF care, all individuals with CF and caregivers should be offered
119 education and preventative, supportive interventions to promote effective coping skills and
120 disease management. For example, behavioral approaches can reduce the risk of distress
121 related to medical procedures. For moderate to severe episodic anxiety associated with medical
122 procedures, that has not responded to behavioral approaches, lorazepam may be considered
123 for short-term use.

124
125 **Screening:**

126 Following a brief explanation and discussion of the rationale for screening mental health issues,
127 all *patients* with CF 12 years or older should be screened for depressive and anxious symptoms

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128 annually. Screening should be done using a valid and reliable measure that produces scores
129 that are clinically relevant. The first step for all patients is to use the Patient Health
130 Questionnaire 9 (PHQ-9), which evaluates the classic symptoms of depression based on the
131 Diagnostic and Statistical Manual of Mental Disorders, and the Generalized Anxiety Disorder 7-
132 item scale (GAD-7), which assesses anxiety (PHQ-9 and GAD-7 <http://www.phqscreener.com/>).
133 For patients who endorse the suicide item on the PHQ-9 (Question 9), the designated person
134 who addresses mental health issues on the CF Team should follow up immediately with that
135 person to determine how serious this risk is. This could include a clinical interview or further
136 assessment. There are formal tools to evaluate this risk. In particular, the Columbia Suicide
137 Severity Rating Scale (C-SSRS; <http://www.cssrs.columbia.edu/ecssrs.html>) is free, well-
138 validated, and available in over 100 country-specific languages. This tool was designed to be
139 used by "lay professionals" (e.g., teacher, law enforcement) and has an online training course
140 and certification available. It is appropriate for children, adolescents and adults (Posner et al.,
141 2011; Mundt et al., 2013).

142
143 Before initiating annual screening, CF teams should identify an appropriate clinician on the
144 team who has training and expertise in mental health issues, develop educational materials on
145 the importance of assessing and treating depression and anxiety, and establish a list of referral
146 sources both within the hospital and in the surrounding communities. It is also important to put
147 a plan in place to address suicidal ideation if the PHQ-9 is used and the suicide item is endorsed
148 (e.g., clinical assessment, clinical interview, visit to Emergency Department).

149
150 Following a brief explanation and discussion of the rationale for screening mental health issues,
151 all *caregivers* of patients 0-17 years should be offered annual screening. When screening
152 caregivers, the PHQ-9 and GAD-7 are also recommended. For patients who endorse the suicide
153 item on the PHQ-9 (Question 9), the designated person who addresses mental health issues on
154 the CF Team should follow up immediately with that person to determine how serious this risk
155 is. This could include a clinical interview or further assessment. There are formal tools to
156 evaluate this risk. In particular, the Columbia Suicide Severity Rating Scale (C-SSRS;
157 <http://www.cssrs.columbia.edu/ecssrs.html>) is free, well-validated, and available in over 100
158 country-specific languages. This tool was designed to be used by "lay professionals" (e.g.,
159 teachers, law enforcement) and has an online training course and certification available. It is
160 appropriate for children, adolescents and adults (Posner et al., 2011; Mundt et al., 2013).

161
162 Some CF centers may choose to omit the question that assesses self-harm on the PHQ-9 and
163 administer the eight-item version (PHQ-8,
164 <http://patienteducation.stanford.edu/research/phq.pdf>). An alternative approach is to use
165 two items from the PHQ-9 on low mood and anhedonia (PHQ-2,
166 http://www.cqaimh.org/pdf/tool_phq2.pdf) and two items from the GAD-7 on feeling
167 anxious/nervous and not being able to stop or control worrying (GAD-2,
168 http://depression.acponline.org/content/all/tools/dcg_o11.pdf). For all caregivers who screen
169 positive, a referral to their primary care provider or mental health specialist is recommended.

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171 For children with CF, ages 7 to 11, whose parents score in the elevated range or who
172 themselves appear to have clinical concerns, referrals for clinical assessment or screening
173 should be made to mental health experts on the team or in the hospital or community.
174

175
176

Clinical Assessment:

177 As a second step for patients with CF 12 years or older who screen positive for depressive
178 and/or anxious symptoms, an assessment is recommended prior to initiation of treatment.
179 When assessing a person who may have depressive or anxious symptoms, identifying the
180 presence, duration and severity of the symptoms is the first step. It is also important to identify
181 pertinent history and risk factors. For example, is there any prior history of depression or
182 anxiety, history of prior treatment and response to treatment(s), family history of psychiatric
183 illnesses, history of comorbid psychiatric diagnoses, severity of CF, presence of complications,
184 or the presence of other chronic illnesses? Treatment decisions should be based on clinical
185 diagnosis and not solely on the results of the screening measure. CF teams will have to decide
186 when referral to a trained mental health professional for further assessment and diagnosis is
187 required, based on the expertise within their teams.
188

189

Intervention

190 A variety of national governments and national or international professional associations have
191 issued evidence-based guidelines for the treatment of depression and anxiety in the general
192 population and in those with chronic illness. Given that minimal research has specifically
193 examined the treatment of depression and anxiety in CF (Goldbeck, L., Fidika, A., Herle, M. &
194 Quittner, A.L. 2014), the GCMH used developmentally appropriate, existing guidelines as a
195 starting point for recommending care for the treatment of children, adolescents, and adults
196 with CF. Although treatment plans require consideration of potential adverse effects and
197 overall burden of care, the risks of not treating depression or anxiety are often heightened in
198 individuals with CF; these risks include not only worsening symptoms of depression or anxiety,
199 but also worse adherence to CF care, and increased health care utilization and costs.
200

201

202 Treatment plans for depression or anxiety in individuals with CF should be developed and
203 implemented in close collaboration with patients and caregivers, the multidisciplinary CF team,
204 and other treatment providers or consultants, such as primary care or mental health specialists.
205 Figure 1 provides a conceptual overview for the screening and treatment process. Figures 2 and
206 3 illustrate our recommended, flexible stepped-care model for prevention, screening, and
207 intervention for depression and anxiety in individuals with CF. Factors including patient age,
208 rating scale scores, and assessment of clinical significance, functional impairment, and safety
209 should be considered in developing a plan of care.

210

211 In addition, interventions may be adjusted to take into account patient/caregiver preference,
212 medical status, psychiatric comorbidities, resource availability, and local practice patterns. The
213 PHQ-9 and GAD-7 can be used both as screening tools and to assess treatment response and
adequacy of the current treatment plan. If depression or anxiety symptoms continue to be

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214 elevated or functioning remains impaired, additional interventions should be offered until
215 symptoms return to the normal range.

216

217 Psychological interventions tailored to individual and family needs are recommended as the
218 first-line approach in all children with CF ages 7-11 with clinically significant depression or
219 anxiety requiring treatment. Specialized consultation should be obtained if psychological
220 interventions are not sufficiently effective.

221

222 Adolescents and adults with CF (ages 12 and above) whose depression or anxiety is in the mild
223 range should receive education, preventive or supportive psychological interventions, and
224 rescreening at the next CF visit. Evidence-based psychological interventions should be offered
225 to all adolescents and adults with CF whose depression or anxiety is of at least moderate
226 severity. Cognitive-Behavioral Therapy (CBT) and Interpersonal Therapy (IPT) are recommended
227 because there is an extensive body of literature supporting their efficacy and use.

228

229 When antidepressant medication is used in individuals with CF, it should generally be
230 prescribed in conjunction with psychological interventions, as part of a comprehensive
231 treatment plan. For those with severe depression, evidence supports the combined use of
232 antidepressants and psychological interventions as the most effective initial therapy. For
233 adolescents and adults with CF and moderate depression or moderate to severe anxiety,
234 antidepressant medication should be considered when psychological interventions are not
235 feasible or fully effective.

236

237 When pharmacotherapy is needed, the selective serotonin reuptake inhibitors citalopram,
238 escitalopram, sertraline, or fluoxetine are appropriate initial choices for most adolescents and
239 adults with CF. Since the pharmacokinetics of psychotropic medication may be altered in CF,
240 optimal dose adjustment requires close monitoring of therapeutic effects, adverse effects, and
241 medical status. Dose reduction may be required in individuals with renal or hepatic impairment,
242 treatment-emergent adverse effects, or drug-drug interactions. Dose increases may be required
243 for individuals with impaired absorption or enhanced hepatic metabolism, partial response to
244 treatment, or drug-drug interactions.

245

246 Prescribing clinicians should be informed of all medications used daily, regularly cycled, or used
247 periodically for CF exacerbations. Linezolid is not recommended for use with serotonergic
248 antidepressants when alternatives are readily available. When both are clinically necessary, the
249 lowest effective doses should be used, with informed consent and monitoring for serotonin
250 syndrome. EKG and electrolyte monitoring can be considered when simultaneous use of
251 multiple medications known to prolong the QTc is clinically necessary. Therapeutic drug
252 monitoring of blood levels, when available, may supplement clinical monitoring for
253 psychotropic medication dosing.

254

255 Medications used for treatment-resistant depression, which may carry increased risks of drug-
256 drug interactions and adverse effects in individuals with CF, are outside the scope of this

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257 guideline. When necessary, they should be prescribed and monitored by a psychiatric specialist
258 in close collaboration with the CF team. Specialized consultation should also be obtained when
259 the psychiatric diagnosis is uncertain, the complexity of the case exceeds the CF team's level of
260 training and experience, or when an urgent safety risk is identified.

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Figure 1: Assessing & Treating Depression & Anxiety in CF

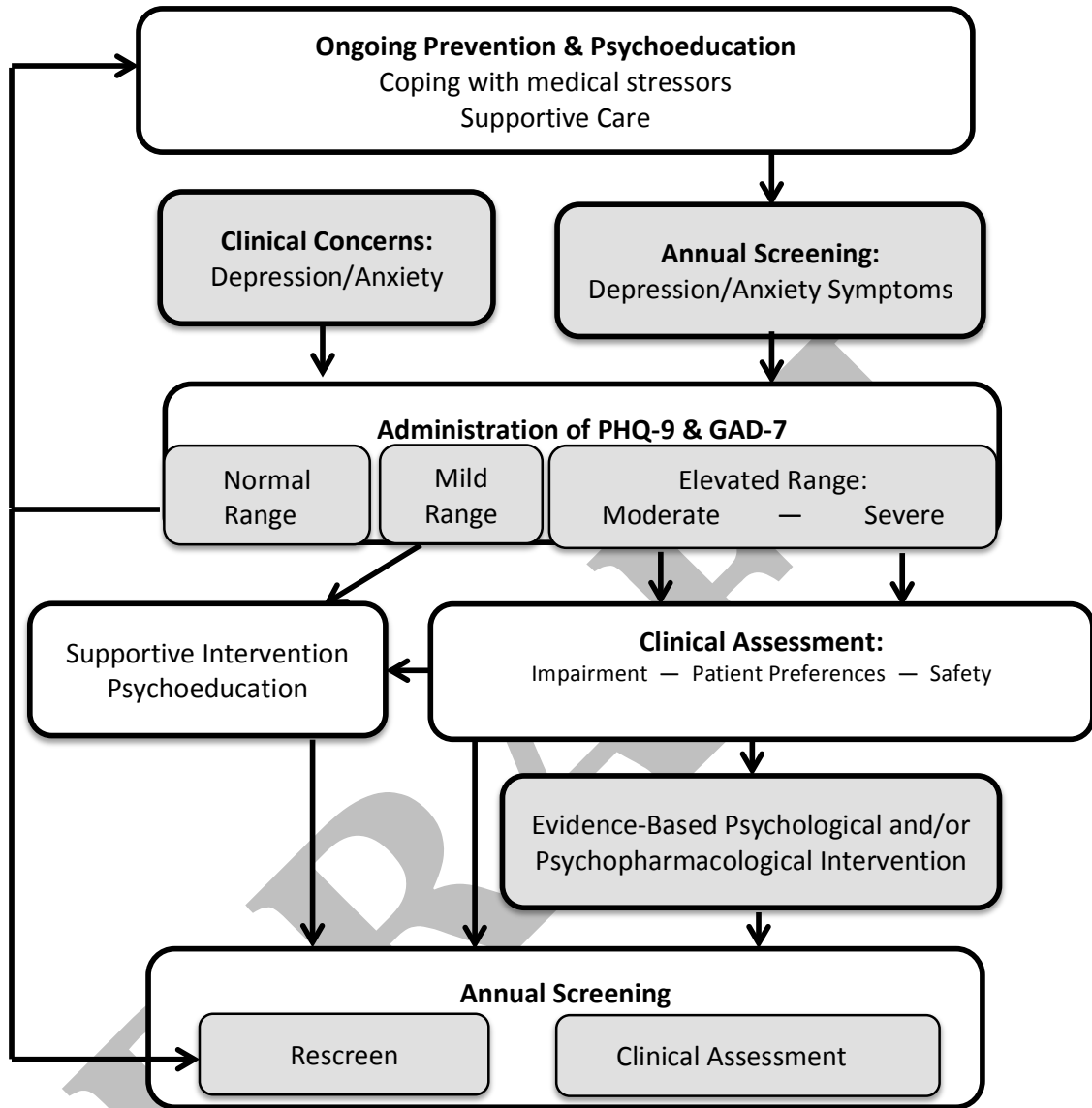
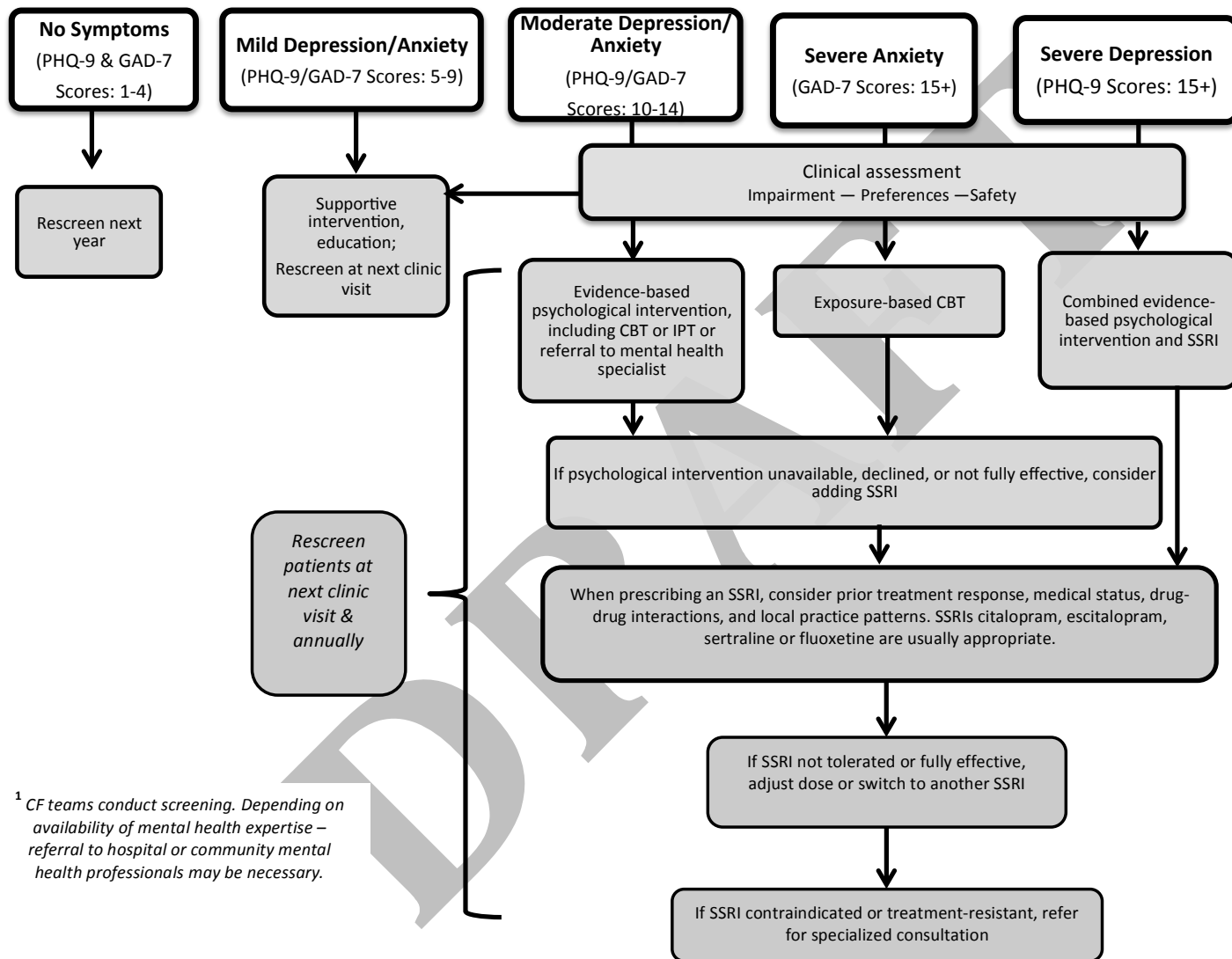


Figure 1 demonstrates our suggested flexible, stepped-care model for prevention, screening, and intervention for depression and anxiety in individuals with CF. Factors including patient age, rating scale scores, and assessment of clinical significance, functional impairment, and safety should be considered in developing a plan of care. In addition, interventions may be tailored to patient/caregiver preference, medical status, psychiatric comorbidities, resource availability, and local practice patterns.

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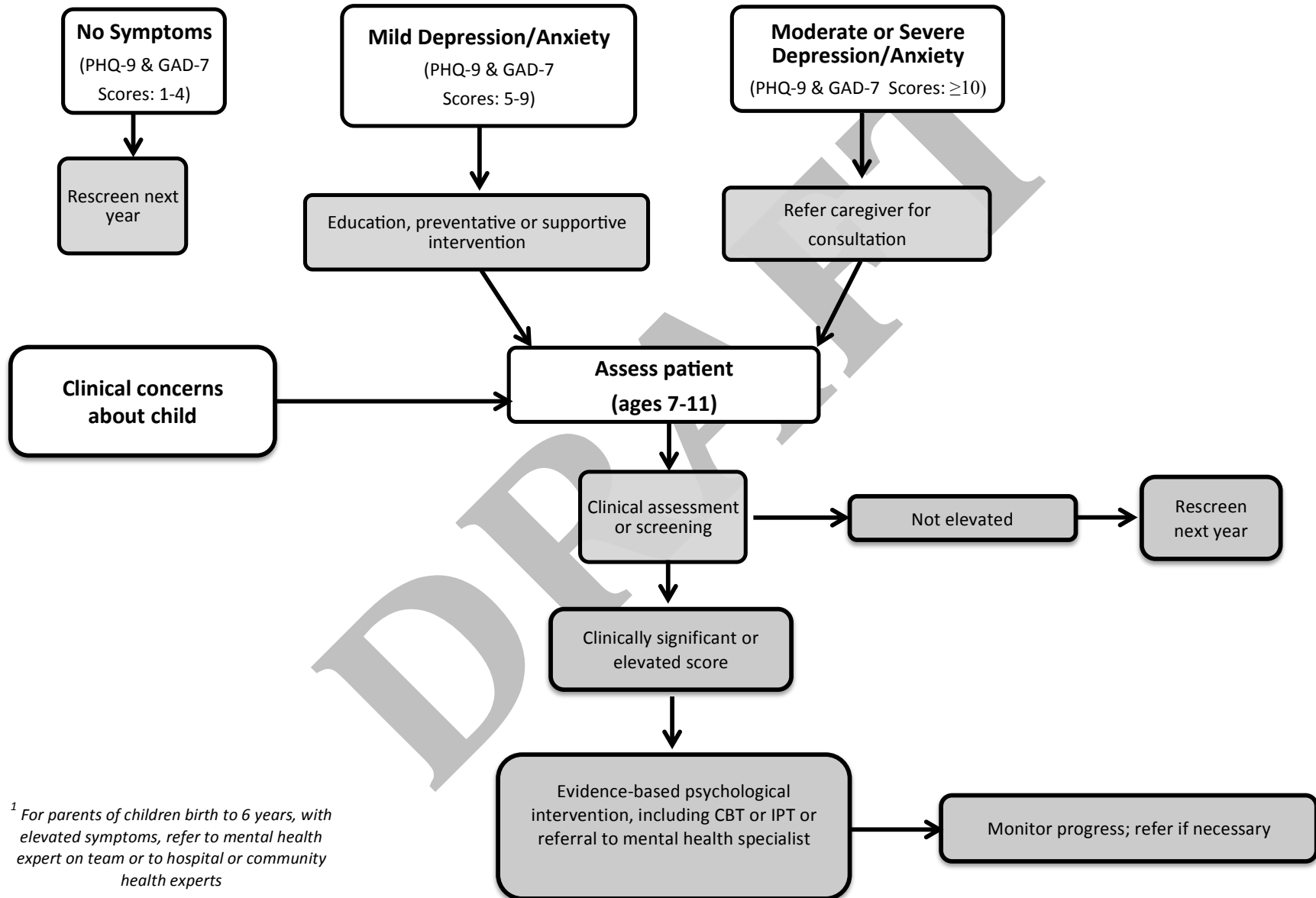
Figure 2: Screening & Treatment for Depression & Anxiety: Algorithm for Individuals with CF (Ages 12-Adulthood)¹



¹ CF teams conduct screening. Depending on availability of mental health expertise – referral to hospital or community mental health professionals may be necessary.

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Figure 3: Screening & Treatment for Depression & Anxiety: Algorithm for Parents/Caregivers¹



¹ For parents of children birth to 6 years, with elevated symptoms, refer to mental health expert on team or to hospital or community health experts

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