What Is Adherence?

- The WHO Adherence Project defines adherence as: the extent to which a person's behavior—taking medication, following a diet, and/or executing lifestyle changes—corresponds with agreed recommendations from a healthcare provider.

Sustaining Daily Care in CF—
A Lifelong Commitment

What Do We Know About Adherence in CF?

- Suboptimal treatment adherence in CF is common and may vary by age, treatment, and measurement methods
- Many tools are available to measure adherence in CF, each with their own advantages and disadvantages
- Poor adherence has significant health-related and financial costs
- There are many barriers to adherence in CF care
- It often takes a diversified approach to address adherence
Adherence Rates Vary by Age

CMPRs by age category. The bottom, midline, and top of each box represent the lower quartile, median, and upper quartile, respectively. The endpoints of the vertical lines represent the minimum and maximum values (● indicates the mean value). The CMPR is the average of the individual drug MPRs.


Longitudinal Rates of Medication Refills by Age Over 5 Years

Adherence Rates Vary by CF Pulmonary Medications

Mean MPRs for various long-term pulmonary medications used in CF. The bottom, midline, and top of each box represent the lower quartile, median, and upper quartile, respectively. The endpoints of the vertical lines represent the minimum and maximum values (● indicates the mean value). The composite MPR is the average of the individual drug MPRs.


Adherence Rates to Ivacaftor (CFTR Modulator)

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Rates of Adherence With Different Measurements

<table>
<thead>
<tr>
<th>Medications/Treatments</th>
<th>Self Reported</th>
<th>Phone Diary</th>
<th>Prescription Refill</th>
<th>Electronic Monitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebulized Medications</td>
<td>36%-90%</td>
<td>36%-57%</td>
<td>68%-72%</td>
<td>8%-100%</td>
</tr>
<tr>
<td>Pancreatic Enzymes</td>
<td>8%-98%</td>
<td>27%</td>
<td>46%</td>
<td>27%-43%</td>
</tr>
<tr>
<td>Airway Clearance</td>
<td>40%-74%</td>
<td>51%-64%</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Overall Rates of Adherence Across Treatments by Measurement Method

Rates of Adherence to Prescribed Nebulizer Treatments: Self Report, Clinician Report, and Electronic Monitoring
### Tools to Address Adherence in CF: Self Report

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inexpensive</td>
<td>Can have inflated estimates of adherence because patients want to “please” their healthcare team</td>
</tr>
<tr>
<td>Easy to complete</td>
<td>Longer recall, less accuracy</td>
</tr>
<tr>
<td>Measures each component of the treatment regimen (eg, alterations in diet)</td>
<td></td>
</tr>
</tbody>
</table>


### Tools to Address Adherence in CF: Daily Phone Diary

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unobtrusive</td>
<td>Labor intensive; requires trained assistants to do the calls</td>
</tr>
<tr>
<td>Well established</td>
<td>Need access to phone, scheduling issues</td>
</tr>
<tr>
<td>Used in many CF studies with good reliability and validity</td>
<td>Limited usefulness for younger children</td>
</tr>
<tr>
<td>Allows healthcare team to gather information about the processes related to poor disease management and identify barriers</td>
<td>Not well suited for treatments that takes less than 5 minutes (ie, oral medications)</td>
</tr>
<tr>
<td>Uses an ecologic momentary assessment technique, which produces data on adherence in “real time,” thereby reducing memory and recall problems</td>
<td>Produces extensive and complex data that require more sophisticated analytic procedures</td>
</tr>
</tbody>
</table>

### Tools to Address Adherence in CF: Pharmacy Refill Records

<table>
<thead>
<tr>
<th><strong>Advantages</strong></th>
<th><strong>Disadvantages/Challenges</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifies which medications have been obtained (type and amount)—not just those that were prescribed</td>
<td>Cannot determine what is actually taken</td>
</tr>
<tr>
<td>Determines drug availability</td>
<td>Does not capture samples dispensed by physicians at their offices or in emergency rooms</td>
</tr>
<tr>
<td>Convenient and easy to obtain</td>
<td>May not be accurate if the prescription is written for more than one month's amount of medication</td>
</tr>
<tr>
<td>Allows for longer history of refills without patient input or recall</td>
<td>Use of auto refill skews the data</td>
</tr>
<tr>
<td>Yields an MPR, which reflects whether a prescription has been refilled</td>
<td></td>
</tr>
</tbody>
</table>

**Advantages**

- Identifies which medications have been obtained (type and amount)—not just those that were prescribed
- Determines drug availability
- Convenient and easy to obtain
- Allows for longer history of refills without patient input or recall
- Yields an MPR, which reflects whether a prescription has been refilled

**Disadvantages/Challenges**

- Cannot determine what is actually taken
- Does not capture samples dispensed by physicians at their offices or in emergency rooms
- May not be accurate if the prescription is written for more than one month's amount of medication
- Use of auto refill skews the data

---

### Tools to Address Adherence in CF: Electronic Monitoring

<table>
<thead>
<tr>
<th><strong>Advantages</strong></th>
<th><strong>Disadvantages/Challenges</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective, rather than subjective (diaries or self report)</td>
<td>Devices can malfunction or data can be lost</td>
</tr>
<tr>
<td>Precise recording of the date, time, and duration of treatments</td>
<td>Measurement is “presumptive” dosing—an assumption that patients ingest what they dispense</td>
</tr>
<tr>
<td>Continuous, long-term measurement that is unaffected by response biases</td>
<td>Monitors can underestimate adherence if patients take out several doses at once to carry with them when they are away from home or to load pill-reminder boxes</td>
</tr>
<tr>
<td>Can identify a variety of adherence issues: under- and over-use of medications, improper technique in taking medications, delayed dosing, and drug “holidays”</td>
<td>Practical issues, such as portability and improper fit between the medication and device may also reduce their utility and are not available for all treatments</td>
</tr>
<tr>
<td>Privacy concerns</td>
<td></td>
</tr>
</tbody>
</table>

**Advantages**

- Objective, rather than subjective (diaries or self report)
- Precise recording of the date, time, and duration of treatments
- Continuous, long-term measurement that is unaffected by response biases
- Can identify a variety of adherence issues: under- and over-use of medications, improper technique in taking medications, delayed dosing, and drug “holidays”

**Disadvantages/Challenges**

- Devices can malfunction or data can be lost
- Measurement is “presumptive” dosing—an assumption that patients ingest what they dispense
- Monitors can underestimate adherence if patients take out several doses at once to carry with them when they are away from home or to load pill-reminder boxes
- Practical issues, such as portability and improper fit between the medication and device may also reduce their utility and are not available for all treatments
- Privacy concerns

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Association of Adherence and Health Outcomes

- Courses of IV Antibiotics
- Lung Function

Suboptimal Adherence Is Associated With Higher Healthcare Costs


What Do We Know About Adherence in CF?

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### Potential Barriers to Treatment Adherence in CF

<table>
<thead>
<tr>
<th>Source of Barrier</th>
<th>Barrier</th>
</tr>
</thead>
</table>
| **Patient and/or Parent** | - Complexity of the treatment regimen  
- Poor social support  
- Competing social and work demands  
- Poor health/fatigue  
- Stigma/embarrassment  
- Frequency of interaction with the healthcare team  
- Financial barriers/access |
| **Healthcare System** | - Lack of perceived benefit  
- Forgetting  
- Side effects  
- Difficulty swallowing pills  
- Disliking the taste  
- Daily habits/routines (eg, vacation, summer, extracurricular activities)  
- Oppositional behavior  
- Mental health (ie, anxiety, depression) |
| **Healthcare Team** | - Costs  
- Health insurance (ie, prior authorization causing delay in obtaining medication or refusal)  
- Access  
- Required to use multiple pharmacies (ie, specialty pharmacies, mail order)  
- Poor communication  
- Lack of providing education (both knowledge and skills)  
- Complexity of care  
- Continuity of care  
- Attitudes and beliefs  
- Lack of time |
What Do We Know About Adherence in CF?

- Suboptimal treatment adherence in CF is common and may vary by age, treatment, and measurement methods.
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- It often takes a diversified approach to address adherence.

Jessica, a 27-Year-Old Woman With CF

- Diagnosed with CF (F508del/F508del)
- Her current medications include:
  - Nebulized albuterol TID
  - Inhaled tobramycin BID 28 days on/28 days off
  - Dornase alfa daily
  - Hypertonic saline BID
  - Fluticasone propionate MDI BID
  - Vest TID
  - Pancreatic enzymes with meals and snacks
  - Multivitamins (ADEK and extra D3)
  - Azithromycin 3x/week
- FEV₁ dropped from 90% predicted (her baseline) to 75% predicted.
- Lost 2 kg in 2 months.

How can you accurately ascertain whether poor adherence is contributing to Jessica’s decline in health status?
Use of a Multipronged Approach to Increase Adherence

Tools for CF care teams:
- Good communication skills: ask open-ended questions, phrase questions in a positive manner, avoid medical jargon, use active-listening skills
- Establish good relationships that foster adherence discussions at every visit
- Help patients identify challenges and barriers
- Normalize adherence
- Individualize care
- Simplify treatment plans whenever possible (eg, use MDI instead of aerosols)
- Provide written treatment plans for home
- Provide adherence education for all care team members
- Employ care team members or consultants who are adept at CBT, problem solving, and/or motivational interviewing
- Assess mental health status (eg, depression, anxiety)


Jessica, a 27-Year-Old Woman With CF

Jessica states that she received a promotion at work and now has new responsibilities that make it difficult to fit in all of her treatments. She adds that she plans to find time to do her treatments soon, but she wants to focus more on her new role at work right now.

What can you do that would likely help improve Jessica’s adherence?
Use of a Multipronged Approach to Increase Adherence

Tools for patients and families:
- Develop a caring, trusting, and mutually respectful relationship with one's CF care team
- Establish a treatment schedule
- Increase knowledge of CF
- Increase self-care skills and independence
- Use phone apps, text messaging, and other reminders
  - [http://myhealthapps.net/app/details/425/cf-medcare](http://myhealthapps.net/app/details/425/cf-medcare);
  - [https://www.mangohealth.com/](https://www.mangohealth.com);
- Practice good communication skills: be open, have an honest dialog, ask for clarification, use active-listening skills
- Be open to new ideas
- Communicate concerns about barriers and challenges regarding treatment plans with care teams


Logan, a 14-Year-Old Boy With CF

- Diagnosed with CF (F508del/W1282X)
- History of *Pseudomonas aeruginosa* infection
- Coughing more than usual, and his FEV₁ has declined to 80% predicted (baseline 103%)
- His mother reports that she feels he is “lazy” with his airway clearance and nebulized treatments
- Logan complains that his mother is “constantly nagging him”

How can you help improve Logan’s adherence to his CF treatment regimen?
Use of a Multipronged Approach to Increase Adherence

Tools for CF care teams:

- Good communication skills: ask open-ended questions, phrase questions in a positive manner, avoid medical jargon, use active-listening skills
- Establish good relationships that foster adherence discussions at every visit
- Help patients identify challenges and barriers
- Normalize adherence
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Use of a Multipronged Approach to Increase Adherence

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- Communicate concerns about barriers and challenges regarding treatment plans with care teams

CF Foundation Commitment to Addressing Adherence

• In November 2012, the CF Foundation developed a Strategic Planning Committee
  – Appointed by the CF Foundation Board of Trustees
  – Made up of 29 individuals representing the CF community
  – Included Individuals with CF, CF family members, care center professionals, researchers, CF Foundation board members/volunteers, chapter and national office leaders
• One of the objectives added to their mission as part of their 5-year plan was addressing adherence:

"We will increase adherence with prescribed therapies to 80% among at least 75% of people with CF"

CF Foundation’s Priority Action Goals for Addressing Adherence

1. We will establish a multidisciplinary stakeholder advisory committee to provide input and guidance for the adherence initiative
2. We will collect prescription refill data on all people with CF to establish an objective measure for monitoring adherence
3. We will develop and implement a validated adherence-barriers assessment that can be deployed by all CF care centers
4. We will design and implement a series of pilot adherence interventions at a network of CF care centers
5. We will plan and implement a multichannel communication campaign to raise awareness and inform people with CF and their families and care providers about the importance of adherence
CF Foundation Success
With Therapies Research Consortium

14 States
7 Adult Care Centers
13 Pediatric Care Centers (5 with potential to recruit adults)

Summary
1. Address adherence at **EVERY** visit using a multifaceted approach:
   - Self report and assess for barriers: “Tell me how you take your enzymes?” “What gets in the way of taking your enzymes at school?”
   - Pharmacy reports: “I see you filled your [dornase alfa] twice in the last 4 months. Tell me how many times you took it last week?”
2. Have a toolkit with multiple interventions that can address adherence in a practical, efficient manner
   - Educational and technology resources (ie, CF Foundation–approved educational materials, phone apps, electronic monitors)
   - Individual written plans of care/discharge instructions
   - Problem solving with goal setting
3. Involve mental health professionals to address complicating factors including depression, anxiety, and complex social situations
4. Remember that this is a **PARTNERSHIP** with patients and families in which we support them in their efforts to adhere to complex CF regimens
Integrated Health and Well-Being

Depression

A Continuum

Normal Mood Lowering

Abnormal Mood Lowering

Abnormal Mood Lowering and Loss of Functioning
Depression

Depressive disorder:
• Pervasive
• Persistent
• Wide range of symptoms
  – Negative views, pessimism
  – Worthlessness, guilt, and/or hopelessness
  – Sleep and appetite disturbance
  – Loss of energy
  – Inability to concentrate
  – Anger or irritability

Major Depressive Disorder: DSM-5 Criteria

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) diminished interest or pleasure

1. Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observation made by others (e.g., appears tearful)

2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation)

3. Significant weight loss when not dieting or weight gain (e.g., change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day

4. Insomnia or hypersomnia nearly every day

5. Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)

6. Fatigue or loss of energy nearly every day

7. Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)

8. Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)

9. Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

Major Depressive Disorder: DSM-5 Criteria

B. The symptoms cause significant distress or impairment in social, occupational, or other important areas of functioning
C. The symptoms are not attributable to the physiological effects of a substance (e.g., a drug abuse, a medication) or another medical condition
D. The disturbance is not better explained by schizoaffective disorder, schizophrenia, schizoaffective disorder, or other specified or unspecified schizophrenia spectrum and other psychotic disorders
E. There has never been a manic episode or a hypomanic episode

Anxiety

Anxiety disorder:
• Worry, anxiety, or fear that interferes with daily functioning
• Maladaptive, excessive, persistent
• Wide range of symptoms
  – Somatic: fatigue, restlessness, ↑ heart rate
  – Cognitive: unwanted thoughts
  – Behavior: avoidance
  – Emotions: anxiety, irritability, hopelessness

Generalized Anxiety Disorder: 
DSM-5 Criteria

A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for ≥ 6 months, about a number of events or activities (such as work or school performance)
B. The individual finds it difficult to control the worry
C. The anxiety and worry are associated with 3 (or more) of the following 6 symptoms (with at least some of symptoms having been present for more days than not for the past 6 months):
   A. Restlessness or feeling keyed-up or on edge
   B. Being easily fatigued
   C. Difficulty concentrating or mind going blank
   D. Irritability
   E. Muscle tension
   F. Sleep disturbance (difficulty falling or staying asleep, or restless, unsatisfying sleep)

D. The anxiety, worry, or physical symptoms cause significant distress or impairment in social, occupational, or other important areas of functioning
E. The disturbance is not attributable to the physiological effects of a substance (eg, a drug of abuse, a medication) or another medical condition (eg, hyperthyroidism)
F. The disturbance is not better explained by another mental disorder (eg, anxiety or worry about having panic attacks in panic disorder, negative evaluation in social anxiety disorder [social phobia], contamination or other obsessions in obsessive-compulsive disorder, separation from attachment figures in separation anxiety disorder, reminders of traumatic events in posttraumatic stress disorder, gaining weight in anorexia nervosa, physical complaints in somatic symptom disorder, perceived appearance flaws in body dysmorphic disorder, having a serious illness anxiety disorder, or the content of delusional beliefs in schizophrenia or delusional disorder)

Depression and Anxiety in Chronic Illness

• For individuals with a chronic illness or caregivers of a child with a chronic illness:
  – Feelings of depression and anxiety are normal responses to a challenging situation
  – These feelings affect our behavior
• Individuals with a chronic illness have a greater risk of experiencing symptoms of depression and anxiety\(^1\),\(^2\)
  – Parent caregivers also have a higher risk\(^3\)


Prevalence of Depression and Anxiety in CF

• TIDES-CF assessed rates of depression and anxiety in patients with CF and parent caregivers in Europe and the US
  – High rates of depression and anxiety were found in patients and caregivers
  – Rates are 2 to 3 times higher than the rates in healthy populations

Depressive Symptoms in CF

- High rates of depression
  - 10% of adolescent patients
  - 19% of adult patients
  - 37% of mothers
  - 31% of fathers
- Differences by age:
  - Greater in adults with CF than adolescents
  - Greater in adolescents when the parent score was elevated


Anxiety in CF

- High rates of anxiety in CF
  - 22% of adolescent patients
  - 32% of adult patients
  - 48% of mothers
  - 36% of fathers
- Non-CF
  - Pediatric: 6% to 20% at least one diagnosis
  - Adult: 29% lifetime prevalence of any diagnosis

Why More Pervasive in CF?

- Medical symptom burden
- Somatic symptom confusion
- School/work problems
- Peer rejection/bullying/relationships (social isolation)
- Complexity of the healthcare/insurance environment
- Medical trauma
- Acute stress
- Illness uncertainty/fear of future
- Pill swallowing
- Needle phobia
- Fear of poor performance in PFT lab
- Fear of hospitalization
- Culturing an undesirable organism
- Antibiotic resistance

Consequences of Depression and Anxiety in CF

- Adherence
  - Depression = lower rates of adherence
  - Anxiety = curvilinear relationship to adherence
  - Possibly mediates relationship between adherence and health outcomes
- Health outcomes
  - More medical symptoms
  - Worse overall health (exacerbations)
  - Greater functional impairment
  - Increased healthcare cost
- HRQOL
  - Decreased HRQOL and life satisfaction

Consequences of Depression and Anxiety in Caregivers

• In the TIDES-CF study¹:
  – Adolescents were approximately 2.5 times more likely to be above the cut-off for depression if a parent was elevated
  – Adolescents were 2.2 times more likely to be above the cut-off for anxiety if a parent was elevated

• Parental depression in CF has been associated with negative effects on a child’s adherence²

International Committee on Mental Health in CF

• CF Foundation and European Cystic Fibrosis Society Consensus Statements for Screening and Treating Depression and Anxiety
  – 22 experts developed recommendations for clinical care over 18 months
  – Physicians, psychologists, psychiatrists, nurses, social workers, pharmacists, parents, adults with CF
  – Created consensus mental health screening and treatment guidelines for people with CF and their caregivers

References:
How to Get Started

- Identify who are the integral players for screening and assessment in your center
  - What will each of them do
- Establish your process for screening:
  - Identify who will administer the screening tools
  - Who will score them
  - How will you keep track of screening scores
- Consider when you will screen
- Compile educational materials
- Develop a list of referral resources
- Communicate to your patients and parents that screening will begin
Flexible, Stepped-Care Model for Individuals With CF

Administration of PHQ-9 and GAD-7

- No Symptoms (1-4)
- Mild Depression/Anxiety (5-9)
- Moderate Depression/Anxiety (10-14)
- Severe Depression (PHQ-9 15+)
- Severe Depression (GAD-7 15+)

Rescreen Next Year

Supportive Intervention

Clinical Assessment
- Impairment
- Patient Preferences
- Safety

Evidence-Based Psychological Intervention (CBT or IPT) or Referral to Mental Health Specialist

Exposure-Based CBT

If Psychological Intervention Unavailable, Declined, or Not Fully Effective, Consider Adding SSRI

Combined Evidence-Based Psychological Intervention and SSRI

SSRI Guidance

Flexible, Stepped-Care Model for Individuals With CF

Administration of PHQ-9 and GAD-7

- **No Symptoms** (1-4)
  - Rescreen Next Year

- **Mild Depression/Anxiety** (5-9)

- **Moderate Depression/Anxiety** (10-14)

- **Severe Depression** (PHQ-9 15+)

- **Severe Depression** (GAD-7 15+)

Supportive Intervention
Flexible, Stepped-Care Model for Individuals With CF

Administration of PHQ-9 and GAD-7

- **No Symptoms** (1-4)
  - Rescreen Next Year
- **Mild Depression/Anxiety** (5-9)
  - Supportive Intervention
- **Moderate Depression/Anxiety** (10-14)
  - Severe Anxiety (GAD-7 15+)
  - Clinical Assessment
    - Impairment
    - Patient Preferences
    - Safety
- **Severe Depression** (PHQ-9 15+)

Evidence-Based Psychological Intervention (CBT or IPT) or Referral to Mental Health Specialist

Flexible, Stepped-Care Model for Individuals With CF

Administration of PHQ-9 and GAD-7

No Symptoms (1-4) → Supportive Intervention
Mild Depression/Anxiety (5-9) → Rescreen Next Year
Moderate Depression/Anxiety (10-14) → Clinical Assessment
Severe Depression (PHQ-9 15+) → Combined Evidence-Based Psychological Intervention and SSRI
Severe Anxiety (GAD-7 15+) → Exposure-Based CBT

Clinical Assessment
Impairment → Patient Preferences → Safety

Evidence-Based Psychological Intervention (CBT or IPT) or Referral to Mental Health Specialist

SSRI Guidance


Flexible, Stepped-Care Model for Individuals With CF

Administration of PHQ-9 and GAD-7

- **No Symptoms** (1-4) → **Rescreen Next Year**
- **Mild Depression/Anxiety** (5-9) → **Supportive Intervention**
- **Moderate Depression/Anxiety** (10-14) → **Severe Anxiety** (GAD-7 15+) → **Severe Depression** (PHQ-9 15+)

**Clinical Assessment**
- Impairment
- Patient Preferences
- Safety

**Exposure-Based CBT**

**Evidence-Based Psychological Intervention (CBT or IPT) or Referral to Mental Health Specialist**

**Combined Evidence-Based Psychological Intervention and SSRI**

**SSRI Guidance**

If Psychological Intervention Unavailable, Declined, or Not Fully Effective, Consider Adding SSRI
Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

Clinical Concerns About Child

Assess Child (Ages 7-11)

Mild Range

Elevated Range

Moderate

Severe

Preventive or Supportive Intervention

Refer Caregiver for Consultation

Evidence-Based Psychological Intervention, Including CBT or IPT, or Referral to Mental Health Specialist

Referral as Appropriate

Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7
Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

Normal Range

Mild Range

Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

Normal Range  Mild Range

Preventive or Supportive Intervention

Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

- Normal Range
- Mild Range
- Elevated Range
  - Moderate
  - Severe

Preventive or Supportive Intervention

Refer Caregiver for Consultation

Evidence-Based Psychological Intervention, Including CBT or IPT, or Referral to Mental Health Specialist

Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

Normal Range  Mild Range  Elevated Range

Mild Moderate Severe

Preventive or Supportive Intervention

Refer Caregiver for Consultation

Assess Child (Ages 7-11)

Evidence-Based Psychological Intervention, Including CBT or IPT, or Referral to Mental Health Specialist

Clinical Concerns About Child

Flexible, Stepped-Care Model for Caregivers

Annual Screening

Administration of PHQ-9 and GAD-7

Normal Range  Mild Range  Elevated Range

Mild Moderate Severe

Preventive or Supportive Intervention

Refer Caregiver for Consultation

Assess Child (Ages 7-11)

Evidence-Based Psychological Intervention, Including CBT or IPT, or Referral to Mental Health Specialist
Flexible, Stepped-Care Model for Caregivers

Administration of PHQ-9 and GAD-7

Normal Range
Mild Range
Elevated Range
Moderate
Severe

 Preventive or Supportive Intervention

Evidence-Based Psychological Intervention, Including CBT or IPT, or Referral to Mental Health Specialist

Clinical Concerns About Child

Assess Child (Ages 7-11)

Refer Caregiver for Consultation

Refer as Appropriate

Screening Tools

- We have reliable, valid tools to measure depression and anxiety
- Patient Health Questionnaire (PHQ-9)
- Generalized Anxiety Disorder-7 (GAD-7)
- It takes less than 10 minutes to perform screening
PHQ-9

- Self administered
- Simple, quick
- Rates frequency of symptoms
- DSM-5 criteria
- Question 9… suicidal ideation
- Effect on functioning

<table>
<thead>
<tr>
<th>Over the PAST 2 WEEKS, how often have you been bothered by the following problems?</th>
<th>Not At All</th>
<th>Several Days</th>
<th>More Than Half the Days</th>
<th>Nearly Every Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling asleep, staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself—or that you’re a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed, or, the opposite—being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Column Totals _______ + _______ + _______.

Add Totals Together _________________________

10. If you checked off any problems, how difficult have those problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

GAD-7

- Self administered
- Simple, efficient
- Rates frequency of symptoms
- Effect on functioning

<table>
<thead>
<tr>
<th>Over the LAST 2 WEEKS, how often have you been bothered by the following problems?</th>
<th>Not At All</th>
<th>Several Days</th>
<th>More Than Half the Days</th>
<th>Nearly Every Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Feeling nervous, anxious, or on edge</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Not being able to stop or control worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Worrying too much about different things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Trouble relaxing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Being so restless that it is hard to sit still</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Becoming easily annoyed or irritated</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Feeling afraid as if something awful might happen</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Add Columns

Total Score

8. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

When did the symptoms
PHQ-9 and GAD-7 Scoring

- Score 0-4  No symptoms
- Score 5-9  Mild
- Score 10-14  Moderate
- Score 15+  Severe

Score ≥ 10…clinical assessment

Mental Health Guidelines: Treatment

- Categorize current depressive and/or anxious episodes into one of 3 levels based on screening tools and your clinical assessment and judgment:
  - Mild depression/anxiety
  - Moderate depression/anxiety
  - Severe depression/anxiety

Treatment of Depression

- **Mild (PHQ-9 score 5-9)**
  - Consider a period of active support and monitoring before starting other evidence-based treatments
  - Provide patient education and rescreen on next visit
- **Moderate (PHQ-9 score 10-14)**
  - Evidenced-based psychotherapy (EBP)
- **Severe (PHQ-9 score ≥ 15)**
  - SSRI and EBP are the optimal treatment approach
- **Complicating factors/conditions**
  - For example, coexisting substance abuse, self injury, suicidal ideation, etc.
  - Consider mental health referral or hospitalization


Treatment of Anxiety

- Treatment planning should consider the severity and impairment of the anxiety disorder
  - **Mild (GAD-7 score 5-9):** supportive interventions and psychoeducation
  - **Moderate (GAD-7 score 10-14) and severe (GAD-7 score ≥ 15):** exposure-based CBT
  - Consider SSRI if exposure-based CBT is unavailable, declined, or not fully effective
  - Monitor **functional impairment** as well as symptom reduction during the assessment and treatment process

Psychologic Intervention

Evidence-based interventions:
- Cognitive behavioral therapy (CBT)
  - Psychoeducation
  - Somatic-management skills training
  - Cognitive restructuring
  - In anxiety: incorporates exposure therapy (slowing/confronting objects/situation that provokes anxiety)
  - In depression: may incorporate behavioral activation (eg, engaging in pleasant activities)
- Interpersonal therapy (IPT)
  - Some evidence supports its role in depression

Pharmacologic Intervention

- Appropriate first-line SSRI antidepressants
  - Citalopram
  - Escitalopram
  - Sertraline
  - Fluoxetine
- Close monitoring of therapeutic effects, adverse effects, drug-drug interactions, and medical comorbidities is recommended
Mental Healthcare Delivery Capabilities

- Currently, our capacity to provide comprehensive mental healthcare is modest
- Survey distributed by CF Foundation and European CF Society\(^1\)
  - 4,000 CF health professionals in EU and North America
  - 1,454 responses (36%)
  - 73% reported no personal experience with mental health screening
  - 48 different scales were used to measure depression and anxiety
  - Approximately one-third of respondents were unsure if they could refer to mental health clinics in their hospital, and less than one-half had up-to-date mental health resources


International Committee on Mental Health

- Guidelines are open access
- Supplementary data:
  - www.ncbi.nlm.nih.gov/pmc/articles/PMC4717439/
    (After accessing this link, click on individual links [eg, Web appendix A] under the header "Supplementary Material")
    - Web Appendices A and B: tables with the prevalence of depression and anxiety across chronic conditions and specifically in CF
    - Web Appendix C: manual of implementation procedures
    - Web Appendix D: summaries of national and international guidelines for the treatment of depression and anxiety
    - Web Appendix D: table comparing first-line medications for depression and anxiety (basic characteristics, dosing, drug-drug interactions, adverse effects, special considerations)
The CF Foundation Mental Health Task Force

• A committee established by the CF Foundation
  – Responsible for supporting implementation of the International Mental Health Guidelines
  – Accessible toolkits for implementation
  – Educational material
  – Request for application from the CF Foundation for mental health coordination provides a vehicle to support these activities in CF centers

Take-Home Messages

• Individuals with CF and their caregivers have a high risk of developing depression and anxiety, which can lead to poor quality of life, reduced adherence, and poor health outcomes
• The Mental Health Guidelines are a step to assist the CF community in the assessment and treatment of depression and anxiety; they include flexible algorithms for screening, diagnosis, and management
• The aim of the CF Foundation Mental Health Task Force is to improve mental healthcare capacity in CF
Contact Information

Call toll-free 866 858 7434
E-mail info@med-iq.com

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Abbreviations/acronyms

BID = twice daily
CBT = cognitive behavioral therapy
CF = cystic fibrosis
CFTR = cystic fibrosis transmembrane conductance regulator
CMPR = composite medication possession ratio
EBP = evidence-based psychotherapy
EM = electronic monitors
EU = European Union
FEV₁ = forced expository volume in 1 second
GAD-7 = Generalized Anxiety Disorder 7-Item Scale
HRQOL = health-related quality of life
IPT = interpersonal psychotherapy
IV = intravenous
MDD = major depressive disorder
MDI = metered dose inhaler
MPR = medication possession ratio
PFT = pulmonary function test
PHQ-9 = Patient Health Questionnaire
SSRI = selective serotonin reuptake inhibitor
TID = three times daily
US = United States
WHO = World Health Organization