MENTAL HEALTH COORDINATOR AWARD:
IMPLEMENTATION OF THE DEPRESSION AND ANXIETY GUIDELINES

Published: February 2, 2018
Application Deadline: April 2, 2018
I. ABOUT THE CYSTIC FIBROSIS FOUNDATION

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

To achieve this mission, various types of awards are offered to support meritorious research and care programs in CF.

II. MENTAL HEALTH COORDINATOR AWARD OVERVIEW

The overall purpose of the Mental Health Coordinator Award is to promote the development of a Collaborative Care Model (CCM) at CF Centers that incorporate a system for prevention, screening for and treatment of anxiety and depression. Thus, the award is designed to facilitate implementation of the depression and anxiety guideline recommendations (refer to the appendix at the end of these Guidelines).

The focus of this Request for Applications (RFA) is to provide seed funding for a CF Mental Health Coordinator (MHC) to programs that have not previously received a MHC award. The MHC is expected to implement annual screening and follow-up; coordinate evidence-based treatment for depression and anxiety; develop and maintain a referral network of community-based mental health practitioners; and, serve as an educator and liaison for mental health care in CF for the CF Center, hospital or institution, community practitioners, and payers. This person will provide basic information about the common symptoms of depression and anxiety, provide follow-up for those individuals scoring in the elevated range, provide interventions to improve patients’/parents’ coping skills, and behavioral interventions for painful medical procedures. He/she will collect data on screening scores and subsequent assessment and follow-up, provision of interventions, and their outcomes. Additionally, he/she will indicate in the patient registry on the annual form if the screening has been completed for the individual with CF.

Funding:
The maximum award amount is $150,000 in direct costs plus eight percent (8%) indirect costs over three (3) years. Allowable costs are the following:

• Salary support and benefits for the MHC role
• Specialized training for the MHC (e.g., CBT training)
• Equipment (items $5,000 or greater)
• Travel expenses up to $2,000 per person, per year to attend specialized training for the MHC role and/or the annual NACFC, unless travel to NACFC is already covered by the site’s center award
• NACFC registration fees

Note: All other costs are non-allowable without prior written approval from the CFF Grants and Contracts Office.
Applicants can choose to allocate the budget request/funding as deemed appropriate to the needs of their program but must conform to the following parameters:

- Maximum direct costs for any one year cannot exceed $80,000.
- The maximum award amount allowable is a function of the number of patients enrolled in the program’s CFF Patient Registry, as follows:

<table>
<thead>
<tr>
<th>Number of Patients in the CFF Registry</th>
<th>Maximum Award Amount Allowable</th>
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<tbody>
<tr>
<td>&gt;70 patients</td>
<td><strong>100 percent:</strong> $150,000 in direct costs plus 8% indirect costs over 3 years</td>
</tr>
<tr>
<td>50 – 70 patients</td>
<td><strong>75 percent:</strong> $112,500 in direct costs plus 8% indirect costs over 3 years</td>
</tr>
<tr>
<td>&lt;50 patients</td>
<td><strong>50 percent:</strong> $75,000 in direct costs plus 8% indirect costs over 3 years</td>
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The amounts requested do not have to be equal for each of the three years of funding requested; lower or higher amounts may be requested in any year as long as the total amount requested over the three years does not exceed the limitations noted above.

The table below illustrates three examples for sites with more than 70 patients. Example #1 shows a site that may already have an individual identified for the MHC role and chooses to budget $50,000 equally over three years. Example #2 shows the site allocating $75,000 over two years. Example #3 shows an allocation in which the Year 1 budget request could be $30,000 for planning, with a hire or adjustment in FTE later in Year 1, and then a higher amount requested for Years 2 and 3. Note that neither the total maximum allowable award amount of $150,000, nor the annual maximum amount of $80,000 in direct costs are exceeded.

<table>
<thead>
<tr>
<th>Example #1</th>
<th>Direct Costs</th>
<th>Indirect Costs (8%)</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$50,000</td>
<td>$4,000</td>
<td>$54,000</td>
</tr>
<tr>
<td>Year 2</td>
<td>$50,000</td>
<td>$4,000</td>
<td>$54,000</td>
</tr>
<tr>
<td>Year 3</td>
<td>$50,000</td>
<td>$4,000</td>
<td>$54,000</td>
</tr>
<tr>
<td><strong>Maximum (Direct Costs)</strong></td>
<td><strong>$150,000</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Example #2</th>
<th>Direct Costs</th>
<th>Indirect Costs (8%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$75,000</td>
<td>$6,000</td>
<td>$81,000</td>
</tr>
<tr>
<td>Year 2</td>
<td>$75,000</td>
<td>$6,000</td>
<td>$81,000</td>
</tr>
<tr>
<td><strong>Maximum (Direct Costs)</strong></td>
<td><strong>$150,000</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Example #3</th>
<th>Direct Costs</th>
<th>Indirect Costs (8%)</th>
<th>Total</th>
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<tbody>
<tr>
<td>Year 1</td>
<td>$30,000</td>
<td>$2,400</td>
<td>$32,400</td>
</tr>
<tr>
<td>Year 2</td>
<td>$60,000</td>
<td>$4,800</td>
<td>$64,800</td>
</tr>
<tr>
<td>Year 3</td>
<td>$60,000</td>
<td>$4,800</td>
<td>$64,800</td>
</tr>
<tr>
<td><strong>Maximum (Direct Costs)</strong></td>
<td><strong>$150,000</strong></td>
<td></td>
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</tr>
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</table>
Specific tasks of the MHC must include the following:

- **Prevention:** Assembly and dissemination of educational materials on the importance of mental health in CF and other chronic diseases.

- **Screening:** Support of strategies for materials related to and dealing with implementation of annual screening for depression and anxiety in children with CF, ages 12 years through adulthood, and of caregivers of children from birth to 17 years using the PHQ-9 and GAD-7.
  - This would also include a plan to immediately address suicidal ideation if it is uncovered.
  - The PHQ-9 and GAD-7 screening tools were chosen because of their strong psychometric properties, their alignment with diagnostic criteria, and their availability for free in all major languages. Please see the attached manual of procedures for implementation in the appendix at the end of these Guidelines.

- **Treatment:** Development of a clearly elucidated strategy to provide psychological interventions, as needed, either within the CF Center or by referral outside the CF Center.
  - Treatment options should include both counseling and medications.
  - The MHC should establish a close liaison with one or more consulting psychiatrists in keeping with the collaborative care model described above, and also keep a list of appropriate mental health providers in the community and offer education and support to these providers on both the medical and psychosocial challenges in CF.

**General Guidelines and Eligibility:**

- This award is only available to CFF-accredited centers and affiliate programs that have not previously received a MHC award. Applicant institutions should keep the following in mind when applying:
  - Smaller centers with pediatric and adult programs that share components of the multidisciplinary team may wish to apply for one MHC for the entire center.
  - Centers with distinct pediatric and adult care teams should consider applying for an award at the program level, i.e. if both programs are interested in implementing the guidelines, then consider submitting two separate applications.
  - Programs that share multidisciplinary team members are encouraged to apply as one center. The Principal Investigator (PI) must be a CF center director, program director, or an associate director.

- The award must go towards hiring additional staff or increasing the full-time equivalents (FTEs) of existing staff who will focus on mental health coordination and/or psychosocial intervention. Funding may not be used to support existing full-time staff in their current role.

- MHCs should have training and expertise in psychological assessment and treatment (examples would include a licensed independent social worker, a licensed psychologist, or a nurse practitioner with specialized psychosocial training). Funding from the award may be used towards obtaining the required training of the MHC.

- Sites receiving awards will submit an annual progress report, as specified below, to document progress and fulfillment of award requirements including documentation of mental health
screening care pathways or algorithms, and compilation of data on screening scores, subsequent assessments, interventions, and outcomes.

- **Year 1 Progress Report:** This report should provide specific details on the contributions by awardee to implement mental health screening and follow-up.
- **Year 2 Progress Report:** In addition to the contributions of the awardee, plans for program sustainability must be described.
- **Year 3 Final Report**

- Funding for Year 2 and Year 3 is contingent upon progress documented in the annual reports.

### III. BACKGROUND

Studies over the last 20 years have made it increasingly clear that depression and anxiety are highly prevalent in individuals with CF, as well as parent caregivers. The International Depression Epidemiological Study (TIDES) found symptoms of depression in 10% of adolescents with CF, 19% of adults with CF, and over 30% of their parent caregivers; the prevalence of symptoms of anxiety was even higher (Quittner et al. Thorax. 2014. 69(12):1090-1097). Anxiety and depression are significant morbidities in themselves but take on even greater importance in CF because of their impact on disease management, and ultimately on the course of the disease. Individuals with CF who report elevated levels of anxiety or depression have evidenced worse adherence to prescribed treatments, higher rates of missed or canceled appointments, worse health-related quality of life, increased health care utilization, and higher health care costs. Depression, in particular, is associated with an increased likelihood of poor adherence and worse health outcomes, including lung function, quality of life and engagement in risky behaviors, such as smoking, drinking, and drug use.

In 2013, CFF and the European Cystic Fibrosis Society (ECFS) formed a guidelines committee to develop recommendations for preventing, screening, and treating anxiety and depression in individuals with CF and parent caregivers. The guidelines recommend specific preventative steps, screening tools, behavioral interventions, and medications for these conditions (Quittner et. al. Thorax. 201671(1):26-34).

Concurrent with the development of the guidelines, a survey was conducted to understand the status of mental health services available at CF centers in the U.S. and Europe (Abbott et al. J Cyst Fibros. 14(4); 533-539). The findings from the 1,454 CF health care professional respondents suggested that, given their current staffing and expertise, most centers are not adequately equipped to implement these guideline recommendations. Most have little to no experience with mental health screening, and a large percentage have no one on the CF care team whose primary role is mental health. Further, many are not aware of how to access mental health support or services either in their institution or in the community. The survey also uncovered staff concerns regarding inadequate training and resources to respond to the guideline recommendations. The most important barriers, aside from a lack of experience with or training in mental health screening, were perceived limitations in staffing, time, and lack of qualified personnel to provide evidence-based interventions or referrals.
Collaborative Care Models:
There is a growing body of literature and data supporting the development of collaborative care models (CCM) for treating psychological disorders. Over the past 15 years, more than 70 randomized controlled trials have established a robust evidence-base for this approach. A recent Cochrane review found collaborative care is associated with significant improvement in depression and anxiety outcomes compared with usual care (Archer et al. Cochrane Database Syst Rev.10:CD006525.). Within the context of chronic illness, integrated collaborative care can improve medical and mental health outcomes including reducing rates of hospitalizations and health care costs. While the CCM was initially conceived as a way to facilitate the support of mental health services by primary care providers, the model has expanded to include development of integrated models of care in the treatment of diabetes, coronary artery disease, asthma, oncology, and to a lesser degree CF.

In CCMs, mental health care is provided by a multidisciplinary team including:

- **A PCP or primary medical team.** Screening and assessment occurs in these settings with the goal of identifying those at risk.
- **Mental health coordinator.** A nurse, licensed independent clinical social worker, or psychologist, who is based in the medical clinic and trained to provide evidence-based care coordination, brief behavioral interventions, and support interventions, such as medications initiated by the physician. In some models, this staff member also provides evidence-based, brief/structured psychotherapy, such as cognitive behavioral therapy (CBT). Interventions may also include web-based groups with a care manager coordinating from individual sites.
- **A mental health consultant, typically a psychologist or psychiatrist.** A provider who advises the medical care treatment team with a focus on patients who present diagnostic challenges or who are not showing clinical improvements. A stepped care approach is often used. Psychiatric consultation can be provided in person, through the use of telephone or tele-video consultation. Another option is to have a team member (Nurse Practitioner/Physician’s Assistant) receive special training/certification in mental health, with use of consulting psychiatrists only for complex cases.

IV. REVIEW AND AWARD
All applications are evaluated by a committee of reviewers. Funding of awards is based on the priority score awarded each application and the recommendations of reviewers. All awards are subject to observance of the regulations and policies of CFF related to that category of support and are contingent upon the availability of CFF funds.

*CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion.*
V. SUBMISSION INFORMATION & GENERAL TIMELINE

Application Deadline: Monday, April 2, 2018 at 5:00 PM (ET)

Submit online through proposalCENTRAL: https://proposalcentral.altum.com/
(Refer to Section VI of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at proposalCENTRAL will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

General Timeline

Application Deadline __________________________ April 2, 2018
Review by Committee ___________________________ mid-to-late May 2018
Notification to Applicants ________________________ June 15, 2018
Earliest Start Date for Awarded Projects _____________ September 1, 2018

VI. FULL APPLICATION GUIDELINES

Applications must be submitted online at proposalCENTRAL: https://proposalcentral.altum.com/

Documents should be typed using:
- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence, as shown in Section VII. ELECTRONIC APPLICATION CHECKLIST. Page numbering is not necessary for all uploaded templates except as noted in the instructions for specific templates in this section.

Log-in at proposalCENTRAL: https://proposalcentral.altum.com/.

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile online before applying. If you are already registered and cannot remember your password, click on the “Forgot Your Username/Password?” link below the “Application Login” fields.

Award opportunities, including this Request for Applications (RFA), are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled “Grant Opportunities” found in the upper right-hand side of the page.
Click on the light blue “Filter by Grant Maker” button to the left and scroll down to locate Cystic Fibrosis Foundation in the list.

Locate the listing for the “Mental Health Coordinator Award” program. Click on the “Apply Now” button in the column on the far right to open the application form.

Applicants may stop at any point but must click the “Save” button before exiting in order to save their work. When logging in to continue, click on the blue tab, “Manage Proposals”, and then the “Edit” button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions.

1. **Title Page:** Enter the title of your project and answer the required questions. Click the “Save” button.

2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #9. Templates available include: Current Circumstances and Plans, Budget Detail, Budget Justification, and Appendices.

3. **Enable Other Users to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Check the “Auto Notify” box and then “Save”.

4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the required information and click “Save”.

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “Save”. Be sure to use the full legal name of the institution.

6. **Budget Summary:** Fill in the start and end date and applicable amounts for the support requested by completing the applicable online fields (Period 1, Period 2, etc.). The total budget requested cannot exceed $150,000 in direct costs over three (3) years plus eight
percent (8%) indirect costs per year, or $80,000 in direct costs plus eight percent (8%) indirect costs per year.

**Note:** The Budget Detail and Budget Justification templates downloaded in Section #2 must also be completed for each year of support requested and uploaded in Section #8.

7. **Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above in PDF format. Click on “Attach Files” and in the next screen select the attachment type from the pulldown menu, enter a description for the attachment in the corresponding field, choose the file to be uploaded, and drag and drop it as indicated in the online form. Click “Upload and Continue”. Do this for each attachment. Click the “Back” button when all required files have been uploaded to go back to the main screen.

Below are instructions specific to each template as well as additional information regarding other application components.

**A. CURRENT CIRCUMSTANCES AND PLANS (template available online)**

Complete the questions asked in the template with regard to the program/center for which this application for a Mental Health Coordinator Award is being submitted. Please respect the page limits noted for each question.

**B. BUDGET DETAIL AND BUDGET JUSTIFICATION (separate templates available online)**

Fill out the Budget Detail and Budget Justification templates individually for each year of support requested. In the space provided on the templates, indicate the year as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Detail(s) match the amounts in the online budget summary in Section #7).

- **Budget Detail – Direct Costs**
  - **Personnel** - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, the institutional base salary of an individual may not exceed the current federal salary cap of $187,000. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

  - **Equipment** - List all items of equipment greater than $5,000 and the cost of each item. If funds are requested to purchase equipment that is equivalent to items listed under “Facilities Available”, justify the duplication. Justify any item of equipment for which the need may not be obvious.
Travel - Travel-related costs to attend specialized training for the MHC role and/or NACFC, unless travel to NACFC is already covered by the site’s center award. Please note: expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF Grants and Contracts Office. **Travel expenses may not exceed $2,000 per person, per year.** Registration fees associated with attending NACFC are in addition to this allowance and should be listed under “Other Expenses.”

**Other Expenses** – Other expenses may include NACFC conference registration fees and other specialized training for the MHC.

- **Budget Detail – Indirect Costs**
  Indirect costs of up to eight percent (8%) may be requested from CFF. Indirect costs may be requested for all expenses except for the following:
  - Major equipment (items over $5,000 in value)
  - Computer software
  - Software licenses
  - Tuition

- **Budget Justification**
  Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Equipment, Travel, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail(s).

C. VERIFICATION OF APPLICANT INSTITUTION’S TAX STATUS (upload as PDF documents)
The CFF Grants and Contracts Office must have a copy of the applicant institution’s current W9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution’s W-9 and IRS documentation verifying the organization’s Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.

D. APPENDICES (template available online, upload document as PDF files, if applicable)
If the individual who will serve as the Mental Health Coordinator is known at the time of submission, please upload the following documents as PDF files:
  - Resume/CV
  - Statement of qualifications, including a training plan, if indicated.

8. **PI Data Sheet:** Fill in the required fields, save and exit.
9. **Validate**: Upon completing the application, click on the “Validate” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “Validate” again.

10. **Print Face Pages**: Follow the prompts on the screen to generate and print a face page. The Face Page will be populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. **Scan and email the signed Face Page to grants@cff.org in conjunction with the application submission on proposalCENTRAL.** (In the subject line indicate “MHC 2018 Signed Face Page”). No hardcopy is required.

11. **Submit**: Click on the blue button with white lettering. CFF will not receive your application unless the submit button is clicked.

**Confirmation**: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

<table>
<thead>
<tr>
<th>For technical support with the online application:</th>
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<tbody>
<tr>
<td>proposalCENTRAL at <a href="mailto:pcsupport@altum.com">pcsupport@altum.com</a> or</td>
</tr>
<tr>
<td>800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For program/content information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFF Grants and Contracts at <a href="mailto:grants@cff.org">grants@cff.org</a> or 301-841-2614</td>
</tr>
</tbody>
</table>
VII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Monday, April 2, 2018 at 5:00 PM (ET)

Applications must be submitted at proposalCENTRAL: https://proposalcentral.altum.com/.

A PDF copy of the signed Face Page should be emailed to CFF (grants@cff.org) by the application deadline. The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. In the subject line indicate “MHC 2018 Signed Face Page”. The complete application must be submitted online via proposalCENTRAL.

Face Page which includes:
- Signatures
  - Principal Investigator (Co-PI’s are not required to sign)
  - The Official authorized to sign on behalf of the Applicant Institution
- Applicant/PI information - (online)
- Complete Institution and PI Contact information, including correct mailing address - (online)

Supporting Documents and Appendices:
- Current Circumstances and Plans – (upload)
- Budget Detail for each year - (upload)
- Budget Justification for each year - (upload)
- Verification of Applicant Institution’s Tax Status - (upload)
  - W-9 (signed and dated within the last three years)
  - 501(c)3 or equivalent IRS tax status letter
- Appendices (upload as PDF documents, if applicable)
  - Resume/CV
  - Statement of qualifications including a training plan, if indicated (if individual who will serve as the Mental Health Coordinator if known at the time of submission)
Appendix C: Manual of procedures and tool kit for implementation

International Committee on Mental Health in Cystic Fibrosis: Cystic Fibrosis Foundation and European Cystic Fibrosis Society’s
Guide to Implementing Depression and Anxiety Screening in CF Centers

Beth Smith, Janice Abbott, Anna Georgiopoulos, Lutz Goldbeck, Alexandra L. Quittner, Sarah Hempstead, Bruce Marshall, Kathryn Sabadosa, Stuart Elborn

This guide was adapted from A Guide to Depression Screening developed at the Cystic Fibrosis Center of University at Buffalo at Women & Children’s Hospital of Buffalo by Beth Smith, M.D., Carla Frederick, M.D., Danielle Goetz, M.D., Lynne Fries, PA-C, MPAS, DPT, Kimberly Rand, LMSW, Christine M. Roach, RN, BSN, and Drucy S. Borowitz, M.D.

How to Get Started:

Before you get started with depression and anxiety screening, identify a core group of people who are interested. “It takes a village" to move this forward and it’s important that this does not land on the shoulders of just one or two people.

Identify:

- **Who** are the integral players for depression and anxiety screening and assessment in your center?
- **What** specifically will each of them do and do they have the knowledge and skills to do it?

The Main Ideas:

- All patients 12 years and older receive annual screening for depression and anxiety.
- Parent caregivers of patients aged 0-17 years are **offered** annual screening for depression and anxiety.
- A stepped process for prevention, screening, assessment and intervention is recommended. Please refer to the Cystic Fibrosis Foundation and European Cystic Fibrosis Society Consensus Statements for Screening and Treating Depression and Anxiety Figure 1: Assessing & Treating Depression & Anxiety in CF.

**Step 1 Screening:**

For **Depression**: Administer the Patient Health Questionnaire-9 (PHQ-9) to adult patients and parent caregivers (appendix 1) and the PHQ-9 **or** PHQ-9 Modified for Teens to adolescent patients 12-17 years (appendix 2). The PHQ-9 informs on depression severity and diagnostic criteria of major depression based on the Diagnostic and Statistical Manual of Mental Disorders (DSM).

For **Anxiety**: Administer the Generalized Anxiety Disorder Questionnaire (GAD-7) to adolescents, adults and parent caregivers (appendix 3). These forms are in the appendix however can also be downloaded free with a full instruction manual at www.phqscreeners.com.
Step 2 Assessment:

Assessment: If the PHQ-9 and/or the GAD-7 score ≥ 10 the patient needs an assessment.

- Assessment should be the shared responsibility of the team however the team must designate who is expected to conduct the assessment per the scope of practice. This may be a mental health specialist on your team or another CF professional with sufficient mental health training and comfort.
- Some teams may decide to refer to psychiatry, psychology, or the patient's primary care physician for further assessment based on the team's resources. For example, teams may choose to refer all patients scoring in the moderate to severe range or patients with certain risk factors.
- An assessment should include risk factors, pertinent history, severity/extent of symptoms and level of impairment, which leads to different interventions using a stepped care approach.
- Patient and parent preference is also considered.

Screening Tools:

- Identify if you will use paper/pencil or computer based questionnaires.
- Who will administer the tools?
- Who will score them?
- Consider when you will screen.

An example could be to screen patients annually in a certain quarter of the year, as many patients are seen quarterly. Here are some tips if you choose this method:
  - If a patient is not seen in that quarter of the year, screen them at their next outpatient visit.
  - If a patient is non-adherent to outpatient appointments or was not seen in that quarter of the year consider screening at the end of an inpatient admission.
  - Begin the next cycle in the same quarter so you do not have to track when individual patients are due for their next screen.
  - Additionally, the team may choose to screen patients any time significant symptoms of depression or anxiety are reported or observed by patients, caregivers, or members of the CF multidisciplinary team.
  - All patients, whether or not they had a positive screen the year before, are screened again the following year.

- PHQ-9 and GAD-7 total scores, together with an assessment, lead to different interventions using a stepped care approach. Patient and parent preference is also considered.
  - The PHQ-9 total score puts the patient into categories:
    1. No or minimal depression: Total Score 0-4
    2. Mild depression: Total Score 5-9
    3. Moderate depression: Total Score 10-14
    4. Severe depression: Total Score ≥ 15
  - The GAD-7 total score puts the patient into categories:
    1. No or minimal anxiety: Total Score 0-4
2. **Mild anxiety**: Total Score 5-9  
3. **Moderate anxiety**: Total Score 10-14  
4. **Severe anxiety**: Total Score ≥ 15

- Refer to [www.phqscreeners.com](http://www.phqscreeners.com) for full scoring instructions for the PHQ and GAD-7 and to Appendix 4 for examples of different scoring methods for the PHQ-9 and PHQ-9 Modified for Teens and appendix 5 for scoring the GAD-7.

- **All patients with a positive screen (Score ≥ 10) receive a follow-up assessment.**

- The PHQ-9 and GAD-7 total score helps assess depression and anxiety severity; however, an **assessment** provides additional information to help **further categorize the severity** and clinical significance of symptoms based on factors such as prior history of depression and/or anxiety, depression/anxiety treatment, stressors, history of comorbid psychiatric diagnoses, severity of CF, and presence of complications.

- There is an **algorithm** of how to manage each of the categories of depression and anxiety severity for individuals with CF 12 years and older. Please refer to the Cystic Fibrosis Foundation and European Cystic Fibrosis Society Consensus Statements for Screening and Treating Depression and Anxiety Figure 2 (Screening & Treatment for Depression & Anxiety: Algorithm for Individuals with CF ages 12-Adulthood). It is important to confirm a clinical diagnosis prior to initiating treatment and use independent clinical judgment and skills in the context of individual clinical circumstances.

- There is also an **algorithm** for managing parent/caregiver depressive and anxiety symptoms. Please refer to the Cystic Fibrosis Foundation and European Cystic Fibrosis Society Consensus Statements for Screening and Treating Depression and Anxiety Figure 3 (Screening & Treatment for Depression & Anxiety: Algorithm for Parents/Caregivers).

- Remember there is a suicidality question in the PHQ-9 (question #9). This is addressed below.

**The work before the work – The “PLAN” part of the P-D-S-A Cycle:**

1. The key to beginning screening is to have a plan for what you will do with a positive screen:

   - You will want to have **educational materials on hand for patients with depression and anxiety**. Offer support, help coping with stress, and provide education and information about depression/anxiety and its management for all patients with a PHQ-9 or GAD-7 score ≥ 5. Depression and anxiety education is an important part of ongoing prevention, as well as an intervention for all levels of depression and anxiety severity.
   - Examples of sample handouts/educational materials are found in Appendix 5. Some additional resources include:
- A comprehensive resource for adolescent depression tools can be found in a toolkit that accompanies the Guidelines for Adolescent Depression in Primary Care (GLAD-PC) and can be downloaded free at www.glad-pc.org.
- Additional educational materials and screening tools for other mental health issues, such as substance abuse, ADHD, oppositional-defiant disorder, and a variety of behavioral health problems are available at www.cappcn.org.
- For adolescent patients the American Academy of Child and Adolescent Psychiatry has developed facts for families, which are concise handouts with up-to-date information on a variety of topics that affect children. (www.aacap.org)

- For pediatric patients, the Massachusetts General Hospital School Psychiatry Program/Mood and Anxiety Disorders Institute has developed resources aimed at parents, teachers, and clinicians for implementing school-based interventions for depression, anxiety, and other mental health disorders (www.schoolpsychiatry.org).
- For adult patients the American Academy of Psychiatry has "Let's Talk Brochures" on psychiatric disorders and their treatments (www.psychiatry.org).

**You will need to identify available resources in your institution and community for the treatment of depression and anxiety for patients with moderate - severe symptoms**

- **Even if your CF team already includes a mental health provider/clinician with appropriate skills and training, it is likely that some individual patients, such as those travelling long distances to their CF center, will need to access additional community resources.**
- **This step must be completed prior to implementing screening and will likely take the most time.**

Here are some thoughts about how to do this:

- Contact Psychology/Psychiatry Departments at your university and ask for resources or contact psychology or consult liaison psychiatry services within your hospital and ask for resources.
- Contact the local office of mental health in your county or region.
- It is recommended when referring patients that you educate the patients/parents on what to ask for. For example: evidence based therapies for depression include Cognitive Behavioral Therapy (CBT) and Interpersonal Therapy (IPT) and evidence based treatment for anxiety includes exposure based CBT. Handouts about CBT for depression and anxiety are found in appendix 6 (www.abct.org). Information about IPT can be found at http://interpersonalpsychotherapy.org. It is also important to educate our referral resources about CF. Appendix 7 has a general handout about cystic fibrosis for mental health care providers.

**You will need to develop a plan for patients with suicidality.**

- For patients or parents/caregivers who screen positive for suicide risk (Question 9 on the PHQ-9), the designated mental health expert on the CF team should follow up immediately to determine how serious the
risk is. This should include a clinical interview or further assessment. There are formal assessment tools, such as the Columbia Suicide Severity Rating Scale (C-SSRS; http://www.ccrs.columbia.edu/ecssrs.html), which can also be used to evaluate this risk.

- Appendix 7 has the Columbia Suicide Severity Rating Scale (CSSRS) for assessing and managing patients with suicidal ideation. This scale or an alternate assessment, should be completed on every patient with a positive response to question 9 on the PHQ-9. This scale is administered in person and is not handed to the patient.
- If using the CSSRS, we recommend members of your team complete the free online training. All members of your team involved in screening are encouraged to complete this training and will receive a certificate of completion.
- Appendix 8 has POSSIBLE triage responses to the Columbia Suicide Severity Rating Scale and suggested interventions however these need to be modified based on your local practice patterns and resources. Other responses are available on the training web-site and again may differ in your algorithm depending on local practices and resources.
- Appendix 9 has an example of an Adult Safety Plan.
- Appendix 10 has an example of a Pediatric Safety Plan.

2. Your team will need to figure out how to communicate with patients and parents/caregivers that screening will be starting. It is important for patients and parents to be aware of the process.
   - Will you send a letter to patients?
   - Do you have a newsletter?
   - Will you do an educational webinar?
   - Other

3. Establish your process for screening in clinic. Decide who will do specific tasks.
   - Who will hand out the screening tools (PHQ-9 and GAD-7)
   - Who will score the PHQ-9 and GAD-7?
   - How will the treating clinician know what was completed and the results?
   - How do patients with positive PHQ-9 and/or GAD-7 receive an assessment?
   - What is the process for looking at question #9 (suicidality) on the PHQ-9 and intervening if necessary? One possibility: The clinician seeing the patient looks at question 9 and if positive intervenes with the help of the social worker/psychologist.
   - Who gets the PHQ-9 and GAD-7 forms at the end of clinic?
   - Are the forms scanned into the patient’s electronic medical record?
   - Consider discussing each patient with a positive score at your team’s next multidisciplinary team meeting.

Implementing the Program – the “DO” part of the P-D-S-A Cycle:

- Now that you’ve prepared your team and your patients/parents, get started!
- You’ve decided who is doing what in clinic, but you also need to decide who is doing what after clinic.
  - How will you keep track of screening scores?
  - Who will enter this data at your site?
• How will you track the patients who screened positive for suicidality, especially those who have an intervention in clinic?

• How will you track that the required follow-up and re-assessment has been completed?

• How will you track patient adherence with recommendations/treatment? It is common for patients with symptoms of depression to not follow through on treatment referrals and/or comply with treatment recommendations. One suggestion is calling patients with moderate to severe depression and/or anxiety after their clinic visit to assess follow-through and compliance with recommendations/treatment and any perceived barriers to either the referral or treatment. Alternatively one could assess follow-through at the next clinic visit.

• Routinely discuss patients who screen positive as part of your weekly pre-clinic/post-clinic team meeting.

Evaluating the Program: The “STUDY” Part of the P-D-S-A cycle:

• Examine your tracking tools to see if you are accomplishing your initial goals:
  o All patients get screened with PHQ-9 and GAD-7 at least once a year.
  o All patients with a positive answer to question #9 (suicidality) have an intervention.
  o All patients with a PHQ-9 or GAD-7 score ≥ 10 have an assessment and an intervention based on their level of depression and/or anxiety.

• Examine your tracking tools to see if you are achieving longer-term goals:
  o Are you re-assessing patients and repeating the PHQ-9 and GAD-7 for those with mild depression/anxiety at the next visit?
  o Are you ensuring follow-up for patients with PHQ-9 or GAD-7 score ≥ 10?
  o If the patient is receiving psychological or psychopharmacological treatment within the center more frequent reassessment may be required for optimal management. For those patients who are referred for psychological/psychiatric treatment, are you re-assessing/repeating the PHQ-9 or GAD-7 for those patients with moderate-severe symptoms at the next clinic visit? Consider whether and how you will communicate the initial and regular rescreening results to clinicians providing mental health treatment within or outside your CF team.
  o On reassessment, if the PHQ-9 or GAD-7 score is < 5 then rescreen at the next annual assessment period.

• Will you elicit feedback from patients/parents on your depression and anxiety screening protocol?
  o If so, how does that alter what you will do next?

Improving your processes: The “ACT” Part of the P-D-S-A cycle:

• As a team, decide what part of your processes should change.
  o Work together as a team to put your new processes in place. Meet periodically to review the process and seek feedback from your team to improve the process.
  o Decide if you need to change or improve your protocol or tracking tools so you can continue to measure the effectiveness of your screening.

• Share your experience, resources and tools generously with other CF Centers