

## Cystic Fibrosis Foundation (CFF) Guidelines Program

### **Mission**

The Cystic Fibrosis Foundation (CFF) supports the development of guidelines for the care of people with CF. The guidelines are used to set a standard of care and serve as a reference for all CFF accredited care centers. The CFF supports development of the following types of guidelines:

- evidence-based guidelines are developed based on systematic review(s) of the best available evidence
- consensus-based guidelines are developed based primarily on the opinions and experiences of experts

### **Target Audience**

Guidelines are developed for members of the CF community including health care professionals at CF-centers, other health care professionals that care for people with CF, as well as for individuals with CF and their families.

### **Scope**

All topics related to the care of people with CF are considered within the scope of the guidelines supported by the CFF. Where appropriate, CFF may refer to or modify existing guidelines from other professional organizations.

### **Guidelines Steering Committee**

The CFF Guidelines Steering Committee directs the CFF guidelines program. The Steering Committee establishes guidelines committees, prioritizes topics and provides general oversight of the program. Oversight includes the final review of developed guidelines to confirm adherence to CFF guidelines standards and to assess the consistency of statements with other related guidelines.

Members of the Guidelines Steering Committee represent various stakeholders including the different health disciplines providing care for people with CF as well as members of the CF community. Members include the current chairs of the two standing guidelines committees (Pulmonary and Nutrition), representatives to the CF Center Committee for each program (pediatric, adult and affiliate), a nurse practitioner, people with CF and their families, staff of the CFF, and the lead of the group completing the systematic review(s). Members, other than CFF staff, the methodologist, and the senior research associate, serve a two-year term that is renewable at the discretion of the CFF. The chairs of the standing guidelines committees serve as co-chairs for the Guidelines Steering Committee. In cases where there are co-chairs of the

standing guidelines committees, the CFF will select one from each committee to serve on the Guidelines Steering Committee.

Current members include:

- Chair of the Nutrition Guidelines Committee
- Chair of the Pulmonary Guidelines Committee
- Adult Program Representative to Center Committee
- Pediatric Program Representative to Center Committee
- Affiliated Program Representative to Center Committee
- Nurse practitioner
- Person with CF
- Parent of child with CF
- Staff from the CF Foundation
- Senior research associate from Dartmouth College
- Methodologist from Johns Hopkins University

### **Guidelines Committees**

There are two standing guidelines committees - pulmonary and nutrition. Other guidelines committees are established as needed. Members of the CF community may apply through an application process to serve on guidelines committees. Members are selected and appointed by the Steering Committee and are chosen to represent different disciplines, care centers and perspectives. Within each guidelines committee, the Steering Committee appoints a chair or co-chairs to lead the development process. Guidelines committees' chairs and members serve a 3-year term that is renewable at the discretion of the CFF. Terms are staggered to allow for overlap of experienced and new members. Other personnel providing support for the committee include, as needed, a technical writer, administrative assistant, and meeting planners.

Training and orientation for new chairs and members is provided annually. Training content includes formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation statements, grading the evidence and the recommendations, and information about the guideline development program and process.

The members of the guidelines committees are expected to:

- participate in refinement of review questions
- read and provide comments on all materials from systematic review team
- critically review draft evidence report
- with other members, review and assess evidence and draft recommendations
- as appropriate and as requested, draft section(s) of the guidelines document
- review comments from peer review process and assist in revision of guidelines, as necessary
- provide input and participate in the dissemination of guidelines

### **Conflict of Interest**

Members of the Steering Committee and guidelines committees submit written statements of real or apparent *conflicts of interest*. The statements are reviewed and considered by CFF Guidelines Staff. Any questions or concerns are brought forward for resolution to the Guidelines Steering Committee. Signed copies of the conflict of interest forms are retained by the CFF Guidelines Staff and can be inspected by any interested party by contacting the CFF. Members are excluded from participation if they have financial interest in a related company or if they have an ongoing consultancy relationship with a company that produces a drug or device being reviewed.

### **Topics**

Currently, investigators at Johns Hopkins University are developing an ontology of CF care that will be used to facilitate access to the guidelines and will also be used to identify gaps. Gaps exist where there is no guideline or where a guideline is considered out of date. Individuals may also submit topics through their representative on the Center Committee.

The Steering Committee considers and prioritizes topics for guideline development. Prioritization is based on a number of factors including whether there is an existing guideline and the date that guideline was developed, the existence of controversy or ambiguity as to the best practice, and the potential impact of a guideline on prompting change in practice and enhancing the care of people with CF. The CF community is encouraged to provide input on the prioritized list of topics.

### **Guideline Process**

The guidelines process is described in the *figure overview*. The steps include:

1. Develop and refine questions
  2. Assess evidence
  3. Draft recommendations
  4. Distribute for review
  5. Dissemination
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1. Develop and refine questions: specific questions, using PICO or other relevant structure, are developed from the topics. Questions are refined by the members of the guidelines committees through review of preliminary search results and through discussion.
  2. Assess evidence: for evidence-based guidelines, the assessment of evidence is explicit and includes the completion of systematic reviews. Currently, the CFF commissions investigators at The Johns Hopkins University to perform the systematic reviews. The systematic reviews inform the discussions and decisions of the guidelines committee in drafting the recommendations.
  3. Draft recommendations: statements are drafted by the guidelines committees' members

and, for evidence-based guidelines, are accompanied by grades of the evidence and of the recommendation. Currently, the CFF uses the grading system developed by the U.S. Preventive Services Task Force (<http://www.ahrq.gov/clinic/uspstfix.htm>).

4. Distribute for review: draft guidelines are posted on port CF for public comment by the CF community. Presentations and requests for feedback may also be made during the NACFC.
5. Dissemination: the guidelines are disseminated to health care providers as well as to people with CF and their families.

All guidelines are reviewed at 3 years after the release date to determine if an update is needed. In addition, updates may be triggered by events such as new evidence or new therapies. The CFF Guidelines Steering Committee determines when an update is required. Indication will be made when a guideline has been reviewed or updated.

### **Dissemination**

Guidelines are disseminated in a number of venues and in a number of formats including:

- on PortCF (<https://portcf.outcome.com/>)
- in the peer-reviewed literature
- in the National Guideline Clearinghouse (<http://www.guidelines.gov/>)

A technical writer may be employed by the CFF to assist with the writing of manuscripts or other materials. Other forms of the guidelines are developed as deemed appropriate. Examples include:

- presentations at conferences and meetings, such as the North American Cystic Fibrosis Conference (NACFC)
- pocket reference guides
- CME courses, including webcasts and online courses
- patient and family education