

## Mental Health in the Era of CFTR Modulators Working Group (formerly, Mental Health Working Group)

Year of report: 2023-2024

Date of initial approval of working group:  
October 2022

Contact details of coordinator, vice coordinator and assistant (if applicable) including ECFS membership numbers:

Coordinator name: Dr. Eddie Landau

Coordinator name: Dr. Sonia

Long term aims of the working group including estimated achievement date:

The landscape of CF has changed dramatically following the introduction of CFTR modulator treatment, with concomitant changes in mental health, which are being reported in the international literature. The long term aims of the MHWG are to carefully follow up on the changes in the MH working field, to study and disseminate new developments. Of course special attention is given to the MH of PWCF who are not (yet) eligible for ETI. Future goals include measuring critical side-effects and learning about their prevalence, etiology, and strategies that successfully mitigate them. Further, as ETI is prescribed for younger children, emotional, behavioural and cognitive issues have emerged. Our current International Mental Health Guidelines only address screening in children and adults beginning at age 12 years. One critical future initiative is to assess the prevalence of depression, anxiety and behaviour problems in children < 12 years.

Long term collaborative aims include:

- Collaborating with our US colleagues on *two new initiatives* that are being considered for funding by the CF Foundation: 1) Conducting TIDES 2.0 an epidemiological study of the prevalence of depression, anxiety, behaviour problems and ETI side-effects in children with CF 18 months through 11 years; and 2) Developing GEMS-CF, a General Mental Health Screener of other mental health comorbidities (e.g., procedural anxiety, substance misuse, attention-deficit disorder). The major goals of this study are: 1) to assess the prevalence of mental health challenges in this young age group, and 2) identify the optimal screening tool for children < 12 years. Results of TIDES 2.0 would likely lead to an updating of the International Mental Health Guidelines to include recommendations for screening mental health in children less than 12 years of age.
- The *2<sup>nd</sup> initiative* is development of a new checklist to quickly (less than 5 minutes) assess adults with CF for other mental health comorbidities such as procedural anxiety or substance misuse. A research proposal to conduct a national psychometric validation of GEMS-CF is now under review at the CF Foundation. If funded, we plan to develop translations of this tool for European CF Centres and conduct psychometric evaluations.

Outcomes already achieved this year (2023-2024):

- We currently have 21 members

This group meets regularly once a month, and we have divided the tasks into four main areas described below. Each member has chosen to focus on one or two of these areas.

### **1. Research**

The Experiences of Kaftrio/Trikafta Mental Health Survey (EUROPE) in pwCF aged  $\geq 12$  years was launched for healthcare providers in Europe, after adapting it from the US version to the European health care system. A SurveyMonkey® format was created and was distributed throughout Europe by ECFS to the multidisciplinary care team. This survey assesses healthcare providers' observations of their patients' experiences with Kaftrio/Trikafta in terms of both the positive and negative effects of ETI. The ECFS Mental Health Working Group adapted the 26-item survey and distributed it through ECFS from April to June, 2023. Respondents estimated the prevalence and impact of ETI on functioning in 5 domains: 1) positive physical and psychological effects, 2) sleep difficulties, 3) cognitive difficulties, 4) worsening mental health, and 5) concerns about the future, including finances.

We are in the process of writing up the data and publishing a paper. The results will be presented at ECFS this year in Glasgow.

### **2. Psychosocial professional resources and education training**

- We have developed a subgroup within the MHWG who are currently working with the ECFS Education committee setting up online syllabus and education modules related to mental health care. We work jointly with the EPSIG.
- We have been adding all of the educational handouts on modulator use and other topics to the MHWG website, with translations for European countries. In collaboration with the CFF Mental Health Advisory Committee (MHAC) in the US, with Dr Anna Georgiopoulos as the US representative, shared handouts (from the MHAC) on a variety of prevalent topics have been added on the website. These materials together with other resources such as the Mental Health screeners have been shared with medical professionals and parent associations across Europe. These have been translated into various Eastern European Languages including Latvian, Macedonian Polish, Romanian, Russian, Serbian, Solvakian, Slovenian and Ukranian; and updated on our website under tools and resources:  
[https://www.ecfs.eu/mental\\_health-tools/guidelines](https://www.ecfs.eu/mental_health-tools/guidelines)

### **3. Organizing the pre-conference workshop jointly with EPSIG:**

**Pre-Conference Short Course Co creating personalised treatment plan: how to live your best life:** Tue 4<sup>th</sup> June. The course will be led by Steve Jones.

### **4. Organizing the tomorrow's lounge and meet the expert session**

Tomorrow's Lounge session: **"Younger Horizons: Mental health screening for children < 12 years in the era of modulators"**: Thursday 8th June, 12:45-13:45

### Lunchtime Webinars

For the past three years the MHWG and EPSIG have organized a series of three lunchtime webinars for the CF MDT.

The aim is to join up for an hour online and discuss prevalent topics related to CF, mental health and psychosocial care and that it be a useful forum for CF team members from all disciplines and from all over the world (we have participants from over 36 countries).

The topics of organised webinars for this year included:

- **Ethical issues in CF Care** – 17<sup>th</sup> April 2024
- **Challenges in the clinic in the era of CFTR modulator therapy: educational and informational insights:** 21st February 2024
- **CFSPID: Don't we all want to know more about it** – 21<sup>st</sup> November 2023

### Network of Colleagues

We have created a network of colleagues around Europe and E. Europe and also involve representatives from the CFF Mental Health Advisory Committee (MHAC) in the US. We all meet once a month on a regular basis to discuss and achieve the aims of the MHWG. In addition, Drs Graziano and Verkelij are involved in the research group and Dr Landau is part of the education group for the CFF MHWG.

Aims for the coming year: 2024-2025

Work on the above described research projects. Continue the work on disseminating knowledge and information concerning MH and MH screening around Europe. Discuss, collaborate and contribute to the ECFS projects, conferences and online meetings.

Summary:

- Maintaining and updating the Mental Health Website including more resources and handouts as well as short- and long-term psychosocial consequences of starting ETI.
- Continue to hold zoom meeting every two months with the whole MHWG and monthly for a core group.
- Hold the Mental Health Working Group Annual General meeting during ECFS Annual Conferences (20-25 participants).
- Publish the results of the research on the "Positive and Negative Impacts of Elexacaftor/Tezacaftor/Ivacaftor: Comparison of Healthcare Providers' Observations in Europe vs US"
- Continue to be involved in conference activities, including pre-conference workshop, tomorrow's lounge and meet the expert.

**New Research Aims:** 1) Conduct TIDES 2.0 if funded in the US; 2) once validated, translate GEMS-CF into European languages; 3) update the international mental health guidelines based on the introduction of ETI and new data on mental health.

Breakdown of expenses (please include total amount received as well as expenditure and, if applicable, the outstanding balance (Euros)):

Pre-conference short course instructor's fee €700, travel (estimated €200) and accommodation for one night (estimated €150), and moderators' registration €300, catering €900: to be split equally between EPSIG and MHWG.

MHWG expenses for above €1,125 = 1,314 Euros

MHWG meeting at Glasgow conference:

Room rental: 1200€ = 1397 Euros

Catering: 650€ = 757 Euros

Budget amount requested for next year:

- Organisation of meetings/networking events, minute meetings, produce newsletters/report, liaison with ECFS, CF Centres and Patient Associations
- Statistical support for analyses of survey data
- Manage website resource content
- Web-based Survey administration
- Training Workshops