

# Mental Health in the Era of CFTR Modulators Working Group

Year of report: 2022- 2023

Date of initial approval of working group:  
October 2022

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

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

1. Coordinator: \_Dr. Eddie Landau –
2. Coordinator: Dr. Sonia Graziano –

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

The landscape of CF has changed dramatically following the introduction of CFTR modulator treatment, with concomitant changes in mental health. The impact of these modulators on CF patients and their families has had unprecedented impact on daily treatment regimens, adherence, and short- and long-term health outcomes. Numerous benefits have been documented for physical health, including improved lung function and BMI, and fewer pulmonary exacerbations and hospitalizations. This has increased opportunities for education and employment, and patients have reported greater optimism about the future. However, in addition to these health benefits, there have been numerous challenges associated with the introduction of highly effective modulators. As reported in case series, case studies and single centre studies, a number of negative side-effects have been reported by patients on Elexacaftor/Tezacaftor/Ivacaftor (ETI), including problems with sleep, cognition, headaches, and challenges with finances. Living with CF in the era of CFTR modulators has had major impacts on both mental health and quality of life, which need to be measured in future studies and addressed clinically. The treatment regimen for CF is also changing, with an opportunity to reduce treatment burden. We need to focus our research efforts on how this has affected mental health in individuals with CF, families and healthcare providers as this landscape shifts. Understanding the effects of highly effective modulators on mental health, adherence and health outcomes will be critical for refining protocols for MH screening and for disseminating and evaluating new interventions to address these challenges.

Our goals for the next two years are:

- Maintaining and updating the Mental Health Website including more resources and handouts on the management of pain, parenting coping skills and short- and long-term psychosocial consequences of starting ETI.
- Developing additional translations of the documents for MDT clinicians and patients/carers, particularly in those regions with less resources. We are interested in pursuing the “twinning” model of care that has been initiated by ECFS to facilitate the integration of mental health care into countries in Eastern Europe. We plan to develop these mentoring relationships during the coming year.
- Documenting MH provision/care paths and best practices in the era of CFTR Modulators.
- Assessing the effects of ETI on physical and mental health across CF Centres in Europe. A survey has already been prepared and was recently sent to healthcare providers around Europe to assess observations of their patients’ experiences with Kaftrio/Trikafta.

- Assessing mental health side effects in patients who are on ETI and evaluating the psychosocial impact of not being eligible for the new modulator across CF Centres in Europe. A brief, ETI side-effects checklist has been developed by Drs. Graziano and Quittner and is being distributed in the US and Europe. Ideally, this assessment would be used prior to and after patients start ETI. Monitoring of ETI side-effects has been recommended in the Interim Clinical Care Guidelines of ECFS.
- Comparing mental health assessment and intervention in Europe and the US. The synergy of working together with the US enables us to better understand and measure the effects of modulators, to better prepare patients, families and healthcare teams, and implement best practices of care.

Examples of achievements of our collaborative work over the past years:

The editorial in the next issue of *Journal of Cystic Fibrosis* has been written on this topic by our co-chair Dr. Eddie Landau entitled: “Cystic Fibrosis in a transformative era: Adapting to changing mental health needs”

#### Publications:

- **Quittner AL, Goldbeck L, Abbott J, et al.** Prevalence of depression and anxiety in patients with cystic fibrosis and parent caregivers: results of The International Depression Epidemiological Study across nine countries. *Thorax* 2014;69(12):1090-1097.
- **Abbott J, Elborn JS, Georgiopoulos AM, et al.** Cystic Fibrosis Foundation and European Cystic Fibrosis Society Survey of cystic fibrosis mental health care delivery. *Journal of cystic fibrosis* 2015;14:533-9
- **Quittner AL, Abbott J, Georgiopoulos AM, et al.** The International Committee on Mental Health: Cystic Fibrosis Foundation and European CF Society consensus statements for screening and treating depression and anxiety. *Thorax* doi:10.1136/thoraxjnl-2015-207488.
- **Graziano S, Landau E, Verkleij M, Georgiopoulos AM, Schechter MS, Abbott J, Quittner AL, Smith BA** (2021). Mental health screening in CF: Thematic analysis of determinants of implementation in Europe and the United States. *J Cyst Fibrosis*, abstract published on 01 Nov 2021.
- **Landau E, Verkleij M, Graziano S, Quittner A.L., Georgiopoulos A.M., Smith B.A., Schechter M.S., Abbott J.** (2021). WS11.5 Mental health screening as an intervention: how patients and caregivers contribute to improving our processes. *J Cyst Fibros*. Abstract published on 01 Jan 2021.
- **Landau E, Verkleij M, Graziano S, Quittner A, Georgiopoulos A, Smith B, Schechter M, Abbott J.** On behalf of the ECFS and CFF Mental Health Working Group/Advisory Committee (2022). Mental health screening as an intervention: patient and caregiver feedback on improving these processes. *Respir Med.* 27;202:106955.
- **Quittner AL, Abbott J, Georgiopoulos A., Goldbeck, L, Smith BA, Hempstead SE, Marshall B, Sabadosa KA, Elborn S. & the International Committee on Mental Health** (2016). International committee on mental health in cystic fibrosis: Cystic Fibrosis Foundation and European Cystic Fibrosis Society consensus statements for screening and treating depression and anxiety. *Thorax*, 71(1):26-34.
- **Quittner, AL, Abbott J, Hussain S, Ong T, Uluer A, Hempstead S, Lomas P, & Smith B.** (2020). Integration of Mental Health Screening and Treatment into Cystic Fibrosis Clinics: Evaluation of Implementation Efforts in 84 Programs Across the United States. *Pediatric Pulmonology*, DOI: 10.1002/ppul.2494.
- **Smith BA, Georgiopoulos AM, Mueller A, Abbott J, Lomas P, Aliaj E, Quittner AL.** Impact of COVID-19 on mental health: Effects on screening, care delivery, and people with cystic fibrosis. *J Cyst Fibros.* 2021 Dec;20 Suppl 3:31-38. doi: 10.1016/j.jcf.2021.08.027.
- **Verkleij M, Georgiopoulos A., Barendrecht H., Friedman D.** (2022). Pilot of a therapist-guided internet-delivered cognitive behavioral therapy intervention for anxiety and depression (eHealth CF-CBT) in Dutch adults with cystic fibrosis. September 2022. *ERS International Congress 2022 abstracts.*
- **Verkleij M, Georgiopoulos AM, Friedman D** (2021). Development and evaluation of an internet-based cognitive behavioral therapy intervention for anxiety and depression in adults with cystic fibrosis (eHealth CF-CBT): An international collaboration. *Internet Interv.* 24:100372.
- **Graziano S, Boldrini F, Quittner AL, Fiocchi AG, Tabarini P.** Stress and mental health in adolescents and young adults with cystic fibrosis 1 year after the COVID pandemic: Findings from an Italian sample. *Pediatr Pulmonol.* 2022 Nov;57(11):2707-2714. doi: 10.1002/ppul.26087.
- **Graziano S, Ullmann N, Rusciano R, Allegorico A, Boldrini F, Rosito L, Quittner AL, Cutrera R, Tabarini P.** Comparison of mental health in individuals with primary ciliary dyskinesia, cystic fibrosis, and parent caregivers. *Respir Med.* 2023 Feb;207:107095. doi: 10.1016/j.rmed.2022.107095.
- **Quittner AL, Barker D, Graziano S, Georgiopoulos AM, Muther E, Verkleij M, Schechter MS, Tillman L, Mueller A, Lomas P, Hempstead S, Smith BA.** National integration of mental health screening and treatment into specialized care for cystic fibrosis: What predicts success? *Pediatr Pulmonol.* 2023 Apr 4. doi: 10.1002/ppul.26400.

- **Georgiopoulos AM.** CFTR modulators and mental health/ Modulateurs du CFTR et santé mentale. Santé Vous Bien (SVB) #46, Montreal, Canada, 2023. <https://www.vivreaveclafibrosekystique.com/publications/publications-sante-vous-bien/>
- Baroud E, Chaudhary N, **Georgiopoulos AM.** Management of neuropsychiatric symptoms in adults treated with elexacaftor/tezacaftor/ivacaftor. *Pediatr Pulmonol.* 2023 Apr 10. doi: 10.1002/ppul.26412. Epub ahead of print. PMID: 37036050.
- Bathgate CJ, Hjelm M, Filigno SS, Smith BA, **Georgiopoulos AM.** Management of Mental Health in Cystic Fibrosis. *Clin Chest Med.* 2022 Dec;43(4):791-810. doi: 10.1016/j.ccm.2022.06.014. PMID: 36344081.

Outcomes already achieved this year (2022-2023):

- We currently have 24 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, and was adapted from the US version to the European health care system. A SurveyMonkey® format was created and is currently being distributed through the ECFS to multidisciplinary care team. The survey was distributed in Europe on April 24 and we plan to distribute the survey at the upcoming ECFS conference in June. This survey will assess healthcare provider observations of their patients' experiences with Kaftrio/Trikafta.

### 2. Psychosocial professional resources and education training

- We have developed 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.
- 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 MHAC in the US, Dr Anna Georgiopoulos as the US representative, has shared handouts on a variety of prevalent topics which have been translated on the website. We are in the process of translating, adapting and creating these new educational materials for CF teams and training opportunities appropriate for mental health in the modulator era.

### 3. Organizing the pre-conference workshop

Pre-Conference Short Course Psychodynamic Aspects in Chronic, Medical Illness: Tue 5<sup>th</sup> June 1300-1700. The course will be led by Dr. Maya Kirszenbaum  
This has been organized jointly with the EPSIG committee.

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

Tomorrow's Lounge session: "Mental health challenges in the era of new modulators": Thursday 8th June, 12:45-13:45

Meet the experts: "Remote psychological counselling tools and strategies": Friday 9th June 2023: 7:30 – 8:20, presented by Dr. Anna Georgiopoulos and Dr. Marieke Verkleij.

### 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:

- **Sleep and Cystic Fibrosis** – 16<sup>th</sup> of November 2022
- **Psychiatric comorbidities and cystic fibrosis: what teams need to know to care patients with extra needs.** - 25<sup>th</sup> of January 2023
- **Modulators and psychosocial impact: What do we know?** – 19<sup>th</sup> of April 2023

### Network of Colleagues

We have created a networks of colleagues around Europe and E. Europe as well having representatives join us 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, Dr Graziano and Dr. Verkelij are involved in the research group and Dr Landau is part of the education group for the CFF MHWG. They act as representatives from the ECFS MHWG to facilitate the sharing of ideas and cooperation on joint projects that advance our research goals and recommendations for best clinical practices.

**Business Plan: What meetings/networking is required to complete the objectives (where meetings are involved, please state probable location and number of participants as well as a mitigation plan should in-person meetings not be possible):**

Continue to hold Telcos on a monthly basis with the whole MHWG

Hold the Mental Health Working Group Annual General meeting during ECFS Annual Conferences (20-30 participants).

Continue to be involved in conference activities, including pre-conference workshop, tomorrow's lounge and meet the expert.

**Budget amount requested for next year (please give the amount in Euros and the 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
- Registration fees for ECFS conference for the co-ordinators