

COMMISSION ON MEDICAL THERAPIES



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Botanicals: Steve Schachter (Chair), Dana Ekstein, Elisabeth Ngo Bum, Siegwad Elsas, Nikolaus Sucher

Dietary Therapy: Eric Kossoff (Chair), Nabil Al Macki, Mackenzie Cervenka, Heung Dong Kim, Jianxiang Liao, Kath Megaw, Janak Nathan, Ximena Raimann Tampier, Rocio Rivera, Adelheid Wiemer-Kruel, Beth Zupec-Kania, Emma Williams

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Pharmacogenomics: Patrick Kwan (Chair), Larry Baum, Martin Brodie, Tracy Glauser, Michael Johnson, Sunao Kaneko, Terence O'Brien, Sanjay Sisodiya, Nigel Tan

Psychobehavioral Therapy: Rosa Michaelis (Co-chair), Markus Reuber (Co-chair), David Rosenstein, Venus Tang, Laura Goldstein, William C. LaFrance Jr., Avani Modi, Janelle Wagner

Aims

To advance the use and development of medical (drugs and other nonsurgical) therapies for epilepsy.

Mission of the Commission

To improve the care of patients with epilepsy by facilitating collaboration among clinicians, scientists and other professionals in fulfillment of the relevant

aspects of the ILAE Strategic Plan. The Commission on Medical Therapies has a broad mandate to review current treatments and to advocate for improvements. The scope of the Commission covers issues related to drug therapies and other nonsurgical interventions, including diets, natural products and psychological approaches, as reflected in the creation of separate task forces.

Commission Activities

June 2013 through June 2014

The Commission has held teleconferences and met at the ECE in Stockholm in July 2014. Activities of individual task forces are listed below:

AED Trials and Regulatory Affairs Task Force

The Task Force held a meeting on regulatory issues, on July 2014 as part of the European Congress on Epileptology in Stockholm, Sweden. It was attended by regulatory representatives: Norman Herskowitz (FDA), Manuel Haas (EMA), N. Yabana, and H. Nakamura (PMDA); Task Force Members: Jacqueline French (chair), Rusty Katz, Patrick Kwan, Emilia Bagiella, Eugen Trink, Jack Pelloch, Alexi Arzimanoglou, Emilio Perucca, Michel Baulac; Observers: Tatsuya Tanaka, Makiko Osawa, Masako Watanabe (Japan Epilepsy Society). The three topics discussed were: Pathway to Monotherapy approval, Extrapolation from Adult Studies to Pediatric Approvals, and Utilizing Time-to-Event Designs for Adjunctive Trials. The meeting was very successful. The European and US regulators agreed they would be willing to entertain a submission by industry using these approaches.

Botanicals Task Force

Continued the development of the Epilepsy Naturapedia, a wiki to be hosted on the ILAE website, that will be the most comprehensive, current and customizable central research hub for bench-to-bedside scientific information on the use of natural products for the treatment of epilepsy.

Dietary Therapy Task Force

The Task Force has had a highly productive first year:

- A website (in English and Spanish) with information and resources on ketogenic diet is now up and fully operational (<http://www.ilae.org/Commission/medther/keto-index.cfm>).
- On October 7, 2014, the Task Force held a meeting in Liverpool, UK, to discuss its past, present

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and future activities. The primary purpose of the meeting was to create a publishable document regarding the minimum requirements for a new ketogenic diet center. Recognizing that the 2009 ketogenic diet consensus statement is very detailed and often perceived as expensive, this document will outline what is truly necessary (vs. optimal perhaps).

Psychobehavioral Therapy Task Force

This is the newest task force of the Commission created in 2014. It has initiated a project to update the previous Cochrane meta-analysis of psychobehavioral interventions published in 2008.

AED Trials and Regulatory Affairs Task Force

This has been a very productive year for the task force:

- A white paper on a unified indication (incorporating both monotherapy and polytherapy) for epilepsy was written and submitted for publication.
- The PEACE (pediatric extrapolation academic consortium in epilepsy) initiative has been working with the FDA and is in the process of submitting a white paper.
- A white paper on time to baseline seizure frequency as an add-on study design is in progress.

Botanicals Task Force

The website is close to completion and launch. Among its many features, Epilepsy Naturapedia enables users to search for information using:

1. Common names
2. Scientific names
3. Names of compounds
4. Names of historical neurologists
5. Historical use
6. Pharmaceutical information
7. Published evidence for use in the treatment of epilepsy

Users may apply for privileges to create new pages or edit existing pages by adding links, images, and their own text.

Dietary Therapy Task Force

- Maintain and update the ketogenic diet website. The website has received many visits and positive comments
- Working on the draft for the ketogenic diet center guideline, which will be submitted to *Epilepsia*.

Psychobehavioral Therapy Task Force

The review proposal has been submitted to the Cochrane Epilepsy Group outlining the review objective and responsibilities of task force members. It will cover a range of psychological or behavior modification techniques, and studies related to adults and children will be analyzed separately. Types of outcomes will include health-related quality of life, psychiatric comorbidities, self-management/self-efficacy, adherence parameters, as well as seizure-related outcomes including seizure frequency and severity/duration. To integrate literature on trials with children we will collaborate with the Self-Management in Pediatric Epilepsy task force that belongs to the managing epilepsy well (MEW) network.

Accomplishments

- Continue work with the regulatory agencies in AED trial design
- Complete and launch the Epilepsy Naturapedia website
- Publication of ketogenic diet center guidelines
- Complete review on psychobehavioral therapy
- Create recommendations on treatment and research based on the meta-analysis of clinical studies and the clinical experience represented by the experts, covering presentation of diagnosis, intervention elements, early phase treatment and treatment maintenance, including a reference to possible health-care system level influences.
- Create minimum requirements for a psychobehavioral treatment center to include individuals and centers providing expert service in a web-based registry in order to facilitate training, treatment and research collaborations.