

2018 Annual Report - Medical Therapies Commission

Co-Chairs

Kimford Meador (USA)

Dong Zhou (China)

Members

Patrick Kwan (Australia)

Sanjeev Thomas (India)

Tim Welty (USA)

Management Committee Liaison

Emilio Perucca (Italy)

Access to Medicines & Treatment Gap Task Force

1. The Access to Medicine and Treatment Gap Task Force had its first Web Conference on 10 October 2017, where an initial work plan was presented and discussed. The proposed plan was to collect data from ILAE member countries on completed or ongoing strategies, projects, and interventions to improve access to medicines to include initiatives on legislation, distribution and logistics, availability, pricing, quality control, and prescribing regulations.
2. During the 2nd Web Conference on 5 February 2018, the majority of the task force members proposed and agreed to start collecting information on access to antiepileptic drugs in their respective countries, and from neighboring countries in their own region, in order to create a map relating to “access to medications.” The Survey on Access to AED has started and is still in progress. The questionnaire was sent to all ILAE Chapters (not only in LMICs and LICs). We had answers from 79 Chapters: 34 from HICs, 18 from UMICs, 19 from LMICs, and eight from LICs. The initial results are interesting, but it is evident that the data is affected by the inequality of the number of chapters across HICs, MICs, and LICs included in the survey. For this reason, the task force is planning to extend the survey to colleagues working in countries without ILAE/IBE Chapters through the network of the Regional ILAE Committees. The task force is going to present the preliminary result of the survey at the International Epilepsy Congress in Bangkok.

Botanicals & Traditional Medicines

1. The task force is working to expand its website with a listing and description of multiple botanicals. They are exploring information on traditional medicines.
2. A symposium on basic science and clinical experiences with Cannabidiol will take place at the German/Austria/Switzerland regional epilepsy conference in Basel, Switzerland on May 8-11, 2019.
3. As a first anticonvulsant of botanical origin, Cannabidiol has been licensed for medical use in the USA under the trade name Epidiolex, by the British company GW Pharmaceuticals. Licensure in Europe is anticipated for 2019.

Dietary Task Force

1. A Dietary workshop is scheduled for 1 July 2018, the last day of AOEC in Bali, Indonesia, supported by the ILAE.
2. Other dietary workshops are also done and planned in this year in Myanmar in March, Bandung, Indonesia in July, Ulaanbaatar, Mongolia in August, and at least one of those workshops will be supported by the ILAE.
3. A strategic task force business meeting is scheduled for 4 October 2018, one day prior to the 6th Global Symposium on Ketogenic Therapies in Jeju, Korea, which is also approved by the ILAE with financial support.

4. Dozens of clinicians and investigators around the world participated in the revised ketogenic diet consensus statement, which was recently published in *Epilepsia Open*, and which provides updated guidelines for implementing dietary therapies for epilepsy in a safe and effective manner.
5. The Dietary Task Force was joined with the organizing committee of "The 6th Global Symposium on Ketogenic Therapy", 5-9 October 2018, and was endorsed by the ILAE. The anticipated attendance for this premiere biennial meeting is approximately eight hundred individuals from around the world.

Emergency Treatment

The task force continues work on producing two evidence-based guidelines:

1. European Guidelines in conjunction with the EAN; and
2. Guidelines for resource poor countries.

Epilepsy in the Elderly

At a teleconference in March 2018, the Task Force on Epilepsy in the Elderly decided to divide responsibility for different aspects of this subject. Individuals volunteered to work on epidemiology and scope of the problem, etiology and pathophysiology, treatment including medications and surgery (interfacing with Surgery Task Force), and prognosis. A literature review is in progress with collection and sharing of references by category via box.com.

Generic Medications

1. A group has been working on the development of a manuscript that will serve an informational and educational basis for understanding generic substitution. This manuscript will help provide a strong background of understanding on the concepts of generic substitution and issues faced in various parts of the world. Our hope is that the group will have a draft manuscript by the European Congress at the end of August 2018.
2. Another group has been working on development of a survey to be sent to ILAE chapters and members. The survey is based on one that was developed by our South American colleagues, as they attempt to address issues of generic substitution in that part of the world. It is designed to help understand the challenges faced in various parts of the world, with the intent of guiding our task force as we develop final products.
3. The task force held a face-to-face meeting during the European Congress on Epileptology in Vienna, Austria.

Psychology

The current goal of the task force is the investigation of barriers to psychological treatment in people with epilepsy. For this purpose, a survey has been drafted and endorsed by the Psychiatry Commission. The survey has been successfully piloted in Australia and we are about to submit an ethics amendment to conduct the survey globally. The Psychology Task Force will also conduct an interactive forum session at the IEC in Bangkok to present and discuss case-based educational activities that relate to the International Epilepsy Curriculum. In addition, the Psychology Task Force is designing an ILAE webpage to provide resources on psychological treatments.

Regulatory Affairs Task Force

We held a very successful session and a general discussion on the regulatory aspects of antiepileptic drug (AED) development during the most recent European Congress on Epilepsy in Vienna. The session was attended by task force members, as well as members of the European Medicines Agency, and Health Canada. Agenda items included: revision of the EMA guidelines on AEDs, extrapolation from adults to children (and from children to adults), and what remains to be done (age range, seizure types, syndromes). New outcome measures: time to event, composite endpoints on seizures (frequency, severity, sleep or awake), composite end points on seizures and comorbidities, and choice of the endpoints (trial population: seizure types within a given syndrome or seizure type(s) across syndromes). As a result of this meeting,

the Regulatory Affairs Task Force, in collaboration with the Pediatric Epilepsy Research Consortium (PERC) and the Pediatric Commission of the ILAE, created a novel trial design intended to address concerns about conduct of infant trials of new therapeutic agents. This trial design is now being considered by the EMA and FDA.

Women/Pregnancy

The Task Force has carried out a survey of available guidelines for the management of epilepsy in pregnancy in the ILAE Chapters. To date, 73 chapters have responded and the results are currently being analyzed. The task force is currently working on a review on epilepsy and pregnancy intended for *Epileptic Disorders*. Drafts of some subsections have been written. This series of articles are also intended for adjustment to be suitable for publication on Wikipedia.

Kimford Meador

Co-Chair, Medical Therapies Commission