

Epilepsy Treatment and Education Task Force

Meeting Minutes
Tuesday, December 13th 2011

WELCOME

Dale Todd called to order the Epilepsy Treatment and Education Task Force at 3:00pm on Tuesday, December 13th, 2011, in Room 518 of the Lucas State Office Building in Des Moines, Iowa.

PRESENT

Members of the Task Force in attendance were Kevin Harris, Dale Todd, Brett Barker, Dr. Todd Janus, Dr. Chasity Mease, Dr. David Friedgood, Dr. Geoff Wall, and Dr. David Moore.

Members of the Task Force not in attendance were Kristin Wells.

Others in attendance were Vic Verni, Jessica Peters, Jill Myers Gadelmann, Kyle Frette, Threase Harms, Mike Triplett, and Jim Henter.

I. Approval of November 15th Meeting Minutes

Dale Todd made a motion to accept the minutes and Kevin Harris seconded. November 15th Meeting Minutes were approved unanimously.

II. Review of Survey Questions for Iowa Neurologists

Dr. Wall presented a draft of the survey for Iowa neurologists concerning manufacturer substitution of anti-epileptic medications. The brief survey includes an introduction explaining the topic at hand and the establishment of the Epilepsy Task Force, and eight questions to be answered with a Likert scale. Answers will remain totally confidential.

Several editing suggestions were made by the Task Force members. The conclusion of the in-depth discussion was to shorten the opening introduction to save time and increase neurologist participation. In addition, small terminology changes are to be made to the introduction, and questions 1 & 7. Question 3 will be removed from the survey after it was decided that it does not help further the focus and productivity of the Task Force's charge.

Question 2a: Dr. Friedgood raised a concern about including a percentage (0-100%) answer, stating it would be a large guess and would vary drastically from neurologist to neurologist. Dr. Wall responded that the Task Force needs to help quantify the potential issue and a best guess from a neurologist would lead to better data than has been previously available. Brett Barker suggested using an "often, rarely, never" scale instead of percentages as a compromise.

Question 8: Dale Todd requested to strike question 8, stating it was not relevant to the scope of the Task Force, explaining cost is an important issue but should not overshadow the main issue at hand. Dr. Wall retorted explaining that cost is the prime mover in this conversation and needs to be included. Dr. Friedgood added that the Task Force's report to the legislature may need a proposal on how to

handle the cost issue, so it is relevant information. Dr. Janus agreed the cost question may not be exactly on target with the charge of the Task Force, but it may be important information further on down the road. The Task Force agreed to keep question 8.

A final draft of the survey will be completed by Dr. Wall, incorporating feedback from Task Force members at today's meeting. It will be sent via email to Task Force members for final approval. All Iowa neurologists will receive the survey via Survey Monkey, allowing only invited neurologists to complete the survey, with the goal to have results by the next Task Force meeting in February.

****Dr. Moore entered the meeting at 3:35pm****

III. Update of Hospital Data

Jill Myers Gadelmann with the Iowa Department of Public Health presented the Task Force with several sets of data on Epilepsy Primary Outpatient/Inpatient Discharge Diagnoses 2008-2010.

Dr. Moore suggested comparing the newly compiled data to a similar timeline of the release of generics on the market, in order to determine if there are any correlations. Dr. Wall stated release dates of generics can be found at the FDA website.

Dr. Janus, Dr. Friedgood, and Dr. Moore remarked the reports have some tantalizing data and potential major trends, and should be analyzed appropriately by an epidemiologist. The Task Force agreed the data needs to be sorted through in-depth by an epidemiologist in order to see if it will yield results relevant to the charge of the Task Force. Dr. Janus will ask his epidemiologist contact to review the data.

Jessica Peters will review anecdotal data from the Epilepsy Foundation's Iowa Office and share with Dr. Moore and the Task Force. If the evaluation of the data does not yield any reasonable results it will then be determined how to proceed, while still considering the client/doctor anecdotal data.

IV. Identification of Additional Stakeholders

The Task Force members discussed additional stakeholders who would provide beneficial and unbiased input to the process, including the insurance industry, Pharmacy Benefit Managers, and legislatures. Members cannot be added to the Task Force, however conference calls and Skype presentation may be utilized at future meetings to assess all angles and stakeholder feedback.

Dr. Moore suggested including healthcare physicians, first responders and others in contact with epilepsy patients/families in the education discussion. Dale Todd proposed focusing on the Task Force's educational component at another meeting.

V. Update on Status FDA Studies

Dr. Wall provided an update on the FDA's process of reviewing bioequivalence of brand name and generic anti-epileptic drugs. He submitted a *Medscape* article, "FDA to Tighten

Standards for Generic Antiepileptic Drug” by Allison Shelley (<http://www.medscape.com/viewarticle/754755>) and an paper entitled, “Factors associated with poor seizure control and increased side effects after switching to generic antiepileptic drugs” by Ramon Edmundo D. Bautista, Walter Gonzales, Deepali Jain.

Dale Todd provided remarks by Rich Denness, Epilepsy Foundation to the FDA Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, dated July 26, 2011.

VI. Wrap Up

Dale Todd motioned for the election of a co-chairperson, Dr. Janus seconded. Dr. Wall nominated Dr. Mease, and all Task Force members were in agreement; Dr. Mease was appointed co-chairperson of the Epilepsy Treatment and Education Task Force.

The next steps:

- The Task Force decided to review a comprehensive list/review of other states’ legislative activity regarding the drug product selection relative to antiepileptic drugs for treatment of epileptic seizures. Dale Todd, Vic Verni and Jessica Peters will gather information and report back at the next Task Force meeting.
- Dr. Wall will finalize the survey draft. It will be distributed to neurologists in January via email.
- Dr. Janus will follow up with his epidemiologist about reviewing the hospital data provided by the IDPH.
- The next Task Force meeting will be open to public comment during the wrap up and adjournment session.
- Task Force agendas, minutes, and relevant resources will be posted to the IDPH website and available to the public.

The next Epilepsy Treatment and Education Task Force meeting was set for Tuesday, February 14th at 3pm with location at the Lucas State Office Building, Room 517/518.

ADJOURNMENT

Co-Chairperson Dale Todd adjourned the Epilepsy Treatment and Education Task Force meeting at 4:30pm.

Minutes submitted by: Jessica Peters

Minutes approved by: