

BRIGHTON COLLABORATION NEWSLETTER

NOVEMBER 2008 - MARCH 2009

Recent Meetings

The CIOMS/WHO Working Group on Vaccine Pharmacovigilance met on October 27-28 at the Public Health Agency of Canada in Ottawa, Canada. This WG agreed to translate prioritized Brighton case definitions and the General Guidelines into WHO languages. Those prioritized case definitions include: HHE, abscess, Aseptic Meningitis, cellulitis, and encephalitis. The translations will cover the case definition with footnotes and an edited preamble and also be accompanied by a one-page description and introduction to the Brighton Collaboration.

Stay tuned for more information!

Recent Publications

The Local Reactions Working Group recently published the overall local reaction definition with guidelines, entitled, "A local reaction at or near injection site: Case definition and guidelines for collection, analysis, and presentation of immunization safety data" in *Vaccine* in October 2008. The Methods Working Group currently has two articles in press (uncorrected proof) in *Vaccine* in October 2008. The first article is entitled, "Guidelines for collection, analysis and presentation of vaccine safety data in surveillance systems." The second article is called, "Guidelines for collection, analysis and presentation of vaccine safety data in pre- and post-licensure clinical studies."

To access the articles, please visit our Document Download webpage at:
http://www.brightoncollaboration.org/intranet/en/index/document_download.html.

You will need to log in first.

Congratulations on a job well done to both working groups!

Working Group Progress

Diarrhea: The Working group completed an online draft of the diarrhea case definition and guidelines. The group welcomes you to review the draft and complete the web-based survey at: <http://www.brightoncollaboration.org/intranet/en/index/surveys.html>. You will need to log in first.

GBS: The working group reconvened on February 13, 2009 and discussed use of the draft GBS case definition and guidelines in retrospective studies. Reviews of the definition were generally favorable. The next call will be held on February 27, 2009 to review the preamble and guidelines.

Local Reactions- Pain at injection site: The Working group had an introductory conference call on January 21, 2009. Team leader, Professor Gary Walco has kindly agreed to lead the scientific discussions of this working group. Another conference call was held on February 25, 2009. Experts on pain, William T. Zempsky (MD), and Gary Walco (PhD) gave presentations on various aspects of pain. The next conference call will take place on March 25.

Viscerotropic Disease: On January 21, 2009 the group had a conference call to review the partial inventory of published VD case reports and start identifying elements and criteria to be used to establish the Brighton case definition. On February 18, 2009, the group continued discussion on elements to be included in the VD definition, such as fever, jaundice, liver dysfunction, and renal dysfunction. The next conference call will be on March 18, 2009.

Viral Vector Vaccines Safety – Cross-Cutting Issues Subgroup: On January 12th the Cross Cutting subgroup discussed reviewing literature and its tentative viral vector template. This generic template should collect safety data regardless of the type of vector, and members can complete the template in regards to their specialized viral vector. On February 3rd, the subgroup welcomed new members including virologists and discussed the STEP clinical Trial Safety Issues, which was recently published in *The Lancet*. The next subgroup call is on March 3, 2009.

Bells Palsy: The working group has completed the first draft case definition with guidelines for data collection, analysis and presentation. Various sections of this draft will be reviewed and discussed prior to its approval by the Steering Committee and its online posting for your review.

Implementation: The working group met on November 25th and 26th to hear linguist Dr. Gabriella Rundblad compare two medical papers in vaccine safety. On January 27th and 28th the IWG brainstormed on new topics for the New Year.