Vaccine. 2009 Apr 6;27(16):2289-97. doi: 10.1016/j.vaccine.2008.11.035. Epub 2008 Dec 4.

Guidelines for collection, analysis and presentation of vaccine safety data in surveillance systems.

Bonhoeffer J[1], Bentsi-Enchill A, Chen RT, Fisher MC, Gold MS, Hartman K, Heininger U, Hoet B, Jefferson T, Khuri-Bulos N, Kohl K, Marcy SM, Nalin D, Pless R, Sanabria-Rojas H, Sleeman K, Wise R; Brighton Collaboration Methods Working Group.
PMID: 19061929

- Jacob Puliyel2014 Mar 05 04:45 a.m.

  IT IS EXPEDIENT BUT IS IT PRUDENT TO LABEL ADVERSE EVENTS FOLLOWING IMMUNIZATION AS 'NOT AN EVENT OF [AEFI]'?

  The old scheme of monitoring signals for vaccine safety (adverse events following immunization – AEFI monitoring), of the Advisory Committee on Causality Assessment Collet JP, 2000 has been overtaken by the Revised WHO Classification of AEFI. The changes have been described in 4 PubMed articles Tozzi AE, 2013, Bonhoeffer J, 2009, Halsey NA, 2012, Williams SE, 2013.

  I wrote two very detailed comments to the article by Tozzi et al Tozzi AE, 2013 on the PubMed Commons which is envisaged as a forum for open constructive criticism and discussion of scientific issues. To facilitate meaningful discussion it has a link to 'Invite an author to comment'. Tozzi and colleagues have not responded so far. PubMed suggests that the main reason for not getting a response is a changed email contact address.

  As this is a matter of patient safety I think it is important that the experts who understand the new scheme must explain why the revision was needed and that it is an improvement over the old scheme - that it will not miss opportunities of picking up new signals by classifying AEFI as 'Not a case of [AEFI]'. I will not repeat the posting but it may be viewed here

  The purpose of this posting is to invite the learned authors of this article on causality assessment Bonhoeffer J, 2009 to respond. The article by Bonhoeffer and colleagues mostly describes a guideline for collection of data which is unexceptional, but the subsequent 'analysis and presentation of vaccine safety data in the surveillance system' may cause signals to be ignored because they are classified as 'Not a case of [AEFI]'. Would the new scheme have picked up and flagged signals of adverse-effects like the RotaShield-reactions, had the scheme been in use in 1998?

  PermalinkShare http://www.ncbi.nlm.nih.gov/pubmed/19061929#cm19061929_3193

- This article was mentioned in a comment by Jacob Puliyel2015 Jan 19 08:02 a.m.

See:Combined hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type B vaccine; Infanrix™ hexa: twelve years of experience in Italy. [Hum Vaccin Immunother. 2014.]

- This article was mentioned in a comment by Jacob Puliyel2014 Mar 12 10:47 p.m.

  See:Assessment of causality of individual adverse events following immunization (AEFI): a WHO tool for global use. [Vaccine. 2013.]