- Combined hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type B vaccine; Infanrix™ hexa: twelve years of experience in Italy.

  Baldo V.Hum Vaccin Immunother. 2014.

Jacob Puliyel2015 Jan 19 08:02 a.m.edited

Apropos the earlier posting there are a couple of other facts that we must consider when looking at the incidence of sudden unexplained deaths immediately following vaccination with Infanrix.

a) The safety assessment document has used the number of doses of vaccine distributed as the denominator. The report acknowledges that all the doses of the vaccine distributed, need not have been utilized.

There can be another argument against using this denominator. As each child is given up to 5 doses (https://www.gsksource.com/gskprm/htdocs/documents/INFANRIX.PDF) and they could die after any one of the doses (and you can die only once), perhaps it would be more appropriate to look at the number of deaths against the number of babies vaccinated (rather than the number of units of vaccine distributed). The appropriate denominator would be about one fifth the denominator used in the report.

b) Appendix 5A in the document sent to the regulator gives the International Event Report in 13 fatal cases. It can be seen in this sample that there were more deaths after the first dose than after the second and more after the second than after the third dose. This is a pattern seen with adverse events following immunization (AEFI) that are causatively related.

c) In May 2005, Zinka and colleagues have reported six cases of sudden infant deaths caused by another hexavalent vaccine (similar to Infanrix), called Hexavac Zinka B, 2006. Marketing authorization in the European Union was withdrawn in August 2005 (Doc.Ref.EMEA/207369/2005).

d) The CIOMS /WHO have revised the widely used Brighton Protocol for assessment of AEFI. The new scheme facilitates misclassification of vaccine related deaths as [Not an AEFI] and this has been discussed on PubMed Commons earlier.
(http://www.ncbi.nlm.nih.gov/pubmed/19061929)
(http://www.ncbi.nlm.nih.gov/pubmed/23452584)
(http://www.ncbi.nlm.nih.gov/pubmed/24021304).

e) In some ways the deaths with Infanrix is similar to deaths seen with the use in Asia of Pentavalent vaccine against 5 disease (DPT, hepatitis B, Hib) Puliyel J, 2013. Some of these deaths have been investigated by the WHO using this revised method and the vaccine had been declared safe.
http://www.who.int/vaccine_safety/committee/topics/hpv/GACVSstatement_pentavalent_June2013.pdf

f) The deaths are completely unnecessary as the vaccines could have been given separately, and separately they have a long track record of safety. One hopes that the findings will result in an honest assessment of the harms being done by these new combined vaccines.

Conclusion

As mentioned earlier there is nothing sacrosanct about the original Brighton Classification (http://www.who.int/vaccine_safety/publications/AEFI_aide_memoire.pdf) but one has to evaluate the two schemes (Brighton vs CIOMS) from the point of view of patient safety to see which scheme would react to rare vaccine related adverse reaction signals early. "The causality scheme that insists on calling all reactions as 'indeterminate' or 'inconsistent/coincidental' just because they were not noticed in the original small clinical trials, undermines the very raison d'être of post marketing surveillance. Patient safety (meaning protecting patients) rather than vaccine safety (protecting vaccines) should be more important."