- 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 Feb 04

  I thank Ferenci and Miller for their responses. I will address the three points made by Dr Ferenci

  1) The data I have quoted (from Table 36) was made available by the manufacturers GSK, to defend the safety record of Infanrix Hexa to the regulatory authority (- the EMA). The data suggests a cluster on and following the day of vaccination. If the reporting is so bad the clusters aren't real, then the data can't/shouldn't be used to defend its safety. If the reporting is good, then the clusters are real too, and the vaccine looks unsafe.

  2) Dr Ferenci writes " ..it is immediately obvious from 3A appendices (pp. 301-522, pp. 857-1064) that no matter which disease-group we look at, the vast majority of spontaneous reports with known time are definitely coming from the first few days!"

  The sources for the the reports in the 3A appendices are different. 3A data is self-reported. It is no crime if a parent does not report to the doctor that their child developed leg pain a few days after being administered Infanrix.

  But SIDS deaths are different and have to be reported mandatorily to those like coroners who must determine the cause of death. They are investigated by professional forensic experts. SIDS are 'deaths under suspicious circumstances' - unexplained death that could be infanticide unless proved otherwise. Forensic experts are unlikely to 'forget' to mention immunization, simply because it was not given on the day of death but on the previous day. Reporting bias is less likely to be an issue with such forensic reports. Under-reporting on all days will of course still occur for all the reasons it occurs for other serious adverse events. But it is difficult to argue convincingly that higher under-reporting is likely on the day just after a vaccine is administered, compared to the day of vaccination.

  3) Finally, Dr Ferenci says that active vaccine safety studies are better than passively acquired data. For well designed, managed and executed studies I wholeheartedly agree with him.

  The TOKEN study aimed to assess comprehensively a possible causal relationship between vaccination and unexplained sudden unexpected death of children between their 2nd and 24th month of life. The study was supported and sponsored by the Paul-Ehrlich-Institute (PEI) and the Federal Ministry of Health (Bundesministerium für Gesundheit). Unfortunately this large study with a wealth of data has not been published in an indexed

peer reviewed journal as yet. It is available here:
http://www.rki.de/DE/Content/Gesundheitsmonitoring/Studien/Weitere_Studien/TOKEN_Studie/Studyreport.pdf?__blob=publicationFile

Parents of children who had died of SIDS were requested to participate in the study. 37.6% (254 cases) could be included in the study, where parental consent was obtained. Tables 31 and 36 show significantly increased risk of unexplained sudden unexpected death in the first 3 days after hexa- or pentavalent vaccination (1st and 2nd year of life).

So it appears that active studies have confirmed that there are two vaccines which cause 'sudden deaths'. I am grateful that the Italian Court has allowed public scrutiny of GSK's PSUR reports held as confidential by the EMA.

Jacob Puliyel