

- [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 Puliye](#) 2015 Jan 22 08:55 a.m. edited

I thank the authors for their response to my comment.

I was presuming that in the countries from where this data was gathered, sudden infant death or SIDS is considered 'unnatural death'. If that is so, these deaths will have been investigated by a competent forensic team and the immunization records will have been examined to check if the infant was up to date with its vaccinations or whether there was an element of neglect. Reporting bias (based on parents perception that vaccine was the trigger for events that lead to the death of their child) would have little or no role under these circumstances.

The authors quote from the 'Guidelines for good pharmacovigilance practices'; that *events that are expected, common and mild, or occur late after vaccination*, are less likely to be reported. That is not applicable here, as *SIDS is completely unexpected and a catastrophic event*.

Further, the analysis in Table 2 of the linked article <http://jacob.puliye.com/paper.php?id=345> (Please download pdf version) shows that there were 42 deaths in the first 3 days and only 16 in the next 3 days. It is difficult to imagine that reporting bias is responsible for this big a change, in so short a time.

We will need to find a more plausible explanation. Otherwise we have to accept that the deaths were caused by the vaccine and the diagnosis of SIDS was wrong.

Jacob Puliye