

Human Papilloma Virus Vaccines and Current Controversy

I fully agree with the views expressed by the authors [1] as far as the role of HPV vaccine in prevention of cervical cancer is concerned. I also agree that the vaccine is safe, devoid of any serious side effects, ethical, and socially desirable. But will it be legally safe to use this vaccine? When the authors have themselves agreed that suspending clinical trial while allowing clinical use is illogical, it does not require to be a legal luminary to conclude that when even the clinical trial of a drug/vaccine is suspended, its clinical use will not only be illogical but illegal too. Will the arguments given by them be valid in a court of law in case of any mishap after this vaccination, which may or may not be related to this vaccine. Every court is going to rule that when even clinical trial was suspended how clinical use can be justified. Moreover, as per media reports, which may or may not be correct, DGHS, Government of India has written to health ministers of all states not to use this vaccine till further orders (The Hindu 8th April, 2010). Therefore, I feel that one should not use this vaccine till the enquiry is finally over and the government clears this vaccine for all purposes. Please specify the official views of Indian Academy of Pediatrics regarding the legality of this vaccine, for the benefit of all members of IAP, especially practitioners.

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REPLY

Dr Singhal's main concern is the legal safety in using the Human Papillomavirus (HPV) vaccine in view of

the suspension of studies with this vaccine. It is beyond our jurisdiction to opine on judicial matters, but we strongly feel that the concern is unfounded.

Studies in question relate to administration of HPV vaccine which seeks to determine vaccine coverage achieved, feasibility, acceptability of HPV vaccination, and implementation costs associated with different vaccination strategies in a variety of socioeconomic settings. Such studies may be put on hold for variety of reasons.

The HPV vaccines used in these studies are commercially available in India and approved by the Drug Controller General of India (DCGI), US Food and Drug Administration (FDA) and European Medicines Agency. The two HPV vaccines used in the project have been prequalified by WHO. The vaccines continue to remain as a licensed product approved by the DCGI.

On safety issue, the WHO position paper on HPV vaccines states that, "in clinical trials, mild and transient local reactions at the site of injection (erythema, pain, or swelling) were 10-20% more frequent among those who received the current HPV vaccines than in their respective control groups, but no systemic adverse reactions assessed to be causally associated with the HPV immunization have been reported" [1]. To date, no deaths have been causally associated with HPV vaccination in India or elsewhere. A joint report of Center for Disease Control and Prevention (CDC) and FDA analyzed adverse events following HPV vaccine administration from June 2006 through December 2008. The report found that after more than 23 million doses were administered nationally, vast majority (94%) of adverse events reported after receiving this vaccine has not been serious. Reported deaths with available records, autopsy reports, or death certificates describe causes other than recent vaccination [2].

Suspension of the study does not equal withdrawal of the license to use it and there is no case to suspend the use of the vaccine in individual practice.

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Re-evaluation of Congenital Hypothyroidism

I read with much interest the work done by Nair, *et al*. [1] in evaluating children with congenital hypothyroidism and the effect of stopping/withholding thyroxine by 3 years of age. I would like to highlight that with a smaller sample and non-normal distribution of data, reporting of medians may be more relevant, as in the case of age at diagnosis. In addition, since repeated measurements of TSH, T4 and T3 were available, repeated measures analysis of variance (RMANOVA), would have been a more appropriate test to be used. If the

assumption of fixed interval between repeated measures is violated or differences are non-normal, Friedman test may be applied. The conclusions drawn that permanent and transient hypothyroidism had significantly different TSH values to begin with and different dosing requirements of thyroxine may still be valid and biologically plausible.

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Esophageal Diverticulum: An Unusual Cause of Recurrent Vomiting and Dysphagia

Symptomatic esophageal diverticula are rare in infants and children [1]. We report a 6-year-old boy with esophageal diverticulum who presented to us with dysphagia, frequent vomiting, and chest pain since one year of age, mimicking a simple gastroesophageal reflux.

On physical examination, his growth was normal. A barium esophagram showed a sac-shaped esophageal diverticulum arising from the left side of the lower third of the esophagus (**Fig 1**). Esophagoscopy demonstrated a broad-based esopha-



FIG. 1 The barium esophagram showed one diverticulum (arrow) arising from the left side of the lower third of the esophagus.