

PRIMUM NON NOCERE

Why has Dr Yogesh Jain, pediatrician formerly at AIIMS and now a public health physician at Jan Swasthya Sahyog, Chattisgarh filed a PIL against the introduction of the pentavalent vaccine into the UIP? This pentavalent vaccine protects against DPT, Hib and Hep B. The Global Alliance for Vaccines and Immunizations (GAVI) and WHO have recommended pentavalent vaccine in developing countries to increase the uptake of the hepatitis B and Hib vaccines. But surprisingly the vaccine is not approved for use in Canada, US, Europe, Australia, UK and Japan.

When Sri Lanka introduced the pentavalent vaccine in 2008, within 3 months there were 4 deaths and 24 reports of hypotonic-hyporesponsive episodes (HHE). The first batch was suspended and when there was another death in the next batch in April 2009, the pentavalent vaccine was replaced by the former DPwT and HepB vaccines. In September 2009, the pentavalent vaccine from Panacea was introduced into Bhutan. In October 2009 the vaccine was suspended after 5 cases of encephalopathy/encephalitis occurred following the vaccine. The reintroduction of the vaccine was followed by another four deaths. Bhutan again stopped using the pentavalent vaccine. The Director of Public Health, Dr Ugen Dophu, noted that there were no more cases of meningoencephalitis among infants the year after the vaccine was withdrawn. Vietnam introduced the pentavalent vaccine in June 2010. By May 2013, a total of 43 serious AEFI with 27 deaths were reported and use of the vaccine was suspended.

The vaccine was reintroduced into Sri Lanka in 2010, following which upto 2012 another 14 deaths have been reported. When the vaccine was introduced into Pakistan, there were 3 deaths one of which was half an hour after vaccination and 2 within 12-14 hours with no other clear etiology documented.

So when the vaccine was introduced into India, to allay public fears the Noel Narayanan Committee was set up to monitor AEFI's. In the first six months after the introduction of the vaccine in Kerala, 40,000 children were vaccinated and five of them died of AEFI. By the end of a year, 14 children had died. It was subsequently introduced in Gujarat, Goa, Haryana, Karnataka, Puducherry and J&K. The death of 8 babies following the pentavalent vaccination in Kashmir triggered off massive protests. Activists protesting against the vaccine estimate that in vaccinating the 25 million birth cohort of India, given the current incidence of serious Hib infections, to save 350 children from Hib related illnesses, 3125 will die from adverse effects of this vaccine. So far around 70 children have died in 5 countries after being vaccinated with various brands of the pentavalent vaccine. We cannot afford to forget the guiding axiom of all good medicine is "Primum non nocere"; above all do no harm (*Global Advisory Committee on Vaccine Safety*

*review of pentavalent safety concerns in four Asian countries' http://www.who.int/vaccine_safety/committee/topics/hpv/GACVSstatement_pentavalent_June2013.pdf; *The Times of India* 3 September 2013; *Indian Journal of Medical Ethics* Vol X No 3 July-September 2013).*

NOBEL PRIZE FOR MEDICINE

During evolution, as complexity increased, the eukaryotic cell differentiated itself from the prokaryotic cell by compartmentalizing functions. This created a new problem of how to transport important molecules from one organelle to another. This mechanism required the development of an intricate system of vesicles which shuttle their cargo between organelles or fuse with the outer membrane of the cell and release their cargo to the outside with breathtaking accuracy of timing and location. Two American and one German scientist share this year's Nobel Prize for Medicine. They have tackled different aspects of how the cell controls transport of various vesicles carrying important substances like neurotransmitters, cytokines, hormones and enzymes. Through their discoveries, Rothman, Randy Schekman and Thomas Südhof have revealed the exquisitely precise control system for the transport and delivery of cellular vesicular transport (http://www.nobelprize.org/nobel_prizes/medicine/laureates/2013/press.html).

POLIO RESURFACES IN EUROPE

In 2002, the WHO declared its European region, including 53 countries, free of polio. Recently, WHO has reported a cluster of cases of acute flaccid paralysis in Deir-ez-Zor, a conflict-ridden province in eastern Syria. Two of the 22 cases were confirmed as polio by national authorities, and on 29 October 2013, the WHO confirmed a total of ten. The reason of course is war. There has been a steep fall in child immunization rates in Syria owing to the ongoing conflict. And since there are 200 non-paralytic cases of polio for every paralytic one, the cluster is probably only the tip of the iceberg.

The situation in Israel is a tad different. Israel's effective sewage-surveillance systems were able to detect the virus before any clinical cases occurred. Galvanized into action, Israel has so far identified 42 people shedding poliovirus in their feces. None of them had symptoms of paralysis, and they had been fully vaccinated with inactivated poliovirus vaccine (IPV). IPV has shown a high level of individual protection, but poor gut immunity, meaning that vaccinated people might still shed the virus in feces. To stop silent transmission, Israel has since August given OPV to more than 890,000 children, and Syria has begun administering OPV to 2.4 million children. The WHO and the Unicef are planning a vaccination campaign in all neighboring countries. (*Nature* 29 October 2013).

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