Pentavalent Vaccine – Critisised in Asian Countries

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Published on 25th March 2019

Every year, more than 2.5 billion doses of vaccines are used globally to immunize children under the age of 10 year. Immunization is the key to protecting children from many complicating diseases, including polio, measles, diphtheria, and tetanus. From 2005 to 2010, global demand for the pentavalent vaccine increased quickly. Pentavalent vaccine has been progressively introduced in Asian countries after the Haemophilus influenzae type b (Hib) vaccine has usually been introduced as a component of a combination pentavalent vaccine, which has replaced the traditional diphtheria–tetanus–whole-cell pertussis (DTwP) or DTPwP-hepatitis B vaccines. This "five-in-one" combination of vaccine protects children from diphtheria, pertussis (whooping cough), tetanus, hepatitis B and Haemophilus influenzae type b (Hib) which causes pneumonia and meningitis. It is less traumatic for babies to receive and easier for administering the vaccine than previous formulations.

As with the introduction of any new vaccine, there has been particular attention to adverse events following immunization (AEFI), which presented challenges in several countries in the WHO South-East Asia and Western Pacific Regions.[1] There is different experience for all four countries that introduced pentavalent vaccines from 3 different manufacturers. Sri Lanka introduced the pentavalent vaccine from Crucell in January 2008, and within 3 months, 4 reports of deaths and 24 reports of suspected hypotonic-hyporesponsive episodes prompted regulatory attention and precautionary suspension of the initial vaccine a lot. But with subsequent death that occurred with the next lot in April 2009 led the authorities to suspend pentavalent vaccine use, and reintroduced the DTwP and hepatitis B vaccination. Bhutan introduced pentavalent vaccine from Panacea in September 2009. The identification of 5 cases with encephalopathy and/or meningoencephalitis shortly after pentavalent vaccination prompted the authorities to suspend vaccination just one month after introduction. India introduced pentavalent vaccine from the Serum Institute of India, and pilot tested in the states of Tamil Nadu and Kerala in December 2011. This was followed by expansion of vaccine usage in other states of India, such as Goa, Pondicherry, Karnataka, Haryana, Jammu and Kashmir, Gujarat and Delhi during the second half of 2012 through the first quarter of 2013. About 83 adverse events following immunization cases, some of which were associated with mortality, have been reported after vaccine introduction. Pentavalent vaccine introduced in Vietnam was from Crucell in June 2010 and up to May 2013, a total of 43 serious AEFI cases were investigated, including 27 with a fatal outcome. Health authority of Vietnam suspended the use of vaccine following the reports of 9 deaths following vaccination between December 2012 and March 2013.

All these serious cases of AEFI in each country were reviewed with independent national and international experts. Reviews have come up with a conclusion that none of the fatal cases could be classified as having a consistent causal association with immunization. Most of the reviews showed that mortality was due to some existing congenital heart diseases or due to some other pre-exisiting conditions. In Sri Lanka and Vietnam vaccine was reintroduced in 2010 and 2012 based on expert review results. The children with known severe congenital heart disease are now vaccinated under close medical supervision.

Why vaccine prequalification is necessary

WHO's vaccine prequalification programme ensures that the vaccines received by two thirds of the world's babies are safe, high-quality and affordable. Currently, 65% of all babies globally are immunized using WHO prequalified vaccines. WHO prequalification give

Cite this article as: Benny PV. Pentavalent Vaccine – Critisised in Asian Countries. IMA Kerala Medical Journal. 2019 Mar 25;12(1):1–2.

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assurance that the vaccines are safe, effective and suit the needs of developing countries.[2]

The prequalification process of an Indian company (Biological E): In 2012, Biological E prequalified its single-vial, liquid formulation of pentavalent, an easier product to transport and administer than the earlier version in two vials (one liquid, one powder, to be mixed). India's National Regulatory Authority licensed the formulation, and the application for prequalifiation was then submitted to WHO. The dossier (provides information that matters to the populations that will use the vaccine, such as stability at different temperatures and potential interaction with other vaccines) was examined by reviewers from within and outside WHO. They also reviewed the product itself by sending samples to a range of reference laboratories and carrying out site inspections. The vaccine was prequalified in less than the 12-month target period for the prequalification process.

Serious or unexpected adverse events can rarely manifest following immunization, and it is important for health care providers as well as public health officials to study. Many challenges are drawn in deciding whether an adverse event is actually caused due to vaccination.[3] The conclusion of investigations and expert review of deaths following pentavalent vaccine in the 4 countries are supportive although not all cases could be fully assessed due to incomplete case information. The importance of thorough clinical investigation of AEFI, and of adequate evaluation of deaths following vaccination including autopsy to identify underlying conditions and any potential alternative causes of death, was verified by the experience of those countries.

World Health Organization's weekly epidemiological updates confirm that pentavalent vaccines provide great public health benefits that accrue from the ability to protect against 5 major threats to health in a single injection, and currently, pentavalent vaccines from 5 different manufacturers prequalified by WHO and considered to be safe, effective and of assured quality.[1]

END NOTE

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Conflict of Interest: None declared

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