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சுகாதார, போசணை மற்றும் சுதேச வைத்திய அமைச்சு
Ministry of Health, Nutrition & Indigenous Medicine

General Circular No: 01-26/2012
Provincial/Regional Directors of Health Services,
Directors of Teaching Hospitals/Specialized Campaigns,
MSS/DMOO of Provincial/Base Hospitals,
Heads of Decentralized Units,
Regional Epidemiologists, Medical Officers (MCH)
Medical Officers of Health.

Revised Guidelines on vaccination of infants with Severe Congenital Heart Diseases

The Epidemiology unit monitors all Adverse Events Following immunization (AEFI) reported through the national AEFI surveillance system to ensure the quality and safety of all vaccines used in the National Immunization programme in Sri Lanka. All serious AEFI including deaths are reviewed by the National Expert Committee on AEFI /vaccine safety to assess the possible causality between the vaccine and the reported AEFI.

The committee having reviewed a few infant deaths following vaccination, where children had histories of *severe* congenital heart diseases, excluded the possibility that deaths could have been caused by the vaccine (antigen or excipient). Vaccinating children with *severe* congenital heart diseases is no known contra indication. Nor does the National Experts' Committee on AEFI/vaccine safety consider *severe* congenital heart disease as a contraindication for vaccination. Paradoxically, it endorses the necessity of vaccination of these infants. However, contrary to this necessity, the experts' committee opines that the vaccine or the vaccination process may have triggered the events (eg. hypotension, tachycardia), which may eventually have led to precipitating the underlying disease and causing the death of these infants. Cardiologists' opinion is that these triggering events could be avoided with close monitoring and necessary prophylactic measures adopted in a hospital setting. Therefore the experts' committee recommends that all infants with previous diagnosed *severe* congenital heart disease conditions listed below should be admitted to a hospital where a paediatrician's service is available for vaccination and should be observed for a mandatory period of 24 hours after vaccination, before being discharged.

Further, the committee was of the view that giving the whole cell Pertussis containing Pentavalent vaccine for children with severe congenital heart disease, may trigger an exaggerated immune response, which could lead to adverse outcomes.

Whereas, the acellular Pertussis containing Hexavalent vaccine has been found to be less immunogenic and could be used for children with severe congenital heart diseases.

Therefore, during vaccination of children with severe congenital heart disease conditions listed below, on the recommendation of the treating consultant paediatrician, the Director of the hospital can purchase the acellular Pertussis containing Hexavalent vaccine locally.

Infants with *severe* congenital heart disease who need hospitalized vaccination are as follows:

1. Cyanotic defects
 - a. Tetralogy of Fallot
 - b. Pulmonary atresia with duct dependent pulmonary circulation,
 - c. Univentricular heart with pulmonary stenosis,
 - d. Tricuspid atresia,
 - e. Any other condition with significant cyanosis (SaO₂<85%)
2. Any cardiac condition with significant left ventricular hypertrophy
 - a. Hypertrophic cardiomyopathy,
 - b. Significant valvar, supra-valvar or sub-valvar aortic stenosis
3. Any condition with significant LV dysfunction (EF<45%)
 - a. Dilated cardiomyopathy,
 - b. any other cardiac condition with significant LV dysfunction
4. Any patient with moderate/severe pulmonary hypertension
5. Cyanotic congenital heart defects palliated with systemic to pulmonary artery shunts (BTshunt) and pulmonary artery banding (PA banding)

It is recommended that cardiac monitoring (pulse, BP and SaO₂) of these infants be carried out preferably for 24 hours after vaccination if the facility is available.

All children with significant cyanosis should be kept well hydrated before and after the vaccination. Blood pressure should be monitored and in the event of hypotension due to fever or vasodilatation, appropriate fluid administration should be done along with other appropriate therapeutic measures.

Please be kind enough to bring the contents of this circular to the notice of all concerned officers in your province/district/institution.

This circular will replace the contents of the previous General Circular No: 01-26/2012 issued on 16/05/2012.



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