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Low-dose Thimerosal in pediatric vaccines: Adverse effects in perspective

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ABSTRACT

Vaccines are prophylactics used as the first line of intervention to prevent, control and eradicate infectious diseases. Young children (before the age of six months) are the demographic group most exposed to recommended/mandatory vaccines preserved with Thimerosal and its metabolite ethylmercury (EtHg). Particularly in the less-developed countries, newborns, neonates, and young children are exposed to EtHg because it is still in several of their pediatric vaccines and mothers are often immunized with Thimerosal-containing vaccines (TCVs) during pregnancy. While the immunogenic component of the product has undergone more rigorous testing, Thimerosal, known to have neurotoxic effects even at low doses, has not been scrutinized for the limit of tolerance alone or in combination with adjuvant-Al during immaturity or developmental periods (pregnant women, newborns, infants, and young children). Scientific evidence has shown the potential hazards of Thimerosal in experiments that modeled vaccine-EtHg concentrations. Observational population studies have revealed uncertainties related to neurological effects. However, consistently, they showed a link of EtHg with risk of certain neurodevelopment disorders, such as tic disorder, while clearly revealing the benefits of removing Thimerosal from children's vaccines (associated with immunological reactions) in developed countries. So far, only rich countries have benefited from withdrawing the risk of exposing young children to EtHg. Regarding Thimerosal administered to the very young, we have sufficient studies that characterize a state of uncertainty: the collective evidence strongly suggests that Thimerosal exposure is associated with adverse neurodevelopmental outcomes. It is claimed that the continued use of Thimerosal in the less-developed countries is due to the cost to change to another preservative, such as 2-phenoxyethanol. However, the estimated cost increase per child in the first year of life is lower than estimated lifetime cost of caring for a child with a neurodevelopmental disorder, such tic disorder. The evidence indicates that Thimerosal-free vaccine options should be made available in developing countries.

1. Introduction

Vaccines are prophylactics used as the first line of intervention to prevent, control, and eradicate infectious diseases. Young children (before the age of 6 months) are the demographic group most exposed to recommended/mandatory vaccines that are preserved with Thimerosal and its metabolite ethylmercury (EtHg). Furthermore, in less-developed countries, this vulnerable demographic range (newborns, neonates, young children) is additionally exposed to EtHg when mothers are immunized with Thimerosal-containing vaccines (TCVs) during pregnancy (Dórea, 2011a). Indeed, in certain circumstances, six TCVs may be given to pregnant mothers: tetanus, up to three doses of hepatitis B, seasonal flu and H1N1 vaccines (Dórea, 2011a).

Modern vaccine development and evaluation require multiple stages involving academia, industry, and federal agencies (Curlin et al., 2011). Because not all immune components elicit an ideal response, vaccines are often formulated to contain an adjuvant, and when bottled in multi-dose vials, a preservative may be justified. In order to be manufactured, vaccines have to be formulated to resist contamination in the production line and during handling and application from multi-dose vials. As a result, some vaccines contain both preservative-Thimerosal and adjuvant-Al.

During vaccine production, no modern toxicity studies are required to detect specific aspects of low-dose EtHg (alone or in combination with Aluminum) in susceptible individuals; rather, non-specific toxicity tests such as body weight changes are frequently used (Sharma et al., 2012). Albeit at low doses, toxic ingredients (such as Thimerosal and adjuvant-Al) are intrinsically part of the vaccine's development and distribution but without modern toxi-testing assessment. Vaccines in general, be they TCVs or Thimerosal-free vaccines, are tested in adults for efficacy and safety related to their immunogenicity (Rebedea et al., 2006). Regardless of the formulation with and without Thimerosal, licensed vaccines show an extremely low rate of adverse events associated with the immune component (Ahmed et al., 2011). The

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