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The Safety of Aluminum Adjuvants in Vaccines

Key points:

- **Adjuvants, including aluminum, help stimulate the immune response to a vaccine increasing the likelihood of a protective immune response and reducing the amount and number of vaccine doses needed.**
- **The cumulative aluminum exposure from vaccines in the first 6 months of life is less than that consumed from dietary sources (both breast milk and formula).**
- **The estimated concentration of aluminum in blood from vaccines administered during the first year of life remains below the minimum risk level.**
- **A nationwide study of 1.2 million children did not find evidence supporting an increased risk for autoimmune, atopic or allergic, or neurodevelopmental disorders associated with cumulative aluminum exposure from early childhood vaccination.**

Aluminum as Adjuvants in Vaccines[1]

- Highly purified vaccine antigens are generally poorly immunogenic because of insufficient stimulation of the innate immune system.
- Adjuvants stimulate the immune system thereby increasing the proportion of the vaccinated population that develops a protective immune response and the duration of the protective immune response.
- Adjuvants may allow for fewer immunizations and reduce the amount of antigen per dose.
- Aluminum has been used as an adjuvant in vaccines to enhance the immune response to purified viral and bacterial antigens.
- Aluminum adjuvants reduce the prevalence and severity of systemic adverse reactions by binding and slowly releasing molecules thereby reducing toxicity.
- Aluminum-containing vaccines include diphtheria, tetanus, and pertussis (DTaP); *Haemophilus influenzae* type b (Hib); pneumococcal conjugate vaccine (PCV); and hepatitis A and B vaccines.
- Aluminum-containing adjuvants have been used for more than 70 years in billions of doses of vaccines and have an excellent safety record.

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The Safety Profile of Aluminum

- The maximum amount of aluminum allowed in human vaccines in the US is 0.85 mg Al/dose. The aluminum content in licensed vaccines ranges from 0.125 to 0.85 mg Al/dose.[2]
- Aluminum is abundant in the environment. Grains and vegetables absorb aluminum from soil. It is daily ingested in food and water.
- Based on studies examining the aluminum exposure of infants, the cumulative aluminum exposure from vaccines in the first 6 months of life is less than that consumed from dietary sources, including both breast milk and formula.[3,4]
- The estimated concentration of aluminum in blood from vaccines administered to infants during the first year of life remains below the minimum risk level.[4]
- Studies evaluating the concentration of aluminum in the blood and hair of infants identified no proven link between the concentration of aluminum in blood and hair and the receipt of vaccines or neurodevelopmental outcomes.[5]

Aluminum-Adjuvanted Vaccines and Chronic Disease

Study evaluating the association between aluminum in vaccines and childhood chronic diseases[6]

- A nationwide cohort study of approximately 1.2 million children, including all children born live in Denmark between1997 and 2018.
- The study examined 50 chronic disorders: 36 autoimmune, 9 atopic or allergic, and 5 neurodevelopmental disorders.
- Uniformly applied policy changes led to systematically different cumulative doses of aluminum received through childhood vaccination across birth cohorts.
- Evaluated the risk of the chronic disorders based on cumulative aluminum amount received (per 1-mg increase) through vaccination during the first 2 years of life.
- The adjusted hazard ratios per 1-mg increase in aluminum exposure:
    - 0.98 (95% CI, 0.94 to 1.02) for any autoimmune disorder
    - 0.99 (CI, 0.98 to 1.01) for any atopic or allergic disorder
    - 0.93 (CI, 0.90 to 0.97) for any neurodevelopmental disorder
- **This nationwide cohort study did not find evidence supporting an increased risk for autoimmune, atopic or allergic, or neurodevelopmental disorders associated with cumulative aluminum exposure from early childhood vaccination.**

- Small relative increases in risk could not be statistically excluded, particularly for some rarer outcomes.
- The Centers for Disease Control and Prevention (CDC) website recently cited data from the Supplementary Figures 4 and 11 of this study in order to raise questions about aluminum exposure and neurodevelopmental disorders.
    - The CDC webpage misrepresents the findings in Supplemental Figure 11 as there were no statistically significant findings or a dose-related response.
    - In Supplemental Figure 4, there was statistically significant increase in Asperger's syndrome in children from the 2007-2018 birth cohort (1.67 CI 1.01-2.27), but the sample size was small (51 children). This was not seen in the 1997-2006 birth cohort. In addition, there was no significant increase or trend towards increase for neurodevelopmental disorders overall or specific diagnoses for either birth cohort. This calls into question the relevance of this finding.

References

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