Immunisation Advisory Centre

VERSION 3

Aluminium in vaccines: a quick guide for healthcare professionals

Key message

All vaccines given to children less than 5 years of age, except measles-mumps-rubella, varicella and rotavirus vaccines, include aluminium salts to enhance the response of the developing immune system and increase protection.

Careful studies have shown that all the vaccines recommended in the first year of life increase aluminium levels by about 50%, compared with diet alone. However, due to the infants' rapid growth and increased capacity to excrete aluminium by the kidneys in the first year of life, levels do not reach even one fifth of the minimum level where toxicity can occur.

A recent study of more than one million Danish children did not show any increase in more than 50 kinds of diseases as the amount of aluminium received through vaccines increased.

Understanding aluminium in our environment

Aluminium is the third most abundant element in the earth's crust and is present naturally in soil, plants, foods, and water. It is also added to some processed foods (e.g. bread and cheese) and is found in the air we breathe.

Newborns already have aluminium in their body from their mother and aluminium is present in breast milk and formula:

- **Baby formula:** ~2.26mg/L
- **Commercial cow's milk:** ~0.7mg/L
- **Human breast milk:** 0.14–0.34mg/L

Aluminium in vaccines given to babies

Concerns about aluminium from vaccines for babies are understandable because of their small body weight and the number of vaccines needed for early protection. However, the benefits of full and timely vaccination for babies are great and total aluminium exposure from vaccines is very small as explained below.

Aluminium salts (e.g., aluminium hydroxide, aluminium phosphate) are used in vaccines for babies as "adjuvants" to "add" to the immune response which would otherwise not be sufficient due to immature immune systems.

It has been shown that the body burden of aluminium from vaccines and diet throughout an infant's first year of life is significantly less than the safe body burden of aluminium (see graph on the following page).

Only non-live vaccines contain aluminium salts. Live vaccines like MMR and varicella do not contain such adjuvants.

Aluminium salts in vaccines in first two years of life:

- Meningococcal B vaccine: 0.25–0.52mg/dose
- DTaP/Hib/polio/Hep B (6 in one) vaccine: <0.85mg/dose
- Pneumococcal vaccine: 0.125mg/dose

Aluminium and the human body

Processing aluminium: Once in the bloodstream, aluminium is processed in the same way – from food or vaccines.

Rapid elimination: After entering the bloodstream, most aluminium is excreted in urine, half within 24 hours.

Comparative exposure: The aluminium from vaccines causes a short-lived "spike" in blood levels but daily intake from food and drink results in greater cumulative exposure over time.

Health considerations: People of all ages with kidney problems can accumulate potentially toxic levels of aluminium over time but are still advised to receive vaccines with aluminium due to higher disease risk. A study of 1.2 million children in Denmark for periods of 3 to 10+ years did not find any evidence of an increased risk of more than 50 diseases including asthma, allergy and neurodevelopmental problems related to the amount of aluminium received from vaccines calculated from the number of vaccines received in the first 5 years of life.

Safety of aluminium in vaccines

Historical usage

Aluminium adjuvants have been used for over 100 years with hundreds of millions of doses administered and a strong safety record.

Research findings

- No evidence links aluminium in vaccines to serious or long-term health issues
- Some studies report small nodules at the injection site, especially if the injection is not deep enough
- Conversely, other studies have reported fewer reactions with aluminium-containing vaccines than without, depending on the overall formulation

Risk vs. benefit

- The benefits of preventing diseases through vaccines with aluminium greatly outweigh any known risks

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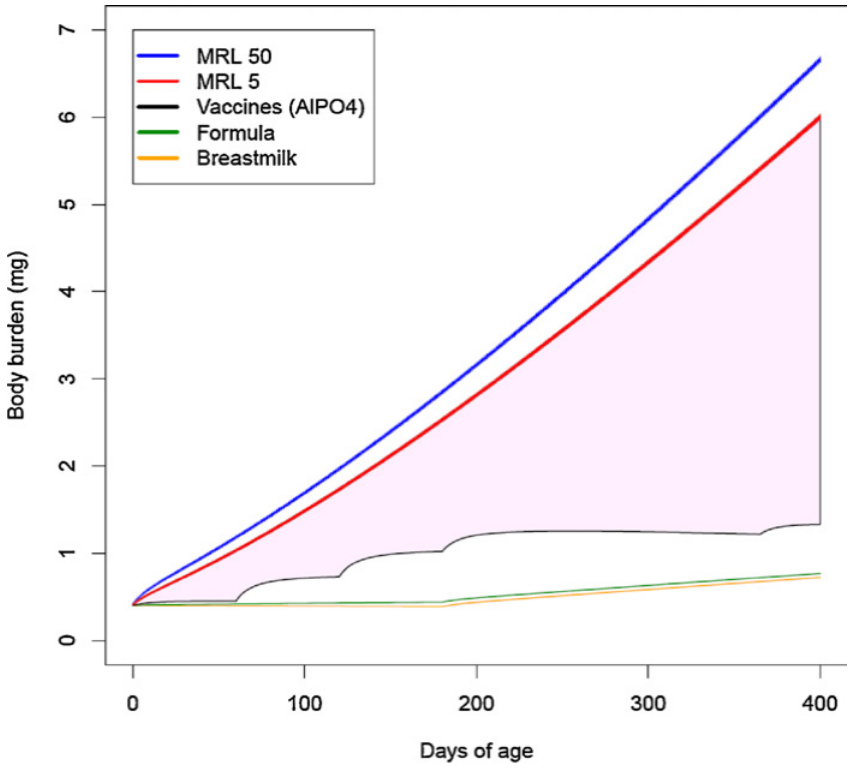
Key points for patient conversations

Purpose of aluminium adjuvant in vaccines
To enhance the immune response to give best protection.

Safety assurance

- No long-term problems in a study of 1.2 million children
- Some short-term local reactions may occur
- Disease prevention surpasses any theoretical risks
- Delaying vaccines to limit aluminium exposure leaves a child vulnerable to dangerous pathogens for much longer than necessary



This graph shows the body burden contributions of aluminium from diet and vaccines relative to current minimum risk levels (MRL) in newborn infants. (Margin of exposure in pink; MRL, established by the Agency for Toxic Substances and Disease Registry).*
Source: Mitkus et al 2011 (ref 6 below), reproduced with permission from Elsevier

** Exposures below this level are considered to be safe, but levels of exposure at or slightly above the MRL may also be safe due to safety factors that are built into the process of calculating the MRL.*

Key reference findings

1. Aluminium and vaccines: Current state of knowledge
While high doses of aluminium can lead to various health issues, the amount present in vaccines is too low to cause any toxic effects. In fact, the aluminium levels in the bodies of people who receive aluminium-containing vaccines are no different from those in unvaccinated individuals. Goullé JP, Grangeot-Keros L. Med Mal Infect 2020 Feb;50:16-21.

2. Blood and hair aluminium levels, vaccine history, and early infant development: a cross-sectional study
Researchers evaluated children aged 9 to 13 months for blood and hair aluminium levels, vaccination history, and cognitive, language, and motor development scores. Children who had received aluminium-containing pharmaceuticals were excluded from the study. The authors found no correlation between aluminium levels in blood or hair and vaccination history, nor between blood aluminium levels and overall developmental status. Karwowski MP, Stamoulis C, Wenren LM, et al. Acad Pediatr 2018;18:161-165.

3. Evidence refuting the existence of autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA)
The authors found two studies disputing the claim of autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA) as proposed by Shoenfeld and coworkers. One study showed that lupus patients did not experience more exacerbations after receiving a hepatitis B vaccine with an aluminium adjuvant. Another study of over 18,000 patients who received allergen-specific immunotherapy with aluminium showed a lower incidence of autoimmune disease than the control group. The authors concluded that current evidence does not support the existence of ASIA. Ameratunga R, Gills D, Gold M, et al. J Allergy Clin Immunol Pract 2017;5:1551-1555.

4. Adverse events after immunization with aluminium-containing DTP vaccines: systematic review of the evidence
The authors reviewed adverse events following exposure to aluminium-containing diphtheria, tetanus, and pertussis (DTP) vaccines, comparing them to identical vaccines without aluminium or with different aluminium levels. In children up to 18 months old, aluminium-containing vaccines were linked to more redness and swelling at the injection site but were not associated with serious adverse events. Jefferson T, Rudin M, Di Pietrantonj C. Lancet Infect Dis 2004;4:84-90.

5. Aluminium-Adsorbed Vaccines and Chronic Diseases in Childhood: A Nationwide Cohort Study
A study of 1.2 million children in Denmark for periods of 3 to more than 10 years did not find any evidence of an increased risk of more than 50 diseases including asthma, allergy and neurodevelopmental problems related to an increase in the amount of aluminium received with changes in the Danish recommended vaccine schedule and number of vaccines received in the first 5 years of life. Andersson NW et al. Annals of Internal Medicine 2025.

6. Updated aluminium pharmacokinetics following infant exposures through diet and vaccination
These authors found that the body burden of aluminium from vaccines and diet throughout an infant's first year of life is significantly less than the safe body burden of aluminium. Mitkus RJ, King DB, Hess MA, Forshee RA, Walderhaug MO. Vaccine 2011 No 28;29(51):9538-43

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