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# Study Reports Aluminum in Vaccines Poses Extremely Low Risk to Infants

The risk to infants posed by the total aluminum exposure received from the entire recommended series of childhood vaccines over the first year of life is extremely low, according to a study by the U.S. Food and Drug Administration (FDA).

This study is important because it provides additional scientific information confirming that the benefits of aluminum-containing vaccines administered during the first year of life outweigh any theoretical concerns about the potential effect of aluminum on infants.

A previous study done by others also concluded that the risk to infants of aluminum in vaccines is not significant.

Aluminum is incorporated into some vaccines as an adjuvant. The purpose of formulating vaccines with adjuvants is to increase the immune response to the antigen (the component of the vaccine that stimulates the immune system to make antibodies). When FDA evaluates a vaccine for safety and effectiveness, an adjuvant such as aluminum, is considered to be a part of the vaccine, rather than a component that is licensed separately.

Vaccines containing an aluminum adjuvant have a demonstrated safety profile of over six decades of use and have only uncommonly been associated with severe local reactions. But because the public has expressed concerns that aluminum in vaccines might pose a risk to infants, FDA performed an updated analysis of the safety of aluminum adjuvants.

The authors of the paper based their calculations of infant exposure to aluminum on the following updated parameters:

- an updated list of recommended vaccines for infants
- baseline aluminum levels at birth
- more recent information on how the body accumulates aluminum
- new information on how the infant kidney filters out potentially toxic substances from the blood
- more accurate information on how quickly aluminum spreads away from the site of vaccine injections and into the body
- the latest information on safety levels for aluminum in the body
- the most recent information on infant weights from age 0 to 60 months

The authors based their calculations on the series of vaccinations that deliver the maximal possible levels of aluminum during an infant's first year of life and the assumption that infants would receive the entire recommended schedule of vaccines during this time. The recommendations for the schedule of vaccinations in the first year of life are those of the Advisory Committee on the Immunization Practices an advisory committee to the Centers for Disease Control and Prevention.

The FDA study found that the maximum amount of aluminum an infant could be exposed to over the first year of life would be 4.225 milligrams (mg), based on the recommended schedule of vaccines. Federal Regulations for biological products (including vaccines) limit the amount of aluminum in the recommended individual dose of biological products, including vaccines, to not more than 0.85-1.25 mg. For example, the amount of aluminum in the hepatitis B vaccine given at birth is 0.25 mg.

Aluminum is found naturally in large quantities in the environment, often consumed through drinking water or ingesting certain foods, such as infant formula. Using the updated parameters, the authors found that the body burden of aluminum from vaccines and diet throughout an infant's first year of life is significantly less than the corresponding safe body burden of aluminum, based on the minimal risk levels established by the Agency for Toxic Substances and Disease Registry.

Furthermore, many infants might not receive the entire series of recommended vaccines or the particular combination of vaccines that delivers the maximum amount of aluminum. Therefore, it is likely that some infants will have even lower aluminum levels than calculated in this study and will be at even lower risk for exposure to aluminum through vaccination.

Keith. LS, Jones DE, Chou CH. Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine* 2002;20(Sppl. 3):513-7.

## Title

"Updated aluminum pharmacokinetics following infant exposures through diet and vaccination."

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- [Innovation and Regulatory Science \(/web/20170515040317/https://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm\)](https://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm)

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