

CDC ROLLOUT PLAN –Vaccine-Associated Aluminum and Risk of Asthma

OVERVIEW INFORMATION

- **Planned Release date:** Sept 23, pre-print publication
- **Publication title:** *Association Between Aluminum Exposure from Vaccines Before Age 24 Months and Persistent Asthma at Age 24-59 Months (Academic Pediatrics); Aluminum adjuvants in childhood vaccines and asthma risk: What do we see? (Commentary, Academic Pediatrics)*

BOTTOM LINE UP FRONT (BLUF)

A new observational study suggests a possible association between exposure to aluminum in some childhood vaccines and development of persistent asthma in children. CDC agrees with the authors that this single observational study does not show that aluminum in some childhood vaccines can cause development of persistent asthma. This CDC-funded study has important limitations that the authors acknowledge, and CDC is not changing the current [routine childhood vaccination recommendations](#) based on this single study. Further investigation is needed to explore the risk of aluminum exposure from routine childhood vaccines on the development of persistent asthma in children; efforts are already underway.

We recognize these results may sound concerning to some parents, but there continues to be overwhelming evidence of the benefits of vaccines. Small amounts of aluminum are added to some vaccines to help the body build stronger immunity. Aluminum adjuvants have been safely used for decades and are included in many routine childhood vaccines but are not used in COVID-19 or influenza vaccines. CDC, FDA, and our partners continue to monitor the safety of all vaccines and are discussing opportunities to collaborate with other researchers and attempt to confirm these findings. CDC will continue to share information in a timely and transparent manner as it becomes available.

CDC KEY MESSAGES

Study Background

- This observational study, published in *Academic Pediatrics*, analyzed information in health records from a group of 326,991 children born between January 1, 2008 and December 31, 2014 who received care at 7 [Vaccine Safety Datalink](#) (VSD) sites. Researchers found a positive association between the total amount of aluminum children received from vaccines given before age 2 years and the development of persistent asthma between ages 2 to 5 years.
- For this analysis, researchers looked at differences between children with and without eczema, because eczema is strongly associated with asthma risk. Therefore, a child with eczema is more likely to develop asthma in general.
 - Among children with and without eczema, 6.0% and 2.1%, respectively, developed persistent asthma.
 - For both children with and without eczema, the average amount of aluminum received from vaccines was about 4 mg.
 - Among children without eczema, each additional 1 mg of aluminum received from vaccines was associated with a 1.2 times higher rate of persistent asthma.
 - The authors found similar results among children with eczema. Among children with eczema, each additional 1 mg of aluminum received from vaccines was associated with a 1.3 times higher rate of persistent asthma.
 - A secondary analysis limited to fully vaccinated children found that the possible association was no longer significant in children with eczema diagnosed through 11 months of age but was significant in children without eczema. This secondary analysis

was done because children who are not fully vaccinated may differ from those who are fully vaccinated in a variety of ways which may be difficult to measure. These differences can make the results harder to interpret.

- Small amounts of aluminum are added to some vaccines to help the body build stronger immunity. Aluminum-containing adjuvants are vaccine ingredients that have been safely used in vaccines since the 1930s.
 - Aluminum adjuvants are included in many routine childhood vaccines, including diphtheria, tetanus, and acellular pertussis; hepatitis B; some formulations of *Haemophilus influenzae* type b [Hib]; and pneumococcal vaccines. Aluminum adjuvants are not used in current COVID-19 vaccines.
 - In this study, administration of all forms of aluminum adjuvants were combined into a single measure of exposure; however, it is possible that different chemical forms of aluminum have different biologic effects.
- Being exposed to things in the environment, like mold or dampness, some allergens, such as dust mites, and secondhand tobacco smoke have been linked to developing asthma. Air pollution and viral lung infection may also lead to asthma. Some of these exposures were not measured in this study.
 - Asthma can be hard to diagnose, especially in children under 5 years of age.
 - A person is more likely to have asthma if someone in their immediate family has asthma.
 - There may be other unrecognized factors that might influence the development of asthma that were not be measured in this study.
- The Institute of Medicine (IOM), now known as the National Academy of Medicine, released a report in 2013 calling for the use of data from existing surveillance systems, such as the Vaccine Safety Datalink, for ongoing research into the safety of the childhood vaccine schedule.
 - CDC's Immunization Safety Office commissioned VSD investigators to develop a [White Paper](#) to assess how the VSD could be used to study the safety of the childhood immunization schedule, published in 2016.
 - Since then, the Vaccine Safety Datalink has published the results of several studies examining the association between the immunization schedule and specific health outcomes, including this current study, with additional studies ongoing or planned.
 - This research was funded by CDC as part of the Vaccine Safety Datalink project. Co-authors from CDC were involved in the design and conduct of the study, interpretation of data, and review and approval of the manuscript.

CDC Talking Points

- Vaccines protect children from getting seriously ill and suffering pain, disability, and even death from diseases like measles and whooping cough.
 - CDC agrees with the authors that this single observational study does not show that aluminum in some childhood vaccines can cause development of persistent asthma.
 - Multiple prior studies have found no association between childhood vaccines and development of asthma.
 - This study is an observational study, which is different from the gold standard of medical evidence, a randomized controlled trial. Establishing cause and effect from observational studies generally requires findings from multiple studies to ensure that the findings are repeatedly found (reproducible) and consistent across all studies.
 - The authors suggest further studies in other large vaccine safety monitoring databases, additional VSD studies to look at allergic diseases other than asthma, and studies to

examine immunologic response after vaccination could provide more data about the possible association found in this study. These additional studies will take time to complete.

- We agree that investigation is warranted.
- CDC is not changing the current [routine childhood vaccination recommendations](#).
- CDC continues to recommend parents and caregivers follow the recommended [immunization schedule](#) to ensure their children get the vaccines they need to protect against serious and sometimes deadly diseases.
 - To help children return safely to school and early care and education programs this fall, it is critical to ensure they are up-to-date on their routine vaccines and have received [recommended COVID-19 vaccines](#).
- CDC, FDA, and NIH are discussing additional studies that can help investigate the potential risk of aluminum exposure from routine childhood vaccines.
- CDC will also be supporting a literature review to identify any other vaccine safety studies that may be relevant to this analysis.
- Given the findings identified in this single study, CDC is also looking for additional data sources that can be analyzed to further evaluate this potential signal. This effort is ongoing, but CDC hopes to have additional information on this to share in the coming months.
- This work demonstrates that CDC takes vaccine safety seriously, that we are responsive to suggestions and feedback from scientific bodies, that we conduct high quality scientific studies, and that we are transparent in communicating vaccine safety findings to the public.

CDC REACTIVE MEDIA STATEMENT

CDC is aware of a new study suggesting a possible association between the total amount of aluminum children received from vaccines given before age 2 years and the development of persistent asthma between ages 2 to 5 years. Previous studies have found no association between childhood vaccines and development of asthma. CDC agrees with the authors that this single observational study has important limitations and does not show that aluminum in some childhood vaccines can cause development of persistent asthma. Additionally, there may be other unrecognized factors that might influence the development of asthma that were not be measured in this study. Small amounts of aluminum are added to some vaccines to help the body build stronger immunity, and have been included in many vaccines for decades, but are not used in COVID-19 or influenza vaccines.

As a result, CDC is not changing the current [routine childhood vaccination recommendations](#), and continues to recommend parents and caregivers follow the recommended [immunization schedule](#) to ensure their children get the vaccines they need to protect against serious and sometimes deadly diseases. CDC continues to strongly recommend that children stay up-to-date on routine vaccines to help children return safely to school and early care and education programs this fall.

CDC funded this study and is sharing this information because we are committed to communicating scientific findings about vaccine safety in a timely and transparent manner. In addition, CDC, FDA, and NIH are discussing additional studies that can help investigate the risk of aluminum exposure from routine childhood vaccines. CDC will continue to monitor the post-licensure safety of all vaccines, explore opportunities for additional high-quality research, and identify possible signals of health problems related to vaccines and the overall immunization schedule.

TOUGH Q&A

- **What is important for parents to know?**
 - A new study suggests a possible association between exposure to aluminum in some childhood vaccines and development of persistent asthma in children. It is important to recognize that this is a single observational study, not an experiment and that other studies have not indicated an association. It is not possible to determine cause and effect based on a single observational study, which could be impacted by other unrecognized factors that might influence the development of asthma in children. Additional analyses and studies that attempt to replicate the findings are an important next step.
 - We recognize the new study results may be concerning for parents and caregivers; however, there continues to be overwhelming evidence of the benefits of vaccines.
 - CDC is not changing the current routine childhood vaccination recommendations based on this single study. CDC, FDA, and our partners continue to monitor the safety of all vaccines and will explore opportunities to collaborate with other researchers and attempt to confirm these findings. CDC will continue to share information in a timely and transparent manner as it becomes available.
- **Is this finding going to result in any revisions in the vaccine schedule for children?**
 - No, CDC is not changing the current routine childhood vaccination recommendations based on this single observational study. There continues to be overwhelming evidence of the benefits of vaccines. CDC, FDA, and our partners continue to monitor the safety of all vaccines and will explore opportunities to collaborate with other researchers and attempt to confirm these findings. Importantly, other studies have not found an association between aluminum and asthma. CDC will continue to share information in a timely and transparent manner as it becomes available.
- **What are the implications of using aluminum in childhood vaccines?**
 - CDC agrees with the authors that a single study with important limitations does not show that aluminum in some childhood vaccines can cause development of persistent asthma. In these types of observational studies, which are not experiments, there are often unrecognized and unmeasured factors that might influence the development of asthma in children.
 - Aluminum adjuvants are added to vaccines to help the body build stronger immunity and are included in many routine childhood vaccines.
 - CDC funded this study because the agency is committed to thoroughly evaluating the safety of vaccines given to children. CDC is sharing this information because the agency is committed to communicating scientific findings about vaccine safety in a timely and transparent manner. CDC will continue to monitor the safety of all vaccines, explore opportunities for additional high-quality research, and identify possible health problems related to vaccines.
- **Why not encourage providers to use the lowest aluminum content formulations possible?**
 - It is not possible to determine cause and effect based on a single observational study, which could be impacted by other unrecognized factors that might influence the development of asthma in children. Additional analyses and studies that attempt to replicate the findings are an important next step.
- **Has aluminum been studied previously?**

- Yes. Aluminum adjuvants have been used in vaccines for decades and aluminum-adjuvanted vaccines have an excellent safety record. This study looked at aluminum exposure in a different way. This study looked at the cumulative aluminum exposure from vaccines before age 24 months. A secondary analysis explored an alternative exposure definition, maximum single-day vaccine-associated aluminum. This study was part of CDC's long-term goal of studying the vaccine schedule, and not only studying individual vaccines.
- **What is the implication of an observational study and why were stronger research studies not undertaken?**
 - Observational studies observe events occurring naturally in a population. Experimental designs, such as the randomized controlled trial, randomize study subjects to intervention groups or control groups. In its 2013 report calling for research into the safety of the childhood vaccine schedule, the IOM recognized the challenges of conducting a randomized controlled trial of vaccinated versus unvaccinated children, and that the gold standard (a randomized controlled trial) could not be performed because it would be unethical to withhold lifesaving vaccines from children. Children who are unvaccinated by (parental) choice are fundamentally different than vaccinated children and not easily compared; therefore, observational studies of vaccinated versus unvaccinated children are not scientifically appropriate.
 - CDC is discussing additional studies with partners that have appropriate data systems to conduct large observational studies and is working with other HHS partners to further assess this issue.
- **Did this study look at children who had vaccines spaced out vs. several vaccines given at once?**
 - No, the main exposure was cumulative aluminum from vaccines during the first two years of life. Spacing of vaccines was not directly assessed in this study.
- **Are there plans to repeat this observational study comparing children who were not vaccinated to children who received the most common amounts of aluminum from vaccines?**
 - Randomized studies of vaccinated versus unvaccinated children are not scientifically appropriate. In its 2013 report calling for research into the safety of the childhood vaccine schedule, the IOM recognized the challenges of conducting a randomized controlled trial of vaccinated versus unvaccinated children, and that the gold standard (a randomized controlled trial) could not be performed because it would be unethical to withhold lifesaving vaccines from children. Children who are unvaccinated by (parental) choice are fundamentally different than vaccinated children and not easily compared. This study did not exclude children who received no vaccines. Some children in the study did not receive any aluminum from vaccines.
- **What other studies are planned or in progress looking at the safety of the childhood schedule?**
 - CDC is discussing additional studies with partners that have appropriate data systems to conduct large observational studies and is working with other HHS partners to further assess this issue.
- **Do families with children with a family history of asthma need to be concerned?**
 - Family history of asthma was not included in the analysis, so this single study does not have information about the risk of developing asthma among children with a family history of asthma. We don't know all the things that can cause asthma, but we do know that genetic, environmental, and occupational factors have been linked to developing asthma. [A person is more likely to have asthma if someone in their immediate family has asthma.](#)

- **Are people exposed to other sources of aluminum (in food, environment, etc?)**
 - Aluminum is the most abundant metal in the world. As a result, it is present throughout the environment, in air, water, and food (such as cereal, flour, cake mix, processed cheese, baby formula, and breast milk). It is also found in many medical aids and consumer goods, such as antacids, buffered aspirin, first aid antibiotics, sunscreens, skin lotions and hygiene products like washes and deodorant. None of these exposures were measured in this study, and ingested aluminum does not appear to accumulate in the body and is probably not harmful.
 - Aluminum exposure through vaccination is not the same as a toxic exposure to aluminum either directly to the lungs or indirectly via ingestion. Aluminum is included as an ingredient in vaccines to trigger an immune reaction, but it could (theoretically) send the immune system down a pathway that may make someone more susceptible to allergic conditions, like asthma. The tendency to develop an allergic condition can play a big part in developing allergic asthma, which is common in children. But not all asthma is allergic asthma

- **What is CDC doing about this?**
 - CDC, FDA, and NIH are discussing additional studies that can help investigate the potential risk of aluminum exposure from routine childhood vaccines. CDC will also be supporting a literature review to identify any other vaccine safety studies that may be relevant to this analysis. Given that these findings have been identified in this single study, CDC is also looking for additional data sources that can be analyzed to further our understanding. This effort is ongoing, but CDC hopes to have additional information on this to share in the coming months that may be related and relevant to this analysis.
 - CDC is not changing the current routine childhood vaccination recommendations based on this single study. CDC, FDA, and our partners continue to monitor the safety of all vaccines and will explore opportunities to collaborate with other researchers and attempt to confirm these findings. CDC will continue to share information in a timely and transparent manner as it becomes available.

- **Vaccines are licensed by FDA after clinical trial - is FDA going to take any actions based on this study?**
 - This single study does not demonstrate a causal association between exposure to aluminum in some childhood vaccines and the development of persistent asthma. Further investigation is needed to explore the risk of aluminum exposure from routine childhood vaccines on the development of persistent asthma in children; efforts are already underway.
 - FDA is not requesting vaccine manufacturers make any changes to their vaccines as a result of this study.