Aluminum in Vaccines: What Pharmacists Should Know

Key Takeaways

- Aluminum in vaccines is minimal compared to dietary sources and is used to enhance immune response.
- The FDA's aluminum exposure limits apply to parenteral nutrition, not vaccines, ensuring safety for healthy individuals.
- Pharmacists are vital in combating vaccine misinformation and promoting vaccine uptake through patient education.
- Aluminum adjuvants have a long history of safe use, contributing to the effectiveness of vaccines against preventable diseases.

Misinformation is fueling parental fears and a concerning drop in childhood vaccines.

If you have spent time on any social media platform recently, you have likely been exposed to many opinions about vaccines and their perceived safety. Many of these opinions are rooted in the investigation of ingredients commonly found in vaccines.

As one of these ingredients, aluminum is often at the forefront of this emerging controversy. Some people incorrectly claim that the amounts of aluminum and aluminum salts, when used as an adjuvant in some vaccines, exceed the safe limits determined by the FDA and may cause an increase in mental illnesses and other chronic conditions in adolescents. This has contributed to an alarming decrease in vaccine rates among children and adolescents, which is quickly becoming a public health crisis.

The FDA closely monitors vaccines and their ingredients, requiring that vaccines undergo a rigorous and extensive development program to determine their safety and effectiveness.1 The FDA considers all the ingredients in a vaccine, and after approving a vaccine, it continuously monitors it for safety.1 The problem pharmacists face today is that misinformation can spread from misleading or inaccurate social media posts, leading to vaccine hesitancy among patients. This is especially problematic for the parents of infants and young children. Social media is a powerful way to transmit information. However, there is little restriction on what can be posted, who can post it, and how the posted information can be potentially manipulated to fit the desired message. Pharmacists, therefore, must be vigilant about educating their patients and providing accurate, science-based information about vaccine safety to combat this dangerous trend.

CONSIDERATIONS FOR ALUMINUM IN VACCINES

The first factor that is crucial to understand is that each ingredient in a vaccine is included in the formulation for a specific purpose. All ingredients help to make a vaccine as effective as possible while maintaining its safety. Ingredients are also used in the smallest quantities possible to achieve the desired effect. In the case of aluminum, it is used as an adjuvant to enhance the immune response of vaccinated individuals. I Some vaccines that contain an aluminum-based adjuvant include diphtheria, tetanus, and pertussis vaccines, the pneumococcal conjugate

vaccines, the human papillomavirus vaccine, and some hepatitis B vaccines.3-6 However, many vaccines administered to adults, children, and adolescents do not contain aluminum adjuvants or are not adjuvanted.

The next factor to consider is the extent of aluminum exposure that occurs through vaccination vs other, naturally occurring, routes. Aluminum is a common environmental substance, occurring naturally in soil, water, air, breast milk, and food. Unprocessed foods contain the least amount of aluminum, with processed foods containing higher amounts.7 Study data show that an average adult in the US eats about 7 to 9 mg of aluminum daily in their food.7 Other forms of exposure to aluminum are through cosmetics, antiperspirants, and pharmaceuticals such as antacids and buffered aspirin.

For infants, the amount of aluminum ingested during the first weeks of their life comes from 2 main sources: food (ie, breast milk and/or formula) and vaccines.

Vaccines that contain aluminum adjuvants contain no more than 0.85 mg/dose, with many with as little as 0.225 mg/dose.7 Comparatively, the concentration of aluminum in human breast milk ranges from 0.0092 mg/L to 0.049 mg/L, depending on the diet of the mother, with soy-based infant formulas ranging from 0.46 mg/L to 0.93 mg/L and milk-based infant formulas containing between 0.058 mg/L and 0.15 mg/L.7 In other words, the aluminum in a vaccine is about the same as that found in 1 liter (about 32 fl oz) of infant formula. In total, infants who are given all CDC Advisory Committee on Immunization Practices—recommended vaccines receive about 4.4 mg of aluminum in the first 6 months of life from vaccine sources.8 Regardless of how an infant is nourished, they will receive more than that in their diet. Breastfed infants ingest about 7 mg, formula-fed infants ingest about 38 mg, and infants who are fed soy formula ingest almost 117 mg of aluminum during their first 6 months.⁹

It is also important to evaluate the standards for safe aluminum concentrations set by the FDA. Many who believe that aluminum-adjuvanted vaccines are unsafe claim that these vaccines exceed the total aluminum exposure published by the FDA of 5 mcg/kg/day (0.005 mg/kg/day).10 They further claim that an infant weighing 10 lb should not receive more than approximately 0.023 mg of aluminum per dose (less than what is used in aluminum-adjuvanted vaccines). The important determinant here is that the FDA's limit of 5 μ g/kg/day is intended only for those who need parenteral nutrition.¹⁰

The FDA specifies that those who are receiving parenteral nutrition are not representative of the average patient and mostly include those who have severely impaired kidney function or infants born prematurely who do not yet have adequate kidney function.10 This is important because 95% of aluminum is excreted through the kidneys.11 In those with proper kidney function, only 0.5% of aluminum from any source remains in the body after 24 hours, and consequently, healthy infants and children are adequately able to eliminate it.¹⁰

It is also important to consider the route of administration. Gastrointestinal absorption through ingestion and intramuscular administration of vaccines do not deliver the total amount of

aluminum at one time, as seen with intravenous parenteral nutrition. Therefore, the systemic exposure of aluminum is spread over a longer period from food and vaccine sources.

Additionally, the Code of Federal Regulations (CFR) set a specific aluminum limit of 0.85 mg/dose to 1.25 mg/dose that is acceptable in biologics, which includes vaccines.12 Executive departments and agencies of the federal government determine the CFR.13 A dose of an aluminum- adjuvanted vaccine does not exceed this threshold.

PHARMACIST COUNSELING

For pharmacists, being armed with this knowledge is crucial when having conversations with patients, especially parents of infants and young children. These conversations can be frustrating, and using motivational interviewing to identify the vaccine barriers is crucial. Pharmacists must also provide scientific evidence to combat the perceived risk resulting from misinformation. When I was the manager of the immunization program for a large retail chain, the importance of pharmacist intervention could not have been more obvious. Data have consistently shown that pharmacists' counseling and interventions have a significant positive effect on patients' uptake of vaccines.¹⁴

Looking ahead, aluminum will continue to be studied and evaluated for efficacy and safety when used in vaccines. Pharmacists should closely examine any future available data. It is important to continue to elevate and confirm that the ingredients used in vaccines are both effective and safe, and to pivot to newer, more efficacious, or safer technology if it becomes available. Based on currently available data, there is robust information supporting the use of aluminum in vaccines.

Although many factors cause vaccine hesitancy, especially among parents, misinformation is one of the most impactful. Social media is a powerful driver of this message and is alarmingly convincing. The good news is that community pharmacists are well positioned as vaccine advocates to combat this issue through education and persistent efforts to increase vaccine rates in their communities. Adjuvants have been used safely in vaccines for decades, with aluminum adjuvants being the most common.15 The simple truth is that adjuvants help vaccines work better, so patients are better protected against preventable diseases.

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