

Concerns about vaccines: ingredients and side effects

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ABSTRACT

Vaccines are among the most effective public health interventions; however, concerns regarding their components and potential adverse effects continue to contribute to vaccine hesitancy. This narrative review aims to critically evaluate the current scientific evidence regarding vaccine ingredients and their alleged side effects. A narrative literature review was conducted using PubMed and Scopus databases. Studies published in English and Turkish over the past 15 years were prioritized, with emphasis on systematic reviews, meta-analyses, and reports from international health authorities (WHO, CDC, EMA). High-quality evidence indicates that commonly discussed vaccine components such as thimerosal, aluminum adjuvants, and formaldehyde are present in quantities that are not associated with clinically significant harm. No causal relationship has been demonstrated between vaccines and autism spectrum disorder. Some hypotheses, such as autoimmune/inflammatory syndrome induced by adjuvants (ASIA), remain controversial and lack robust clinical validation. The current body of scientific evidence strongly supports the safety of vaccines. Misinterpretation of low-quality studies and misinformation contribute significantly to public concerns. Strengthening evidence-based communication is essential to reduce vaccine hesitancy.

Keywords: Vaccines, immunization, adverse effects

INTRODUCTION

Vaccination represents one of the most successful and cost-effective interventions in modern medicine, significantly reducing morbidity and mortality associated with infectious diseases.^{1,2}

Vaccines undergo a rigorous development and regulatory approval process before being introduced into routine use. Development begins with preclinical studies, including laboratory and animal testing, to evaluate safety, immunogenicity, and appropriate dosage. Following submission of the necessary regulatory documentation, vaccines progress through phase I, II, and III clinical trials, which assess safety, immune response, and efficacy in increasingly larger populations. Because vaccines are administered to healthy individuals, particularly children, regulatory agencies require extensive evidence regarding both efficacy and safety. Following approval, post-marketing surveillance and, when necessary, phase IV studies continue to monitor vaccine safety and effectiveness in real-world settings. These processes ensure that licensed vaccines meet strict standards of quality, safety, and efficacy before and after public use.³

Global immunization programs have prevented millions of deaths annually and contributed to the eradication or control of several life-threatening diseases.

Despite the success of vaccination programs, concerns regarding vaccine safety have increased worldwide.⁴ These concerns are frequently driven by misinformation, misinterpretation of scientific findings, and the dissemination of low-quality evidence.⁵ Vaccine hesitancy has been identified by the World Health Organization (WHO) as one of the top threats to global health.²

Understanding the scientific basis of these concerns is essential for clinicians, policymakers, and public health professionals. This review aims to critically evaluate the evidence on vaccine ingredients and their potential adverse effects, distinguishing scientifically supported findings from unsupported claims.

METHODS

A structured narrative review was conducted. Searches were performed between January 2024 and February 2024.

Search Strategy

A comprehensive search was conducted in PubMed and Scopus databases covering publications from 2008 to 2023. The following keywords and Boolean combinations were used: “vaccine safety,” “vaccine ingredients,” “adjuvant

toxicity,” “thimerosal,” “aluminum vaccines,” “formaldehyde vaccines,” “autism and vaccines.”

Selection Criteria

The inclusion and exclusion criteria of the review were:

Inclusion criteria:

- Systematic reviews and meta-analyses
- Large cohort and case-control studies
- Reports and guidelines from WHO, CDC, EMA
- English and Turkish publications

Exclusion criteria:

- Low-quality studies (small sample size, lack of control group)
- Opinion articles or non-peer-reviewed publications
- Studies without clear methodology

Data Evaluation

Priority was given to high-level evidence (systematic reviews, meta-analyses, large cohort studies). Findings were synthesized narratively, focusing on consistency, biological plausibility, and reproducibility.^{1,2,4,5}

A total of 324 records were identified. After removal of duplicates (n=68), 256 records were screened by title and abstract. Following full-text assessment, 72 publications met the inclusion and exclusion criteria and were included in the review (Figure).

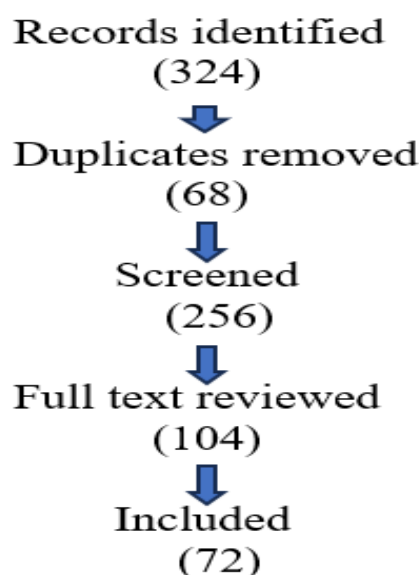


Figure. Literature search and study selection process

RESULTS

Vaccine ingredients and their side effects found as a result of the literature review are stated below:

Mercury (Thimerosal)

Thiomersal contains ethylmercury, which differs significantly from methylmercury in its pharmacokinetics. Ethylmercury is eliminated from the body more rapidly and does not accumulate to toxic levels.⁶ Extensive epidemiological studies and meta-analyses have demonstrated no association between

thimerosal-containing vaccines and neurodevelopmental disorders, including autism.^{7,8} Most currently licensed vaccines don't contain thimerosal. In formulations where it remains present, only trace amounts are used.^{1,4} WHO recommends reducing the use of mercury in all areas and promoting the use of mercury-free alternatives.⁹

Aluminum Adjuvants

Aluminum salts are used to enhance immune responses. Exposure to aluminum from water, food and environmental sources exceeds exposure from vaccines. Pharmacokinetic studies indicate low absorption and efficient renal elimination of vaccine-derived aluminum. Available epidemiological and toxicological evidences have not demonstrated an association with neurological or autoimmune disorders.^{1,4,10-12} Current evidence supports the safety of aluminum-containing vaccines.

Formaldehyde

Formaldehyde is a naturally occurring compound involved in normal metabolic processes. Vaccine concentrations are substantially lower than endogenous levels. The studies have not shown any association between vaccine-related formaldehyde exposure and adverse health outcomes.^{3,13}

Antibiotics, Gelatin and Polysorbate 80

Residual antibiotics used during vaccine production are present in negligible amounts and are not associated with clinically significant allergic reactions.³ Antibiotics known to cause severe hypersensitivity (e.g., penicillin, cephalosporins and sulfa drugs) are not used. Gelatin, used as a stabilizer in some vaccines, has been associated with rare allergic reactions; however, these events are extremely uncommon and manageable in clinical settings.¹⁴ Polysorbate 80 is widely used in pharmaceuticals and has not been shown to cause significant adverse effects at doses used in vaccines.¹⁵

Autoimmune Diseases and ASIA Syndrome

Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA) has been proposed as a possible explanation for vaccine-related autoimmune phenomena. However, epidemiological studies have not demonstrated an increased risk of autoimmune disease following vaccination.^{1,11,16}

Autism

The proposed association between vaccines and autism has been extensively investigated. Meta-analyses and large population-based studies involving more than one million children have consistently reported no increased risk of autism following vaccination or exposure to vaccine components such as thimerosal.^{7,8,17}

Allergic Reactions

Vaccine-associated allergic reactions may include urticaria, angioedema, bronchospasm, gastrointestinal symptoms, and anaphylaxis. Severe allergic reactions are rare, and most events are mild and self-limiting.^{13,18}

Rare Adverse Events and Signal Detection

Although vaccines are generally safe, rare adverse events may occur and are often detected through post-marketing surveillance systems. Examples include Guillain-Barré syndrome following influenza vaccination and rare thrombotic events associated with certain COVID-19

vaccines. These events are extremely rare. Available risk-benefit analyses indicate that the benefits of vaccination substantially outweigh the associated risks.^{1,19,20} The ability to detect such rare events highlights the effectiveness of global pharmacovigilance systems.

DISCUSSION

Strength and Consistency of Evidence

Evidence regarding vaccine safety is derived from large cohort studies, case-control studies, and meta-analyses conducted in diverse populations. A Danish nationwide cohort study involving more than 650,000 children found no association between MMR vaccination and autism, including among high-risk groups. Similarly, large meta-analyses have reported no increased risk of neurodevelopmental disorders following vaccination.^{7,8,17} Pharmacokinetic and toxicological studies further support these findings by demonstrating that exposure to vaccine ingredients such as aluminum remains well below established safety thresholds.^{10,20}

Biological Plausibility and Mechanistic Evidence

Biological plausibility is an important consideration when evaluating vaccine safety concerns. Proposed associations between vaccines and conditions such as autism, neurotoxicity, or autoimmune diseases have not been supported by established biological mechanisms or epidemiological evidence. In particular, concerns regarding thimerosal and aluminum are inconsistent with known pharmacokinetic and toxicological data.^{6,10,20} Regarding autoimmune diseases, while immune activation is a theoretical concern, large epidemiological studies and systematic reviews have not demonstrated increased incidence following vaccination.^{11,21} The ASIA hypothesis, although biologically intriguing, remains unsupported by reproducible clinical evidence and lacks standardized diagnostic criteria.¹⁶

Risk Benefit Balance

A key issue in vaccine hesitancy is the discrepancy between perceived and actual risk. Rare adverse events often receive disproportionate attention in traditional and social media. This may contribute to cognitive biases, including the availability heuristic, which can influence public perceptions of vaccine risk.^{5,20} For example, the risk of anaphylaxis following vaccination is approximately 1 per million doses.¹⁴ Whereas the risks associated with vaccine-preventable diseases—such as measles-related encephalitis or death—are significantly higher.^{1,21} Despite this, public perception often overestimates vaccine risks and underestimates disease risks. This imbalance is further exacerbated by misinformation and anecdotal reports, which are often perceived as more compelling than statistical evidence.^{5,20}

Regulatory Oversight and Pharmacovigilance

Vaccines are subject to some of the most rigorous safety monitoring systems in medicine. Pre-licensure evaluation includes multiple phases of clinical trials assessing safety, immunogenicity, and efficacy.¹ Post-marketing surveillance systems such as:

- VAERS (Vaccine Adverse Event Reporting System)
- EudraVigilance (European Union)
- WHO Global Pharmacovigilance Database

enable continuous monitoring of adverse events in real-world settings.^{1,19}

Importantly, these systems are designed to detect even rare adverse events. For example, the identification of rare thrombotic events associated with certain COVID-19 vaccines demonstrates the sensitivity and effectiveness of pharmacovigilance systems.¹⁹

Misinformation and the Role of Digital Media

The rapid spread of misinformation—particularly through social media—has significantly contributed to vaccine hesitancy.^{5,23} False claims frequently rely on emotional narratives, selective interpretation of data, or discredited studies. One notable example is the Wakefield study, which falsely linked MMR vaccination to autism. The article was subsequently retracted because of serious ethical and methodological concerns.²⁴ Recent evidence suggests that misinformation disseminated through social media remains one of the strongest predictors of vaccine hesitancy, highlighting the importance of evidence-based risk communication strategies.^{25,26} Combating misinformation requires proactive strategies, including digital literacy, fact-checking, and engagement with trusted healthcare professionals.

Clinical and Public Health Implications

Healthcare professionals are central to addressing vaccine hesitancy. Evidence suggests that physician recommendation is one of the strongest predictors of vaccine acceptance.²⁷ Effective communication strategies include acknowledging patient concerns, providing clear evidence-based explanations, using risk comparisons (e.g., disease risk versus vaccine risk), and avoiding dismissive language. From a public health perspective, maintaining high vaccination coverage is essential for achieving herd immunity and preventing outbreaks. Even small declines in vaccination rates can lead to the re-emergence of previously controlled diseases, as observed in recent measles outbreaks in several countries.²² Recent reports from WHO and EMA continue to support the favorable benefit-risk profile of licensed vaccines and emphasize the importance of ongoing pharmacovigilance and transparent risk communication.^{28,29}

Limitations

Although the overall evidence base is strong, certain limitations exist. Rare adverse events may not be detected during pre-licensure trials because of limited sample sizes. In addition, observational studies remain susceptible to residual confounding. Nevertheless, the consistency of findings across different study designs and populations strengthens confidence in the overall conclusions.

CONCLUSION

Vaccines are among the safest and most effective public health interventions. Combating vaccine-related misinformation and providing clear, evidence-based communication to the public are critical for sustaining confidence in vaccination programs and maintaining adequate vaccination coverage.

ETHICAL DECLARATIONS

Peer Review Process

This review was externally peer-reviewed.

Conflict of Interest

The author declare no conflicts of interest.

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Author Contributions

Author is solely responsible for the conception, data collection, analysis, and writing of this manuscript.

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