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The Role of Thiomersal in Vaccine Preservation: Examining the Evidence Against a Link to Autism

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Abstract

Thiomersal functions as an ethylmercury-based preservative that protects multi-dose vaccines from microbial contamination. The late 1990s brought forth worries about ASD potentially being caused by thiomersal which led regulatory agencies to evaluate its safety. The body quickly eliminates ethylmercury compared to methylmercury, decreasing the toxicity risk. The CDC together with WHO and IOM along with extensive epidemiological research and large-scale cohort and case-control analyses have established that ASD does not result from thiomersal vaccines. The continued increase in autism prevalence since thiomersal was eliminated from pediatric vaccines proves that the hypothesis is incorrect. Research into mechanisms and toxicology shows no possible biological route that connects thiomersal exposure to autism spectrum disorder development. The scientific consensus about vaccine safety remains unchanged despite ongoing public worries that lead to vaccine hesitancy. The review demonstrates scientific evidence showing thiomersal safety in vaccines while stressing the need to combat misinformation to sustain public trust in immunization programs.

Keywords: Thiomersal, Autism, Vaccine

Abbreviations and Acronyms

AAP-	Academy of Pediatrics
ASD-	Autism Spectrum Disorder
CDC-	Center for Disease Control
FDA-	Food and Drug Administration
GACVs -	Global Advisory Committee on Vaccine Safety
GAVI -	Global Alliance for Vaccines and Immunization
GPRD -	General Practice Research Database
Hib -	Hemophilus Influenza Type B
IOM -	Institute of Medicine
LMICs -	Low and Middle-Income Countries
MMR -	Measles, Mumps and Rubella
PHS -	Public Health Service
TCVs -	Thiomersal-Containing Vaccines
U.S -	United States
UK -	United Kingdom
VSD -	Vaccine Safety Data-Link
WHO -	World Health Organizations

1. Introduction

Preservatives in vaccines function as critical elements that protect multi-dose vials from microbial contamination. The process of needle insertion into vials multiple times allows bacteria and fungi to enter which may damage both vaccine safety and effectiveness. The preservatives function to preserve sterility while keeping vaccines safe for use throughout their shelf life. Thiomersal (ethylmercury compound) served as a preservative to stop bacterial and fungal development in numerous vaccines. Phenol functions as an antimicrobial agent which was utilized in certain older vaccine formulations. The modern vaccine industry uses 2-phenoxyethanol as a replacement for thiomersal in their products [1]. The World Health Organization (WHO) together with the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) established strict guidelines to guarantee vaccine preservatives do not endanger safety. The use of thiomersal preservatives in multi-dose vaccines became limited after numerous regions expressed safety concerns about its possible neurological side effects [2].

1.1. Introduction to Thiomersal (Ethylmercury Compound) As A Widely Used Preservative

Thiomersal is an organomercury compound that has been used as a preservative in vaccines since the 1930s. It is composed of approximately 49.6% mercury by weight and is metabolized in the body into ethylmercury and thiosalicylate. Unlike methylmercury (a well-documented neurotoxin found in contaminated seafood), ethylmercury has a shorter half-life and is rapidly eliminated from the body, reducing the risk of accumulation and toxicity [3]. Thiomersal was used in Diphtheria-Tetanus-Pertussis (DTP) vaccines, Hepatitis B vaccines, Influenza vaccines, and Other multi-dose vaccines. Although it has been effective in preventing microbial contamination, thiomersal has been phased out or reduced in pediatric vaccines in several countries as a precautionary measure, although it is still used in some adult and multi-dose formulations [4].

1.2. Brief Mention of the Controversy Regarding Thiomersal and Autism

During the late 1990s and early 2000s, the controversy about thiomersal and autism started because people believed mercury in vaccines might cause ASD to increase. The theory emerged from incorrect assumptions that ethylmercury in thiomersal behaves like methylmercury which has proven neurotoxic properties. The 1999 CDC and FDA decision: Health agencies in the U.S. removed thiomersal from most childhood vaccines as a precautionary step rather than because of scientific evidence of harm. The 2001 IOM report that established thiomersal exposure had no reliable scientific evidence to support a link with autism. The Anti-vaccine movement asserts that various groups along with public figures maintained the belief that thiomersal-containing vaccines caused autism even though scientific evidence showed otherwise. Multiple large-scale epidemiological research conducted in the U.S. along with Denmark Sweden and other nations discovered no evidence of autism causation by thiomersal vaccines. The elimination of thiomersal from pediatric vaccines failed to lower autism incidence rates thus disproving the autism-vaccine connection. The scientific consensus does not stop public concern from existing which leads to vaccine hesitancy and misinformation that create difficulties for public health initiatives [5].

1.3. Thiomersal in Vaccines

Chemical Composition and Mechanism of Action as a Preservative

Thiomersal (also spelled thimerosal) is an organomercury compound with the chemical formula $C_9H_9HgO_2S$. It contains 49.6% mercury by weight and is metabolized into ethylmercury and thiosalicylate in the body. Ethylmercury is more readily excreted than methylmercury, which is a known neurotoxin and does not accumulate in tissues to toxic levels [6].

1.4. Mechanism of Action

Thiomersal functions as a bacteriostatic and fungistatic agent that stops microbial growth in multi-dose vials. The mechanism of action includes: The compound disrupts bacterial and fungal cell membranes which results in cell death and also interferes with enzymatic and metabolic processes in microbial cells to prevent bacterial and fungal growth in vaccines. The antimicrobial properties of thiomersal made it suitable for use in vaccines and biological products including ophthalmic solutions and immune globulins [7].

1.5. Historical Use in Multi-Dose Vaccines

Since the 1930s thiomersal has functioned as a preservative in vaccines to stop contamination within multi-dose vials. The use of multi-dose vaccines which enable several draws from one vial proves more budget-friendly and practical for scarce resource areas. The practice of multiple needle insertions into vials raises bacterial and fungal contamination risks thus preservatives such as thiomersal serve an essential purpose. The vaccine products that used thiomersal as an ingredient included DTP vaccines, Hepatitis B vaccines, Haemophilus influenza type B (Hib) vaccines, Influenza vaccines (some versions), and Meningococcal vaccines. The late 1990s saw numerous high-income nations including the United States and European countries take steps to eliminate thiomersal from pediatric vaccines because of public worries about mercury and autism despite ongoing WHO support for thiomersal in multi-dose vaccines throughout developing nations [8].

1.6. Regulatory Guidelines and Safety Assessments by WHO, CDC and FDA

The safety of thiomersal in vaccines has been evaluated by several health organizations including WHO which has not found any evidence of toxicity from thiomersal in vaccines. A 2006 WHO report established that thiomersal-containing vaccines are safe and do not cause neurodevelopmental disorders including autism. Thiomersal-containing multi-dose vaccines are still recommended by WHO for use in low- and middle-income countries because they are cheap and easy to distribute. The CDC has also supported studies that

have shown that there is no link between thiomersal and autism. In 1999, the CDC and American Academy of Pediatrics advised the phasing out of thiomersal in pediatric vaccines as a precaution, but there was no evidence of harm. The CDC still uses thiomersal-containing vaccines where necessary, especially in adult influenza vaccines. The FDA 1999 performed a risk assessment and found no evidence of harm from thiomersal exposure in infants. Most routine childhood vaccines in the U.S. were reformulated to eliminate or reduce thiomersal by 2001. However, multi-dose influenza vaccines and some tetanus vaccines still contain thiomersal. A 2004 IOM report found that there is no evidence that thiomersal causes autism. It recommended that no more research be done on this hypothesis since the available evidence went against the claim [9,10].

1.7. Scientific Evidence on Thiomersal and Autism

Extensive scientific research has found no credible evidence linking thiomersal exposure from vaccines to autism despite ongoing concerns among certain groups. Multiple epidemiological studies together with large-scale cohort and case-control investigations as well as international comparisons and meta-analyses have shown that thiomersal-containing vaccines do not cause ASD [11].

1.8. Overview of Key Epidemiological Studies (CDC, WHO, IOM Reports)

The Centers for CDC, WHO, and IOM (now part of the National Academy of Medicine) have conducted extensive reviews of the available data on thiomersal and autism. Their conclusions are based on rigorous epidemiological research. The CDC has looked at thiomersal-containing vaccines and autism risk many times. Thompson et al. conducted a CDC-funded study in 2004 that used data from the Vaccine Safety Datalink (VSD) and found no increased risk of autism or other neurodevelopmental disorders in children exposed to thiomersal. A 2010 CDC review concluded that vaccines, including those containing thiomersal, do not cause autism. WHO's Global Advisory Committee on Vaccine Safety (GACVS) reviewed all available evidence in 2006 and concluded that: Thiomersal-containing vaccines are safe. There is no increased risk of neurodevelopmental disorders, including autism. The benefits of thiomersal-containing vaccines far outweigh the theoretical risks. A 2001 IOM report analyzed epidemiological data and concluded that available studies do not support a causal relationship between thiomersal and autism. In 2004, an updated IOM report strongly reaffirmed this conclusion, stating that there was no justification for further research into the thiomersal-autism hypothesis [13,14].

1.9. Findings from Large-Scale Cohort and Case-Control Studies

Multiple cohort and case-control studies with proper design investigated the connection between thiomersal exposure and autism. The research has shown no association between thiomersal exposure and autism in multiple studies. The Danish Cohort Study (Hviid et al., 2003) investigated more than 467,000 children who were born from 1990 to 1996. The Danish government eliminated thiomersal from childhood vaccines in 1992. The research revealed no reduction in autism cases following thiomersal's removal from vaccines. The increase in autism diagnoses persisted which indicated that thiomersal was not the cause while other elements such as diagnostic criteria changes and rising awareness played a role in the growing ASD numbers [14]. United Kingdom Case-Control Study (Andrews et al., 2004), the data was obtained from the General Practice Research Database (GPRD) in the UK. The children were divided into different groups based on the amount of thiomersal they were exposed to. There was no association between thiomersal exposure and autism. The risk of ASD or other neurodevelopmental disorders was not increased with higher thiomersal exposure [15]. CDC Case-Control Study (Price et al., 2010), conducted a retrospective case-control study of children born between 1994 and 1999 in the United States. The study analyzed thiomersal exposure in 256 children with ASD and 752 neurotypical children. The research found no link between thiomersal exposure and autism risk. The results showed that children who received higher thiomersal exposure had reduced ASD risk but this finding most likely stemmed from random chance [16].

1.10. Comparisons of Autism Prevalence in Countries That Have Removed Thiomersal from Vaccines

The strongest evidence against a thiomersal-autism link emerges from observing autism prevalence changes in nations that discontinued thiomersal from vaccines. The removal of thiomersal from vaccines should result in decreased autism rates if it causes autism. However, this has not been the case. Denmark (Removal in 1992). The removal of thiomersal occurred from childhood vaccines in 1992. Autism rates continued to rise after thiomersal was removed [17]. Sweden (Removal in 1993). No decrease in autism cases after thiomersal removal. Autism diagnoses increased, suggesting changes in diagnostic practices rather than vaccine-related causes [18]. United States (Phase-out by 2001). Routine childhood vaccines in the U.S. no longer contained thiomersal by 2001. Autism rates continued to climb, due to improved awareness, diagnostic criteria, and genetic factors. The CDC reports that autism prevalence has not decreased since thiomersal was removed from vaccines. These findings provide strong evidence that thiomersal does not contribute to autism, as autism rates have remained stable or increased in regions where thiomersal was phased out [19].

1.11. Insights from Meta-Analysis and Systematic Reviews

Multiple research projects have been analyzed through meta-analyses to establish more definitive findings. Taylor et al. (2014) – Systematic Review of 10 Studies. The research examined ten significant studies about vaccines and autism together with thiomersal-related investigations. Research results showed that thiomersal does not cause autism. The authors concluded that "the hypothesized link between vaccine components and autism is not supported by epidemiological evidence" [20]. The research by Demicheli et al. (2012) presented a Cochrane Review about vaccines and ASD. The researchers analyzed data from millions of children across multiple studies. The study revealed no

reliable evidence to support a link between thiomersal and autism. The review established that vaccine preservatives including thiomersal have undergone extensive testing and do not cause any harm [21]. IOM Meta-Analysis (2011). Multiple cohort and case-control studies were reviewed. No link between thiomersal and autism was found. The report concluded that thiomersal should not be a public health concern [22].

1.12. Mechanistic and Toxicological Considerations

Research conducted on thiomersal (ethylmercury) toxicology and pharmacokinetics demonstrates that autism has no proven connection to this substance. The mercury exposure worries derive from the documented neurotoxic effects of methylmercury which differs from thiomersal. The pharmacokinetic profile of ethylmercury from thiomersal shows fast elimination and lower neurotoxic effects. The scientific community has not established any biologically sound process by which thiomersal could lead to ASD [23].

1.13. Difference Between Ethylmercury (Thiomersal) and Methylmercury (Neurotoxic Concerns)

The main misunderstanding about thiomersal and autism stems from the incorrect comparison between ethylmercury and methylmercury. Methylmercury (CH_3Hg^+) – Known Neurotoxin, highly lipophilic, leading to bioaccumulation in the body, especially in the brain and nervous system. Has a long half-life (~50 days in humans), causing prolonged exposure and potential neurotoxicity. The main sources of this substance are polluted fish products and industrial emissions. Research shows that exposure to this substance caused neurological damage in fetuses and young children during the Minamata disease outbreak in Japan (1950s). Ethylmercury ($CH_3CH_2Hg^+$) – Thiomersal Breakdown Product. The half-life of this compound in infants is approximately 7 days and it leaves the body at a fast rate. The compound does not accumulate in the brain or other body tissues. The main route of excretion is through the feces which minimizes the potential harm to the body systems. Research shows that the doses of thiomersal used in vaccines do not cause any neurotoxic effects. Methylmercury is highly toxic, while ethylmercury is rapidly eliminated and less toxic. The research on the neurotoxicity of methylmercury cannot be used to make conclusions about thiomersal. The recommendations regarding mercury exposure (e.g., fish consumption advisories) are not relevant to thiomersal. The comparison between Ethylmercury and methylmercury is scientifically incorrect and misinterprets the toxicological data [24].

1.14. Pharmacokinetics and Elimination of Ethylmercury in Infants

Multiple research studies have investigated the metabolic processes and excretion methods of ethylmercury in vaccine recipients. Pichichero et al. (2002) – Ethylmercury Elimination in Infants. The researchers measured mercury blood levels in newborns and infants who received thiomersal-containing vaccines. The elimination rate of ethylmercury from the body showed a half-life of approximately seven days. The mercury concentrations stayed well below the toxic threshold levels. The majority of mercury exited the body through stool samples thus preventing significant systemic accumulation [25]. Burbacher et al. (2005) – Ethylmercury vs. Methylmercury in Primates. The authors compared brain mercury concentrations in primates that received thiomersal-containing vaccines versus methylmercury. Ethylmercury cleared much faster than methylmercury. Lower mercury accumulation in the brain with thiomersal exposure. Further supported the conclusion that thiomersal does not have the neurotoxic effects seen with methylmercury. These pharmacokinetic properties further weaken any proposed link between thiomersal and autism [26].

1.15. Lack of Plausible Biological Mechanisms Linking Thiomersal to Autism

The scientific evidence shows that thiomersal lacks any plausible biological mechanism to cause autism. Experimental research has demonstrated that vaccine doses of thiomersal do not produce neurotoxic effects. Research has demonstrated that neurodevelopmental damage does not occur even when exposure levels exceed normal vaccine doses. The pathways that lead to neurodevelopmental changes remain unaffected by this substance. Autism develops mainly from genetic factors and multiple environmental influences rather than mercury exposure. Research has failed to demonstrate that thiomersal affects synaptic development neuronal migration and neurotransmitter function which plays essential roles in autism development [27]. Animal model research has not yielded consistent results. High-dose ethylmercury exposure experiments in animals have not resulted in autistic-like behavioral outcomes. Genetic models of autism demonstrate key characteristics that support the genetic basis of ASD. Research has not established any connection between vaccine components and autism-related immune or inflammatory pathways. Research initially proposed that vaccines containing thiomersal might cause immune dysfunction leading to ASD. Research has proven the theory wrong by showing that thiomersal-containing vaccines do not trigger abnormal immune responses [28].

1.16. Policy Response and Public Perception

The controversy about thiomersal-containing vaccines (TCVs) and autism has affected vaccine policies, public trust, and global health recommendations. Although the scientific evidence is overwhelming that thiomersal does not cause autism, policy decisions in the late 1990s and early 2000s resulted in the removal or reduction of thiomersal from pediatric vaccines as a precautionary measure. However, thiomersal is still used in some vaccines, especially multi-dose vials, because it is an essential preservative. The public perception of thiomersal is still influenced by vaccine hesitancy, misinformation, and conspiracy theories, which makes it important to have effective science communication to address public fears and regain confidence in immunization programs [29].

1.17. Removal or Reduction of Thiomersal in Pediatric Vaccines

In July 1999, the U.S. Public Health Service (PHS) and the American Academy of Pediatrics (AAP) suggested that

thiomersal should be eliminated or its amount should be reduced in routine childhood vaccines. This decision was made based on the precautionary principle, in order not to increase the total amount of mercury exposure to infants, rather than based on direct evidence of harm. Manufacturers eliminated thiomersal from pediatric vaccines by 2001, except for some influenza vaccines. Global Perspectives on Thiomersal Removal. The WHO carried out several safety assessments and found no adverse effects associated with thiomersal exposure. Nevertheless, several high-income countries also removed thiomersal from vaccines, mainly because of public pressure rather than scientific evidence. However, many low- and middle-income countries (LMICs) still use thiomersal-containing multi-dose vaccines because they are cheaper and more convenient. Impact of Thiomersal Reduction on Autism Rates. If thiomersal was a cause of autism, then removing it from vaccines should have resulted in a decrease in autism prevalence. However, autism rates continued to increase globally, even after thiomersal was removed, which further undermines the supposed connection. Countries such as Denmark, Sweden, and Canada, which got rid of thiomersal in the early 1990s, did not experience any decrease in autism rates. The decision to remove thiomersal was precautionary, not evidence-based. Autism prevalence did not decrease after thiomersal removal, which goes against the hypothesis of a causal link [30,31].

1.18. Continued Use in Certain Influenza and Multi-Dose Vaccines

Thiomersal remains in use for pediatric vaccines but most products no longer contain it except for: Multi-dose vials of Vaccines: The use of thiomersal remains crucial in multi-dose vaccine vials especially in low-resource areas because contamination risks remain high. The WHO backs the ongoing utilization of thiomersal in multi-dose vaccines because it stops bacterial and fungal contamination. DTP vaccines along with meningococcal and certain hepatitis B vaccines utilize thiomersal as an ingredient. Influenza Vaccines: Multiple-dose vial formulations of influenza vaccines continue to contain thiomersal as an ingredient. The thiomersal-free single-dose flu vaccines exist in the market but they come at a higher cost. The Global Alliance for Vaccines and Immunization (GAVI) and WHO have consistently stated that thiomersal-containing vaccines are both safe and essential for worldwide vaccination initiatives. The global distribution of vaccines depends on thiomersal which maintains its importance, especially in multi-dose vials. The WHO together with the CDC and FDA maintain their support for thiomersal's safety and essential nature [32].

1.19. Public Concerns, Vaccine Hesitancy and Misinformation

The scientific evidence showing no autism connection to thiomersal has failed to stop public worries because of incorrect information combined with media coverage and anti-vaccine activism. The thiomersal-autism scare started spreading during the late 1990s when autism diagnoses began rising. The scientific evidence showing no link between thiomersal and autism did not stop media outlets and activist groups from continuing to spread their concerns. The anti-vaccine movement relies on debunked research starting with the 1998 Wakefield study which presented false evidence that the Measles, Mumps, and Rubella (MMR) vaccine causes autism. Social media platforms have intensified vaccine skepticism by allowing false information about vaccine ingredients including thiomersal to spread. The fear of thiomersal along with vaccines has resulted in decreased vaccination rates among certain population groups. The reluctance to get vaccinated has caused preventable diseases like measles pertussis and diphtheria to reappear. The scientific evidence showing no harm from thiomersal has not managed to eliminate public fears about this substance. Social media continues to spread false information which maintains vaccine reluctance among the public [33].

1.20. Communication Strategies to Address Public Fears

The fight against false information about vaccines requires proper communication approaches to establish trust from the public. Public health agencies need to provide transparent explanations about their vaccine policy decisions. The safety of thiomersal requires scientific data to properly address public concerns about it. Medical experts should demonstrate the scientific consensus about thiomersal safety by referencing the agreement between WHO, CDC, FDA, and leading researchers. Real-world evidence showing autism rates did not decrease after thiomersal removal serves to build the argument. The fight against vaccine misinformation requires community leaders' healthcare providers and educators to share accurate vaccine information. The collaboration between social media platforms and public health agencies should focus on identifying and fixing false information. The scientific approach must be balanced with emotional and ethical considerations because people tend to respond to their feelings rather than logical reasoning. The use of patient testimonials and trusted voices from pediatricians and community leaders should accompany testimonials to reassure hesitant parents [34].

2. Conclusion

Thiomersal functions as an effective preservative in vaccines for many decades despite extensive scientific research which has proven that it does not cause autism. Multiple studies and global health organizations including the CDC, WHO, and IOM have not found any credible evidence that links thiomersal to autism despite initial public concerns. The medical community continues to support the safe use of thiomersal in specific vaccines since multi-dose formulations do not cause any adverse effects on neurodevelopment. The ongoing controversy about thiomersal demonstrates why we need to combat vaccine hesitancy by using scientific evidence and clear information in our policy-making process.

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Consent for publication

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I (the author) took responsibility, for every aspect of this review article. From coming up with the topic and researching extensively to writing the manuscript with care and attention to detail. I also made sure to revise the content for integrity before approving the final version of the manuscript and taking accountability for all the work done.

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