The Thimerosal Controversy

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Background

In the early 1920s, a major public health concern was vaccine contamination with bacteria and other germs, which could result in the death of children receiving the vaccines from tainted vials. In the book "The Hazards of Immunization", Sir Graham S. Wilson depicts an occurrence of contamination that happened in Australia in 1928 in which twelve out of twenty-one children died after receiving the vaccine for diphtheria due to multiple staphylococcal abscesses and toxemia (FDA). This incident spurred the development of preservatives for multi-dose vials of vaccine. In 1928, Eli Lilly was the first pharmaceutical company to introduce thimerosal, an organomercury compound that is approximately 50% mercury by weight, as a preservative that would thwart microbial growth (FDA). After its introduction as a germocide, thimerosal was often challenged for its efficacy rather than its safety. The American Medical Association (AMA) published an article that questioned the effectiveness of the organomercury compounds over the inorganic mercury ones (Baker, 245). In 1938 manufacturers were required to submit safety-testing information to the Food and Drug Administration (FDA). Although preservatives had already been incorporated into many vaccines, it was not until 1968 that preservatives were required for multi-dose vials in the United States Code of Federal Regulations (FDA). In 1970s the American population, increasingly concerned about environmental contamination with heavy metals, began to have reservations about the safety of organomercury and the controversy regarding thimerosal ensued after.

The Controversy

In 1990s, the use of thimerosal as a preservative became controversial and was targeted as a possible cause of autism because of its mercury content. There are different types of mercury that an individual can be exposed to. One form of mercury that commonly accumulates in fish is methyl mercury; it differs from the form that is present in thimerosal, ethylmercury. Due to structural differences, the toxicity of methylmercury and ethylmercury also differ—the former being more toxic than the latter.

In the 1970s, environmental agencies identified that mercury has neurotoxic effects in children, in particular the mercury content found in fish. Historical events led to the association between mercury toxicity, neurodevelopment, and autism. The Minimata Bay disaster in Japan, for example, was the result of large amounts of chemicals, including methylmercury, being dumped into the bay in the early 1950s (Baker, 246). The toxic levels of mercury led to severe neurological impairments among Japanese children who lived nearby (Baker, 246). The impairments seen in methylmercury toxicity are similar to those seen in autistic children, such as difficulty in learning, a tendency toward repetitive behaviors, and intestinal problems.

Given the historical concerns towards mercury, the controversy surrounding thimerosal escalated when the use of thimerosal in vaccines became more widely known to parents in the late 1990s. Around the same time, the Wakefield study linking autism to the Measles-Mumps-Rubella (MMR)

vaccine was published in The Lancet, which consequently heightened the controversy, even though thimerosal was never used in the MMR vaccine. Due to the public outcry on behalf of thimerosal being present in vaccines, the ethylmercury preservative was hastily removed from all single dose vials, as per order of the FDA. This action taken by government agencies further led to the confusion regarding the safety level of thimerosal. While government agencies asserted that thimerosal was completely safe in the amounts found in vaccines, the descision to remove the preservative sent mixed messages as to whether the vaccine actually was safe.

The Vaccine Skeptics

SafeMinds is one of the organizations that impugns the safety of thimerosal and includes in the mission statement that one of the goals is to "eradicate" autism and other diseases brought on by mercury accumulation and toxicity. The SafeMinds organization is able to connect autism and thimerosal by pointing to research studies done on the safety of thimerosal and on the correlation between vaccines and autism diagnosis.

There are some contradictions and difficulties with the assertions of SafeMinds website asserts that vaccines are a causal factor in 68% of boys with autism; however, the study was funded and carried out by another vaccine-skeptical group, Generation Rescue. Immediately after stating that conclusion, the website acknowledges that autism occurred in boys who did not receive vaccines. Another point of vaccine skeptism is evident when the SafeMinds group compares the timelines of the number of autism diagnosis with the addition of new childhood vaccines. Lastly, the SafeMinds organization cites a study done on animals as support for the toxicity of thimerosal. It is important to note that the website articles and links also fail to distinguish between ethyl mercury and methyl mercury and could allow for confusion among the general public about the safety of vaccines.

Generation Rescue, an organization founded by Jenny McCarthy, is an example of an autism activist group that focuses on providing support to those affected by autism and to isolating a cause of the disease. Generation Rescue identifies thimerosal as a cause of autism by providing site visitors with a document by Dr. Amy Yasko titled "Autism: A Twisted Tale of Virus and Thimerosal." This article is written in scientific language and may be difficult for a lay reader to fully comprehend. Dr. Yasko explains that thimerosal does not completely degrade to ethyl mercury and the remaining thimerosal gets incorporated into DNA and RNA. Besides being hard to eliminate from the body, the thimerosal-containing nucleotides, Dr. Yasko contends, can then affect other cellular enzymes and the consequences are higher levels of metabolites that are present in autistic children (Yasko). Generation Rescue provides alternative vaccine schedules and pediatricians willing to follow these schedules.

Government Responses: Removing Thimerosal as a Precaution

Government agencies such as the Center for Disease Control (CDC), the Food and Drug Administration (FDA), and the Institute of Medicine (IOM) continue to support vaccinations and argue on behalf of their safety. The FDA and CDC both provide web pages that specifically deals with thimerosal use in vaccines and their possible connection to autism. These pages address questions regarding the nature of the preservative, why and in what concentrations thimerosal is used, and the side effects and safety of thimerosal inorder to alleviate any concerns about thimerosal and autism. Both websites acknowledge that there is a public concern between autism and thimerosal by providing research that looks at the incidence of autism and its relation to vaccinations. The FDA website also provides a table of childhood vaccines and what preservatives are used in each vaccine.

Additionally, the FDA Modernization Act of 1997 allowed for a complete review of thimerosal and it was found that some infants could have been exposed to cumulative levels of thimerosal during the first six months that are higher than recommended (FDA). *Pediatrics* published an article on infants receiving the hepatitis B vaccine shortly after birth and found that the mercury concentration for those infants was markedly increased. In 1999, thimerosal was hastily removed from or reduced in most single-dose vaccines (CDC). By 2001, thimerosal had been removed from all vaccines with the exception of the flu vaccine for which multi-dose vials are a necessity (CDC). In 2003 the last single-dose vial of vaccine containing thimerosal expired (CDC).

In 2004, the IOM published an article, titled "Immunization Safety Review: Vaccines and Autism," which reviewed the safety of using thimerosal as a preservative. After examining many studies done on thimerosal, the IOM concluded that there was no causal relationship between autism and thimerosal in vaccines. Additionally, the article found that most of the mechanisms claimed to link thimerosal exposure with autism are theoretical. The CDC recently conducted a study in 2010 on thimerosal exposure to children and pregnant women and did not find any correlation between thimerosal and autism diagnosis. Thimerosal is still present in vaccines today, but only in multi-dose vials and seasonal flu vaccines. Multi-dose vials are inexpensive and easily stored and can have major implications in eradicating diseases that are still public health issues in developing countries.

Conclusion

Historically, there has always been a degree of concern related to vaccination. While public health policy in the early 1900s was more concerned with the contamination of vaccine vials with microbes, such as tetanus, that could cause serious illness and potentially death, current vaccination concerns are centered on the apprehension of chemicals 'contaminating' vaccines. The modern day vaccination controversy regarding chemical contamination began as a result of environmental concerns regarding industrial by-products and heavy metals and intersected with the history of autism prevalence. It is important to understand the historical shift of contamination sources in understanding how the controversy regarding thimerosal came into contention.

Resources

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