2021-08-09

Responding to Parents' Questions Regarding Polysorbate 80, Aluminum, and Thimerosal in Vaccines

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A scholarly paper submitted to the faculty of
Brigham Young University
in partial fulfillment of the requirements for the degree of

Master of Science

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ABSTRACT

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Vaccines save millions of lives worldwide every year. Nevertheless, misinformation regarding vaccine ingredients circulates on various media platforms and may negatively influence parental decisions regarding childhood vaccinations. Three vaccine ingredients commonly associated with parental vaccine concerns include polysorbate 80, aluminum, and thimerosal. Common misconceptions about polysorbate 80 and neurological sequela exist within the vaccine hesitant community. Additionally, aluminum has been incorrectly connected to chronic disease in children. Though proven that thimerosal does not cause autism, vaccine critics have now inaccurately reformed the argument claiming that it is the combination of thimerosal and aluminum that causes autism. The purpose of this literature review is to provide a response to these common queries by discussing the safety of polysorbate 80, aluminum, and thimerosal in vaccines. By demonstrating that vaccine ingredients pose no threat to health, nurse practitioners can provide accurate information to parents who can then make a well-informed decision regarding childhood vaccinations.

Keywords: polysorbate 80, aluminum, thimerosal, vaccine hesitancy, vaccine refusal, additives

ACKNOWLEDGEMENTS

I am so grateful for the many people who have helped me in my journey of becoming a Nurse Practitioner. First and foremost, to the man I call MR. Mom, the calm to my storm, my rock, my better half, my eternal companion; Dewayne Hugh, thank you for the consistent encouragement, and thank you for taking on the responsibilities and challenges of motherhood so gracefully, so that I could achieve my dreams. To my three children, Isaac Hugh, Caleb Hugh, and Ivy Hugh, thank you for your unconditional love and emotional support. Also, my siblings, Carolina Townsend, Elisa Arthur, and Andres Sosa, thank you for cheering me on when the tasks felt daunting and overwhelming. Special appreciation is given to my Dad, Saul Sosa (R.I.P), for his courageous sacrifice of immigrating to the United States so I could pursue a better future. To my professor, Beth Luthy, I will always remember your words of enthusiasm and encouragement, and for your deep seeded belief in me that I can make a difference in this world, as a Nurse Practitioner. Thank you to all the BYU professors for your unconditional support over the last two years. Lastly, to the many exceptional people who have impacted me on my path in my professional career, I thank you.

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Vaccines are one of the most important public health achievements of all time (Oldfield & Stewart, 2016). In fact, because of vaccines, infectious diseases such as polio have been eliminated from the United States and the incidence of other diseases such as diphtheria, tetanus, pneumonia, and varicella have dramatically decreased since the implementation of the corresponding vaccine (Centers for Disease Control and Prevention [CDC], 2019a). The World Health Organization (WHO) (2019a) estimates that vaccines have prevented a minimum of 10 million worldwide deaths and millions more were protected from vaccine-preventable illness between 2010 and 2015 alone.

Without question, vaccines have radically reduced the spread of highly virulent diseases, such as measles and pertussis, thus also preventing the morbidity and mortality associated with these illnesses. For example, in the 1940s to early 1950s nearly all children acquired measles infection by the age of 15 years (CDC, 2020). However, as a result of the CDC's sedulous implementation of the measles, mumps, rubella (MMR) vaccine, measles was no longer endemic in the United States by the year 2000 (CDC, 2020). Prior to the development of the pertussis vaccine, approximately 200,000 cases of pertussis were reported every year. Once the pertussis vaccine was introduced in the United States, however, the incidence of pertussis decreased by 80% (CDC, 2018a).

Despite the fact that healthcare providers (HCPs), such as nurse practitioners (NPs), are the most prominent and influential source of vaccine-related information (Tabacchi et al., 2017), some parents still rely on alternative sources for vaccine information, especially vaccine safety information (Damnjanovic et al., 2018). With the growing population of vaccine-concerned

parents, the specific information sources utilized by parents strongly influences vaccine decisions (Glanz et al., 2015). Some parents have turned to various media outlets to retrieve information regarding childhood vaccinations (Chung, Schamel, Fisher, & Frew, 2017); however, these parents may also develop a fear of vaccination side effects that are so prominently portrayed through the media and through word of mouth with friends and family members (Chung et al., 2017; Rossen et al., 2019). YouTube, for example, is just one media outlet for vaccine information but is often utilized as a platform to share vaccine misinformation. In fact, 65.5% of the vaccine-related videos on YouTube discouraged the use of vaccinations (Basch et al., 2017).

As part of parental vaccine concerns regarding safety, the question of vaccine ingredients is of particular interest for some parents who hesitate or refuse to vaccinate their children (Lieu et al., 2017). Parents who hesitate or refuse to vaccinate their children share specific concern regarding vaccine ingredients (Saada et al., 2015). In fact, parental concern regarding vaccine ingredients is the second most commonly cited reason for adopting a nontraditional vaccine schedule (Lieu et al., 2017). The belief among these parents is that vaccine ingredients may lead to chronic disease states, cancer (Saada et al., 2015), brain damage, or behavioral problems (McKee & Bohannon, 2016). Additionally, some parents with concerns regarding childhood vaccinations believe vaccine ingredients may also contribute to the development of autoimmune disease, seizures, and food allergies (Evrony & Caplan, 2017).

Communicating effectively with vaccine-hesitant or vaccine-refusing parents can be challenging for HCPs (Kempe et al., 2015) for a variety of reasons, including the fact that HCPs often have inadequate information to sufficiently address parents' questions (Paterson et al., 2016). Nevertheless, NPs must be able to successfully address parental concerns regarding vaccinations through educational efforts and effective communication strategies

(Papachrisanthou & Davis, 2019). Therefore, the purpose of this article is to discuss three common ingredients that vaccine-hesitant or vaccine-refusing parents deem as unsafe by explaining the ingredients' purpose and safety, thus providing NPs with the information needed to effectively alleviate parental concerns.

Parental Questions

Parental Question 1: Which vaccines include polysorbate 80?

Parental Question 2: Is polysorbate 80 safe for ingestion and injection?

Parental Question 3: Does polysorbate 80 cross the blood brain barrier and lead to neurological problems?

Parental Question 4: Which vaccines contain aluminum and thimerosal?

Parental Question 5: Are metals such as aluminum and thimerosal in vaccines toxic to children?

Parental Question 6: Can the aluminum in vaccines cause chronic disease in children?

Methods

A review of the literature was conducted, focusing on articles published within the last 5 years. The review included publications regarding common reasons for parental refusal of childhood vaccinations, as well as to identify vaccine ingredients of concern to parents. Searched databases included CINAHL, MEDLINE, Pub Med and Google Scholar. While this search yielded articles, the search criteria were then expanded to include books outlining how vaccine beliefs have evolved over the past 200 years. Furthermore, websites authored by well recognized and highly reputable organizations, such as the Centers for Disease Control and Prevention (CDC) and the WHO, were reviewed to identify the history of vaccines, particularly how

vaccines have minimized the spread of preventable diseases. In addition, Publichealth.org and CDC websites were reviewed to evaluate the safety of common vaccine ingredients.

Inclusion criteria comprised articles, books, and websites regarding infant and childhood vaccinations. Search terms included the following key words: MMR, Hep B, Dtap, HIB, exemption, additive, active ingredient, preservative, sorbitol, polysorbate 80, aluminum, mercury, thimerosal, and emulsifiers. Articles were then narrowed by searching for terms such as harm, adverse effects, side effects, vaccine injury, and Autism. Articles regarding adult and travel vaccinations were excluded.

Results

Polysorbate 80

Parental Question 1: Which vaccines include polysorbate 80?

Response. Polysorbate 80 is a common vaccine ingredient and is found in vaccines: DTaP (Infanrix), DTaP-IPV (Kinrix and Quadracel), DTaP-HepB-IPV (Pediarix), DTaP-IPV/Hib (Pentacel), Hep B (Heplisav-B), HPV (Gardasil 9), Influenza (Fluad, Fluarix, Flucelvax, and Flulaval), Men B (Trumenba), PCV13 (Prevnar 13), Rotavirus (RotaTeq), Tdap (Boostrix), and Zoster (Shingrix) (CDC, 2019b).

Parental Question 2: Is polysorbate 80 safe for ingestion and injection?

Background. The use of polysorbate 80 in vaccinations has gained worldwide interest over the last few years in the vaccine-hesitant community and on various Internet sites (Commonwealth of Australia, 2018; World Health Organization [WHO], 2017). In websites such as The Vaccine Reaction, Vaccine Impact, the Truth Snitch, and the Children's Health Defense, and books such as *Miller's Review of Critical Vaccine Studies*; *Vaccination Voodoo: What you don't know about Vaccines*; and *Vaccine Epidemic: How Corporate Greed, Biased Science, and*

Coercive Government Threaten our Human Rights, our Health, and our Children, vaccine skeptics report polysorbate 80 has not been properly researched and, consequently, the safety of polysorbate 80 in vaccines cannot be established.

Response. Polysorbate 80 is a necessary stabilizing agent in oral and injected vaccinations, and is also an emulsifier that keeps fat soluble and water soluble substances mixed in solutions (Offit & Bodenstab, 2019; Oxford Vaccine Group, 2019; United States Food and Drug Administration [USFDA], 2018a). Polysorbate 80 is a safe substance commonly found in ice cream, frozen custard, ice milk, and fruit sherbet (USFDA, 2018b). Ice cream, for example, contains 170,000 micrograms of polysorbate 80 in a ½ cup serving to slow melting time and to make the ice cream smoother. Comparatively, the oral vaccination Rota Teq has only a minute amount, 170 - 860 micrograms, of polysorbate 80 (Offit & Bodenstab, 2019; Merck Canada Inc., 2018). Additionally, the PCV 13 is an injectable vaccine that contains an even smaller amount of 100 micrograms of polysorbate 80 (Institute for Vaccine Safety, 2018) in comparison to the Rota Teq vaccine. The polysorbate 80 in the PCV 13 vaccines prevents clumping in solution and allows the vaccine to be more readily available for use (Gadzinowski et al., 2015). Furthermore, the safety of polysorbate 80 has been established in injectable forms. In a double blind, randomized, control study of 500 infants who received a dose of PCV 13 vaccine, either with or without polysorbate 80, demonstrated no differences in adverse effects or systemic reactions (Gadzinowski et al., 2015).

Parental Question 3: Does polysorbate 80 cross the blood brain barrier and lead to neurological problems?

Background. Because polysorbate 80 has been known to affect the blood brain barrier (BBB), vaccine opponents describe it as a vehicle carrying vaccines directly into the brain

(Brownstein, 2019). Similarly, vaccine opponents claim that the presence of polysorbate 80 allow for toxic vaccine ingredients, such as aluminum, to also cross the BBB (Truth Snitch, 2017). For example, vaccine opponents believe the presence of polysorbate 80 and aluminum in some vaccines explains why some children faint, experience seizures, or suffer other neurological problems after receiving vaccines (Vaccine Choice Canada, 2015). Correspondingly, other vaccine rivals suggest that the polysorbate 80 and aluminum in vaccines can cause Autism or other developmental learning disabilities (Palevsky, 2018a; Palevsky, 2018b). Furthermore, some vaccine opponents report that once aluminum and other neurotoxins cross the BBB, conditions such as encephalitis and irreversible brain damage can occur (Habakus & Holland, 2011; Parpia, 2016).

Response. The BBB prevents the transportation of 98% of small molecules and 100% of large molecules from entering the brain (Chacko et al., 2018; Tian et al., 2011). Polysorbate 80 is purposefully added to certain medications to allow the passage of impenetrable substances into the brain to create viable treatment options for brain cancers, brain tumors, Alzheimer's and Parkinson's diseases (Chacko et al., 2018; Khemariya & Khemariya, 2016). For small molecules to pass into the brain, 3-30 mg/kg polysorbate 80 is required in the solution (Chacko et al., 2018; Pardridge, 2005). However, most vaccines contain less than 0.1 mg of polysorbate 80, with influenza vaccine (Fluad) having the highest concentration of polysorbate 80 at only 1.175 mg (Institute for Vaccine Safety, 2018). Thus, the amount of polysorbate 80 utilized in vaccines is at least three times lower than the amount required to cross through the BBB.

Aluminum and Mercury

Parental Question 4: Which vaccines contain aluminum and thimerosal?

Response. Aluminum is found in DT (generic), DTaP (Daptacel and Infanrix), DTaP-IPV-Hep B (Pediarix), DTaP-IPV (Quadracel), DTaP-IPV-Hib (Pentacel), Hib (PedvaxHIB), Hep A (Havrix and Vaqta), Hep B (Engerix-B and Recombivax), Hep A-Hep B (Twinrix), HPV (Gardasil 9), Japanese Encephailitis (Ixiaro), Men B (Bexsero and Trumenba), PCV13 (Prevnar 13) (CDC, 2019b).

Thimerosal is an ethylmercury preservative that is the most widely utilized form of organic mercury (CDC, 2015b). Thimerosal is found in Influenza (Afluria, AfluriaQuad, Flucelavax Quad, Flulaval Quad, Fluvirin, FluZone Quad), Japanese Encephalitis (JE-Vax), and Td (generic) vaccines (Institute for Vaccine Safety, 2018).

Parental Question 5: Are metals such as aluminum and thimerosal in vaccines toxic to children?

Background. Some vaccine opponents advocate for the removal of all aluminum and thimerosal from vaccines stating that these substances are heavy metals, noxious for children, and can have long lasting consequences to the health of children (Tomljenovic & Shaw, 2012). For example, the Vaccine Resistance Movement (n.d.) claims that the metals present in vaccines, such as aluminum and thimerosal, have an affinity for the brain and affect the neurological development in young children causing conditions such as Autism (Vaccine Resistance Movement, n.d.). Even after the removal of thimerosal from almost all vaccines in 2001 (CDC, 2015b), vaccine opponents suggest that the reason Autism rates continued to rise is because the presence of aluminum in other vaccines prevents the removal of thimerosal from the body (Mercola, 2010; Mercola, 2011).

Response. Aluminum has been used in the construction of vaccines for over 90 years and boosts the immune system's response to a vaccination. When a small amount of aluminum is added to a vaccine, smaller amounts of the antigen creates an adequate immune response, thereby lessening the number of vaccines needed to achieve a satisfactory level of immunity (Fernandez, 2016; Offit & Bodenstab, 2018). Most childhood vaccines contain 0.125 mg - 0.85 mg of aluminum per dose, which is well below the minimum risk level of 1-2 mg/kg of body weight per day (Fernandez 2016; Keith et al., 2002; Mitkus et al., 2011).

The fact that there are different types of mercury, ethylmercury versus methylmercury, can be confusing for parents who are concerned about a link between vaccines and Autism. Methylmercury is the potentially toxic form of mercury found in soil, water, air, fish, and shellfish. Ethylmercury, a safe component of thimerosal, is utilized in vaccines to prevent the growth of bacteria in multi-dose vials, thereby persevering the vaccine. Because ethylmercury is safely and quickly metabolized by the body and excreted through stool, it is a safe additive in vaccines (USFDA, 2018c). Aside from the nine scientific research studies disproving the thimerosal-Autism theory of the 1990s (Offit & Bodenstab, 2018), up to 127 genes have now been identified in the pathophysiology of Autism (Gasparini et al., 2015). Furthermore, a 10-year investigation of presumed seizures and encephalopathy conditions secondary to receiving vaccines revealed that most children already had a pre-existing neurological or genetic disorder (Lateef et al., 2015). To date, there is no link between Autism and any vaccine or vaccine ingredient, such as thimerosal (CDC, 2015a; Madsen et al., 2002; Taylor et al., 2014).

Parental Question 6: Can the aluminum in vaccines cause chronic disease in children?

Background. The belief that vaccine ingredients, such as aluminum, trigger an autoimmune response in the body is common among vaccine antagonists. Such a reaction is

known as autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and was first recognized as a condition in an article by Miller (2016) in the *Journal of American Physician and Surgeons*. ASIA is hypothesized to be a cause of several conditions including multiple sclerosis, macrophagic myofasciitis, chronic fatigue, chronic diffuse myalgia, arthralgia and impaired psychomotor control (Miller, 2016). The information in Miller's (2016) article has been widely propagandized via websites such as Clinical Neurology News and the Children's Health Defense.

Response. Aluminum is the third most bountiful element in the earth and is found in air and water (Fernandez, 2016; Keith et al., 2002), as well as in food such as herbs, spices (López et al., 2000), leavening agents, anticaking agents, coloring agents (Soni et al., 2001), pancake mix, waffle mix, baking powder, and cheeses (Saiyed & Yokel, 2005). By 6-months of age, breastfed infants will consume 10 mg of aluminum in breastmilk, while infants who drink formula will have consumed 30-120 mg of aluminum (Offit & Moser, 2011). In contrast, the collective amount of aluminum found in all recommended vaccines during the first 6 months of life is only 4 mg (Meissner, 2017), much less than what infants consume from formula or breastmilk. In fact, the amount of aluminum in vaccines is so negligible that when blood samples are obtained before and after the administration of a vaccine, the amount of aluminum present in blood is undetectable(Offit & Moser, 2011). Thus, aluminum is a safe ingredient in vaccines (USFDA, 2015).

Discussion

Communicable diseases for which there are no vaccines can become worldwide pandemics. The recent and devastating effects of the novel coronavirus (COVID-19) on healthcare systems worldwide demonstrates, firsthand, the importance of vaccines. The first

outbreak of COVID-19 was reported to the WHO on December 31, 2019. In the absence of a viable vaccine, COVID-19 spread to every continent within a 3-month period, infecting more than one million people and resulting in over 52,000 deaths. On March 11, 2020, the WHO (2020) declared the COVID-19 epidemic had become a pandemic. The rapid infectious rates and increase in disease severity created a shortage in medical resources including ventilators, oxygen, hospital beds in the intensive care unit, personal protective equipment, and a shortage in medical staff (Ranney et al., 2020; Supady et al., 2021). Similar to COVID-19, the Spanish Flu of 1918 infected 33% of the globe and took the lives of 500 million people worldwide. Because there was no vaccine against the Spanish Flu, the only means of protection against the disease was social distancing, quarantining, and hand washing (CDC, 2019c).

Unfortunately, with vaccine hesitancy and vaccine exemptions on the rise (Damjanovic, et. al, 2018; Wang et al., 2014), vaccine-preventable diseases may return, mutate, or become resistant and place those who are vaccinated at-risk of developing a community acquired disease. In order to protect the public from highly infectious and airborne diseases, such as measles, vaccination rates must be between 90-95% (Sadarangani, 2016); however, approximately 86% of children receive the first dose of measles vaccine and less than 70% of children complete the measles vaccine series (WHO, 2019d). In fact, the infamous Disneyland measles outbreak in 2014 was fueled by a measles vaccination rate of only 43% in the communities surrounding the theme park (Evrony & Caplan, 2017).

Outbreaks of measles infection, like other vaccine-preventable diseases, have global implications. As a result of declining vaccination rates, measles is now endemic in 12 European countries, and resulted in 140,000 deaths worldwide during 2019 (WHO, 2019c; 2019d). Prior to the administration of the measles vaccine in the United States, nearly 3 to 4 million people

contracted the disease, deaths ranged from 400-500, and approximately 1,000 people developed encephalitis every year (CDC, 2018b). Because of the catastrophic effects of highly virulent diseases, such as measles, the WHO (2019b) declared vaccine hesitancy a threat to global health. In addition to the declining vaccination rates of measles, vaccination rates of Haemophilus influenzae type b, pneumococcal, hepatitis A, hepatitis B, and rotavirus vaccination rates are also well below the 90% benchmarks (Hill et al., 2016), and pose a risk to community members. As a result, if vaccination rates continue to decline, the worldwide population could suffer similar catastrophic consequences as COVID-19 or the Spanish Flu.

Implications for Clinical Practice

In an era when information and, unfortunately, misinformation is easily accessible through various media sources, it is important for NPs to stay abreast of common vaccine misconceptions and know how to effectively respond to parents' vaccine questions. Because NPs are such a trusted source of health information (Traczynski & Udalova, 2018), they are in a position of tremendous influence when it comes to the vaccine-related decisions of parents. NPs must know how to effectively respond to parental vaccine questions, especially common questions regarding vaccine ingredients, otherwise parents may instead rely upon unreliable media sources (McKee & Bohannon, 2016). When NPs are prepared to respond to parental concerns regarding vaccine ingredients with accurate, research-based information, parents can truly make well-informed decisions regarding childhood vaccines.

Conclusion

Because infectious diseases can have globally catastrophic effects, it is pivotal that NPs are well-educated on the misinformation propagated by vaccine opponents regarding vaccines. Parents often question the safety and purpose of vaccine ingredients such as polysorbate 80,

aluminum and thimerosal. By becoming educated on common parental concerns regarding polysorbate 80, aluminum, and thimerosal, the NP will be well positioned to alleviate parents' concerns and assist parents in making informed decisions regarding vaccines.

References

Basch, C. H., Zybert, P., Reeves, R., & Basch, C. E. (2017). What do popular YouTube™ videos say about vaccines? *Child: Care, Health & Development, 43*(4), 499-503. https://doi.org/10.1111/cch.12442

Brownstein, D. (2019). *Toxic polysorbate 80 found in most vaccines.* http://vaccineimpact.com/2019/toxic-polysorbate-80-found-in-most-vaccines/

Centers for Disease Control and Prevention. (2015a). *Vaccine safety: Autism*. https://www.cdc.gov/vaccinesafety/concerns/autism.html

Centers for Disease Control and Prevention. (2015b). *Thimerosal in vaccines.* https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html

Centers for Disease Control and Prevention. (2016a). *Measles.* http://www.cdc.gov/measles/cases-outbreaks.html

Centers for Disease Control and Prevention. (2018a). *Pertussis.* https://www.cdc.gov/vaccines/pubs/pinkbook/pert.html

Centers for Disease Control and Prevention. (2018b). *Measles: History of measles*. https://www.cdc.gov/measles/about/history.html

Centers for Disease Control and Prevention. (2019a). *14 diseases you almost forgot about (thanks to vaccines).* https://www.cdc.gov/vaccines/parents/diseases/child/14-diseases.html

Centers for Disease Control and Prevention. (2019b). *Vaccine excipients summary: Excipients included in U.S. vaccines, by vaccine.* https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipienttable-2.pdf

Centers for Disease Control and Prevention. (2019c). *Influenza 1918 pandemic.* https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html

Centers for Disease Control and Prevention. (2020). *Measles (Rubeola): History of Measles.* https://www.cdc.gov/measles/about/history.html

Chacko, B., Palasisamy, S., Gowrishankar, N., Honeypriya, J., & Sumathy, A. (2018). Effect of surfactant coating on brain targeting polymeric nanoparticles: A review. *Indian Journal of Pharmaceutical Sciences, 80*(2), 215-222. https://doi.org/10.4172/pharmaceuticalsciences.1000348

Chung, Y, Schamel, J., Fisher, A., & Frew, P. M. (2017). Influences on immunization decision making among US parents of young children. *Maternal Child Health Journal, 21*(12), 2178-2187. https://doi.org/10.1007/s10995-017-2336-6

Commonwealth of Australia. (2018). *Questions about vaccination.* Australian Government Department of Health. https://www.health.gov.au/sites/default/files/documents/2020/04/questions-about-vaccination-questions-about-vaccination.pdf

Damnjanovic, K., Graeber, J., Ilic, S., Lam, W. Y., Lep, Z., Morales, S., ...Vingerhoets, L. (2018). Parental decision-making on childhood vaccination. *Frontiers in Psychology, 9*, 735. https://doi.org/10.3389/fpsyg.2018.00735

Evrony, A., & Caplan, A., (2017). The overlooked dangers of anti-vaccination groups' social media presence. *Human Vaccines & Immunotherapeutics, 13*(6), 1-2. https://doi.org/10.1080/21645515.2017.1283467

Fernandez, S. (2016). Aluminum in vaccines: Addressing parents' concerns. *Pediatric Annals, 45*(7), e233. https://doi.org/10.3928/00904481-20160606-01

Gadzinowski, J., Tansey, S., Wysocki, J., Kopińska, E., Mazda-Stanislawska, E., Czajka, H., Karbol, P., Pietrzyk, J., Baker, S., Giardina, P., Gruber, W., Emini, E., & Scott, D. (2015). Safety and immunogenicity of a 13-valentine pneumococcal conjugate vaccine manufactured with and without polysorbate 80 given to healthy infants at 2, 3, 4 and 12 months of age. *Pediatric Infectious Disease Journal, 34*(2), 180-185. https://doi.org/10.1097/INF.0000000000000511

Gasparini, R., Panatto, D., Lai, P. L., & Amicizia, D. (2015). The "urban myth" of the association between neurological disorders and vaccinations. *Journal of Preventive Medicine and Hygiene, 56*(1), E1–E8.

Glanz, J. M., Kraus, C. R., & Daley, M. F. (2015). Addressing parental vaccine concerns: Engagement, balance, and timing. *PLoS Biology, 13*(8), e1002227. https://doi.org/10.1371/journal.pbio.1002227

Habakus, L. K., & Holland, M. (2011). *Vaccine epidemic: How corporate greed, biased science, and coercive government threaten our human rights, our health, and our children.* Skyhorse Publishing.

Hill, H. A., Elam-Evans, L. D., Yankey, D., Singleton, J. A., & Dietz, V. (2016). Vaccination coverage among children aged 19-35 months. *Morbidity and Mortality Weekly Report,* 65(39), 1065-1071. http://dx.doi.org/10.15585/mmwr.mm6539a4external icon

Institute for Vaccine Safety. (2018). *Vaccine excipients per 0.5 mL dose.* http://www.vaccinesafety.edu/components-Excipients.htm

Keith, L. S., Jones, D. E., & Chou, C. H. (2002). Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine, 3*(20 Suppl), S13-S17. https://doi.org/10.1016/s0264-410x(02)00165-2

Kempe, A., O'Leary, S. T., & Kennedy, A. (2015). Physician response to parental requests to spread out the recommended vaccine schedule. *Pediatrics, 135*(4), 666-677. https://doi.org/10.1542/peds.2014-3474

Khemariya, R., & Khemariya, P. (2016). New-fangled approach in the management of Alzheimer by formulation of polysorbate 80 coated chitosan nanoparticles of rivastigmine for brain delivery and their in vivo evaluation. *International Journal of Current Research in Medical Sciences, 2*(2),18-29.

Lateef, M., Johann-Liang, R., Kaulas, H., Hasan, R., Williams, K., Caserta, V. & Nelson, K. (2015). Seizures, encephalopathy, and vaccines: Experience in the National Vaccine Injury Compensation Program. *Journal of Pediatrics, 166*(3), 576-581. https://doi.org/10.1016/j.jpeds.2014.10.054

Lieu, T. A., Zikmund-Fisher, B. J., Choe, C., Ray, G. T., & Wittenberg, E. (2017). Parents' perspectives on how to improve the childhood vaccination process. *Clinical Pediatrics, 56*(3), 238-246. https://doi.org/10.1177/0009922816649001

López, F. F., Cabrera, C., Lorenzo, M. L. & López, M. C (2000). Aluminum levels in spices and aromatic herbs. *Science of the Total Environment, 257*(2-3): 191-197. https://doi.org/10.1016/S0048-9697(00)00520-9

Madsen, K. M., Hviid, A., Vestergaard, M., Schendel, D. & Wohlfahrt, J. (2002). A population-based study of measles, mumps, and rubella vaccination and autism. *New England Journal of Medicine, 347*(19), 3623-3629. https://doi.org/10.1056/NEJMoa021134

McKee, C., & Bohannon, K. (2016). Exploring the reasons behind parental refusal of vaccines. *Journal of Pediatric Pharmacology and Therapeutics, 21*(2), 104-109. https://doi.org/10.5863/1551-6776-21.2.104

Meissner, H. C. (2017). *Do you know what is contained in a vaccine and why?* https://www.aappublications.org/news/2017/09/26/IDSnapshot092617

Merck Canada Inc. (2018). *Product monograph: RotaTeq ® - Rotavirus vaccine, live, oral, pentavalent 2 mL solution.* https://www.merck.ca/static/pdf/ROTATEQ-PM_E.pdf

Mercola, J. (2010). *New warning about everyday poison linked to Alzheimer's, ADHD, and Autism.* https://articles.mercola.com/sites/articles/archive/ 2010/03/20/david-youbinterview-february-2010.aspx

Mercola, J. (2011). *Aluminum: The neurotoxin far worse than mercury.* https://articles.mercola.com/sites/articles/archive/2011/09/21/could-this-be-the-most dangerous-aspect-of-vaccines.aspx

Mitkus, R. J., King, D. B., Hess, M. A., Forshee, R. A. & Walderhaug, M. O. (2011). Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. *Vaccine*, *29*(51), 9538-9543. https://doi.org/10.1016/j.vaccine.2011.09.124

Miller, N. Z. (2016). Aluminum in childhood vaccines is unsafe. *Journal of American Physician and Surgeons*, *21*(4), 109-117.

Offit, P. A., & Bodenstab, H. M. (2018). *Vaccine ingredients- Aluminum.* https://www.chop.edu/centers-programs/vaccine-education-center/vaccineingredients/aluminum

Offit, P. A., & Bodenstab, H. M. (2019). *Vaccine ingredients*. https://www.chop.edu/centers-programs/vaccine-education-center/vaccineingredients/thimerosal

Offit, P. A. & Moser, C. A. (2011). *Vaccines and your child: Separating fact from fiction.* Columbia University Press.

Oldfield, B. J., & Stewart, R. W. (2016). Common misconceptions, advancements, and updates in pediatric vaccination administration. *Southern Medical Journal, 109*(1), 38-41. https://doi.org/10.14423/SMJ.0000000000000399

Oxford Vaccine Group. (2019). *Vaccine ingredients.* http://vk.ovg.ox.ac.uk/vaccine-ingredients

Palevsky, L. B. (2018a). *Polysorbate 80: Dangerous and toxic.* https://www.learntherisk.org/news/polysorbate/

Palevsky, L. B. (2018b). *Aluminum and vaccine ingredients: What do we know? What don't we know?* https://cdn2.hubspot.net/hubfs/2206747/NorthportWellnessCenter_July2018/PDF/Aluminum_and_Vaccin.pdf

Papachrisanthou, M. M., & Davis, R. L. (2019). The resurgence of measles, mumps, and pertussis. *The Journal for Nurse Practitioners, 15*(6), 391-395. https://doi.org/10.1016/j.nurpra.2018.12.028

Pardridge, W. M. (2005). The blood-brain barrier: Bottleneck in brain drug development. *NeuroRx, 2*(1),3–14. https://doi.org/10.1602/neurorx.2.1.3

Parpia, R. (2016). Polysorbate 80: A risky vaccine ingredient. https://thevaccinereaction.org/2016/01/polysorbate-80-a-risky-vaccine-ingredient/

Paterson, P., Meurice, F., Stanberry, L. R., Glismann, S., Rosenthal, S. L., & Larson, H. J. (2016). Vaccine hesitancy and healthcare providers. *Vaccine, 34*(52), 6700-6706. https://doi.org/10.1016/j.vaccine.2016.10.042

Ranney, M. L., Griffeth, V., & Jha, A. K. (2020). Critical supply shortages – The need for ventilators and personal protective equipment during the Covid-19 pandemic. *New England Journal of Medicine, 382*(e4). https://doi.org/10.1056/NEJMp2006141

Rossen, I., Hurlstone, M. J., Dunlop, P. D., & Lawrence, C. (2019). Accepters, fence sitters, or rejecters: Moral profiles of vaccination attitudes. *Social Science & Medicine, 224*(2019), 23-27. https://doi.org/10.1016/j.socscimed.2019.01.038

Saada, A., Lieu, T. A., Morain, S. R., Zikmund-Fisher, B., & Wittenberg, E. (2015). Parents' choicesand rationales for alternative vaccination schedules: A qualitative study. *Clinical Pediatrics, 54*(3), 236-243. https://doi.org/10.1177/0009922814548838

Sadarangani, M. (2016). *Herd immunity: How does it work? https://www.ovg.ox.ac.uk/news/herd-immunity-how-does-it-work*

Saiyed, S. M., & Yokel, R. A. (2005). Aluminum content of some foods and food products in the USA, with aluminum food additives. *Food Additive Contaminants, 22*(3), 234-244. https://doi.org/10.1080/02652030500073584

Soni, M. G., White, S. M., Flamm, W. G., & Burdock, G. A. (2001). Safety evaluation of dietary aluminum. *Regulatory Toxicology and Pharmacology, 33*(1), 66-79. https://doi.org/10.1006/Raphael.2000.1441

Supady, A., Curtis, J. R., Abrams, D., Lorusso, R., Bein, T., Joachim Boldt, P., Brown, C. E., Duerschmied, D., Metaxa, V., & Brodie, D. (2021). Allocating scarce intensive care resources during the COVID-19 pandemic: Practical challenges to theoretical frameworks. *Lancet Respiratory Medicine, 9*(4), 430-434. https://doi.org/10.1016/S2213-2600(20)30580-4

Tabacchi, G., Costantino, C., Cracchiolo, M., Ferro, A., Marchese, V., Napoli, G., …& the ESCULAPIO Working Groups. (2017). Information sources and knowledge on vaccination in a population from southern Italy: The EXCULAPIO project. *Human Vaccines & Immunotherapeutics, 13*(2), 339-345. https://doi.ort/10.1080/21645515.2017.1264733

Taylor, L. E., Swerdfeger A. L., & Eslick, G. D. (2014). Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies. *Vaccine, 34*(29), 3623-3629. https://doi.org/10.1016/j.vaccine.2014.04.085

Tian, X. H., Lin, X. N., Wei, F., Feng, W., Huang, Z. C., Wang, P., Ren, L., & Diao, Y. (2011). Enhanced brain targeting of temozolomide in polysorbate-80 coated polybutylcyanoacrylate nanoparticles. *International Journal of Nanomedicine*, (6) 445–452. https://doi.org/10.2147/IJN.S16570

Tomljenovic, L., & Shaw, C. A. (2012). Mechanism of aluminum adjuvant toxicity and autoimmunity in pediatric populations. *Lupus, 21*, 223-230. https://doi.org/10.1177/0961203311430221

Truth Snitch. (2017). *Polysorbate 80 in vaccines: Is it safe?*https://truthsnitch.com/tag/does-polysorbate-80-allow-toxic-vaccine-ingredients-to-cross-the-blood-brain-barrier/

Traczynski, J., & Udalova, V. (2018). Nurse practitioner independence, health care utilization, and health outcomes. *Journals of Health Economics, 58*, 90-109. https://doi.org/10.1016/j.jhealeco.2018.01.001

United States Food and Drug Administration. (2015). *Study reports aluminum in vaccines poses extremely low risk to infants.* https://wayback.archive-it.org/7993/20170405003134/https:/www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm284520.htm

United States Food and Drug Administration. (2018a). *Common ingredients in U.S. licensed vaccines.* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines

United States Food and Drug Administration. (2018b). *Food additives permitted for direct addition to food for human consumption.* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.840&SearchTerm=polysorbate

United States Food and Drug Administration. (2018c). *Thimerosal in vaccines questions and answers.* https://www.fda.gov/vaccines-blood-biologics/vaccines/thimerosal-vaccines-questions-and-answers

Vaccine Choice Canada. (2015). *When vaccine ingredients cross the blood brain barrier – A formula for disaster.* https://vaccinechoicecanada.com/vaccine-ingredients/when-vaccine-ingredients-cross-the-blood-brain-barrier-a-formula-for-disaster/

Vaccine Resistance Movement. (n.d.). *VRM articles.* https://vaccineresistancemovement.org/

Wang, E., Clymer, J., Davis-Hayes, C., & Buttenheim, A. (2014). Nonmedical exemptions from school immunization requirements: A systematic review. *American Journal of Public Health, 104*(11), e62–e84. https://doi.org/10.2105/AJPH.2014.302190

World Health Organization. (2017). *Vaccine safety and false contraindications to vaccination: Training manual.* http://www.euro.who.int/__data/assets/pdf_file/0009/351927/WHO-VaccineManual.pdf

World Health Organization. (2019a). *The power of vaccines: Still not fully utilized.* https://www.who.int/publications/10-year-review/vaccines/en/

World Health Organization. (2019b). *Ten threats to global health in 2019.* https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019

World Health Organization. (2019c). *Measles in the WHO European Region.* http://www.euro.who.int/__data/assets/pdf_file/0010/410779/Measles-Sitrep-2-Aug2019_.pdf?ua=1

World Health Organization. (2019d). More than 140,000 die from measles as cases surge worldwide: infants and young children most at risk of fatal complications, health agencies warn. https://www.who.int/news/item/05-12-2019-more-than-140-000-die-from-measles-as-cases-surge-worldwide

World Health Organization. (2020). *WHO director-general's opening remarks at the media briefing on COVID-19 – 11 March 2020.* https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

Table 1

Parental Education Handout Regarding Polysorbate 80

Vaccine Ingredient	Vaccines	Parental Concern	Ingredient Purpose	Facts
Polysorbate 80	DTaP • Infanrix DTaP-IPV • Kinrix • Quadracel DTaP-HepB-IPV • Pediarix DTaP-IPV/Hib • Pentacel Hep B • Heplisav-B HPV • Gardasil 9 Influenza • Fluad • Fluarix • Flucelvax • Flulaval Men B • Trumenba PCV13 • Prevnar 13 Rotavirus • Rota Teq Tdap • Boostrix Zoster • Shingrix	• Polysorbate 80 is not well researched and may not be safe. • Polysorbate 80 crosses the blood brain barrier and causes: ○ Fainting ○ Seizures ○ Autism ○ Developmental learning disabilities ○ Encephalitis ○ Irreversible brain damage.	Polysorbate 80 is a stabilizing agent in oral and injected vaccinations and is an emulsifier that keeps fat soluble and water soluble substances mixed in solutions.	• Polysorbate 80 is safe and well-studied. • Polysorbate 80 is a common ingredient in ice cream that slows melting time and makes ice cream smoother. Half a cup of ice cream has 170,000 mcg of polysorbate 80. • To cross blood brain barrier, 3-30 mg/kg is needed. • Most vaccines contain less than 0.1 mg polysorbate 80. • Fluad has the highest concentration of polysorbate 80 at 1.175 mg. • Polysorbate 80 in vaccines is at least three times lower than the amount needed to disrupt the blood brain barrier. • Study of 500 infants who received vaccines with and without polysorbate 80 showed no differences in adverse effects or systemic reactions.

Table 2

Parental Education Handout Regarding Aluminum

Vaccine Ingredient	Vaccines	Parental Concern	Ingredient Purpose	Facts
Aluminum	DT • Generic DTaP • Daptacel • Infanrix DTaP-IPV-Hep B • Pediarix DTaP-IPV • Quadracel DTaP-IPV-Hib • Pentacel Hib • PedvaxHIB Hep A • Havrix • Vaqta Hep B • Engerix-B • Recombivax Hep A-Hep B • Twinrix HPV • Gardasil 9 Japanese Encephalitis • Ixiaro Men B • Bexsero • Trumenba PCV13 • Prevnar 13	• Aluminum is a neurotoxin that can build up in an infant's immune system and reach toxic levels that affects the brain. • Aluminum causes: ○ Autism ○ Delays in neurological development ○ Auto-immune/inflammatory Syndrome Induced by Adjuvants which causes multiple sclerosis, macrophagic myofasciitis, chronic fatigue, chronic diffuse myalgia, arthralgia and impaired psychomotor control.	○ Aluminum boosts the immune system response to vaccines. ○ Aluminum allows for fewer antigens in vaccines and the overall number of vaccines needed in a series to obtain adequate immunity.	• Aluminum is the third most bountiful element on earth. • Aluminum is found in air, water, and foods. • By 6-months of age, breastfed infants consume 10 mg of aluminum in breastmilk. • By 6-months of age, formula-fed infants consume 30-120 mg of aluminum in formula. • Most vaccines contain 0.125 – 0.85 mg of aluminum per dose which is well below the minimum risk level of 1-2 mg/kg of body weight per day. • All vaccines recommended during the first 6-months of life collectively includes 4 mg of aluminum. • When blood samples are collected before and after administering vaccines containing aluminum, the aluminum level in blood is unchanged.

Table 3

Parental Education Handout Regarding Thimerosal

Vaccine Ingredient	Vaccines	Parental Concern	Ingredient Purpose	Facts

Thimerosal	Influenza
	• Afluria
	• AfluriaQuad
	• Flucelavax Quad
	• Flulaval Quad
	• Fluvirin
	• FluZone Quad
	Japanese Encephalitis
	• JE-Vax
	Td
	• Generic
		• Thimerosal is an ethylmercury preservative that can build up in an infant's immune system and reach toxic levels that affects the brain.
		• Thimerosal causes:
		  ○ Autism
		  ○ Delays in neurological development
		  ○ Seizures
		  ○ Encephalopathy
			• Thimerosal prevents bacterial growth in multi-dose vaccine vials.	• Thimerosal is safely and quickly metabolized by the body.
				• Nine separate research studies have definitively disproven any link between thimerosal and Autism.
				• A 10-year investigation proved there is no correlation between thimerosal and seizures and encephalopathy.