ABSTRACT: The primary mission of the American College of Pediatricians (ACPeds) is to promote the optimal well-being of children based on the best available science. Therefore, the ACPeds supports the Center for Disease Control’s (CDC) Advisory Committee on Immunization Practices (ACIP) vaccination schedule. However, ACPeds also acknowledges that there are controversial issues concerning childhood and adolescent immunization. These issues include health benefits and limitations, ethical standards, safety controls, government and physician mandates, parental rights, risk-benefit assessments, and associated responsibilities. While previous position statements have addressed some of these issues, the purpose of this statement is to elucidate ACPeds’ pro-vaccine stance while addressing valid ongoing ethical controversies.

Historical Benefits of Vaccines

For physicians who have practiced medicine over the past two to three decades, the benefits of vaccines have been remarkable, particularly those against pneumococcus, Haemophilus influenzae type b (Hib), chickenpox, and rotavirus. These medical advances followed the marked reduction of pertussis, diphtheria, tetanus, polio, measles, mumps, and rubella resulting from vaccines developed in the 1940’s through 1960’s. Vaccines have made those diseases so rare that most parents, and even some health professionals, today, take their prevention for granted.

Other vaccines, while useful, have not been as universally beneficial. Influenza vaccines, while beneficial, have had more limitations in effectiveness than most others and must be administered every year. Hepatitis A vaccines have been very effective, but a large segment of the U.S. population is at low risk of disease exposure, and hepatitis A rarely is a serious risk to children. Hepatitis B vaccines have also been effective in protecting against serious liver disease (potential for cirrhosis, liver cancer, and death) for those contracting the virus through perinatal transfer, blood exposure, or sexual activity. Yet, the vast majority of the U.S. population is not at significant risk for contracting Hepatitis B even in the absence of receiving the vaccine. Human papillomavirus (HPV) vaccine, introduced to the market in 2006, has already had a positive impact on reduction of genital warts and cervical dysplasia (precursor of cervical cancer). It also has the potential to make a significant impact on other HPV-induced cancers, especially oropharyngeal cancer resulting from oral sex. At the same time, those committed to sexual exclusivity with their future and/or present spouse are at very low risk of contracting sexually acquired HPV, and even lower risk of getting HPV-induced cancer.

To date, the most important vaccine success has been the systematic use of the smallpox vaccine to eliminate that deadly disease from the population. Now immunization programs are close to eliminating polio and have the potential to eliminate measles and rubella.

Vaccine Safety

Vaccine safety has been rigorously regulated by the Food and Drug Administration (FDA). Thousands of trial vaccine recipients are monitored for safety and effectiveness prior to release to the general public, and ongoing safety studies may continue after licensure.
Safety was behind the adoption of the acellular pertussis vaccine over 20 years ago to replace the whole cell form which produced more side effects. Since its introduction, however, the acellular form has proven to be less effective, but authorities are unwilling to trade safety for efficacy. Some researchers are considering using a single priming dose of whole cell pertussis vaccine to boost efficacy.

Inactivated polio vaccine replaced live attenuated polio vaccine in the U.S. over 15 years ago because of very rare (1 in over 20 million doses) cases of live vaccine causing paralytic disease. Likewise, the original rotavirus vaccine was removed from the market due to a post-licensure determined association with intussusception that was so rare that they were not detected in the original vaccine trials of almost twenty thousand patients.

The HPV vaccine has had extensive safety trials, but a potential effect on long term fertility has not been ruled out, for the following reasons: 1) saline placebos (a standard in determining safety and efficacy) were not routinely used in human trials, 2) a high percentage of female recipients in trials, as well as those post-licensure, have been treated with hormone-based contraceptives that can mask ovarian dysfunction, 3) Vaccine Adverse Event Reporting System (VAERS) revealed a very strong (almost exclusive) association of menstrual cycle disruption for over 3 months post vaccination with Gardasil® (arguably a disproportionality safety signal according to CDC guidelines), and 4) there has been a recent study reporting a marked reduction in pregnancy rates for women 25-29 years old who received HPV vaccine compared to those who did not receive it. This correlational evidence does not establish a causal relationship between HPV vaccination and ovarian dysfunction, but does warrant further study.

**Autism Concerns Unfounded**

Immunization has been unfairly implicated by some as a cause of autism. There is actually a preponderance of evidence that vaccines do not cause autism. For the development of autism, both genetic and environmental influences are largely linked to the architecture and function of neuronal synaptic membranes. Instrumental to the proper function of synaptic membranes are long-chain polyunsaturated fatty acids. Most known environmental risk factors for autism such as male vs. female hormones, oxidants, pollutants, prematurity, multiplicity, and maternal diabetes limit supplies of those fatty acids. Vaccines, on the other hand, have no known major role in synaptic function.

**Ethical Concerns and Recommendations**

In light of the historical and current benefits afforded by vaccines, the ACPeds strongly recommends that children be immunized following ACIP guidelines. There is no rigorous science to support alternative immunization schedules. There are, however, conflicts of interest that may be contributing to vaccine hesitancy and need to be resolved. All research, development, and utilization of vaccines should be governed by strict scientific and ethical standards. Vaccine review boards should be composed only of individuals with no conflicts of interest or financial ties to vaccine-related companies. Vaccine safety studies should use saline in controls since other non-antigenic ingredients like adjuvants and polysorbate 80 might have separate adverse effects. Long term (5-20 years) follow-up studies should be done to expose potential side effects that otherwise might go undetected, such as autoimmunity and decreased fertility after immunization.

Another ethical concern is that a number of currently utilized pediatric vaccines are made using cell cultures derived from fetuses aborted in the 1960’s. These vaccines include MMR, Proquad (MMRV), Varivax, and Vaqta (for Hepatitis A) by Merck, Imovax (for rabies), Quadracel (DTaP-IPV), and Pentacel (DTaP-IPV-Hib) by Sanofi Pasteur, and Havrix (for Hepatitis A) by GlaxoSmithKline. This poses a moral dilemma for some parents and health professionals. Therefore, the ACPeds recommends that cell lines or other products involving electively aborted fetuses not be utilized in the development of future vaccines. Alternative animal cell lines and products, or possibly cell lines from human sources such as...
induced pluripotent cells, umbilical cord blood, and/or miscarriages (with parental consent) should be used instead.\textsuperscript{18}

**Conflicting Rights and Responsibilities**

There are two potentially conflicting rights regarding government immunization mandates – the right of the state to protect public health, and the right of parents to direct the care of their children. The ACPeds supports government vaccine requirements for attendance at publicly-licensed child care facilities and schools when lack of vaccination of each individual attendee could pose a significant threat to public health. At the same time, individuals and parents should have the right to refuse medical interventions, including vaccines, based on medical, religious, and/or conscientious reasons. This right comes with significant consequences such as being prohibited from attending such facilities, and being susceptible to contracting potentially serious vaccine-preventable diseases (as well as potentially spreading them to other individuals). One way to respect both perspectives is to limit mandates to certain vaccines. Government mandates for vaccines that often have low efficacy against targeted diseases (influenza) and for vaccines against diseases that are less severe (hepatitis A) or low risk for certain populations (hepatitis B and HPV) are less indicated than mandates for highly effective vaccines against diseases that are both severe and easily spread in general populations, such as measles, pertussis, pneumococcus, and Hib. Obviously, health professionals should recommend vaccines even in the absence of government mandates, except when the child suffers from a condition that warrants exemption, such as severe immunodeficiency or an allergy to vaccine components. However, when caring for vaccine hesitant families, healthcare professionals should make especially strong recommendations for the most effective vaccines targeted toward the most virulent diseases.

Many healthcare professionals have certain minimum standards they require of their patients, and this can include vaccine compliance. Their vaccine requirements typically emanate from a concern for the health of their patients and for others exposed to unvaccinated patients, particularly those too young to be vaccinated and those who are immunocompromised. While practitioners should have the right to do what they think is best, a modicum of flexibility seems appropriate, realizing that parents should likewise have the right to do what they think is best for their children, short of abuse or neglect. Their consent or lack of consent is their right after being informed appropriately about risks and benefits involved. The ACPeds recommends that, in as much as it is possible, pediatricians work with vaccine hesitant families to provide care for and, through education, maximally vaccinate their children. If all pediatricians simply refuse to accept these families, their children will have limited access to well child care and continuity of care.

**Summary**

In summary, while there may be conflicts of interest and ethical issues regarding regulation, production, and utilization of vaccines, the ACPeds affirms that childhood immunizations have played and continue to play an integral role in maintaining the health of individuals and the public at large. The currently available vaccines are, in general, safe and effective, and the best available research indicates no link between vaccination and autism. Parents are encouraged to immunize their children under the direction of their healthcare professional for the benefit and well-being of the child. When a society vaccinates, its children benefit.

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**References:**


