To Vaccinate or Not To Vaccinate: That is the Ethical Question

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The debate over mandatory vaccinations is one that has gained a lot of attention over the last few years. More and more parents are opting out of having their children vaccinated. Reasons for this shift include fear of harm from the vaccines, beliefs that they are not necessary, infringement on their right of freedom, and religious, medical or philosophical reasons. This paper will cover the history of vaccine implementation, list the current rules and regulations regarding vaccinations, and evaluate the risk versus benefit ratio with their use. It will also explore the reasons for parent hesitation to their administration. Finally, it will address ethical theories and concepts present in this debate and how they affect the role of the pharmacist.

The implementation of mandatory vaccination in the United States originated with the smallpox epidemic in 1809 in the state of Massachusetts. At this time, smallpox had claimed the lives of many people and was one of the worst communicable disease outbreaks in history. The law stated that all citizens of that state over the age of 21 would be vaccinated. Even at this point in history, there was opposition to this requirement. This law was argued in the case Jacobson vs. Massachusetts as to whether or not human rights were being violated. The petitioner argued that compulsory vaccination was an infringement on the right to care for one’s own body and an assault on personal character. The court ruled in favor of the state noting that this was a reasonable regulation established with the intention to protect public health and safety. (Welborn 2)
Most current vaccination laws for children entering school are the result of measles outbreaks in the 1960’s and 1970’s. There are currently only three exceptions for which parents can choose to not vaccinate their children. These include medical, religious, and philosophical rationales. Each state has its own number of requirements: all have exceptions for medical reasons, most for religious reasons, and the least exemptions exist for philosophical reasons. In Michigan, the current law allows exemptions based on all three grounds. Currently, Michigan’s law for school entry with regards to vaccination is as follows:

Rule 6:

(a) "Certificate of immunization" means a medical, health department, school, or personal record which indicates the dates when each dose of a vaccine was given to an individual and which is certified by a health professional or local health department.

(b) "Exemption" means a temporary or permanent waiver of 1 or more of the specific immunization requirements for medical, religious, or other reasons.

(c) "Medical exemption" means a written statement from a physician that a vaccination is medically contraindicated for a particular child for a specified period of time.

(d) "Religious or other exemption" means a written statement which is signed by the parent, guardian, or person in loco parentis of a child, which certifies that immunization is in conflict with religious or other convictions of the signer, and which includes the name and date of birth of
the child.

(e) "Vaccine" means an agent for immunization against an infection or disease caused by an infectious agent.

(2) A child who is 2 months through 3 months of age and who is registered in a program of group residence or care shall have received at least all of the following vaccines:

(a) One dose of any appropriate diphtheria vaccine.

(b) One dose of any appropriate tetanus vaccine.

(c) One dose of any appropriate pertussis vaccine.

(d) One dose of any appropriate poliovirus vaccine.

(e) One dose of any appropriate Haemophilus influenzae type b vaccine.

(f) One dose of any appropriate hepatitis B vaccine or a laboratory finding of hepatitis B immunity or disease satisfies this requirement.

(g) Effective January 1, 2007, 1 dose of any appropriate pneumococcal conjugate vaccine. (5)

On September 12, 2006, 3 months after the Food and Drug Administration (FDA) licensed a vaccine against human papillomavirus (HPV), Michigan lawmakers became the first in the United States to propose that vaccination be compulsory for girls entering sixth grade. Parents who objected would be able to opt out of the requirement under the same provisions that apply to other vaccinations. The bill passed the state senate by an overwhelming margin a week later and awaits consideration by the house. (Colgrove 1)

The implementation of childhood vaccinations has resulted in the highest immunization coverage levels to date. This coverage has yielded record, or near record,
low levels of vaccine-preventable diseases. For example, the first 6 states to implement the mandatory vaccinations over 31 weeks saw a 90% reduction in the incidence of measles compared to the rest of the country. (3)

Many parents feel as though the vaccinations that their children are scheduled to receive are unnecessary. Perhaps their beliefs might change if they were present in the time where these diseases existed. For example, the polio vaccine was licensed in the United States in 1955. During 1951 to 1954, an average of 16,316 paralytic polio cases and 1,879 deaths from polio were reported each year. As of 1991, polio caused by wild-type viruses had been eliminated from the Western Hemisphere. A second example of disease eradication is meningitis caused by *Haemophilus influenzae* type b (Hib). A physician entering practice today may never have the opportunity to witness this type of meningitis. Before the introduction of effective vaccines, in 1988, about one in 200 children, under the age of five, developed invasive Hib disease. Hib was the leading cause of bacterial meningitis in children under age five, which accounted for about 60 percent of all cases. Affected children became hearing impaired at a rate from 15 to 30 percent and about 420 children died every year despite antibiotic therapy.

In the 1960’s, rubella also commonly known as German measles, caused a serious epidemic. During a one year outbreak, 20,000 children fell victim to the disease which presented as deafness, blindness, heart disease, mental retardation, and other birth defects inflicted by the rubella virus infecting their pregnant mothers. Today, the effective polio vaccine ensures that no harm is posed by the rubella virus to expecting mothers. (Satcher 1)
The individual and community immunity provided by vaccines help make it one of the most cost-effective health interventions. The cost of caring for individuals afflicted with these diseases, from supportive care, to pharmacotherapy, to hospital stays has been greatly reduced. The value of vaccines also extends beyond childhood. Adults carry the greatest vaccine-preventable disease burden for the U.S. population. It is estimated that an average of 23,000 persons, primarily 65 and older, die from complications of influenza illness during epidemics. Over 10,000 more die from pneumococcal infections such as pneumonia annually. Many of these deaths could have been prevented by vaccination. Hospitalization of adults with these infections can put financial burden on the individuals, family, hospitals and government. Currently safe and effective, but highly under-utilized vaccines, exist that can help to reduce the $10 billion dollars a year in societal costs brought about by vaccine-preventable diseases in adults. (Satcher 1)

There has been talk about Human Papillomavirus vaccine (HPV) policy options recently. There will surely be opposing views as to whether or not the vaccine should be mandatory for young women. As with the previously discussed childhood vaccines, the risk vs. benefit ratio must be evaluated. It must be noted that HPV is the primary cause of cervical cancer and is acquired primarily by sexual contact. HPV is currently the most prevalent sexually transmitted infection in the United States. For the year 2005, it was estimated that 10,370 new cervical cancer cases and 3710 deaths were reported. (Zimmerman 1) An estimated 80% of sexually active persons over the age of 50 will have been infected with at least one serotype of HPV. (Zimmerman 2) With these
epidemiologic facts and numbers, it is clear that the vaccine which protects against this virus may play a large role in the near future.

So far, this paper has covered the positive impacts of vaccination. They have played the largest role in the eradication of many serious, often fatal viruses. They have also been economically effective by cutting down the expenses of caring for those affected by vaccine-preventable diseases. It is now time to switch sides of the debate and examine reasons why parents or adults might not choose to vaccinate themselves or their children.

One of the main reasons that parents exempt their children from vaccination is the fear of causing harm. Some serious adverse events, whether there is a real threat or not, have been associated with vaccination. Some of these include autism, multiple sclerosis and sudden infant death syndrome. Many studies have been conducted evaluating the relationship between the measles, mumps and rubella (MMR) vaccine and autism. One such study was conducted in the UK and included 498 children with autism born between 1979 and 1998. The results indicated that:

- The percentage of children with autism who received MMR vaccine was the same as the percentage of unaffected children in the region who received MMR vaccine.
- There was no difference in the age of diagnosis of autism in vaccinated and unvaccinated children.
- The onset of "regressive" symptoms of autism did not occur within 2, 4, or 6 months of receiving the MMR vaccine (3)
The link to autism is believed to involve the preservative used in the vaccine preparations, thimerosal. It is a mercury derivative that has been used since the 1930’s. According the Centers for Disease Control (CDC), there is no convincing scientific evidence to support the theory that this compound is linked to neurodevelopmental diseases, such as autism. However, in July 1999, manufacturers of vaccines agreed to reduce or eliminate this material from their products. More recently, in 2001, thimerosal is no longer used in recommended childhood vaccinations with the exception of certain influenza vaccines. (3)

VAERS (vaccine adverse event report system) is the national program that has been established to monitor the safety of vaccines after licensing and is jointly administered by the CDC and the FDA. These two bodies analyze VAERS data to identify potential new vaccine safety concerns that may need further study. As with any other type of medication that is foreign to the body, there is a potential for unanticipated reactions. With this program in place, there is a certain amount of surveillance ensuring that the products are safe.

A second reason that parents do not choose to vaccinate their children is that vaccinations are thought to be unnecessary. As previously stated, most adults making this decision for their children did not bear witness to the devastating effects of vaccine-preventable diseases. Therefore, a false sense of security as a result of disease eradication may exist. The feeling that vaccines are unnecessary also arises with diseases that are primarily transmitted by IV drug use or sexual contact. For example, the primary route of infection for the Hepatitis B virus is serological or by close sexual contact. Parents might feel that the administration of this vaccine means that their children will be
involved with IV drug use or engage in sexual contact with an infected partner. In some cultures it might “prove unacceptable as it could be felt that a ‘good’ woman should have no need of such a thing”. (Zimmerman 5)

The same argument goes for the debate against the HPV vaccine. HPV is the most common sexually transmitted disease. Parents may not want to believe that their children are, or will become sexually active at a young age; however, HPV prevalence is highest in 14-19 year old age group. The percentage of females reporting being sexually active from grades 9 through 12 are 29%, 38%, 50%, and 60% respectively. (Zimmerman 2)

The risk for contraction of HPV is real, and being proactive in getting vaccinated does not mean that your child will become sexually active. It means that if they do decide to engage in intercourse, they will be protected from this harmful virus and reduce their risk of cervical cancer.

In an article discussing HPV vaccine policy options, the author demonstrates how parents might feel different about common recommended vaccines and the most current proposed HPV vaccine:

“The historical examples of measles and smallpox, which were among the diseases that led to public health immunization laws, are diseases which can be transmitted by the airborne route; thus, other children would be at risk from an infected child merely by the infected child’s presence in the classroom”. (Zimmerman 4)

He goes on to explain how these diseases differ from the HPV virus which is transmitted by sexual contact. It might be more logical to mandate vaccination for school entry for a
disease which is transmitted by the respiratory route or casual contact. It is a lot more controversial to vaccinate against a sexually transmitted infection in school age children.

Potential harms from this vaccine might include reductions in safer sex practices and screening for cervical cancer. It might also give a misconception that the HPV vaccine would protect against other sexually transmitted diseases. This is a risk that can be reduced by proper education provided to parents and the immunized children. Doctors, pharmacists and other healthcare professionals are the greatest resource for parents and their children who have questions about HPV. If the stigma associated with this vaccine can be overcome, then its benefits may truly outweigh its risk.

A third reason that parents might not vaccinate their children, or even themselves, is because of the cost of these vaccines. It is unfair to mandate certain vaccines for school entry if the parents cannot afford the cost. For example, from personal pharmacy experience, the HPV vaccine is only covered under certain insurance plans and is quite costly if the individual is paying out of pocket. It is not uncommon for young women to forgo the vaccine because of their individual insurance plan or parent’s coverage. It is worth arguing that something to be mandated by the government for these children should be covered. If not, is it not as though we are putting those without adequate coverage at risk of contracting HPV and potentially cervical cancer.

Other reasons for exempting children from vaccines are for medical, religious or philosophical reasons. Medical reasoning is for certain children who have allergies to components of the vaccination, or are severely immunocompromised. In these cases, it is necessary to exempt these children in order to protect them from harm. Religious exemptions are in effect in all states except for 2. Examples could include thoughts of
keeping the body “pure” or relying on relationships with God and his healing power to maintain health.

A recent study questioned reasons why parents chose to exempt their children from vaccination. A survey was given to parents of exempt children which included: verification that their child had not received 1 or more of the vaccines required for school entry, whether the child received the complete or less-than-complete number of doses for each vaccine series, and the reasons why they chose to forgo vaccination. Results showed that the most common reasons stated for not vaccinating related to perceived vaccine safety, including (not mutually exclusive) that the vaccines might cause harm and that they might overload the immune system. Other reasons reported were the perception that the child was not at risk for the disease, that the disease was not dangerous, that vaccines might not work, or because of ethical, moral or religious beliefs. The ethical and moral issues included use of aborted cell lines, fetal tissue and blood, and animal testing as well as opposition to the requirements. (Salmon 3)

It is important to evaluate the impact of parents choosing not to vaccinate their children. There are studies that have surveyed parents of children who have exempted their children from vaccines. In one such study, the impact of health consequences arising from non-medical exclusions was evaluated. The results found that “children in the United States with nonmedical exemptions between 1985 and 1992 were 35 times more likely to contract measles than vaccinated children”. (Salmon 1) This raises the question of whether the decision that the parents made based on religious or philosophical reasoning is truly in the best interest of the children. This is where the ethical debate over mandatory vaccination is present. Many ethical principles can be
applied to state mandates over childhood vaccinations. These include the theories of utilitarianism, beneficence, non-malificience, justice and autonomy.

Utilitarianism is the ethical doctrine that the moral worth of an action is solely determined by its contribution to overall utility. It is thus a form of consequentialism, meaning that the moral worth of an action is determined by its outcome and that the ends justify the means. In the debate over mandatory vaccination, this theory is a weighing of vaccine-induced immunity versus the adverse reactions. The moral worth of vaccination is the outcome of children protected against vaccine-preventable diseases. The eradication of diseases such as smallpox surely justifies the administration of its vaccine.

It has been argued that the utilitarianistic approach compromises personal integrity. “Concerns exist that utilitarianism tramples individual liberties and conscience (e.g., forced to choose the “lesser of evils”) which is the type of charge made by vaccine critics about US vaccine policy options”. (Zimmerman 5) The principle has also lost popularity due to its use as a defense strategy used by Nazi physicians in war crimes trial. It might also exclude minority groups that do not satisfy the preference to the majority of the population. (Zimmerman 4)

The principle of beneficence also applies to this issue. Beneficence is the act of doing good and helping others. This coincides with utilitarianism in that immunized children are prevented from spreading viruses to others. Vaccines “do good” by protecting from disease. It is for the greater good of the community. The term “herd immunity” is immunity experienced by members of society benefiting from each other’s inability to spread communicable disease. Herd immunity is very important for those
who are unable to get vaccinated due to allergies or immunosuppression. The adverse reactions experienced by these vaccines (mostly local reactions) are not significant enough to overcome its benefits.

Another ethical theory that can be applied to this debate is that of nonmaleficence. Nonmaleficence is distinguished from beneficence by doing no harm. It does not imply an act toward the good.(11) This approach could be used to defend children who are not immunized. Technically speaking, they are not doing any harm by not being vaccinated. They are not directly causing harm to others, however they could be causing harm indirectly. Those individuals who rely on herd immunity to stay protected against communicable disease may be subject to greater risk. An act of nonmaleficence has the potential to occur each time a child is exempt from vaccination.

Other theoretical harms that fall under the nonmaleficence category in dealing with the HPV vaccine are the potential decreases in safe sex practice or decreased use of cytology screening for cervical cancer. Confusion over what the vaccine will protect against could potentially lead to other sexually transmitted infections. Also, screening for cervical cancer may not take place due to the false assumption that it is not necessary.

The concept of justice is another ethical principle that must be addressed in this debate. Justice means equitable treatment for all citizens regardless of socioeconomic factors. With that in mind, justice would mean that these mandatory vaccines are available to all individuals who need them. In the United States, the Vaccines for Children (VFC) Program is in place to cover vaccination costs to uninsured and Medicaid-insured children. The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because
of inability to pay. VFC was created as a new entitlement program to be a required part of each state's Medicaid plan and was officially implemented in October 1994. The eligibility requirements for this program include children through 18 years of age who meet at least one of the following criteria:

- Medicaid eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program)
- Uninsured: A child who has no health insurance coverage
- American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- Underinsured: A child who has commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).

By providing parents with the option of vaccination their children by covering the costs under the VFC program, childhood immunizations meet justice requirements in this debate.
The problem that arises is with adults who are uninsured or are not covered for vaccinations. For example, there are many adults who get immunized with the pneumococcal vaccine, influenza vaccine or hepatitis vaccines later in life. Since the VFC program has a cutoff point of 18 years old, the government is not offering equitable treatment to these individuals. In order to make the HPV vaccine just under this principle would therefore mean vaccinating children up to the age of 18 or expanding the criteria to include women in the age group indicated by the vaccine. If not, equitable treatment is not given to women over the age of 18 who wish to receive the vaccine but cannot afford it.

The final ethical principle that is present in this debate is that of autonomy. Under this concept, individuals have the right to make their own choices and decisions. Autonomy “reflects the concept of inherent worth of the individual and to violate it is in essence, to treat someone as less than a person”. (Zimmerman 5) Under these conditions, this freedom of choice should be given to parents (and not the government) to be responsible for deciding whether their children should get vaccinated. These sentiments are expressed by the creator of the Vaccine Information and Awareness organization: “Ostensibly the issue is vaccinations, however, the real issue is Freedom Of Choice. Along with that freedom comes the responsibility to question, research, and decide if vaccinations are prudent for our own child…It must be the right of each individual parent to make that choice, not a government entity that has no children”. (Schumacher 1)

Each pharmacist has a code of ethics that defines how they behave in their practice. The argument of mandatory vaccinations falls within several codes. One that encompasses all factors in this debate is that a pharmacist serves individual, community,
and societal needs. On one hand, the pharmacist’s obligation is to the patient, who may or may not want to receive a vaccination. It is the responsibility of the pharmacist to respect the patient’s wishes regardless if he/she feels differently. A pharmacist must recognize individual self-worth and the principle of autonomy for each patient. He/she must respect cultural differences among patients which might entail refusal of certain vaccines. The ethical problem comes in when this patient could be putting others at risk of harm by not getting vaccinated. In this sense, the pharmacist also must consider what is in the best interest of the community. It is possible that this pharmacist also has patients who are at risk of infection by a virus due to a weakened immune system or an allergy to the vaccine. At this point, in which patient does the pharmacist’s loyalty lie?

The code which encourages pharmacists to promote awareness of one’s own health is a good way to overcome these barriers. By providing relevant information, facts and relative risks associated with childhood vaccination, parents and individuals will be in a better position to make their decision. By participating in their own health decisions, patients have more control and understand the reasons why they are being vaccinated, not simply that the government has forced this upon them.

The debate over mandatory vaccination is one that has gained attention in recent years. Now that all states have exemptions for vaccines, it is essential that information is provided to parents making the decision for their children. Based on the results of many surveys, most parents avoid vaccines because they fear they will cause harm or are not necessary. Relevant studies evaluating these risks must be readily available as well as awareness over the potential dangers of the resurgence of vaccine-preventable disease. Many ethical principles can be applied to this debate, mainly the balance between
autonomy and community safety. It is likely that this debate will continue in years to follow with the manufacturing of new vaccines and the emergence of vaccine-preventable disease.

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References


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11. Wikipedia search: Nonmaleficence