Ethics of Vaccinations

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The purpose of this paper is to investigate the ethics involved with vaccinations, with an emphasis on childhood vaccinations. There are several ethics issues that need to be discussed regarding this topic. Is it ethical that vaccinations be “forced” on the population? Is it ethical for the individuals who do refuse to get them to do so? Is it ethical for healthcare providers to not serve or to treat differently those who do not receive them? Can pharmacists play a role in clarifying public issues with immunizations, and do they have the potential to influence the mistrust in vaccinations? To fully understand this topic, we must first realize the current laws and exemptions allowed for when it comes to children receiving immunizations and explore reasons why people choose not to undertake or complete vaccinations for their children. We will then analyze immunization trends in the demographics. The issue of media influences will be examined, followed by an explanation of how vaccines are monitored. We will also evaluate cost as a barrier, and finally, implications from a healthcare practice perspective will be tackled with an emphasis on pharmacists.

The discovery and implementation of childhood vaccinations is one of the most significant health care milestones in history. Thanks to vaccines, we have completely eradicated smallpox and no longer bear witness on a regular basis to other devastating diseases such as polio, measles, mumps, rubella, diphtheria, pertussis, and tetanus. In addition, influenza, hepatitis, and even chicken pox are preventable. Unfortunately, with the perceived eradication and non-threatening nature of these major diseases, there is a growing trend of parents becoming complacent about getting their children properly vaccinated. Many parents in recent generations have never had to witness the effects of these disease states firsthand. Rather than focusing on the benefits of vaccinations, the focus of media these days seems to be on the adverse effects and potential harmful effects on vaccinations. There is a growing number of school-aged children who are unvaccinated or undertervaccinated in the United States, and an effort is being made to investigate these reasons. Are fears or objections associated with vaccinations legitimate? Do we need to crack down own our vaccinations laws? Is this ethical?

What are the lawful requirements of vaccinations in the United States? Currently all 50 states have enacted compulsory vaccination laws. The modern era of compulsory vaccination laws started with a handful of states in the late 1960s. Once the states that started the laws showed overwhelming evidence in the reduction of disease occurrences against the states that did not, most followed suite. By the mid 1970s, the federal government made an effort to get all states on board, and by 1981, 95% of all children entering school had been immunized. All states have at minimum required immunization against diphtheria, measles, rubella, and polio prior to school entry and in addition, the states may specify further mandatory immunizations and recommendations.¹

In Michigan, the requirements are specified under chapter 333 of the public health code, article 9 (supportive personal health services), part 92 (immunization). The list for school-aged children is detailed and extensive:

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¹ Source: Government website, statistics on vaccination rates and laws, as of 2023.
6) A child who is 4 years through 6 years of age and who is entering school shall be in compliance with all of the following immunization requirements:

   (a) Have received 4 doses of any appropriate diphtheria vaccine and, if a dose was not received on or after the fourth birthday, a booster dose at school entry.

   (b) Have received 4 doses of any appropriate tetanus vaccine and, if a dose was not received on or after the fourth birthday, a booster dose at school entry.

   (c) Have received 4 doses of any appropriate pertussis vaccine and, if a dose was not received on or after the fourth birthday, a booster dose at school entry.

   (d) Have received 3 doses of any appropriate polio vaccine and, if a dose was not received on or after the fourth birthday, a booster dose at school entry.

   (e) Have evidence of measles immunity as shown by either of the following:

      (i) Two doses of any appropriate live measles vaccine received after the first birthday, not less than 28 days apart.

      (ii) Laboratory evidence of measles immunity.

   (f) Have evidence of mumps immunity as shown by either of the following:

      (i) Two doses of any appropriate live mumps vaccine received after the first birthday, not less than 28 days apart.

      (ii) Laboratory evidence of mumps immunity.

   (g) Have evidence of rubella immunity as shown by either of the following:

      (i) Two doses of any appropriate live rubella vaccine received after the first birthday, at least 28 days apart.

      (ii) Laboratory evidence of rubella immunity.

   (h) Three doses of any appropriate hepatitis B vaccine, beginning with the 2000-2001 school year.

   (i) Beginning with the 2002-2003 school year, have evidence of varicella immunity as shown by any of the following:

      (i) One dose of any appropriate live varicella vaccine at or after 12 months of age.

      (ii) Laboratory evidence of varicella immunity.

      (iii) A parent, guardian, person in loco parentis, or physician statement that the child has had varicella disease.

Specifications are also made for children less than four years of age in a group residence or care, and for children in school aged 7-18.

Section 9211 states that: (1) A parent, guardian, or person in loco parentis applying to have a preschool aged child registered in a program of group residence, care, or camping shall present to the operator of the program at the time of registration or not later than the
first day of the program a certificate of immunization or a statement of exemption under section 9215. What are these “exemptions” and how easy are they to obtain? 

Exemptions are categorized as either fitting into medical reasons, religious reasons, or personal/philosophical reasons. All states allow for medical reasons (such as being immunocompromised or allergic) which requires documentation from a medical doctor. Forty-eight states allow for religious exemptions, with the two exceptions of Mississippi and West Virginia. According to the National Vaccine Information Center’s website, “The religious exemption is intended for people who hold a sincere religious belief opposing vaccination to the extent that if the state forced vaccination, it would be an infringement on their right to exercise their religious beliefs”. Some states are more stringent and require membership to certain churches who document opposition to procedures that would include vaccinations, and some may require signed documentation from spiritual advisors. In others, a simple check mark is sufficient. Eighteen states currently allow for philosophical exemptions, and Michigan is included in this number. Often times this claim must be applied to all vaccinations for a child, and not just particular ones. This particular category of exemptions gives seed to a lot of debate as it is contributing to vaccine complacency. Exemptions are becoming convenient to obtain.

What are some of the contributing factors associated with refusals to get children vaccinated in the U.S.? In an article published in the Archives of Pediatrics and Adolescents from May 2005 titled “Factors Associated with Refusal of Childhood Vaccines Among Parents of School-aged Children”, the authors sought to determine why the rate of nonmedical exemptions to requirements has been increasing and to explore the differences in perceptions of vaccines between parents of fully vaccinated children and those without full or any vaccinations. Surveys were sent to parents of both exempt and fully vaccinated school-aged children in the states of Colorado, Massachusetts, Missouri, and Washington. 391 surveys were returned from parents with exempted children (48.6% return rate) while 976 were returned from parents with fully vaccinated children (59.9% return rate).

In the results analysis, it was found that the parents of children with nonmedical exemptions were older than the median age of parents with non-exempted children. They were also more likely to have higher than the median level of education, defined as “some college”. Incomes between the two sets of parents were similar. Of the parents who chose against vaccinating their children, the reasoning were as follows: the vaccines might cause harm (68.6%), they might overload the immune system (49.1%), the child was not (perceived) at risk for the disease (37.2%), the disease was “not dangerous” (20.9%), the vaccine might not work (13%), and a broad category of ethical/moral issues (9%). These issues included the use of aborted cell lines, fetal tissue and blood, and animal testing as well as opposition to requirements. These parents were also more likely to report low perception of vaccine safety and efficacy, a low level of trust in the government, less confidence in medical, public health and government sources, and more confidence in alternative medical professionals compared with parents of vaccinated children. It was notable that of the parents with exempted children, 75% had only exempted certain
vaccines, indicating the parents seem to be selective in vaccinations acquired rather than opposing them all together.\textsuperscript{4}

Is there a difference in the demographics of parents and households with children who are undervaccinated versus completely unvaccinated? Smith, Philip et al. investigated this and other matters in a \textit{Pediatrics} article in 2004 titled “Children Who Have Received No Vaccines: Who are They and Where Do They Live?” The authors searched for trends in data from the National Immunization survey that looked at children between 19 and 35 months of age between the years 1995 and 2001. Compared to fully vaccinated children, undervaccinated children were more likely to be black than Hispanic or non-Hispanic white, younger, and foreign born versus born in the U.S. These children were more likely to have a mother who was young, widowed, divorced or separated, and an education achievement of high school or below a college degree. They were also more likely to live in a household with the annual income below the poverty level than in a household with an annual income greater than $75,000. Interestingly, when parents of unvaccinated children were compared to the undervaccinated, they were found to (significantly) be more likely to have a mother older than 30 years of age versus ages 20-29, and also with a college education versus 12 years or less of education. These children were also more likely to live in a household with an annual income at or exceeding $75,000. Of these parents, 70% claimed that a doctor was not influential in shaping their vaccination decisions for their children, while only 22.9% of undervaccinated children supported this claim.\textsuperscript{5}

Another interesting analysis done in this article was that of the estimated rates of unvaccinated children per 100,000 children (aged 19-35 months) according to state and the District of Columbia. Rates were seen to be significantly higher in those states allowing for philosophical exemptions. Of the top 50 counties in numbers of unvaccinated children, 7 counties were in California and 5 were in other western states. The top county listed was Los Angeles, CA. Interestingly, the next highest region was Detroit, MI (in combining Wayne, Oakland, and Macomb counties, which were all in the top 50).\textsuperscript{5} Further evidence of this local problem comes from the fact that in the 2003-2004 school year, 5.7% of Michigan school entrants claimed an exemption (while only 6 other states had exemption rates of 3% or higher.) \textsuperscript{3}

While certainly not every incidence of non-vaccination or undervaccination can be attributed to philosophical objections, there seems to be a growing trend in this direction. Is it constitutional and lawful to have vaccination laws in the first place? Aren’t we free to make our own health care decisions and do whatever we want with our bodies (and certainly our children’s bodies)? From a societal standpoint, its easy to see that these laws are in place for the greater good of all. Following the rule will keep your child out of risk, and likewise, other children will not be putting your child at risk because they will be immune also. This logic seems to be applied when we consider laws we have enacted that prohibit driving while intoxicated or taking illegal street drugs. Even smoking laws are in place in some states outright banning smoking from public places. The logic is basically the same: smoking creates a health hazard for the surrounding public when someone chooses to do it, therefore we can stop people from doing it if they are posing a health threat to
other people. Having children and people in public institutions and schools who are unvaccinated and potentially carrying or spreading severe diseases poses a threat to other children (even if they are vaccinated) and give threat to cost burdens on the health care system that could have easily been avoided. The fact that exemptions can be obtained seems to make the laws less restrictive or controlling. However, is the easy method of getting one (as easy as a simple, undisputed check mark in some cases) becoming such a problem that we need to eliminate or crack down on them?

In recent years, it seems that the main focus on vaccinations has been the adverse effects and the negative associations assumed from them rather than their success at curbing the occurrence of severe diseases. Vaccines have been associated with acute and chronic diseases with no known cause such as autism, multiple sclerosis, and sudden infant death syndrome from the measles-mumps-rubella, hepatitis B, and diptheria-tetanus-pertussis vaccines respectively. Its hard for the general public to differentiate scientific evidence from circulating hypotheses or opinions seen and heard in the media, especially the world wide web, which has become a health information resource for most adults. In a 2001 article by John D Grabenstein from Hospital Pharmacy titled “The Individual Perspective: Did This Vaccine Harm This Person?” Grabenstein explains that people are entranced with stories about individuals like themselves.

“Media stories exploring relationships between vaccines and adverse events often follow a pattern. The story focuses on a family, and a member of this family has autism, multiple sclerosis, or some other heart-rendering health condition. The family searches for an explanation for the tragedy. Family members may state, or the narrator may imply, that vaccination could or should be considered the reason for the tragedy.”

One particular controversy in the administration of vaccines in recent history was the use of thimerosal as a preservative in vaccinations. Thimerosal is an ethylmercury based preservative that has been linked to contributing to neurodevelopmental diseases, such as autism, in children. Concerns were that doses of organic mercury obtained through vaccinations were exceeding the guidelines. It was suggested that the rise in autism in the early 1990s coincided with the recommendation of administering Haemophilus Influenza B and Hepatitis B vaccines (adding to the total accumulation of thimerosal exposure from other vaccines received). Stehr-Green and colleagues investigated this correlation in the American Journal of Preventative Medicine article titled “Autism and Thimerosal-Containing Vaccines: Lack of Consistant Evidence for an Association.” In this study, the incidence and rise of autism was compared between the United States, Sweeden, and Denmark. In all three countries, the rise of autism followed a similar trend of rising in the 1985-1989 period, with an accelerated increase in the early 1990s. Thimerosal content in vaccines in Sweeden and Denmark had been lower than the U.S. throughout the 1970s and 1980s, had decreased in content in the late 1980s, and had been eliminated by the early 1990s. In contrast, the average dose in U.S. vaccines increased throughout the 1990s (and the increased rise in autism had already started by the mid 1980s).

In 1999, the FDA completed a comprehensive review on the issue of using thimerosal as a preservative in vaccines and concluded that there was no evidence of harm
aside from local hypersensitivity reactions.\textsuperscript{6} As per the FDA website on thimerosal: “As a precautionary service, the Public Health Service (including the FDA, National Institutes of Health (NIH), Center for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA) and the American Academy of Pediatrics issued two Joint Statements urging vaccine manufacturers to reduce or eliminate thimerosal in vaccines as soon as possible.” Currently, there are only a few vaccines that have very trace amounts of thimerosal (<0.5 \textmu g Hg/ mL).\textsuperscript{8}

The anti-vaccination movement has been around since the very first use of vaccinations when Jenner published his work on smallpox at the end of 19th century. Opposition from the time parallels modern day concerns: assertion of the risks posed by immunatization, basic rights and religious and personal freedom from unwanted government interferences.\textsuperscript{1} There are a plethora of websites accessible supporting the anti-vaccination movement. One example is titled “Think Twice-Global Vaccine Institute”. Emotional stories, a description of vaccine “rights”, and articles are provided, along with some FAQs. Examples of these FAQ as they appear on the website follow:

Q: When I told my doctor that I am not going to have my children vaccinated, he (she) became very angry and told me that he will not treat them, and that I am no longer welcome in his office. Do you have a list of doctors in my area who will respect my decision to not vaccinate and still treat my children?

A. Your situation is not uncommon. Many pediatricians refuse to treat children when their parents object to the shots. This is just one tactic doctors employ in an effort to intimidate moms and dads into vaccinating against their will. You should be thankful that this dysfunctional relationship with your health practitioner has been terminated.

The response goes on to encourage searching for a homeopathic or naturopathic doctor.

Q: My daughter never had a vaccination. I have recently been informed by my brother’s wife that she feels my daughter is a danger to her 2 month old son, and does not want her around for the first 18 months of his life. Her pediatrician told her that my daughter was a "disease carrier" and could give it to anyone around her.

A. Some doctors will say anything to get parents to vaccinate, even if it doesn’t make sense or is an outright lie. They spread this incredible baloney to make parents like you feel guilty, and to create tension between parents of vaccinated and non-vaccinated children. It is a ploy to coerce you into vaccinating your child.

First of all, how could your non-vaccinated child be a danger to the vaccinated child? If the vaccines are effective, then the baby should be protected. Actually, it's the vaccinated children who spread disease. Many of the disease
outbreaks that we are warned about today, are caused by, and occur in, recently vaccinated children. Of course, vaccines are bound to have adverse effects just by nature of what they are and how they are administered. In the past, lawsuits sprung up and threatened to discourage pharmaceutical companies from wanting to even manufacture vaccines. In 1986 Congress passed the National Childhood Vaccine Injury Act, allowing for government-based compensations for vaccine-related injuries. The government decided to be liable in order to promote overall public health welfare and to not deter the manufactures from supplying vaccines. In addition to the compensation act, the Vaccine Adverse Event Report System (VAERS) was created at this time for people to report injuries or complications related to vaccine administration. According to the the FDA website, VAERS is monitored by both the FDA and CDC. “VAERS accepts reports of adverse events that may be associated with U.S. licensed vaccines from health care providers, manufacturers, and the public. The FDA continually monitors VAERS reports for any unexpected patterns or changes in rates of adverse events.... In addition to analyzing individual VAERS reports, the FDA also analyzes patterns of reporting associated with vaccine lots.” Reports of events following vaccinations are encouraged even if there is uncertainty if the vaccine or another product caused the event. Data is continuously reviewed by both the FDA and CDC and trends in specific lots are monitored.

Economic reasons are not a likely factor contributing to the decline in vaccination administration in the U.S. In August of 1993, Congress passed the Omnibus Budget Reconciliation Act (OBRA) that created the Vaccines for Children (VFC) program. It is also known as section 1928 of the Social Security Act. The program supplies vaccines to children with families who cannot provide them by providing free vaccines to the doctors that serve them. It is administered on the level of the national government by the CDC. Children who are eligible include:

- those 18 years of age or younger
- those eligible for Medicaid
- those with no health insurance
- those who are Native American or Alaskan Native
- those who have health insurance but it does not cover immunizations (in this case, children must go to a Federally Qualified Health Center or Rural Health Clinic for immunizations.

Through this program, vaccines are free of charge, with the exception that some states may choose to charge an “administrative fee.” This fee can vary by state or region, with the maximum charge listed as $17.55 on the VFC website. Furthermore:

If a patient cannot afford to pay the administrative fee being charged by the provider, the law requires that the provider must still administer the vaccine to the patient. Parents of children enrolled in Medicaid programs should not be charged an administrative fee. To be reimbursed the provider should bill the state Medicaid program.
Diseases covered include diphtheria, Hib, Hepatitis A and B, influenza, measles, meningococcal disease, mumps, pertussis, pneumococcal disease, polio, rotavirus, rubella, tetanus, and varicella. Vaccines can be received via the VFC program at private doctors offices, private clinics, hospitals, public health clinics, community health clinics, and select schools in some states.

We know that there are programs closely monitoring the side effects of vaccines and programs that allow for all children, regardless of socioeconomic status, to receive vaccinations. Despite this, it might seem reasonable from some parents’ perspectives to neglect getting all of the recommended vaccinations or to bypass them completely when it is so easy to get an exemption, the scheduled calendar of doses seems too complex, and the perceived danger and risk that vaccines protect against appears minimal. It is also easy to assume that if "everyone else" is getting their children vaccinated, than their own child will be protected by association. Compounding these ideas is the threat of the potentially harming adverse effects circulating in the media.

People with a scientific knowledge base realize there is little credibility to a lot of health information accessible on the internet, and also realize that there is no scientific data linking vaccinations with severe complications or disease states. Healthcare professionals have a duty to explain the risks involved with neglecting vaccinations, both to the child at hand and to those that surround him or her. After all, should the child get sick in a manner clearly preventable with immunization, the parents will be returning to the original caregivers in search of help and treatment, and it will be costly. From the perspective of a physician, giving each patient optimal healthcare is supposed to be the number one priority, and likewise parents of children expect the same from their physicians. If parents do not agree to a protective mechanism in aiding their child's health that is so fundamental to optimal health care, is it the doctor's obligation to support this decision?

Pharmacists have the opportunity to play a vital role in advocating the administration of childhood vaccines. Pharmacists are a very accessible source of information and have the potential to expand their roles in immunizations, according to an article in *U.S. Pharmacist* from 2004 titled “Childhood Immunizations: Information for Pharmacists.” In the inpatient setting,

Pharmacists can recommend routine immunizations for hospitalized patients with no contraindications, participate in the formulary review of new vaccines and vaccine-specific medication use evaluations, obtain vaccination histories from inpatients or their caregivers, and educate patients, caregivers, and other health care professionals about recommendations for immunization and vaccine safety.

In the outpatient setting,

They can obtain immunization histories from patients and their caregivers, provide information about vaccines to patients and consumers, offer patients immunization resources, report adverse events, educate patients who are receiving vaccines, host other health care professionals to give childhood immunizations, display the current recommended immunization schedule in the pharmacy, and even participate in giving immunizations to patients.
Pharmacist can become certified in vaccination administration through the APhA. In fact, 40 states already have provisions allowing for them to participate in this role.\textsuperscript{13}

It is evident that pharmacists can play a role in helping with the undervaccination problem. Pharmacists can educate the public and help clarify information that individuals may be receiving causing them to avoid having their children vaccinated. What is the proper way for a pharmacist to handle refusals for immunizations despite efforts at advising against this decision? How far is too far to push? We know that the principles of vaccination are to provide not only protection to an individual child, but to provide better health from a societal standpoint. Yet, it is someone’s individual decision to seek health care and treatment for themselves. In the case of childhood vaccinations, it is not even the child who is able to make these decisions for themselves, and to some health care practitioners this is seen as child neglect.

Pharmacists in practice are faced with ethical dilemmas such as providing means of contraception and abortion in outpatient settings and participating in medication administration for terminally ill patients that may accelerate the end of a patient’s life. Some practitioners are so fundamentally opposed to these types of health care decisions that they will not provide care to such patients, and currently in most cases and with some provisions, this decision is permissible. In the case of childhood immunizations, this principle is not quite as practical. Typically pharmacists in practice will not know the immunization records of the children they are serving, but it could be very useful to ask if the child is up to date. Since this is such a prominent health care problem right now, it is the pharmacist’s duty to realize the problem, and to be able to educate the public on knowledge gaps or misconceptions. Pharmacists are accessible and have the potential to play a role—being indifferent to the problem would itself be unethical.

Undervaccination and nonvaccination is becoming a growing concern in health care. Ethically this issue has several standpoints. With all of the media controversy surrounding vaccinations, can government and society force the issue that children be vaccinated? Is it ethical to allow for the ease of exemptions currently granted when considering the safety of society as a whole? Is it unethical for parents to neglect getting their children immunized? Can health care providers force the issue? In this paper we reviewed the laws involved in vaccinations and the means of getting out of them. Understanding which parents were not getting their children vaccinated, and the possible reasons behind the decisions were also evaluated. Finally, we discussed the important role of health care providers, especially pharmacists, in tackling this issue.
References

2. Grabenstein, John D. The Invidual Perspective: Did This Vaccine Harm This Person? Hospital Pharmacy 2001; Volume 36, 413-420.