

THE LIMITATIONS OF THE ROLE OF PARENTS IN INFORMED CONSENT FOR CHILDREN

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ABSTRACT

Vaccines are one of the most successful methods used for preventing infectious diseases. However, there has been an increased public concern regarding the adverse effects of vaccines, especially among parents who are concerned about the false link between autism and vaccine. Evidence shows there is an increasing incidence of parental vaccine refusal resulting in outbreaks. This recent emergence puts a limitation on the role of parents in autonomous determination for their children, under the age of consent. In this review, we aim to identify vaccine safety concerns among parents and to evaluate the role of parents in giving informed consent on behalf of their children.

Autonomy, although an ethical principle afforded to the parents of under-age children must be reviewed in the context of the results of the studies reviewed as parental refusal seems prevalent with the false belief that vaccines cause more harm to children than good.

Keywords: Vaccines, injections, ethics, safety

INTRODUCTION

In the late 1900s, several vaccines including polio, measles, tetanus, pertussis and tuberculosis were introduced and used to decrease mortality rates. However, the safety of the whole cell pertussis vaccine was questioned by anti-vaccine movements in the 1970s in the United Kingdom (1). Further questions were raised about the harm caused by vaccines when autism was linked to the MMR vaccine in 1998 by Andrew Wakefield, creating a worldwide crisis and making parents question the benefits of vaccines (2).

Resistance to vaccination has been present in the United States since the late 1800s when the smallpox became an epidemic in the United States, as a result of which attempts were made to enforce vaccination which led to the Anti-vaccination Society of America being formed and in the United Kingdom, similar anti-vaccination movements were formed against mandatory vaccinations which quickly spread across Europe (3).

HISTORY OF VACCINE REFUSAL

Even though, the introduction and use of vaccines in the 20th century led to a remarkable decrease in childhood morbidity, disease outbreaks and mortality rates, many parents still refuse to get their children vaccinated or they choose to delay their children getting vaccinated. This group of parents is referred to as vaccine-hesitant parents (4). Parental hesitancy or complete refusal in getting their children vaccinated is a problem which needs to be addressed as it is having a negative impact on the health of children and the rest of the population (5). The renaissance of outbreaks of vaccine-preventable diseases, including measles (6,7) has raised the question of how vaccine hesitancy or refusal leads to the spread of life-threatening infections, having severe impact on the public health. However, concern regarding the benefits etc. potential harm that can be caused by vaccines is not a new concern observed amongst parents and has been an issue of debate since the 18th century when the concept of vaccination was first established through the use of cowpox virus to provide immunity against smallpox (3,8).

CURRENT IMPACT OF VACCINE REFUSAL ON PUBLIC HEALTH

It has been found out that parental refusal of vaccination for children resulted in an increase of prevalence of vaccine-preventable diseases nationally (9,10). It has been shown that the number of measles cases has increased nationally due to parental vaccine refusal. Furthermore, according to the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report, 24 states reported 118 cases of measles between 1st January and 20th May, 2011, and of these 118 cases (89%) were unvaccinated individuals. It is crucial to note that since 1996, this is the highest number of measles cases to be reported (11).

In the last 4 years, there has been an increase in number of cases of measles associated with refusal of vaccination by parents. In San Diego County, there was an outbreak of measles in 2008 and there was found to be an association between children developing measles and parents intentionally refusing vaccination (10). Furthermore, there was a large measles outbreak in 2011 and it was found that most of the children affected by the outbreak were not vaccinated because their parents were unsure about the safety of the measles, mumps and rubella (MMR) vaccine (12,13).

Studies have shown that in the United States, approximately 12.5% of children under the age of 2 years old are not vaccinated as a result of parental refusal and many doctors have reported that they experience at least one child being refused by parents for vaccine each month (5,14). In the recent National Immunization Survey conducted in the school year 2013-14, it was found that in 11 states, approximately 4% of children going to kindergarten were exempted from mandatory school entry vaccinations (15), which means the risk exposure for children is increased, increasing the risks of vaccine-preventable disease outbreaks. Current outbreaks in pertussis have been associated with under-vaccination as a 2013 study investigating the association between pertussis and under-vaccination in children between 3 to 36 months of age found that there was a strong association between under-vaccination and pertussis as those children who were under-vaccinated for 3 doses of DTaP vaccine were 18.56 times more likely to be diagnosed with pertussis than those children who were vaccinated. Out of all 644 cases of measles were recorded in 2014 with 23 outbreaks having a negative impact on 27 states (14). Vaccine refusal by parents appears to be having an alarming negative impact on the public health, which means

it is important to confront this issue in order to maintain effective vaccination programs. To understand whether it is ethical or not to vaccinate children even after their parents' refusal, it is important to understand the factors that contribute to the decisions are made by parents.

FACTORS CONTRIBUTING TO VACCINE REFUSAL

Studies and surveys investigating the reasons for vaccination refusal found several different factors contributed to the decision made by parents, however, the most common reason given was the fear regarding safety issues and the concern that vaccine benefits did not outweigh the risks associated with vaccines (16,17). Many questions were raised and controversy over vaccine safety began as the diphtheria/tetanus/pertussis (DTP) vaccine was falsely assumed to be the cause of sudden infant death syndrome (SIDS). In 1933, 2 cases were recorded of infants who died within 2 hours of receiving pertussis vaccines at ages 4 and 11 days. Even though, the first recorded cases date back to early 1900s, there was no major concern until March 1979 when the Tennessee Department of Health reported 4 sudden deaths of infants within 24 hours of them receiving their first DPT vaccines. However, upon investigations, no evidence was found to support the claim that DPT vaccines caused sudden infant deaths (18).



Figure 1: Conditions Associated with Vaccines

Since the introduction of vaccination, there have been issues based on religious grounds too. When vaccination was first introduced, some Christians believed that using vaccines would be going against the will of God because if God has decreed that an individual dies due to a certain disease then why should human beings try to interfere and change this (19). According to the Islamic Shariah law, vaccinations are prohibited as there is concern that they contain pig blood or any other derivatives of it because consuming pig or any of its body part is prohibited in Islam (20).

THE ROLE OF PARENTAL AUTONOMY IN CHILDHOOD VACCINATION

In a medical context, autonomy is simply the ability or the right of an individual to make decisions about their treatments and the right to refuse from receiving any type of treatment or medication they do not want. The concept of autonomy is central to the concept of informed consent (21). However, infants do not have the capacity to make any decisions about their health or whether they want to be vaccinated or not, and as a result, in such situations, parents have the right to make decisions for their children. The problem that needs to be addressed is that many pediatricians/nurses face difficulties when they are faced with parents who refuse to get their children vaccinated based on non-medical reasons, such as those mentioned in figure 1. Such situations present doctors with ethical challenges and questions the role of parental autonomy because the parents making a wrong decision about their child's health, not only puts the child's life at risk but also increases the risk for the rest of the population (22).

MATERIAL AND METHODS

Two online journal databases, Pubmed and Science Direct were used to carry out in-depth searches between January 2005 and April 2016 to retrieve studies investigating the reasons for why parents refuse to get their children vaccinated and to identify the most frequently occurring causes of concern amongst parents.

To ensure the study selection process was specific and to minimize bias, the inclusion criteria (figure 2) was set before the search was carried out and only studies that matched the inclusion criteria were reviewed and the rest were excluded based on the exclusion criteria (figure 2).

As seen in figure 3, the initial search generated 460 results using the two online databases and after thorough evaluation of the search results, only 5 studies were eligible to be included in the review.

✓ INCLUSION CRITERIA	✗ EXCLUSION CRITERIA
<input checked="" type="checkbox"/> Studies published within the last 11 years	<input checked="" type="checkbox"/> Studies published before 2005
<input checked="" type="checkbox"/> Studies in English language	<input checked="" type="checkbox"/> Studies in any other language than English
<input checked="" type="checkbox"/> Full-text articles	<input checked="" type="checkbox"/> Studies not evaluating reasons for parental refusal for vaccines
<input checked="" type="checkbox"/> Human trial	<input checked="" type="checkbox"/> Abstracts only
<input checked="" type="checkbox"/> Studies investigating parental concerns regarding vaccine refusal	<input checked="" type="checkbox"/> Animal studies

Figure 2: The Inclusion and Exclusion Criteria Used to Select Studies to be Included in this Review

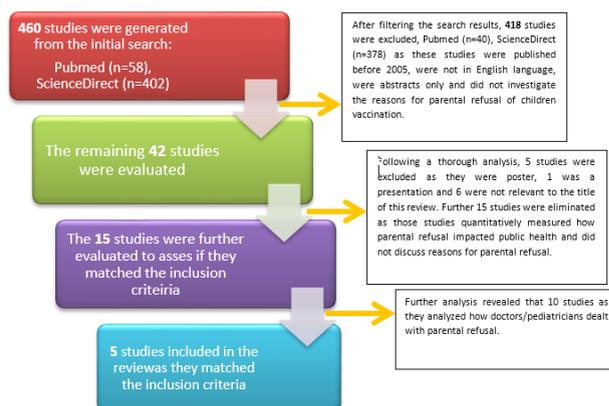


Figure 3: Systematic Process used to Gather and Evaluate Studies to Include in this Review

RESULTS

After a thorough analysis of search results generated from online databases, 5 studies (23-27) were included in this review as they met the inclusion criteria that was set before conducting the search. All the studies included were published within the last 11 years and the main aim of the studies was to investigate the reasons for parental concerns in regards to getting their children getting their vaccinated.

In 2009, Salmon et al (23) carried out a case-control study investigating parental vaccine refusal in Wisconsin. They found that 57% of the parents who did not get their children vaccinated stated that they believed that vaccines might cause more harm than good to their children. Even though, the parents in the control group had got their children vaccinated, 34% of them were still worried that if their children receive more vaccinations than they need, their immune system could be weakened. Other reasons given by the parents for not getting their children vaccinated included the fear that the children might get autism (31%), the parents believed that their child was not at risk for diseases (37%) and 38% of the parents believed that it was better for their child to get natural diseases than vaccines. Various vaccine related beliefs were also stated in the survey and the participants were asked to either choose if they agreed or strongly agreed with the results. It was found that only 61.1% of the parents of the children who refused vaccines believed that vaccinations are getting better and safer over time as a result

of developed medical research, compared to 94.4% of parents in the control group either agreeing or strongly agreeing with this vaccine related belief. Another significant finding was that 26.3% of parents who refused vaccines agreed or strongly agreed with the belief that the harm caused by vaccinations outweigh the benefits, compared to only 2.3% of parents in the control group agreeing with this belief.

Salmon et al (24) also conducted a study in 2005 in which their aim was to understand why parents claimed non-medical exemptions for their children and they also wanted to explore different perceptions of vaccines and vaccine information sources between parents of exempt and fully vaccinated children. This was also a case-control study in which surveys were mailed to parents of 815 exempt children and 1630 parents of fully-vaccinated children. Most of the exempt children (53.1%) had not received the varicella vaccine and 75.5% exempt children at received at least one vaccine. It was found that the most frequent reasons for obtaining exemptions were that the parents were concerned that vaccines might cause more harm than good (69%) and that vaccinating their children might overload the child's immune system leading a weakened immune system (49%). Several other reasons given by parents for refusing to get their children vaccinated included the beliefs that the child was not at risk of developing the disease (37.2%), the vaccines might not be effective (13%), the disease was not dangerous (20.9%). Ethical and moral issues such as use of aborted cell lines and fetal tissue and testing vaccines on animals were also some of the reasons given by 9% of parents of exempt children. Further 9% of the parents obtained exemptions on religious grounds. When the beliefs related to benefits of vaccines were evaluated, it was found that only 47% of parents of exempt children reported that getting fully vaccinated was beneficial for their children, compared to 95.5% of the parents of fully-vaccinated children who strongly believed that vaccinations had a huge positive impact on their child's health.

Khan et al (25) carried out a qualitative study in 2015 in the Khyber Pakhtoon Khawa (KPK) province in Pakistan in which they investigated the challenges faced by health workers and to explore the factors leading to parental refusal for oral polio vaccination (OPV). The results showed that majority of the health workers experienced aggressive public behavior and received security threats. It was reported that the common concerns expressed by parents for refusing the OPV vaccine was on religious grounds as they stated that the vaccine was

not permitted in Islam as it said to contain the blood of monkeys and pigs. Parents were also concerned as they believed that the purpose of vaccinating the children was to induce sterility. The health workers also reported that many parents strongly believed that there were conspiracies against them and by vaccinating their children, they would be helping the CIA achieve their agendas .

A qualitative study assessing the opinions, beliefs and attitudes about vaccination, of parents who refuse to get their children vaccinated found that majority of the parents believed that it was better for their child to suffer from any of the vaccine preventable diseases as they were natural and beneficial to the body as these diseases help the child's body and immune system stronger. Some parents also argued that vaccines haven't been effective in decreasing the prevalence of vaccine preventable diseases and so, therefore they are not necessary. It was reported that the one of the most frequent causes of concerns was regarding the safety of vaccines and their associated adverse effects. Some parents also believed that vaccines were extremely damaging for the body, were highly toxic and had unknown adverse effects which were more severe than the diseases these vaccines are supposed to prevent. The parents of children who refused vaccines also believed that vaccination programs are based on biased studies and have other hidden interests other than disease prevention (26).

Another study was conducted in 2015 which investigated the reasons given by parents who accepted or refused for their daughters to have the HPV vaccine. 806 parents responded to the mail-in questionnaire and it was found that 88% of the parents agreed to have their daughters vaccinated as they believed the benefits outweighed the risks of the vaccine. However, those parents who refused to have their daughters vaccinated justified their decision by giving reasons including the fear of unknown adverse effects related to the vaccine and that they believed their daughter had low susceptibility to developing cervical cancer so their daughter was not at risk, therefore, she did not need the vaccine. Even though 88% of parents agreed to have their daughters vaccinated, both groups of parents were still unsure and had some doubts about the vaccine (27).

DISCUSSION

The results of this review are important for several reasons, but the most important reason being that these results very clearly show that the parents who make de-

cisions to not get their children vaccinated do not have a proper understanding of vaccine-related benefits and that their beliefs are based on false assumptions. In all the studies reviewed, the results showed that the most common reasons for vaccine refusals were concerns regarding vaccine safety and the belief that the children did not need to be vaccinated as they had low susceptibility to developing vaccine-preventable diseases.

The results of the 2015 study carried out in KPK, Pakistan showed that parents based their decisions to refuse vaccines on beliefs that vaccines were conspiracies against the Pakistani government (25). Such beliefs, combined with results from other studies reviewed demonstrate a strong need for people to be educated (28) about the importance of vaccination and how the benefits outweigh the risks and most importantly, that vaccines play an important role in strengthening the immune system and decreasing the risk of any individual suffering from infectious, harmful diseases. From all the studies included in this review, it was observed that all parents, regardless of whether they chose to get their children vaccinated or refused to get them vaccinated, received information regarding vaccines from health care professionals, however, parents who refused to get their children vaccinated were always more likely to consult other sources for more information. The problem with this could be that not all sources provide scientific information and could actually provide these parents with inaccurate information, misleading them and negatively influencing their decisions (29,30). Studies have shown that usually, the parents preferred source of information is health care professionals. In 2009, the National Center for Immunization and Respiratory Diseases conducted a survey, the results of which showed that for parents, when making decisions regarding vaccinating their children, the most important source of guidance was the child's doctor or nurse. 86% of the participants included in the survey reported that they actually followed the doctor's advice because they trusted that the information given to them was accurate. Another study reported that 76% of the participants trusted their doctors advice in regards to getting their child vaccinated and about the safety of vaccines, compared to only 2% who reported that they did not trust their doctors information at all (38). These studies highlight the role of the doctor in vaccine-acceptance by parents. Taking these results into consideration, it is important to undertake different strategies to deal with parents who refuse to get their children vaccinated. Rather than agreeing with the parents and turning away the children of parents who refuse vaccines, it may be better to discuss in-depth with the parents what the-

ir concerns are and educate them about the benefits of vaccines.

These results question the parent's role and credibility in deciding whether their children should be vaccinated or not. It can be argued that parents feel like they know best and they would not make decisions which would cause harm to their children, however, it is crucial to understand that such parents make their decisions based on inaccurate information, especially because they are more likely to consult other sources, than just their doctor before making any decisions. It is also important to realize that parents refusal for getting their children vaccinated has led to an increase in the outbreak of vaccine preventable diseases such as measles. Despite measles being eliminated in 2000, there was an outbreak of measles in US in 2011, which not only had a huge impact on public health but also placed a huge economic burden on the United States health departments. In that year, a total of 222 cases of measles were reported from 31 states with the median age of patients being 14 years of age, 14% of the patients were under 12 months of age and 26% were between 1-4 years of age. 65% of the affected patients were unvaccinated and 21% had an unknown vaccination status. According to the Centers for Disease Control and Prevention (CDC), the cost of managing these cases cost up to \$5.3 billion. Treatment of each individual case was estimated to cost \$11,933 to \$29,833 (31). In the light of these findings, it is extremely crucial to know that treatment of vaccine preventable diseases costs significantly more than vaccinating children. Parents not having an in-depth understanding about vaccines and their benefits is causing vaccine preventable diseases such as measles, to re-emerge, which is a problem because these diseases were so close to being declared eradicated in Europe (42).

CONCLUSION

This review was carried out to investigate the reasons for which increasing number of parents do not vaccinate their children and to address the issue of limitation of parental autonomy in deciding whether their children should be vaccinated or not.

From the results of the studies included in this review, it can be concluded that most of the parents refuse to get their children vaccinated as they are concerned about vaccines causing more harm than good and they also believe that vaccines are not safe as they lead to a weakened immune system of infants which causes au-

to-immune diseases. It is also widely believed that vaccines are toxic, aggressive to the body and have the ability to change the body's natural processes, but they consider vaccine-preventable diseases to be beneficial for the body and believe that they are very easy to treat so it is better for children to suffer from vaccine-preventable diseases because it also strengthens their immune system. However, it is hard to understand why parents would refuse to get their children vaccinated as their purpose is to prevent the development and spread of severe diseases. Vaccine-associated side-effects are overestimated and are perceived as more severe than vaccine-preventable diseases and associated complications.

Vaccine programs are starting to become less effective due to the limited understanding of the purpose of vaccines and the associated potential harm caused by them. However, the effectiveness of the vaccine is not the only factor that needs to be taken into consideration but other factors, such as the patients willingness to get vaccinated should also be taken into account. The problem with underage children is that they cannot give consent for being vaccinated or make decisions for themselves, as a result of which it is the parents who are asked for consent to get their children vaccinated.

The questions that needs to be asked here is how it makes sense for parents to decide if it is safe for their children to get vaccinated or not when they do not even understand the purpose of vaccinations or how beneficial vaccines actually are.

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