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Ethically Addressing Vaccine Hesitancy in Pediatric Populations

By

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Of Master of Science

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## **I. Abstract**

Vaccines are highly regarded in the scientific and medical community for their efficacy in the prevention of disease; yet the prevalence of misinformation and mistrust surrounding vaccines is growing in communities around the world. Specifically observed in the United States (US) as an increase in vaccination exemption rates, this trend of vaccine hesitancy is leading to an increasing number of parents and caregivers to either refuse or delay vaccinations from the recommended schedule. As a result, an increasing number of outbreaks of diseases such as measles and pertussis, thought to be on the verge of elimination, have spiked. While health professionals direct attention to this issue, it is important to have a firm understanding of the epidemiology of vaccine hesitancy; as well as a familiarity with leading strategies in addressing it. As much of the focus is placed upon efficacy of interventions, it is equally important to recognize the ethical implications of these interventions and how they improve or impede the patient-provider relationship. Interventions of education, presumptive language, motivational interviewing, mandatory vaccine policy, and modified vaccination schedules were evaluated for efficacy and compliance with the four pillars of medical ethics: patient autonomy, beneficence non-maleficence, and justice. Consistent themes throughout the literature found that the most important element for improving vaccination efficacy is ensuring a level of trust between the parent/caregiver and provider.

## **II. Introduction**

Vaccines are considered one of the greatest advancements in health technology in modern history. The discovery and implementation of vaccinations have forever changed the way humans view and manage certain infectious diseases. By exposing humans to muted or nullified

versions of diseases in order to help them build up immunities, vaccinations have proven to be very successful in disease prevention and in some cases disease elimination.<sup>1</sup>

The World Health Organization (WHO) declared the first eradicated disease, smallpox, in 1980 as a result of a robust global vaccination program.<sup>2</sup> Four of the six WHO regions have made significant progress in immunization programs especially pertaining to measles, due to achieving immunization rates of over 90%.<sup>1</sup> The United States (US), in particular, declared the elimination of endemic measles in the year 2000. According to the US Center for Disease Control and Prevention (CDC), childhood vaccine administration has greatly reduced the prevalence and mortality of 14 potentially deadly diseases (Table 1).<sup>3</sup>

Currently, the majority of children in the US receive the recommended scheduled vaccinations.<sup>4</sup> However, during the past decade there have been a growing number of parents and caregivers (caregivers will be henceforth referred to as parents) that are choosing to delay or refuse the administration of recommended pediatric vaccinations to their children; despite the overwhelming evidence of efficacy.<sup>4</sup> The reasons that parents are becoming increasingly vaccine hesitant are quite varied; from lack of trust, to religious and moral objection, to concerns about safety. In addition to the health and safety of the individual child, the major concern with this phenomenon is that there would be a loss in the percentage of vaccinated individuals needed to maintain “herd immunity” to many of the currently preventable diseases.

The most recent example of such an instance is the increase in measles cases over the last 10 years in the US. According to the CDC, there were over 1249 documented cases of measles in 2019. 89% of these cases were not vaccinated against the condition.<sup>5</sup> And even though pertussis infection remains endemic in the United States, research has shown the incidence has been steadily on the rise since its lowest point in 1976.<sup>5</sup> Since 2010 major measles and pertussis

outbreaks have been reported in the states of California, Oregon, and Washington, with a large majority of the related cases being either unvaccinated, or under-vaccinated.<sup>6</sup>

The challenge of combating this trend increasingly falls on healthcare providers, and public health officials. They must tactfully navigate strategies to serve parents and patients by improving vaccination uptake and adherence to evidence based immunization schedules. When designing and implementing strategies aimed at addressing the trend of vaccine hesitancy, it is important to analyze interventions not only on their efficacy, but also the ethicality of such interventions.

This paper intends to use the research available to gain a better understanding of parental vaccine hesitancy; present the most prominent interventions to address hesitancy; and analyze these interventions within the four pillars of medical ethics (patient autonomy, beneficence, non-maleficence, and justice). Ethical analysis will incorporate both the consequentialist and deontological theory of ethics. In consequentialist theory of ethics, the focus is primarily on the sum of the results of individual actions. In deontological theory of ethics, the focus is primarily on the individual actions themselves.<sup>7</sup> For the purpose of this paper, consequentialist theory can be viewed as a focused benefit on the community, whereas deontological theory can be viewed as a focused benefit on the individual child and parent. Interventional recommendations will then be extrapolated to help providers address vaccine hesitancy in a manner that balances both ethicality and efficacy.

### **III. Background: Literature Review**

#### *Defining Vaccination Hesitancy*

In order for health professionals to truly be engaged in effective dialogue for vaccination hesitancy with parents, there should be a clear understanding of what vaccine hesitancy is and

what are the main factors causing it. In 2015, the WHO Strategic Advisory Group of Experts (SAGE) defined vaccine hesitancy as a “delay in acceptance or refusal of vaccination despite availability of vaccination services.”<sup>8</sup> This definition was agreed to be the most adequate, because vaccine hesitancy lies on a continuum between those who accept vaccines without doubt, and those who completely refuse all vaccines with doubt. This vaccine hesitancy definition also includes those that choose to vaccinate on a delayed or alternative schedule. This distinction is important as vaccine hesitancy is traditionally confused with vaccine refusal.<sup>8</sup>

The term was created to depolarize anti-vaccination rhetoric, which was shown to negatively stigmatized parents that are cautious about vaccination programs.<sup>8</sup> Providers are typically able to distinguish someone who is vaccine hesitant versus someone who refuses all vaccinations based on discussions regarding administration of vaccinations. Instead of refusing all vaccinations, a parent who is vaccine hesitant will be more likely to ask questions, request an alternative vaccination schedule or make requests to postpone or delay certain vaccinations.<sup>4</sup>

#### *Prevalence of Vaccine Hesitancy*

In the US, the childhood vaccination rate has remained consistently high over the past 5 years<sup>9</sup> as a result of robust vaccination programs, and legislation requiring vaccinations for entry into schools and daycare. However there is a concerning trend of an increase in parents claiming vaccine exemptions (medical or non-medical reasons for a child to be legally excused from vaccination requirements) to these state laws. A systematic review done by Bednarczyk et al looked at national and state trends of both medical and non-medical vaccine exemptions from 2011-2018.<sup>9</sup> They reviewed school entry vaccination data reported to the CDC and state health departments. The results found relatively stable vaccination rates throughout the target years, as well as a stable rate of medical exemptions for vaccinations ranging from 0.2% to 0.3%. There

was an increase in the national rate of non-medical exemptions from 1.2% to 2.0%. The article also found that students placed in US private schools, were approximately two times more likely to have a non-medical exemption than those in public schools.<sup>9</sup>

In addition, research has found a significant amount of vaccine hesitancy in expectant parents. In a 2018 study, researchers surveyed 610 expectant mothers and 38 expectant fathers to assess attitudes concerning vaccinations.<sup>10</sup> The results found that 8.2% of the expectant parents met the definition of vaccine hesitant. The study also found an association between vaccine hesitancy and mothers who were non-Hispanic white, married, and over 30 years old. Women who had up to a college degree were 2.2 times more likely to be vaccine hesitant than those with more than a four- year degree. The biggest correlation was found in that expectant mothers that did not receive an annual influenza vaccination were 7.2 times more likely to be vaccine hesitant.<sup>10</sup>

#### *Factors Producing Vaccine Hesitancy*

The reasons that parents fall under this vaccine hesitant category are many. A WHO study published in 2018 surveyed 194 member states over 3 years and asked for the top reasons that they experienced vaccine hesitancy in parents.<sup>11</sup> The 3 most consistent themes from the survey were 1) risk-benefit profile, 2) lack of knowledge, and 3) sociological factors. Hesitancy due to the perceived risk-benefit profile of vaccinations appeared in an average of 23% of the responses over the course of the study. Factors in the category consisted of beliefs and fears about the safety of vaccination, with special consideration directed towards fear of side effects. Lack of knowledge made up an average of 13% of the responses. The authors noted that this response mostly related to the lack of knowledge that the parents had surrounding the need and benefits of vaccinations. Rounding out the top three reasons for vaccine hesitancy with 10% of

the responses, was sociological concerns. This category included factors such as religion, culture, gender, and socioeconomic issues surrounding vaccines.<sup>11</sup>

In addition to the WHO survey results, a global meta-synthesis literature review was conducted by Diaz et al in 2019.<sup>12</sup> The review surveyed 27 studies representing 1557 responses, from 9 countries. From the studies, they were able to identify five factors reported by parents leading to vaccine hesitancy: 1) risk conceptualization, 2) mistrust, 3) alternative health beliefs, 4) philosophical view/ responsibility, and 5) parent's information. Risk conceptualization was cited in 22 of the 27 studies reviewed. The authors noted that risk conceptualization not only included the perceived risks of receiving the vaccine, but also the contextual risk (the likelihood that the child would contract the disease), and the target disease risk (the severity of the disease if contracted by the child). Mistrust was also cited in 22 out of the 27 studies. The studies specifically cited feelings of mistrust of the financial motives of health/pharmaceutical institutions; the integrity and competency of providers; and the manipulation of how official health information is presented in the media, with focus on how side effects are minimized. Alternative health beliefs were again identified in 22 out of the 27 studies and focused on the parental beliefs that the presumed toxins used in vaccines, along with the dosing schedule, would interfere with the development of the child's natural immune system. The philosophical view/ responsibility theme was cited in 18 of the 27 studies, and was centered on the parent's responsibility to make the best decision for their child based upon their world belief system. Parental information was identified as a theme in 16 of the 27 studies. Most notably the lack of information provided by health providers was most often cited. This was followed by lack of objective information and information retrieved from other sources (i.e. word of mouth, parenting and lifestyle magazines).<sup>12</sup>

In 2019 Gidengil et al did a systematic review of 71 studies to assess attitudes towards vaccines specifically in the US.<sup>13</sup> Of the parental beliefs that were classified as vaccine hesitant, or at risk of being vaccine hesitant, three themes stood out. The leading theme identified in 36 of the 71 studies was potential adverse effects by vaccines. Aside from autism, the leading fears expressed were: damaging the child's natural immune system, development and neurological disorders, behavior disorders, diabetes, liver problems, cancer, and death. The second major theme was mistrust, identified in 11 of the 71 studies. While some studies did reference mistrust of physicians and institutions (i.e. healthcare and government systems), the belief that vaccines are distributed and produced for profit, and not prevention, was the most common belief. The third theme identified in 6 of the 71 studies is the lack of necessity of vaccinations. This belief largely held that the naturally acquired immunity (i.e. from infection with a pathogen) is better than artificial acquired immunity gathered from inoculation. Also included in this belief grouping is that there are more "natural" methods to obtaining the same health benefits in vaccines and that controlling the child environment can decrease the likelihood that the child comes in contact with the target disease; thus not needing the vaccination. Other beliefs mentioned in the literature, but were not as prominent, were: lack of effectiveness, strong sense of autonomy, and moral/ religious objections.<sup>13</sup>

### *Strategies for Vaccine Hesitancy*

Administration of vaccinations has become a hallmark of preventative care in the developed world. And while access to vaccinations still remains the priority, research is growing as to how to increase the uptake of available vaccines and combat vaccination hesitancy. A systematic review by Dube et al in 2015 analyzed 15 literature reviews to assess the most effective strategies for addressing vaccine hesitancy.<sup>14</sup> Results of the study found that parent

centered education was statistically effective in improving a parent's intention to vaccinate their child, however there was no evidence that the intervention improved actual vaccination rates.

The review went on to state that though there has not been any convincing evidence to improve vaccination uptake, the logic framework suggests that the most effective interventions: 1) increase community demand for vaccinations; 2) enhance access to vaccinations; and 3) are provider-based and have empirical support.<sup>14</sup> For the purposes of this paper the five intervention strategies chosen for addressing vaccine hesitancy are: 1) patient education, 2) mandatory vaccination policies 3) motivational interviewing, 4) presumptive language, and 5) modified vaccination schedules.

### *Education*

One of the mainstay responses to vaccination hesitancy from providers is increasing focus on parent education about the vaccine. It is important to start this education as early as possible because research is making it more apparent that attitudes and thoughts about vaccination decisions for parents are starting as early as pregnancy. Danchin et al completed a study that followed 975 mothers pre and post birth.<sup>15</sup> The study found that 49% of first time mothers had significantly more concerns about vaccinations during pregnancy; and 73% had already come to a decision about vaccinations by the time the child was born. The study also concluded that first time mothers are more likely to be vaccine hesitant, however there is a strong evidence to suggest that mothers who have been adequately educated on vaccines have more of a willingness to vaccinate.<sup>15</sup>

One of the more difficult aspects of educating patients, especially those that are concerned with vaccinations, is the time component. A 2011 study cited a survey of 596 physicians, of which 53% reported spending 10-19 minutes per office visit educating patients on

vaccinations; and 8% reported spending over 20 minutes per visit.<sup>16</sup> Considering that the average provider-patient interaction during an office visit lasts an average of 20 minutes, that is a sizeable percentage of time. The fact that misinformation is readily accessible also presents a challenge in educating patients. One of the strongest myths providers have to combat is the exaggerated harm profile of vaccinations, and their link to neurological disease.<sup>17</sup> In the end, the nature of vaccine hesitancy is so complex that there is not strong evidence to suggest that education alone is very effective.<sup>14</sup>

### *Mandatory Vaccination Policy*

In most resource-rich countries, especially the United States, legislation has been used to increase the uptake of vaccinations and ensure that the compliance rate is elevated. Since state sponsored vaccination programs are linked to admission of schools and daycares, this makes vaccination mandatory for all children; with the exception of qualified exemptions. The two categories of exemptions are medical and non-medical. Medical exemptions are given by health providers in the rare case that the side effect, or danger of an adverse reaction to the vaccine is severe. Non-medical exemptions are given on the basis of moral, religious, or philosophical objections to the vaccine. According to the National Conference of State Legislatures, currently only 5 states have outlawed non-medical exemptions (California, Mississippi, West Virginia, New York and Maine).<sup>18</sup> Forty-five states and Washington D.C. allow religious exemptions and 15 also allow philosophical exemptions.<sup>18</sup>

As noted previously, there is a gradual increase for parents requesting exemptions for vaccinations, which has resulted in increases in the presentation of vaccine preventable diseases.<sup>19</sup> This increase in exemptions has also been found to be associated with a geographic clustering phenomenon. Lieu et al looked at observed data from the Kaiser Permanente Northern

California database (prior to the 2016 law disallowing non-medical exemptions) and found 5 statistically significant geographical clusters of under-vaccinated children. The under-vaccination rate inside the cluster ranged from 18-23% while the under-vaccination rate outside the cluster was 11%.<sup>20</sup> There is a strong case to be made for policy to play a substantial role in combating vaccine hesitancy. Studies have shown that areas with more stringent vaccine exemption laws have better vaccine compliance.<sup>21</sup>

### *Motivational Interviewing*

Originally developed for substance abuse, motivational interviewing has become a very popular tool amongst health professionals in helping to engage the patient in changing a specific attitude or behavior. Instead of simply providing the patient with information, it takes into account the patient's beliefs on the issue and helps them come to the necessary solution. Motivational interviewing is based on the three principles of cultivating a partnership with the patient; targeting a shared goal; and understanding and adapting to the patients needs. A study in Canada done by Gagneur et al decided to look into the effects of motivational interviewing when it comes to promoting vaccine uptake with new parents.<sup>22</sup> In the study, researchers would conduct a motivational interviewing session with previously screened mothers 24-48 hours after delivery. Researchers found a child vaccination rate increase of 3.2%, 4.9% and 7.3% at 3, 5, and 7 months respectfully compared to infants whose moms were not exposed to motivational interviewing.<sup>22</sup> While research is still being conducted as to the practical impacts of motivational interviewing in vaccine hesitancy; well documented benefits of motivational interviewing as it corresponds to behaviors such as smoking cessation, dental carry prevention, and self-care are encouraging.<sup>23-25</sup>

### *Presumptive Language*

Currently presumptive language training (also known as announcement training), teaches providers to operate under the assumption that parents are planning to vaccinate their children. It is the best practice recommended by the CDC. The main basis for this strategy was highlighted in a 2015 observational study done by Opel et al.<sup>26</sup> In the study researchers recorded 111 physician and parent vaccine discussions and observed whether or not the parent would agree to the vaccine recommendation by the provider. The results showed that when the provider used presumptive language, 89.9% of parents received all vaccinations by the end of the visit in contrast to 16.7% of parents when participatory language was used. However the study found only 63.8% of the parents that received presumptive language reported a high rated visit experience, compared to 95.8% of the parents that received participatory language.<sup>26</sup> It is also important to note that using presumptive language still maintains following proper protocols for obtaining informed consent. The strength in this strategy is the rephrasing of the prompt to present vaccines to the parents in a non-pressured way; with the goal of normalizing the intervention.

### *Modified Vaccine Schedules*

Vaccination schedules in the US were designed and recommended by the Advisory Committee on Immunization Practices (ACIP).<sup>27</sup> It is a schedule designed to promote maximum vaccine coverage by aligning vaccine administration with routine well child visits. Alterations or modifications to the current CDC vaccination schedule are not recommended by the CDC, ACIP, or the American Academy of Pediatrics (AAP), due to the increase risk of under vaccination, and increased health care costs due to multiple visits.<sup>27</sup>

A cross-sectional online survey by Mohanty et al assessed the prevalence of modified vaccine schedules amongst providers.<sup>28</sup> Representing all four chapters of the AAP, 374

physicians were surveyed. 58% reported frequent requests for modified or alternative immunization schedules, and 24% reported feeling comfortable using them. The study also found that providers that work at practices that allow for modified vaccinations schedules are more likely to have a high number of modified schedule requests from parents; and are more likely to believe that refusal of requests would negatively affect the provider-patient relationship.<sup>28</sup>

#### *Four Pillars of Medical Ethics*

In order to evaluate the ethicality of each of the discussed strategies, a widely accepted ethical standard must be used. The four pillars of medical ethics, also known as the four principles of biomedical ethics, was put forth by Tom Beauchamp and James Childress in 1985.<sup>29</sup> This philosophical framework is widely used by, and taught to health providers to help them engage in ethical decision making. The core tenets of medical ethics are patient autonomy, beneficence, justice, and non-maleficence. Autonomy requires that the patient or caregiver be given the freedom and power of the decision maker when it comes to health procedures. In order for patient autonomy to be fully realized, it must be free of coercion, and requires all of the risks and benefits to the procedure to be fully understood. Beneficence requires that the intervention is in the patient's best interest and that all efforts have been made to give the patient the maximum benefit. Non-maleficence is very similar to beneficence, yet the focus is on the risks associated with the intervention. This requires ensuring no harm or minimal harm, in the context of a greater benefit, is done to the patient. Justice speaks mostly to the equitability of the treatment being provided to the patient in that it is upholding all laws and not discriminating against the patient in any way.<sup>29</sup>

## **IV. Methods**

### *Inclusion Criteria*

In order to meet the inclusion criteria for the literature review an article had to be relevant to at least one of four points. 1) The article focus must address childhood vaccinations 2) The article focus must address epidemiology of vaccine hesitancy 3) The article focus must address vaccination in relationship to ethics. 4) The article focus must address strategies to increase vaccine uptake.

### *Article Collection Method 1*

The acquisition of articles for the background literature was conducted using the PubMed database accessed through Augsburg University Lindell Library. The initial search was conducted using the Medical Subject Heading (MeSH) term search:

“(“Vaccination”[Mesh]) AND (“Vaccination/ethics”[Mesh] OR “Vaccination/legislation and jurisprudence”[Mesh] OR “Vaccination/trends”[Mesh] OR “Hesitancy”[Mesh] OR “Childhood”[Mesh])”

The search yielded 2,790 results. The PubMed search parameters were then limited to articles classified as “systematic reviews”, “review”, or “meta-analysis” with a publication within the last 10 years (since 2010). The remaining 243 articles were screened by title and abstract based upon the inclusion criteria set. 8 articles were selected with this method.

### *Article Collection Method 2*

Subsequent PubMed searches were done using various combinations of the key words: “vaccine”, “hesitancy”, “ethics”, “United States”, and “prevalence”. All search parameters were limited to articles classified as “systematic reviews”, “review”, or “meta-analysis” with a

publication within the last 10 years (since 2010). The articles were screened by title and abstract based upon the inclusion criteria set. 22 articles were selected with this method.

#### *Article Collection Method 3*

Searches were conducted using the search engine Google Scholar. Keywords included “vaccine hesitancy”, “vaccination prevalence”, and “modified vaccination schedule”. Results that met inclusion criteria were then verified by searching the article by title and author on the PubMed database. Other articles included in the literature review were selected from the “similar articles” listing on articles selected by the three above methods if they a) met inclusion criteria and b) were not redundant to previous articles. The total number of articles reviewed were 30.

### **V. Discussion**

Vaccination hesitancy has the potential to do a lot of damage to public health in the US as well as countries around the world. The growing distrust that parents have towards health providers, and the medical community at large, is something that needs to be addressed. This is why it is increasingly vital that health providers act with integrity, and within the ethical framework established by the four pillars. Not only do these serve to help provide quality care to patients, these also set the stage to establish a relationship of trust with the families that providers serve. Each of the strategies reviewed for the management of vaccine hesitant parents has unique strengths and weaknesses when evaluated in the context of the four pillars.

#### *Analysis of Strategies Under the Four Pillars*

##### *Autonomy*

Patient autonomy, or in this case parental autonomy, requires that the parent have final say over the decision of whether or not to have their child vaccinated. To operate under the full scope of the autonomy principle of ethics, it will require a conversation to be had with the parent to

understand the exact reasoning that they are hesitant on the vaccination, as well as allow the parent to be fully informed to make the best decision possible.

The education strategy accomplishes this goal very well as it requires ensuring the patient is well informed about the research available regarding vaccines. Motivational interviewing also fits well in encouraging patient autonomy, as the strategy is founded upon establishing open communication with the hope of achieving the common goal of making a decision in the best interest of the child and community. As discussed previously, modification of vaccination schedules is also another strategy used often as a last resort, and is growing in popularity amongst patients. Two strategies that challenge the autonomy component of medical ethics are mandatory vaccine policies and announcement training.

As previously discussed, mandatory vaccination policy has been an effective strategy for vaccine compliance in the US, but it does not fully embrace the autonomy of the parent in the decision making process. As far as public sentiment goes, a systematic review by Gualano et al in 2018 found that while there is a general decrease in opposition to mandatory vaccinations from 12% in 2010 to 10.8% in 2016; in certain areas of the US, such as rural Ohio, 47% of the respondents felt that parents should have the right to refuse vaccinations without penalty (e.g. limiting access to public education).<sup>30</sup>

Some states are pressing for even more stringent mandatory vaccination policies. In 2016 California passed a bill getting rid of the non-medical exemption status for vaccinations which was successful in decreasing the unvaccinated kindergarten rate in 2017 from 7.15% to 4.42%. However by 2018 the percentage of kindergarteners who were not up-to-date in their vaccinations increased from 0.45% to 4.87%. This change was largely attributed to vaccination workarounds and parents opting to pull their children from the public education system.<sup>31</sup> This

phenomenon echoes a study from Germany where individuals responses to compulsory vaccinations were observed. In the study of 297 participants, they found that those who already had a somewhat negative perception of vaccines experienced increased anger with the vaccinations that were mandatory, and resulted in a 39% decrease in the uptake of vaccines that were voluntary.<sup>32</sup>

Presumptive language also pushes the bounds of the parent's autonomy. While presumptive language has been proven effective in increasing vaccine uptake with patients<sup>26</sup>; the challenge to patient autonomy is a lot more subtle than mandatory policies. Using presumptive language, providers are trained to presume that parents are ready to vaccinate rather than to engage in a dialogue to understand their thoughts and feelings about the vaccine.<sup>33</sup> While this method does not create a penalty for those who choose not to vaccinate their children, it does call into question the adequacy of informed consent. According to The Joint Commission, informed consent consists of five required elements: 1) the nature of the procedure, 2) the risks and benefits and the procedure, 3) reasonable alternatives, 4) risks and benefits of alternatives, and 5) assessment of the patient's understanding of elements 1 through 4.<sup>34</sup> Presumptive language can be felt as a type of coercive technique that sits in contrast to the goals of informed consent, and promoting autonomy of the parent.

### *Beneficence*

Beneficence requires that the intervention will provide the patient with maximum benefit. In pediatric vaccination conversation it must be understood that both the parent and provider share the desire for the child to receive the maximum benefit from any intervention. The challenge for the provider is implementing a strategy that allows maximum benefit to the child but also allows the parent to trust that benefit as well.

Education, motivational interviewing, mandatory vaccine policy, and announcement training all support the goals of beneficence in addressing vaccination hesitancy. Each of these strategies operate with the main focus on the maximizing the benefits of vaccination for the child.

However the strategy of modified vaccination schedules does not fit under the role of providing maximum benefit to the child . A national survey in 2013 gathered that 1 in 10 parents intentionally delayed vaccinations.<sup>27</sup> The reason this issue is particularly important is that a delay in vaccinations has been linked to progressive under vaccinations. A Smith et al study observed over 2900 parents and found that of the 21.8% of the parents that chose to delay vaccinations only 35.4% received all recommended vaccines by 19 months.<sup>35</sup>

The benefit of vaccinations is not only seen in the individual, but even more so in the community at-large. As the number of vaccinated individuals in a population increases, the protective vaccination benefit increases in the community. Under vaccination has been highly suspected as the source of many disease outbreaks such as measles, which had been declared as eliminated in 2000. Phadke et al reviewed the association between under- vaccinated or unvaccinated populations and measles and pertussis outbreaks from 2000 to 2016. They found that inadequately vaccinated individuals comprised a substantial portion of measles outbreak cases, and they posed a risk to populations whose vaccinations were up to date.<sup>6</sup>

### *Non-Maleficence*

Non-maleficence is the aspect of ensuring that the intervention does not harm the patient. Fear or concern for adverse effects of vaccines is the most reported reason parents give for being hesitant. From invention, vaccinations have always had opposition due to concerns of their safety, but arguably the biggest controversy arose when a 1998 Lancet study claimed an association of the Measles-Mumps-Rubella (MMR) vaccine to Autism Spectrum Disorder

(ASD). After further reviews found many errors with the methods of the original study, and follow up studies obtained evidence contrary to its conclusion; the study was thrown out and the article was retracted in 2010.<sup>36</sup> However the mistrust it sparked in the safety of vaccines still impacts many parents today. The most recent study done on the association of MMR and ASD was captured in 2019, when DeStefano et al reviewed 11 studies containing data from four countries spanning the time period of 1979 to 2012. All of the studies found that there was no statistical association between MMR vaccination and ASD.<sup>17</sup> Other leading concerns for vaccine hesitant parents are on the number of vaccinations over- taxing the immune system, and the binding agents used in vaccine formulations, (i.e. mercury and aluminum). It is important for providers to reassure parents that vaccines are constantly being tested, and educate them on the methods used which have deemed them safe.<sup>37</sup>

But even in combating myth, it is important for the provider to be honest, and not downplay potential adverse effects. A 2013 study sought out to assess the relationship between informed risk and perceived risk involving vaccinations. They found that messages strongly indicating “no risk” actually led to higher perceived vaccination risk than a weak negation of risk.<sup>38</sup> In order to act in the full scope of ethical practice, providers need to be honest about the adverse effects that have been found to be associated with vaccinations.

As discussed previously, a growing response to the concern for potential side-effects of vaccines is requests for a modified vaccination schedule. However the longer a child goes without recommended vaccinations, the higher the risk is of the child contracting a disease and potentially transmitting it to others. All of the other strategies discussed earlier serve to promote the tenant of non-maleficence, but the education strategy focuses on it the most. Through providing the parent a complete understanding of the risks and benefits of vaccines administered,

the provider not only helps the parent make an informed decision, but most importantly, they increase the level of trust in the provider-patient relationship.

### *Justice*

Justice is focused on the equity and equality of the interventions not solely for the patient but also for the society at large. Unlike other medical interventions, vaccination doesn't just affect the individual patient, but because of the contagious nature of diseases, it affects the community outside of the household. Those who are elderly, or immunocompromised also rely on the upkeep of herd-immunity in order to thrive, as they themselves are more susceptible to disease.

Implementation of vaccinations also addresses inequity. Andre et al highlighted that globally, the burden of infectious disease falls disproportionately on disadvantaged populations due to lack of access to quality care. As a result, vaccination programs have often lead to extended life expectancy, increase in travel and mobility, as well as cease fires in middle eastern regions.<sup>4</sup>

In the US specifically researchers highlight the economic impact of vaccination programs. They estimate that a 5 % decline in only MMR coverage would result in a 3-fold increase in measles infections in children ages 2 to 11; and an additional public sector cost of \$2.1 million dollars annually.<sup>39</sup> The case can be made that implementation of vaccination programs is a form of societal justice and the strategies of education, motivational interviewing, announcement training, and mandatory vaccine policies all fall under the support of the call for justice as they address vaccine hesitancy in a prompt and timely manner.

The one exception would be a modified vaccination schedule. As previously stated, not only would a delay in vaccinations increase healthcare costs, but it would also put the child and others at risk for contracting preventable diseases.

### *Consequentialism vs Deontology*

Consequentialism is the theory of ethics where actions should be judged as right and wrong based on the consequence they produced. In the scope of the discussion of this paper, the overall goal is to increase vaccine uptake and reduce the number of children who are unvaccinated or under vaccinated. If this is the case, then the strategies that make the most sense are mandatory vaccine policy implementation and to a lesser extent announcement training. With these strategies the thought process is centrally focused on getting as many children vaccinated in an efficient manner.

The other side to consider is deontology. Deontological ethics is the theory that the actions themselves and not the consequences should be judged as right and wrong. Following this theory the goal becomes less of increasing vaccine uptake as quickly and efficiently as possible and more about how to encourage patients to do so within the bounds of their own autonomy. The strategies brought into focus with this line of reasoning would be education, motivational interviewing, and to a lesser extent implementing modified vaccination schedules.

### *Other Considerations*

#### *Information Acceptance*

The education strategy is the foundational aspect to medical providers as it is the bedrock of all four of the ethical pillars. Educating the parent on the importance of the vaccine, its benefits, and the associated risks, enables a true sense of autonomy because it gives the parent the tools to be informed and included in the decision making process. Education also allows the provider to engage the parent in a conversation to increase their awareness of issues surrounding vaccinations, and more accurately address their concerns. However with the prevalence and accessibility of incomplete or misinformation, it becomes increasingly difficult for providers to

use the education strategy alone. As communities become more polarized on various issues, social and people networks are becoming increasingly better predictors of vaccine behavior no matter how much evidence the parent is presented with.<sup>40</sup> While education is very important, providers not only need to be aware of factors that play into how parents accept information. Currently in the US, people are increasingly seeking guidance and information from friend groups and internet sources that engage them at an emotional and relational level that scientifically accurate data does not. Providers must learn to adjust their education practices. There is a growing belief that providers that use anecdotal stories and personal experience may have better success in achieving compliance, over data alone.<sup>16</sup> More research is needed to assess the value and efficacy of designing more effective ways to present parents with accurate scientifically based information surrounding vaccines.

### *Informed Consent*

As previously mentioned, adequate informed consent is an important aspect of ethically based care for any patient. However the growing struggle and mistrust in the general population has made it more difficult for providers to present information in the traditional sense. The presumptive language strategy has been well documented as very effective in increasing vaccination uptake in vaccine hesitant parents. The benefits associated with vaccination uptake along with the reduced time investment have helped to establish presumptive language as a popular and well received strategy amongst health providers. Since the intervention strategy operates under the assumption that the caregiver will accept the vaccination, the provider must also consider how they are to address the issue of informed consent. Currently in the US there is no federal law requiring informed consent with administration of vaccinations. Each state has different requirements. However there is a federal requirement that every parent be given a

Vaccine Information Sheet (VIS-a form displaying the benefits and risks with the associated vaccines) as provided in the National Childhood Vaccine Injury Act.<sup>41</sup> As more state governments move towards more stringent vaccination policies, ethical implementation of informed consent will become even more challenging to define.

### *Paternalism*

One of the issues associated in combating vaccine hesitancy is the aspect of paternalism. Paternalism is defined as “a system under which an authority undertakes to supply needs or regulate conduct of those under its control in matters affecting them as individuals as well as in their relations to authority and to each other”.<sup>42</sup> Paternalism is not in and of itself unethical, however the level to which it is used must be carefully considered. Especially in the US where individual and personal freedom is so highly valued. But as the world becomes more interconnected, so to do the consequences of individual decisions. As far as policy is concerned there is a constant dilemma between leaders intervening for the best interest of the child and community; and allowing parents to choose freely, even at the expense of poor outcomes. Mandatory vaccine policies, while many times outside of the health providers scope, is a very effective strategy in addressing the vaccine hesitant trend. Linking vaccinations to public schools and daycare eligibility gives parents a stronger incentive to accept the recommendation of the health provider. The policy intervention strategy aligns most consistently with the pillar of justice, as it directly addresses the benefits of equity and socioeconomic improvement; as most childhood vaccinations can be covered by the state. However as providers, it is important to recognize the feelings of loss of control and autonomy that parents face when met with these types of policies. The policies put in place do not leave room for a discussion and with the ending of non-medical exemptions in some states, parents are faced with the options of either

removing their kids from public institutions, or going against their personal beliefs. Providers can use this opportunity to educate parents on the communicable nature of the disease and help them focus on the altruistic aspect of vaccinations.

#### Vaccination Injury Compensation Program

The US public vaccination requirement also brought about the establishment of patient protections in the event of rare adverse reactions that may occur. The National Vaccination Injury Compensation Program (VICP) was established in 1986 as a result of lawsuits that were filed against vaccine companies and health providers that threatened to cause vaccine shortages and decreased vaccination rates. By taking on the liability of vaccine adverse reactions, the federal government was able to ensure adequate supplies of vaccines and stabilize associated costs.<sup>43</sup> The program also serves to establish and maintain a forum for individuals found to be injured by certain vaccines, and compensate families through the National Vaccine Injury Compensation Trust Fund. The federal government also created the Vaccine Adverse Event Reporting System (VAERS), as a way severe adverse reactions to vaccines can be reported. While the intended purpose of these programs is to remove barriers to vaccine production, some do not view it as a positive. Healthcare providers must be aware that mistrust of pharmaceutical industry and government agencies ranked high on factors producing vaccination hesitancy. Some parents view the transfer of financial liability from vaccine manufacturers to government agencies as an indication that vaccines are less regulated, less studied, and less safe than other medical products. While this stands as a policy issue, often outside of the providers control, it may be wise to be aware of, and prepared for, parents with these concerns.

#### *Privilege*

At face value a modified vaccination schedule would seem like the best of both worlds. But as previously discussed it is only fully supported by the ethical pillar of patient autonomy. While there is a growing desire and trend for parents to have independent decision making capacities in the lives of their children, the conclusions that they reach may not always be the best as evidenced by available research. In addition to the endangerment of the child and the public, there is also the question of privilege that coincides with delayed vaccination. As stated previously modified vaccination schedules are associated with increased visits to the health provider which translated to increased health costs. This type of strategy favors families that are able to both have increased access to health services, and can afford the added medical costs that come with added visits.

Of course arguments can be made that not all modified schedules look the same, and there are some prominent providers that promote the use of modified schedules for certain families. However the research currently available does not support modified vaccination schedules, and currently associates them with higher risk than benefits.

### *Motivational Interviewing*

Motivational interviewing seems to be gaining steam in many sectors of health education when it comes to encouraging a patient to change a belief or behavior. When looking at the causes of vaccine hesitancy it becomes more apparent that motivational interviewing will be increasingly important in changing the culture with vaccine hesitant parents. In motivational interviewing the central premise is opening up a dialogue with the parent, hearing their concerns about vaccinations and working through it with them. In asking leading questions, the provider is helping the parent convince themselves of the importance of vaccinations encouraging their autonomy and making the relationship less paternalistic and more mutualistic.

It is important for the provider to understand that motivational interviewing is a process, and may require multiple consultations. While the other strategies are more reflective of a more immediate response time, motivational interviewing can tend to take longer for patients to get on board with a vaccination plan. The other consideration to note is training. While some aspects of motivational interviewing might seem intuitive, providers must be trained well with the tool at the risk of doing more harm than good.

### *Dismissal From Practice*

In the discussions about vaccine hesitancy, it is important to note a shift in healthcare communities regarding the change in policy in providers dismissing patients from their practice. In 2016 the American Academy of Pediatrics issued guidance that made it acceptable to dismiss patients and parents that chose to refuse vaccinations, but cautioned use as a last resort after all other strategies have been tried.<sup>44</sup> Ethically there is much debate on this issue. Some see it as a policy motivator similar to the legislative policies for schools, and hope it has the same efficacy. But some view it as antithetical to the philosophy of health care providers.

A 2018 study out of Canada highlighted that dismissal of patients from practice due to not following vaccine schedules did not lead to positive outcomes. The study went on to conclude that dismissal of patients is not in the best interest of the patients, or the community; and that the best approach to increase vaccine uptake is a positive provider-patient relationship.<sup>45</sup> Studies on these policies still need to be evaluated for efficacy, however the implementation is very telling of the seriousness of the issues surrounding adequate vaccinations.

### *Recommendations for Health Providers*

Ethically addressing parents that may be vaccine hesitant can be a very complicated and delicate process. In these situations, it is important to remember that establishing a level of trust

with the parent should be the first priority; as it creates a foundation for you both to work from. No matter what intervention strategy is used, the most effective component is the parent's trust in the competence and the intention of the provider. Education should be at the foundation of any intervention strategy, as the goal of the provider should not only be to get successful compliance, but also to get buy-in from the parents. Consistent with the CDC Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)<sup>46</sup>, presumptive language is the most balanced intervention strategy of efficacy and ethicality. Not only does it have evidence of an effective and efficient strategy; but if done properly, it allows the opportunity for parents to exercise their autonomy by inviting them into the decision making process. However if that strategy is not successful, educating the parent by accurately listening to and addressing their specific concerns is the next step. The provider should keep in mind that it may be necessary to address more of the emotional concerns parents have with vaccinations over the statistics. In these instances honest but positive stories, personal experiences, and anecdotes may be beneficial. No matter what intervention is used, it is vitally important to maintain an open dialogue in a way that is non-judgmental. Studies increasingly show that consistent multi-faceted approaches are the most effective ways to engage parents and increase vaccine uptake.

## **VI. Conclusion**

In many ways the trends observed surrounding vaccinations are a product of their success. The fact that people are no longer concerned about diseases, once so pervasive, is a testament to the effectiveness of vaccination programs. Vaccination hesitancy remains a very complex issue given the nature of its prevalence. Unlike many other healthcare interventions, it affects not only the individual patient but members of the community at large. This is why the

ethical view of vaccinations must be viewed from more of a consequentialist perspective than an deontological one.

Still as much care and consideration as possible must be given to the thoughts and feelings of the parent, if the provider is to retain their foundation of trust. At the end of the day, both providers and parents who are vaccine hesitant want the same thing; a safe and well child. As the debates and research continues as to the best way to approach vaccination hesitancy, the important thing to remember is to assume the best about the patients, listen to their concerns, and help guide them on a path that will keep the child and community safe and healthy.

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## VIII. Appendix

Preventable Diseases	Associated Vaccines
Diphtheria	DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine
Pertussis (Whooping cough)	
Tetanus	
Haemophilus Influenza Type B (Hib)	Hib (Haemophilus Influenza Type B) Vaccine
Hepatitis A	Hepatitis A Vaccine
Hepatitis B	Hepatitis B Vaccine
Influenza	Flu (Influenza) Vaccine
Measles	MMR (Measles, Mumps, Rubella) Vaccine
Mumps	
Rubella	
Pneumococcal Disease	PCV13 (Pneumococcal Conjugate Vaccine)
Polio	Polio Vaccine
Rotavirus	Rotavirus Vaccine
Varicella (Chickenpox)	Varicella Virus

**Table 1. This table lists the 14 most notable diseases with reduced prevalence in the United States as a result of the national vaccination program.** <sup>17</sup>



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