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# Motivational interviewing for vaccine hesitant parents

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BOSTON UNIVERSITY  
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Thesis

**MOTIVATIONAL INTERVIEWING FOR  
VACCINE HESITANT PARENTS**

by

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B.S., University of California, Santa Barbara, 2012

Submitted in partial fulfillment of the  
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# **MOTIVATIONAL INTERVIEWING FOR VACCINE HESITANT PARENTS**

**MEREDITH JOHNSON**

## **ABSTRACT**

### Background

The widespread use of vaccines led to significant decline in multiple potentially fatal infectious diseases. Recently, there has been an increase in vaccine hesitancy. Measles and pertussis outbreaks throughout the United States have put a spotlight on this urgent healthcare issue. Motivational interviewing is a counseling tactic that is gaining popularity and is being studied for its efficacy in preventative medicine and psychological disorders. It aims to inspire people to make behavioral changes through collaborative relationships with their provider by understanding how current actions do not translate into their health goals.

### Literature review findings

Vaccine hesitancy is growing. Communities with decreased immunization rates are associated with a higher risk of disease outbreak. Increasing rates of undervaccinated children are likely due to increases in non-medical exemptions. Many parents, regardless of their vaccine hesitancy status, are concerned about vaccine safety. Vaccine hesitant parents refuse vaccines due to philosophical and religious beliefs, conspiracy theories, and safety concerns. Parents feel that providers do not adequately address their concern. Providers report not having the training to discredit parental concerns. The majority of parents describe their child's pediatrician as their most trusted source of vaccine information. Parents who receive vaccine information from a provider are more likely to

comply with the recommended childhood vaccine schedule. The most efficient way to discuss vaccines with parents has yet to be determined.

#### Proposed project

This is a proposed QI research project for the Pediatric Clinic at Boston Medical Center. Providers would be trained in motivational interviewing during several sessions that included lectures and small group practice sessions with systematic feedback. During the intervention, parents who refuse vaccines for their child, aged 0-6 years old, will receive motivational interviewing from the provider. The proportion of the vaccine hesitant parents who accept the offered vaccine after will be analyzed. The pre and post intervention vaccination rates for the entire clinic will also be assessed. Data collection will be performed through retrospective chart review. The project aims to increase provider confidence on vaccine counseling, educate providers on reasons for hesitancy, and improve compliance with the CDC recommended vaccine schedule.

#### Conclusion

While most Americans continue to vaccinate their children according to the CDC's recommended schedule, constant vigilance is required to maintain high immunization rates to protect our communities. Motivational interviewing is goal-oriented to alter a specific behavior and would allow providers to engage in an open, persuasive dialogue about parental vaccine concerns.

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## LIST OF ABBREVIATIONS

ACIP.....	Advisory Committee on Immunization Practices
BMC.....	Boston Medical Center
CDC.....	Centers for Disease Control and Prevention
CI.....	Confidence Interval
DTaP.....	Diphtheria, Tetanus, and Pertussis Vaccine
Hib.....	Haemophilus influenzae Type b Vaccine
HPV.....	Human Papillomavirus
IRB.....	Institutional Review Board
IPV.....	Inactivated Poliovirus Vaccine
LAIV.....	Live Attenuated Influenza Vaccine
MI.....	Motivational Interviewing
MINT.....	Motivational Interviewing Network of Trainers
MMR.....	Measles, Mumps, Rubella Vaccine
OR.....	Odds Ratio
PACV.....	Parent Attitudes about Childhood Vaccine Survey
PCV.....	Pneumococcal Conjugate Vaccine
QI.....	Quality Improvement
RR.....	Risk Ratio
SAGE.....	Strategic Advisory Group of Experts
TIV.....	Trivalent Influenza Vaccine
U.S. ....	United States of America

VHP.....Vaccine Hesitant Parent  
VPD.....Vaccine Preventable Disease  
WHO..... World Health Organization

## INTRODUCTION

### Background

Vaccines have proven to be one of the most successful healthcare interventions by decreasing the spread of infectious disease.<sup>1,2</sup> The use of vaccines has reduced the incidence of several potentially fatal infectious illnesses worldwide including, but not limited to, small pox, polio, measles, and Haemophilus influenzae type b (Hib).<sup>1</sup> There are currently seventeen vaccine preventable diseases (VPDs) as a result of immunizations administered to children and adults.<sup>3</sup>

It is estimated that during the lifetime of children born between 1994 and 2013 vaccinations will prevent an estimated 322 million illness, 21 million hospitalizations, and 732,000 deaths by the Center for Disease Control and Prevention (CDC) in the United States (U.S.).<sup>4</sup> The CDC currently recommends nine childhood vaccines during a child's first 6 years of life with the goal of providing children lifelong immunity to most of these pathogens.<sup>4,5</sup> (Appendix)

Over the past 15 years, refusal of these potentially life saving vaccines has increased, leading to the emergence of VPDs.<sup>6</sup> When VPD rates were high, the fear of the illness provided motivation to vaccinate a child.<sup>6</sup> Due to the widespread use of vaccines, and the resulting decrease in occurrence of these diseases most Americans have not been exposed to the devastating effects these diseases can have on children.<sup>1,4,7</sup> The result has been a shift in fear of disease to fear of the vaccine.<sup>1,4,7</sup>

## **Statement of the Problem**

Vaccine hesitancy is defined as the delay in acceptance or refusal of vaccines despite availability of vaccination services by the Strategic Advisory Group of Experts (SAGE), an advisory group for the World Health Organization (WHO) on immunizations and vaccine preventable illnesses.<sup>8</sup> Vaccine hesitant parents (VHPs) are a heterogeneous group, presenting with a large variety of beliefs toward vaccines and the recommended vaccination schedule.<sup>8,9</sup> The myth about the development of autism from the MMR vaccine is most publically known due to social media and celebrity campaigning.<sup>10</sup> VHPs state religious and philosophical beliefs, safety concerns, government and pharmaceutical conspiracies, and ambiguity aversion as reasons for refusal.<sup>1,11,12</sup> The philosophical beliefs held by VHPs include the following: natural immunity is better than an artificial or man-made immunity, children receive too many vaccinations during one visit, and reliance on herd immunity to protect the child.<sup>11</sup> Ambiguity aversion occurs when an individual prefers to take a known risk, such as contracting disease, rather than an unknown risk, such as the potential side effects of a vaccine.<sup>1</sup> VHPs may underimmunize their child by personally selecting which vaccines they believe their child needs, use an alternate vaccination schedule, or refuse all recommended vaccines.<sup>9</sup>

Parents who choose to not vaccinate their children according to the CDC's recommended immunization schedule put their child at a higher risk of becoming infected with a VPD.<sup>13</sup> The increasing rate of undervaccinated children has led to the increased risk of transmitting a VPD as well.<sup>1</sup> For example, in 2000, the U.S. was thought to have eradicated the endemic transmission of measles, but since then, the U.S. has had

numerous outbreaks attributed to the decreased vaccination rate.<sup>1,13, 14</sup> In 2014, there was a record number of 667 measles cases.<sup>15,16</sup> The cases were reported from 27 states during 23 different outbreaks.<sup>15,16</sup> Additionally, a highly publicized outbreak in California that was found to have originated at Disneyland in December 2015 infected 147 people.<sup>17</sup> According to the CDC's review of this outbreak, over 80% of the people affected from January 2015 to April 2015 were unvaccinated, including infants, who are too young to be vaccinated, and children with true contraindications to vaccinations (Table 2).<sup>16</sup> High vaccination rates are required in communities to protect those individuals who do not meet the criteria to be vaccinated.<sup>1</sup>

Providers have struggled to find efficient ways to discuss the advantages and necessity of vaccinations with VHPs.<sup>18,19</sup> The era of “medical paternalism” is being replaced as people desire a shared decision making dynamic with their healthcare provider.<sup>1,19</sup> The majority of parents continue to believe their child's healthcare provider is the most influential source of information regarding vaccines and safety.<sup>1</sup> Medical professionals have reported feeling they lack the training to discredit many of the anti-vaccination messages parents have heard through social media, the internet, or from word of mouth.<sup>19</sup> There is a need for specific attention to training medical professionals about vaccine hesitancy to allow them to be better prepared for these crucial conversations.<sup>20</sup> Appointment times are already rushed; therefore, there is no time to waste using ineffective approaches. To be successful in educating and discussing the importance of vaccines with parents, providers need to share effective strategies with each other as well.

While this is a heavily researched topic, frequent research and updating best practices should be done to ensure that providers do not fall behind on this evolving topic.<sup>21</sup>

Motivational interviewing (MI) is defined as a “client centered yet directive method for enhancing intrinsic motivation to change by exploring and resolving client ambivalence.”<sup>23</sup> It is a therapeutic approach that was first described by Carl Rogers over 25 years ago.<sup>23, 24</sup> This technique is gaining popularity as it has shown to be effective for counseling people who suffer from alcohol or substance abuse disorders.<sup>23</sup> Healthcare professionals and researchers are hoping to use MI for other clinical problems, such as medication compliance, smoking cessation, weight loss, and several psychiatric illnesses.<sup>23</sup>

### **Hypothesis**

Pediatric providers will increase vaccination rates and decrease vaccine hesitancy by implementing MI with vaccine hesitant parents after participating in an educational curriculum focused on vaccine hesitancy and MI training.

### **Objectives and specific aims**

Vaccine hesitancy has created an opportunity for the healthcare community to become strong advocates for childhood vaccinations. To do this successfully, the reasons for refusal need to be thoroughly understood. Healthcare providers need to be able to effectively educate and communicate openly with parents without being judgmental. By

understanding the reasons for vaccine hesitancy, providers will be able to see both sides of the script and be more persuasive when discussing the importance of immunizations.

The use of MI on VHP will be explored. One of the initial steps in MI is to appropriately assess the patient's readiness to change.<sup>23</sup> If the VHP is unwilling to change their mind, then the provider may waste valuable time. The technique can also be adapted to create personalized counseling by addressing the parent's specific reason for refusal.

The most valuable aspects are that MI allows the parent to engage in an open conversation with the medical provider and to be involved in the decision making.

The specific goals for this proposal are as follows:

1. To train providers in motivational interviewing
2. To analyze the change in vaccination rates by measuring the proportion of VHPs who accept the offered vaccine after receiving MI
3. To increase vaccination rates for the recommended childhood vaccines

## REVIEW OF THE LITERATURE

### Overview

Vaccinations have proven to be a major healthcare innovation, saving millions of lives since their creation (Table 1).<sup>1,6</sup> Despite the effectiveness of vaccines, our society is experiencing an increase in vaccine hesitancy and refusal, resulting in undervaccination in many communities throughout the U.S.<sup>1, 13, 25, 26</sup>

**Table 1. Decrease in VPDs in the U.S. after Implementation of National Immunization Recommendations<sup>3</sup>**

Condition	Annual Average Number of Pre-vaccine Cases in U.S.	Number of Cases Reported in 2012 <sup>a</sup>	Reduction (%) in Cases After Widespread Vaccination
Smallpox	29,005	0	100
Diphtheria	21,053	1	99
Measles	530,217	55	99
Mumps	162,344	229	99
Pertussis	200,752	48,277	76
Polio (paralytic)	16,316	0	100
Rubella	47,745	9	>99
Congenital Rubella Syndrome	152	2	99
Tetanus	580	37	94
Haemophilus influenzae type b infection	20,000	30 <sup>b</sup>	99
Hepatitis A	117,333	2,890 <sup>a</sup>	98
Hepatitis B (acute)	66,232	18,800 <sup>a</sup>	72
Invasive pneumococcal infection (all ages)	63,067	31,600	50
Invasive pneumococcal infection (<5 years old)	16,069	1,800	89
Varicella	4,085,120	216,511	95

<sup>a</sup> Except for hepatitis A and B, where 2011 figures are shown from CDC's Viral Surveillance, 2011

<sup>b</sup> An additional 13 type b infections are estimated to have occurred from the 210 H. influenzae infections of unknown type in children under age 5 years old.

Vaccines were created by Edward Jenner in 1796.<sup>27</sup> Prior to his discovery, the process of variolation was used to create immunity from smallpox.<sup>27</sup> Smallpox survivors appeared to be protected from recurrent infection.<sup>27</sup> Researchers at the time attempted to make inoculations from the pus or scab of an infected individual.<sup>27</sup> This process is called variolation.<sup>27</sup> The procedure led to the transmission of a localized, less severe form of smallpox at the site of inoculation in some recipients and systemic smallpox infections in others.<sup>27</sup> It was the only hope of protection against the smallpox endemics that continued to occur worldwide with devastating effects.<sup>27</sup> In 1774, Benjamin Jesty, a farmer in England discovered the link between cowpox and smallpox.<sup>27</sup> Jesty found that his two dairymaids, who had previously contracted cowpox, did not become infected with smallpox despite being exposed by several family members.<sup>27</sup> He believed that exposure to cowpox provided immunity to smallpox.<sup>27</sup> To test his theory, he successfully inoculated his wife and two sons with serum from cowpox lesions.<sup>27</sup> Jenner, a physician in England, took Jesty's hypothesis a step further.<sup>27</sup> He performed an inoculation experiment on a healthy eight year old boy using the purulent material from a dairymaid's cowpox sore.<sup>27</sup> The boy initially suffered from an acute cowpox infection.<sup>27</sup> After six weeks, Jenner variolated him using the standard procedure at the time.<sup>27</sup> The boy had a localized reaction, but no constitutional symptoms, illustrating his immunity.<sup>27</sup> This was labeled the discovery of the first vaccine.<sup>27</sup> Centuries and several revisions later, the smallpox vaccine globally eradicated smallpox as of December 1979.<sup>27</sup>

Vaccines are biologic substances intended to provoke the immune system to create a neutralizing response against a specific target.<sup>28</sup> They can protect individuals

from viral, bacterial, and toxin related illnesses.<sup>28</sup> Some vaccines may decrease the severity of an infection, such as the rotavirus vaccine, or reduce the likelihood of an infection's complications, such as the zoster vaccine for adults.<sup>3</sup> Others reduce the transmission of infectious pathogens, leading to the protection of unimmunized people.<sup>3</sup>

There are two main forms of immunization, active and passive. Active immunization occurs when an antigen is in the vaccine and the recipient's immune system creates antibodies to the antigen, leading to cell mediated immunity.<sup>30</sup> Active immunization aims to provide lifelong, or at least long-term immunity, and is therefore preferred over passive immunization.<sup>30</sup> These vaccines may contain inactivated or live, attenuated viral or bacterial components, toxoids, subunits, or conjugate pathogens.<sup>28, 29,</sup>  
<sup>31</sup> A live, attenuated vaccine contains a weakened form of the pathogen.<sup>29,31</sup> An inactivated vaccine means the pathogen has been killed, so it can not replicate inside the recipient.<sup>31</sup> Toxoid vaccines contain inactivated toxins.<sup>27</sup> These toxins are emitted from bacterium and cause specific disease.<sup>29</sup> For example, tetanus is caused by the neurotoxin released by *Clostridium tetani* bacteria, known as tetanospasmin.<sup>29</sup> Therefore, to have immunity from this disease, the vaccine must create protection from the toxin, not the bacteria. Subunit vaccines use specific parts of the pathogen that will provoke the immune response.<sup>32</sup> Conjugate vaccines are created with pieces of the pathogen biochemically linked to a carrier protein, which creates a stronger immune response by the host.<sup>32</sup> The pneumococcal vaccine recommended for children uses the capsular polysaccharide of 13 streptococcus pneumonia serotypes.<sup>33</sup> It is bound to a carrier

protein, the diphtheria toxoid, which allows the host's immune system to mount a greater response to the vaccine, providing a higher level of protection.<sup>29</sup>

Passive immunization occurs when there is transfer of immunity with preformed immunologic products, known as immune globulins.<sup>30,34</sup> This can be a natural process, such as the transfer of IgG across the placenta from mother to fetus, or therapeutic process, by administering the immune globulins.<sup>34</sup> Maternal IgG protection to the fetus only lasts six months after birth, which illustrates the child's need for further protection through vaccines.<sup>34</sup> Therapeutic passive immunization, such as in response to rabies, botulism, or tetanus exposure, may only last weeks to months and would theoretically require constant immunization to maintain protection.<sup>34</sup>

Vaccines made with live attenuated virus can provide protection to the community as well.<sup>35</sup> Herd immunity is defined as the resistance of a group against invasion and spread of an infectious agent as a result of a majority of people being immunized.<sup>7,35</sup> It can be the result of natural immunity or immunization.<sup>35</sup> The vaccine must alter the transmission of the virus by inducing IgA production to have this effect.<sup>35</sup> For example, the live polio vaccine provokes secretory IgA production in the gut, which prevents infection from virulent polio virus.<sup>35</sup> The live attenuated virus in the polio vaccine replicates in the recipient, but not enough to cause the host to become ill.<sup>35</sup> The replication process allows the live attenuated virus to be spread to other members of the community, eliciting protection to more individuals.<sup>35</sup> Vaccines made with a killed or inactivated pathogen only protect the individual as no IgA is produced in response to the vaccine.<sup>35</sup> The herd immunity threshold is the lowest proportion of individuals in a

community that need to be vaccinated to provide protection to the population.<sup>7</sup> The threshold proportion is different for each vaccine and population. If the community meets the threshold percentage, then the members of that community have protection against the pathogen, including those who cannot get vaccinated due to medical contraindications (Table 2).<sup>7</sup>

The CDC recommends that all children should be vaccinated according to the universal vaccine timeline (Appendix) provided by the CDC.<sup>4,5</sup> The CDC recommends that vaccines which require multiple doses should not be administered early, but does allow a four day grace period for administration date.<sup>5,36</sup>

The contraindications should be reviewed before administering any vaccine. The only absolute contraindication that applies to all vaccines is the personal history of a severe allergic reaction, such as anaphylaxis after receiving a vaccination or after exposure to a vaccine component.<sup>36</sup> Anaphylaxis due to a vaccine or component of the vaccine typically begins minutes after administration.<sup>36</sup> Prodromal signs may include flushing, facial edema, urticaria, pruritus, angioedema, wheezing, or dyspnea.<sup>36</sup> Anaphylaxis is rare, occurring in one in one million doses of vaccines.<sup>37</sup> Children who are immune compromised should not receive live, attenuated vaccines until immune status has returned to normal function.<sup>36</sup> These children may receive inactivated vaccines.<sup>36</sup> A child with a moderate to severe acute illness, with or without a fever, may still receive all vaccines.<sup>36</sup> In such instances, it is reasonable to consider delaying vaccination until symptoms resolve.<sup>36</sup> Children with a mild illness should continue to receive the recommended vaccinations according to the CDC's schedule.<sup>36</sup> The Advisory Committee

on Immunization Practices (ACIP) does not recommend the live attenuated influenza vaccine (LAIV) for the 2016 – 2017 season due to its low efficacy.<sup>36</sup> The inactivated trivalent influenza vaccine (TIV) is recommended yearly for children over six months.<sup>36</sup>

**Table 2. Childhood Vaccine Contraindications<sup>36</sup>**

<b>Vaccine</b>	<b>Contraindications</b>
DTaP	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> <li>• Encephalopathy with otherwise no known case, within 7 days of administration of previous dose of DTaP</li> </ul>
IPV	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> </ul>
MMR	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> <li>• Pregnancy</li> <li>• Known severe immunodeficiency such as hematologic and solid tumors, receiving chemotherapy, congenital immunodeficiency, long term immunosuppressive therapy, and those with HIV infection who are severely immune compromised</li> </ul>
Hib	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> </ul>
Hepatitis B	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> </ul>
Hepatitis A	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> </ul>
Varicella	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> <li>• Known severe immunodeficiency such as hematologic and solid tumors, receiving chemotherapy, congenital immunodeficiency, long term immunosuppressive therapy, and those with HIV infection who are severely immune compromised</li> </ul>
TIV	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to vaccine component, including egg protein</li> </ul>
Rotavirus	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after previous dose or to a vaccine component</li> <li>• Severe Combined Immunodeficiency</li> </ul>
PCV	<ul style="list-style-type: none"> <li>• Severe allergic reaction (anaphylaxis) after a dose of PCV7, PCV13, or any diphtheria toxoid containing vaccine or component of listed vaccine</li> </ul>

Food allergies are rarely a determining factor in receiving childhood vaccines.<sup>37</sup> The influenza vaccine contains egg protein; therefore, children with a history of anaphylactic reaction after eating eggs should not receive this vaccine.<sup>37</sup> The ACIP recommends that people who can tolerate lightly cooked eggs without a reaction can receive the LAIV.<sup>37</sup> The measles and mumps vaccine viruses from the MMR vaccine are grown in chick embryo fibroblast tissue, but have been proven safe for people with egg or egg protein allergies.<sup>37</sup> None of the recommended childhood vaccines contain gelatin, a common question for pediatricians.<sup>36</sup>

A study by McCarthy et al. utilized the VSD to investigate the deaths of children aged 9 to 26 years old between January 1, 2005 and December 31, 2011 who received a vaccine within 30 days prior to death.<sup>38</sup> VSD data from 6 healthcare sites were reviewed.<sup>38</sup> There were 1100 deaths within 12 months of a vaccination.<sup>38</sup> 76 of these deaths fit the criteria of being within 30 days of a vaccination, but only 59 of the deaths had adequate medical records for review.<sup>38</sup> A team of CDC physicians reviewed the cases and agreed on the causes of death.<sup>38</sup> The team found that none of the deaths were associated with a vaccine related cause.<sup>38</sup> The study discovered that 0 to 30 days after at least one vaccine, there was a reduced risk of death (RR =.57) due to non-external causes and in deaths due to all causes (RR= .72).<sup>38</sup> All childhood vaccines were associated with relative risk ratios under 1, indicating a decreased risk.<sup>38</sup> McCarthy et al. notes confounding bias is likely responsible because the majority of the study's participants have comorbidities.<sup>38</sup> The study focuses on adolescents and not children, but it is likely still generalizable in regard to the vaccines that crossover from the CDC's childhood

recommended schedule to the adolescent recommended schedule. Larger sample sizes would be needed to adequately investigate each vaccine individually.<sup>38</sup>

#### Barriers to vaccination

Vaccine hesitancy is not the only reason parents do not vaccinate their children. A narrative study performed by Thompson et al. reviewed 43 studies to explore possible reasons for the gap in the rate of vaccine coverage in children.<sup>12</sup> The study found five major nonsocio-demographic reasons (Table 3) that encompass all identified elements of vaccine uptake.<sup>12</sup> They are referred to as the “5As” and include access, affordability, awareness, acceptance, and activation.<sup>12</sup> The study mostly reviewed articles from the U.S., United Kingdom, and Australia.<sup>12</sup> Developed countries were highly represented in this study; therefore, the results are applicable to the U.S.<sup>12</sup> The studies focused on several types of vaccinations, but a majority of the studies were based on MMR and influenza vaccines.<sup>12</sup>

**Table 3. Five Major Nonsocio-demographic Reasons for Vaccine Uptake<sup>12</sup>**

<b>5As</b>	<b>Definition</b>
Access	The ability of individuals to be reached by, or to reach recommended vaccines
Affordability	The ability of individuals to afford vaccinations, both in terms of financial and non-financial costs (e.g. time)
Awareness	The degree to which individuals have knowledge of the need for, and availability of recommended vaccines and their objective benefits and risks
Acceptance	The degree to which individuals accept, question, or refuse vaccination
Activation	The degree to which individuals are nudged towards vaccination uptake

Each state in the U.S. has its own immunization laws for children entering school or daycare.<sup>25,39</sup> To varying degrees, states permit different types of exemptions that allow children to continue to attend school or daycare without immunizations. VPD outbreaks are associated with higher exemption rates.<sup>39</sup> Exemptions may qualify the child to not receive a specific vaccine or, in rare cases, all of the required vaccines.<sup>40</sup> There are three types of exemptions, which include medical, religious, and philosophical.<sup>40</sup> A medical exemption can occur when the administration of a vaccine would be dangerous for the child's health.<sup>25</sup> For example, a child with medical contraindications, such as undergoing chemotherapy or a history of anaphylaxis to the vaccine, would be able to receive a medical exemption.<sup>25</sup> Another example of a medical exemption is proof of immunity, such as the documentation of the child's varicella IgE antibody level.<sup>25</sup> A religious exemption is allowed when the family's religious belief system is not congruent with vaccinations.<sup>25</sup> Lastly, there are philosophical exemptions. This is the most rare type allowed in the U.S., that is based on the parent's personal beliefs.<sup>25</sup> The reasons vary greatly, but may include fear of safety, distrust in the government's monitoring of vaccines, and fear that vaccines may cause chronic disease.<sup>25</sup> The laws and requirements regarding philosophical exemptions vary greatly among each state that allows them.<sup>41</sup> In 2016, all 50 states allow medical exemptions, 47 states allow religious exemptions, and 17 states allow philosophical exemptions.<sup>40, 41</sup>

## Vaccine hesitancy

Vaccine hesitancy began alongside the creation of the first vaccine.<sup>9</sup> Jenner's smallpox vaccine sparked controversy in his community for several reasons.<sup>9,27</sup> People were concerned about the risks versus the benefits of the disease.<sup>9</sup> Others voiced concerns of bestiality, because the source of the smallpox vaccine was originally from cows.<sup>1</sup> Still, others debated the ethics of the vaccine, whether it was a human's right to change divine will and the notion of individual freedom against shared responsibility.<sup>1,27,42</sup> These concerns continued in the U.S. in the 1850s during the implementation of the smallpox vaccine.<sup>41</sup>

Parents continue to be worried about the safety, ethics, and necessity of vaccines for their children.<sup>1,6,25,26</sup> People are concerned about the government's role in individual health.<sup>41</sup> The cause of the recent rise in vaccine hesitancy is multifactorial. The use of social media and wide availability of the Internet have likely contributed, because information is quickly spread, regardless of its validity.<sup>9</sup> While the majority of parents in the U.S. continue to vaccinate their children, many parents have skewed information on the role and safety of vaccines.<sup>1,9</sup> Vaccines have become victims of their own success.<sup>1</sup> As the incidence of VPDs decrease, people forget the devastating effects they have allowing the risk of vaccination to appear greater than the risk of disease.<sup>1,8,25</sup>

In 2009, the National Immunization Survey (NIS) conducted a random digit dial survey of parents with children aged 19 to 35 months which revealed that 39.8% of parents had delayed or refused at least one dose of a CDC recommended vaccine.<sup>43</sup> In 2003, the same study was performed and showed 21.8% of parents in this demographic

had delayed or refused vaccines.<sup>44</sup> Another 25.8% of parents had delayed one or more doses, 8.2% refused one or more dose, and 5.8% of parents had both delayed and refused one or more dose of a vaccine.<sup>44</sup>

VSD data based on ICD 9 codes and medical record reviews from 2004 to 2010 performed by Glanz et al. illustrated that out of 323,247 children, 13% of children were under-vaccinated due to parental decision.<sup>45</sup> A direct measure of vaccine hesitancy is monitoring the number of non-medical exemptions in schools.<sup>26</sup> Parents must fill out paperwork and actively get these exemptions approved, likely indicating a high level of vaccine hesitancy.<sup>26</sup> In the 2013 to 2014 school year, the median state level of non medical exemptions nationally was 1.7%.<sup>26</sup> This number appears low and manageable; however, the data must be examined locally to see the true effect of underimmunization. In Washington State, 3.5% of children had non medical exemptions in the 2013 to 2014 school year, with counties peaking at 9% and school districts reporting up to 30% to 50% of children with non medical exemptions.<sup>26</sup> From 2005 to 2009, the percentage of exemptions in school children in Utah rose from 2.8% to 3.3%.<sup>25</sup>

#### Consequences of vaccine hesitancy

There are four major factors that increase VPD incidence.<sup>3</sup> They include low rates of immunization, leading to an increase in the number of susceptible individuals, an alteration in the infectious agent allowing it to escape vaccine protection, waning vaccine induced immunity, and lastly, a localized large inoculum.<sup>3</sup>

A review of published literature by Phadke et al. examined the association between vaccine delay or exemption and the epidemiology of measles and pertussis with recent outbreaks within the U.S.<sup>13</sup> Literature on measles outbreaks was reviewed from the declaration of measles eradication on January 1, 2000 to November 30, 2015.<sup>13</sup> The measles vaccine was introduced in 1963 and measles was declared eradicated from the U.S. in 2000.<sup>1,13,14</sup> Strong immunization program efforts and the introduction of a second dose in 1990 led to this success.<sup>13,14</sup> There was one case of measles per 1 million people in the U.S. in 1997 through 1999.<sup>2</sup> Yet, due to declining vaccination rates, the United States continues to have cases from foreign transmission.<sup>1,13</sup> Most often, researchers have found individuals acquire measles outside of the U.S. and introduce the pathogen into the community after returning home.<sup>1,13</sup> Eighteen published measles studies were found with 1416 documented measles cases.<sup>13</sup> The age of individuals affected ranged from 2 weeks old to 84 years old, with 178 children under 12 months affected.<sup>13</sup> Of those, 970 had known vaccination status.<sup>13</sup> 574 of the 970 cases were unvaccinated, but age eligible for vaccinations.<sup>13</sup> Of the 575 unvaccinated individuals who had measles, 405 or 70.6% were unvaccinated with non-medical exemptions.<sup>13</sup> Researchers also reviewed the cumulative epidemic curve, analyzing weekly transmission.<sup>13</sup> Unvaccinated people made up a larger fraction of the total measles cases in the earliest weeks of the outbreak.<sup>13</sup> Children who were not vaccinated against measles were found to have 35 times greater risk to contract measles compared to vaccinated children.<sup>13</sup> In 2011, the majority of measles cases reported occurred in states that allow philosophical exemptions, such as Washington, California, Utah, Arizona, Texas, Minnesota, and Pennsylvania.<sup>41</sup>

Pertussis continues to be endemic in the U.S.<sup>13</sup> Literature on pertussis outbreaks by Phadke et al. was reviewed from the point of lowest incidence, January 1, 1977 through November 30, 2015.<sup>13</sup> After the invention of the vaccine in 1940, there was a significant decrease in incidence.<sup>13</sup> By 1976, only 1010 cases were reported in the U.S.<sup>13</sup> Since then, pertussis incidence has increased with over 10,000 cases reported each year for the past 10 years.<sup>13</sup> In 2004, 25,827 cases were reported, the largest amount since 1959.<sup>13</sup> The increase in incidence was blamed on the switch from the whole cell to the acellular pertussis vaccine and the waning immunity found in older populations.<sup>13</sup>

Thirty two articles were found on pertussis outbreaks with 10,609 people of known vaccination status affected.<sup>13</sup> Ages involved ranged from 10 days old to 87 years old.<sup>13</sup> During 2010, in California alone, 4,415 children, aged 6 months to 18 years old with known vaccination status were diagnosed with pertussis.<sup>13</sup> Of those children, 45% or 2001 children were not up to date on the associated age appropriate vaccine versus pertussis, DTaP.<sup>13</sup> Again in California, in 2014, 222 children under the age of 1 year were diagnosed with pertussis.<sup>12</sup> Over half of these children were age eligible to receive a dose of DTaP; yet, only 53 of the children had received at least one dose.<sup>13</sup> Outbreaks of pertussis have been documented in Florida, Massachusetts, Arizona, Delaware, Oregon, and Washington.<sup>13</sup> Analysis of these outbreaks showed high transmission to people with appropriate age recommended pertussis vaccine coverage.<sup>13</sup> The cause was found to be waning immunity, illustrating the importance of booster immunizations in adult populations.<sup>13</sup> It was estimated that individuals with an exemption to the DTaP vaccine are at a risk of 20 times greater than a vaccinated individual to get pertussis.<sup>13</sup>

Phadke et al also performed case reviews of 6 observational studies on pertussis outbreaks in the U.S. which have shown schools and communities with higher exemptions rates to have higher rates of pertussis, including among highly vaccinated population.<sup>13</sup> The case review found states that allow philosophical exemptions have approximately a 1.5 elevated incidence of pertussis compared to states without philosophical exemptions.<sup>13</sup> The potential loss of herd immunity puts an entire community, and possibly the state, at risk for a VPD outbreak.<sup>1,13</sup>

### **Existing research**

#### Reasons parents refuse vaccines

Over the past few decades several surveys have been performed to assess parental vaccine hesitancy. In 1999, a national telephone survey of parents with children under the age of 6, indicated that 87% of parents considered vaccination extremely important, 25% thought a child's immune system could be weakened by too many immunizations at one visit, and 23% believed children receive too many immunizations.<sup>26,46</sup> A similar survey of parents with children from one to six years old was performed in 2010 by the 2010 HealthStyles Panel.<sup>26,47</sup> The study showed 77% of parents had concerns about vaccines.<sup>26,47</sup> Of these, 36% had concerns about receiving too many shots at one visit, 30% were concerned about the risk of autism, 26% believed the ingredients were unsafe, and 17% did not believe vaccines were properly checked for safety in children.<sup>26,47</sup>

In 2009, a HealthStyles consumer mail panel survey was used to research vaccine attitudes, concerns, and information sources utilized.<sup>48</sup> Of the 4556 respondents, only the

475 with at least one child under the age of 6 were included in the study.<sup>48</sup> 74.5% of these parents reported their youngest child had already received all the CDC recommended vaccines and 18.9% reported they planned on vaccinating their child along with the recommended schedule.<sup>48</sup> 79% of those parents were confident or very confident in vaccine safety and 79.8% believed vaccines were important for children's health.<sup>48</sup> However, 21.9% of parents did somewhat or strongly agree about the concern of overwhelming the child's immune system.<sup>48</sup> Parents were also asked to fill out a separate questionnaire of 11 potential vaccine concerns.<sup>48</sup> The top concern was pain for the child at 44%.<sup>51</sup> 34.2% reported concern over too many vaccines in one appointment, 26.2% were concerned about the risk of autism, while 13.5% were concerned about other chronic illness caused by vaccines.<sup>48</sup> 22.1% and 13.2% were concerned about the ingredients in vaccines and whether vaccines were tested appropriately, respectively.<sup>48</sup> 20.8% of parents reported they have no concerns about vaccines at all.<sup>48</sup>

A review article by McKee and Bohannon discussed findings from 10 articles relating to reasons for vaccine hesitancy.<sup>11</sup> Four major categories were identified as reasons for refusal, which include the following: religious reasons, personal or philosophical beliefs, safety concerns, and a desire for more information.<sup>11</sup> Some parents believed their child would benefit from contracting vaccine preventable illnesses to allow their immune system to become stronger.<sup>11</sup> Natural immunity to pathogens has not shown to be superior to vaccine acquired immunity.<sup>11</sup> Other personal belief reasons included that VPDs are rare; therefore, the child has a low risk of coming in contact with an affected individual.<sup>11</sup> Negative marketing on "processed" foods or synthetic materials has also

affected vaccine hesitancy, as many parents desire to use “natural” or “organic” products.<sup>4,26</sup> The artificial composition of vaccines needs further explaining to parents who share this concern.<sup>26</sup> Thimerosal, a preservative, has been described as a significant toxin through the media as an agent that causes devastating side effects, such as autism, brain damage or developmental issues.<sup>50</sup> After thimerosal was thoroughly researched, no such claims were proven.<sup>11,56</sup> Researchers concluded that while high doses of thimerosal could potentially be dangerous, the extremely low levels found in the multi-dose vials of vaccines posed no risk.<sup>11,56</sup> Nonetheless, thimerosal has been removed from all vaccines given to children under the age of 6 years old, except for a trace amount in the Trivalent Influenza Vaccine (TIV).<sup>10, 50</sup> Parents also report concerns about children receiving too many vaccinations in one appointment for fear of overworking the child’s immune system.<sup>11</sup> Parents in this category often have minimal education on how the immune system operates and that all humans are exposed to thousands of pathogens daily.<sup>11</sup>

In a case control study by Salmon et al. of parents in Colorado, Massachusetts, Missouri, Washington, and Wisconsin who exempted their children from at least one vaccine, between 57% and 68.6% of them believed vaccinations caused harm to children.<sup>25</sup> Other concerns reported were fear of overwhelming the immune system, believing their child was not at risk for a VPD, belief that natural immunity would be superior to artificial immunity, and risk of autism.<sup>25</sup>

In Utah, parents who were seeking philosophical exemptions for their child were asked to participate in a study by Luthy et al. regarding reasons for exemption.<sup>25</sup> Parents were asked to complete a 16 question survey.<sup>25</sup> Of the 801 surveys completed, 66.8% of

parents reported a concern about safety, including side effects, chronic disease, such as autism and epilepsy, and immune system overload.<sup>25</sup> 287 parents responded to the open ended question on the survey regarding their overall vaccine perception.<sup>25</sup> Commonly listed answers included safety and efficacy concerns, the superior benefit of natural immunity and healing methods, and the desire to solidify the need for parental decision making.<sup>25</sup> This study may not be generalizable to the entire U.S. population as it was focused in Utah. The survey used has not yet been validated on other populations.<sup>25</sup>

#### Strategies for approaching vaccine hesitant parents

A cross sectional study done by Opel et al., performed in 9 pediatric practices around Seattle, Washington, investigated the types of approaches providers use to communicate with VHPs from September 2011 to August 2012.<sup>52</sup> The two formats used were participatory and presumptive.<sup>52</sup> The presumptive interview format "...linguistically presupposed that parents would vaccinate, such as declarations that shots would be given (eg, "Well, we have to do some shots")..."<sup>55</sup> The participatory format "...linguistically provided parents with relatively more decision-making latitude, such as polar interrogatives (eg, "Are we going to do shots today?") and open interrogatives..."<sup>55</sup> The study enrolled parents of children aged 1 to 19 months who were found to be vaccine hesitant on the Parent Attitude about Childhood Vaccine (PACV) Survey.<sup>52</sup> The study included visits with 16 different providers which were video recorded with specific attention to vaccine discussions.<sup>52</sup> A total of 55 vaccine discussions were analyzed.<sup>52</sup> The study found that among all parents, 83% of parents declined vaccine recommendations

when the provider began the conversation with a participatory format ( $p < .001$ ).<sup>52</sup> Meanwhile, 26% declined when the provider began with a presumptive format ( $p < .001$ ).<sup>52</sup> For VHPs alone, this continued to be true.<sup>52</sup> In the regression analysis, the providers' use of participatory formats in vaccine discussions was associated with a significant increase of parental resistance to their recommendations ( $OR = 14.2$ ).<sup>52</sup> The study also illustrated that in the 19 conversations where the parent demonstrated resistance to the provider's vaccine recommendations, 9 ultimately accepted the recommendations at the end of the appointment with persistent counseling.<sup>52</sup> This showcases the importance of a continued conversation between the provider and parent. There are several limitations to this study. First, providers and parents may act differently during videotaped conversations than during a normal, private discussion.<sup>52</sup> Follow up vaccine discussions were not recorded; therefore, the true impact of the conversation cannot be assessed.<sup>52</sup> The study enrolled parents who were white, English speaking from a single geographical location with a known higher socioeconomic status, so the actions of the parents may not be generalizable.<sup>52</sup>

Horne et al. investigated the change in vaccine attitude after receiving an intervention based on the risks of VPDS.<sup>53</sup> The goals of the interventions include showing VHPs the risk of their child contracting a VPD was higher than the risk of severe side effects from vaccines.<sup>53</sup> In this randomly controlled study, participants were assigned to the disease risk intervention, autism correction intervention, or a control intervention.<sup>53</sup> Participants in the disease risk group read three informational articles from the CDC's website, including a letter from a mother whose child contracted measles, pictures of

children with VPDs, and an article of succinct warnings about the importance of vaccines.<sup>53</sup> Participants in the autism correction group received information from the CDC explaining the research that refutes the association between vaccines and autism.<sup>10,</sup><sup>53</sup> The control group was asked to read about an unrelated scientific topic.<sup>53</sup> Before and after completing the assigned intervention, participants completed a five item vaccine attitude scale to measure their general attitude toward immunization.<sup>53</sup> The disease risk intervention demonstrated the largest change in pre and post intervention survey scores ( $p=.003$ ,  $d=.41$ ).<sup>53</sup> The study concludes that by focusing on the potential dangers of VPDs, providers may be able to persuade parents to vaccinate their children.<sup>53</sup> The autism correction and control interventions showed similar results, with no significant change ( $p=.017$ ).<sup>53</sup> Future studies may be needed to examine the long term effects of these interventions.<sup>53</sup>

A study by Masaryk and Hatokova published in the Journal of Health Psychology in 2016 reviewed how parents viewed pro-vaccine interventions in Slovakia.<sup>19</sup> The study participants were divided into two groups.<sup>19</sup> The first group consisted of female students, ranging from 19 to 26 years old, who were completing an undergraduate course.<sup>19</sup> The second group consisted of mothers from 26 to 45 years old with children under the age of 5.<sup>19</sup> Each group was split into four focus groups.<sup>19</sup> All women were white, Slovak nationals.<sup>19</sup> The four interventions were the same used in Horne et al.<sup>19,53</sup> They included autism correction, disease risk, disease narrative, and disease images and were focused on the MMR vaccination.<sup>19</sup> The groups were asked to discuss and rate the messages on several topics with a scale of 1 to 5, with one being excellent and five being inadequate.<sup>19</sup>

Both groups rated the messages understandable with a mean of 1.36.<sup>19</sup> The mean persuasiveness was 2.74 for autism correction, 2.68 for disease risks, 3.61 for disease narrative, and 3.36 for disease images.<sup>19</sup> Participants in both groups expressed feelings of manipulation and emotional blackmail by the disease narrative and images.<sup>19</sup> They felt the intent of the messages was too obvious which detracted from the goal.<sup>18</sup> There were reports of participants not understanding how the disease narrative and images related to vaccines, because they did not know what diseases the vaccines prevented.<sup>19</sup> The four interventions focused on the negative effects and publicity related to vaccines and VPDs, which created more fear and distrust in the source of the information.<sup>19</sup> A more positive approach may allow the provider to empower the target audience.<sup>19</sup> The study may not be generalizable to the U.S., as it was performed in Slovakia.

#### Parent provider interactions

In the 2009 HealthStyles consumer mail panel survey, parents were asked to list the top 3 sources for vaccine information.<sup>48</sup> 81.7% included their child's doctor or nurse.<sup>48</sup> 86.5% of the participants reported somewhat or strongly agreeing that they typically follow the recommendations of their child's healthcare provider, and 84% agreeing they trust their pediatrician's advice.<sup>48</sup>

A mixed method study performed at Kaiser Permanente Colorado examined the parental vaccine decision making process and parent pediatrician trust.<sup>55</sup> Seven focus groups of twenty four parents total were conducted with VHPs from 2008 to 2010.<sup>55</sup> Parents with children under 4 years old who were under vaccinated or unvaccinated for

personal, non medical reasons were included.<sup>55</sup> In the second part, 443 participants were asked to complete a sixteen question survey, with 9 Likert scale questions and 6 dichotomous or categorical questions.<sup>55</sup> 97% of parents who accepted vaccinations reported a high level of trust in their pediatrician, while 69% of parents who delayed vaccines and 38% of parents who refused vaccines reported the same high level of trust ( $p < .0001$ ).<sup>55</sup> Parents who refused vaccines (OR =35.7,  $p < .001$ ) and delayed vaccines (OR 8.4,  $p = .0006$ ) were more likely to have a low level of trust in the pediatrician compared to parents who accepted vaccines.<sup>55</sup> Of parents who refused vaccines, 26.7% reported their pediatrician adequately discussed the risks of vaccines with them, but 88.9% in this same group reported the pediatrician discussed the benefits of vaccines ( $p = .006$ ,  $p = .001$ ).<sup>55</sup> For parents who delayed vaccines, 41.7% thought risks were discussed appropriately, while 90.2% thought benefits were discussed adequately ( $p = .006$ ,  $p = .001$ ).<sup>55</sup> This may illustrate the benefits of vaccines were not enough to settle parental fears about the potential risks of vaccines.

Wheeler and Bутtenheim reviewed the medical record data of 237 provider parent interactions of well-baby visits from December 2009 to April 2011 at a private practice in an anonymous city to discover more about parental decision making.<sup>56</sup> This study showed that 19% of parents received vaccine information from family and friends and 21% received information from the Internet.<sup>56</sup> The majority of parents, 55% received information from their children's provider.<sup>56</sup> Medical record analysis showed that parents who based their vaccine decisions on non provider based information were associated with higher odds of reporting vaccine hesitancy.<sup>56</sup> The OR predicting a parent's intention

to use an alternative vaccination schedule for their child was .19 if the parent received vaccine information from the doctor and peaked at 10.57 for parents using books as the source of information ( $p < .05$ ,  $p < .01$ ).<sup>56</sup> The study names vaccine information books by Dr. Robert Sears as a commonly named source.<sup>56</sup> The odds ratio for having no concerns when receiving information from the provider was 2.92 ( $p < .001$ ).<sup>56</sup> The odds ratios for having no concerns about vaccines when receiving information from family and friends and the internet were 0.03 and 0.17, respectively ( $p < .001$ ,  $p < .05$ ).<sup>56</sup>

A randomized trial was performed in Washington by Henrikson et al. to assess whether a communication intervention for physicians could improve their confidence in conversations about vaccine hesitancy.<sup>57</sup> This two arm clinic level cluster randomized trial was performed in 47 outpatient pediatric and family medicine clinics from March 2012 to December 2013.<sup>57</sup> Mothers were contacted postpartum in four hospitals and given information about the study.<sup>57</sup> Participation was optional for mothers and physicians.<sup>57</sup> The clinics were randomized into control and interventions groups.<sup>57</sup> The intervention clinics received a 45 minute specific training session on a new strategy, called “Ask, Acknowledge, Advise” developed by Vax Northwest.<sup>57</sup> Physicians received informational handouts to review and six months of monthly newsletters with a link to a webinar version of the training.<sup>57</sup> The “Ask” portion of this strategy encourages parents to voice questions and concerns.<sup>57</sup> During the “Acknowledge” section the physician was instructed to establish open communication, show empathy for the parent’s concerns, and gain the parent’s trust.<sup>57</sup> Then, during the “Advise” portion the physician should state their recommendations to the parents and describe the risks and benefits of vaccines.<sup>57</sup>

The control clinics did not receive information on this communication strategy.<sup>57</sup> The PACV survey was used to measure maternal vaccine hesitancy before and after the intervention.<sup>57</sup> 347 mothers completed the study.<sup>57</sup> The intervention had no effect on vaccine hesitancy ( $p = .78$ ).<sup>57</sup> The secondary outcome included measuring the physician's confidence in communicating with VHPs about vaccines with a six single item, self efficacy survey before and after the study.<sup>57</sup> 70% of the control group's physicians reported confidence discussing vaccine hesitancy, compared to 58% of intervention group's physicians at baseline ( $p=.06$ ).<sup>57</sup> The intervention showed no significant effect on physician self efficacy at the 6 month follow up.<sup>57</sup> The limitations of the study by Henrikson et al. include that only 67% of the physicians in the intervention group attended the training and attendance was only monitored by a sign in sheet; therefore, there is not an adequate way to determine if the physicians were properly trained.<sup>57</sup> There was also no way to track if physicians utilized the online training information.<sup>57</sup> The study recommends further investigation into communication training of providers with long term training and longer follow up intervals to create new habits of communication tactics.<sup>57</sup>

#### Motivational interviewing

MI is a form of counseling patients by establishing the patient's motivation to change or form a decision.<sup>23,24</sup> Most MI research involves mental health outcomes, however, there has been an increased interest in MI for medical care discussions. MI aims to counsel the patient through a collaborative partnership between the provider and patient to motivate

change.<sup>24</sup> There are two main tactical components to MI.<sup>24</sup> The relational component is described as an “empathetic, affirming, non-judgmental and autonomy –supportive counseling style intended to create a safe environment in which clients can explore their own wishes, fears, and concerns.”<sup>24</sup> The technical component utilizes “strategies aimed at eliciting clients’ in session change talk and decreasing their sustain talk with the overarching goal of evoking commitment to change.”<sup>24</sup> MI is built on the characteristics of collaboration, evocation, acceptance, and compassion toward the patient.<sup>24</sup> The acronym “RULE, Resist, Understand, Listen, and Empower” is used to remember the four guiding principles of performing MI.<sup>24</sup> Training modules recommend providers focus on using open ended questions, positive affirmations when the patient makes a change, while reflecting on and summarizing the patient’s concerns and beliefs.<sup>24</sup>

A meta-analysis performed by Lundahl et al. in 2013 investigated the efficacy of MI in a range of medical care settings for a variety of general medical conditions.<sup>58</sup> Inclusion criteria consisted of randomized studies comparing patients in a medical care setting who received MI against patients who didn’t receive MI and must have been performed.<sup>58</sup> Studies were excluded if the goal of treatment was to aid with addiction or behavioral health.<sup>58</sup> 48 studies were reviewed, with a total of 51 comparisons analyzed.<sup>58</sup> The average length of MI intervention was 106 min with an average of 2.6 sessions.<sup>58</sup> Providers, on average, received 18 hours of MI training.<sup>58</sup> MI was shown to have statistical significance and a positive impact on 63% of the conditions researched. (Table 4).<sup>58</sup> The overall odds ratio for the 51 comparisons was 1.55 (p value<.001).<sup>58</sup> In other targeted outcomes, such as decreasing blood glucose, increasing medication compliance,

and increasing safe sex behavior, MI displayed positive odds ratios, but without statistical significance.<sup>58</sup> Targeted outcomes of eating disorders and self care were the only two with odds ratios less than 1.<sup>58</sup> MI did not have significantly different outcomes in the eight different types of medical settings ( $p=.60$ ).<sup>58</sup> The total amount of intervention time approached statistical significance ( $p=.06$ ); however, the meta analysis illustrated the number of MI sessions was not associated with positive outcome.<sup>58</sup> This may indicate that more time spent in one session may be more beneficial than multiple sessions.<sup>58</sup> The strict inclusion criteria and difference in number of studies per treatment outcome are limitations to the study.<sup>58</sup>

**Table 4. Overall MI effects by Targeted Outcome<sup>58</sup>**

<b>Targeted Outcome</b>	<b>Odds Ratio</b>	<b>p-Value</b>
Decrease in Blood Pressure	1.65	<.001
Decreasing HIV viral load	2.15	<.001
Decreasing number of dental caries	1.85	<.001
Decreasing amount of alcohol use	2.31	<.001
Decreasing amount of marijuana use	3.22	<.001
Increasing tobacco abstinence	1.34	<.05
Increasing quality of life	2.21	<.001
Self Monitoring	2.14	<.001
Intention to change	1.97	<.001

Prior to the study described above, Lundahl and Burke reviewed four meta-analyses in 2009 to explore the value and applicability of MI in clinical practice.<sup>59</sup> When MI was compared with weak comparison groups, such as no treatment or waitlists, a 14% to 20% difference in success was found after an average of two to three MI sessions.<sup>59</sup> MI compared to strong comparison groups, such as 12 step programs or cognitive behavioral therapy showed a 2% to 15% difference, suggesting MI is beneficial, but may not be

more beneficial than active treatments.<sup>59</sup> The review found MI requires less treatment time than other therapies investigated.<sup>59</sup> The average MI face to face time was 100 minutes less than comparison therapies.<sup>59</sup> None of the meta analyses showed associations between age or gender and positive outcomes.<sup>59</sup>

In a study by Joseph et al. a form of MI, called brief negotiated interviewing, was assessed for efficacy of counseling mothers about the benefits of human papillomavirus (HPV) vaccine for their daughters.<sup>60</sup> The CDC recommend beginning the vaccine series for boys and girls between ages 11 and 12.<sup>61</sup> The study was a randomized control, pilot trial and was performed in Boston, Massachusetts.<sup>60</sup> Mother daughter units were recruited from April 2011 and September 2013.<sup>60</sup> The study includes 100 Haitian American and 100 African American mother daughter units.<sup>60</sup> All daughters had not received a dose of the HPV vaccine.<sup>60</sup> All daughters were between 11 and 15 years old.<sup>60</sup> The pairs were randomized into control and intervention groups.<sup>60</sup> The control group received the standard of care, a low literacy HPV informational sheet.<sup>60</sup> The intervention group received brief negotiating interviewing by trained providers for approximately 20 to 30 minutes.<sup>60</sup> The session focused on the mother's beliefs and concerns about the vaccine and was intended to provide the mother information while being considerate of her concerns.<sup>60</sup> The primary goal of the study was for the daughters to receive the first dose of the HPV vaccine within 1 month of the intervention.<sup>60</sup> The proportion of mothers who consented to their daughters receiving the first dose was not significantly different, 56% in the intervention group and 51% in the control group ( $p=.47$ ).<sup>60</sup> The secondary outcome was a change in knowledge about the HPV vaccine among the mothers in the intervention

group measured through a pre and post intervention survey.<sup>60</sup> The post intervention survey demonstrated an increase in the mean score from 6 to 10.2, showing a significant difference of 5.3 in HPV vaccine knowledge ( $p < .0001$ ).<sup>60</sup> While vaccination rates did not increase, the intervention is a reasonable tactic to increase vaccine knowledge.<sup>60</sup>

Limitations of this study include the short follow up time period of only one month.

Reasons for not scheduling an appointment within a month may have been due to socioeconomic factors unrelated to vaccine acceptance.

## **METHODS**

### **Study design**

The study is a quality improvement (QI) research project that will seek to evaluate the change in vaccination rates for children of VHPs after receiving MI intervention by trained healthcare providers.

### **Study population and sampling**

The parental study population will be recruited from a single pediatric clinic located at Boston Medical Center (BMC). Parents of children aged 0 to 6 years old will be eligible for the study. The CDC's recommended childhood immunization schedule includes the recommended vaccines for children in this age range.<sup>6,35</sup> Appointments with eligible children for their respective age appropriate vaccines will be monitored during a six month time period for the intervention phase. Visits for children with true medical contraindications (Table 2) for the vaccine will be excluded from the study. The parents of these children will not receive the MI intervention. All providers, including physicians, residents, nurse practitioners, and physician assistants at this clinic will be required to participate in MI training and the QI study.

### **Recruitment**

All parents of children aged 0 to 6 years, who schedule visits at Boston Medical Center's pediatric clinic will be eligible for the study. If the parent demonstrates vaccine hesitancy during the appointment, the provider will initiate the MI intervention.

Healthcare providers at BMC's pediatric clinic will be required to attend the MI training sessions. The training sessions will be scheduled into normal work hours to avoid overtime and inconvenience to the providers.

### **Intervention**

The study will be organized using the "Plan, Do, Study, Act" model, also known as the PDSA model for quality improvement projects.

#### **Plan**

The Healthy People 2020 goal for all children aged 19 months to 35 months old to receive DTaP, IPV, MMR, Hib, Hepatitis B, varicella, and PCV immunizations is 80.0%.<sup>62</sup> The current vaccination rate at BMC's Pediatric clinic for children under 6 years old is 70%. This includes DTaP, IPV, MMR, Hib, Hepatitis A, Hepatitis B, varicella, PCV, and influenza vaccine acceptance data. The goal for this study will be to have a post-intervention vaccination rate of greater than 80% to meet the Healthy People 2020 goal.<sup>62</sup> The project also aims to obtain greater than 50% vaccine acceptance from the VHPs after receiving MI by the provider.

At BMC's Pediatric Clinic, providers see approximately 350 children per week between the ages of 0 and 6 years old. Using this information, it can be estimated that the clinic will see 8,400 children in this age range during the six-month intervention phase. The clinic has 170 vaccine related visits per week, where children are deemed eligible to receive a vaccine. This amounts to 4,080 vaccine related visits over six months. The

power calculation using the projected sample size of 4,080 eligible vaccination visits during the intervention phase and an alpha of 0.05 projects a post-hoc power of 1.<sup>63</sup>

The CDC's childhood immunization schedule (Appendix) will be used as the guide for each provider's vaccine recommendations. Vaccine hesitant parents in this study will be defined as parents who deny age appropriate vaccines for their child. A vaccine acceptance occurs when a parent is offered the recommended vaccine(s) for their child, aged 0 to 6 years old, and accepts the vaccine. A vaccine refusal will be counted when a parent of a child in the same age range refuses the recommended vaccines.

Do

Prior to the beginning of the study, providers must attend a 1-hour lecture provided by the primary investigator discussing the main reasons for refusal of vaccines. This lecture will be integrated into the department's Grand Rounds schedule. The training curriculum will be composed of multiple sessions, led by either an MI trainer or the primary investigator. The training sessions will include lectures, demonstrations, coaching sessions with small group practice, and systematic feedback sessions.<sup>64</sup> During the department's Grand Rounds, another 1-hour lecture and demonstration will be given about MI. Two additional sessions intended for small group practice and coaching will be held. This curriculum will ideally be held over a six-week period. The training sessions will be scheduled during regular work hours, with the aim to increase provider enthusiasm and compliance. Providers will be required to sign-in to all sessions to monitor attendance.

An MI trainer must observe each provider to ensure his or her skills are adequate prior to the intervention phase.

VHPs will be counseled using MI upon refusing the age appropriate vaccines for their child, as recommended by the CDC and WHO.<sup>7,36</sup> The time allotment for the intervention sessions will be dictated by the clinic's appointment scheduling and by provider discretion. Parents who remain hesitant after MI will be encouraged to return to the clinic for additional counseling. There will be no limit on the number of sessions. Parents who accept the vaccines will not receive the intervention. The historical vaccination rate calculated from the pre-intervention phase will be used as the control.

## Study

This project will measure two main outcomes.

- 1) The overall vaccination rates, pre-intervention and post-intervention
- 2) The proportion of VHPs who accepted the offered vaccine after the intervention

Data will be collected through a chart review. Prior to MI training, visits of children from 0 to 6 years old will be reviewed during the designated six-month time span. The vaccination acceptance rate will be assessed. It will include all childhood vaccines (Appendix). During the six-month intervention phase of this study, the clinic's overall vaccination acceptance rate will also be assessed through chart review. After the intervention phase, the total number of vaccine hesitant parents seen in the clinic will be counted. The number of these parents who accept the offered vaccine after receiving the

MI intervention will also be counted. The proportion of VHPs who accept the offered vaccine after MI will be analyzed.

Additional data (Table 5) will be evaluated during the retrospective chart review. The project will examine whether VHPs refused all vaccines or specific vaccines. The desired use of a modified vaccine schedule compared to following the CDC’s recommended vaccine schedule will be monitored.

Vaccination acceptance rates from pre and post intervention time periods will be analyzed using a paired t-test to evaluate the change in acceptance. The main focus will be the proportion of vaccine hesitant parents who accept the offered vaccine after receiving MI. This will be analyzed with a z-test for proportions.

**Table 5. Study Variables and Measures**

Pre Intervention	<ul style="list-style-type: none"> <li>• Historical vaccination acceptance rate</li> </ul>
Post Intervention	<ul style="list-style-type: none"> <li>• Vaccination acceptance rate</li> <li>• Total number of vaccine hesitant parents seen</li> <li>• Number of vaccine hesitant parents seen who accepted vaccine after receiving intervention</li> <li>• Number of vaccine hesitant parents seen who declined vaccine after receiving intervention</li> <li>• Number of MI visits completed by a vaccine hesitant parent prior to acceptance of vaccine</li> <li>• Number of vaccine hesitant parents who refuse all childhood vaccines</li> <li>• Number of vaccine hesitant parents who refuse specific childhood vaccines</li> </ul>

Act

After the completion of the intervention's designated time period, the change in vaccine acceptance by VHPs will be assessed to determine if MI had a positive impact on improving vaccination rates. The clinic's pre and post intervention vaccination rates will be reviewed. Statistical significance of both of these outcomes will be determined. The most commonly refused vaccines will be discussed among providers to explore specific strategies to help with acceptance. The average number of MI sessions attended per VHP who eventually accepted the offered vaccine will be examined to determine if multiple sessions should be required for future implementation. Feedback from providers who participated in this study will be obtained to see how the MI training or the MI intervention could be improved. The MI training curriculum and intervention phase will be edited according to this feedback. The project may be re-implemented in an appropriate amount of time as determined by feedback. This intervention may continue to be repeated as long as the feedback received indicates it remains relevant and effective.

## Timeline and Resources

**Table 6. Timeline for Study**

June 2017 - August 2017	<ul style="list-style-type: none"> <li>• IRB submission and approval</li> <li>• Reasons for Vaccine Refusal lecture Development</li> <li>• MI training Curriculum Development</li> </ul>
September 2017 – November 2017	<ul style="list-style-type: none"> <li>• Retrospective Pre Intervention Chart Review</li> </ul>
December 2017- March 2018	<ul style="list-style-type: none"> <li>• Reasons for Vaccine Refusal Lecture</li> <li>• MI Training Sessions I-V</li> </ul>
April 2018-September 2018	<ul style="list-style-type: none"> <li>• Six Month Intervention Phase: MI Implementation</li> </ul>
October 2018 – December 2018	<ul style="list-style-type: none"> <li>• Post Intervention Chart Review</li> <li>• Data Analysis</li> <li>• Submit manuscript for peer review</li> </ul>

The primary investigator will perform the project’s supervision, chart review, data collection, and data entry. A statistician will be hired to assist with data analysis. The primary investigator and Motivational Interviewing Network of Trainers (MINT) will develop the MI training curriculum. For this study, EMR access for BMC’s Pediatric clinic will be required. A MI trainer will also be hired to conduct and organize the MI training curriculum.

**Table 7. Budget for QI Study and MI Training**

<b>Line Item</b>
Administrative Support <ul style="list-style-type: none"> <li>• Clerical Wages</li> <li>• Statistical consulting</li> <li>• MINT consulting</li> </ul>
Supplies and Expenses <ul style="list-style-type: none"> <li>• Microsoft Excel</li> <li>• Microsoft PowerPoint</li> <li>• EMR access</li> </ul>

### **Institutional Review Board**

This research QI study will be submitted for review to the Boston University Medical Campus IRB for expedited review under the 45 CFR 46. 101 criteria. This study will employ new interviewing methodologies. This study will not collect any protected health information during the retrospective chart review. All information collected will be depersonalized.

## CONCLUSION

### Discussion

This study focuses on the relationship between pediatric providers and parents. It aims to explore the influential role that healthcare providers have on parental decision making. MI has not previously been researched as an intervention for increasing childhood vaccination rates. MI encourages nonjudgmental, informative discussions and can be used to showcase a common goal of parents and providers, which is to protect children and the community from unnecessary risk.

There are several limitations to this QI research study. First, MI is not an easy skill to learn. MI incorporates open dialogue without a predetermined script.<sup>24</sup> Providers must be able to speak freely and intuitively in response to parental concerns. To master MI, the providers must continually practice the skill. Therefore, it could be inferred that providers may be more successful in altering vaccination rates the longer they use the technique. In this study, patient interactions will not be monitored. The providers' competency in MI will only be directly assessed during training, not during the intervention phase. The length of MI intervention will not be monitored. Some parents may receive several sessions and others may only receive one. The appropriate counseling time needed may be researched at a later date.

The goal of this QI study is to assess the preliminary success of MI with VHPs and increase vaccination rates at BMC's Pediatric Clinic. The results of this study may not be generalizable to all demographics. BMC typically has a diverse population; however, the demographics of children and parents will not be recorded.

## Summary

Vaccine hesitancy is growing in the U.S.<sup>13</sup> Communities with decreased immunization rates are associated with a higher risk of a VPD outbreak.<sup>13</sup> Efforts should be heightened to communicate and educate parents about vaccine safety and benefits. Vaccines are victims of their own success.<sup>8</sup> Parents who refuse vaccines truly believe they are doing what is best for their child, but are commonly misinformed about the pathophysiology of vaccines.<sup>8</sup> In order to provide the highest level of care, it is vital that providers understand why parents refuse or delay vaccine doses for their children.<sup>11</sup> The varying reasons parents are hesitant to vaccinate their children can not be addressed uniformly.<sup>7</sup>

There have been increasing rates of unvaccinated and undervaccinated children in the U.S., likely due to the substantial increase in the number of children with nonmedical exemptions.<sup>25,26</sup> Many parents, regardless of their vaccine hesitancy status, are concerned about the side effects and safety of vaccines.<sup>25,26</sup> The field of vaccine hesitancy will continue to evolve as parents continue to be misinformed about vaccinations. The reasons for refusal may continue to grow as parents are influenced by a wide variety of sources.<sup>11,42</sup> Parents are found to receive vaccine information from a variety of sources, including the Internet, social media, celebrities, books, as well as family and friends.<sup>55,56</sup> However, the majority of parents describe their child's healthcare provider as their most trusted source of vaccine and healthcare information.<sup>55,56</sup> Parents who receive vaccine information from a provider are more likely to be compliant with the recommended childhood vaccine schedule.<sup>48,55,56</sup>

Many strategies have been attempted to effectively address vaccine hesitancy. A provider's conversations with a VHP can play an integral role in decreasing vaccine hesitancy. Poor communication can lead to further rejection of vaccines and the dissatisfaction of care.<sup>54</sup> The most efficient way to discuss vaccines with parents has yet to be determined. Parents have become increasingly inquisitive and involved in their children's healthcare choices. They want healthcare decisions to be a shared responsibility between them and the pediatrician.<sup>1</sup> Attacking a parent's beliefs often has a "back fire" effect, causing the parents to become more unlikely to vaccinate their child.<sup>53</sup> The majority of Americans are unfamiliar with the symptoms and potentially fatal effects of VPDs.<sup>19, 53</sup> Parents report feeling their concerns and the specific risks of vaccines are not adequately addressed by their child's provider.<sup>55</sup> Meanwhile, providers describe a lack of confidence in their vaccine counseling skills.<sup>57</sup> Providers are failing to provide VHPs with enough evidence and support to change their perspective.<sup>19</sup>

MI has shown to be beneficial for several medical treatment outcomes, including but not limited to decreasing alcohol consumption, increasing tobacco abstinence, and reducing blood pressures.<sup>58</sup> MI is goal-oriented to alter a specific behavior.<sup>59</sup> The intervention aims to inspire people to make behavioral changes through collaborative relationships with their provider where the patient eventually sees how their current behavior does not translate into their future or overall health goals.<sup>59</sup> Some studies show that MI is as effective as current active therapies for medical health issues, but requires a shorter amount of direct interaction.<sup>59</sup> Providers who initiate an open dialogue to address parental concerns may improve patient satisfaction. The ongoing debate of freedom of

choice versus public health protection can be explored and discussed between providers and parents.

This project aims to demonstrate the effectiveness of MI on vaccine acceptance and improve the overall patient care provided at BMC's Pediatric Clinic. By providing a quality MI training program, this study aims to increase provider confidence on vaccine counseling, improve provider communication skills, educate providers on reasons for hesitancy, and improve compliance with the CDC recommended vaccine schedule. An unmeasured benefit of the project may be an increase in knowledge of VPDs for parents. Providers will also be able to use their new MI skills for other healthcare conversations.

### **Clinical and/or public health significance**

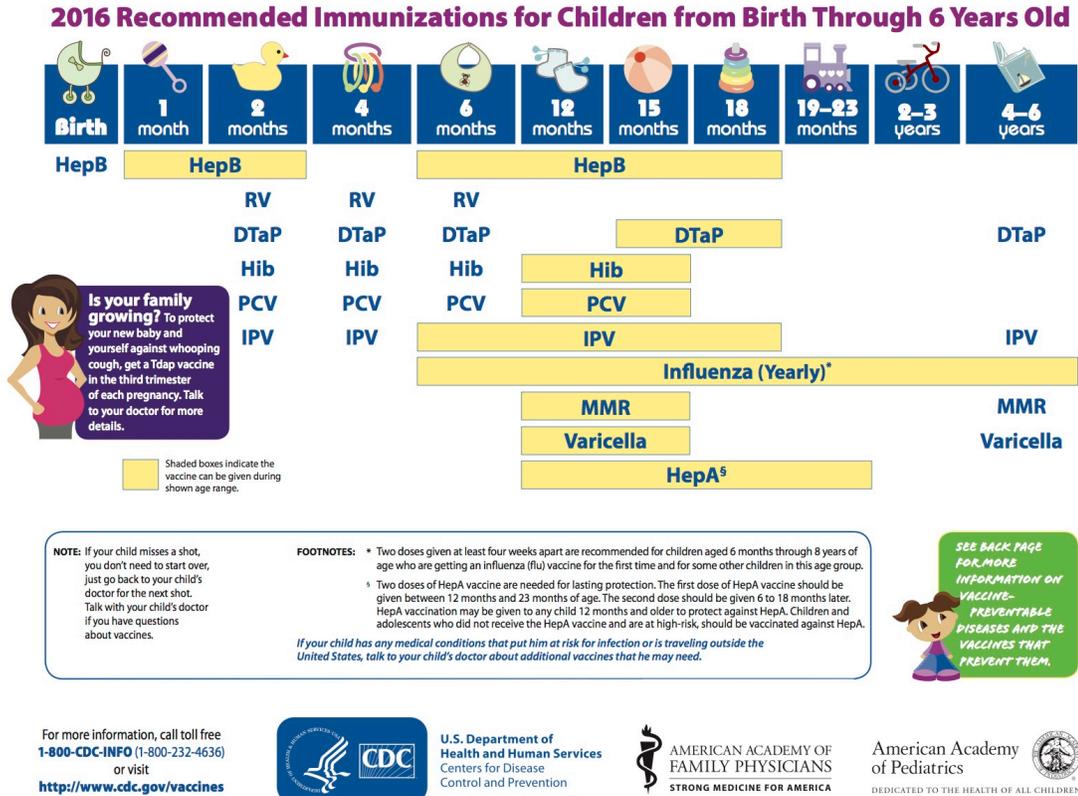
SAGE believes health communication will be an integral aspect of the success of any vaccine promotion project.<sup>63</sup> The impact of health communication between providers and parents was first demonstrated during the human immunodeficiency virus/acquired immunodeficiency syndrome epidemic where there was no treatment and the main tool was prevention with social and behavioral changes.<sup>63</sup> SAGE concludes that poor communication tactics could damage vaccine acceptance among VHPs.<sup>63</sup> For a health communication strategy to be effective to address vaccine hesitancy, SAGE recommends several components.<sup>63</sup> First, immunization programs should include proactive and methodical communication planning.<sup>63</sup> Strategies for providers to respond to VHPs should be organized at the onset of any program.<sup>63</sup> Second, the program should reinforce that provider patient communication is a two way process.<sup>63</sup> It is important for providers

to understand the parent's perspective prior to discussing this emotional topic.<sup>63</sup> The future of the pro-vaccination movement should place emphasis on communication with VHPs.<sup>41</sup>

The new President of the U.S., Donald Trump, has reportedly asked Robert F. Kennedy Jr. to head a potential government commission regarding vaccine safety. Mr. Kennedy is known to be anti-vaccinations. He has publically stated he believes that vaccines can lead to autism, even though this has been widely discredited.<sup>10</sup> The medical community fears this may worsen vaccination rates around the U.S. and add to the confusion about vaccine safety. It may even lead to mass infectious disease spread with reemergence of VPDs because of lower vaccination rates. Providers must be on high alert during this political change to continue to protect children and susceptible communities. The recent presidential election highlighted the advantages and disadvantages of the ever-increasing information technology. Our society has access to information from a seemingly limitless number of resources without a means to check on the reliability or credibility of the information. Medical professionals must remain engaged with their community and be cognizant of the information proliferating over the Internet so they may continue to provide care and education based on the best objective medical science available. Increasing awareness and learning efficient strategies for these frank discussions is extremely important, as all providers must educate patients about the benefits and successes of vaccines for all age groups.

## APPENDIX

**Figure 1: Recommended Immunization Schedule<sup>36</sup>**



## LIST OF JOURNAL ABBREVIATIONS

Acad Pediatr	Academic Pediatrics
Am Fam Physician	American Family Physician
Am J Epidemiol	American Journal of Epidemiology
Am J Public Health	American Journal of Public Health
Ann Intern Med	Annals of Internal Medicine
BMC Pediatr	BioMed Central Pediatrics
BMJ Open	BMJ: British Medical Journal
Clin Pediatr (Phila)	Clinical Pediatrics
Cogn Behav Pract	Cognitive and Behavioral Practice
Contemp Clin Trials	Contemporary Clinical Trials
Health Aff	Health Affairs
Hum Vaccin Immunother	Human Vaccines & Immunotherapeutics
J Am Osteopath Assoc	The Journal of the American Osteopathic Association
J Bioeth Inq	Journal of Bioethical Inquiry
J Family Med Prim Care	Journal of Family Medicine and Primary Care
J Health Psychol	Journal of Health Psychology
J Infect Dis	The Journal of Infectious Diseases
J Sch Nurs	The Journal of School Nursing
JAMA	The Journal of the American Medical Association
JAMA Pediatr	The Journal of the American Medical Association Pediatrics
JPPT	The Journal of Pediatric Pharmacology and Therapeutics

Med Decis Making	Medical Decision Making: an International Journal of the Society for Medical Decision Making
MMWR	Morbidity and Mortality Weekly Report
Motiv Interviewing	Motivational Interviewing : Training, Research, Implementation, Practice.
Patient Educ Couns	Patient Education and Counseling.
Pediatrics	Pediatrics
Proc Natl Acad Sci USA	Proceedings of the National Academy of Sciences of the United States of America
Przegl Epidemiol	Przegląd Epidemiologiczny
Public Health Rep	Public Health Reports
Vaccine	Vaccine

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**CURRICULUM VITAE**

