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The Effect of Education on Parental Attitudes and Beliefs Towards Vaccines

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Abstract:

Introduction: The importance, safety, and efficacy of vaccines has been questioned more than ever despite the clear and significant effectiveness of vaccines to reduce the incidence of severe illnesses.[1] Currently, the only required education before administering vaccines is the Vaccine Information Statements (VIS), which is provided by the Center for Disease Control (CDC) at each vaccination visit. These statements outline benefits and risks of vaccines but are written at an above-average reading level and do not directly address specific vaccine concerns. Many vaccine concerns can be assuaged with proactive education by providers at early well-child visits.

Objective: To determine the best methods for providers to educate parents about vaccines.

Methods: 241 studies were found through Pubmed and Pediatric Journal searches. 93 records were screened, and 14 articles were assessed for eligibility. Three randomized trials were chosen and a systematic review was performed for each.

Intervention: All studies provided an easy-to-read pamphlet that addressed specific questions about vaccine safety, importance, and efficacy. One study (Williams, et al) also provided a video addressing common vaccine concerns.

Results: In all studies, supplemental educational information led to improved attitudes about vaccines. None of the studies reported a significant change in the number of on-time vaccines received. Mothers in all groups stated they preferred to receive vaccine information prior to the first visit when vaccines were administered.

Conclusion: Easy-to-understand, accessible information addressing vaccine concerns provides more confidence in recommended vaccination schedules as compared to receiving the standard VIS. Providing these educational handouts prior to the first vaccination visit eases parent concerns without taking additional provider time.

Introduction:

Vaccines have been monumental in the development of modern healthcare since the smallpox vaccination became a widespread medical tool in the late eighteenth century, largely due to the work of Edward Jenner.[2] Just over 200 years later, smallpox has been eradicated, and the devastating consequences of other vaccine-preventable diseases (VPDs) such as rabies, tuberculosis, measles, and polio, have been minimized through the broad use of vaccines. Vaccines have been so effective that the United States requires vaccinations for children to attend schools and day cares. This began in 1827 with Boston, Massachusetts' requirement for children to provide proof of vaccination prior to starting school.[3] Today, most vaccines provide immunity over 90% of the time. For example, since the onset of vaccine use for mumps, measles (Appendix A), pertussis, and rubella, these VPDs have all decreased in incidence by over 97%. Polio has been eradicated in the United States, and even the influenza vaccine, which changes each year, decreases the chance of contracting the flu by 50-60%.[1,4] In conjunction with better overall hygiene and sanitation, vaccines have revolutionized preventative medicine and are vital to preventing diseases that once devastated entire nations.

Vaccines work by training the body to fight off certain antigens. A vaccine is made up of an inactivated, weakened, or altered form of a specific pathogen that, when injected, does not cause the disease but does start the body's immune reaction to make T-lymphocytes and B-lymphocytes, or antibodies, to that specific antigen.[5] If and when the body comes in contact with the re-exposure to the pathogen, memory cell activation triggers the production of these antibodies so that the antigen is destroyed without causing illness.

There are several types of vaccines. Live, attenuated vaccines contain a weakened version of the virus they prevent so that immunocompetent individuals will not become ill with exposure to the vaccine but will build up the necessary cytotoxic T-cells to fight off any exposure to the full-strength disease in the future. The Measles-Mumps-Rubella-Varicella vaccine (MMRV) is an example of a live attenuated vaccine and is extremely effective. Inactivated vaccines also fight viruses but use a dead version of the virus. This method is still effective in creating immunity but takes more doses of the vaccine to be effective. The polio vaccine is an inactivated vaccine currently used in the United States. Toxoid and conjugate vaccines both create immunity to bacterial illnesses. Toxoid vaccines involve injecting patients with a weakened version of an antigen that produces a toxin, or poison, in the body. This works in a similar way to live-attenuated vaccines and allows the body's immune system to learn how to fight off such bacteria. Both diphtheria and tetanus are toxoid illnesses that are prevented with toxoid vaccines. Conjugate vaccines, however, protect against bacteria with polysaccharide-coatings on the outside of each cell, which make it difficult for the immune system to detect and destroy the antigen. The conjugate vaccines physically link to the polysaccharide coating so that the immune system can better target the bacteria. The *Haemophilus influenzae* type B (Hib) vaccine is an example of a conjugate vaccine and has decreased the incidence of Hib-related diseases, including meningitis and pneumonia, in children by 99% in the United States.[6] Lastly, subunit vaccines contain partial bacteria or virus cells so that the patient is only exposed to the parts of the antigen that cause disease. This type of vaccine allows fewer side effects to occur with the administration of the vaccine. Pertussis is an example of a disease targeted by a subunit vaccine. Upon initial exposure to a vaccine or antigen, the body takes up to several weeks to make an adequate immune response. Vaccines allow this immune response to occur without the actual consequences of the disease which can mean the difference between life and death, especially in children whose immune systems are not yet fully mature.

Despite the clear and significant effectiveness of vaccines to reduce and sometimes eliminate, the incidence of a number of severe illnesses, the importance, safety, and efficacy of vaccines has been questioned since their inception.[1] Both historical and recent campaigns against vaccines involve concerns about the adverse side effects of vaccinations, the actual necessity of mass vaccinations, and the fear that vaccines cause, instead of prevent, their targeted diseases.[3] In fact, because vaccines work so well, the need for continuing vaccinations is currently questioned more than ever. Widespread vaccination leads to 'herd immunity,' which means that a critical number of those in the community are immunized and allows those who cannot receive vaccines for medical reasons, such as those who are immunocompromised, to still have some protection against VPDs. This works because the spread of the disease among the majority who are immunized is contained, and there is less of a chance of VPDs reaching those who are not vaccinated.[7] This concept, however, has led to those who fear adverse side effects of vaccinations, even if their children are immunocompetent, to refuse vaccinations and instead rely on herd immunity. The flaw in this course of action is that without enough vaccinated individuals, herd immunity fails and the risk of VPD outbreaks increases.[8]

The specifics regarding why parents are increasingly choosing to not vaccinate or follow alternative vaccination schedules mostly concentrates on vaccine safety for the individual. A study conducted in 2009 found that 54% of parents surveyed were concerned about serious side effects of vaccines, and 25% of parents believed some vaccines cause autism in healthy children.[9] This concern regarding autism having a direct relationship with vaccine administration began when a 1998 study published false results supporting the idea that vaccines cause an increase in autism incidence in children. This study was then fully retracted in 2010, and the author's medical license revoked due to manipulating evidence, but the belief still stands. This sustained, unproved belief is exacerbated by a lack of education about vaccines and their side effects, as well as the fact that autism is commonly first diagnosed at the same age at which children receive a large portion of their vaccinations. Additionally, a study published in 2013 stated that among parents who were surveyed and opted for an alternative vaccine schedule for their child, 38% believed that vaccines overtaxed a child's immune system.[10] This same study noted that 10% of the parents who opted for an alternative vaccination schedule that was more spread out used physicians as a source of information about vaccines, whereas 36% used friends and family, and 36% used the internet.[10] The high number of false concerns paired with parents using the internet and peers for information on vaccines over medical providers highlights the need for more proactive education for parents about the safety and efficacy of vaccines. Currently, the only required education for parents regarding vaccines is the Vaccine Information Statement (Appendix B) which is provided by the Center for Disease Control (CDC). These statements outline the benefits and risks of receiving a vaccine and must be given for each dose of a vaccine provided.[11] This process, however, has been criticized due to a lack of time allotted for parents to review the statements before their child receives the vaccine.[12] VIS are also written at a 10th grade reading level, which is higher than the 7th to 9th grade reading level of the average American.[13, 14]

Vaccines are central to knocking out major diseases that plague children as well as the population as a whole. In recent years, however, parental fears combined with the lack of education given to parents has led to a decrease in vaccinations in the United States. This trend could lead to the return of vaccine preventable diseases. Many of these fears can be assuaged with proactive education by providers at early well-child visits. It is imperative to determine the best methods for providers to educate parents on vaccine safety, importance, and efficacy to prevent these VPDs and continue to eliminate such ailments.

Clinical Question:

Among vaccine-hesitant parents of children, do new vaccine educational materials, compared to the standard Vaccine Information Statements (VIS), positively affect attitudes and beliefs towards vaccines (figure 1)?

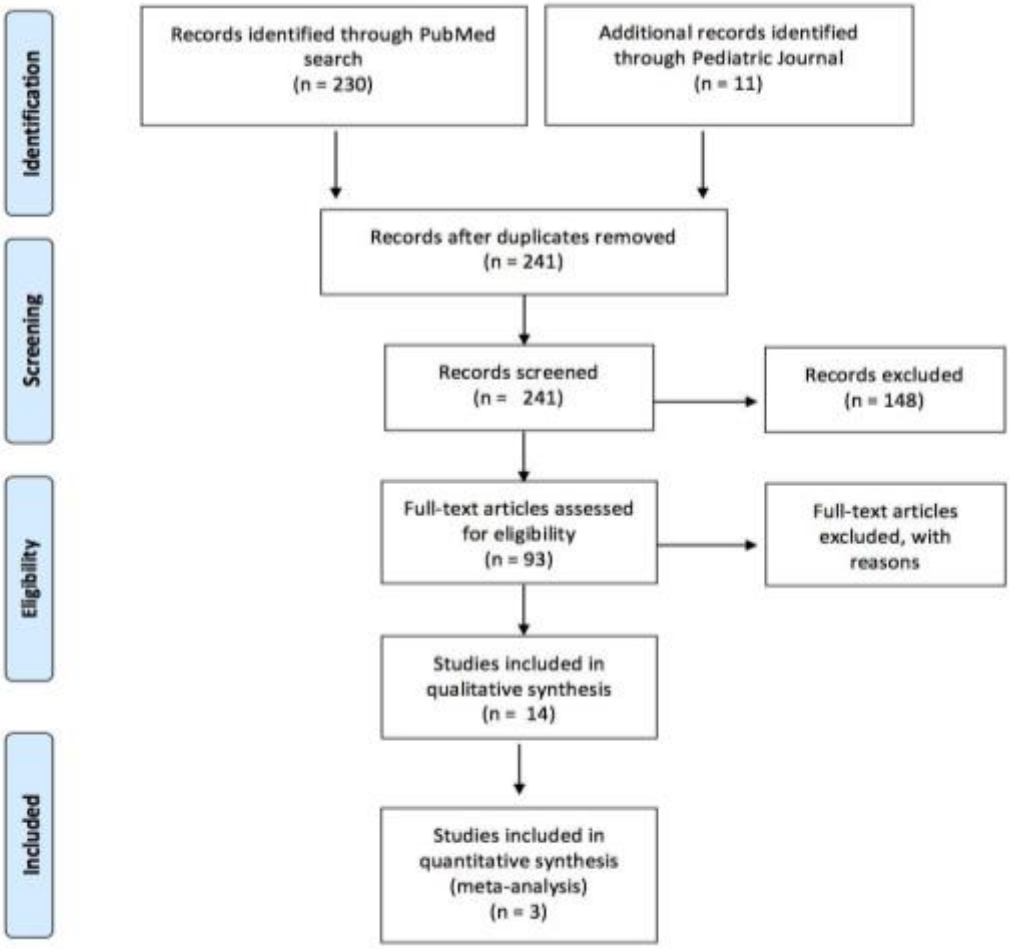
Figure 1: Study PICO used to formulate the clinical question

Population	Vaccine hesitant parents of children
Intervention	New vaccine educational materials
Comparison	Standard Vaccine Information Statements (VIS)
Outcome	Positively affect attitudes and beliefs towards vaccines

Methods:

A literature search was conducted on September 13th 2016, using the terms "vaccinations," "vaccines," "attitudes," "adult," and "published after 2009." The PubMed search found a total of 230 articles after using the filters for "Full Text" and "English." The Pediatric Journal search found 11 articles. Combining both searches resulted in a total of 241 articles with no duplicates to remove. The 241 articles were screened and 148 articles were excluded, including studies that addressed adverse effects of vaccines (n= 37), surveys of vaccine hesitant parents (n=25), guidelines and recommendations (n=9), and other irrelevant topics not focused on childhood vaccines (n=77). The remaining 93 articles were then assessed for eligibility and 79 were excluded based on irrelevant interventions (n= 54), provider centered interventions (n=10), and studies with no measurable outcomes (n=15). 14 studies were left for further analysis and the final 3 articles were included in this study for qualitative synthesis. The PRISMA flow chart outlines the process by which the articles were found (Figure 2).

Figure 2: PRISMA Flow Chart



The PRISMA outlines the process by which the study's articles were found. 241 studies were found through Pubmed and Pediatric Journal. 93 records were screened and 14 articles were assessed for eligibility. Finally, 3 studies were included in the qualitative synthesis.

Results:

Study 1: *Attitudes and Beliefs of Parents Concerned About Vaccines: Impact of Timing of Immunization Information.* Vannice, et al.[12]

Objective:

To evaluate the impact of giving information about vaccines and time for parents to review this information prior to starting childhood vaccine schedules on the attitudes and beliefs regarding the safety of vaccines.

Study Design:

The study recruited mothers over age eighteen who presented at outpatient obstetric and outpatient pediatric clinics at both Vanderbilt University in Nashville, Tennessee, and Palo Alto Medical Clinic in Palo Alto, California between February 2006 and May 2007. A third study site was originally included, but later withdrew, bringing to total sample size from 460 to 272 mothers. The 272 mothers were separated into four groups. Seventy-nine mothers were randomly assigned to the pre-natal visit group, meaning that they were given vaccine materials and time to review the information sheets at a visit prior to the births of their children. Seventy-seven mothers were assigned to the one-week well child visit group, sixty-one to the two-month visit group, and sixty-six mothers were assigned to the "all-time-points" group, in which mothers were given vaccine materials to review at each of the three visits in the study. Eleven mothers in the all-time-points group failed to complete all three surveys and were removed from the study, leaving this group with fifty-five participating mothers.

At the screening portion of the study, mothers were given a survey of five questions that assessed their beliefs concerning vaccines. Each mother, depending on her answers, was labeled either a "health-advocate," "fence-sitter," or "worried" (Table 1). Mothers who did not have concerns about vaccines were not included in the study.

When participating mothers arrived at their visit, they were given a packet with educational materials in addition to the required Vaccine Information Statement (VIS) provided by the CDC. The additional information pamphlet was a two-sided pamphlet that addressed vaccine-safety questions specifically, such as why children need vaccines and when they should not receive vaccines. Up to thirty minutes were given to each mother to review the materials and complete a post-test questionnaire that again assessed the attitudes toward vaccines. This post-test included questions about the necessity and safety of vaccines.

Once all data was collected, the survey answers were analyzed for each separate time group. Stata 9 was used for statistical analysis of all results, which were stratified for location, education level, trimester of prenatal care initiation, race, if this was the mother's first child or not, income, and vaccine-attitude label (Table 1).

Table 1: Definitions of Health-Advocates, Fence-Sitters, and Worried[15]

Vaccine Attitude Label	**Vaccines are necessary**	**Without vaccines my child may get a disease and cause others**	**Vaccines are safe**	**Serious side effects occur with immunizations**	**Medical professionals have the child's best interest at heart**

		to get the disease			
Health-Advocates	Agree	Slightly agree	Slightly agree	Neutral	Agree
Fence-Sitters	Slightly agree	Slightly agree	Slightly agree	Neutral	Neutral
Worried	Slightly disagree	Slightly disagree	Strongly disagree	Agree	Slightly disagree

Inclusion Criteria:

Mothers had to be eighteen years of age or older and attend one of the participating clinics. Each mother also had to have some concerns about vaccines which was determined by the mother's label. Only those who were either considered a health advocate, fence-sitter, or worried parent (Table 1) were included, while those who were immunization advocates or who trusted the medical provider's recommendations completely were not included in the study.

Results:

The responses to each of the five questions were adjusted to correspond to odds ratios with 95% confidence intervals. In the two-month and prenatal groups, the odds of responding positively to questions about vaccine safety were significantly higher when mothers were given the additional vaccine information for three of the five questions asked. In the one-week group, four out of the five questions received significantly more positive responses after reviewing the informational pamphlet. Regarding the timing of the information given, there was no significant difference between the groups. It was more crucial that the mothers were given easy-to-read information and allotted time to review it, than the timing of the education. In Table 2, the raw data that showed statistical significance was analyzed further to find out the likelihood ratios for giving the additional educational information to mothers.

Table 2: Results and Analysis for statistically significant results only

"Vaccines are Safe" - 1 week group			n=77	LR+: 0.51
	Safe	Not safe		LR-: 4.58
Screening	62	15		OR: 1.18
Intervention	75	2		
"Vaccines do not overtax a child's immune system"				
Prenatal group			n=79	LR+: 0.52

	Do not overtax	Overtax	
Screening	49	30	LR-: 2.8
Intervention	71	8	OR: 1.34

1 week group		n=77	LR+: 0.54
	Do not overtax	Overtax	LR-: 2.18
Screening	39	38	OR: 1.34
Intervention	62	15	

2 month group		n=61	LR+: 0.58
	Do not overtax	Overtax	LR-: 1.94
Screening	34	27	OR: 1.43
Intervention	50	12	

"If I vaccinate my child, he/she will probably not have a serious adverse effect" - 1 week group		n=77	LR+: 0.47 LR-: 1.87 OR: 0.95
	No serious ADE	Serious ADE	
Screening	16	61	
Intervention	40	37	

Sn: Sensitivity, Sp: Specificity, LR+: Positive Likelihood Ratio, LR-: Negative Likelihood Ratio, OR: Odds Ratio

Study Critique:

The study used the two-month vaccine group as the control group because this is when parents are typically given the Vaccine Information Statement (VIS) as required by law. This visit is when the child is receiving the vaccine, so the parents do not typically have a lot of time to review the information sheet prior to the vaccination. This is a weakness of this study because even the two-month visit group was given an easy-to-read, colorful pamphlet with additional information about the safety of vaccinations and was given additional time to review the information. This is not the typical standard of education that occurs at two-month well child checks and therefore is not a true control group. This could have skewed the results because

researchers are unaware of the attitudes and beliefs of parents who are only given VIS sheets immediately prior to vaccine administration.

Including the additional information pamphlet that was given to each mother would have benefitted the article. While the pamphlet was described as colorful and easy-to-read, and the information on the pamphlet was said to include answers to questions specifically regarding vaccine safety, such as "Why do children need so many vaccinations," "Why does my child have to receive so many vaccines in one visit," and "When should my child not receive vaccines," it would be beneficial for researchers to read what information was given. This would also benefit clinicians reading the article by giving an example of effective vaccine education that can improve parent attitudes and beliefs about vaccines.

Each mother included in the study was labeled as a "health-advocate," "fence-sitter," or "worried." These terms were taken from a previous study (Table 1) and were not defined in the current article. Defining these terms would give researchers a better understanding of what the original attitudes and beliefs about vaccinations were for each mother, without having to do additional, extensive research.

Tables presenting results for this study were clear, well-labeled, and easy to understand. Two tables displayed results, one giving the raw data and another with the odds ratios of each intervention group at a 95% confidence interval. This sufficiently allowed the reader to visualize the significance of each group's change in attitudes and beliefs.

The discussion section of this article showed insight into the limitations of the study. The authors noted that while attitudes towards vaccines did improve in all intervention groups, it appeared that giving mothers time to read easy-to-understand information about vaccines was more important than the timing of the education. It also touched on issues outside of the main intervention of the study, such as requests of providers to have more information to give patients about vaccines and the concept that parents who receive extra vaccine information from providers are less likely to go to other, less reliable, sources about vaccinations and therefore less likely to be misinformed. These outside ideas contributed well to the main assertion of the paper that additional education is warranted, wanted, and beneficial to mothers.

Study 2: *A Randomized Trial to Increase Acceptance of Childhood Vaccines by Vaccine-Hesitant Parents: A Pilot Study.* Williams, et. al.[16]

Objective:

To evaluate the effect of educational intervention on improving attitudes and on-time vaccinations in vaccine-hesitant parents.

Study Design:

The researchers conducted a clustered randomized trial at two pediatric practices in Tennessee, clustered meaning that groups were randomly given different educational interventions rather than individuals. The clinics were assigned as intervention or control sites by a coin flip. The participants were recruited by having the health care providers ask all parents of infants at two-week well-child visits if they were willing to enroll in the study.

The validated Parent Attitudes about Childhood Vaccines (PACV) survey (Appendix C) was distributed to all eligible parents to measure their acceptance of childhood immunizations, or level of "vaccine hesitancy." The PACV is scored from 0 to 100, with increasing scores corresponding to an increasing vaccine hesitant attitude. Those who scored greater than 25 on the

PACV survey were enrolled in the study and asked to provide their demographic information as well as what sources they typically use for trusted vaccine information.

A total of 369 parents took the PACV survey. The 122 parents who had PACV scores greater than 25 were enrolled in the study. Parents at the control site (n=67) were provided with routine care. Parents at the intervention site (n=55) received the educational intervention, including a handout on vaccine concerns, a handout on how to find accurate medical information on the internet, and an eight-minute video addressing concerns of vaccine-hesitant parents as well as vignettes of children contracting vaccine-preventable illnesses.

The intervention group filled out the PACV survey again right after viewing the video to measure any immediate attitude changes. Follow-up PACV surveys were distributed to both groups at the two-month well-child visit to measure any changes in parental attitude. Additionally, medical records were reviewed of all enrollees after the infants turned twelve weeks old to assess if they received the recommended vaccines.

The Wilcoxon rank sum test was used to compare differences in the PACV scores from the initial two week visit and the later, two-month visit. To assess the trend of vaccines received on time between the two groups, Pearson's chi-square test was used by comparing the differences among the control and intervention groups who did not receive all recommended two month vaccines by twelve weeks old.

Inclusion Criteria:

English speaking parents older than the age of eighteen with a full-term infant younger than one month old. Eligible parents scored greater than 25 on the PACV survey and attended one of the two pediatric practices in Tennessee.

Results:

In assessing the differences in PACV scores, both groups improved in their scores at the two-month visit, but the intervention site had a statistically significant improvement compared with the control site. There was a median difference of 6.7 points less vaccine-hesitant PACV score compared to the control group (p=0.049) (Table 3).

In assessing vaccine completion rates, approximately 80% of enrolled infants received all recommended two month vaccines and less than 10% of infants in each group received none of the recommended vaccines after twelve weeks of age. This indicated that there was no significant difference in on-time completion of all recommended vaccines among the two groups. Additionally, it was found that there was no association between those who identified the internet as a source of trusted vaccine information and those who did not complete their vaccines on time (P=0.977, Pearson's chi-square test).

This study concluded that educational materials are important in addressing concerns about vaccines before the first visit requiring vaccines and that this can be done without using additional provider time. By dispersing the educational materials in the clinics, the parents can trust the information, since this study reported that health care providers are the most trustworthy source of information (Table 4). Although the study showed that the use of educational materials resulted in less vaccine hesitancy, the educational materials did not correlate with a change in vaccination status.

Table 3: Changes in PACV score among the intervention and control groups

	Intervention Group (95% Confidence Interval)	**Control Group** (95% Confidence Interval)
PACV Score at 2 weeks	43.7 (39.7-47.7)	41.3 (37.4-45.3)
PACV score at 2 months	32.9 (27.3-38.6)	34.5 (29.7-39.2)
Mean Difference between PACV scores at 2 weeks and 2 months	10.8 points	6.8 points
Received all recommended 2 month vaccines, n (%)	54 (82%)	44 (83%)
No vaccines by 12 weeks, n (%)	5 (7.6%)	5 (9.4%)

Table 4: Sources of trustworthy vaccine information

Source	**Percentage**
Health Care Provider	86.9%
Internet	39.3%
Friends	26.2%
Family	25.4%
News or media	13.9%

Study Critique:

This study only reached parents in two private practices in Tennessee, resulting in a small sample size that is not inclusive of the general US population. Furthermore, the study was conducted as a clustered randomized control trial, which means the groups of trial participants are randomized as a whole group rather than individual participants themselves. This method lowers the statistical power of the study since there are only two groups to compare (small sample size) and assumes that everyone in each group is similar. The researchers did mention that the two groups were significantly different in their household income and accounted for this by adjusting for income in the regression analysis, which showed that the results remained significant.

The PACV surveys (Appendix C) were conducted in person, which could make parents more inclined to give less vaccine-hesitant responses due to social desirability bias. Furthermore, by completing the survey before meeting with the provider, the control group could have been primed to ask more vaccine questions, thus increasing their knowledge and leading to a less vaccine hesitant PACV score.

Additionally, the researchers could not account for discrepancies in vaccine education among the two groups due to different providers at the two sites. This could have potentially influenced the PACV scores.

Lastly, the researchers included participants who scored a 25 or greater on the PACV survey and other studies have found that parents who scored greater than 50 on the PACV were more under-immunized. Therefore, this could have created a dilutional effect of the intervention by including more parents who were less vaccine hesitant.

Study 3: *Differential maternal responses to a newly developed vaccine information pamphlet.* Klein, et. al.[17]

Objective:

To evaluate mother's preferences for a newly developed vaccine information pamphlet compared to the standard Vaccine Information Statements (VIS), measuring changes in attitudes and determining maternal preference for the timing of its distribution.

Study Design:

A randomized study was carried out among new mothers from the inpatient maternity wards at Lucile Packard Children's Hospital at Stanford and from Vanderbilt University's maternity ward and outpatient pediatric clinics.

To identify mothers with concerns about immunizations, a survey was provided to all eligible mothers and their score stratified them into three different groups, the "Fencesitters," "Worrieds," and "Health Advocates." Each label is defined in Table 1.

A total of 350 mothers took the screening survey, which resulted in 226 eligible mothers that classified into the three different groups. Then the mothers were randomized into three intervention groups. One group (n=75) received the new vaccine information pamphlet, the second group (n=76) received the Vaccine Information Statements (VIS) for each of the separate vaccines [diphtheria-tetanus-acellular pertussis (DTaP), hepatitis B, inactivated poliovirus, *Haemophilus influenza* type B, pneumococcal conjugate, measles-mumps-rubella (MMR) and varicella vaccines], and the third group (n=75) received both the new vaccine information pamphlet and the VIS handouts. The new vaccine information pamphlet and the VIS handouts are both written by the CDC.

After the mothers reviewed the materials, they completed a survey that assessed their preferences for the educational handouts, preferred time to receive and review the immunization information, and changes in attitudes and beliefs about immunizations.

Chi-squared or Fischer's exact test was used to assess the preferences of study materials. The preferences among the intervention group that reviewed both information sheets were additionally analyzed using the t-test to calculate the difference in score between the pamphlet and VIS for each mother and assess if the mean difference was greater than zero. Odds ratios were calculated to analyze attitude and belief changes from pre-test to post-test in each intervention group. Results were adjusted for location site, race, and language.

Inclusion Criteria:

Mothers older than the age of eighteen who received prenatal care and had a newborn under eighteen days old. They also had to have some concerns about vaccines, including only "Fencesitters," "Worrieds," and "Health Advocates." The Stanford location included mothers

who spoke English or Spanish due to their large Hispanic population and adequate bilingual staff. The Vanderbilt locations only enrolled English speaking mothers as they only used English study materials.

Results:

Mothers evaluating different educational materials on vaccine information showed that both the VIS and new pamphlet were helpful, trustworthy, and useful in opening the conversation about vaccines with providers. Overall, the new pamphlet was preferred over the VIS due to it being more visually appealing and easy to understand (Table 5).

The new pamphlet and the VIS did not show an increased belief in the safety of vaccines or a decreased belief that vaccines can cause serious side effects. However, mothers who reviewed the new pamphlet alone reported an increase in confidence in vaccines and reduced immunization concerns (Table 6). This indicated that the new pamphlet addresses other factors, like efficacy and side effects of the vaccine that may contribute to a mother feeling confident in vaccines, compared to just vaccine safety that the VIS emphasizes.

The researchers found that although there were no significant differences in demographics among the mothers in the intervention groups, demographic characteristics among mothers at the two sites were significantly different. Vanderbilt mothers were more likely to be younger and African American, whereas the Stanford mothers were more likely to be older, have higher incomes, and have completed more education. Both sites reported an increased confidence after reviewing the new pamphlet. The Stanford mothers, however, were less likely to have an increase in confidence in the safety of vaccines after reviewing the new pamphlet. The researchers interpreted this data to mean that mothers of higher socioeconomic status were not as interested in additional vaccine information and collected their information elsewhere. Alternatively, lower socioeconomic status mothers had less availability of vaccine information to counter their vaccine concerns. This supports the need for more research in developing targeted educational materials to address certain socioeconomic groups' specific concerns in order to improve parental confidence in vaccines.

In response to the preference for when to receive immunization information, mothers reported an interest in receiving the material during pregnancy and/or health check-ups before the first immunization visit, instead of during the first immunization visit. By distributing information before the first immunization visit, parental satisfaction with vaccines may increase since they would have time to review the educational materials and be prepared to discuss their specific concerns with a health provider.

Table 5: Maternal Ratings of VIS and New Pamphlet

Characteristic	**VIS (SD)**	**Pamphlet (SD)**	**Difference between pamphlet and VIS (SD)**	**95% CI**	**P-Value**	**Preference**
Visual appeal[a]	2.5 (0.8)	3.4 (0.7)	0.91 (1.08)	0.66-1.16	< 0.0001	Pamphlet
Trustworthiness[b]	3.1 (0.6)	3.2 (0.5)	0.09 (0.41)	-0.001 to	0.05	Both

				0.19		
Ease of understanding[c]	3 (0.8)	3.3 (0.7)	0.29 (0.87)	009-0.49	0.005	Pamphlet
Helpfulness[d]	3.1 (0.6)	3 (0.7)	-0.09 (0.71)	-0.26 to 0.07	0.25	Both
Is the material helpful in discussing vaccines with providers?[e]	2 (0.1)	1.9 (0.2)	-0.03 (0.23)	-0.08 to 0.03	0.32	Both
a: Responses scored for each material as "not appealing" = 1, "somewhat appealing" = 2, "appealing" = 3, or "very appealing" = 4.						
b: Responses scored for each material as "not trustworthy" = 1, "somewhat trustworthy" = 2, "trustworthy" = 3, or "very trustworthy" = 4.						
c: Responses scored for each material as "not easy" = 1, "somewhat easy" = 2, "easy" = 3, or "very easy" = 4.						
d: Responses scored for each material as "not helpful" = 1, "somewhat helpful" = 2, "helpful" = 3, or "very helpful" = 4.						
e: Responses scored for each material as "no" = 1, and "yes" = 2.						
SD: Standard Deviation, CI: Confidence Interval, VIS: Vaccine Information Statement						

Table 6: Changes in attitudes and beliefs among the different intervention groups

	VIS alone-Adjusted Odds Ratio (95% CI)	Pamphlet alone-Adjusted Odds Ratio (95% CI)	VIS and Pamphlet-Adjusted Odds Ratio (95% CI)
Increased confidence in vaccines	0.92 (0.57-1.47)	2.22 (1.26-3.93) P-value= 0.02	6.93 (2.27-21.17) P-value= 0.001
Increased belief in safety of vaccines	1.35 (0.83-2.02)	1.33 (0.93-1.89) P-value= 0.95	1.43 (0.99-2.07) P-value= 86
Decreased belief that multiple vaccines overload the immune system	1.34 (0.87-2.08)	2.93 (1.84-4.66) P-value= 0.02	2.71 (1.65-4.44) P-value= 0.04
Agreement that provider has child's best interest at heart	0.67 (0.37-1.22)	2.21 (1.15-4.26) P-value= 0.009	1.0 (0.61-1.63) P-value= 0.32
Decreased belief that vaccines cause serious side effects	0.94 (0.59-1.49)	1.45 (0.94-2.22) P-value= 0.18	1.13 (0.70-1.84) P-value= 0.57

P-value reflects whether change in attitude from pre to post is different between the material reviewed versus VIS alone
CI: Confidence Interval, VIS: Vaccine Information Statement

Study Critique:

The article did not include an example of the new vaccine pamphlet and only described what was displayed on it. A picture of the new pamphlet would have been beneficial to provide an example of effective vaccine education.

The table results were clearly labeled and easy to read. The preference of either the new pamphlet, VIS, or both were nicely displayed for each characteristic evaluated (visual appeal, trustworthiness, ease of understanding, etc.). The table also included the scoring of each characteristic, which was beneficial in understanding where the data came from. However, the article included mean scores and odds ratios without providing any raw data.

When evaluating the different vaccine information materials, the definition of "appeal" was not specifically defined, leaving the interpretation up to the mothers and making the results even more subjective than necessary. Additionally, this study mainly focused on measuring maternal attitudes and beliefs. They did not address any changes in knowledge after reading the vaccine materials or evaluate changes in immunization rates.

Discussion:

Major Findings:

The Health Belief Model for health behaviors outlines six steps involved in motivating individuals to take preventative action against disease (Table 7). This model states that perceived susceptibility of contracting a disease, perceived severity of the disease, and perceived benefits of taking action toward preventing the disease are essential parts in motivating patients to comply with any preventative medical intervention. Vaccine-preventable disease prevalence and severity have been trivialized in the United States, leading to a decrease in the motivation and confidence in vaccines, and therefore a decrease in mothers who abide by the recommended vaccination schedule for their children. Our research set out to find if new and innovative educational materials that are more reader-friendly have a positive effect on these early steps of the health-behavioral model. The goal is for an increase in knowledge about the prevalence and severity of vaccine-preventable diseases as well as an increase in confidence about vaccines to lead to the return of higher compliance of recommended vaccinations for children. Currently, approximately one in twelve children do not receive at least one major vaccination at the recommended time.[18]

Three studies that explored the use of different vaccine information methods on the attitudes towards vaccines held by mothers of infants were examined. Two of the studies used colorful, easy-to-read pamphlets to educate mothers about vaccines and address common vaccine questions, while one study used two handouts and an eight-minute video to educate mothers about vaccine safety and importance. Across all three studies, there was a significant improvement in the attitudes and beliefs of mothers towards vaccine safety and importance when given additional educational information. An overview of the characteristics of each study is provided below (Table 8). When educational information was given to parents at the one-week well-child visit, Vannice et al. found statistically significant results for those exposed to the new

educational pamphlets in regards to the attitudes toward vaccine safety, the idea that vaccines do not overtax a child's immune system, and that children who are vaccinated will not have serious side effects. Williams, et al. had statistically significant improvement in the Parent Attitudes About Childhood Vaccines (PACV) score (Appendix C) when the mothers were given the educational handouts and video. Klein, et al. reported statistically significant results for improving mothers' confidence levels in vaccines when the mothers were given the new vaccine pamphlet. None of the studies displayed a significant difference in the actual immunization rates after education, but attitudes and beliefs about vaccines were improved across all three studies. According to the health belief model, this is the first step towards improving vaccination compliance.

Table 7: Health Belief Model[19]

Concept	**Definition**	**Application**
Perceived Susceptibility	One's opinion of chances of getting a condition	Define population(s) at risk, risk levels; personalize risk based on a person's features or behavior; heighten perceived susceptibility if too low.
Perceived Severity	One's opinion of how serious a condition and its consequences are	Specify consequences of the risk and the condition
Perceived Benefits	One's belief in the efficacy of the advised action to reduce risk or seriousness of impact	Define action to take; how, where, when; clarify the positive effects to be expected.
Perceived Barriers	One's opinion of the tangible and psychological costs of the advised action	Identify and reduce barriers through reassurance, incentives, assistance.
Cues to Action	Strategies to activate "readiness"	Provide how-to information, promote awareness, reminders.
Self-Efficacy	Confidence in one's ability to take action	Provide training, guidance in performing action.

Table 8: Overview of Studies

	Study 1: Vannice, et al.[12]	Study 2: Williams, et al.[16]	Study 3: Klein, et al.[17]
Objective of Study	To evaluate the impact of giving information about vaccines and time for parents to review this information prior to starting childhood vaccine schedules on the attitudes and beliefs regarding the safety of	To evaluate an educational intervention in improving attitudes and on-time vaccinations in vaccine-hesitant parents	To evaluate mother's preferences for a newly developed vaccine information pamphlet compared to the standard Vaccine Information Statements (VIS), measuring changes in attitudes towards

	vaccines		vaccines
Enrollment Method	Screened by physicians at outpatient obstetric and outpatient pediatric clinics in Nashville, TN, and Palo Alto, CA	Physicians screened new mothers at a pediatric practice in Tennessee	Mothers at an inpatient maternity wards at Stanford and Vanderbilt University and at an outpatient pediatric clinic were solicited and screened
Number of Participants	272	122	226
Duration of study (Time intervals studied)	16 months total, 3-4 months per subject (Prenatal, 1-week well-child visit, 2-month vaccination visit)	3 months per subject (screening, 2-week visit, 2-month visit, 12 week assessment of vaccination status)	9 months (single day survey given to mothers with newborns < 18 days old)
Interventions	A new, 2-sided, easy-to-read, visually-appealing pamphlet that directly address common vaccine questions	1. 8-minute video 2. educational handout on common vaccine concerns 3. handout with written instructions on how to find accurate medical information on the internet	New vaccine intervention pamphlet developed by the CDC that addressed all vaccines recommended for the first two years of life and answers to common vaccine questions
Source of funding	Center for Disease Control and Prevention (CDC), Vaccine Attitudes and Risk Perception (VARP), Clinical Immunization Safety Assessment (CISA)	Vanderbilt Institute for Clinical and Translational Research, Agency for Healthcare Research Quality	Centers for Disease Control and Prevention (CDC), Vaccine Attitudes and Risk Perception (VARP), and Clinical Immunization Safety Assessment (CISA), America's Health Insurance Plans Vaccine Safety Fellowship Program

Limitations and reliability of results:

All three studies were limited by location. Each was based out of clinics in one or two areas, which meant that the U.S. population as a whole was not well represented. Additionally, these studies all drew from similar populations, focusing on clinics in either Tennessee, Palo Alto, California, or both areas. Without having a true representation of the United States population, it is difficult to know how these interventions would work on a larger scale.

Legally, medical providers must provide patients with Vaccine Information Statements (VIS), which outline the risks, benefits, and procedures for vaccinations. Without being able to fully withhold giving educational information to some patients, these studies were unable to have

a true control group. This limited the studies because every subject received some educational information from providers, and the effectiveness of the newer, reader-friendly information was not the only factor in shaping the attitudes and beliefs of each mother.

The outcome measured in each of the studies was difficult to quantify, providing another limitation to how well each study can relay the effectiveness of new vaccine information materials. Attitudes and beliefs by individual mothers is a personal, subjective, and abstract measure, making it near impossible to standardize and difficult to quantify. For example, in the post-intervention surveys, the wording "strongly agree" regarding the statement "vaccines are safe," as seen in Vannice, et al., has different meanings from mother to mother.

Strengths:

A lack of obvious bias was a strength of each study. The major funding for Vannice, et al. and Klein, et al. was through the Center for Disease Control (CDC) and Vaccine Attitudes and Risk Perception, neither of which had a potential monetary gain from the results of the studies. Williams, et al., was funded mainly by Vanderbilt Institute for Clinical and Translational Research, which was also the clinical setting at which the study took place. This potential bias could have meant providers were more passionate about promoting the videos and pamphlets produced by Vanderbilt University, but the wording and attitudes by providers about each intervention is unknown.

Another strength of the three studies examined was the degree of follow up. Every subject was seen at consistent intervals due to the standardization of well child checks for infants and the degree of follow up was consistent due to the standardization of recommended vaccination schedules. In Klein, et al., a single day survey was used, meaning that the mothers took their screening surveys, reviewed the educational materials, and took their post-intervention surveys in the same visit, guaranteeing consistent follow up.

Weaknesses:

The statistical analysis for the studies, especially Williams, et al., was a major weakness during our research. Williams, et al. did not include any raw data from the surveys conducted after each intervention. This made it difficult to assess the reliability of the study and the true effect that the video and educational handouts used as interventions had on mother's beliefs. Sample size was another weakness of each study, ranging from 122 subjects to 272 subjects. With 16,000,000 children in the United States, a sample size of 385 should have been utilized for each study to capture a true representation of the population at a 5% confidence interval. Another perceived weakness was the lack of involvement of other caregivers other than mothers in Vannice, et al. and Klein, et al. These two studies did not mention fathers or other guardians, but only included mothers of children as the decision makers for each infant's healthcare. This is not realistic of the home situation of U.S. parents as a whole, as fathers and other caregivers also have influence on the vaccination schedule utilized for children.

Conclusion:

Pediatricians face opposition to childhood vaccinations every day and need a way to combat the concerns of vaccine hesitant parents. Vaccines have been extremely effective in eliminating and reducing the number of vaccine-preventable diseases, but vaccine importance, safety, and efficacy are still questioned. Providers must respect parental rights to make their own medical decisions, but also consider public health consequences. Our research explored the most

effective intervention techniques that providers can use to educate hesitant parents and combat the major concerns of the recommended vaccination schedule.

Providers can start by giving parents vaccine information before the two-week well child visits where vaccines are given. This will allow parents time to review the vaccine information and not be pressured to make a decision right then. By giving the educational materials before the well visit, this can open up the conversation between the provider and parents as well as pre-emptively address parental concerns and questions without taking additional provider time.

The educational materials must be at an appropriate reading level and be visually appealing, without being too wordy. The content addressed should target the average parent and not providers. Focusing on safety is important, but materials also needs to include reasons for vaccinating and vaccine importance in relation to individual and herd immunity.

These initiatives can provide accurate educational information and dismiss false beliefs by providing targeted messages. The goal of these educational interventions is to increase positive parental attitudes toward vaccine safety, efficacy and importance.

Future research is needed to be carried out to include a wider population base. This will further identify effective interventions in relaying accurate information in an efficient manner to maintain and improve confidence in vaccines among parents across the nation.

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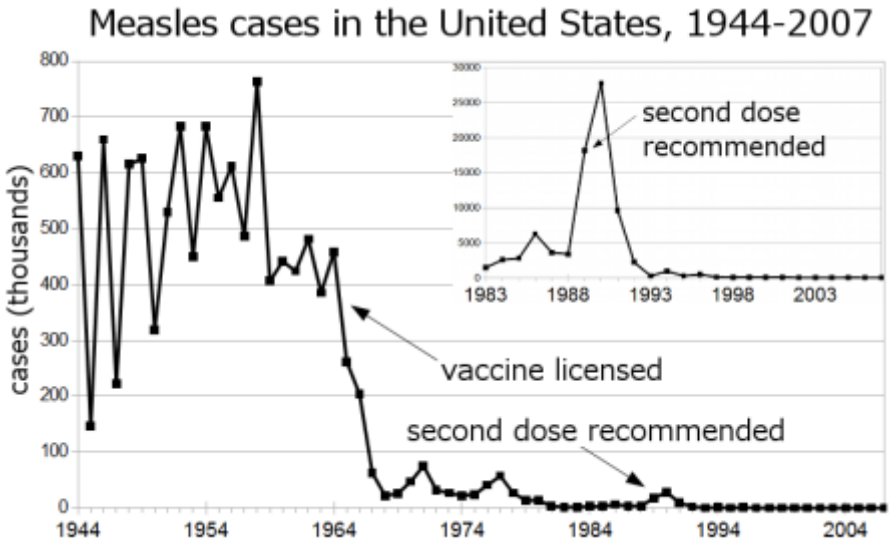
Appendix A: Incidence of Reported Measles Cases between 1944-2007[20,21]



Number of Reported Measles Cases in the US, 2007-2014	
Year	Reported Cases
2007	43
2008	140
2009	71
2010	63
2011	220
2012	55
2013	187
2014	667

Appendix B: MMRV Vaccine Information Statement (VIS)[22]

VACCINE INFORMATION STATEMENT

MMRV Vaccine

(Measles, Mumps, Rubella and Varicella)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

What You Need to Know

1 Measles, Mumps, Rubella and Varicella

Measles, **M**umps, **R**ubella, and **V**aricella (chickenpox) can be serious diseases:

Measles
- Causes rash, cough, runny nose, eye irritation, fever.
- Can lead to ear infection, pneumonia, seizures, brain damage, and death.

Mumps
- Causes fever, headache, swollen glands.
- Can lead to deafness, meningitis (infection of the brain and spinal cord covering), infection of the pancreas, painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)
- Causes rash and mild fever; and can cause arthritis, (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Varicella (Chickenpox)
- Causes rash, itching, fever, tiredness.
- Can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- Can re-emerge years later as a painful rash called shingles.

These diseases can spread from person to person through the air. Varicella can also be spread through contact with fluid from chickenpox blisters.

Before vaccines, these diseases were very common in the United States.

2 MMRV Vaccine

MMRV vaccine may be given to children from 1 through 12 years of age to protect them from these four diseases.

Two doses of MMRV vaccine are recommended:
- The first dose at **12 through 15 months of age**
- The second dose at **4 through 6 years of age**

These are *recommended* ages. But children can get the second dose up through 12 years as long as it is at least 3 months after the first dose.

Children may also get these vaccines as 2 separate shots: **MMR** (measles, mumps and rubella) and **varicella** vaccines.

1 Shot (MMRV) or **2 Shots** (MMR & Varicella)?

- Both options give the same protection.
- One less shot with MMRV.
- Children who got the first dose as MMRV have had more fevers and fever-related seizures (about 1 in 1,250) than children who got the first dose as separate shots of MMR and varicella vaccines on the same day (about 1 in 2,500).

Your doctor can give you more information, including the Vaccine Information Statements for MMR and Varicella vaccines.

Anyone 13 or older who needs protection from these diseases should get MMR and varicella vaccines as separate shots.

MMRV may be given at the same time as other vaccines.

3 Some children should not get MMRV vaccine or should wait

Children should not get MMRV vaccine if they:
- Have ever had a life-threatening allergic reaction to a previous dose of MMRV vaccine, or to either MMR or varicella vaccine.
- Have ever had a life-threatening allergic reaction to any *component* of the vaccine, including gelatin or the antibiotic neomycin. Tell the doctor if your child has any severe allergies.
- Have HIV/AIDS, or another disease that affects the immune system.
- Are being treated with drugs that affect the immune system, including high doses of oral steroids for 2 weeks or longer.
- Have any kind of cancer.
- Are being treated for cancer with radiation or drugs.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Check with your doctor if the child:

- Has a history of seizures, or has a parent, brother or sister with a history of seizures.
- Has a parent, brother or sister with a history of immune system problems.
- Has ever had a low platelet count, or another blood disorder.
- Recently had a transfusion or received other blood products.
- Might be pregnant.

Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMRV vaccine. Children who are only mildly ill may usually get the vaccine.

Ask your doctor for more information.

4 What are the risks from MMRV vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMRV vaccine causing serious harm, or death, is extremely small.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox.

Most children who get MMRV vaccine do not have any problems with it.

Mild problems

- Fever (about 1 child out of 5).
- Mild rash (about 1 child out of 20).
- Swelling of glands in the cheeks or neck (rare).

If these problems happen, it is usually within 5–12 days after the first dose. They happen less often after the second dose.

Moderate problems

- Seizure caused by fever (about 1 child in 1,250 who get MMRV), usually 5–12 days after the first dose. *They happen less often when MMR and varicella vaccines are given at the same visit as separate shots (about 1 child in 2,500 who get these two vaccines), and rarely after a 2nd dose of MMRV.*
- Temporary low platelet count, which can cause a bleeding disorder (about 1 child out of 40,000).

Severe problems (very rare)

Several severe problems have been reported following MMR vaccine, and might also happen after MMRV. These include severe allergic reactions (fewer than 4 per million), and problems such as:

- Deafness.
- Long-term seizures, coma, lowered consciousness.
- Permanent brain damage.

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)

MMRV Vaccine

5/21/2010

42 U.S.C. § 300aa-26

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Appendix C: Descriptive Characteristics and content of the PAVC Survey[23]

Content Domain	Item	Response Format
Immunization Behavior	Have you ever delayed having your child get a shot for reasons other than illness or allergy?	Yes No Don't know
	Have you ever decided not to have your child get a shot for reasons other than illness or allergy?	Yes No Don't know
	How sure are you that following the recommended shot schedule is a good idea for your child?	0 (Not at all sure) to 10 (Completely sure)
	It is my role as a parent to question shorts.	Strongly Agree Agree Not sure Disagree Strongly Disagree
	If you had another infant today, would you want him/her to get all the recommended shots?	Yes No Don't know
	Overall, how hesitant about childhood shots would you consider yourself to be?	Not at all hesitant Not too hesitant Not sure Somewhat hesitant Very hesitant
Beliefs about Vaccine Safety and Efficacy	Children get more shots than are good for them.	Strongly Agree Agree Not sure Disagree Strongly Disagree
	I believe that many of the illnesses shots prevent are severe	Strongly Agree Agree Not sure Disagree Strongly Disagree
	It is better for my child to develop immunity by getting sick than to get a shot	Strongly Agree Agree Not sure Disagree Strongly Disagree
	It is better for children to get fewer vaccines at the same time.	Strongly Agree Agree Not sure Disagree Strongly Disagree
	How concerned are you that your child might have a serious side effect from a shot?	Not at all concerned Not too concerned Not sure Somewhat concerned Very concerned

	How concerned are you that any one of the childhood shots might not be safe?	Not at all concerned Not too concerned Not sure Somewhat concerned Very concerned
	How concerned are you that a shot might not prevent the disease?	Not at all concerned Not too concerned Not sure Somewhat concerned Very concerned
	Do you know anyone who has had a bad reaction to the shot?	Yes No Don't know
Attitudes about Vaccine Mandates and Exemptions	The only reason I have my child get shot is so they can enter daycare or school	Yes No Don't know
Trust	I trust the information I receive about shots.	Strongly Agree Agree Not sure Disagree Strongly Disagree
	I am able to openly discuss my concerns about shots with my child's doctor.	Strongly Agree Agree Not sure Disagree Strongly Disagree
	All things considered, how much do you trust your child's doctor?	0 (Do not trust at all) to 10 (Completely trust)