

## Taking a Shot at Immunization Adherence Group Visits for Vaccine-Averse Parents

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### Abstract

**Introduction:** Decreased vaccination rates in children have played a role in the deaths of several children in the United States over the last decade. Interventions to date have been ineffective at changing vaccination patterns. No studies have evaluated a conciliatory patient-centered approach where parent concerns were acknowledged and addressed in a group setting.

**Methods:** Vaccine-averse parents with incompletely vaccinated children were recruited from a family medicine practice. These parents attended three group visit sessions centered on vaccine safety and efficacy. Pre and post surveys were given at each session. The children's vaccination records were examined in the year prior and the year following the groups. One year after the group visits, parents were interviewed about their attitudes toward vaccination.

**Results:** There were no significant attitude changes in parents attending the group visits. In the year following the visits, the percentage of recommended vaccines that children had received did not increase. Interviews with parents revealed a broad range of concerns about vaccines and a widespread desire for a longer-term study designed to address these concerns.

**Conclusions:** Surveys and vaccination records revealed no significant change in attitudes or behavior after three group visit sessions, consistent with other research on interventions with vaccine-averse parents. The phone interviews demonstrated a desire for further research into long-term effects of vaccines, with most parents stating that they would consider changing their beliefs if the research was free from commercial bias, addressed their concerns, and was extended out over a long period of time.

## Introduction

Vaccinations are one of the most successful public health interventions, saving an estimated 2 to 3 million lives every year.<sup>1</sup> Despite this, there has been an increase in parental concern regarding childhood vaccines in the United States.<sup>2,3</sup> This has led to reduced vaccination rates in certain communities, which has played a role in recent disease outbreaks resulting in several deaths.<sup>4,5</sup> The vaccination rate nationwide for seven common vaccines (DTaP, MMR, polio, Hib, varicella, and PCV) for children aged 19 to 35 months was 72.2% in 2015, and was 78.5% in Massachusetts.<sup>6</sup>

Parental reasons for vaccination nonadherence include concerns about the risk of adverse effects, chemicals used in vaccines, use of fetal stem cell lines in vaccine production, and others.<sup>7</sup> Though many studies have tried to address vaccine hesitancy, a meta-analysis in 2013 found no evidence that interventions had any positive effect.<sup>8</sup> In fact, directly challenging parents' viewpoints can lead to reduced intent to vaccinate.<sup>9</sup>

To date, no studies have tried a conciliatory approach in which patients' specific concerns were not dismissed and were the focus of the discussion. We hypothesized that the increased rapport associated with this approach might make patients more likely to modify their stance on vaccination.

## Methods

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Subjects were recruited by creating a registry of children who were behind on their vaccines and who were patients at Family Practice Group (FPG) in Arlington, Massachusetts. Parents of these children were invited to participate in a three-session group visit series. This process yielded six mothers with a total of 12 children from 2 months to 6 years old. Two additional children were born the following year. These parents attended some or all of three 1-hour group sessions, which were held at FPG on a weekday evening.

During each session, participants received handouts addressing specific vaccines.<sup>10</sup> Participants were given a chance to read each handout, and to voice concerns they had about each vaccine. Their questions were answered, followed by discussion on vaccine-preventable diseases and the vaccines themselves. Anticipated concerns of the parents regarding each vaccination were addressed.<sup>7</sup> Before and after each group session, participants completed a Likert-scale survey on safety and efficacy of the vaccines discussed and intent to vaccinate.

Participants were given letter codes to protect identity. Participant codes were the same for pre and post surveys in each individual session, but each participant's code was not the same across sessions.

Responses to the 40 questions in the pre- and post-session surveys were analyzed, with the average, standard deviation, and *P*-value calculated for each question. The average, standard deviation, and *P*-value of the pooled answers were calculated also.

One year after the completion of the three monthly group sessions, we accessed the vaccination records of the participants' children. Percentages of vaccines recommended by the Centers for Disease Control and Prevention (CDC) that were administered at the start of the sessions, as well as 1 year later, were calculated for each child. The recommended total for each child was calculated using the CDC vaccination schedule.<sup>11</sup>

Four of the six participants completed a 30-minute phone interview about attitudes toward vaccination 1 year after the group visit sessions. We also interviewed one parent who was invited to attend the group visits but could not. The interviews were recorded and coded by a member of the research team using the interview guide as a template.

Institutional review board (IRB) approval was obtained from the Tufts University IRB.

## Results

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Survey response rates at each session were 100%, although not every parent was able to come to every session.

Only two out of 40 survey questions showed a statistically significant difference in response between the pre- and post surveys ( $P < 0.05$ ). These questions were "Do you trust doctors' information on vaccines?" ( $P=0.03$ ) and "Is the Hepatitis A vaccine safe?" ( $P=0.03$ ). The post-survey responses for these two questions displayed a more favorable attitude regarding vaccines. Pooled responses to all questions also revealed more favorable attitudes toward vaccines, with the average increasing from 4.02 to 4.39 ( $P=0.04$ ).

The average number of vaccines given per child modestly increased from 6.14 before the groups to 7.00 one year after, but the number of recommended vaccines increased substantially. As such, the percentages of recommended vaccines that the average child received decreased from 36% to 33%.

The majority of participants were appreciative of the group visits, but left with similar concerns to when they arrived. All parents expressed a desire for further research addressing a wide variety of concerns about vaccine safety or efficacy. Four themes emerged from the phone interviews, which are outlined in Tables 1 through 4 below.

### Theme 1: Positive Feedback for the Group Visit Environment

There was universal expression of appreciation for the creation of a safe place for parents to discuss their concerns about vaccines without fear of judgment. Parents also spoke highly of the vaccine handouts and the efforts by research staff to answer any questions parents had between group visits.

### **Theme 2: Resistance to and Mistrust of the Medical System**

Most participants expressed concern that current scientific literature on vaccines could not be trusted, as much of it was conducted by researchers with ties to the pharmaceutical industry. Most also said that while they appreciated the group visits, they did not intend to change their vaccination behavior as a result.

### **Theme 3: Varied Vaccine Concerns**

Parents cited a wide variety of concerns with vaccines. These ranged from unknown short-term and long-term effects to religious concerns over the use of fetal stem cells in vaccines. Some parents were concerned that vaccine side effects are underreported and expressed a desire for more accurate data.

### **Theme 4: Interest in Future Research**

All participants expressed an interest in obtaining further data on vaccines, with most saying that they would trust a study done by physicians without pharmaceutical ties and that they would follow the results of such a study if it addressed their most pressing concerns.

## **Discussion**

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The qualitative section of the study failed to demonstrate any change in vaccination behavior over the course of the study, though there was a statistically significant increase in overall favorability toward vaccines. The two individual questions with statistically significant responses were likely due to Type I error, given that 5% of the 40 questions had *P*-values under 0.05, the same number as expected by chance.

There are several possible reasons for lack of an observed effect. The study was underpowered, with a sample size of six. It's also possible that this type of intervention, like many others in the literature, is not effective in changing vaccination behaviors in this population. Further, it could be that holding the vaccine counseling in a group visit setting as opposed to one-on-one increased the sense of community and resolve across the participants, and negated any effect that the nonconfrontational atmosphere had. Additionally, responses over time could not be linked within each individual respondent, due to the need to preserve anonymity. The quantitative analysis, therefore, violates statistical assumptions of independence of measurements, which should be considered as an additional limitation of the study.

The qualitative portion of the study revealed that there was great appreciation for health professionals who worked to hear the concerns of vaccine-averse parents and listen to what they had to say. While this approach may not change opinions on vaccines, it does seem to increase feelings of trust and rapport with parents.

The interviews also showed that there was a strong desire among this group for research addressing their specific concerns about potential vaccine side effects. At the same time, it showed that many of the sources for data that physicians rely on might not be viewed as reliable by this population. There was widespread skepticism about studies funded solely by the CDC or National Institutes of Health (NIH), with four of the five mothers expressing concerns that such research would be subject to bias due to perceived CDC and NIH ties to the pharmaceutical industry. All of the parents expressed interest in a large, longitudinal study designed with input from vaccine-averse parents as well as pediatricians and family physicians. Additionally, the funding sources would have to be free from perceived pharmaceutical ties.

Future studies conducted in line with these criteria (without industry, CDC or NIH funding, and with parent engagement) may be better received by vaccine-averse parents, and could potentially change the vaccination patterns of vaccine-averse parents and reduce morbidity and mortality related to vaccine aversion. More research is needed to explore this possibility in detail.

## Tables and Figures

**Theme 1: Positive Feedback for the Group Visit Environment**

Subtheme	Exemplar Quotes
<b>Felt comfortable in the non-judgmental atmosphere</b>	<p>"It was a comfortable and safe place to be honest with my concerns without being judged or looked down upon."</p> <p>"They weren't confrontational, they were very willing to discuss with you, to share their opinions and hear your opinions in a respectful manner." "It was a very warm and welcoming and accepting atmosphere that made me and I think the other participants feel confident in their ability to share with the group, and I think that made us all more receptive to the information that [the research team] was trying to give us."</p> <p>"They acknowledged the unknown, which makes you feel safe... that made me feel like I didn't have to be on the defensive or fight. They approached it with a genuine desire to hear and weren't just trying to push their own agenda"</p>
<b>Liked the lack of scare tactics</b>	<p>"They were much better than the CDC handouts by a long shot... they actually gave you information, and weren't just trying to scare you."</p>
<b>Appreciated vaccine handouts</b>	<p>"The main thing was the way information about vaccines were presented in the first place. That was one way that I definitely found useful." "[The vaccine handouts] were definitely better than anything you get at the doctor's office or that you get from the CDC."</p>
<b>Appreciated inter-session research by study team</b>	<p>"There were some questions that we would bring up at one of the sessions, and then by the next session the medial students would have researched it and looked at different angles about the question and presented research... the honesty about that."</p>

## Theme 2: Resistance to and Mistrust of the Medical System

Subtheme	Exemplar Quotes
<b>Group visits didn't change opinions</b>	<p>"[The group visits] led me to a place of greater understanding, but it did not in any way change my mind on my decision I had made to not vaccinate."</p> <p>"I still feel like at the end of the day, whether you vaccinate or you don't you're making a choice as a parent that could have consequences either way"</p>
<b>Mistrust of medical system</b>	<p>"I feel like within the CDC there are a lot of people supporting and funding it who have internal interests, and I feel like it's follow the money".</p> <p>"I feel like any group fully working by themselves will have an agenda to push at the end of the day"</p> <p>"I have heard or have read that pediatricians or doctors in general are motivated financially by the pharmaceutical industry."</p> <p>"I hear those talks about how the pharmaceutical companies are interested in producing more and more vaccines, and so I'm not sure if [studies done by the CDC] are completely honest."</p> <p>"I wouldn't trust the CDC because of the whistleblower that came out and said they altered the statistics on autism for African-American boys."</p>

### Theme 3: Varied Vaccine Concerns

Subtheme	Exemplar Quotes
<b>Concern about connection to childhood conditions</b>	<p>"I would like to look at the effects of combination vaccines. I would like to see the allergies, like what does peanuts in vaccines or eggs in vaccines have to do with peanut allergies or egg allergies."</p> <p>"I had read an article about how Japan delayed their vaccinations and their rate [of SIDS] decreased. The same time window that we give vaccines is the same window that we see SIDS."</p> <p>"Immunocompromised things, or just allergies or asthma, childhood things that we say are just common now but that we didn't used to see a lot of."</p> <p>"I would want to see the effects on not just physical health but mental health. I'm concerned about autism, for one."</p>
<b>Concern about various long-term effects</b>	<p>"If they found out that 30 years later there was a thyroid issue, is it, I don't know, is it from vaccines? I don't know how they would find this, but the data certainly, I think, on all health issues would be helpful."</p> <p>"Are we even able to know the long term effects [of vaccines]? They do alter our bodies and make them do things that they wouldn't do without the vaccines. How does that play on underlying long-term health things like allergies or asthma or childhood cancer, even? Are we messing with things to get protection in one area but then opening up this other area because of that?"</p> <p>"I'd like to know about long-term health outcomes in children who are fully vaccinated, partially vaccinated, or unvaccinated. Overall are they healthier, incidence of obesity, different illness, not necessarily just illness that are being vaccinated for."</p>
<b>Concern about the number/ timing of vaccines</b>	<p>"My first concern is whether all vaccinations are all absolutely necessary. Do I need to introduce so many, you know, expose my child's body to so many reactions for something, is it even a threat?"</p> <p>"My biggest concern would be... how many there are compared to when I was a kid. The amount of vaccines there are, how they're distributed, you don't really have options about separating them."</p> <p>"I don't feel comfortable vaccinating my babies because there are a lot of unknowns... their bodies are so little and they're growing and their immune systems are trying to build."</p>
<b>Concern about fetal stem cell use in preparation of MMR vaccine</b>	<p>"The way the MMR is produced it actually uses cell lines that come from aborted children, and for me that's a very big moral and religious issue. That's one I'll always say no to without discussing other options"</p>
<b>Concern about underreporting of side effects</b>	<p>"I'd like to know the true side effect rate. Swelling at the injection site, fever, even smaller stuff. Does it happen as frequently if you give 5 vaccines at once, or if you spread them out?"</p> <p>"The long-term safety data is not adequate, just in terms of the day-to-day or moderate side effects, most people don't report those and even if they told their doctor they wouldn't follow up"</p>
<b>Concern about vaccine ingredients</b>	<p>"The ingredients that are in some of the vaccines that seem really unsafe for humans to inject into themselves, some of the heavy metals."</p> <p>"My biggest concerns with the vaccines are the toxins, and their effect on the body."</p>

#### Theme 4: Interest in Future Research

Subtheme	Exemplar Quotes
Would trust a study done by physicians	<p>"I'd trust more a big panel of doctors and people with different viewpoints"</p> <p>"In some ways maybe I'd find a study done by pediatricians more credible than a study done by the CDC."</p>
Would vaccinate if a study adequately addressed their concerns	<p>"I would use the vaccine, because personally I am not against vaccination, I've never been against vaccines."</p> <p>"Would I give it to my children? I guess I would, sure. If it was credible enough, sure."</p> <p>"I think that yes... If I looked at it and I considered it safe, I'd more than likely give [my child] the vaccine."</p>

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