Previsit Screening for Parental Vaccine Hesitancy: A Cluster Randomized Trial

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abstract

OBJECTIVE: To evaluate the effect of vaccine hesitancy screening on childhood vaccine uptake.

METHODS: We conducted a cluster randomized controlled trial in pediatric primary care clinics in Washington state. Vaccine-hesitant parents (VHPs) with a healthy newborn receiving health supervision at participating clinics were eligible. VHPs were identified by using a 4-item version of the validated Parent Attitudes About Childhood Vaccines Survey (PACV). Before their child’s 2- and 6-month health supervision visits, VHPs at intervention clinics completed the 15-item PACV embedded in a survey containing placebo items. Intervention providers received a summary of parents’ 15-item PACV responses and interpretation of their PACV score; discretion was given to providers regarding how they acted on this information. VHPs at control clinics completed only the placebo survey items, and their child’s provider received a summary of their responses; control providers remained blinded to parent VHP status. Our outcome was child immunization status at 8 months of age expressed as percent of days underimmunized. We compared outcomes in control and intervention participants using t test and linear mixed-effects regression.

RESULTS: We enrolled 24 clinics (12 in each arm) and 156 parents (65 in the intervention arm). Parent characteristics were similar across arms except more intervention (versus control) parents had a first-born child (60.9% vs 44%; P = .04). No significant difference in outcome was detected between arms (25.2% [95% confidence interval: 16.0% to 34.5%] vs 19.1% [95% confidence interval: 12.0% to 26.3%] mean days underimmunized in the intervention and control arms, respectively).

CONCLUSION: Vaccine hesitancy screening was not significantly associated with days underimmunized.

WHAT’S KNOWN ON THIS SUBJECT: Barriers to improving the vaccine discussion exist, including provider difficulty in accurately identifying parental vaccine concerns and insufficient time during health supervision visits to discuss vaccine concerns. Previsit screening to identify vaccine-hesitant parents has the potential to address these barriers.

WHAT THIS STUDY ADDS: Previsit parental vaccine hesitancy screening and disclosure of results to providers was not significantly associated with improved vaccine uptake at 8 months of age. Future studies to evaluate the effect of linking screening with a provider behavior intervention are needed.

Dr Opel conceptualized and designed the study, coordinated and supervised data collection, performed data analysis, and drafted the manuscript; Dr Henrikson contributed to the study design, coordinated and supervised data collection, and reviewed and revised the manuscript; Ms Lepere conducted data collection, assisted in drafting portions of the initial manuscript, and reviewed and revised the manuscript; Ms Hawkes conducted data collection and reviewed and revised the manuscript; Dr Zhou contributed to the study design, assisted in and supervised data analysis, and reviewed and revised the manuscript; Dr Dunn contributed to the study design, assisted in the coordination and supervision of data collection, and reviewed and revised the manuscript; Dr Taylor contributed to the study design, assisted in the coordination and supervision of data collection, supervised data analysis, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

This trial has been registered at www.clinicaltrials.gov (identifier NCT02708745).

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Components of provider vaccine discussions with parents are associated with increased vaccine acceptance.\textsuperscript{1–3} However, several parent- and provider-level barriers to improving the vaccine discussion exist. Parents have trouble openly discussing their vaccine concerns with providers,\textsuperscript{4,5} providers struggle to accurately identify parental vaccine concerns,\textsuperscript{6} and both cite insufficient time during health supervision (HS) visits to adequately discuss vaccines.\textsuperscript{7–13}

Screening parents before vaccine visits by using a parent-report measure to identify those who are vaccine hesitant has the potential to address these barriers.\textsuperscript{13,14} Previsit use of parent-report measures are already well established in the pediatric primary care setting to identify family\textsuperscript{15,16} and child psychosocial issues,\textsuperscript{17,18} child developmental delay,\textsuperscript{19,20} and behavioral health problems.\textsuperscript{21–23} Parent-report measures have also been found to be an efficient way to triage visits that may require more time for assessment,\textsuperscript{24} enhance provider-parent communication by facilitating discussion of parental concerns,\textsuperscript{25} increase early identification of problems and access to beneficial interventions,\textsuperscript{26,27} and improve outcomes.\textsuperscript{28}

Previously, we developed and validated a parent-report measure, the Parent Attitudes About Childhood Vaccines (PACV) survey, to identify vaccine-hesitant parents (VHPs) and their specific vaccine concerns.\textsuperscript{29,30} The PACV is based on health belief model concepts that have been shown to influence parent vaccination behavior, contains 15 items, and takes <5 minutes to complete. PACV scores predict child underimmunization, substantiating its use as a potential screening tool.\textsuperscript{31}

Our aim in this study was to evaluate the effect of identifying VHPs before HS visits using the PACV on childhood vaccine uptake. We hypothesized that pre-HS screening for parental vaccine hesitancy and communicating parental hesitancy scores and specific vaccine concerns to their child’s provider before HS visits would improve childhood vaccine uptake.

**METHODS**

We conducted a cluster randomized controlled trial (cRCT) in pediatric primary care clinics in Washington state from May 2016 until June 2018. This study was registered with clinicaltrials.gov (identifier NCT02708745) as the Screening for Hesitancy to Optimize Talk (SHOT) trial and approved by the Seattle Children’s Institutional Review Board and the Washington State Institutional Review Board. Parent participants provided written informed consent.

**Setting and Population**

Clinics were recruited from Kaiser Permanente Washington (KPWA) primary care clinics located within 5 counties in western Washington state and a private multiclinic pediatric group practice based in King County. We selected these practice groups because (1) the KPWA population is large, stable, and insured through a single health plan; has had an accurate and well-maintained electronic immunization registry since 1991\textsuperscript{32}; and is the same setting we used to evaluate the PACV\textsuperscript{31} and because (2) the private pediatric group practice administers the most childhood vaccines in Washington state. KPWA clinics were eligible if they had administered >200 vaccine doses to children <2 years of age in the year before enrollment (2014–2015). Clinics were enrolled over 2 distinct time periods (February 2016–May 2016 and February 2017–May 2017), with clinics in the first enrollment period being from KPWA and those in the second enrollment being from both practice groups.

**Participants**

Parents were eligible if they were ≥18 years old, were English speaking, had a child ≥2 months of age born at ≥35 weeks’ gestation being seen for HS by a provider at a participating clinic, and were vaccine hesitant. Parents with children ≤2 months old receiving pediatric care at participating clinics were identified by using automated visit data (KPWA) or the clinic’s daily appointment schedule. Parents were screened for additional eligibility criteria by study staff by phone (KPWA only) or in person at or before their child’s 2-month HS visit at a participating clinic.

We limited eligibility to VHPs because changing the vaccination behavior of this group is of primary interest.\textsuperscript{33,34}

To prevent the administration of the main component of the intervention (the full 15-item PACV), vaccine hesitancy was defined as a hesitant response to ≥2 items on the validated 4-item Parent Attitudes About Childhood Vaccines (PACV-4) survey (Supplemental Table 3). The PACV-4 was embedded in a larger survey with questions about other infant care topics (car seat safety, feeding, and infant sleep and crying) written de novo or adapted from an existing survey\textsuperscript{35} to minimize participant and ascertainment bias. Parents received a $10 gift card at enrollment.

**Randomization**

Clinics were the unit of randomization. Participating clinics were randomized by the study biostatistician (C.Z.) using a matched-pair, cluster randomization design with matching being based on the number of vaccine doses administered to children <2 years of age in the year before enrollment. Matching and randomization were done separately for each clinic enrollment period. Dr Zhou randomized clinics to the 2 study arms but was blinded to which arm
was the intervention and which was the control. To further minimize participant and ascertainment bias, we described the study to clinic providers in general terms as 1 in which we seek to determine the impact of soliciting parent attitudes regarding preventive care topics before HS visits on compliance with preventive care recommendations. Study arm allocation was concealed from clinics and participating parents whose child was receiving HS at those clinics.

**Intervention**

Enrolled parents at an intervention clinic completed the 15-item PACV on an electronic tablet on check-in before their child’s 2-month HS visit as well as their child’s 6-month HS visit (see the Supplemental Information for study definitions for each visit). Similar to the PACV-4 at enrollment, the 15-item PACV was embedded within a placebo survey that queried about parental attitudes toward 3 pediatric preventive care topics (breastfeeding, infant sleep, and vitamin D) by using items adapted from existing surveys.\(^{36-38}\) Subsequently, up to 3 survey items that the parent answered negatively or ambivalently (ie, the “not sure” response) from each of the 4 preventive care topics queried (vaccines, breastfeeding, infant sleep, and vitamin D) were programmed to populate a 1-page summary sheet (Supplemental Information). Parental vaccine concerns were accompanied by a visual representation of the parent PACV score and how this score was associated with future underimmunization based on previous work.\(^{31}\)

The child’s provider was given the 1-page summary sheet by clinic or study staff before entering the patient’s room for the child’s 2- and 6-month HS visits. KPWA providers were also alerted that they were seeing a study patient by entering a short message into the Scheduling Notes section of the child’s EpicCare (Epic Systems Corporation, Verona, WI) electronic health record.

In control clinics, study procedures were identical except that parents completed a placebo survey that only included questions related to breastfeeding, infant sleep, and vitamin D and their child’s provider received a summary sheet that included items with negative or ambivalent responses to only these topics (Supplemental Information). Control providers therefore remained blinded to the parent’s vaccine hesitancy status. In both arms, discretion was given to providers regarding how to use or integrate information on the summary sheet into the clinic visit.

**Data Collection**

In addition to completing the PACV-4 before enrollment as well as the intervention or placebo surveys during the study, parents completed a baseline survey at enrollment that was administered by study staff. This survey included demographic items and variables that have been shown to be associated with underimmunization (birth order of their child, household income, marital status, parent self-designated race and/or ethnicity, sex, and number of children in their household).\(^{39-42}\) Parents received $15 at the completion of their 6-month HS visit.

**Analysis**

Our primary outcome was a child’s immunization status at 8 months 0 days of age as determined by their medical chart. For those participants who had neither a 2- nor 6-month visit, or did not have a 6-month visit, we cross-referenced their chart immunization record with the Washington State Immunization Information System. We expressed immunization status as the percentage of days underimmunized from birth to 8 months for 16 doses of 6 vaccines recommended during this interval (2 doses of hepatitis B vaccine; 3 doses of rotavirus vaccine; 3 doses of diphtheria, tetanus, and acellular pertussis [DTaP] vaccine; 2 doses of inactivated polio virus [IPV] vaccine; 3 doses of *Haemophilus influenzae* type B [HiB] vaccine; and 3 doses of pneumococcal conjugate vaccine). We chose to use the percentage of days underimmunized because it is a sensitive measure of immunization status that accounts for missed vaccine doses and delay in receipt of vaccines.\(^{43}\) If a dose was never received, the maximum number of days late a child could be for that dose was their age in days at 8 months 0 days (244 days) minus the latest age in days in which that dose should have been received. To obtain the percentage of days underimmunized from birth to 8 months, we summed the days late across all 16 doses and divided this by the maximum cumulative number of days a child could be late if they had received no vaccine doses by 8 months (967 days).

We conducted an intention-to-treat (ITT) analysis to assess the effect of allocation arm on our primary outcome. Parents were the unit of analysis. Consistent with ITT, parent participants were analyzed in the study arm they were assigned at enrollment even if their child, in the rare event, received a study visit at another participating clinic. We also conducted (1) a subgroup analysis of the effect of allocation arm on the primary outcome by PACV-4 score and (2) per-protocol (PP) analyses to explore the effect of allocation arm on the primary outcome only among those participants who completed both study visits.

We examined baseline characteristics among control and intervention parents using Pearson’s \(x^2\) tests (or Fisher’s exact tests) for categorical variables and \(t\) tests for continuous variables to assess for any unbalanced confounders between the control and intervention arms. To
compare our primary outcome of percent of days underimmunized between the control and intervention arms, we applied t tests as well as linear mixed-effects regression with clinic-specific random effects to account for within-clinic clustering. We adjusted for unbalanced parent characteristics between arms in the mixed-effects models. Analysis was conducted by using Stata 14.2 (Stata Corp, College Station, TX).

Sample Size
When using data from a previous study,31 children of parents with a positive PACV-4 result had a mean percentage of days underimmunized of 27.1% (SD 33.3) from birth to 8 months of age for 4 vaccines combined (hepatitis B, DTap, HiB, and IPV). To be able to detect with 90% power an 18.2% decrease in the percentage of days of underimmunization (which corresponds to 30 days per vaccine, a clinically meaningful decrease because it equals the 1-month recommended interval a parent has before their child is considered late for a vaccination dose44), we needed to enroll 160 parent-newborn pairs total with 80 per arm (assuming α = .05 and an intraclass correlation coefficient for within-clinic correlation of 0.02).45 For 80% power, we needed to enroll 112 parent-newborn pairs total with 56 per arm.

RESULTS
We enrolled 24 clinics (12 in each arm), 17 from KPWA and 7 from the private multiclinic pediatric group (Fig 1). Overall, we enrolled 156 parents at participating clinics, 65 of whom were in the intervention arm. Parent characteristics were similar across arms with the exception that more intervention (versus control) parents had a first-born child (Table 1). Parent PACV-4 scores also did not significantly differ by clinic (P = .23).

The mean percent of days underimmunized among all child participants at 8 months of age was 21.7% (SD 35.6). In ITT analyses, the mean percent of days underimmunized of child participants at intervention clinics (25.2%; 95% confidence interval [CI]: 16.0% to 34.5%) compared with control clinics (19.1% [95% CI: 12.0% to 26.3%]) was not significantly different (P = .29) even after adjusting for unbalanced confounders between allocation arms (Table 2). We also found no significant difference in the mean percent of days underimmunized by allocation arm among PACV-4 score subgroups (Supplemental Table 4). In PP analyses involving 117 (75%) participants, the mean percent of days underimmunized among child participants at intervention clinics (21.7%; 95% CI: 12.0% to 31.3%) compared with control clinics (9.8%; 95% CI: 3.6% to 15.9%) was significantly higher (P = .03), which persisted after adjusting for unbalanced confounders between allocation arms (mean difference in percent of days underimmunized, 13.9%; 95% CI: 3.0% to 24.8%).

DISCUSSION
We conducted a cRCT to determine the effect of previsit screening for vaccine hesitancy on childhood vaccine uptake. We found that identification of parental vaccine hesitancy using the validated 15-item PACV before the 2- and 6-month HS visits resulted in no significant difference in the immunization status
of children by 8 months of age. Two important points are worth noting. First, there is a need for rigorous evaluations of interventions designed to reduce parental vaccine hesitancy or refusal. Although publications on the topic of vaccine hesitancy are plentiful, few pertain to the evaluation of an intervention intended to address it. This study helps address that gap. Second, strategies that are effective in addressing vaccine hesitancy largely remain elusive, with the evidence base generally being limited and of low quality. Our negative results do not change this conclusion.

There are several possible explanations for our findings. The most obvious explanation is that previsit vaccine hesitancy screening with communication of screening results to the child’s provider truly has no positive effect on parental vaccine behavior. An alternative explanation is that there is a positive effect but only in the presence of additional interventions, such as coupling parent screening with training for providers to address identified parental vaccine concerns. Evidence for low provider self-efficacy in vaccine communication supports this explanation. A third explanation is that our ability to observe a positive effect was blunted by unmeasured existing processes at participating clinics that involved communicating parental vaccine concerns to the child’s provider before the HS visit (such as staff asking parents about vaccine concerns at check-in), especially if these processes predominated in control clinics.

A fourth explanation is that there may be a positive effect, but this effect only becomes noticeable with use of the outcome of days underimmunized beyond 8 months of age. Alternatively, there may be a positive effect by 8 months of age but only with immunization outcomes other than days underimmunized. For instance, previsit vaccine hesitancy screening may result in fewer parents spreading out vaccines, manifesting as fewer vaccination visits and

### Table 1: Demographics of the Study Population

<table>
<thead>
<tr>
<th>Relationship to child: mother</th>
<th>Overall (N = 156)</th>
<th>Intervention (n = 65)</th>
<th>Control (n = 91)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Relationship to child: mother</td>
<td>102 (68.9)</td>
<td>41 (64.1)</td>
<td>61 (72.6)</td>
<td>.26</td>
</tr>
<tr>
<td>Parent age: ≥30 y</td>
<td>111 (75.0)</td>
<td>45 (70.3)</td>
<td>66 (78.5)</td>
<td>.25</td>
</tr>
<tr>
<td>Parent’s marital status: married or living with a partner</td>
<td>138 (93.8)</td>
<td>59 (93.6)</td>
<td>79 (89.0)</td>
<td>.92</td>
</tr>
<tr>
<td>Parent education: ≥4 y college degree</td>
<td>104 (70.2)</td>
<td>46 (71.9)</td>
<td>58 (69.0)</td>
<td>.70</td>
</tr>
<tr>
<td>Household income: &gt;$75,000</td>
<td>96 (67.6)</td>
<td>43 (66.2)</td>
<td>53 (67.0)</td>
<td>.83</td>
</tr>
<tr>
<td>Parent race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaskan native</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>.53</td>
</tr>
<tr>
<td>Asian</td>
<td>39 (26.9)</td>
<td>14 (21.9)</td>
<td>25 (30.9)</td>
<td>.92</td>
</tr>
<tr>
<td>Black or African American</td>
<td>14 (9.7)</td>
<td>7 (10.9)</td>
<td>7 (8.6)</td>
<td>.92</td>
</tr>
<tr>
<td>Native Hawaiian and/or Pacific Islander</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>.92</td>
</tr>
<tr>
<td>White</td>
<td>78 (53.7)</td>
<td>35 (54.6)</td>
<td>43 (53.0)</td>
<td>.92</td>
</tr>
<tr>
<td>&gt;1 race</td>
<td>14 (9.7)</td>
<td>8 (12.5)</td>
<td>6 (7.4)</td>
<td>.92</td>
</tr>
<tr>
<td>Parent ethnicity: Hispanic and/or Latino</td>
<td>9 (6.1)</td>
<td>5 (7.9)</td>
<td>4 (4.8)</td>
<td>.53</td>
</tr>
<tr>
<td>Children in household</td>
<td>175 (50.6)</td>
<td>38 (58.4)</td>
<td>37 (44.0)</td>
<td>.92</td>
</tr>
<tr>
<td>1</td>
<td>75 (50.6)</td>
<td>38 (58.4)</td>
<td>37 (44.0)</td>
<td>.92</td>
</tr>
<tr>
<td>≥2</td>
<td>76 (51.3)</td>
<td>39 (59.9)</td>
<td>37 (44.0)</td>
<td>.92</td>
</tr>
<tr>
<td>First-born child</td>
<td>76 (51.3)</td>
<td>39 (59.9)</td>
<td>37 (44.0)</td>
<td>.92</td>
</tr>
<tr>
<td>4-item PACV score</td>
<td>2 (47.1)</td>
<td>27 (42.9)</td>
<td>45 (50.0)</td>
<td>.92</td>
</tr>
<tr>
<td>3</td>
<td>51 (33.3)</td>
<td>23 (36.6)</td>
<td>28 (31.1)</td>
<td>.92</td>
</tr>
<tr>
<td>4</td>
<td>30 (19.6)</td>
<td>13 (20.6)</td>
<td>17 (18.9)</td>
<td>.92</td>
</tr>
</tbody>
</table>

- Comparison of parent demographics by study arm using Pearson χ² test or, when cell size <5, Fisher’s exact test.
- Numbers do not equal the total because of missing data.
- Four-item PACV scored on a 1 to 4 scale, and higher scores correspond with greater vaccine hesitancy.

### Table 2: Association of Study Arm on Child’s Immunization Status

<table>
<thead>
<tr>
<th>Study Arm</th>
<th>% d Underimmunized, Mean (95% CI)</th>
<th>Unadjusted β Coefficient</th>
<th>95% CI</th>
<th>Adjusted β Coefficient*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>19.1 (12 to 26.3)</td>
<td>Ref</td>
<td>—</td>
<td>Ref</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>25.2 (16 to 34.5)</td>
<td>5.9</td>
<td>—9.9 to 21.7</td>
<td>8.3</td>
<td>—7.5 to 24.0</td>
</tr>
</tbody>
</table>

—, not applicable.

* P = .29 (t test).

- Linear mixed-effects regression with clinic-specific random effects to account for within-clinic correlation.
- Adjusted for first-born child.
a higher number of vaccinations received per visit. In addition, screening may result in less delay in receipt of doses within specific vaccines series. To explore these possibilities, we conducted secondary analyses using these alternative outcomes but found no significant association between these outcomes and study arm allocation (Supplemental Information).

Although our PP analysis was exploratory, the results of this analysis are provocative. One possible explanation for finding that the intervention had a negative effect on immunization status is that provider knowledge of a parent’s hesitancy status immediately before a HS visit constrains his or her ability to use communication strategies known to be effective in improving parental vaccine acceptance. For instance, providers, armed with the knowledge that the parent they are about to see is vaccine hesitant, may have felt that a participatory format (eg, “How do you feel about shots today?”) was appropriate to initiate the vaccine conversation. Participatory formats, however, are associated with more underimmunization compared with presumptive formats, such as, “So, she’s going to get shots today.”

It is also possible that the act of screening for vaccine hesitancy may trigger hesitancy in parents. Data, however, suggest this is not the case. In separate studies, we found that mean PACV scores were highly concordant at baseline and the 8-week follow-up (23.8 and 21.9, respectively), and PACV scores at 6 and 24 months were lower (ie, less hesitancy) than PACV scores at baseline.

This study has several strengths and limitations. Our cRCT design minimizes contamination as well as selection, ascertainment, and participant biases. Measurement of immunization status is also a strength, although exclusion of vaccines recommended beyond 8 months of age is a limitation. Use of multiple practice settings enhances the applicability of our results, yet generalizability is hindered by the study’s single geographic area. Study efficiency could have been improved by matching participating clinics on additional variables, such as immunization rates. We also did not collect data on participants’ total number of visits, a variable that could affect immunization status. In principle, this variable should be balanced across study arms with our cRCT design, but this could be explored (and accounted for, if needed) in future studies. Lastly, the study sample was less underimmunized than expected, limiting our ability to detect the intended effect size.

CONCLUSIONS
Our study did not detect a statistically significant association between previsit vaccine hesitancy screening followed by communication of screening results to the child’s provider and childhood vaccine uptake at 8 months of age. Studies with a more longitudinal and complete measurement of immunization status involving participants from multiple geographic areas are needed to confirm this finding.

ACKNOWLEDGMENT
We thank Jeff Wright, MD, for his assistance with this study.

ABBREVIATIONS
CI: confidence interval
cRCT: cluster randomized controlled trial
D TaP: diphtheria, tetanus: and acellular pertussis
HiB: Haemophilus influenzae type B
HS: health supervision
IPV: inactivated polio virus
ITT: intention-to-treat
KPWA: Kaiser Permanente Washington
PACV: Parent Attitudes About Childhood Vaccines Survey
PACV-4: 4-item Parent Attitudes About Childhood Vaccines Survey
PP: per-protocol
VHP: vaccine-hesitant parent
REFERENCES


