**Parental Experiences with Vaccine Information Statements:
Implications for Timing, Delivery, and Parent-Provider Immunization Communication**

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Abstract

Objective: We examined Vaccine Information Statements (VIS) dissemination practices and parental use and perceptions.

Methods: We conducted a national online panel survey of 2,603 US parents of children aged <7. Primary outcomes included reported VIS receipt, delivery timing, reading experiences, and perceived utility.

Results: Most parents received a VIS (77.2%; [95% CI: 74.5-79.7%]), 59.7% [56.6-62.7%] before vaccination but 14.5% [12.5-16.8%] after; 15.1% [13.0-17.6%] were unsure of receipt status or timing; 10.7% [9.0-12.6%] never received a VIS. Less than half who received a VIS before vaccination completed it before vaccination (46.2% [42.4, 50.0%]), but most who read at least some found the information useful (95.7% [93.8-97.0%]). Parents who delayed or refused at least one recommended non-influenza vaccine reported fewer opportunities to ask providers VIS questions.

Conclusions: Most parents report receiving VIS before vaccination as per federal guidelines. Continued effort is needed to enhance VIS distribution practice and parent-provider VIS content communication.

Abstract Word Count: 150/150

Keywords: *Vaccine Confidence, Vaccine Acceptability, Vaccine Delay, Vaccine Hesitancy, Vaccine Refusal, Vaccine Information Statement, Children, Pediatric Populations, Parents*

Introduction

Since 1986, the Centers for Disease Control and Prevention (CDC) has created and disseminated Vaccine Information Statements (VIS) in accordance with the National Childhood Vaccine Injury Act (NCVIA).^{1,2} VIS provide vaccine-preventable diseases information, immunization risks and benefits, and details on the Vaccine Injury Compensation Program.^{2,3} The NCVIA requires healthcare providers to give VIS to patients or, in the case of minors, their parent/guardian prior to immunization(s) administration.

A substantial body of research exists on exposure to vaccine information and its role in shaping parental attitudes toward immunizations.⁴⁻⁷ Although VIS provision is mandated, few studies describe VIS and vaccine consent-dissemination practice⁸ and how they inform vaccine decision-making⁹ and facilitate parent-provider communication.¹⁰ Therefore, we examined VIS utility and delivery practices, including timing, reading opportunities, and time for content discussion with providers.¹⁰

Methods

Study design and sample

In 2012, we conducted a nationally representative, web-based panel survey of U.S. parents/guardians of children aged <7 years.¹¹ The panel was previously constructed using random digit dialing and address-based sampling; our participants were selected from panel members using probability-proportional-to-size sampling. Our response rate was 56.6% (2,792/4,933 panelists contacted) with 93.2% survey completion rate (2,603/2,792 respondents). Post-stratification weights allowed adjustment for sampling strategy, nonresponse rates, and differences between sample and population characteristics.

41 ***Measurement***

42 We measured parental VIS experiences and beliefs, opinions, and attitudes towards childhood
43 immunization. For their most recent VIS receipt, respondents reported timing of receipt, amount read
44 before and after vaccine administration, and VIS utility for immunization decision-making. Those who
45 reported VIS receipt before immunization administration (or were unsure) were asked available reading
46 time prior to vaccination and whether they were given the opportunity to ask questions about the VIS
47 before immunization receipt.

48 Parents' reported vaccination decisions for their youngest child were classified into four groups
49 to represent the vaccine confidence spectrum: "non-hesitant acceptors," "hesitant acceptors," "delayers,"
50 or "refusers." "Non-hesitant acceptors" reported accepting or working to catch up on all recommended
51 non-influenza vaccines, discounting delays due to child illness or insufficient vaccine supply. "Hesitant
52 acceptors" also reported accepting all vaccines, but after having considered delay or refusal of at least
53 one vaccine. "Delayers" reported delaying some or all recommended vaccines, but did not refuse any
54 immunizations. "Refusers" declined at least one vaccine.

55 ***Data Analysis***

56 We applied survey weights to calculate population estimates and 95% confidence intervals (CI)
57 for VIS items. Pair-wise rate differences examined bivariate associations between perceived VIS
58 usefulness and opportunity to ask questions, tested using bivariate survey-weighted logistic regression.
59 Multiple logistic regression was used to adjust for other relevant VIS items, taking VIS usefulness as the
60 dependent variable. Pair-wise differences were also employed to explore relationships between
61 vaccination decision group and VIS items. We conducted analyses using SPSS version 21.0 and the
62 SPSS Complex Samples Module (IBM SPSS Inc., Chicago, IL).

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Results

Participant characteristics indicate that we captured a diverse group of U.S. parents (Table 1), with 2,093 of the 2,603 respondents (Pop. Est. 77.2% [CI: 74.5-79.7%]) reported *ever receiving* a VIS during their youngest child's immunization visits (Table 2). Table 2 displays population estimates for VIS items among the parents asked that item (e.g. timing of VIS receipt estimates are reported as a percentage of parents who had received a VIS). To estimate compliance with federal regulations, we also estimated timing of VIS receipt together with non-receipt for the entire population of parents: 59.7% [56.6-62.7%] received their most recent VIS before vaccine administration, 14.5% [12.5-16.8%] received their most recent VIS after vaccine administration, 10.7% [9.0-12.6%] had never received a VIS, 15.1% [13.0-17.6%] were unsure about the status or timing of VIS receipt.

[Table 1 about here]

[Table 2 about here]

Of participants that had ever received a VIS (n = 2,093), most received it “during the visit, but before vaccine administration” (69.1% [65.8-72.2%]), followed by “during the visit, but after vaccine administration” (15.4% [13.2-18.0%]), “before the visit” (8.2% [6.5-10.3%]), “after the visit” (3.4% [2.2-5.1%]), and “unsure” (3.9% [2.8-5.3%]) (Table 2). Subsequently, if participants received VIS before visit, before vaccine administration, or were unsure, they were asked how much they read before the vaccine administration. The majority of this group reported having read some (35.4% [31.8-39.2%]) or all (46.2% [42.4-50.0%]) of the VIS and having ≤ 30 minutes to read the VIS (58.2% [54.3-62.0%]). Most of these parents also reported having the opportunity to ask questions about the information in the VIS (78.6% [75.3-81.6%]).

Of parents who read at least some of the VIS before immunization, the majority responded that the information was helpful (95.7% [93.8-97.0%]). Additionally, those who reported having had the

opportunity to ask VIS questions found it useful more often (96.7% [94.9-97.9%]) than those who did not (75.8% [58.2-87.5%]) (Pair-wise test: $p < 0.001$). Opportunity to ask questions remained significantly associated with increased VIS usefulness even after employing logistic regression to adjust for reading opportunity, amount read prior to vaccination, and vaccine decision group (Outcome: usefulness; Odds Ratio: 10.3 [3.9-27.4]; $p < 0.001$).

Association between vaccination decision group and VIS experience, with pair-wise tests

“Refusers” were less likely to find VIS to be helpful (69.7% [50.4-83.9%]) than “non-hesitant acceptors” (97.7% [95.7-98.8%]) ($p < 0.001$), “hesitant acceptors” (95.4% [90.3-97.9%]) ($p < 0.001$), and “delayers” (87.5% [77.2-93.5%]) ($p = 0.042$); “delayers” found VIS helpful less often than “non-hesitant acceptors” ($p < 0.001$) and “hesitant acceptors” ($p = 0.047$) (Table 3). “Delayers” were more likely to report not having had time to read the VIS before vaccination (27.4% [18.2-39.0%]) than “non-hesitant acceptors” (13.5% [10.5-17.1%]) ($p = 0.003$) and “hesitant acceptors” (15.6% [10.7-22.1%]) ($p = 0.037$). “Delayers” were also more likely to report not having been given the opportunity to ask questions about the VIS (20.8% [12.7-32.2%]) than “non-hesitant acceptors” (5.7% [3.9-8.2%]) ($p < 0.001$) and “hesitant acceptors” (8.7% [5.4-13.6%]) ($p = 0.011$). “Refusers” were also more likely to report not having been given the opportunity to ask questions (19.9% [7.2-44.1%]) than “non-hesitant acceptors” ($p = 0.022$). “Refusers,” were less likely to have read all of the VIS before vaccination (26.5% [15.9-40.7%]) than “non-hesitant acceptors” (47.2% [42.6-51.8%]) ($p = 0.008$) and “hesitant acceptors” (47.7% [38.7-56.8%]) ($p = 0.014$). Other pair-wise differences were not statistically significant ($p > 0.05$).

[Table 3 about here]

Discussion

The majority of parents reported receiving VIS(s) before or during their child's vaccination visit. While 59.7% of parents reported receiving their most recent VIS prior to vaccine administration as required by US law, 14.5% reported receipt after vaccination and 10.7% reported never receiving a VIS.¹² However, these results reflect parent's recall of VIS receipt so likely overestimate late or absent receipt. Together with the 15.1% of parents unsure of VIS receipt or timing, this suggests VISs may not be a memorable part of the vaccination experience for some (though not most) parents.

Most parents, however, reported very positive VIS experiences. Most who reported receiving VIS(s) had time to read it and were given the opportunity to ask questions before vaccination, and found the information helpful. Yet, a significant proportion reported not having opportunity to read or ask questions about VIS information. This indicates missed opportunities to provide comprehensive vaccine information for informed decision-making. This is especially important for parents lacking vaccine confidence who may have specific vaccination concerns about particular vaccines (e.g., MMR) not addressed through their own research.¹³⁻¹⁵

Although VIS experience was overall positive regardless of parents' reported vaccine decision, VIS utilization and perceived usefulness was significantly lower among parents expressing less vaccine confidence (i.e., those delaying or refusing at least one vaccine). These parents were also more likely to report not having had the opportunity to ask questions about the VIS information. Our findings suggest that more evaluation is needed to improve VIS utility and satisfaction for delayers and refusers.

Inaccurate information on vaccine risks and benefits and waning perceived seriousness of vaccine-preventable diseases may affect parents' vaccine decision for their children.^{16,17} Providing opportunities to read and process VIS information and address concerns can help parents make informed decisions, improve VIS usefulness, and potentially decrease vaccine hesitancy. New avenues are

suggested for both VIS format and delivery modalities to enhance opportunity for discussion. Targeted and tailored information delivered via web, mobile devices, and apps could substantially increase VIS involvement, enhancing acceptability.¹⁸ These strategies have shown to be effective for other forms of health education.^{18,19} New technology-based delivery approaches with alternative presentation of “plain language” materials holds significant promise to help inform and educate parents. These approaches help address concerns outside time-constrained clinical visits and reduce time needed to absorb information.²⁰⁻²²

Vaccine decisions and VIS use were self-reported and may be subject to recall bias and social desirability bias. As the sample included parents of children <7 years, there may be time lag between the child’s last immunization visit and the survey date. Our focus on the most recent VIS receipt without vaccine type specification prevented analysis of the varying type and number of VISs that parents may have been exposed to. Parental VIS comprehension was not assessed; we recommend future evaluation of health literacy. Finally, we cannot draw causal inferences about associations between vaccine decision and VIS experience.

Conclusion

A majority of parents reported VIS receipt before vaccine administration, yet improvements are needed for distribution timing and clinical communication. Additional studies are needed to evaluate content and test different modalities for timely information delivery and efficient clinical communication.

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223 Table 1: Characteristics of Survey Respondents (N=2,603)

	Unweighted Frequency	Unweighted Percentage
Gender		
Male	719	27.6
Female	1884	72.4
Age		
18 – 24	391	15.0
25 – 34	1023	39.3
35 – 44	997	38.3
45 and over	192	7.3
Ethnicity		
Hispanic / Latino	363	13.9
Not Hispanic / Latino	2224	85.4
<i>Missing or Refused</i>	<i>16</i>	<i>0.6</i>
Race		
White only	2059	79.1
Black or African American only	260	10.0
Other single race ^a	193	7.5
Multiple race	55	2.1
<i>Missing or Refused</i>	<i>36</i>	<i>1.4</i>
Vaccination Decision		
Non-Hesitant Acceptor ^b	1761	67.7
Hesitant Acceptor ^c	493	18.9

Delayer ^d	191	7.3
Refuser ^e	147	5.6
<i>Missing</i>	<i>11</i>	<i>0.4</i>

224 ^a Includes American Indian, Alaska Native, Asian, Native Hawaiian, Pacific Islander, Hispanic and non-Hispanic others

225 ^b Parents who accepted all recommended non-influenza vaccines and those actively working to catch up

226 ^c Parents who specified as having thought about delaying/refusing any vaccine but accepted all recommended non-
 227 influenza vaccines or are actively working to catch up

228 ^d Parents who indicated delay, or possible delay, but unsure, of at least one non-influenza vaccine, but did not refuse any

229 ^e Parents who indicated refusal, or possible refusal, but unsure, of at least one non-influenza vaccine

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232 **Table 2.** Parental experiences with VIS and the perceived utility of VIS on immunization decision-making

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	Unweighted Frequency	Est. (95% CI)
Have you ever received a Vaccine Information Statement (VIS) when you took your youngest child for vaccines? (n = 2,603) ^a		
Yes [†]	2093	77.2% (74.5, 79.7%)
No	251	10.7% (9.0, 12.6%)
Unsure	246	12.1% (10.1, 14.4%)
When did you get the VIS? (n = 2,093) ^b †		
During vaccination visit, but <i>before</i> vaccination	1460	69.1% (65.8, 72.2%)
During vaccination visit, but <i>after</i> vaccination	349	15.4% (13.2, 18.0%)
Before arriving for child's vaccination visit	153	8.2% (6.5, 10.3%)
After leaving child's vaccination visit	58	3.4% (2.2, 5.1%)
Unsure	71	3.9% (2.8, 5.3%)
How much time did you have to read the sheet before your youngest child was supposed to receive their vaccination? (n = 1,684) ^c ‡		
More than half hour	198	13.2% (10.7, 16.3%)
A half hour or less	992	58.2% (54.3, 62.0%)
I did not have time to read the sheet before my child was vaccinated	277	15.1% (12.6, 18.0%)
I don't remember	212	13.4% (11.0, 16.2%)
How much of the sheet did you read before your youngest child was supposed to receive their vaccination? (n = 1,684) ^d ‡		
All of it	736	46.2% (42.4, 50.0%)

Some of it	630	35.4% (31.8, 39.2%)
None of it	196	10.3% (8.3, 12.7%)
I don't remember	120	8.2% (6.3, 10.5%)
Were you given the opportunity to ask questions about the information in the sheet before your child was supposed to receive their vaccination? (n = 1,684) ^e ‡		
Yes	1324	78.6% (75.3, 81.6%)
No	139	7.7% (5.9, 9.9%)
I don't remember	217	13.8% (11.3, 16.6%)
How much of the sheet did you read after your youngest child was supposed to receive their vaccination? (n = 2,093) ^f †		
All of it	939	43.8% (40.4, 47.3%)
Some of it	641	31.9% (28.7, 35.3%)
None of it	339	15.6% (13.3, 18.3%)
I don't remember	157	8.7% (7.0, 10.8%)
Was the information in the sheet helpful to you? (n = 1,366) ^g §		
Yes	1290	95.7% (93.8, 97.0%)
No	72	4.3% (3.0, 6.2%)

234 Est. (95% CI): Weighted population estimates and 95% confidence interval

235 Missing or Refused: ^a n = 13; ^b n = 2; ^c n = 5; ^d n = 2; ^e n = 4; ^f n = 17; ^g n = 4

236 † Participants who remembered ever receiving a VIS were asked these follow-up questions

237 ‡ Only participants who received a VIS 1) before arriving for child's vaccination visit, 2) during vaccination visit, but before
238 vaccination, or 3) were unsure of timing were asked these questions.

239 § Estimates among parents who reported reading some or all of the VIS before vaccination.

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241 **Table 3.** Parental experiences with VIS and the perceived utility of VIS by vaccine decision group

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	Non-Hesitant Acceptor Est. (95% CI)	Hesitant Acceptor Est. (95% CI)	Delayer Est. (95% CI)	Refuser Est. (95% CI)
How much time did you have to read the sheet before your youngest child was supposed to receive their vaccination?				
	n = 1172	n = 301	n = 118	n = 79
More than half hour	14.1% (11.0, 18.0%)	10.4% (5.8, 18.0%)	16.0% (8.1, 29.3%)	7.2% (3.2, 15.5%)
A half hour or less	58.5% (53.8, 63.0%)	61.7% (52.6, 70.0%)	46.4% (33.7, 59.6%)	56.0% (37.5, 73.0%)
I did not have time	13.5% (10.5, 17.1%)	15.6% (10.7, 22.1%)	27.4% (18.2, 39.0%)	24.2% (12.2, 42.5%)
I don't remember	13.9% (11.1, 17.3%)	12.4% (7.3, 20.2%)	10.1% (5.3, 18.5%)	12.5% (3.4, 36.8%)
How much time did you have to read the sheet before your youngest child was supposed to receive their vaccination?				
	n = 1172	n = 303	n = 117	n = 79
All of it	47.2% (42.6, 51.8%)	47.7% (38.7, 56.8%)	45.1% (32.4, 58.4%)	26.5% (15.9, 40.7%)
Some of it	34.1% (29.9, 38.6%)	39.2% (30.8, 48.3%)	33.3% (22.4, 46.5%)	43.4% (26.6, 61.8%)
None of it	10.2% (7.8, 13.1%)	6.4% (4.1, 9.9%)	15.6% (9.1, 25.3%)	20.7% (8.2, 43.4%)
I don't remember	8.5% (6.4, 11.3%)	6.8% (3.7, 12.1%)	6.0% (2.3, 14.9%)	9.4% (1.7, 38.8%)
Were you given the opportunity to ask questions about the information in the sheet before your child was supposed to receive their vaccination?				
	n = 1172	n = 303	n = 117	n = 79
Yes	80.0% (76.0, 83.4%)	81.2% (74.6, 86.3%)	65.3% (52.8, 75.9%)	64.1% (42.7, 81.1%)
No	5.7% (3.9, 8.2%)	8.7% (5.4, 13.6%)	20.8% (12.7, 32.2%)	19.9% (7.2, 44.1%)
I don't remember	14.4% (11.4, 17.9%)	10.2% (6.6, 15.4%)	13.9% (7.8, 23.5%)	16.0% (5.4, 38.7%)
Was the information in the sheet helpful to you? [†]				
	n = 954	n = 250	n = 90	n = 65
Yes	97.7% (95.7, 98.8%)	95.4% (90.3, 97.9%)	87.5% (77.2, 93.5%)	69.7% (50.4, 83.9%)

No	2.3% (1.2, 4.3%)	4.6% (2.1, 9.7%)	12.5% (6.5, 22.8%)	30.3% (16.1, 49.6%)
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243 Est. (95% CI): Weighted population estimates and 95% confidence interval

244 † Among those parents who had an opportunity to read at least some of the VIS prior to vaccination

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