Office-Based Educational Handout for Influenza Vaccination: A Randomized Controlled Trial

Vanessa P. Scott, MD, MS,[a,b] Douglas J. Opel, MD, MPH[c], Jason Reifler, PhD,[d] Sharon Rikin, MD, MS,[b,e] Kalpana Pethe, MD,[a,b] Angela Barrett[a], Melissa S. Stockwell, MD, MPH[a,b,f]

Affiliations: [a]Department of Pediatrics, Columbia University, New York, NY, United States; [b]NewYork Presbyterian Hospital, New York, NY, United States; [c]Seattle Children's Research Institute and Department of Pediatrics, University of Washington School of Medicine, Seattle, WA, United States; [d]Department of Politics, University of Exeter, Exeter, Devon, United Kingdom; [e]Department of Medicine, Columbia University, New York, NY, United States; [f]Department of Population and Family Health, Columbia University, New York, NY, United States.

Address correspondence to:
Melissa S. Stockwell, MD, MPH
Division of Child and Adolescent Health, Columbia University
622 W. 168th Street - VC 417; New York, NY 10032
Tel: 212-342-5732; Fax: 212-305-8819; Email: mss2112@cumc.columbia.edu

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Abbreviations:
aOR – Adjusted odds ratio
IQR – Interquartile range
PACV – The Parent Attitudes about Childhood Vaccines Survey Tool
PACV-5 – The Short-Scale (5 question) Parent Attitudes about Childhood Vaccines Survey Tool
RCT – Randomized controlled trial

Key words: influenza vaccine, parent education, child vaccine receipt, health communication, educational intervention

Table of Contents Summary: This study evaluates brief, clinic-based educational interventions for parents vs. usual care with child influenza vaccine receipt.

What's Known on this Subject:

Educational interventions have been positively associated with parental intent to vaccinate their child. However, analysis of the relationship between clinic-based educational interventions and pediatric influenza vaccine receipt (rather than parental intent only) is limited.

What This Study Adds:

A brief educational intervention given to parents in the waiting room prior to a pediatric provider visit may help improve child influenza vaccine receipt.

Contributors' Statement Page:

Vanessa P. Scott: Dr. Scott conceptualized and designed the study, analyzed the data, drafted the initial manuscript, and approved the final manuscript as submitted.

Melissa S. Stockwell: Dr. Stockwell conceptualized and designed the study, took part in the analysis of the data, reviewed and revised manuscript, and approved the final manuscript as submitted.

Douglas J. Opel, Jason Reifler, Sharon Rikin, Kalpana Pethe: Drs. Opel, Reifler, Rikin and Pethe aided in the conceptualization and design of the study, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Angela Barrett: Ms. Barrett helped design the data collection instruments, coordinated and supervised data collection at all sites, and approved the final manuscript as submitted.

Abstract

Objective: Assess the impact of a parent educational intervention about influenza disease on child vaccine receipt.

Design/Methods: A convenience sample of parents of children ≥6 months-old with a visit at two New York City pediatric clinics between August 2016-March 2017 were randomized (1:1:1) to receive either usual care, an educational handout about influenza disease based on local data, or an educational handout about influenza disease based on national data. Parents received the handout in the waiting room prior to their visit. Primary outcomes were child influenza vaccine receipt on day of clinic visit and by end of season. Multivariable logistic regression assessed associations between intervention and vaccination, adjusting for variables that were significantly different between arms.

Results: Parents who received an intervention (vs. usual care) had greater odds of child influenza vaccine receipt by end of season (74.9% vs 65.4%, aOR 1.68, 95% CI: 1.06-2.67), but not on day of clinic visit. Parents who received the national data handout (vs. usual care) had greater odds of child influenza vaccine receipt on day of clinic visit (59.0% vs 52.6%, aOR 1.79, 95% CI 1.04-3.08), but not by end of the season. There was no significant relationship between parents who received the local data handout (vs. usual care) and child influenza vaccine receipt on day of clinic visit or by end of season.

Conclusion: Providing an educational intervention in the waiting room prior to a pediatric provider visit may help increase child influenza vaccine receipt.

Clinical Trial Registration: ClinicalTrials.gov NCT02907580

Introduction

Every year in the United States, influenza accrues more than $10 billion in direct medical costs and has negative health consequences for children, the elderly and those at high-risk of medical complications.[1] Approximately 8 out of 100 children are infected with influenza each year in the U.S., 20 to 77 out of 100,000 are hospitalized, and an average of 113 children die.[2,3] Vaccination against influenza is the most effective way to prevent the disease. However, despite the recommendations by Centers for Disease Control and Prevention (CDC)[4] and the American Academy of Pediatrics[5] for all children 6 months or older to receive the yearly influenza vaccine, U.S. child influenza vaccination rates of 58% nationally remain below the Healthy People 2020 goal of 80%.[6,7]

Vaccine hesitancy, which has been linked to vaccine delay or refusal, is on the rise, challenging public health endeavors to increase influenza prevention.[8-11] Parental refusal is often based on concerns about the safety and effectiveness of vaccines or false beliefs.[9,11-13] Healthcare providers create promotional health information resources to educate and encourage behavior change in parents and patients.[14-17] The content and wording of educational handouts is important to examine carefully. For example, pro-vaccine educational handouts attempting to disprove myths or change parental views may reduce MMR vaccination intention among vaccine hesitant parents.[18] A similar finding has been shown in specific groups of adults and the influenza vaccine.[19] Clinic-based educational interventions have had both significant and nonsignificant positive associations with vaccine attitudes and behaviors, but not with improving vaccine uptake.[20] Investigating the relationship between brief educational interventions as adjuncts to the pediatric visit and child influenza vaccine receipt is warranted.

The goal of this randomized controlled trial (RCT) was to assess whether providing parents with an educational handout about influenza disease and the influenza vaccine affects child vaccine receipt, relative to usual care. Furthermore, we examined whether using data from a parent's local neighborhood versus national data derived from the CDC had an added benefit. Our primary hypothesis was that parents who received any educational handout (vs. usual care) would be more likely to have their child vaccinated against influenza. We additionally hypothesized that an intervention derived from local data would be more beneficial.

Methods

Participants

Between August 2016-March 2017, a convenience sample of parent-child dyads at two pediatric clinics affiliated with an academic medical center in an underserved area in Northern Manhattan, New York City, were asked to participate in the study. Dyads were eligible if the parent spoke and read either English or Spanish and the child was ≥6 months old, without a contraindication to the influenza vaccine (including egg allergy), had not already received the influenza vaccine that season (by parent report), and was not there for an influenza vaccine only visit. We calculated that a sample size of 200 parent-child dyads per each of the 3 arms (600 total) would provide 80% power to detect a 10% difference among arms using chi-square analysis and α=0.05, and a sample size of 300 per arm would detect a difference of 8%.

Study Design

In this RCT, 1071 parents were approached in the waiting room by a bilingual (English/Spanish) research assistant prior to their provider visit, as possible without interfering with clinic registration or clinical care. All eligible, consented parents completed a baseline survey which assessed demographics (age, sex, race/ethnicity, parent education, primary language, child's insurance, parent type), whether their child was "sick on day of clinic visit," child's history of medical problems and overall health, parental influenza vaccine attitudes and beliefs, knowledge of influenza disease, and intent to vaccinate both their child and themselves against influenza on the day of clinic visit and by the end of the season (Appendix A). Questions were derived from previously used surveys and based on the Health Belief Model. Vaccine hesitancy was assessed at baseline using a 5-question short-scale version[21] of the validated 15-question Parent Attitudes about Childhood Vaccines (PACV) survey tool (Appendix B).[22,23]

After the baseline survey, parent-child dyads were randomized into one of three arms (1:1:1 ratio) using sequentially numbered, opaque, sealed envelopes prepared (by author VPS) using randomly permutated block (generated by author MSS), and stratified by patient's primary language (English or Spanish). Dyads were allocated to their study arm (by research assistant AB) and received either 1) an educational intervention based on national data, 2) an educational intervention based on local data, or 3) usual care only. Both educational interventions consisted of a single page paper handout which parents read in the waiting room. The local data intervention highlighted the risk of influenza, the seriousness of the influenza disease including referring to a study that showed many people who think they have the flu actually do not, and vaccine coverage data from the community.[24] Information that the "flu shot does not cause the flu" was also included by referring to a local study in which participants did not have flu-like or

cold symptoms more often after the influenza vaccine (Appendix C.1). The national data intervention highlighted the risk of influenza and vaccine coverage data using national data from CDC, and information that the "flu shot does not cause the flu" by citing a national study which showed that people who received a "flu shot vs a saltwater shot did not have more flu-like symptoms"[25-27] (Appendix C.2). After reading the educational handout, intervention arm parents were given a post-survey which assessed intent to vaccinate. They then saw their child's pediatric provider for their regular visit. Parents in the usual care arm answered the baseline survey only and proceeded to their child's visit. Providers were unaware of the parent's participation in the study. The child's medical record was reviewed at the end of the influenza season in June 2017 and the date of influenza vaccine receipt was documented, which included synchronization with the New York Citywide Immunization Registry to capture vaccines received outside of our clinics. Parents were given a $5.50 New York City subway card for their participation. The study was approved by the Institutional Review Board at Columbia University.

Measures

The primary outcomes were child influenza vaccine receipt on day of clinic visit and by the end of the influenza season (i.e. children vaccinated on day of clinic visit plus by end of influenza season), as abstracted from the medical record. The primary explanatory variable was any educational intervention (vs. usual care). Secondary variables were educational intervention subgroups (local and national), parental intent to vaccinate, vaccine hesitancy, and attitudes and beliefs surrounding influenza and the influenza vaccine. The last documented response was used for parental intent to vaccinate their child; baseline survey intent for the usual care arm and post-survey intent for the educational intervention arms. For vaccine hesitancy, PACV-5 questions

were answered on a 5 point Likert scale and scored numerically (0,1, or 2), then summed on a scale from 0 to 10 according to previously used methods.[21] Scores were categorized as low (0-4), moderate (5-6), and high (7-10) vaccine hesitancy and dichotomized (≤6 for low/moderate vaccine hesitancy vs. ≥7 for high vaccine hesitancy) for regression analysis. Influenza attitude and belief variables were collapsed from a 4 or 5 point Likert Scale into 2 categories.

Statistical Analysis

An intention-to-treat analysis was performed as the primary analysis. A per-protocol analysis was also conducted which excluded parents who did not complete the study or children who had already received the influenza vaccine that season (but parent reported they had not been vaccinated). Frequency statistics, chi square and Fisher's exact analyses were used for describing characteristics of the participants in each study arm, depending on variable type (categorical vs. continuous). In the primary analysis, multivariable logistic regression was used to assess the association between any educational intervention and usual care arms with child influenza vaccine receipt, adjusting for any baseline differences ($p \leq 0.10$) among study arms. In secondary regression analyses, we assessed the intervention subgroups individually with vaccine receipt (local data intervention vs. usual care and national data intervention vs. usual care), adjusting for baseline differences, as well as parental intent to vaccinate, vaccine hesitancy, and influenza vaccine beliefs/knowledge with child vaccine receipt, adjusting for study arm. Statistical analyses were conducted with SAS statistical software (version 9.4; SAS Institute Inc. Cary, NC).

Results

Of 1071 parent-child dyads approached, 501 were eligible, 402 were enrolled (80%) and 400 were analyzed (Figure 1). Median child and parent age was 4.3 (IQR 1.5-9.5) and 33.0 (IQR 27.0-40.0) years, respectively. As reported by their parent, most children were Latino, publicly insured, with good to excellent health, and nearly one third of children had a medical problem and one third were sick on the day of clinic visit. Parents were mostly Latino mothers, half had a high school education or less, and one third had previously refused the influenza vaccine for their child and/or themselves. Arms were well-balanced with the exception of caregiver education between the intervention arms and usual care (Table 1). For the subgroups, differences between the national data intervention and usual care arms included caregiver education and child sick on day of clinic visit, and between the local data intervention and usual care arms included child's insurance and pre-intervention parental intent to vaccinate child by end of season (Appendix D Table 1). Of note, vaccine hesitancy level was not significantly different between the study arms (Table 1, Appendix D Table 1). Overall, on the day of clinic visit, 56.8% of child participants received the influenza vaccine and 71.8% by the end of the influenza season (100% were inactivated influenza vaccine).

Parents who received an educational intervention vs. usual care had greater odds of having their child vaccinated against influenza by the end of the season (74.9% vs. 65.4%, aOR 1.68, 95% CI: 1.06-2.67), however there was not a significant association with vaccination on the day of clinic visit (58.8% vs. 52.6%, aOR 1.36 95% CI 0.89-2.09), after adjusting for caregiver education (Table 2). Parents who received the national data intervention (vs. usual care) had greater odds of child influenza vaccine receipt on the day of clinic visit (59.0% vs. 52.6%, aOR

241 1.79, 95% CI 1.04-3.08), but not by the end of the season, after adjusting for caregiver education
242 and child sick on day of clinic visit (Table 2). There was no significant association for parents in
243 the local data intervention study arm (vs. usual care) with child influenza vaccine receipt on day
244 of clinic visit or by the end of the influenza season, after adjusting for child's insurance and pre-
245 intervention likelihood to vaccinate by end of the season (Table 2). There was no interaction
246 between vaccine hesitancy level and study arm in these models. In per protocol analyses (n =
247 380), parents who received any intervention (75.1% vs 64.6%, aOR 1.78, 95% CI: 1.11-2.86),
248 the national data intervention (73.1% vs. 65.4%, aOR 1.76, 95% CI 1.003-3.10) or the local data
249 intervention (76.7% vs. 65.4%, aOR 1.87, 95% CI 1.07-3.27) had higher odds of vaccinating
250 their child by the end of the season compared to usual care parents.
251
252 Across all three study arms, parental intent to vaccinate (likely vs. unlikely) was associated with
253 child influenza vaccine receipt on both the day of clinic visit (69.7% vs. 21.6%, aOR 8.38, 95%
254 CI 4.85-14.34) and by the end of season (87.4% vs. 29.4%, aOR 18.26, 95% CI 9.94-33.52),
255 after adjusting for caregiver education and child sick that day. Of the parents who reported "very
256 likely" to vaccinate (n=251), most did so (89.6%), and of the parents who reported "somewhat
257 likely" to vaccinate their child (n=110), 74.6% did so by the end of the season.
258
259 Children of parents with low/moderate vs. high vaccine hesitancy had increased odds of
260 influenza vaccine receipt by the end of the season (74.0% vs. 58.6%, aOR 1.93, 95% CI 1.07-
261 3.48) and on day of clinic visit (58.5% vs. 44.8%, aOR 1.77, 95% CI 1.01-3.10), after adjusting
262 for study arm. Parents who reported "no or little concern" (vs. somewhat/very concerned") with
263 serious influenza vaccine side effects (68.3% vs. 45.2%, aOR 5.1, 95% CI 3.0-8.5), parents who
264 reported that the influenza vaccine is "somewhat/very effective" (vs. "somewhat/very

ineffective") (67.3% vs. 31.9%, aOR 4.34, 95% CI 2.67-7.05), and parents who did not believe you can "get the flu from the flu shot" (vs. those who believe you can) (65.3% vs. 52.6%, aOR 1.62, 95% CI 1.03-2.55), had increased odds of having their child vaccinated against influenza on the day of clinic visit, after adjusting for study arm and child sick on day of clinic visit. Parent's belief regarding influenza illness severity was not associated with vaccine receipt. Findings were similar for child vaccine receipt by the end of the season.

Discussion

In this randomized controlled trial, we found that providing an educational handout for parents was associated with increased child influenza vaccine receipt by the end of the influenza season. While pro-vaccine educational materials have been previously studied, researchers have primarily assessed parental vaccine hesitancy and intent to vaccinate,[18,19,28,29] a different timeline or mode of delivery (e.g. text message reminder),[29] or focused on adolescent only, adult or pregnant women populations.[30-34] This is one of the first studies to use experimental design to evaluate the effect of an educational handout intervention in the clinic setting on child influenza vaccine receipt. Our study adds that a very brief educational intervention for caregivers prior to seeing a healthcare provider may have lasting effects by helping to increase pediatric vaccine uptake by the end of the season, and that an educational handout based on national data may improve influenza vaccination rates on the day of the clinic visit.

We found that using a targeted approach of the parent's local community as the data source did not yield additional benefit to child vaccine receipt.[35] The difference in magnitude of the number of children affected by influenza, and in particular the influenza-related pediatric deaths,

289 (national: 85-171 yearly vs. local: 4 yearly) may have made the national data intervention more
290 impactful in this community. Also, discussing the higher influenza vaccine coverage rate in the
291 parent's local community (80% vs. the lower national rate of 60%) may have not lead to our
292 hypothesized social desirability impact. Lastly the local data intervention referred to a study that
293 showed many people in the community who think they have the flu actually do not. Instead of
294 encouraging parents to vaccinate their child because the influenza disease is much more serious
295 than a cold, perhaps parents were negatively influenced by stating their community members
296 were wrong.
297
298 Parents with high vaccine hesitancy were less likely to vaccinate their child against influenza
299 both on the day of clinic visit and by the end of the season. Previous studies have found similar
300 associations with vaccine hesitancy and intent, vaccine attitudes, receipt of routine childhood
301 immunizations, or influenza vaccine declination in the hospital setting.[8,23,36-38] Our study extends
302 this relationship to influenza vaccine receipt in the outpatient setting. The PACV-5 (short-scale
303 PACV) used in this study may help to efficiently screen parents in the primary care setting. The
304 PACV-5 has been previously analyzed,[21] and future research which validates this tool in various
305 demographics may be useful. Parental beliefs of influenza vaccine effectiveness, that the flu shot
306 does not cause the flu, or minimal side effect concerns were also associated with child influenza
307 vaccine receipt. Future interventions to promote influenza vaccine effectiveness may be most
308 useful for impacting child vaccine coverage.
309
310 Self-reported vaccine intent is often used as a surrogate outcome measure instead of receipt in
311 vaccine research. Our findings show that parental intent to vaccinate was significantly
312 associated with child vaccine receipt, although only 89.6% of parents "very likely" to vaccinate

313 by the end of the season did so. For studies where vaccine receipt cannot be captured, our results
314 support parental intent to vaccinate their child as a very good, but not perfect, proxy for vaccine
315 receipt.
316
317 The strengths of this study include its randomized controlled trial design and assessment of
318 baseline vaccine hesitancy and intent to vaccinate to decrease confounding effects. Pediatric
319 providers were unaware of the parent's study participation, minimizing social desirability bias.
320 Assessing influenza vaccine receipt through the child's medical record improves understanding
321 of the relationship between self-reported parental intent to vaccinate and whether or not that
322 aligns with vaccine receipt.
323
324 Study limitations include use of a convenience sample, which may introduce selection bias.
325 Because the predominant reason for ineligibility was prior child influenza vaccine receipt that
326 season, those parents who were eligible to enroll, especially later in the season, may have a lower
327 intent to vaccinate or higher vaccine hesitancy. Overall child influenza vaccination rate in this
328 study was 71.8%, slightly less than the 74.1% influenza average vaccine rate for all pediatric
329 patients seen at those sites. While this may have resulted in a lower pediatric vaccine receipt
330 rate, these parents are an important target population in which to assess the impact of pro-vaccine
331 educational intervention on their decision-making. Eligible parents who refused to participate
332 (20%) may have been certain of their decision regarding the influenza vaccine, however we were
333 unable to view their child's medical record to measure receipt. Our study population was
334 primarily English and Spanish speaking parents in one urban underserved neighborhood, which
335 may limit generalizability. There were some differences among study arms, however they were
336 adjusted for in regression analysis. We were underpowered due to administrative constraints and

with more power we may have seen significant differences in other comparisons. Lastly, we were unable to control the conversation between the pediatric provider following study enrollment, which may have varied. However, use of an experimental design helps to minimize these unmeasurable differences.

Conclusion

In conclusion, a brief educational intervention given in the waiting room prior to a pediatric visit may help increase child influenza vaccine receipt. Future research which addresses office-based, pro-vaccine educational interventions in a various demographics and geographic locations is warranted. Comparing modes of information delivery (paper handout, text-messaging, video, interactive social media) with the goal of including a wider demographic and cost-effectiveness analyses may help increase child influenza vaccine receipt and promote feasibility of implementation.

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