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]

abstract

OBJECTIVES: To assess the impact of a parent educational intervention about influenza disease on child vaccine receipt.

METHODS: A convenience sample of parents of children ≥6 months old with a visit at 2 New York City pediatric clinics between August 2016 and March 2017 were randomly assigned (1:1:1) to receive either usual care, an educational handout about influenza disease that was based on local data, or an educational handout about influenza disease that was based on national data. Parents received the handout in the waiting room before their visit. Primary outcomes were child influenza vaccine receipt on the day of the clinic visit and by the end of the season. A multivariable logistic regression was used to assess associations between intervention and vaccination, with adjustment for variables that were significantly different between arms.

RESULTS: Parents who received an intervention (versus usual care) had greater odds of child influenza vaccine receipt by the end of the season (74.9% vs 65.4%; adjusted odds ratio 1.68; 95% confidence interval: 1.06–2.67) but not on the day of the clinic visit. Parents who received the national data handout (versus usual care) had greater odds of child influenza vaccine receipt on the day of the clinic visit (59.0% vs 52.6%; adjusted odds ratio 1.79; 95% confidence interval: 1.04–3.08) but not by the end of the season.

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

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

Dr Scott conceptualized and designed the study, analyzed the data, and drafted the initial manuscript; Dr Stockwell conceptualized and designed the study, took part in the analysis of the data, and reviewed and revised the manuscript; Drs Opel, Reifler, Rikin, and Pethe aided in the conceptualization and design of the study and reviewed and revised the manuscript; Ms Barrett helped design the data collection instruments and coordinated and supervised data collection at all sites; and all authors approved the final manuscript as submitted.

This trial has been registered at www.clinicaltrials.gov (identifier NCT02907580).

DOI: https://doi.org/10.1542/peds.2018-2580

Accepted for publication Apr 17, 2019

Address correspondence to Melissa S. Stockwell, MD, MPH, Division of Child and Adolescent Health, Columbia University, 622 W 168th St, VC 417, New York, NY 10032. E-mail: mss2112@cumc.columbia.edu

WHAT'S KNOWN ON THIS SUBJECT: Educational interventions have been positively associated with parental intent to vaccinate the 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 before a pediatric provider visit may help improve child influenza vaccine receipt.

To cite: Scott VP, Opel DJ, Reifler J, et al. Office-Based Educational Handout for Influenza Vaccination: A Randomized Controlled Trial. *Pediatrics.* 2019;144(2):e20182580

Every year in the United States, influenza accrues >$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 of 100 children are infected with influenza each year in the United States, 20 to 77 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 recommendations by the 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, US 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] Health care 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 are important to examine carefully. For example, pro-vaccine educational handouts attempting to disprove myths or change parental views may reduce measles-mumps-rubella vaccination intention among parents who are vaccine hesitant.[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.

Our goal for 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 (versus 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 and March 2017, a convenience sample of parent-child dyads at 2 pediatric clinics affiliated with an academic medical center in an underserved area in Northern Manhattan, New York City, was asked to participate in the study. Dyads were eligible if the parent spoke and read either English or Spanish and if 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 χ^2 analysis and $\alpha = .05$, and calculated that a sample size of 300 per arm would detect a difference of 8%. De-identified individual participant data will not be made available.

Study Design

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

After the baseline survey, parent-child dyads were randomly assigned into 1 of 3 arms (1:1:1 ratio) by using sequentially numbered, opaque, sealed envelopes that were prepared (V.P.S) by using permuted block randomization (generated by M.S.S.) and were stratified by the patient's primary language (English or Spanish). Dyads were allocated to their study arm by a research assistant (A.B.) and received either (1) an educational intervention that was based on national data, (2) an

educational intervention that was based on local data, or (3) usual care only. Both educational interventions consisted of a single-page paper handout that parents read in the waiting room. In the local data intervention, we highlighted the risk of influenza, the seriousness of the influenza disease (including referring to a study that revealed that many people who thought they had the flu actually did not have it), 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 that revealed that participants did not have flu-like or cold symptoms more often after the receipt of the influenza vaccine (Supplemental Information). In the national data intervention, we highlighted the risk of influenza and vaccine coverage data using national data from the CDC and information that the "flu shot does not cause the flu" by citing a national study that revealed that people who received a "flu shot vs a saltwater shot did not have more flu-like symptoms"[25–27] (Supplemental Information). After reading either educational handout, parents in the intervention arms were given a postsurvey that was used to assess their 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 influenza vaccine receipt date 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 the clinic visit day and by the end of the influenza season (ie, children vaccinated on the clinic visit day plus by the end of the influenza season), as abstracted from the medical record. The primary exposure variable was any educational intervention (versus usual care). Exposure variables used in secondary analyses included educational intervention subgroups (local and national), parental intent to vaccinate, vaccine hesitancy, and attitudes and beliefs regarding influenza and the influenza vaccine. The last documented response was used for parental intent to vaccinate the child: baseline survey intent for the usual-care arm and postsurvey 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 were dichotomized ($\leq$6 for low and moderate vaccine hesitancy versus $\geq$7 for high vaccine hesitancy) for the regression analysis. Parental intent to vaccinate and influenza attitude and belief variables were collapsed from a 4- or 5-point Likert scale to 2 categories.

Statistical Analysis

An intention-to-treat analysis was performed as the primary analysis. A per-protocol analysis was also conducted; parents who did not complete the study or children who had already received the influenza vaccine that season (but the parent reported that they had not been vaccinated) were excluded. Frequency statistics, χ^2, and Fisher's exact tests were used for describing characteristics of the participants in each study arm, depending on variable type (categorical versus continuous). In the primary analysis, multivariable logistic regression was used to assess the association of any educational intervention (versus usual care) with child influenza vaccine receipt, adjusting for any baseline differences ($P \leq .10$) among arms. In secondary regression analyses, we assessed (1) the association of intervention subgroups individually (local data intervention versus usual care and national data intervention versus usual care) with vaccine receipt, adjusting for baseline differences, and (2) the association of (a) parental intent to vaccinate, (b) vaccine hesitancy, and (c) influenza vaccine beliefs and/or knowledge with child vaccine receipt, adjusting for 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. Eligible unenrolled participants were either not interested (88%) or did not want their child's vaccine records viewed (12%; Fig 1). The median child and parent age was 4.3 (interquartile range 1.5–9.5) and 33.0 (interquartile range 27.0–40.0) years, respectively. Most children were Hispanic, publicly insured, and had good to excellent health, nearly one-third had a medical problem, and one-third were sick on the clinic visit day. Parents were mostly Hispanic 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 (Table 1). For the subgroups, differences between the national data intervention and usual-care arms included caregiver education and the child being sick on the clinic visit day; differences

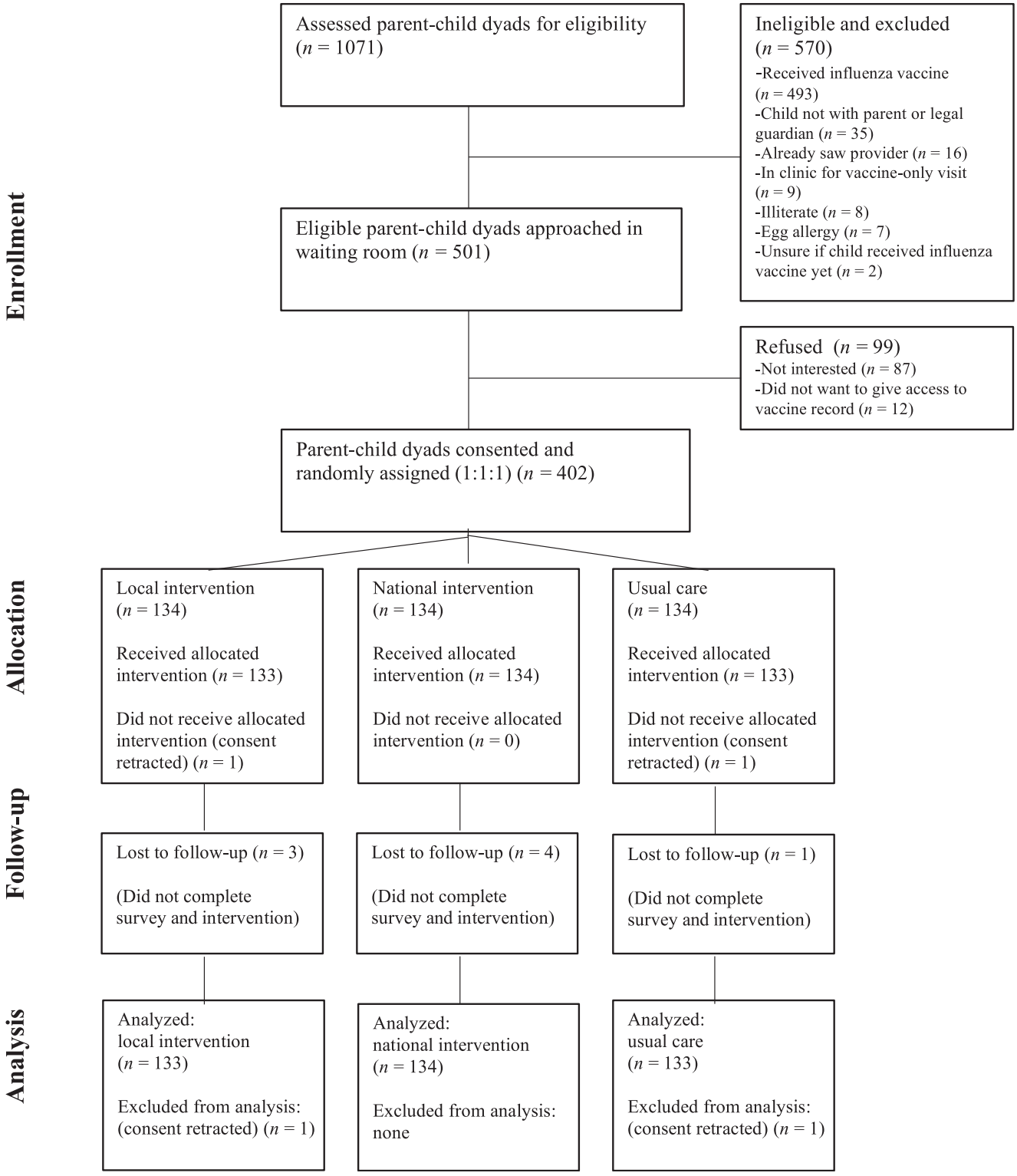

FIGURE 1
Participant flow diagram.

between the local data intervention and usual-care arms included the child's insurance and preintervention parental intent to vaccinate the child by the end of season (Table 1, Supplemental Table 3) Of note, the vaccine-hesitancy level was not significantly different between the arms (Table 1, Supplemental Table 3). Overall, on the clinic visit day, 56.8% of child participants received the influenza vaccine, and 71.8% of child

TABLE 1 Baseline Demographics of Parent and Child Participants by Study Arm

Characteristics	Usual Care (n = 134)	Any Intervention (n = 266)	P
Parent			
Parental age, y, median (IQR)	32.0 (27.0–39.0)	33.0 (28.0–41.0)	.36
Parent at visit, mother versus other, % (n)	94.6 (124)	97.3 (257)	.25
Parent race and/or ethnicity Hispanic, % (n)	91.7 (122)	89.7 (236)	.52
Parent education high school or less, % (n)	59.4 (79)	46.2 (123)	.01
Primary language, any English versus Spanish, % (n)	53.4 (71)	59.0 (157)	.28
History of ever refusing influenza vaccine, % (n)[a]	38.6 (51)	36.6 (97)	.69
Parental vaccine hesitancy (PACV-5), % (n)			
High versus low and moderate vaccine hesitancy	13.5 (18)	15.0 (40)	.70
Preintervention parental intent to vaccinate child on day of clinic visit likely, % (n)	66.7 (88)	69.9 (186)	.51
Preintervention parental intent to vaccinate child by end of season likely, % (n)	70.5 (93)	77.4 (206)	.13
Preintervention parental intent to vaccinate self by end of season likely, % (n)	60.6 (80)	60.5 (161)	.99
Child			
Child age, y, median (IQR)	4.5 (1.4–9.4)	4.1 (1.5–9.5)	.99
Child sex female, % (n)	53.4 (71)	48.7 (130)	.38
Child race and/or ethnicity Hispanic, % (n)	89.5 (119)	88.3 (233)	.72
Public insurance, % (n)	98.5 (131)	95.5 (255)	.16
Child's health, poor or fair, % (n)	10.5 (14)	12.7 (34)	.52
Child has medical problems, % (n)	25.6 (34)	31.1 (83)	.25
Child sick on day of clinic visit, % (n)	29.3 (39)	32.7 (87)	.49

P values were attained by using χ^2 or Fisher's exact tests for categorical variables and t tests for continuous variables. IQR, interquartile range.

[a] History of parental refusal of influenza vaccine other than for illness or allergy.

participants received the influenza vaccine by the end of the influenza season (100% were inactivated influenza vaccine).

Parents who received an educational intervention versus usual care had greater odds of having their child vaccinated against influenza by the end of the season (74.9% vs 65.4%; adjusted odds ratio [aOR] 1.68; 95% confidence interval [CI]: 1.06–2.67); however, there was not a significant association with vaccination on the clinic visit day (58.8% vs 52.6%; aOR 1.36; 95% CI: 0.89–2.09) after we adjusted for caregiver education (Table 2). Parents who received the national data intervention (versus usual care) had greater odds of their child receiving the influenza vaccine on the clinic visit day (59.0% vs 52.6%; aOR 1.79; 95% CI: 1.04–3.08), but not by the end of the season, after we adjusted for caregiver education and the child being sick on the clinic visit day (Table 2). There was no significant association for parents in the local data intervention study arm (versus usual care) with child influenza vaccine receipt on the clinic visit day or by the end of the influenza season after we adjusted for the child's insurance type and preintervention likelihood to vaccinate by end of the season (Table 2). There was no interaction between vaccine-hesitancy level and study arm in these models. In per-protocol analyses (n = 380), parents who received any intervention (75.1% vs 64.6%; aOR 1.78; 95% CI: 1.11–2.86), either the national data intervention (73.1% vs 65.4%; aOR 1.76; 95% CI: 1.003–3.10) or the local data intervention (76.7% vs 65.4%; aOR 1.87; 95% CI: 1.07–3.27), had higher odds of vaccinating their child by the end of the season compared with parents in the usual-care arm.

Across all 3 arms, parental intent to vaccinate (likely versus unlikely) was associated with child influenza vaccine receipt both on the clinic visit day (69.7% vs 21.6%; aOR 8.38; 95% 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) after we adjusted for caregiver education and the child being sick on the clinic visit day. Of the parents who reported "very likely" to vaccinate (n = 251), most did so (89.6%), and of the parents who reported "somewhat likely" to vaccinate (n = 110), 74.6% did so by the end of the season.

Children of parents with low or moderate versus high vaccine hesitancy had increased odds of influenza vaccine receipt by the end of the season (74.0% vs 58.6%; aOR 1.93; 95% CI: 1.07–3.48) and on the clinic visit day (58.5% vs 44.8%; aOR 1.77; 95% CI: 1.01–3.10) after we adjusted for study arm. Parents who reported "no or little concern" (versus "somewhat/very concerned") about serious influenza vaccine side effects (68.3% vs 45.2%; aOR 5.1; 95% CI: 3.0–8.5), parents who reported that the influenza vaccine is "somewhat/very effective" (versus "somewhat/very ineffective") (67.3% vs 31.9%; aOR 4.34; 95% CI: 2.67–7.05), and parents who did not believe (versus those who did believe) you can "get the flu from the flu shot" (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 clinic visit day after we adjusted for study arm and the child being sick on the clinic visit day. Parental belief regarding influenza illness severity was not associated with vaccine receipt.

TABLE 2 Association of Educational Interventions Versus Usual Care With Receipt of the Influenza Vaccine on the Day of the Clinic Visit and by the End of the Influenza Season

	Influenza Vaccine Receipt on Day of Clinic Visit		Influenza Vaccine Receipt by End of the Influenza Season[a]		Did Not Receive the Influenza Vaccine
	% (*n*)	aOR (95% CI)	% (*n*)	aOR (95% CI)	% (*n*)
Usual care	52.6 (70)	—	65.4 (87)	—	34.6 (46)
Any intervention	58.8 (157)	1.36 (0.89–2.09)[b]	74.9 (200)	1.68 (1.06–2.67)[b]	25.09 (67)
Local	58.7 (78)	1.23 (0.61–1.7)[c]	76.7 (102)	1.35 (0.74–2.47)[c]	23.3 (31)
National	59.0 (79)	1.79(1.04–3.08)[d]	73.1 (98)	1.73 (0.997–3.01)[d]	26.9 (36)

—, not applicable.

[a] Children vaccinated on the day of the clinic visit plus those vaccinated by the end of the influenza season.

[b] After controlling for caregiver education.

[c] After controlling for the child's insurance type and preintervention parental intent to vaccinate the child by the end of the season.

[d] After controlling for caregiver education and the child being sick on the day of the clinic visit.

Findings were similar for child vaccine receipt by the end of the season.

DISCUSSION

In this RCT, we found that providing an educational handout for parents was associated with increased child influenza vaccine receipt by the end of the influenza season. Although pro-vaccine educational materials have been previously studied, researchers have primarily assessed parental vaccine hesitancy and intent to vaccinate,[18,19,28,29] have used a different time line or mode of delivery (eg, text-message reminder),[29] or have focused on adolescent-only, adult, or pregnant women populations.[30–34] This study is 1 of the first studies in which an experimental design is used to evaluate the effect of an intervention with educational handouts in the clinic setting on child influenza vaccine receipt. We found that a brief educational intervention for caregivers before seeing a health care provider may have lasting effects by helping to increase pediatric vaccine uptake by the end of the season, and we found that an educational handout that is based on national data may improve influenza vaccination rates on the clinic visit day.

We also found that using a targeted approach of the parent's local community as the data source did not yield an additional benefit to child vaccine receipt.[35] The difference in magnitude of the number of children affected by influenza and, in particular, of the number of influenza-related pediatric deaths (national: 85–171 yearly versus local: 4 yearly) may have made the national data intervention more impactful in this community. Discussing the higher influenza vaccine coverage rate in the parent's local community (80% versus the lower national rate of 60%) may not have led to our hypothesized social desirability impact. Lastly, in the local data intervention, we referred to a study that revealed that many people in the community who thought they had influenza actually did not have it. Instead of encouraging parents to vaccinate their child because the influenza disease is much more serious than a cold, perhaps parents were negatively influenced by our stating that their community members were wrong.

Parents with high vaccine hesitancy were less likely to vaccinate their child against influenza both on the clinic visit day and by the end of the season. Previous studies have revealed similar associations between vaccine hesitancy and intent, vaccine attitudes, receipt of routine childhood immunizations, or influenza vaccine declination in the hospital setting.[8,23,36–38] Our study extends this relationship to influenza vaccine receipt in the outpatient setting. The PACV-5 used in this study may help to efficiently screen parents in the primary care setting. The PACV-5 has been previously analyzed,[21] and future research that validates this tool in various demographics may be useful. Parental beliefs of influenza vaccine effectiveness, parental beliefs that the flu shot does not cause the flu, or minimal concerns about side effects were also associated with child influenza vaccine receipt. Future interventions to promote influenza vaccine effectiveness may be most useful for impacting child vaccine coverage.

Self-reported vaccine intent is often used as a surrogate outcome measure instead of receipt in vaccine research. Our findings reveal that parental intent to vaccinate was significantly associated with child vaccine receipt, although only 89.6% of parents "very likely" to vaccinate by the end of the season did so. For studies in which vaccine receipt cannot be captured, our results reveal that parental intent to vaccinate the child is a good, but not perfect, proxy for vaccine receipt.

The strengths of this study include its RCT design and our assessment of baseline vaccine hesitancy and intent to vaccinate to decrease confounding effects. Pediatric providers were

unaware of the parent's study participation, minimizing social desirability bias. Assessing influenza vaccine receipt through the child's medical record improves understanding of the relationship between self-reported parental intent to vaccinate and whether that aligns with vaccine receipt.

Study limitations include the use of a convenience sample, which may introduce selection bias. Because the predominant reason for ineligibility was previous child influenza vaccine receipt that season, those parents who were eligible to enroll, especially later in the season, may have a lower intent to vaccinate or a higher vaccine hesitancy. The overall child influenza vaccination rate in this study was 71.8%, slightly less than the 74.1% influenza average vaccine rate for all pediatric patients seen at those sites. Although this may have resulted in a lower pediatric vaccine receipt rate, these parents are an important target population in which to assess the impact of a pro-vaccine educational intervention on decision-making.

There may have been sampling bias introduced by the eligible parents who refused to participate (20%) because they may have been certain of their decision to receive or refuse the influenza vaccine. We were unable to view their child's vaccine record to assess the magnitude or direction of this bias. Our study population was primarily English- and Spanish-speaking parents in an urban underserved neighborhood, which may limit generalizability. There were some differences among study arms; however, they were adjusted for in the regression analysis. We were underpowered because of administrative constraints, and with more power, we may have seen significant differences in other comparisons. Lastly, we were unable to control conversations between the pediatric providers and the parents after study enrollment, which may have varied. However, use of an experimental design helps to minimize these unmeasurable differences.

CONCLUSIONS

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

ABBREVIATIONS

aOR: adjusted odds ratio
CDC: Centers for Disease Control and Prevention
CI: confidence interval
PACV-5: Short-Scale (5-question) Parent Attitudes About Childhood Vaccines Survey Tool
RCT: randomized controlled trial

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Stockwell was an unremunerated coinvestigator for an unrelated, investigator-initiated grant from the Pfizer Medical Education Group; the other authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Dr Scott was funded by the Health Resources and Services Administration and by the Ruth L. Kirschstein National Research Service Award Institutional Research Training grant (T0BHP293020100). Dr Reifler received funding from the European Research Council under the European Union Horizon 2020 Research and Innovation Programme (grant 682758).

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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Pediatrics 2019;144;
DOI: 10.1542/peds.2018-2580 originally published online July 10, 2019;

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