

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

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22

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31

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33 **Data sharing statement:** De-identified individual participant data will not be made available.
34

35 **Abbreviations:**

36 aOR – Adjusted odds ratio

37 IQR – Interquartile range

38 PACV – The Parent Attitudes about Childhood Vaccines Survey Tool

39 PACV-5 – The Short-Scale (5 question) Parent Attitudes about Childhood Vaccines Survey Tool

40 RCT – Randomized controlled trial
41

42 **Key words:** influenza vaccine, parent education, child vaccine receipt, health communication,
43 educational intervention
44

45 **Table of Contents Summary:** This study evaluates brief, clinic-based educational interventions
46 for parents vs. usual care with child influenza vaccine receipt.
47

48 **What's Known on this Subject:**

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

52

53

54 **What This Study Adds:**

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

57 **Contributors' Statement Page:**

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

60

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

64

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

68

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

71 **Abstract**

72

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

75

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

84

85 **Results:** Parents who received an intervention (vs. usual care) had greater odds of child influenza
86 vaccine receipt by end of season (74.9% vs 65.4%, aOR 1.68, 95% CI: 1.06-2.67), but not on day
87 of clinic visit. Parents who received the national data handout (vs. usual care) had greater odds of
88 child influenza vaccine receipt on day of clinic visit (59.0% vs 52.6%, aOR 1.79, 95% CI 1.04-
89 3.08), but not by end of the season. There was no significant relationship between parents who
90 received the local data handout (vs. usual care) and child influenza vaccine receipt on day of
91 clinic visit or by end of season.

92

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

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97 **Clinical Trial Registration:** ClinicalTrials.gov NCT02907580

98 **Introduction**

99

100 Every year in the United States, influenza accrues more than \$10 billion in direct medical costs
101 and has negative health consequences for children, the elderly and those at high-risk of medical
102 complications.¹ Approximately 8 out of 100 children are infected with influenza each year in the
103 U.S., 20 to 77 out of 100,000 are hospitalized, and an average of 113 children die.^{2,3} Vaccination
104 against influenza is the most effective way to prevent the disease. However, despite the
105 recommendations by Centers for Disease Control and Prevention (CDC)⁴ and the American
106 Academy of Pediatrics⁵ for all children 6 months or older to receive the yearly influenza vaccine,
107 U.S. child influenza vaccination rates of 58% nationally remain below the Healthy People 2020
108 goal of 80%.^{6,7}

109

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

122

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

130

131 **Methods**

132

133 *Participants*

134 Between August 2016-March 2017, a convenience sample of parent-child dyads at two pediatric
135 clinics affiliated with an academic medical center in an underserved area in Northern Manhattan,
136 New York City, were asked to participate in the study. Dyads were eligible if the parent spoke
137 and read either English or Spanish and the child was ≥ 6 months old, without a contraindication
138 to the influenza vaccine (including egg allergy), had not already received the influenza vaccine
139 that season (by parent report), and was not there for an influenza vaccine only visit. We
140 calculated that a sample size of 200 parent-child dyads per each of the 3 arms (600 total) would
141 provide 80% power to detect a 10% difference among arms using chi-square analysis and
142 $\alpha=0.05$, and a sample size of 300 per arm would detect a difference of 8%.

143

144

145 *Study Design*

146 In this RCT, 1071 parents were approached in the waiting room by a bilingual (English/Spanish)
147 research assistant prior to their provider visit, as possible without interfering with clinic
148 registration or clinical care. All eligible, consented parents completed a baseline survey which
149 assessed demographics (age, sex, race/ethnicity, parent education, primary language, child's
150 insurance, parent type), whether their child was "sick on day of clinic visit," child's history of
151 medical problems and overall health, parental influenza vaccine attitudes and beliefs, knowledge
152 of influenza disease, and intent to vaccinate both their child and themselves against influenza on
153 the day of clinic visit and by the end of the season (Appendix A). Questions were derived from
154 previously used surveys and based on the Health Belief Model. Vaccine hesitancy was assessed
155 at baseline using a 5-question short-scale version²¹ of the validated 15-question Parent Attitudes
156 about Childhood Vaccines (PACV) survey tool (Appendix B).^{22,23}

157

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

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

183

184 *Measures*

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

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

198

199 *Statistical Analysis*

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

214

215

216

217 **Results**

218

219 Of 1071 parent-child dyads approached, 501 were eligible, 402 were enrolled (80%) and 400
220 were analyzed (Figure 1). Median child and parent age was 4.3 (IQR 1.5-9.5) and 33.0 (IQR
221 27.0-40.0) years, respectively. As reported by their parent, most children were Latino, publicly
222 insured, with good to excellent health, and nearly one third of children had a medical problem
223 and one third were sick on the day of clinic visit. Parents were mostly Latino mothers, half had a
224 high school education or less, and one third had previously refused the influenza vaccine for their
225 child and/or themselves. Arms were well-balanced with the exception of caregiver education
226 between the intervention arms and usual care (Table 1). For the subgroups, differences between
227 the national data intervention and usual care arms included caregiver education and child sick on
228 day of clinic visit, and between the local data intervention and usual care arms included child's
229 insurance and pre-intervention parental intent to vaccinate child by end of season (Appendix D
230 Table 1). Of note, vaccine hesitancy level was not significantly different between the study arms
231 (Table 1, Appendix D Table 1). Overall, on the day of clinic visit, 56.8% of child participants
232 received the influenza vaccine and 71.8% by the end of the influenza season (100% were
233 inactivated influenza vaccine).

234

235 Parents who received an educational intervention vs. usual care had greater odds of having their
236 child vaccinated against influenza by the end of the season (74.9% vs. 65.4%, aOR 1.68, 95%
237 CI: 1.06-2.67), however there was not a significant association with vaccination on the day of
238 clinic visit (58.8% vs. 52.6%, aOR 1.36 95% CI 0.89-2.09), after adjusting for caregiver
239 education (Table 2). Parents who received the national data intervention (vs. usual care) had
240 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

265 ineffective”) (67.3% vs. 31.9%, aOR 4.34, 95% CI 2.67-7.05), and parents who did not believe
266 you can “get the flu from the flu shot” (vs. those who believe you can) (65.3% vs. 52.6%, aOR
267 1.62, 95% CI 1.03-2.55), had increased odds of having their child vaccinated against influenza
268 on the day of clinic visit, after adjusting for study arm and child sick on day of clinic visit.
269 Parent’s belief regarding influenza illness severity was not associated with vaccine receipt.
270 Findings were similar for child vaccine receipt by the end of the season.

271

272 **Discussion**

273

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

285

286 We found that using a targeted approach of the parent’s local community as the data source did
287 not yield additional benefit to child vaccine receipt.³⁵ The difference in magnitude of the number
288 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

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

341

342 **Conclusion**

343

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

351

352

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354

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