

1 **Title:** Understanding Parents' Views toward the Newly Enacted HPV Vaccine School Entry
2 Policy in Puerto Rico: a qualitative study

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20 **Abstract**

21 **Background:** Human papillomavirus vaccine (HPV) is an important tool for prevention of HPV-
22 related cancers. In Puerto Rico, the Secretary of Health established a school entry requirement of
23 at least 1 dose of HPV vaccination in girls and boys aged 11 and 12 years taking effect in August
24 2018. Our study aims to examine parents' views and opinions of the process of implementing the
25 new HPV vaccination school entry policy in Puerto Rico, and understand barriers and facilitators
26 related to this HPV immunization policy.

27 **Methods:** Three focus group (n=12) and eight in-depth semi-structured interviews were
28 performed, along with a survey. The interviews were recorded and transcript by our staff members.
29 Through a thematic analysis were identified emergent themes.

30 **Results:** Lack of information in relation to the policy were the theme most mentioned in the
31 interviews. Moreover, participants expressed that previous negative experiences, from friends or
32 family member, adverse effect and the lack of communication from school and healthcare
33 providers deter them from the decision of vaccinated their kids. Barriers in the process of soliciting
34 an exemption was discussed.

35 **Conclusion:** Most barriers mentioned by participants who express hesitation about vaccinating
36 their kids with the HPV vaccine, are modifiable providing parents information about the mandate's
37 implementation, and educational materials that address their concerns related to the vaccine's side
38 effects. Implementation of this efforts, however, need to consider impacting the school (teachers,
39 principal directors, and administrative staff), the government and parents. This multilevel approach
40 will help to improve the dissemination of information about HPV vaccination in order to clarify
41 doubts and misinformation among hesitant parents.

42 **Keywords: HPV vaccine, school entry policy, hesitant parents, Hispanic**

43

44 **Background**

45 The HPV vaccine has been recognized as the best tool for prevention against human
46 papillomavirus (HPV) and its related cancers, as it substantially reduces the risk of developing
47 cervical cancer, especially when administered at young ages. The Advisory Committee on
48 Immunization Practices recommends the HPV vaccine as a routine vaccine for girls (since 2006)
49 and boys (since 2011) at ages 11–12 years old, with catch up recommended for older ages¹. Result
50 from the 2019 National Immunization Survey show that 54.2% of adolescents aged 13-17 in the
51 United States of America (US) were up-to-date with the complete immunization series for HPV²,
52 which represented only a slight increase from 2018 (51.1%).³ However, despite its
53 recommendation and the proven effectiveness around the world⁴, overall national HPV vaccine
54 uptake remains far from the goal that was established a decade ago in Healthy People 2020 of
55 80.0% .⁵

56 School-entry-requirements have been established as an evidence-based strategy to increase
57 vaccination among children and youth.⁶ However, only five US states or territories (Virginia,
58 District of Columbia, Rhode Island, Hawaii and Puerto Rico) have included the HPV vaccine as a
59 requirement for school entry.⁷ Despite these efforts at the policy level, parents' beliefs and attitudes
60 on childhood vaccination still constitute one of the main challenges for increasing the uptake of
61 HPV and other vaccines.⁸ According to the World Health Organization in 2014, vaccine hesitancy
62 is defined as a delay in acceptance or refusal of vaccination despite availability of vaccination
63 services.⁹ Only a handful of qualitative studies have examined hesitant parents' perceptions,

64 barriers, and facilitators regarding mandatory HPV vaccination for school-entry, and their results
65 are inconsistent. Vercruyse and co-authors found that most parents agreed with the school-
66 located provision of HPV vaccine, but they had weak support for school-entry requirement because
67 it might provoke a public backlash that could further hinder vaccination efforts.¹⁰ Another study
68 reported that the parents perceived the HPV vaccination to be similar to other routine vaccines for
69 school entry when adding the benefit of cancer prevention.¹¹ Only one study¹² was conducted in a
70 state where HPV vaccination is already mandatory for school entry (Virginia); therefore, parents'
71 statements regarding the perception of a vaccine school-entry requirement in other states were
72 hypothetical in context.

73 Due to the high incidence rate of HPV-related cancers in Puerto Rico¹³ and the recent increase in
74 cervical cancer observed,¹⁴ the Secretary of Health established a school entry requirement of at
75 least one dose of HPV vaccination in girls and boys aged 11 and 12 years, which took effect in
76 August 2018. This requirement has been amended annually, now including adolescents 11-16
77 years old.¹⁵ This study aimed to examine the perceptions of parents and guardians whose children
78 were not in compliance with the new HPV vaccination school entry policy in Puerto Rico after it
79 took effect in August 2018.

80 **Methods**

81 **Study Design and Sample:** We conducted a qualitative observational study design. Twenty adults
82 participated in focus groups (n=12) or in-depth semi-structured interviews (n=8), which were
83 conducted between April to November 2019, 8-15 months after the HPV school entry policy took
84 effect in Puerto Rico. Those eligible were parents or guardians (i.e. participants) of boys and/or
85 girls aged 11 and 12 years old, who lived in San Juan or surrounding municipalities and were not

86 vaccinated against HPV at the time of the focus group or interview (i.e., did not comply with the
87 recent HPV school entry requirement) .

88 **Recruitment:** Several strategies were used to recruit the study participants. Flyers with
89 information from the study were posted in places such as nearby clinical settings, including
90 Federally Qualified Health Clinics, pediatric clinics and hospitals. Also, we distributed flyers to
91 parents in several activities in the community and/or schools (sports, health fair and social
92 activities) and discussed briefly with them (if requested), information of the study (objective), and
93 their expected role in this study. Contact information was requested among those who were
94 interested. Moreover, door-to-door outreach in public housing complexes, along with their
95 community leader and the social workers were conducted to identify potential participants. Lastly,
96 we posted recruitment materials on Facebook to promote the study and increase the engagement.
97 Those potential participants interested on our study were screened by phone to determine their
98 eligibility by a staff member. For those who qualified, an appointment for the focus group or
99 interview was scheduled. A total of 20 participants (all women) between the ages of 23 to 68 years
100 old, mainly residents of the municipality of San Juan (80%) were recruited. An informed consent
101 form after discussing it and agreed with the study was signed by all study participants.

102 **Data Collection Procedures.** Before the interview, a questionnaire in Qualtrics (SAP,
103 Utah/Seattle, US) was completed by the participants. A semi-structured discussion guide was used
104 for the focus groups and in-depth interviews, with open-ended questions that prompted participants
105 to discuss the following topics: perception of general vaccine, HPV vaccine and the new school
106 entry requirement policy; practice and procedure of the sources of information, influencers, and
107 willingness to change. Focus groups lasted 40-60 minutes, and the in-depth interviews lasted
108 around 20-40 minutes. All interviews were audio recorded and transcribed verbatim. A separate

109 staff member reviewed the transcriptions for validation. The focus groups were held in private
110 conference rooms and the in-depth interviews were face-to-face or over the phone. Participants
111 received \$25.00 to compensate for their time.

112 **Data Analyses**

113 Qualitative data management and analysis was performed using Atlas.ti 8.0 (Scientific Software
114 Development GmbH, Berlin, Germany). Using thematic analysis,¹⁶ parental/guardian barriers
115 and/or facilitators of compliance with the HPV vaccine school requirement were identified. First,
116 one of the members (DML) performed the initial coding, and another member (VCL) reviewed the
117 identification of the codes selected and the quotes linked to the coding. Second, both members
118 reviewed the codes several times, until met a consensus to define them, as well, to determine the
119 emerging codes.^{17,18} Twenty-three codes were identified and classified into five main themes
120 (supplementary appendix with the most emerging themes is provided in Table A). Data from the
121 socio-demographic questionnaire was analyzed using Stata for Windows, version 13 (Stata
122 Corporation, College Station, Texas, US). Measurements of central tendency and dispersion were
123 used for continuous variables, whereas percentages were used to describe categorical variables.

124 All these methods were in accordance with relevant guidelines, literature review, and regulations
125 approved by the Institutional Review Board of the University of Puerto Rico, Medical Sciences
126 Campus (*protocol A8060218*).

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130 **Results**

131 Most participants reported having less than some college education (70%) and an annual income
132 of less than \$15,000 (68.4%). The vast majority of the participants' children were enrolled in public
133 school (80.0%) and had the Medicaid government health insurance (70.0%). Many of the
134 participants (80.0%) indicated they had heard about HPV vaccine, mainly through health
135 providers. Despite this, over half of them (55.0%) were unaware that the HPV vaccine was a
136 school-entry requirement (Table 1).

137 **Table 1**

138 **Knowledge about HPV and the HPV school entry policy**

139 Most of the participants were aware about how many doses are required to complete the series,
140 and that HPV is a sexually transmitted disease. Few mentioned the association between this
141 vaccine and cancer prevention. Despite their knowledge about the vaccine, some participants
142 indicated that they had never heard about the new HPV vaccine school-entry requirement. One of
143 them expressed the constant promotion of this vaccine through the mass media (TV, Facebook,
144 newspaper), but she never noticed it in the immunization record (commonly known in Puerto Rico
145 as the '*green sheet*', required for the school-entry) for this new scholar year (2018-2019).

146 *"A lot of promotion about the [HPV] vaccine, but I did not know that it was mandatory to vaccinate*
147 *them for school, [I mean], that it existed in the green sheet of vaccines..."*

148 **Communication**

149 The lack of communication between the parents and the schools in relation to the vaccine
150 requirements was commonly mentioned. All the participants said that is in the annual school

151 enrollment period when they have more interaction with the school staff. Participants expressed
152 that the information provided by the school was general in content: a paper with the list of all the
153 materials, vaccination requirements and a request of a medical evaluation, if it applies. They also
154 discussed that their children's schools lacked opportunities for explaining or clarifying doubts
155 about the vaccine requirement. Only two participants remembered receiving a notification from
156 the school about the HPV vaccine being including in immunization requirements. Some
157 participants expressed that the school nurse called them to remind them about the deadline to
158 vaccinate their child, but no further explanation was provided.

159 Although most participants indicated that they received information related to the HPV vaccine
160 from their healthcare providers, most of them verbalized that the experience was insufficient. The
161 participants said that the only information they received by pediatricians was that "*it is mandatory*"
162 or "*you need it for school*".

163 *"[When] you go to a pediatrician's office, the only thing that they tell you is that you have to give*
164 *[to your child] the vaccine, and that's it!"*

165 In contrast, participants who made the decision to request a medical exemption indicated that their
166 providers gave them an orientation. In this orientation, the provider explained the pros and cons of
167 the vaccine regarding their child's condition. One of the participants said that she felt that the
168 provider respected her privacy when he talked with her because was a 'closed-door' conversation
169 and he did not judge her.

170 The other topic mentioned regarding communication was mass media. Almost all the focus groups
171 and interviews mentioned the TV advertisements from a national pharmaceutical company (add
172 ref)-regarding the HPV vaccine, and for some, this was the only media source of information about

173 the vaccine. Some participants expressed that the sense of guilt the advertisement promoted made
174 them feel blame about the future of their children.

175 *"TV blames you and makes you a bad parent. The ad blames you and makes you a bad parent."*

176 However, this advertisement made some of them thinking to eventually vaccinate their children
177 because if they can prevent to something bad happened to them, they will do it. . Facebook and
178 the internet were the tools used by these participants to find information about vaccines. However,
179 they stated that they were aware that the information found on social media and websites would
180 not necessarily be accurate.

181 **Attitudes and Beliefs**

182 Previous negative experiences, from friends or family members were commonly expressed in the
183 interviews as a potential trigger to influence negatively the parents' opinion of the HPV vaccine.
184 Some participants disclosed in the interview their children's pre-existing medical conditions and
185 indicated that was the main reason that they had more concerns about how the components of the
186 vaccine and its potential adverse effects could affect their children. Instead, two participating
187 grandparents mentioned that they agree with vaccination because they knew what it means to live
188 without them. Personal experience in relation to their youth and the how the lack of medicines and
189 other preventive vaccines caused many people to die were the reasons for their position to the
190 vaccination.

191 The benefits of the vaccine was mentioned less often among study participants. Some participants
192 expressed that they did not completely reject the intention to vaccinate their children, but they were
193 hesitant regarding the age in which the HPV vaccine is required for the school entry policy in

194 Puerto Rico (11-12 years old). Instead, they said they thought that the vaccine should be
195 administered when their children get older.

196 *"I think that if he is not sexually active... I think that [when] he turns 15 years old, he can be*
197 *[vaccinated]. [W]hen he [can] understand, and we can talk about that topic. [A] 11 and 12 [year-*
198 *old] boy [does] not [understand] what the vaccine is for or what it is used for."*

199 In other cases, the participants felt the requirement to vaccinate their children to go to school was
200 imposed on them because there is no other option. One of the participants said that the government
201 offers access to education to anyone, however it did not make sense if they impose the vaccination
202 on the children.

203 **Barriers**

204 The main barrier identified by the participants was lack of information. The main topics concerning
205 lack of information were the pros and cons of the HPV vaccination, and concerns about what
206 happened if the vaccination series is interrupted. The other barrier identified was worry about
207 possible adverse effects. Concerns regarding alleged associations with autism, paralytic effects,
208 an allergic reaction, and deathly consequence were expressed, even though the scientific evidence
209 has not found these associations to be present. Most of the participants said that seeing, listening,
210 or reading this kind of (mis)information made them mistrust the HPV vaccine.

211 *"I talked with other parents and hearing news too, and all those things, like increasing [my doubts]*
212 *and make me not want to allow [my child] to get the vaccine."*

213 Our analysis evaluated two types of access: to the vaccine and access to vaccine exemptions. The
214 issues reported with the access to the vaccine were the supply on the vaccination center, availability
215 of time to coordinate an appointment, and the cost of getting the immunization record signed. Two

216 participants mentioned the high cost of the vaccine as a general issue but not as having a direct
217 impact.

218 Three participants indicated that they went through the process of obtaining an exemption for the
219 HPV vaccine. The main barriers they cited were the complexity and the cost of the process. They
220 explained that it was a tedious and a bureaucratic process to identify a healthcare provider or
221 religious leader that would attest to the exemption, find a lawyer to sign the affidavit, and
222 coordinate the appointments. Since the exemption was required to be renewed every year, they
223 had to incur the cost and go through the effort every year.

224 *" If it's necessary, I'll do it again [to avoid] putting things in my daughter that I do not consider*
225 *necessary."*

226 **Recommendations**

227 Participants recommended that two primary information sources – health care providers and
228 schools should disseminate the information and education about the HPV vaccine and the
229 vaccination requirement for school-entry. Health care providers, specifically, those who
230 administer vaccines, the participants said that they should be aware of the components of vaccines,
231 their benefits and potential adverse effects, in order to be able to explain this information to parents
232 who have questions. For the school, the participants suggested providing orientation sessions for
233 parents and students whenever there are new changes to the requirements for school-entry. Other
234 recommendations from the participants were to use the social media and mass media to inform the
235 community, and that the messages should not focus on using the fear factor.

236 *"[In] the orientation, the pros and cons have to be indicated but not using the fear factor to impose*
237 *or obligate a person to vaccinate [her/his] child."*

238 **Discussion**

239 This qualitative study explored the perception of mothers about the HPV vaccine and the newly
240 enacted HPV school entry requirement. Although most of the participants acknowledged HPV
241 infection and were aware of the HPV vaccine, only one mentioned the importance of this vaccine
242 for cancer prevention and most of them unknown about the policy. Our result is similar to others
243 studies about the lack of knowledge of the association between HPV vaccine and cancer prevention
244 in this population, but in contrast about knowledge on the HPV vaccine dose schedule.^{19,20} On the
245 other hand, hesitation towards vaccination in relation to early age of administration and side effects
246 was discussed. Lack of awareness and understanding of the new policy was commonly mentioned,
247 with resistance to this policy for the imposition of the government to their parental decisions
248 regarding their child health²¹ Issues such as lack of communication between them and the schools
249 regarding this new policy was also mentioned. It was also discussed that although some of them
250 acknowledged receiving information regarding the HPV vaccine from their health providers, this
251 information was insufficient, leading to a sustained hesitancy in the process and in the vaccine
252 pros and cons.

253 Despite this ascertainment, less than half of the participants are in agreement to vaccinate their
254 children against HPV in the future, therefore the delay in acceptance or refusal of the HPV vaccine
255 despite availability of vaccination services and the enactment of the policy is not motivated by
256 strong philosophical views to vaccination overall. In our study, hesitation to the HPV vaccine did
257 not translate other adolescent immunizations or refusal of all required vaccines. 13 of the 20
258 participants reported that their children had all the vaccines required by the school, except HPV
259 vaccine. Low parental agreement to administrate the HPV vaccine on teenagers has been observed
260 in other studies.^{22,23} However, similar to our findings, the main barrier reflected to explain the

261 participants' position has been the lack of information.^{12,24,25} Participants in this study were most
262 interested to know about : the pros and cons of the HPV vaccine, duration of vaccine effectiveness
263 and potential side effects in order to make an informed decision about vaccinating against HPV.

264 The literature suggests that a poor or inadequate communication between parents and health
265 providers could negatively influence parent's decision and contribute to hesitant behaviour.^{26,27}

266 The influence of the healthcare providers' recommendation has on the parents' decisions on
267 vaccination uptake (in general) is constantly reported.^{26,28,29} This is also consistent with a previous
268 household survey in Puerto Rico conducted prior the requirement (2008), in which 89% of parents
269 of daughters in vaccine recommended age-groups reported that they would vaccinate them if the
270 doctor recommended it.³⁰ Different strategies for health providers have been developed to train
271 providers to deliver an effective communication where the trust with the parents can be built, and
272 a strong recommendation of vaccine can be given.³¹

273 MacDonald and co-author¹⁵ has suggested that other factor associated with vaccine hesitancy are
274 individual and group influence based on personal perception, personal experience and the social
275 media. All our participants mentioned personal stories or negative experience from someone
276 regarding to the adverse effects of the vaccines. Previous negative experiences with a vaccine
277 could lead a parent to be hesitant and mistrust the effectiveness and safety of the vaccination in
278 general.^{34,35} Unfortunately, when these stories get disseminated via social media, people rely more
279 on this anecdotal, experience-based information than evidence-based information¹⁴. Besides, the
280 spread of misinformation through these media could get more impact due to easy access.
281 Understanding the scope and variability of the current sentiment toward the HPV vaccine and its
282 policy could inform the development of an education campaign to combat the negative
283 misinformation using these same channels of delivery^{34,36,37}.

284 In August 2018, the HPV vaccine was included as a vaccine required to school-entry on girls and
285 boys between 11 – 12 years old. We collected our data a couple of months after this new policy
286 was enacted. More than half of our participants were unaware about this policy, despite a year
287 prior (June 2017) information to the public from the Puerto Rico Department of Health was
288 provided.³² Our findings suggested the lack of establish strategies of communication between the
289 school and the parents increased the confusion and hesitancy in relation to this requirement.
290 Similar to our studies^{33,34}, parents have recommended workshops in a school setting given the
291 accessibility and confidence. Since the HPV vaccine is a school requirement, it is of the utmost
292 importance that the schools have trained school personnel and, likewise, integrate parents and
293 students in the process to enhance the engagement ³⁵. On the other hand, it was mentioned the
294 challenges in obtaining an exemption to opt out for the HPV vaccine (not necessary the other
295 adolescent vaccine). The Puerto Rico Department of Health have a strict exception requirement as
296 only allows medical and religious exemption for vaccination (no philosophical). ³⁶ The rate of
297 exemption in Puerto Rico is still unknown. Further efforts needs to explore if exception requests
298 have increased in Puerto Rico due to the implementation of the HPV vaccine in August 2018 and
299 how (if any) impacted to uptake of other adolescent vaccines over time.

300 **Strengths and limitations**

301 Mandatory vaccination for school entry has been used to increase vaccination uptake, make catch-
302 up, or reduce the gap between population groups for other vaccines in the past and more recently
303 for HPV in five states and territories.¹³ To our knowledge, this is the first qualitative study in PR
304 that describes parental perspectives about the HPV vaccine school entry requirement, and portray
305 challenges in the exemption process. This study is one of the few which evaluated the parental
306 perspective about HPV vaccine policy on a US territory where it was enacted. Regardless this

307 effort, our study has several limitations worth discussing. First, despite several outreach and
308 community engagement efforts performed, a small sample of participants was recruited. Potential
309 participants expressed time constraints as well as indicated worries of being exposed to the public
310 spotlight (due to their views on vaccination). All our participants were women despite our
311 recruitment process was opened for anyone. Understanding the fathers' perception could help us
312 getting additional insight on vaccines and these new requirements and understand potential
313 divergent family dynamics in the decision of vaccinating (or not) their children against HPV.³⁷

314 **Conclusion**

315 Most of the barriers discussed in our study are modifiable with the implementation of educational
316 programs, health communication strategies across agencies responsible for the implementation,
317 public acceptability, and political acceptability to support this policy.^{33,38-40} According to an
318 unpublished preliminary results using data of 2010 through 2019 provided by the Puerto Rico
319 Immunization Registry from our research team, a subtle but significant increase in HPV
320 vaccination (initiation, not completion against HPV) has been observed after implementing the
321 requirement. However, at this time, we are unaware if the COVID-19 pandemic has made an
322 impact on parental perception to the school required vaccines. This area should be explored to
323 target educational interventions that might help address and boost parental concerns, maintain a
324 high rate of the first dose, and increase completion and adherence to the HPV vaccine schedule of
325 the second dose giving it emergency status. Understanding the progression of parental
326 perceptions over the course of the policy implementation, and how current scenarios might impact
327 their decisional process, should help us to develop effective interventions that respond to the
328 identified barriers and facilitators in the future.

329 **Abbreviations**

330 HPV: human papillomavirus

331 US: United States of America

332

333 **Declaration**

334 *Ethics approval and consent to participate:* The Institutional Review Board of the University of
335 Puerto Rico, Medical Sciences Campus (protocol A8060218), approved this study. After
336 discussing the informed consent form and agreed with the study, this was signed by all study
337 participants.

338 *Consent for publication:* Not applicable.

339 *Availability of data and materials:* The datasets used and/or analyzed during the current study
340 are available from the corresponding author on reasonable request.

341 *Competing interests:* VCL has received compensation from Merck and Co., Inc. for consultancy
342 in June 2020. APO reported has received personal fees from serving as a consultant for Merck
343 (October 2019) outside the submitted work. The other authors have declared that they have no
344 competing interest.

345 *Funding:* This work was supported by National Cancer Institute (NCI), grant R01CA232743-
346 01A1 (“Implementation of School-Entry Policies for Human Papillomavirus Vaccination”)
347 within University of Puerto Rico Comprehensive Cancer Center. The National Cancer Institute
348 had no role in the study design; collection, analysis, and interpretation of the data; writing of the

349 manuscript; or decision to publish. The content is solely the responsibility of the authors and
350 does not necessarily represent the official views of the NCI.

351 **Authorship contributions:** VCL, was funding acquisition, supervision, conceptualization,
352 methodology, writing-original draft preparation, investigation and validation. DTML's
353 contribution was methodology, writing-original draft preparation, formal analysis and
354 investigation. RSA's contribution was methodology, formal analysis, investigation, writing-
355 reviewing and editing. ODM's contribution was formal analysis, investigation, writing- reviewing
356 and editing. APO's contribution was writing- reviewing and editing. MF's contributions were
357 writing-reviewing and editing. PCH's contribution was funding acquisition, formal analysis,
358 investigation, writing- reviewing and editing.

359 **Acknowledgments:** This publication was supported by the Comprehensive Cancer Center of the
360 UPR (a public corporation of the Government of Puerto Rico created in virtue of Law 230 of
361 August 26, 2004 as amended). The content is entirely the responsibility of the authors and does
362 not necessarily represent the official views of the Comprehensive Cancer Center UPR. We thank
363 Dr. Katelyn Wells, Manuel E Rivera, Vilnery Rivera Figueroa and, Glizette Arroyo Morales for
364 your support and collaboration.

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497 **Figures and Tables**

498 **Table 1: Description of our 20 women participants**