

1           A QUALITATIVE STUDY OF HEALTHCARE PROVIDER AWARENESS AND  
2           INFORMATIONAL NEEDS REGARDING THE NINE-VALENT HPV VACCINE

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40 **Abstract**

41

42 The 9-valent Human Papillomavirus (HPV) vaccine, 9vHPV, was licensed in the U.S. in December, 2014.  
43 We assessed healthcare provider (HCP) awareness of the newly approved vaccine and identified  
44 questions HCPs have about the vaccine. As part of a larger study, we used semi-structured interviews to  
45 ask 22 pediatric HCPs about their awareness of 9vHPV, questions they have about the vaccine, and  
46 questions they anticipate from patients and parents. Interviews were audio-recorded and transcribed  
47 then analyzed using inductive content analysis. Over half were aware of the vaccine but few HCPs  
48 claimed to be familiar with it. HCPs indicated several questions with common themes pertaining to  
49 efficacy, side effects, and cost. Only half of HCPs believed patients or parents would have questions. The  
50 results suggest strategies and areas for health systems and public health organizations to target in order  
51 to resolve unmet educational needs among HCPs regarding 9vHPV.

52

53

54 Keywords: HPV, awareness, healthcare provider, vaccine, sexually transmitted infection, education

55

56 **Introduction**

57 Human Papillomavirus (HPV) is the most common sexually transmitted infection in the U.S.[1] HPV  
58 Infection is a risk factor for genital warts, cervical cancer, anal cancer, penile cancer, and oropharyngeal  
59 cancers. In the U.S. an estimated 360,000 people will be diagnosed with genital warts, 12,000 women  
60 will be diagnosed with cervical cancer, and over 4,000 will die from cervical cancer this year [1, 2].

61  
62 Currently, there are three vaccines for HPV prevention. The bivalent vaccine, 2vHPV, protects against  
63 HPV types 16 and 18, which are responsible for about 70% of cervical cancers[3]. The quadrivalent  
64 vaccine, 4vHPV, also protects against HPV-16 and 18, as well as HPV-6 and 11, the two types that cause  
65 about 90% of genital warts [3]. At the end of 2014, the U.S Food and Drug Administration approved a  
66 nine-valent vaccine (9vHPV) that protects against the four HPV types in 4vHPV as well as five additional  
67 oncogenic types. 9vHPV has the potential to prevent up to 90% of cervical cancers, and many vulvar,  
68 vaginal, and anal cancers as well as 90% of genital warts [4].

69  
70 2vHPV is licensed for females ages 9-26 and 4vHPV is licensed for males and females ages 9-26. 9vHPV is  
71 licensed for females ages 9-26 and males age 9-15 [5]. The Advisory Committee on Immunization  
72 Practices (ACIP) recommends routine vaccination for boys and girls ages 11-12 and catch up vaccination  
73 for women through age 26, men up through age 21, and for men who have sex with men or are  
74 immunocompromised through age 26 [6]. In February, 2015 ACIP issued the same age-based  
75 recommendations for 9vHPV as it did for 4vHPV [7]. ACIP further stated that if a patient returns for the  
76 second or third dose and the first dose HPV vaccine product is not available, any available HPV vaccine  
77 can be used to continue or complete the series[7].

78

79 Despite the substantial benefits of being immunized, vaccination rates remain unacceptably low in the  
80 U.S. In 2014, only 60.0% of adolescent girls and 41.7% of adolescent boys ages 13 through 17 received  
81 one or more doses of HPV vaccine[8]. Given the already low uptake, implementation of a new HPV  
82 vaccine (i.e., 9vHPV) could further complicate administration processes, thereby keeping uptake low.  
83 Therefore it is important to examine provider knowledge and attitudes regarding HPV vaccination and  
84 administration processes to maximally support uptake and, as a result, population health.

85

86 Healthcare provider (HCP) recommendation is one of the strongest predictors of vaccine uptake [9-11].  
87 Furthermore, a lack of HCP recommendation is a primary reason for non-vaccination [12, 13]. The  
88 purpose of this study was to assess early HCP awareness of 9vHPV as well as identify questions HCPs  
89 might have regarding 9vHPV. It is important to ascertain provider knowledge, especially given the  
90 interchangeability of 4vHPV and 9vHPV in the ACIP recommendations and the confusion this may cause  
91 in conjunction with the introduction of the new vaccine. Additionally, we wanted to ascertain any  
92 questions HCPs anticipate from parents and patients in order to assist them in addressing patient  
93 concerns.

94

## 95 **Materials and methods**

96

97 We conducted semi-structured in-person qualitative interviews from January to March, 2015.

98 Qualitative methodology is ideal when exploring an area where little is known because it allows the  
99 investigators to identify, via in-depth analysis, relevant personal and contextual factors [14]. Participants  
100 were recruited from five urban community pediatric clinics in the Eskenazi Health System, which serves  
101 predominantly low-income patients in the Indianapolis area. Over 70% of this pediatric patient  
102 population is on Medicaid.

103 Interviews lasted 15-30 minutes, and participants were compensated with a gift card. Interview  
104 questions about 9vHPV centered on vaccine awareness, anticipated patient and parent questions, and  
105 general questions regarding the vaccine. Twenty-nine HCPs were eligible to be interviewed and 22  
106 consented and completed the interview. Participants were recruited until saturation was reached, i.e.,  
107 we were acquiring no new information from the interviews [15]. Interviews were digitally recorded then  
108 transcribed. Qualitative analysis was performed using inductive content analysis [16]. Transcripts of the  
109 interviews were read to identify meaningful themes, then two investigators independently coded each  
110 interview according to those themes. The codes were reviewed and areas of disagreement were  
111 resolved through discussion. The study was approved by the Institutional Review Board of Indiana  
112 University (Study No. 1408987170).

113

## 114 **Results**

### 115 *Healthcare Provider 9vHPV Awareness*

116 The sample consisted of 21 pediatricians and one pediatric nurse practitioner. They were mostly female  
117 (n=17) and averaged 14.1 years in practice. Twelve had heard of 9vHPV but six of these indicated they  
118 did not know much about it. Eight participants indicated they had not heard of 9vHPV and 2 stated they  
119 had “heard a rumor” but that they did not know much about it. For themes and exemplar quotes, see  
120 Table 1.

121

### 122 *HCP Questions*

123 When the HCPs were asked what questions they have about 9vHPV, they indicated they would like to  
124 know more about efficacy (n=7), side effects (n=6), added protection over 4vHPV (n=5), dosing schedule  
125 (n=5), cost (n=5), and safety (n=4). Some HCPs indicated that they would like general information either

126 for their own knowledge or to help them answer questions from patients or parents (n=5). Additionally,  
127 four providers wanted to know when it would be available.

128

### 129 *Anticipated Parent and Patient Questions*

130 Twenty-one of the HCPs were asked if they thought patients or parents would have questions about  
131 9vHPV. Eleven said they did not think they would have any questions at all. When asked why, four  
132 indicated they did not think patients or parents would have questions beyond those they already have  
133 had about 4vHPV. These HCPs also noted that there were not any additional questions for the  
134 pneumococcal vaccine when it went from 7-valent to 13-valent. Furthermore, three indicated that  
135 patients do not understand the science behind vaccines enough to know the difference between  
136 valencies and therefore would not have any additional questions.

137

138 Interestingly, although the majority of HCPs indicated they did not expect questions about 9vHPV, most  
139 did go on to list possible questions patients might have. HCPs anticipated questions regarding side  
140 effects (n=9), effectiveness (n=3), and safety (n=3). Some thought parents would want to know if the  
141 new vaccine was really necessary or better than 4vHPV (n=5). Four of the HCPs (19%) thought that their  
142 patients would want long-term data due to perceived lack of real world experience with the new vaccine  
143 (see Table 1).

144

### 145 **Discussion**

146 HCP recommendation is one of the strongest predictors of HPV vaccine uptake. In this sample, just over  
147 half of HCPs were aware of the 9vHPV vaccine. Increasing HCP awareness of the licensing and  
148 recommendations for 9vHPV will be pivotal in increasing vaccine uptake. HCPs had questions about the  
149 vaccine mainly regarding efficacy, safety, side effects, cost, and dosing schedule. While the results

150 indicate there is a need to increase HCP awareness, it is likely that as 9vHPV becomes more readily  
151 available, HCPs will become more aware of the vaccine through marketing and educational campaigns.

152  
153 Most HCPs did not anticipate that parents or patients would have questions about 9vHPV. This finding is  
154 particularly interesting in light of a recent study by Fontenot *et al.* which found that parents had many  
155 questions about 9vHPV, including concerns about safety and whether yet another HPV vaccine might be  
156 developed in the near future [17]. However, the differences between what the providers in this study  
157 anticipated and what Fontenot *et al.* found could be due to different patient populations. The majority  
158 of participants in the Fontenot study were married, employed full time, and had at least some college  
159 education whereas the providers in this study serve economically disadvantaged populations. However,  
160 it is reasonable to infer that parents will have questions about a new HPV vaccine, given the negative  
161 media attention that arose with the first generation HPV vaccines [18, 19]. HCPs who did anticipate  
162 questions indicated there would potentially be questions from parents and patients regarding side  
163 effects, safety, effectiveness, and necessity of the vaccine. Now that 9vHPV is licensed and  
164 recommended, these results indicate a need to increase awareness and knowledge among HCPs. Given  
165 that physicians continue to hold misconceptions about 4vHPV, it will be particularly important to  
166 address areas of awareness and education regarding 9vHPV [20]. Additionally, there are unmet  
167 educational needs among HCPs regarding the new vaccine, specifically regarding safety, side effects, and  
168 efficacy. Furthermore, HCPs may also need assistance in anticipating and addressing patient questions.

169  
170 This study is among the first to assess HCP awareness and questions regarding 9vHPV, but it has  
171 limitations. Participants were a convenience sample of HCPs in a health system that generally serves  
172 minority and economically disadvantaged patients, so responses may not be representative of the  
173 broader experiences of HCPs. Selection bias might have occurred and the HCPs who agreed to

174 participate might have different attitudes about vaccination than the participants who did not respond  
175 to recruitment e-mails.

176

177 **Conclusions**

178 HCPs have unmet educational needs regarding 9vHPV. HCPs need educational tools to anticipate and  
179 answer questions from parents and patients. To our knowledge, this is the first study to assess HCP  
180 awareness of 9vHPV licensing as well as questions HCPs have about the vaccine. Awareness of  
181 information deficits can help health systems and public health agencies create and target educational  
182 materials to provide information on the efficacy and safety of the new 9vHPV.

183



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194 REFERENCES

- 195 1. Centers for Disease Control and Prevention. *Genital HPV infection—CDC Fact Sheet*. 2014,  
196 Atlanta, GA. Accessed from: <http://www.cdc.gov/std/hpv/hpv-factsheet-march-2014.pdf>
- 197 2. Centers for Disease Control and Prevention. *Cervical Cancer Statistics*. (2014), Atlanta, GA.  
198 Accessed from: <http://www.cdc.gov/cancer/cervical/statistics/>
- 199 3. Centers for Disease Control and Prevention. *HPV vaccine information for clinicians—Fact sheet*.  
200 2012, Atlanta, GA. Accessed from: <http://www.cdc.gov/std/HPV/STDFact-HPV-vaccine-hcp.htm>
- 201 4. Food and Drug Administration. *FDA approves Gardasil 9 for prevention of certain cancers caused*  
202 *by five additional types of HPV*. 2014, Silver Spring, MD. Accessed from:  
203 <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm426485.htm>
- 204 5. Food and Drug Administration. *December 10, 2014 Approval letter—GARDASIL 9*. 2014, Silver  
205 Spring, MD. Accessed from:  
206 <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm426520.htm>
- 207 6. Markowitz, L.E., Dunne, E.F., Saraiya, M., Chesson, H.W., Curtis, C.R., Gee, J., Bocchini, J.A.,  
208 Unger, E.R., *Human papillomavirus vaccination: recommendations of the Advisory Committee on*  
209 *Immunization Practices (ACIP)*. MMWR Recomm Rep, 2014. **63**: p. 1-30.
- 210 7. Petrosky, E., Bocchini, J.A., Hariri, S., Chesson, H., Curtis, C.R., Saraiya, M., Unger, E.R.,  
211 Markowitz, L.E., *Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination*  
212 *recommendations of the Advisory Committee on Immunization Practices*. MMWR Morb Mortal  
213 Wkly Rep, 2015. **64**(11): p. 300-304.
- 214 8. Reagan-Steiner, S., Yankey, D., Jeyarajah, J., Elam-Evans, L.D., Singleton, J.A., Curtis, C.R.,  
215 MacNeil, J., Markowitz, L.E., Stokley, S., *National, Regional, State, and Selected Local Area*  
216 *Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2014*. MMWR  
217 Morb Mortal Wkly Rep. **64**(29): p. 784-792.
- 218 9. Bendik, M., Mayo, R.M. and Parker, V.G, *Contributing factors to HPV vaccine uptake in college-*  
219 *age women*. Journal of Cancer Education, 2009. **24**: p. 17.

- 220 10. Centers for Disease Control and Prevention, *National and state vaccination coverage among*  
221 *adolescents aged 13-17 years--United States, 2011*. MMWR. Morbidity and mortality weekly  
222 report, 2012. **61**(34): p. 671-677.
- 223 11. Brewer, N.T., Gottlieb, S. L., Reiter, P. L., McRee, A. L., Liddon, N., Markowitz, L., Smith, J. S.,  
224 *Longitudinal predictors of human papillomavirus vaccine initiation among adolescent girls in a*  
225 *high-risk geographic area*. Sex Transm Dis, 2011. **38**(3): p. 197-204.
- 226 12. Liddon, N.C., Hood, J.E., and Leichliter, J.S., *Intent to receive HPV vaccine and reasons for not*  
227 *vaccinating among unvaccinated adolescent and young women: findings from the 2006-2008*  
228 *National Survey of Family Growth*. Vaccine, 2012. **30**(16): p. 2676-82.
- 229 13. Zimet, G.D., Weiss, T.W., Rosenthal, S.L., Good, M.B., Vichnin, M.D., *Reasons for non-vaccination*  
230 *against HPV and future vaccination intentions among 19-26 year-old women*. BMC women's  
231 health, 2010. **10**(1): p. 27.
- 232 14. Patton, M.Q., *Qualitative evaluation and research methods*. 4th ed. 2014: SAGE Publications, inc.
- 233 15. Guest, G., Bunce, A., and Johnson, L., *How many interviews are enough? An experiment with*  
234 *data saturation and variability*. Field methods, 2006. **18**(1): p. 59-82.
- 235 16. Elo, S. and H. Kyngäs, *The qualitative content analysis process*. Journal of advanced nursing,  
236 2008. **62**(1): p. 107-115.
- 237 17. Fontenot, H., Domush, V., and Zimet, G.D., *Parental Attitudes and Beliefs Regarding the Nine-*  
238 *Valent HPV Vaccine*. Journal of Adolescent Health, 2015. **57**:595-600.
- 239 18. Haber, G., Malow, R.M., and Zimet, G.D., *The HPV vaccine mandate controversy*. Journal of  
240 pediatric and adolescent gynecology, 2007. **20**(6): p. 325-331.
- 241 19. Zimet, G.D., Rosberger, Z., Fisher, W.A., Perez, S., Stupiansky, N.W., *Beliefs, behaviors and HPV*  
242 *vaccine: Correcting the myths and the misinformation*. Preventive Medicine, 2013.
- 243 20. Hofstetter, A.M. and Rosenthal, S.L., *Factors impacting HPV vaccination: lessons for health care*  
244 *professionals*. Expert review of vaccines, 2014. **13**(8): p. 1013-1026.

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Concept	Theme	Exemplar Quotes
<i>HPV Vaccine Awareness</i>		
	Aware (n=12)	“I’ve heard of it but I haven’t gotten a lot of literature about it.” “Yes. Can't wait for it to come to my clinics.”
	Does not know much (n=6)	“I might have heard something about it, but I am not terribly familiar with it.” “I have [heard of HPV9], but honestly I don’t know that much about it.”
	Unaware (n=8)	“No. But honestly I don’t even know what the current one is.” “I don’t think I’ve heard about anything new regarding any sort of HPV vaccine.”
	Heard a Rumor (n=2)	“Vaguely, yes, I’ve heard rumors”
<i>HCP Questions</i>		
	Efficacy (n=7)	“Just as long as it’s equally efficacious and I believe it is.”
	Side Effects (n=6)	“Just the adverse side effects for my patients and making sure that they’re knowledgeable about it.”
	Additional Protection (n=5)	“How much more coverage do you get against all the different types of HPV that cause cervical cancer?”
	Dosing Schedule (n=5)	“Do you have any idea what the recommended dosing schedule for that one is; is it also three vaccinations?”
	Cost (n=5)	“I'm waiting to see the degree at which cost will impact its availability, so whether that's going to affect our ability to stock it in clinic or whether patients will have the differential coverage for it from their insurers based on whether they're getting the Quadrivalent or Nanovalent.”
	General Information (n=5)	“I just want to look at that information myself. I just haven’t done it yet.” “I don’t feel like I know a lot about it right now, so I think that would be the main thing is just getting informed about it.”
	Safety (n=4)	“I guess with vaccines you always -- as a provider when you’re counseling people on it, you want to make sure you know about safety, side effects, everything.”
<i>Anticipated parent/patient questions</i>		
	Parents will not have questions (n=11)	“No I don’t think so. I think that they trust in me so that if recommend a vaccine that they know that it is something that their child needs.”
	No more than HPV4 questions (n=4)	R: “I don’t know that the 9-valent will have any more questions by parents.” INT: “As opposed...as compared to the quadrivalent?” R: “Yes.”  “I don't think it's going to bring up any new questions because it's not a totally new vaccine. It's the same vaccine, just more parts to it because nothing really happened when we switched from 7 to 13 on the pneumococcal. Nobody questions it.”
	Lack of scientific understanding (n=3)	“No. I think for my clinic population I would say no. That’s just based on other vaccine modifications that haven’t spurred any increase in questions about the strains. I got a lot

		more questions about Thimerosal and whether that's included versus like the actual, what's included in the vaccine from a scientific standpoint, if that makes any sense."
<i>Anticipated Questions</i>		
	Side Effects (n=9)	"If there's any side-effects to worry about. That's usually the biggest one."
	Safety (n=3)	"I think parents are more concerned about safety than they are even about efficacy and what it prevents and how helpful it is."
	Effectiveness (n=3)	"I think they'd have the same questions [as the physician], like does it -- how well does it work and what are the side effects, how safe is it?"
	Necessity of Vaccination (n=5)	"They'll want to know about how—some of them will ask how long has it been given? Is it necessary? Is it better? Is it—that kind of thing."
	Long-term Data (n=4)	"Probably the same in regards to what would happen if they take this vaccination and potentially what would happen in the next five years after receiving it."