PUBLIC HEALTH XXX (2018) 1–4

Available online at www.sciencedirect.com

Public Health

journal homepage: www.elsevier.com/puhe

Short Communication

Operationalizing outcome measures of human papillomavirus vaccination among adolescents

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ARTICLE INFO

Article history:
Received 18 October 2017
Received in revised form
17 January 2018
Accepted 18 February 2018
Available online xxx

Keywords:
Human papillomavirus vaccine
Immunization schedule
Adolescent
Gender

ABSTRACT

Objectives: When examining vaccination coverage, researchers must make decisions about how to define outcome measures based on many factors, including the timing of doses. Different operationalizations of the same outcome can often lead to different findings and can affect the ability to make comparisons across studies. This methodological article aimed to illustrate the implications of two options for operationalizing human papillomavirus (HPV) vaccination based on timing: initiation of the first dose at any age vs before the 13th birthday (on time).

Study design: Cross-sectional observational design.

Methods: The 2014 National Immunization Survey for Teens (N = 16,439 adolescents aged 13–17 years) was analyzed using multivariate logistic regression for each outcome measure and effect modification by gender.

Results: Age was positively associated with initiation at any age but negatively associated with on-time initiation. Gender modified the effect of race/ethnicity for both measures of initiation, but the pattern across groups was different for the two outcomes. Gender modified the effect of provider recommendation for initiation at any age, while gender modified the effects of age and region for on-time initiation.

Conclusion: Decisions of how to operationalize outcomes of HPV vaccine initiation among adolescents can lead to different conclusions about the role of age and gender differences for several predictive variables. To inform the development of public health efforts that promote on-time HPV vaccination among male and female adolescents, researchers should consider the importance of dose timing when operationalizing outcome measures. We recommend including on-time receipt of the HPV vaccine as an outcome measure.

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https://doi.org/10.1016/j.puhe.2018.02.022
0033-3506/

Operationalization refers to the process of defining how a concept or phenomenon will be measured, which forces the researcher to make decisions about specific parameters for each variable. In the case of vaccination, choices must be made regarding timing, number of doses, or denominator limitations.[1] Different operationalizations of the same concept can often lead to different findings and can affect the ability to make comparisons across studies.[1]

Human papillomavirus (HPV) vaccination has been recommended in the US for female adolescents since 2006 and males since 2011.[2] In the US, HPV vaccine is primarily administered in primary care or public health department settings, with limited access in other settings such as schools or pharmacies. Through the federal Vaccines for Children program, children younger than 18 years can receive the vaccine at no cost if they are publicly insured under Medicaid, underinsured (i.e. coverage does not include vaccines), uninsured, or American Indian or Alaskan Native. However, uptake of the vaccine has been slow, particularly among males.[3]

HPV vaccination is recommended at 11–12 years, with late vaccination available through age 26 years.[2] Less than 13 years, immune response is highest and virus exposure is low.[4] However, most studies assessing determinants of HPV vaccine coverage among adolescents in the US have operationalized HPV vaccination based on doses received at any age before 18 years.[3,5,6] Very few studies have examined determinants of on-time vaccination before age 13 years, and they primarily used data on females only.[7–9] The decision of how to operationalize the timing of HPV vaccination, that is, any age vs on-time vaccination, could potentially lead to different conclusions about patterns of vaccination coverage and opportunities for interventions to promote adherence with the recommended immunization schedule. This methodological article aimed to illustrate the implications of operationalizing the outcome of HPV vaccination at any age vs on time.

This study used a cross-sectional observational design. The National Immunization Survey for Teens (NIS-Teen) is a nationally representative public health survey of a stratified, probability sample of households in the US.[3] NIS-Teen consists of a random digit–dialed household survey of parents of adolescents aged 13–17 years and verification of vaccination histories from healthcare providers.[10] Details of the NIS-Teen methodology, response rate, and sample characteristics have been published elsewhere.[3] The NIS-Teen documentation advises to use the subset of adolescents with provider-verified data to generate estimates of vaccine coverage, due to the low reliability of parent-reported vaccination for adolescents.[10] The 2014 NIS-Teen Public-Use Data File contained 38,703 adolescents. First 17,646 adolescents (45.6%) were excluded from the analysis because provider-verified immunization data were not available; then, 2142 (5.5%) were excluded because their self-reported race/ethnicity was Asian or other, given the small numbers and heterogeneity of this group. Finally, 2476 (6.4%) cases with missing data on the variables included in the analyses were excluded. The final analytical sample size was 16,439 adolescents.

The following two alternatives for operationalizing HPV vaccination were examined:

1) Initiation at any age: received one or more doses of HPV vaccine at any age (1 = yes, 0 = no);
2) On-time initiation: received one or more doses of HPV vaccine before the 13th birthday (1 = yes, 0 = no).

The independent variables were gender (female, male), age (13–14 years, 15–17 years), race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic of any race), family poverty (above federal poverty line, below federal poverty line), geographic region (South, Northeast, Midwest, West), having received a healthcare provider recommendation for HPV vaccine (no, yes), health insurance (insured, uninsured), doctor visits in the past year (0 or 1, more than 1), parent's education (less than college degree, college degree or higher), and parent's marital status (unmarried, married). Data were analyzed with SAS, version 9.4, using multivariate logistic regression procedures that accounted for the complex sampling design. First, the base models were estimated for each outcome variable, including all of the independent variables listed previously. Next, an interaction term with gender and each of the nine independent variables was added to the base model one at a time, in nine separate models for each outcome variable. Two-tailed statistical significance level was set at alpha <0.05.

The sample comprised 52% males and 48% females (data not shown). Approximately 60% of the adolescents were 15–17 years old at the time of the survey. The racial/ethnic composition was 61% non-Hispanic white, 15% non-Hispanic black, and 24% Hispanic of any race. A larger portion of the adolescents (39%) were from the South vs other regions. The percentage of parents reporting that they had received a healthcare provider recommendation for HPV vaccine was 54.2% for males and 75.7% for females ($P < 0.0001$). Among all 13- to 17-year-olds, 43.1% of males and 60.7% of females received at least one dose of HPV vaccine at any age, while 15.6% of males and 38.2% of females received the first dose on time before the 13th birthday.

In the base multivariate logistic regression model for HPV vaccine initiation at any age (Table 1), the odds of ever receiving at least one dose of HPV vaccine was lower for teens who were male (adjusted odds ratio [AOR] = 0.68; 95% confidence interval [CI], 0.60–0.78) but higher for those who were 15–17 years old (AOR = 1.32; 95% CI, 1.15–1.52), Hispanic (AOR = 1.75; 95% CI, 1.42–2.15), black (AOR = 1.29; 95% CI, 1.04–1.59), poor (AOR = 1.58; 95% CI, 1.28–1.94), living in the West (AOR = 1.31; 95% CI, 1.06–1.63), and received a provider recommendation (AOR = 6.45; 95% CI, 5.50–7.55). In the stratified models, two variables had significantly different effects by gender, race/ethnicity (higher odds for Hispanic males and black females, $P = 0.004$) and provider recommendation (stronger positive effect for males, $P = 0.003$).

Next, we replicated the same models for HPV vaccine initiation before age 13 years (Table 1). In the base model, only the effect of age differed from the first model, with older adolescents having lower odds of on-time vaccination (AOR = 0.37; 95% CI, 0.32–0.43). In the stratified models, the effect modification by gender was significant for age (stronger negative effect for males, $P < 0.001$), race/ethnicity (higher odds for Hispanic males and black males, $P = 0.01$), and region

Please cite this article in press as: Odoh C, et al., Operationalizing outcome measures of human papillomavirus vaccination among adolescents, Public Health (2018), https://doi.org/10.1016/j.puhe.2018.02.022