

# Early Outcomes of a Multilevel Human Papillomavirus Vaccination Pilot Intervention in Federally Qualified Health Centers

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## ABSTRACT

**OBJECTIVE:** Human papillomavirus (HPV) vaccine coverage in the United States remains low compared with other adolescent vaccines. As the largest primary care network in the United States, safety net clinics such as federally qualified health centers (FQHCs) serve patients at a disproportionate risk of HPV-related cancers. In this pilot project, the American Cancer Society (ACS) leveraged its primary care workforce to implement quality improvement interventions in the unique context of 30 FQHC systems across the country, including 130 clinic sites reaching >20,000 adolescents in a variety of geographic settings.

**METHODS:** FQHC systems were randomly selected to receive either a \$90,000 2-year grant, a \$10,000 3-month grant, or training and technical assistance without funding. All 3 intervention groups conducted provider training and education, completed a capacity assessment tool, and measured HPV vaccination rates. Annual HPV vaccine series initiation and completion rates for active, 11- to 12-year-old patients were measured to evaluate project outcomes.

**RESULTS:** HPV vaccine series initiation rates among 11- to 12-year-old patients increased by 14.6 percentage points from a baseline of 41.2% before the intervention (2014) to the intervention year (2015). Changes in HPV second dose and series completion rates were not statistically significant. Meningococcal and tetanus, diphtheria, and acellular pertussis vaccination rates also increased significantly, by 13.9 and 9.9 percentage points from baseline rates of 49.1% and 52.5%, respectively.

**CONCLUSIONS:** The first year of this pilot project showed early success, particularly with HPV vaccine series initiation. On the basis of these promising results, ACS is expanding clinical quality improvement projects to increase HPV vaccination across the country.

**KEYWORDS:** cancer prevention; cervical cancer; federally qualified health center; human papillomavirus; human papillomavirus vaccination; intervention; public health; vaccines

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HUMAN PAPILLOMAVIRUS (HPV) causes approximately 33,000 cancers each year in the United States, and the cost of preventing and treating HPV-related cancers is over \$7 billion USD each year.<sup>1,2</sup> HPV vaccination is the gold standard for prevention of HPV-related diseases and cancers; its efficacy has been shown in numerous clinical trials.<sup>3</sup> The Food and Drug Administration licensed the first HPV vaccine, the quadrivalent vaccine, in 2006, the bivalent vaccine in 2009, and the latest 9-valent vaccine in 2014. Despite vaccine availability, HPV vaccine coverage in the United States remains low compared with other adolescent vaccines. Data from 2015 show that only 63% of girls and 50% of boys had initiated the 3-dose HPV vaccine series, and only 42% of girls and 28% of boys had completed the series.<sup>4</sup> In the same year, 86.4% of adolescents had received at least 1 dose of the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine and 81.3% had received at least 1 dose of the meningococcal vaccine.

Federally qualified health centers (FQHCs) play an essential role in addressing health care disparities. FQHCs serve patients at a disproportionate risk of HPV-related cancers.<sup>5,6</sup> As the largest primary care network in the United States, safety net clinics such as FQHCs serve >25 million uninsured and underinsured patients and provide a rich landscape to study HPV vaccination.<sup>5,7</sup> Although HPV vaccine series initiation tends to be higher among children who can access vaccination benefits through the Vaccines for Children program or who have Medicaid,<sup>8</sup> completion of the series still remains critically low compared with the Healthy People 2020 goals, and boys still lag behind girls in initiation as well as completion of the vaccine series.<sup>8,9</sup>

Specific barriers to initiation and completion of the HPV vaccine in the FQHC setting include missed opportunities to administer the vaccine,<sup>5,10</sup> parental hesitancy,<sup>11,12</sup> provider perception of parental interest in the vaccine, and a

provider's ability to give a confident recommendation.<sup>8,14</sup> Additional systemic barriers within FQHCs include competing priorities and limited funding to implement preventive health measures for patients.<sup>9,10,13,14</sup> Interventions to increase HPV uptake have taken various approaches, including quality improvement (QI), organizational system changes, electronic health record (EHR) modifications, provider education, and patient recall initiatives. All of these intervention methods have shown promising results.<sup>8,9,11,15</sup> System-focused interventions appear to aid in standardizing patient care to reduce missed opportunities, whereas provider-focused interventions teach providers how to give confident recommendations for HPV vaccination that in turn increase patient receptivity and follow-up. QI in particular has shown great promise as an approach to improve adolescent vaccination rates,<sup>16</sup> albeit one that requires significant investment of time and presents data management challenges.<sup>17</sup>

### PROGRAM OVERVIEW

The American Cancer Society (ACS) is a nationwide, community-based, voluntary health organization dedicated to the eradication of all cancers, whose initiatives include developing, implementing, and researching cancer prevention interventions. ACS views the underuse of the HPV vaccine as a major concern, because the vaccine has the potential to dramatically reduce the rates of HPV-related cancers and associated mortality. In an effort to address this concern, the ACS, with support from the Centers for Disease Control and Prevention (CDC), created the HPV Vaccinate Adolescents against Cancers (VACs) program to increase HPV vaccination rates for adolescents ages 11 to 12 years. A central component of this broader program is piloting evidence-based, QI interventions with FQHC partners across the United States.

ACS primary care systems staff, whose job function is to engage FQHCs and other primary care systems to increase cancer prevention and early detection efforts, implemented the project. In preparation for the project, ACS primary care systems staff received advanced training in QI processes, HPV vaccination science, and evidence-based strategies to increase HPV vaccination. Staff were tasked with providing FQHCs in-person and virtual technical assistance throughout the intervention, evidence-based project tools to maximize sustainable effects, on-site provider and staff training related to HPV vaccination prioritization, and networking with local, state, and national resources.

## METHODS

### FQHC SELECTION AND SAMPLE

Thirty FQHC systems were selected to participate in the project. FQHC partners were selected on the basis of a review of existing relationships with ACS, FQHC capacity, interest in participating in the project, and an adolescent patient population of at least 400. ACS staff had some level of engagement with 676 FQHC systems at the start of project planning. After narrowing the pool on the basis of adolescent patient population and FQHC and ACS staff capacity, 82

systems were selected to complete a HPV vaccination self-assessment tool to determine level of interest and capacity for implementing new HPV vaccination efforts. A total of 57 self-assessment forms were returned. From these, 30 FQHC systems were randomly selected for participation, and each was randomly placed in 1 of the 3 intervention groups. Most FQHC systems implemented the intervention in multiple clinic sites, up to a maximum of 10 sites. The intervention was implemented in a total of 130 clinic sites. See [Table 1](#) for a description of FQHC characteristics.

The original study design included as a control group the remaining 27 FQHC systems that submitted a self-assessment but were not randomly selected for participation. However, the complexity of calculating HPV vaccination rates presented an obstacle to this study design. Most control FQHCs did not submit follow-up vaccination rate data. Upon further investigation, the control FQHCs that did go to the effort of calculating and submitting data had decided to work with their ACS staff partners to implement HPV interventions anyway. These challenges made this group unviable as a control, and led us to abandon this element of the study design.

Of the 30 FQHCs that started the project, 4 left the project within the first 3 months because of loss of key personnel (QI director, chief medical officer), a disruptive transition to a new EHR system, or loss of the ACS primary care staff partner. Of the 26 FQHCs that participated fully in the project, 20 were able to submit accurate vaccination rates. These 20 systems formed the study sample for outcome evaluation. The 6 systems that were unable to submit accurate vaccination rates cited a variety of reasons, including a change in EHR software, lack of capacity due to staff turnover, and lack of confidence in data quality. All 20 systems that submitted accurate 2014 baseline vaccination rates also submitted 2015 rates.

### INTERVENTION DESIGN

The 30 FQHC systems were randomly selected to receive either a \$90,000 2-year grant, a \$10,000 3-month grant, or training and technical assistance without funding, with 10 FQHCs per funding group. All 3 intervention groups were expected to engage with ACS in conducting provider training and education, complete a capacity assessment tool, and measure HPV baseline rates during an initial, 3-month capacity-building phase. Training and education focused on preparing providers to make an effective recommendation for HPV vaccination, whereas capacity assessment and rate calculation, both system-focused interventions, led FQHCs to better understand their current state, find room for improvement, systematize care, and measure change. In addition, the \$90,000 and \$10,000 groups were tasked with making modifications to their EHRs that would support the HPV vaccination project. The \$90,000 group was also expected to implement at least 1 specific evidence-based strategy to increase HPV vaccination rates, such as provider assessment and feedback, standing orders for HPV vaccination, provider prompts, and patient reminders. However, although only the

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