

# Evaluation of Human Papillomavirus Vaccination After Pharmacist-Led Intervention: A Pilot Project in an Ambulatory Clinic at a Large Academic Urban Medical Center

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## Abstract

**Objectives:** Despite the safety and efficacy of the human papillomavirus (HPV) vaccine, many persons are still not receiving it. The purpose of this pilot project was to evaluate the number of first doses of the 9-valent HPV (9vHPV) vaccination administered after a pharmacist-led intervention in the Adult Family Planning Clinic at Grady Health System (GHS), a large academic urban medical center in Atlanta, Georgia.

**Methods:** The pilot project had 3 phases: pre-intervention (November 15, 2016, through March 31, 2017), active intervention (November 15, 2017, through December 29, 2017), and post-intervention (December 30, 2017, through March 31, 2018). The pre-intervention phase was used as a historical control. The active intervention phase consisted of pharmacist interventions in the clinic and patient and health care provider education. The post-intervention phase evaluated the durability of pharmacist-led interventions performed and education provided during the active phase.

**Results:** Eighty-nine first-dose 9vHPV vaccines (of the 3-dose series) were administered to young adults aged 18-26 during the project period (November 15, 2017, through March 31, 2018); none were administered during the pre-intervention phase. Of 89 patients who received a first 9vHPV vaccine dose, 20 patients also received a second 9vHPV vaccine dose. During the project period, 166 doses of 9vHPV vaccine (first, second, or third doses) were administered.

**Conclusion:** This pharmacist-led intervention led to an increase in the number of young adult patients receiving their first dose of the 9vHPV vaccination series. With the support of other health care providers, pharmacist-led initiatives can expand vaccine-related health literacy and facilitate access to immunization services.

## Keywords

human papillomavirus, HPV, vaccine, pharmacist, 9-valent human papillomavirus vaccine, 9vHPV, vaccination, Gardasil, cancer prevention

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. As of 2017, 79 million persons aged 15-59 years were infected with HPV, and approximately 14 million persons become infected each year.<sup>1</sup> Although most HPV infections are asymptomatic, are transient, and do not cause disease, persistent HPV infection can lead to cervical, vulvar, vaginal, anal, penile, and oropharyngeal cancer.<sup>1</sup> In the United States, approximately 34 800 new cases of HPV-attributable

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cancers occur each year.<sup>2</sup> A 9-valent HPV (9vHPV) vaccine (Gardasil 9; Merck & Co, Whitehouse Station, NJ) is commercially available in the United States and is approved by the US Food and Drug Administration (FDA) for the prevention of HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 in persons aged 9-45 years.

The Advisory Committee on Immunization Practices recommends a 2-dose schedule for children and adolescent girls and boys who initiate the vaccination series at ages 9-14 years. A 3-dose schedule is recommended for persons who initiate the vaccination series at ages 15-26 years and for immunocompromised persons.<sup>3</sup> The need for multiple doses to achieve optimal protection can be a logistical challenge for recipients of all ages, and failure to complete the vaccination series is common.<sup>4</sup>

According to the 2018 National Immunization Survey–Teen, 51.1% of US adolescents aged 13-17 years were up to date with the recommended HPV vaccination series during 2017-2018; 68.1% of male and female adolescents aged 13-17 years received their first dose of the HPV vaccine series. In Georgia, 68.7% received a first dose of the HPV vaccine.<sup>4</sup> These findings highlight an opportunity for catch-up vaccination for persons who did not initiate or complete their vaccination during adolescence.

Studies have found that recommendations by a health care provider and high levels of vaccine-related knowledge among patients and health care providers are associated with an increased likelihood of vaccination.<sup>5-11</sup> Pharmacists can play a key role in increasing HPV vaccination rates through direct (vaccine administration, improved accessibility) and indirect (screening, education, recommendations) methods. Studies have evaluated the effect of pharmacist-led interventions on increasing rates of pneumococcal, hepatitis B, influenza, and HPV vaccination, but most of these studies occurred in a community pharmacy setting.<sup>12-15</sup> Calo et al<sup>5</sup> assessed the advantages and challenges of implementing pharmacy-located HPV vaccination services in 5 US states. Their pilot project resulted in 13 HPV vaccine doses administered to adolescents aged 13-17 years and 3 HPV vaccine doses administered to age-eligible young adults. Their challenges included low levels of demand from parents, poor levels of engagement among pharmacy staff members, lack of third-party reimbursement, and limited integration into primary care systems. They identified opportunities to make community pharmacies a more successful setting for adolescent HPV vaccination, including by expanding third-party reimbursement, increasing public awareness of pharmacists' immunization training, and improving care coordination with primary care providers. To our knowledge, pharmacist involvement in HPV vaccination outside the community pharmacy setting has not been reported in the literature.

Grady Health System (GHS), located in Atlanta, Georgia, is a safety-net hospital that serves a diverse population consisting primarily of adults who have multiple comorbid conditions, poor healthy literacy, and low

income and are under- or uninsured. GHS has 13 ambulatory-care clinics, 7 of which are located on the main hospital campus. Among them is the Adult Family Planning Clinic, which serves men and women aged  $\geq 18$ . The multidisciplinary Adult Family Planning Clinic staff consists of health educators, nurses, advanced practitioners, and attending physicians, but it does not generally include a pharmacist. In this clinic, patients receive contraceptive services, screening and treatment for sexually transmitted diseases, and preventive care. The number of HPV vaccinations administered in this clinic is low; 17 HPV vaccines were administered from January 2011 through December 2016. GHS pediatric clinics have higher rates of HPV vaccination than adult clinics. During 2015-2017, 1365 pediatric patients aged 9-17 years were seen in 7 pediatric GHS clinics, 65% ( $n = 887$ ) of whom received the first dose of the HPV vaccine at GHS (unpublished data, GHS, 2015-2017). Rates of HPV vaccination at GHS pediatric clinics were similar to rates of first-dose HPV vaccination in Georgia (68.7% among adolescents aged 13-17 years),<sup>4</sup> yet they still fell below the Healthy People 2020 target of 80% for adolescents aged 13-15 years.<sup>3</sup>

Although HPV vaccination rates are below the Healthy People goal in all regions of the United States, they are disproportionately lower for adolescent girls in the South. The South Atlantic Region (including Florida, Georgia, North Carolina, South Carolina, Virginia, and West Virginia) also has the highest rates of cervical, anal, and oral cavity/oropharyngeal cancers compared with other US regions.<sup>16,17</sup> From 2008 to 2012, the incidence of HPV-associated cancers in Georgia was 12.6 per 100 000 population among all persons.<sup>18</sup> Rahman et al<sup>17</sup> found that women aged 18-26 living in the South and West were less likely to initiate and complete the 3-dose HPV vaccine series than women living in the Northeast. Despite educational efforts to increase HPV vaccination rates, geographic disparities and barriers such as lack of physician recommendation, low levels of awareness of vaccine benefits, irregular preventive care, non-mandatory regulations by school districts or the government, and health insurance coverage have resulted in low vaccination rates.<sup>5-17</sup>

Our pilot project focused on increasing the number of HPV vaccinations among patients aged 18-26 years in the GHS Family Planning Clinic. The FDA's expanded approval for administration of the vaccine to adults aged 27-45 occurred after our project proposal had been completed. Higher pediatric vaccination rates are likely due to increased provider vaccination awareness during a pediatric visit, periodic wellness visits that align with a widely accepted vaccination schedule, and vaccination funding initiatives.<sup>18</sup> Perhaps most well-known, Vaccines for Children (VFC) is a federally funded program in which qualifying patients aged  $\leq 18$  years receive vaccines free of charge.<sup>19</sup> Patients aged  $> 18$  years use health insurance coverage, pay out of pocket, or seek financial assistance to

receive the HPV vaccine. In addition, family planning providers and adult patients may not always think about vaccinations as part of their day-to-day workflow or expected clinic visits.<sup>20</sup> We hypothesized that having a multidisciplinary approach and pharmacy-led intervention would be novel, facilitate vaccine access, and provide support and education to clinic staff members and patients. The primary objective of our pilot project was to evaluate the number of first doses of the 9vHPV vaccinations (of the 3-dose series) after a pharmacist-led intervention in the Adult Family Planning Clinic at GHS. Secondary objectives were to assess the number of second-dose vaccines administered and the number and type of pharmacist-led interventions. An evaluation of third-dose vaccination rates was outside the scope of this project.

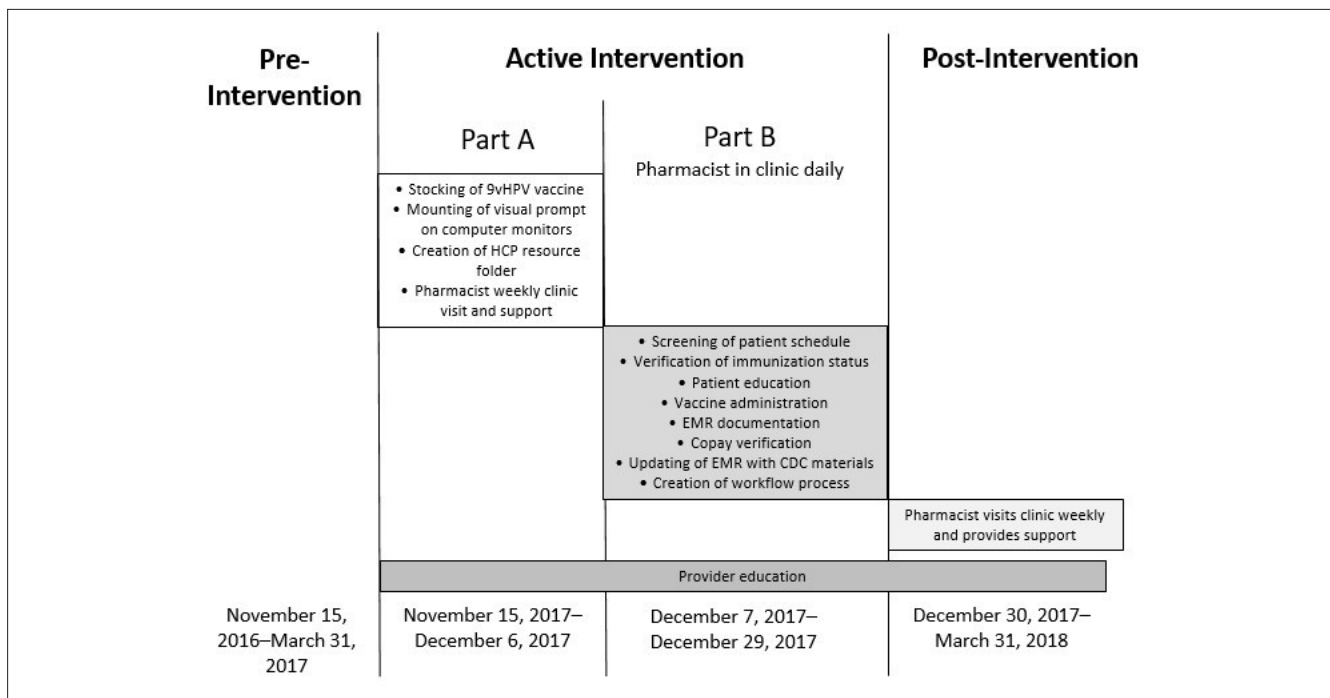
### Methods

We included in the evaluation all patients aged 18-26 years who attended the GHS Adult Family Planning Clinic during the study period. We excluded patients who were aged <18 years or >26 years, were pregnant or lactating, were incarcerated, or had a severe allergy to 9vHPV vaccine ingredients.<sup>3</sup> The Emory University Institutional Review Board determined that no review was required.

### Project Description

The project design was a descriptive pre/post-intervention evaluation in 3 phases (Figure 1). The first phase, the pre-intervention phase, took place from November 15, 2016, through March 31, 2017. The second phase, the active intervention phase, had 2 parts: November 15 through December 6, 2017 (Part A), and December 7 through December 29, 2017 (Part B). The second phase was divided because of pharmacist time constraints. The third phase, the post-intervention phase, took place from December 30, 2017, through March 31, 2018.

Before this quality improvement project, the 9vHPV vaccine stock in the clinic was reserved for patients who qualified for VFC only, thereby limiting vaccine access to non-VFC-qualified patients. During Part A of the active intervention, the pharmacist's first action was to add 9vHPV vaccine stock for VFC-qualified and non-VFC-qualified patients, allowing health care providers to use the 9vHPV vaccine for patients aged ≥18 (Figure 1). All clinic providers and staff members participated in 2 formal 60-minute pharmacist-led education sessions about the purpose of the pharmacist-driven quality improvement project, HPV prevention, vaccine recommendations and dosing schedule, vaccine accessibility, and availability of patient resources. Fifteen to 20 clinic staff members and health care providers attended both education sessions. In



**Figure 1.** Phases of a pharmacist-led intervention designed to increase HPV vaccinations among patients aged 18-26 years at Grady Health System's Adult Family Planning Clinic in Atlanta, Georgia, 2017-2018. Abbreviations: 9vHPV, 9-valent human papillomavirus; CDC, Centers for Disease Control and Prevention; EMR, electronic medical record; HCP, health care provider.

addition, the pharmacist mounted a visual prompt on clinic computer monitors with the statement, “Is the patient a candidate for the HPV vaccine?” and created a resource folder containing HPV educational materials for health care providers from the Centers for Disease Control and Prevention in English and Spanish that could be accessed through a shared drive.

During Part B of the active intervention, 1 pharmacist was present in the Adult Family Planning Clinic daily. Pharmacist-led activities included daily screening of the clinic schedule to identify patients aged 18-26 years who were eligible for vaccination, verification of patient immunization status, provision of patient vaccine education, vaccine administration, and assistance with copay verification. In addition, the pharmacist provided the EPIC ambulatory team with updated Centers for Disease Control and Prevention–sponsored HPV patient education materials. These educational materials were uploaded into the electronic medical record (EMR), which could be printed and distributed to patients. For all eligible patients, the pharmacist verified whether the patients had received HPV vaccine doses by using the Georgia Registry of Immunization Transactions and Services (GRITS), as required in the state of Georgia. The pharmacist reconciled the information obtained from GRITS with the patient’s immunization status in GHS’s EMR, EPIC, and then documented the patient’s immunization status. The pharmacist added the phrase “needs evaluation for HPV vaccine” to the patient’s problem list in EPIC. In addition, the pharmacist provided education to patients about the benefits and risks associated with HPV vaccination. If an insured patient chose to receive the vaccine, the pharmacist verified the necessary copay. Uninsured patients receiving financial assistance from GHS did not have to pay for the vaccine.

Working with the Adult Family Planning Clinic medical directors, the pharmacist designed a workflow that incorporated health educators’ screening of information on patients the day before their arrival (Figure 2). Health educators in the Adult Family Planning Clinic are consulted for education and outreach pertaining to human sexuality, sexually transmitted infections, and pregnancy prevention for adolescents, parents, and community-based organizations. They also advocate for the prevention of HPV by promoting awareness and encouraging eligible patients to complete the 9vHPV vaccination series. The pharmacist also designed a workflow for nurses and health care providers to assist with patient screening on the day of the visit (Figure 3). Clinic staff members documented patient education and administration of the vaccine in EPIC.

During the post-intervention phase, the pharmacist was no longer present in the clinic daily because of time constraints but continued to provide support through weekly clinic visits, responding to questions about 9vHPV vaccination, and ensuring adequate stock of the vaccine in the clinic.

Health care provider education was conducted longitudinally, starting with the Part A intervention phase and continuing throughout the post-intervention phase.

We evaluated the long-term sustainability of the intervention by tracking the number of 9vHPV vaccines administered after the post-intervention phase, during a follow-up phase, from April 2018 through July 2019.

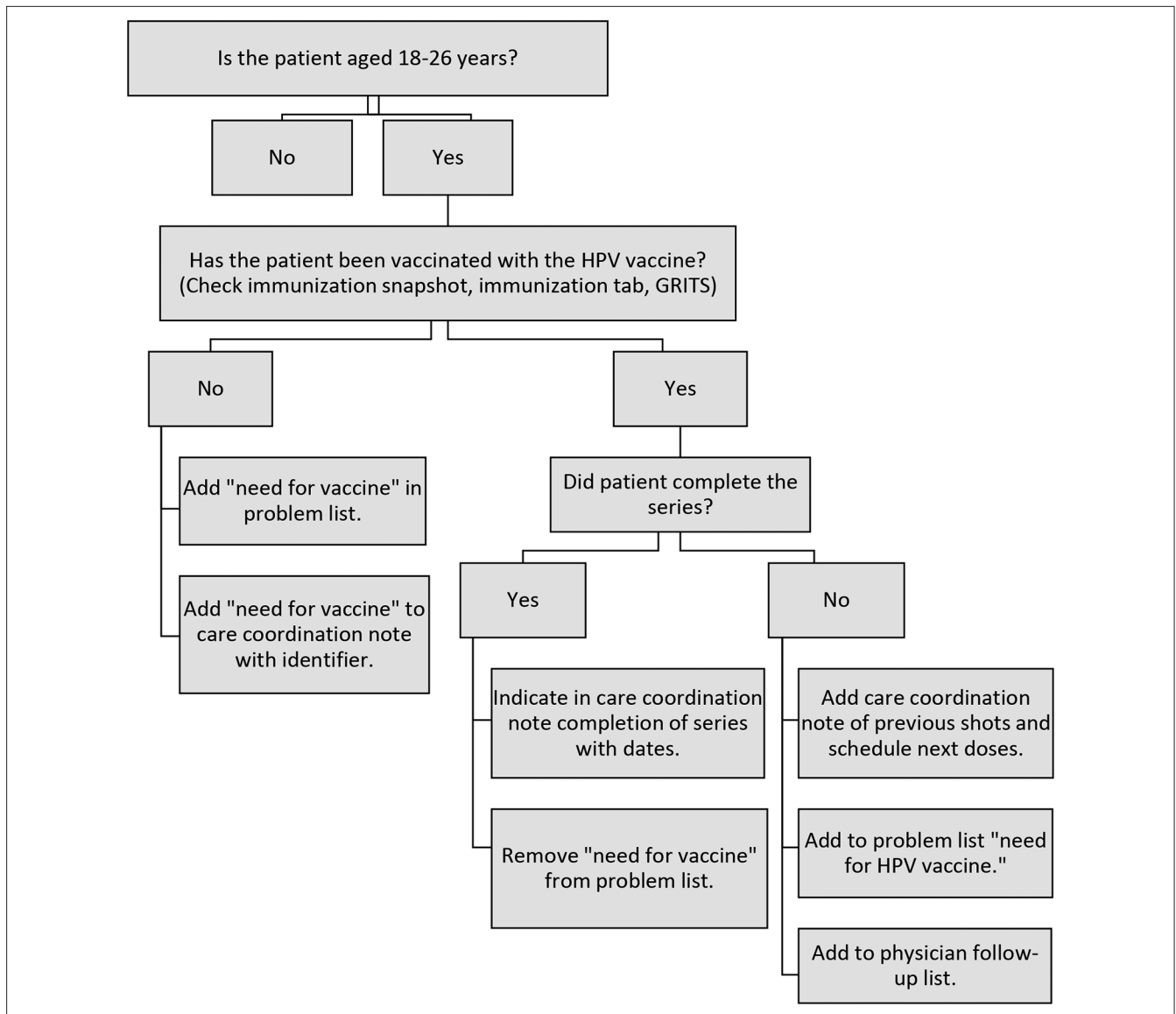
## Analysis

We obtained data on the number of patients in the pre-intervention phase from an institution-generated report, including the number of patients aged 18-26 years who visited the Adult Family Planning Clinic from November 15, 2016, through March 31, 2017, and the number of 9vHPV vaccines administered in the clinic during the same period. We selected this date range to obtain data on baseline vaccine administration before our active intervention and post-intervention phases. During the data analysis for the active intervention and post-intervention phases, a pharmacist screened the Adult Family Planning Clinic schedule and identified the total number of patients who were eligible to receive the vaccine. Then, we counted the total number of 9vHPV vaccines administered during each phase. Because a pharmacist was present on a daily basis in the clinic during Part B of the active phase, the pharmacist was able to document reasons for not administering the vaccine among eligible patients.

## Results

During the pre-intervention phase, no HPV vaccines were administered. During the active intervention phase, 242 patients (1 male, 241 female) were screened and identified by the pharmacist as being of appropriate age to receive vaccination. Patients who did not arrive for their appointment ( $n = 81$ ), who had already completed the HPV vaccine series ( $n = 71$ ), or who were lactating or pregnant ( $n = 9$ ) were excluded (Figure 4); the male patient did not arrive for the appointment. Eighty patients, all female, were identified for potential vaccination, 34 of whom received their first dose ( $n = 23$ ), second dose ( $n = 5$ ), or third dose ( $n = 6$ ) of 9vHPV vaccine while at the clinic. Forty-six patients were not vaccinated. Reasons for not vaccinating were the following: the patient desired further education and time to review ( $n = 15$ ), the health care provider did not discuss the vaccine because the clinic visit was for post-sexual assault care or miscarriage care ( $n = 3$ ), the health care provider forgot to discuss the vaccine ( $n = 21$ ), or the patient refused the vaccine ( $n = 7$ ).

Overall, 166 9vHPV vaccine doses were administered from December 7, 2017, through March 31, 2018 (Part B and the post-intervention phases): 54% ( $n = 89$ ) were first doses, 12% ( $n = 20$ ) were second doses, and 34% ( $n = 57$ ) were third doses. Of the 89 first doses, 23 were administered in December 2017,



**Figure 2.** Pharmacist-led intervention workflow that incorporated screening by health educators of information on patients visiting Grady Health System's Adult Family Planning Clinic on the day before patients' arrival, Atlanta, Georgia, 2017-2018. The intervention was designed to increase HPV vaccinations among patients aged 18-26 years. Abbreviations: GRITS, Georgia Registry of Immunization Transactions and Services; HPV, human papillomavirus.

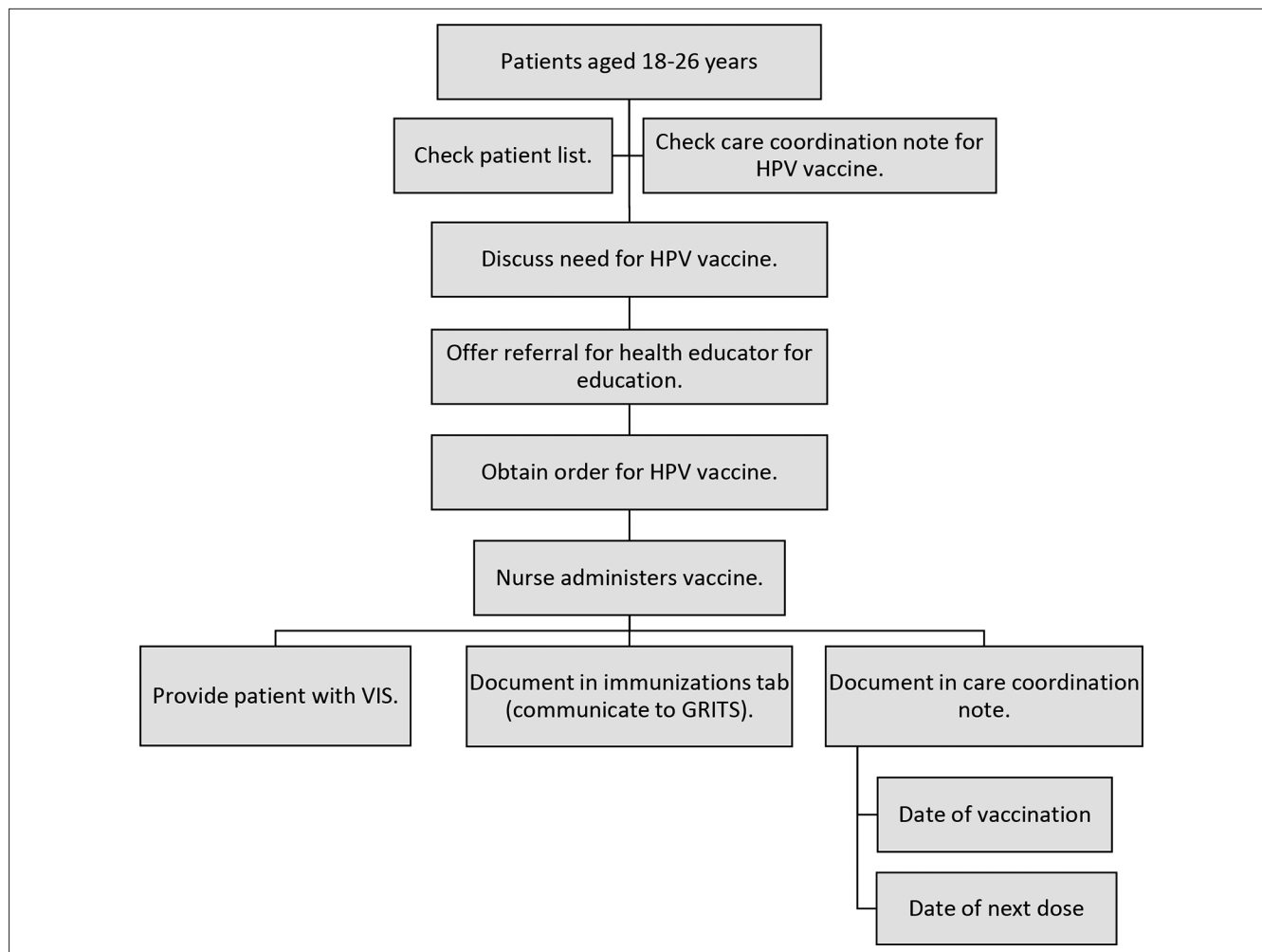
28 in January 2018, 18 in February 2018, and 20 in March 2018. Of the 20 second doses, 9 were administered in February 2018 and 4 were administered in March 2018, during the post-intervention period. Of the 20 patients who received a second dose, 13 patients had also received their first 9vHPV vaccine dose during a visit that took place in December 2017, when the pharmacist was in the clinic on a daily basis, or in January 2018, when the pharmacist was in the clinic on a weekly basis. The remaining 35% (n = 7) of patients who received a second dose had received their first dose before the active intervention or post-intervention period. Of the 57 patients who received a third 9vHPV vaccine dose, 30 (53%) patients had received

previous HPV vaccine dose(s) and completed the 3-dose series during the active and post-intervention periods from December 7, 2017, through March 31, 2018.

During the follow-up period (April 2018 through July 2019), 107 doses of 9vHPV vaccine were administered to patients aged 18-26 years.

## Discussion

In this pilot study, a pharmacist-led, multidisciplinary intervention in a hospital-based clinic led to modifications in the

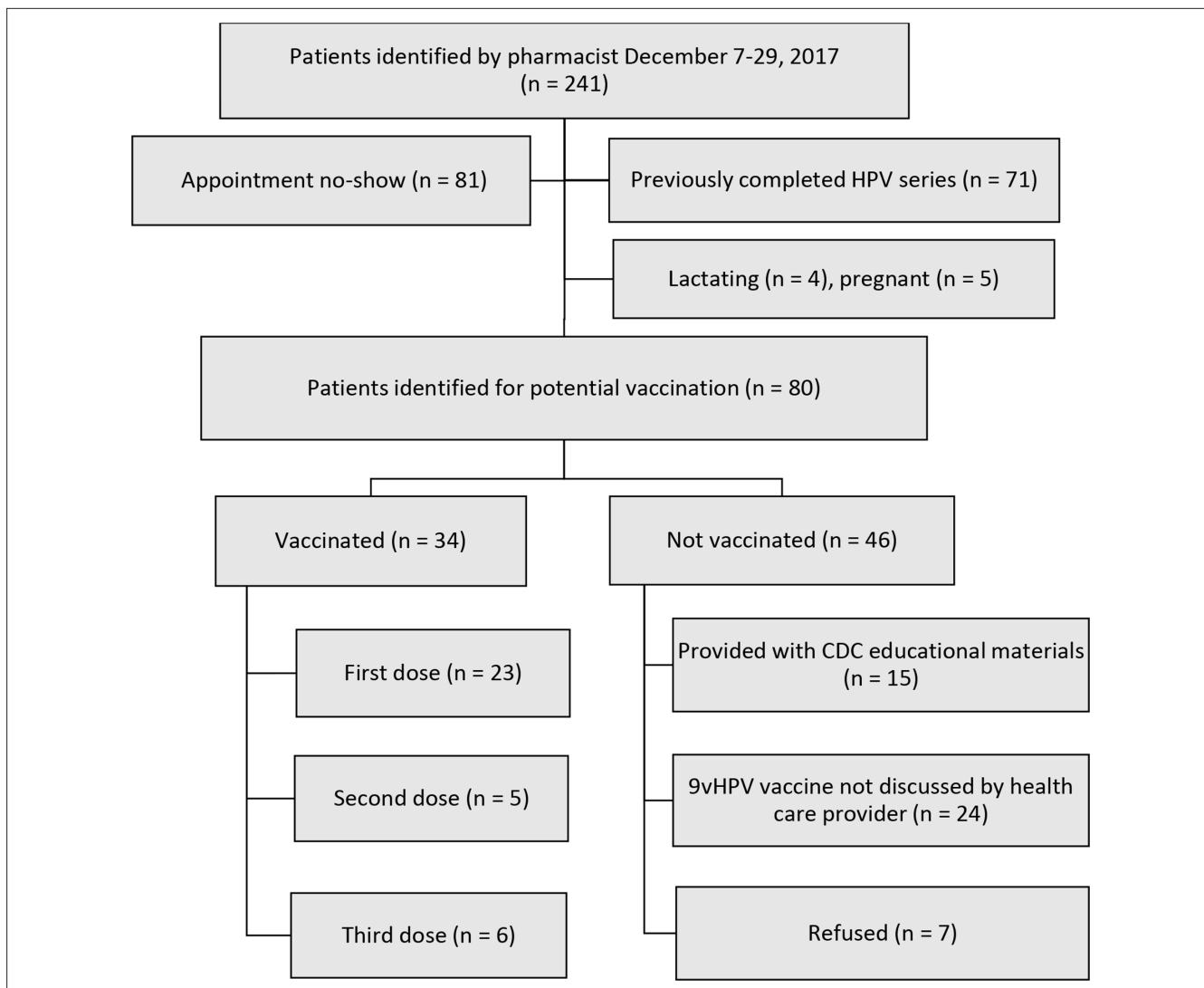


**Figure 3.** Pharmacist-led intervention workflow that incorporated screening by nurses and health care providers of patients visiting Grady Health System’s Adult Family Planning Clinic on the day of the visit, Atlanta, Georgia, 2017-2018. The intervention was designed to increase HPV vaccinations among patients aged 18-26 years. Abbreviations: GRITS, Georgia Registry of Immunization Transactions and Services; HPV, human papillomavirus; VIS, vaccine information statement.

workflow and an increase in initiation of the 9vHPV vaccination among a population that is rarely targeted for HPV vaccination initiatives: patients aged 18-26 years attending a family planning clinic. Results from this project suggest that opportunities exist for catch-up vaccination in this priority population through an approach that establishes multidisciplinary relationships, facilitates vaccine access, and aligns priorities for clinic staff members through educational efforts focused on the benefits of HPV vaccination. Family planning visits do not typically focus on vaccinations, but with this pilot project, we helped family planning providers advocate and promote HPV vaccination. Health care providers in the clinic targeted a unique patient population that can benefit from HPV prevention and education, even more so with the recent expanded approval of vaccine administration to patients up to age 45.

In addition, the pharmacist-led intervention led to the creation of new Adult Family Planning Clinic workflows. These

new pharmacist-designed workflows increased the number of doses of 9vHPV vaccination administered while the pharmacist was in the clinic on either a daily or weekly basis. Although the pharmacist was not present on a daily basis after December 29, 2017, the 2 workflows designed by the pharmacist in collaboration with clinic providers led to increased 9vHPV vaccination activity during the post-intervention period compared with the pre-intervention period. More 9vHPV vaccines were administered during the follow-up period—when a pharmacist was not in the clinic—than during the pre-intervention phase. However, more doses of vaccine were administered during the active and post-intervention phases than during the follow-up period, demonstrating that some, but not all, elements of the new workflows may have sustained HPV vaccination rates after the intervention ended. Over time, the pharmacist-led education provided during this pilot project, along with a heightened awareness of HPV vaccine necessity among clinic



**Figure 4.** Study flow during Part B of the active intervention phase, December 7-29, 2017, in pharmacist-led intervention designed to increase HPV vaccinations among patients aged 18-26 years at Grady Health System's Adult Family Planning Clinic in Atlanta, Georgia, 2017-2018. Abbreviations: CDC, Centers for Disease Control and Prevention; HPV, human papillomavirus.

personnel, may lead to an increase in the number of patients who complete the 3-dose HPV vaccine series.

### Limitations

This project had several limitations. First, the pilot project was conducted in a single clinic at one institution, which limited the external validity of our results. Second, because of the project's short duration, we could not evaluate completion of the entire 3-dose series. Third, selection bias may have occurred because patients who visit the Adult Family Planning Clinic are seeking contraceptive services, screening, and/or treatment for sexually transmitted diseases and preventive care. As such, they may be more receptive to receiving the HPV vaccine than patients who do not seek these services or have access to them. In addition, young women tend to access reproductive health care rather

than primary care<sup>19</sup>; therefore, a pharmacist-led intervention in this setting may have had a bigger effect on this patient population than a pharmacist-led intervention at a primary care clinic. One male patient was identified in the appointment schedule during the active intervention phase as being vaccine-eligible, but he did not arrive for his scheduled appointment. As such, this evaluation included only female patients. Conducting the pharmacist-led intervention in a different clinic may have led to an increased number of men who were eligible to receive the HPV vaccine.

Fourth, because the clinic had only VFC stock available before the intervention, adding non-VFC stock during the intervention may have led to increased vaccination, thus making it difficult to assess the effectiveness of pharmacist-led education and implementation of new workflow

processes. Fifth, communication problems occurred between state vaccination data in GRITS and the EMR, leading to inaccuracies in the patient's vaccination history and, thus, impairing the ability of clinic staff members to readily identify vaccine-eligible patients. The most accurate way to review a patient's vaccine history is to verify each person in the GRITS database; however, this type of review may have been too time consuming for clinic staff members. Finally, the 9vHPV vaccine series can be ordered only by physicians or advanced practice practitioners in Georgia (ie, nurse practitioners, certified nurse midwives, physician assistants). No protocol is available that allows nurses to order the vaccine in the EMR. The restriction in 9vHPV vaccine ordered led to increased clinic time, especially for patients who were only presenting for a routine nurse visit.

### Future Directions

The results of this evaluation were presented to the Vaccine Expert Panel at GHS with the goal of assessing the feasibility of expanding a similar initiative at other clinics. For example, efforts to reach out to unvaccinated male patients may lead to additional vaccines being administered and to cancer prevention in this patient population. The Adult Family Planning Clinic setting was not ideal for targeting male patients; therefore, other primary care settings may need to be considered.

Even though HPV vaccines continued to be administered at GHS after the active pharmacist-led intervention ended, fewer vaccines were administered. This finding suggests the need for a reiterative process to ensure the successful continuation of this initiative. A nonpharmacist could be trained to complete many screening and education activities. The development of a nurse-driven protocol would allow nurses to order the 9vHPV vaccine in the EMR without having to ask a physician or advanced practice practitioner to do so. In Georgia, nurses can administer the HPV vaccine to patients aged <18 years when a patient consents.<sup>21</sup> Given the variable clinic volume of the Adult Family Planning Clinic, it would not be feasible to have a full-time pharmacist on-site; however, the pharmacy department is considering a pharmacist-led vaccine program through the addition of a pharmacist who would rotate through GHS's 13 ambulatory-care clinics to screen for patients who are eligible for vaccine, including the 9vHPV vaccine.

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