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Pharmacist authority to provide HPV vaccine: Novel partners in cervical cancer prevention

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HIGHLIGHTS

- Most US states let pharmacists provide HPV vaccine, though the rules governing provision varied widely across states.
- The ability of pharmacists to provide HPV vaccine was highly dependent upon patient age.
- Pharmacist authority to immunize was similar for HPV, Tdap, and meningitis vaccines.

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ABSTRACT

Objectives. While the provision of cervical cancer prevention services in the United States has expanded to new settings beyond clinics that give Pap smears, prevention efforts are being hampered by relatively low human papillomavirus (HPV) vaccine coverage. Pharmacies are an underused setting to deliver HPV vaccine. To better understand this opportunity, we sought to classify pharmacists' authority to administer HPV vaccine in each US state.

Methods. For each US state and the District of Columbia (for simplicity, we refer to these 51 regions as states), we interviewed a member of the state's pharmacy association, member of the state board of pharmacy, or a faculty member at a school or college of pharmacy.

Results. Most states (80%) allowed pharmacists to provide HPV vaccine to adult women ages 19 and older, and 61% of states allowed provision to girls age 12. The mechanism for pharmacists to immunize was highly variable across states. For example, a 12 year-old girl seeking HPV vaccine could receive it from a pharmacist in 31% of states under a protocol between a specific physician and pharmacist, in 24% with an HPV vaccine prescription, and in 6% without prior physician approval. Pharmacists' authority was broadest on the west coast and limited on the east coast. Pharmacist authority to provide HPV, Tdap, and meningitis vaccines was very similar, but it was highly dependent on patient age.

Conclusions. US states' laws governing pharmacists' ability to offer HPV vaccine varied widely. One consequence is that newly expanded cervical prevention efforts underuse pharmacists.

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Introduction

Persistent human papillomavirus (HPV) infection can cause cervical cancer, several other cancers (vaginal, vulvar, anal and oropharyngeal) and genital warts [1]. An estimated 14 million people are newly infected in the United States each year [1]. In 2013, about 12,340 women were diagnosed with cervical cancer, and 4,030 died of this largely preventable disease [2]. National guidelines recommend routinely providing HPV vaccine to girls ages 11–12 and catch-up vaccination up to age 26 [3]. Guidelines recommend routine provision of HPV vaccine to boys ages 11–12, with catch-up vaccination up to age 21 [4]. These prophylactic HPV vaccines are nearly 100% effective at preventing precancerous genital lesions attributable to the specific HPV vaccine types [3,5].

Low HPV vaccine uptake in the US is permitting a cascade of unnecessary disease, treatment and deaths. By 2012, just over half (54%) of girls ages 13 to 17 in the US had received the first HPV vaccine dose, and only about one third (33%) had received all three recommended doses [6,7]. HPV vaccine initiation increased only 5 percentage points

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between 2010 and 2012, with no change between 2011 and 2012 [6]. About 21% of males had received at least one dose of HPV vaccine by 2012, and only 7% had received all three doses [7]. Barriers to HPV vaccination include health care providers not routinely recommending the vaccine to 11–12 year-olds, relatively high cost, uncertain insurance coverage, and parent concerns [8–12] leading to refusal or deferral of vaccination provision [8,13]. Infrequent visits to primary care providers by adolescents compound these challenges [13].

Innovative ways to increase HPV vaccine coverage include provision in novel settings. Some have suggested a greater role for obstetricians and gynecologists (OBGYNs), who have been forward thinking about HPV vaccine. Most OBGYNs (90%) who stock vaccines have HPV vaccine [14]. However, only 27% of their eligible patients initiate the vaccination series, and less than a third of patients who initiate the series with OBGYNs received all three doses [14]. Other challenges include that OBGYNs see few 11–12 year-old girls, the age for routine HPV vaccine provision, and OBGYNs do not treat boys. Other promising settings include school health centers and sexually transmitted infection clinics, and initiating mass vaccination clinics in schools.

An especially promising novel setting for HPV vaccine delivery is pharmacies [14]. Benefits of pharmacies include longer hours of operation (e.g. evenings and weekends), typically not requiring an appointment, and ability to do claims adjudication in real time [15]. People make about 250 million visits annually to pharmacies, which are usually closer to people's homes than their primary care physicians' offices. Adolescents may be more likely to visit pharmacies than visit a primary care provider [16]. This access to diverse populations helps pharmacists to provide thousands of vaccine doses per year [17,18]. The general public accepts pharmacists as immunizers for adults [19] and adolescents [20], and several national organizations endorse vaccine provision in pharmacies [21]. Prior to 2004, seasonal influenza immunization rates among adults aged 18 or older increased notably in states where legislation allowed pharmacists to immunize as compared to states where such legislation did not exist [22]. Other studies show the benefits of expanding the role of pharmacists in the healthcare system, including those that show that pharmacists can effectively provide screening and identify individuals at risk for HIV, diabetes, cardiovascular disease and colorectal cancer [23–25]. Pharmacists can improve clinical outcomes of patients with HIV, hypertension, and dyslipidemia through medication therapy management services [26,27].

We sought to better understand opportunities and challenges to pharmacist provision of HPV vaccine as part of national cervical cancer prevention efforts. To address this question, we examined the laws that regulate pharmacist administration of the three commonly recommended adolescent vaccines: HPV, tetanus-diphtheria-pertussis (Tdap) and meningococcal. We also assessed whether pharmacists are able to immunize through prescriptive authority, protocols or standing orders, or by prescription.

Methods

Participants

Participants were one pharmacy organization representative from each of the 50 states as well as the District of Columbia between January and April 2012. For the sake of simplicity, throughout this paper we refer to all 51 regions as states. We first attempted to contact a representative from the Board of Pharmacy in each state. If that representative was unavailable or unable to answer survey questions, we then asked a member of the state pharmacy association. In the event that neither a representative of the Board of Pharmacy nor a member of the state pharmacy association was available or able to answer survey questions, we reached out to a pharmacist in the state who was involved with immunization. In such cases, we identified the pharmacist by searching websites of schools of pharmacy for faculty involved with immunization implementation. In some instances, representatives from state pharmacy associations suggested that we interview other pharmacists including practicing pharmacists in community pharmacies. Respondents did not receive incentives for their participation.

Procedures

The interviewer (JC) was a pharmacy student at the time of the study and had completed a certificate training program on pharmacy immunization. To complete the interviews he used a standardized survey administered by telephone. The University of North Carolina IRB reviewed the study protocol and deemed it to be non-human subjects research.

Measures

The survey is available online: http://www.unc.edu/~ntbrewer/hpv.htm. We pilot tested the survey with two community pharmacists who were active immunizers in North Carolina (although not the HPV vaccine items, as North Carolina law did not permit pharmacists to provide HPV vaccine at that time). The survey used 30 mostly closed-ended questions to assess respondent demographics and, for each of the three vaccines (HPV vaccine, Tdap and meningitis), authority of pharmacists to administer the vaccine, minimum age for patients to receive the vaccine, required training for vaccination authority, and steps pharmacists took after vaccine administration (e.g. contact the patient's primary care provider or record doses delivered in a state vaccination registry.) The survey also assessed expected upcoming changes in legislation regarding pharmacist immunization.

Prior to conducting the survey, we developed a taxonomy of 5 mutually exclusive tiers to classify the authority that states granted pharmacists to administer vaccines, based in part on the system used by the American Pharmacist Association (Table 1). In Tier 1 states, pharmacists may administer the vaccine without prior approval from a prescriber, or a public official has permitted the use of his or her name on supervision agreements. Supervision agreements may refer to standing orders, protocols, collaborative practice agreements, or similar documents. In Tier 2 states, pharmacists may administer the vaccine upon the signing of a supervision agreement with a prescriber. This supervision agreement allows pharmacists to administer the vaccine to patients regardless of their primary care doctor. Tier 3 states are similar to Tier 2 states, with the only difference being that in Tier 3 states, the supervision agreement is limited only to patients of the prescriber who signed the supervision agreement. Tier 4 states allow pharmacists to administer the vaccine only to patients who present a prescription from a prescriber. Pharmacists in Tier 5 states may not administer the vaccine.

We used the survey responses to classify states into these five tiers according to pharmacists' authority to administer HPV, Tdap, and meningitis vaccines. Thus, each state could in theory have had a different tier designation for each of the three vaccines.

Table 1
Tiers of pharmacist vaccination authority, in 2012.

	Pharmacists can administer vaccine…
Tier 1	without prior approval from a prescriber, or a public official has permitted the use of his or her name on supervision agreements.
Tier 2	upon the signing of a supervision agreement with a prescriber. This supervision agreement allows pharmacists to administer vaccine to patients regardless of the primary care doctor whom the patients see.
Tier 3	upon signing a supervision agreement with a prescriber. This supervision agreement allows pharmacists to administer vaccine only to patients of the prescriber who signed the supervision agreement.
Tier 4	only to patients who present a prescription from a prescriber.
Tier 5	Pharmacists cannot administer vaccine.

Note. Supervision agreements include standing orders, protocols, and collaborative practice agreements.

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