



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



Noel T. Brewer<sup>a,b</sup>, Jake K. Chung<sup>c</sup>, Hannah M. Baker<sup>d</sup>, Mitchel C. Rothholz<sup>e</sup>, Jennifer S. Smith<sup>b,d,\*</sup>

<sup>a</sup> Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina, Campus Box 7440, Chapel Hill, NC 27599, USA

<sup>b</sup> Lineberger Comprehensive Cancer Center, University of North Carolina, 101 Manning Drive, Chapel Hill, NC 27514, USA

<sup>c</sup> Eshelman School of Pharmacy, University of North Carolina, Pharmacy Lane, Chapel Hill, NC 27599, USA

<sup>d</sup> Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina, Campus Box 7435, Chapel Hill, NC 27599, USA

<sup>e</sup> American Pharmacists Association, 2215 Constitution Ave, NW, Washington, DC 20037, USA

### 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.

### ARTICLE INFO

Available online 19 December 2013

#### Keywords:

Pharmacist  
Vaccine policy  
HPV  
Tdap  
Meningococcal

### 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

\* Corresponding author at: Gillings School of Global Public Health, University of North Carolina, 2103 McGavran–Greenberg Hall CB7435, 135 Dauer Drive, Chapel Hill, NC 27599, USA.

E-mail address: [JenniferS@unc.edu](mailto:JenniferS@unc.edu) (J.S. Smith).

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	<u>without prior approval</u> 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 <u>regardless of the primary care doctor</u> whom the patients see.
Tier 3	upon signing a supervision agreement with a prescriber. This supervision agreement allows pharmacists to administer vaccine only to <u>patients of the prescriber</u> who signed the supervision agreement.
Tier 4	only to patients who present a <u>prescription</u> from a prescriber.
Tier 5	Pharmacists <u>cannot</u> administer vaccine.

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

**Table 2**  
Respondent characteristics.

	n (%)
<i>Organization</i>	
State Board of Pharmacy	10 (20)
State Pharmacy Association	31 (61)
School of Pharmacy	6 (12)
Other	4 (8)
<i>Occupation</i>	
Pharmacist	40 (78)
Non-pharmacist	11 (22)

Note. n = 51 (50 states and District of Columbia, referred to here as a state for the sake of simplicity).

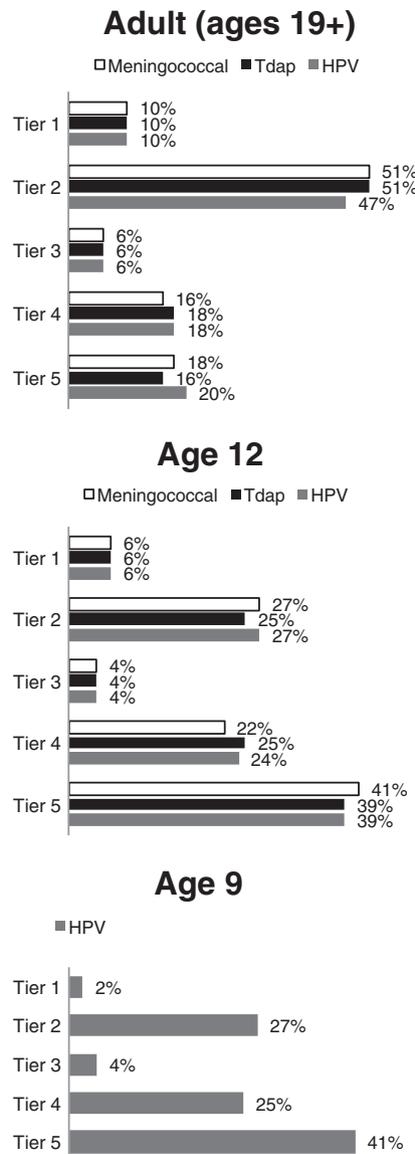
**Results**

Most respondents were from state pharmacy associations (61%) or were members of state boards of pharmacy (20%) (Table 2). Respondents were licensed pharmacists (78%) or administrators within either the state boards of pharmacy or state pharmacy associations (22%).

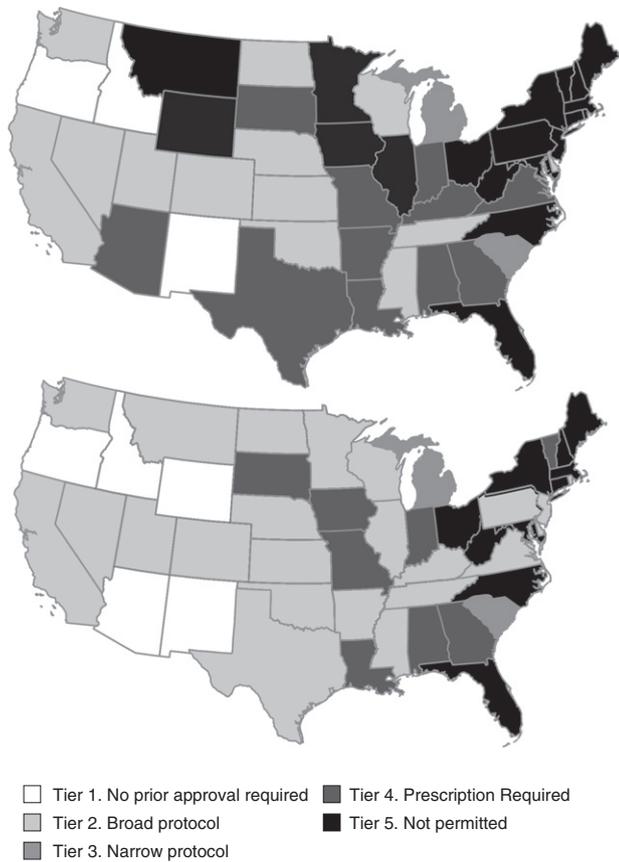
Most states' laws (80%) allowed pharmacists to administer HPV vaccine to adult women (ages 19 years or older), 61% to girls age 12, and 59% to girls as young as age 9 (Fig. 1). The mechanism permitting HPV vaccine provision by pharmacists was highly variable. For example, pharmacists could provide HPV vaccine to a 12 year-old girl in 6% of states without prior approval from a physician (Tier 1), in 31% of states under some type of protocol with a physician (Tiers 2 or 3), and in 24% of states with an HPV vaccine prescription from a physician (Tier 4)(Fig. 1). However, 39% of states would not allow a pharmacist to provide HPV vaccine to a 12 year-old girl under any circumstances.

While most states fit fairly well into one of the five tiers, the District of Columbia did not. In D.C., pharmacists may administer HPV, Tdap, or meningococcal vaccine to patients of any age, but the pharmacist must have a written protocol with a patient's physician. For adults, this description fits into Tier 3 for each of the three vaccines. For children ages 18 and younger, however, vaccination required a written prescription in addition to a protocol with the patient's physician. As a minor patient would need a prescription to receive HPV, Tdap, or meningococcal vaccine, we classified D.C. into Tier 4 for these three vaccines.

Pharmacists had similar authority across the three adolescent vaccines (Fig. 1). Tier 2 was the most common tier for adults (47% for



**Fig. 1.** Pharmacist authority to administer adolescent vaccines, in 2012. (HPV vaccine authority was for females.) Note. n = 51 (50 states and District of Columbia, referred to here as a state for the sake of simplicity).



**Fig. 2.** Pharmacist authority to administer HPV vaccine to 12 year-old girls (top) and adult women (bottom), in 2012.

HPV [females only], 51% for both Tdap and meningococcal), and Tier 5 was the most common tier for 12 year-olds (39% for HPV [females only] and Tdap, 41% for meningococcal).

The most permissive states were clustered on the west coast, while the least permissive were more often on the east coast. Fig. 2 illustrates this finding for authority to provide HPV vaccine to adult women and adolescent girls age 12. Ten states did not permit pharmacists to administer HPV vaccine: Connecticut, Florida, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Ohio, and West Virginia. These states, with the exceptions of Maine and Ohio, also prevented pharmacists from administering Tdap vaccine. Similarly, these states, with the exception of Ohio, prevented pharmacists from administering meningococcal vaccine (Table 3). Five (50%) of the nine states in HPV vaccine Tier 5 were considering legislation that would allow pharmacists to provide the vaccine. Of the 41 states where pharmacists could administer HPV vaccine in some capacity, all permitted the administration of all 3 recommended doses.

Most states (86%) required pharmacists to receive immunization training certificates prior to attaining authority to immunize. Half of the states (50%) required pharmacists to contact patients' primary care providers or the signers of the supervision agreements after administering vaccines. About one quarter of states (23%) required pharmacists to enter data into a state immunization registry.

**Discussion**

Cervical cancer prevention efforts in the US are expanding beyond clinics that offer Pap tests into clinics that can offer HPV vaccine. However, these efforts are hampered by relatively low HPV vaccine coverage. Routine provision of HPV vaccine in pharmacies could address many of the central reasons for low coverage, including low access, missed opportunities, and public misunderstanding of the vaccine [28]. To improve adolescent vaccine coverage, the CDC and the American Cancer Society have endorsed immunization of adolescents in alternative settings, including pharmacies [28,29], as has the President's Cancer Panel [30]. Our findings illustrate some of the opportunities and challenges to pharmacists immunizing adolescents. While US pharmacists' ability to immunize across the adolescent vaccine spectrum was very similar for HPV, Tdap and meningococcal vaccines, it

**Table 3**  
State policies on pharmacist vaccination authority, in 2012.

State	Adult (age 19+)	12 year-old	9 year-old (HPV vaccine only)	State	Adult (age 19+)	12 year-old	9 year-old (HPV vaccine only)
Alabama	4	4	4	Nebraska	2	2	2
Alaska	2	2	2	Nevada	2	2	2
Arizona	1	4	4	New Hampshire	5	5	5
Arkansas	2	4	4	New Jersey	2	5	5
California	2	2	2	New Mexico	1	1	1
Colorado	2	2	2	New York	5	5	5
Connecticut	5	5	5	North Carolina	5	5	5
Delaware	2	2	2	North Dakota	2	2	2
Florida	5	5	5	Ohio	5H 2TM	5	5
Georgia	4	4	4	Oklahoma	2	2	2
Hawaii	4	5	5	Oregon	1	1	4
Idaho	1	1	5	Pennsylvania	2	5	5
Illinois	2	5	5	Rhode Island	2	5	5
Indiana	4	4	4	South Carolina	3	3	3
Iowa	4	5	5	South Dakota	4	4	4
Kansas	2	2	2	Tennessee	2	2H 5TM	2
Kentucky	2	4	4	Texas	2	4	4
Louisiana	4	4	4	Utah	2	2	2
Maine	5HM 2T	5HM 4T	5	Vermont	4	5	5
Maryland	5	5	5	Virginia	2	4	4
Massachusetts	5	5	5	Washington	2	2	2
Michigan	3	3	3	West Virginia	5	5	5
Minnesota	2	5	5	Wisconsin	2	2	2
Mississippi	2	2	2	Wyoming	1	5	5
Missouri	4HT 2M	4HT 2M	4				
Montana	2	5	5	District of Columbia	3	4	4

Note. HPV vaccine authority is only for females. H = HPV vaccine; T = Tetanus-diphtheria-acellular pertussis vaccine; M = Meningococcal vaccine.

varied widely across the states. Pharmacist vaccination authority was also highly dependent upon patient age.

Our findings show little difference in pharmacists' authority to administer HPV vaccine to a 12 year-old girl as compared to a 9 year-old girl, as only 2 states had administration rules that varied regarding 9 and 12 year-olds (Idaho and Oregon) (Table 3). Reviewing the placement of states into tiers for a 12 year-old girl, it is apparent that most states' laws prevented, or severely limited, pharmacists' ability to improve vaccine coverage among adolescents. Having the authority to immunize adolescents allows pharmacists to serve the relatively older "catch up" population (for HPV vaccine, age 13 to 18). However, to have the most meaningful impact on immunization rates, pharmacists would need to receive broader vaccination authority in the critical age group of 11 to 12 year-olds.

Expanding pharmacists' ability to provide HPV vaccine could potentially improve coverage rates, though several stakeholder groups have concerns about supporting the medical home. The American Academy of Pediatrics (AAP) defines the medical home as a primary care setting that is accessible, continuous, comprehensive, family centered, coordinated, compassionate and culturally effective [31]. The AAP's concerns regarding retail clinics include the potential for lack of access to a complete medical history, fragmentation of care, and the loss of an opportunity to screen for illnesses or to provide support and follow-up for chronic conditions or family issues [32]. Support among practitioners themselves has been mixed. A 2004 study of family physicians in North Carolina found low support for pharmacists as vaccinators, with reasons including concern for continuity of care as well as the ability of pharmacists to handle potential adverse reactions to vaccines [33]. In contrast, a more recent national study found broad support, with 78% of pediatricians supporting vaccination in alternative settings for healthy children ages 5–18 [34]. Options that would preserve the medical home include a primary care provider delivering the first dose of HPV vaccine or other adolescent vaccines at a preventive care visit, and a pharmacist delivering additional vaccine doses to complete the HPV vaccine series. OBGYNs could participate in a similar arrangement to help ensure that patients receive second and third HPV vaccine doses. Another possibility would be to systematically link all vaccinations given within the pharmacy to the medical home via electronic records.

Even with expanded authority, pharmacists will face several challenges. Pharmacists will need to gain in-network status to be reimbursed by private insurance, otherwise their clients will likely have to pay large out of pocket costs for the vaccine doses. Cost to patients may continue to be a barrier at pharmacies that are not in-network providers on common private insurance plans [28]. However, getting a vaccine at a pharmacy may help people miss less time at work or school and have lower vaccination fees. Pharmacists will need to become Vaccines for Children (VFC) program providers to be able to provide vaccines to uninsured adolescents through this program. CDC has issued guidance to state VFC programs clarifying that pharmacists are eligible to be VFC providers for adolescent patients [35]. Some states have yet to permit pharmacist access to their statewide vaccine registries. Finally, in the absence of a physician recommendation of or a spontaneous patient request for HPV vaccine, pharmacists will need to develop demand for their services with approaches that could include direct to consumer marketing, in-store promotions, and partnerships with primary care providers.

Findings of this study are similar to the findings of an annual review of pharmacist-administered immunizations by the American Pharmacist Association (APhA) in collaboration with the National Alliance of State Pharmacy Associations (NASPA) [36]. However, we felt that these data did not provide a full picture of the legal and regulatory environment for pharmacy-based immunizations. Our review offers several important additional details to those provided by the APhA/NASPA annual review. One important difference provided in our study is that we distinguish between Tier 2 and Tier 3 authorities. While this difference may seem minor, the potential pool of patients who could be immunized upon the signing of a protocol with a single physician is far

greater in a Tier 2 state as compared to a Tier 3 state. Furthermore, Tier 2 authority is one of the most common, whereas Tier 3 authority is relatively rare.

Our study helps to clarify state policies that establish the specific circumstances under which pharmacists may administer HPV, Tdap, and meningococcal vaccination in the United States. Previous studies of pharmacist immunization authority have not explored these differences between vaccination authority by tiers across states. A limitation of this study is that we interviewed only one individual per state. As state policies are liberalizing steadily over time, our analysis reflects a snapshot in time but will require regular updates. Data we obtained may be incomplete as we interviewed only one informant per state and did not directly examine each state's laws.

Our findings have clear implications for public health efforts. More than 200,000 pharmacists have completed a 20 hour certificate training program covering immunizations across the lifespan, preparing them to assume these expanded immunization roles and to be an integral part of the immunization neighborhood for this patient population [37]. Just as pharmacists' authority to immunize varies, the focus for increasing immunization in a pharmacy setting will vary depending on the level of authority currently granted by each state. For Tier 1 states, the focus should not involve expanding pharmacist authority, as it is already quite broad, but rather on educating providers and the public about the immunization services that pharmacists can provide. While some benefit would be derived from enacting legislation to move Tier 2 states into Tier 1, time may be better spent for Tier 2 states by identifying providers or public health officials who are willing to partner with pharmacists on supervision agreements. Tier 3 states (limited to provider-specific protocols) would be better served by a combination effort aimed at enacting legislation to move states into Tier 2, and by identifying providers who are willing to partner with pharmacists on supervision agreements. Unlike Tier 2 states, this second aim would require a notable effort, as multiple providers would have to partner with each pharmacist or pharmacy to reach a large pool of patients. Pharmacists in Tier 4 states are currently very restricted in their ability to provide immunizations, and efforts to increase immunization rates in these states should revolve around enacting legislation that allows for broader authority of pharmacists to immunize. Reaching out to individual providers in Tier 4 states would be even less productive than doing so in Tier 3 states, as each provider would likely have to refer individual patients to specific pharmacists in order to obtain immunizations. As Tier 5 states currently prevent pharmacists from providing immunizations, increasing immunization rates (by way of pharmacy) in these states may only be achieved by enacting legislation to allow pharmacists to immunize. Including pharmacists as partners can help achieve broad HPV vaccine coverage as part of our nation's cervical cancer prevention efforts.

#### Conflict of interest statement

Dr. Jennifer Smith has received grants or been a paid consultant for GlaxoSmithKline and Merck. Dr. Noel Brewer has received research funding from GlaxoSmithKline and Merck, has served on a paid advisory board for Merck, and has been a paid speaker for Merck. The wife of Dr. Mitchell Rothholz is an employee of Merck, and he has also been a member of the Merck Global Advisory Board for Adult Vaccines, with the term ending in December 2012. Dr. Chung and Hannah Baker have no conflicts of interest to report.

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