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Early Policy Responses to the Human Papillomavirus Vaccine in the United States, 2006–2010



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ABSTRACT

Purpose: To examine the policies state governments pursued and enacted across the United States in the 5-year period after the U.S. Food and Drug Administration licensed the human papillomavirus (HPV) vaccine in 2006, including the timing and number of bills introduced, the policies proposed, and the legislative success of HPV vaccine policy proposals.

Methods: Content abstraction and analysis of state-level HPV vaccine–related bills across the 50 states and the District of Columbia introduced between 2006 and 2010.

Results: All but five states (Alaska, Delaware, Idaho, New Hampshire, and Wyoming) introduced HPV vaccine bills between 2006 and 2010. Two-thirds of all bills were introduced in 2007. In all, 141 bills were introduced and 23% or 32 bills were enacted. Of the bills that were enacted, 43.8% provided information for parents and schools about the vaccine; 37.5% provided public financing for HPV vaccines; 34.4% were classified as other policies; 25% created awareness campaigns; 25% required private insurance coverage of the HPV vaccination; 12.5% included voluntary vaccination, and 9.4% mandated vaccination for school entry. One bill reversed prior mandatory vaccination policies. Overall, 91% of enacted HPV vaccine bills did not refer to mandated vaccinations but adopted alternate policy strategies in response to the availability of the new HPV vaccine.

Conclusions: Nationwide, states responded to the new HPV vaccine by introducing policies designed to increase the availability of information about the vaccine, provide funding, and regulate private insurance coverage rather than require vaccination for school entry.

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IMPLICATIONS AND CONTRIBUTION

After the human papillomavirus (HPV) vaccine was licensed, many states introduced bills requiring vaccination for school entry. We measure the success of these bills and show that while school entry policies were mostly unsuccessful, legislatures enacted many other policies to encourage uptake of the HPV vaccine.

The development of the prophylactic human papillomavirus (HPV) vaccine was hailed as a scientific and public health breakthrough in the prevention of cervical cancer [1]. The U.S. Food and Drug Administration (FDA) approved the quadrivalent

vaccine (Gardasil) in 2006 [2,3]. Gardasil prevents infection from HPV because of variants 16 and 18 [4,5], which account for 70% of all cervical cancers, and variants 6 and 11 that can lead to genital warts [6]. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) added the quadrivalent (HPV4) vaccine to the immunization schedule for girls aged 11–12 years in 2006 [7] and recommended funding the vaccine under the Vaccine for Children Program in 2006. In 2009, the FDA approved the bivalent vaccine that protects against

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variants 16 and 18 (Cervarix), and that year, Gardasil was licensed for use in males for prevention of genital warts [8]. The FDA extended the application of the vaccine to anal cancer in males and females in December 2010 [8]. In December 2011, the ACIP recommended routine vaccination of males aged 11–12 years with Gardasil administered as a 3-dose series [8].

Early on, enacting HPV vaccine policies was seen as potentially politically challenging [9–12]: given that the vaccine prevented sexually transmitted diseases and was initially approved for young girls starting in middle school. Immediately after its approval, however, elected officials in state legislatures eagerly introduced legislation to encourage the uptake of the vaccine in their states and many state legislators seemed supportive of HPV vaccine policies [13]. As more states proposed mandating vaccination as a requirement of school entry, however, earlier predictions that the vaccine would be a politically contentious issue suddenly appeared prescient and controversy grew [14–16], especially around mandatory vaccination policies [11,17,18].

Research has explored the ethical, legal, and political debates surrounding the introduction of the HPV vaccine [9,19] including case studies of specific states [20]. Most studies have focused on mandatory vaccination policy [12,21,22]. Less is known about the range of policy approaches contemplated and adopted by states and the success of policies other than mandatory vaccination. To understand early policy responses to the introduction of the HPV vaccine, we compiled a unique data set of 141 HPV vaccine-related bills introduced in the United States between 2006 and 2010. We coded policies mentioned in these bills by topic and tracked which bills were enacted in order to characterize national trends in the success and failure of state-level HPV vaccine bills.

Our detailed analysis of bill content in 50 states and the District of Columbia reveals the full range of policy strategies pursued after the HPV vaccine was introduced. HPV vaccine bills incorporating policies other than mandated vaccination were passed at similar rates (and sometimes at higher rates) than other bills; furthermore, states introducing and passing legislation included a mix of traditionally “red” and “blue” states. Our large sample, along with a detailed analysis of state bills, offers a more complete understanding of the policy options states can potentially explore; it also indicates that there is some support for HPV vaccine legislation when bills include policies other than mandated vaccination.

Methods

The National Conference of State Legislatures’ (NCSL) regularly updated list, “HPV Vaccine: Introduced Legislation” [23], was used to find HPV vaccine bills. The NCSL identified bills using databases State Net, LexisNexis, and Westlaw. We also searched state legislative Web sites using terms “HPV,” “human papillomavirus,” (with the Boolean operator AND) “vaccine.” Bills introduced in the 50 states and the District of Columbia between January 1, 2006 and December 31, 2010 were included. The NCSL included an executive order, which was included in our sample.

Bills were defined as legislative proposals, which included resolutions passed in state legislatures. Resolutions were included in the sample to make the study comparable with other studies of legislative rates of enactment, but as discussed in the following, resolutions are different from other bills. To be eligible, bills had to refer to the HPV vaccine or vaccination, or immunization. Nine

bills were excluded on this basis, because they referred to HPV but not the HPV vaccine or immunization against HPV.

To check the accuracy of our sample, we also checked state and District of Columbia codes using LexisNexis and the National Cancer Institute’s State Cancer Legislative Database (SCLD) of laws [24]. We found that three bills were not included on the NCSL list, but only one was eligible for inclusion. The status of one bill in the sample was revised from “not enacted” to “enacted.” The final sample included 141 unique legislative bills (including one executive order).

Two coders used content analysis methods [25] and worked independently. The initial coding schema included categories of financing, information, and mandatory vaccination. These definitions drew on the SCLD database of cancer-related laws [24]. These categories were refined and a more detailed schema was used that included a fourth category of “backlash bills” for opposing mandatory vaccination.

Finance bills were coded as either expanding access to vaccinations using public funding and/or mandating private insurance coverage of the vaccine. Information bills included those designing, creating, producing, and/or disseminating informational materials on the HPV vaccine (e.g., fact sheets, usually for distribution to schools, parents, and school-aged females). Awareness bills included bills that proposed broader dissemination of information on the HPV vaccine to the public, such as the development of public awareness campaigns and Web sites.

The SCLD database [24] of state laws distinguishes among vaccination requirement laws. The term “mandates” or “mandatory” vaccination is used in most discussions of vaccination requirements [10,12,16,17,21,22,26]. Bills requiring HPV vaccinations for school entry were coded as mandatory vaccination if the law mentioned “required” or “mandated” vaccination. If the bill explicitly stated the HPV vaccine was “not required for school entry,” we coded the bill as “voluntary vaccination.” However, it should be noted that states also have existing laws that provide exemptions from vaccination requirements.

Bills included in the “other policies” code were sufficiently distinct from existing categories but not numerous enough to warrant a separate category; for example, seven bills proposed tracking of immunization rates, three bills proposed adding HPV to a teen vaccine program, and one bill would give the state Health and Human Services Commissioner the power to modify or delete immunizations. Determining the number of coding categories and a minimum frequency count requires considering the advantages of adding a separate code; one guideline is a maximum of seven categories [27]. If the topic was both infrequent and sufficiently distinct from existing categories, it was coded as other. Second, all bills that were resolutions were coded as other. Resolutions are often expressions of sentiment, intent, or positions on issues, and do not have the force of law [24–28].

Eleven bills mentioning studies of the HPV vaccine and cervical cancer and designations of certain months as HPV vaccination awareness months were legislative resolutions and coded as other. Four bills adding HPV vaccine information to the school sex education curriculum were coded as other, because they focused on changes to school curriculums rather than distribution of informational materials. One bill relating to funding of educational materials was coded as other, because although the bill referred to education materials, the category of funding specifically referred to vaccine provision or mandating insurance coverage. Two bills encouraging schools to give parents HPV information were not included in the information category

because they did not require the design, creation, production, and/or dissemination of information materials.

The date the bill was introduced and passed (if applicable) was recorded, although the time to legislation is not necessarily comparable across states, however, given variation in state legislative terms. Each bill was coded according to whether it became a law or failed. Legislative histories or statements on the progress of a bill available on state legislative Web sites were used to code the status of the bill and also checked in the SCLD (as mentioned previously) [24]. Bills were considered enacted based on NSCL criteria: if they were enrolled, ratified, passed by the legislature and signed into law by the Governor; or if the legislature had a sufficient majority to make gubernatorial assent unnecessary [28]. Bills that died in committee were withdrawn by the bill's author, or postponed indefinitely, vetoed, never progressed, or enacted but were repealed in the same session were coded as failed.

We explored the possibility of tracking the stage in the legislative process at which bills failed. However, many state legislatures have rules that essentially force bills to go through particular steps; thus bills would seem to proceed further than they would without those rules. For example, 22 states must hold hearings on all bills, 18 must report all bills referred, and others have processes for formally “killing” bills while others do not. Each of these powers can vary by chamber [29].

Ninety-five percent of the sample was tested for reliability using the program ReCal [30]. Not all bills in the sample (5%) were tested because we subsequently added legislative resolutions in the sample to make the selection comparable with studies of legislative enactment rates and because the checks described earlier required adding a bill to the sample. Krippendorff alpha was .87 for vaccine policies (a variable which coded school entry requirements as mandatory or voluntary) and .93 for HPV vaccine information and awareness campaigns. Public funding and mandated insurance benefits scored 1.0 in both categories. All discrepancies between the two raters were resolved and corrected by the lead author.

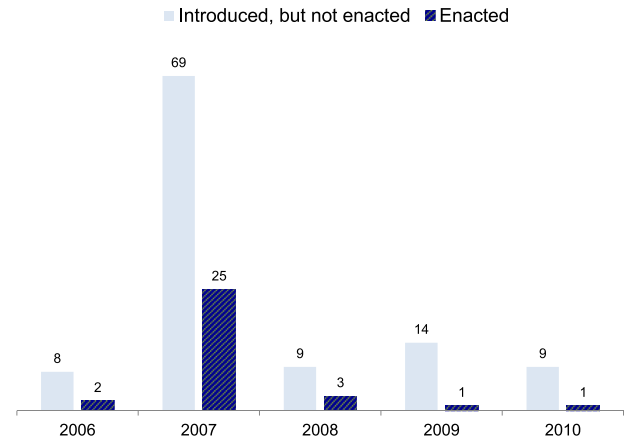
Results

Between January 2006 and December 2010, 141 bills (including one executive order) related to HPV vaccination were introduced in 45 states and the District of Columbia. Two-thirds (94 bills) of all HPV vaccine-related bills were introduced in 2007 (Figure 1). Examples of bills by topic are shown (Table 1). On average, most bills proposed 1.7 policies per bill. Bills could have multiple policies, so the number of bill topics is greater than the number of bills.

New York proposed the most bills (13 bills), followed by Texas (9), New Jersey (8), Michigan (7), Iowa, and Pennsylvania (6 each). Most states approved at least one bill, although Colorado, New Jersey, and Texas adopted 25% of the 32 HPV vaccine laws. The most populous state, California, did not enact any HPV vaccine legislation. Five states (not shown) did not introduce any HPV vaccine legislation during the time studied: Alaska, Delaware, Idaho, New Hampshire, and Wyoming.

Twenty-six states and the District of Columbia enacted 32 bills. On average, enacted bills took 96 days to become law. The overall rate of enactment for HPV vaccine bills introduced was 23%.

A total of 241 policy interventions were identified (Table 2), including requiring vaccination for school entry, creating public awareness programs, providing direct programmatic funding of



Note: Includes the District of Columbia.

Figure 1. Human papillomavirus vaccine bills introduced and enacted in the United States between 2006 and 2010.

vaccine provision. States also proposed regulating private insurance coverage for HPV vaccination, and some states sought to reverse earlier policies relating to mandatory vaccination.

Forty-one percent of introduced bills referred to the production and dissemination of information on the HPV vaccine; 28.4% required private insurance coverage for HPV vaccination; 27% proposed public funding for HPV vaccination; 27.7% referred to mandatory vaccination; 22.7% were classified as “other” policies; 12.1% referred to awareness campaigns, and 8.5% of the bills introduced referred to voluntary vaccination. Five bills proposed removing prior mandated vaccination policies.

Among enacted bills, creation and dissemination of information about the vaccine to parents and schools was mentioned in 43.8% of bills and 37.5% of enacted bills provided public funding for vaccines. A little over one-third (34.4%) of bills mentioned other policies, 25% of bills required private insurance coverage of the vaccine, and 25% of bills referred to general awareness campaigns. Voluntary vaccination requirements (12.5%) and mandatory vaccination requirements (9.4%) and a single backlash law accounted for the smallest category of enacted bills.

Table 3 displays state-by-state variations in the bills introduced and enacted, by topic. States across the United States introduced legislation, including states from the northeast, southeast, south, midwest, and western states. Mandatory vaccination bills were successfully enacted by Texas, Virginia, and Washington DC.

Discussion

The aim of the study was to understand the nature of early HPV vaccine-related policy proposals and assess which policies were successfully enacted. Drawing on a unique 50-state (and Washington DC) data set, we compiled and coded bills drawn from primary legislative sources. We review HPV vaccine policies proposed throughout the United States and describe the early state-level policy responses to the licensing of HPV vaccines in the first 5 years after it was available.

Researchers have explored states' responses to the new HPV vaccine, but typically this has been analyzed in specific states or

Table 1
Types of human papillomavirus (HPV) policies and examples of bills introduced in the United States

Category	Specific policies	Example
Financing	Public funding	South Dakota, HB 1061 c 201: Public funding for HPV vaccine programs. (2007, passed)
	Private insurance coverage	Nevada, S 1230 c. 527: Private insurers required to cover the HPV vaccine. (2007, passed)
Vaccine information	Educational materials and publications	Illinois HB 2033: Department of Health to distribute information about the HPV virus and vaccine. (2009, failed)
	Awareness campaigns	Iowa SB 326: Public awareness program for human papillomavirus infection vaccination. (2007, failed)
Vaccination and/or school entry requirements	Mandatory vaccination	Virginia S 1230/Chapter 922: Females to receive the HPV vaccination before the sixth grade for school attendance. (2007, passed)
“Backlash” policies	Voluntary vaccination	New York A 3203/S 1983: Voluntary vaccination. (2010, failed)
	Reversal of prior HPV vaccine policies	Virginia, HB 686: Removal of the HPV vaccine from the list of required vaccinations. (2010, failed)
Other	HPV vaccine awareness months, study taskforces, adding to a teen vaccine program or school curriculum, funding educational materials, tracking vaccine rates, encouraging schools to give parents information, and expanding executive authority to modify or delete immunizations.	Maryland, Chapter No. 191, H.B. 1049: Taskforce for HPV vaccine, 2007.

subsets of states [20,31]. Studies have also explored the ethical, legal, and political aspects of the HPV vaccine and the nature of the public debate around the vaccine [10–12,16,17,19,21]. Generally, discussion of the policy response to the new vaccine has focused on legislative proposals to mandate vaccination. This is somewhat understandable, given the effectiveness of vaccine requirements in encouraging vaccination of children: this approach has worked well for many communicable diseases.

However, there are two advantages to considering the nationwide response beyond mandated vaccination policies. First, a national sample allows us to understand how often and where HPV legislation was introduced and passed. There was a concern that the HPV vaccine would not be well received in states with more conservative views regarding premarital sex and sexuality [9–12]. Yet HPV legislation was passed at rates comparable to state legislation overall: the enactment rate for HPV legislation is only slightly less than the 2007 rate of enactment for all bills: 27.5% of state bills introduced were successful [32]. Obesity prevention legislation success rates range between 17% and 27% [33,34]. In addition, legislation has also been introduced in states where Republican presidential candidates tend to prevail—“red” states [35], such as Kentucky, Mississippi, Texas, Utah, and Virginia. Some traditionally blue states, such as California, failed to enact HPV vaccine legislation or only passed one bill (New York).

A second advantage of this approach is that capturing the legislative response across all states allows inclusion of states that did not introduce mandatory vaccination bills and tracks laws that states adopted with relative ease. Although mandatory vaccination requirements were mentioned in 39 bills or 27% of all bills introduced in the United States, not all states introduce these mandates and <10% of enacted bills included mandatory vaccine requirements. In comparison, 44% of enacted bills included informational requirements and 25% of bills enacted required insurance coverage of the vaccine. Although these policies alone are unlikely to substantially increase HPV vaccination rates, policies such as these are a necessary component of vaccination policy [36,37]. In the absence of a HPV vaccine mandate, these policies may serve to complement other mandatory vaccination requirements, indeed states with tetanus vaccination requirements have higher rates of HPV vaccination [26].

Our study has limitations, including the potential for subjectivity, which is one risk of content analysis methods. To address this problem, two coders assessed the bills. Intercoder reliability analysis was assessed for 95% of the bills, rather than a sample of bills. Discrepant codes were resolved using consensus between the two coders and the lead author. As a study of new bills specifically referring to HPV vaccines, we capture new policies introduced in the legislative process but not existing laws already

Table 2
Policies included in state human papillomavirus vaccine bills introduced and enacted 2006–2010

Policies included in bills ^a	Introduced bills that included this policy (n = 141), n (%)	Enacted bills that included this policy (n = 32), n (%)	Percentage enacted
“Backlash” or reversals of mandated vaccination laws	5 (3.5)	1 (3.1)	20
General awareness campaigns	17 (12.1)	8 (25.0)	47.1
Mandated vaccination for school entry	39 (27.7)	3 (9.4)	7.7
Other policies	32 (22.7)	11 (34.4)	34.4
Private insurance coverage for vaccine	40 (28.4)	8 (25.0)	20.0
Production and dissemination of vaccine information	58 (41.1)	14 (43.8)	24.1
Public funding for vaccines	38 (27.0)	12 (37.5)	31.6
Voluntary vaccination for school entry	12 (8.5)	4 (12.5)	33.3

The sample includes 50 states and the District of Columbia.

^a One hundred forty-one bills were introduced and 32 bills were enacted. The percentages do not add up to 100%, because the denominator is the number of bills introduced or enacted: on average, bills included 1.7 policies per bill.

Table 3
States introducing and enacting human papillomavirus (HPV) vaccine policies 2006–2010

State	Public funding	Private insurance coverage	Vaccine information	Awareness campaigns	Mandated vaccination	Voluntary vaccination	Backlash bills	Other
Alabama			○			○		○
Arizona	○	○	○			○		○
Arkansas				○		○		
California		○	○		○			○
Colorado	●	●	●	●	○	●		●
Connecticut	○		○	○	○			○
District of Columbia					●			
Florida		○	○		○			
Georgia		○	○		○			
Hawaii	○	○	○					○
Illinois	●	●	○		○			●
Indiana			●			●		
Iowa	○	○	●	○				●
Kansas			○		○			○
Kentucky	○		○	○	○	○		
Louisiana		○	●					
Maine	●	●	●	●	○			
Maryland			○	●	○			●
Massachusetts	○				○			
Michigan			●		○			●
Minnesota	●		○	○	○			●
Mississippi	○	○	○		○			○
Missouri	○	○	●		○	○		○
Montana			○					○
Nevada	●	●						
Nebraska								●
New Jersey	○	○	●	●				
New Mexico	●	●	○		○			●
New York	●	○	○		○	○		○
North Dakota								●
North Carolina		●		●				
Ohio					○			
Oklahoma					○			
Oregon		●						
Pennsylvania	●	○	●	○				●
Rhode Island		●						
South Carolina	○				○			
Tennessee								
South Dakota	●					●		
Texas	●	●	●	●	●		●	
Utah	●	●		●				
Vermont	○				○			
Virginia		○	○		●		○	
Washington			●			●		
West Virginia					○			
Wisconsin			○					

●, Enacted policy; ○, Introduced but not enacted policy.

Each circle represents at least one bill or enactment. Because the same topic can be introduced more than once, the number of dots does not equal the total number of bills introduced.

Alaska, Delaware, Idaho, New Hampshire, and Wyoming did not introduce or pass any HPV vaccine legislation.

encompassing the HPV vaccine but not specifically mentioning the vaccine. This is common in studies that rely on searches using keywords. [34] The data set does not allow us to highlight particular subpopulations or address the role of health disparities or particular populations at risk such as lesbian, bisexual, or transgender populations. Finally, although we present the frequencies of introduced and adopted legislation, we do not control for state characteristics such as economic conditions or the political composition of the legislature sometimes associated with adoption of policies such as obesity prevention [38].

The study shows how states took this role on in the first 5 years after the vaccine was available; since that time, the scientific understanding of the vaccine and the indications for its use have steadily expanded. To assess subsequent developments

since 2010, we reviewed the NCSL [23] summary list of bills introduced that refer to the HPV vaccine introduced after January 1, 2011 through February 2014. Since 2011, 31 bills were introduced across all the topics in our codebook, with 16 bills introduced in 2011–2012 and 15 bills introduced in 2013–2014. Notably, six insurance coverage bills were introduced, despite new federal requirements for coverage of the vaccine; five mandatory vaccination bills were introduced. Georgia, Hawaii, Indiana, Iowa, Kentucky, New Jersey Ohio, and South Carolina each introduced bills. New York introduced the most bills (7) followed by Virginia (5). Between 2011 and 2012, no bills were passed. Two bills that passed between 2013 and 2014 included an awareness month resolution (Pennsylvania) and a bill allowing pharmacists to administer the vaccine (Indiana).

States are likely to continue to be important venues for vaccine policymaking, although federal public funding for childhood vaccines continues to be available through the Vaccines for Children program, and the Patient Protection and the Affordable Care Act now requires private insurers to cover ACIP-approved vaccines at no cost to the patient. Political support for public health laws at the state level may be stronger than support at the federal level. The enactment rate (23%) for state HPV vaccine bills is substantially higher than health bills in Congress, (1973–2002), where just 4% of bills succeeded. Less than one percent of bills relating to the prevention of communicable diseases succeeded in Congress. Meanwhile, successful public health initiatives are flourishing in cities such as New York City. [39] For the most part vaccination efforts will remain in the hands of the state and local public health authorities. Although HPV vaccination mandates continue to be mostly unsuccessful, opportunities to enact vaccine legislation at the state level may still be more successful than legislation introduced at the federal level.

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