

RESEARCH PAPER



State statutes and regulations related to human papillomavirus vaccination

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ABSTRACT

A cross-sectional analysis of human papillomavirus (HPV) vaccine statutes and regulations from states and the District of Columbia in the United States (U.S.) was conducted from September–November 2018 to advance analyses of policy impact on HPV vaccination uptake. A search was conducted using WestlawNext, a legal research database. Statutes and regulations relevant to the study were analyzed and coded based on their legal attributes into ten broad coding questions and several sub-questions. Of the 212 laws identified by the initial search string, 93 (43.9%) reference HPV vaccination in statute or regulation. An additional three laws were added following subsequent review. There was a total of 52 statutes and 44 regulations from 34 states and the District of Columbia. Most laws were related to developing and distributing HPV vaccination materials for parents, and mechanisms to fund and reimburse for the vaccination. This study can be used by policymakers in jurisdictions that are considering establishing HPV vaccination promotion interventions in state law and highlighting the limited statutory and regulatory efforts that have been implemented to promote HPV vaccination. Importantly, this study can also be used to conduct evaluations of the efficacy of statutory and regulatory strategies in increasing HPV vaccination rates.

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Introduction

The vaccine to prevent human papillomavirus (HPV) related cancers has been approved for use in the United States since 2006.¹ As of 2017, the national coverage for ≥ 1 dose of HPV vaccine among adolescents was 65.5% overall.² There are lower levels of uptake among teens living in non-metropolitan statistical areas (MSA) compared to those living in MSA principal cities (59.3% vs. 70.1%).² Those living below the poverty level have higher vaccination rates compared to those at or above the poverty level (73.3% vs 53.7%).² There are continued increases in uptake among boys (62.6% in 2017 compared with 56.0% in 2016).² While not as high as compared with countries such as Australia, which has projected the near elimination of cervical cancer within the next 10 years,³ HPV vaccine uptake in the United States has improved over time. However, it has been hampered by the lack of a unified approach to vaccination both across and within states. This diversity is reflected in the variation of vaccination rates across states and regions with Northeastern, Midwestern, and Western states seeing higher rates of HPV vaccination coverage than Southern and Southwestern.^{2,4,5} Several studies have attempted to demonstrate the impact of state policies on vaccine uptake; focusing on particular states and specific policies such as HPV vaccine school-entry requirements^{6–8} or policies requiring vaccine education for parents.^{8,9} As observed by Durham et al.,¹⁰ and Roberts et al.,¹¹ variability in HPV vaccine uptake across the United States is probably a function, at least in part, of a collection of structural elements, such as law and policy.

It is at this juncture that a full description of HPV vaccine policies and laws is needed. Over the years, organizations such as the National Conference of State Legislatures (NCSL) and Immunization Action Coalition have conducted reviews of introduced and enacted state legislation focused on HPV vaccine.^{12,13} Researchers have also explored state requirements related to HPV vaccination and school-entry requirements^{6–8} and pharmacist vaccination authority,^{14–17} providing analyses of the political, social, and ethical considerations related to HPV vaccine mandates.^{18–23} Still, others focused on administrative aspects of policy affecting vaccine access²⁴ and their impact on vaccination rates.¹¹

While helpful, some of this research focuses exclusively on legislative activity.^{25,26} Additionally, much of the existing HPV vaccination law literature relies on data generated by NCSL.^{8,9,11,21,26,27} While this information is incredibly valuable for strategic planning, developing policy priorities, and giving an idea of the existing landscape of laws, it cannot be relied on for scientific studies. NCSL largely reviews legislation and not regulation, which is a serious limitation given that state legislatures often delegate broad rulemaking authority to agencies to promote public health.²⁸ And, vaccination requirements are regularly passed via agency rulemaking, including HPV vaccination requirements in states like Rhode Island and Virginia, among others.²⁹ NCSL does not (1) outline search strings; database or databases used; (2) dates searches were conducted (currently the site only includes the date in which the page was updated). Because of these issues, NCSL cannot truly provide sound

empirical data on which to base a study whose methodology and analyses can be reproduced.^{30–32}

The need for a comprehensive description of state law across all subject areas from school requirements to vaccine access, to funding would help advance analyses of policy impact on HPV vaccination uptake. Additionally, there is a need for an analysis that includes both statutes (law enacted by legislatures and signed by governors) and regulations (law developed by state agencies and associated with statute) given that both mechanisms are used to advance HPV vaccination. Finally, developments in the field of legal epidemiology – “the scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population” – have identified best practices for systematically conducting and analyzing laws in relation to public health.³³ This study implements these best practices. To the best of our knowledge, this is the first study of state HPV vaccination requirements that derived data using legal epidemiological methods across statutes and regulations on a breadth of topical areas including mandates, education, scope of practice, and financing.

Here we describe the results of a cross-sectional analysis of U.S. state (including DC) statutes and regulations related to HPV vaccination collected in September – November 2018. The analysis identified state laws currently in effect in fall, 2018 regardless of their initial effective date. These statutes and regulations were analyzed and coded based on their legal attributes into ten broad coding questions and several sub-questions (Table 1). Additionally, this article – because it specifically highlights references to HPV in statutes and regulations at the state level – identifies how legislatures and agencies prioritize HPV vaccination-related issues regardless

of federal policies. For the purpose of this article, we will refer to both statutes and regulations as laws given that they are both legally binding and states use both mechanisms to establish vaccination requirements.

Results

Of the 212 laws pulled from the search, 93 (43.9%) reference HPV vaccination in statute or regulation in 34 states and the District of Columbia. An additional three provisions were included in the results that clarified or expanded on provisions that were already collected. There are 52 statutes and 44 regulations in total (Table 2). State laws focus on a number of issues around HPV vaccination including vaccine finance, school-entry requirement, vaccine recommendation, public awareness, program development, vaccine access, vaccine education, plan development, and vaccine reporting.

Of the jurisdictions with law focused on HPV vaccination, only DC, Virginia and Rhode Island mandate HPV vaccination as a condition for school attendance. (Table 3) While Rhode Island and DC’s laws are gender neutral, Virginia’s is specific to female students only. DC’s law specifically references CDC vaccination standards and, while all states allow school vaccination exemptions, DC and Virginia create a specific parental opt-out for HPV vaccination. For example, Virginia’s administrative code states: “Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent’s or guardian’s sole discretion, may elect for the parent’s or guardian’s child not to receive the HPV vaccine.” Four other states (Arizona, Louisiana, South Carolina, West Virginia) explicitly exclude HPV vaccination from school vaccination requirements.

Table 1. Coding questions and sub-questions.

Question	Code
I. Does state law reference HPV Vaccination?	No Yes
II. Does state law mandate HPV vaccination as a requirement for school entry?	No Yes
II.A If no, does state law exclude HPV vaccination as a requirement for school entry?	No Yes
II.B If no, does state law recommend HPV vaccination or require the development and distribution of materials regarding the HPV vaccination to or for parents?	Offer Recommend Education
III. Does state law incorporate HPV vaccination into its educational curriculum?	No Yes
IV. Does state law establish other HPV vaccination requirements for children?	Youth Camp Assessment Foster Care
V. Does state law establish laws related to consent by minors for STI vaccination?	No Yes
VI. Does state law expressly provide pharmacists with the authority to vaccinate for HPV?	No Yes
VII. Under state law, is HPV vaccination explicitly required to be covered by individual or group insurance plans?	No Yes
VIII. Does state law establish other mechanisms to cover, fund, or reimburse for HPV vaccination?	No Yes
IX. Does state law require the reporting of HPV vaccination data?	No Yes
X. Does state statute or regulation establish special measures, task forces, or special awareness activities related to cervical cancer vaccination?	Public Awareness State Agency Program Strategic Plan

Table 2. Reference to HPV vaccination in relevant statutes and regulations by U.S. States and the District of Columbia, 2018.

State	State Law References HPV Vaccination	# of Statutes*	# of Regulations*
Alabama	No	0	0
Alaska	Yes	0	1
Arizona	Yes	1	0
Arkansas	Yes	0	2
California	No	0	0
Colorado	Yes	5	1
Connecticut	No	0	0
Delaware	Yes	0	1
Florida	No	0	0
Georgia	No	0	0
Hawaii	Yes	4	0
Idaho	No	0	0
Illinois	Yes	3	1
Indiana	Yes	3	0
Iowa	Yes	3	0
Kansas	No	0	0
Kentucky	No	0	0
Louisiana	Yes	1	4
Maine	Yes	0	6
Maryland	Yes	0	1
Massachusetts	Yes	0	2
Michigan	Yes	2	0
Minnesota	No	0	0
Mississippi	Yes	0	1
Missouri	Yes	1	0
Montana	No	0	0
Nebraska	No	0	0
Nevada	Yes	9	0
New Hampshire	Yes	0	1
New Jersey	Yes	1	0
New Mexico	Yes	2	0
New York	No	0	0
North Carolina	Yes	5	0
North Dakota	Yes	1	0
Ohio	Yes	0	1
Oklahoma	Yes	0	1
Oregon	Yes	1	2
Pennsylvania	Yes	2	0
Rhode Island	Yes	0	1
South Carolina	Yes	1	0
South Dakota	No	0	0
Tennessee	No	0	0
Texas	Yes	2	0
Utah	Yes	1	0
Vermont	No	0	0
Virginia	Yes	1	5
Washington	Yes	1	0
West Virginia	Yes	0	7
Wisconsin	No	0	0
Wyoming	Yes	0	3
Washington DC	Yes	2	3

*Laws may include the similar language or requirements across separate individual provisions.

While only three jurisdictions require HPV vaccination as a condition for school attendance under state law, other states have established additional strategies to promote

HPV vaccination in school children. (Table 3) Four states (Arkansas, Delaware, West Virginia, Wyoming) recommend HPV vaccination in law. South Carolina allows its Department of Health and Environmental Control to offer HPV vaccination to adolescent students. Additionally, 12 states require or recommend the development or distribution of information to parents related to HPV vaccination for parents. Two states (Iowa and Texas) require HPV vaccination information to be incorporated into education curricula.

States also have laws that promote childhood vaccination in non-educational settings. This includes the requirement in Maine that youth camps and similar programs assess HPV vaccination status of their campers. Arkansas requires foster parents to assist in ensuring children are vaccinated for recommended vaccinations, including HPV.

Laws that seek to improve HPV vaccine access include those that provide vaccination authority to pharmacists and allow minors the ability to give consent for the vaccination (Table 4). Five states (Hawaii, Indiana, Iowa, West Virginia, Wyoming) and Washington DC expressly provide pharmacists with the authority to vaccinate for HPV by listing it in law. As noted by Dingman & Schmit, many states provide general authority to vaccinate without listing each vaccine-preventable disease by name. The express listing of HPV indicates that state legislators and agencies specifically considered HPV in their policymaking process.¹⁴

Illinois allows minors 12 years or older to consent to HPV vaccination and Utah allows minors to consent if they are an abandoned minor as represented by the patient. Some jurisdictions require individual and group health insurance plans to cover HPV vaccination while numerous states require HPV vaccine coverage via Medicaid and other health programs. These laws assure the coverage of HPV vaccination by individual, group, HMO, and health benefit insurance plans via Medicaid, or through other public health programs such as public health or family planning (Alaska, Colorado, Illinois, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nevada, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, and West Virginia).

Finally, public health strategies are also incorporated into statutes and regulations. West Virginia and Washington DC require their departments of health to collect HPV vaccination data. Colorado, North Dakota, Texas, and Washington DC require public awareness activities. Further, Colorado, Illinois, and Indiana require the establishment of department of health programs or strategic plans that include activities related to HPV vaccination.

No single coding question included results from more than one-third of the jurisdictions, and many states had laws related only to one aspect of HPV access such as educational materials or vaccine financing. Eight of the ten coding questions included results from six or fewer states. The coding questions that had the most state activity were related to developing and distributing HPV vaccination materials for parents and those related to mechanisms to fund and reimburse for the vaccination.

Table 3. States with laws related to school entry, parental education, U.S. States and District of Columbia – 2018.

	State law mandates HPV vaccination as school-entry requirement	State law excludes HPV vaccination as school-entry requirement	State law recommends HPV vaccination for school children	State law requires the development and distribution of materials regarding the HPV vaccination to parents	State law allows the department of health to offer HPV to students	State law requires incorporation of HPV vaccination information into educational curriculum
Arizona		X				
Arkansas			X			
Delaware			X			
Illinois					X	
Indiana					X	
Iowa						X
Louisiana		X			X	
Michigan					X	
Missouri					X	
New Jersey					X	
North Carolina					X	
Rhode Island	X					
South Carolina		X			X	
Texas						X
Virginia	X				X	
Washington					X	
West Virginia		X	X			
Wyoming			X			
Washington DC	X				X	
State Total	3	4	4	12	1	2

Discussion

Despite finding that 34 states and the District of Columbia reference HPV vaccination in statutes or regulation, there were remarkably few state laws on this topic, and few states with laws across multiple coding categories as outlined above.

The observation that HPV vaccination education was a common policy outcome among states enacting law related to HPV vaccination may be an artifact of what Abiola et al. observed: that vaccine education policy emerged as a negotiated outcome in 2006 state legislative policy processes due to the initiation of an HPV vaccination policy agenda by Merck and Women in Government, the non-partisan association of women state legislators.²³ Findings from our study suggest continued state reluctance to develop a policy to expand HPV vaccination. However, the fact that 17 states implemented financing policy to expand HPV vaccine access may indicate that, today in the United States, healthcare financing of HPV vaccination is the most achievable policy change and has benefits, because such policy structurally impacts access to HPV vaccination uptake as shown in populations that are usually un/underinsured.² These more innocuous, but potentially impactful policies may, in fact, change the HPV vaccination environment, despite the fact that the majority of states have not made HPV vaccination the “default choice.”³⁴

Even within the states that have a number of HPV vaccination-related laws, one cannot presume that a higher number of statutes and regulations indicates a comparatively higher commitment to improving HPV vaccination access across states.

This is because individual states and individual acts or rulemaking within a state can vary substantially in terms of the length of a single provision when it is codified. For example, a state with ten provisions is not necessarily more active than a state with two, if the two provisions run for a much longer period than the ten. Further, the number of results generated in the collection of laws for this study might be a function of the search, where search strings can be crafted more narrowly or more broadly with adjustments in the terms and connectors. While the number of provisions is not necessarily an indicator of commitment, the study found that there were nearly as many individual regulatory provisions in our results as individual statutory provisions. This reinforces the value of research across both legislation and rulemaking.

Overwhelmingly, jurisdictions tend to use statutes and regulations to promote HPV vaccination, such as financial incentives or requirements for public education campaigns as opposed to laws that limited vaccination. However, there are still laws that function in practice to curb vaccination. State laws that explicitly exclude HPV vaccination from school-entry requirements and those in DC and Virginia that create an express parental opt-out for the vaccination are such examples. Opt-out provisions that provide so much discretion to parents on HPV vaccination that, in practice, there is no realistic way to enforce the requirements.^{35–38}

Another emerging issue which has been explored elsewhere is the tendency to focus on females for HPV related policy and interventions.^{38–41} Virginia’s language of limiting its

Table 4. States with laws that promote vaccine access, U.S. States and District of Columbia – 2018.

	State law allows consent by minors for STI vaccination	State law expressly provides pharmacists with the authority to vaccinate for HPV	HPV vaccination is explicitly required to be covered by individual or group insurance plans under state law	State law establishes other mechanisms to cover, fund, or reimburse for HPV vaccination
Alaska				X
Colorado			X	X
Hawaii		X		
Illinois	X		X	X
Indiana		X		
Iowa		X		
Louisiana				X
Maine				X
Maryland				X
Massachusetts				X
Mississippi				X
Nevada			X	X
New Hampshire				X
New Mexico			X	X
Ohio				X
Oklahoma				X
Oregon			X	
Pennsylvania				X
Utah	X			
West Virginia		X		X
Wyoming		X		
Washington		X		
DC				
State Total	2	6	5	15

school-entry requirements to only female students does not reflect CDC guidelines⁴¹ and shifts the burden of cervical cancer prevention entirely to female students. As we note elsewhere,⁴⁰ this is likely reflective of the changing science around HPV and the delay in reflecting such science in policy, as Virginia enacted this law in 2007,⁹ the same year that CDC's Advisory Community on Immunization Practices (ACIP) issued its first recommendations related to HPV vaccination.⁴² These recommendations exclusively applied to females.⁴² Following evolving data on the efficacy of HPV in clinical trials, ACIP's recommendations and guidelines began contemplating male vaccination in 2009 with additional changes in policy in subsequent years.⁴³ DC's statutory code contemplates both male and female students in their school vaccination statute, and its regulatory code applies neutrally to students generally. Similarly, Rhode Island's regulatory code establishes vaccination requirements for students without reference to gender. That said, a study of the gendering of HPV vaccination law across time would be an important contribution to the literature.

This study is subject to several limitations. First, other mechanisms independent of statutes and regulations can be used to promote HPV vaccination that was not collected as part of this study. This includes state agency policies such as state cancer plans, local government actions, and case law. Nor does this study include a summary of all federal laws that might impact HPV vaccination. Additionally, the study did not analyze the funding, implementation, or enforcement of these laws, which affect the impact of these laws in practice.

Next, laws that do not expressly reference HPV vaccination can also be relevant to HPV vaccination promotion. For example, laws that promote cancer and sexually transmitted infection prevention or those that fund public health prevention activities might impact HPV vaccination rates. There is, for example, some evidence that non-targeted adolescent vaccine school requirements may in fact impact HPV vaccination rates.⁷

This study can be used by policymakers in jurisdictions that are considering establishing HPV vaccination promotion interventions in state law and highlighting the limited statutory and regulatory efforts that have been implemented to promote HPV vaccination. Importantly, this study can also be used to conduct evaluations of the efficacy of statutory and regulatory strategies in increasing HPV vaccination rates.

Methods

This study utilized legal epidemiological research methods to collect and analyze statutes and regulations.^{30–33} These practices include utilizing a standardized search string; utilizing the same database or databases to collect laws across all jurisdictions, developing inclusion and exclusion criteria, preserving laws separately from the database in the event of changes to the language, and developing a detailed research procedure that can be made available to a requestor.^{30–33}

Statutes and regulations from the 50 states and Washington, DC, were collected on September 3, 2018 using WestlawNext, an online legal database. The following search string was crafted based on the database's terms, connectors

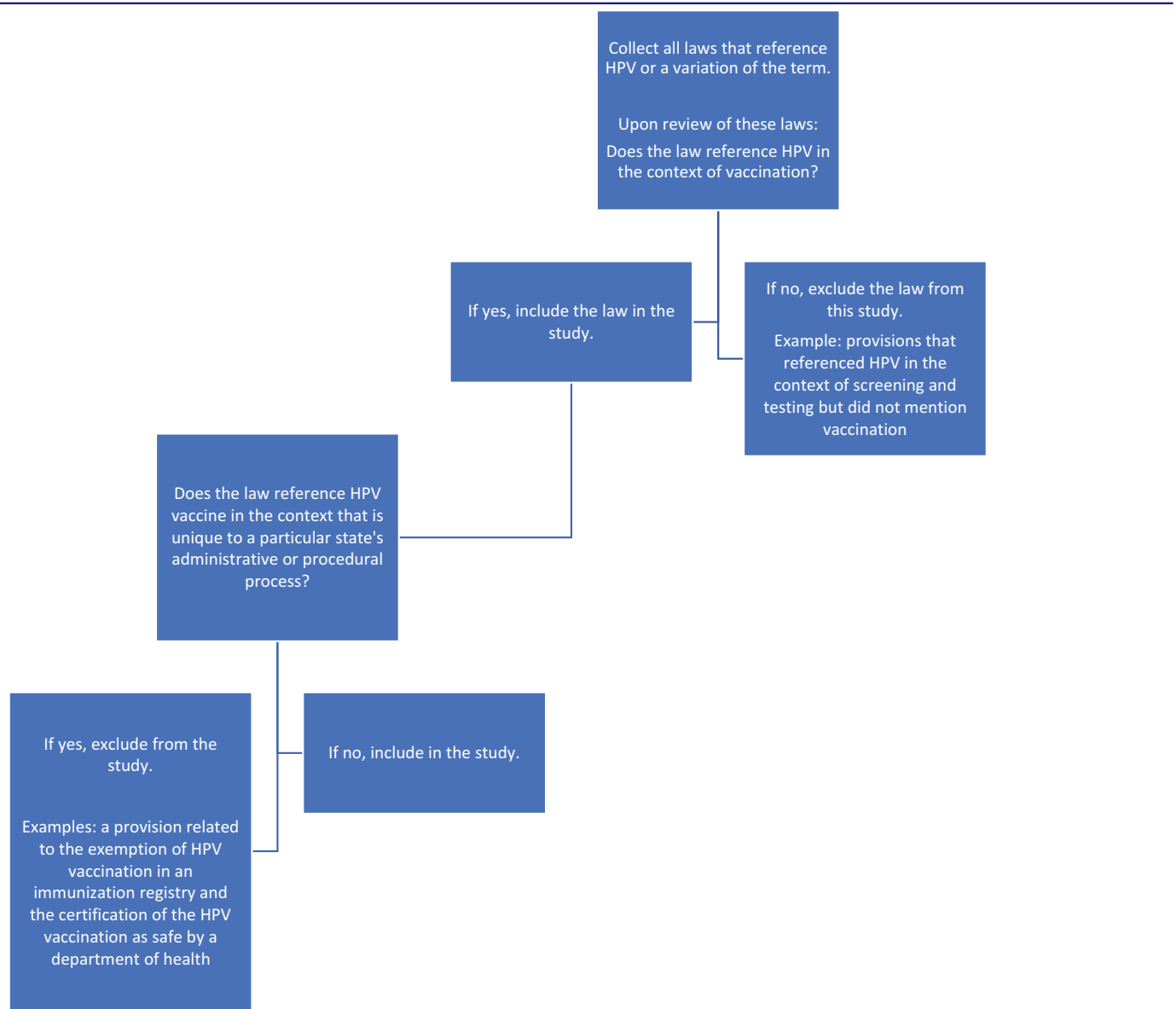
and relevant terminology to identify laws that referenced HPV vaccination: adv: SD((cancer/5 vaccin! immuniz!) (s.t.i. s.t.d. “sexual health” “sexually transmitted infection” “sexually transmitted disease”/5 vaccin! immuniz!) h.p.v. “human papillomavirus” gardasil cervical).

From this search, 212 statutes and regulations were identified. Following an initial review of these laws, additional statutes and regulations were added to the dataset when referenced in the provisions already collected and were relevant to HPV vaccination, or when additional provisions from the same sections or chapters of the code clarified the requirements of the original statutes and regulations. These were collected in October and November 2018. All statutes and regulations generated from the search were preserved in pdf format, and the research process was recorded in a research procedure document.

Inclusion criteria were developed following a research team conference and held that only laws expressly referencing HPV vaccination were considered relevant in this study (Table 5). Thus, for example, provisions that referenced HPV in the context of screening and testing but did not mention vaccination were excluded. At least two additional laws that mentioned HPV vaccination but were found to be both unique to the specific jurisdiction’s administrative or procedural process in that state were also excluded from the analysis. These included a provision related to the exemption of HPV vaccination in an immunization registry and the certification of the HPV vaccination as safe by a department of health. These exclusion criteria were documented in the research procedure.

Statutes and regulations relevant to the study were analyzed and coded based on their legal attributes into ten broad coding questions and several sub-questions (Table 1). These

Table 5. Inclusion and exclusion criteria flow chart.




coding questions were revised as nuances across states were identified. The analysis sought to describe the legal attributes, variabilities, and nuances in the laws across jurisdictions.

Disclosure of potential conflicts of interest

Within the last year Gregory Zimet received an honorarium from Sanofi Pasteur for work on the Adolescent Immunization Initiative and received travel support from Merck to attend a conference on HPV vaccination.

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