"Revisiting HPV Disease Policy at the State Level: Are There Next Steps?"
Meeting Summary of Potential Next Steps

On August 16, 2013, The National Coalition of STD Directors (NCSD) and the American Sexual Health Association (ASHA) convened a small group of stakeholders from the policy, HPV, immunization and sexual health fields to brainstorm potential policy actions to enhance HPV disease awareness with a particular focus on scaling up HPV vaccination rates (Appendix A: Participant List).

The purpose of this meeting was two-fold: 1) discuss lessons learned from past and current HPV disease practices and policies; and 2) develop three to five policy actions to scale up HPV disease awareness and prevention. The meeting attendees were provided with a primer paper in advance of the meeting which can be found here (Appendix B: Meeting Concept and Appendix C: Meeting Primer). We hope both the primer document and this brief meeting report provides some helpful thinking from experts in the field for those interested in moving HPV policy forward at the state or federal level.

Over the course of the meeting itself, a number of important issues emerged, leading and aligning with the following potential next steps and policy actions. This summary report opted to include seven key points that surfaced during the meeting.

Next Steps:

1. **Create and support dissemination of a tool box of state and/or local policy initiatives that de-emphasize school-focused mandates.**
   There was a lengthy discussion that focused on the role of school-based mandates in improving vaccination rates. One perspective suggested that mandates are an effective tool to achieve near universal vaccination rates when overall existing coverage is already high. In the case of HPV vaccination however, there is a sense that it "strong-arms" a majority of the affected population into getting the vaccine. Moreover, as a policy, they have not proven politically palatable. The group discussed moving away from mandates as a way to increase vaccination rates. For states still interested in mandates, encourage the use of language such as "requirements." There was a sense that the "mandate" language has become too loaded and arouses immediate opposition. In addition, assistance could be provided to interested policymakers with model legislation for requirements, including an analysis of what are acceptable exemptions or opt-outs from the requirement.

Possible Policy Action:

- **Develop model legislative language for "requirements" and exemptions or opt-outs.**
- **Develop model legislative language for other HPV disease prevention and awareness policies, such as "inform and offer" legislation and minor consent as highlighted in the meeting primer document.**
- **Provide technical assistance to states/localities interested in pursuing HPV related legislation, policy guidance and/or regulatory changes.**

2. **Gain a greater understanding of the range of investments by the Department of Health and Human Services (DHHS), broadly, and the Centers for Disease Control and Prevention (CDC), specifically, in order to advance HPV disease awareness and prevention**.
   There was a strong feeling that CDC is doing a large amount of work across several centers and divisions to advance the prevention of HPV disease, but that the advocates may not be well acquainted with all that is being done and how it fits into the role of advocates to advance greater awareness of HPV disease and increase vaccination rates. Specific groups include the national Advisory Committee on Immunization Practices (ACIP) and numerous CDC Divisions including Immunization Services, STD Prevention, Cancer Prevention and Control, and Adolescent and School Health. There may be other efforts underway as well in other parts of DHHS.

   Possible Policy Action: To be determined, but align to support CDC's efforts and possibly include federal-level advocacy for increased resources to CDC to support HPV disease awareness and increase vaccination rates. More immediately, participants sought some type of presentation from DHHS and its agencies on the work currently being conducted.

3. **Strengthen outreach with providers to educate on the existing vaccination recommendation.**
   In order to increase HPV vaccination rates, healthcare providers must make strong HPV vaccination recommendations to parents of adolescents. A number of efforts are underway, including at CDC, to increase provider education and communication regarding HPV vaccination, but clearly, more is needed at the provider, parent/caregiver, and age-appropriate patient levels. It was felt that a number of professional associations of providers could also partner with other groups and support greater education of providers about following the ACIP vaccination recommendation. Target groups might include organizations of primary care physicians (e.g. family physicians, obstetricians/gynecologists, internal medicine doctors, pediatricians and other adolescent medicine specialists, etc.) as well as nurse practitioners, physician assistants, pharmacists, and other types of direct caregivers for adolescents and families.

   Possible Policy Action:

   - **Support the allocation of actual dollars and other policy efforts to fund efforts to advance provider communication and recommendations.**

- **Work with provider professional associations to develop and/or strengthen policies and initiatives that advance provider understanding and comfort in discussing and providing HPV vaccination.**

4. **Facilitate learning opportunities between adolescent health care providers and those working in cancer prevention & clinical oncology to increase provider awareness and focus on HPV disease prevention.**
   Meeting attendees felt that critical learning opportunities are not occurring among adolescent health care providers, who can vaccinate and prevent certain HPV-related cancers through vaccination, and those providers working with patients who develop HPV-related cancers. Such learning opportunities could help illustrate the importance of early vaccination, create dialogue among the providers operating on each end of this continuum, and ultimately, scale up vaccination among adolescent-serving healthcare providers.

   Possible Policy Action: Engage provider networks to host such exchanges and allocate resources to create supplementary materials to extend the dialogue beyond those directly contacted and engaged. Policymakers themselves – from legislators to healthcare provider organization CEOs – could act as key catalytic actors in getting parties to the table.

5. **Request temporary exemption for safety net programs – such as reproductive health, STD clinics, pharmacies in certain states, etc. – to deliver HPV vaccine to adolescents (less than 18 years of age) who are eligible for Vaccines for Children (VFC) coverage.**
   Safety net providers often lack the resources or even key patient audiences to make provision of all adolescent health vaccines a part of their services. Yet, they can and do make significant contributions to HPV vaccination rates, but cost and availability remain a challenge. In discussing possible financing mechanisms, meeting attendees discussed having a temporary exemption for safety net programs to provide HPV vaccination utilizing VFC funding—without requiring the site to provide other adolescent vaccines, a current requirement of VFC funding. This network of providers can play a key role, in particular, with the "catch up" vaccinations of older eligible patients. This exemption could have a "sunset" policy built in—meaning once a certain percentage of overall population coverage was reached (ex. 80%), the exemption would end.

   Possible Policy Action: Advocates would work toward securing this exemption. Additional resources would be needed to support technical assistance to safety net providers on how to apply for VFC funding once the exemption is secured. Advocates should continue to pursue other creative ways to fund vaccination, as well as educate insured consumers and their providers about its coverage under the Affordable Care Act as a covered preventive service.

6. **Connect with 317 Coalition for advocacy and funding of HPV vaccination.**
   Section 317 of the Public Health Service Act provides a safety net program of grants to states to immunize children, adolescents and adults who have no other means to pay for vaccinations. To

help increase HPV vaccination and ensure funding, advocacy for Section 317 at the Federal level may be necessary. National organizations interested in increasing HPV vaccination can partner with immunization organizations to education policymakers on the importance of Section 317. With discretionary funding from the federal government for health services diminishing, more needs to be done to show the importance of this infrastructure, especially for vaccines that need higher up-take rates, like HPV.

Possible Policy Action: Advocates in support of increased awareness of HPV disease prevention should work with and participate in the 317 Coalition.

7. **Create HPV policy-related project in a select number of states to test strategies.** National organizations can partner to secure funding from various sources including industry, immunization organizations, cancer prevention groups, STD prevention organizations, and reproductive health organizations or foundations, to pilot various policy strategies in a small number of states to increase HPV disease awareness and increase vaccination rates.

   Possible Policy Action: Secure funding for state or local advocates to advance various strategies to support increased vaccination uptake. Exact strategies would be determined by state and local partners and national advocates can learn from these efforts and begin to disseminate best policy practices.

During the rich discussion among meeting participants, many other issues surfaced, which though they may not be associated with potential policy actions, we felt nonetheless compelled to highlight as important:

1. A three dose vaccine schedule is not ideal. Hopes were expressed for a single dose vaccine to be developed and/or additional research to show protective value of less than all three doses for existing vaccines.
2. Advocates and program implementers should capitalize on investments into school-based health centers and their delivery of sexual health services through CDC's Division of Adolescent and School Health (DASH) as a way to increase HPV vaccination.
3. Additional efforts are needed to analyze the complexities of vaccine registries and the confidentiality issues presented by minors receiving the HPV vaccine. Additional materials may be warranted, for example, an information toolkit on how to code these vaccines (especially for minors in those states that do not require a parent's consent) so that they do not show up on public vaccine registries.
4. Establishing additional incentives for providers that may increase vaccination rates. For example, working toward a Healthcare Effectiveness Data and Information Set (HEDIS) measure for HPV vaccination.
5. Stronger and immediate efforts are needed to increase vaccination rates of boys.

6. There is a need to address “catch-up” with the now-20-year olds who are still unvaccinated. One thought was to consider specific resources aimed at gynecologists. Many women use gynecologists as their primary care doctor, increasing their understanding of vaccination and HPV and getting them on board with recommending and providing it can be an important step in this “catch up” of young adult women.
7. Focus on other levers to get HPV vaccination worked into the rare healthcare provider visits of young people. For example, can HPV vaccination be added to forms for sports physical or included along with other adolescent vaccine platforms?
8. Focus on health disparities, in the south as one example of a geographic focus. What can be done about populations in southern states that are disproportionately not getting the HPV vaccine and have higher rates of cervical cancer?

Note: These steps represent ideas discussed by the HPV meeting attendees; they do not represent a consensus agreed upon by the majority of the group and should not be treated as such.

Appendix A: Participant List

Revisiting HPV Disease Policy at the State Level: Are There Next Steps?
Friday, August 16, 2013
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Appendix B: Meeting Concept Paper

"Revisiting HPV Disease Policy at the State Level: Are There Next Steps?" Meeting

Concept:

Human Papillomavirus (HPV) is the most common sexually transmitted disease in the United States with over 6 million new cases occurring each year. Currently there are two HPV vaccines; a quadrivalent vaccine manufactured by Merck which prevents HPV 6, 11, 16, and 18 and a bivalent vaccine manufactured by GlaxoSmithKline which prevents HPV 16 and 18. Both vaccines are FDA approved for use in females ages 9-26 years and the quadrivalent vaccine is approved for use in males ages 9-26 years. The Advisory Committee on Immunization Practices (ACIP) recommends vaccination for both females and males to prevent anogenital cancers, including cervical and anal cancers, as well as genital warts (quadrivalent vaccine only).

Following the initial ACIP recommendations for HPV vaccinations for females in 2007, many states attempted to scale up HPV vaccination through school entry mandates for females; however only Virginia and the District of Columbia were successful. During this time period, other HPV vaccination policies were enacted including mandating insurance coverage of the vaccine, implementation of public education campaigns, and funding for free vaccines. Over the past few years new HPV legislation and polices have dwindled.

Additionally, new developments in diagnostics have advanced the ability of clinicians to make better decisions around patient management, including the most appropriate follow-up diagnostic procedures, treatment options, and monitoring.

Over the course of time, many lessons have been learned; more research regarding males and HPV related cancers has been published; and new ACIP recommendations have been released. Despite the initial policy initiatives and public media campaigns, HPV vaccination numbers for series completion (3 doses) remain low – 35% for females and 1% for males. Testing rates also remain low and not well understood by both providers and patients alike. Given this information and a variety of other factors including full implementation of the Affordable Care Act, it is time to revisit and coordinate policy efforts to ensure access to and effectively increase the number of young people who are fully aware of HPV disease and the need for vaccination and testing.

The National Coalition of STD Directors (NCSD) and the American Sexual Health Association (ASHA) are bringing together a small group of stakeholders from the policy, HPV, immunization and sexual health fields to brainstorm potential policy actions to scale up HPV disease awareness with a particular focus on bringing HPV vaccination to scale across the United States and especially in areas with low vaccination numbers, such as the South. An additional emphasis is also on the role of public health STD programs in advancing HPV disease awareness and policy development.

Purpose

The purpose of this meeting is to:

1) Discuss lessons learned from past and current HPV disease practices and policies
2) Develop three to five policy actions to scale up HPV disease awareness and prevention

Potential Invitees:

- National Non-Profit Partners working in sexual health, immunization and/or cervical cancer
- Legislative and Advocacy Focused Non-Profits
- National Public Sector Partners working in sexual health such as agencies of the Department of Health and Human Services
- Industry Partners

Appendix C: Meeting Primer

"Revisiting HPV Disease Policy at the State Level: Are There Next Steps?"
Meeting Primer

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Current State of Human Papillomavirus Disease

Human Papillomavirus or HPV is a sexually transmitted disease (STD) that encompasses over 100 unique strains. HPV is the most common sexually transmitted disease (STD). According to estimates from the U.S. Centers for Disease Control and Prevention (CDC), almost every sexually active person will become infected with HPV at some point in their life.[i] In 2008, there were an estimated 14 million new HPV cases.[ii] Young people ages 15 - 24, who make up only 25% of the sexually active population, accounted for 49% of those new cases.[iii]

While most HPV infections clear the body within one to two years, others are more persistent and can lead to precancer and/or cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers as well as genital warts. Annually, 33,369 HPV-associated cancers are diagnosed.[iii] The CDC estimates that 26,000 new cancers are attributable to HPV annually.[iv] The two most common HPV attributable cancers are cervical followed by oropharyngeal.[v] Annually there are 300,000 new cases of genital warts with a 40% recurrence leading to multiple clinical visits, treatments, and psychosocial stigma.[vi] Another possible but rare outcome of HPV is recurrent respiratory papillomatosis (warts in the throat).[vii]

HPV Prevention - Current Vaccine Recommendations

Today, there are two FDA approved vaccines that prevent certain types of HPV - a bivalent HPV vaccine, Cervarix (GlaxoSmithKline), and a quadrivalent HPV vaccine, Gardasil (Merck). Cervarix is directed against two oncogenic types (HPV 16 and 18) and Gardasil is directed against the same two oncogenic types as well as two nononcogenic types (HPV 6 and 11).

The Advisory Committee on Immunization Practices (ACIP), recommends the bivalent or quadrivalent HPV vaccine for females aged 11-12 years, but the series may be started as early as age 9. For females ages 13 to 26 who have not been vaccinated or who have not completed the series, either vaccine is recommended. If a female reaches the age of 26 before the vaccination series is completed, remaining doses can be administered after age 26. ACIP recommends vaccination with either vaccine for prevention of cervical cancers and precancers in females. The quadrivalent HPV vaccine is indicated for use in females to prevent vulvar and vaginal cancer; cervical cancer, genital warts; anal cancer and other associated precancerous lesions due to HPV 6, 11, 16, and 18.[viii] For males, the ACIP recommends the quadrivalent HPV vaccine for ages 11-12 years, but may be started as early as nine years old and given through 26 years old, to prevent genital warts and anal cancer.[ix] Both vaccines might provide protection against some other HPV-related cancers in addition to cervical cancer, but this research is ongoing.

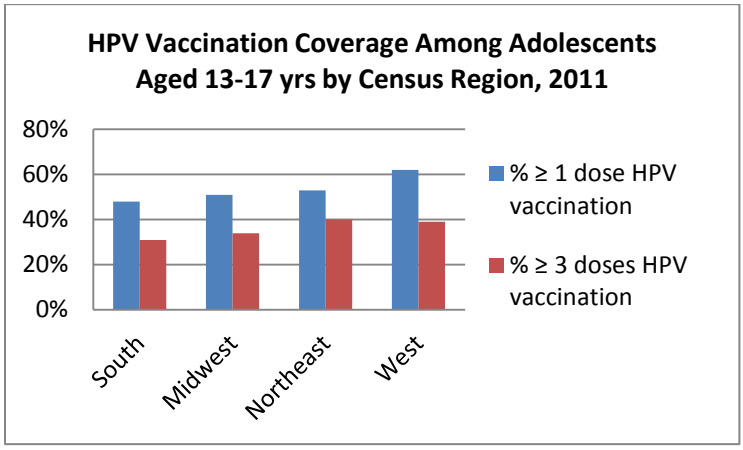
These ACIP recommendations are even more important with the passage of the Affordable Care Act (ACA). The ACA requires group and individual private insurance plans to cover certain preventive health services without any co-pays or costs to the patient. These include all services that receive an "A" or a "B" rating by the U.S. Preventive Services Task Force (USPSTF); all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP); certain children's services; and women's preventive services identified by the U.S. Department of Health and Human Services (HHS).

HPV Vaccine Data

In the U.S. in 2012, 53.8% of females aged 13-17 years received at least one dose and 33.4% received at least 3 doses of the HPV vaccination; similar numbers were found in 2011.[x] According to the CDC, if the HPV vaccine was administered at the same time as other vaccines, coverage for at least one dose would have been 92.6%.[xi] For males in the same age range, 8% received at least one dose and 1.3% received at least 3 doses of the HPV vaccination (2011).[xii] This is only a slight increase from 2010 data.

When you look across the nation, there appears to be some differences by regions. In the South (census region) fewer females are getting the vaccine than other areas of the United States.[ix] According to the CDC, only 48% of females aged 13 – 17 in the South received one or more of the recommended HPV vaccination shots as compared to 53% in the Northeast, 51% in the Midwest, and 62% in the West.[ix] In addition, just 31% of females aged 13 - 17 in the South received all three shots as compared to 40% in the Northeast, 34% in the Midwest and 39% in the West.[ix]

Figure 1



Regardless of the HPV vaccination coverage rates, it appears that vaccine-type HPV prevalence has decreased among females 14-19 years of age since 2006. HPV infections (HPV-6, 11, 16 and 18) decreased from 11.5% from 2003-2006 to 5.1% from 2007-2010, representing a 56% reduction in girls ages 14 -19 years.[xiii] Other research shows declines in rates of genital warts from 2.9 per 1,000 person-years in 2006 to 1.8 in 2010.[xiv] Experts suggest that factors contributing to this decline could be herd immunity, high effectiveness with less than three doses of the vaccine, and/or changes in sexual behaviors.[xv]

HPV Screening and Testing Recommendations

Current national recommendations for HPV screening and testing only apply to women. The United States Preventive Services Task Force (USPSTF) recommends screening for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and HPV DNA-type specific testing every 5 years (A Recommendation).[xvi] Again, with the passage of the ACA, this "A" Recommendation means that group and individual private insurance plans must cover these cervical cancer screenings without any co-pays or costs to the patient. In addition, because of the ACA, health plans must also cover high-risk HPV DNA testing in women with normal cytology results without any co-pays or costs to the patient.[xvii]

The USPSTF has no screening recommendations for oral, penile, or anal cancer. While there are no national recommendations for anal cancer screening, many experts recommend screening HIV positive individuals for abnormal changes to the lining of the anal canal.[xviii] For example, the New York State Department of Health's AIDS Institute, also the member of the National Coalition of STD Directors for the state of New York, recommends that an anal Pap test be done at baseline and annually thereafter for certain populations such as men who have sex with men (MSM); any patient with a history of anogenital condylomas; or women with abnormal cervical and/or vulvar histology.[xix]

HPV Policy Background

After the FDA approval of Gardasil in 2006 and the 2007 ACIP recommendations for vaccination of girls ages 11-12 years, policy efforts across the nation exploded. Since 2006, forty-one states and the District of Columbia, introduced HPV-vaccine related legislation ranging from school entry mandates to educational campaigns; however only twenty-two states have enacted any such legislation.

The majority of HPV-vaccine related legislation that passed since 2006 was related to funding the vaccine and educational efforts. Legislation related to funding included requiring insurance companies to provide coverage; adding the HPV vaccine to the list of Medicaid benefits; and allocating funding to offer the HPV vaccine. Legislation related to education included establishing public awareness campaigns or coalitions; providing HPV and HPV vaccine information to parents of girls entering sixth grade; and developing and distributing educational materials.

In 2007, twenty-four states and the District of Columbia, introduced legislation to mandate the HPV vaccine for schools.[xx] Since then legislation related to mandates has significantly dropped off; only five states have pursued mandates since 2007.[xxi] Texas was the only state to enact a mandate through executive order from the governor; however that was later over turned through legislation. Virginia and the District of Columbia were successful in passing school mandates however both have very broad opt-out policies. For example in Virginia, parents may opt-out their child for religious conflicts; medical issues; or for any other reason because HPV is not communicable in a school setting.[xxii]

While many states attempted to enact HPV vaccine mandates, most were unsuccessful. There are a variety of factors for these failures. One factor was the sexual nature of HPV transmission. This led to misinformation including a connection, not supported by research, between the HPV vaccine and promiscuity. This is similar to other disproven myths like sex education or condom distribution leading to early sex. The HPV vaccine also made parents nervous that they would have to have a conversation with their child about sex before they were ready. And lastly, many thought that if HPV is spread through sexual contact and not through casual contact, then a school mandate was unnecessary.

Another factor leading to unsuccessful mandate legislation was vaccine safety and efficacy concerns. Some felt that the vaccine had not been available for a sufficient period of time to establish it as safe and effective, regardless of the science used to inform the FDA that ultimately led to its approval. In addition, misinformation about adverse effects was abundant in the media.

The third factor was related to concerns that vaccine manufacturers were overly involved in setting the policy agenda. Vaccine manufacturers are often involved in providing information to legislators as well as policy recommendations. In this case, there was a well-publicized scrutiny of Merck, the manufacturer of Gardasil, citing that the company put its weight behind pursuing school-entry mandates. In addition, some also expressed concern about financial contributions to groups of legislators and political campaigns. Some concerns were raised over Merck's funding, through unrestricted educational grants, to Women in Government (WIG), a group of women state legislators

from across the nation, who had identified cervical cancer as a priority. Many of WIG members pursued HPV-vaccine related legislation in their own states. In Texas, following the governor's executive order mandating HPV-vaccine for girls, there was a controversy over Governor Perry's relationship with his former chief of staff who also worked as a Merck lobbyist and a $5,000 campaign contribution from Merck. This led to media stories and other political figures saying that vaccine companies were buying legislation/legislatures. The veracity of the coverage and claims is suspect, but it nonetheless clouded the potential public health benefit of scaled up HPV vaccination.

HPV Policy – Moving Forward

HPV related legislation has slowed down in the most recent legislative sessions. Following a strong push towards school mandated vaccines, many states have not pursued any HPV related legislation. There are still states who are trying to repeal HPV related legislation or specifically excluded the HPV vaccine in other related vaccine legislation for example Georgia and North Carolina. For example, in 2013 officials in North Carolina added at least six vaccines to the list of vaccines that pharmacists could administer; however the HPV vaccine was not included.[xxiii]

A few states continue to introduce bills for school mandates. In 2013, at least 3 states – Virginia (proposed to add males to current mandate), Kentucky, and New York - attempted to pass school mandates, though none became law. Instead of pursing mandates, some states are looking toward "inform and offer" legislation that provides information to parents and opportunities to have their child vaccinated. South Carolina attempted such efforts in 2011-2012 and while it passed both the House and Senate, the Governor vetoed the bill. The South Carolina law would have specifically allowed the Department of Health and Environmental Control to offer (not mandate) the cervical cancer vaccination series to adolescent enrolling in the seventh grade and allow for the development of information materials regarding the vaccine.[xxiv]

There continues to be an interest in building public awareness about cervical cancer and HPV through coalition building; recognition of January as cervical cancer awareness month; or by providing parents with educational materials through schools. Finally some states are pursuing legislation beyond education and school mandates including minor consent laws and pharmacists' administered vaccine.

Minor Consent Laws

Currently all 50 states and the District of Columbia allow minors to consent to STD services (11 states require the minor to be a certain age); however some of those laws and regulations specifically use the language of STD "testing" and "treatment". In some instances, the specificity of the language related to "testing and treatment" may leave out services deemed to be "preventive" in nature, such as the HPV vaccination. As a result, states such as California have closed a cap in their minor consent laws related to STD services and added STD prevention to their minor consent laws. In 2011, AB 499 in California was signed into law. This allows a minor who is 12 years of age or older to consent to medical care related to the prevention of a sexually transmitted diseases.[xxv] This year, New York State attempted to pass legislation to amend their minor consent law and allow minors to consent to preventive medical care for STDs. This legislation is still pending. Both California and New York are examples of possible future legislation for other states.

Pharmacists Administered Vaccine

Another policy pathway to increase vaccination has been expanding the array of healthcare practitioners permitted to administer the vaccine. For example, in 2013 legislation was passed in Indiana to add the

HPV vaccine to the list of vaccines that pharmacists are allowed to give to clients with a doctor's prescription. Forty-one other states currently allow pharmacists to administer the HPV vaccine through either established protocols or through a doctor's prescription; however various states have age requirements limiting who can receive the vaccine.[xxvi] As of June 2012, ten states had no age restrictions but seventeen states required the patient to be at least 18 or 19 years old; this falls outside of the ACIP recommended initiation of the HPV vaccine at 11-12 years old. Possible future legislation could recommend eliminating or lowering the age restrictions to allow for HPV vaccination initiation within recommendations.

Moving Forward

Newly published science on the effectiveness and continued safety of the HPV vaccine may provide policymakers and advocates an opportunity to revisit and/or pursue HPV policy with more robustness. However, the downside to such a decline in HPV infections, given low vaccine completion rates, may also give those opposed to the HPV vaccine an opportunity to say that higher vaccine uptake may be unwarranted. However, the data on other cancers and HPV are still in their infancy and such conclusions are at best, premature and shortsighted. Still, it is a weak flank to consider in policy discussions.

What is clear is that we are not gaining ground in scaling up this important public health initiative and in particular, the policy efforts to stimulate HPV vaccine uptake and broader HPV disease awareness have virtually stalled. It is time to consider if indeed there are "next steps" on the policy front and if so, to reinvigorate efforts to advance those policies.

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