

COMMENTARY

Increasing HPV vaccination through policy for public health benefit

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ABSTRACT

Vaccines against specific types of human papillomavirus (HPV) linked to cancer and other diseases have been met with mixed acceptance globally and in the United States. Policy-level interventions have been shown to be effective in increasing public health benefit. Government policies and mandates may result in improved HPV vaccination coverage and reduced disease burden, and alternative policies that improve unhindered access to HPV vaccination may allow success as well. The purpose of this commentary is to summarize policy efforts to maximize the public health benefit of HPV vaccination. We examine selected examples of HPV vaccination policy in global contexts and in the United States.

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Vaccination against prominent types of anogenital human papillomavirus (HPV) has the potential to dramatically reduce HPV-associated diseases, including cancer. In 2014, the World Health Organization (WHO) reiterated support for HPV vaccination to be included in national immunization programs emphasizing the potential public benefit of vaccination, exemplary safety profile, and cost-effectiveness among other advantages.¹ In the United States (US), the Advisory Committee on Immunization Practices has recommended HPV vaccination since 2006.² However, uptake of HPV vaccination has varied greatly globally and in the US and is lower than optimal for public health benefit. Numerous factors have been cited as barriers to uptake, e.g., lack of health care provider recommendation, concerns about safety, concerns about side effects, and general lack of awareness and knowledge about HPV vaccination. A system-level, sustainable approach to increasing uptake and effectively tempering barriers is through public health policy as demonstrated in the case of routine childhood immunization.³ The purpose of this commentary is to summarize policy efforts to maximize the public health benefit of HPV vaccination.

Globally, 2 countries – Rwanda and Australia – have demonstrated the ability to dramatically increase uptake of HPV vaccination through population-level intervention, i.e. policy.^{4,7} In 2011, the Rwandan Ministry of Health partnered with the manufacturer of the quadrivalent HPV vaccination (Merck & Company) to address a tremendously high burden of cervical cancer through HPV vaccination.⁶ School-based vaccination was used to increase uptake of HPV vaccination among girls enrolled in school.⁶ For those girls not enrolled in school, community-based approaches were used. These approaches with the support of the Ministry of Health resulted in reaching greater than 90% coverage among females of sixth grade age.⁶ Rwanda is noted as a low-income country with significant

challenges on its public health system yet demonstrated substantial improvement in HPV vaccination using a public-private partnership to support school- and community-based HPV vaccination, which resulted in dramatic improvement that has been sustained over time.⁶ Subsequent reductions in disease burden will emerge over time in Rwanda saving millions in medical treatment costs and lives. In Australia, such reductions in HPV-associated disease have already been captured. Australia has led the world in HPV vaccination by starting and sustaining a nationally-financed HPV vaccination program that has already shown reductions in HPV-associated diseases.^{4,5,7} National-level policy and financing contributed to the implementation of an HPV vaccination program for females aged 12–26 y.⁴ A surveillance system was established along with the national vaccination program to measure the short- and long-term effects of the program.⁴ The WHO recommendation for widespread HPV vaccination is based on solid evidence with policy evolving as a key strategy in efforts to reduce the global burden of preventable cancers, such as cervical cancer and other HPV-associated cancers.

In the US, HPV vaccination policy has been much more stilted and has met with much more controversy. Widespread childhood vaccination has never fully recovered from the MMR/autism controversy.⁸ While ultimately this was found to be false, many American parents continue to decline immunizations for their child over fears of harm, resulting in a measles outbreak over much of the US in 2014. On the other hand, the Hepatitis B vaccine reveals an American success story. After its introduction in 1982, the Hepatitis B vaccine was only recommended to certain “at risk” individuals. Over a 10-year period, there was no notable decline in disease rates. In 1991, universal newborn vaccination resulted in dramatic declines in disease. This policy was enacted across all states in a relatively short period of time via public health authority without any

legislative action. Finally in 2007, a school mandate helped get rates of Hepatitis B vaccination to over 90% with elimination of much of the racial disparities that previously existed.

The first HPV vaccine, Gardasil (Merck & Company), was licensed by the Food and Drug Administration in June 2006. Shortly after, the Advisory Committee on Immunization Practices recommended that all adolescent girls receive the HPV vaccine as part a routine adolescent vaccination visit around age 11–12 y old.² Catch-up vaccination was recommended up to age 26 with administration as early as age 9. At the time, this met with controversy among immunization authorities internationally as it was recommended for girls only and many felt this would lead to a stilted rollout and diminish the message. At the time, the HPV vaccine was not FDA approved for boys, unlike in other countries where it was approved for boys and girls at the same time. Even more problematic, the US does not have a national immunization program. Immunization programs are run by the states and only receive federally funded immunizations for a portion of the children in the state who qualify for the federal Vaccines for Children (VFC) program. Ultimately, the decision of who will receive which vaccines and requirements for vaccination are set on a state by state basis.

Shortly after recommendation by the Advisory Committee on Immunization Practices, in an unprecedented use of executive authority, then Governor Rick Perry of Texas issued an executive order in 2007 for all 11- and 12-year old girls in Texas to receive the HPV vaccine. This order was almost immediately overturned by a vote of the Texas legislature before it could be enacted but the story made national news after it was revealed that Gov. Perry had financial ties to Merck and Company. In the same year, Women in Government (WIG), a national organization of female state legislators, took on the HPV vaccine across the nation and many WIG members introduced HPV vaccine legislation in their respective states, including in South Carolina. State mandates passed in 2 states, Virginia and New Mexico. In Virginia, the bill was signed into law with almost no news coverage of the story. In New Mexico, the governor vetoed the bill which made national news. He cited “protecting our girls” among his reasons not to sign the legislation further vilifying the HPV vaccine. Other states have passed various HPV vaccine-related legislation to improve funding, education, and access to the vaccine but no other state has passed a bill requiring the vaccine for entry into school. The District of Columbia City Council passed an HPV school mandate in 2008. Per protocol, this would have to be either approved or rejected by Congress; however, no action was taken after Congress declined to intervene and the HPV school mandate became law.

Since 2007, opposition to the Virginia school mandate has increased and multiple attempts have been made to overturn the law although these have all been defeated in committee. The mandate took effect in October of 2008 thus allowing the state health department a year to educate parents, thus essentially the first year was the 2009 school year. At least one study evaluating the efficacy of the HPV vaccine mandate shows no difference in HPV vaccine rates in central Virginia between 2008 and 2014 (Pierce et al., unpublished data). The NIS-Teen data tell a similar story. Virginia HPV vaccination rates still lag behind many states that have universal coverage and widespread support.

In July 2015, Rhode Island enacted a school mandate for HPV vaccination. The Rhode Island Department of Health released a requirement for incoming seventh graders to have been vaccinated. As with other policy-level attempts in the US, the school mandate was opposed. Legislative action was not required, and the Rhode Island Department of Health appeared to act in the interest of public safety. It is important to note that Rhode Island has had among the highest levels of HPV vaccination coverage in the US. Outspoken opponents decried the action, but other states may be observing the case of Rhode Island in the U.S with great interest. HPV-associated diseases pose a tremendous financial burden in addition to psychosocial burden among those afflicted.

In South Carolina, a state in the southeastern US with elevated rates of cervical cancer and low HPV vaccination uptake, the General Assembly (state legislature) has considered HPV vaccination policy as part of the Cervical Cancer Prevention Act over the past several years and legislative sessions. The story of policy – or attempted policy – in South Carolina is interesting because of lagging HPV vaccination coverage in an environment with high disease burden.

The Cervical Cancer Prevention Act (H.3136) was first introduced by Representative Joan Brady, a member of WIG, in 2007 following the Advisory Committee on Immunization Practices recommendation for girls. This initial bill would have required girls entering seventh grade to have received the HPV vaccination series. The current Governor of South Carolina (Governor Nikki Haley) was a state representative who co-sponsored the legislation. Controversy followed the introduction of the Cervical Cancer Prevention Act once the South Carolina Baptist Association vocally opposed the bill. Rep. Brady moved to table the bill without further action.

In 2011, during the 119th session of the South Carolina General Assembly, Representative Bakari Sellers sponsored the Cervical Cancer Prevention Act (H.4497). This new version of the bill would have increased access to HPV vaccination and included efforts to increase awareness and knowledge among parents. This version of the Cervical Cancer Prevention Act passed both chambers of the legislature but was vetoed by Governor Haley. In an attempt to overturn the Governor’s veto, the House sustained the veto after a lawmaker shared a personal story in which his own daughter had reacted violently to receiving the vaccine.

Again, in 2013, during the 120th session, Rep. Sellers introduced the Cervical Cancer Prevention Act (H.3236), which was an identical version to the previous in the 119th session. The bill progressed favorably through the House but stalled in the Senate without a final vote prior to the end of the session. For a fourth time, the Cervical Cancer Prevention Act was introduced in 2015 in the House (H.3204) by Representative Beth Bernstein and in the Senate (S.278) by Senator Brad Hutto. In its most recent version, the Cervical Cancer Prevention Act would have provided information on HPV vaccination to parents through mailed educational materials and increased access to HPV vaccination through the South Carolina State Vaccine Program, which currently does not include HPV vaccination as a covered immunization. Despite widespread, bipartisan support, a small number of legislators derailed the progress of the legislation. These legislators have shared inaccurate

information about HPV vaccination as part of the debate about the Cervical Cancer Prevention Act. This has resulted in unnecessary politicization of HPV vaccination. The South Carolina Department of Health and Environmental Control has refused to add HPV vaccination to the State Vaccine Program without formal direction from the state legislature. The state legislature has failed to provide formal direction. These actions have resulted in stagnant HPV vaccination levels in the state, which has excessive disease burden as evidenced by elevated incidence and mortality of cervical cancer and other types of HPV-associated cancers. The potential benefits of policy remain at an impasse. Considerable political capital and advocacy resources have been devoted to passing the Cervical Cancer Prevention Act – in all its versions – since the first version was introduced in 2007 to no avail.

Policy-level intervention has demonstrated success in some settings and posed challenges in others. Many of the greatest achievements in public health and overall population health have occurred due to pro-public health policies. To accelerate uptake of HPV vaccination, policy remains a largely untapped tool. However, policy change can occur on many levels not requiring governmental intervention, such as in the case of South Carolina. The state health department has the ability to exert public health authority and add HPV vaccination to the State Vaccine Program. A practice of clinicians may implement standing order policies to prompt recommendation of HPV vaccination and include a series of steps to promote HPV vaccination as the default. Expanding authority to pharmacists to vaccinate, consistent with recommendations, is another example of using policy to increase access to HPV vaccination. These are 3 examples of policy-level interventions that can facilitate increased uptake of HPV vaccination. More research is needed to better understand opportunities for policy interventions and the implementation process.

As discussed here, universal vaccine coverage and widespread support for vaccination will result in rapid HPV vaccine uptake as seen in Australia, Rwanda, and in the US in Rhode Island. However, HPV vaccine school mandates as a policy intervention have met with and have created significant controversy. Ultimately, alternative policies that improve unhindered access to HPV vaccination may allow more success, such as improving vaccine insurance coverage, allowing pharmacists the authority to vaccinate anyone in the recommended age range to include adolescents, and standing orders.

However, before true successes can be seen in the US on the scale of Australia and Rwanda, improved awareness and education is needed to alert the public to the dangers of HPV and HPV-related diseases, most notable HPV-associated cancers, and the safety of the vaccine. Awareness and education may be insufficient but necessary when presented with opportunity for vaccination.

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Dr. Brandt is a member of the Merck US HPV Advisory Board. No other potential conflicts of interest were disclosed.

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