



## Politics, Parents, and Prophylaxis — Mandating HPV Vaccination in the United States

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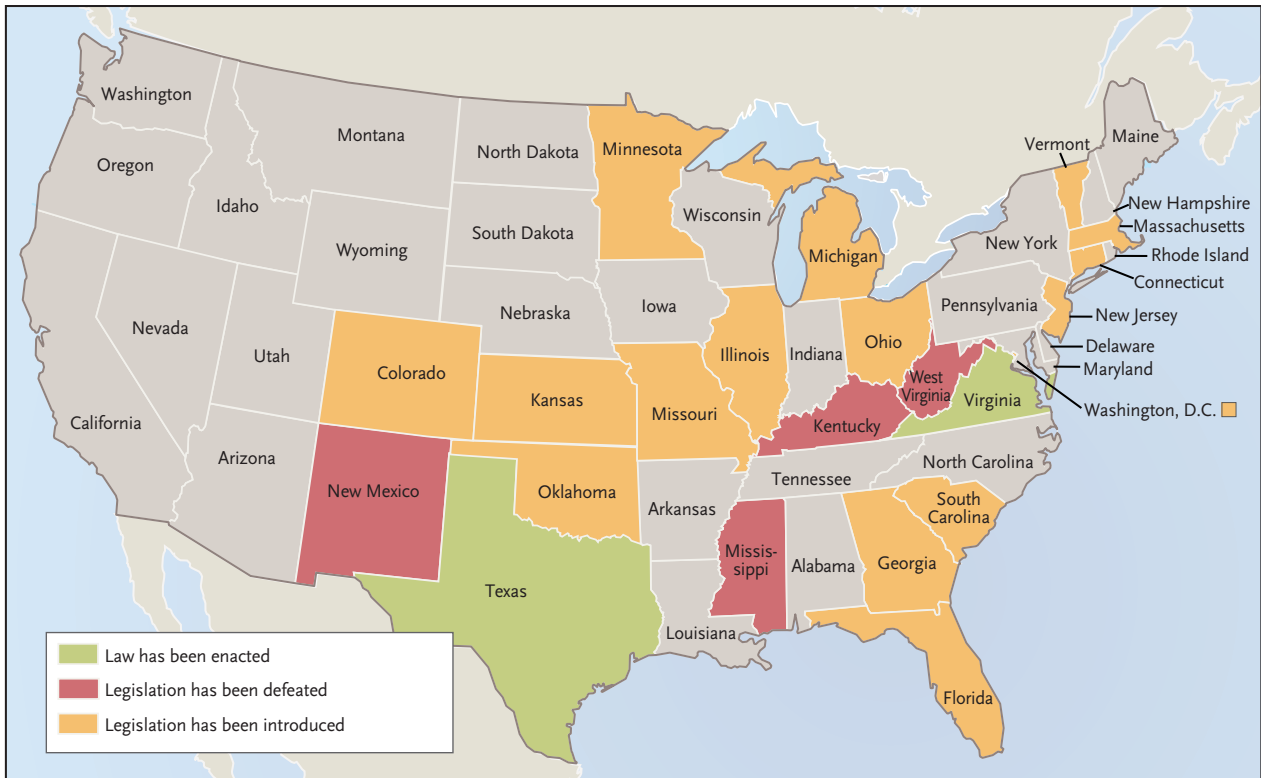
Cancer prevention has fallen victim to the culture wars. Throughout the United States, state legislatures are scrambling to respond to the availability of Merck's human papillomavirus (HPV)

vaccine, Gardasil, and to the likely introduction of GlaxoSmithKline's not-yet-approved HPV vaccine, Cervarix, which have been shown to be effective in preventing infection with HPV strains that cause about 70% of cases of cervical cancer. At the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP) has voted unanimously to recommend that girls 11 and 12 years of age receive the vaccine, and the CDC has added Gardasil to its Vaccines for Children Program, which provides free immunizations to impoverished or underserved children.

Yet despite this federal imprimatur, access to these vaccines has already become more a political than a public health question. Though the more important focus might be on the high cost of the vaccines — a cost that poses a genuine obstacle to patients, physicians, and insurers — concern has focused instead on a purported interference in family life and sexual mores. This concern has resulted in a variety of political efforts to forestall the creation of a mandated vaccination program. In Florida and Georgia, for example, efforts to increase adoption of the vaccine

have been stalled by legislative maneuvering. The Democratic governor of New Mexico has announced that he will veto a bill that mandates vaccinations. And the Republican governor of Texas came under fire (and under legal attack from his own attorney general) when he issued an executive order to the same effect, mandating that all girls entering the sixth grade receive the vaccine; the policy was attacked as an intrusion on parental discretion and an invitation to teenage promiscuity. But all these measures included a parental right to opt out, whether on religious or secular grounds. The opposition seemed more about acknowledging the realities of teenage sexuality than about the privacy and autonomy of the nuclear family.

For more than a century, it has



#### State Laws and Proposed Legislation Mandating HPV Vaccination.

All legislation mandating HPV vaccination includes some form of parental opt-out. The Texas mandate is the result of an executive order from the governor, and its legality is being challenged by the attorney general of Texas. There is also legislation under consideration in Texas that would prohibit a mandate. If passed, it would override the executive order. The Virginia law was passed by the legislature and signed by the governor. The New Mexico legislation was passed by the House and Senate and was then vetoed by the governor. Bills in California and Maryland have been withdrawn for consideration, and the bill in South Carolina has been tabled. Neither Alaska nor Hawaii has considered a mandate. Legislation that makes provisions for funding is under consideration in many states but is not shown here. The various bills would require insurance companies to cover vaccination, allocate state funds, direct agencies to apply for federal funds, or some combination. Information is from the National Conference of State Legislatures and is accurate as of April 27, 2007.

been settled law that states may require people to be vaccinated, and both federal and state court decisions have consistently upheld vaccination mandates for children, even to the extent of denying unvaccinated children access to the public schools. State requirements vary as to the range of communicable diseases but are often based on ACIP recommendations. School-based immunization requirements represent a key impetus for widespread vaccination of children and adolescents<sup>1</sup> and are enforceable even when they allegedly conflict with personal or religious beliefs.<sup>2</sup> In practice,

however, these requirements usually feature exceptions that include individual medical, religious, and philosophical objections.

HPV-vaccination mandates, which are aimed more at protecting the vaccinee than at achieving herd immunity, have been attacked as an unwarranted intrusion on individual and parental rights. The constitutionality of vaccination mandates is premised on the reasonableness of the risk-benefit balance, the degree of intrusion on personal autonomy, and, most crucial, the presence of a public health necessity. On the one hand, to the

extent that required HPV vaccination is an example of state paternalism rather than community protection, mandatory programs lose some of their justification. On the other hand, the parental option to refuse vaccination without interfering in the child's right to attend school alters this balance. Here the mandates act less as state imperatives and more as subtle tools to encourage vaccination. Whereas an opt-in program requires an affirmative effort by a parent, and thus misses many children whose parents forget to opt in, an opt-out approach increases vaccination rates among

children whose parents have no real objection to the program while perfectly preserving parental autonomy.

Opposition to HPV vaccination represents another chapter in the history of resistance to vaccination and, on some levels, reflects a growing trend toward parental refusal of a variety of vaccines based on the (erroneous) perception that many vaccines are more risky than the diseases they prevent. In most cases, pediatricians have largely restricted themselves to educating and counseling objecting families, since it is rare that the risks posed by going unvaccinated are so substantial that refusal is tantamount to medical neglect. In the case of HPV vaccine, parents' beliefs that their children will remain abstinent (and therefore uninfected) until marriage render it even more difficult to make the case for mandating a medical form of prevention. Even with an opt-out program, critics may argue that the availability of a simple and safe alternative — that is, abstinence — undermines the argument for a state initiative that encourages vaccination through mandates coupled with an option for parental refusal.

But experience shows that abstinence-only approaches to sex education do not delay the age of sexual initiation, nor do they decrease the number of sexual encounters.<sup>3</sup> According to the CDC, though only 13% of American girls are sexually experienced by 15 years of age, by 17 the proportion grows to 43%, and by 19 to 70%.<sup>4</sup> School-based programs are crucial for reaching those at highest risk of contracting sexually transmitted diseases, and despite the relatively

low rate of sexual activity before age 15, the programs need to begin with children as young as 12 years: the rates at which adolescents drop out of school begin

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to increase at 13 years of age,<sup>1</sup> and younger dropouts have been shown to be especially likely to engage in earlier or riskier sexual activity.

Another fear among those who oppose mandatory HPV vaccination is that it will have a disinhibiting effect and thus encourage sexual activity among teens who might otherwise have remained abstinent. This outcome, however, seems quite unlikely. The threat of pregnancy or even AIDS is far more immediate than the threat of cancer, but sex education and distribution of condoms have not been shown to increase sexual activity. Indeed, according to a study conducted by researchers at the University of Pennsylvania, it is the comprehensive sex-education approaches that include contraceptive training that “delay initiation of sexual intercourse, reduce frequency of sex, reduce frequency of unprotected sex, and reduce the number of sexual partners.”<sup>5</sup> Opposition to the HPV-vac-

ination mandates, then, would seem to be based more on an inchoate concern: that to recognize the reality of teenage sexual activity is implicitly to endorse it.

Public health officials may have legitimate questions about the merits of HPV vaccine mandates, in light of the financial and logistic burdens these may impose on families and schools, and also may be uncertain about adverse-event rates in mass-scale programs. But given that the moral objections to requiring HPV vaccination are largely emotional, this source of resistance to mandates is difficult to justify. Since, without exception, the proposed laws permit parents to refuse to have their daughters vaccinated, the only valid objection is that parents must actively manifest such refusal. Such a slight burden on parents can hardly justify backing away from the most effective means of protecting a generation of women, and in particular, poor and disadvantaged women, from the scourge of cervical cancer. To lighten that burden even further, the governor of Virginia has proposed that refusals need not even be put in writing. Perhaps it is time for parents who object to HPV vaccinations to take a lesson from their children and heed the words of Nancy Reagan: Just say no.

**An interview with Professor Charo can be heard at [www.nejm.org](http://www.nejm.org).**

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## Introducing HPV Vaccine in Developing Countries — Key Challenges and Issues

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Related articles, pages 1915 and 1928

More than any other cancer, cervical cancer reflects striking global health inequity. It is the second most common cancer among women worldwide, with about 493,000 new cases diagnosed annually (see map). Of 274,000 deaths due to cervical cancer each year, more than 80% occur in developing countries, and this proportion is expected to increase to 90% by 2020.<sup>1</sup> Affecting relatively young women, it is the largest single cause of years of life lost to cancer in the developing world. The deaths of women who are in their most productive years have a devastating effect on the well-being of their families, resulting, for example, in decreases in school attendance and nutritional status among their children.

A new quadrivalent human papillomavirus (HPV) vaccine has now been proved to be effective in preventing cervical intraepithelial neoplasia grade 2 and grade 3 caused by HPV types 16 and 18 (see reports by the FUTURE II Study Group on pages 1915–1927 and by Garland and colleagues on pages 1928–1943). According to meta-analyses, these two types of

HPV account for an estimated 70% of all cervical cancers worldwide, representing a slightly higher fraction in developed regions (72 to 77%) than in less developed regions (65 to 72%).<sup>2</sup> Longer follow-up will be required to establish the degree of protection against other oncogenic strains (including HPV types 31, 33, 35, 45, 52, and 58), but the preliminary data are encouraging. Long-term monitoring will determine the durability of protection and the need for booster immunization. This vaccine has been studied in 27,000 women in 33 countries and is licensed in more than 60 countries. Results from the bivalent HPV-16/HPV-18 vaccine demonstrate similar efficacy. These data constitute sufficient evidence to support global policy recommendations for the introduction of either HPV vaccine.

Considerations for policymakers debating the use of HPV vaccine in any particular country will include that country's disease burden, its health care infrastructure, and its capacity for initiating and sustaining an immunization program for adolescents. Other considerations include the afford-

ability and cost-effectiveness of vaccination relative to other programs competing for resources and the likelihood of cultural acceptability, political will, and public support.

Ultimately, the field effectiveness of HPV vaccine will require improved systems for providing health care to adolescents. Socio-cultural sensitivities in this area abound, although concern about vaccinating adolescents against a sexually transmitted infection have been tempered by an emphasis on the vaccine's role in cancer prevention. Yet in environments characterized by mistrust of governmental health care initiatives, vaccination programs targeted toward young women may be misunderstood as attempts to control fertility — misapprehensions that have held sway in some countries even with regard to immunization campaigns against poliovirus and tetanus. If such fears can be allayed, an adolescent immunization program, possibly school-based, could be designed to deliver other adolescent health services and immunizations against tetanus, measles, rubella, meningococcus, typhoid, or even, ultimately, the