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CDC Recommends HPV Vaccine for girls between the ages of 11 and 12: *How advocates can build upon this positive momentum*

The pervasive and frequently symptom-free sexually transmitted disease Human Papillomavirus Virus (HPV) kills. HPV is the cause of 99 percent of cervical cancer cases in the United States, and every year cervical cancer takes the lives of more than 3,700 of the 9,710 women affected by it, according to the Center for Disease Control (CDC). Priced at $360 dollars, the vaccine Gardisil®, manufactured by Merck, protects against 4 types of HPV including strains 16 and 18 which alone are responsible for causing 70 percent of cervical cancers in the United States.

The FDA has recently approved Gardisil®, declaring it effective in combating the spread of HPV. This action led to a recommendation of the Center for Disease Control (CDC)'s Advisory Committee on Immunization Practices (ACIP) that the HPV Vaccine be routinely administered to girls between the ages of 11 and 12 years of age and approved for as-needed administration for women up to age 26. Accordingly, Gardasil® becomes the first gender-based vaccine to prevent a cancer-causing sexually transmitted infection to be included on the list of all immunizations that young girls should receive.

Another important outcome of the ACIP recommendation is that Gardasil® must be covered by the federal Vaccines for Children Program (VFC) which provides no-cost immunizations to children covered by Medicaid, Alaska-Native and American Indian children and some uninsured and underinsured children up to age 18.[1] Children and their physicians receive vaccines at no cost through VFC. In 2004, the VFC program purchased approximately 40 percent of the total number of doses of routinely recommended pediatric vaccines distributed in the United States.[2] Thus the ACIP recommendation is critical to ensuring the promise of the Gardasil® vaccine to low-income communities and communities of color which have an increased risk of developing cervical cancer.

HPV and Public Health Programs

Will the HPV vaccine reach those populations most in need? The United States has long battled the disparity that exists in administering vaccines between those individuals with higher incomes and health insurance, compared to those with lower-incomes and no health insurance. In response to this, the Vaccination Assistance Act of the Public Health Service Act was implemented in 1962 in response to incomplete and unequal coverage of childhood vaccines. It was not until 1989 that Medicaid law specifically codified immunizations as a mandatory component of the

[1] See 42 U.S.C. s. 1396d(r)(1)(B)(iii) stating that EPSDT shall at a minimum provide appropriate immunizations…. for pediatric vaccines; 1396s(c)(2)(B)(i) stating that the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed…

[2] Available at: http://www.cdc.gov/programs/immun10.htm.

Medicaid program for individuals under 21 and specified coverage in accordance with ACIP standards. VFC was later created in 1993.

If the ACIP and corresponding VFC recommendations are followed, the HPV vaccine will be available to many adolescent girls in low-income families, as part of the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program, Medicaid's pediatric benefits package.[3] Early detection and prevention are the hallmarks of the EPSDT program.[4] EPSDT requires that medical screens must include appropriate immunizations according to age and health history. Vaccines are to be administered by "program-registered providers" who are entitled to receive the vaccine without charge for either the vaccine or for its delivery. Providers then distribute the vaccines at no cost to children. Program-registered providers can provide vaccines in accordance with state law without regard to whether the provider otherwise participates in Medicaid.[5]

Although providers cannot deny administration of a pediatric vaccine to a vaccine-eligible child because the parent cannot pay, the provider is not required to administer a vaccine to every child who seeks one. As is always the case with Medicaid law, the extent of participation is left to the provider as providers do not have to participate in the Medicaid program, however, if they choose to, they must adhere to the requirements of the EPSDT program. In these instances however, the child is entitled to receive the vaccine.

Another program that administers vaccines to children of low-income families is the State Children's Health Insurance Program (SCHIP), which provides health insurance to children of "near-poor" families who are ineligible for Medicaid. Like Medicaid, SCHIP mandates that all state plans cover the cost and administration of childhood vaccines. Gardisil® should be administered by state SCHIP programs as well.

Despite government efforts in the United States to eliminate the barriers low-income children face in receiving immunizations and vaccines through the Medicaid and SCHIP programs, 9 million children in this country still go without any form of health insurance. Although the VFC does serve some uninsured children, it is these children that may go without receiving the HPV vaccine, thus maintaining the current level of the risk of getting cervical cancer, while the risk is greatly decreased for those with insurance.

Among those who are uninsured, children of color are disproportionately represented, as twenty percent of Hispanic children are uninsured, compared to 9 percent of African-American children and 6 percent of non-Hispanic white children.[6] Thus, cervical cancer disparities among women of color will persist unless uninsured girls have access to the vaccine and uninsured women (among whom women of color also are overrepresented) have access to appropriate preventive services.

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[3] The changes made to Medicaid in the Deficit Reduction Act of 2006 do not affect the EPSDT requirements of immunizations. See www.nhelp.org, *The Deficit Reduction Act of 2005: Congress Targets Beneficiaries for Cuts (June '06)* pages 27-31.

[4] *See* National Health Law Program, Child Health law and Policy Project, April 2003, *Toward a Healthy Future; Medicaid Early and Periodic Screening, Diagnostic and Treatment Services For Poor Children and Youth.*

[5] *See* 42 U.S.C. § 1396s(c)(1)(A).

[6] See www.rwfj.org/files/newsroom/ckfresearchreportfinal.pdf.

Health Disparities

HPV and its direct link to cervical cancer raise several issues involving public health, racial and economic health disparities, and human rights. The statistics indicating racial disparities in cervical cancer rates alone are alarming. Vietnamese American women suffer from cervical cancer at five times the rate of White American women. The National Cancer Institute noted that there is a need to focus prevention and control efforts on this one group.

In addition, the American Cancer Society reports that Black and Latina women suffer from higher rates of this cancer compared to their White peers. Latina women develop cervical cancer at twice the rate of White women and African-American women develop cervical cancer 50 percent more than White women. These disparities have been attributed to the lower rates in which minority women access pap smears.

With HPV being the most common sexually transmitted infection in the U.S. with 6.2 million cases diagnosed annually,[7] and 99 percent of all cervical cancers being caused by HPV, this vaccine in conjunction with routine pap smears has the potential to nearly eradicate cervical cancer in this country. Ensuring that VFC, Medicaid, SCHIP and, in addition, Community Health Centers cover this vaccine is a step in the right direction, but a plan of action must be taken to ensure that *all* girls in the appropriate age group receive this vaccine. This is more than an entitlement issue; it is also a human rights issue.

Assessing the Human Rights Impact of the HPV vaccine

Health disparities, like these disparities in the rates of cervical cancer, highlight the need for equal access to health care coverage in the United States. Access is at the heart of the concept of health as a human right. And as the United States continues to side-step implementation of a universal health care system, millions of children continue to go uninsured and lack access to routinely administered vaccines and immunizations that would protect their health, and, in some instances, the health of others.

International human rights treaties and agreements recognize the right to health as a human right. The International Covenant on Economic, Social, and Cultural Rights states in article 12.1 that human beings have the "right to the highest attainable standard of health." The right to health embodies the concepts of freedoms and entitlements. Each person has the right to be free to control one's health and body which includes their sexual and reproductive freedom, and at the same time, they have a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable standard of health. The government has a duty and an obligation to respect, protect and actively fulfill all of these rights and freedoms regarding health. The importance of ensuring these health rights is in many instances a prerequisite to the enjoyment of other freedoms.

Additionally, advocates may want to begin a dialogue on the benefits of using the human right *to enjoy scientific progress* in their advocacy to make Gardasil® available to all of those in

[7] The Centers for Disease Control and Prevention, HPV and HPV Vaccine – Information for Healthcare Providers, June 2006.

need. The World Health Organization highlighted a paper on *Considerations in Formulating Reproductive Health Laws*, which states that the right to enjoy the benefits of scientific progress can be invoked where women are denied access to antiprogestin drugs for non-surgical abortion or to emergency contraception that they want.[8]

Also, the human right *to enjoy scientific progress* was used successfully by NGO's advocacy, which brought attention to the growing disparities and inequities between the wealthy populations and the poorer populations of the world regarding the access to the life-lengthening anti-retroviral and therapies available for HIV/AIDS patients. The United Nations General Assembly Special Session (UNGASS) in its 2001 Declaration of Commitment on HIV/AIDS stated that "The full realization of human rights and fundamental freedoms for all is an essential element in a global response to the HIV/AIDS pandemic….and the right to enjoy the benefits of scientific progress requires that HIV/AIDS prevention, treatment, care and support be based on sound analysis and evidence." A definite connection can be drawn with the HPV vaccine to ensure that it is administered in such a way as to adequately respond to the needs of not just wealthy women, but also minority, lower-income women who experience higher rates of cervical cancer.

Recommendations

Advocates should, first and foremost, take note of this issue. Advocates have a chance at the state level to not only advocate for incremental change in making sure that their individual state Medicaid and SCHIP programs cover this vaccine but can also use this issue as a vehicle to begin using the human rights framework and dialogue to support the position of equal access to this vaccine and health care for all.

Call your state Medicaid/SCHIP/Community Health Centers/County Health Department directors. Ask the directors if these programs will cover Gardasil®. If the answer is "no" or, "we don't know yet" advocates should conduct administrative, legislative, and if necessary, legal advocacy to enforce Medicaid and SCHIP rules and to work with community clinics to ensure access.

Spread the word. Remember, if programs like EPSDT are to work, advocates need to continue to reach out to the communities that are eligible for services, help people to enroll *and* then make sure that they receive the services they are entitled to.

Stay involved. Abstinence-only proponents have successfully prevented an FDA approval of administering Emergency Contraception (EC) over-the-counter which is in direct contrast to the FDA's scientist's recommendations. Likewise, abstinence-only proponents opposed Gardasil® administered to young girls out of fear that administering the HPV vaccine would encourage young girls to become sexually active. There is no known nexus between vaccine administration to prevent the spread of HPV strains that cause cervical cancer and the onset of sexual activity. Public health advocates must be aware and be involved in the FDA approval process just as abstinence-only advocates are.

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Learn about human rights. Begin to embrace the human rights principles and language. Encouraging the United States to ratify international human rights treaties and embrace human rights principles is a powerful avenue for eliminating health disparities here in the U.S. and worldwide.