COMMONWEALTH of VIRGINIA

Department of Health

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Joint Commission on Health Care
Human Papillomavirus (HPV) Vaccine
Status Report
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HPV Vaccine:
In June 2006, the quadrivalent HPV vaccine (GARDASIL ™), manufactured by Merck and Co., was licensed for use among females aged 9-26 years for prevention of HPV-type-related cervical cancer, cervical cancer precursors, vaginal and vulvar cancer precursors, and anogenital warts.

The national Advisory Committee on Immunization Practices (ACIP) submitted their recommendations for the use of HPV vaccine to the Centers for Disease Control and Prevention (CDC) in June 2006. The CDC updated and clarified wording in the ACIP document and published the recommendation in the March 12, 2007 edition of the *Morbidity and Mortality Weekly Report (MMWR)*.

Clinical trials indicate that the vaccine has high efficacy against HPV types 6, 11, 16, and 18, thus preventing most cases of persistent HPV infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions, and genital warts from these HPV types among vaccinated females who have not already been infected by them. No evidence exists of protection against disease caused by HPV vaccine types with which females are infected at the time of vaccination, and protection would not be expected against HPV types not included in the vaccine. Females infected with one or more HPV types before vaccination would be protected, however, against disease caused by the other vaccine HPV types.

The vaccine is administered by intramuscular injection and the recommended schedule is a 3-dose series with the second and third doses administered two and six months after the first dose. The recommended age for vaccination of females is 11-12 years. Vaccine can be administered as young as age nine years. Catch-up vaccination is recommended for females aged 13-26 years who have not been previously vaccinated. Vaccination is not a substitute for routine cervical cancer screening, and vaccinated females should have cervical cancer screening as recommended.

GlaxoSmithKline has also developed a vaccine against HPV, Cervarix™, targeted at types 16 and 18, that is currently under review by the U.S. Food and Drug Administration (FDA). Having a second vaccine available will enhance vaccine supply.

Current Status:
Since July 2006, local health departments have administered 1,686 doses of HPV vaccine to Vaccines for Children (VFC) program[1] eligible females (11-18 years of age); females enrolled in the 6th grade, and all other females 11-12 years of age. HPV vaccine is also being administered to VFC program eligible females 11-18 years of age by over 2,000 private providers and Community Heath Centers participating in the VFC program. To date, 12,400 doses have been distributed to these facilities.

Future Plans:
The Division of Immunization is also developing a three-pronged educational and outreach initiative targeting: a) the parents of preteens and adolescents; b) all females 11-26 years of age; and c) health care providers administering care to preteens and adolescents. As required by the enactment of HB2035 and SB1230 from the 2007 session of the General Assembly, educational material will be distributed through local health departments statewide and, through a partnership with the Department of Education, to all 132 school districts. The educational material will inform parents about HPV and its association with cervical cancer, why they should consider vaccinating their children, the risks and benefits associated with vaccination, and whom to contact if they need additional information. Information provided to physicians will be tailored to their areas of specialization (i.e. pediatricians vs. gynecologists).

Health departments will tabulate from school records the number of students that have received the vaccine. School and health department officials will assume that the parents of students for whom there is no record of HPV vaccination have elected to not have their children immunized against HPV.

These expanded vaccination and educational/outreach initiatives will be supported by the $1.4 General Assembly appropriation for FY 2008.

Future Needs:
It is expected that per-dose-costs of the vaccine will increase and that the scope of vaccine usage may be expanded to include males. Both changes are likely to drive the need for additional appropriations to cover the associated costs.

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[1] Through the VFC program, public purchased vaccine is available at no charge to enrolled public and private health care providers for eligible children. Children 18 years of age and under that meet at least one of the following criteria are eligible for VFC vaccine: 1) Medicaid eligible; 2) Uninsured; 3) American Indian or Alaska Native; 4) Underinsured – defined as a child whose health insurance benefit plan does not include vaccinations.