REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

Higher Rates of Cervical Cancer among Minority Women

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

REPORT DOCUMENT NO. 169

COMMONWEALTH OF VIRGINIA
RICHMOND
2008

Code of Virginia § 30-168.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

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Preface

In January 2005, Governor Mark R. Warner issued Executive Directive 5, creating a task force to study the problem of cervical cancer among women in the Commonwealth. Jane H. Woods, Secretary of Health and Human Resources, chaired the task force which consisted of 20 individuals including physicians, college professors, and Virginia Department of Health (VDH) staff. The task force report was issued in November 2005, and included five recommendations. One of the recommendations was to "request the Joint Commission on Health Care to further study racial, ethnic, and cultural disparities in cervical cancer incidence to identify causes and develop a plan to address findings."

Rates of cervical cancer, though decreasing for women of all racial/ethnic groups, are still higher for minority women and the incidence of cervical cancer continues to increase with age for minority women whereas the incidence of cervical cancer for White women peaks in the mid forties. Further, Black women in our State are more likely to be diagnosed at an advanced stage of disease and have twice the mortality rate from cervical cancer compared to White women.

Higher rates of cervical cancer and mortality are primarily a result of racial and ethnic minorities being more likely to have lower socioeconomic status, lower levels of education, and, for some minority groups, a higher likelihood of cultural norms that discourage women from having regular Pap tests and pelvic exams. The result is a lower probability of initial screening and diagnostic follow-up which can lead to higher incidences of cervical cancer, a later stage of diagnosis, and ultimately the increased likelihood of mortality for minority women. Strategies which could significantly reduce these disparities include the school mandate for the human papillomavirus (HPV) vaccination, educational programs designed to be culturally appropriate for specific minority communities, and greater access to screening and treatment through such programs as Virginia's "Every Woman's Life." Based on the study findings, JCHC voted to take no action at this time.

On behalf of the Joint Commission and staff, I would like to thank Dr. Jennifer Young, Fellow of Gynecologic Oncology at the University of Virginia Health System, for her presentation, "HPV Vaccination of Women Aged 16-26 in Virginia" and Dr. Carl Armstrong, Office of Epidemiology, Virginia Department of Health, for his presentation on the current status of the HPV vaccine. Information from both presentations is included in the final report.

Kim Snead
Executive Director

June 2008

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Higher Rates of Cervical Cancer among Minority Women

Executive Summary

Authority for Study

In January 2005, Governor Mark R. Warner issued Executive Directive 5, creating a task force to study the problem of cervical cancer among women in the Commonwealth. Jane H. Woods, Secretary of Health and Human Resources, chaired the task force which consisted of 20 individuals including physicians, college professors, and Virginia Department of Health (VDH) staff. The task force report was issued in November 2005, and included five recommendations. One of the recommendations was to "request the Joint Commission on Health Care to further study racial, ethnic, and cultural disparities in cervical cancer incidence to identify causes and develop a plan to address findings."

Background

Cervical cancer is the second most prevalent deadly cancer in women worldwide. Each year approximately 14,000 women in America are diagnosed with cervical cancer and 4,000 deaths occur annually in the United States.[1] The good news is the incidence and mortality rate of invasive carcinoma of the cervix have decreased by 75 percent in the past 40 years, mostly due to increasing rates of annual pelvic exams, Pap tests, and other screening measures.

Infection with some strains of the human papillomavirus (HPV) has been found to be highly associated with the development of cervical intraepithelial neoplasia (CIN), a precancerous condition of the cervix.[2] HPV is the most common sexually transmitted disease in the United States with over 6 million people infected each year. The prevalence of HPV peaks in the teen/early twenties years, with onset of sexual activity, and can be as high as 80 percent in this age group. A woman in the U.S. has an 80 percent risk of contracting HPV before age 50. For women with persistent HPV infection, precancerous lesions can develop within 3-5 years. If these lesions go untreated, cervical cancer can develop within 8-10 years of HPV infection (Figure 1).

With the availability of HPV vaccines, in combination with annual screening procedures, cervical cancer is a disease that can be stopped. As one physician stated, "Cervical cancer is now a preventable disease and any woman presenting

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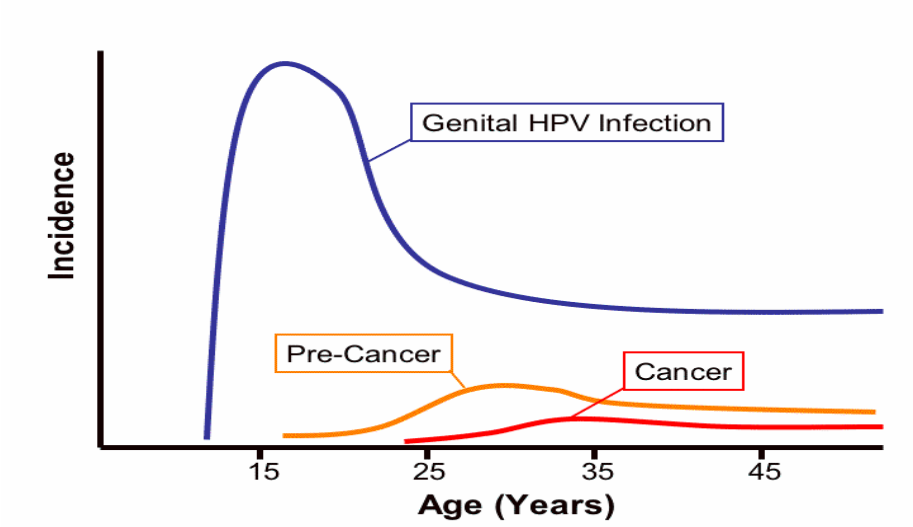
[1] www.americanprogress.org (2006)

[2] Miller, Suzanne M. et al. 1997. "Enhancing Adherence Following Abnormal Pap Smears Among Low-Income Minority Women: A Preventative Telephone Counseling Strategy." Journal of the National Cancer Institute. Vol. 89, No. 10, May 21.

Figure 1
HPV Disease Incidence by Patient Age



http://content.nejm.org/content/vol353/issue20/images/large/01f2.jpeg

with invasive cervical cancer should be viewed as a failure of screening."[3] Even though advances have been made in reducing the incidence of cervical cancer in the United States, it is troubling that rates of cervical cancer are still higher for minority women. The current study addresses this problem and provides possible explanations for the trend.

Rates of Cervical Cancer among Minority Women

"In Virginia, there are substantial racial, ethnic, and regional disparities for cervical cancer incidence, mortality, and stage of diagnosis. Every Virginian has a vested interest in addressing such disparities and ensuring that all women have access to appropriate preventative screenings and timely access to life saving treatments. By addressing the causal factors of cervical cancer, the overall health of women, especially those at high-risk for this cancer, may be improved."[4]

Incidence of cervical cancer for most women peaks in the mid forties, however, for minority women, particularly Black women, the incidence of cervical cancer continues to increase with age. Further, data from Virginia demonstrate that Black women in our State are more likely to be diagnosed at an advanced stage of disease and have twice the mortality rate from cervical cancer compared to White women (Figures 2-3).

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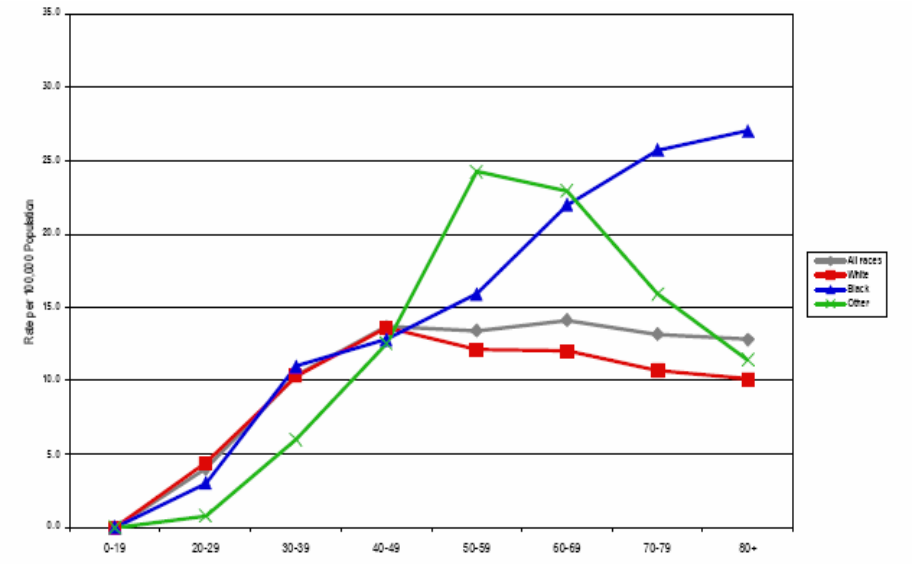
[3] Garner, Elizabeth I.O. 2003. "Cervical Cancer: Disparities in Screening, Treatment, and Survival." Cancer Epidemiology, Biomarkers, and Prevention. Vol. 12, pgs. 242-247. pg. 242.
[4] Report of Governor's Task Force on Cervical Cancer, 2005. pg. 4

Figure 2
Age Adjusted Incidences of Cervical Cancer by Race



Source: Report of Governor's Task Force on Cervical Cancer. 2005

Figure 3
SEER Incidence Rates & Trends of Cervical Cancer

	Rate 2000-2004	APC* 1995-2004
White (Non-Hispanic)	7.2	-2.9*
Black	11.4	-4.9*
Hispanic	13.8	-3.6*
Asian / Pacific Islander	9.0	-5.9*
American Indian / Alaska Native	6.6	----

Source: SEER (Surveillance, Epidemiology, and End Results) Cancer Statistics Review, 1995-2004 *Annual Percent Change (P<.05)

While there has been a more dramatic decrease in rates of cervical cancer among minority women, the rates for all minority groups are still significantly higher than for White women. The Hispanic population has the highest incidence rate of all racial/ethnic groups and rates are five times higher among Vietnamese women than for Whites. For African American women, the rate is 1.5 times higher.

Figure 4
% Distribution of Cervical Cancer by
Stage at Diagnosis & Race, VA. 1998-2002

	Localized	Regional	Distant	Unstaged
White	55	30	8	7
Black	45	36	12	7
Other	44	38	11	8

Source: Virginia Cancer Registry 2005

The disparity between White and minority women not only includes rates of incidence, but also stage of diagnosis. For White women, cervical cancer is more likely to be caught in the early localized stage. Minority women have greater incidences of cancer being diagnosed at the later, more life-threatening, stages.[5] The later stage of diagnosis leads to lower survival rates for minorities (Figure 5). However, even after controlling for stage of diagnosis, minority women still have lower survival rates than White women. The death rate for African American women is twice the rate for White women (Figure 6).

Figure 5
5 Year Survival Rates of Cervical Cancer, 1996-2003

	All Stages	**Local**	**Regional**	**Distant**	**Unstaged**
White	**72.9**	**92.8**	**56.4**	**17.5**	**59.8**
<50	81.0	94.5	62.9	24.4	70.3
50+	59.9	88.3	50.1	12.0	47.9
Black	**62.2**	**85.7**	**48.2**	**9.2**	**56.5**
<50	67.6	86.6	50.6	9.3	65.9
50+	55.0	84.0	45.8	8.9	48.6

Source: Virginia Cancer Registry 2005

[5] Cancer Stages: Localized=limited to organ in which cancer began with no evidence of spreading; Regional=cancer has spread from the primary site to nearby lymph nodes or organs and tissues; Distant=cancer has spread from the primary site to distant organs or lymph nodes; and Unstaged=cancer for which there is not enough information to indicate a stage. (Source: SEER Cancer Statistics Review, 2003)

Figure 6
U.S. Death Rates & Trends of Cervical Cancer

	Rate 2000-2004	APC* 1995-2004
White (Non-Hispanic)	2.2	-3.3*
Black	4.9	-4.7*
Hispanic	3.3	-3.3*
Asian / Pacific Islander	2.4	-4.5*
American Indian / Alaska Native	4.0	-1.6

Source: SEER Cancer Statistics Review, 1995-2004
*Annual Percent Change (P<.05)

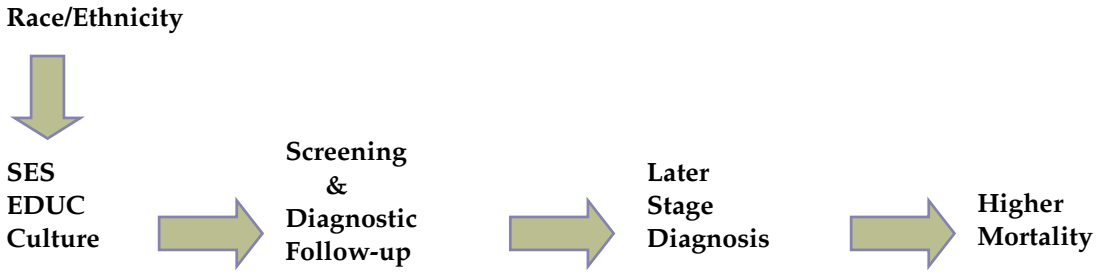
Causal Factors for Higher Rates of Cervical Cancer among Minority Women. Higher rates of cervical cancer and mortality are primarily a result of racial and ethnic minorities being more likely to have lower socioeconomic status, lower levels of education, and, for some minority groups, a higher likelihood of cultural norms that discourage women from having regular Pap tests and pelvic exams. The result is a lower probability of initial screening and diagnostic follow-up which can lead to higher incidences of cervical cancer, a later stage of diagnosis, and ultimately the increased likelihood of mortality. Forty-six to 56 percent of women diagnosed with cervical cancer had not had a Pap test within three years of the diagnosis and minority women with cervical cancer are less likely to have been screened by a Pap test than White women with the disease. Even when women are screened, the screening must be followed by prompt notification of test results, adequate patient follow-up, and appropriate and timely treatment in order to be effective. For minority women, this process is more likely to be incomplete.

The annual gynecological exam is one that most women do not look forward to experiencing, but it is the crucial first step in diagnosing and treating cervical cancer. For some minority women, especially Vietnamese and Korean women, cultural norms discourage women from having pelvic exams and Pap tests. In these groups it is generally considered inappropriate for a woman to disrobe in front of a stranger, even a physician, and especially if the individual is male. For women of other minority groups (e.g. Black and Hispanic) the lack of screening is more likely to be an economic problem. Due to past and present discrimination and inequality, minorities are more likely to live below the poverty line, have lower-paying jobs, and/or lack health insurance. All of these

economic conditions make it less probable that a woman will have a designated primary care physician/gynecologist and a yearly gynecological exam. Because of the lack of consistent screening, minority women tend to have cervical cancer diagnosed at a later, more life-threatening, stage.

Diagnostic follow-up also is a factor that varies by racial/ethnic group. In large part, the lower rates of follow-up among minority women are a result of having no insurance, low income, and/or being underinsured. However, education also is an important factor. When the results of a Pap test show an abnormality, many women do not fully understand the meaning of these results, underestimate their importance, and unfortunately delay returning to the physician for a follow-up exam. As is the case of the lack of screening, poor follow-up of abnormal pap test results can lead to cervical cancer being treated at a later stage, increasing the likelihood of mortality (Figure 7).

Figure 7
Causes of Higher Cervical Cancer Rates Among Minorities



HPV Vaccine

Exhibit A contains the presentation given by Dr. Carl Armstrong on the development of new vaccines to prevent cervical cancer and VDH's HPV vaccination program. Dr. Armstrong, of the Office of Epidemiology within VDH, presented to JCHC in October 2007.

Exhibit A
Presentation to the Joint Commission on Health Care
Human Papillomavirus (HPV) Vaccine
Status Report by Dr. Carl Armstrong
October 15, 2007

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[6] 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

[6] 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.

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.

Survey of Providers on Attitudes toward HPV Vaccine[7]

Dr. Jennifer Young, Fellow of Gynecologic Oncology at the University of Virginia Health System, conducted a survey of physicians regarding the level of support among physicians, patients, and parents for the HPV vaccination. Dr. Young presented the results of her work at the September 19, 2007 JCHC meeting.

The objectives of the study were to identify barriers to patients, parents, and providers that prevent vaccination of young women, describe current distribution of the HPV vaccine in this age group, and determine provider opinion regarding current and future policies to improve HPV vaccination rates. The focus of the study was women ages 16-26 because women in this age group are unaffected by the current school vaccination mandate, are at high risk of

[7] Information in this section is from Dr. Jennifer L. Young's presentation, "HPV Vaccination of Women Aged 16-26 in Virginia", to the JCHC during the September 19, 2007 meeting.

failing to comply with the current recommendations, are rarely seen in pediatric offices and usually receive their health maintenance through their gynecologist (who often do not provide vaccinations for their patients). Further, these women make up the largest percentage of Virginia's uninsured population.

Gynecologists and family practitioners were surveyed given they are the primary doctors for the majority of adolescent and young women. A series of mailings were employed to increase the overall response rate. A total of 1000 practitioners (500 from each specialty) were mailed surveys. A total of 395 physicians returned the survey (169 general practitioners and 216 obstetrician-gynecologists) resulting in a response rate of 45 percent. The survey was conducted by the University of Virginia Center for Survey Research and the answers kept confidential prior to data being given to the investigators. The questionnaire included information about the demographics of the physician and the practice, experience with vaccines in general, knowledge of HPV, and the HPV vaccine, barriers to HPV vaccination, and opinions on current policy options to increase vaccination rates. Obstetrician-gynecologists and family practitioners were very similar in demographics, experiences, and opinions (Figure 8).

Figure 8
Demographics of Providers Surveyed

	FP	OB/Gyn	p-value
Age (mean)	49.1	47.9	0.372
Gender (%)			0.815
Male	60.6	61.8	
Female	39.4	38.2	
Years in practice (range)	28.3	16.7	0.114
Location of practice (%)			0.60
Urban	27	16.2	
Suburban	51.5	57.6	
Rural	17.2	22.9	
Other	4.3	3.3	
Practice size (%)			0.269
Solo practice	15.2	10.5	
Small group practice	36	36.7	
Large group practice	37.2	34.8	
Multi-specialty practice	4.3	9.0	
Other	7.3	9.0	

The HPV vaccine is currently offered in a 3-dose regimen at a cost of $120 per injection or $360 total. This is only for the medication and does not include any additional charges by the practice for storage or delivery of services. The Federal Vaccines for Children program covers the HPV vaccine for children who qualify for Medicaid. Most private insurance companies also cover the HPV vaccine for girls aged 11-12. However, this coverage differs significantly in terms of dollars reimbursed and the age range of coverage may not match with the CDC recommendations.

Doctors were asked their opinion regarding current policy options to improve HPV vaccination rates in Virginia (Figure 9). The majority of providers would support vaccination programs through health departments, mandatory insurance coverage, and mandatory insurance coverage as part of the global package to be given in the postpartum period.

Figure 9
Provider Views on HPV Vaccine Policies

Policy options	Providers in Favor
Health department vaccination programs	91%
School-based vaccination programs	54%
Mandatory insurance coverage	73%
Mandatory insurance coverage during postpartum care	74%

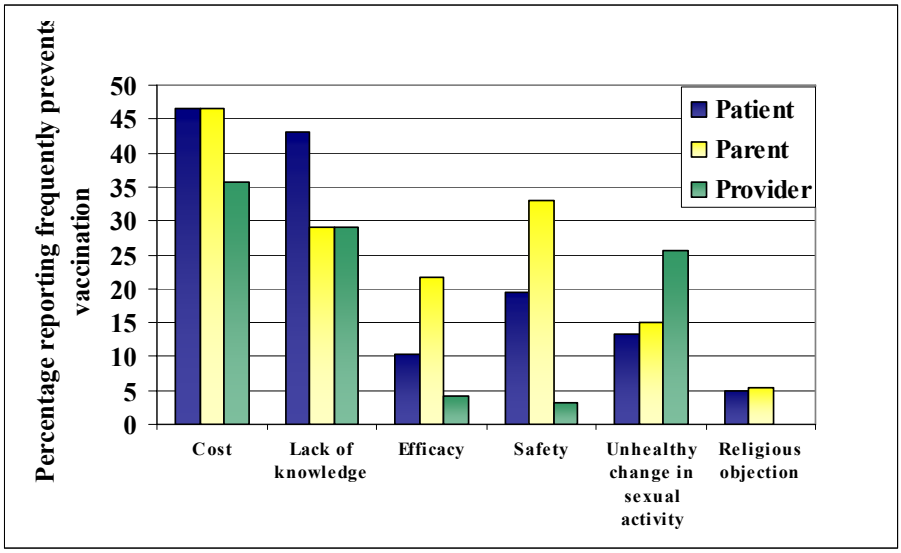
Respondents also were asked their opinion of the current school mandate in Virginia. Specifically respondents were asked if they felt the same bill should be passed in other states. The majority of physicians (59.4%) support the current school mandate requiring HPV vaccination prior to entry into the sixth grade (Figure 10).

Figure 10
Provider View on Virginia's School Mandate for HPV Vaccination

Opinion	Percentage of providers
Strongly favor	37%
Somewhat favor	22.4%
Somewhat oppose	34%
Strongly oppose	0.8%
Other	6.4%

In summary, Figure 11 compares the barriers reported by providers, parents, and patients. Cost and education stand out as common barriers for all three stakeholders. Concerns about change in sexual behavior and religious objection are much less significant.

Figure 11
Summary of Barriers to HPV Vaccination



Conclusion

> Because any effort to reduce cervical cancer rates may also result in the reduction of other chronic conditions, decrease health disparities, and improve overall women's health, it is important that both public and private sectors focus attention on this important public health problem.[8]

The results of this study indicate that higher rates of cervical cancer and mortality among minority women is a failure of screening and timely treatment, primarily due to lower levels of education, cultural norms, and the high correlation between race/ethnicity and class status. Strategies which could significantly reduce the disparities associated with cervical cancer for minority women include the HPV vaccination school mandate, educational programs, and greater access to screening and treatment through such programs as Virginia's "Every Woman's Life."

School Mandate for HPV Vaccination: The HPV vaccine, though still controversial, should reduce the rates of cervical cancer in a few decades as girls and young women receive the vaccine and thus do not develop the precancerous condition, cervical intraepithelial neoplasia (CIN) that if left untreated can lead to cervical cancer in approximately 10 years after HPV infection. However, to have a significant impact on low-income women (who are disproportionately minority women) the HPV vaccination needs to be mandatory and the cost covered for those who cannot afford to pay the high price of the vaccine. Given the school mandate for HPV vaccination, the Vaccines for Children program; and the level of support by physicians, parents, and patients indicated in Dr. Young's study, it is likely that the HPV vaccine will have a positive effect on women in all racial and ethnic groups.

Educational Programs: Even with the development of the HPV vaccine, more public awareness programs are needed to educate women about the importance of yearly gynecological exams and the meaning and significance of abnormal results. Many physicians have stressed that women should not rely exclusively on the HPV vaccine to protect themselves from cervical cancer. All women need to continue to have yearly gynecological exams as well. Efforts to identify and encourage women to be screened and follow-up with treatment must include culturally sensitive and appropriate methods in order to facilitate informed decision making about preventative health within minority communities.

[8] Report of the Governor's Task Force on Cervical Cancer, 2005.

Greater Access to Screening and Treatment: The Virginia Breast and Cervical Cancer Early Detection Program (BCCEDP), also known as Every Woman's Life, plays an important role in providing screening and access to treatment for minority women. The program operates under the Breat and Cervical Cancer Mortality Prevention Act of 1990 which authorizes the Centers for Disease Control and Prevention to develop and implement a national program. The annual budget for Virginia's program is $2.44 million (federal funding through the CDC) and $405,176 GFs received in July, 2006 for the 2006-2007 biennium. The federal funding only pays for screening/diagnosis and treatment of women 40-64 years old, through Medicaid. The State funding opened the program to younger women by providing diagnostics for women 18-39 years old who already came to the program with an abnormality or symptomatic for breast or cervical cancer. In other words, it does not pay for actual screening of women in this age group.

The Every Woman's Life program is operated through VDH which contracts with 23 approved network providers (i.e. screening sites) throughout Virginia to provide free mammograms, clinical breast exams, Pap tests, and pelvic exams. VDH makes payments to providers using Title 15 funds for screening and diagnosis. Most of these providers are local health and other public clinics. Non-network providers (most of which are private clinics) receive no funding from the CDC program, but are accepted as partnering with the program. Patients screened and/or diagnosed by these providers can be eligible for treatment through Medicaid. Increasing funding by an additional $405,176 GFs per biennium would enable the program to diagnose more women age 18-39 years and, therefore, reduce the number of late stage diagnoses of cervical cancer which are more likely to result in complications and death.

During the 2008 General Assembly Session, HB 1227 was introduced by Delegate Vanderhye as a way to increase the number of women eligible for the Every Woman's Life program. The bill, which was not passed[9], would have increased access to the Breast and Cervical Cancer Prevention Treatment Act (BCCPTA) by allowing additional providers to refer women diagnosed with breast or cervical cancer to the VDH Every Woman's Life (EWL) program for eligibility verification and referral to Medicaid for treatment under the BCCPTA. The BCCPTA which was enacted in 2000 established a new state coverage option under Medicaid. Three options for state coverage were allowed and in 2001, the Virginia General Assembly passed legislation to allow for Option 1 treatment service. Option 1 was the most restrictive option; it requires that women be screened for breast and cervical cancer under EWL in order to qualify for treatment under the BCCPTA. In 2008, to allow more low-income, uninsured

[9] Left in House Appropriations Committee - $836,000 GF fiscal impact

women access to Medicaid treatment, EWL proposed expanding to Treatment Option 3, which allows women who meet the EWL eligibility criteria but are screened by a non-EWL provider to be eligible for treatment. It is estimated that approximately 150 additional women would have been eligible for treatment under the BCCPTA if the Treatment Option had been expanded from 1 to 3 via HB 1227. Since the bill was not passed, a core group (Delegate Vanderhye, American Cancer Society, Virginia Breast Cancer Foundation, Komen for the Cure) continues to work on locating funds for the proposed expansion.

Policy Options

☑ **Option 1:** Take no action.

Option 2: Introduce budget amendment (amount to be determined) to fund the staffing of Every Woman's Life (VABCCEDP) providers in underserved health districts.

Additional Options resulting from Jennifer L. Young's and Carl Armstrong's presentations:

Option 3: Introduce budget amendment (amount to be determined later) to increase current appropriations (above the $1.4 million approved for FY 08) to cover the increase in cost of administering the HPV vaccine due to expected rise in per-dose costs and the covering of males (most likely through the Vaccines for Children program).

Option 4: Introduce legislation for mandatory insurance coverage of the HPV vaccine.

Public Comments

No public comments were received for any of the policy options.

JCHC Staff for this Report
Michele L. Chesser, Ph.D.
Senior Health Policy Analyst

HPV Vaccination of women aged 16-26 in Virginia

Jennifer L. Young, MD, MPH, Ruth G. Bernheim, JD, MPH, Mark R. Conaway, PhD, Mark H. Stoler, MD, Thomas C. Guterbock, PHD, Laurel W. Rice, MD

University of Virginia Health System

September 19, 2007

Overview

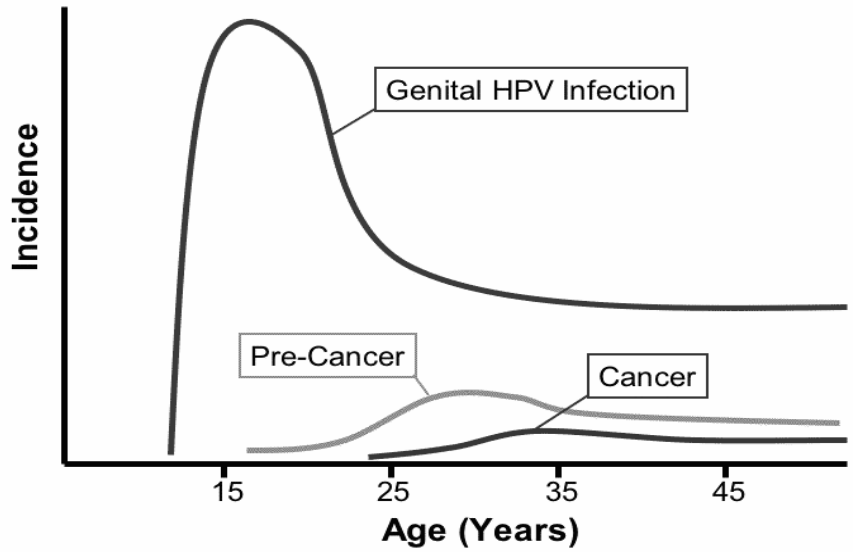
- **Background**
- **Survey design**
- **Survey results**
- **Conclusions**
- **Policy issues**

Human papillomavirus (HPV)

- **Most common sexually transmitted disease**
  - **6.2 million people infected each year[1]**
  - **Prevalence 20 million cases in US[1]**
- **Lifetime risk: 80% for women by age 50**
- **Prevalence in sexually active teenagers: 64-82%[2]**
  - **28% of 14 year olds sexually active[3]**

1. CDC. Genital HPV Infection. 2004
2. Fraser et al. Ped Infect Dis J 2005.
3. Grunbaum JA et al. MMWR 2004.

HPV disease incidence by patient age



http://content.nejm.org/content/vol353/issue20/images/large/01f2.jpeg

Governor's Task Force on Cervical Cancer Recommendations 2005
Hon. Jane H. Woods, Chair

- Implement a public health education campaign to address HPV and cervical cancer
- Explore opportunities to broaden funding for emerging technology
- Follow the CDC's Advisory Committee on Immunization Practices (ACIP) guidelines and if necessary, allocate funding.

The HPV Vaccine

- Quadrivalent vaccine: Gardasil® (Merck&Co, Inc.)
  - Approved by the FDA June 2006
  - Viral types 6,11,16,18
  - Tested in over 25,000 young women aged 9-26[1]
    - 95% efficacy in preventing HPV infection
    - 98.5% efficacy in preventing persistent disease necessary for cervical cancer[1]
    - Most efficacious if given before onset of sexual activity
    - Younger age at vaccination associated with more pronounced immune response

1.FUTURE II study group. NEJM 2007; 356:1915.

The HPV vaccine

- **Bivalent vaccine: Cervarix® (GlaxoSmithKline)**
  - **Pending FDA approval**
  - **Viral types 16,18**
  - **Tested in over 30,000 women aged 15-25[1]**
    - **95% efficacy in prevention of first HPV infection**
    - **100% efficacy in preventing persistent disease**
    - **Protection lasts at least 5 years**
    - **Studies ongoing evaluating cross-reactivity with other viral types**

1. Harper DM et al. Lancet 2004; 364:1757.

Center for Disease Control

- **Advisory Committee on Immunization Practice (ACIP) Recommendation**
  - **Routine vaccination of girls ages 11-12**
  - **Catch-up vaccination up to age 26**

Current Coverage of the HPV vaccine

- 3 shot regimen costing $120/injection or $360 total
- Coverage ≤ 18 years old
  - Public: Federal Vaccines for Children program for Medicaid qualifiers
  - Private: Most insurance companies cover but age range and reimbursements differ
- Coverage > 18 years old
  - Public: No Medicaid allocation
  - Private: Most insurance companies cover but age range and reimbursements differ

Study focus: women ages 16-26

- Unaffected by recently passed school mandate
- Largest percentage of Virginia's uninsured aged 19-32
  - 77,000 Pap tests at VDH local health centers
  - 15,000 Pap tests performed at CHC
  - 41,000 women seen at Free Clinics for acute care
- No longer seen by a pediatrician
- Gynecology practices: poor compliance with vaccination programs

Gynecologists and vaccination

- Schrag et al 2003 – Vaccination practices among Ob-gyns
  - Only 10% offer all vaccines recommended to adult women
  - Despite recommendation for flu vaccine in pregnancy, only 44% gave routinely
  - 41% believe women should get vaccinated elsewhere
- Raley et al 2004 – Attitudes regarding HPV vaccine
  - Majority intend to provide HPV vaccine
  - < 60% of Ob-gyns routinely obtain vaccination information

Study objectives

- Identify barriers to patients, parents, and providers that prevent vaccination of young women
- Describe current distribution of the HPV vaccine in this age group
- Determine provider opinion regarding current and future policies to improve HPV vaccination rates

Survey design

- Provider knowledge, attitudes, and behaviors regarding HPV vaccination for women aged 16-26
- Gynecologists and Family Practitioners
  - 1000 subjects, 500 from each specialty, who currently practice in the state of Virginia
- Tailored Design Survey Method conducted by Center for Survey Research at UVa
- Questionnaire included
  - Demographics
  - HPV and vaccine related treatment experience
  - Barriers to vaccination
  - Policy opinion

Survey results

- 395 respondents
  - 169 family practitioners
  - 216 ob-gyns
- Response rate 45.4%
- Obstetrician-gynecologists and family practitioners similar in attitudes and behaviors related to HPV vaccine

Demographics of providers surveyed

	FP	OB/Gyn	p-value
Age (mean)	49.1	47.9	0.372
Gender (%)			0.815
Male	60.6	61.8	
Female	39.4	38.2	
Years in practice (range)	28.3	16.7	0.114
Location of practice (%)			0.60
Urban	27	16.2	
Suburban	51.5	57.6	
Rural	17.2	22.9	
Other	4.3	3.3	
Practice size (%)			0.269
Solo practice	15.2	10.5	
Small group practice	36	36.7	
Large group practice	37.2	34.8	
Multi-specialty practice	4.3	9.0	
Other	7.3	9.0	

Provider attitudes regarding HPV vaccine

POSITIVE

- 94% confident in vaccine's safety
- 94% confident in vaccine's efficacy
- 91% anticipate decreased rates of abnormal pap tests
- 92% anticipate decreased rates of cervical cancer

NEGATIVE

- 35% concerned about decreasing compliance with pap tests
- 26% concerned it will increase unprotected intercourse

Provider implementation of HPV vaccine

- 72% of providers currently offer the HPV vaccine
  - Another 16% plan to offer vaccine in the near future
- $25-$50 charge per injection on average over the cost of the vaccine
- Most common age of vaccination 19-22 years old
- 70.2% recommend the HPV vaccine to all women in this age range
  - 24.3% selectively recommend
  - 5.5 % never recommend

Factors associated with physician recommendation of HPV vaccine

- Logistic regression
  - Compared doctors who actively recommended the HPV vaccine to those who did not
    - More likely to be female
    - More likely to treat higher % public insurance pts
    - More experience treating HPV-related diseases
  - Compared doctors who offered the HPV vaccine in their practices to those who did not
    - Report less barriers to vaccination
    - More experience treating HPV diseases

Providers

Identified vaccination barriers

	% Responding "almost always" or "often"
Inadequate reimbursement	35.7%
Concern about increased likelihood of unprotected Intercourse if vaccinated	24.9%
No vaccine in stock	23.6%
Lack of time to adequately discuss	19.4%
Concern about earlier age of sexual initiation if vaccinated	14.3%
Lack of patient-oriented educational materials	9.6%
Concern about vaccine efficacy	4.3%
Staff is too busy to vaccinate	4.2%
Concern about vaccine safety	3.1%

Patient experience with HPV vaccine

- 36% of patients aged 16-26 have been vaccinated against HPV
  - 26% vaccinated in the provider's office
  - 10% vaccinated elsewhere
- 12% have declined HPV vaccination
- 30% considering HPV vaccination

Patients

Identified vaccination barriers

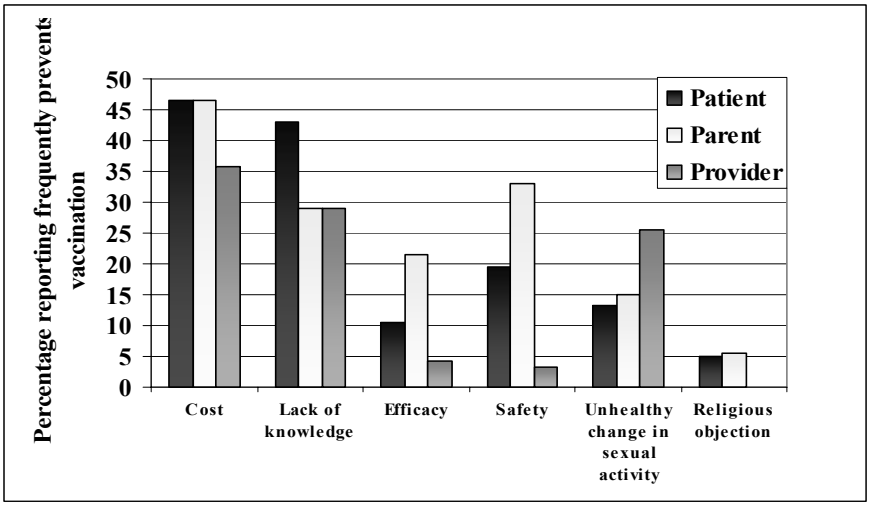
	% Responding "almost always" or "often"
Cost	46.5%
Lacks awareness about HPV infection	43.0%
Concern about vaccine safety	19.4%
Lack of parental consent	11.0%
Concern about vaccine efficacy	10.4%
Stigma associated with an STI	5.4%
Opposes vaccination on religious/moral grounds	5.1%

Parents

Identified vaccination barriers

	% Responding "almost always" or "often"
Cost	46.9%
Concerns about vaccine safety	31.5%
Lacks awareness about HPV infection	29.4%
Concerns about vaccine efficacy	20.7%
Concern that vaccination may be tacit approval of sexual intercourse	14.4%
Concern that vaccination may increase sexual risk-taking	10.6%
Stigma associated with an STI	6.6%
Opposes vaccination on religious/moral grounds	4.2%

Summary of Barriers to HPV vaccination



Provider views on HPV vaccine policies

Policy options	Providers in Favor
Health department vaccination programs	91%
School-based vaccination programs	54%
Mandatory insurance coverage	73%
Mandatory insurance coverage during postpartum care	74%

Provider view on Virginia's school mandate for HPV vaccination

Opinion	Percentage of providers
Strongly favor	37%
Somewhat favor	22.4%
Somewhat oppose	34%
Strongly oppose	0.8%
Other	6.4%

Overall 59.4% of providers support the school mandate

Conclusions

- Cost and education remain significant barriers to HPV vaccination
- Vaccination refusal may be less prevalent than expected
- Providers support policies to improve HPV vaccination rates among women aged 16-26

Current policy issues

- **Current funding allocation for the school mandate may be inadequate**
- **National leadership for school mandates in other states**
- **Health department based programs for vaccination of young women without coverage or access**
- **Mandatory insurance coverage**
- **Improved patient education**

"None of us is going to be satisfied if the only women getting the vaccine are the same women already covered by screening programs."

- John Schiller
National Cancer Institute

Virginia Joint Commission on Health Care

Staff Report: Higher Rates of Cervical Cancer Among Minority Women

Michele Chesser, PhD
Senior Health Policy Analyst
September 19, 2007

Introduction

- Report of the Governor's Task Force on Cervical Cancer, 2005
  - In January 2005, Governor Mark R. Warner issued Executive Directive 5, creating the task force.
  - Task force chair: Jane H. Woods, Secretary of Health and Human Resources.
  - Report completed November, 2005.
  - Recommendation 1 of 5: Request the Joint Commission on Health Care to further study racial, ethnic, and cultural disparities in cervical cancer incidence to identify causes and develop a plan to address findings.

Introduction

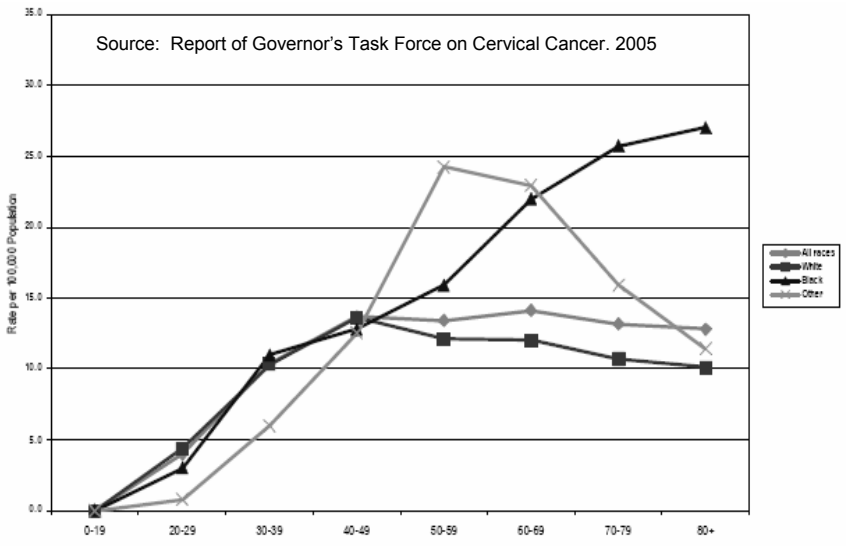
"In Virginia, there are substantial racial, ethnic, and regional disparities for cervical cancer incidence, mortality, and stage of diagnosis. Every Virginian has a vested interest in addressing such disparities and ensuring that all women have access to appropriate preventative screenings and timely access to life saving treatments. By addressing the causal factors of cervical cancer, the overall health of women, especially those at high-risk for this cancer, may be improved."

(Report of Governor's Task Force on Cervical Cancer. P. 4)

Racial/Ethnic Disparities in Cervical Cancer Rates

- Higher incidence of cervical cancer among minority women
- Higher rates of cervical cancer mortality among minority women
- Cervical cancer in minority women more likely to be diagnosed at later stages

Age Adjusted Incidences of Cervical Cancer by Race



SEER Incidence Rates & Trends of Cervical Cancer

	Rate 2000-2004	APC* 1995-2004
White (Non-Hispanic)	7.2	-2.9*
Black	11.4	-4.9*
Hispanic	13.8	-3.6*
Asian / Pacific Islander	9.0	-5.9*
American Indian / Alaska Native	6.6	----

Source: SEER (Surveillance, Epidemiology, and End Results) Cancer Statistics Review, 1995-2004 *Annual Percent Change (P<.05)

% Distribution of Cervical Cancer by Stage at Diagnosis & Race, VA. 1998-2002

	Localized	Regional	Distant	Unstaged
White	55	30	8	7
Black	45	36	12	7
Other	44	38	11	8

Source: Virginia Cancer Registry 2005

5 Year Survival Rates of Cervical Cancer, 1996-2003

	All Stages	Local	Regional	Distant	Unstaged
White	**72.9**	**92.8**	**56.4**	**17.5**	**59.8**
<50	81.0	94.5	62.9	24.4	70.3
50+	59.9	88.3	50.1	12.0	47.9
Black	**62.2**	**85.7**	**48.2**	**9.2**	**56.5**
<50	67.6	86.6	50.6	9.3	65.9
50+	55.0	84.0	45.8	8.9	48.6

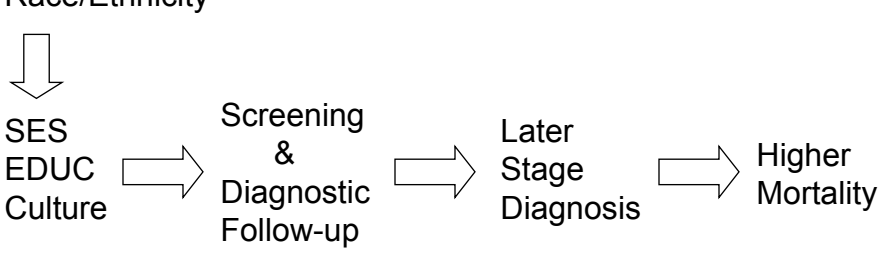
Source: SEER Cancer Statistics Review, 1996-2003

U.S. Death Rates & Trends of Cervical Cancer

	Rate 2000-2004	APC* 1995-2004
White (Non-Hispanic)	2.2	-3.3*
Black	4.9	-4.7*
Hispanic	3.3	-3.3*
Asian / Pacific Islander	2.4	-4.5*
American Indian / Alaska Native	4.0	-1.6

Source: SEER Cancer Statistics Review, 1995-2004
*Annual Percent Change (P<.05)

Causes of Higher Cervical Cancer Rates Among Minorities



Conclusion

- Senator Whipple, in consultation with the director of the Every Woman's Life program, plans to introduce a budget amendment to increase the number of women eligible for Medicaid funding of cervical cancer treatment.
  - This will require changing Virginia's optional coverage from Option 1 to 3 of the federal Breast and Cervical Cancer Prevention and Treatment Act (BCCPTA) of 2000.
    - Option 1: Women whose clinical services were provided all or in part by the CDC program (Current option selected by Va.)
    - Option 3: Women who are screened by any provider that has been authorized by the state, as a CDC grantee to provide screening activities

Conclusion

- Need to increase the number of Every Woman's Life (VABCCEDP) providers in underserved health districts.
  - I.e. Northern Virginia, Piedmont, Crater (Petersburg area)
  - Funds needed for staffing these sites
- VDH is currently investigating the problem of late diagnosis.
  - Many women go beyond the 60 days required by the CDC to receive a diagnosis after an abnormal Pap test. May be due to lack of availability of colpolists.

Policy Options

Option 1: Take no action.

Option 2: Introduce budget amendment (amount to be determined later) to fund the staffing of Every Woman's Life (VABCCEDP) providers in underserved health districts.

Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on October 31, 2007. Comments may be submitted via:
  - E-mail (sareid@leg.state.va.us)
  - Facsimile (804/786-5538) or
  - Mail to Joint Commission on Health Care
    P.O. Box 1322
    Richmond, Virginia 23218
- Comments will be summarized and presented to JCHC's members during its November 8th meeting.

List of Sources

- Baker, P.J, DG Hoel, LC Mohr, SR Lipsitz and DT Lackland. 2000. **Racial, age, and rural/urban disparity in cervical cancer incidence.** Annals of Epidemiology, Volume 10, Issue 7, October, Pages 466-467
- Bazargan, Mohsen; Shahrzad H. Bazargan, Muhammad Farooq and Richard S. Baker. 2004. **Correlates of cervical cancer screening among underserved Hispanic and African-American women.** Preventive Medicine, Volume 39, Issue 3, September, Pages 465-473.

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- Miller, Suzanne and K. Siejak, C. Schroeder, C. Lerman, E. Hernandez, and C Helm. 1997. **Enhancing Adherence Following Abnormal Pap Smears Among Low-Income Minority Women: A Preventive Telephone Counseling Strategy.** Journal of the National Cancer Institute. Vol. 89, No. 10. May 21.
- Ries LAG, Melbert D, Krapcho M, Mariotto A, Miller BA, Feuer EJ, Clegg L, Horner MJ, Howlader N, Eisner MP, Reichman M, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2004, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2004/, based on November 2006 SEER data submission, posted to the SEER web site, 2007.
- **Report of the Governor's Task Force on Cervical Cancer**. 2005. Secretary of Health and Human Resources.

List of Sources

- Virginia Department of Health. Kathleen Rocco, RD, MPH. Every Woman's Life. Program Director. Kathy.Rocco@vdh.virginia.gov
- Virginia Department of Health. Mary Zoller, MPA. Mary.Zoller@vdh.virginia.gov

Internet Address

Visit the Joint Commission on Health at its new website:
http://jchc.state.va.us/

Address:
900 East Main Street, 1st Floor West
P O Box 1322
Richmond, VA 23218

Appendix A
Executive Directive 5 (2005)

GOVERNOR'S TASK FORCE ON CERVICAL CANCER

Importance of the Issue

Cervical cancer is a significant public health and women's health issue. In the United States there are an estimated 12200 cases of cervical cancer and 4,100 related deaths annually. Cervical cancer, most prevalent in women between the ages of 35-55, is also among the most preventable forms of cancer, through early detection.

By virtue of the authority vested in me as Governor under Article V of the *Constitution of Virginia* and under the laws of the Commonwealth, including but not limited to Chapter 1 of Title 2.2, I hereby create the Governor's Task Force on Cervical Cancer.

The Task Force

The task force will initially consist of 15 members appointed by the Governor and serving at his pleasure. Additional members may be appointed by the Governor at his discretion. The task force will be chaired by the Secretary of Health and Human Resources. Staff support will be provided by the Office of the Secretary of Health and Human Resources, the Department of Health, and the Department of Medical Assistance Services.

Responsibilities of the Task force

The task force will be responsible for the following:

1) Fostering forward thinking collaboration toward early detection;
2) Bringing additional energy, visibility, accountability, and public awareness to the issue of cervical cancer:
3) Identifying approaches to allow the state to meet or exceed its Healthy People 20 10 goals with respect to cervical cancer;
4) Developing strategies to reduce the incidence of cervical cancer in the Commonwealth: and

5) Making policy recommendations as are deemed appropriate to the Governor and General Assembly,

The task force shall also examine other related issues as appropriate.

Reporting Requirements

The task force shall issue a preliminary report to the Governor and General Assembly by November 1, 2005.

Effective Date of the Executive Directive

This Executive Directive shall be effective upon its signing and shall remain in full force and effect until January 14, 2006, unless sooner amended or rescinded by further executive directive.

Given under my hand this 4th day of January 2005.

_____

Mark R. Warner. Governor

Joint Commission on Health Care

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