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CME ACTIVITY

Preventing Cervical Cancer

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Introduction and Background

The American Cancer Society estimates that in 2010, about 12,200 new cases of invasive cervical cancer and about 4,210 deaths from cervical cancer will occur. Invasive cervical cancer incidence has decreased by 70% over the last five decades; while at one time it was the leading cause of cancer death among women, it currently ranks 13th for cancer deaths among women in the United States.¹ Each year, preventable cases of cervical cancer continue to be diagnosed and significant disparities persist with black, Hispanic, and low-income women at much higher risk for developing the disease. For many women in Los Angeles County, cervical cancer remains a serious health threat.

National cervical cancer incidence rates indicate that Hispanic and black women are disproportionately affected² and, in Los Angeles County, Hispanics and Asian/Pacific Islander (API) women have higher rates. (Table 1)

Subgroup analyses also reveal that Korean and Vietnamese women have

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Cervical cancer is one of the most preventable types of cancer in the United States, yet each year, thousands of women will develop invasive cervical cancer and more than 4,000 women will likely die from this condition in 2010. When found early, cervical cancer can usually be cured, but cervical cytology testing (Pap test) rates have declined to 83% and inconsistent adherence to guidelines results in both overuse and underuse, increased costs, and increased harm to some patients. Additionally, two vaccines are available to prevent cervical cancer, but nationally, only 1 out of 4 adolescent females between 13 and 17 years of age has received the recommended 3 doses of human papillomavirus (HPV) vaccine. This CME activity addresses common barriers to cervical cancer screening and vaccination and provides resources to support preventive efforts.

Table 1. Cervical Cancer Incidence and Mortality Rates for U.S. and Los Angeles County by Ethnicity

Ethnicity	Cervical Cancer Incidence Per 100,000 Persons		Cervical Cancer Mortality Per 100,000 Persons	
	National ¹	LA County ²	National ¹	LA County ³
Overall	8.1	10.0	2.4	3.3
White	7.9	7.5	2.2	3.1
Black	10.1	7.6	4.4	3.7*
Hispanic	12.0	14.3	3.1	4.0
Asian/Pacific Islander	7.5	9.3	2.1	2.7
American Indian/ Alaskan Native	7.7	**	2.4	**

1 2003-2007 SEER data

2 1998-2007 USC Cancer Surveillance Program data

3 2006 LA County Department of Public Health, Data Collection and Analysis Unit

* Estimate is statistically unstable | ** Cell sizes less than 5 – data not reported due to confidentiality



incidence rates higher than the average rate among API women. In addition, women living at the lowest socioeconomic status (SES) level have rates three or more times higher than those at the highest SES level.³ Although cervical cancer mortality rates have declined for all race/ethnic groups over the last decade, the decline has not been proportionate. Nationally, rates are highest among black women and, in Los Angeles County, rates are highest among Hispanic women.³

Link Between HPV and Cervical Cancer

Infection with high-risk strains of HPV, generally acquired sexually, is the most important risk factor for cervical cancer. HPV, found in 99.7% of cases of invasive cervical cancer, is a necessary but insufficient precursor of invasive cervical cancer. Host factors such as age, nutritional status, immune function, and smoking influence the incorporation of viral DNA into host cervical cells. In the United States, peak incidence and prevalence of HPV infection occur among women age 15 through 24 years, but most infections in younger women are transient with 90% clearing within 2 years. HPV infections in older women are much less prevalent but carry a higher risk of progression to cervical neoplasia. Natural history studies confirm that in the vast majority of cases, the course of infection and cervical abnormalities that do progress do so in an orderly fashion from less to more severe lesions. Two HPV vaccines are available in the United States, but vaccination rates remain low and increased efforts are required to improve coverage levels.

Impact of Cervical Cytology

With the advent of cervical cytology testing (Pap test) in 1941 and the subsequent institution of cervical cancer screening programs, marked reductions in cervical cancer incidence and mortality have followed. Worldwide, cervical cancer remains the leading cause of cancer death in many developing countries where routine cervical cancer screening programs have not been implemented. In the United States, a majority of cases of invasive cervical cancer occur in women who are not adequately screened. It is estimated that among women diagnosed with cervical cancer each year, 50% have never had cervical cytology testing and another 10% had not been screened within 5 years before diagnosis.

Annual cervical cancer screening rates in the United States have declined from a peak of 87% in 2000-2002, to 83% in 2008 and remain below the 2010 Healthy People target of 90%. Factors such as income and educational level influence screening rates, with women in the lowest income bracket and educational level having the lowest screening rates, at 72% and 74% respectively. In Los Angeles County, there are racial/ethnic disparities with Asian/Pacific Islanders having statistically significant lower screening rates (70%) than all other ethnic groups. Uninsured women also have low screening rates, 77% compared with 90% among women who are privately insured.³

When found and treated early, cervical cancer can usually be cured. The 5-year survival rate for localized invasive cervical cancer is 91%, compared to 17% for metastatic disease.² Because of cervical cancer screening, noninvasive cervical cancer or pre-cancerous lesions are diagnosed four times more often than invasive cancer. The treatment of these precancerous lesions can essentially preclude the development of invasive cervical cancer, making cervical cancer a highly preventable cancer; no woman should die of it.

When treated early, cervical cancer often can be cured. The 5-year survival rate for localized invasive cervical cancer is 91% versus 17% for metastatic disease.

Challenges to Improving Cervical Cancer Screening

To further reduce cervical cancer morbidity and mortality in the United States, physicians should follow the accepted screening standard of care, which maximizes the benefits and minimizes the harms of screening. Research indicates that physicians believe it is important to adhere to cervical cancer screening guidelines. However, gaps in knowledge, understanding, and adoption of recommended guidelines contribute to low levels of guideline adherence. In one study, only 57% of physicians were found to adhere to published cervical cancer screening guidelines.⁴ Guideline-inconsistent care results in overuse of screening among women at average risk for cervical cancer, under-screening in certain groups at higher risk, and concomitant increased health care costs and increased harms to patients.

Impact of the HPV Vaccine on Cervical Cancer

In June 2006, the first HPV vaccine (HPV4) was approved by the Food and Drug Administration (FDA). This highly effective and safe vaccine provides protection against two high-risk HPV types that cause 70% of cervical cancers and two low-risk HPV types that cause 90% of genital warts. In 2009, a second vaccine (HPV2) was FDA-approved. It protects against the two high-risk HPV types that cause 70% of cervical cancers. Although the full promise of these vaccines will only be realized in the decades to come, they represent important new tools in the fight against cervical cancer.

Although the introduction of two HPV vaccines will likely lead to significant declines in cervical cancer cases, it will not eliminate the need to conduct routine cervical cancer screening. While the vaccines are nearly 100% effective in preventing the types of HPV that cause most cervical cancer, they do not protect against other HPV virus types that lead to 30% of cervical cancer cases. In addition, many sexually active

women have already been infected with HPV and vaccination does not treat existing infections. Thus, it is important to continue routine screening efforts to identify cervical cancer cases early.

Challenges to Improving HPV Vaccination Rates

Although both HPV vaccines are safe and effective in preventing cervical cancer, vaccine uptake remains low. The 2009 National Immunization Survey results reveal that less than 50% of adolescent girls aged 13 through 17 years in the U.S. had received 1 or more doses of HPV vaccine and only one-quarter had received all recommended doses.⁹ Several barriers may contribute to low coverage levels: limited patient and provider knowledge of HPV and vaccination guidelines, parental and physician concerns regarding vaccine safety and efficacy, a disinclination to vaccinate 11- to 12-year-olds against a sexually transmitted infection, cost and reimbursement issues, limited use of recommended immunization practices, and limited competence in counseling about vaccine risks and benefits.

Cervical Cancer Screening Guidelines

The United States Preventive Services Task Force (USPSTF) issued cervical cancer screening guidelines in January 2003 that serve as the basis for the recommendations that follow. In addition, the cervical cytology guidelines issued from the American College of Obstetricians and Gynecologists (ACOG) in December 2009 will be used to supplement recommendations where new research supports a change in practice. (Table 2)

Initiation of Screening

Cervical cancer screening should begin at age 21 years and not before. Guidelines promoted in 2003 recommended initiation of screening 3 years after the onset of sexual activity but no later than 21 years of age. New research provides strong evidence that screening among women younger than 21 years should no longer be performed due to the potential harms

during management of abnormal cytology results among adolescents.

Dysplasia is found commonly among adolescents due to a high prevalence of infection with HPV and active squamous metaplasia occurring in the cervix during adolescence, but 90%-95% of low-grade lesions in adolescent women, as well as many high-grade lesions regress to normal. Thus, the incidence of cervical cancer is very low in younger women, with only 0.1% of cases of cervical cancer occurring before 21 years and the incidence rate as low as 1-2 cases per 1,000,000 women aged 15 through 19 years.

Management of dysplasia among adolescents results in procedures such as excision or ablation of the cervix. Recent studies have found an association between poor pregnancy outcomes among women previously treated for cytological outcomes and a significant increase in premature births and low-birth-weight neonates in women who had undergone excisional procedures of the cervix. Therefore, the benefits of screening are clearly offset by the potential harms for this group.

Screening Intervals

Annual cervical cytology is not indicated for women of average risk. The USPSTF found no direct evidence that annual screening achieves better outcomes than screening every 3 years. In the past, because the sensitivity of a single Pap test for high-grade lesions has been 60%-80%, organizations have recommended annual Pap tests until a specified number (usually two or three) are cytologically normal before lengthening the screening interval. However, modeling studies suggest little added benefit from more frequent screening for most women. Also, annual screening has been shown to triple the number of follow-up interventions compared with triennial screening.

The 2009 ACOG guidelines recommend screening every 2 years for women aged 21 through 29 years, and every 3 years

Table 2. Cervical Cancer Screening Recommendations for Average-Risk Women Using Cervical Cytology

Intervention	Recommendation
Initiation of Screening	Age 21 years
Screening Intervals	Every 2 years for women ages 21-29 years
	Every 3 years for women ages 30 years and older
Cessation of Screening	Ages 65-70 years with 3 or more documented, consecutive, technically satisfactory, normal tests, and no abnormal tests in the previous 10 years
	After total hysterectomy for benign causes
Co-testing with HPV Test	There is no clear benefit over cytology alone; if used, should be done for women ages 30 years and older, no more often than every 3 years
Liquid-based Cytology	There is no preference for use of this test over conventional methods of cervical cytology

for women 30 years and older with three consecutive normal cervical cytology test results in the past. The more frequent testing interval for younger women reflects the role age plays in the sensitivity of the screening. The rate of dysplasia decreases as the number of sequential negative Pap test results increases; however, a negative cervical cytology screening result confers less protection among women younger than 30 years than in older women.

More frequent screening may be needed in women with the following risk factors: HIV infection; immunosuppression; exposure to diethylstilbestrol in utero; and previous treatment for CIN 2, CIN 3, or cancer. It is also important that medical histories be adequately assessed for new patients, given that frequent recall errors in timing and results of recent screening may put women at higher risk for dysplasia.

Age to Discontinue Screening

The USPSTF, ACOG, and American Cancer Society (ACS) agree that women aged 65 through 70 years who have been adequately screened in the recent past can discontinue screening. Evidence is limited to define “adequate recent screening.” However, based on available evidence, the ACS guidelines recommend that older women can safely stop screening if they have had three or more documented, consecutive, technically satisfactory normal/negative cervical cytology tests, and have had no abnormal/positive cytology tests within the last 10 years.⁶

Although the risk of cervical cancer and yield of screening declines steadily through middle age, older women who have never been screened have the highest incidence and mortality from cervical cancer. Almost 20% of new cervical cancer cases occur in women 65 years and older. Therefore, screening is recommended in older women who have not been previously screened, when information about previous screening is unavailable, or when screening is unlikely to have occurred in the past (e.g., among women from countries without screening programs).

Screening Recommendations after Hysterectomy

Routine cytology screening after total hysterectomy for benign disease (i.e., no evidence of cervical neoplasia or cancer) should be discontinued given the low yield of screening and potential harms from false-positive results among these women. Clinicians should confirm that a total hysterectomy was performed, through surgical records or by inspecting for the absence of a cervix. Screening should be continued when there is a history of CIN 2 or CIN 3, or invasive cancer, or when the indications for hysterectomy are uncertain.

Acceptable Screening Methodologies

Both liquid-based and conventional methods of cervical cytology are acceptable for screening. In its 2003 guidelines, the USPSTF concluded there was insufficient evidence to determine whether liquid-based cytology was more effective than conventional cytology in reducing cervical cancer incidence or mortality. Currently, liquid-based cytology is used in the majority of cervical cytology screenings in the U.S.

Recommended Cervical Cancer Screening Counseling Messages

- Cervical cancer is a preventable condition. Pap tests can find cancer and precancer at an early stage when it can be treated and cured. Most cervical cancers are found in women who have not had regular Pap tests.
- In the past, the Pap test was recommended every year but now we know that women with average risk can get screened every 2 or 3 years depending on their age. How often we test may depend on their history and past Pap test results. Because cervical cancer takes many years to develop, screening every 2 or 3 years is enough time to find changes before the cancer develops.
- Getting Pap tests more often than you need them can increase your chances of having a false-positive test (abnormal test results when there is no disease). Further tests would be needed to find out whether there is a real problem.
- Pap tests are not recommended in women younger than 21 years of age because cervical cancer is rare at this age. Removal of tissue from the cervix that usually occurs as a follow-up of abnormal Pap results may affect a women’s ability to have a normal pregnancy.
- Most women who have been screened with Pap tests on a regular basis can stop screening between ages 65 and 70. The risk of developing cervical cancer is low in older women who have received regular screening.

The disadvantages of liquid-based compared with conventional cytology are the lower specificity and higher cost. The key advantage is the ability to test for HPV, gonorrhea, and chlamydia infection directly from the same sample. Studies of specimen adequacy have found minimal differences in rates of unsatisfactory results between the two modalities; however, liquid-based cytology may be superior in women with cervical bleeding or obscuring inflammation. Although liquid-based cytology may be more sensitive in detecting low-grade cervical abnormalities, there is no evidence that liquid-based cytology improves the detection of high-grade lesions. The USPSTF does not state a preference for this test.

Role of the HPV Test in Primary Screening

Testing for high-risk HPV as a primary screening modality, either as an adjunct to or in place of cervical cytology testing, has been proposed. Although using HPV DNA testing alone or with cervical cytology for screening increases the sensitivity, there is poor specificity and a corresponding poor positive predictive value. This lower specificity is marked among younger women given the high rate of transient, acute HPV infection in women of this age. The specificity improves significantly in women over age 30 years but remains lower than for cytology alone.

The 2009 ACOG guidelines recommend the combination of cytology and HPV DNA testing as an appropriate screening test for women 30 years and older. If both tests are negative, rescreening should occur no sooner than 3 years. The costs of this combined screening modality are significantly higher due to the costs of the initial screening tests and from the additional follow-up studies inherent in utilizing a modality with lower specificity. Until there is clear evidence that this modality is superior to cytology alone or there is evidence to support prolonging the interval of screening further, there does not appear to be a clear benefit for using cytology with HPV DNA testing for screening. At the time of the USPSTF guidelines release in 2003, HPV DNA testing for primary cervical cancer screening had not been approved by the FDA.

Counseling Patients about Cervical Cancer Screening Options

Research indicates that physicians believe it is important to adhere to cervical cancer screening guidelines, but studies suggest gaps in knowledge, understanding, and adherence to recommended guidelines. This results in continued annual Pap test screening and other practices that are often not consistent with guidelines.^{7,8} Overuse of screening tests contributes to increased health care costs and increased harms, such as false-positive results, unnecessary procedures, and over-treatment. It is crucial to comply with evidence-based clinical guidelines to maintain a positive balance of the benefits and risks of Pap tests.

Barriers to physicians' adoption of new guidelines may be associated with a fear that patients will not seek annual health screenings if there is no need for an annual Pap test. However, studies show that women's top reasons for annual visits did not include to receive a Pap test, but rather to stay healthy and to maintain continuity with their physician. Research also shows that women are willing to reduce their screening frequency, accept a 3-year interval for Pap tests if their physician thinks it is best for them, and to end screening if recommended by their physician.⁹

HPV Vaccinations

HPV infection causes more than 99% of cervical cancers and up to 70% of other genital and oropharyngeal cancers in the U.S.¹⁰ HPV infection also leads to genital warts, which may impact a significant number of men and women in Los Angeles

County, with 5% of patients visiting Los Angeles County Public Health STD clinics in 2009 diagnosed with genital warts (7% of males and 2% of females presenting for care).

Two HPV vaccines licensed for use in the U.S. protect against the virus types that cause most cervical cancer tumors, and one protects against genital warts. Approximately 70% of cervical cancerous tumors are caused by HPV viral types 16 or 18, and about 90% of genital warts are caused by viral types 6 and 11.¹⁰ The bivalent HPV2 vaccine (Cervarix, GlaxoSmithKline) protects against two oncogenic types (HPV 16 and 18). The quadrivalent HPV4 vaccine (Gardasil, Merck) protects against two oncogenic types (HPV 16 and 18) and two non-oncogenic types (HPV 6 and 11). Thus, prophylactic immunization could prevent many tumors, warts, and genital cancers; reduce treatment costs; prevent distressing treatment; and reduce deaths.

Current HPV Vaccination Rates

Data from the 2009 National Immunization Survey (NIS) suggest that HPV vaccination coverage rates among adolescents 13 through 17 years of age have increased but remain low. Nationally, female adolescents who received ≥ 1 dose of HPV vaccine increased from 37% in 2008 to 44% in 2009. Those who received ≥ 3 doses increased from 18% to 27%.¹¹ HPV vaccine initiation was higher among those living below the poverty level, and completion rates were highest among whites and American Indian/Alaskan Natives. (Table 3)

Recommendations of the Advisory Committee on Immunization Practices

The bivalent HPV2 vaccine, which is directed at oncogenic types HPV 16 and 18, is licensed for females 10 through 25 years of age. The quadrivalent HPV4 vaccine, which is directed at two oncogenic types (HPV 16 and 18) and two non-oncogenic types (HPV 6 and 11), is licensed for use in females and males 9 through 26 years of age.¹¹ Both vaccines are administered in a 3-dose schedule. (Figure 1)

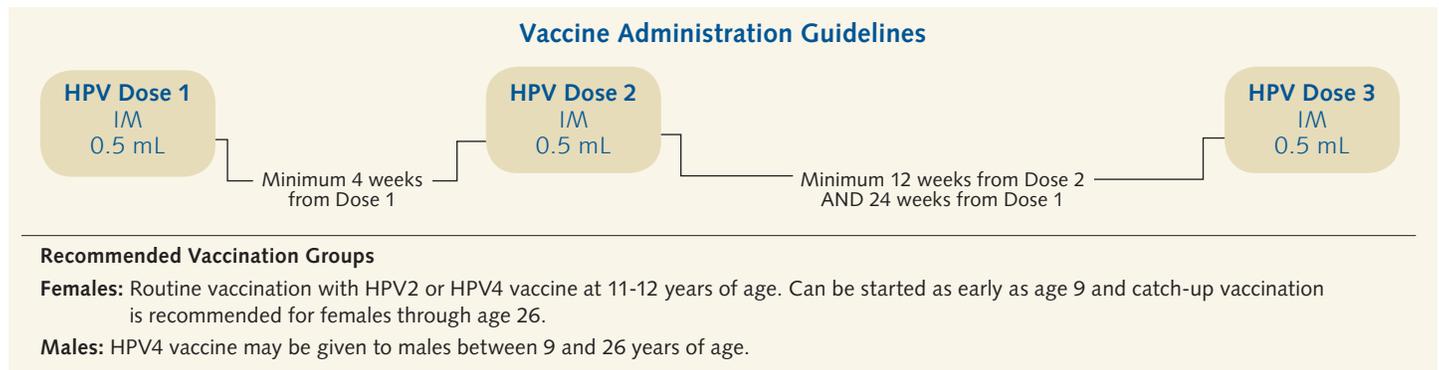
Routine Vaccination of Females

The Advisory Committee on Immunization Practices (ACIP) recommends initiating the 3-dose HPV vaccination series for females at age 11 or 12 years during a preadolescent visit to the doctor, preferably before sexual activity begins.¹² Immunogenicity studies have found that antibody titers are

Table 3. Estimated HPV Vaccine Coverage Rates among Adolescents Aged 13-17 Years by Race/Ethnicity and Poverty Level – National Immunization Survey – Teen, United States, 2009

Number of HPV Doses	Race/Ethnicity						Poverty Level	
	White (n=14,107)	Black (n=2,047)	Hispanic (n=2,479)	American Indian/ Alaskan Native (n=258)	Asian (n=444)	Other (n=731)	Below Poverty Level (n=2,506)	At or Above Poverty Level (n=16,781)
≥ 1 dose	43.9 (41.8-46.1)	44.6 (39.9-49.5)	45.5 (40.3-50.8)	52.3 (39.0-65.2)	41.5 (29.5-54.5)	42.2 (31.5-53.6)	51.9 (47.0-56.8)	42.5 (40.5-44.5)
≥ 3 doses	29.1 (27.3-31.0)	23.1 (19.1-27.6)	23.4 (19.7-27.6)	29.6 (20.0-41.4)	22.1 (14.7-31.8)	21.5 (13.6-32.2)	25.5 (21.4-30.1)	26.8 (25.1-28.4)

Figure 1. Human Papillomavirus Vaccine (HPV2 and HPV4) Recommendations



highest among those who have been vaccinated at a younger age. Catch-up vaccination is recommended for females aged 13-26 years who have not been vaccinated previously or who have not completed the 3-dose series.

ACIP recommends vaccination of females with either bivalent (HPV2) or quadrivalent (HPV4) HPV vaccines to prevent cervical cancers and pre-cancers. Both HPV vaccines have comparable efficacy and similar safety profiles; therefore, ACIP has not stated a preference for and does not recommend the use of one HPV vaccine over the other. Providers should educate patients about both vaccines to help them make an informed decision about which vaccine to receive.

Permissive Vaccination of Males

ACIP permits the use of quadrivalent HPV4 vaccine in males ages 9 through 26 years for the prevention of genital warts, but stopped short of universally recommending vaccination. If given, the 3-dose series should be initiated during the preadolescent visit at 11 or 12 years of age, as post-vaccination antibody titers were significantly higher in males aged 9 through 15 years compared with males aged 16 through 26 years.¹² This also increases the likelihood of receipt before initiation of sexual activity.

Vaccine Administration Guidelines

ACIP guidelines for dosing and administration are the same for HPV4 and HPV2, and for females and males.¹³

- The maximum age for administration for both vaccines is 26 years.
- Although the minimum age for administration for both vaccines is 9 years, the first dose should be administered at the preadolescent visit at age 11-12 years old.
- The second dose is administered 1 to 2 months after the first dose, with a 4-week minimum interval.
- The third dose is administered 6 months after the first dose, with a minimum interval of 12 weeks between the second and third dose, and 24 weeks between the first and third dose.
- Doses administered in a shorter interval than that recommended must be readministered. If intervals are longer than minimum intervals, the vaccine series does not need to be

restarted. Recommended routine dosing intervals should be used for series catch-up when the vaccine is administered to individuals between 13 through 26 years of age.

- Each dose in the 3-dose series is 0.5 mL, administered intramuscularly, preferably in the deltoid muscle.

Vaccine Efficacy

HPV4 Efficacy

Quadrivalent HPV vaccine has been found to have high efficacy for prevention of HPV types related to cervical precancer and genital warts in women 16 through 26 years of age. Clinical efficacy for 3 doses was determined to be 100% for prevention of HPV types 16- or 18-related cervical intraepithelial neoplasia (CIN 2/3) or adenocarcinoma in-situ (AIS). Efficacy against HPV types 6, 11, 16, or 18 related to genital warts among females was 99%.¹⁴ There was no waning immunity found after a 5-year follow-up.

Among males 16 through 26 years of age, the 3-dose vaccine series prevented 89% of genital warts related to HPV types 6, 11, 16, or 18, with high seroconversion rates. Median duration of protection at the time of the efficacy analysis was approximately 2.3 years.¹²

HPV2 Efficacy

The efficacy of HPV2 was evaluated in several clinical trials in females aged 15 through 26 years. Efficacy against HPV 16- or 18-related CIN 2/3 or AIS was 93%.¹⁵ In a post-hoc analysis, cross protection of HPV 31-related CIN2/3 was evident with 89% efficacy noted. Duration of immunity with HPV2 vaccine is approximately 6 years for women who received all three scheduled doses.

Vaccine Safety and Adverse Events

All vaccines are studied in stringent clinical trials before licensure. Over 29,000 males and females participated in HPV4 vaccine clinical trials. The most common adverse events were mild to moderate pain, swelling, or erythema at the injection site. Systemic adverse events such as fever were reported by a similar proportion of vaccine and placebo recipients. Vaccine-related serious adverse events occurred in <0.1% of persons, and the proportion of reports in the vaccine

groups were similar to those in the control groups.¹⁶ No deaths that occurred during the trials were considered vaccine-related.¹⁷

HPV2 vaccine was licensed for use in Australia and Europe in 2007, two years prior to licensure by the FDA in the United States. In the U.S., more than 30,000 females participated in clinical trials. Pain, redness, and swelling at the injection site were the most common events reported, and fatigue, headache, and myalgia were the most common general symptoms reported. Proportions of persons reporting a serious adverse event were similar in vaccine and control groups.¹³

Adverse Events Reports Following HPV Vaccination

The Vaccine Adverse Events Reporting System (VAERS) is a national vaccine safety surveillance system that collects information about possible adverse events that occur after vaccination. VAERS reports represent adverse events that are suspected but not proven to be caused by a vaccine. Thus, the data are limited but can be useful in assessing vaccine safety.

Since vaccine licensure, VAERS has received less than 15 reports of suspected adverse events in the U.S. following HPV2 vaccination.¹⁴ As of May 31, 2010, approximately 29.5 million doses of HPV4 were distributed in the U.S., and there were 16,140 VAERS reports of adverse events following HPV4 vaccination in the U.S. Of these reports, 92% were considered to be non-serious.¹⁴

Non-Serious Adverse Event Reports (HPV4)

VAERS defines non-serious adverse events as those other than hospitalization, death, permanent disability, and life-threatening illness. The vast majority (92%) of the adverse events reports following HPV4 vaccination were non-serious events such as fever, pain, swelling at the injection site (the arm), headache, nausea, and fainting. Fainting is common after injections, especially in adolescents. Falls after fainting can be prevented by having the patient sit down for their vaccination and by closely observing the patient for 15 minutes after vaccination.

Serious Adverse Event Reports (HPV4)

VAERS defines serious adverse events as events that require hospitalization, or result in permanent disability, life-threatening illness, and death. Eight percent of adverse events reported following HPV4 vaccination were characterized as serious. No serious event reports were found to be caused by the vaccine.

Post-licensure Study Finds HPV4 Vaccine to Be Safe

A joint post-licensure study conducted by the CDC and FDA analyzed adverse events after HPV4 vaccine administration between June 2006 and December 2008. The report suggests that the HPV4 vaccine continues to be safe and effective and that the benefits of vaccination continue to outweigh associated risks. The rate of most adverse events following HPV vaccination was comparable to the rate of the same events following administration of other vaccines (i.e., meningitis and Tdap) in the same age group (9-26 years of age). There were disproportional reports of syncope and blood clots, but

these were not proven to be caused by the vaccine. Further investigation regarding this finding was recommended.

Vaccine Storage and Handling Guidelines

To ensure the potency and viability of vaccines, proper storage and handling per the manufacturer's recommendations are essential. See Figure 2 for recommended vaccine storage practices. Excessive heat or cold will reduce the potency of the vaccine, thus increasing the risk that patients will not be protected against the vaccine-preventable disease for which they received the vaccine.¹⁸

HPV2 and HPV4 are inactivated vaccines that must be stored in the refrigerator within a temperature range of 36° F to 46° F (2° C to 8° C). These vaccines should not be exposed to freezing temperatures and should be protected from light.

Recommended HPV Vaccination Counseling Messages

The most important factor encouraging HPV vaccination is a physician recommendation. Women who receive a strong physician recommendation are up to four times as likely to be vaccinated against HPV as those who receive a weaker recommendation.¹⁹ A 2009 study conducted in Los Angeles County also found a physician recommendation to be a strong predictor of HPV vaccine uptake among low-income ethnic minority girls.²⁰

Most physicians feel comfortable counseling patients on and administering HPV vaccine²¹ but recent research suggests a need to enhance counseling efforts. Nearly one-third of the parents of low-income girls participating in a 2009 Los Angeles County study were not aware of the HPV vaccine, and two-thirds of the parents of unvaccinated children stated that they did not have enough information to make a decision about the vaccine. Further, differences were found across race/ethnicity, with only 20% of Chinese parents reporting that they had sufficient information to make a decision about the vaccine.²⁰

In busy offices, it can be challenging to find the time to talk to patients and/or parents about vaccines, but a short conversation, educational materials, and referrals to reliable information sources can help them make the best decision about the HPV vaccine. Consider the research findings and proposed messages outlined in Table 4 when talking to patients and/or parents about HPV vaccination. Finally, patients/parents who decline vaccination may reconsider vaccination later; therefore, consider recommending the vaccine again at a future visit.

Patients' Background and Culture May Influence Vaccine Acceptance

Overall, there do not appear to be significant differences in vaccine acceptance among racial/ethnic groups, but patients' backgrounds and cultures may influence vaccination decisions. For instance, cultural values may influence who makes decisions about vaccination. In some Hispanic families, the father or grandmother may wish to be involved, even if he or she is not present at the office visit. Physicians may wish to discuss the vaccine with those present, provide educational

materials for the family, and schedule a follow-up visit to further discuss and provide the vaccine.

A recent study in Los Angeles County suggested that Hispanic and Asian parents may feel that their children are less at risk for HPV infection than girls of other ethnic groups.²⁰ In addition, some parents may not be comfortable openly discussing sexuality with their children present.²² In these instances, physicians may wish to focus the discussion on the result of HPV infection, cancer, rather than on the transmission route, sexual activity.

Some groups may be less trusting of the medical establishment and vaccinations. For instance, some research suggests that black parents may be more likely to believe that giving their daughter HPV vaccine is like conducting an experiment,²³ or that HPV vaccine may cause future health problems and/or problems getting pregnant.²⁰ For families who are skeptical about the value of the vaccine, it may be advisable to stress that doctors and experts agree that HPV vaccines are safe, that the vaccines have a proven record, and that you personally believe in the vaccines for your patients and your own family.

For minors, a decision to vaccinate is a shared decision among the physician, patient, and parent. Thus, it is important to engage adolescents in the discussion and consider how teen perceptions and beliefs, such as fear of needles, fear of disclosing sexual activity to parents, and low-risk perception, may influence their vaccination decision.

Finally, language and acculturation issues may impact vaccination. Whenever possible, offer translation services and educational materials in the patients' preferred language. For a list of educational resources in multiple languages, see the Resources box on page 11.

Proven Strategies for Improving Screening and Vaccination Rates

To promote cervical cancer screening, facilitate screening and vaccination services, and reduce missed opportunities to provide these preventive services, physician offices and clinics may implement the following strategies recommended by the Task Force on Community Preventive Services (Task Force).

- **Reminder-recall systems** are widely recommended for increasing cervical cancer screening and immunization rates. Reminders notify patients (and/or parents) when a service such as a Pap test or HPV vaccine is due. Recalls notify patients when the service is overdue. These activities can be done via mail, e-mail, automated or real-time phone calls, or text messages.

The California Immunization Registry (CAIR) facilitates vaccine reminder/recall activities and consolidates records from multiple providers. For more information, visit www.immunizelink.org.

- **Provider feedback and reminders** have been found to improve cervical cancer screening and immunization rates. Feedback gives providers information and data on their effectiveness in providing recommended screening and/or vaccinations. Reminders inform providers when individual clients are due for screenings or vaccinations. These include notes in client charts and alerts from electronic health records and/or immunization registries like CAIR.

- **Multi-component activities that include education** have improved immunization rates. One-on-one education and patient educational media, such as brochures and videos, have improved cervical cancer screening rates.

Patients and parents may be uncertain about cancer screenings and vaccinations, especially when recommendations are new. Physicians should address concerns, be empathetic listeners, be prepared to answer patients' questions, and refer patients and/or parents to reliable sources of information.

- **Multi-component interventions that expand access or reduce out-of-pocket cost** have been proven to increase immunization rates. However, the Task Force found insufficient evidence to recommend strategies for reducing structural barriers and reducing out-of-pocket costs for cervical cancer screening.

Adolescents may consider school and extracurricular activities a priority. Providing evening and weekend office hours may improve access to immunization services.

To reduce costs, providers may participate in the Vaccines for Children (VFC) Program and/or pharmaceutical Vaccine Patient Assistance Programs.

Different strategies may be needed to improve vaccination coverage levels for adolescents because teens may not present for preventive care, fear needles, not wish to disclose sexual activity, have a low-risk perception, and not have a consistent primary care provider.²³

Conclusion

As noted, cervical cancer is one of the most preventable types of cancer in the United States and can be often be cured when found early. Routine cervical cytology testing, along with vaccination against HPV, can significantly reduce the number of cases and deaths, but gaps in patient and provider knowledge, limited use of recommended office-based practices, and limited competence in counseling patients have led to inconsistent adherence to screening guidelines and relatively low immunization coverage levels.

To prevent cervical cancer and identify cases early when the prognosis is best, health care providers are encouraged to initiate cervical cytology testing at 21 years of age, adhere to age-appropriate screening intervals, cease screening at 65-70

Figure 2

Refrigerator Setup for Storing Vaccines

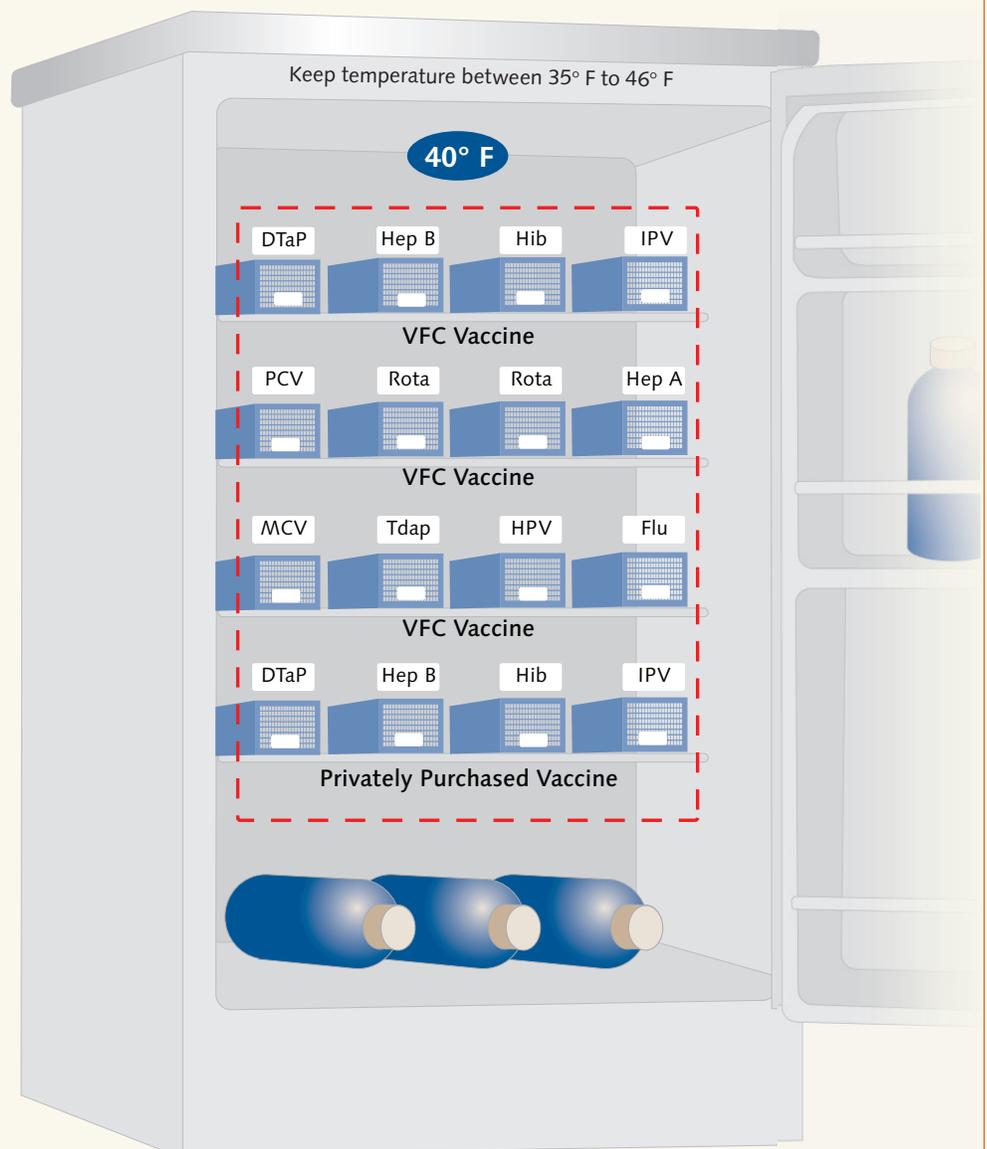
Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Refrigerate all vaccines except MMRV, Varicella, and Zoster.

DOs

- Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccination.
- Group vaccines by pediatric, adolescent, and adult type.
- Separate the Vaccines for Children (VFC) Program vaccine supply from privately purchased vaccine.
- Keep baskets 2-3 inches from walls and other baskets.
- Keep vaccines in their original boxes until you are ready to use them.
- Store only vaccine and other medication in vaccine storage units.
- Keep vaccines with shorter expiration dates to the front of the shelf.
- Notify the VFC Program if you have vaccine that will expire in 3 months or less that you will not be able to use.

DON'Ts

- No vaccine stored in refrigerator doors.
- No vaccine in solid plastic trays or containers.
- No food in refrigerator.
- No vaccine in drawers or on floor of refrigerator.



Refrigerator-Only Unit

Almost all of the space is usable (inside dashed lines)

Figure adapted from the California Department of Public Health, Immunization Branch

Table 4. Recommended HPV Vaccination Counseling Messages

The Facts	The Messages
<p>Patients and parents who know the risks of HPV and cervical cancer are more likely to accept vaccination, but many people are not aware of the link between HPV and cancer.</p>	<ul style="list-style-type: none"> • HPV is a common infection. About 1 in 6 people in the U.S. are infected with HPV. • HPV causes most cases of cervical cancer and can cause genital warts and other types of cancer. • Cervical cancer can be serious. About 3 out of every 10 people diagnosed with it will die within 5 years of diagnosis.
<p>Cervical cancer prevention may be the primary motivation for seeking vaccination²⁴ and higher perceived vaccine effectiveness increases vaccine acceptance.²⁵</p>	<ul style="list-style-type: none"> • HPV is a common infection and the HPV vaccine is very good at preventing the types of HPV that cause most cases of cervical cancer and genital warts. • The vaccine does not treat existing HPV infections, so it's important to get vaccinated before becoming sexually active. • Getting all three doses of HPV vaccine gives the best protection.
<p>Confidence in vaccine safety is a significant factor in being vaccinated. You may be able to overcome safety concerns by convincing patients that the benefits of vaccination outweigh any potential risks.</p>	<ul style="list-style-type: none"> • Doctors and health experts agree that the HPV vaccines are safe and effective. • HPV vaccines were and continue to be studied in thousands of people and have been found to be safe. The most common side effect is soreness in the arm, where the shot is given. The benefits of preventing cervical and other cancers greatly outweigh the minimal risk of more serious side effects. • Some teens faint after they get vaccines so I ask my patients to sit down for their shot and wait here for 15 minutes after getting the vaccine.
<p>Some parents might not be comfortable with younger adolescents getting vaccinated, but only a minority believe that HPV vaccination might lead to increased sexual activity.</p>	<ul style="list-style-type: none"> • Now is the time to protect your child against cancer. Vaccinate your child on-time so she/he is protected before becoming sexually active. The HPV vaccine is also more effective (works better) for pre-teens than for teens and young adults. • You know your child the best, but we know that 60% of 17-year-old females have had sex. Even if your child only has sex with their spouse later in life, there is no guarantee that she/he won't be infected by their spouse. Getting vaccinated now protects your child now and later. • Getting vaccinated does not increase sexual activity. Asking your child to use a seatbelt does not give them permission to drive recklessly. Nor does asking your child to receive HPV vaccine give them permission to have sex.
<p>A personal endorsement may help convince patients/parents to accept vaccination.</p>	<ul style="list-style-type: none"> • Tell your patients personal stories about families that were impacted by HPV. See stories at www.whychoose.org and www.shotbyshot.org. • Let parents know why you personally believe in the HPV vaccine for yourself, your patients, and your own family.

years of age if cessation criteria are met, use recommended screening methodologies, and promote screening to patients using recommended counseling messages.

Routine provision of 3 doses of HPV vaccine will also likely lead to significant declines in cervical cancer cases. Thus, providers are encouraged to initiate the HPV vaccine series between ages 11 and 12, provide catch-up vaccinations through 26 years of age, adhere to approved dosing and administration guidelines, address questions and concerns

about vaccination, and use strategies such as reminder/recall systems to increase vaccine uptake. By implementing these recommendations, providers have the opportunity to protect women in LA County from HPV and cervical cancer. 

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Free Continuing Medical Education Credit

To obtain CME credit, complete the eLearning module on “Preventing Cervical Cancer” at <https://publichealth.lacounty.gov/elearning>

This educational activity is offered by the LA County Department of Public Health (LAC-DPH). The LAC-DPH is accredited by the Institute for Medical Quality and the California Medical Association to provide continuing medical education (CME) for physicians licensed in California and contiguous states. The LAC-DPH takes responsibility for the content, quality and scientific integrity of this CME activity. The LAC-DPH designates this educational activity for a maximum of 1.0 AMA PRA Category 1 Credit toward the California Medical Association's Certification in Continuing Medical Education and the American Medical Association Physician's Recognition Award. Each physician should only claim those hours of credit he/she actually spent in the educational activity.

Resources to Support Cervical Cancer Screening and HPV Vaccination

Resources for Low-Cost or No-Cost Services

Cervical Cancer Screening Resources

- LA County Department of Public Health's Office of Women's Health: Call 1-800-793-8090 for cervical cancer screening appointments for low-income, uninsured women. Operators are available Monday-Friday, 8 am-5 pm and speak English, Spanish, Cantonese, Mandarin, Korean, Vietnamese, and Armenian.
- Cancer Detection Programs—Every Woman Counts: 1-800-511-2300, www.cdph.ca.gov/programs/CancerDetection
- Family PACT: 1-800-942-1054, www.familypact.org

Vaccination Resources

- Vaccines for Children (VFC) Program www.eziz.org/pages/VFCoverview.html
Provides vaccines, including HPV vaccines, at no cost for eligible children through 18 years of age. Any California-licensed physician or health care organization serving VFC-eligible children can enroll.
- Vaccine Patient Assistance Programs www.merck.com/merckhelps/vaccines/home.html www.gskforyou.com/18_programs.htm
Provides replacement doses for vaccine doses used for eligible adults, at no cost to the patient or provider

Patient Educational Materials

Cervical Cancer

- National Cancer Institute: 1-800-4-CANCER www.cancer.gov/cancertopics/pdq/screening/cervical/patient/allpages
- American Cancer Society: 1-800-227-2345 www.cancer.org/AsianLanguageMaterials/index
- Centers for Disease Control and Prevention 1-800-CDC-INFO, www.cdc.gov/cancer/cervical/
- FDA—Office of Women's Health: (301) 796-9440 www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm116718.htm

Vaccination

- Asian American Network for Cancer Awareness www.aancart.org/apicem/
- California Department of Public Health www.eziz.org/resources/materials_healthpros_pats.html

- Centers for Disease Control and Prevention www.cdc.gov/vaccines/spec-grps/preteens-adol/07gallery/posters.htm or www.cdc.gov/hpv/

Clinical Guidelines

Cervical Cancer

- U.S. Preventive Services Task Force www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm
- American College of Obstetricians & Gynecologists (202) 638-5577 www.acog.org/acog_districts/dist_notice.cfm?recno=13&bulletin=3161
- American Cancer Society www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer

Vaccination

- Advisory Committee on Immunization Practices HPV Vaccination Recommendations www.cdc.gov/vaccines/pubs/ACIP-list.htm#hpv

Other Resources

Cervical Cancer and Vaccination

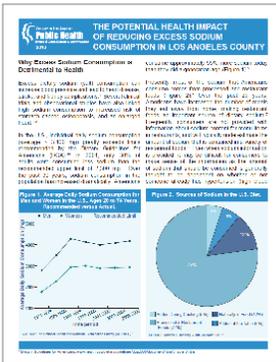
- Guide to Community Preventive Services www.thecommunityguide.org
Summary of interventions that have been proven to improve cancer screening and immunization rates

Vaccination

- CDC "Update on HPV Vaccine Recommendations for Pre-teens" Podcast www2c.cdc.gov/podcasts/player.asp?f=1165490
- "The HPV Vaccine: What Providers Should Know" Fact Sheet www.eziz.org/PDF/IMM-869.pdf
- California Immunization Registry (CAIR) www.immunizelink.org or (213) 351-7411
Secure, web-based, confidential system that allows physicians to view, update, and store immunization records for vaccines given in their practice and by other providers

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New Report Finds Decreasing Salt Intake Could Save Lives by Reducing Hypertension

Recent estimates from a health impact analysis conducted by the Los Angeles County Department of Public Health suggest that reducing population sodium consumption, or salt intake, even by a modest amount, has the potential to greatly reduce the number of cases of hypertension in Los Angeles

County and save millions of dollars in annual treatment costs.

This analysis is featured in “The Potential Health Impact of Reducing Excess Sodium Consumption in Los Angeles County,” a new report released in October.

The study found that if adult Angelenos, who on average take in about 50% more sodium than recommended, could collectively decrease their average consumption by just 20% (687 mg of sodium) per day, it would result in a decrease of about 52,629 hypertension cases in the county and an annual cost savings of \$102 million. These estimates account for both adults with and without existing hypertension.

In the U.S., individual daily sodium consumption (average > 3,400 mg) greatly exceeds limits recommended by the Dietary Guidelines for Americans (DGA). In 2004, only 30% of adults were consuming less sodium than the recommended upper limit of 2,300 mg. The DGA, published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture, currently recommends that each person consumes, at most, 6 mg of salt (2,300 mg of sodium or 1 teaspoon of salt) per day. This figure is even lower (1,500 mg or 2/3-teaspoon per day) for those who have high blood pressure, are over 40 years of age, or are of African-American descent.

Excess dietary sodium consumption can increase blood pressure and lead to heart disease, stroke, and renal complications. Clinical trials and observational studies have also linked high sodium consumption to increased risk of stomach cancer, osteoporosis, and left ventricular hypertrophy.

What Can Be Done

Reduction in sodium consumption can be accomplished with minimal impact on taste, if carried out gradually. There are several national, state, and local strategies that can be implemented including the following:

- Implementing venue-based or venue-specific food policies that set nutrition standards on all foods purchased, served, or sold by institutions locally, such as schools or hospitals.
- Increasing awareness through public education and through patient counseling about the recommended daily sodium limit and the benefits of lowering sodium consumption.
- Importantly, physicians can play a vital role in helping patients reduce salt intake by integrating sodium reduction as

part of their treatment plans for hypertension and/or cardiovascular disease. A list of low-sodium recipes can be found at www.dashdiet.org and www.mayoclinic.com/health/low-sodium-recipes/RE00101.

The full report may be viewed online at www.publichealth.lacounty.gov.

Rising Rate of Type 2 Diabetes Among Adults Coincides with Upswing in Obesity

A recent analysis of surveillance data from the Los Angeles County Health Survey reveals that from 1997 to 2007, diabetes increased from 6.6% to 9.1% in all adults living in Los Angeles County. Type 2 diabetes, which is primarily caused by obesity, accounted for over 90% of these cases. This increase in diabetes prevalence coincided with the rising rates of adult obesity in the county, which increased from 14.3% to 22.2% during the same period (1997-2007).

This information is included in a new *LA Health* report titled, “Trends in Diabetes: A Reversible Health Crisis.” This report, which was created through the collaborative efforts of the LA County Department of Public Health and the American Diabetes Association of Los Angeles, may be viewed at www.publichealth.lacounty.gov/ha.

The report, which was released in November, includes LA County statistics, such as...

- In 2007, about 650,000 adults reported ever being diagnosed with diabetes.
- Obesity rates among adults with diabetes (44%) were more than double that of adults without diabetes (20%).
- Among younger adults age 18-39 years old, obesity rates were more prevalent among Latinos (27%) and African Americans (23%) versus whites (14%) and Asians/Pacific Islanders (12%).
- Adults living in households below the federal poverty level (FPL) were twice as likely to have diabetes compared to households at or above 200% of the FPL. This disparity is likely due to higher rates of risk factors for diabetes among those living in poverty, such as obesity and physical inactivity.

The Department of Public Health recognizes the need for policies that ensure more opportunities for physical activity and greater access to nutritious produce and food products in communities. The department is also engaging the diabetes community, health care providers, and patients with diabetes or prediabetes to facilitate greater access to timely and appropriate medical care, including use of evidence-based preventive services.



Rx for Prevention is published 10 times a year by the Los Angeles County Department of Public Health. If you would like to receive this newsletter by e-mail, go to www.publichealth.lacounty.gov and subscribe to the ListServ for *Rx for Prevention*.

Rx for Prevention

Promoting health through prevention in Los Angeles County

Upcoming Training

Immunization Training Resources for Clinicians

The Los Angeles County Department of Public Health Immunization Program, the California Department of Public Health, the CDC and other entities offer a variety of web-based and in-person immunization training programs for clinicians and staff. Some programs offer CMEs and CEUs at no charge.

Visit www.ph.lacounty.gov/ip/trainconf.htm for a list of upcoming trainings.



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Index of Disease Reporting Forms

All case reporting forms from the LA County Department of Public Health are available by telephone or Internet.

Animal Bite Report Form

Veterinary Public Health (877) 747-2243
www.publichealth.lacounty.gov/vet/biteintro.htm

Animal Diseases and Syndrome Report Form

Veterinary Public Health (877) 747-2243
www.publichealth.lacounty.gov/vet/disintro.htm

Adult HIV/AIDS Case Report Form

For patients over 13 years of age at time of diagnosis
HIV Epidemiology Program
(213) 351-8196
www.publichealth.lacounty.gov/HIV/hivreporting.htm

Pediatric HIV/AIDS Case Report Form

For patients less than 13 years of age at time of diagnosis
Pediatric AIDS Surveillance Program
(213) 351-8153
Must first call program before reporting
www.publichealth.lacounty.gov/HIV/hivreporting.htm

Confidential Morbidity Report of Tuberculosis (TB) Suspects & Cases

Tuberculosis Control (213) 744-6160
www.publichealth.lacounty.gov/tb/forms/cmr.pdf

Lead Reporting

No reporting form. Reports are taken over the phone.
Lead Program (323) 869-7195

Reportable Diseases & Conditions

Confidential Morbidity Report
Morbidity Unit (888) 397-3993
Acute Communicable Disease Control
(213) 240-7941
www.publichealth.lacounty.gov/acd/reports/CMR-H-794.pdf

Sexually Transmitted Disease Confidential Morbidity Report

(213) 744-3070
www.publichealth.lacounty.gov/std/providers.htm (web page)
www.publichealth.lacounty.gov/std/docs/H1911A.pdf (form)

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