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SUPPLEMENT TO
THE JOURNAL OF
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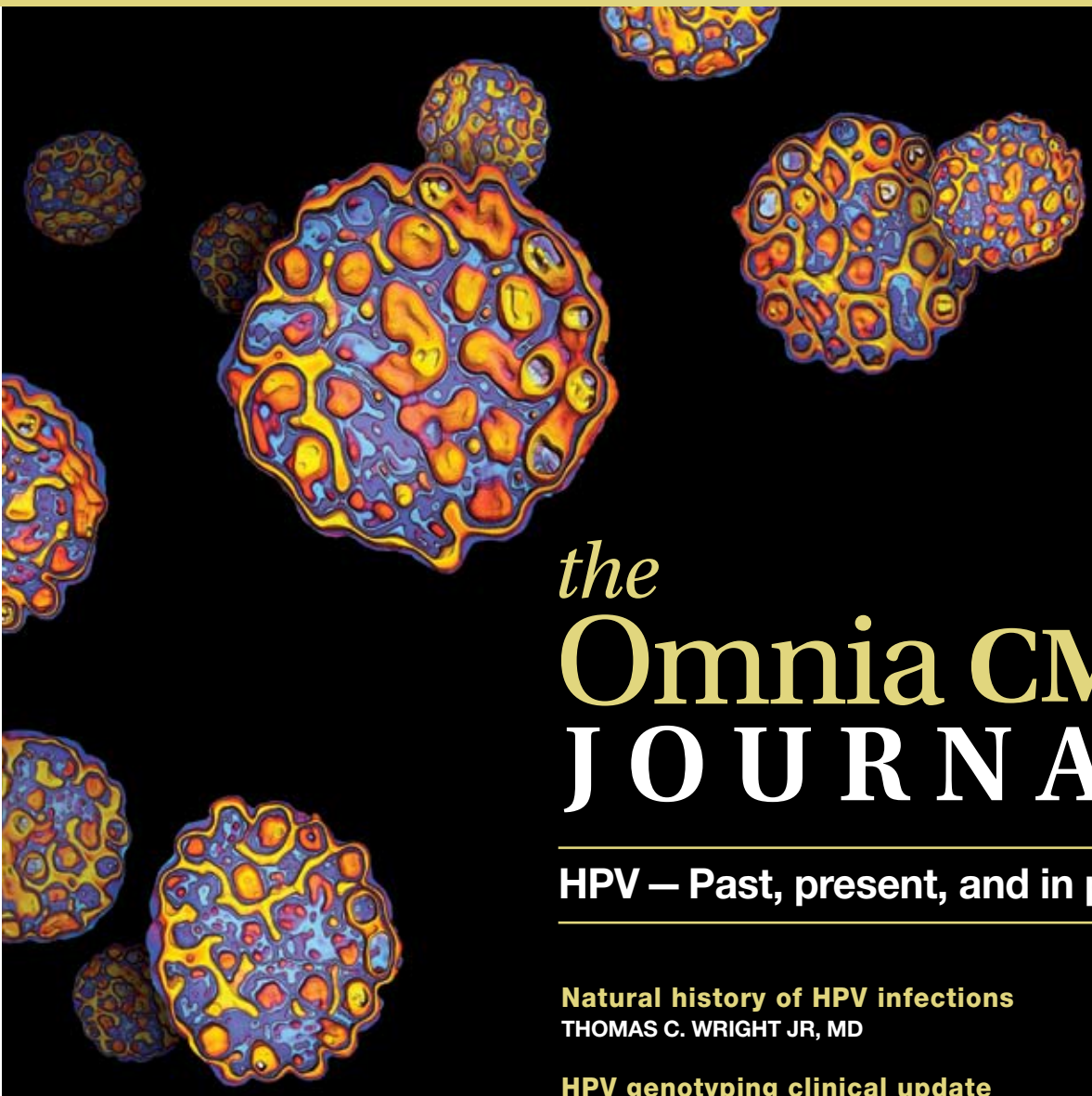

the Omnia CME JOURNAL

HPV — Past, present, and in practice

Natural history of HPV infections
THOMAS C. WRIGHT JR, MD

HPV genotyping clinical update
AMERICAN SOCIETY FOR COLPOSCOPY AND CERVICAL PATHOLOGY

Integrating HPV vaccination into your practice: Overcoming common barriers
BARBARA LEVY, MD, FACOG, FACS

This supplement was submitted by Omnia Education. Selected topics resulted from a process that included a review of needs assessments, quality improvement data, an expert-needs survey, which included medical advisory board input, and peer-reviewed literature.

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The Omnia CME Journal

HPV—PAST, PRESENT, AND IN PRACTICE

CONTENTS

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This activity is supported by independent educational grants from Merck & Co., Inc., and QIAGEN Inc.

COURSE DESCRIPTION

This supplement addresses some important issues regarding human papillomavirus (HPV) and its effect on women. Even though most clinicians have a general understanding of the natural history of HPV and HPV DNA testing, many are using HPV DNA testing inappropriately. In addition, the knowledge base on HPV keeps expanding with well-validated, molecular tests that determine which women are infected with high-risk types of HPV. More news is available on a highly effective vaccine that prevents infection for the 2 most important high-risk types of HPV—HPV 16 and 18.

This volume of *The Omnia CME Journal* is titled "HPV: Past, present, and in practice." Dr Thomas Wright's article focuses on what we have recently learned about the natural history of HPV infections. The second is a reprint of a recent Clinical Update from the American Society of Colposcopy and Cervical Pathology (ASCCP) on HPV assays. The third by Dr Barbara Levy is an article on implementing HPV vaccination in your office. All 3 are focused with the intent of providing you with key clinical points in an easy-to-digest format.

Additional ASCCP educational materials for 2008 Consensus Guidelines may be obtained by going to:

http://www.asccp.org/bookstore.shtml
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Release Date: September 1, 2009
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Target audience

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Disclosure and conflicts of interest: The views and opinions expressed in this educational activity are those of the authors and do not necessarily represent the views of Omnia Education, Merck & Co., Inc., or QIAGEN Inc. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings.

Thomas C. Wright Jr, MD, has disclosed affiliations with Merck & Co., Inc., GlaxoSmithKline, Gen-Probe Incorporated, and Roche Molecular Systems, Inc.

Barbara Levy, MD, FACOG, FACS, has nothing to disclose.

Judy Smith has nothing to disclose.

Andrea J. Singer, MD, has disclosed affiliations with Procter & Gamble Pharmaceuticals and sanofi-aventis.

Educational objectives

At the conclusion of this activity, participants should be able to:

- Examine new data emerging from both natural history studies and clinical trials of the HPV vaccines to better understand the age distribution of anogenital human papillomavirus (HPV) infections and target populations for using HPV DNA testing.
- Examine new data emerging from both natural history studies and clinical trials of the HPV vaccines to better understand the temporal relationships between initial exposure to HPV, development of cytological abnormalities, and development of biopsy-confirmed cervical intraepithelial neoplasia (CIN 2,3) lesions.
- Apply techniques and implement an office system to identify all women eligible for the HPV vaccine and use appropriate coding for services in order to incorporate HPV vaccination into a busy primary care practice environment.

Medical editor and reviewer

Judy Smith, Medical editor, Exton, Pennsylvania

Andrea J. Singer, MD, Associate Professor, Medicine and Obstetrics and Gynecology, Georgetown University Medical Center, Washington, District of Columbia

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Omnia SM EDUCATION

SUPPLEMENT TO
THE JOURNAL OF FAMILY PRACTICE
September 2009

NATURAL HISTORY OF HPV INFECTIONS

Thomas C. Wright Jr, MD

Professor of Pathology
College of Physicians and Surgeons
of Columbia University
New York, New York

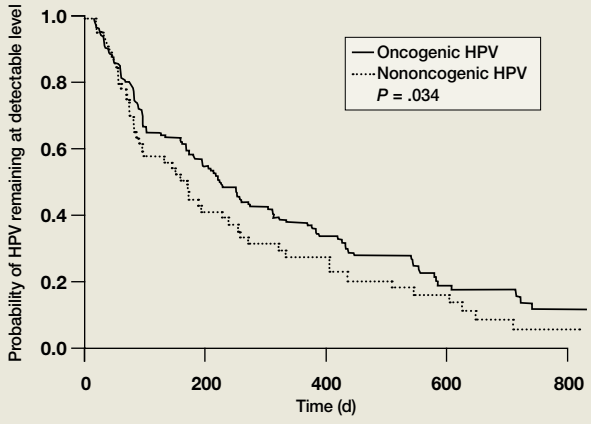
Over the last several years there have been a huge number of advances in our understanding of the biology and natural history of human papillomavirus (HPV). A PubMed search indicates that during the first 5 months of 2009, more than 1300 articles on HPV were published, of which about 500 were related to HPV vaccines. Given this widespread interest, the primary focus of this article is to update clinicians on new knowledge regarding the natural history of HPV infections.

Transmission of HPV

Most papillomavirus infections are transmitted through close skin-to-skin or mucosa-to-mucosa contact. Epidemiologic studies clearly indicate that sexual intercourse is the primary route for anogenital HPV infection.[1] Infection is relatively uncommon in women who have not had intercourse, and there is a strong and consistent relationship between the number of both lifetime and recent sexual partners and the prevalence of HPV in women. There is also a strong association between having had a recent new sexual partner(s) and incident anogenital HPV infection. Consistent condom use reduces—but does not eliminate—HPV transmission.[2] In a prospective study on college students who initiated sexual intercourse either after or immediately prior to enrollment, the overall rate of anogenital HPV infection was 89 per 100 patient-years of follow-up in those whose partners rarely used condoms during sexual intercourse, compared with 38 per 100 patient-years of follow-up among those whose partners always used condoms.

Disclosure:
Thomas C. Wright Jr, MD, has disclosed affiliations with Merck & Co., Inc., GlaxoSmithKline, Gen-Probe Incorporated, and Roche Molecular Systems.

FIGURE 1 Clearance of HPV infections



HPV, human papillomavirus.

Kaplan-Meier estimates of clearance time of high-risk (HR) and low risk (LR) HPV infection. The median clearance time for high-risk HPV was 226 days.

Penetrative sexual intercourse is not a requirement for HPV transmission. Both oral and digital HPV infections occur, and there is evidence that digital-genital and oral-genital contact can result in the transmission of HPV, albeit at relatively low rates. In a study of college students from Seattle, the 2-year cumulative incidence of HPV infections was 38.8% in those who were sexually active at enrollment.[3] Among college students who remained virginal, the 2-year cumulative incidence of HPV was 9.7% in those who reported nonpenetrative sexual contact, but only 1.3% in those who reported no sexual contact whatsoever. HPV also can be transmitted perinatally.[1]

Although the clinical significance of HPV perinatal transmission is unknown, this route of transmission is well documented. A recent study of oral and genital HPV infections in infants born to both HPV-positive and HPV-negative women detected HPV DNA in 6% of the infants at birth, 13% at 6 weeks after birth, and 9% between 3 to 24 months of age.[4] Approximately half of the HPV infections in infants were oral and half were genital. Interestingly, persistence of HPV infection was uncommon in the newborns—only 1.4% had the same HPV type detected on 2 or more occasions. Therefore, most of these infections appear to be very transient, and it is unlikely that the majority have adverse clinical consequences.

Initial HPV infections and prevalence of HPV in the population

Most sexually active adolescents and women become infected with HPV within several years of initiating sexual activity. A prospective follow-up study of sexually naïve college students found that within 12 months of initiating sexual intercourse, 30% became HPV positive; within 48 months, 54% were HPV positive.[3] Other follow-up studies of adolescents and young women have found that with repeated testing and long-term follow-up, HPV is detected in more than two-thirds over a several-year period.[5-7]

Women with transient HPV infections often develop cytological abnormalities while they are actively shedding HPV DNA. This occurs because productive HPV infections result in cytological abnormalities in the infected epithelial cells. Cells with these cytological features are found in about one-third of HPV-infected women and result in a diagnosis of either low-grade squamous intraepithelial lesions (LSIL) or atypical squamous cells of undetermined significance (ASC-US).[8] If followed, cytological abnormalities continue to be detected for approximately 1 to 2 years, but by 4 years, the risk of having an abnormal cervical cytology is similar to that of women in the general population.[9]

The majority of HPV infections are self-limited and spontaneously clear within a several-year period as a result of cell-mediated immunity. In one study, two-thirds of adolescents infected with low-risk HPV types spontaneously cleared their infections by 12 months, as did over half of those infected with high-risk HPV types (**FIGURE 1**).[5] By 23 months, more than 80% had cleared their HPV infections. In another follow-up study of adolescents and young women with LSIL, 91% of HPV-infected individuals cleared their infections after 36 months of follow-up.[10] However, many women who spontaneously clear one specific type of HPV become infected

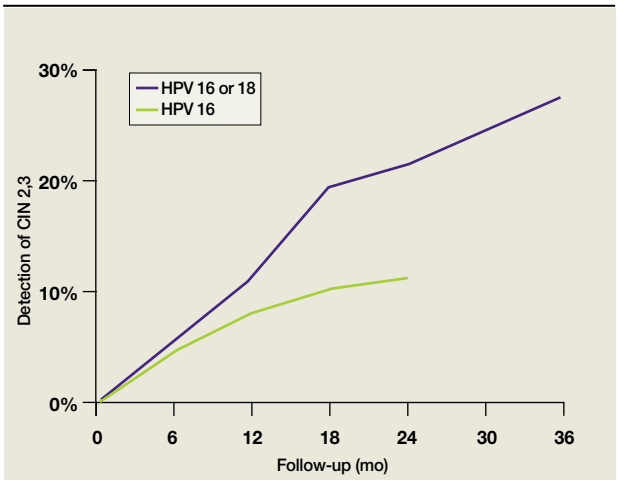
with another HPV type. This is part of the reason that infection with multiple types of HPV is quite common in sexually active adolescents and young women.

The natural history of HPV infections explains the prevalence of HPV infection in women in the general population. Since infection is sexually transmitted and is usually transient, the prevalence of HPV infections is highest among sexually active women in their 20s. With increasing age, women tend to have fewer new sexual partners, and prevalence decreases. After age 45, the prevalence of high-risk HPV infections tends to stabilize, and less than 5% of women in the general population are DNA positive for high-risk types of HPV. The prevalence of HPV DNA positivity drops to less than 3% of women with a normal cervical cytology result.[11]

It is unclear how many HPV-infected women who become HPV DNA negative actually have complete viral clearance and how many continue to harbor the viral genome in the basal cells of the squamous epithelium, but at such a low copy number that they cannot be detected using standard molecular tests. Such undetectable, low-level infections are usually referred to as "latent infections" and are similar to the latent infections that are seen with herpes simplex virus and varicella zoster. The finding that almost all HIV-infected individuals become HPV DNA positive as they become more profoundly immunosuppressed suggests that HPV viral latency clearly occurs.[12]

Reactivation of a latent infection secondary to senescence of HPV-directed cellular immunity could easily explain many of the HPV infections that are detected in older women with a previously normal screening history and no new sexual partners.[8] Currently, it is impossible to distinguish between reactivation of a latent HPV infection and a newly acquired infection. It should also be noted that the risk for subsequently developing either cervical intraepithelial neoplasia (CIN) 2,3 or cervical cancer after reactivation of a latent infection appears to be relatively low in women who have a history of 3 or more normal cervical cytology results.[13] This conclusion is based on the fact that although 4% to 5% of women 45 years and older are at high risk for becoming HPV DNA positive at any single point in time, the risk that these women will have CIN 2,3 or cervical cancer detected during routine screening is minimal (≤0.05%).[13]

FIGURE 2 **Cumulative detection of CIN 2,3 after incident HPV infections in two studies**



HPV, human papillomavirus.

After incident HPV 16 infection (green line) and after incident HPV 16 or 18 infection (blue line).

Modified from Winer RL, et al. J Infect Dis. 2005;191:731-738 (blue line); Mao C, et al. Obstet Gynecol. 2006;107:18-27 (green line).

Persistent HPV infections and the development of CIN 2,3

Only about 10% of HPV infections persist for more than 3 years. The longer a specific HPV infection persists, the lower the probability that the lesion will clear spontaneously and the higher the probability that a CIN 2,3 lesion or cervical cancer will develop.[8] Prevalent HPV infections detected at the time of cervical cancer screening tend to persist longer in older women compared to younger women. This may be due to the fact that the infections identified in older women are more likely to represent infections that have already been persistent for several years, whereas infections in younger women are more likely to represent recently acquired infections. There is no established definition of what constitutes clinically important persistence, but most management recommendations consider persistence for 12 months to be clinically significant and therefore warrant colposcopy.

TABLE Detection of CIN 2,3 or cancer

HPV status	Percent with CIN 2+*
HPV negative	0.4%
HPV 16	37%
HPV 18	26%
HPV 31	37%
HPV 33	48%
HPV 52	26%
HPV 58	30%

CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus.

*Percentage of women diagnosed with CIN 2,3 or cancer during a 4-year follow-up period.

Modified from Naucler P, et al. Br J Cancer. 2007;97:129-132.

Since high-risk HPV DNA is detected in almost all CIN 2,3 lesions and invasive cervical cancers, it is clear that persistence of infection with a high-risk HPV is a requirement for the development of these lesions. New data demonstrate that the time required for an initial HPV infection to progress to a CIN 2,3 lesion can be quite short. In college-aged women, incident infection associated with any HPV type results in an 11% cumulative incidence of biopsy-confirmed CIN 2,3 by 36 months.[14] For incident HPV 16 or HPV 18 infections, the cumulative incidence of CIN 2,3 at 36 months is 27% (**FIGURE 2**). Similarly, Mao et al followed young women in the placebo arm of an HPV 16 vaccine trial and found that all but one case of CIN 2,3 occurring after an incident HPV 16 infection developed within 12 months (**FIGURE 2**).[15] It should be emphasized, however, that it takes almost a decade for a CIN 2,3 lesion to progress to invasive cervical cancer; therefore, it is safe to extend the screening interval to 3 years or more in women who are found to be both high-risk HPV DNA and cytology negative during routine screening.

We also have a much better understanding of the risk of being diagnosed with CIN 2,3 or cervical cancer in older, high-risk HPV DNA-positive women. In a records linkage study of Danish women who were initially cytologically negative after 3 years, CIN 2,3 or cervical cancer had been diagnosed in 6.3% of high-risk HPV-positive women.[16] The cumulative detection of CIN 2,3 was 11.3% and 22.9% after 5 and 10 years of follow-up, respectively. In comparison, CIN 2,3 was diagnosed after 10 years of follow-up in only 1.9% of the HPV-negative women. A Swedish study that included all women, irrespective of cytology results, detected CIN 2,3 in 37% of women who were HPV 16 positive and 26% of those who were HPV 18 positive after 4 years of follow-up (**TABLE**).[17] Importantly, in this Swedish study, CIN 2,3 lesions were detected in a substantial number of women infected with other high-risk types of HPV, including HPV 31, 33, 52, and 58. This finding contrasts with the results from a study by the National Cancer Institutes (NCI), at Kaiser, Portland, Oregon.[18] In a Kaiser follow-up study of 20,810 women, the cumulative detection of CIN 3 after 10 years of follow-up was 20.7% in HPV 16-positive women >30 years of age with negative cytology; 17.7% for those with HPV 18; 1.5% for those with other high-risk types of HPV; and 0.5% for HPV DNA-negative women. ■

TAKE-HOME POINTS

- HPV infections are common, and approximately half of young women become infected within 4 years of initiating sexual activity.
- The predominant mode of transmission of HPV is by sexual intercourse; consistent use of condoms reduces, but does not prevent, transmission.
- More than 80% of HPV infections spontaneously clear over a 3-year period.
- Less than 5% of women in the general population are high-risk HPV positive by the age of 45 years.
- HPV 16 and HPV 18 are quite oncogenic, and about 1 out of 4 infected individuals will develop CIN 2,3 over a 3-year period.

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Omnia EDUCATION

SUPPLEMENT TO
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INTEGRATING HPV VACCINATION INTO YOUR PRACTICE:

Overcoming common barriers

Barbara Levy, MD, FACOG, FACS
Medical Director
Women's Health and Breast Center
Franciscan Health System
Federal Way, Washington

Incorporating routine human papillomavirus (HPV) vaccination into a busy medical practice is a multistep process. This article addresses the practical aspects of that process—from identifying women for whom the vaccination is appropriate[1,2] and educating them about the benefits and potential risks of HPV vaccination,[3] to counseling them about the cost of receiving the series of injections. Ensuring that the practice will not be financially disadvantaged is clearly an essential step, requiring that procedures for correct coding and payment policy for vaccination will be adopted.

Initiating the office program

It is critical that all medical office personnel understand the overwhelming benefits of HPV vaccination and know which women are appropriate candidates for the vaccine. The staff is our window to the world—they receive and triage telephone queries from current and potential patients. It is crucial that misinformation does not occur at this level.

I find it helpful to have a champion in the office for each new procedure or technique that I begin to incorporate into the practice. This will be the staff member who expresses an interest in the particular issue and who is eager to read and learn about it. I provide that person with the basic materials and then arrange time to meet and discuss any questions or concerns.

Disclosure
Barbara Levy, MD, FACOG, FACS, has nothing to disclose.

This staff member becomes the "go to" person for everyone else in the office. Patients with concerns or questions regarding HPV vaccination can be directed to the identified staff member without disrupting the physician's schedule.

Billing

In addition to the clinical information available about HPV, it is important for the staff to clearly understand the coding and billing policies of your major payers.[4] Initiate a discussion with each of the major provider representatives to determine their payment policies and be sure that your "go to" person is informed of what you learn. Assure that your payers know the invoice cost to you for providing the vaccine. You should know their policies regarding coverage for vaccination at the time of another office visit. Under almost all circumstances, a vaccination administration fee as well as the cost of the product should be paid separately.

Once you understand the payers' procedures, it will be possible to create an office payment policy for HPV vaccination so that the practice is quickly compensated for the out-of-pocket expenses related to vaccine purchase. These policies should be written and provided to patients and their families, stapled to the clinical information handouts they receive. Create the policy to protect the practice in the event that patient coverage changes during the 6-month period in which the 3 doses will be administered. Remember that copayments and deductibles may apply and that, even though coverage is provided, the patient may be responsible for a significant portion of the cost. Many large payers have online access to patient eligibility information as well as an estimate of the amount of the deductible the patient may still owe. However, it may not be feasible for your staff members to access this information in real time during peak office hours while performing their other duties.

One option may be to collect the full amount of the vaccine and administration fee and hold that until the insurance reimbursement is received. At that time, a refund to the patient can be generated, or the funds may be held until the series of 3 vaccines are completed. This encourages patients to complete the 3 doses in a timely manner and assures that you will be paid even if the patients' insurance coverage lapses.

Office implementation

To maximally serve our patients, we should modify current office intake questionnaires and history forms to include the status of HPV vaccination. This will help to flag those women who are candidates for, but have not yet received, the vaccination. Each encounter with an eligible patient is an opportunity to encourage HPV vaccination. We have placed patient education materials in our waiting room and in each of our examination rooms so that patients and their families can acquire valid, reliable information about HPV infection and vaccination. This often prompts questions from patients about their children and whether they should receive the vaccine. It can become a practice-building tool as patients recognize the expertise and excellent care we provide and then recommend our practice to their friends and family.

We have created packets of information regarding HPV infection, vaccination, and frequently asked questions. Also included in the packet is a copy of our office payment policies, options for the underserved to receive HPV vaccination, and informed consent documents. These are distributed to anyone who has questions about HPV, including all women in the appropriate age group and women referred for management of abnormal cervical cytology. Advisory Committee on Immunization Practices (ACIP) and American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines for HPV vaccination are included in the packet to dispel some of the misinformation that many women have received from other sources.[5,6]

To optimize protection for our patients, all 3 doses of vaccine should be administered. By implementing a recall system, just as we do for follow-up of abnormal cervical cytology, we encourage patients to return for their 2-month and 6-month doses. The chart is flagged so that we will know that the patient is due for her vaccine booster whenever she returns for care. We use special preprinted chart forms or stickers to identify patients who have received HPV vaccine counseling and administration. Appropriate

postinjection patient observation helps make documentation consistent and quick.

Capturing the work involved in counseling

Bill patients for an evaluation and management service at whichever level is appropriate for the amount of time you have spent counseling the patient if you are seeing her for a medical problem in addition to the HPV vaccine counseling.[7] Here are some appropriate codes to use for billing: 99212 = 10 minutes; 99213 = 15 minutes; 99214 = 25 minutes; and 99215 = 40 minutes. If the encounter is solely for HPV vaccine counseling and risk factor reduction, the counseling codes 99401 to 99404 should be used: Code 99401 = 15 minutes, code 99402 = 30 minutes, code 99403 = 45 minutes, and code 99404 = 60 minutes. In addition to these codes, you may code for administration of the immunization—90471—as well as for the quadrivalent HPV vaccine itself—90649.

Vaccine storage and handling

The quadrivalent HPV vaccine is supplied in single-use 0.5 cc vials or prefilled syringes, which require refrigeration and storage, protected from light at 2˚ to 8˚C (36˚ to 46˚F). Follow all appropriate OSHA guidelines with respect to sharps, needles, and medication labeling.[8]

Conclusions

Integrating HPV vaccination into a busy practice requires minimal effort. There should be no financial downside if an office payment policy is established after researching reimbursements offered by local payers. Patients and their families will benefit from the educational materials you provide. This will frequently translate into a practice-building opportunity.

It is our obligation to provide optimal care for our patients. Providing HPV vaccination in our offices for as many eligible women as possible is the right thing to do, and it can be done easily and affordably for you and your patients. ■

TAKE-HOME POINTS

- Successful vaccination programs require enthusiastic staff buy-in and staff education.
- Understanding coverage decisions by major payers will enable a coherent office payment policy that prevents delays in payment for the vaccine and its administration.
- Alter intake forms and follow-up questionnaires to include HPV vaccination status in order to identify all young women who are candidates for vaccination when they enter the practice for any reason.
- In most cases, payers will pay for the vaccine, as well as its administration, in addition to any other evaluation and management or counseling service provided on the same date of service. Capture the time spent counseling using codes 99401 to 99404.

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THE OMNIA CME JOURNAL: HPV—Past, present, and in practice

Please complete the posttest and activity evaluation. To receive a CME certificate, fax or mail the completed form to the location provided at the bottom of page S15.

POSTTEST

Natural history of HPV infections

1. **What percentage of female college students become infected with HPV within 12 months of initiating sexual intercourse?**
   ☐ 10% ☐ 30% ☐ 50% ☐ 75%
2. **What percentage of young women clear their HPV infections within a 3-year period?**
   ☐ 25% ☐ 50% ☐ 75% ☐ 80%
3. **Does consistent condom use help prevent HPV infections in female college students?**
   ☐ Yes ☐ No
4. **What percentage of women who are high-risk HPV DNA positive and then subsequently become "clear" of their HPV infection truly clear their lesion?**
   ☐ 25% ☐ 50% ☐ 100% ☐ Unknown
5. **What percentage of women 30 years and older who have a negative Pap test but who are HPV 16 DNA positive will develop CIN 2,3 after 10 years of follow-up?**
   ☐ 2% ☐ 10% ☐ 20% ☐ 40%

HPV genotyping clinical update

1. **Which of the following is a recommended use of high-risk HPV DNA testing?**
   ☐ During a comprehensive workup for an STI
   ☐ To decide whether or not to vaccinate a sexually active woman against HPV
   ☐ LSIL in a postmenopausal woman
   ☐ ASC-US in a 20-year-old college student
2. **Is genotyping for HPV 16 and 18 recommended for women 21 years and older who have ASC-US cytology and are high-risk HPV DNA positive?**
   ☐ Yes ☐ No
3. **Which approach is useful for a woman 30 years or older who has cervical cytology within normal limits but is high-risk HPV DNA positive?**
   ☐ Repeating both the HPV test and the cytology in 12 months
   ☐ Genotyping for HPV 16 and 18, and referring those with HPV 16 or 18 for colposcopy
   ☐ Both approaches are considered useful

Integrating HPV vaccination into your practice

1. **How can HPV vaccination questions to the office be addressed without increasing clinician time?**
   ☐ Put information on the website
   ☐ Tell patients they will need to make an appointment to discuss their questions
   ☐ Identify a "champion" in the office who becomes knowledgeable about HPV vaccination
   ☐ All of the above
2. **What is the easiest method for capturing eligibility information about patients as they arrive for an appointment ?**
   ☐ Modify the intake questionnaire to address HPV status
   ☐ Have the nurse question each patient
   ☐ Look up their billing information to see whether HPV vaccination has been billed
   ☐ None of the above
3. **What is the most effective billing practice to ensure adequate compensation for the HPV vaccine?**
   ☐ Precertify patients each time they come for vaccine
   ☐ Collect from patients and have them bill their insurance provider
   ☐ Have patients prepay for the first vaccine then bill their insurance provider
   ☐ Have patients purchase the vaccine themselves then administer it in the office
4. **Is it correct to code for vaccine counseling separate from a problem-related evaluation and management service provided on the same day?**
   ☐ Yes ☐ No
5. **Based on these articles, what 2 new patient care strategies do you plan to use that you have not used before?**
   _____
   _____
6. **What challenges or barriers might you face as you work to implement these strategies?**
   _____
   _____
   _____

ACTIVITY EVALUATION

Please circle or check the correct answer to each question. 5 = Strongly agree 1 = Strongly disagree

1.	The articles met the stated objectives.	5 4 3 2 1
2.	The articles are relevant to my current clinical practice needs.	5 4 3 2 1
3.	Disclosure of faculty relationships with commercial organizations was made available to me before the articles were presented.	☐ True ☐ False
4.	The commercial supporters were acknowledged in print.	☐ True ☐ False
5.	The articles were balanced and free of commercial bias.	☐ True ☐ False
6.	If trade names were used, trade names of all products discussed were used.	☐ True ☐ False
7.	Any off-label drug use and/or investigational drug use not yet approved by the FDA was disclosed before or during the activity.	☐ True ☐ False
8.	If you answered "false" to any of the above questions, please provide details in the comments section below.	

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