Immunizing Adolescents against Human Papillomavirus (HPV) and Meningococcal Disease: What You Need to Know

The Illinois Academy of Family Physicians
Expert Panel

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Learning Objectives

- Understand current guidelines for immunizing adolescents against human papillomavirus (HPV) and meningococcal disease.
- Educate patients and their parents/guardians about the importance of immunization.
- Develop an office-wide strategy to improve the immunization rate with adolescent patients (e.g., patient recall and reminder systems, standing orders).
Vaccine-Preventable Disease and Adolescents
HPV: The Most Common Sexually-Transmitted Infection in the US

Estimated number of new and existing (total) sexually transmitted infections

-United States, 2008

<table>
<thead>
<tr>
<th>Disease</th>
<th>Estimated Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis</td>
<td>117,000</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>270,000</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>422,000</td>
</tr>
<tr>
<td>HIV</td>
<td>908,000</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>1,570,000</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>3,710,000</td>
</tr>
<tr>
<td>HSV-2</td>
<td>24,100,000</td>
</tr>
<tr>
<td>HPV</td>
<td>79,100,000</td>
</tr>
</tbody>
</table>

Total: 110,197,000

HPV Incidence is High Among Adolescents and Young Adults

Estimated number of new sexually transmitted infections
- United States, 2008

Hepatitis B: 19,000
HIV*: 41,400
Syphilis: 55,400
HSV-2: 776,000
Gonorrhoea: 820,000
Trichomoniasis: 1,090,000
Chlamydia: 2,860,000
HPV: 14,100,000

Total: 19,738,800

Young people (15-24) represent 50% of all new STIs

Meningococcal Disease Incidence in the US

From 2005-2011, 800-1,200 cases of meningococcal disease occurred annually in the US.

Vaccine-Preventable Mortality

- In the US, HPV causes ~17,000 cancers in women and ~9,000 cancers in men each year.\textsuperscript{1}
- An estimated 4,000 US women die from HPV-related cancers each year.\textsuperscript{1}
- Meningococcal disease caused 75 deaths in the US in 2012.\textsuperscript{2}

Estimated Vaccination Coverage Among 13-17 Year-Olds (2013)

### Vaccination Coverage Among 13-17 Year-Olds – Illinois (2013)

<table>
<thead>
<tr>
<th></th>
<th>Females (n=8,264)</th>
<th>Males (n=9,554)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥ 1 MenACWY</td>
<td>≥ 1 HPV</td>
</tr>
<tr>
<td><strong>US Overall</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>77.8 ± 1.1</td>
<td>57.3 ± 1.9</td>
</tr>
<tr>
<td><strong>Illinois</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>79.0 ± 4.5</td>
<td>53.2 ± 7.6</td>
</tr>
</tbody>
</table>

Immunization Schedules for Adolescents: An Overview
Who Makes National Vaccine Recommendations?

Immunization recommendations for the United States are developed by the CDC’s Advisory Committee for Immunization Practices (ACIP).

- Consists of 15 experts vetted by the US Dept of Health and Human Services.
- Collaborates with 30 professional organizations, including AAFP and AAP, to develop recommendations for pediatric and adult immunizations.
- Meets three times annually to discuss relevant new findings.

Source: CDC. Advisory Committee on Immunization Practices (ACIP).
http://www.cdc.gov/vaccines/acip/about.html.
ACIP Considerations for Vaccine Recommendations

- Vaccine safety and effectiveness when administered at a specific age.
- Severity of disease.
- The number of people who will likely contract the disease if there is no vaccine.
- Vaccine efficacy for a given age, based on immune response.

ACIP Vaccine Recommendations

- Specific recommendations for 23 vaccines (adults and/or children)
- General Recommendations on Immunization
- Immunization of healthcare personnel
- Guidelines and recommendations for emergency situations

Links to all of the above are available at: http://www.cdc.gov/vaccines/hcp/acip-recs/index.html.

ACIP Immunization Schedules for Children and Adolescents

- Each year, ACIP publishes immunization schedules for persons age birth-18 years that summarize recommendations for routine vaccines.
  - Recommended immunization schedule
  - “Catch-up” immunization schedule
- Schedules are approved by ACIP, AAP, and AAFP.
- CDC provides easy-to-read versions for parents, Spanish-language and pocket-sized versions, interactive tools, and tools to display schedules on the practice’s website.

Links to all of the above are available at:
http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Staying Informed

To know when CDC changes any schedule or releases schedules on new platforms:

- Sign up with CDC for email reminders.
- Display schedules on the practice’s website using code provided by CDC (The schedules that appear on your webpage will always be current; when CDC updates a schedule, your page will automatically display the update).

Links to these tools are available at: http://www.cdc.gov/vaccines/schedules/syndicate.html

Preventing HPV with Bivalent and Quadrivalent Vaccines
Burden of HPV Infection

- HPV is the most common sexually-transmitted infection in the US (~14.1 million new cases/year).\(^1\)
- Most sexually active men and women will get HPV at some point in their lives.\(^1\)
- HPV incurs the highest direct medical costs of all STDs other than HIV.\(^2\)
- The total direct lifetime medical cost of treating new HPV cases acquired each year is ~$1.7 billion.\(^2\)

HPV=Human Papillomavirus; STDs=Sexually transmitted diseases.

Risk of Acquiring HPV Declines with Age

Transmission of HPV

- Sexual contact with an infected partner necessary\textsuperscript{1}
  - Intercourse with penetration not strictly necessary\textsuperscript{1,2}
- Incubation period ranges from three weeks to several months
- Source contact usually has subclinical infection.

**Sources:** \textsuperscript{1}Schiffman M, et.al. *J Natl Cancer Inst Monogr* 2003;31:14-19; \textsuperscript{2}Marrazzo JM, et.al. *Am J Public Health* 2001;91:947–52.
# HPV Types Associated with Benign and Malignant Disease

<table>
<thead>
<tr>
<th>HPV Types</th>
<th>Manifestations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low-Risk</strong></td>
<td><strong>HPV 6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81</strong></td>
</tr>
<tr>
<td></td>
<td>Low-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>Condylomata acuminata (Genital warts)</td>
</tr>
<tr>
<td><strong>High-Risk</strong></td>
<td><strong>HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, 82</strong></td>
</tr>
<tr>
<td></td>
<td>Low-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>High-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>Cervical cancer</td>
</tr>
<tr>
<td></td>
<td>Other anogenital cancers</td>
</tr>
<tr>
<td></td>
<td>Oropharyngeal cancers</td>
</tr>
</tbody>
</table>

Factors Associated with Increased Risk in Women

- **Age**\(^1,2\)
- **Sexual behavior**\(^1,2\)
  - Increased risk associated with >number of male sexual partners\(^1,2,3\)
  - Risk increases with earlier age of first sexual intercourse\(^4\)
- **Sexual behaviors of previous male sexual partners**\(^1,2\)
- **Immunologic status**\(^2\)
  - HPV more likely in immuno-suppressed women

**Sources:**
Factors Associated with Increased Risk in Men

- Lifetime number of sexual partners\(^1\)
- Number of recent sexual partners\(^1\)
- Uncircumcised\(^1\)
- Same-sex encounters\(^2\)

**Sources:**  
\(^2\) Chin-Hong PV. *J Infect Dis* 2004;190:2070-76.
Natural History of Cervical Carcinogenesis

- HPV infection does not automatically lead to cervical cancer.

However,

- Nearly 100% of women with cervical cancer are infected with HPV.

HPV4: Quadrivalent HPV Vaccine

- Licensed by FDA in 2006
- Composed of HPV L1 protein, the major capsid protein of HPV
- Non-infectious; no oncogenic potential
- Not a live vaccine
- Protects against HPV 6, 11, 16, and 18
- Highly efficacious in preventing:
  - Persistent HPV infection
  - Cervical cancer precursor lesions
  - Vaginal and vulvar cancer precursor lesions
  - Genital warts
  - Anal cancer precursor lesions

HPV2: Bivalent HPV Vaccine

- Licensed by FDA in 2009
- Composed of HPV L1 protein, the major capsid protein of HPV
- Not a live vaccine
- Non-infectious; no oncogenic potential
- Protects against HPV 16 and 18
- Highly efficacious in preventing:
  - Cervical cancer precursor lesions

Source: CDC. *MMWR* 2010;59(20):626-629.
Indications for HPV2 & HPV4

- Licensed for use in:
  - Females aged 9-26 to prevent genital warts and vaginal, vulvar, and cervical precancers
  - Males aged 9-26 to prevent genital warts
  - People aged 9-26 to prevent anal cancer

- ACIP recommends routine HPV vaccination of females (either HPV2 or HPV4) and males (HPV4) at age 11 or 12 with 3 doses of vaccine

- Catch-up vaccination for females ages 13-26 years and for males ages 13-21 years

- Most effective if administered before HPV exposure through sexual contact.

Sources: ¹CDC. MMWR 2010;59(20): 626-629; ²CDC. MMWR 2011;60:1705-1708; ³CDC. MMWR 2010; 59(20):630-632.
Schedules for HPV2 and HPV4

- Administered as 3-dose series, with 2^{nd} and 3^{rd} doses at 1-2 and 6 months after initial dose.
- Minimum intervals between the 1^{st} and 2^{nd} injections and the 2^{nd} and 3^{rd} injections are 4 and 12 weeks, respectively.
- Minimum interval between 1^{st} and 3^{rd} doses is 24 weeks.
- If schedule is interrupted, series does not need to be restarted.
- Vaccines can be co-administered with different inactivated or live vaccines.
- The same HPV vaccine should be used for the entire series when feasible.

Sources: CDC. *MMWR* 2010;59(20): 626-629; CDC. *MMWR* 2010; 59(20):630-632.
Precautions and Contraindications for HPV2 and HPV4

- Not recommended for use in pregnant women
- Can be administered to immunosuppressed persons and those with minor acute illnesses
- Contraindicated for persons with immediate hypersensitivity to yeast
- Syncope may occur following vaccination in some individuals; may be more common in adolescents
- Prefilled syringes of HPV2 should not be used in persons with anaphylactic latex allergy.

Safety Issues

- Adverse events (AEs) reported in clinical trials were mild to moderate.\(^1,2\)
- Common local AEs include injection-site events (pain, swelling, erythema).\(^1,2\)
- Common systemic AEs include fever and nausea (HPV4)\(^1\) and fatigue, headache, and myalgia (HPV2).\(^2\)
- Lactating women may take HPV vaccines*.\(^2\)

*No data are available on the use of HPV2 in lactating women.

Caveats for HPV Vaccination

- Vaccination is not a substitute for routine cervical cancer screening.
- Vaccinated females should have routine cervical cancer screening as recommended.
- Vaccine does not protect against disease caused by HPV types with which recipient is infected at the time of vaccination.
- Persons infected with one or more of the vaccine HPV types before vaccination would be protected against disease caused by the other vaccine HPV types.
- Vaccination has no therapeutic effect on an existing HPV infection, existing genital warts, or on an abnormal Pap test.

Source: CDC. *MMWR* 2010;59(20):626-629.
Recommendations for Meningococcal Disease Vaccination
Meningococcal Disease at a Glance

- Meningococcal disease is caused by the bacterium *Neisseria meningitidis*, common in children ages 2-18.
- ~800-1,200 cases per year in US.
- 10-15% of cases are fatal, with another 11-19% causing brain damage and other serious side effects.
- Incubation period usually 1-4 days.
- Circulating bacterial antibody critical for protection.

Risk of Acquiring Meningitis Rises in Late Adolescence

Meningococcal disease -- United States, 2002-2011.

Transmission and Risk Factors

- *N. meningitidis* colonizes nasopharyngeal mucosal surfaces and is transmitted through direct contact with large droplet respiratory secretions from carriers.

- Risk factors:
  - Antecedent viral infection
  - Household crowding
  - Chronic underlying illness
  - Active and passive smoking

The risk for meningococcal disease among U.S. college students is higher for those residing in dormitories than for other types of accommodations. Kissing and the sharing of drinking glasses/water bottles and utensils can potentially lead to infection.

MCV4: Tetravalent Meningococcus Vaccine

- Two conjugate vaccines licensed by FDA in 2005 (Menactra) and 2010 (Menveo)
- Not live vaccines
- Target serogroups A, C, Y, and W-135
- Serogroup antigens conjugated to diphtheria toxoid protein
- May be administered concomitantly with other recommended vaccines
- Efficacious in preventing:
  - Invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y, and W-135

Based on analysis of data available as of 2010, ACIP concluded that ~50% of persons vaccinated 5 years earlier had bacterial antibody levels protective against meningococcal disease.

More than 50% of persons immunized at age 11 or 12 may no longer be protected when they reach higher-risk ages (16-21 years).

Source: CDC. *MMWR* 2011;60(3):72-76.
Routine Meningitis Vaccination in Adolescents (ACIP, 2010)

- ACIP recommends routine vaccination (1 dose) at age 11 or 12 with booster dose at 16 years.
- Adolescents who receive first dose at ages 13-15 years should receive a one-time booster at age 16-18.
- Those receiving a first dose at or after age 16 years do not need a booster.
- HIV-infected adolescents should follow this booster schedule but receive 2 primary doses, 2 months apart.

ACIP does not recommend routine vaccination of healthy persons not at increased risk after age 21 years.

Source: CDC. *MMWR* 2011;60(3):72-76.
# Meningitis Vaccination of At-Risk Patients Ages 2-55 (ACIP, 2010)

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Primary Series</th>
<th>Booster Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent complement component deficiency* or asplenia</td>
<td>2 doses, 2 months apart</td>
<td>Every 5 years; At the earliest opportunity if a 1-dose primary series administered, then every 5 years</td>
</tr>
<tr>
<td>Prolonged increased risk for exposure‡</td>
<td>1 dose</td>
<td>Age 2-6 years: after 3 years Age ≥ 7 years: after 5 years if person remains at risk</td>
</tr>
</tbody>
</table>

*Such as C5-C9, properidin, factor H, or factor D; ‡Travelers or residents of countries where meningococcal disease is epidemic or hyperendemic.

Source: CDC. *MMWR* 2011;60(3):72-76.
Precautions and Contraindications for MCV4

- Not recommended for use in pregnant women:
  - **Menactra**: FDA Pregnancy Category: C
  - **Menveo**: FDA Pregnancy Category: B
- Can be administered to immunosuppressed persons and those with minor acute illnesses
- Contraindicated for persons with known hypersensitivity to vaccine components (Menactra and Menveo), history of Guillain-Barre syndrome or hypersensitivity to rubber latex (Menactra)
- Syncope may occur following vaccination in some individuals.

**Sources:** Prescribing Information for Menactra and Menveo. Accessed May 22, 2014.
Safety Issues

- Most adverse events (AEs) reported in clinical trials were mild to moderate.
- Common local AEs include injection-site events (pain, swelling, erythema).
- Common systemic AEs include fatigue, headache, and myalgia.

Educating Adolescents and their Guardians about Immunization
Vaccines Make the Headlines: Could MMR Vaccine Cause Autism?

“Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children…”

Vaccines Make the Headlines

Headlines, 2004:
After partial retraction by The Lancet.

Retraction—Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

Following the judgment of the UK General Medical Council’s Fitness to Practise Panel on Jan 28, 2010, it has become clear that several elements of the 1998 paper by Wakefield et al are incorrect, contrary to the findings of an earlier investigation. In particular, the claims in the original paper that children were “consecutively referred” and that investigations were “approved” by the local ethics committee have been proven to be false. Therefore we fully retract this paper from the published record.

The Editors of The Lancet
The Lancet, London NW1 7BY, UK


Patient-Based Barriers to Immunization

- Lack of knowledge about vaccine efficacy
- Lack of belief of vaccine efficacy
- Concerns about safety
- Vaccination not recommended/discussed by provider
- Reimbursement or insurance concerns.

Provider-Based Barriers to Immunization

- Uncertainty about patient’s vaccination status
- Lack of standing orders regarding vaccination
- Lack of office-based systems or procedures to promote vaccination
- Limited time allotted for visit
- Concerns about vaccine efficacy in immunocompromised patients.

Parental Concerns

- Vaccine ingredients
- Vaccine schedules
- Studies about vaccines and autism
- Paying for vaccines
- Finding reliable online vaccine information
- Immunizing children with allergies
- Lost records and extra doses
- Vaccine safety
- Who should not be immunized

Adolescent-Specific Challenges

- **Disease knowledge and misperceptions** (e.g., the relationship between HPV and certain cancers)
- **School requirements** — most adolescent vaccines are not required by schools; parents may feel that these immunizations are unimportant
- **Access** — adolescents are less likely to have regular preventive health care visits than infants/children
- **HPV-specific concerns** (e.g., discussions of adolescent’s potential sexual activity; “newness” of the vaccine)

Providers should use every opportunity to immunize adolescents (e.g., sports physicals, flu shots, prescription renewals, acute care visits).
Establishing a Successful Dialogue

- Take time to listen
- Solicit and welcome questions
- Don’t be offended and don’t offend
- Tailor the balance of scientific and anecdotal information
- Acknowledge vaccine benefits and risks
- Respect parent’s authority
- Reduce stress of shots.

Both parties should share information and ask questions when discussing vaccines.

Vaccine Q&A:
Discussing Immunization (1)

“I have heard that vaccines can cause autism.”

“Autism is a burden for many families and people want answers—including me. I can share with you well-designed and conducted studies that show that vaccines do not cause autism.”

Vaccine Q&A: Discussing Immunization (2)

“I’m worried about the side effects of vaccines. I don’t want my child to get any vaccines today.”

“I’ll worry if your child doesn’t get vaccines today, because the diseases can be very dangerous. Let’s look at the VIS together and talk about how rare vaccine side effects are.”

Vaccine Q&A: Discussing Immunization (3)

“You really don’t know if vaccines cause any long-term effects.”

“We have years of experience with vaccines and no reason to believe that vaccines cause long-term harm. I understand your concern, but I truly believe that the risk of diseases is greater than any risks posed by vaccines.”

Post-Visit Follow-Up

- Parent expresses doubt or worry about vaccination
- Document parent’s questions/concerns
- Follow-up a few days later

The 11-12-Year Wellness Checkup: A Great Time to Immunize

- Catch-up on missed childhood vaccines
- Immunize for Tdap, Flu, MCV4, and HPV
- Dispel rumors about vaccines
- Increase vaccine awareness in minority/at-risk patients
- More reliable opportunity to immunize than during adolescent acute-care visit

Immunization at the 11-12-year wellness checkup is endorsed by the CDC, AAFP, and AAP.

Implementing Office-Wide Strategies to Improve Adolescent Immunization Rates
Interventions to Improve Vaccination Coverage (USPSTF)

US Preventive Services Task Force strongly recommends:

- Client reminder/recall (charts, computer, email)
- Multi-component interventions that include education
- Methods to provide assessment and feedback to providers (e.g., retrospective evaluation of performance)
- Standing orders for non-physician personnel to describe or deliver vaccinations without direct physician involvement at the time of interaction.

The Role of Office Staff in Immunization

- Provide Educational Materials
- Answer Questions
- Administer Vaccines (Standing Orders)

High Vaccination Rate

Educational Materials for the Office

- CDC Vaccine Information Statements (VIS)*
- Handouts for patients and parents (e.g., flyers from CDC’s “Pre-Teen Vaccine Campaign”)
- Other print materials (brochures, cards, posters) that promote immunization.
- Materials for parents who wish to delay or refuse vaccination for their child (e.g., materials from Provider Resources for Vaccine Conversations with Parents from CDC, AAFP, AAP).

*Federal law requires that VIS be handed out whenever certain vaccinations are given (e.g., before each dose).

Strategies to Vaccinate Adolescents

- Vaccinate during non-primary care visits (e.g., acute care, flu shots, sports/school physicals, prescription renewals)
- Provide extended immunization hours (e.g., the “flu clinic” model)
- Establish standing orders for nurses to administer vaccines
- Consider alternate immunization sites, such as schools.
- Engage pharmacists as partners.
I-CARE: An Immunization Resource for Illinois Providers

Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE) is a web-based immunization record-sharing application developed by IDPH.

Illinois Vaccines for Children (VFC) providers must register for and use I-CARE.

Source: IDPH. About ICARE. http://www.idph.state.il.us/health/vaccine/abouticare.htm
What Can I-CARE Do?

- Allows registered public and private health care providers to share immunization records of IL residents with other providers statewide.
- Provides many functionalities of interest to providers (e.g., vaccination forecasting needs, appointment scheduling, remind/recall notices, school physical forms with immunization portion completed).
- Tracks vaccine use, inventory, and ordering for VFC providers.

Source: IDPH. About ICARE. [http://www.idph.state.il.us/health/vaccine/abouticare.htm](http://www.idph.state.il.us/health/vaccine/abouticare.htm)
Enrolling in I-CARE

- Fill out I-CARE Provider Site Enrollment Form and mail/fax to IDPH.
- Fill out/sign Individual User Agreement for each provider in practice (may be returned to IDPH via email at DPH.ICARE@illinois.gov)

*Note: 4-6 weeks may be required to complete registration.

Source: IDPH. Enrolling in ICARE. http://www.idph.state.il.us/health/vaccine/enrollinginicare.htm
Uploading Records to I-CARE

- Open an account with the IDPH Web Portal
- Verify that EMR system supports HL7 format (I-CARE accepts immunization data in HL7 v2.3.1 or v2.5.1).
- Send data either using IDPH’s Secure File Transfer Protocol (SFTP; unidirectional batch upload) system or directly in the application (HTTPS).
- HL7 files can be manually or automatically transferred depending on the capabilities of the EMR system.

# I-CARE: Where to Go for Help

<table>
<thead>
<tr>
<th>Request</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information and enrollment forms</td>
<td><a href="http://www.idph.state.il.us/health/vaccine/icarerefs.html">http://www.idph.state.il.us/health/vaccine/icarerefs.html</a></td>
</tr>
<tr>
<td>Additional assistance</td>
<td><a href="mailto:DPH.ICARE@illinois.gov">DPH.ICARE@illinois.gov</a></td>
</tr>
<tr>
<td>Assistance transmitting data from EMR to I-CARE</td>
<td><a href="mailto:DPH.HL7ICARE@illinois.gov">DPH.HL7ICARE@illinois.gov</a></td>
</tr>
</tbody>
</table>

**Source:** [IDPH. Enrolling in ICARE.](http://www.idph.state.il.us/health/vaccine/enrollinginicare.htm)
Conclusions

- Adolescents are at risk for vaccine-preventable HPV- and meningococcal-associated diseases.
- ACIP provides recommendations for immunizing adolescents against these and other diseases.
- These vaccines can be administered at the 11-12-year wellness visit and at other types of visits (e.g., sports physicals, acute care visits, flu shots, prescription renewals).
- Vaccination is an educational process and a dialogue between the provider, parent/guardian, and patient.
- Immunization rates can be improved with educational materials, standing orders, and office-level assessment.
Additional Information

- Contact the Illinois Academy of Family Physicians
  - iafp@iafp.com
  - (630) 435-0257