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Pediatric Review is published monthly for the medical staff of Children's Hospital by the Public Affairs Department. For information about *Pediatric Review*, call (504) 896-9373.

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Pediatric Update HPV Vaccine: It Does Take a Village



By **Rodolfo Bégué, M.D.**, chief of the Infectious Diseases department at Children's Hospital and professor of pediatrics at LSU Health Sciences Center. This issue of *Pediatric Review* is intended for pediatricians, family physicians and all other interested medical professionals. For CME purposes, the author has no relevant financial relationships to disclose.

OBJECTIVES

At the end of this activity, the participant should be able to:

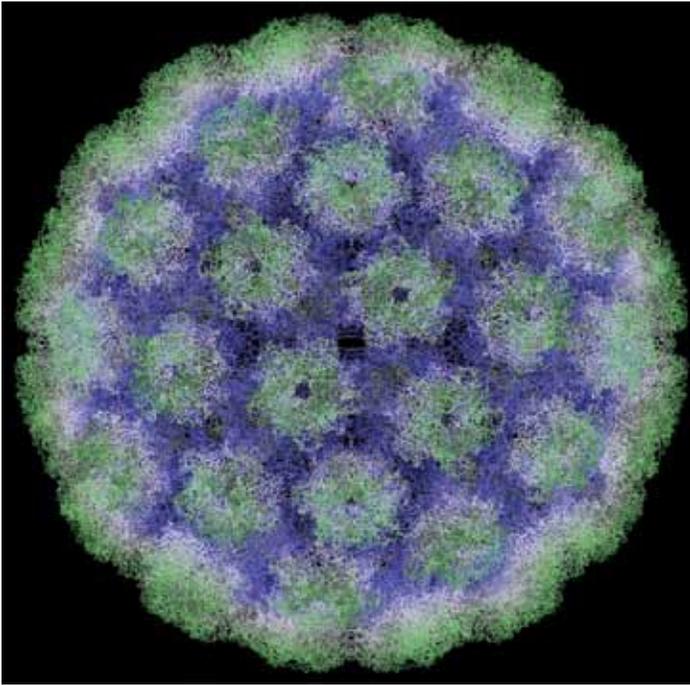
1. explain how HPV is transmitted
2. describe the cancerous effects HPV can have on men and women
3. better understand how pediatricians and care-givers may treat HPV with vaccines

INTRODUCTION

Harald zur Hausen was born in 1936 in the German city of Gelsenkirchen. Because it was a center of coal production and oil refining, his hometown was heavily bombed by Allied air raids during World War II. While his family survived, his life was chaotic and school closings made his education fragmented, to say the least. He eventually entered University of Bonn to study medicine where, while a clinician by training, he developed a profound interest in basic science and became "fascinated to work on virus-induced chromosomal modifications." This interest took him to the United States to Children's Hospital of Philadelphia in 1965, to study the newly discovered Epstein-Barr Virus (EBV) and its association with Burkitt's Lymphoma. In 1969, he became the first to describe the persistence of virus DNA (EBV) in a human malignancy (nasopharyngeal carcinoma). With this back-

ground it was only natural that in 1972 he would turn to the study of cervical cancer. By then, cervical cancer was thought to have an infectious origin, and herpes simplex virus type 2 (HSV-2) was the main suspect. But Hausen did not find HSV-2 in any of his specimens. Since he had read clinical reports describing genital warts progressing into carcinoma, and since genital warts had been shown by electron microscopy to contain papilloma virus (HPV), the obvious hypothesis was that HPV may also cause cervical cancer. By 1974 his group isolated HPV from plantar warts but that HPV would not react with genital warts or cervical cancer specimens; thus he suspected there were different types of HPV. In 1979, his group isolated HPV from a genital wart (HPV-6 first, then HPV-11), and in 1983 they finally isolated two HPV types (16 and 18) from cervical cancer biopsies. So, his hypothesis — revolutionary in those days — that most, if not all, cervical cancers are caused by infection with one of the oncogenic types of HPV (mainly 16 and 18) proved to be true. In recognition of this discovery, Dr Hausen was awarded the 2008 Nobel Prize in Medicine and Physiology (at age 72, 36 years after he started his work on HPV). Once the concept was discovered, it was time to put it to good use and translate it into some sort of prevention or treatment.

This is where basic researchers entered the field. Papilloma viruses were first recognized in rabbits in 1933, but interest in these viruses didn't spur investigation until the first human counterpart (HPV) was described. Many researchers painstakingly put together the pieces of the life cycle of the virus and the immune response and zeroed in on the virus' major outside protein, L1, since it was noted that antibodies to L1 could neutralize the virus and render the person immune. Unfortunately, purifying L1 was difficult because growing HPV in the lab was difficult. So, where Mother Nature doesn't provide, you have to make it yourself. By fishing DNA pieces, in the early 1990s the



HPV Virus

HPV genome was eventually cloned and put into cell lines capable of expressing L1. To everyone's amazement — and delight — L1 could not only be produced in great quantities, but once purified the molecules would also spontaneously aggregate and assemble into little particles that pretty much looked like the real viruses — so-called viral like particles (VLPs). VLPs are crucial because they are the shell without the internal contents (so not being the full virus they do not replicate and they do not cause disease) and — more importantly — because to the immune system they look like the real thing, they elicit a great immune response (in fact VLPs are about 100 times more immunogenic than separate molecules). So, now that there was a good “candidate” vaccine, it was time to make a “real” vaccine.

This is where the pharmaceutical industry took over. But making a “real” vaccine is no easy task. It took about 15 years (from the early 1990s to mid-2000s) to figure out the best production system (which turned out to be *Saccharomyces cerevisiae*, a.k.a. “brewer's yeast”), fermentation conditions (salinity, pH, temperature, etc), packaging method (VLPs were unstable and needed to be broken and reassembled in the lab), compatibility of various HPV types (so they would not interfere with each other), and many other variables - all of which increased production costs. But with enough time HPV-L1 VLPs could be produced reliably and consistently; It was time for testing. First, testing in vitro to show VLPs formation; then in animals to show immunogenicity; and then in humans (more than 60,000 volunteers) to find optimal dosing, show safety, immunogenicity and efficacy — a slow but neces-

sary process. In the end, VLPs based on HPV L1 protein proved to be safe, 98% immunogenic and 100% effective in preventing infection by HPV — looks like we do have a vaccine! It is time to translate all this product development into public health intervention.

And, so it did: based on these findings, two HPV vaccines were commercially produced and eventually licensed by the Federal Drug Administration (FDA): in 2006 Gardasil (MSD) and in 2009 Cervarix (GSK). Gardasil contains HPV types 6 and 11 (the two types that account for 90% of genital warts) as well as types 16 and 18 (the two types that account for 70% of cases of cervical cancer). Cervarix, on the other hand, contains the two types implicated in cervical cancer (16 and 18) but not the two implicated in genital warts (6 and 11). FDA licensure was followed by official recommendations by the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP). Both vaccines are now recommended as a 3-dose series at 0, 1 and 6 months for subjects 9 – 26 years of age, the target population being adolescents at the 11 – 12 year-old visit. But, here is the difference: Cervarix is recommended for girls only while Gardasil is recommended for girls and boys. Until recently Gardasil was also recommended only for girls and with permissive use for boys. But in October 2011, the Advisory Committee on Immunization Practices (ACIP) voted to move use of Gardasil for boys from permissive to recommended (the ACIP advises CDC; we still have to hear a formal statement by CDC and AAP). But the government doesn't make things easy on anyone, so be aware that the age recommendation for males is 9 – 21 years instead of 9 – 26 years as for females. Maybe one day they will reconcile the two age recommendations; meanwhile, there is still the permissive use of the vaccine for boys 21 – 26 years old.

So, after four decades of work, it is time for the pediatrician and his patient to put the vaccine to good use. Unfortunately, use of HPV vaccine has been less than auspicious. There are some problems with the use of this vaccine. It targets adolescents, who are notoriously difficult for follow up; it requires three visits, which only amplifies the problem; and it is expensive for vaccine standards at \$100 – \$150 per dose. None of these are insurmountable problems, and it should be viewed in the context of the potential benefit. In the United States, 70% of sexually active people will become infected with HPV. In 2007, cervical cancer was the 8th most common type of cancer in American women with 12,280 new cases and 4,021 deaths; and the rates are higher for African-American and Hispanic women. Worldwide the problem is worse: cervical cancer is the 5th most common form of cancer with 471,000

new cases and 275,000 deaths every year. And frequency is increased in less developed regions; for example, in Central America and southern Africa cervical cancer ranks first among cancers in women. Yet, after all these years of work, involvement of basic scientists and clinicians, academia and private industry, and commitment by the public sector, there is a disconnect here: the vaccine is not being used as much as indicated. In the United States, as of 2009, only 40% of girls had started HPV vaccination and only half of them had completed the series; utilization being less among the groups that need it the most — minority women. Studies show that the factor that most strongly influences use of the vaccine is recommendation by the provider, which doubles the chances that the child will initiate a vaccine series. Utilization is expected to improve, but time is of the essence, and the pediatrician has the key for change. Educating parents and recommending the vaccine can go a long way. Decreasing prices, better subsidy and reimbursement would also go a long way.

The vaccine is not a panacea, though. Even if perfect protection is conferred, it covers types responsible for only 70% of cervical cancer. The corollary is that gynecologic exams and Pap smears will still be required (even though not as frequent as before) and low level atypia — if DNA typing shows an HPV-type that is not oncogenic — may not need drastic interventions but just close follow-up. HPV vaccine is the first vaccine specifically developed to prevent cancer (with the added benefit of preventing genital warts and other problems). Because it was targeted for cervical cancer, it was targeted for girls — now with indication expanded to boys — and because this is a cancer asso-

ciated with sexual activity, it has brought reluctance from some segments of the population, but the bottom line is it has the potential to prevent cancer. True that whether clinical cervical cancer (not just infection) is indeed prevented and whether protection is life-long still have to be proven. Proving those will take few decades, but data so far makes the two scenarios very likely. Meanwhile, it may not be wise to wait.

HPV INFECTION: MAIN POINTS

- HPV causes genital warts and various cancers: cervix, vulva, vagina, penis, anus, head and neck
- Close to 200 HPV types have been described: types 6 and 11 cause 90% of genital warts, and types 16 and 18 cause 70% of cervical cancers
- 20 million Americans are currently infected with HPV and 6.2 million are newly infected annually
- 1 million Americans develop genital warts every year
- About 18,000 HPV associated cancers in women and 7,000 cancers in men occur in the United States every year

HPV VACCINE: MAIN POINTS

- HPV4 (Gardasil, MSD): contains types 6, 11, 16 and 18
- HPV2 (Cervarix, GSK): contains types 16 and 18
- Recommended for routine immunization at 9 – 26 years of age (preferred age: 11 – 12 years) with 3 doses (0, 1 – 2 and 6 months)
- HPV2 for girls only; HPV4 for girls and boys



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Children's Hospital receives CARF accreditation

Rehabilitation Program recognized for ongoing innovation and standards of performance

The Commission on Accreditation of Rehabilitation Facilities (CARF) has granted Children's Hospital a three-year accreditation to the hospital's Rehabilitation Program. CARF officially recognizes health and human service providers as having met standards for quality of service. The accreditation process applies sets of standards to service areas and business practices during an on-site survey.

CARF accreditation provides a visible symbol that assures the public of a provider's commitment to continually enhance the quality of services and programs with a focus on the satisfaction of the persons served. Rehabilitation programs earning CARF accreditation are recognized for their ongoing innovation and continued conformance to the standards of performance.

The Gilda Trautman Newman Rehabilitation Center at Children's Hospital provides comprehensive interdisciplinary, team-oriented, family-centered inpatient services to patients from birth through 21 years. The unit specializes in treating patients with brain injury, cerebral palsy, developmental disability, feeding disorder, limb deficiency, myelodysplasia, neuromuscular disease, rheumatic disease, seizure disorder, spinal cord injury, stroke, ventilator dependence, and other congenital or acquired disabling disorders, and offers consulting medical services in more than 40 pediatric specialties.

"We know that we do a great job, but it's always nice to

get the validation from an organization such as CARF," said Mary Perrin, Children's Hospital's vice president of hospital operations. "With the CARF accreditation we will continue to grow our Rehabilitation Program accepting those patients who previously were directed to CARF accredited facilities by their insurers. The standards for performance and management will guide our performance improvement and give us concrete goals going forward."

Family Centered Care

When a child is injured or disabled it affects the entire family — especially when rehabilitative care is necessary. Team members provide a framework to help each family adjust to the child's individual abilities and offer emotional support to preserve and strengthen the family during hospitalization. Recognizing and incorporating each family's unique qualities and individual cultural and religious beliefs is important to the success of the program.

The goal of the center is to provide pediatric rehabilitative care in which the team maximizes the development of independent and productive life skills through training. An individual, comprehensive treatment plan is developed for each patient and frequently reviewed by the interdisciplinary team. Discharge preparation incorporates school planning, vocational referrals, community reintegration and access issues.

The comprehensive rehabilitative services and compassionate care provided by the center’s dedicated staff have dramatically improved the quality of life for thousands of children. We are extremely proud of our past accomplishments, but we never lose sight of our goal — “healing one child at a time.”

Functional Pediatric Treatment

The rehabilitation goal for children and adolescents is to concentrate on restoring abilities by helping them adapt to their new skills or gaining abilities never achieved because of congenital disorders. Each patient is followed using a criteria-based system to evaluate functional skill development with respect to medical status, motor skills, cognitive and communicative abilities, self-care capabilities, and the family’s needs. Today’s strength resulted from the hospital’s solid foundation as a rehabilitation hospital, beginning in 1955. That strong commitment to pediatric rehabilitation continues, and it is even stronger today.

Case Study

Nicholls State University student Linsey Rogers is studying to be an occupational therapist, influenced by her treatment in Children’s Hospital’s Rehabilitation Program following a near-fatal automobile accident. Paramedics had to cut away the smashed driver’s side of Linsey’s Toyota Camry before they could get to her. When they did, she was unresponsive and not breathing. She was rushed to the hospital where doctors discovered her pelvis was cracked in five places, the bones in her left

leg were broken; she had a collapsed lung, severe brain injury and required a respirator to breathe.

After a month in a coma she awoke. When she did, she thought she was in New York City, the year was 1836 and the president was George Washington. She was immediately transferred to Children’s Hospital for rehabilitative therapy, where she would have to re-learn how to eat, talk, hold herself upright and go to the bathroom.

“I thought there was no way she would be able to come back,” her mom, Natalie LeBoeuf, said. “At first, her doctors told us to expect her to be a vegetable for the rest of her life. That’s what they told us to expect.”

Natalie said Linsey started making progress once she was transferred to Children’s. “She reached one milestone, then another and another really fast.”

Soon, Linsey returned to school. Although she has to spend more time studying, her grades never slipped and she graduated at the top of her class at South Terrebonne High School, and is now majoring in biology at Nicholls.

“There were things I didn’t think I’d be able to do that I’m doing today,” Linsey said. “My therapist helped me get to where I am today. When I think about how far I’ve come, I’m amazed. I think it’s a miracle,” she said. “I’m so thankful that I want to dedicate my career to helping others.”

“I’m so impressed with Children’s Hospital,” Natalie said. “The therapists brought her back. I tell everyone to come here,” she said. “It’s a special place.”

Children’s Hospital Rehabilitation Program Outcomes • July 2010 – June 2011

| Impairment | 91% of our school age children returned to school | | | | |
|---------------------------------------|---|-------------------------------|-----------------------|-----------------|-----------|
| | Cases | Average Length of Stay (days) | Wee Fim Rating Change | Sim. Facilities | |
| Stroke | 6 | 10 | 13.15 | 28.28 | |
| Traumatic Brain Injury (TBI) | 28 | 33 | 26.33 | 28.25 | |
| Non-Traumatic Brain Injury | 13 | 18 | 19.50 | 22.90 | |
| Neuro Condition | 10 | 20 | 36.87 | 23.90 | |
| Spinal Cord Injury (SCI) | 9 | 18 | 29.67 | 25.17 | |
| Pain Condition | 0 | 0 | 0 | 0 | |
| Multi Major Trauma/Ortho | 13 | 36 | 36.55 | 29.00 | |
| Failure to Thrive (FTT)/Debility | 1 | 4 | 22.0 | 19.63 | |
| Amputation/Cardiac | 2 | 23 | 14.50 | 17.90 | |
| Totals/Average | 79 | 18 | 25.11 | 25.02 | |
| Ages of Patients Seen | 0 – 3 years | 3 – 5 years | 5 – 7 years | 7 – 10 years | 10+ years |
| | 15 | 13 | 12 | 7 | 32 |
| Location of Patients by Parish/County | | | | | |
| Acadia | Evangeline | Orleans | St. Landry | | |
| Assumption | Grant | Ouachita | St. Tammany | | |
| Avoyelles | Harrison County, MS | Pearl River County, MS | Tangipahoa | | |
| Beauregard | Iberia | Plaquemines | Terrebonne | | |
| Caddo | Jefferson | Rapides | Vermilion | | |
| Calcasieu | Lafayette | St. Bernard | Washington | | |
| Chenango County, NY | Lafourche | St. Charles | Webster | | |
| East Baton Rouge | Livingston | St. James | | | |

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Dimitriades, Victoria ^[M, BR] (504) 896-9589
 Ochoa, Augusto ^[M, L] (504) 896-9589
 Paris, Ken ^[M, L] (504) 896-9589
 Sorensen, Ricardo ^[M] (504) 896-9589

Amputee Clinic

Gonzales, Tony (504) 896-9569

Cardiology

Ascutto, Robert ^[BR] (504) 896-9751
 Gajewski, Kelly (504) 896-9751
 Lilje, Christian (504) 896-9751
 Ross-Ascutto, Nancy ^[BR] (504) 896-9751
 Sernich, Steffan (504) 896-9751
 Siwik, Ernest (504) 896-9571
 Stopa, Aluizio (504) 896-9571

Cardiothoracic Surgery

Caspi, Joseph (504) 896-3928
 Dorotan, Jaime (504) 896-3928
 Pettitt, Timothy (504) 896-3928

Children at Risk Evaluation (CARE) Center

Jackson, Jamie (504) 896-9237
 Wetsman, Ellie ^[BR] (504) 896-9237

Cleft/Craniofacial

Moses, Michael (504) 896-9857
 St. Hilaire, Hugo (504) 896-9857

Clinical Trials

..... (504) 894-5377

Cochlear Implants

Arriaga, Moises (504) 896-2141
 Marks, Herbert (504) 896-2141

Craniofacial/Genetics

Lacassie, Yves ^[M] (504) 896-9857
 Marble, Michael (504) 896-9857
 Zambrano, Regina (504) 896-9857

Cystic Fibrosis

Levine, Stephen (504) 896-9436
 Pepiak, Derek (504) 896-9436

Dental

Mobile Dental Program 34-BRUSH
 Ritwik, Priyanshi (504) 896-9580

Dermatology

Poole, Jeffrey (504) 896-9532

Developmental/High Risk

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Diabetes

Chalew, Stuart (504) 896-9441
 Gomez, Ricardo (504) 896-9441
 Stender, Sara (504) 896-9441
 Vargas, Alfonso (504) 896-9441

Down Syndrome

Lacassie, Yves ^[M] (504) 896-9254
 Marble, Michael (504) 896-9254
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Endocrinology

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