

Maternal DTaP Vaccine Protected Newborns

BY M. ALEXANDER OTTO

FROM THE ANNUAL MEETING OF THE
INFECTIOUS DISEASES SOCIETY OF
AMERICA

VANCOUVER, B.C. – Infants born to women who receive diphtheria-tetanus-acellular pertussis vaccine during pregnancy have higher pertussis antibody levels during their first few months of life than infants born to unvaccinated

VITALS

Major Finding: Newborns in the DTaP group had substantially higher antibody concentrations than infants in the control group prior to the start of their primary DTaP series, and the differences were statistically significant.

Data Source: Prospective cohort study involving 70 women and their infants; some of the mothers received DTaP vaccine during pregnancy.

Disclosures: Dr. Hardy-Fairbanks said she had no conflicts of interest. The study was funded by Sanofi-Pasteur, maker of Daptacel DTaP vaccine.

women, Dr. Abbey Hardy-Fairbanks reported.

The levels are sufficient to protect infants against pertussis prior to their

first diphtheria-tetanus-acellular pertussis (DTaP) shot at around 2 months, a period of “significant pertussis morbidity and mortality,” said Dr. Hardy-Fairbanks, an ob.gyn. at the University of Iowa, Iowa City.

“This is the first evidence to document that pertussis immunization during pregnancy is likely to be beneficial to infants when they are most vulnerable to pertussis disease.”

CERVARIX®

[Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant]

Suspension for Intramuscular Injection

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

1.1 Indications: CERVARIX® is indicated for the prevention of the following diseases caused by oncogenic human papillomavirus (HPV) types 16 and 18 [see *Clinical Studies (14) of full prescribing information*]: cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma *in situ*, and cervical intraepithelial neoplasia (CIN) grade 1. CERVARIX is approved for use in females 10 through 25 years of age. **1.2 Limitations of Use and Effectiveness:** CERVARIX does not provide protection against disease due to all HPV types [see *Clinical Studies (14.3) of full prescribing information*]. CERVARIX has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity [see *Clinical Studies (14.2) of full prescribing information*]. Females should continue to adhere to recommended cervical cancer screening procedures [see *Patient Counseling Information (17)*]. Vaccination with CERVARIX may not result in protection in all vaccine recipients.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration: Shake vial or syringe well before withdrawal and use. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. CERVARIX also should be inspected visually for cracks in the vial or syringe prior to administration. If any of these conditions exist, the vaccine should not be administered. With thorough agitation, CERVARIX is a homogeneous, turbid, white suspension. Do not administer if it appears otherwise. **2.2 Dose and Schedule:** Immunization with CERVARIX consists of 3 doses of 0.5 mL each, by intramuscular injection according to the following schedule: 0, 1, and 6 months. The preferred site of administration is the deltoid region of the upper arm. Do not administer this product intravenously, intradermally, or subcutaneously.

4 CONTRAINDICATIONS

Severe allergic reactions (e.g., anaphylaxis) to any component of CERVARIX [see *Description (11) of full prescribing information*].

5 WARNINGS AND PRECAUTIONS

5.1 Syncope: Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with CERVARIX. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position. **5.2 Latex:** The tip cap and the rubber plunger of the needleless prefilled syringes contain dry natural latex rubber that may cause allergic reactions in latex sensitive individuals. The vial stopper does not contain latex. **5.3 Preventing and Managing Allergic Vaccine Reactions:** Prior to administration, the healthcare provider should review the immunization history for possible vaccine hypersensitivity and previous vaccination-related adverse reactions to allow an assessment of benefits and risks. Appropriate medical treatment and supervision should be readily available in case of anaphylactic reactions following administration of CERVARIX.

6 ADVERSE REACTIONS

The most common local adverse reactions (≥20% of subjects) were pain, redness, and swelling at the injection site. The most common general adverse events (≥20% of subjects) were fatigue, headache, myalgia, gastrointestinal symptoms, and arthralgia.

6.1 Clinical Studies Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. There is the possibility that broad use of CERVARIX could reveal adverse reactions not observed in clinical trials.

Studies in Females 10 Through 25 Years of Age: The safety of CERVARIX was evaluated by pooling data from controlled and uncontrolled clinical trials involving 23,713 females 10 through 25 years of age in the pre-licensure clinical development program. In these studies, 12,785 females (10 through 25 years of age) received at least one dose of CERVARIX and 10,928 females received at least one dose of a control. Data on solicited local and general adverse events were collected by subjects or parents using standardized diary cards for 7 consecutive days following each vaccine dose (i.e., day of vaccination and the next 6 days). Unsolicited adverse events were recorded with diary cards for 30 days following each vaccination (day of vaccination and 29 subsequent days). Parents and/or subjects were also asked at each study visit about the occurrence of any adverse events and instructed to immediately report serious adverse events throughout the study period. These studies were conducted in North America, Latin America, Europe, Asia, and Australia. Overall, the majority of subjects were white (59%), followed by Asian (26%), Hispanic (9%), black (3%), and other racial/ethnic groups (3%). **Solicited Adverse Events:** The reported frequencies of solicited local injection site reactions and general adverse events are presented in Table 1. An analysis of solicited local injection site reactions by dose is presented in Table 2. Local reactions were reported more frequently with CERVARIX when compared with the control groups; in ≥84% of recipients of CERVARIX, these local reactions were mild to moderate in intensity. Compared with dose 1, pain was reported less frequently after doses 2 and 3 of CERVARIX, in contrast to redness and swelling where there was a small increased incidence. There was no increase in the frequency of general adverse events with successive doses.

BRIEF SUMMARY

Table 1. Rates of Solicited Local Adverse Reactions and General Adverse Events in Females 10 Through 25 Years of Age Within 7 Days of Vaccination (Total Vaccinated Cohort^a)

Adverse Reaction/Event	CERVARIX (10-25 yrs) %	HAV 720 ^b (15-25 yrs) %	HAV 360 ^c (10-14 yrs) %	Al(OH) ₃ Control ^d (15-25 yrs) %
Local Adverse Reaction	N = 6,431	N = 3,079	N = 1,027	N = 549
Pain	91.8	78.0	64.2	87.2
Redness	48.0	27.6	25.2	24.4
Swelling	44.1	19.8	17.3	21.3
General Adverse Event	N = 6,432	N = 3,079	N = 1,027	N = 549
Fatigue	55.0	53.7	42.3	53.6
Headache	53.4	51.3	45.2	61.4
GI ^e	27.8	27.3	24.6	32.8
Fever (≥99.5°F)	12.8	10.9	16.0	13.5
Rash	9.6	8.4	6.7	10.0
	N = 5,881	N = 3,079	N = 1,027	—
Myalgia ^f	49.1	44.9	33.1	—
Arthralgia ^f	20.8	17.9	19.9	—
Urticaria ^f	7.4	7.9	5.4	—

^a Total vaccinated cohort included subjects with at least one documented dose (N).

^b HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)₃].

^c HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of Al(OH)₃].

^d Al(OH)₃ Control = control containing 500 mcg Al(OH)₃.

^e GI = Gastrointestinal symptoms, including nausea, vomiting, diarrhea, and/or abdominal pain.

^f Adverse events solicited in a subset of subjects.

Table 2. Rates of Solicited Local Adverse Reactions in Females 10 Through 25 Years of Age by Dose Within 7 Days of Vaccination (Total Vaccinated Cohort^a)

Adverse Reaction	CERVARIX (10-25 yrs) %			HAV 720 ^b (15-25 yrs) %			HAV 360 ^c (10-14 yrs) %			Al(OH) ₃ Control ^d (15-25 yrs) %		
	Post-Dose	1	2	3	Post-Dose	1	2	3	Post-Dose	1	2	3
N	6,415	6,197	5,936	3,070	2,919	2,758	1,027	1,021	1,011	546	521	500
Pain	86.9	76.2	78.7	65.6	54.4	56.1	48.5	38.5	36.9	79.1	66.8	72.4
Pain, Grade 3 ^e	7.5	5.7	7.7	2.0	1.4	2.0	0.8	0.2	1.6	9.0	6.0	8.6
Redness	27.8	29.6	35.6	16.6	15.2	16.1	15.6	13.3	12.1	11.5	11.5	15.6
Redness, >50 mm	0.2	0.5	1.0	0.1	0.1	0.0	0.1	0.2	0.1	0.2	0.0	0.0
Swelling	22.7	25.2	32.7	10.5	9.4	10.5	9.4	8.6	7.6	10.3	10.4	12.0
Swelling, >50 mm	1.2	1.0	1.3	0.2	0.2	0.2	0.4	0.3	0.0	0.0	0.0	0.0

^a Total vaccinated cohort included subjects with at least one documented dose (N).

^b HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)₃].

^c HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of Al(OH)₃].

^d Al(OH)₃ Control = control containing 500 mcg Al(OH)₃.

^e Defined as spontaneously painful or pain that prevented normal daily activities.

The pattern of solicited local adverse reactions and general adverse events following administration of CERVARIX was similar between the age cohorts (10 through 14 years and 15 through 25 years).

Table 3. Rates of Unsolicited Adverse Events in Females 10 Through 25 Years of Age Within 30 Days of Vaccination (≥1% For CERVARIX and Greater Than HAV 720, HAV 360, or Al(OH)₃ Control) (Total Vaccinated Cohort^a)

Adverse Event	CERVARIX % (N = 6,654)	HAV 720 ^b % (N = 3,186)	HAV 360 ^c % (N = 1,032)	Al(OH) ₃ Control ^d % (N = 581)
Headache	5.3	7.6	3.3	9.3
Nasopharyngitis	3.6	3.4	5.9	3.3
Influenza	3.2	5.6	1.3	1.9
Pharyngolaryngeal pain	2.9	2.7	2.2	2.2
Dizziness	2.2	2.6	1.5	3.1
Upper respiratory infection	2.0	1.3	6.7	1.5
Chlamydia infection	2.0	4.4	0.0	0.0
Dysmenorrhea	2.0	2.3	1.9	4.0
Pharyngitis	1.5	1.8	2.2	0.5
Injection site bruising	1.4	1.8	0.7	1.5
Vaginal infection	1.4	2.2	0.1	0.9
Injection site pruritus	1.3	0.5	0.6	0.2
Back pain	1.1	1.3	0.7	3.1
Urinary tract infection	1.0	1.4	0.3	1.2

^a Total vaccinated cohort included subjects with at least one dose administered (N).

^b HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)₃].

^c HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of Al(OH)₃].

^d Al(OH)₃ Control = control containing 500 mcg Al(OH)₃.

Physicians “should consider vaccination of women during pregnancy with DTaP,” she said at the meeting.

In the prospective cohort study, 16 (23%) of 70 pregnant women received DTaP vaccine; 54 (77%) pregnant women selected as controls did not and had not been vaccinated for at least 2 years.

Four of the women (25%) in the DTaP group were vaccinated in the first trimester, eight (50%) in the second, and four (25%) in the third. Vaccination did not cause any adverse pregnancy outcomes.

Maternal blood and cord blood were collected at delivery.

Blood was also collected from children before and after their primary DTaP series and toddler booster doses at 12-18 months.

Blood samples were measured for pertussis antigens, including pertussis toxoid, filamentous hemagglutinin, pertactin, and fimbriae, by enzyme-linked immunosorbent assay.

Newborns in the DTaP group had higher pertussis antibody concentrations than their mothers, “showing efficient placental transfer of antibodies

to the infant,” Dr. Hardy-Fairbanks said.

They also had substantially higher concentrations than infants in the control group prior to the start of the primary DTaP series, and the differences were statistically significant.

However, at month 7, following completion of the DTaP series, infants born to vaccinated mothers had slightly lower antibody levels than infants in the control group.

The differences were not statistically significant, but “may represent some blunting of the infant immune response

to the [vaccine],” Dr. Hardy-Fairbanks said.

By the time they got their toddler booster doses, however, antibody levels “were essentially equivalent” in the two groups, she said. ■

Possible Blunted Immune Response?

Dr. Sarah Long thanked the study authors for their work. “Your findings are so very helpful. We don’t have this kind of information.”

She was concerned, however, that infants born to vaccinated mothers mounted only a blunted immune response to their primary DTaP vaccine series, and wondered if responses would be blunted to other vaccines. The study’s presenter said the question is currently being investigated, but so far that does not appear to be the case.

DR. LONG is the chief of the section of infectious diseases at St. Christopher’s Hospital for Children in Philadelphia. She said she had no conflicts of interest.

VIEW ON THE NEWS

New Onset Autoimmune Diseases (NOADs): The pooled safety database, which included controlled and uncontrolled trials which enrolled females 10 through 25 years of age, was searched for new medical conditions indicative of potential new onset autoimmune diseases. Overall, the incidence of potential NOADs, as well as NOADs, in the group receiving CERVARIX was 0.8% (95/12,533) and comparable to the pooled control group (0.8%, 87/10,730) during the 4.3 years of follow-up (mean 3.0 years) (Table 4). In the largest randomized, controlled trial (Study 2) which enrolled females 15 through 25 years of age and which included active surveillance for potential NOADs, the incidence of potential NOADs and NOADs was 0.8% among subjects who received CERVARIX (78/9,319) and 0.8% among subjects who received Hepatitis A Vaccine [720 EL.U. of antigen and 500 mcg Al(OH)₃] control (77/9,325).

Table 4. Incidence of New Medical Conditions Indicative of Potential New Onset Autoimmune Disease and New Onset Autoimmune Disease Throughout the Follow-up Period Regardless of Causality in Females 10 Through 25 Years of Age (Total Vaccinated Cohort^a)

	CERVARIX (N = 12,533)	Pooled Control Group ^b (N = 10,730)
	n (%) ^c	n (%) ^c
Total Number of Subjects With at Least One Medical Condition	95 (0.8)	87 (0.8)
Arthritis ^d	9 (0.0)	4 (0.0)
Celiac disease	2 (0.0)	5 (0.0)
Dermatomyositis	0 (0.0)	1 (0.0)
Diabetes mellitus insulin-dependent (Type 1 or unspecified)	5 (0.0)	5 (0.0)
Erythema nodosum	3 (0.0)	0 (0.0)
Hyperthyroidism ^e	14 (0.1)	15 (0.1)
Hypothyroidism ^f	30 (0.2)	28 (0.3)
Inflammatory bowel disease ^g	8 (0.1)	4 (0.0)
Multiple sclerosis	4 (0.0)	1 (0.0)
Myelitis transverse	1 (0.0)	0 (0.0)
Optic neuritis/Optic neuritis retrobulbar	3 (0.0)	1 (0.0)
Psoriasis ^h	8 (0.1)	11 (0.1)
Raynaud’s phenomenon	0 (0.0)	1 (0.0)
Rheumatoid arthritis	4 (0.0)	3 (0.0)
Systemic lupus erythematosus ⁱ	2 (0.0)	3 (0.0)
Thrombocytopenia ^j	1 (0.0)	1 (0.0)
Vasculitis ^k	1 (0.0)	3 (0.0)
Vitiligo	2 (0.0)	2 (0.0)

^a Total vaccinated cohort included subjects with at least one documented dose (N).

^b Pooled Control Group = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)₃], Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of Al(OH)₃], and a control containing 500 mcg Al(OH)₃.

^c n (%): number and percentage of subjects with medical condition.

^d Term includes reactive arthritis and arthritis.

^e Term includes Basedow’s disease, goiter, and hyperthyroidism.

^f Term includes thyroiditis, autoimmune thyroiditis, and hypothyroidism.

^g Term includes colitis ulcerative, Crohn’s disease, proctitis ulcerative, and inflammatory bowel disease.

^h Term includes psoriatic arthropathy, nail psoriasis, guttate psoriasis, and psoriasis.

ⁱ Term includes systemic lupus erythematosus and cutaneous lupus erythematosus.

^j Term includes idiopathic thrombocytopenic purpura and thrombocytopenia.

^k Term includes leukocytoclastic vasculitis and vasculitis.

Serious Adverse Events: In the pooled safety database, inclusive of controlled and uncontrolled studies, which enrolled females 10 through 72 years of age, 5.3% (862/16,142) of subjects who received CERVARIX and 5.9% (814/13,811) of subjects who received control reported at least one serious adverse event, without regard to causality, during the entire follow-up period (up to 7.4 years). Among females 10 through 25 years of age enrolled in these clinical studies, 6.4% of subjects who received CERVARIX and 7.2% of subjects who received the control reported at least one serious adverse event during the entire follow-up period (up to 7.4 years).

Deaths: In completed and ongoing studies which enrolled 57,323 females 9 through 72 years of age, 37 deaths were reported during the 7.4 years of follow-up: 20 in subjects who received CERVARIX (0.06%, 20/33,623) and 17 in subjects who received control (0.07%, 17/23,700). Causes of death among subjects were consistent with those reported in adolescent and adult female populations. The most common causes of death in the vaccine and control groups were motor vehicle accident and suicide, followed by neoplasm, autoimmune disease, infectious disease, homicide, cardiovascular disorders, and death of unknown cause. Among females 10 through 25 years of age, 31 deaths were reported (0.05%, 16/29,467) of subjects who received CERVARIX and 0.07%, 15/20,192 of subjects who received control.

6.2 Postmarketing Experience: In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for CERVARIX since market introduction (2007) are listed below. This list includes serious events or events which have suspected causal association to CERVARIX. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination. **Blood and Lymphatic System Disorders:** Lymphadenopathy. **Immune System Disorders:** Allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema, erythema multiforme. **Nervous System Disorders:** Syncope or vasovagal responses to injection (sometimes accompanied by tonic-clonic movements).

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration: There are no data to assess the concomitant use of CERVARIX with other vaccines. Do not mix CERVARIX with any other vaccine in the same syringe or vial. **7.2 Hormonal Contraceptives:** Among 7,693 subjects 15 through 25 years of age in Study 2 (CERVARIX, N = 3,821 or Hepatitis A Vaccine 720 EL.U., N = 3,872) who used hormonal contraceptives for a mean of 2.8 years, the observed efficacy of CERVARIX was similar to that

observed among subjects who did not report use of hormonal contraceptives.

7.3 Immunosuppressive Therapies: Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to CERVARIX [see Use in Specific Populations (8.6)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Clinical Studies: Overall Outcomes:** In clinical studies, pregnancy testing was performed prior to each vaccine administration and vaccination was discontinued if a subject had a positive pregnancy test. In all clinical trials, subjects were instructed to take precautions to avoid pregnancy until 2 months after the last vaccination. During pre-licensure clinical development, a total of 7,276 pregnancies were reported among 3,696 females receiving CERVARIX and 3,580 females receiving a control (Hepatitis A Vaccine 360 EL.U., Hepatitis A Vaccine 720 EL.U., or 500 mcg Al(OH)₃). The overall proportions of pregnancy outcomes were similar between treatment groups. The majority of women gave birth to normal infants (62.2% and 62.6% of recipients of CERVARIX and control, respectively). Other outcomes included spontaneous abortion (11.0% and 10.8% of recipients of CERVARIX and control, respectively), elective termination (5.8% and 6.1% of recipients of CERVARIX and control, respectively), abnormal infant other than congenital anomaly (2.8% and 3.2% of recipients of CERVARIX and control, respectively), and premature birth (2.0% and 1.7% of recipients of CERVARIX and control, respectively). Other outcomes (congenital anomaly, stillbirth, ectopic pregnancy, and therapeutic abortion) were reported less frequently in 0.1% to 0.8% of pregnancies in both groups. **Outcomes Around Time of Vaccination:** Sub-analyses were conducted to describe pregnancy outcomes in 761 women [N = 396 for CERVARIX and N = 365 pooled control, HAV 360 EL.U., HAV 720 EL.U., and 500 mcg Al(OH)₃] who had their last menstrual period within 30 days prior to, or 45 days after a vaccine dose and for whom pregnancy outcome was known. The majority of women gave birth to normal infants (65.2% and 69.3% of recipients of CERVARIX and control, respectively). Spontaneous abortion was reported in a total of 11.7% of subjects (13.6% of recipients of CERVARIX and 9.6% of control recipients) and elective termination was reported in a total of 9.7% of subjects (9.9% of recipients of CERVARIX and 9.6% of control recipients). Abnormal infant other than congenital anomaly was reported in a total of 4.9% of subjects (5.1% of recipients of CERVARIX and 4.7% of control recipients) and premature birth was reported in a total of 2.5% of subjects (2.5% of both groups). Other outcomes (congenital anomaly, stillbirth, ectopic pregnancy, and therapeutic abortion) were reported in 0.3% to 1.8% of pregnancies among recipients of CERVARIX and in 0.3% to 1.4% of pregnancies among control recipients. It is not known whether the observed numerical imbalance in spontaneous abortions in pregnancies which occurred around the time of vaccination is due to a vaccine-related effect. **Pregnancy Registry:** Healthcare providers are encouraged to register pregnant women who inadvertently receive CERVARIX in the GlaxoSmithKline vaccination pregnancy registry by calling 1-888-452-9622. **8.3 Nursing Mothers:** In non-clinical studies in rats, serological data suggest a transfer of anti-HPV-16 and anti-HPV-18 antibodies via milk during lactation in rats. Excretion of vaccine-induced antibodies in human milk has not been studied for CERVARIX. Because many drugs are excreted in human milk, caution should be exercised when CERVARIX is administered to a nursing woman. **8.4 Pediatric Use:** Safety and effectiveness in pediatric patients younger than 10 years of age have not been established. The safety and effectiveness of CERVARIX have been evaluated in 1,193 subjects 10 through 14 years of age and 6,316 subjects 15 through 17 years of age. [See Adverse Reactions (6.1) and Clinical Studies (14.5) of full prescribing information.] **8.5 Geriatric Use:** Clinical studies of CERVARIX did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects. CERVARIX is not approved for use in subjects 65 years of age and older. **8.6 Immunocompromised Individuals:** The immune response to CERVARIX may be diminished in immunocompromised individuals [see Drug Interactions (7.3)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: CERVARIX has not been evaluated for its carcinogenic or mutagenic potential.

17 PATIENT COUNSELING INFORMATION

Provide the Vaccine Information Statements prior to immunization. This is required by the National Childhood Vaccine Injury Act of 1986 and are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines). Inform the patient, parent, or guardian: Vaccination does not substitute for routine cervical cancer screening. Women who receive CERVARIX should continue to undergo cervical cancer screening per standard of care. CERVARIX does not protect against disease from HPV types to which a woman has previously been exposed through sexual activity. Since syncope has been reported following vaccination in young females, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Information regarding potential benefits and risks associated with vaccination. Report any adverse events to their healthcare provider. Safety has not been established in pregnant women. CERVARIX is not recommended for use in pregnant women or women planning to become pregnant during the vaccination course. Register women who receive CERVARIX while pregnant in the pregnancy registry by calling 1-888-452-9622.

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Full prescribing information for CERVARIX is available at www.cervarix.com. CRX-4BRS



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Paternal Postpartum Depression High

FROM JAMA

A significant number of men experience prenatal and postpartum depression, and the rate is marginally higher in the United States than in other countries, according to a meta-analysis of 43 studies.

The overall rate of paternal depression was 10.4%, with a U.S. rate of 14.1% vs. 8.2% in other countries. The study also reported maternal depression at a rate of 23.8%, with a moderate positive correlation between maternal and paternal depression.

The findings suggest that “more efforts should be made to improve screening and referral, particularly in light of the mounting evidence that early paternal depression may have substantial emotional, behavioral, and developmental effects on children,” noted James F. Paulson, Ph.D., and his colleague Sharnail D. Bazemore of the department of pediatrics at Eastern Virginia Medical School in Norfolk (JAMA 2010;303:1961-9). The correlation between paternal and maternal depression “also suggests a screening rubric – depression in one patient should prompt clinical attention to the other,” the investigators wrote.

The meta-analysis included studies from 16 countries and involved 28,004 new and expectant fathers aged 18 years or older.

—Kate Johnson