

HIV-Risky Business Persists Among Adolescents

BY HEIDI SPLETE
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WASHINGTON — The findings of a large survey reinforce the ongoing prevalence of risky sexual and substance abuse behavior among young people that could promote the spread of HIV infection, Angulique W. Outlaw, Ph.D., said in a poster at the Ryan White CARE Act meeting on HIV treatment.

To investigate the prevalence of risky

behaviors and teens’ and young adults’ attitudes toward HIV, Dr. Outlaw of the Children’s Hospital of Michigan, in Detroit, and her colleagues surveyed 751 adolescents and young adults aged 13-24 years, who received HIV counseling and testing in community-based venues. These included field locations such as parks and public events (38%), health clinics (24%), detention facilities (23%), and community drop-in centers (15%).

Overall, 12% of the respondents identi-

fied themselves as men who have sex with men (MSM) exclusively, 5% were men who have sex with men or women, 28% were high-risk heterosexuals, 54% were moderate- or low-risk heterosexuals, and 1% were “other.”

The number of respondents who defined themselves as MSM exclusively was higher than expected, Dr. Outlaw said in an interview.

A total of 82% of the respondents reported having sex without using a con-

dom, and 23% reported having a sexually transmitted disease (chlamydia or gonorrhea) within the past 90 days.

In addition, 58% reported any alcohol use during the past year, 46% reported using marijuana during the past year, and 43% reported having sex in conjunction with alcohol or drug use.

Females were significantly less likely to use condoms compared with males, and they also had a significantly higher incidence of STDs.

Younger respondents (aged 13-18 years) reported significantly more marijuana use and had significantly higher rates of gonorrhea and chlamydia compared with those aged 19-24 years.

The survey also included questions about attitudes toward HIV and HIV testing. Overall, 56% of the respondents felt that they had placed themselves at risk for HIV during the past year, and 82% said they were “definitely ready” to get tested for HIV.

The study participants appeared to be receptive to HIV education and testing.

A majority of 89% said that they would “definitely” return for HIV test results, and 77% did return. The returning subjects included a majority of both 13- to 18-year-olds (72%) and 19- to 24-year-olds (87%).

Although the researchers did not include the results of the respondents’ HIV tests, data published in 2004 by the Centers for Disease Control and Prevention indicated that 13% of HIV infections in the United States that year occurred in 13- to 24-year-olds, and ongoing research suggests that the incidence of new HIV infections in young people aged 13-24 in the United States has not declined.

The study was limited by the use of self-reports and a convenience sample, the investigators said.

PEDIARIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined)

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

CONTRAINDICATIONS: Hypersensitivity to any component of the vaccine, including yeast, neomycin, and polymyxin B, is a contraindication (see DESCRIPTION in complete prescribing information). Do not use PEDIARIX after a serious allergic reaction (e.g., anaphylaxis) temporally associated with a previous dose of this vaccine or with any components of this vaccine. Because of the uncertainty as to which component of the vaccine might be responsible, do not give further vaccination with any of these components; or, refer such individuals to an allergist for evaluation. The following events are contraindications to administration of PEDIARIX: encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause; progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy. Do not vaccinate individuals with these conditions until a treatment regimen has been established and the condition has stabilized.

WARNINGS: Administration of PEDIARIX is associated with higher rates of fever relative to separately administered vaccines. In a safety study that evaluated medically attended fever after PEDIARIX or separately administered vaccines when coadministered with 7-valent pneumococcal and Hib conjugate vaccines, infants who received PEDIARIX had a higher rate of medical encounters for fever within the first 4 days following the first vaccination. In some infants, these encounters included the performance of diagnostic studies to evaluate other causes of fever (see ADVERSE REACTIONS). 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 is latex-free. If any of the following events occur in temporal relation to receipt of DTaP or a vaccine containing an acellular pertussis component, consider carefully whether to give any pertussis vaccine, including PEDIARIX: temperature of ≥40.5°C (105°F) within 48 hours not due to another identifiable cause; collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours; persistent, inconsolable crying lasting ≥3 hours, occurring within 48 hours; seizures with or without fever occurring within 3 days. If Guillain-Barré syndrome occurs within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including PEDIARIX, should be based on careful consideration of the potential benefits and possible risks. If tetanus toxoid is withheld, other available vaccines should be given, as indicated. The decision to administer a pertussis-containing vaccine to individuals with stable central nervous system (CNS) disorders must be made by the physician on an individual basis, with consideration of all relevant factors, and assessment of potential risks and benefits for that individual. Advise the parent or guardian of the potential increased risk involved (see PRECAUTIONS). For children at higher risk for seizures than the general population, an appropriate antiepileptic may be administered at the time of vaccination and for the ensuing 24 hours according to the respective prescribing information recommended dosage to reduce the possibility of post-vaccination fever. The ACIP has published guidelines for vaccination of persons with recent or acute illness (www.cdc.gov/nip).

PRECAUTIONS: PEDIARIX should be given with caution in children with bleeding disorders such as hemophilia or thrombocytopenia and in children on anticoagulant therapy, with steps taken to avoid the risk of hematoma following the injection. Before the injection of any biological, the physician should take all reasonable precautions to prevent allergic or other adverse reactions. Epinephrine injection (1:1,000) and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur. Immunosuppressed individuals, including those receiving immunosuppressive therapy, may not develop the expected immune response. The ACIP has published guidelines for vaccination of persons on such therapies (www.cdc.gov/nip). **Drug Interactions:** For information regarding concomitant administration with other vaccines, refer to DOSAGE AND ADMINISTRATION in complete prescribing information. Do not mix PEDIARIX with any other vaccine in the same syringe or vial. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** PEDIARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility. **Pregnancy:** Pregnancy Category C: PEDIARIX is not indicated for women of child-bearing age. Animal reproduction studies have not been conducted with PEDIARIX. It is not known whether PEDIARIX can cause fetal harm when administered to a pregnant woman or if PEDIARIX can affect reproductive capacity. **Geriatric Use:** PEDIARIX is not indicated for use in adult populations.

Pediatric Use: Safety and effectiveness of PEDIARIX in infants younger than 6 weeks of age have not been evaluated. PEDIARIX is not recommended for persons 7 years of age or older.

ADVERSE REACTIONS: A total of 23,849 doses of PEDIARIX have been administered to 8,088 infants who received one or more doses as part of a 3-dose primary series during 14 clinical studies. The most common adverse reactions observed in clinical trials were local injection site reactions (pain, redness, or swelling), fever, and fussiness. In comparative studies, administration of PEDIARIX was associated with higher rates of fever relative to separately administered vaccines (see WARNINGS and ADVERSE REACTIONS Table 1). The prevalence of fever was highest on the day of vaccination and the day following vaccination. More than 96% of episodes of fever resolved within the 4-day period following vaccination (i.e., the period including the day of vaccination and the next 3 days). In the largest of the 14 studies, conducted in Germany, safety data were available for 4,666 infants who received PEDIARIX administered concomitantly at separate sites with 1 of 4 *Haemophilus influenzae* type b (Hib) vaccines at 3, 4, and 5 months of age and for 768 infants in the control group that received INFRARIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed), Hib conjugate vaccine, and oral poliovirus vaccine (OPV) separately. Data on adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days). Infants were also monitored for unsolicited adverse events that occurred within 30 days following vaccination using diaries which were returned at subsequent visits and were supplemented by spontaneous reports and a medical history as reported by parents. More than 95% of study participants were white.

In a US study, the safety of PEDIARIX administered to 673 infants was compared to the safety of separately administered INFRARIX, ENGERIX-B® (Hepatitis B Vaccine (Recombinant)), inactivated poliovirus vaccine (IPV) in 335 infants. In both groups, infants received Hib and 7-valent pneumococcal conjugate vaccines concomitantly at separate sites. All vaccines were administered at 2, 4, and 6 months of age. The study was powered to evaluate fever >101.3°F following dose 1. Data on solicited adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days) and are presented in Table 1. Telephone follow-up was conducted 1 month and 6 months after the third vaccination to inquire about serious adverse events. At the 6-month follow-up, information also was collected on new onset of chronic illnesses. 638 subjects who received PEDIARIX and 313 subjects who received INFRARIX, ENGERIX-B, and IPV completed the 6-month follow-up. Among subjects in both study groups combined, 69% were white, 18% were Hispanic, 7% were black, 3% were Oriental, and 3% were of other racial/ethnic groups.

The adverse event information from clinical trials provides a basis for identifying adverse events that appear to be related to vaccine use and for approximating rates. However, because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. As with any vaccine, there is the possibility that broad use of PEDIARIX could reveal adverse events not observed in clinical trials.

Deaths: In 14 clinical trials, 5 deaths were reported among 8,088 (0.06%) recipients of PEDIARIX and 1 death was reported among 2,287 (0.04%) recipients of comparator vaccines. Causes of death in the group that received PEDIARIX included 2 cases of Sudden Infant Death Syndrome (SIDS) and one case of each of the following: Convulsive disorder, congenital immunodeficiency with sepsis, and neuroblastoma. One case of SIDS was reported in the comparator group. The rate of SIDS among all recipients of PEDIARIX across the 14 trials was 0.25/1,000. The rate of SIDS observed for recipients of PEDIARIX in the German safety study was 0.2/1,000 infants (reported rate of SIDS in Germany in the latter part of the 1990s was 0.7/1,000 newborns). The reported rate of SIDS in the United States from 1990 to 1994 was 1.2/1,000 live births. By chance alone, some cases of SIDS can be expected to follow receipt of pertussis-containing vaccines.

Serious Adverse Events: Within 30 days following any dose of vaccine in the US safety study in which all subjects received concomitant pneumococcal and Hib conjugate vaccines, 7 serious adverse events were reported in 7 subjects (1% [7/673]) who received PEDIARIX (1 case each of pyrexia, gastroenteritis, and culture negative clinical sepsis and 4 cases of bronchiolitis) and 5 serious adverse events were reported in 4 subjects (1% [4/335]) who received INFRARIX, ENGERIX-B, and IPV (ulteropelvic junction obstruction and testicular atrophy in one subject and 3 cases of bronchiolitis).

Onset of Chronic Illnesses: In the US safety study in which all subjects received concomitant pneumococcal and Hib conjugate vaccines, 21 subjects (3%) who received PEDIARIX and 14 subjects (4%) who received INFRARIX, ENGERIX-B, and IPV reported new onset of a chronic illness during the period from 1 to 6 months following the last dose of study vaccines. Among the chronic illnesses reported in the subjects who received PEDIARIX, there were 4 cases of asthma and 1 case each of diabetes mellitus and chronic neutropenia. There were 4 cases of asthma in subjects who received INFRARIX, ENGERIX-B, and IPV.

Seizures: In the German safety study over the entire study period, 6 subjects in the group that received PEDIARIX reported seizures. Two of these subjects had a febrile seizure, 1 of whom also developed afebrile seizures. The remaining 4 subjects had afebrile seizures, including 2 with infantile spasms. Two subjects reported seizures within 7 days following vaccination (1 subject had both febrile and afebrile seizures, and 1 subject had afebrile seizures), corresponding to a rate of 0.22 seizures per 1,000 doses (febrile seizures 0.07 per 1,000 doses, afebrile seizures 0.14 per 1,000 doses). No subject who received concomitant INFRARIX, Hib vaccine, and OPV reported seizures. In a separate German study that evaluated the safety of INFRARIX in 22,505 infants who received 66,867 doses of INFRARIX administered as a 3-dose primary series, the rate of seizures within 7 days of vaccination with INFRARIX was 0.13 per 1,000 doses (febrile seizures 0.0 per 1,000 doses, afebrile

seizures 0.13 per 1,000 doses). Over the entire study period in the US safety study in which all subjects received concomitant pneumococcal and Hib conjugate vaccines, 4 subjects in the group that received PEDIARIX reported seizures. Three of these subjects had a febrile seizure and 1 had an afebrile seizure. Over the entire study period, 2 subjects in the group that received INFRARIX, ENGERIX-B, and IPV reported febrile seizures. There were no afebrile seizures in this group. No subject in either study group had seizures within 7 days following vaccination.

Other Neurological Events of Interest: No cases of hypotonic-hyporesponsiveness or encephalopathy were reported in either the German safety study or the US safety study.

Solicited Adverse Events: Table 1 presents data from the US safety study on solicited local and systemic adverse events within 4 days of vaccination with PEDIARIX or INFRARIX, ENGERIX-B, and IPV, administered concomitantly with Hib and 7-valent pneumococcal conjugate vaccines. In this study, medical attention (a visit to or from medical personnel) for fever within 4 days following vaccination was sought in the group who received PEDIARIX for 8 infants after the first dose (1.2%), 1 infant following the second dose (0.2%), and 5 infants following the third dose (0.8%) (Table 1). Following dose 2, medical attention for fever was sought for 2 infants (0.6%) who received separately administered vaccines (Table 1). Among infants who had a medical visit for fever within 4 days following vaccination, 9 of 14 who received PEDIARIX and 1 of 2 who received separately administered vaccines, had one or more diagnostic studies performed to evaluate the cause of fever.

Safety of PEDIARIX after a previous dose of hepatitis B vaccine: Limited data are available on the safety of administering PEDIARIX after a previous dose of hepatitis B vaccine. In 2 separate studies, 160 Moldovan infants and 96 US infants, respectively, received 3 doses of PEDIARIX following 1 previous dose of hepatitis B vaccine. Neither study was designed to detect significant differences in rates of adverse events associated with PEDIARIX administered after a previous dose of hepatitis B vaccine compared to PEDIARIX administered without a previous dose of hepatitis B vaccine.

Table 1. Percentage of US Infants With Solicited Local Reactions or Systemic Adverse Events Within 4 Days of Vaccination* at 2, 4, and 6 Months of Age With PEDIARIX Administered Concomitantly With Hib Conjugate Vaccine and 7-valent Pneumococcal Conjugate Vaccine (PCV7) or With Separate Concomitant Administration of INFRARIX, ENGERIX-B, IPV, Hib Conjugate Vaccine, and PCV7 (Modified ITT cohort)

	PEDIARIX, Hib Vaccine, & PCV7			INFRARIX, ENGERIX-B, IPV, Hib Vaccine, & PCV7		
	Dose 1	Dose 2	Dose 3	Dose 1	Dose 2	Dose 3
Local†						
N	671	653	648	335	323	315
Pain, any	36.1	36.1	31.2	31.9	30.0	29.8
Pain, grade 2 or 3	11.5	10.9	10.6	9.0	8.7	8.9
Pain, grade 3	2.4	2.5	1.7	2.7	1.5	1.3
Redness, any	29.9*	37.2	40.1	18.2	32.8	39.0
Redness, >5 mm	6.0*	9.6*	12.7*	1.8	5.9	7.3
Redness, >20 mm	0.9	1.2*	2.8	0.3	0.0	1.9
Swelling, any	17.3*	26.5*	28.7	9.6	20.4	24.8
Swelling, >5 mm	5.8*	9.6*	9.3*	1.8	5.0	4.1
Swelling, >20 mm	1.9*	2.5*	3.1	0.6	0.0	1.3
Systemic						
N	667	644	645	333	321	311
Fever†, ≥100.4°F	27.9*	38.8*	33.5*	19.8	30.2	23.8
Fever†, >101.3°F	7.0	14.1*	8.8	4.5	9.7	5.8
Fever†, >102.2°F	2.2*	3.6	3.4	0.3	3.1*	2.3
Fever†, >103.1°F	0.4	1.4	1.1	0.0	0.3	0.3
Fever†, M.A.	1.2*	0.2	0.8	0.0	0.6	0.0
N	671	653	648	335	323	315
Drowsiness, any	57.2	51.6	40.9	54.0	48.3	38.4
Drowsiness, grade 2 or 3	15.8	13.8	11.4	17.6	12.4	11.1
Drowsiness, grade 3	2.5	1.2	0.9	3.6	0.6	1.9
Irritability/Fussiness, any	60.5	64.9	61.1	61.5	61.6	56.5
Irritability/Fussiness, grade 2 or 3	19.8	27.9*	25.2*	19.4	21.1	19.4
Irritability/Fussiness, grade 3	3.4	4.4	3.5	3.9	3.4	3.2
Loss of appetite, any	30.4	30.6	26.2	27.8	26.6	23.8
Loss of appetite, grade 2 or 3	6.6	7.8*	5.9	5.1	3.4	5.4
Loss of appetite, grade 3	0.7	0.3	0.2	0.6	0.3	0.0

Modified ITT cohort = all vaccinated subjects for whom safety data were available
N = number of infants for whom at least one symptom sheet was completed; for fever, numbers exclude missing temperature recordings or tympanic measurements.
M.A. = Medically attended (a visit to or from medical personnel).
Grade 2 defined as sufficiently discomforting to interfere with daily activities.
Grade 3 defined as preventing normal daily activities.
* Within 4 days of vaccination defined as day of vaccination and the next 3 days.
† Local reactions at the injection site for PEDIARIX or INFRARIX.
‡ Rectal temperatures or axillary temperatures increased by 1°C to derive equivalent rectal temperature.
§ Rate significantly higher in the group that received PEDIARIX compared to separately administered vaccines [p value < 0.05 (2-sided Fisher Exact test) or the 95% CI on the difference between groups (Separate minus PEDIARIX) does not include 0].

Postmarketing Reports With PEDIARIX: Worldwide voluntary reports of adverse events received for PEDIARIX since market introduction of this vaccine are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of PEDIARIX or other vaccines or drugs. 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 vaccine exposure. *Cardiac Disorders:* Cyanosis. *Gastrointestinal Disorders:* Diarrhea, vomiting. *General Disorders and Administrative Site Conditions:* Fatigue, injection site cellulitis, injection site induration, injection site itching, injection site nodule/lump, injection site pain, injection site reactions, injection site redness, injection site swelling, injection site warmth, irritability, limb pain, limb swelling, pyrexia, Sudden Infant Death Syndrome. *Immune System Disorders:* Anaphylactic reaction, anaphylactoid reaction, hypersensitivity. *Infections and Infestations:* Upper respiratory tract infection. *Investigations:* Abnormal liver function tests. *Metabolism and Nutrition Disorders:* Anorexia. *Nervous System Disorders:* Bulging fontanelle, convulsions, depressed level of consciousness, febrile convulsion, hypotonia, hypotonic-hyporesponsive episode, lethargy, somnolence. *Psychiatric Disorders:* Crying, insomnia, irritability, nervousness, restlessness, screaming, unusual crying. *Respiratory, Thoracic and Mediastinal Disorders:* Apnea, dyspnea. *Skin and Subcutaneous Tissue Disorders:* Angioedema, erythema, rash, urticaria. *Vascular Disorders:* Pallor, petechiae.

Postmarketing Reports With INFRARIX and/or ENGERIX-B: Worldwide voluntary reports of adverse events received for INFRARIX and/or ENGERIX-B in children younger than 7 years of age but not already reported for PEDIARIX are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of INFRARIX and/or ENGERIX-B or other vaccines or drugs. 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 vaccine exposure. *Blood and Lymphatic System Disorders:* Idiopathic thrombocytopenic purpura^{1a}, lymphadenopathy^{1b}, thrombocytopenia^{1c}. *Gastrointestinal Disorders:* Abdominal pain¹, intussusception^{1a}, nausea¹. *General Disorders and Administrative Site Conditions:* Asthenia¹, malaise¹. *Hepatobiliary Disorders:* Jaundice¹. *Immune System Disorders:* Anaphylactic shock¹, serum sickness-like disease¹. *Musculoskeletal and Connective Tissue Disorders:* Arthralgia¹, myalgia¹. *Nervous System Disorders:* Encephalopathy¹, headache¹. *Skin and Subcutaneous Tissue Disorders:* Alopecia¹, erythema multiforme¹, pruritus^{1a} Stevens-Johnson syndrome¹. [¹ Following INFRARIX; ^a Following ENGERIX-B.]

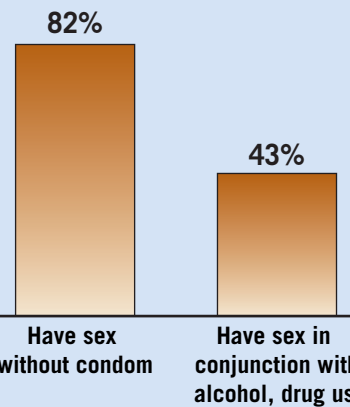
Reporting Adverse Events: Report the occurrence following immunization of any event set forth in the Vaccine Injury Table from the National Childhood Vaccine Injury Act including: Anaphylaxis or anaphylactic shock within 7 days, encephalopathy or encephalitis within 7 days, brachial neuritis within 28 days, or an acute complication or sequelae (including death) of an illness, disability, injury, or condition referred to above, or any events that would contraindicate further doses of PEDIARIX. These events should be reported to VAERS. The VAERS toll-free number is 1-800-822-7967. Reporting forms may also be obtained at the VAERS website at www.vaers.hhs.gov.

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Youth Put Themselves at Risk of Contracting HIV



Note: Based on a study of 751 people aged 13-24 years.
Source: Dr. Outlaw