Impact of the Sequential IPV/OPV Schedule on Vaccination Coverage Levels—United States, 1997

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In January 1997, the Advisory Committee on Immunization Practices (ACIP) recommended adoption of a sequential inactivated poliovirus vaccine (IPV)-oral poliovirus vaccine (OPV) vaccination schedule. The schedule of injections of IPV at 2 months and 4 months of age, followed by OPV at 12-18 months and again at 4-6 years was intended to minimize the risk for vaccine-associated paralytic poliomyelitis (VAPP) while maintaining population immunity to the potential introduction of wild-type poliovirus. To determine whether this change may result in reduced or delayed vaccination coverage because parents or physicians might be reluctant to administer multiple injections at a single visit, CDC investigated the impact of the change to a sequential IPV-OPV vaccination schedule at two large West coast health maintenance organizations (HMOs). This report summarizes the results of the investigation and indicates that changing to an initial two doses of IPV was not associated with decreases in vaccination coverage levels of routinely recommended vaccinations.

This study focused on children enrolled at Group Health Cooperative of Puget Sound (GHC), a Seattle-based HMO with approximately 530,000 members, and Kaiser Permanente of Northern California (KPNC), an Oakland-based HMO with approximately 2.8 million members. Both sites have automated vaccination tracking systems that allow for assessment of vaccination coverage by region, clinic, and individual patient. Beginning in April 1997, GHC adopted the ACIP guidelines for the sequential IPV schedule as an option for physicians and families. Within KPNC, each of its 17 medical centers made a local decision about whether and when to adopt the IPV schedule. Children in the study were born during October 1, 1996-June 30, 1997; residents in King, Pierce, Thurston, and Kitsap counties, Washington, and all counties of the KPNC region; had been continuously enrolled during the first 12 months of life; and had received at least one polio vaccination (N=1745 GHC and 15,707 KPNC enrollees). Up-to-date status, defined as receipt of two polio vaccinations, three diphtheria and tetanus toxoids and pertussis/acellular pertussis (DTP/DTaP) vaccinations, and two Haemophilus influenzae type b and two hepatitis B vaccinations administered after age 3 weeks, was measured at age 12 months.

The percentage of GHC children who received their first polio vaccine as IPV increased from 18% during the fourth quarter of 1996, to 19% in the first, 34% in the second, and 82% in the third quarter of 1997. Among GHC clinics that had at least 20 children in the evaluation, the percentage of children who received IPV during the third quarter of 1997 ranged from 81% to 98%. In comparison, at KPNC, the percentages by quarter were 10%, 15%, 24%, and 36%, respectively; among KPNC clinics that had at least 20 children in the evaluation, the percentage of children who received IPV during the fourth quarter ranged from 8% to 58%. Among GCH clinics that had at least 20 children in the evaluation, the percentage of children who received IPV during the fourth quarter ranged from 6% to 98%. Among GHC children who received IPV as their first polio vaccination, vaccination up-to-date status by age 12 months for routinely recommended vaccines was 82%, 83%, and 82% in the first three quarters following implementation, and among those receiving OPV, vaccination up-to-date status was 82%, 81%, and 79%, respectively. At KPNC, the quarterly up-to-date percentages were 90%, 89%, and 91% for children receiving IPV, and 92%, 90%, and 91% for children receiving OPV.

After adjusting for sex, trends over time, Medicaid status, and primary clinic, GHC children receiving IPV as their first polio vaccination were as likely to be up-to-date at age 12 months as children receiving OPV (risk ratio [RR]=1.1; 95% confidence interval [CI]=1.0-1.3). KPNC children receiving IPV as their first polio vaccination also were as likely as those receiving OPV to be up-to-date (RR=1.0; 95% CI=0.9-1.0). At GHC, children enrolled in Medicaid had lower coverage levels at age 12 months (71% up-to-date among Medicaid enrollees compared with 83% among nonenrollees); KPNC Medicaid enrollees and non-Medicaid enrollees had similar up-to-date status (90% compared with 91%, respectively). Among GHC Medicaid enrollees, vaccination with IPV was not significantly associated with a decreased up-to-date status (68% at age 12 months among IPV recipients compared with 73% at age 12 months among OPV recipients). At KPNC, Medicaid enrollees receiving IPV were as likely to be up-to-date as those receiving OPV (91% compared with 90%, respectively).

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CDC Editorial Note: The findings in this report indicate that use of IPV for the initial polio vaccine doses in these two West coast HMOs was not associated with decreases in vaccination coverage levels. These findings are consistent with evaluations conducted in other settings, including clinics serving children from low-income families.

An important ancillary finding from the study was that the sequential polio
vaccination schedule was implemented to a much greater degree in the HMO that used a more centralized decision making process than in the HMO that relied on local decision making (82% compared with 36%, respectively, for the percentage of children who received IPV for their initial polio vaccination). In the United States, use of IPV increased from 6% of all polio vaccine doses distributed in 1996 to 29% in 1997 (CDC, unpublished data, 1998).

Despite the increased use of IPV, four cases of VAPP have occurred in the United States since January 1997. All cases were associated with receipt of the first or second dose of OPV vaccine in an all OPV schedule; three cases were in OPV recipients, and one case was in an adult contact of an OPV recipient.

To further reduce the incidence of VAPP by decreasing reliance on OPV for the initial doses of poliovirus vaccine, in October 1998, ACIP changed the routine childhood polio vaccination schedule. Use of OPV is no longer recommended for the first two doses except in special circumstances (e.g., a child whose parents do not accept the recommended number of injections or who will be traveling to areas with endemic polio). OPV remains the vaccine of choice for mass vaccination campaigns to control outbreaks associated with wild poliovirus.

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**Osteoporosis Among Estrogen-Deficient Women—United States, 1988-1994**

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1 table omitted

**Osteoporosis**

**Among Estrogen-Deficient Women—United States, 1988-1994**

**Each year in the United States, hip fractures result in approximately 300,000 hospital admissions and an estimated $9 billion in direct medical costs.** Most of these fractures result from osteoporosis among women who experience accelerated bone loss after natural or surgically induced menopause. Measurement of bone mineral density (BMD) is the best tool available to assess osteoporotic fracture risk for women after menopause; a reduction of one standard deviation (SD) in femoral BMD is comparable to a 14-year increase in age on the risk for hip fracture. A technology that allows highly accurate and precise measurement of BMD is dual energy x-ray absorptiometry (DXA). CDC’s Third National Health and Nutrition Examination Survey (NHANES III) was the first nationally representative survey that used DXA to estimate osteoporosis prevalence based on BMD in the U.S. population, providing baseline information for assessing national prevention and intervention needs for this disease. This report compares self-reported health information with BMD measurements from NHANES III conducted during 1988-1994; the findings indicate that most estrogen-deficient women in the United States who had femoral osteoporosis based on BMD were unaware of this condition, reflecting the evolving nature of research and clinical practice regarding osteoporosis.

NHANES III collected data through household interviews and direct standardized physical examinations using specially equipped mobile examination centers. A total of 14,646 men and nonpregnant women aged ≥20 years (excluding those with histories of fractures on both hips) underwent DXA scanning of the proximal femur. This represented 78% of the eligible interviewed sample, and 88% of the eligible examined sample. The analysis for this study was restricted to women who reported natural or surgically induced (i.e., bilateral oophorectomy) menopause and who had never used exogenous hormones. Women with these characteristics were considered to be at high risk for osteoporosis and thus had been identified previously as appropriate candidates for BMD testing. Women with BMD results that were unacceptable for technical reasons were excluded from the analysis (2%). The final analytic sample comprised 2314 women.

All estimates were generated using SUDAAN. Estimates were stratified by selected risk factors for osteoporosis (i.e., age, race, body mass index [BMI], and whether menopause had been induced surgically) and possible confounders of self-reporting (i.e., education or income level, urban or rural residence, healthcare use, and usual source of care). Prevalence estimates of osteoporosis based on BMD were calculated using the World Health Organization (WHO) diagnostic criteria, which defined osteoporosis as a BMD value >2.5 SD below the mean of a young adult reference group. Prevalence is reported for the total femur region because this skeletal site was chosen for standardization of femur BMD between different DXA densitometers. Prevalence of self-reported osteoporosis was estimated based on responses to the question, “Has a doctor ever told you that you had osteoporosis, sometimes called thin or brittle bones?” The concordance was the percentage of women who reported a diagnosis of osteoporosis out of women with femoral osteoporosis based on BMD measurements.

Among the study group of 2314 women, 17% (95% confidence interval [CI]=15.5%-19.0%) had a femoral BMD value that met WHO’s definition for osteoporosis, and 5% (95% CI=4.3%-6.6%) reported having been told by a doctor they had osteoporosis. Based on BMD results, the prevalence of osteoporosis was significantly higher among...
women aged \( \geq 65 \) years (29.5\%) than among younger women (5.7\%), among non-Hispanic white women (18.7\%) than among all women of other racial/ethnic groups (11.6\%), and among women with a BMI <25 (33.3\%) than among women with a BMI \( \geq 25 \) (8.0\%). The prevalence also was higher among women with bilateral oophorectomy than among those with natural menopause, but the difference was not statistically significant. Among women who self-reported having had osteoporosis diagnosed, risk for osteoporosis was higher among non-Hispanic whites, but there were no significant differences for women in other risk categories. Self-reported data also suggested the prevalence was lower among women aged \( \geq 65 \) years than among younger women.

Women’s knowledge of their osteoporosis varied more by socioeconomic status (SES) and by health-care factors than by BMD measurements. Self-reported prevalence estimates generally were significantly lower among women with income at or below poverty level† (2.2\%) and women not seen by a doctor for \( \geq 6 \) months (2.6\%). Although sample sizes in some of these strata were too small to detect statistical significance, lower SES and fewer health-care resources were associated with lower self-reported prevalence of osteoporosis. A similar association was not found in BMD measurements, which showed no differences between most of these categories or slightly higher prevalence among women with lower education levels or women with income at or below poverty level.

Overall, 7% of women whose osteoporosis was diagnosed by BMD were aware of their condition. The concordance between self-reported and BMD data was low in all population subgroups, particularly for women with lower SES and fewer health-care resources (range: 1%-5%) compared with women with higher SES and more health-care resources (range: 8%-10%).

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FDA Approval of a Fourth Acellular Pertussis Vaccine for Use Among Infants and Young Children

ON JULY 29, 1998, THE FOOD AND DRUG Administration (FDA) licensed North American Vaccine, Inc. (Beltsville, Maryland) to distribute a combined diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) (Cerviva™)† for the first four doses of the diphtheria and tetanus toxoids and pertussis vaccination series administered to infants and children aged 6 weeks-6 years. Cerviva™ is the fourth acellular pertussis vaccine to be licensed for use in infants and young children in the United States.† Vaccine doses should be administered at ages 2, 4, 6, and 15-20 months. Data are insufficient to evaluate the use of Cerviva™ as a fifth dose among children aged 4-6 years who have received Cerviva™ for the previous four doses. Additional information about the immunogenicity and safety of a fifth dose following four previous doses of the same acellular pertussis vaccine is being collected and should be available before these infants are aged 4-6 years and require a fifth dose.

The Advisory Committee on Immunization Practices (ACIP), the Committee on Infectious Diseases, the American Academy of Pediatrics, and the American Academy of Family Physicians recommend that children routinely receive a series of five doses of vaccine against diphtheria, tetanus, and pertussis before age 7.‡ The first four doses should be administered at ages 2, 4, 6, and 15-18 months, and the fifth dose at age 4-6 years.

The following evidence supports the use of Cerviva™ for the first four doses of the diphtheria, tetanus, and pertussis vaccination series:

1. The rates of local reactions, fever, and other common systemic symptoms following receipt of Cerviva™ inoculations were significantly lower than those following whole-cell pertussis vaccination (administered as diphtheria and tetanus toxoids and pertussis vaccine [DTP]) for doses one through three in controlled clinical studies.ª

2. Efficacy of three doses of Cerviva™ against pertussis disease was assessed in a double-blind, randomized, placebo-controlled trial in Sweden using Cerviva™-EU, a vaccine containing the same amount of pertussis toxoid (40 µg) per dose as Cerviva™ but more diphtheria toxoid (25 Lf versus 15 Lf) and more tetanus toxoid (7 Lf versus 6 Lf).ª Infants were randomly assigned to be vaccinated with either Cerviva™-EU or DT (Diphtheria and Tetanus Toxoids Adsorbed Vaccine, Statens Seruminstitut, Copenhagen, Denmark) at ages 3, 5, and 12 months. The main observation period started 30 days after the third dose of vaccine and lasted a mean of 17 months. In this trial, pertussis was defined according to the World Health Organization case definition (i.e., a paroxysmal cough illness lasting ≥21 days and confirmed by culture, serology, or epidemiologic link to a culture-positive household contact). Starting 1 month after the third dose, the vaccine efficacy of Cerviva™-EU against WHO-defined pertussis was 72% (95% confidence interval=62%-78%).ª Although a serologic correlate of protection for pertussis has not been established, the antibody response to pertussis toxoid in U.S. infants after doses of Cerviva™ at 2, 4, 6, and 15-20 months of age was comparable to that achieved in a previous trial among infants in Sweden in whom efficacy was demonstrated after three doses at 3, 5, and 12 months of age. Because of the reduced frequency of adverse reactions and demonstrated efficacy, the ACIP recommends a licensed DTaP for all five doses of the routine diphtheria, tetanus, and pertussis vaccination series and for the remaining doses in the series for children who have started the vaccination series with whole-cell DTP vaccine.ª The ACIP considers the data to be insufficient in terms of safety and efficacy to express a preference between different acellular pertussis vaccine formulations.

Whenever feasible, the same DTaP vaccine should be used throughout the entire vaccination series. No data exist on the safety, immunogenicity, or efficacy of different DTaP vaccines when administered interchangeably in the primary or booster vaccination of a child. However, if the vaccine provider does not know or have available the type of DTaP vaccine the child to be vaccinated had received previously, any of the licensed DTaP vaccines may be used to complete the vaccination series.ª

†The WHO criteria did not specify the reference group in terms of skeletal site, age, or race/ethnicity. In this study, non-Hispanic white women aged 20-29 years were used as the reference group.§

‡Poverty status is based on family income and household size using the Census poverty thresholds.

§Public Law 105-33, Balanced Budget Act of 1997.

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4 available

†Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed, Cerviva™, manufactured and distributed by North American Vaccine, Inc., Beltsville, Maryland. Marketed by Ross Products Division, Abbott Laboratories, Inc. The diphtheria and tetanus toxoid components are produced by the Statens Seruminstitut, Copenhagen, Denmark. Final formulation and release of Cerviva™ are conducted by North American Vaccine, Inc.

§Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or U.S. Department of Health and Human Services.