Teen childbearing can have negative health, economic, and social consequences for mothers and their children (1) and costs the United States approximately $9.4 billion annually (2). During 1991–2014, the birth rate among teens aged 15–19 years in the United States declined 61%, from 61.8 to 24.2 births per 1,000, the lowest rate ever recorded (3). Nonetheless, in 2014, the teen birth rate remained approximately twice as high for Hispanic and non-Hispanic black (black) teens compared with non-Hispanic white (white) teens (3), and geographic and socioeconomic disparities remain (3,4), irrespective of race/ethnicity. Social determinants associated with teen childbearing (e.g., low parental educational attainment and limited opportunities for education and employment) are more common in communities with higher proportions of racial and ethnic minorities (4), contributing to the challenge of further reducing disparities in teen births.

To examine trends in births for teens aged 15–19 years by race/ethnicity and geography, CDC analyzed National Vital Statistics System (NVSS) data at the national (2006–2014), state (2006–2007 and 2013–2014), and county (2013–2014) levels. To describe socioeconomic indicators previously associated with teen births, CDC analyzed data from the American Community Survey (ACS) (2010–2014). Nationally, from 2006 to 2014, the teen birth rate declined 41% overall with the largest decline occurring among Hispanics (51%), followed by blacks (44%), and whites (35%). The birth rate ratio for Hispanic teens and black teens compared with white teens declined from 2.9 to 2.2 and from 2.3 to 2.0, respectively. From 2006–2007 to 2013–2014, significant declines in teen birth rates and birth rate ratios were noted nationally and in many states. At the county level, teen birth rates for 2013–2014 ranged from 3.1 to 119.0 per 1,000 females aged 15–19 years; ACS data indicated unemployment was higher, and education attainment and family income were lower in counties with higher teen birth rates. State and county data can be used to understand disparities in teen births and implement community-level interventions that address the social and structural conditions associated with high teen birth rates.

NVSS natality files are compiled annually by CDC’s National Center for Health Statistics and include demographic information, such as maternal age, race, and Hispanic ethnicity, for births in all 50 states and the District of Columbia (DC) (3). CDC calculated teen birth rates (number of births per 1,000 females aged 15–19 years) at the national, state, and county level, and birth rate ratios (the birth rates for black
teens and for Hispanic teens compared with white teens), as measures of disparities at the national and state level. This report includes national data for 2006–2014. For state-specific comparisons, 2 years of data were combined for 2006–2007 and 2013–2014 to provide reliable estimates for each race/ethnicity group (numerators ≥20). Changes over time were evaluated using a Z-test (for birth rates based on counts ≥100), or through a comparison of Poisson probability distributions (for birth rates based on counts <100, and for birth rate ratios). County-specific data were reported for 2013–2014 combined, and excluded counties with <20 teen births in total, resulting in a final data set accounting for 76% of all counties and 99% of all teen births in the United States.

The most recent 5-year estimate (2010–2014) from the U.S. Census Bureau’s ACS was used to describe key socioeconomic indicators. The ACS is a continual nationwide survey that collects detailed information on demographic, social, economic, and housing characteristics (5). Three markers of economic opportunity and perceived potential for future opportunities, previously used as indicators of social determinants for teen childbearing (6), were selected (i.e., percentage of the population aged ≥16 years unemployed, percentage of the population aged ≥25 years with an associate’s degree or higher, and median family income). The value for each indicator was compared between U.S. counties in highest and lowest quintiles of teen birth rates for 2013–2014. T-tests were used to evaluate differences (p<0.05).

Nationally, from 2006 to 2014, the teen birth rate declined 41% overall (from 41.1 per 1,000 to 24.2 per 1,000). The largest decline occurred among Hispanics (51%, from 77.4 to 38.0), followed by blacks (44%, from 61.9 to 34.9), and then whites (35%, from 26.7 to 17.3) (Figure 1). Correspondingly, the birth rate ratio for Hispanic teens and black teens compared with white teens declined from 2.9 to 2.2 and from 2.3 to 2.0, respectively.

The teen birth rate and racial/ethnic disparities for 2013–2014 ranged widely across states (Table). In some states, these disparities reflected very low rates of birth among white teens. For example, in New Jersey, the teen birth rate among whites (4.8) was well below the national rate for this group (18.0); whereas teen birth rates in this state among blacks (27.4) and Hispanics (31.3) were also lower than the national rates for these groups (blacks: 37.0; Hispanics: 39.8), they were approximately 6–7 fold higher than the rate for whites. In other states, disparities reflected birth rates for black and Hispanic teens that exceeded national rates for these groups. For example, in Nebraska, the birth rate for white teens (16.2) approximated the national rate, whereas rates for black and Hispanic teens (42.6 and 53.9, respectively) far exceeded the national rate for these groups. Finally, other states had smaller disparities, because teen birth rates were relatively high among all racial/ethnic groups. In Arkansas, for example, the teen birth rate was above the national rate for whites (37.7), blacks (54.6) and Hispanics (46.5).
From 2006–2007 to 2013–2014, the overall birth rate for teens declined significantly in every state, with the percentage decline ranging from 13% (North Dakota) to 48% (Arizona). In nearly every state, there was a significant decline for all three racial/ethnic groups assessed (Table). In many states disparities also declined significantly from 2006–2007 to 2013–2014; the birth rate ratio declined significantly for black teens compared with white teens in 28 states and for Hispanic teens compared with white teens in 37 states (p<0.05). However, states with the largest percentage decline in teen births did not necessarily have the largest declines in racial/ethnic disparities (Table).

U.S. county-level teen birth rates for 2013–2014 ranged from 3.1 to 119.0, with median rates of 14.6 and 57.1 for the counties in the lowest and highest quintiles for teen birth rates, respectively (Figure 2). Many counties with teen birth rates in the highest quintile were clustered in the south and southwest; some states with low overall birth rates also had counties in the highest quintile.

Data from ACS indicated that among counties in the highest quintile for teen birth rates, the mean percentage of the population aged ≥16 years unemployed, mean percentage of the population aged ≥25 years with an associate’s degree or higher, and mean family income were 10.5%, 19.9% and $46,005, respectively. By comparison, values for all three socioeconomic indicators were more favorable among counties in the lowest quintile for teen birth rates, at 7.6%, 40.4% and $73,967, respectively (p<0.001, for all comparisons).

Discussion

Significant declines in racial/ethnic disparities have accompanied the historic decline in the overall teen birth rate in the United States since 2006. Nationally, and in many states, the largest decline occurred among Hispanic teens followed by black and then white teens. Nonetheless, racial/ethnic and geographic disparities remain, both within and across states, and even where large declines in teen birth rates have occurred. The variation in county-level data reinforces the need to use local data to focus teen pregnancy prevention efforts on communities with the greatest need.

To address persistent disparities in teen births, the U.S. Department of Health and Human Services (HHS) Office of Adolescent Health partnered with CDC during 2010–2015 to fund community-wide initiatives in nine communities with some of the highest teen birth rates in the United States (7,8).
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### Abbreviation: NA = not applicable.

* Number of births per 1,000 females aged 15–19 years.

† Teens categorized as black or white were non-Hispanic. Teens categorized as Hispanic might be of any race. Other racial ethnic populations were too small for meaningful analysis.

§ Birth rate for non-Hispanic black teens divided by the birth rate for non-Hispanic white teens.

¶ Birth rate for Hispanic teens divided by the birth rate for non-Hispanic white teens.

** Overall for the United States, and unless otherwise indicated for individual states, the decline from 2006–2007 to 2013–2014 was significant (p<0.05).

†† The decrease from 2006–2007 to 2013–2014 was not statistically significantly (p>0.05).
This effort focused on black and Hispanic teens and integrated activities that addressed social determinants of health at the community level (8). Participating communities examined local data to develop their activities. Examples of activities included presenting community-specific teen birth data to civic leaders; encouraging health care providers to offer evening and weekend hours and low-cost services to increase access; having teen-focused, culturally appropriate materials available during health care visits; and implementing evidence-based teen pregnancy prevention programs to reach teens of both sexes both inside and outside of schools (e.g., through Job Corps, alternative schools, churches, and community colleges) (8). Preliminary data (9) indicate that each community increased the number of teens who received reproductive health services and evidence-based interventions, as well as the proportion of teens who received moderately or highly effective contraceptive methods. Many aspects of the community-wide initiatives have been incorporated in Teen Pregnancy Prevention Replication grants awarded in 2015 by the Office of Adolescent Health to communities with the greatest need (10).

The findings in this report are subject to at least three limitations. First, teen birth rate estimates for some racial/ethnic groups (i.e., American Indian/Alaskan Natives and Asian Pacific Islanders in all states; blacks in Montana; Hispanics in Vermont; and all racial/ethnic groups by county) were not available at the state and county level because of small population sizes. Second, while this report examined each major race/ethnicity group overall, there are differences in teen birth rates among subgroups within these populations, such as Mexican, Puerto Rican, and Cuban persons of Hispanic ethnicity (3). Finally, information on economic data, unemployment, and educational attainment provides useful information about community context for preventing teen pregnancy, but does not provide a direct link with individual-level factors.

Despite substantial declines in teen births in the United States, disparities by race/ethnicity and geography persist.
Morbidity and Mortality Weekly Report

Summary

What is already known about this topic?
Despite record declines in the rate of births among teens, racial/ethnic and geographic disparities persist.

What is added by this report?
From 2006 to 2014, the birth rate for teens aged 15–19 years declined 41% overall (from 41.1 to 24.2 per 1,000 females). The greatest decline was for Hispanics (51%), followed by non-Hispanic blacks (44%), and non-Hispanic whites (35%). From 2006–2007 to 2013–2014, the overall birth rate for teens declined significantly in every state, with declines ranging from 13% in North Dakota to 48% in Arizona; the birth rate ratio also declined for black teens compared with white teens in 28 states and for Hispanic teens compared with white teens in 37 states. County-level teen birth rates for 2013–2014 ranged from 3.1 to 119.0 per 1,000 females aged 15–19 years; unemployment was higher, and education attainment and family income were lower in counties with higher teen birth rates.

What are the implications for public health practices?
Community-level interventions that address the social conditions associated with high teen birth rates might further reduce racial/ethnic and geographic teen birth disparities in the United States. State and county-level data can be used to identify populations with the greatest need.

highlighting the continuing need for teen pregnancy prevention efforts. Understanding disparities in teen birth rates and the multiple causes at the local level can help target effective interventions for populations with the greatest need (4). Ongoing efforts to integrate social determinants of health into teen pregnancy prevention program play a critical role in addressing racial/ethnic and geographical disparities observed in teen births in the United States.

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References

Opioid Prescriptions Among Women of Reproductive Age Enrolled in Medicaid — New York, 2008–2013

Brian K. Gallagher, MS1; Yejee Shin, MS1; Patrick Roohan, MS2

Exposure to opioids during pregnancy can lead to adverse infant outcomes, including neonatal abstinence syndrome (1) and birth defects (2). Ascertaining opioid prescriptions for women who become pregnant or have no indication of contraceptive use is important to determine the number of women who are at potential risk for adverse fetal outcomes. The New York State (NYS) Department of Health (DOH) analyzed data for women aged 15–44 years (i.e., reproductive-aged women) enrolled in Medicaid to examine opioid drug prescriptions during 2008–2013. On the basis of Medicaid drug claims for any drug with an opioid ingredient, prescriptions were identified for the enrolled population of reproductive-aged women and for three subgroups: women whose diagnosis, procedure, and drug codes indicated contraceptive use or infertility; women who were not using contraceptives and not infertile; and women who had had a live birth during the reporting year. During 2008–2013, among all women of reproductive age, 20.0% received a prescription for a drug with an opioid component; the proportion was highest (27.3%) among women with an indication of contraceptive use or infertility, intermediate (17.3%) among women who had no indication of contraceptive use, and lowest (9.5%) among women who had had a live birth. Although New York’s proportion of opioid prescriptions among female Medicaid recipients who had a live birth is lower than a recent U.S. estimate (3), these results suggest nearly one in 10 women in this group may have been exposed to opioids in the prenatal period.

To determine the prenatal period, Medicaid records for a 1-year cohort of women were matched with vital statistics birth records. Among enrolled women who had a live birth, the mean gestational age in days for each pregnancy-related ICD-9 primary diagnosis code was calculated and used to compute the average prenatal period. Using this approach, the prenatal period was defined as the 280 days preceding the date of a live birth for women with an indication of “late” pregnancy (ICD-9 code 645), 252 days for women with an indication of “multiple gestation” (ICD-9 code 651), or “antepartum hemorrhage” (ICD-9 code 641); as 238 days for women with an indication of “preterm labor” (ICD-9 code 644); and 270 days for all other live births (ICD-9 codes 650, 652, 654–657, 659, 660–666, or 669). Prescription of an opioid was ascertained during the prenatal period for women with an ICD-9 and Current Procedural Terminology code indicating a live birth, and for the entire reporting period for all other women of reproductive age. Women were identified as infertile using an approach similar to the Centers for Medicare & Medicaid Services developmental measure for pre- and interconception health (5). This approach uses diagnosis codes as well as procedure codes indicating hysterectomy, bilateral oophorectomy, or premature menopause occurring in the reporting year to identify women who cannot become pregnant. Contraceptive use during the reporting year was ascertained using diagnosis, procedure, and drug codes to identify female sterilization, or use of an intrauterine device, hormonal implant, injectable contraception, oral contraception, birth control patch, vaginal ring, or diaphragm. Results are reported for all women enrolled in Medicaid for whom opioid drugs were prescribed and for three subgroups: women with an indication of contraceptive use or infertility; women with no indication of contraceptive use; and, during pregnancy, women who had a live birth during 2008–2013. The percentage of overall prescribing does not include opioids prescribed to women before pregnancy, on the date of delivery, or after pregnancy for women who had a live birth.

During 2008–2013, the average number of women aged 15–44 years and continuously enrolled in Medicaid was 800,908; the number ranged from 675,717 in 2008 to 903,721 in 2013 (Table). The average proportion of women...
of reproductive age who received prescriptions for opioids during 2008–2013 was 20.0%, ranging from a low of 18.7% in 2008 to a high of 20.9% in 2011. The average proportion of opioid prescriptions for women with an indication of contraceptive use or infertility was 27.3%, with a range of 25.8% in 2008 to 28.2% for 2012. The average proportion of opioid prescriptions for women with no indication of contraceptive use was 17.3%, with a range of 16.0% in 2008 to 20.0% during 2008–2013. The average proportion of prenatal opioid prescriptions was 9.5%, ranging from 8.8% in 2008 to 10.0% in 2010 and 2011.

Discussion

During 2008–2013, an average of 20.0% of reproductive-aged women enrolled in Medicaid in New York (average total = 800,908) received a prescription for opioids at least one time. Previous studies have examined opioid prescriptions among women of reproductive age enrolled in Medicaid, and women enrolled in Medicaid experiencing a live birth (3,4). During 2008–2012, an estimated 39.4% of reproductive-aged women enrolled in Medicaid in a selection of U.S. states received opioid prescriptions (4), a higher proportion than New York’s overall proportion of 20.0% during a similar period. Because data used for the U.S. results did not allow a geographic breakdown of prescribing, a direct comparison with the findings from New York is not possible. A study that examined opioid prescriptions in Medicaid-enrolled women who had a live birth during 2000–2007 reported that in the United States overall, 21.6% of these women had received opioid prescriptions, including 9.3% in the Northeast (3) and 9.6% in New York (R. Desai, personal communication, June 9, 2015), proportions which are similar to New York’s 9.5% during 2008–2013. Regional differences in opioid prescriptions for males and females in the Medicaid program have also been reported for the fee-for-service population during 1996–2002; New York was in the lowest opioid prescription quintile (6). Geographic variation in opioid prescribing has also been reported for the U.S. population (males and females); in 2008, the proportion of residents receiving opioid prescriptions in New York was low compared with other states (7).

New York has a history of prescription monitoring, beginning in 1972, with a program to regulate Schedule II controlled substances. In 2012, monitoring was enhanced by implementation of the Internet System for Tracking Over-Prescribing, or I-STOP, prescription monitoring program for Schedule II, III and IV controlled substances. These programs, adopted in response to concerns about the abuse and diversion of controlled substances, might contribute to the lower proportion of opioid prescribing in New York compared with opioid prescribing in most other states and the United States overall.

The findings in this report are subject to at least four limitations. First, ascertainment of opioid prescriptions was based on medications dispensed in the outpatient setting, and it is not known whether women took the prescribed medicine. Second, women who paid for drugs containing opioids without using Medicaid and women who received opioids while using Medicaid services in an inpatient or emergency department setting were not identified. Third, women with no indication of contraceptive use in this analysis might be using nonprescribed contraceptive methods (e.g., condoms) or might not have a male sexual partner or be sexually active; therefore, the number of women who might have had a pregnancy at risk for opioid exposure is smaller than what is presented. Finally, so that New York results could be compared with recent U.S. results (4), the opioid prescription experience of women of reproductive age was restricted to recipients continuously...
enrolled in New York State Medicaid during each reporting year. However, the health and social characteristics of women continuously enrolled in Medicaid could differ from those of women with limited enrollment, and the proportion of opioid prescriptions for women with limited enrollment might differ from that of women with continuous enrollment.

During 2008–2013, a lower proportion of Medicaid-enrolled, reproductive-aged women in New York received prescriptions for opioid drugs when compared with corresponding proportions reported for the United States. The proportion of women who received opioid prescriptions was lowest during the prenatal period for women who had a live birth (9.5%), intermediate for women with no indication of contraceptive use or infertility (17%), and highest for women with an indication of contraceptive use or infertility (27%).

Opportunities exist for physicians and other health care providers treating women of reproductive age who are pregnant or might become pregnant to use other effective nonopioid pharmacologic or nonpharmacologic treatments to reduce the risk for adverse pregnancy outcomes. Fewer than 6,500 women per year in this study population received prescriptions for opioids during pregnancy. However, further study is required to determine the reason for prescribing opioids rather than other pain medication, and whether, for women with chronic pain, the prescribed dose and duration are consistent with CDC’s opioid prescribing guideline (8) or, for women with other pain presentations, whether other prescribing recommendations are being followed. Additional analyses of opioid prescriptions should also include comparisons of all Medicaid-eligible women with those with continuous enrollment.

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References

Food and Drug Administration Approval for Use of Hiberix as a 3-Dose Primary Haemophilus influenzae Type b (Hib) Vaccination Series

Elizabeth C. Briere, MD

On January 14, 2016, GlaxoSmithKline Biologicals (Research Triangle Park, North Carolina) received approval from the Food and Drug Administration (FDA) to expand use of Hiberix (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]) for a 3-dose infant primary vaccination series at ages 2, 4, and 6 months. Hiberix was first licensed in the United States in August 2009 for use as a booster dose in children aged 15 months through 4 years under the Accelerated Approval Regulations, in response to a Haemophilus influenzae type b (Hib) vaccine shortage that lasted from December 2007 to July 2009 (1). Expanding the age indication to include infants provides another vaccine option in addition to other currently licensed monovalent or combination Hib vaccines recommended for the primary vaccination series.* Hiberix contains 10µg purified capsular polyribosyl ribitolphosphate (PRP) conjugated to 25µg tetanus toxoid (PRP-T) and is supplied as a single-dose vial of lyophilized vaccine to be reconstituted with saline diluent. For the 3-dose primary series, a single (0.5 mL) dose should be given by intramuscular injection at ages 2, 4, and 6 months; the first dose may be given as early as age 6 weeks. The recommended catch-up schedule for PRP-T vaccines (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) should be followed. As previously recommended, a single booster dose should be administered to children aged 15 months through 18 months; to facilitate timely booster vaccination, Hiberix can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization (1–3).

Immunogenicity and Safety

Immunogenicity and safety data for the use of Hiberix as a primary vaccination series in infants are from a phase three, single-blind, randomized, multicenter study conducted among 4,003 healthy infants treated at 67 sites in the United States (4). Noninferiority of Hiberix to ActHIB (U.S.-licensed monovalent Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate], manufactured by Sanofi Pasteur, Swiftwater, PA) was assessed 1 month after completion of the primary series (after dose 3) using anti-PRP antibody concentrations ≥0.15µg/mL and ≥1.0µg/mL. Based on animal and human studies, anti-PRP levels of ≥0.15µg/mL and ≥1.0µg/mL provide protection from invasive Hib disease in the short- and long-term, respectively.

For each study group, Hiberix was coadministered with recommended routine childhood vaccines (Pediarix [diphtheria and tetanus toxoids and acellular pertussis (DTaP)/hepatitis B (HepB)/inactivated poliovirus (IPV)]; Prevnar13 [Pneumococcal 13-valent Conjugate Vaccine], and Rotarix [Rotavirus Vaccine, Live, Oral Suspension]), and noninferiority of immune responses to antigens contained in the coadministered vaccines, with the exception of Rotarix, was assessed. Adverse events with onset <31 days after each vaccination were recorded and physician-verified serious adverse events were reported from time of vaccination through 6 months after vaccination.

Immunogenicity. Approximately 2,000 infants were included in the immunogenicity assessment. One month after dose 3, anti-PRP concentrations ≥0.15µg/mL and ≥1.0µg/mL were achieved in 96.6% and 81.2% of infants who received Hiberix, respectively, and in 96.7% and 89.8% of infants who received ActHIB, respectively. Noninferiority criteria were met for anti-PRP response ≥0.15µg/mL, but were not met for anti-PRP response ≥1.0 g/mL. Noninferiority criteria were met for the following antigens contained in coadministered vaccines: 13 serotypes of Streptococcus pneumoniae; poliovirus types 1, 2, and 3; hepatitis B; pertussis toxin, filamentous hemagglutinin, and pertactin; diphtheria; and tetanus.

An open label study compared Pentacel (DTaP/IPV/Hib combination vaccine) and Hiberix at 1 month after dose 3; noninferiority was not assessed as a primary objective. The percentages of infants with titers ≥0.15µg/mL and ≥1.0µg/mL were higher after the 3rd dose of Hiberix (96.6% and 81.2%, respectively) than after the 3rd dose of Pentacel (92.5% and 78.3%, respectively).

*PedvaxHib (Haemophilus b Conjugate Vaccine [Meningococcal Protein Conjugate] manufactured by Merck & Co., Kenilworth, NJ) (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm253644.htm); ActHIB (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate], manufactured by Sanofi Pasteur, Swiftwater, PA) (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094028.htm); Pentacel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine, manufactured by Sanofi Pasteur) (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094030.htm); and MenHibrix (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine, manufactured by GlaxoSmithKline Biologicals, Research Triangle Park, NC) (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm308566.htm).
Safety. Approximately 3,500 vaccinated infants were included in the safety assessment. Injection site pain, irritability, and drowsiness were the most frequently reported adverse events; rates were similar for Hiberix, ActHIB, and Pentacel. Fever >103.1°F (39.5°C) occurred in <1% of infants in all study groups. No deaths occurred. Nonfatal serious adverse events were reported for 3.6%, 4.6%, and 4.0% of infants receiving Hiberix, ActHIB, and Pentacel, respectively; one serious adverse event in the Hiberix group was considered related to vaccine administration (afebrile seizure 14 days after dose 1; the patient had no apparent seizure disorder at 1 month after dose 3).

Further information is available in the package insert (http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf).

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1. CDC. Licensure of a Haemophilus influenzae type b (Hib) vaccine (Hiberix) and updated recommendations for use of Hib vaccine. MMWR Morb Mortal Wkly Rep 2009;58:1008–9.
Counterfeit Norco Poisoning Outbreak — San Francisco Bay Area, California, March 25–April 5, 2016

Kathy T. Vo, MD; Xander M.R. van Wijk, PhD; Kara L. Lynch, PhD; Alan H.B. Wu, PhD; Craig G. Smollin, MD

On April 26, 2016, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

On March 28, 2016, two patients were evaluated at the Contra Costa Regional Medical Center emergency department (ED) in Contra Costa County, California, for nausea, vomiting, central nervous system depression, and respiratory depression, 30 minutes after ingesting what appeared to be Norco, a prescription opioid pain medication that contains acetaminophen and hydrocodone. The patients purchased the drug from a friend a few days earlier. The two cases of drug intoxication were reported to a Contra Costa County Health Department public health official who subsequently notified the California State Health Department.

Three days earlier, the Sacramento County Division of Public Health had released a Drug Overdose Health Alert regarding multiple poisoning overdoses related to ingestion of fentanyl-contaminated counterfeit Norco in Sacramento County (1). All staff members at the California Poison Control System (CPCS) were alerted to increase vigilance for potential cases. In the subsequent 2 weeks, the CPCS San Francisco Division identified an additional five cases in three Bay Area counties (Alameda, San Francisco, and Santa Clara), including one case in a patient (patient 1) that was reported retrospectively (Table). All patients reported to the CPCS San Francisco Division had various signs and symptoms of opioid intoxication after ingestion of the illicit product, and all recovered without clinical sequelae within 24 hours.

Although analyses of product and patient specimens from Sacramento County were reported to have contained fentanyl, all cases in the Bay Area also contained promethazine, which had not been reported as an additive in previous counterfeit or adulterated fentanyl-containing products. Fentanyl is a synthetic opioid analgesic that is a full \( \mu \)-opioid receptor agonist (one of the three opioid receptors through which opioids exert their pharmacologic actions) and has 100 times the potency of morphine (2). Fentanyl is available in many formulations, and its unique physicochemical properties, particularly its high lipophilicity, allow it to quickly enter the central nervous system and are responsible for its high potency (2) and high potential for abuse. Fentanyl is not currently formulated for oral administration in pill or tablet form, however, and its presence in pill form is a marker for an illicitly produced product. Promethazine, a phenothiazine derivative, is routinely prescribed for the treatment of nausea, vomiting, and motion sickness. Promethazine use has recently been reported to be common among chronic opioid users and is thought to potentiate the “high” from opioids (3).

Initial Case Reports

Patient 2 was a man aged 36 years who went to the ED with his girlfriend (patient 3), concerned that he was experiencing an adverse reaction to an illicitly purchased drug. He bought what he believed to be Norco tablets from a friend a few days earlier and described the tablets as having the inscription “M367,” and looking exactly like Norco tablets that had been previously prescribed to him after a shoulder cartilage repair. He had ingested half of one street-purchased tablet approximately 12 hours earlier, and two additional tablets 30 minutes before arriving in the ED. In the ED, he was afebrile with stable vital signs and blood oxygen saturation 99% on room air. Electrolytes and blood chemistries were within normal ranges. Physical examination was notable for lethargy. He was administered a 0.4-mg dose of intramuscular naloxone with transient improvement in his mental status; however, 1.5 hours later, he experienced respiratory depression with a decline in his oxygen saturation to 90%, which improved with administration of supplemental oxygen. Acetaminophen level was <10 \( \mu \)g/mL. Urine drug screen was positive for opiates. He was observed for 6 hours and discharged home.

Patient 3, a woman aged 30 years, came to the ED with her boyfriend (patient 2), also having ingested two of the street-purchased “Norco” tablets 30 minutes before arrival. After ingestion, she complained of dizziness and became unresponsive, and her boyfriend initiated cardiopulmonary resuscitation and contacted emergency responders, who noted that her blood oxygen saturation was 93% on room air. A 0.4-mg dose of IV naloxone was administered, and on arrival at the ED, her physical exam was notable for lethargy and bradypnea (8 breaths/minute), and blood oxygen saturation of 98% on 2 L of oxygen via nasal cannula. She received a second 0.4-mg dose of IV naloxone 6 hours after arrival. Laboratory results were normal except for a slightly elevated white blood cell count (13,400/\( \mu \)L [normal = 4,000–10,000]). Acetaminophen level was <10 \( \mu \)g/mL and urine drug screen was positive for opiates. She had persistent nausea and vomiting, and was admitted to the hospital for...
overnight observation. Her symptoms improved, and she was discharged home 32 hours after her arrival.

**Laboratory Analyses**

Tablets purchased by another patient (patient 6) were provided to the hospital staff. The tablets and serum specimens from all seven patients were analyzed using liquid chromatography high-resolution mass spectrometry (4). Levels of fentanyl, acetaminophen, and hydrocodone were quantified. Additional drugs were also detected in the serum (Table).

Analysis of a tablet obtained from patient 6 indicated that it contained 3.5 mg of fentanyl, 2.3 mg of promethazine, 39.2 mg of acetaminophen, and trace amounts of cocaine. All patients had serum fentanyl levels of 1.6–10.1 ng/mL (therapeutic range

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Date</th>
<th>Age (yrs)</th>
<th>Sex</th>
<th>Serum fentanyl (ng/mL)</th>
<th>Serum hydrocodone (ng/mL)</th>
<th>Serum acetaminophen (μg/mL)</th>
<th>Additional drugs identified in serum</th>
<th>Drugs identified in urine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March 25</td>
<td>34</td>
<td>Male</td>
<td>8.4</td>
<td>&lt;1.0 (LLOQ)</td>
<td>0.04</td>
<td>Alprazolam, Chlorpheniramine, Diazepam, Nordiazepam, Norfentanyl, Promethazine</td>
<td>Specimen not available</td>
</tr>
<tr>
<td>2</td>
<td>March 28</td>
<td>36</td>
<td>Male</td>
<td>9.8</td>
<td>3.4</td>
<td>0.24</td>
<td>Benzoylecgonine, Diazepam, Dihydrocodeine, Diphenhydramine, Levamisole, Nordiazepam, Norfentanyl, Oxycodone</td>
<td>Specimen not available</td>
</tr>
<tr>
<td>3</td>
<td>March 28</td>
<td>30</td>
<td>Female</td>
<td>3.8</td>
<td>3.1</td>
<td>1.19</td>
<td>Dihydrocodeine, Lamotrigine*, Lorazepam, Norfentanyl, Promethazine, Topiramate*, Trazodone*</td>
<td>Specimen not available</td>
</tr>
<tr>
<td>4</td>
<td>April 2</td>
<td>18</td>
<td>Female</td>
<td>1.6</td>
<td>Not detected</td>
<td>0.20</td>
<td>Naloxone*, Norfentanyl, Promethazine, Theophylline</td>
<td>Specimen not available</td>
</tr>
<tr>
<td>5</td>
<td>April 2</td>
<td>17</td>
<td>Male</td>
<td>10.1</td>
<td>&lt;1.0 (LLOQ)</td>
<td>0.34</td>
<td>11-nor-9-carboxy-THC, Alprazolam, Naloxone*, Norfentanyl, Promethazine</td>
<td>Acetaminophen, Alprazolam, Fentanyl, Hydrocodone, Methamphetamine, Naloxone*, Norfentanyl, Promethazine</td>
</tr>
<tr>
<td>6</td>
<td>April 5</td>
<td>54</td>
<td>Male</td>
<td>3.7</td>
<td>6.4</td>
<td>0.42</td>
<td>Benzoylecgonine, Gabapentin*, Levamisole, Naproxen*, Norfentanyl, Promethazine</td>
<td>Benzoylecgonine, Cocaethylene, Cocaine, Codeine, Fentanyl, Gabapentin*, Hydromorphone, Hydrocodone, Hydromorphone, Naproxen*, Norfentanyl</td>
</tr>
<tr>
<td>7</td>
<td>April 5</td>
<td>19</td>
<td>Female</td>
<td>4.9</td>
<td>Not detected</td>
<td>0.39</td>
<td>11-nor-9-carboxy-THC, Lidocaine, Naloxone*, Norfentanyl, Promethazine</td>
<td>Specimen not available</td>
</tr>
</tbody>
</table>

*Confirmed as patient’s prescribed medication or received before specimen collection.

**Abbreviations:** LLOQ = lower limit of quantification; THC = tetrahydrocannabinol.
for analgesia = 0.6–3.0 ng/mL), with all except one (patient 4) in excess of the therapeutic range (5). All patients had detectable acetaminophen and hydrocodone, these counterfeit tablets predominantly contained fentanyl and promethazine. Prior to this outbreak in the Bay Area, counterfeit or adulterated fentanyl-containing products had not previously been reported to include promethazine as an additive. Promethazine likely potentiates the opioid effect.

What are the implications for public health practice?

The distribution of counterfeit tablets represents a major public health threat given the potentially lethal nature of the tablets. Health care providers should be aware of this and other concurrent outbreaks and notify local poison centers and health departments of suspected cases. Collaborative efforts among public health, medical, and law enforcement officials are essential for a rapid and effective response.

Discussion

Response to this outbreak has included notification of the California Department of Public Health, local media outlets, and law enforcement officials. On April 4, 2016, the Drug Enforcement Administration (DEA) launched an anonymous tip line in San Francisco. No information has been released regarding the source of the counterfeit tablets, and an investigation is ongoing.

The distribution of counterfeit medications, especially those containing fentanyl, is an emerging and serious public health threat. Opioid abuse is the fastest-growing drug problem in the United States; despite prevention strategies at federal, state, and local levels, deaths caused by ingestion of opioid analgesics continue (6). In addition to prescription drug abuse, nonpharmaceutical illicitly produced opioid-containing products have received much attention in recent years. Fentanyl, in particular, was responsible for more than 1,000 deaths during 2005–2007 (7). In March 2015, DEA issued a nationwide alert about the dangers of illicitly produced fentanyl and fentanyl compounds, describing these products as a threat to health and public safety (8). In California, during October–December 2015, seven persons, including two who died, were found to have been exposed to fentanyl-adulterated counterfeit Xanax (9).

Efforts to identify the source of the current counterfeiting are ongoing. Patients with signs and symptoms of acute opioid overdose including central nervous system and respiratory depression, and in whom larger doses of naloxone are required to reverse symptoms, should raise suspicion for intoxication with a counterfeit product containing fentanyl. Physicians should inquire about the illegal purchase of prescription medications in these cases and notify their local poison control centers and health departments. Efforts should also be made to communicate to the general public the significant risks to life and health when purchasing what appears to be prescription medications from any source other than a reputable pharmacy or health care provider, because it might be difficult to distinguish a counterfeit pill from the legitimate pharmaceutical product (Figure).

FIGURE. Photo of four counterfeit Norco “M367” tablets obtained from patient 6 during the investigation of a counterfeit Norco poisoning outbreak — San Francisco Bay Area, California, 2016

Photo/California Poison Control System, San Francisco Division

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References


Notes from the Field

Primary Amebic Meningoencephalitis Associated with Exposure to Swimming Pool Water Supplied by an Overland Pipe — Inyo County, California, 2015

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On June 17, 2015, a previously healthy woman aged 21 years went to an emergency department after onset of headache, nausea, and vomiting during the preceding 24 hours. Upon evaluation, she was vomiting profusely and had photophobia and nuchal rigidity. Analysis of cerebrospinal fluid was consistent with meningitis.* She was empirically treated for bacterial and viral meningoencephalitis. Her condition continued to decline, and she was transferred to a higher level of care in another facility on June 19, but died shortly thereafter. Cultures of cerebrospinal fluid and multiple blood specimens were negative, and tests for West Nile, herpes simplex, and influenza viruses were negative. No organisms were seen in the cerebrospinal fluid; however, real-time polymerase chain reaction testing by CDC was positive for *Naegleria fowleri*, a free-living thermophilic ameba found in warm freshwater that causes primary amebic meningoencephalitis, an almost universally fatal infection.

Inyo County Health and Human Services staff members initiated an epidemiologic investigation to determine the probable source of infection. Interviews revealed that the decedent’s only fresh water contact in the 2 weeks preceding illness onset was in a privately owned swimming pool in a desert environment on June 11 and 12. The pool had not been chemically treated until moments before swimming began, when an unknown amount of commercial liquid chlorine was added to the water as “shock” treatment.

An environmental investigation of the swimming pool site on July 29 found that the source water for the pool was piped overland 1.5 miles from a mountain spring. The water temperature at the point where the spring water entered the pipe was 50°F (10°C) on the day of the site survey, with an ambient temperature of >100°F (>38°C) at 11 a.m. The overland transmission pipe had been installed in the 1960s. First, water cascaded down a canyon in a surface stream. For the last 1.5 miles before it entered the pool, the water was captured in a pipe. The top of the pipe was rusted out, having been compromised by root systems in many places, so that it essentially became a trough. Water temperature at the swimming pool entrance on the day of the site survey was 98°F (37°C), with an ambient temperature of 106°F (41°C) at 12 noon. No drinking water systems were connected to this overland transmission pipe. *N. fowleri* was not detected in water samples collected from either the mountain spring source or the swimming pool over a period of 1 month after the patient’s exposure.

The epidemiologic investigation and the finding of extremely warm water in the swimming pool suggests that the pool supplied by spring water via an overland pipe was the exposure that resulted in infection with *N. fowleri*. This represents the first time this type of exposure to *N. fowleri* has been reported in the United States and continues to highlight the changing epidemiology and expanding geography of this pathogen (1,2). In Australia, several cases in the 1960s and 1970s related to nasal exposure with untreated drinking water piped for hundreds of miles overland were reported (3). This case highlights the importance of operating and maintaining properly treated swimming pools (http://www.cdc.gov/healthywater/swimming/protection/pool-user-tips-factsheet.html) and the role of water distribution systems as potential environments for the proliferation of *N. fowleri*.

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Ibne Ali, PhD, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC.

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Reference


* The cerebrospinal fluid white blood cell count was 94 cells/mm³ with 84% mononuclear cells and 16% neutrophils (normal = 0–5 cells); red blood cell count was 679 cells/mm³ (normal = 0 cells); protein was 205 mg/dL (normal = 15–45 mg/dL); and glucose was 48 mg/dL (normal = 40–70 mg/dL). Serum glucose was 128 mg/dL.
Health Care–Associated Hepatitis A Outbreak — Texas, 2015

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On August 27–28, 2015, the Texas Department of State Health Services received calls from Fort Bend County and Harris County health departments requesting postexposure prophylaxis (PEP) recommendations for contacts of two nurses (patients A and B) with confirmed hepatitis A virus (HAV) infection. Both nurses had symptom onset during August 15–19 and worked for the same pediatric home health care agency in another jurisdiction. Because of the proximity of the onset dates, a common source exposure was suspected. The state and local health departments began an investigation to identify potentially exposed patients, their families, and other agency personnel; offer PEP; and identify the source of exposure.

Interviews were conducted with the agency and patients A and B to identify their patients, the dates they visited each patient household, the services provided in the homes, and any other shared exposures. During their incubation and infectious periods (August 1–28), patients A and B cared for a total of 12 children but had only one patient in common (a hepatitis A–vaccinated pediatric transplant recipient), and no other common exposures. Because the two nurses worked shifts of 10–12 hours in patients’ homes using standard precautions, and B to identify their patients, the dates they visited each patient household, the services provided in the homes, and other agency personnel; offer PEP; and identify the source of exposure.

CDC recommends PEP, consisting of a single dose of monoclonal hepatitis A (hepA) vaccine or immunoglobulin (IG, 0.02 mL/kg), within 2 weeks of exposure to HAV for previously unvaccinated persons (1). HepA vaccine is preferred for healthy persons aged 12 months–40 years. (2) Vaccination with a 2-dose series of hepA vaccine is recommended for children aged 12–23 months. In the United States, coverage with 2 doses of hepA vaccine is the lowest (58%) of all recommended childhood vaccines among children aged 19–35 months (58%) (4). Vaccination for adults aged ≥19 years is recommended only for persons at high risk (2); coverage among adults aged ≥19 years in 2013 was only 9% (3,5). Health care personnel are not considered at high risk for HAV infection because nosocomial hepatitis A infrequently occurs. Transmission to health care personnel usually occurs when the source patient has unrecognized hepatitis and is fecally incontinent or has diarrhea (6,7). Underdiagnosis might be especially prevalent in pediatric patients aged ≤5 years, who typically are asymptomatic (1), or in immunocompromised patients of any age. Although standard precautions are recommended for health care personnel working with diapered or incontinent patients without an infectious etiology for their symptoms, contact precautions are recommended when HAV or another infectious etiology is suspected or confirmed (8).

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References

Announcement

Amyotrophic Lateral Sclerosis (ALS) Awareness Month — May 2016

May is Amyotrophic Lateral Sclerosis (ALS) Awareness Month. ALS, also known as Lou Gehrig’s disease, is a progressive, fatal, neurodegenerative disorder of upper and lower motor neurons. The cause of ALS is not known, and no cure exists. Persons with ALS usually die within 2–5 years of diagnosis.

In October 2010, the Agency for Toxic Substances and Disease Registry (ATSDR) launched the congressionally mandated National ALS Registry (https://wwwn.cdc.gov/als/Default.aspx) to collect and analyze data regarding persons with ALS in the United States. The goals are to determine the incidence and prevalence of ALS, characterize the demographics of those living with ALS, and examine potential risk factors for the disease. ATSDR released the first National ALS Registry report in July 2014 for persons living with ALS in the United States during October 19, 2010–December 31, 2011 (1) and expects to release the second report this summer that covers 2012–2013. During the period covered by the first report, approximately 12,000 persons were identified with ALS, or approximately four in every 100,000 persons. ALS is more common in whites, males, non-Hispanics, and persons aged 60–69 years. These findings are consistent with well-established European ALS registries and small epidemiologic studies that have been conducted in the United States.

ALS, like most noninfectious diseases, is not a notifiable disease in the United States. To collect data on cases, the Registry uses data from existing national databases, including the Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs, as well as information provided by persons with ALS through the Registry’s secure online system. Online registrants also can take brief surveys regarding potential risk factors for the disease (e.g., occupational, military, smoking, alcohol, and residential histories).

In the fall of 2016, the Registry will launch the National ALS Biorepository. The Biorepository is a tool for all qualified researchers to request a wide variety of high-quality biologic samples, collected from a national sample of enrollees in the National ALS Registry, to help study ALS. For example, researchers might be able to analyze genetic variations as well as possible biomarkers in patients with ALS. Both in-home (e.g., blood, urine, and hair) and postmortem specimens (e.g., brain, spinal cord, and cerebral spinal fluid) will be collected from interested patients enrolled in the Registry. Furthermore, epidemiologic data from completed patient surveys will be matched with patient specimens, making the Biorepository a rich data source for researchers to better understand ALS.

ATSDR is collaborating with the ALS Association (http://www.alsa.org), Muscular Dystrophy Association (http://www.mda.org), Les Turner ALS Foundation (http://lestonturnerals.org), and other organizations to make all persons with ALS and their families aware of the opportunity to enroll in the National ALS Registry. Additional features have been added to enhance the Registry for patients and researchers, including state and metropolitan area–based ALS surveillance to assist in evaluating the completeness of the Registry and to provide local incidence and prevalence data; a research notification system to link persons with ALS to researchers who are conducting epidemiologic studies and clinical trials; Registry-funded external research to better understand the etiology of ALS and to prioritize topics for future risk factor surveys that persons with ALS will be able to participate in through the National ALS Registry web portal; and mobile “apps” to help find the nearest ALS clinics and support groups.

Reference

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Distribution of Long-Term Care Staffing* Hours,† by Staff Member Type and Sector — United States, 2014

In 2014, aides provided more hours of care in the major sectors of long-term care than the other staffing types shown. Aides accounted for 60% of all staffing hours in nursing homes, compared with licensed practical or vocational nurses (21%), registered nurses (13%), activities staff members (5%), and social workers (2%). Aides accounted for 75% of all staffing hours in residential care communities, in contrast to activities staff members (11%), registered nurses (7%), licensed practical or vocational nurses (6%), and social workers (1%). In adult day services centers, aides provided 41% of all staffing hours, followed by activities staff members (32%), registered nurses (12%), licensed practical or vocational nurses (9%), and social workers (6%).


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