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# Obesity Prevalence Among Low-Income, Preschool-Aged Children — New York City and Los Angeles County, 2003–2011

Recent studies have reported evidence of a leveling (1) and decline in childhood obesity prevalence in New York (2,3) and California (4). However, some areas of the United States continue to experience increases in the prevalence of childhood obesity (5). To assess differences and changes over time in early childhood obesity in the two most populous cities in the United States, obesity prevalence among low-income, preschool-aged children enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in New York City (NYC) was compared with obesity prevalence among WIC-enrolled children in Los Angeles County (LAC) during 2003-2011. In NYC, from 2003 to 2011, obesity prevalence decreased among blacks, whites, and Hispanics, but increased among Asians. In LAC, obesity prevalence decreased among Asians and increased and then decreased among blacks and Hispanics from 2003 to 2011. Hispanic WIC-enrolled children had the greatest prevalence of obesity for all years in both areas. In 2011, the obesity prevalence among Hispanics in NYC was 19.1%, compared with 21.7% in LAC. Comparisons of obesity prevalence data among cities and states might suggest interventions and policies to help reverse childhood obesity increases in some populations.

NYC and LAC were chosen for study because they have the two largest populations of WIC participants and have different climates, unique built and policy environments, and readily available anthropometric data for children aged 3 or 4 years. In addition to pregnant or postpartum, breastfeeding women, WIC serves infants and children aged <5 years.\* In both New York and California, height and weight measures of WIC participants are taken every 6 months by WIC staff members trained according to standard protocols, or measures are taken at physicians' offices within 60 days of the WIC certification visit. A recent study of

height and weight measures taken in WIC clinics demonstrated that they are both valid and reliable estimates of true height and weight (6). Height is recorded to the nearest one-quarter inch (6.35 mm) and weight to the nearest one-quarter pound (113 g). Date of birth and race/ethnicity for each child are reported to WIC staff members by the parent or caregiver. All of these data are entered into statewide information systems in New York or California; thus, identical measures are available in the two states. All data for this study were extracted from New York and California WIC administrative data systems for the period 2003–2011. For each calendar year, the most recent height and weight measures were obtained among children aged 3 or 4 years who were active WIC participants during the month of March; children could be measured at both age 3 and age 4 years, with their measurements included in the respective calculations by age level. For consistency, NYC WIC data followed the same inclusion criteria as LAC WIC.

Recorded measures of height and weight were converted to metric equivalents, and body mass index (BMI) was computed as weight in kilograms divided by height in meters squared. Obesity was defined as an age- and sex-specific BMI at or above the 95th reference percentile of the 2000 CDC growth charts for the United States.† Biologically implausible measurements

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<sup>\*</sup>Eligibility criteria for WIC include a family income ≤185% of the poverty income threshold, based on U.S. Poverty Income Guidelines, available at http://aspe.hhs.gov/poverty/12poverty.shtml. A person who participates or has family members who participate in certain other benefit programs, such as Medicaid or Aid to Families with Dependent Children/Temporary Assistance to Needy Families, automatically meets the income eligibility requirement.

<sup>†</sup>Available at http://www.cdc.gov/growthcharts.

were excluded from analysis. The prevalence of obesity by age, race/ethnicity, and geographic area was calculated for each year from 2003 to 2011. Race/ethnicity was categorized as follows: Hispanic, black, white, Asian and "other." In this report, persons identified as Hispanic might be of any race. Persons identified as black, white, Asian, or other race are non-Hispanic. The five racial/ethnic categories are mutually exclusive.

The number of children aged 3 or 4 years participating in WIC in NYC each year ranged from 53,247 in 2003 to 67,428 in 2011. In LAC, the number of participating children ranged from 149,503 in 2003 to 147,292 in 2011. Among children enrolled in the NYC WIC, the Hispanic population increased from 44.0% of the total in 2003 to 46.4% in 2011, the white population increased from 12.5% to 13.9%, and the Asian population increased from 5.8% to 12.9%; the black population decreased from 28.2% of the total in 2003 to 23.9% in 2011, and the "other" group decreased from 9.5% to 2.9%. Among children enrolled in the LAC WIC, the Hispanic population increased from 82.6% of the total in 2003 to 85.5% in 2011, and the "other" group" increased from 0.4% to 2.1%. The black population decreased from 7.9% of the total in 2003 to 6.3% in 2011, the white population decreased from 4.9% to 2.8%, and the Asian population decreased from 4.1% to 3.3% (Table).

In 2003, obesity prevalence among WIC children aged 3 or 4 years was lower in LAC (16.3% and 17.2%, respectively) than in NYC (18.9% and 19.9%, respectively). However, by 2005, obesity prevalence in LAC had exceeded NYC for both age groups and continued to do so throughout the study period. From 2005 to 2009, obesity prevalences in NYC continued to decrease, whereas in LAC prevalences among children aged 3 years increased until 2008 and then decreased from 2009 to 2011, and prevalences among children aged 4 years increased until 2009 and then decreased (Figure 1).

With the exception of 2011 in LAC, the prevalence of obesity was higher among children aged 4 years than among children aged 3 years in both areas each year throughout the study period (Figure 1). From 2003 to 2009, the prevalence of obesity decreased among NYC WIC-enrolled children aged 3 or 4 years from 18.9% to 15.1% and from 19.9% to 17.2%, respectively. In contrast, from 2003 to 2009, the prevalence of obesity increased among LAC WIC-enrolled children aged 3 or 4 years from 16.3% to 21.0% and from 17.2% to 22.4%, respectively. From 2009 to 2011, obesity prevalence decreased from 21.0% to 20.5% among LAC WIC-enrolled children aged 3 years and from 22.4% to 20.3% among those aged 4 years and stayed relatively flat among NYC WIC-enrolled children (Figure 1).

Hispanics not only accounted for the largest proportion of WIC children in both cities, but also had the highest prevalence of obesity every year (Figure 2). In NYC, obesity prevalence among

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<sup>§</sup> For all years of NYC data and 2003–2005 LAC data, "other" included the subcategories multirace, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and "refused." For 2006–2011 LAC data, "other" included American Indian or Alaska Native and "refused."

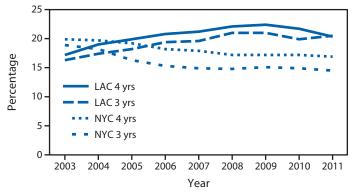
TABLE. Percentage of children aged 3–4 years enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children, by age and race/ethnicity — New York City and Los Angeles County, 2003–2011

Characteristic	2003	2004	2005	2006	2007	2008	2009	2010	2011
Characteristic	%	%	%	%	%	%	%	%	%
New York City									
Total no.	53,247	55,808	59,385	58,993	57,353	57,970	63,539	65,088	67,428
Age (yrs)	%	%	%	%	%	%	%	%	%
3	56.3	56.6	55.5	55.4	55.4	55.3	55.3	55.7	55.1
4	43.7	43.4	44.5	44.6	44.6	44.7	44.7	44.3	44.9
Race/Ethnicity*									
Asian	5.8	6.1	6.8	8.1	9.0	9.8	10.9	11.7	12.9
Black	28.2	28.0	28.3	28.0	26.8	25.8	25.0	24.3	23.9
Hispanic	44.0	44.6	45.7	47.2	47.5	47.9	47.8	47.8	46.4
White	12.5	12.1	12.2	12.6	12.7	12.8	12.8	12.8	13.9
Other <sup>†</sup>	9.5	9.2	6.9	4.1	4.0	3.8	3.5	3.2	2.9
Los Angeles County									
Total no.	149,503	148,377	144,171	139,863	133,646	137,148	137,714	142,878	147,292
Age (yrs)	%	%	%	%	%	%	%	%	%
3	51.6	51.4	51.0	51.3	51.8	51.8	51.8	52.6	51.9
4	48.4	48.6	49.0	48.7	48.2	48.2	48.2	47.4	48.1
Race/Ethnicity*									
Asian	4.1	4.2	4.1	3.8	3.8	3.7	3.6	3.4	3.3
Black	7.9	7.6	7.3	6.7	6.6	6.6	6.7	6.4	6.3
Hispanic	82.6	83.0	83.6	85.6	85.6	85.5	85.5	85.7	85.5
White	4.9	4.9	4.7	3.1	3.1	3.0	3.0	2.9	2.8
Other	0.4 <sup>§</sup>	0.4 <sup>§</sup>	0.3 <sup>§</sup>	0.9 <sup>†</sup>	0.9†	1.2 <sup>†</sup>	1.3 <sup>†</sup>	1.7 <sup>†</sup>	2.1†

<sup>\*</sup> Persons identified as Hispanic might be of any race. Persons identified as white, black, Asian, or other race are non-Hispanic. The five racial/ethnic categories are mutually exclusive.

Hispanic children decreased from 24.0% in 2003 to 19.7% in 2009 and was 19.1% in 2011. Obesity prevalence among Hispanic children in LAC increased from 17.8% in 2003 to 23.0% in 2009 and then decreased to 21.7% in 2011. Among black WIC-enrolled children in NYC, obesity prevalence decreased from 17.7% in 2003 to 15.0% in 2006, then leveled off, whereas among white children, a gradual decline in obesity prevalence was observed,

FIGURE 1. Prevalence of obesity\* among children aged 3–4 years enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children, by age — New York City and Los Angeles County, 2003–2011



**Abbreviations:** NYC = New York City; LAC = Los Angeles County.

from 10.6% in 2003 to 8.9% in 2011. Among Asian children in NYC, a slight increase in obesity prevalence was observed, from 11.5% in 2003 to 11.9% in 2011 (Figure 2).

In LAC, among all racial/ethnic populations of WIC-enrolled children except Asians, an increase in obesity prevalence was observed from 2003 to 2008, with the increase continuing to 2009 among Hispanics, followed by a decrease to 2011 among Hispanics and blacks. Obesity prevalence decreased among Asians in LAC from 13.9% in 2004 to 11.3% in 2011.

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#### **Editorial Note**

Changes in obesity prevalence from 2003 to 2011 among low-income, preschool-aged children enrolled in WIC in NYC and LAC differed overall and by age and racial/ethnic population. In NYC, obesity prevalence decreased among all populations except Asians and blacks over the study period; among blacks, the prevalence decreased from 2003 to 2007 and then increased. In LAC, obesity prevalence decreased among Asians and increased

<sup>†</sup> Includes multirace, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and "refused."

<sup>§</sup> Includes American Indian or Alaska Native and "refused."

<sup>\*</sup> Obesity was defined as an age- and sex-specific body mass index at or above the 95th reference percentile of the 2000 CDC growth charts for the United States.

New York City, New York Los Angeles County, California 25 25 20 20 Percentage Percentage 15 15 10 10 Asian Black Black Hispanic White White 2004 2006 2007 2008 2009 2010 2004 2008 2009 2010 2011 2003 2005 2003 2005 2006 2007

FIGURE 2. Prevalence of obesity\* among children aged 3–4 years enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children, by race/ethnicity† — New York City and Los Angeles County, 2003–2011

and then decreased among blacks and Hispanics from 2003 to 2011. These patterns are consistent with national data indicating that increases in obesity prevalence among preschool-aged and school-aged children have leveled off (1) and with reports of declines in childhood obesity in New York (3) and California (4). The LAC patterns also are similar to those for fifth, seventh, and ninth graders who underwent California physical fitness testing in their schools. Data for that age group show an increase in obesity prevalence from 18.9% in 1999 to 23.3% in 2005, before decreasing to 22.4% in 2010 (Los Angeles County Department of Public Health, unpublished data, 2012).

Year

The divergent changes and relatively higher prevalence observed among children enrolled in WIC in LAC are consistent with the epidemiology of childhood obesity in the United States described in the mid-2000s (5). Potential explanations for the differences observed between NYC and LAC might include sociodemographic differences in the populations enrolled in WIC, differential changes in the built environment, and differences in the timeframe and details of populationwide obesity prevention policies. Higher proportions of Hispanic children, among whom obesity is more prevalent (1), were enrolled in WIC in LAC than in NYC each year; differences in the racial/ethnic composition of children enrolled in WIC partially explain the relatively higher prevalence estimates in LAC than in NYC during the study period.

In addition, the makeup of the Hispanic populations in NYC and LAC differ considerably, with large numbers of persons from the Caribbean in NYC and from Mexico and Central American in LAC (7). More research is needed to examine the reasons behind increased obesity risk among Hispanic children. The observed upward and downward shifts in obesity prevalence among Asian children in NYC and LAC, respectively, further suggest that the divergent changes observed in the two areas might be explained, in part, by changing demographics of their respective Asian subpopulations. According to the 2010 Census population estimates, the predominant Asian subpopulations in LAC are Chinese and Filipino, whereas the two largest Asian subpopulations in NYC are Chinese and Asian Indian (8).

Year

With regard to the potential role of differences and changes in the built environment in the two areas, a greater probability of obesity has been found among children in neighborhoods with the most unfavorable social conditions, such as unsafe surroundings (e.g., poor housing and lack of access to sidewalks, parks, and recreation centers), than among children not facing such conditions (9). Recent analyses linking WIC early childhood obesity data with neighborhood environment data in LAC suggest that neighborhood food environments (e.g., fast food restaurants and convenience stores) might increase obesity risk, particularly among children in Spanish-speaking households (10). Thus,

<sup>\*</sup> Obesity was defined as an age- and sex-specific body mass index at or above the 95th reference percentile of the 2000 CDC growth charts for the United States.

† Persons identified as Hispanic might be of any race. Persons identified as Asian, black, or white are non-Hispanic. The four racial/ethnic categories are mutually exclusive.

#### What is already known on this topic?

After several decades of increasing prevalence of obesity among children, recent reports indicate that in some areas of the United States, including New York and California, the prevalence might be stabilizing or even decreasing.

#### What is added by this report?

This report compares obesity prevalence among children in New York City and Los Angeles County who were enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children. In New York City, the prevalence of obesity among children aged 3 or 4 years in this group decreased from 18.9% and 19.9%, respectively, in 2003 to 14.5% and 16.9%, respectively, in 2011. In Los Angeles County, obesity prevalence among children aged 3 or 4 years in this group increased from 16.3% and 17.2% in 2003 to 21.0% and 22.1%, respectively, in 2008, before decreasing from 21.0% and 22.4% in 2009 to 20.5% and 20.3%, respectively, in 2011. Obesity prevalence also differed by racial/ethnic population.

#### What are the implications for public health practice?

Obesity prevalence remains high among certain populations of children in both New York and Los Angeles. Interventions targeted to those populations with higher prevalence might be considered to help reduce the prevalence of obesity.

explorations of differences in the built environment might shed light on the divergent data in NYC and LAC.

During the past decade, NYC implemented multiple interventions to address childhood obesity (2), and these efforts took place earlier in NYC than they did in LAC. Thus, it is possible that interventions and policies aimed at prevention of childhood obesity might have taken effect earlier in NYC than in LAC. As part of its Eat Well, Play Hard initiative for comprehensive childhood obesity prevention, since 2001 the New York state WIC program has been promoting consistent, positive messages related to age-appropriate physical activity, fruit and vegetable consumption, low-fat/nonfat milk consumption, breastfeeding, and TV viewing/screen time. California was involved in the Fit WIC initiative in a few regions around the state and began regional efforts to enhance WIC staff health and wellness in 2004, but did not begin a statewide nutrition education campaign that involved all of LAC until early 2009. This campaign focused on the upcoming changes to WIC food packages, and provided an enhanced wellness module for WIC staff members as well as focused training and education for staff members and participants on avoiding overfeeding and increasing consumption of whole grain, fruits and vegetables, and lower fat milk. The timing of these intervention efforts in each area appear to align well with decreases in the prevalence of childhood obesity observed in NYC in 2004 and LAC in 2010. However, more research is needed to assess the success of state and regional efforts focused on reducing childhood obesity in the past decade.

The findings in this report are subject to at least three limitations. First, the data represent only those participants in WIC and from whom height and weight measures were obtained during each year of the study. Second, information on the national origin of WIC participants was not available; therefore, it was not possible to assess whether changes in the proportions of racial/ethnic subpopulations might have contributed to changes in obesity prevalence in the two areas. Finally, this comparative analysis of childhood obesity prevalence in LAC and NYC constitutes an exploratory ecologic study because no simultaneous comparison of prevalence was made for a specific exposure during the study period.

Evidence of recent improvement in obesity prevalence among preschool-aged children enrolled in LAC WIC, which serves nearly three times as many children aged 3 and 4 years as NYC WIC, suggests that some areas with large numbers of WIC-enrolled children might need more time than others to complete the full adoption and implementation of policies and environmental strategies for obesity prevention. In addition, the difference in childhood obesity prevalence among WIC-enrolled preschool-aged children in NYC and LAC corroborates recent evidence of geographic variation in childhood obesity prevalence in the United States and lends support to the need for further investigations of the potential role of changes in demographics and environments, and the effects of populationwide obesity prevention policies.

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# Interruptions in Supplies of Second-Line Antituberculosis Drugs — United States, 2005–2012

Second-line drugs (SLDs) are essential for treating multidrug-resistant and extensively drug-resistant tuberculosis (MDR TB\* and XDR TB<sup>†</sup>). Drug shortages, in which supplies of all clinically interchangeable versions of a given Food and Drug Administration (FDA)-regulated drug become inadequate to meet actual or projected user demand, have been well-documented in many areas of medicine; for several years, drug shortages in the United States have affected the availability of SLDs for treatment of TB. In November 2010, a nationwide survey of TB control programs conducted by the National Tuberculosis Controllers Association (NTCA) indicated that shortages and other problems that hinder access to SLDs interfere with patient care and could promote the development of drug resistance as well as the transmission of drug-resistant Mycobacterium tuberculosis. This report focuses on the growing issue of TB drug shortages and summarizes the findings of that survey, which indicated that 26 (79%) of the 33 responding health departments, representing approximately 75% of the U.S. TB burden, reported MDR TB during 2005-2010. Of these 26, 21 (81%) faced difficulties with SLD procurement, citing nationwide shortages (100%), shipping delays (71%), lack of resources (62%), and a complicated procurement process related to investigational new drug (IND) protocols (48%) as the main reasons. Adverse outcomes or other problems related to difficulties with SLD procurement were reported by 19 (90%) of 21 jurisdictions, with treatment delay (58%), a treatment lapse or interruption (32%), or the use of an inadequate regimen (32%) most commonly reported. Potential solutions for alleviating SLD shortages include stockpiling drugs centrally, sharing SLDs among jurisdictions, obtaining drugs from foreign manufacturers, and taking advantage of new legal requirements for drug suppliers to report shortages and impending shortages to FDA within a specified timeframe. Reliable, consistent access to SLDs will require the collaboration of CDC, FDA, state and local health departments, national health professional societies, and the pharmaceutical industry.

TB is caused by the bacterium *M. tuberculosis*, which is most typically transmitted through the air from one person to another. For most TB cases, cure is achieved with a standard combination of drugs. For the treatment of confirmed or

suspected TB disease, isoniazid, rifampin, pyrazinamide, and ethambutol are the four first-line drugs used worldwide as a 6-month standard regimen. In contrast, MDR TB generally requires 18–24 months of treatment with five or six drugs that are less effective, more toxic, and more costly than first-line drugs. As a result, MDR TB causes greater morbidity, and, overall, patient outcomes are worse.

Currently, CDC and FDA are collaborating to identify solutions to ameliorate a national shortage of isoniazid (1). SLD shortages also can disrupt treatment of drug-susceptible TB in patients who cannot tolerate first-line drugs and can complicate the treatment of MDR TB and XDR TB, putting patients and communities at greater risk for morbidity and mortality. For example, in April 2011, shortages of capreomycin and amikacin, two SLDs used to treat MDR TB and XDR TB, posed a serious threat for a father and his infant who had MDR TB. Despite intensive efforts by public health personnel to obtain the two drugs, the initiation of treatment was delayed by 8 days for both patients, prolonging the father's infectious period and thereby increasing the risk for transmission to the community. The infant, who had basilar meningitis and severe communicating hydrocephalus, was placed in a particularly dangerous situation. TB meningitis in young children is a medical emergency, and delays in treatment lead to worse outcomes (2), such as severe cognitive impairment, epilepsy, and death (3).

In November 2010, NTCA, an organization of state, local, and territorial health officials, surveyed its membership in 50 states, 10 large cities, five territories, and the three freely-associated Pacific Island nations. An NTCA web-based questionnaire addressed medication procurement issues, costs, and treatment delays related to interruptions in SLD access. The survey was sent to NTCA members who had a functioning e-mail address (61 [90%] of 68 members), and those surveyed had 1 month to respond to the questionnaire.

Of the 61 surveyed jurisdictions, 33 (54%) responded. Of those jurisdictions that responded, 29 (88%) represented state TB programs, four (12%) represented large cities, and 26 (79%) reported having had an MDR TB case in the past 5 years. Of these 26, 21 (81%) stated that their program had faced challenges obtaining MDR TB drugs in the past 5 years (Table), citing reasons such as nationwide shortages (21 [100%]), shipping delays (15 [71%]), lack of resources to pay for SLDs (presumably meaning that neither the program, the patient, nor a health insurer could afford the drugs) (13 [62%]), and a complicated procurement process related to

<sup>\*</sup>MDR TB is caused by *Mycobacterium tuberculosis* that is resistant to at least isoniazid and rifampin, the two most potent of the four first-line anti-TB drugs. Ethambutol and pyrazinamide are the other two first-line TB drugs.

<sup>&</sup>lt;sup>†</sup>XDR TB is MDR TB with additional resistance to any fluoroquinolone and at least one of the injectable TB drugs (kanamycin, capreomycin, and amikacin).

TABLE. Number and percentage of local, state, and territorial health departments experiencing challenges in obtaining second-line drugs (SLDs)\* for tuberculosis treatment in the past 5 years, by selected characteristics — National Tuberculosis Controllers Association member survey, United States, 2010

Characteristic	No.	(%)
Faced any challenges obtaining SLDs in the	21/33	(64)
past 5 years		
Nationwide shortages	21/21	(100)
Shipping delays	15/21	(71)
Medications too expensive for their program	13/21	(62)
Medications too expensive for uninsured	10/21	(48)
Delays caused by IND protocol submission	10/21	(48)
Medications too expensive for insured patients	8/21	(38)
Payer bureaucracy	7/21	(33)
Adverse effects and other problems		
Substantial staff time diverted by drug procurement	13/19	(68)
Delay in starting treatment	11/19	(58)
Treatment lapse and interruption	6/19	(32)
Inadequate regimen	6/19	(32)

**Abbreviation:** IND = investigational new drug.

IND protocols (10 [48%]). Of the 21 jurisdictions reporting challenges with drug procurement, 19 reported adverse outcomes or other problems, such as treatment delay (11 [58%] of 19), a treatment lapse or interruption (six [32%] of 19), the use of an inadequate regimen (six [32%] of 19), and substantial staff time expended for drug procurement (13 [68%] of 19).

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#### **Editorial Note**

In the United States in recent years, interruptions in access to SLDs have hindered MDR TB and XDR TB treatment. CDC does not formally monitor SLD supplies, but TB control officials in local and state health departments request assistance from CDC when they encounter difficulties with drug procurement. Since 2005, CDC has received reports of difficulty obtaining each of the following SLDs: streptomycin, cycloserine, ethionamide, rifabutin, amikacin, capreomycin, and kanamycin. Shortages of rifampin also have been reported, and, in the past 2 months, a national shortage of isoniazid has

developed (1). Shortages of MDR TB medications have been experienced by most U.S. TB programs that have diagnosed and reported MDR TB cases. In 2010, most (130 [73%] of 178) of these reports of SLD shortages involved sterile injectable antibiotics essential for the treatment of MDR TB. Since September 2011, the availability of injectable SLDs for MDR TB treatment has been precarious. Kanamycin is no longer produced in the United States, streptomycin has been intermittently unavailable because of increased international demand, and capreomycin and amikacin have been available on an intermittent basis in only small amounts because of manufacturing problems and lack of raw materials.

Drug shortages in the Unites States have become increasingly common. In 2005, a total of 61 impending drug shortages were reported to FDA; in 2010, there were 178. FDA maintains a website to alert the public of drug shortages and their causes (4). A recent FDA review of medical product shortages underscored the complexity of the problem, identifying poor drug quality leading to product recalls as the most common cause for a shortage. Difficulties procuring raw materials and components also were problems. Early notification to FDA can help prevent some impending shortages. For example, in 2010, of 178 drugs with impending drug shortages, FDA was able to prevent shortages of 38 (21%); in 2011, 195 shortages were prevented (5,6), and, as of November 1, 2012, shortages of at least 150 drugs had been prevented in 2012 (Jouhayna Saliba, PharmD, Center for Drug Evaluation and Research, FDA; personal communication; 2013).

As with any drug shortage, SLD shortages can contribute to adverse outcomes such as delays and interruptions in treatment, the need to use potentially less effective treatment regimens, prolonged infectiousness and increased transmission of drug-resistant TB in the community, the further development of drug resistance, and worse outcomes for patients (7). Additionally, drug shortages lead to rationing, increased drug costs, and inefficient use of staff time, and increase the risk for medication errors because regimens must be adjusted, leading to confusion over drug administration schedules, adverse reactions, and interactions (8).

In March 2011, the Federal Advisory Council for the Elimination of Tuberculosis, which provides recommendations for TB elimination to the U.S. Department of Health and Human Services, formed a workgroup to design strategies for improving SLD access. In November 2011, a recurrent bimonthly national forum of 60 TB experts (including members of the Federal Advisory Council for the Elimination of Tuberculosis, state TB controllers, members of the CDC-funded Regional Training and Medical Consultation Centers, patient advocacy groups, and personnel from CDC and FDA),

<sup>\*</sup> Including capreomycin, kanamycin, amikacin, moxifloxacin, levofloxacin, para-aminosalicylate sodium, cycloserine, ethionamide, linezolid, and clofazimine.

#### What is already known on this topic?

Drug shortages, defined as situations in which the total supply of all clinically interchangeable versions of a given Food and Drug Administration (FDA)–regulated drug is inadequate to meet the current or projected demand at the user level, are a well-documented problem in many areas of medicine.

#### What is added by this report?

A nationwide survey of U.S. tuberculosis (TB) control programs showed that 81% of responding jurisdictions that reported having a multidrug-resistant TB case have experienced shortages of second-line drugs (SLDs) for TB treatment and that these shortages have resulted in adverse outcomes for programs and patients. The main reasons cited include nationwide shortage (100%), shipping delays (71%), lack of resources (62%), and a complicated procurement process related to investigational new drug protocols (48%). Shortages of SLDs have contributed to delays (58%) and interruptions in treatment (32%) and the need to use potentially less effective treatment regimens (32%), and can prolong infectiousness, increase transmission of drug-resistant TB in the community, further the development of acquired drug resistance, and lead to worse outcomes for patients.

#### What are the implications for public health practice?

Potential solutions for improving continuity of SLD supplies include the sharing of drugs in short supply among state and local TB programs, centralized drug stockpiling, obtaining drugs from foreign manufacturers when not available in the United States, and having CDC be responsible for a nationally centralized investigational new drug application protocol for certain drugs to expedite access to these drugs for all U.S. patients. On July 9, 2012, the FDA Safety and Innovation Act of 2012 was signed into law. In the law, Congress provided FDA with authorities to combat shortages of drug products in the United States and imposed requirements on manufacturers regarding early notification to FDA of issues that could lead to a potential shortage or disruption in supply of a product.

convened by National Jewish Health to discuss clinical and programmatic issues specific to MDR TB and XDR TB, assessed the findings of the NTCA survey and data from FDA and CDC in the context of case presentations. Potential solutions for improving continuity of SLD supplies were suggested by the TB experts present, although no report resulted from the meeting; these proposed solutions included the sharing of drugs in short supply among state and local TB programs, centralized drug stockpiling, obtaining drugs from foreign manufacturers when not available in the United States, and having CDC be responsible for a nationally centralized IND application protocol for certain drugs to expedite access to these drugs for all U.S. patients. Currently, CDC is responsible for nine IND protocols and is developing such a proposal for clofazimine, an SLD.

The findings in this report are subject to at least one limitation. Because of the low response rate (54%) to the NTCA survey, the results might not be representative of the nation's experience with SLD shortages generally.

On July 9, 2012, the FDA Safety and Innovation Act of 2012 was signed into law. In the law, Congress provided FDA with authorities to combat shortages of drug products in the United States and imposed requirements on manufacturers regarding early notification to FDA of issues that could lead to a potential shortage or disruption in supply of a product.

In October 2011, Executive Order 13588 directed FDA and the U.S. Department of Justice to take action to combat drug shortages, protect consumers, and prevent deliberate price inflation (9). Maintaining access to SLDs will require the collaboration of CDC (because of its role as the central component of the national TB program), FDA, and other partners, including the Global Drug Facility, the Treatment Action Group, local and state health departments, national and international health professional societies, and the pharmaceutical industry. To report information about shortages or supply issues, manufacturers can send updates by e-mail to drugshortages@fda.hhs.gov. State and local health departments, health-care professionals, and patients also are encouraged to notify FDA of shortages, using the same e-mail address.

#### **Acknowledgment**

Members of the Drug Shortage Workgroup of the Federal Advisory Council for the Elimination of Tuberculosis.

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### Global Control and Regional Elimination of Measles, 2000–2011

Widespread use of measles vaccine since 1980 has led to a substantial decline in global measles morbidity and mortality; measles elimination\* has been achieved and sustained in the World Health Organization (WHO) Region of the Americas (AMR) since 2002. In 2010, the World Health Assembly established three milestones for measles eradication to be reached by 2015: 1) increase routine coverage with the first dose of measlescontaining vaccine (MCV1) for children aged 1 year to ≥90% nationally and ≥80% in every district or equivalent administrative unit; 2) reduce and maintain annual measles incidence to <5 cases per million; and 3) reduce measles mortality by 95% from the 2000 estimate (1). The Global Vaccine Action Plan (GVAP) includes monitoring progress toward achievement of goals to reduce or eliminate measles in four WHO regions by 2015 and five WHO regions by 2020 (2). This report updates the previous report (3) and describes progress in global control and regional elimination of measles during 2000-2011. Estimated global MCV1 coverage increased from 72% in 2000 to 84% in 2011, and the number of countries providing a second dose of measles-containing vaccine (MCV2) through routine services increased from 97 (50%) in 2000 to 141 (73%) in 2011. During 2000–2011, annual reported measles incidence decreased 65%, from 146 to 52 cases per 1 million population, and estimated measles deaths decreased 71%, from 542,000 to 158,000. However, during 2010–2011, measles incidence increased, and large outbreaks of measles were reported in multiple countries. To resume progress toward achieving regional measles elimination targets, national governments and partners are urged to ensure that measles elimination efforts receive high priority and adequate resources.

#### **Immunization Activities**

WHO and the United Nations Children's Fund (UNICEF) use annual data from administrative records and surveys reported by national governments to estimate MCV1 coverage among children aged 1 year. Since 2003, countries also have reported the number of districts with ≥80% MCV1 coverage. During 2000–2011, estimated global MCV1 coverage increased from 72% to 84%; for 2011, estimated MCV1

\*Measles elimination is defined as the absence of endemic measles transmission in a defined geographic area (e.g., region or country) for ≥12 months in the presence of a well-performing surveillance system.

coverage in three WHO regions was ≥90% (Table 1). The number of countries with ≥90% MCV1 coverage increased from 83 (43%) in 2000 to 123 (63%) in 2011. Of countries reporting district-level MCV1 coverage, the proportion reaching ≥80% MCV1 coverage in ≥80% of districts increased from 49% (72 of 148) in 2003 to 56% (87 of 156) in 2011; in 2011, 34% (53 of 156) reported ≥80% MCV1 coverage in all districts. Of the estimated 20.1 million infants who did not receive MCV1 in 2011 through routine immunization services, 11.1 million (55%) were in five countries: India (6.7 million), Nigeria (1.7 million), Ethiopia (1.0 million), Pakistan (0.9 million), and the Democratic Republic of the Congo (DRC) (0.8 million).

During 2000–2011, the number of countries providing a second dose of measles-containing vaccine (MCV2) through routine services increased from 97 (50%) to 141 (73%). Overall, 225 million children received measles vaccination during 39 supplemental immunization activities (SIAs) conducted during 2011. Among those 39 SIAs, 17 (44%) had >95% reported measles vaccine coverage, 12 (31%) included rubella vaccination, 15 (38%) included oral polio vaccination, and 14 (36%) included one or more child health interventions, in addition to vaccinations (Table 2).

#### **Disease Incidence**

During 2000–2011, the number of countries reporting annual measles surveillance data to WHO increased from 169 (88%) to 188 (97%). Effective measles surveillance includes case-based surveillance with laboratory testing to confirm cases. During 2004–2011,\*\* the number of countries using case-based surveillance increased from 120 (62%) to 182 (94%).†† During 2000–2011, the number of countries with access to standardized quality-controlled testing through the WHO Measles and Rubella Laboratory Network increased from 71 (37%) to 191 (98%).§§

<sup>&</sup>lt;sup>†</sup> Target dates for measles elimination have been set by four additional WHO regions: 2012 in the Western Pacific Region, 2015 in the Eastern Mediterranean Region and in the European Region, and 2020 in the African Region. The South-East Asia Region has a target to reduce measles mortality by ≥95% from the 2000 estimate by 2015.

WHO/UNICEF estimates of national immunization coverage are available at http://www.who.int/immunization\_monitoring/ routine/immunization\_coverage/en/index4.htm.

SIAs generally are carried out using two approaches. An initial, nationwide catch-up SIA targets all children aged 9 months-14 years, with the goal of eliminating susceptibility to measles in the general population. Periodic follow-up SIAs then target all children born since the last SIA. Follow-up SIAs generally are conducted nationwide every 2–4 years and target children aged 9–59 months; their goal is to eliminate any measles susceptibility that has developed in recent birth cohorts and to protect children who did not respond to the first measles vaccination.

<sup>\*\*</sup> Data for years before 2004 were not available.

<sup>††</sup> Countries without case-based measles surveillance include Algeria, Comoros, Guinea-Bissau, India, Mauritius, Monaco, Morocco, Seychelles, San Marino, Somalia, Sao Tome and Principe, and Thailand.

SS Countries without access to standardized quality-controlled testing by the WHO Measles and Rubella Laboratory Network in 2011 included Cape Verde, Sao Tome and Principe, and Seychelles.

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TABLE 1. Estimates of coverage with the first dose of measles-containing vaccine (MCV1) administered through routine immunization services among children aged 1 year, reported measles cases, and incidence, by World Health Organization (WHO) region, 2000 and 2011

	2000				2011											
	% coverage	No. of reported measles		% countries with incidence <5 per		mated es deaths	% coverage	No. of reported measles	% decline from	Measles incidence (cases per million	% decline from	% countries with incidence <5 per			% mortality reduction 2000 to	
WHO region	with MCV1	* cases†	population)§	million	No.	(95% CI)	with MCV1*	cases†	2000	population)§	2000	million	No.	(95% CI)	2011	in 2011
African	54	520,102	838	8	338,000	(216,000– 736,000)		194,364	63	227	73	46	55,000	(23,000– 338,000)	84	35
Americas	92	1,755	2.1	89	<100	_	92	1,372	22	1.5	31	94	<100	_	_	0
Eastern Mediterranear	72 <mark>n</mark>	38,592	88	17	54,000	(32,000– 100,000)		35,923	7	61	31	45	30,000	(19,000– 56,000)	45	19
European	91	37,421	50	45	400	(100– 2,400)		37,073	1	43	14	44	100	(0–180)	62	0
South-East Asia	61	78,558	51	0	137,000	(95,000– 205,000)		65,161	17	36	30	27	71,000	(52,000– 100,000)	52	45
South-East Asia (excluding India)	77	39,723	80	0	49,000	(24,000– 97,000)		35,822	10	61	24	30	15,000	(8,000– 30,000)	70	9
India	55	38,835	37	0	88,000	(71,000– 108,000)		29,339	24	24	36	0	56,000	(44,000– 70,000)	36	35
Western Pacific	85	177,052	106	30	13,000	(4,000– 46,000)		21,050	88	12	89	62	1,000	(200– 30,000)	90	1
Total	72	853,480	146	38	_	(347,000– 1,091,000)		354,922	58	52	65	55	158,000	(94,000– 527,000)	71	100

Abbreviation: CI = confidence interval.

During 2000–2011, the number of measles cases reported worldwide each year decreased 58%, from 853,480 to 354,922, and measles incidence decreased 65%, from 146 to 52 cases per million population per year, with declining cases and incidence reported in all WHO regions (Table 1). During 2000-2011, AMR maintained measles incidence at <5 cases per million; in 2011, reported incidence in the Western Pacific Region (WPR) was 12 cases per million, a historic low (Figure). However, since reaching a low of 278,417 reported cases worldwide in 2008, annual reported cases have increased each year. From 2010 to 2011, a decrease in reported measles cases in WPR, from 49,460 to 21,050 cases, was offset by increases in reported cases, from 10,072 to 35,923 in the Eastern Mediterranean Region (EMR), 52,529 to 65,161 in the South-East Asia Region (SEAR), 186,675 to 194,364 in the African Region (AFR), and 30,625 to 37,073 in the European Region (EUR). In addition, the percentage of countries with reported measles incidence <5 cases per million population decreased, from a high of 122 (67%) of 183 reporting countries in 2008 to 104 (55%) of 188 reporting countries in 2011. During 2011, large measles outbreaks were reported by DRC (134,042 cases), India (29,339), Indonesia (21,893), Nigeria (18,843), Somalia (17,298), France (14,949), Zambia (13,324), Chad (8,650), Philippines (6,538), Sudan (5,616), Italy (5,189), Pakistan

(4,386), Romania (4,189), Spain (3,802), Uganda (3,312), Ethiopia (3,255), and Afghanistan (3,013).

#### **Mortality Estimates**

Many countries, particularly those with the highest disease burden, lack data on the number of measles deaths; therefore, WHO has developed a model to estimate mortality using reported numbers of cases, measles vaccination coverage through routine vaccination and SIAs, the age distribution of reported cases, and age-specific, country-specific case-fatality ratios (4,5). The addition of 2011 measles vaccination coverage and case data for all countries, and updating of data for the period before 2011 for some countries, led to new mortality estimates for 2000–2011. During 2000–2011, estimated measles deaths decreased 71%, from 542,000 to 158,000; all regions and India had substantial reductions in estimated measles mortality, ranging from 36% to 90% (Table 1).

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<sup>\*</sup> Coverage data: WHO/UNICEF estimates of national immunization coverage. Geneva, Switzerland: World Health Organization; 2012. Available at http://www.who.int/immunization\_monitoring/routine/immunization\_coverage/en/index4.html.

<sup>†</sup> Reported case data source: Measles reported cases. Geneva, Switzerland: World Health Organization; 2011. Available at http://apps.who.int/immunization\_monitoring/en/globalsummary/timeseries/tsincidencemea.htm. Americas 2011 data source: Measles, rubella, and congenital rubella syndrome surveillance data tables. Washington, DC: Pan American Health Organization; 2012. Available at http://ais.paho.org/phip/viz/im\_vaccinepreventablediseases.asp.

<sup>§</sup> Population data: United Nations, Department of Economic and Social Affairs, Population Division (2011). World population prospects: the 2010 revision, CD-ROM edition. Any country not reporting data on measles cases for that year was removed from the numerator and denominator.

TABLE 2. Measles supplementary immunization activities (SIAs\*) and the delivery of other child health interventions, by country — World Health Organization (WHO) regions, 2011

			Children reached in		Other interventions delivered						
	Age group		targeted age		Oral polio	Vitamin	Insecticide- treated	Deworming	Tetanus toxoid	Rubella	
WHO region/ country	targeted	Extent of SIA*	No.	(%)†	vaccine	Α	bednets	medication	vaccination	vaccination	
Africa											
Angola	9-59 mos	National	4,635,248	(85)	Yes	Yes		Yes			
Benin	9-59 mos	National	1,411,065	(104)							
Burkina Faso	9-59 mos	National	2,865,517	(113)							
Central African Republic	6-47 mos	National	516,563	(84)	Yes	Yes		Yes			
Côte d'Ivoire	9-59 mos	National	5,820,653	(95)	Yes						
Democratic Republic of	Varied by	Rollover —	16,793,925	(99)	Yes						
the Congo	province	national <sup>§</sup>									
Equatorial Guinea	9–47 mos	Rollover — national	11,658	(50)							
Ethiopia	9–47 mos	Rollover — national and subnational¶	7,806,201	(96)							
Gambia	9-59 mos	National	294,579	(95)		Yes					
Liberia	9-59 mos	National	574,458	(103)	Yes	Yes		Yes			
Mali	9–47 mos	National	4,616,957	(94)							
Mauritania	9–59 mos	National	510,155	(96)							
Mozambique	9-47 mos	National	3,974,977	(104)		Yes		Yes			
Nigeria	6-59 mos	National	28,483,907	(91)	Yes	Yes	Yes	Yes			
Tanzania	6 mos-15 yrs	National	6,686,683	(97)	Yes						
Americas											
Bolivia	2-6 yrs	National	869,377	(95)						Yes	
Brazil	1–6 yrs	National	16,813,682	(98)						Yes	
Chile	1–5 yrs	National	886,802	(75)						Yes	
Costa Rica	1–9 yrs	National	620,209	(94)						Yes	
Columbia	10-19 yrs	National	7,801,850	(89)						Yes	
Ecuador	6 mos-14 yrs	National	4,700,526	(95)						Yes	
Mexico	9 mos-59 yrs	National	7,653,521	(99)						Yes	
Peru	1–4 yrs	National	2,033,123	(87)						Yes	
Eastern Mediterranean											
Afghanistan	9–59 mos and 9 mos–10 yrs	Subnational	1,430,510	(95)	Yes				Yes		
Pakistan	6-59 mos	Subnational	9,679,499	(95)	Yes				Yes		
Saudi Arabia	9 mos-18 yrs	National	8,270,316	(97)					Yes		
Somalia	6-59 mos	Subnational	2,080,546	(90)	Yes	Yes	Yes	Yes	Yes		
South Sudan	6–59 mos and 6 mos–14 yrs	National	1,513,864	(97)	Yes						
Sudan	9–59 mos	Rollover — national	5,073,092	(99)	Yes						
Yemen	9–59 mos and 6 mos–14 yrs	Subnational	157,146	(63)	Yes						
Europe											
Uzbekistan	1–14 yrs	National	7,502,957	(99)						Yes	
South-East Asia											
India	9 mos-10 yrs	Rollover — national	30,628,456	(90)							
Indonesia	9–59 mos	Rollover — national	11,544,190	(97)	Yes						
Timor Leste	6 mos-14 yrs	National	454,209	(92)							

See table footnotes on page 30.

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#### **Editorial Note**

During 2000–2011, increasing routine measles vaccination coverage worldwide, combined with regular SIAs in countries lacking high coverage with 2 doses of MCV, contributed to a 65% decrease in reported measles incidence and a 71%

TABLE 2. (Continued) Measles supplementary immunization activities (SIAs\*) and the delivery of other child health interventions, by country — World Health Organization (WHO) regions, 2011

			el 11 1		Other interventions delivered					
	Ago group		Children reached in targeted age group				Insecticide- treated	Deworming	Tetanus toxoid	Rubella
WHO region/ country	Age group targeted	Extent of SIA*	No.	(%)†	vaccine	A	bednets	medication	vaccination	vaccination
Western Pacific										
Cambodia	9-59 mos	National	1,504,216	(100)	Yes	Yes		Yes		
Federated States of Micronesia	12–83 mos	Rollover — national	4,889	(96)		Yes		Yes		Yes
Laos	9 mos-19 yrs	National	2,614,002	(97)						Yes
Papua New Guinea	6–35 mos	Rollover — national	464,973	(83)		Yes				
Philippines	9 mos-8 yrs	National	15,649,907	(84)		Yes	Yes	Yes		Yes
Total			224,954,408							

<sup>\*</sup> SIAs generally are carried out using two approaches. An initial, nationwide catch-up SIA targets all children aged 9 months to 14 years, with the goal of eliminating susceptibility to measles in the general population. Periodic follow-up SIAs then target all children born since the last SIA. Follow-up SIAs generally are conducted nationwide every 2–4 years and generally target children aged 9–59 months; their goal is to eliminate any measles susceptibility that has developed in recent birth cohorts and to protect children who did not respond to the first measles vaccination. The exact age range for follow-up SIAs depends on the age-specifc incidence of measles, first dose of measles-containing vaccine coverage, and the time since the last SIA.

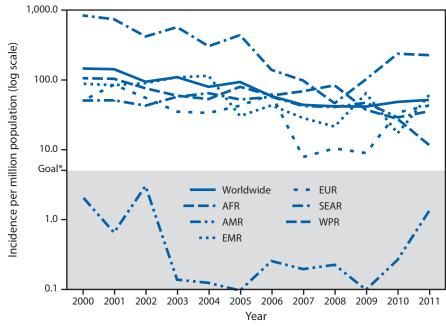
reduction in estimated measles mortality. Measles elimination has been achieved and maintained in AMR (6), and WPR is approaching its measles elimination goal. However, since 2008, large outbreaks of measles in AFR, EMR, EUR, and SEAR have stalled progress toward regional measles control and elimination targets.

Field investigations of recent measles outbreaks found most cases were among unvaccinated persons, suggesting the main underlying cause was persistent gaps in immunization coverage, despite overall increased measles vaccine coverage (7,8). All five countries with the largest number of infants who did not receive MCV1 through routine immunization services in 2011 had large outbreaks of measles during 2011, highlighting the importance of a strong immunization system. In addition, poor quality SIAs and delays in planned SIAs have resulted in low coverage, contributing to the increased number of measles-susceptible children and ongoing measles virus transmission.

In 2011, estimated global measles mortality increased from the 2010 estimate, and 99% of the measles mortality burden was in AFR, EMR, India, and other SEAR countries. In India, the 36% decrease in estimated measles mortality during 2001–2011 mainly resulted from the National Measles Catch-up Programme to provide MCV2, beginning in 2010, with MCV2 introduction in routine

services in states with reported MCV1 coverage ≥80%, and with SIAs followed by MCV2 introduction in routine services in states with reported MCV1 coverage <80%. To prevent measles epidemics and associated morbidity and mortality, WHO recommends that all children receive 2 doses of measlescontaining vaccine (9).

 $FIGURE.\,Reported\,measles\,incidence\,per\,million\,population,\,by\,World\,Health\,Organization\,region\,and\,worldwide,\,2000-2011$ 



**Abbreviations:** AFR = African; AMR = Americas; EMR = Eastern Mediterranean; EUR = European; SEAR = South-East Asia; WPR = Western Pacific.

 $<sup>^\</sup>dagger$  Values > 100% indicate that the intervention reached more persons than the estimated target population.

<sup>§</sup> Rollover national campaigns started the previous year or will continue into the next year.

<sup>&</sup>lt;sup>¶</sup> Subnational campaigns were in response to large measles outbreaks (Afghanistan, Ethiopia, Somalia, and Yemen) or natural disasters (Pakistan).

<sup>\*</sup> As a milestone to measles eradication, the World Health Organization has set a goal of reducing the global incidence of measles to <5 cases per million population by 2015.

#### What is already known on this topic?

During 2000–2010, global coverage with the first dose of measles-containing vaccine (MCV1) increased from 72% to 85%, >1 billion children received a second opportunity for measles immunization during measles supplemental immunization activities, and global reported measles cases decreased until 2008, then increased in 2010. By 2010, 40% of countries had not met the incidence target of <5 cases per million. As milestones toward eventual global measles eradication, the 2010 World Health Assembly endorsed a series of targets to be met by 2015.

#### What is added by this report?

The Global Vaccine Action Plan (GVAP) will monitor progress toward achievement of regional measles elimination targets. Estimated global MCV1 coverage increased from 72% in 2000 to 84% in 2011, and the number of countries providing a second dose of measles-containing vaccine (MCV2) through routine services increased from 97 (50%) in 2000 to 141 (73%) in 2011. During 2000–2011, annual reported measles incidence decreased 65%, from 146 to 52 cases per million population, and estimated measles deaths decreased 71%, from 542,000 to 158,000.

#### What are the implications for public health practice?

During 2010–2011, measles incidence has increased and large measles outbreaks have been reported in multiple countries. To resume progress toward achieving regional measles elimination targets, national governments and partners are urged to ensure that these efforts receive high priority and adequate resources to achieve GVAP targets.

The findings in this report are subject to at least three limitations. First, vaccination coverage estimates in this report include biases resulting from inaccurate estimates of the sizes of the target populations, inaccurate reporting of doses delivered, and inclusion of SIA doses given to children outside the target age group. Second, biases in surveillance data can occur because not all patients seek care and not all of those who seek care are reported. The use of measles surveillance data to estimate measles mortality improved on previously used methods that did not account for the effect of periodic outbreaks on mortality. Finally, the accuracy of the measles mortality model results is affected by biases in all model inputs, including country-specific measles vaccination coverage and measles case-based surveillance data.

In April 2012, the Measles and Rubella Initiative ¶ launched the 2012–2020 Global Measles and Rubella Strategic Plan to

integrate rubella and measles elimination efforts, and provide strategies and guiding principles to resume progress toward regional measles elimination targets (10). The GVAP for the 2011-2020 Decade of Vaccines\*\*\* provides strategic objectives and recommended activities for increasing ownership, accountability, and vaccination coverage, as well as indicators for monitoring their impact through achievement of regional measles elimination targets (2). The GAVI Alliance commitment in 2012 to support eligible countries to introduce rubella vaccine using combined measles-rubella SIAs targeting children aged 9 months-14 years provides a unique opportunity to boost population immunity to both measles and rubella.††† The combination of new resources from immunization partners and commitments by countries to fully implement measles control and elimination strategies will help resume progress toward achieving regional measles targets.

††† Additional information available at http://www.gavialliance.org/library/news/gavi-features/2012/partners-launch-plan-to-eliminate-measles-rubella.

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<sup>55</sup> The Measles and Rubella Initiative is a partnership established in 2001 as the Measles Initiative, spearheaded by the American Red Cross, CDC, the United Nations Foundation, UNICEF, and WHO. Additional information available at http://www.measlesinitiative.org.

<sup>\*\*\*</sup> The Decade of Vaccines is a collaboration between the World Health Organization, UNICEF, the Bill & Melinda Gates Foundation, the GAVI Alliance, the U.S. National Institute of Allergy and Infectious Diseases, the African Leaders Malaria Alliance, and others to extend, by 2020 and beyond, the full benefit of immunization to all persons worldwide.

# Early Estimates of Seasonal Influenza Vaccine Effectiveness — United States, January 2013

On January 11, 2013, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

In the United States, annual vaccination against seasonal influenza is recommended for all persons aged ≥6 months (1). Each season since 2004-05, CDC has estimated the effectiveness of seasonal influenza vaccine to prevent influenzaassociated, medically attended acute respiratory infection (ARI). This season, early data from 1,155 children and adults with ARI enrolled during December 3, 2012-January 2, 2013 were used to estimate the overall effectiveness of seasonal influenza vaccine for preventing laboratory-confirmed influenza virus infection associated with medically attended ARI. After adjustment for study site, but not for other factors, the estimated vaccine effectiveness (VE) was 62% (95% confidence intervals [CIs] = 51%-71%). This interim estimate indicates moderate effectiveness, and is similar to a summary VE estimate from a meta-analysis of randomized controlled clinical trial data (2); final estimates likely will differ slightly. As of January 11, 2013, 24 states and New York City were reporting high levels of influenza-like illness, 16 states were reporting moderate levels, five states were reporting low levels, and one state was reporting minimal levels (3). CDC and the Advisory Committee on Immunization Practices routinely recommend that annual influenza vaccination efforts continue as long as influenza viruses are circulating (1). Persons aged ≥6 months who have not yet been vaccinated this season should be vaccinated. However, these early VE estimates underscore that some vaccinated persons will become infected with influenza; therefore, antiviral medications should be used as recommended for treatment in patients, regardless of vaccination status. In addition, these results highlight the importance of continued efforts to develop more effective vaccines.

To make these interim 2012–13 VE estimates, prospective enrollment of patients at any of the outpatient medical facilities affiliated with the five study sites of the U.S. Influenza Vaccine Effectiveness (Flu VE) Network\* began after at least 2 consecutive weeks of laboratory-confirmed cases of influenza were identified through local surveillance.† Details of methods

<sup>†</sup> Beginning enrollment dates were December 3, 2012, in Pittsburgh; December 9, 2012, in Temple; December 17, 2012, in Marshfield and Ann Arbor; December 26, 2012, in Seattle; and January 2, 2013, in Detroit.

used by the U.S. Flu VE Network have been published previously (4). Trained study staff members reviewed appointment schedules and lists of clinical symptoms and complaints to identify patients with ARI and approached potentially eligible patients (or parents/guardians) to complete a brief screening survey. Patients were eligible for enrollment if they 1) were aged ≥6 months on September 1, 2012, and thus were eligible for vaccination; 2) reported an ARI with onset ≤7 days earlier; and 3) had not been treated with influenza antiviral medication (e.g., oseltamivir). Consenting participants completed an enrollment interview. Because date and type of vaccination were not available for this early estimate, participants were considered vaccinated if they reported having received at least 1 dose of any 2012–13 influenza vaccine before enrollment. At one study site, vaccine receipt was confirmed by a real-time Internet-based vaccine registry (http://www.recin.org) that captures 95% of all influenza vaccinations in that population (5).

Respiratory specimens were collected from each patient using nasal and oropharyngeal swabs, which were placed together in a single cryovial with viral transport medium. Only nasal swabs were collected for patients aged <2 years. Specimens were tested at U.S. Flu VE Network laboratories using CDC's real-time reverse transcription—polymerase chain reaction (rRT-PCR) protocol for detection and identification of influenza viruses using dual-labeled probe chemistry. VE was estimated as 100% X (1 – odds ratio) using logistic regression, adjusting for study site (4). Stratified analyses were performed by influenza virus type.

Of the 1,155 children and adults with ARI enrolled during December 3, 2012–January 2, 2013, at the five study sites, 416 (36%) tested positive for influenza A or B virus by rRT-PCR; 236 (57%) of these were influenza A, and 180 (43%) were influenza B viruses (Table 1); among 158 subtyped influenza A viruses, all (100%) were influenza A (H3N2) viruses. The 2012–13 seasonal influenza vaccination rate among influenza cases was 32%, compared with 56% among influenza-negative controls. The overall VE (adjusted for study site) for all ages against influenza A and B virus infection associated with medically attended ARI was 62% (CI = 51%–71%) (Table 2). The vaccination rate was lower among influenza B cases (26%) than influenza A cases (37%). The stratified VE against influenza A was 55% (CI = 39%–67%) and against influenza B was 70% (CI = 56%–80%).

<sup>\*</sup>The U.S. Flu VE Network includes Group Health Cooperative (Seattle, Washington), the Marshfield Clinic Research Foundation (Marshfield, Wisconsin), the University of Michigan School of Public Health (the University of Michigan School of Public Health, partnered with the University of Michigan Health System, Ann Arbor, and the Henry Ford Health System, Detroit), the University of Pittsburgh Schools of the Health Sciences (the University of Pittsburgh Schools of the Health Sciences, partnered with UPMC, Pittsburgh, Pennsylvania), and Scott and White Healthcare (Temple, Texas).

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#### **Editorial Note**

The early onset of the 2012-13 influenza season offered an opportunity to provide an early VE estimate. Overall, the estimate suggests that the 2012-13 influenza vaccine has moderate effectiveness against circulating influenza viruses, similar to a summary VE estimate from a meta-analysis of randomized controlled clinical trial data (2). Influenza vaccination, even with moderate effectiveness, has been shown to reduce illness, antibiotic use, doctor visits, time lost from work, hospitalizations, and deaths (6). Results for the 2012-13 season indicate that vaccination has reduced the risk for influenza-associated medical visits by approximately 60%, demonstrating the benefits of influenza vaccination during the current season. Influenza activity is likely to continue for several more weeks in the United States. As always, vaccination efforts should continue as long as influenza viruses are circulating. Persons aged ≥6 months who have not yet received the 2012-13 influenza vaccine should be vaccinated. As of January 4, 2013, >128 million doses of influenza vaccine had been distributed in the United States for

#### What is already known on this topic?

In the United States, annual vaccination against seasonal influenza is recommended for all persons aged ≥6 months. An overall moderate effectiveness for influenza vaccines of approximately 60% has been estimated from a summary of randomized clinical trials. Influenza vaccination, even with moderate effectiveness, can reduce illness, antibiotic use, doctor visits, time lost from work, hospitalizations, and deaths.

#### What is added by this report?

Based on data from 1,155 children and adults with acute respiratory illness enrolled during December 3, 2012–January 2, 2013, at five study sites with outpatient medical facilities in the United States, the overall estimated effectiveness of the 2012–13 seasonal influenza vaccine for preventing medically attended, laboratory-confirmed influenza virus infection was 62%.

#### What are the implications for public health practice?

Interim VE estimates indicate the 2012–13 influenza vaccine has moderate effectiveness against circulating influenza viruses, similar to a summary estimate from randomized clinical trials. Vaccination efforts should continue as long as influenza viruses are circulating. Any persons aged ≥6 months who have not received vaccination this season should be vaccinated. However, some vaccinated persons will become infected with influenza. Therefore, antiviral medication should be used as recommended for treatment in patients regardless of their vaccination status.

the 2012–13 season, from approximately 135 million doses that were anticipated to be available for the U.S. market. At this time, some vaccine providers might have exhausted their vaccine supplies. Persons seeking vaccination might need to call more than one provider to locate vaccine.§

These early estimates indicate that some vaccinated persons will become infected with influenza, despite having been vaccinated. Therefore, antiviral medications should be used as recommended for treatment in patients regardless of their vaccination status (♂).\*\* Antiviral treatment can reduce the duration of illness and complications associated with influenza. Early antiviral treatment is recommended for persons with suspected influenza with severe or progressive illness (e.g., hospitalized persons) and those at high risk for complications from influenza, no matter how severe the illness. Antiviral treatment should be started as early as possible, preferably within 48 hours after illness onset. Among hospitalized patients, however, treatment should be initiated on admission; several studies suggest that antiviral treatment reduces mortality and illness severity among hospitalized adults, even when initiated ≥48 hours after

<sup>§</sup> An influenza vaccine locator is available at http://flushot.healthmap.

<sup>\*\*</sup> A complete summary of guidance for antiviral use is available at http://www.cdc.gov/flu/professionals/antivirals/index.htm.

TABLE 1. Number and percentage of outpatients aged ≥6 months with acute respiratory illness, by influenza virus test result and study site — U.S. Influenza Vaccine Effectiveness Network,\* United States, December 3, 2012–January 2, 2013

		Patients by influenza test result							
	Influenza	A viruses	Influenza	B viruses	Influenza-	negative	Total p	atients	
Location	No.	(%)	No.	(%)	No.	(%)	No.	(%)	
Washington	8	(21)	1	(3)	29	(76)	38	(3)	
Wisconsin	77	(20)	127	(32)	190	(48)	394	(34)	
Michigan	18	(19)	8	(8)	70	(73)	96	(8)	
Pennsylvania	83	(33)	0	_	168	(67)	251	(22)	
Texas	50	(13)	44	(12)	282	(75)	376	(33)	
All sites	236	(20)	180	(16)	739	(64)	1,155	(100)	

<sup>\*</sup> The U.S. Flu VE Network includes Group Health Cooperative (Seattle, Washington), the Marshfield Clinic Research Foundation (Marshfield, Wisconsin), the University of Michigan School of Public Health (the University of Michigan School of Public Health, partnered with the University of Michigan Health System, Ann Arbor, and the Henry Ford Health System, Detroit), the University of Pittsburgh Schools of the Health Sciences (the University of Pittsburgh Schools of the Health Sciences, partnered with UPMC, Pittsburgh, Pennsylvania), and Scott and White Healthcare (Temple, Texas).

TABLE 2. Number and percentage of persons vaccinated with 2012–13 seasonal trivalent influenza vaccine among influenza-positive case-patients and influenza-negative controls, and vaccine effectiveness\* against all influenza viruses and influenza virus types A and B among 1,155 outpatients with acute respiratory illness — U.S. Influenza Vaccine Effectiveness Network, United States, December 3, 2012–January 2, 2013

	Influenza-positive case	es	Influenza-negative conti	Vaccine effectiveness		
Virus	No. vaccinated/Total	(%)	No. vaccinated/Total	(%)	(%)	(95% CI)
Influenza A and B	133/ <b>416</b>	(32)	411/ <b>739</b>	(56)	(62)	(51–71)
Influenza A only	87/ <b>236</b>	(37)	411/ <b>739</b>	(56)	(55)	(39-67)
Influenza B only	46/ <b>180</b>	(26)	411/ <b>739</b>	(56)	(70)	(56-80)

**Abbreviation:** CI = confidence interval.

illness onset (7). The decision to initiate antiviral treatment should not wait for laboratory confirmation of influenza and should not be dependent on insensitive assays, such as rapid influenza diagnostic tests.

Although these early VE estimates differ for influenza A and influenza B virus infection, the CIs overlap, and the actual difference might be less. Early observations from the U.S. Flu VE Network are consistent with data from national domestic surveillance, which indicates that most influenza A viruses circulating in the United States thus far are influenza A (H3N2) viruses (3). Of the subset of influenza A (H3N2) viruses and B viruses characterized at CDC this season, the majority are antigenically like the influenza A (H3N2) and B component of the 2012–13 seasonal vaccine (3).

The findings in this report are subject to at least four limitations. First, VE can differ for patients of different ages, and age data were not yet available from all sites. However, VE estimates from one site (Wisconsin) differed little before (69%) and after age-adjustment (66%) (Edward Belongia, Marshfield Clinic Research Foundation, personal communication, January 2013). Second, vaccination status was self-reported;

dates of vaccination were not available, except from one site; and vaccine formulation was not known. However, experience from prior seasons suggests that few persons are vaccinated <2 weeks from illness onset (4), a period when vaccine might not be effective yet, and self-reported influenza vaccine status was sensitive and fairly specific compared with documented vaccination at an immunization registry (5). Vaccination dates will be available for subsequent VE estimates. Third, VE estimates for prior seasons were reduced after adjusting for potential confounding factors (4), and the fully adjusted VE estimate for this season likely will be lower, also. Observational VE studies, such as those used for the current estimates, have greater potential for confounding and bias relative to randomized clinical trials, particularly when diagnostic test specificity is low (8). However, the U.S. Flu VE Network study design attempts to minimize bias and confounding through systematic screening of eligible patients and use of a highly sensitive and specific endpoint (rRT-PCR-confirmed influenza). Finally, subsequent VE estimates might change during the season if circulating viruses or population immunity change over the course of the season.

<sup>\*</sup> Adjusted for study site.

<sup>&</sup>lt;sup>†</sup> The U.S. Flu VE Network includes Group Health Cooperative (Seattle, Washington), the Marshfield Clinic Research Foundation (Marshfield, Wisconsin), the University of Michigan School of Public Health (the University of Michigan School of Public Health, partnered with the University of Michigan Health System, Ann Arbor, and the Henry Ford Health System, Detroit), the University of Pittsburgh Schools of the Health Sciences (the University of Pittsburgh Schools of the Health Sciences, partnered with UPMC, Pittsburgh, Pennsylvania), and Scott and White Healthcare (Temple, Texas).

CDC will monitor VE throughout the season and provide updates. Although influenza vaccines are the best tool for prevention of influenza currently available, more effective vaccines are needed. Antiviral medications continue to be an important adjunct in the treatment and control of influenza and should be used as recommended, regardless of patient vaccination status.

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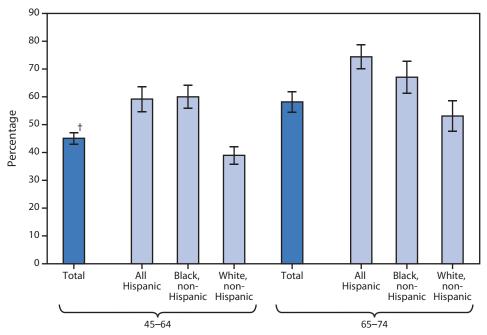
### **Erratum**

#### Vol. 62, No. 1

In the report, "Vital Signs: Binge Drinking Among Women and High School Girls—United States, 2011," one of the numbers in the first sentence of the Introduction was incorrectly stated. The sentence should read as follows: "Excessive alcohol use\* among women and girls accounted for an estimated average of 23,000 deaths† and **633,000** years of potential life lost (YPLL)§ in the United States each year during 2001–2005."

#### FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

### Prevalence of Moderate and Severe Periodontitis\* Among Adults Aged 45–74 Years, by Race/Ethnicity and Age Group — National Health and Nutrition Examination Survey, United States, 2009–2010



Race/Ethnicity and age group (yrs)

During 2009–2010, 45% of adults aged 45–64 years had moderate or severe periodontitis. In that age group, the prevalence of moderate or severe periodontitis was significantly higher for Hispanic and non-Hispanic black adults (59% and 60%, respectively) compared with non-Hispanic white adults (39%). Among adults aged 65–74 years, 58% had moderate or severe periodontitis. Hispanics had a higher prevalence of periodontitis (74%) compared with non-Hispanic whites (53%).

Source: Eke PI, Dye BA, Wei L, Thornton-Evans GO, Genco RJ. Prevalence of periodontitis in adults in the United States: 2009 and 2010. J Dent Res 2012;91:914–20.

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<sup>\*</sup> Severe periodontitis was defined as the presence of two or more interproximal sites with ≥6 mm attachment loss and one or more interproximal sites with ≥5 mm probing depth. Moderate periodontitis was defined as two or more interproximal sites with ≥4 mm attachment loss or two or more interproximal sites with ≥5 mm probing depth.

<sup>† 95%</sup> confidence interval.

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