

Severe Silicosis in Engineered Stone Fabrication Workers — California, Colorado, Texas, and Washington, 2017–2019

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Silicosis is an incurable occupational lung disease caused by inhaling particles of respirable crystalline silica. These particles trigger inflammation and fibrosis in the lungs, leading to progressive, irreversible, and potentially disabling disease. Silica exposure is also associated with increased risk for lung infection (notably, tuberculosis), lung cancer, emphysema, autoimmune diseases, and kidney disease (1). Because quartz, a type of crystalline silica, is commonly found in stone, workers who cut, polish, or grind stone materials can be exposed to silica dust. Recently, silicosis outbreaks have been reported in several countries among workers who cut and finish stone slabs for countertops, a process known as stone fabrication (2–5). Most worked with engineered stone, a manufactured, quartz-based composite material that can contain >90% crystalline silica (6). This report describes 18 cases of silicosis, including the first two fatalities reported in the United States, among workers in the stone fabrication industry in California, Colorado, Texas, and Washington. Several patients had severe progressive disease, and some had associated autoimmune diseases and latent tuberculosis infection. Cases were identified through independent investigations in each state and confirmed based on computed tomography (CT) scan of the chest or lung biopsy findings. Silica dust exposure reduction and effective regulatory enforcement, along with enhanced workplace medical and public health surveillance, are urgently needed to address the emerging public health threat of silicosis in the stone fabrication industry.

Investigation and Results

California. In January 2019, the California Department of Public Health identified, through review of hospital discharge

data for silicosis diagnoses (*International Classification of Diseases, Tenth Revision* [ICD-10] code J62.8), a Hispanic man aged 37 years who was hospitalized in 2017 (CA-1) (Table). He worked at a stone countertop fabrication company during 2004–2013, mainly with engineered stone. His work tasks included polishing slabs and dry-cutting and grinding stone edges. Workplace measurements during a California Division of Occupational Safety and Health inspection in 2009 showed respirable crystalline silica levels up to 22 times higher than the permissible exposure limit (PEL) of 0.1 mg/m³ in effect in California at that time.[†] After developing respiratory symptoms in 2012, he had a chest CT scan, which revealed findings of silicosis. Pulmonary function testing showed restrictive defects with reduced diffusion capacity; surgical lung biopsy showed mixed dust pneumoconiosis with polarizable particles

[†] A permissible exposure limit (PEL) is the highest permissible level of exposure for a specific substance for an employee, as established under state or federal occupational safety and health regulations. The PEL cited here is for exposure as an 8-hour time-weighted average, which represents an employee's average airborne exposure to a particular substance during an 8-hour work shift.

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consistent with silica. He concurrently received a diagnosis of scleroderma, with positive anti-Scl-70 and antinuclear antibodies. He died from silicosis in 2018 at age 38 years.

Further investigation of patient CA-1's place of employment, in collaboration with the California Division of Occupational Safety and Health, identified two additional silicosis cases among stone fabricators. The first patient (CA-2) was a Hispanic man who worked at the same company during 2003–2016 and died in 2018 at age 36 years. He had a history of rheumatoid arthritis with positive rheumatoid factor and cyclic citrullinated peptide antibodies. He was hospitalized in 2016 with respiratory symptoms and chest CT findings of silicosis but was lost to medical follow-up. After his death, investigators obtained lung tissue from autopsy, which showed silicotic nodules and alveolar proteinosis (indicating accelerated silicosis). The third case occurred in a Hispanic man aged 36 years who had worked at the company for 11 years and received a silicosis diagnosis in 2018 (CA-3). Since initiation of this investigation, three additional employees of the same stone fabrication company, all Hispanic men aged 35–59 years (CA-4, CA-5, and CA-6), have screened positive for silicosis by chest radiograph, with diagnoses subsequently confirmed by chest CT.

Colorado. In January 2019, a Colorado physician specializing in occupational lung disease observed an increasing number of silicosis cases in her practice and undertook a systematic review of electronic medical records for patients she had seen during June 2017–December 2018 with a silicosis diagnosis

(ICD-10 code J62.8). Typically, the physician saw two cases of silicosis in a year; however, during June 2017–December 2018, seven cases of silicosis were identified (CO-1–CO-7), all among employees of stone fabrication companies (Table). Two workers were female, and all seven of the workers were Hispanic. They had worked at 12 Colorado companies during 1984–2018, most of which employed <50 workers. Five patients reported cutting, grinding, and polishing mainly engineered stone; two reported only bystander exposure to engineered stone dust during workplace housekeeping duties.

All seven patients had chest CT findings consistent with silicosis. Four had undergone diagnostic lung biopsy before occupational medicine referral. One biopsy was prompted by findings on chest CT, and three patients had received a rheumatoid arthritis diagnosis based on positive autoimmune serology testing and erosive joint disease with lung biopsies showing findings of silicosis. Two patients had latent tuberculosis infection diagnosed by positive interferon-gamma release assays and negative sputum cultures. Pulmonary function was abnormal in five patients; one had severe restrictive lung disease, and four had exertional hypoxemia indicated by arterial blood gas testing. Six patients had two or more chest images for comparison; five showed progressive silicosis evidenced by increased profusion of lung nodules over time. Patients were medically removed from any ongoing silica exposure and counseled on workers' compensation and the need for long-term medical follow-up. The federal Occupational Safety and Health Administration and the Colorado Department of

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TABLE. Demographic, occupational, and clinical features of 18 silicosis cases in stone fabrication workers — California, Colorado, Texas, and Washington, 2017–2019

State-Patient no.	Age range (yrs) at diagnosis	Decade of first exposure* (total yrs)	Chest CT abnormalities	Pulmonary function test findings (FEV ₁ , FVC, and DLCO percentage predicted; FEV ₁ /FVC ratio)	Other associated conditions
CA-1†	30–39	2000s (9 yrs)	Diffuse ground glass and solid centrilobular nodules; mediastinal lymphadenopathy	FEV ₁ : 35% [§] FVC: 33% [§] FEV ₁ /FVC: 86% DLCO: 13% [§]	Scleroderma
CA-2†,¶	30–39	2000s (13 yrs)	Bilateral ground glass opacities and nodules	Not performed	Rheumatoid arthritis
CA-3	30–39	2000s (11 yrs)	Diffuse, upper lung predominant perilymphatic nodules	FEV ₁ : 77% [§] FVC: 83% FEV ₁ /FVC: 76% DLCO: 70% [§]	None
CA-4	40–49	2000s (14 yrs)	Subpleural nodules with upper lobe predominance; mild mediastinal lymphadenopathy	FEV ₁ : 73% [§] FVC: 79% [§] FEV ₁ /FVC: 75% DLCO: 57% [§]	None
CA-5	30–39	2000s (14 yrs)	Upper lobe architectural distortion and ground glass micronodules; mediastinal lymphadenopathy.	FEV ₁ : 58% [§] FVC: 71% [§] FEV ₁ /FVC: 67% [§] DLCO: 73% [§]	None
CA-6	50–59	2000s (16 yrs)	Bilateral upper lobe fibronodular scarring; calcified mediastinal lymphadenopathy.	FEV ₁ : 94% FVC: 96% FEV ₁ /FVC: 98%	None
CO-1	40–49	2000s (12 yrs)	Upper lung predominant perilymphatic nodules	FEV ₁ : 86% FVC: 92% FEV ₁ /FVC: 76% DLCO: 96%	Latent tuberculosis infection
CO-2	60–69	1980s (23 yrs)	Diffuse perilymphatic nodules; calcified mediastinal lymphadenopathy	FEV ₁ : 57% [§] FVC: 48% [§] FEV ₁ /FVC: 91% DLCO: 62% [§]	Rheumatoid arthritis
CO-3	50–59	2000s (13 yrs)	Upper lung predominant nodules; calcified mediastinal lymphadenopathy	FEV ₁ : 82% FVC: 82% FEV ₁ /FVC: 80% DLCO: 102%	Latent tuberculosis infection
CO-4	40–49	2000s (17 yrs)	Diffuse centrilobular nodules; upper lung ground glass opacities; calcified mediastinal lymphadenopathy	FEV ₁ : 96% FVC: 92% FEV ₁ /FVC: 82% DLCO: 74% [§]	None
CO-5	50–59	1980s (23 yrs)	Upper lung predominant nodules; calcified mediastinal lymphadenopathy	FEV ₁ : 105% FVC: 104% FEV ₁ /FVC: 80% DLCO: 90%	Rheumatoid arthritis
CO-6	40–49	1990s (22 yrs)	Upper and middle lung predominant nodules	FEV ₁ : 105% FVC: 103% FEV ₁ /FVC: 82% DLCO: 102%	None
CO-7	40–49	1990s (24 yrs)	Upper lung predominant nodules; mild paraseptal emphysema; calcified mediastinal lymphadenopathy	FEV ₁ : 90% FVC: 83% FEV ₁ /FVC: 86% DLCO: 77% [§]	Rheumatoid arthritis

See table footnotes on next page.

TABLE. (Continued) Demographic, occupational, and clinical features of 18 silicosis cases in stone fabrication workers — California, Colorado, Texas, and Washington, 2017–2019

State-Patient no.	Age range (yrs) at diagnosis	Decade of first exposure* (total yrs)	Chest CT abnormalities	Pulmonary function test findings (FEV ₁ , FVC, and DLCO percentage predicted; FEV ₁ /FVC ratio)	Other associated conditions
TX-1	50–59	2010s (2 yrs)	Bilateral lower lobe ground glass opacities and scattered nodules	FEV ₁ : 65% [§] FVC: 70% [§] FEV ₁ /FVC: 73%	None
TX-2	50–59	1980s (31 yrs)	Multiple bilateral pulmonary nodules; ground glass opacities in lower lobes and calcified hilar lymphadenopathy	FEV ₁ : 118% FVC: 115% FEV ₁ /FVC: 80%	None
TX-3	50–59	1980s (31 yrs)	Upper lobe predominant reticular and partially calcified nodular opacities with bilateral partially calcified hilar and mediastinal lymphadenopathy	FEV ₁ : 89% FVC: 102% FEV ₁ /FVC: 69% [§]	None
TX-4	40–49	2010s (2 yrs)	Upper lobe predominant nodules with bilateral hilar and mediastinal lymphadenopathy	FEV ₁ : 54% [§] FVC: 55% [§] FEV ₁ /FVC: 79%	None
WA-1	30–39	2010s (6 yrs)	Diffuse, upper lung predominant nodules with early conglomeration; mediastinal lymphadenopathy	FEV ₁ : 41% [§] FVC: 44% [§] FEV ₁ /FVC: 77% DLCO: 32% [§]	None

Abbreviations: CA = California; CO = Colorado; CT = computed tomography; DLCO = diffusing capacity for carbon monoxide; FEV₁ = forced expiratory volume in 1 second; FVC = forced vital capacity; TX = Texas; WA = Washington.

* Exact years of employment suppressed for patient confidentiality.

† Patient died from silicosis.

[§] Abnormal pulmonary function test defined as FEV₁<80% predicted, FVC<80% predicted, FEV₁/FVC<70%, and DLCO <80% predicted. Global Lung Function Initiative reference values (2012) were used to calculate percentage predicted values for spirometry; DLCO was based on reference values in Crapo RO, Morris AH. Standardized single-breath normal values for carbon monoxide diffusing capacity. *Am Rev Respir Dis* 1981;123:185–9. For some cases, only spirometry was performed; therefore, DLCO is not reported.

[¶] Silicosis diagnosed based on postmortem review of lung tissue.

Public Health and Environment were informed of these cases as occupational sentinel health events needing follow-up to protect other potentially exposed workers.

Texas. During March–April 2019, the Texas Department of State Health Services received reports of an apparent cluster of silicosis cases among workers at an engineered stone countertop manufacturing and fabrication facility. Twelve cases were identified as meeting the National Institute for Occupational Safety and Health surveillance case definition for silicosis.[§] Four of the 12 workers (TX-1–TX-4) had silicosis diagnoses confirmed by chest CT (Table); the remaining eight workers screened positive by chest radiograph but did not have confirmatory findings on chest CT. All four of the persons with confirmed silicosis were men aged 40–59 years; two were Hispanic, and two were non-Hispanic black. Three worked as fabricators, and one worked in engineered stone slab casting and stripping. Work tasks included cutting, sanding, gluing, and finishing engineered stone countertops. Pulmonary function testing was abnormal in two patients, with findings of moderate to severe restriction.

Washington. In May 2018, Washington's Occupational Respiratory Disease Surveillance Program, through routine surveillance of workers' compensation data, identified a case of biopsy-confirmed silicosis in a Hispanic man aged 38 years who

had worked in stone countertop fabrication during 2012–2018 (WA-1) (Table). His work tasks included cutting, polishing, and lamination of both natural and engineered stone. Chest CT demonstrated findings of silicosis, and lung biopsy found conglomerate areas of fibrosis and polarizable particles. Pulmonary function testing showed a severe restrictive defect and reduced diffusion capacity. He received a diagnosis of progressive massive fibrosis (the most advanced form of silicosis) and has had progressive lung function decline, necessitating referral for lung transplantation evaluation. Washington's Division of Occupational Safety and Health was informed of this case and completed a workplace inspection.

Discussion

Although silicosis outbreaks have been reported among engineered stone fabrication workers in other countries (2–5), only one such case has been reported previously in the United States (7). This report describes 18 additional cases of silicosis, including two fatalities, occurring in four states among mainly Hispanic stone fabrication workers who worked principally with engineered stone materials. As reported in other countries, most of the workers in this series (11 of 18) were aged <50 years, with severe, progressive disease. Engineered stone contains substantially more silica than does natural stone (>90%, compared with <45% in granite) (6), exposing workers

[§] <https://www.cdc.gov/niosh/topics/surveillance>.

to higher amounts of silica dust. In recent years, engineered stone countertops have become increasingly popular; quartz surface imports to the United States increased approximately 800% during 2010–2018.[§]

In addition to silicosis, two patients had latent tuberculosis infection, and five had concurrent autoimmune disease; autoimmune disease has also been documented among workers in this industry in other countries (8). Silicosis was not suspected in several patients with autoimmune disease until they underwent lung biopsy, underscoring the importance of taking an occupational history in patients with autoimmune diseases to improve recognition of workplace silica exposure.

Silicosis is preventable through effective workplace exposure controls; in the stone fabrication industry, this can include tools equipped with water feeds and well-designed local exhaust ventilation, and, when needed, appropriate respiratory protection.^{**} Updated occupational silica standards, with more stringent requirements for exposure prevention and monitoring, medical surveillance, and a lower respirable crystalline silica PEL of 0.05 mg/m³, have been implemented since 2016 at the federal and state levels.^{††}

Despite availability of exposure controls and recent passage of more stringent silica standards, exposure control and medical surveillance for silicosis in the stone fabrication industry remain challenging. As of 2018, there were an estimated 8,694 establishments and 96,366 employees in the stone fabrication industry in the United States.^{§§} Many stone fabrication shops are small-scale operations that might face safety challenges, including limited awareness, expertise, and investment in exposure-control technologies, that can result in inadequate worker protection. In addition, many employees in this industry are Hispanic immigrants, who might be especially vulnerable to workplace health hazards because they might have fewer employment options and diminished access to medical care and face threat of retaliation if they report workplace hazards or file workers' compensation claims (9). As a result, these

Summary

What is already known about this topic?

Respirable crystalline silica exposure causes silicosis, a disabling and sometimes fatal lung disease. Clusters of cases have been reported internationally among stone countertop fabrication workers, but only one U.S. case in this industry has been reported previously.

What is added by this report?

Eighteen cases of silicosis, including two fatalities, are reported among stone fabrication workers in four states. Several patients also had autoimmune disease and latent tuberculosis infection.

What are the implications for public health practice?

Stone fabrication workers, especially those working with engineered stone, are at risk for silicosis. Given the serious health hazard and significant number of workers at risk, additional efforts are needed to reduce exposures and improve disease surveillance.

workers might not seek medical attention until symptoms are severe and disease is advanced.

The findings in this report are subject to at least two limitations. First, requirements for employee medical screening under the silica standard have only recently been established in most jurisdictions; many at-risk employees likely have not been screened for silicosis. Second, public health surveillance for silicosis varies across jurisdictions; the cases described in this report were identified through record review from an individual clinical practice (Colorado), state-based respiratory disease surveillance using workers' compensation (Washington) or hospital discharge data (California), and employer or health care provider reports to a public health agency (Texas). Without systematic screening and surveillance of all at-risk workers, prevalence of silicosis and its associated conditions in stone fabrication workers in the United States remains unknown.

Given mounting evidence of silicosis risk among stone fabrication workers, the government of Queensland, Australia, initiated screening in 2018 for all at-risk employees. Ninety-eight cases of silicosis have been identified among 799 workers (12%) examined (10). These findings suggest that there might be many more U.S. cases that have yet to be identified.

Silicosis is preventable; the cases reported here highlight the urgent need to identify stone fabrication workers at risk and prevent further excess exposure to silica dust. Stone fabrication employers should be aware of this serious risk to their employees' health and ensure that they adequately monitor and control exposures in compliance with the updated silica standards. To identify silicosis among already-exposed workers, employers should conduct required medical surveillance, and both employers and health care providers should notify appropriate public health agencies when cases are identified.

[§] <https://dataweb.usitc.gov/>.

^{**} Additional information regarding controlling silica dust exposures is available at <https://www.cdph.ca.gov/silica-stonefabricators> and at <https://www.cdc.gov/niosh/topics/silica/>.

^{††} These standards are promulgated and enforced by either state agencies (as in California and Washington), or the federal Occupational Safety and Health Administration. The relevant regulations are: 29 Code of Federal Regulations, Section 1910.1053 (Respirable Crystalline Silica); Title 8 California Code of Regulations, Sections 5155 (Airborne Contaminants), 1532.3 (Occupational Exposures to Respirable Crystalline Silica – Construction), and 5204 (Occupational Exposures to Respirable Crystalline Silica – General Industry); Washington Administrative Code Chapter 296–840 (Respirable Crystalline Silica).

^{§§} Data from the Bureau of Labor Statistics quarterly census of employment and wages (<https://www.bls.gov/cew/data.htm>) for North American Industrial Classification System (NAICS) industry code 327911 (Cut Stone and Stone Product Manufacturing) and NAICS code 423320 (Masonry Material Merchant Wholesalers). At time of access, data for 2018 were preliminary.

State health departments and CDC can work together to standardize and improve public health surveillance for silicosis across jurisdictions. Effective disease surveillance and regulatory enforcement are crucial to address the emerging silicosis threat in the stone fabrication industry.

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Prescription Opioid Use in Patients With and Without Systemic Lupus Erythematosus — Michigan Lupus Epidemiology and Surveillance Program, 2014–2015

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Rheumatic diseases are a leading cause of chronic, noncancer pain. Systemic lupus erythematosus (SLE) is a chronic autoimmune rheumatic disease characterized by periodic flares that can result in irreversible target organ damage, including end-stage renal disease. Both intermittent and chronic musculoskeletal pain, as well as fibromyalgia (considered a centralized pain disorder due to dysregulation of pain processing in the central nervous system), are common in SLE. Opioids are generally not indicated for long-term management of musculoskeletal pain or centralized pain (fibromyalgia) because of lack of efficacy, safety issues ranging from adverse medical effects to overdose, and risk for addiction (1,2). In this study of 462 patients with SLE from the population-based Michigan Lupus Epidemiology and Surveillance (MILES) Cohort and 192 frequency-matched persons without SLE, nearly one third (31%) of SLE patients were using prescription opioids during the study period (2014–2015), compared with 8% of persons without SLE ($p < 0.001$). Among the SLE patients using opioids, 97 (68%) were using them for >1 year, and 31 (22%) were concomitantly on two or more opioid medications. Among SLE patients, those using the emergency department (ED) were approximately twice as likely to use prescription opioids (odds ratio [OR] = 2.1; 95% confidence interval [CI] = 1.3–3.6; $p = 0.004$). In SLE, the combined contributions of underlying disease and adverse effects of immunosuppressive and glucocorticoid therapies already put patients at higher risk for some known adverse effects attributed to long-term opioid use. Addressing the widespread and long-term use of opioid therapy in SLE will require strategies aimed at preventing opioid initiation, tapering and discontinuation of opioids among patients who are not achieving treatment goals of reduced pain and increased function, and consideration of nonopioid pain management strategies.

The MILES Cohort includes patients with SLE from the precursor MILES Surveillance Registry (3), which comprised persons with incident and prevalent SLE during 2002–2005. Briefly, the Registry source population included residents of Wayne and Washtenaw counties in southeastern Michigan, a region encompassing Detroit and Ann Arbor (population approximately 2.4 million). All MILES Registry patients still living in or near this region during the 2014–2015 recruitment

and enrollment period were eligible for inclusion in the Cohort. During this period, 192 persons who did not have SLE were recruited from a random sample of households in this region and frequency-matched to SLE patients by age, sex, race, and county of residence. Males were oversampled among this group to attain roughly equivalent numbers of males in both groups. Ethics approval was obtained from the Institutional Review Boards of the University of Michigan and Michigan Department of Health and Human Services; written, informed consent was obtained from all participants.

Data were collected through structured interviews conducted during February 2014–September 2015. Self-reported data included all prescription medications currently being taken and duration of use; long-term opioid use was defined as use for >1 year. ED use was considered one or more visits to an ED within the last 12 months. Patient-reported outcome measures included fibromyalgia* (4), pain and physical function,[†] and depression and anxiety.[§] Measures specific to patients included SLE duration, disease activity (5), and SLE-related damage resulting from disease or its treatment (6).

Chi-squared tests or independent two-sample t-tests were used for comparisons between groups. Two multivariable logistic regression models were used to evaluate factors associated with opioid use in the total study population (patients and nonpatients) and in SLE patients only. In multivariable analyses, potential confounders included the following a priori-specified covariates: age, sex, race, income, education, unemployment, health insurance type, patient-reported measures (ED use, fibromyalgia, pain, physical functioning, depression, anxiety; and, for SLE patients, illness duration, activity, and damage). Stata (version 15.1; StataCorp) was used for analyses.

The study population included 462 SLE patients and 192 nonpatients. Patients were more often female, unemployed, and more frequently reported ED use, fibromyalgia, pain, poor

* Based on survey criteria for fibromyalgia.

[†] Based on RAND Medical Outcomes Study Short-Form-Survey instrument subscales, with reversed scores so that higher scores represent worse states. https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form.html.

[§] Based on National Institutes of Health Patient-Reported Outcomes Measurement Information System short forms 8b (depression) and 8a (emotional distress-anxiety). <http://www.healthmeasures.net/explore-measurement-systems/promis>.

physical function, depression, and anxiety (Table 1). Overall, 143 (31%) patients and 15 (8%) nonpatients were currently using prescription opioids ($p < 0.01$). Among persons currently using prescription opioids, median duration (3 years) and interquartile range (IQR) (first and third quartiles) were similar among patients and nonpatients (IQR = 1 and 5 years, and 2 and 3 years, respectively; $p = 0.91$). Among patients using prescription opioids, 97 (68%) were on therapy for >1 year (Table 2), and 31 (22%) were using two or more opioid medications concomitantly.

Within the total study population, the odds of opioid use among SLE patients were 3 times higher than for nonpatients (OR = 3.4, 95% CI = 1.7–6.6; $p < 0.001$) after accounting for demographic, psychosocial, and clinical factors (Table 3). In analyses of both the total study population and SLE patients only, prescription opioid use was twice as likely among persons who had at least one ED visit in the last 12 months (total population: OR = 2.2, 95% CI 1.4–3.6), SLE patients only: OR = 2.1, 95% CI = 1.3–3.6). Pain and reduced physical functioning were also significantly associated with opioid use

TABLE 1. Sociodemographic characteristics and patient-reported outcomes in patients with systemic lupus erythematosus (SLE) and frequency matched persons without SLE — Michigan Lupus Epidemiology and Surveillance (MILES) Program, 2014–2015

Characteristic	No. (%) or mean (SD)		P-value [†]
	SLE patients (n = 462)	Persons without SLE* (n = 192)	
Age (yrs), mean (SD)	53.3 (12.3)	53.6 (14.0)	0.78
Sex[§]			
Female	430 (93.1)	154 (80.2)	<0.01
Male	32 (6.9)	38 (19.8)	
Race			
White	233 (50.4)	107 (55.7)	0.47
Black	208 (45.0)	77 (40.1)	
Other/Unspecified	21 (4.5)	8 (4.2)	
Income below U.S. median	237 (51.3)	114 (59.4)	0.16
Education level			
Less than high school	41 (8.9)	16 (8.3)	0.76
High school diploma/GED	46 (10.0)	26 (13.5)	
Some college/Associate degree	201 (43.5)	83 (43.2)	
Bachelor's degree	88 (19.1)	37 (19.3)	
Graduate/Professional degree	85 (18.4)	30 (15.6)	
Unemployed[¶]	176 (38.1)	55 (28.6)	0.02
Insurance			
Private/Other	206 (44.6)	96 (50.0)	0.20
Medicaid/Medicare	246 (53.2)	89 (46.4)	
Uninsured	10 (2.2)	7 (3.6)	
Emergency department use	213 (46.1)	56 (29.2)	<0.01
Fibromyalgia	190 (41.1)	25 (13.0)	<0.01
Pain score,^{**}†† mean (SD)	48.2 (27.0)	28.4 (27.8)	<0.01
Physical function score,^{**}†† mean (SD)	43.8 (30.2)	24.7 (27.9)	<0.01
Depression score,^{††} mean (SD)	51.8 (9.9)	49.0 (9.1)	<0.01
Anxiety score,^{††} mean (SD)	52.4 (10.1)	49.5 (9.2)	<0.01
Prescription opioid use			
Prescription opioid use (current)	143 (31.0)	15 (7.8)	<0.01
Duration opioid use (years; median, IQR) ^{§§}	3 (1, 5)	3 (2, 3)	0.91
Concomitant use of ≥2 opioids ^{§§}	31 (21.7)	0 (0)	0.04
SLE-specific measures			
SLE duration, years (median, IQR)	19.0 (14.0, 26.0)	NA	NA
SLE activity score (mean, SD) ^{††}	12.9 (8.1)	NA	NA
SLE damage score (median, IQR) ^{††}	5.0 (3.0, 8.0)	NA	NA

Abbreviations: GED = General Educational Development certificate; IQR = interquartile range (25th percentile, 75th percentile); NA = not applicable; SD = standard deviation.

* Persons without SLE were frequency matched by age, sex, race, and county.

† P-values calculated by Pearson's chi-squared test (categorical data) or two-sample t-test (continuous data).

§ Males were oversampled in persons without SLE to have roughly equivalent numbers of males in both groups.

¶ Considered unemployed if aged <65 years, not working over last 12 months, and not in school.

** For both the pain and physical function measures, scores were reversed from their original RAND Medical Outcomes Study 36-item Short-Form-Survey instrument values so that higher scores represent worse pain and physical functioning, respectively.

†† Higher score is worse.

§§ Among persons with current prescription opioid use.

TABLE 2. Characteristics of persons reporting current prescription opioid use — Michigan Lupus Epidemiology and Surveillance (MILES) Program, 2014–2015

Factor	No. (%) of prescription opioid users	
	SLE patients (n = 143)	Nonpatients (n = 15)
Opioid use ≥1 year		
Yes	97 (67.8)	12 (80.0)
No	46 (32.2)	3 (20.0)
Age group (yrs)		
18–44	36 (25.2)	1 (6.7)
45–64	82 (57.3)	10 (66.7)
≥65	25 (17.5)	4 (26.7)
Sex		
Female	135 (94.4)	12 (80.0)
Male	8 (5.6)	3 (20.0)
Race		
White	59 (41.3)	6 (40.0)
Black	76 (53.2)	8 (53.3)
Other/unknown	8 (5.6)	1 (6.7)
Income		
Income <U.S. median	96 (67.1)	13 (86.7)
Income ≥U.S. median	37 (25.9)	2 (13.3)
Education		
Less than high school	22 (15.4)	3 (20.0)
High school diploma/GED	17 (11.9)	5 (33.3)
Some college/Associate degree	76 (53.2)	4 (26.7)
Bachelor's degree	14 (9.8)	3 (20.0)
Graduate/Professional degree	14 (9.8)	0 (0.0)
Employment		
Unemployed	81 (56.6)	9 (60.0)
Employed and/or in school	62 (43.4)	6 (40.0)
Insurance		
Private/Other	37 (25.9)	3 (20.0)
Medicaid/Medicare	105 (73.4)	12 (80.0)
None	1 (0.7)	0 (0.0)
Patient-reported outcomes		
Emergency department use		
Yes (in last 12 months)	96 (67.1)	9 (60.0)
No	45 (31.5)	6 (40.0)

See table footnotes on next column.

when assessing the total population and SLE patients only; for each one standard deviation increase (worsening) in pain and physical function scores, the odds of opioid use were approximately 35% and 12% higher, respectively.

Discussion

In this study documenting the extent of prescription opioid use in patients with SLE, nearly one third of SLE patients in a well-characterized cohort used prescription opioids during 2014–2015, compared with 8% of frequency-matched persons without SLE. Approximately 70% of the SLE patients taking prescription opioids were on opioid therapy for >1 year. The higher odds of prescription opioid use among patients persisted after accounting for several factors in multivariable models. ED use in the last 12 months was associated with opioid use in both the total population and among SLE patients.

TABLE 2. (Continued) Characteristics of persons reporting current prescription opioid use — Michigan Lupus Epidemiology and Surveillance (MILES) Program, 2014–2015

Factor	No. (%) of prescription opioid users	
	SLE patients (n = 143)	Nonpatients (n = 15)
Fibromyalgia		
Yes	89 (62.2)	10 (66.7)
No	54 (37.8)	5 (33.3)
Pain score*[†]		
<70	60 (42.0)	6 (40.0)
≥70	83 (58.0)	9 (60.0)
Physical function score*[†]		
<70	73 (51.1)	12 (80.0)
≥70	70 (49.0)	3 (20.0)
Depression score^{†,§}		
<56.2	74 (51.8)	8 (53.3)
≥56.2	67 (46.9)	7 (46.7)
Anxiety score^{†,§}		
<62.3	99 (69.2)	13 (86.7)
≥62.3	42 (29.4)	2 (13.3)
SLE-specific measures		
SLE duration		
<15 yrs	29 (20.3)	NA
≥15 yrs	113 (79.0)	NA
SLE activity score[†]		
SLAQ <12	37 (25.9)	NA
SLAQ ≥12	106 (74.1)	NA
SLE damage score[†]		
LDIQ <5	41 (28.7)	NA
LDIQ ≥5	102 (71.3)	NA

Abbreviations: GED = General Educational Development certificate; LDIQ = lupus damage index questionnaire; NA = not applicable; SLAQ = systemic lupus activity questionnaire; SLE = systemic lupus erythematosus.

* For both the pain and physical function measures, scores were reversed from their original RAND Medical Outcomes Study 36-item Short-Form-Survey instrument values so that higher scores represent worse pain and physical functioning, respectively. Cut-points reflect 2 standard deviations from the mean.

[†] Higher score is worse.

[§] Patient-Reported Outcomes Measurement Information System depression and anxiety score cut-points were based on PROsetta Stone mapping to the Center for Epidemiologic Studies Depression and Generalized Anxiety Disorder 7-item scales, respectively.

The widespread and long-term use of prescription opioids among this cohort of patients with SLE was striking given lack of evidence regarding safety and efficacy of opioids for treating chronic pain associated with rheumatic disease (1,7). Particularly concerning is that some of the less appreciated medical risks associated with long-term opioid use, such as myocardial infarction, immunosuppression, and osteoporosis (8), are potentially compounded in persons with SLE, whose baseline risks for these comorbidities are elevated because of the underlying disease and adverse effects of immunosuppressive and glucocorticoid therapies. Further, recent preliminary data suggest that opioids are associated with increased mortality in lupus.[¶]

[¶] <https://acrabstracts.org/abstract/opioid-use-and-death-in-chronic-pain-patients-with-systemic-lupus-erythematosus/>.

TABLE 3. Factors associated with prescription opioid use, based on separate multivariable logistic regression models* for the total study population and systemic lupus erythematosus (SLE) patients only — Michigan Lupus Epidemiology and Surveillance (MILES) Program, 2014–2015

Characteristic	Total study population (n = 654)			SLE patients only (n = 462)		
	Prescription opioid use prevalence	OR (95% CI)	p-value	Prescription opioid use prevalence	OR (95% CI)	p-value
Patient status						
Nonpatient	7.8%	referent	NA	NA	NA	NA
SLE	31.0%	3.36 (1.72–6.57)	<0.001	NA	NA	NA
Age (yrs)	NA	1.00 (0.98–1.02)	NS	NA	0.99 (0.96–1.01)	NS
Sex						
Male	15.7%	referent	NA	25.0%	referent	NA
Female	25.2%	0.80 (0.35–1.86)	NS	31.4%	0.78 (0.28–2.17)	NS
Race						
White	19.1%	referent	NA	25.3%	NA	NA
Black	29.5%	1.01 (0.62–1.66)	NS	36.5%	1.03 (0.60–1.76)	NS
Other/Unknown	31.0%	1.14 (0.35–3.70)	NS	38.1%	1.10 (0.30–4.07)	NS
Income						
>U.S. median	14.6%	referent	NA	18.7%	referent	NA
≤U.S. median	31.1%	1.21 (0.68–2.14)	NS	40.5%	1.14 (0.62–2.11)	NS
Education (yrs)	NA	0.93 (0.84–1.02)	NS	NA	0.92 (0.83–1.02)	NS
Employment						
Employed and/or in school	16.1%	referent	NA	21.7%	referent	NA
Unemployed	39.0%	1.32 (0.82–2.11)	NS	46.0%	1.21 (0.72–2.03)	NS
Insurance						
Private	13.3%	referent	NA	18.0%	referent	NA
Medicaid/Medicare	34.9%	1.45 (0.82–2.56)	NS	42.7%	1.60 (0.85–3.00)	NS
None	5.9%	0.39 (0.03–4.27)	NS	10.0%	0.43 (0.04–4.79)	NS
Patient-reported outcomes						
Emergency department use						
No visits	13.4%	referent	NA	18.3%	referent	NA
≥1 visit last 12 mos	39.0%	2.22 (1.39–3.55)	0.001	45.1%	2.14 (1.27–3.59)	0.004
Fibromyalgia						
No	13.4%	referent	NA	19.9%	referent	NA
Yes	46.1%	1.50 (0.89–2.54)	NS	46.8%	1.18 (0.64–2.16)	NS
Pain score^{†,§}	NA	1.35 (1.19–1.53)	<0.001	NA	1.36 (1.18–1.58)	<0.001
Physical function score^{†,§}	NA	1.11 (1.00–1.24)	0.047	NA	1.13 (1.00–1.27)	0.042
Depression score[§]	NA	1.01 (0.97–1.05)	NS	NA	1.01 (0.97–1.05)	NS
Anxiety score[§]	NA	0.97 (0.94–1.01)	NS	NA	0.98 (0.94–1.02)	NS
SLE-specific measures						
SLE duration (years)	NA	NA	NA	NA	1.02 (0.99–1.05)	NS
Activity (SLAQ score) [§]	NA	NA	NA	NA	1.01 (0.96–1.06)	NS
Damage (LDIQ score) [§]	NA	NA	NA	NA	0.98 (0.92–1.05)	NS

Abbreviations: CI = confidence interval; LDIQ = lupus damage index questionnaire; NA = not applicable; NS = not significant; OR = odds ratio; SLAQ = systemic lupus activity questionnaire; SLE = systemic lupus erythematosus.

* Each multivariable model includes all listed factors (i.e., odds ratios are adjusted for all other variables listed in the table): SLE versus nonpatient status (for total population model), age, sex, race, income, education, employment, health insurance, emergency department use, fibromyalgia, pain score, physical function score, depression score, and anxiety score. The SLE patient only model also included SLE duration, SLE activity score, and SLE damage score.

† For both the pain and physical function measures, scores were reversed from their original RAND Medical Outcomes Study 36-item Short-Form-Survey instrument values so that higher scores represent worse pain and physical functioning, respectively. For the regression models, the (reversed) pain and physical function scores were scaled by their standard deviations of 10; therefore, each unit change represents one standard deviation change.

§ Higher score is worse.

Whereas rheumatic diseases are a leading cause of chronic, noncancer pain (7), data on opioid use and associated outcomes in persons with rheumatic diseases are limited. One recent study of Medicare beneficiaries with rheumatoid arthritis estimated regular opioid use (three or more filled prescriptions or one or more filled 90-day prescription per calendar year) at approximately 40% (9). Together with the findings

from this analysis, the prevalent use of opioids in at least two patient populations with rheumatic diseases supports the need for better understanding of prescribing patterns, risk factors associated with opioid initiation and long-term continuation, and pharmacoepidemiology related to adverse medical effects of opioids in these patients. Effective interventions in this population will need to couple tailored approaches for tapering

Summary**What is already known about this topic?**

Opioids are generally not indicated for pain in systemic lupus erythematosus (SLE) and other rheumatic diseases because of limited efficacy and risks for addiction and adverse health effects.

What is added by this report?

Nearly one third of patients with SLE in an established Michigan cohort used prescription opioids, with approximately two thirds of those using for >1 year. Emergency department use was associated with increased prescription opioid use.

What are the implications for public health practice?

Risks for long-term opioid therapy, including osteoporosis and cardiovascular disease, are concerning in SLE patients given their increased underlying risks for these comorbidities. Strategies for reducing opioid use are needed in rheumatic disease populations. Clinicians managing SLE, including providers in emergency departments, need to be aware of these risks and consider nonopioid pain management strategies.

and discontinuing opioids when indicated, along with prevention of opioid initiation and consideration of nonopioid pain management strategies.

Interventions to address opioid use in patients with rheumatic diseases will require a better understanding of pain management for patients with these complex, chronic conditions, whose sources of pain might be multiple, persistent, and severe, and which must be accurately diagnosed to be appropriately treated. Sources of SLE-related pain can include active inflammatory disease resulting in peripheral pain (e.g., arthritis), damage accrual attributable to the disease or its treatment (e.g., steroid-induced osteonecrosis or vertebral fractures), or centralized pain disorders, such as fibromyalgia, the prevalence of which is higher in patients with SLE than in the general population (4).

The findings in this report are subject to at least five limitations. First, prescription data were self-reported, which limited the ability to examine sources of opioid prescribing or dosing patterns in more detail and could have been subject to underreporting attributable to social desirability bias. Second, since the original SLE registry reflected the demographics of southeastern Michigan (which is predominantly black and white), Asians, Hispanics, and other groups were not well represented, and results might not be generalizable to the wider SLE population. Third, this report addresses prescription opioid use, but information on other potential opioid sources is unavailable. Fourth, these data reflect 2014–2015; trends in opioid prescribing and usage might have changed since then. Finally, the cross-sectional nature of this analysis precludes assessing temporal relationships for factors associated with prescription opioid use. Strengths of this study include

starting from a population-based SLE registry, inclusion of relatively large numbers of well-defined patients with SLE, comparing to age-, sex-, race-, and county-matched persons without SLE, and use of validated patient-reported outcome measures to assess psychosocial and lupus-specific factors in relation to prescription opioid use.

In conclusion, during 2014–2015, one third of patients in a SLE cohort in southeastern Michigan were using prescription opioids, most for longer than 1 year. Given the risks for opioid therapy and the lack of pain efficacy data in SLE, it is important that clinicians managing SLE, including providers in EDs, be aware of the potential adverse effects of opioid therapy in these patients, consider nonopioid pain management strategies, and be familiar with guidance for opioid tapering or discontinuation when patients are not achieving treatment goals of reduced pain and increased function or when otherwise indicated (2).

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Progress Toward Poliovirus Containment Implementation — Worldwide, 2018–2019

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Among the three wild poliovirus (WPV) types, type 2 (WPV2) was declared eradicated globally by the Global Commission for the Certification of Poliomyelitis Eradication (GCC) in 2015. Subsequently, in 2016, a global withdrawal of Sabin type 2 oral poliovirus vaccine (OPV2) from routine use, through a synchronized switch from the trivalent formulation of oral poliovirus vaccine (tOPV, containing vaccine virus types 1, 2, and 3) to the bivalent form (bOPV, containing types 1 and 3), was implemented. WPV type 3 (WPV3), last detected in 2012 (1), will possibly be declared eradicated in late 2019.* To ensure that polioviruses are not reintroduced to the human population after eradication, World Health Organization (WHO) Member States committed in 2015 to containing all polioviruses in poliovirus-essential facilities (PEFs) that are certified to meet stringent containment criteria; implementation of containment activities began that year for facilities retaining type 2 polioviruses (PV2), including type 2 oral poliovirus vaccine (OPV) materials (2). As of August 1, 2019, 26 countries have nominated 74 PEFs to retain PV2 materials. Twenty-five of these countries have established national authorities for containment (NACs), which are institutions nominated by ministries of health or equivalent bodies to be responsible for poliovirus containment certification. All designated PEFs are required to be enrolled in the certification process by December 31, 2019 (3). When GCC certifies WPV3 eradication, WPV3 and vaccine-derived poliovirus (VDPV) type 3 materials will also be required to be contained, leading to a temporary increase in the number of designated PEFs. When safer alternatives to wild and OPV/Sabin strains that do not require containment conditions are available for diagnostic and serologic testing, the number of PEFs will decrease. Facilities continuing to work with polioviruses after global eradication must minimize the risk for reintroduction into communities by adopting effective biorisk management practices.

Background

Since the Global Polio Eradication Initiative began, the number of reported WPV cases has declined from an estimated 350,000 WPV cases in 125 countries during 1988 to

66 cases in two countries with ongoing endemic transmission during 2019 (as of August 20, 2019); an estimated 18 million paralytic poliomyelitis cases have been prevented during the past 30 years.† Although WPV transmission is now limited to two countries, 14 countries (as of September 17, 2019) currently have circulating VDPVs (cVDPVs) (i.e., rare strains of poliovirus that have genetically mutated from the vaccine strain and reverted to neurovirulence during replication as they circulate in communities) (Global Polio Eradication Initiative, unpublished data, 2019). cVDPVs can emerge in areas with low immunization coverage and cause outbreaks of paralytic poliomyelitis. Immunodeficiency-associated VDPVs can emerge in persons with primary immunodeficiencies and can be excreted for years, even by persons who are treated for their immunodeficiency. Immunodeficiency-associated VDPVs are rare; 111 cases have been documented since 1962. To provide immunity to type 2 poliovirus, a single dose of inactivated poliovirus vaccine (IPV) was introduced into the immunization schedule in most OPV-using countries before the global switch from tOPV to bOPV in 2016, and more recently in all other OPV-using countries. IPV provides serologic immunity to all three types of poliovirus, resulting in protection against paralytic poliomyelitis. However, studies indicate that the extent of mucosal immunity in the intestine conferred by IPV is significantly less than that provided by OPV (4); therefore, OPV continues to be used for outbreak responses to stop poliovirus transmission. When WPV eradication is achieved, countries hosting PEFs should continue the use of IPV, and all other countries without PEFs should maintain IPV in their routine immunization schedule for at least 10 years after global withdrawal of all OPV (5).

Once global polio eradication is achieved, and mass vaccination campaigns are no longer conducted, population immunity to polioviruses will decline. Thus, the consequences of any poliovirus introduction into communities from a facility containment breach would be severe. To mitigate this risk, all 194 WHO Member States resolved at the 68th World Health Assembly in 2015 to ensure that all polioviruses would be held only in specially certified poliovirus containment facilities (6).

* <http://polioeradication.org/wp-content/uploads/2016/07/GCC-report-26-27-Feb-2019-20190227.pdf>.

† <https://www.who.int/news-room/fact-sheets/detail/poliomyelitis>.

A revised WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII), released in 2015 (5), outlines the biorisk management requirements for laboratories, vaccine production sites, and other facilities retaining polioviruses (Figure). The Containment Certification Scheme to support GAPIII (GAPIII-CCS), which defined a process for independent certification of facilities, was endorsed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and released in 2016 (7).

Global Poliovirus Containment Progress

GAPIII outlined a phased approach to poliovirus containment, beginning with PV2 materials. Phase I focuses on national facility surveys to identify and reduce the number of facilities retaining those materials; Phase II outlines activities related to certification of all PEFs retaining PV2 materials; and Phase III includes the final containment of all types of WPV, VDPV, and OPV/Sabin polioviruses (2). Phase I and Phase II activities are currently being implemented in parallel. A previous report indicated that Phase I inventories for facilities retaining PV2 infectious materials were complete (8). However, the most recent data show that because of previous underreporting, some WHO regions report an increase in the number of facilities holding PV2 materials, although the number of PEFs has decreased globally. In 2016, approximately 100 PV2 facilities worldwide intended to become GAPIII-certified; this number declined to 86 in 2017, to 81 in 2018, and to 74 as of August 1, 2019 (Table). This reduction in candidate PEFs occurred in part because many facility managers elected not to implement the rigorous requirements for containment certification and have ceased or will soon cease working with PV2 materials. The remaining 74 facilities are located in 26 countries, 25 of which have established NACs to oversee facility compliance and certification, with the final country working through its domestic legal process to establish a NAC.

In addition to identifying facilities retaining WPV and cVDPVs, countries are also required to identify laboratories retaining potentially infectious materials (i.e., specimens collected for other purposes in countries where WPV and cVDPVs were in circulation). Laboratories with a high probability of handling or storing potentially infectious poliovirus materials include those working with enteric or respiratory disease agents and facilities engaged in nutrition research or environmental studies. To aid countries in identifying facilities retaining potentially infectious materials, WHO published *Guidance to Minimize Risks for Facilities Collecting, Handling or Storing Materials Potentially Infectious for Polioviruses* in 2018 (9). The rollout of this guidance included ongoing country technical support, targeted country visits, webinars, and WHO-led national and

Summary

What is already known about this topic?

After certification of eradication of wild poliovirus type 2 in 2015, World Health Organization Member States committed to contain all poliovirus materials safely.

What is added by this report?

Twenty-six countries have designated 74 poliovirus type 2 poliovirus-essential facilities to retain poliovirus type 2 materials; these countries need to begin the certification process before the end of 2019. Upon certification of wild poliovirus type 3 eradication and expanded manufacture of monovalent oral poliovirus type 2 to combat ongoing vaccine-derived poliovirus type 2 outbreaks, the number of designated poliovirus-essential facilities will increase.

What are the implications for public health practice?

After the world is certified polio-free, all poliovirus serotypes ultimately will require secure containment because any release into communities could result in widespread transmission.

regional workshops. Global implementation of this guidance has been challenging because of its labor-intensive nature and application to thousands of laboratories worldwide.

By resolution of WHO Member States at the 71st World Health Assembly in 2018, all facilities designated to retain PV2 materials (including OPV2/Sabin type 2 infectious materials) are required to be enrolled in the certification process through NACs by December 31, 2019. To date, seven NACs have submitted 13 applications to GCC; seven have been accepted by the GCC Containment Working Group, which conducts the reviews.[§] Facility auditing by GAPIII-CCS-qualified auditors is required to certify a PEF. Auditor qualification is ongoing; 142 auditor trainees from 27 countries have passed preliminary GAPIII-CCS training, and 10 lead auditors will be fully qualified by the end of 2020.

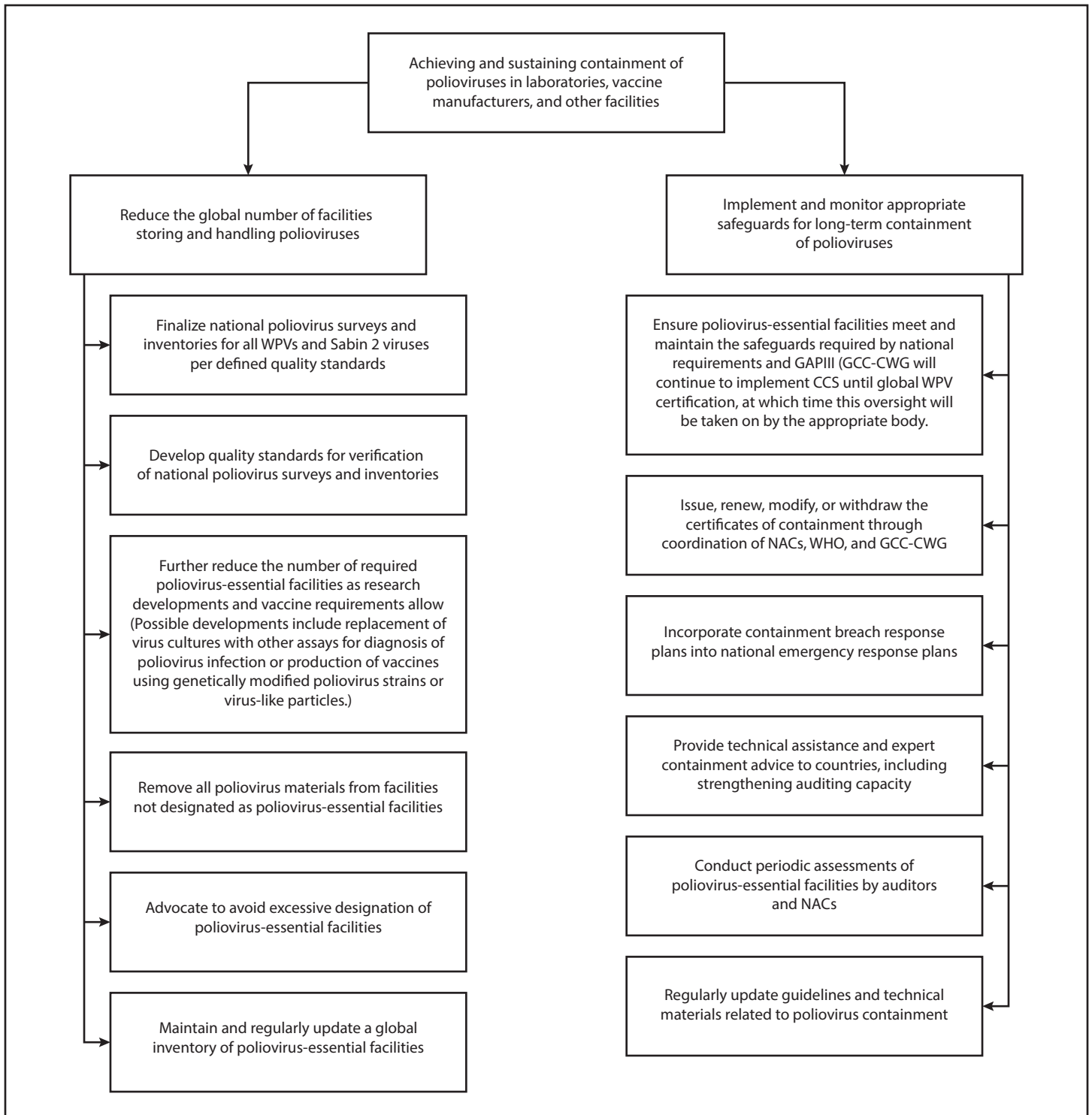
If WPV3 is declared eradicated, poliovirus type 3 containment would begin with a focus on WPV3 and VDPV type 3. OPV3/Sabin type 3 containment processes would not begin until OPV3 is withdrawn from routine immunization programs and campaigns, currently scheduled as part of the global withdrawal of bOPV after WPV type 1 (WPV1) is also eradicated. The 71st World Health Assembly resolution urged countries to accelerate completion of national surveys for WPV1 and WPV3 infectious and potentially infectious materials (10).

cVDPV2 Outbreak Containment Challenges

After declaration of WPV2 eradication in 2015, a coordinated global switch from tOPV to bOPV for routine

[§] <http://polioeradication.org/wp-content/uploads/2016/07/rolling-timeline-for-containment-certification-applications-20190710.pdf>.

FIGURE. Planned major poliovirus containment activities of the Polio Endgame Strategy — worldwide, 2019–2023



Abbreviations: CCS = Containment Certification Scheme; GAPIII = WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use; GCC-CWG = Global Commission for the Certification of Poliomyelitis Eradication Containment Working Group; NAC = national authority for containment; WHO = World Health Organization; WPV = wild poliovirus.

TABLE. Number of designated poliovirus-essential facilities (PEFs) retaining poliovirus type 2 (PV2) materials* and established national authorities for containment (NACs), by World Health Organization (WHO) region — worldwide, August 2019[†]

WHO region	Type of PV2 materials retained, no. of facilities						Facility types, no.		
	No. of countries	No. of NACs	No. of PEFs	Only WPV/VDPV type 2	Both WPV/VDPV type 2 and OPV/Sabin type 2	Only OPV/Sabin type 2	Vaccine production		
							Salk (WPV)-IPV	Sabin-IPV [§]	Diagnostic or research laboratories
African Region	1	1	1	0	1	0	0	0	1
Region of the Americas	5	5	18	6	4	8	1	0	17
Eastern Mediterranean Region [¶]	2	2	3	0	1	1	0	2	1
European Region	11	10	34	3	20	11	5	2	27
South-East Asia Region	2	2	2	0	1	1	0	1	1
Western Pacific Region	5	5	16	0	4	12	0	11	5
Total	26	25	74	9	31	33	6	16	52

Abbreviations: IPV = inactivated poliovirus vaccine; OPV = oral poliovirus vaccine; VDPV2 = type 2 vaccine-derived poliovirus; WPV = wild poliovirus; WPV2 = wild poliovirus type 2.

* Includes WPV2/VDPV2 and OPV2/Sabin type 2.

[†] Data as of August 1, 2019.

[§] Includes potential future producers in different clinical and preclinical phases of Sabin-IPV development.

[¶] One PEF in this region does not currently retain PV2 material but is pursuing certification for future work.

immunization and supplementary immunization activities took place in 2016. To mitigate the risks associated with the withdrawal of OPV2, SAGE recommended that all OPV-using countries introduce at least 1 dose of IPV into their routine immunization program. As a result of challenges in reaching unimmunized and underimmunized children in some areas before the switch, an increasing number of circulating VDPV type 2 (cVDPV2) outbreaks have been reported since the switch, including three in 2016, four in 2017, six in 2018, and 14 to date in 2019. The increasing number of cVDPV2 outbreaks after the switch has led to a corresponding increase in monovalent OPV2 (mOPV2, containing type 2 vaccine virus) outbreak response immunization activities, resulting in a projected administration of 312 million doses by the end of 2019. The ongoing challenges with cVDPV2 outbreaks and the increased need for mOPV2 could lead vaccine manufacturers to restart mOPV2 production and enrolling facilities in GAPIII certification, increasing the global poliovirus containment workload. Intensified coordination among multiple WHO and United Nations Children's Fund teams and country authorities will be crucial to ensuring uninterrupted availability of mOPV2 produced under applicable biorisk management controls. cVDPV2 outbreaks subsequent to mOPV2 use will require countries with facilities handling infectious and potentially infectious materials to repeat PV2 surveys once the outbreaks have ended.

Discussion

The new Global Polio Eradication Initiative Polio Endgame Strategy 2019–2023 (1) contains three important pillars: eradication, integration, and containment/certification. The containment section focuses on further reducing the number

of PEFs and the implementation and monitoring of safeguards for long-term containment of polioviruses. After global eradication of all WPVs and eventual bOPV cessation, fully certified containment of all polioviruses in research and quality control laboratories, vaccine manufacturing facilities, biomedical facilities, and biological repositories is crucial. Containment efforts include minimizing the number of facilities retaining poliovirus materials and ensuring that all poliovirus research facilities comply with containment guidelines. Ongoing poliovirus research facilitates the development and deployment of alternative, genetically stable polioviruses that are safe to use in vaccination and that can be produced and used outside containment.

Researchers have made important progress in replacing Sabin strains for diagnostic and serologic assays (e.g., with genetically stable novel OPVs) (4) and in developing IPV made from Sabin and safer poliovirus strains to reduce risks from the use of live WPV in IPV production. These advances will result in a requirement for fewer poliovirus containment facilities and a corresponding reduction in overall risk for poliovirus release.

Since GAPIII was published in 2015, the addition of Guidance to Minimize Risks for Facilities Collecting, Handling or Storing Materials Potentially Infectious for Polioviruses and recommendations from the WHO Containment Advisory Group have resulted in modifications to poliovirus containment requirements, including the removal of full GAPIII requirements for handling poliovirus RNA and OPV2/Sabin type 2 potentially infectious material.^{¶,***} An update to GAPIII, highlighting these approved changes, is anticipated

[¶] <http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-supporting-groups/>.

^{***} <http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>.

by the end of 2020. After polio eradication, maintaining the global polio-free status will require vigilance and, for facilities retaining poliovirus, strict adherence to GAPIII requirements.

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Errata

Vol. 68, No. 36

In the report “Severe Pulmonary Disease Associated with Electronic-Cigarette–Product Use — Interim Guidance” an author’s affiliation should have read as follows:

Dana Meaney-Delman, MD¹² ¹²**Division of Birth Defects and Infant Disorders, National Center on Birth Defects and Developmental Disabilities, CDC.**

In addition, the following person should have been included among the members of the CDC 2019 Lung Injury Response Group:

Livia Navon (Center for Preparedness and Response, Division of State and Local Readiness, assigned to the Illinois Department of Health).

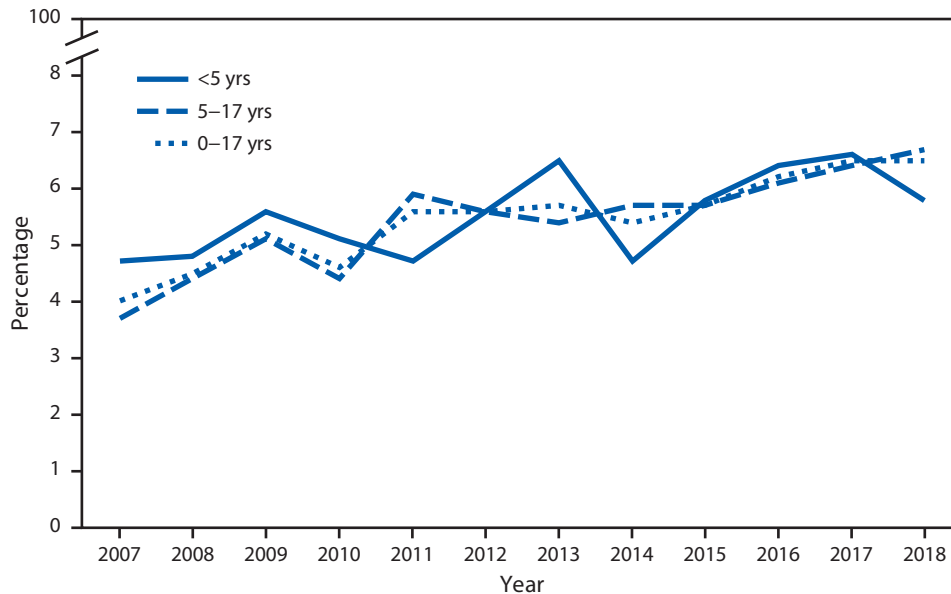
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In the report “Notes from the Field: Interventions to Reduce Measles Virus Exposures in Outpatient Health Care Facilities — New York City, 2018,” on page 791, the Acknowledgments should have read “L. Hannah Gould, New York City Department of Health and Mental Hygiene; Mona Marin, Jennifer Wright, **Zeshan Chisty**, CDC; all staff members from participating health care facilities in New York City.”

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage of Children Aged <18 Years with a Food or Digestive Allergy in the Past 12 Months,* by Age Group — National Health Interview Survey, 2007–2018†



* Based on the response of “yes” to the survey question, asked of the parent or guardian, “During the past 12 months, has [child’s name] had any kind of food or digestive allergy?”

† Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population and are derived from the National Health Interview Survey sample child component.

During 2007 to 2018, the percentage of children aged 0–17 years with a food or digestive allergy in the past 12 months increased from 4.0% in 2007 to 6.5% in 2018. Among children aged <5 years, the percentage of food or digestive allergies increased from 4.7% to 5.8%, and among children aged 5–17 years, the percentage of food or digestive allergies also increased from 3.7% to 6.7%.

Source: National Health Interview Survey, 2007–2018 data. <https://www.cdc.gov/nchs/nhis.htm>.

Reported by: Alison Filbey; Benjamin Zablotzky, PhD, bzablotzky@cdc.gov, 301-458-4621; Carla Zelaya, PhD.

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