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Public Health Surveillance and Reporting for Human Toxoplasmosis — Six States, 2021

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Toxoplasmosis is caused by infection with the zoonotic parasite *Toxoplasma gondii*. Although disease tends to be mild (e.g., self-limiting influenza-like symptoms) or asymptomatic in immunocompetent persons, toxoplasmosis is more severe in immunocompromised persons, who can develop potentially fatal encephalopathy (*1*). In addition, primary infections acquired during pregnancy might result in a range of adverse outcomes, including fetal ocular infection, cranial and neurologic deformities, stillbirth, and miscarriage (*1*,*2*). An estimated 11% of the U.S. population aged ≥6 years are seropositive for toxoplasmosis, based on analysis of sera collected through the National Health and Nutrition Examination Survey during 2011–2014 (*3*). Toxoplasmosis is not a nationally notifiable disease in the United States, and currently no national public health surveillance data are available; however, it is reportable in eight states. To better understand how surveillance data are collected and used, reviews of state-level toxoplasmosis surveillance were conducted during June–July 2021 using semistructured interviews with health officials in six states (Arkansas, Kentucky, Minnesota, Nebraska, Pennsylvania, and Wisconsin) where toxoplasmosis is currently reportable. Why or when toxoplasmosis became reportable could not be determined, and many of the states had limited capacity to respond to reported cases. Case definitions varied considerably in terms of clinical description, laboratory criteria, and case classification (i.e., confirmed, probable, or suspect), limiting disease estimates and comparisons among states. Implementation of a standardized case definition would help ensure that cases are counted consistently, enabling better use of surveillance data to characterize disease. Identifying newly acquired cases is challenging because most acute cases among immunocompetent persons (including pregnant women) are asymptomatic, disease among immunocompromised persons is likely reactivation of latent disease, and congenital infections might not manifest until later in life.

Members of the family Felidae (cats) are definitive hosts for *T. gondii*. Humans can be infected through various routes, including fecal-oral contamination from cats; consumption of undercooked contaminated meat, contaminated unwashed fruits or vegetables, contaminated water, and unpasteurized milk; vertical transmission from an infected mother; and organ transplantation. Toxoplasmosis is likely underdiagnosed in the United States: approximately 90% of infections among immunocompetent persons are asymptomatic or nonspecific and self-limiting (*1*); when symptoms are present, they can potentially mimic other more frequently encountered illnesses,

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including influenza and tickborne-diseases such as Lyme disease or anaplasmosis; thus, physician awareness and clinical suspicion of toxoplasmosis might be low, resulting in delays in or missed opportunities for diagnosis and case identification (*4*,*5*). No national maternal toxoplasmosis screening program currently exists, and most infants born with congenital toxoplasmosis appear normal at birth (*1*,*2*). Because reactivation of toxoplasmosis during immunocompromise can be rapidly fatal, and outcomes of congenital infection can be severe, toxoplasmosis surveillance could help improve awareness and understanding of disease prevalence and transmission routes and identify opportunities for prevention and control.

States where toxoplasmosis is reportable were identified using the State Reportable Conditions Assessment query tool on the Council of State and Territorial Epidemiologists (CSTE) website* and supplemented by reviewing reportable diseases lists accessed from state health department websites for inclusion of toxoplasmosis. A modified version of a qualitative questionnaire used for Chagas disease surveillance (*6*) was developed to identify why toxoplasmosis was designated a reportable condition in the state, how cases are reported and by whom, what actions are taken after case identification, how surveillance data are used and disseminated, whether nonhuman data are collected and used, and whether formal toxoplasmosis maternal screening programs are in place (*6*). State public health veterinarians were contacted by email and invited to participate either by telephone or virtual interview or to complete the questionnaire. The purpose and scope of the project, as well as a copy of the questionnaire, were included in this initial email. This activity was reviewed by CDC and was conducted consistent with applicable federal law and policy.†

As of April 2021, toxoplasmosis is reportable in eight states (Arkansas, Delaware, Hawaii, Kentucky, Minnesota, Nebraska, Pennsylvania, and Wisconsin); among these states, public health personnel from six (Arkansas, Kentucky, Minnesota, Nebraska, Pennsylvania, and Wisconsin) agreed to participate and were interviewed. The historic dates when toxoplasmosis became reportable and the reasons for initiating surveillance could not be determined. Toxoplasmosis had been reportable for as long as could be remembered and reviewing historical case data could not further elucidate a starting date. Several possible reasons were suggested for why toxoplasmosis was made reportable, including monitoring disease prevalence, a need to identify the source of infection, the effect of toxoplasmosis on pregnancy, congenital transmission, and outbreak identification. In addition, whether any substantial changes had occurred in how surveillance data were collected since toxoplasmosis became reportable also could not be determined.

Case definitions were provided by the states and varied considerably in both clinical and laboratory criteria and how cases are classified (Table). Variations in clinical descriptions

* https://www.cste.org/group/SRCAQueryRes

† 45 C.F.R. part 46; 21 C.F.R. part 56.

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TABLE. Toxoplasmosis surveillance case definitions — six states, 2021

State	Clinical description	Laboratory criteria	Case classification
Arkansas	Cervical lymphadenopathy and/or influenza-like illness and/or ocular infection with vision loss	Elevated *Toxoplasma gondii*–specific IgG, IgM, IgA, and/or IgE titers (presumptive) Isolation of *T. gondii* in blood/fluids; detection of tachyzoites in tissue; and/or detection using PCR (confirmatory)	Probable: a clinically compatible case or asymptomatic person* with laboratory results indicative of presumptive infection Confirmed: a clinically compatible case with confirmatory laboratory results
Kentucky	Fever, lymphadenopathy, and/or lymphocytosis Immunocompromised persons: above, plus myocarditis, pneumonia, and/or cerebral signs Infection during pregnancy: congenital anomalies or infant mortality	Single antibody titer (suspect) Significant change in paired specimen antibody titers; demonstration of *T. gondii* in tissues/fluids; detection by PCR; and/or specific IgM or increasing titer in sera in congenital infection (confirmed)	Probable: a clinically compatible illness that is laboratory suspect Confirmed: a clinically compatible illness that is laboratory confirmed; clinical diagnosis and laboratory confirmed
Minnesota	Influenza-like illness, fever, lymphadenopathy, ocular pain, chorioretinitis, encephalitis, other systemic manifestations	Positive IgM test with or without positive IgG test (without confirmation at reference laboratory) (probable) Demonstration of *T. gondii* in any tissue; or *T. gondii* diagnosis by ocular exam; or positive PCR; or positive IgM confirmed at reference laboratory; or low IgG avidity test (confirmatory) Positive IgG with negative or equivocal IgM; or positive IgG and positive IgM on screening but negative IgM by confirmatory test; or high IgG avidity (chronic)	Probable: a clinically compatible illness with positive IgM test and without confirmation at reference laboratory Confirmed: a clinically compatible illness with any of the listed confirmatory laboratory criteria Chronic: laboratory results indicative of infection acquired in the distant past
Nebraska	Fever, lymphadenopathy, malaise, myalgia, lymphocytosis, and/or elevated liver enzymes Immunocompromised: chorioretinitis, myocarditis, pneumonia, and/or encephalitis Neonatal infection: fever, rash, jaundice, and/or chorioretinitis Infection during pregnancy: infant death or congenital abnormalities	Detection of *T. gondii* in tissue or by PCR; and/or IgG/IgM change in paired serology; in infants, demonstration of specific IgM or increasing titer in paired sera (confirmed)	Confirmed: a clinically compatible illness that is laboratory confirmed
Pennsylvania	Immunocompetent: lymphadenopathy and/or ocular infection (uveitis) Immunodeficient: encephalitic symptoms with or without pulmonary/cardiac involvement Newborn infants (early pregnancy infection): fever, lymphadenopathy, microcephaly, megalocephaly, rash, and/or anemia Newborn infants (third trimester infection): ocular complications/ developmental delays in later life	Sequential sera displaying fourfold rise in *T. gondii*–specific IgG antibody titer (supportive) Demonstration of *T. gondii* organisms in tissue; demonstration of tachyzoites in tissue by histopathology; and/or positive PCR (confirmatory)	Probable: a case that meets the clinical case definition and has only supportive laboratory results Confirmed: a case that meets the clinical case definition and is laboratory confirmed Suspect: a case that meets clinical case definition and has other laboratory testing, or no laboratory testing was performed
Wisconsin	Fever, lymphadenopathy, and/or lymphocytosis Immunocompromised: above, plus myocarditis, pneumonia, and/or cerebral signs Infection during pregnancy: congenital anomalies or infant mortality	Change in paired specimen antibody titer; demonstration of *T. gondii* in tissues/ fluids; detection by PCR; and/or specific IgM† or increasing titer in sera in congenital infection (confirmed)	Confirmed: a clinically compatible illness that is laboratory confirmed

Abbreviations: Ig = immunoglobulin; PCR = polymerase chain reaction; *T. gondii* = *Toxoplasmosis gondii*.
* Asymptomatic persons with laboratory evidence of presumptive infection are counted as a probable case at the time of initial report.
† Demonstration of IgM antibody in adults does not meet case definition.

included a separate description for immunocompromised persons (all states except Arkansas and Minnesota); a separate description for infection acquired during pregnancy (Kentucky, Nebraska, and Wisconsin); further separation based on timing of infection during pregnancy (early versus late; Pennsylvania); and a category for chronic infection status (Minnesota). Signs and symptoms used in each clinical description category were similar but not consistent. Variations in laboratory criteria included whether paired or sequential antibody testing was confirmatory (all states except Arkansas and Pennsylvania); single antibody titers as presumptive/suggestive criteria (Arkansas and Kentucky); criteria for congenital infection in infants (Kentucky, Nebraska, and Wisconsin); and a criterion that included testing at a reference laboratory (Minnesota). Among the variations in case classification were that Nebraska and Wisconsin had only a "confirmed" case classification and no "probable" classification, Pennsylvania also included a "suspect" classification, and Minnesota's case classifications specified "confirmed," "probable," and "chronic."

After notification of a case, all states attempt to investigate to determine exposure and clinical history; however, investigation depends on resource availability. Laboratories are the primary reporting source in all states, although physicians might also report cases. No state reported having formal maternal screening programs for toxoplasmosis; however, maternal screening is frequently recorded as the reason for testing on case report forms submitted to the state health department (Minnesota). No states collected nonhuman data as a routine part of toxoplasmosis surveillance. The Nebraska state public health veterinarian indicated that their office receives data from the state veterinary diagnostic laboratory about toxoplasmosis diagnosed in animals. Although such reports contain the animal owner's city and zip code, they do not name the owner and are not formally integrated with the human case surveillance program.

Dissemination of surveillance data occurs through public reports posted to state health department websites (Arkansas, Minnesota, and Wisconsin) or updates to toxoplasmosis case counts in annual disease tables available on the state health department website (Kentucky). In two states (Nebraska and Pennsylvania), reports are distributed internally within the agency, but not externally.

Discussion

Standardized surveillance case definitions provide a common, accepted set of criteria to ensure that cases of disease are classified and counted consistently, irrespective of jurisdiction.[§] Surveillance data provide an evidence base about disease prevalence, including who is affected, where, and how, to guide the development, implementation, funding, monitoring, and evaluation of disease control activities[¶] (*7*).

[§] https://ndc.services.cdc.gov/ (Accessed March 2, 2022).
[¶] https://www.cdc.gov/nndss/about/index.html (Accessed March 2, 2022).

Important differences were identified in case classifications and laboratory and clinical criteria used in surveillance case definitions, making it difficult to compare case counts or disease prevalence among states. Toxoplasmosis poses unique challenges for public health surveillance, primarily in identifying acute illnesses, which are the more important target for public health action (e.g., identifying and mitigating the source of infection). Once infected, persons are presumed to remain infected for life (even with treatment[**]) and likely maintain detectable antibody levels, even without reverting to or showing signs of active disease (latent or chronic infections) (*1*). Toxoplasmosis among immunocompromised persons more commonly represents reactivation of latent infection rather than newly acquired infection (*1*). Congenital infections might not manifest until later in life. Commercially available serology assays, which typically examine immunoglobulin (Ig) G and IgM antibody levels, cannot reliably differentiate between acute and chronic infection: IgM antibodies might remain elevated for ≥18 months after infection (*8*), and IgG might be present during acute infections (*9*). A combination of advanced serologic tests, such as IgG avidity testing or IgA or IgE antibody levels, available only through a reference laboratory,[††] are necessary to serologically differentiate between acute and chronic infection. Direct detection methods such as polymerase chain reaction or histologic examination of tissue sections or smears of body fluid are more definitive in demonstrating active infection but are most useful in immunocompromised patients (*1*).

The findings in this report are subject to at least two limitations. First, only six of the eight states that conduct toxoplasmosis surveillance participated in the assessment; case definitions or processes for toxoplasmosis surveillance in Delaware or Hawaii were not able to be reviewed. Because of the length of time toxoplasmosis has been reportable in these states, most historic questions could not be answered. Second, this evaluation was conducted during the SARS-CoV-2 B.1.617.2 (Delta) variant surge of the ongoing COVID-19 pandemic, which might have affected staff member availability to gather historical information on procedures for toxoplasmosis investigation and response.

Developing and implementing a standardized case definition in states where toxoplasmosis is reportable could help ensure that surveillance data are collected in a standardized way and establish common goals for surveillance. As a result of this review, the participating states have decided to proactively develop a CSTE position statement for a standardized surveillance case definition for toxoplasmosis.

[**] https://www.cdc.gov/parasites/toxoplasmosis/prevent.html; https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html
[††] https://www.sutterhealth.org/services/lab-pathology/toxoplasma-serology-laboratory

Summary

What is already known about this topic?

Toxoplasmosis, a zoonotic parasitic disease that can result in severe adverse outcomes, is not a nationally notifiable illness in the United States; no national level surveillance data are available.

What is added by this report?

In 2021, toxoplasmosis was reportable in eight states. Among six states that participated in a surveillance evaluation, case definitions varied considerably, and a need for development and implementation of a standardized case definition was identified.

What are the implications for public health practice?

Implementing a standardized case definition would help ensure that cases are counted consistently. Toxoplasmosis surveillance could increase awareness among physicians and public health personnel but is dependent upon health department resources. Identifying newly acquired cases is important for surveillance but is challenging because most acute cases among immunocompetent persons (including pregnant women) are asymptomatic, disease among immunocompromised persons are likely reactivations of latent disease, and congenital infections might not manifest until later in life.

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Pediatric HIV Case Identification Across 22 PEPFAR-Supported Countries During the COVID-19 Pandemic, October 2019–September 2020

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During 2020, an estimated 150,000 persons aged 0–14 years acquired HIV globally (*1*). Case identification is the first step to ensure children living with HIV are linked to life-saving treatment, achieve viral suppression, and live long, healthy lives. Successful interventions to optimize pediatric HIV testing during the COVID-19 pandemic are needed to sustain progress toward achieving Joint United Nations Programme on HIV/AIDS (UNAIDS) 95–95–95 targets.* Changes in HIV testing and diagnoses among persons aged 1–14 years (children) were assessed in 22 U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-supported countries during October 1, 2019–September 30, 2020. This period corresponds to the two fiscal quarters before the COVID-19 pandemic (i.e., Q1 and Q2) and the two quarters after the pandemic began (i.e., Q3 and Q4). Testing was disaggregated by age group, testing strategy, and fiscal year quarter. During October 2019–September 2020, PEPFAR supported 4,312,343 HIV tests and identified 74,658 children living with HIV (CLHIV). The number of HIV tests performed was similar during Q1 and Q2, decreased 40.1% from Q2 to Q3, and increased 19.7% from Q3 to Q4. The number of HIV cases identified among children aged 1–14 years (cases identified) increased 7.4% from Q1 to Q2, decreased 29.4% from Q2 to Q3, and increased 3.3% from Q3 to Q4. Although testing in outpatient departments decreased 21% from Q1 to Q4, testing from other strategies increased during the same period, including mobile testing by 38%, facility-based index testing (offering an HIV test to partners and biological children of persons living with HIV) by 8%, and testing children with signs or symptoms of malnutrition within health facilities by 7%. In addition, most tests (61.3%) and cases identified (60.9%) were among children aged 5–14 years (school-aged children), highlighting the need to continue offering HIV testing to older children. These findings provide important information on the most effective strategies for identifying CLHIV during the COVID-19 pandemic. HIV testing programs should continue to use programmatic, surveillance, and financial data at both national and subnational levels to determine the optimal mix of testing strategies to minimize disruptions in pediatric case identification during the COVID-19 pandemic.

Monitoring, evaluation, and reporting indicators† from 22 of 50 PEPFAR-supported countries were analyzed to assess changes in the number of HIV tests conducted and the number of cases identified among children during the two fiscal quarters before the start of the COVID-19 pandemic (October 2019–March 2020) and the two fiscal quarters after the pandemic began (April–September 2020). These 22 countries were selected because they account for >80% of CLHIV not receiving HIV treatment globally. Percent positivity was calculated by dividing the number of positive test results by the total number of tests reported. HIV test outcomes are reported overall, and by country, age group, testing strategy, and fiscal year quarter. Testing strategies include provider-initiated testing and counseling (PITC) in outpatient departments, tuberculosis clinics, malnutrition services, well-child clinics (for infants and children aged <5 years), and inpatient wards; index testing in facility and community settings; voluntary counseling and testing (VCT) initiated by clients; and mobile testing in the community. This protocol was reviewed in accordance with CDC human research protection procedures, determined to be a non-research public health program activity, and conducted consistent with applicable federal law and CDC policy.§

Of the 4,312,343 HIV tests conducted among children in the 22 countries, approximately one quarter (22.6%)

* The UNAIDS 95–95–95 strategy to reach HIV epidemic control by 2030 calls for 95% of all persons living with HIV (PLHIV) to know their status; 95% of diagnosed PLHIV to be receiving antiretroviral treatment; and 95% of PLHIV receiving antiretroviral treatment to be virally suppressed (defined as <200 copies of HIV per mL of blood).

† Monitoring, evaluation, and reporting indicators: number of persons who received HIV testing services and their test results and number of persons receiving positive test results for HIV.

§ 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

occurred in South Africa. Among the 74,658 cases identified (representing an overall 1.7% positivity rate), approximately one half (54.7%) were in Mozambique, Nigeria, South Africa, and Tanzania, with Mozambique identifying the most cases (12,367; 16.6%) (Table 1). The majority of tests conducted (61.3%) and of cases identified (60.9%) were among school-aged children (Table 1). Percent positivity was highest among children aged 5–9 years (2.1%) followed by those aged 1–4 (1.8%) and 10–14 (1.5%) years.

The number of HIV tests conducted among children decreased 40.1% from Q2 to Q3 across all 22 countries at the start of the COVID-19 pandemic but increased 19.7% from Q3 to Q4 as programs began making shifts in their HIV testing strategies. Similarly, the number of cases identified decreased 29.4% from Q2 to Q3 but increased 3.3% from Q3 to Q4. Seventeen of the 22 countries reported that the number of cases identified increased from Q3 to Q4. By Q4, case identification had surpassed pre–COVID-19 levels in six countries, (Q4:Q1 ratio ≥1.0), returned to pre–COVID-19 levels in three countries (Q4:Q1 ratio >0.95–<1.0), and remained below pre–COVID-19 levels in 13 countries (Q4:Q1 ratio <0.95) (Table 2).

Approximately one half (47.9%) of HIV tests were conducted in outpatient department settings, followed by facility-based index testing (12.1%), well-child clinics (8.1%), and mobile testing (5.4%). PITC in outpatient departments identified the largest number of cases (24,812; 33.2%), followed by facility-based index testing (24,372; 32.6%), community-based index testing (5,922; 7.9%), and VCT (5,034; 6.7%). Similarly, the percent positivity was highest for PITC in tuberculosis clinics (5.4%), followed by facility-based index testing (4.6%), community-based index testing (3.6%), and VCT (2.6%). Facility and community-based index testing, combined, identified the most cases across the four quarters (40.5%; positivity rate = 4.4%), despite only representing 18.3% of all testing.

By Q4, the number of tests conducted returned to pre–COVID-19 levels (Q4:Q1 ratio >0.95) for three strategies: mobile testing, facility-based index testing, and PITC among malnourished children (Table 3). However, the number of tests conducted was <75% of pre–COVID-19 levels in Q4 for PITC in inpatient wards and well-child clinics, VCT, and index testing in community settings. The number of cases identified decreased from Q2 to Q3 across all strategies except inpatient wards, where the number increased by 28.8% and the percentage of HIV-positive test results nearly doubled from 1.2% to 2.2%. By Q4, case identification only reached pre–COVID-19 levels for facility-based index testing and PITC among malnourished children.

Discussion

Findings from this report suggest progress toward reaching the UNAIDS 95–95–95 targets for CLHIV were negatively affected during the COVID-19 pandemic, especially during April–June 2020. Although the number of HIV tests conducted and cases identified increased from Q3 to Q4, the overall number of children diagnosed with HIV during Q4 remained below pre–COVID-19 levels. Although more resource intensive (*2*), index testing remains a priority for identifying children before they develop advanced disease, and during the COVID-19 pandemic when children and caregivers are less likely to seek outpatient services (*3*). Prioritizing the identification and testing of the biological children of key populations (i.e., persons who engage in sex work, men who have sex with men, persons who inject drugs, persons who identify as transgender, and persons who are incarcerated in prisons and other closed settings) living with HIV is also critical given their increased risk and vulnerabilities (*4*).

Although community index testing and mobile testing did not identify as many cases as did PITC, they also remain important strategies to identify children unable to access health care (*5*), and to limit potential exposures at health care facilities during the COVID-19 pandemic. In a similar recent analysis of 16 countries, those countries that maintained or increased community-based testing, including index testing, were able to mitigate declines in the number of cases identified during the COVID-19 pandemic (*5*). In the current analysis, the number of tests conducted and cases identified in community-based index testing during Q4 did not reach pre–COVID-19 levels, although this strategy did have a relatively high percent positivity in Q4. Community-based testing strategies are often more expensive than facility-based approaches (*6*). Therefore, each country program will have to determine the cost-benefit ratio of different testing strategies using national and subnational data to guide decisions on which strategies to implement for pediatric case finding. Orphans and vulnerable children programs, which are integral to community-based care for CLHIV, can also provide support to facilitate HIV testing (*7*). Programs might consider accelerating policies allowing the distribution of oral self-test kits to caregivers to screen their biological children aged ≥2 years for HIV to reduce barriers to HIV testing, decrease visits to health care facilities, and close gaps in elicitation and testing of biological contacts (*8*).

Children infected through perinatal transmission might be seen at health care facilities (e.g., tuberculosis clinics, malnutrition clinics, and inpatient wards) with advanced disease if they are not diagnosed through other testing strategies. In this analysis, the percent positivity was highest for PITC in tuberculosis clinics; testing in inpatient wards was the only strategy

TABLE 1. Number of tests and number and percentage of children and adolescents aged 1–14 years identified with HIV, by age group — 22 PEPFAR-supported countries, October 2019–September 2020

Country	No. of HIV tests conducted (%)				No. of HIV-positive tests (%)			
	All	1–4 yrs	5–9 yrs	10–14 yrs	All	1–4 yrs	5–9 yrs	10–14 yrs
Angola	**6,949**	2,874 (41.4)	2,281 (32.8)	1,794 (25.8)	381 (5.5)	174 (6.1)	129 (5.7)	78 (4.3)
Botswana	**4,524**	1,556 (34.4)	367 (8.1)	2,601 (57.5)	43 (1.0)	15 (1.0)	16 (4.4)	12 (0.5)
Burundi	**23,349**	13,392 (57.4)	5,130 (22.0)	4,827 (20.7)	414 (1.8)	143 (1.1)	143 (2.8)	128 (2.7)
Cameroon	**104,328**	39,852 (38.2)	32,773 (31.4)	31,703 (30.4)	1,906 (1.8)	840 (2.1)	639 (1.9)	427 (1.3)
Côte d'Ivoire	**117,773**	47,254 (40.1)	34,567 (29.4)	35,952 (30.5)	1,148 (1.0)	538 (1.1)	316 (0.9)	294 (0.8)
DRC	**98,410**	35,296 (35.9)	32,888 (33.4)	30,226 (30.7)	4,087 (4.2)	1,637 (4.6)	1,454 (4.4)	996 (3.3)
Eswatini	**27,618**	8,028 (29.1)	6,864 (24.9)	12,726 (46.1)	449 (1.6)	116 (1.4)	112 (1.6)	221 (1.7)
Ethiopia	**354,066**	230,396 (65.1)	51,330 (14.5)	72,340 (20.4)	1,451 (0.4)	619 (0.3)	394 (0.8)	438 (0.6)
Haiti	**33,772**	16,321 (48.3)	8,130 (24.1)	9,321 (27.6)	452 (1.3)	185 (1.1)	124 (1.5)	143 (1.5)
Kenya	**297,984**	79,364 (26.6)	85,125 (28.6)	133,495 (44.8)	4,693(1.6)	1,803 (2.3)	1,515 (1.8)	1,375 (1.0)
Lesotho	**61,645**	19,731 (32.0)	16,105 (26.1)	25,809 (41.9)	226 (0.4)	83 (0.4)	45 (0.3)	98 (0.4)
Malawi	**155,859**	73,200 (47.0)	30,423 (19.5)	52,236 (33.5)	3,028 (1.9)	1,300 (1.8)	711 (2.3)	1,017 (1.9)
Mozambique	**637,575**	222,439 (34.9)	201,503 (31.6)	213,633 (33.5)	12,367 (1.9)	4,753 (2.1)	4,524 (2.2)	3,090 (1.4)
Namibia	**12,268**	5,245 (42.8)	3,398 (27.7)	3,625 (29.5)	251 (2.0)	100 (1.9)	78 (2.3)	73 (2.0)
Nigeria	**405,589**	122,720 (30.3)	114,727 (28.3)	168,142 (41.5)	9,471 (2.3)	3,817 (3.1)	2,785 (2.4)	2,869 (1.7)
Rwanda	**8,963**	1,957 (21.8)	3,452 (38.5)	3,554 (39.7)	147 (1.6)	70 (3.6)	49 (1.4)	28 (0.8)
South Africa	**972,761**	441,881 (45.4)	211,183 (21.7)	319,697(32.9)	10,726 (1.1)	3,561 (0.8)	2,638 (1.2)	4,527 (1.4)
South Sudan	**36,577**	14,554 (39.8)	8,953 (24.5)	13,070 (35.7)	475 (1.3)	274 (1.9)	101 (1.1)	100 (0.8)
Tanzania	**236,162**	89,164 (37.8)	74,053 (31.4)	72,945 (30.9)	8,282 (3.5)	3,370 (3.8)	2,684 (3.6)	2,228 (3.1)
Uganda	**354,014**	81,255 (23.6)	81,065 (23.5)	182,694 (53.0)	5,031 (1.5)	2,089 (2.6)	1,542 (1.9)	1,400 (0.8)
Zambia	**244,555**	89,148 (36.5)	64,176 (26.2)	91,231 (37.3)	7,153 (2.9)	2,835 (3.2)	2,104 (3.3)	2,214 (2.4)
Zimbabwe	**126,602**	32,891 (26.0)	14,663 (11.6)	79,048 (62.4)	2,477 (2.0)	893 (2.7)	665 (4.5)	919 (1.2)
Total	**4,312,343**	**1,668,518(38.7)**	**1,083,156 (25.1)**	**1,560,669 (36.2)**	**74,658 (1.7)**	**29,215 (1.8)**	**22,768 (2.1)**	**22,675 (1.5)**

Source: PEPFAR Monitoring, Evaluation, and Reporting Database, Data for Accountability, Transparency, and Impact Monitoring database, October 2019–September 2020.
Abbreviations: DRC = Democratic Republic of the Congo; PEPFAR = U.S. President's Emergency Plan for AIDS Relief.

TABLE 2. Number of tests and number and percentage of children and adolescents aged 1–14 years identified with HIV, by quarter — 22 PEPFAR-supported countries, October 2019–September 2020

Country	No. of HIV tests conducted					Ratio Q4 versus Q1*	No. of HIV-positive tests (%)					Ratio Q4 versus Q1*
	All	Oct–Dec 2019	Jan–Mar 2020	Apr–Jun 2020	Jul–Sep 2020		All	Oct–Dec 2019	Jan–Mar 2020	Apr–Jun 2020	Jul–Sep 2020	
Angola	**6,949**	1,477	2,173	1,336	1,963	1.33	**381 (5.5)**	86 (5.8)	101 (4.6)	68 (5.1)	126 (6.4)	1.47
Botswana	**4,524**	3,376	667	209	272	0.08	**43 (1.0)**	16 (0.5)	11 (1.6)	10 (4.8)	6 (2.2)	0.38
Burundi	**23,349**	5,817	5,642	6,452	5,438	0.93	**414 (1.8)**	100 (1.7)	106 (1.9)	123 (1.9)	85 (1.6)	0.85
Cameroon	**104,336**	20,320	22,297	29,540	32,179	1.58	**1,905 (1.8)**	319 (1.6)	505 (2.3)	534 (1.8)	547 (1.7)	1.71
Côte d'Ivoire	**117,773**	34,491	32,157	26,602	24,523	0.71	**1,148 (1.0)**	284 (0.8)	302 (0.9)	259 (1.0)	303 (1.2)	1.07
DRC	**98,410**	22,811	27,226	23,610	24,763	1.09	**4,087 (4.2)**	894 (3.9)	1,096 (4.0)	1,001 (4.2)	1,096 (4.4)	1.23
Eswatini	**27,618**	5,489	7,971	2,839	11,319	2.06	**449 (1.6)**	110 (2.0)	144 (1.8)	72 (2.5)	123 (1.1)	1.12
Ethiopia	**354,075**	135,267	108,439	50,760	59,609	0.44	**1,451 (0.4)**	535 (0.4)	436 (0.4)	228 (0.4)	252 (0.4)	0.47
Haiti	**33,772**	9,038	10,469	5,024	9,241	1.02	**452 (1.3)**	107 (1.2)	133 (1.3)	78 (1.6)	134 (1.5)	1.25
Kenya	**297,985**	94,057	79,212	57,048	67,668	0.72	**4,689 (1.6)**	1,246 (1.3)	1,440 (1.8)	971 (1.7)	1,032 (1.5)	0.83
Lesotho	**61,645**	30,726	22,387	4,803	3,729	0.12	**226 (0.4)**	79 (0.3)	88 (0.4)	34 (0.7)	25 (0.7)	0.32
Malawi	**155,859**	62,284	40,349	21,721	31,505	0.51	**3,028 (1.9)**	1,062 (1.7)	728 (1.8)	514 (2.4)	724 (2.3)	0.68
Mozambique	**637,570**	173,106	201,520	125,967	136,977	0.79	**12,367 (1.9)**	3,096 (1.8)	3,875 (1.9)	2,626 (2.1)	2,770 (2.0)	0.89
Namibia	**12,268**	3,236	3,749	3,006	2,277	0.70	**251 (2.0)**	66 (2.0)	67 (1.8)	68 (2.3)	50 (2.2)	0.76
Nigeria	**405,589**	94,283	104,003	83,941	123,362	1.31	**9,471 (2.3)**	2,489 (2.6)	2,386 (2.3)	2,166 (2.6)	2,430 (2.0)	0.98
Rwanda	**8,963**	2,159	2,233	2,207	2,364	1.09	**147 (1.6)**	46 (2.1)	34 (1.5)	33 (1.5)	34 (1.4)	0.74
South Africa	**972,760**	265,547	318,778	168,309	220,126	0.83	**10,726 (1.1)**	3,514 (1.3)	3,682 (1.2)	1,728 (1.0)	1,802 (0.8)	0.51
South Sudan	**36,577**	11,430	9,529	7,464	8,154	0.71	**475 (1.3)**	112 (1.0)	160 (1.7)	93 (1.2)	110 (1.3)	0.98
Tanzania	**236,162**	58,561	71,216	59,803	46,582	0.80	**8,282 (3.5)**	2,356 (4.0)	2,411 (3.4)	2,050 (3.4)	1,465 (3.1)	0.62
Uganda	**345,016**	102,383	118,751	49,706	74,176	0.72	**5,031 (1.5)**	1,155 (1.1)	1,769 (1.5)	982 (2.0)	1,125 (1.5)	0.97
Zambia	**244,555**	81,290	72,208	47,150	43,907	0.54	**7,153 (2.9)**	2,159 (2.7)	1,863 (2.6)	1,652 (3.5)	1,479 (3.4)	0.69
Zimbabwe	**126,602**	51,328	52,754	10,051	12,469	0.24	**2,479 (2.0)**	828 (1.6)	844 (1.6)	362 (3.6)	445 (3.6)	0.54
Total	**4,312,357**	**1,268,476**	**1,313,730**	**787,548**	**942,603**	**0.74**	**74,655 (1.7)**	**20,659 (1.6)**	**22,181 (1.7)**	**15,652 (2.0)**	**16,163 (1.7)**	**0.78**

Source: PEPFAR Monitoring, Evaluation, and Reporting Database, Data for Accountability, Transparency, and Impact Monitoring database, October 2019–September 2020.
Abbreviations: DRC = Democratic Republic of the Congo; PEPFAR = U.S. President's Emergency Plan for AIDS Relief; Q1 = quarter 1; Q4 = quarter 4.
* Q1 (Oct–Dec 2019) and Q4 (Jul–Sep 2020).

that had an increase in cases identified during the first quarter of the COVID-19 pandemic. Universal testing at these entry points is therefore crucial, particularly during the COVID-19 pandemic when children might seek care with more advanced disease. In addition, most tests conducted (61.3%) and cases identified (60.9%) were among school-aged children. This finding highlights the ongoing need for both early infant diagnosis to identify and link children to treatment at an earlier age and HIV testing services among older children because studies indicate children infected during breastfeeding can survive into adolescence even without treatment (*9*).

The findings in this report are subject to at least four limitations. First, although countries follow PEPFAR monitoring and reporting guidance, data quality and reporting by testing strategy vary across countries. This caveat is particularly true for community-based testing in which contacts of known persons living with HIV might not always be accurately reflected under index testing. Second, PEPFAR indicators monitor the number of tests conducted, not the number of persons tested. Thus, the number of tests conducted and HIV-positive test results returned might be higher than the number of persons who received testing. Third, the impacts, restrictions, and adaptations to the COVID-19 pandemic varied across countries. This analysis cannot fully account for the impact of these variations on the results presented. Further qualitative assessments might provide a more in-depth understanding of how COVID-19 affected the provision and uptake of HIV testing across multiple waves of the pandemic. Finally, some countries did not use all the testing strategies included in this analysis.

Summary

What is already known about this topic?

Identifying and linking children living with HIV to treatment is essential to reduce morbidity and mortality.

What is added by this report?

During the first 3 months of the COVID-19 pandemic, HIV testing and case identification among children and adolescents aged 1–14 years in 22 PEPFAR-supported countries decreased by 40.1% and 29.4%, respectively. Although outpatient testing decreased (21%), testing increased for other strategies, including mobile (38%), facility-based index (8%), and malnutrition (7%), suggesting these strategies can mitigate the impact of COVID-19 on pediatric case identification.

What are the implications for public health practice?

HIV testing programs can use programmatic, surveillance, and financial data to determine the optimal mix of testing strategies during the COVID-19 pandemic.

Case identification is the first step to ensure CLHIV are linked to life-saving treatment, achieve viral suppression, and live long, healthy lives. During the COVID-19 pandemic, many PEPFAR-supported countries experienced disruptions in case identification among CLHIV. Six countries (Angola, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Eswatini, and Haiti), however, were able to exceed pre–COVID-19 case identification levels, using a combination of high yield strategies, including facility index testing, mobile testing, and testing children with signs or symptoms of malnutrition. These findings provide important information for countries and programs on the most effective strategies for

TABLE 3. Number of children and adolescents aged 1–14 years receiving testing, identified as HIV-positive, and percent positivity by HIV testing strategy — 22 PEPFAR-supported countries, October 2019–September 2020

HIV testing strategy	No. of HIV tests conducted (%)					Ratio Q4 versus Q1*	No. of HIV-positive tests (%)						Ratio Q4 versus Q1*
	All	Oct–Dec 2019	Jan–Mar 2020	Apr–Jun 2020	Jul–Sep 2020		All	Percent Positivity†	Oct–Dec 2019	Jan–Mar 2020	Apr–Jun 2020	Jul–Sep 2020	
Outpatient department	**2,065,526 (47.9)**	585,548 (46.2)	616,578 (46.9)	402,996 (51.2)	460,404 (48.8)	0.79	**24,812 (33.2)**	1.2	6,625 (1.1)	7,808 (1.3)	5,039 (1.3)	5,340 (1.2)	0.81
Index (facility)	**523,931 (12.1)**	127,743 (10.1)	140,453 (10.7)	117,241 (14.9)	138,494 (14.7)	1.08	**24,327 (32.6)**	4.6	6,154 (4.8)	7,000 (5.0)	5,491 (4.7)	5,682 (4.1)	0.92
Index (community)	**162,966 (3.8)**	47,751 (3.8)	62,559 (4.8)	19,950 (2.5)	32,706 (3.5)	0.68	**5,922 (7.9)**	3.6	1,806 (3.8)	1,956 (3.1)	950 (4.8)	1,210 (3.7)	0.67
Inpatient wards	**168,420 (3.9)**	49,425 (3.9)	49,144 (3.7)	33,924 (4.3)	35,927 (3.8)	0.73	**2,337 (3.1)**	1.4	582 (1.2)	590 (1.2)	760 (2.2)	405 (1.1)	0.70
Tuberculosis clinics	**39,378 (0.9)**	10,128 (0.8)	12,073 (0.9)	8,147 (1.0)	9,030 (1.0)	0.89	**2,124 (2.8)**	5.4	674 (6.7)	618 (5.1)	470 (5.8)	362 (4.0)	0.54
Malnutrition clinics	**27,513 (0.6)**	6,406 (0.5)	7,287 (0.6)	6,986 (0.9)	6,834 (0.7)	1.07	**284 (0.4)**	1.0	75 (1.2)	77 (1.1)	59 (0.8)	73 (1.1)	0.97
VCT	**192,269 (4.5)**	67,926 (5.4)	50,780 (3.9)	32,189 (4.1)	41,374 (4.4)	0.61	**5,034 (6.7)**	2.6	1,578 (2.3)	1,504 (3.0)	960 (3.0)	992 (2.4)	0.63
Well-child clinics§	**349,315 (8.1)**	112,522 (8.9)	104,654 (8.0)	62,483 (7.9)	69,656 (7.4)	0.62	**2,591 (3.5)**	0.7	858 (0.8)	664 (0.6)	602 (1.0)	467 (0.7)	0.54
Mobile	**233,476 (5.4)**	49,386 (3.9)	74,792 (5.7)	41,168 (5.2)	68,130 (7.2)	1.38	**3,015 (4.0)**	1.3	835 (1.7)	885 (1.2)	597 (1.5)	698 (1.0)	0.84
All other strategies	**549,563 (12.7)**	211,641 (16.7)	195,410 (14.9)	62,464 (7.9)	80,048 (8.5)	0.38	**4,209 (5.6)**	0.8	1,472 (0.7)	1,079 (0.6)	724 (1.2)	934 (1.2)	0.63
Total	**4,312,357**	**1,268,476**	**1,313,730**	**787,548**	**942,603**	**0.74**	**74,655**	**1.7**	**20,659 (1.6)**	**22,181 (1.7)**	**15,652 (2.0)**	**16,163 (1.7)**	**0.78**

Source: PEPFAR Monitoring, Evaluation, and Reporting Database, Data for Accountability, Transparency, and Impact Monitoring database, October 2019–September 2020.
Abbreviations: PEPFAR = U.S. President's Emergency Plan for AIDS Relief; Q1 = quarter 1; Q4 = quarter 4; VCT = voluntary counseling and testing.
* Ratio of the number of tests conducted and positive test results received comparing Q1 (Oct–Dec 2019) and Q4 (Jul–Sep 2020).
† Number of HIV-positive test results divided by the total number of tests conducted.
§ For infants and children aged <5 years.

identifying CLHIV during the COVID-19 pandemic. HIV testing programs should continue to use programmatic, surveillance, and financial data at both national and subnational levels to determine the optimal mix of testing strategies to minimize disruptions in pediatric case identification during the COVID-19 pandemic surges and other public health crises.

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Safety Monitoring of COVID-19 mRNA Vaccine First Booster Doses Among Persons Aged ≥12 Years with Presumed Immunocompromise Status — United States, January 12, 2022–March 28, 2022

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Persons with moderate to severe immunocompromising conditions are at risk for severe COVID-19, and their immune response to COVID-19 vaccination might not be as robust as the response in persons who are not immunocompromised* (*1*). The Advisory Committee on Immunization Practices (ACIP) recommends that immunocompromised persons aged ≥12 years complete a 3-dose primary mRNA COVID-19 vaccination series followed by a first booster dose (dose 4) ≥3 months after dose 3 and a second booster dose (dose 5) ≥4 months after dose 4.† To characterize the safety of first booster doses among immunocompromised persons aged ≥12 years during January 12, 2022–March 28, 2022, CDC reviewed adverse events and health impact assessments reported to v-safe and the Vaccine Adverse Event Reporting System (VAERS) during the week after receipt of an mRNA COVID-19 first booster dose. V-safe is a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination. VAERS is a passive surveillance system for all vaccine-associated adverse events co-managed by CDC and the Food and Drug Administration (FDA). A fourth mRNA dose reported to v-safe or VAERS during January 12, 2022–March 28, 2022, was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person because no other population was authorized to receive a fourth dose during that period (*2*,*3*). In the United States, during January 12, 2022–March 28, 2022, approximately 518,113 persons aged ≥12 years received a fourth dose. Among 4,015 v-safe registrants who received a fourth dose, local and systemic reactions were less frequently reported than were those following dose 3 of their primary series. VAERS received 145 reports after fourth doses; 128 (88.3%) were nonserious and 17 (11.7%) were serious. Health care providers, immunocompromised persons, and parents of immunocompromised children should be aware that local and systemic reactions are expected after a first booster mRNA COVID-19 vaccine dose, serious adverse events are rare, and safety findings were consistent with those previously described among nonimmunocompromised persons (*4*,*5*).

V-safe is a voluntary, smartphone–based U.S. active safety surveillance system established by CDC to monitor adverse events after COVID-19 vaccination (https://vsafe.cdc.gov/en/). The v-safe platform allows registrants to report receipt of a COVID-19 booster dose; new registrants enter information about all doses received. Coincident with authorization for a booster dose in persons with moderate-to-severe immunocompromising conditions, v-safe was updated to allow registrants to enter information about a fourth dose. Registrants aged ≤15 years are enrolled by a parent or guardian. Health surveys sent daily during the first week after administration of each dose include questions about local injection site and systemic reactions and health impacts.§ CDC's v-safe call center contacts registrants who indicate that medical care was sought after vaccination and encourages completion of a VAERS report, if indicated.

VAERS is a U.S. national passive safety surveillance system that monitors adverse events after vaccination and is managed by CDC and FDA (*6*). VAERS accepts reports from health care providers, vaccine manufacturers, and the general public.¶ VAERS reports of hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death are classified as serious.** VAERS staff members assign Medical Dictionary for Regulatory Activities (MedDRA) preferred terms to the findings included in VAERS reports.†† Serious reports to VAERS were reviewed by CDC and FDA physicians to form

* https://doi.org/10.1101/2021.07.08.21259776

† https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

§ Health surveys are sent for the most recent dose entered via text messages that link to web-based surveys on days 0–7 after receipt of a vaccine dose; then weekly through 6 weeks after vaccination; and then at 3, 6, and 12 months after vaccination. Local injection site reactions include itching, pain, redness, and swelling. Systemic reactions include abdominal pain, myalgia, chills, diarrhea, fatigue, fever, headache, joint pain, nausea, rash, and vomiting. Health impacts include inability to perform normal daily activities, inability to work or attend school, and receipt of medical care.

¶ Health care providers are encouraged by CDC and FDA to report adverse events to VAERS and are required by COVID-19 vaccine Emergency Use Authorizations to report certain adverse events after vaccination to VAERS, including death. https://vaers.hhs.gov/faq.html

** VAERS reports are classified as serious based on the Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr

†† Each VAERS report might be assigned at least one MedDRA preferred term. A MedDRA-coded event does not indicate a medically confirmed diagnosis. https://www.meddra.org/how-to-use/basics/hierarchy

a consensus clinical impression. For reports of death, death certificates and autopsy reports are requested and reviewed by CDC physicians to form an impression about cause of death. Reports of myocarditis and pericarditis, rare adverse events that have been associated with mRNA-based COVID-19 vaccines, were identified by searching for selected MedDRA preferred terms; CDC staff members attempted to collect information about clinical course and determined whether the case definition was met.[§§]

In v-safe, a fourth mRNA dose administered ≥3 months after dose 3 to a registrant aged ≥12 years during January 12, 2022–March 28, 2022 (data processed April 17, 2022) was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person; this cutoff date was chosen to reduce overlap with fourth doses administered as a second booster to adults aged ≥50 years, which was recommended on March 29, 2022. The odds of reporting an adverse reaction or health impact after a fourth versus a third dose were compared using a multivariable generalized estimated equations model that accounted for demographic variables, vaccine manufacturer, and repeated measures; p-values <0.05 were considered statistically significant. VAERS adverse event reports after a fourth dose among immunocompromised persons were described by seriousness classification (serious versus nonserious), demographic characteristics, and MedDRA preferred terms; a report of a fourth mRNA dose administered to a person aged ≥12 years during January 12, 2022–March 28, 2022 (data processed April 17, 2022) that did not include MedDRA preferred terms for vaccine error was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person. SAS software (version 9.4; SAS Institute) was used to conduct all analyses. These surveillance activities were reviewed by CDC and conducted consistent with applicable federal law and CDC policy.[¶¶]

Review of v-safe Data

Overall, 4,015 v-safe registrants reported receiving a fourth dose during January 12, 2022–March 28, 2022, and were presumed to be immunocompromised persons receiving a booster dose; 2,194 persons (54.6%) received mRNA-1273 (Moderna) vaccine and 1,821 (45.4%) BNT162b2 (Pfizer-BioNTech) vaccine. The median registrant age was 62 years (range = 12–94 years); 2,489 (62.0%) were female. In the week after vaccination, local injection site reactions and systemic reactions were reported by 1,605 (73.2%) and 1,470 (67.0%) Moderna vaccine recipients, respectively, and by 1,209 (66.4%) and 1,155 (63.4%) Pfizer-BioNTech vaccine recipients, respectively (Table 1). The most frequently reported adverse reactions after dose 4 of either vaccine were injection site pain, fatigue, headache, and myalgia. Local injection site reactions were less frequently reported after dose 4 (70.1%) than after dose 3 (81.7%) (p<0.001); systemic reactions also were less frequently reported after dose 4 (65.4%) than after dose 3 (76.8%) (p<0.001) (Figure).

In the week after dose 4 vaccination, 24.7% of Moderna vaccine recipients and 21.7% of Pfizer-BioNTech vaccine recipients reported they were unable to complete their daily activities, and approximately 9% of registrants reported they were unable to attend work or school (Table 1). Fewer than 2% of registrants reported receipt of medical care during the week after dose 4; most who did require care received it through a telehealth appointment. Two registrants reported receiving care at a hospital during the week after dose 4 vaccination. The v-safe call center contacted both these registrants; one completed a VAERS report, and the other indicated the report was accidental or unrelated to vaccination. Inability to work or attend school was less frequently reported after dose 4 (9.2%) than after dose 3 (13.8%) (p<0.001); inability to perform daily activities was less frequently reported after dose 4 (23.4%) than after dose 3 (34.5%) (p<0.001) (Figure). Receipt of medical care was rarely and similarly reported after receipt of either dose 4 (1.8%) or dose 3 (1.9%) (p = 0.70).

Review of VAERS Data

VAERS received 421 reports from persons who received a fourth dose during January 12–March 28, 2022; 276 (65.6%) of these reports listed a vaccine error. Among reports noting a vaccine error, 225 (81.5%) indicated that no adverse health event occurred.

The remaining 145 (34.4%) reports were presumed to be for immunocompromised persons who received a fourth dose. Among these, 105 (72.4%) reports were for events among females, and the median age was 62 years. Most reports were for nonserious events (128; 88.3%) (Table 2); the nonserious events most commonly reported included headache (30; 23.4%), fatigue (26; 20.3%), and pain (22; 17.2%). One nonserious, preliminary report of myocarditis remains under review. There were 17 (11.7%) reports of serious adverse events. One report of death was received from a manufacturer

[§§] In VAERS, acute myocarditis was defined as presence of new onset or worsening of one or more of the following signs or symptoms: chest pain, pressure, discomfort, dyspnea, shortness of breath, pain with breathing, palpitations, or syncope; or two or more of the following signs or symptoms in children aged ≤11 years: irritability, vomiting, poor feeding, tachypnea, or lethargy; and one or more new finding of elevated troponin, electrocardiogram findings consistent with myocarditis, abnormal cardiac function or wall motion on echocardiogram, cardiac magnetic resonance imaging findings consistent with myocarditis, or histopathologic findings consistent with myocarditis; and no other identifiable cause for these findings.

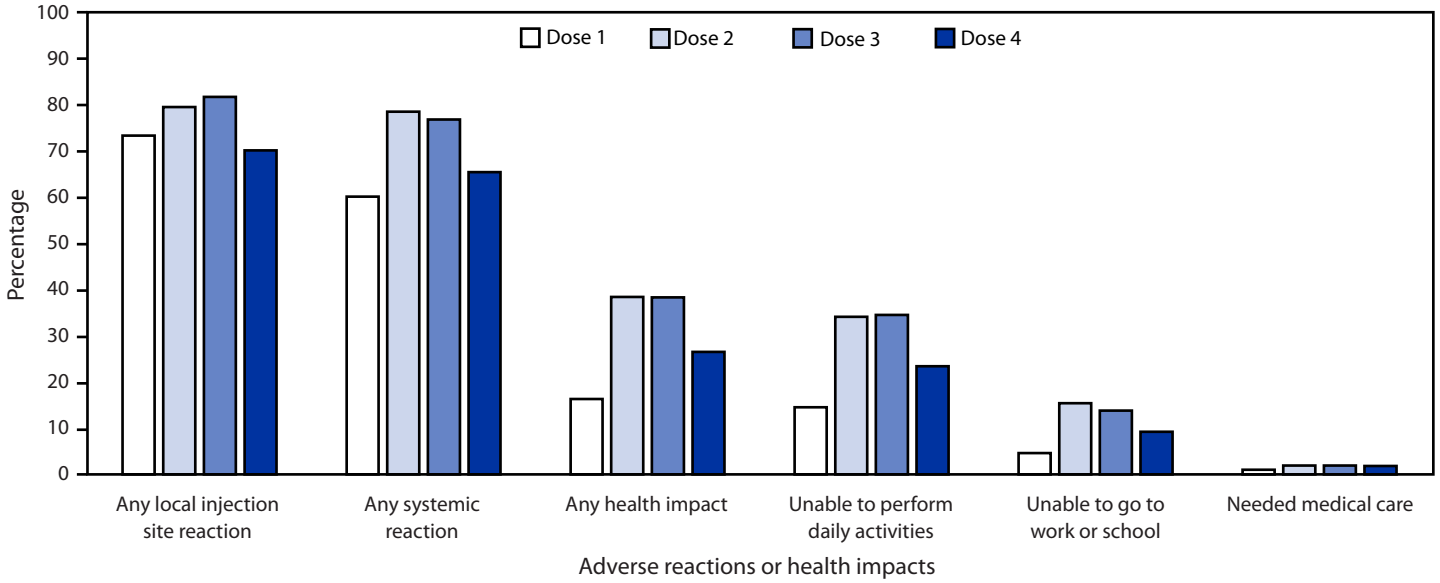
[¶¶] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

TABLE 1. Adverse reactions and health impacts reported* to v-safe after receipt of a presumed mRNA COVID-19 vaccine booster† dose among immunocompromised persons (N = 4,015) — United States, January 12–March 28, 2022

Event	No. (%) reporting reaction or health impact after receipt of presumed booster dose		
	Moderna (n = 2,194)	Pfizer-BioNTech (n = 1,821)	Total (N = 4,015)
Any local injection site reaction	1,605 (73.2)	1,209 (66.4)	**2,814 (70.1)**
Pain	1,512 (68.9)	1,157 (63.5)	**2,669 (66.5)**
Swelling	534 (24.3)	293 (16.1)	**827 (20.6)**
Redness	369 (16.8)	197 (10.8)	**566 (14.1)**
Itching	254 (11.6)	155 (8.5)	**409 (10.2)**
Any systemic reaction	1,470 (67.0)	1,155 (63.4)	**2,625 (65.4)**
Fatigue	1,164 (53.1)	884 (48.5)	**2,048 (51.0)**
Headache	863 (39.3)	676 (37.1)	**1,539 (38.3)**
Myalgia	833 (38.0)	659 (36.2)	**1,492 (37.2)**
Joint pain	544 (24.8)	425 (23.3)	**969 (24.1)**
Fever	504 (23.0)	371 (20.4)	**875 (21.8)**
Chills	501 (22.8)	325 (17.8)	**826 (20.6)**
Nausea	295 (13.4)	248 (13.6)	**543 (13.5)**
Diarrhea	152 (6.9)	141 (7.7)	**293 (7.3)**
Abdominal pain	126 (5.7)	127 (7.0)	**253 (6.3)**
Rash	40 (1.8)	35 (1.9)	**75 (1.9)**
Vomiting	21 (1.0)	29 (1.6)	**50 (1.2)**
Any health impact	608 (27.7)	455 (25.0)	**1,063 (26.5)**
Unable to perform normal daily activities	543 (24.7)	395 (21.7)	**938 (23.4)**
Unable to attend work or school	203 (9.3)	165 (9.1)	**368 (9.2)**
Received medical care	39 (1.8)	34 (1.9)	**73 (1.8)**
Telehealth	20 (0.9)	14 (0.8)	**34 (0.8)**
Clinic	8 (0.4)	11 (0.6)	**19 (0.5)**
Emergency visit	4 (0.2)	8 (0.4)	**12 (0.3)**
Hospitalization	1 (0.05)	1 (0.1)	**2 (0.05)**

* Percentage of registrants who reported a reaction or health impact ≥1 during days 0–7 after vaccination.
† A fourth mRNA dose ≥3 months after dose 3 administered to a participant aged ≥12 years was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person. Registrants aged ≤15 years must be enrolled by a parent or guardian.

FIGURE. Adverse reactions and health impacts reported to v-safe* after receipt of COVID-19 vaccine doses among persons with presumed immunocompromised status† (N = 4,015), by vaccine dose — United States, January 12–March 28, 2022



* The odds of reporting an event following dose 3 and booster dose were compared for registrants who completed at least one v-safe health check-in survey on days 0–7 after booster dose and ≥1 other dose using a multivariable generalized estimating equations model. This model adjusted for demographic variables and vaccine manufacturer and accounted for repeated measures among doses reported by each registrant ("unable to go to work or school" and "needed medical care" were not adjusted because of small numbers). P-values <0.05 were considered statistically significant. All dose 3 and booster dose differences were statistically significant (p<0.001) except "needed medical care."
† A fourth mRNA dose ≥3 months after dose 3 administered to a registrant aged ≥12 years was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person. Registrants aged ≤15 years must be enrolled by a parent or guardian.

TABLE 2. Reports to the Vaccine Adverse Event Reporting System of nonserious and serious events after receipt of a presumed mRNA COVID-19 vaccine booster* dose among immunocompromised persons (N = 145) — United States, January 12–March 28, 2022

Reported event	No. (%) reporting
Nonserious VAERS reports	**128 (100)**
Symptom, sign, diagnostic result, or condition (MedDRA PT†)	
Headache	30 (23.4)
Fatigue	26 (20.3)
Pain	22 (17.2)
Fever	18 (14.1)
Chills	15 (11.7)
Dizziness	12 (9.4)
Nausea	11 (8.6)
Rash	9 (7.0)
Conditional aggravated	8 (6.3)
Diarrhea	8 (6.3)
Injection site pain	8 (6.3)
Myalgia	8 (6.3)
Arthralgia	7 (5.5)
Erythema	7 (5.5)
Pain in extremity	7 (5.5)
Serious VAERS reports§,¶	17 (100)
Clinical impression	
Acute myocardial infarction	1 (5.9)
Anaphylactic reaction	1 (5.9)
Congestive heart failure	1 (5.9)
Chronic obstructive pulmonary disease exacerbation	1 (5.9)
Cerebrovascular accident	1 (5.9)
Diabetic ketoacidosis	1 (5.9)
Disseminated herpes zoster	1 (5.9)
Elevated liver enzymes, vomiting and diarrhea, fever, and arthralgia	1 (5.9)
Heart palpitations	1 (5.9)
Hyperglycemia; burning sensation in upper limb	1 (5.9)
No adverse event reported; vaccine received during mental health hospitalization	1 (5.9)
Pulmonary alveolar hemorrhage	1 (5.9)
Pulmonary embolism	1 (5.9)
Respiratory failure resulting in death in patient with pulmonary fibrosis	1 (5.9)
Respiratory syncytial virus pneumonia	1 (5.9)
Septic shock	1 (5.9)
Urosepsis	1 (5.9)

Abbreviations: MedDRA PT = Medical Dictionary for Regulatory Activities preferred term; VAERS = Vaccine Adverse Event Reporting System.

* A fourth mRNA dose not administered in error among persons aged ≥12 years during January 12, 2022–March 28, 2022, was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person. Reports indicating a vaccine error (276) were omitted from this analysis in an attempt to only include fourth doses administered as booster doses to immunocompromised persons.

† Signs and symptoms in VAERS reports are assigned MedDRA PTs by VAERS staff members. Each VAERS report might be assigned one or more MedDRA PTs, which can include normal diagnostic findings. A MedDRA PT does not indicate a medically confirmed diagnosis.

§ VAERS reports are classified as serious if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.

¶ Serious reports to VAERS were reviewed by Food and Drug Administration and CDC physicians to form a consensus clinical impression based on available data.

Summary

What is already known about this topic?

Additional doses of COVID-19 vaccine are recommended for immunocompromised persons, and 518,113 fourth doses were presumed administered to this population during January–March, 2022.

What is added by this report?

Among presumed immunocompromised persons aged ≥12 years, local and systemic reactions were less frequently reported to v-safe after mRNA booster (dose 4) than after primary series dose 3. Only 17 serious adverse events were reported to VAERS.

What are the implications for public health practice?

Serious adverse events after mRNA booster (dose 4) are rare. Immunocompromised persons aged ≥12 years should receive a first booster ≥3 months after a 3-dose primary COVID-19 vaccination series and a second booster ≥4 months after the first booster.

regarding a patient with pulmonary fibrosis who developed respiratory failure; at the time of publication, no further information was available, and follow-up continues.

Discussion

This report presents safety findings from v-safe and VAERS after receipt of COVID-19 vaccine booster doses during a period when a fourth mRNA dose was recommended only for persons with immunocompromising conditions. Reports to v-safe and VAERS after mRNA booster vaccination among persons who received a fourth dose were similar to previous reports that assessed safety data after dose 3 mRNA booster vaccination among nonimmunocompromised persons (*4*,*5*).

Local and systemic reactions and health impacts were less frequently reported to v-safe after receipt of dose 4 than after dose 3 of the primary series among persons with presumed immunocompromise. Similarly, in previous analyses, among all v-safe registrants aged ≥18 years who received a homologous mRNA booster, systemic reactions were less frequent after dose 3 vaccination than after dose 2 (*5*). Among adolescents aged 12–17 years who received a homologous Pfizer-BioNTech third dose, reactions were reported to v-safe with equal or slightly higher frequency after receipt of that booster dose than after dose 2 (*4*).

Most reports to VAERS related to booster doses among persons with presumed immunocompromise were nonserious; the most common adverse events reported were similar to those reported by persons aged ≥18 years after an mRNA booster (*5*). Serious reports to VAERS among persons with presumed immunocompromise included a range of adverse events; no unusual or unexpected reporting patterns were detected.

The findings in this report are subject to at least six limitations. First, v-safe is a voluntary program; therefore, data might not be representative of the vaccinated U.S. population. Second, it is possible that vaccinees who experience an adverse event could be more likely to respond to v-safe surveys and the reported prevalence of adverse events might overestimate the actual prevalence. Third, as a passive surveillance system, VAERS is subject to reporting biases and underreporting, especially of nonserious events (*6*). Fourth, v-safe does not collect information on immunocompromise, and VAERS does not ask about immunocompromising health conditions; therefore, it is not possible to confirm that vaccine recipients included in this analysis were immunocompromised. Fifth, this report did not examine pattern of reporting by heterologous and homologous vaccination. Finally, a report to v-safe or VAERS alone cannot be used to assess causality.

ACIP recommends that moderately or severely immunocompromised persons aged ≥12 years receive a first booster dose ≥3 months after completion of a 3-dose primary COVID-19 vaccination series and a second booster dose ≥4 months after the first booster. Preliminary safety findings for booster doses among persons with presumed immunocompromise are similar to those among nonimmunocompromised persons; reactions are reported less frequently after booster vaccination than after the last dose of a primary series. It is important that health care providers, immunocompromised persons, and parents of immunocompromised children be advised that local and systemic reactions are expected after a booster dose, and that serious adverse events are rare. CDC and FDA will continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

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Rapid Diagnostic Testing for Response to the Monkeypox Outbreak — Laboratory Response Network, United States, May 17–June 30, 2022

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As part of public health preparedness for infectious disease threats, CDC collaborates with other U.S. public health officials to ensure that the Laboratory Response Network (LRN) has diagnostic tools to detect *Orthopoxviruses*, the genus that includes *Variola virus*, the causative agent of smallpox. LRN is a network of state and local public health, federal, U.S. Department of Defense (DOD), veterinary, food, and environmental testing laboratories. CDC developed, and the Food and Drug Administration (FDA) granted 510(k) clearance* for the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set (non-variola Orthopoxvirus [NVO] assay), a polymerase chain reaction (PCR) diagnostic test to detect NVO. On May 17, 2022, CDC was contacted by the Massachusetts Department of Public Health (DPH) regarding a suspected case of monkeypox, a disease caused by the *Orthopoxvirus Monkeypox virus*. Specimens were collected and tested by the Massachusetts DPH public health laboratory with LRN testing capability using the NVO assay. Nationwide, 68 LRN laboratories had capacity to test approximately 8,000 NVO tests per week during June. During May 17–June 30, LRN laboratories tested 2,009 specimens from suspected monkeypox cases. Among those, 730 (36.3%) specimens from 395 patients were positive for NVO. NVO-positive specimens from 159 persons were confirmed by CDC to be monkeypox; final characterization is pending for 236. Prompt identification of persons with infection allowed rapid response to the outbreak, including isolation and treatment of patients, administration of vaccines, and other public health action. To further facilitate access to testing and increase convenience for providers and patients by using existing provider-laboratory relationships, CDC and LRN are supporting five large commercial laboratories with a national footprint (Aegis Science, LabCorp, Mayo Clinic Laboratories, Quest Diagnostics, and Sonic Healthcare) to establish NVO testing capacity of 10,000 specimens per week per laboratory. On July 6, 2022, the first commercial laboratory began accepting specimens for NVO testing based on clinician orders.

LRN was established in 1999† as a partnership among CDC, the Federal Bureau of Investigation, and the Association of Public Health Laboratories, with the goal of ensuring a laboratory infrastructure across the United States that can respond quickly and effectively to biothreats, chemical threats, and emerging infectious diseases (*1*). LRN provides the framework to rapidly distribute laboratory diagnostic tests, standardized reagents, and standard operating procedures, and to train laboratory personnel, report laboratory test results, and provide critical communication during routine and emergency responses. LRN includes approximately 110 U.S. laboratories, primarily state and local public health and DOD laboratories, as well as veterinary, food, and environmental testing laboratories. LRN laboratories are required to participate in proficiency testing exercises to ensure competency for laboratory test methods distributed to the network.

To effectively respond to a potential *Orthopoxvirus* outbreak, CDC subject matter experts worked with LRN to design, develop, and validate an assay to detect NVOs, such as *Vaccinia, Cowpox, Monkeypox,* and *Ectromelia* viruses, if suspected cases were identified. The NVO assay first received 510(k) clearance by FDA in 2005 and was cleared again in 2018 to update the labeling and use of reagents. The NVO assay does not differentiate *Monkeypox virus* from other O*rthopoxviruses*. NVOs are not endemic in the United States; however, the NVO assay has been used to detect cases of *Vaccinia virus* infection associated

* https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

† https://emergency.cdc.gov/lrn/usmap.asp

with vaccination and two imported cases of monkeypox from travelers in 2021 (*2*).

CDC recommends that for each patient, clinicians collect two specimens, each from multiple lesions, preferably from different locations on the body and from lesions with differing appearances (*3*). The CDC *Monkeypox virus* testing algorithm includes NVO testing, and if results are positive for *Orthopoxvirus*, further characterization testing at CDC (*4*). A subset of specimens was characterized at CDC by a *Monkeypox virus* specific real-time PCR assay and genetic sequencing.[§] The median LRN laboratory testing turnaround time was calculated from the time of specimen receipt by LRN testing laboratories to arrival of NVO test results at CDC. Testing capacity was estimated and reported by LRN laboratories. This report describes NVO testing by LRN during May 17–June 30, 2022. This investigation was reviewed by CDC and conducted consistent with applicable federal law and CDC policy.[¶]

As of June 10, 68 U.S. LRN laboratories, located in 47 states and the District of Columbia, had implemented the NVO assay updated in 2018 and tested specimens from patients with probable monkeypox cases. These laboratories reported an estimated total testing capacity of 8,000 specimens per week. LRN laboratories reported that capacity of NVO testing laboratories was limited by reagent availability and the requirement for manual DNA extraction. To increase testing throughput and build capacity, the NVO assay was rapidly updated to include additional controls, automated extraction, and real-time PCR instrumentation in collaboration with FDA; the updated assay received 510(k) clearance on June 10, 2022. As of June 30, 2022, 78 LRN laboratories had implemented the NVO assay and have reported a total testing capacity of 24,000 specimens per week with implementation of substantial operational changes such as adding extra shifts, reassigning personnel, and shifting testing priorities based on laboratory emergency response plans.

During May 17–June 30, a total of 2,009 specimens were tested in LRN laboratories (Table); 730 (36.3%) specimens from 395 persons across 31 jurisdictions (including 29 states, District of Columbia, and Puerto Rico) were confirmed positive for *Orthopoxvirus* using the NVO assay. One positive specimen from each patient (159) was sent to CDC and further characterized as *Monkeypox virus* belonging to the West African clade; as of June 30, 236 confirmed *Orthopoxvirus* cases were pending characterization. The median LRN laboratory testing turnaround time was 30.7 hours for all results (Table).

Although LRN laboratories provide initial recognition and detection of emerging infectious diseases, rapid expansion of nationwide testing capacity was indicated for this outbreak. Therefore, CDC obtained 510(k) clearance from FDA on June 23 to enable CDC to provide the NVO assay to five large commercial laboratories under a licensing agreement that included CDC training and test verification before the start of testing. This expansion of testing provides additional test capacity and electronic laboratory reporting to public health authorities, makes testing more accessible, and streamlines diagnostic testing for multiple, possible infections. When fully operational, these five national commercial laboratories are anticipated to increase weekly testing capacity nationwide by approximately 10,000 specimens per laboratory.

Discussion

CDC and LRN have collaborated with public health partners to prepare for *Orthopoxvirus* outbreaks, enabling rapid public health response through the development and expansion of testing capacity and medical countermeasures to prevent the spread of disease. Laboratory preparedness efforts included NVO test validation, FDA 510(k) clearance, distribution, and verification of diagnostic tests to detect NVO. This response highlights the importance of preparedness against emerging infectious diseases and the need to further strengthen and expand LRN to include other partners to enhance testing capability and increase surge testing capacity.

Because monkeypox disease has been rare in the United States, CDC's NVO assay is the only FDA 510(k)–cleared assay to detect NVO; at the onset of this outbreak, use of the assay was limited to LRN laboratories. The 510(k) clearance facilitated rapid testing and detection of a rare, high-risk, and emerging pathogen by LRN laboratories by maintaining competency and biosafety practices, results reporting, and collaborating with public health authorities, all essential to the initial national response.

CDC recommends that U.S. health care providers be alert for patients who have rash illnesses consistent with monkeypox (*5*) and include NVO testing as part of their clinical workup. Clinicians who suspect a case of monkeypox can contact their local or state health department[**] for specimen submission guidance. A rapid turnaround time for test results is critical to quickly initiate public health action to better control the spread of monkeypox disease. Treatment is the same for all NVO infections; thus, a positive test result for an *Orthopoxvirus*

[§] https://www.biorxiv.org/content/10.1101/2022.06.10.495526v1

[¶] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[**] https://cdn.ymaws.com/www.cste.org/resource/resmgr/poc/epioncall_update1622.pdf

TABLE. Number of specimens* tested for non-variola *Orthopoxvirus* and testing turnaround times, by week — Laboratory Response Network, United States, May 17–June 30, 2022

Date range, 2022	No. of specimens tested	No. (%) positive for NVO†	Median turnaround time from specimen receipt to CDC report, hrs	
			All	Positive
May 17–23	25	16 (64.0)	34.1	34.1
May 24–30	57	3 (5.3)	28.2	23.7
May 31–Jun 6	164	38 (23.2)	30.0	19.2
Jun 7–13	334	80 (24.0)	28.4	27.4
Jun 14–20	350	138 (39.4)	25.2	25.3
Jun 21–27	647	237 (36.6)	37.9	44.7
Jun 28–30	432	218 (50.4)	30.9	37.0
Total, May 17–Jun 30	**2,009**	**730 (36.3)**	—	—
Cumulative median	—	—	**30.7**	**30.2**

Abbreviation: NVO = non-variola *Orthopoxvirus*.
* Number of specimens exceeds number of cases because some persons had multiple specimens collected for testing.
† All paired specimens sent to CDC were confirmed as *Monkeypox virus*.

Summary

What is already known on this topic?

The Laboratory Response Network (LRN) includes U.S. laboratories validated to perform the non-variola *Orthopoxvirus* (NVO) assay.

What is added by this report?

During May 17–June 30, 2022, LRN laboratories tested 2,009 specimens from patients with suspected monkeypox. Among these, 730 (36%) specimens from 395 patients were positive for NVO. Specimens from 159 persons with NVO-positive results were confirmed by CDC to be monkeypox; confirmatory testing is pending for 236. LRN laboratories have increased testing capacity from 8,000 per week in June because of NVO assay updates.

What are the implications for public health practice?

LRN laboratories' rapid results enable prompt patient treatment and prevention of further transmission. Expansion of testing to five large national laboratories will increase ease of access to testing.

using the NVO assay is immediately actionable, leading to the use of antiorthopoxviral treatment, if warranted, and allowing public health authorities to initiate isolation, contact tracing, monitoring, investigation, and postexposure prophylaxis of exposed contacts (*5*). In addition, if monkeypox is suspected based on clinical signs and symptoms, clinicians can initiate treatment, advise patients to isolate while awaiting test results, and take measures to prevent further transmission, like limiting close contact with others or avoiding the sharing of potential contaminated items. Tecovirimat (TPOXX) can also be prescribed as treatment for people with monkeypox, and two vaccines, JYNNEOS and ACAM2000 (*6*) can be provided to close contacts as postexposure prophylaxis.

By the end of June 2022, <10% of the available nationwide LRN NVO testing capacity had been used. Despite the high capacity, some clinicians and patients reported challenges navigating public health testing procedures, including acquiring public health approvals for testing. Expansion to five commercial laboratories starting the week of July 5 should make testing more accessible, increase convenience for providers and patients by both using existing provider-laboratory relationships and eliminating the need for prior public health approval, and further augment national capacity. Expanded testing access via both LRN and commercial laboratories provides the opportunity to identify all cases of *Orthopoxvirus* to enhance monitoring and response to the outbreak.

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Notes from the Field

Outbreak of *Salmonella* Enteritidis at a Correctional Facility Using Mechanically Separated Chicken — Nebraska, 2022

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On January 14, 2022, the Lincoln-Lancaster County (Nebraska) Health Department (LLCHD) notified the Nebraska Department of Health and Human Services (NDHHS) of two cases of laboratory-confirmed *Salmonella* in inmates at a correctional facility (facility A). LLCHD initiated an investigation in collaboration with NDHHS to identify the source of the outbreak and develop recommendations. The investigation linked consumption of mechanically separated chicken to illness. Mechanically separated chicken, which is produced at chicken processing facilities by separating edible chicken from bone and cartilage under pressure, is frequently purchased for use in institutions, such as prisons, jails, and correctional facilities because of its affordability (*1*,*2*).

Staff members at facility A reported approximately 100 inmates experienced gastrointestinal symptoms during a period of a few days; no staff member reported illness. LLCHD conducted open-ended interviews with ill inmates. Because the facility was experiencing a concurrent outbreak of COVID-19, and access to inmates for interviews was limited, it is likely that additional cases existed among noninterviewed and untested inmates beyond the total cases identified in the investigation. Inmates who were designated food handlers were prioritized for interviews because of transmission risk to others; untested inmates were able to seek care through facility A medical staff. A probable case was defined as the onset of diarrhea, stomach cramps, or vomiting during January 9–11, 2022, but without a positive stool culture, in an inmate at facility A; a confirmed case was defined as isolation of *Salmonella* serotype Enteritidis highly related to the outbreak strain (within three alleles) by core genome multilocus sequence typing in a clinical specimen. LLCHD conducted an environmental assessment on January 15, 2022. A list of food handlers, food menus for January, and temperature logs were requested. During the environmental assessment, a sample of raw, unopened mechanically separated chicken from a 50-lb intact box from the same shipment used to prepare a meal on January 8, 2022, was collected for testing.

A total of 15 cases of *S.* Enteritidis infection were identified, including five confirmed and 10 probable cases. The median patient age was 39 years (range = 24–62 years); 93% were male and two patients were hospitalized. All 15 cases occurred in food workers, all of whom reported eating chili that had been prepared from the raw mechanically separated chicken product.

S. Enteritidis that genetically matched the outbreak strain was isolated from the raw mechanically separated chicken sample. The Food Safety and Inspection Service agency of the U. S. Department of Agriculture (USDA) was notified by NDHHS of the poultry product matching the outbreak. However, *Salmonella* spp. are not considered adulterants of raw poultry products because *Salmonella* is regularly present on poultry products, and safe standard cooking practices typically destroy *Salmonella* bacteria; therefore, no regulatory action was taken* (*3*).

The environmental assessment identified potential food safety risks in both incomplete thawing and cooking processes for mechanically separated chicken. Qualitative interviews revealed that the mechanically separated chicken product was sometimes still frozen or partially frozen at the time of cooking; this process was also observed by LLCHD on a follow-up site visit. Cooking temperatures were not routinely monitored while food was being prepared, and LLCHD was unable to verify that the mechanically separated chicken product reached a safe internal cooking temperature before being served.

LLCHD provided recommendations for prevention of foodborne outbreaks to facility A, which included policies for excluding ill workers from food preparation, increased thawing time for mechanically separated chicken under refrigeration, routine monitoring and recording of cooking temperatures, and adjustment of meals to smaller preparation volumes to mitigate food safety risks. LLCHD worked with facility management to implement new policies and procedures for food safety practices.

This outbreak of *S.* Enteritidis was associated with mechanically separated chicken and substandard cooking processes. Mechanically separated chicken products routinely tested by USDA have indicated a higher prevalence of *Salmonella* spp. (82.9%) than ground chicken (39.0%) and other comminuted chicken products (41.7%) sampled and tested during June 1, 2013–December 31, 2014 (*4*). Mechanically separated chicken is typically used as an ingredient in other processed meat products, such as hot dogs, which can be thermally processed to ensure they are cooked to a safe internal temperature (*1*). Several previous state and multistate salmonellosis outbreaks have implicated mechanically separated chicken as the source of infection in correctional facilities† (*1*). Populations who

* https://www.fsis.usda.gov/sites/default/files/media_file/2021-09/FSIS-GD-2013-0003.pdf

† https://www.cdc.gov/salmonella/heidelberg-01-14/index.html

are obligated to eat in certain locations and who have limited choice regarding what they eat are dependent on societal responsibility to ensure their health and the facility's food safety procedures (*5*). Mitigating the risks of food handling and processing and cooking in vulnerable populations and institutions requires two key actions: 1) providing a less highly contaminated poultry product in the absence of contamination threshold regulatory requirements for poultry products and 2) implementing a preventive food safety management system to ensure thawing, cooking, and cooling processes meet food safety requirements.

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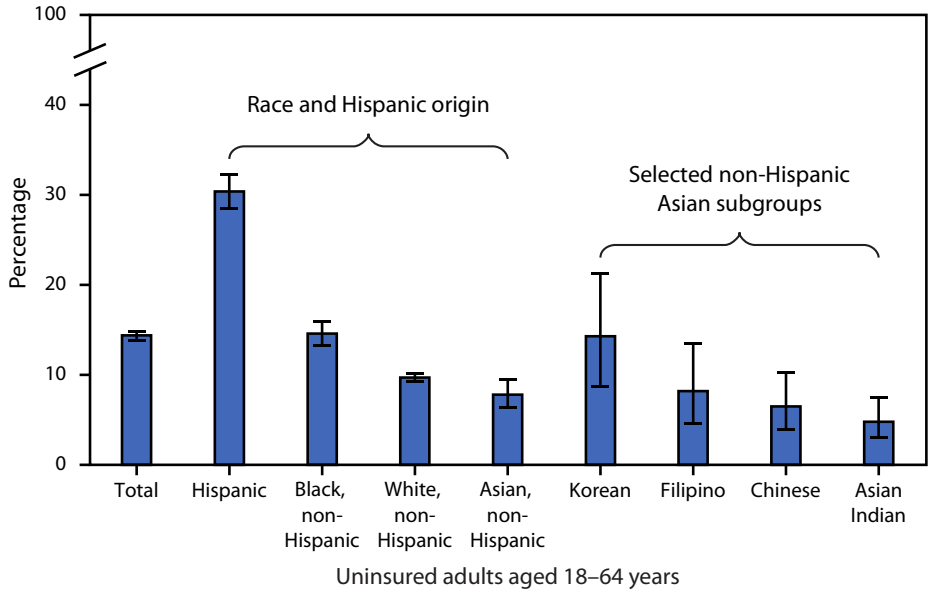
QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Uninsured Adults Aged 18–64 Years,† by Race, Hispanic Origin, and Selected Asian§ Subgroups — National Health Interview Survey, United States, 2019–2020



* With 95% CIs indicated by error bars.
† Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population and are derived from the 2019 and 2020 National Health Interview Survey.
§ Asian, non-Hispanic includes other Asian subgroups, which are not shown.

During 2019–2020, the percentage of U.S. adults aged 18–64 years who were uninsured was 14.4%. Among all race and Hispanic origin groups, non-Hispanic Asian adults (7.8%) were the least likely to be uninsured followed by non-Hispanic White (9.7%), non-Hispanic Black (14.6%), and Hispanic adults (30.4%). Among the non-Hispanic Asian subgroups shown, adults of Korean (14.3%) origin were more likely to be uninsured than adults of Asian Indian (4.8%) and Chinese (6.5%) origin. Other observed differences were not statistically significant.

Source: National Health Interview Survey, 2019 and 2020 data. https://www.cdc.gov/nchs/nhis.htm

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