

## Progress Toward Achieving and Sustaining Maternal and Neonatal Tetanus Elimination — Worldwide, 2000–2022

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### Abstract

Tetanus remains a considerable cause of mortality among undervaccinated mothers and their infants following unhygienic deliveries, especially in low-income countries. Strategies of the maternal and neonatal tetanus elimination (MNTE) initiative, which targets 59 priority countries, include strengthening antenatal immunization of pregnant women with tetanus toxoid-containing vaccines (TTCVs); conducting TTCV supplementary immunization activities among women of reproductive age in high-risk districts; optimizing access to skilled birth attendants to ensure clean deliveries and umbilical cord care practices; and identifying and investigating suspected neonatal tetanus cases. This report updates a previous report and describes progress toward MNTE during 2000–2022. By December 2022, 47 (80%) of 59 priority countries were validated to have achieved MNTE. In 2022, among the 50 countries that reported coverage with  $\geq 2$  doses of TTCV among pregnant women, 16 (32%) reported coverage of  $\geq 80\%$ . In 2022, among 47 validated countries, 26 (55%) reported that  $\geq 70\%$  of births were assisted by skilled birth attendants. Reported neonatal tetanus cases worldwide decreased 89%, from 17,935 in 2000 to 1,995 in 2021; estimated neonatal tetanus deaths decreased 84%, from 46,898 to 7,719. However, the global disruption of routine immunization caused by the COVID-19 pandemic impeded MNTE progress. Since 2020, reported neonatal tetanus cases have increased in 18 (31%) priority countries. Integration of MNTE strategies into priority countries' national postpandemic immunization recovery activities is needed to achieve and sustain global elimination.

### Introduction

Maternal and neonatal tetanus\* remains a substantial cause of mortality among undervaccinated mothers and their infants following unhygienic delivery, especially in low-income countries (1). In 1989, the World Health Assembly endorsed neonatal tetanus elimination.<sup>†</sup> This activity was relaunched in 1999 as the maternal and neonatal tetanus elimination (MNTE)<sup>§</sup>

\*Tetanus is an infection caused by *Clostridium tetani*, a bacterium that produces a potent toxin. Maternal tetanus occurs during pregnancy or within 6 weeks of the end of pregnancy and might occur during abortion, miscarriage, or birth with unhygienic delivery. Neonatal tetanus occurs during the first 28 days of life, after either the cutting of the umbilical cord under nonsterile conditions or applying nonsterile traditional remedies to the umbilical stump in an infant who does not have passively (transplacentally) acquired maternal antibodies (i.e., the mother is not immune to tetanus).

<sup>†</sup>The occurrence of  $< 1$  neonatal tetanus case per 1,000 live births per year in every district in every country.

<sup>§</sup>Neonatal tetanus elimination is considered a proxy for maternal tetanus elimination; the same strategies for elimination are common to both.

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initiative, targeting 59 priority countries.<sup>¶</sup> Because tetanus spores cannot be eliminated from the environment, and tetanus infection does not confer immunity, elimination requires ongoing active immunization with a tetanus toxoid-containing vaccine (TTCV). To protect infants from tetanus susceptibility at birth, women of reproductive age (usually 15–49 years) should be vaccinated with  $\geq 2$  doses of TTCV (TTCV2+), and immunization is recommended for undervaccinated pregnant women early in the third trimester (2). The MNTE initiative includes four strategies: 1) providing antenatal immunization of pregnant women with TTCV2+; 2) conducting TTCV supplementary immunization activities (SIAs)\*\* in selected high-risk districts,<sup>††</sup> targeting women of reproductive age for TTCV immunization; 3) supporting clean delivery and umbilical cord care practices through access to skilled birth

attendants<sup>§§</sup>; and 4) identifying and investigating suspected neonatal tetanus cases with reliable surveillance (2,3). Since the MNTE initiative began in 1999, the estimated proportion of neonatal mortality attributed to tetanus decreased 84%, from 2% in 2000 to 0.3% in 2021.<sup>¶¶</sup> The remaining risk for maternal and neonatal tetanus infection is concentrated in low-income communities with low TTCV coverage and limited access to hygienic delivery. This report summarizes progress toward achieving and sustaining MNTE during 2000–2022 and updates a previous report (4).

## Methods

### Immunization Activities, Deliveries by Skilled Birth Attendants, and Surveillance

To estimate TTCV coverage among pregnant women through routine immunization services and the number of neonates protected from tetanus at birth,<sup>\*\*\*</sup> the World Health Organization (WHO) and UNICEF use vaccination coverage

<sup>¶</sup> Afghanistan, Angola, Bangladesh, Benin, Burkina Faso, Burma, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Comoros, Republic of the Congo, Côte d'Ivoire, Democratic Republic of the Congo, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Haiti, India, Indonesia, Iraq, Kenya, Laos, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Namibia, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Sudan, Togo, Turkey, Uganda, Tanzania, Vietnam, Yemen, Zambia, and Zimbabwe. The creation of Timor-Leste in 2002 and South Sudan in 2011 increased the number of priority countries to 59.

\*\* Mass vaccination campaigns conducted in three rounds to administer 3 doses of TTCV to women of reproductive age in high-risk districts.

<sup>††</sup> Districts considered to be at high risk because the estimated neonatal tetanus case rate exceeds one per 1,000 live births, clean delivery coverage is <70%, and 3-dose TTCV coverage among pregnant women during the previous 5 years is <80%.

<sup>§§</sup> A doctor, nurse, midwife, or health worker trained in providing lifesaving obstetric care, including giving necessary supervision, care, and advice to women during pregnancy, childbirth, and the postpartum period.

<sup>¶¶</sup> Neonatal mortality data were unavailable for 2022. <https://platform.who.int/data/maternal-newborn-child-adolescent-ageing/indicator-explorer-new/mca/number-of-neonatal-deaths---by-cause>

<sup>\*\*\*</sup> The status of an infant born to a mother who received 2 doses of TTCV during the previous birth,  $\geq 2$  doses with the last dose received  $\leq 3$  years before the last delivery,  $\geq 3$  doses with the last dose received  $\leq 5$  years earlier,  $\geq 4$  doses with the last dose received  $\leq 10$  years earlier, or receipt of  $\geq 5$  previous doses.

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survey data and administrative data<sup>†††</sup> received from member countries (5). WHO and UNICEF also receive summaries of the number of women of reproductive age receiving TTCV during SIAs (6). The percentages of births assisted by skilled birth attendants are estimated from country health facility reports and coverage survey estimates (7). WHO recommends nationwide, case-based neonatal tetanus surveillance, active surveillance through regular visits to reporting sites (8), and country reports of neonatal tetanus case counts.<sup>§§§</sup> Because most neonatal deaths occur in remote areas, which might lead to underreporting, neonatal tetanus deaths are estimated using mathematical models that project cause-specific neonatal mortality using Bayesian and multinomial frameworks (9). This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.<sup>¶¶¶</sup>

### Validation of Maternal and Neonatal Tetanus Elimination

Once a country's surveillance data indicate that neonatal tetanus incidence has declined to <1 case per 1,000 live births in all districts, prevalidation assessments are conducted (3). Benchmarks for validating MNTE achievement include reaching <1 neonatal tetanus case per 1,000 live births, ≥80% routine TTCV2+ coverage among pregnant women, and ≥70% of deliveries assisted by skilled birth attendants. Assessments might also review supplementary measures, including TTCV2+ SIA coverage among women of reproductive age, antenatal care coverage,<sup>\*\*\*\*</sup> infant coverage with 3 doses of diphtheria, tetanus, and pertussis vaccine,<sup>††††</sup> socioeconomic indices, field visits to determine health system performance, validation surveys in the poorest performing districts, and assessment of long-term plans for sustaining elimination.<sup>§§§§</sup>

### Maintenance of Maternal and Neonatal Tetanus Elimination

Once MNTE has been validated, WHO recommends that countries conduct annual neonatal tetanus risk analyses as part of immunization program reviews, and postvalidation assessments every 5 years, to determine whether elimination has been

sustained and take any necessary corrective actions (3). The following indicators were used to determine maintenance of MNTE countries' performance: 1) ≥80% TTCV2+ coverage among pregnant women accessing antenatal care, 2) ≥90% routine immunization TTCV coverage among children and adolescents (i.e., receipt of 3 primary infant doses and 3 booster doses), 3) ≥70% of deliveries by a skilled birth attendant, and 4) ≥90% of infants protected at birth against tetanus (2).

## Results

### Immunization Activities

In 2022, among 59 priority countries, 50 (85%) reported antenatal TTCV2+ coverage data; 16 (32%) of these reported ≥80% TTCV2+ coverage. During 2000–2022, a total of 52 (88%) priority countries conducted TTCV SIAs (Table). Among 41 countries with 2000 and 2022 data available, TTCV2+ coverage increased in 30 (73%). Worldwide, the proportion of infants protected at birth increased from 74% in 2000 to 86% in 2022 (Figure 1), and the number of priority countries that achieved MNTE increased from 1 (2%) of 57 in 2000 to 47 (80%) of 59 in 2022 (Figure 2).

During 2000–2022, SIAs provided TTCV2+ to 177 million (70%) of 252 million women of reproductive age targeted to receive vaccination. During 2021–2022, seven countries conducted TTCV SIAs, vaccinating 13 million women of reproductive age. However, by the end of 2022, 68 million women who were targeted for protection by TTCV SIAs remained unreached.

### Deliveries Assisted by Skilled Birth Attendants

In 2022, among 47 priority countries with available data, 26 (55%) reported that ≥70% of births were assisted by skilled birth attendants (Table). Compared with the most recent report (4), the proportions of births assisted by skilled birth attendants was higher in 12 countries (Afghanistan, Burkina Faso, Cambodia, Chad, Côte d'Ivoire, Egypt, Kenya, India, Malawi, Mauritania, Niger, and Nigeria) in 2022 than in 2020.

### Neonatal Tetanus Surveillance and Incidence

Among the 59 MNTE priority countries, 11 (19%) reported zero neonatal tetanus cases in 2022; however, seven countries reported more cases in 2022 than in 2000 (Table). Worldwide, reported neonatal tetanus cases decreased by 89%, from 17,935 in 2000 to 1,995 in 2021. Estimated neonatal tetanus deaths decreased 84%, from 46,898 in 2000 to 7,719 in 2021, accounting for 2% and 0.3% of all-cause neonatal mortality, respectively (Figure 1). Since 2020, reported neonatal tetanus cases have increased in 18 (31%) priority countries, including 13 previously validated countries.

<sup>†††</sup> Administrative data to calculate the number of neonates protected at birth estimates the number of doses administered through routine services (numerator) divided by the number in target group (denominator) × 100.

<sup>§§§</sup> <https://www.who.int/data/gho/data/indicators/indicator-details/GHO/neonatal-tetanus---number-of-reported-cases>

<sup>¶¶¶</sup> 45 C.F.R. part 46.102(l)(3), 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.

<sup>\*\*\*\*</sup> Antenatal care coverage is the percentage of females aged 15–49 years with a live birth who received antenatal care provided by a skilled birth attendant at least once during pregnancy.

<sup>††††</sup> [https://www.who.int/data/gho/data/indicators/indicator-details/GHO/diphtheria-tetanus-toxoid-and-pertussis-\(dtp3\)-immunization-coverage-among-1-year-olds-\(-\)](https://www.who.int/data/gho/data/indicators/indicator-details/GHO/diphtheria-tetanus-toxoid-and-pertussis-(dtp3)-immunization-coverage-among-1-year-olds-(-))

<sup>§§§§</sup> <https://cdn.who.int/media/docs/default-source/immunization/mnte/who-ivb-18.15-eng.pdf>

TABLE. Indicators of achievement of maternal and neonatal tetanus elimination — 59 priority countries,\* 2000–2022

Country	Year of MNTE validation	≥2 TTCV doses among pregnant women, % <sup>†,§</sup>			Newborns protected at birth, % <sup>¶</sup>			Women of reproductive age vaccinated during TTCV SIA <sup>**</sup>		Skilled birth attendant at delivery, % <sup>††</sup>			No. of neonatal tetanus cases <sup>§§</sup>		
		2000	2022	% Change 2000–2022	2000	2022	% Change 2000–2022	No. of TT2+/Td2 doses administered	% Vaccinated	2000 <sup>¶¶</sup>	2022 <sup>¶¶</sup>	% Change 2000–2022	2000	2022	% Change 2000–2022
		Bangladesh***	2008	89	47	–48	89	98	10	1,438,374	47	12	59	388	376
Benin***	2010	81	89	10	87	83	–5	1,399,461	97	66	78	19	52	18	–65
Burkina Faso <sup>†††</sup>	2012	NA	93	NA	57	95	67	2,306,835	91	38	96	154	22	1	–95
Burma	2010	81	55	–32	79	88	11	8,170,763	87	57	NA	NA	41	14	–66
Burundi	2009	28	60	114	51	87	71	679,222	55	25	77	204	16	0	–100
Cambodia	2015	40	69	72	58	93	60	2,099,471	79	32	99	210	295	7	–98
Cameroon	2012	40	54	35	54	81	50	2,687,461	85	56	69	23	279	40	–86
Chad	2019	12	84	598	39	75	92	3,222,840	84	14	47	245	142	269	89
China	2012	NA	NA	NA	NA	NA	NA	NA	NA	97	NA	NA	3,230	18	–99
Comoros	2009	40	78	96	57	83	46	160,767	55	62	NA	NA	NA	2	NA
Côte d'Ivoire	2013	78	72	–8	76	83	9	5,924,527	85	63	84	34	30	27	–10
Democratic Republic of the Congo	2019	25	96	284	45	80	78	10,342,937	92	61	85	40	77	15	–81
Egypt	2007	71	97	37	80	88	10	2,518,802	87	61	97	59	321	1	–100
Equatorial Guinea	2016	30	21	–30	61	60	–2	26,466	9	65	NA	NA	NA	0	NA
Eritrea	2003	25	65	160	80	99	24	NA	NA	28	NA	NA	4	0	–100
Ethiopia	2017	32	NA	NA	54	85	57	13,210,107	84	6	50	789	20	NA	NA
Gabon <sup>†††</sup>	2013	16	43	171	39	83	113	79,343	90	86	95	11	8	8	0
Ghana	2011	73	63	–13	69	90	30	1,666,666	87	47	79	68	80	0	–100
Guinea-Bissau***	2012	NA	30	NA	49	80	63	312,669	98	32	54	69	NA	3	NA
Haiti	2017	NA	37	NA	41	78	90	2,785,588	88	24	42	75	40	NA	NA
India	2015	80	85	7	85	93	9	7,643,440	94	43	89	110	3,287	65	–98
Indonesia	2016	81	70	–14	82	83	1	1,442,264	50	66	95	43	466	21	–95
Iraq	2013	55	NA	NA	75	73	–3	111,721	96	65	96	47	37	NA	NA
Kenya <sup>†††</sup>	2018	51	65	27	68	85	25	4,463,695	67	43	89	109	1,278	NA	NA
Laos	2013	45	5	–89	58	93	60	968,323	90	17	64	286	21	NA	NA
Liberia	2011	25	64	156	51	90	76	288,984	57	51	84	66	152	12	–92
Madagascar	2014	40	51	27	58	75	29	2,705,588	72	47	46	–3	13	19	46
Malawi	2002	61	1	–98	84	90	7	NA	NA	56	96	73	12	5	–58
Mali <sup>§§§</sup>	2023	62	70	13	50	83	66	4,158,201	49	41	67	66	73	3	–96
Mauritania	2015	NA	29	NA	44	81	84	586,277	76	53	70	32	NA	0	NA
Mozambique <sup>†††</sup>	2010	61	NA	NA	75	84	12	605,640	79	48	68	42	42	105	150
Namibia	2001	60	36	–41	74	90	22	NA	NA	76	NA	NA	10	0	–100
Nepal	2005	60	93	55	67	91	36	4,537,864	86	12	77	549	134	3	–98
Niger	2016	31	80	158	63	83	32	2,184,277	92	16	44	178	55	20	–64
Philippines	2017	58	NA	NA	55	91	65	1,034,080	78	58	84	46	281	54	–81
Republic of the Congo	2009	39	83	114	67	87	30	273,003	91	83	91	9	2	8	300
Rwanda***	2004	NA	76	NA	81	97	20	NA	NA	31	94	201	5	7	40
Senegal	2011	45	100	123	62	96	55	359,845	92	58	75	29	0	1	NA
Sierra Leone	2013	20	84	320	53	93	75	1,704,814	102	37	87	134	36	5	–86
South Africa	2002	65	NA	NA	68	88	29	NA	NA	91	NA	NA	11	0	–100
Tanzania	2012	77	90	17	79	90	14	987,575	NA	43	64	46	48	13	–73
Timor-Leste	2012	NA	34	NA	NA	85	NA	24,141	53	24	NA	NA	NA	1	NA
Togo	2005	47	74	58	63	83	32	262,130	87	35	69	96	33	12	–64
Turkey	2009	36	68	89	50	97	94	1,242,674	58	83	97	17	26	0	–100
Uganda	2011	42	59	41	70	81	16	2,448,527	86	39	NA	NA	470	NA	NA
Vietnam***	2005	90	88	–2	86	96	12	367,842	69	59	96	63	142	33	–77
Zambia	2007	61	NA	NA	78	83	6	330,030	81	42	80	91	130	50	–62
Zimbabwe	2000	60	NA	NA	76	89	17	NA	NA	NA	86	NA	16	0	–100

See table footnotes on the next page.

**Validation of Maternal and Neonatal Tetanus Elimination**

During 2000–2022, 47 (80%) of the 59 priority countries were validated to have achieved MNTE (Table). No countries achieved validation during 2020–2022; however, MNTE was validated in Mali in 2023.

**Maintenance of Maternal and Neonatal Tetanus Elimination**

As of 2022, among 47 MNTE-validated countries, 15 (32%) achieved ≥90% coverage with 3 primary doses of routine immunization TTCV. TTCV booster doses were included in the routine immunization schedule for children aged 12–23 months in 14 (30%) of those countries, and for children



TABLE. (Continued) Indicators of achievement of maternal and neonatal tetanus elimination — 59 priority countries,\* 2000–2022

Country	Year of MNTE validation	≥2 TTCV doses among pregnant women, % <sup>†,§</sup>			Newborns protected at birth, % <sup>¶</sup>			Women of reproductive age vaccinated during TTCV SIAs**		Skilled birth attendant at delivery, % <sup>††</sup>			No. of neonatal tetanus cases <sup>§§</sup>		
		2000	2022	% Change 2000–2022	2000	2022	% Change 2000–2022	No. of TT2+/ Td2 doses administered	% Vaccinated	2000 <sup>¶¶</sup>	2022 <sup>¶¶</sup>	% Change 2000–2022	2000	2022	% Change 2000–2022
		<b>Maternal and neonatal tetanus elimination not validated by the end of 2023</b>													
Afghanistan	—	20	92	361	32	60	88	5,212,394	45	14	62	332	139	20	–86
Angola	—	NA	39	NA	60	65	8	7,097,552	84	NA	50	NA	131	239	82
Central African Republic	—	20	84	320	36	65	81	2,595,415	42	32	40	27	37	38	3
Guinea	—	43	90	109	79	80	1	4,957,272	49	49	55	14	245	85	–65
Nigeria***	—	NA	43	NA	57	67	18	13,820,506	51	35	51	44	1,643	55	–97
Pakistan	—	51	66	29	71	86	21	28,219,661	81	23	68	196	1,380	509	–63
Papua New Guinea***	—	10	36	256	24	65	171	450,739	15	39	56	45	138	13	–91
Somalia	—	22	74	234	47	57	21	497,561	27	19	32	65	966	0	–100
South Sudan	—	NA	51	NA	NA	65	NA	6,247,983	56	NA	40	NA	NA	0	NA
Sudan	—	34	NA	NA	61	81	33	7,365,615	86	NA	NA	NA	88	NA	NA
Yemen	—	31	24	–23	54	73	35	3,612,931	51	27	NA	NA	174	132	–24

Abbreviations: MNTE = maternal and neonatal tetanus elimination; NA = not available; SIA = supplementary immunization activity; TT2+ and Td2+ = ≥2 doses of tetanus toxoid and tetanus-diphtheria toxoid; TTCV = tetanus toxoid–containing vaccine; WHO = World Health Organization.

\* Afghanistan, Angola, Bangladesh, Benin, Burkina Faso, Burma, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Comoros, Côte d’Ivoire, Democratic Republic of the Congo, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Haiti, India, Indonesia, Iraq, Kenya, Laos, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Namibia, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Republic of the Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Tanzania, Timor-Leste, Togo, Turkey, Uganda, Vietnam, Yemen, Zambia, and Zimbabwe.

† TTCV data from WHO/UNICEF Joint Reporting Form on Immunization (2000–2022).

§ Includes first-year SIA conducted in Bangladesh in 1999 and first- and second-year SIAs conducted in Ethiopia in 1999.

¶ Protected at birth data from WHO/UNICEF Joint Reporting Form on Immunization (2000–2022).

\*\* SIA data from WHO/UNICEF MNTE Database, as of March 2024.

†† Skilled birth attendant data from WHO Global Health Observatory Data Repository (2000–2022).

§§ Neonatal tetanus case data from WHO Global Health Observatory Data Repository (2000–2022).

¶¶ Includes skilled birth attendant surveys conducted within 5 years for years 2000 and 2022.

\*\*\* Administrative ≥2-dose TTCV coverage among women of reproductive age was used when official data were unavailable for selected country.

††† Skilled birth attendant data were extracted from country-specific demographic health surveys. <https://www.dhsprogram.com/data/available-datasets.cfm>

§§§ MNTE was not validated in Mali by the end of 2022; however, elimination was validated in 2023.

and adolescents aged 4–7 and 9–15 years in 11 (23%) countries. In 46 (98%) countries, ≥70% of infants were protected at birth against tetanus; and in 26 (55%), ≥70% of births were assisted by a skilled birth attendant (Table). Six countries have conducted postvalidation assessments.

### Discussion

Substantial progress has been made toward global MNTE, with 80% of priority countries validated as having achieved elimination by the end of 2022. TTCV2+ coverage increased in 30 priority countries, and in 26 countries, skilled birth attendants assisted in ≥70% of births. Since 2000, 52 priority countries have conducted TTCV SIAs. During 2021–2022, seven countries yet to achieve MNTE conducted SIAs, reaching 13 million (42%) women of reproductive age with TTCV2+ and contributing to a 16% increase in the number of infants protected at birth. Worldwide, during 2000–2022, the number of reported neonatal tetanus cases declined by 89%, from 17,935 to 1,995, and estimated neonatal tetanus mortality decreased 84%, from 46,898 to 7,719, since 2000. In addition, by 2022 four of six geopolitical zones in Nigeria,

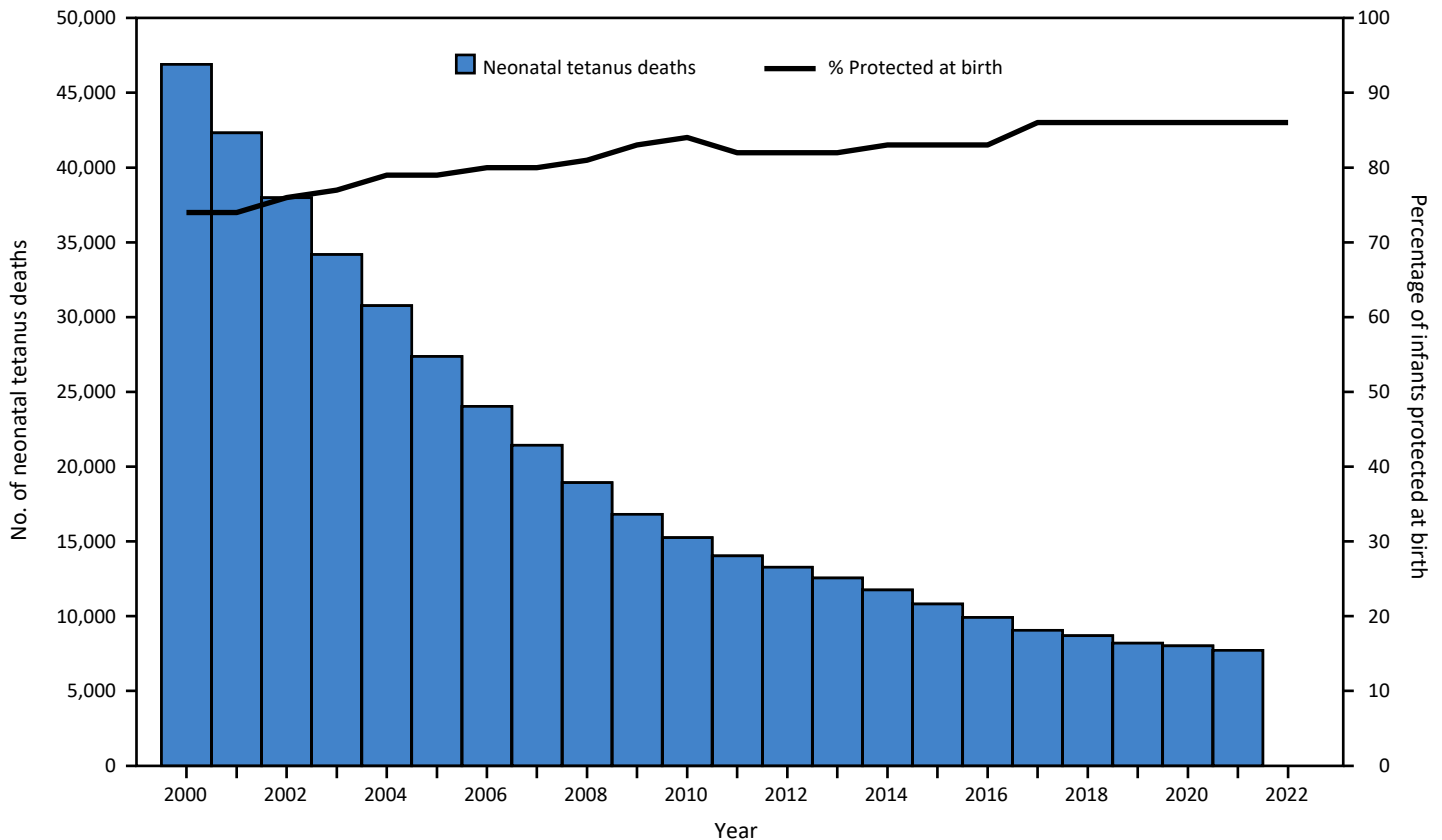
and Punjab province in Pakistan were validated to have achieved elimination.<sup>¶¶¶</sup>

Although progress has been substantial, challenges to MNTE remain, some of which were amplified by the COVID-19 pandemic and its global disruption of immunization services.<sup>\*\*\*\*</sup> Many countries that have not yet validated MNTE have fragile health systems with barriers to improving vaccination coverage and accessing skilled birth attendants. For example, in countries experiencing political instability and conflict, more areas might be hard to reach, magnifying the challenges to providing immunization and safe hygienic deliveries, as well as ensuring reliable detection of and response to occurrent neonatal tetanus cases. Recovery of national immunization programs has been challenging in some countries that experienced increases in some vaccine-preventable diseases in the wake of the COVID-19 pandemic.

¶¶¶ [https://www.who.int/initiatives/maternal-and-neonatal-tetanus-elimination-\(mnte\)/the-partnership](https://www.who.int/initiatives/maternal-and-neonatal-tetanus-elimination-(mnte)/the-partnership)

\*\*\*\* <https://www.who.int/news/item/15-07-2021-covid-19-pandemic-leads-to-major-backsliding-on-childhood-vaccinations-new-who-unicef-data-shows>

FIGURE 1. Estimated number of neonatal tetanus deaths<sup>\*,†</sup> and estimated percentage of infants protected at birth<sup>§,¶</sup> against tetanus — worldwide, 2000–2022<sup>\*\*</sup>



**Abbreviations:** TTCV = tetanus toxoid-containing vaccine; WHO = World Health Organization.

\* The number of deaths is estimated from mathematical models that compute the yearly incidence and mortality for each country using the baseline rate of neonatal tetanus before TTCV introduction and promotion of clean deliveries, with adjustment for the estimated proportion of women vaccinated with TTCV and deliveries assisted by trained personnel.

† Neonatal tetanus data from Child and Adolescent Cause of Death Estimation Group.

§ Protected at birth data from WHO/UNICEF Joint Reporting Form on Immunization (2000–2022).

¶ The status of an infant born to a mother who received 2 doses of TTCV during the last birth,  $\geq 2$  doses with the last dose received  $\leq 3$  years before the last delivery,  $\geq 3$  doses with the last dose received  $\leq 5$  years earlier,  $\geq 4$  doses with the last dose received  $\leq 10$  years earlier, or receipt of  $\geq 5$  previous doses.

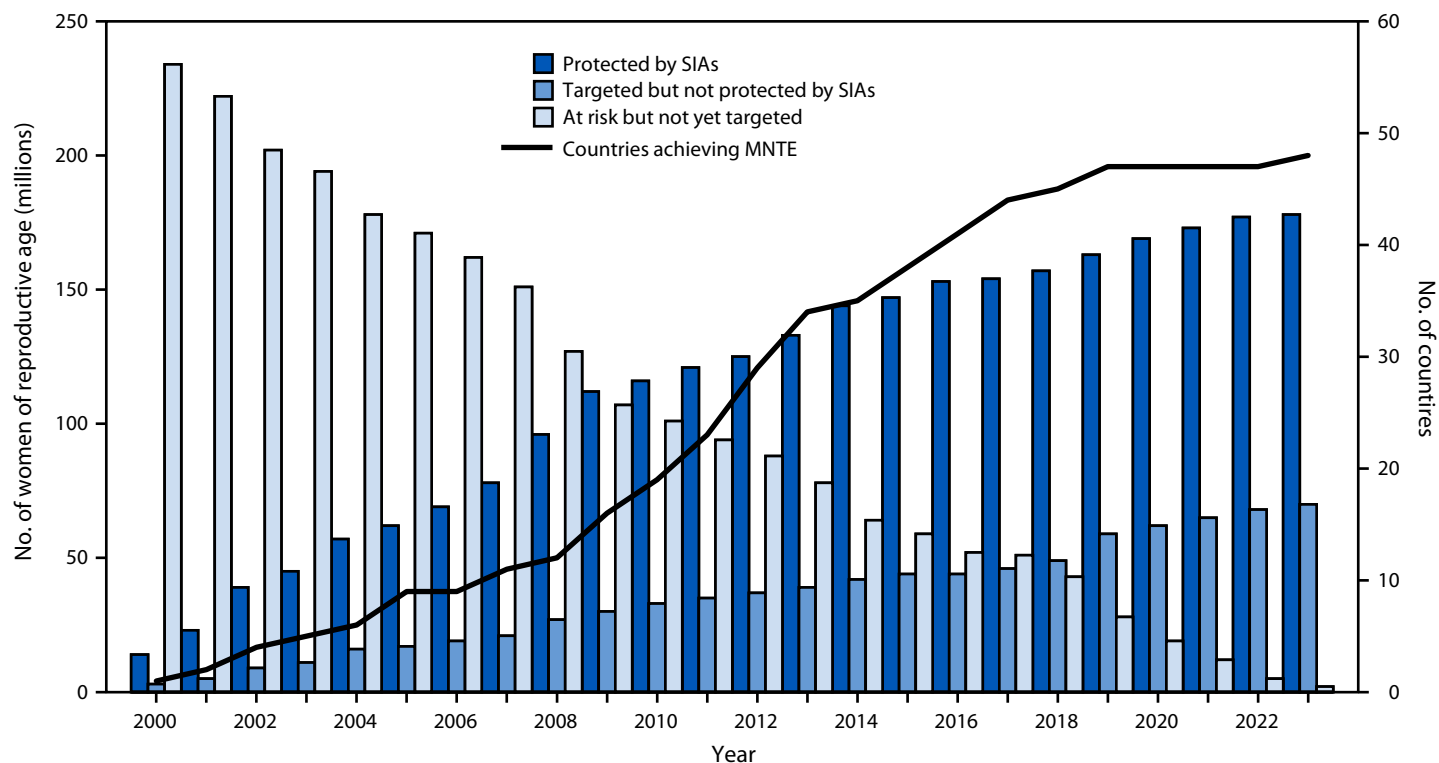
\*\* Death data for 2022 were not available.

In addition to continuing measures to achieve global MNTE, more attention is needed to ensure that elimination is sustained in countries previously validated to have achieved MNTE. Since 2020, reported neonatal tetanus cases have increased in 13 previously validated countries. This increase might indicate better surveillance system sensitivity; however, it might also reflect lack of protection at birth and the need for improved antenatal vaccination measures. By 2022, only one third of 43 MNTE-validated countries sustained  $\geq 80\%$  TTCV2+ coverage, and in 12 MNTE-validated countries, fewer than 70% of births were assisted by skilled birth attendants. As of 2022, fewer than one third of validated countries had introduced  $\geq 1$  TTCV booster dose into their routine immunization schedule. This slow introduction might be attributed to lower prioritization of MNTE activities after validation because of

funding constraints, putting countries at risk for reemergence of neonatal tetanus (3).

Sustaining MNTE requires strong commitments from priority countries and the global community. Countries will need to improve resource and program efficiency by integrating postvalidation assessments with immunization program reviews and TTCV booster dose vaccination with other immunization activities (e.g., school vaccination programs). Innovative activities to integrate neonatal tetanus case-based surveillance into surveillance for other vaccine-preventable diseases, such as polio and measles, might support system efficiency and sustainability, and public engagement might help raise awareness and strengthen community-based vaccine-preventable disease surveillance systems (8).

**FIGURE 2.** Number of women of reproductive age protected by tetanus toxoid–containing vaccine\* received during supplementary immunization activities, number targeted† but not yet vaccinated, number not yet targeted,‡ and number of countries achieving maternal and neonatal tetanus elimination — 59 priority countries,¶ worldwide, 2000–2022



Source: WHO/UNICEF Maternal and Neonatal Tetanus Elimination Database, as of March 2024.

Abbreviations: MNTE = maternal and neonatal tetanus elimination; SIAs = supplementary immunization activities; WHO = World Health Organization.

\* Protected with 2 doses of tetanus toxoid or tetanus and diphtheria toxoids.

† Women of reproductive age included in SIA coverage goals.

‡ Women of reproductive age estimated to be living in high-risk districts, which are yet to be targeted for tetanus toxoid–containing vaccine SIAs, primarily for programmatic reasons.

¶ Afghanistan, Angola, Bangladesh, Benin, Burkina Faso, Burma, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Haiti, India, Indonesia, Iraq, Kenya, Laos, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Namibia, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Timor-Leste, Togo, Turkey, Uganda, Tanzania, Vietnam, Yemen, Zambia, and Zimbabwe.

## Limitations

The findings in this report are subject to at least three limitations. First, reported TTCV2+ coverage among pregnant women can underestimate actual protection because it does not account for women who received TTCV doses in previous pregnancies but were unvaccinated during their current pregnancy (2). Second, whereas MNTE validation is based on district-level assessments, reports of immunization coverage used in this update are based on national estimates and might obscure interdistrict differences. Finally, neonatal deaths are estimated using mathematical models (9); thus, estimates are subject to model assumptions.

## Implications for Public Health Practice

MNTE has been included in the WHO Immunization Agenda 2030<sup>††††</sup> global strategy as an endorsed vaccine-preventable disease elimination target. As part of the worldwide effort to increase immunization coverage after the COVID-19 pandemic, integration of MNTE activities with those of other vaccine-preventable diseases is needed to improve progress toward MNTE. One such strategy includes promoting a life course approach to vaccination by integrating TTCV booster doses in school health programs and in other life course immunization platforms (10). Promotion of equitable access to health services, such as clean deliveries, is also important to achieving MNTE.

†††† <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

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## Summary

## What is already known about this topic?

Tetanus causes considerable mortality among undervaccinated mothers and their infants following unhygienic deliveries, especially in low-income countries. The maternal and neonatal tetanus elimination initiative targets 59 priority countries.

## What is added by this report?

During 2000–2022, 47 priority countries achieved maternal and neonatal tetanus elimination, contributing to global declines in neonatal tetanus cases (89%) and neonatal tetanus deaths (84%). Despite progress, the global disruption of routine immunization caused by the COVID-19 pandemic impeded elimination progress. Since 2020, reported neonatal tetanus cases have increased in 18 (31%) priority countries.

## What are the implications for public health practice?

Integration of maternal and neonatal tetanus elimination strategies into priority countries' national immunization activities is needed to achieve and sustain elimination globally.

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# Childhood Lead Exposure Linked to Apple Cinnamon Fruit Puree Pouches — North Carolina, June 2023–January 2024

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## Abstract

Lead exposure is toxic even at low levels, resulting in impairments that can affect a child's lifelong success. In North Carolina, testing for lead is encouraged for all children at ages 1 and 2 years and required for children covered by Medicaid; investigations are performed to identify potential exposure sources for children with blood lead levels (BLLs)  $\geq 5$   $\mu\text{g}/\text{dL}$ . During June–August 2023, routine lead testing identified four asymptomatic North Carolina children with BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$ . Home investigations identified only WanaBana brand apple cinnamon fruit puree pouches as a potential exposure source; product samples contained 1.9–3.0 ppm of lead. An expanded nationwide investigation led to identification of approximately 500 cases of childhood lead exposure believed to be linked to consumption of apple cinnamon purees, including 22 cases in North Carolina. Fewer than one half (45%) of the 22 North Carolina cases were among children covered by Medicaid. A coordinated multiagency communication strategy was implemented in North Carolina to notify consumers of the hazard and provide recommendations for preventing further exposure. The Food and Drug Administration issued a nationwide public health advisory on October 28, 2023; 2 days later, the manufacturer issued a voluntary recall. Routine testing of young children for lead exposure, combined with thorough environmental investigations, can identify emerging sources of lead exposure and limit further harm.

## Introduction

North Carolina encourages testing of all children for lead at ages 1 and 2 years and requires testing for children enrolled in Medicaid. All blood lead test results for children aged  $<6$  years are reportable to the North Carolina Department of Health and Human Services (NCDHHS) Childhood Lead Poisoning Prevention Program (CLPPP) (1). A child aged  $<6$  years with two consecutive capillary or venous blood lead levels (BLLs)  $\geq 5$   $\mu\text{g}/\text{dL}$  within a 12-month period is considered to have a confirmed, reportable lead level and is eligible for a home investigation conducted by a registered environmental health specialist (field investigator) from the applicable county health

department to identify the likely source of lead exposure.\* When edible or consumer products are suspected as a source of lead exposure, environmental samples are collected from the home and analyzed by the North Carolina State Laboratory of Public Health (NCSLPH) Inorganic Chemistry Laboratory.† Edible or consumer products with lead levels above North Carolina's reportable limits ( $\geq 1.0$  ppm for most spices and foods) are reported to the Food and Drug Administration (FDA). Medical providers of children with confirmed BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$  are advised to use the North Carolina Clinical Follow-Up Schedule§ to monitor the child's BLL and to provide additional case management as warranted. During June–August 2023, routine lead testing identified four asymptomatic children in three unrelated households with BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$  who are the focus of this report, triggering home investigations to identify and remove sources of exposure.

## Investigation and Results

### Household A

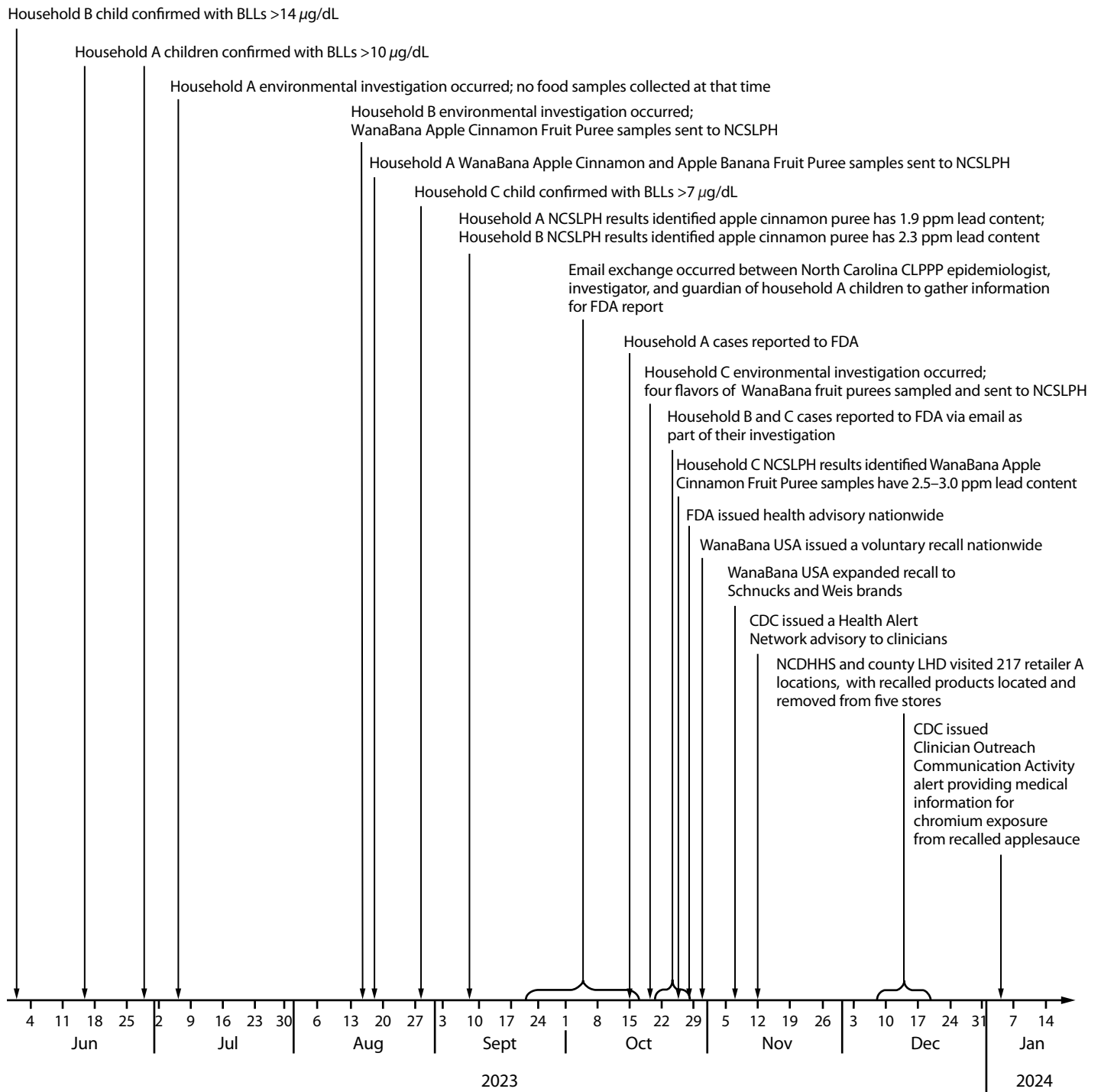
During June 2023, routine blood lead testing identified two siblings, aged 1 and 3 years, living in a western North Carolina county, each of whom had two consecutive BLLs  $\geq 10$   $\mu\text{g}/\text{dL}$  within a 12-month period (Figure). An environmental investigation conducted in July did not yield any potential sources as the likely cause of lead exposure. The field investigator

\* An environmental investigation consists of visits to the home and potentially other addresses where the child regularly visits or spends time (defined by North Carolina General Statute Sect.130A–131.7[14]), such as child care facilities; the collection of water and environmental samples (dust, soil, and paint); and x-ray fluorescence analyzer readings in addition to an interview. The investigation usually concludes when the likely source is identified, which can take weeks of waiting for laboratory results or additional site visits. [https://www.ncleg.net/EnactedLegislation/Statutes/PDF/ByChapter/Chapter\\_130A.pdf#page=108](https://www.ncleg.net/EnactedLegislation/Statutes/PDF/ByChapter/Chapter_130A.pdf#page=108)

† NCSLPH provides essential laboratory support to CLPPP partners. This support is accomplished through the American Industrial Hygiene Association's Lead Assessment Program accredited testing of dust wipes, paint chips, and soil samples and through analytical screening of many other matrices, including spices, ceremonial powders, herbal remedies, cosmetics, toys, and foods. Food testing for lead is performed on inductively coupled plasma mass spectrometry instrumentation following Environmental Protection Agency method 6020B.

§ [https://ehs.dph.ncdhhs.gov/hhcehb/cehu/lead/docs/ClinicalFollowUpSchedule\\_3.18.22.pdf](https://ehs.dph.ncdhhs.gov/hhcehb/cehu/lead/docs/ClinicalFollowUpSchedule_3.18.22.pdf)

FIGURE. Response timeline\* of an investigation of childhood lead exposure linked to consumption of WanaBana Apple Cinnamon Fruit Puree pouches — North Carolina, June 2023–January 2024



**Abbreviations:** BLLs = blood lead levels; CLPPP = Childhood Lead Poisoning Prevention Program; FDA = Food and Drug Administration; LHD = local health department; NCDHHS = North Carolina Department of Health and Human Services; NCSLPH = North Carolina State Laboratory of Public Health.

\* Confirmation of the case is based on the date of the second consecutive BLLs  $\geq 5$  µg/dL. The order of the environmental investigations was based on when the site visit was conducted.

suspected that a food item commonly consumed by both children could be the source, because children aged 1 year and 3 years have different hand-to-mouth behavior, yet the siblings' BLLs rose simultaneously. On a food log, the parents recalled that both siblings ate WanaBana fruit puree pouches. In mid-August, the field investigator sent samples of apple cinnamon and apple banana flavor WanaBana fruit pouches taken from the home to the NCSLPH. Results obtained in September indicated that the apple cinnamon flavor contained 1.9 ppm lead<sup>‡</sup>; the North Carolina CLPPP was notified. On October 17, an initial report including laboratory results, packaging photos, lot numbers, and place of purchase (retailer A) was submitted to FDA.

### Household B

During June 2023, a child aged 2 years living in a different western North Carolina county was identified through routine testing to have two consecutive BLLs >14 µg/dL. An environmental investigation conducted in mid-August by the same field investigator who conducted the household A investigation did not identify any potential sources as the likely cause of lead exposure. However, when asked about food or spice consumption, the child's parent mentioned that the child consumed applesauce pouches purchased from retailer A. A sample of WanaBana Apple Cinnamon Fruit Puree obtained from the home was sent to NCSLPH. In early September, NCSLPH reported that the sample contained 2.3 ppm lead.

### Household C

During August 2023, a child aged 1 year living in a third western North Carolina county was identified through routine testing to have two consecutive BLLs ≥7 µg/dL. During preliminary interviews and water sample collection at the child's home in September, none of the usual property-related lead sources were identified. During a home investigation in mid-October, the field investigator administered North Carolina CLPPP's spice and home remedy survey.\*\* The survey collects information that FDA requires to take public health action, including questions about spices, ceremonial powders, and alternative medicines, and is available in multiple languages. Using the survey, the investigator asked about consumption of cinnamon applesauce, which revealed that family members had

purchased more than 90 pouches of four flavors of WanaBana fruit puree pouches for the child from three locations of retailer A in North Carolina and Kentucky.

While at the home, the field investigator contacted the NCSLPH Inorganic Chemistry Laboratory to develop a comprehensive sampling plan. This plan included testing whole, unopened pouches of four flavors (apple cinnamon, pineapple and banana, apple and banana, and mango and banana) found in the home and the pouch material. Water, soil, and dust samples were also submitted. On October 24, NCSLPH reported that three different lot numbers of the apple cinnamon product contained lead in concentrations ranging from 2.5 to 3.0 ppm.

## Public Health Response

### Initial Response and Health Advisory

After FDA was alerted on October 17 that lead had been detected in a food product from household A, North Carolina public health officials and FDA worked together with county health departments to determine whether other children might have been exposed. North Carolina public health officials provided FDA with additional laboratory test results and the results of environmental investigations from households A, B, and C, including where affected lots were purchased, and collected product to test from retailer A locations across the state. North Carolina public health agencies also collaborated with the North Carolina Department of Agriculture and Consumer Services (NCDACS) laboratory, which provided retail product analysis, confirming NCSLPH results. Within 2 weeks, FDA confirmed North Carolina's findings and issued a nationwide public health advisory. On October 28, North Carolina and FDA disseminated press releases urging consumers to dispose of contaminated products and contact their medical providers for testing (2,3). North Carolina public health officials notified all county health departments and the state's child care licensing agency of the advisory. In accordance with North Carolina protocol for reporting food sample results during field investigations, households A, B, and C were advised to discard the apple puree products based on the initial NCSLPH product testing results. Follow-up testing indicated that BLLs among the affected children declined, adding confidence that the source had been identified.

### Voluntary Nationwide Product Recall

On October 30, WanaBana USA issued a voluntary nationwide recall of all lots of apple cinnamon fruit puree pouches that was expanded on November 9 to include private label brands Schnucks Apple Sauce with Cinnamon and Weis Cinnamon Apple Sauce (4). After the recall, NCSLPH continued to

<sup>‡</sup> FDA has developed draft guidance for action levels for lead in processed food intended for infants and young children: 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards and puddings, and single-ingredient meats; 20 ppb for root vegetables (single-ingredient); and 20 ppb for dry infant cereals. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children>

\*\* <https://ehs.dph.ncdhhs.gov/docs/forms/cehu/SpiceandHomeRemedySurvey0000000000FINAL-English-fillable.pdf>

test WanaBana products collected statewide from homes and stores, demonstrating consistently elevated lead concentrations (1.9–5.8 ppm). On November 13, CDC issued a nationwide Health Alert Network advisory that indicated multiple states had reported to FDA potential cases of high BLLs among children consuming recalled cinnamon-containing applesauce and recommended that clinicians report cases to their local health authorities (5).

### Nationwide Investigation

After the recall, CDC launched a nationwide effort to systematically identify cases of BLLs greater than the CDC reference value of 3.5  $\mu\text{g}/\text{dL}$  among children associated with consumption of the implicated products<sup>††</sup>. By January 2024, a total of 22 cases among children in North Carolina (all with BLLs  $\geq 5 \mu\text{g}/\text{dL}$ , based on investigations going back to spring 2023) were identified and reported to CDC (Table). Of the 22 North Carolina cases, 10 (45%) were among children enrolled in Medicaid, and no typical sources of potential lead exposure were identified for any of the children with confirmed cases. On January 5, 2024, FDA reported that the source of lead in the involved products was cinnamon obtained from Ecuador, which also contained chromium in the form

<sup>††</sup> [https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html?CDC\\_AAref\\_Val=https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html](https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html?CDC_AAref_Val=https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html)

of lead chromate (6). A total of 519 cases nationwide were reported to CDC from state and local health departments as of March 22, 2024 (6).

### North Carolina Recall Audit

The NCDHHS's Environmental Health Section notified local food banks, child care center operators, and school food service managers of the recall through a statewide listserv. County health department staff members were advised to look for the recalled product during routine inspections of schools, child care centers, and institutional facilities. NCDHHS worked with NCDACS and the North Carolina Association of Local Health Directors' leadership to ensure that recalled products were removed from retailer A stores. During 217 store visits conducted December 8–19 by county health department staff members, products were removed from five stores.

### Discussion

Routine lead testing and environmental investigations in North Carolina resulted in the identification of a novel source of lead exposure that was ultimately linked to approximately 500 cases of childhood lead exposure nationwide, including 22 cases in North Carolina. In addition to following Centers for Medicare & Medicaid Services requirements for lead testing of Medicaid-enrolled children, CDC currently recommends focusing testing efforts on children having sociodemographic risk factors (e.g., being a racial or ethnic minority, living

**TABLE. Selected characteristics of children with confirmed blood lead levels\*  $\geq 5 \mu\text{g}/\text{dL}$  and exposure to lead-contaminated WanaBana Apple Cinnamon Fruit Puree pouches (N = 22) — North Carolina, June 2023–January 2024**

Characteristic	Investigated blood lead cases, according to CDC case definitions, <sup>†</sup> no. (%)			
	Confirmed	Probable	Suspected	Total
No. of cases (%)	11 (50)	6 (27)	5 (23)	22 (100)
Age, mos, mean (range)	19 (12–37)	21 (12–26)	19 (12–33)	20 (12–37)
Age, mos, median (IQR)	15 (13–23)	22 (17–26)	18 (13–21)	17 (13–25)
Male sex	7 (64)	5 (83)	2 (40)	14 (64)
Race				
Asian	2 (18)	1 (17)	0 (—)	3 (14)
Black or African American	2 (18)	1 (17)	2 (40)	5 (23)
White	5 (45)	3 (50)	3 (60)	11 (50)
Unknown	2 (18)	1 (17)	0 (—)	3 (14)
Hispanic or Latino ethnicity <sup>§</sup>	0 (—)	1 (17)	1 (20)	2 (9)
Enrolled in Medicaid	3 (33)	3 (50)	4 (80)	10 (45)
Initial BLL, $\mu\text{g}/\text{dL}$ , mean (range)	15.2 (5.5–23.0)	9.1 (5.4–16.6)	7.1 (4.8–10.3)	11.7 (4.8–23.0)
Confirmatory BLL, $\mu\text{g}/\text{dL}$ , mean (range)	12.9 (8.1–23.5)	9.2 (5.2–15.9)	8.0 (5.5–12.8)	10.8 (5.2–23.5)
Product lead level, ppm, mean (range)	3.0 (1.9–5.8)	NA	NA	3.0 (1.9–5.8)

**Abbreviations:** BLL = blood lead level; NA = not available.

\* In North Carolina, a child has a confirmed high BLL when they have a blood lead concentration of  $\geq 5 \mu\text{g}/\text{dL}$  determined by the lower of two consecutive blood tests within a 12-month period. The initial test might be from a capillary sample; however, the confirmatory test is preferably performed on a venous blood sample. Children with confirmed BLL 5–9  $\mu\text{g}/\text{dL}$  are eligible for a home investigation to determine the source of exposure. When BLLs are confirmed  $\geq 10 \mu\text{g}/\text{dL}$ , investigations are mandatory. Only those children eligible for an investigation (i.e., with BLLs  $\geq 5 \mu\text{g}/\text{dL}$ ) are included in the data reported.

<sup>†</sup> [https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html?CDC\\_AAref\\_Val=https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html](https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html?CDC_AAref_Val=https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html)

<sup>§</sup> Persons of Hispanic or Latino (Hispanic) origin might be of any race but are categorized as Hispanic; all racial groups are non-Hispanic.



in a low-income household, or having environmental lead exposures) and those living in housing built before 1978.<sup>§§</sup> However, fewer than one half of the North Carolina cases were among children enrolled in Medicaid, and no typical potential sources of lead exposure were identified as the likely cause for one half of the children, including those from households A, B, and C. This finding suggests that the recommendation for routine lead testing of all young children in North Carolina at ages 1 and 2 years might have led to detection of cases that would not otherwise have been identified and resulted in earlier identification and removal of a novel exposure source.

Although lead-contaminated paint, water, dust, and soil are the most recognized lead hazards, other products have been found to contain lead, including candies, spices, ceremonial powders, and alternative medicines (7–9). As older houses containing lead-based paint are renovated or demolished, environmental sources have become less frequent. Awareness of other sources, such as spices adulterated with lead chromate, is important (10).

This investigation highlights the potential benefits of broader routine blood lead testing for earlier detection of novel sources of lead exposure, such as foods and spices. Coordinated inter-agency collaboration and communication are essential for effectively detecting and responding to these events to prevent further harm.

<sup>§§</sup> <https://www.cdc.gov/lead-prevention/php/news-features/updates-blood-lead-reference-value.html>

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County and regional registered environmental health specialists and lead nurses at the 86 health departments who were involved in the initial and ongoing investigations, Scott Carpenter, Gabrielle Carter, Caroline Cheshire, Savannah Kent, North Carolina Department of Health and Human Services Environmental Health Section; Daniel Gaines, Anita MacMullan, North Carolina Department of Agriculture and Consumer Services; Michele Howard, Amanda Osteen, Food and Drug Administration; Susan Kansagra, North Carolina Department of Health and Human Services; Michael Beuhler, North Carolina Poison Control Center.

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### Summary

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

Lead exposure is toxic even at low levels, especially in young children. In North Carolina, investigations are performed to identify potential exposure sources for children with blood lead levels (BLLs)  $\geq 5$   $\mu\text{g}/\text{dL}$ .

#### What is added by this report?

During June–August 2023, routine testing identified four children in three unrelated North Carolina homes with BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$ . Investigations identified WanaBana Apple Cinnamon Fruit Puree pouches as the likely exposure source. A collaborative multilevel response led to detection of approximately 500 cases of childhood lead exposure potentially linked to consumption of apple cinnamon purees nationwide. Voluntary recall of the implicated products prevented additional exposures.

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

Routine BLL testing of young children and environmental investigations can help identify emerging sources of lead exposure.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Carissa Moore reports owning stock in Amazon and being a member of Sam's Club, both of which were vendors of the recalled product. Scott M. Shone is an elected member of the board of directors of the Association of Public Health Laboratories. Edward H. Norman reports support from the North Carolina Department of Health and Human Services for attendance at meetings and membership in the Lead and Environmental Hazard Association. No other potential conflicts of interest were disclosed.

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## Notes from the Field

### Schedule I Substances Identified in Nootropic Gummies Containing *Amanita muscaria* or Other Mushrooms — Charlottesville, Virginia, 2023–2024

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Since late 2023, according to conversations between investigators and smoke shop employees, gas stations and smoke shops in Virginia have been selling mushroom gummies, marketed as nootropics (substances taken to enhance cognitive function) or psychedelics. These gummies are labeled to contain either *Amanita muscaria* or proprietary mushroom nootropic blends. Unlike other hallucinogenic mushrooms that contain the Drug Enforcement Administration (DEA) schedule I substance psilocybin, *A. muscaria* is currently legal.\* *A. muscaria* contains ibotenic acid and muscimol and is used less commonly as a hallucinogen than are psilocybin-containing mushrooms because *A. muscaria* can cause undesired symptoms, including gastrointestinal upset, agitation, and seizures (1–3). During September 2023–June 2024, five patients, including one child, were evaluated in Virginia after ingestion of gummies listing *A. muscaria* as an ingredient. Because the actual contents of these novel mushroom gummies are unknown, samples from five brands were obtained for testing using liquid chromatography–mass spectrometry.

#### Investigation and Outcomes

During September 1–November 20, 2023, the Blue Ridge Poison Center (BRPC) in Charlottesville, Virginia managed four cases of illness in adults who had intentionally ingested mushroom gummies labeled to contain the *A. muscaria* mushroom and were evaluated in an emergency department (ED). All patients experienced tachycardia, confusion, anxiety or somnolence, and nausea, and one patient reported chest pain. Two patients received benzodiazepines, three received antiemetics, and all four received intravenous fluids. All patients were discharged from the ED within 12 hours. In June 2024, BRPC managed an accidental ingestion of two *A. muscaria* mushroom gummies by a child aged 3 years who was hospitalized with symptoms of somnolence and vomiting. The child required no interventions and was discharged 1 day later.

\* Schedule I substances are defined as drugs with no currently accepted medical use and a high potential for abuse. <https://www.dea.gov/drug-information/drug-scheduling>

All patients managed by BRPC were reported to ingest different mushroom gummy brands, but all brands taken by the patients were labeled to contain muscimol,<sup>†</sup> ibotenic acid,<sup>§</sup> and muscarine.<sup>¶</sup> To determine whether these mushroom nootropics also contained other substances, investigators purchased six packages (five different brands) during October at gas stations and smoke shops near BRPC for testing. Because the specific brands reported by the patients were not available at these shops, investigators purchased three brands listing the same ingredients. In addition, two brands that were labeled to contain unspecified mushroom nootropics but were not labeled with *A. muscaria* were also purchased. Samples were analyzed by the University of Virginia Health Toxicology Laboratory using liquid chromatography–quadrupole time of flight on a Sciex X500R mass spectrometer. A qualitative untargeted approach was employed using independent data acquisition and substances identified using retention times, mass accuracy, and library matching.\*\*

Mushroom gummies in four of the six bags tested were found to contain unlabeled psilocybin or psilocin, both of which are schedule I substances not currently legal in Virginia, where they were sold (Table). Additional unlabeled substances were found, including caffeine, ephedrine, and mitragynine (an opioid agonist commonly known as kratom). Ibotenic acid, muscimol, and muscarine were not present in the matching library, and their presence in the gummies was undetermined.

<sup>†</sup> A naturally occurring psychoactive component found in *A. muscaria* and related mushrooms that displays sedative/hypnotic, depressant, and hallucinogenic activity. The compound works as a gamma-aminobutyric acid type A agonist. <https://pubchem.ncbi.nlm.nih.gov/compound/Muscimol>

<sup>§</sup> A naturally occurring psychoactive compound found in *A. muscaria* and *Amanita pantherine* mushrooms that works as a glutamate agonist. Signs and symptoms of intoxication include agitation, euphoria, and seizures. <https://pubchem.ncbi.nlm.nih.gov/compound/ibotenic%20acid>

<sup>¶</sup> A naturally occurring component of *Inocybe* and *Clitocybe* mushrooms. Found in trace amounts in *A. muscaria*. Signs and symptoms of intoxication include cholinergic symptoms such as headache, nausea, vomiting, and miosis. Effects can be reversed with anticholinergic drugs, such as atropine. <https://pubchem.ncbi.nlm.nih.gov/compound/muscarine>

\*\* High-resolution mass spectrometry allows for identification of unknown compounds. The technique used for analysis in this report matched various parameters to those in an established library to identify compounds that were then confirmed by comparing the samples with standard materials. This qualitative technique is useful to identify compounds present in a sample. The compounds must be included in the library and be present in the sample at concentrations that allow for accurate identification to be positive. The limit of detection for every compound in the library was not determined. Negative results do not necessarily mean the compound is not present, only that it is unable to be detected.

**TABLE. Analysis\* of contents of five brands of mushroom gummies marketed as nootropics and listing *Amanita muscaria* or other mushrooms as ingredients — Charlottesville, Virginia, 2023**

Brand	Listed product ingredients	Identified compounds*
Diamond Shruumz Sour Peach Apple	Mushroom nootropic, <sup>†</sup> caffeine, and lion's mane, chagas, and reishi mushrooms	Psilocin
Diamond Shruumz Rainbow	Mushroom nootropic, <sup>†</sup> caffeine, and lion's mane, chagas, and reishi mushrooms	Psilocin and caffeine
Urb Magic Amanita Mushroom Watermelon	Muscimol, ibotenic acid, muscarine, and <i>A. muscaria</i> extracts	Psilocybin, psilocin, hordenine, and 2-phenethylamine
Wonderland Legal Psychedelics Cherry Nirvana	<i>A. muscaria</i> extract, blue lotus extract, and reishi, lion's mane, and cordyceps mushrooms	Psilocin, N,N-dimethyltryptamine, caffeine, and mitragynine
Psilly's Legal Psychedelic Mushrooms Fruit Punch	Fly agaric ( <i>A. muscaria</i> ) extract and hemp-derived extract	Ephedrine
Tryp mushroom gummies	Lion's mane, reishi, cordyceps, maitake, and turkey tail mushroom extract and hemp extract	None

\* Analysis conducted in the University of Virginia Health Toxicology Laboratory using liquid chromatography–quadrupole time of flight mass spectrometry. The testing instrument did not have capability to test for muscimol, ibotenic acid, muscarine, or the mushrooms indicated as ingredients on the product labels, although those mushrooms (lion's mane, chagas, reishi, cordyceps, maitake, and turkey tail) are not psychogenic.

<sup>†</sup> Unspecified mushroom ingredients used to enhance cognition.

## Preliminary Conclusions and Actions

The presence of the DEA schedule I substances psilocybin and psilocin in products legally sold at retail shops in Virginia represents a potential risk to the public. Further, the presence of mitragynine in one product is concerning because repeated mitragynine ingestion can increase the risk for opioid dependence (4). Whether persons who ingest gummies indicated to contain *A. muscaria* or other nootropics are aware that they might be receiving psilocybin or other substances represented as *A. muscaria* or if they desire the *A. muscaria* itself is unknown. Separate from the investigation described in this report, on June 12, 2024, CDC released a health advisory reporting that CDC, the Food and Drug Administration, and America's Poison Centers<sup>††</sup> are investigating cases of severe acute illnesses potentially associated with consuming one brand of mushroom gummies and chocolate bars, and are providing guidance for clinicians, public health practitioners, and the public.<sup>§§</sup> Persons who believe they are purchasing gummies containing *A. muscaria* or other mushroom-containing gummies sold as psychedelics or nootropics should be aware that these products might contain undisclosed and potentially harmful substances. Clinicians should be aware that adults who consume these gummies can experience signs and symptoms that include hallucinations, altered mental status, tachycardia, and gastrointestinal upset. Mushroom gummy intoxication might appear similar to cannabis intoxication and can be included in the differential diagnosis of pediatric patients with unexplained

### Summary

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

Gummies listing the hallucinogenic mushroom *Amanita muscaria* or other unnamed mushrooms as ingredients have been marketed as “nootropics” (substances taken to enhance cognitive function). *A. muscaria* can cause hallucinations, agitation, gastrointestinal upset, and seizures.

#### What is added by this report?

During September 2023–June 2024, five persons required hospital evaluation after ingesting gummies labeled to contain *A. muscaria*. Five brands of gummies marketed as mushroom-containing nootropics were analyzed; three contained unlabeled Drug Enforcement Administration schedule I substances psilocybin and psilocin.

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

Health care providers and the public should be aware that edible products marketed as mushroom-containing nootropics might contain undisclosed ingredients and have been linked to severe illness. Persons who experience symptoms after consuming these products should seek immediate medical attention.

somnolence or altered mental status (5). Urine drug screens commonly used in health care facilities do not usually detect the substances identified in these gummies<sup>¶¶</sup>; additional testing could be considered based on discussions with a poison control center or local health authorities.

<sup>¶¶</sup> <https://emergency.cdc.gov/han/2024/han00509.asp>

<sup>††</sup> <https://nida.nih.gov/research-topics/drug-testing#detect>

<sup>§§</sup> <https://poisoncenters.org/>

Persons who purchase products advertised as psychedelic or nootropic mushroom gummies should be aware that package labels might not accurately represent the contents and that these products could contain substances that might produce unexpected and potentially toxic effects. Health care providers should counsel patients and caregivers that mushroom-containing edible products marketed with claims of health benefits might contain undisclosed ingredients and have been linked to illness requiring hospital care. Persons who experience symptoms after consuming these products should seek immediate medical attention.

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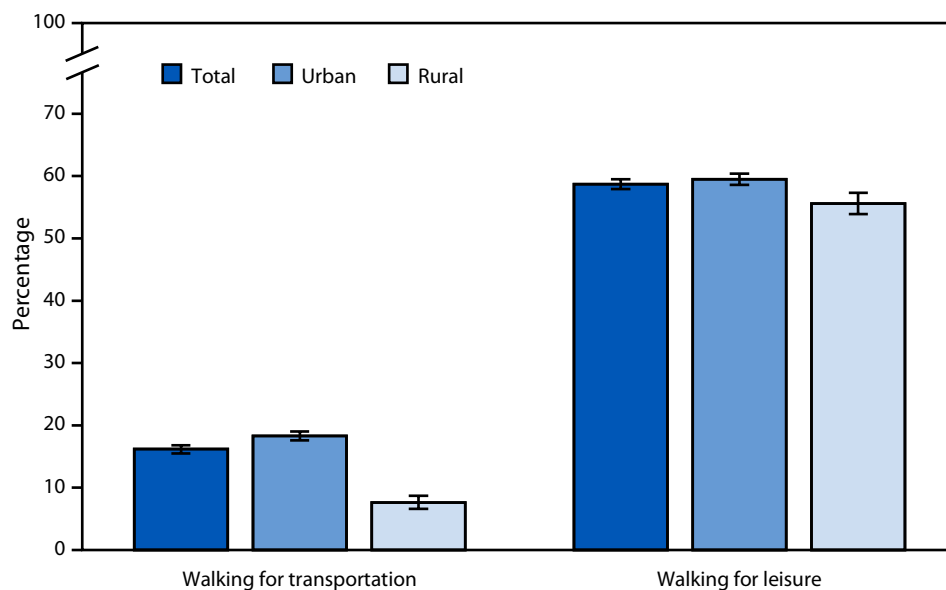
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## QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

## Percentage\* of Adults Aged $\geq 18$ Years Who Walked for Transportation and Walked for Leisure in the Past 7 Days,<sup>†</sup> by Urban-Rural Status<sup>§</sup> — United States, 2022



\* With 95% CIs indicated by error bars. Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population.

<sup>†</sup> Based on "yes" responses to the following questions: "The next questions are about walking for transportation. This is walking you might have done to travel to and from work, to do errands, or to go from place to place. In the past 7 days, did you walk for transportation?" and "Sometimes you may walk for fun, relaxation, exercise, or to walk the dog. In the past 7 days, did you walk for any of these reasons?"

<sup>§</sup> Urban-rural status is determined by the Office of Management and Budget's February 2013 delineation of metropolitan statistical areas (MSAs), in which each MSA must have at least one urban area of  $\geq 50,000$  inhabitants. Areas with  $< 50,000$  inhabitants are grouped into the rural category.

In 2022, among adults aged  $\geq 18$  years, 16.2% walked for transportation in the past 7 days, and 58.7% walked for leisure in the past 7 days. Urban residents were more likely than rural residents to walk for transportation and leisure.

**Supplementary Table:** <https://stacks.cdc.gov/view/cdc/157542>

**Source:** National Center for Health Statistics, National Health Interview Survey, 2022. <https://www.cdc.gov/nchs/nhis/index.htm>

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For more information on this topic, CDC recommends the following link:  
<https://www.cdc.gov/nccdphp/dnpao/features/getting-more-active-minutes/index.html>



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