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Elevated Blood Lead Levels in a Pregnant Woman and her Family from Traditional Kansa (Bronze) and Pital (Brass) Metalware — New York City, 2024

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Abstract

Lead exposure, even at low levels, can cause detrimental health effects across all ages. The New York City (NYC) Department of Health and Mental Hygiene receives blood lead results for NYC residents who are tested for lead and routinely conducts investigations to determine sources of lead exposure. In July 2024, blood lead surveillance activities in NYC revealed high levels of lead in traditional kansa (bronze) and pital (brass) metalware from Nepal. Use of these metalware items for preparing and serving food and drinks was associated with blood lead levels above CDC's blood lead reference value of 3.5 µg/dL in a pregnant woman, her spouse, and their child (range = $6-18.7 \mu g/dL$). Clinicians and public health professionals should be aware that traditional metalware from around the world can contain high levels of lead, and when used to prepare or serve food and drinks, can be communal sources of lead exposure.

Introduction

Persons of all ages can experience detrimental health effects of lead exposure, even at low levels.* In New York City (NYC), lead exposure is commonly associated with lead-based paint, especially among young children who engage in hand-tomouth behavior, and with occupational lead hazards among adults who work in the construction industry. Through routine surveillance activities, the NYC Department of Health and Mental Hygiene (DOHMH) has also identified various consumer products from around the world containing high levels of lead, including traditional ceramic and metalware used by members of many communities for preparing or serving food (1).

Methods

New York law requires that health care providers conduct blood lead testing for pregnant women determined to be at risk for lead exposure, based on the recommended assessment at their first prenatal visit.[†] Blood lead testing is also mandatory for children aged 1 and 2 years and adults with occupational lead exposure. §,¶ The NYC DOHMH receives all blood lead results for NYC residents who are tested for lead (2). Follow-up actions by NYC DOHMH are initiated at threshold blood lead levels (BLLs) of 3.5 µg/dL for children and pregnant women and 5 µg/dL for nonpregnant adults.** NYC DOHMH also recommends testing household members of persons with BLLs above the threshold. During follow-up investigations, NYC DOHMH administers a risk assessment questionnaire to identify potential lead sources and, when applicable, conducts environmental testing for lead in paint, dust, and consumer products such as spices, cultural powders, and

- † Lead Exposure in Pregnancy NYC DOHMH § Lead Exposure in Children NYC DOHMH; Lead Exposure in Adults NYC DOHMH
- 5 Occupational Safety and Health Standards for Lead OSHA
- ** Blood Lead Level Guidance CDC; CDC Updates Blood Lead Reference Value | Childhood Lead Poisoning Prevention - CDC

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^{*}Lead - ToxFAQs - Agency for Toxic Substances and Disease Registry

health remedies (2). Measurements of lead in paint are conducted using a Viken Detection handheld x-ray fluorescence (XRF) device and dust wipe samples are analyzed for lead by an accredited laboratory using Environmental Protection Agency method 7000B.†† Samples of consumer products suspected to contain lead, and which might be mouthed or ingested, are collected and sent to an accredited laboratory for analysis using the appropriate analytical methods. Certain consumer products such as ceramic or metalware are also screened for lead using the handheld XRF device before laboratory testing. Lead test results, risk assessments, and case notes are stored using a proprietary structured query language server database (3).

In this investigation, 33 XRF paint measurements and six dust wipe samples were collected for lead testing. In addition, 17 consumer product samples were tested for lead: spices (six samples), powders used for religious purposes (two), and imported metalware used to prepare or serve food and drinks (nine). The spices and powders were analyzed for lead using Environmental Protection Agency method SW6020. Metal cookware and dishware, which included four metalware items, were screened for lead using the Viken Detection handheld XRF device, and when feasible, analyzed for leachable lead using the ASTM International (formerly the American Society for Testing and Materials) C738 standard test method for Food and Drug

Administration (FDA) guidance (4). Lead results were compared with regulatory standards or available reference limits. The regulatory guideline for lead in paint is 0.5 mg/cm², and the guidelines for lead in dust are $10 \mu g/ft^2$ for floors, $50 \mu g/ft^2$ for windowsills, and $100 \mu g/ft^2$ for window troughs. The reference limits used as guidance for lead in the spices and powders were 2 ppm and 10 ppm, respectively (5,6). The metalware leachate lead concentrations were compared with the FDA regulatory guidance for silver-plated hollowware, which is 7 mg/L(4). The NYC DOHMH institutional review board determined that this activity did not constitute human subjects research.

Results

In July 2024, prenatal testing detected a venous BLL of $11.2~\mu g/dL$ in an asymptomatic woman aged 28 years, who was 11 weeks pregnant. Venous BLLs were $18.7~\mu g/dL$ for the woman's asymptomatic spouse, aged 27 years, and $6~\mu g/dL$ for their child, aged 7 years. Risk assessment interviews revealed that the pregnant woman's spouse had lived in the United States for 5 years. The spouse traveled to Nepal in April 2024, at which time the pregnant woman and the child returned with him to the United States.

None of 33 XRF paint measurements or six dust wipe measurements collected at the family's home exceeded the regulatory guidelines for paint or dust. No lead-based paint hazards were identified in the child's school. Lead concentrations in the spices and powders used for religious purposes were below reference limits. However,

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^{††} Flame Atomic Absorption Spectrophotometry - EPA

^{§§} Inductively Coupled Plasma - Mass Spectrometry - EPA

⁵⁵ Standard Test Method for Lead and Cadmium Extracted from Glazed Ceramic -ASTM International

four of the nine metalware items referred to as *kansa* (composed mainly of copper and tin [bronze]) and *pital* (composed mainly of copper and zinc [brass]) (7), that the family had purchased in Nepal, had XRF lead concentrations exceeding NYC DOHMH's reference limit of 0.4 mg/cm²; the leachate lead concentration for three of these items far exceeded FDA guidance limits for similar products (e.g., silver-plated hollowware) (Figure). The four items included a large cauldron (XRF lead concentration = 5.2–15.1 mg/cm² and leachate lead concentration = 18.6 mg/L); a small cauldron (XRF lead concentration = 4.7–9.9 mg/cm² and leachate lead concentration = 41.4 mg/L); cup 1 (XRF lead concentration = 13.7 mg/cm² and leachate lead concentration = 3.9 mg/L); and cup 2 (XRF lead concentration = 3.7 mg/cm²; leachate lead concentration was not tested).

NYC DOHMH advised the family to stop using the implicated metalware products. By September 2024, BLLs decreased to 1.7 μ g/dL for the woman and 10.7 μ g/dL for her spouse. By October 2024, BLLs decreased to 8 μ g/dL for the spouse and to 3 μ g/dL for the child.

Discussion

Substantial lead exposure was identified among members of a family associated with use of *kansa* and *pital* metalware for food and drinks. These types of traditional metalware products are widely used in South Asian communities for food and drink or in religious practices (7). Lead can be added to these types of metalware vessels to improve malleability or reduce production costs. Although *kansa* and *pital* are chemically distinct, the terms often are used interchangeably by community members. In Ayurveda, the ancient traditional medical system from India, *kansa* usage is believed to have health benefits (7).

These findings underscore evidence that traditional metalware can pose a considerable risk for lead exposure. A recent study tested traditional metalware imported from several countries and available for purchase in the United States (8). The metalware items were tested using simulated cooking and storage conditions, and the items, especially those from Afghanistan and India, leached lead at levels that exceeded recommended dietary limits. One of the metalware items with a high lead leachate level was a *pital* brass pot imported from India.

NYC DOHMH surveillance of local stores during 2017–2022 detected leachable lead at levels far exceeding reference limits in numerous samples of bronze and brass metalware from South Asia (1). U.S. federal regulations permit the sale of such products if they are correctly labeled stating that the article is not for food use (4). Although NYC DOHMH has taken enforcement actions to restrict businesses from selling similar products without correct labeling, this requirement might not be sufficient to prevent persons from using these culturally ingrained products for food and drinks. Also, the labels often are only in English, limiting accessibility to non-English speakers. Moreover, regulatory restrictions are limited to products being sold in the United States, which excludes items that are personally hand-carried into the United States from abroad, as was the case for the metalware items described in this report.

Although the affected family adhered to NYC DOHMH's recommendation to stop using the metalware, risk communication can be challenging, especially when addressing risk factors with cultural significance. Among certain communities, these products are culturally integrated and passed down through generations. The items often are perceived as safe, or even beneficial for health and well-being. Raising awareness among communities about the lead risks associated with use of these products can help reduce exposure. NYC is an ethnically diverse city, and NYC DOHMH's blood lead surveillance program provides an opportunity to identify lead-containing consumer products from around the world. Even small case investigations can reveal previously unrecognized lead sources and be important contributions to improving public health. Broader collaboration among public health agencies, clinical providers, and governmental and nongovernmental entities

FIGURE. Kansa (bronze) and pital (brass) metalware* used by three family members with elevated blood lead levels — New York City, 2024



Photos/New York City Department of Health and Mental Hygiene

^{* (}A) Large cauldron used for preparing foods or liquids, (B) small cauldron used for serving foods or liquids, (C) cup 1 used for serving water during meals, and (D) cup 2 used for serving tea. All metalware was purchased in Nepal.

Summary

What is already known about this topic?

Traditional metalware can contain high levels of lead, which can leach into food and drinks.

What is added by this report?

In July 2024, blood lead screening in New York City identified a pregnant woman and two family members with blood lead levels above CDC's blood lead reference value of 3.5 μ g/dL. Elevated lead levels were found in traditional *kansa* (bronze) and *pital* (brass) metalware from Nepal that the family used to prepare and serve food and drinks.

What are the implications for public health practice?

Clinicians and public health professionals should be aware that imported metalware from around the world can be communal sources of lead exposure when used to prepare or serve food and drinks.

are needed to develop and implement strategies for reducing global lead exposures from traditional consumer products.

Implications for Public Health Practice

Clinicians and public health professionals should be aware that certain imported metalware from around the world can be communal sources of lead exposure when used to prepare or serve food and drinks. Knowing that lead might be added to objects that have cultural significance, such as *kansa* and *pital* metalware, can aid in the identification of lead sources. These types of metalware products are frequently used within the South Asian community, which is already at risk for potential lead exposures from other traditional consumer products (1,5,9,10).

Health care providers, in partnership with public health officials, can serve as trusted sources of health information, by counseling families on how to reduce exposures to known lead sources. Health care providers also play an important role in testing BLLs of persons at risk for exposure to lead. The role of clinicians varies by jurisdiction. In NYC, where testing of young children is mandated, clinicians are required to conduct blood lead tests and report the findings; NYC DOHMH primarily oversees the identification of lead sources in homes and offers guidance for addressing them. When testing is based on a risk assessment, as it is in NYC for children aged >2 years and pregnant persons, or in jurisdictions where routine testing is not mandated, clinicians must be especially vigilant in identifying lead risk factors and testing those persons at risk for exposure. This report highlights the importance of considering testing other household members when one person is found to have an elevated BLL, especially when imported products might be potential communal sources of lead exposure.

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Notes from the Field

HeatRisk Forecasts and Emergency Department Visits for Heat-Related Illness — New York, May-September 2024

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Introduction

From 1901 to 2022, average temperatures in New York increased by approximately 2.6°F (1.4°C) (*I*). In New York, heat preparedness measures have included assessing associations between heat and health outcomes (*2*), calibrating heat advisory thresholds based on health effects, and building partnerships to bolster heat mitigation and adaptation. During spring 2024, the National Weather Service, in partnership with CDC, released HeatRisk for the continental United States. The HeatRisk index* provides a health-based heat forecast up to 7 days in advance of hot weather; the 5-level color scale (range = 0 [green]: little to no risk to 4 [magenta]: extreme risk for heat-related impact) accounts for the unique heat-related health risks in different places and times of year, and the heat duration, including both daytime and nighttime temperatures (*3*,*4*).

Investigation and Outcomes

During May–September 2024, the New York State Department of Health (NYSDOH) evaluated HeatRisk 24-hour forecasts and associated heat-related illness (HRI). Daily county-level HeatRisk forecasts were downloaded[†] for the 57 New York counties (outside of New York City [NYC]). NYSDOH Electronic Syndromic Surveillance System[§] HRI emergency department (ED) visits were defined as those with *International Classification of Diseases, Tenth Revision* codes T67 (effects of heat and light), X30 (exposure to excessive natural heat–hyperthermia), L55 (sunburn), X32 (exposure to sunlight), or relevant chief complaints (e.g., sunstroke, heatstroke, heat exhaustion, or sunburn). HRI ED visits were aggregated to county-day[§] counts and linked with the county-day HeatRisk

forecasts and county population.** For each region,†† and for New York (outside of NYC), HRI rates were calculated by summing the total number of HRI ED visits and dividing by the cumulative region or county population for each HeatRisk level (i.e., little to no risk, minor risk, moderate risk, major risk, or extreme risk for HRI). This project represents public health practice by NYSDOH, and institutional review board review was not required. This activity was also reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.§§

Across all regions, at least 79% of county-days had HeatRisk forecasts in the little to no risk or minor risk levels, and none had more than 0.3% of county-days in the extreme risk level (Figure). In six of the seven regions and in New York (outside of NYC), HeatRisk forecasts indicating a higher level of risk were associated with higher HRI rates (Figure). In the Capital District region, no HRI ED visits occurred on the few county-days in the extreme risk level, and in the Hudson Valley, Long Island, and Northeast regions, no county-days had an extreme risk for HRI, although each region's HRI rate increased with increasing HeatRisk forecast through the major risk levels.

Preliminary Conclusions and Actions

The findings suggest that HeatRisk forecasts can be used to increase awareness about health risks from heat exposure, provide a resource for state and local agencies to implement response actions, and empower the public and public health professionals to take steps to minimize exposure. The accessibility of HeatRisk might be improved through incorporation into mobile device weather apps. Further study is warranted to explore possible uses for HeatRisk in preventing heat-related harm (e.g., as an early-warning tool to prevent heat-related adverse health outcomes).

§§ 45 C.F.R. part 46.102(I)(2), 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.

^{*} How to use the HeatRisk Tool and Air Quality Index | Heat Health | CDC

[†] National Environmental Public Health Tracking Network Data Explorer (Accessed May 16, 2025).

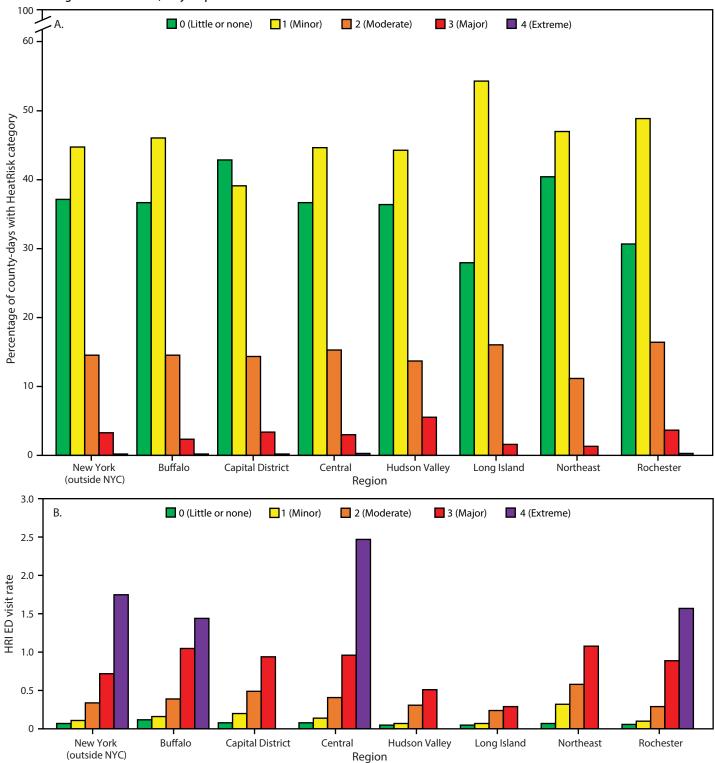
[§] Electronic Syndromic Surveillance System (ESSS)

⁵A county-day represents each combination of county and day for the study period (i.e., for the 57 counties, each day during May–September represents 57 county-days).

^{**} American Community Survey 5-Year Data (2009–2023)

^{††} Regions were adapted from county groupings used by the Electronic Syndromic Surveillance System. *Buffalo* (eight counties): Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, and Wyoming; *Capital District* (13 counties): Albany, Columbia, Delaware, Fulton, Greene, Montgomery, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, Warren, and Washington; *Central* (13 counties): Broome, Cayuga, Chenango, Cortland, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, Tioga, and Tompkins; *Hudson Valley* (seven counties): Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, and Westchester; *Long Island* (two counties): Nassau and Suffolk; *Northeast* (five counties): Clinton, Essex, Franklin, Hamilton, and St. Lawrence; and *Rochester* (nine counties): Chemung, Livingston, Monroe, Ontario, Schuyler, Seneca, Steuben, Wayne, and Yates.

FIGURE. Percentage of county-days* with heat-related risks (A) and emergency department visit rates † for heat-related illness (B), by HeatRisk level § and region ¶ — New York, May–September 2024



Abbreviations: ED = emergency department; HRI = heat-related illness; NYC = New York City.

^{*} Number of county-days in HeatRisk level for region divided by total county-days in region. A county-day represents each combination of county and day for the study period (i.e., for the 57 counties, each day during May–September represents 57 county-days).

 $^{^{\}dagger}$ HRI ED visits per 100,000 population.

[§] National Weather Service | HeatRisk (Accessed May 16, 2025).

Total number of counties = 57; by region: Buffalo (eight), Capital District (13), Central (13), Hudson Valley (seven), Long Island (two), Northeast (five), and Rochester (nine).

Summary

What is already known about this topic?

Exposure to heat is associated with adverse health outcomes including heat-related illness (HRI).

What is added by this report?

In this ecological analysis, the HeatRisk index, a color and number index developed by the National Weather Service in partnership with CDC to communicate heat-related health risk, was associated with higher rates of HRI emergency department visits in New York (outside of New York City), during May—September 2024.

What are the implications for public health practice?

The association between HeatRisk forecasts indicating higher levels of risk and higher HRI rates in New York (outside of New York City) supports the use of HeatRisk as a tool to increase awareness about heat exposure.

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Estimated Current and Future Congenital Rubella Syndrome Incidence with and Without Rubella Vaccine Introduction — 19 Countries, 2019–2055

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Abstract

Rubella is a leading cause of vaccine-preventable birth defects. Rubella virus infection during early pregnancy can result in miscarriage, fetal death, stillbirth, or a constellation of birth defects known as congenital rubella syndrome (CRS). This report describes current and future estimated CRS incidence in countries that have not yet introduced rubella-containing vaccine (RCV) into their national childhood immunization schedules and the estimated effect of implementing a recent recommendation to introduce RCV into these programs even if population coverage with measles-containing vaccine is <80%. During 2000–2022, the number of countries that introduced RCV increased from 99 (52%) of 191 in 2000 to 175 (90%) of 194 in 2022. By the end of 2023, 19 lower- and middle-income countries had not yet introduced RCV. In 2019, an estimated 24,000 CRS cases occurred in these countries, representing 75% of the estimated 32,000 cases worldwide. In a modeling study estimating the effect of RCV introduction in these countries during 2025-2055, an estimated 1.03 million CRS cases are projected to occur without RCV. In contrast, fewer than 60,000 cases are estimated if RCV is introduced with catch-up and follow-up supplementary immunization activities, averting more than an estimated 986,000 CRS cases over 30 years. Based in part on these estimates, in September 2024, the World Health Organization Strategic Advisory Group of Experts on Immunization recommended removing the ≥80% coverage threshold and instituting universal RCV introduction in these countries. RCV introduction in these 19 countries during 2025-2030 could rapidly accelerate progress toward rubella and CRS elimination worldwide.

Introduction

Rubella is a leading cause of vaccine-preventable birth defects. Rubella virus infection usually produces a mild febrile rash illness in children and adults. However, infection during pregnancy, especially in the first trimester, can result in miscarriage, fetal death, stillbirth, or a constellation of birth defects known as congenital rubella syndrome (CRS). Caring for CRS cases is costly, and rubella vaccination has been shown to be cost-effective in high- and middle-income countries. However, no similar studies have been conducted in low-income countries in Africa or Asia (1). A single dose of rubella-containing

vaccine (RCV) can provide lifelong protection against rubella (1). The World Health Organization (WHO) Global Vaccine Action Plan 2011–2020* included a target to achieve rubella elimination in at least five of the six WHO regions by 2020, and the WHO Immunization Agenda 2030† includes rubella elimination as a critical impact goal.

During 2000–2022, the number of countries that included RCV in their childhood immunization schedules increased from 99 (52%) of 191 in 2000 to 175 (90%) of 194 in 2022 (2,3). However, the 2020 WHO Rubella Vaccine Position Paper (1) maintained WHO's 2011 recommendation that countries planning to introduce RCV into their immunization programs should have attained ≥80% coverage with the first dose of measles-containing vaccine (MCV1) through routine vaccination or ≥80% coverage with an MCV dose through supplementary immunization activities (SIAs) (1). The rationale for the 80% coverage threshold is to avoid suboptimal RCV postintroduction vaccination coverage, which would have the effect of reducing, but not eliminating, rubella transmission; shifting the age of infection to older children, adolescents, and young adults who were not immune; increasing the interval between rubella outbreaks; and increasing the risk for rubella infection among nonimmune women of childbearing age, potentially leading to a paradoxical increase in cases of CRS compared with the prevaccine rubella epidemiology. Any change to the 80% coverage requirement would require recommendation by the WHO Strategic Advisory Group of Experts (SAGE) on Immunization, the principal independent advisory group to WHO for vaccines. 9

The recommended strategy for introducing RCV into national immunization programs is through an initial catchup SIA using combined measles and rubella (MR) vaccine for all children aged 9 months—14 years, followed immediately by introduction of MR vaccine into the routine childhood immunization schedule (1). WHO recommends that countries then

^{*}Global vaccine action plan 2011-2020

[†] Immunization Agenda 2030

[§] Achieving ≥80% coverage with MCV1 during routine vaccinations or a supplementary dose of MCV during SIAs is used as a means to demonstrate the country's ability to achieve these levels of RCV coverage following introduction, because RCV is administered as a combined measles-rubella or measles-mumps-rubella vaccine.

Strategic Advisory Group of Experts on Immunization

achieve and maintain ≥80% coverage with ≥1 dose of RCV (as a combined MR vaccine) delivered through routine services or SIAs (1). Follow-up MR SIAs, usually focusing on children aged <5 years, are conducted every 3–4 years to reduce measles susceptibility in the population and prevent outbreaks. This report describes the estimated current and future estimated CRS incidence in the 19 countries** that had not introduced RCV by the end of 2023, and the impact of implementing the September 2024 recommendation by WHO SAGE for universal introduction of RCV in these countries (4).

Methods

Immunization Activities

Each year, countries report vaccination data to WHO and UNICEF using the electronic Joint Reporting Form (eJRF). †† WHO and UNICEF estimate coverage with the first and second MCV doses administered through routine immunization services §§ for all countries, using annual administrative coverage data (the number of vaccine doses administered divided by the estimated target population), national coverage estimates, and vaccination coverage surveys. For this report, 2019–2023 eJRF data were reviewed. World Bank income groupings for fiscal year 2024 (based on July 2023 data) ¶ and the World Bank index of fragile and conflict-affected countries for 2023*** were used to categorize countries' income and vulnerability status.

Rubella and CRS Surveillance

Rubella surveillance relies on the measles surveillance system to detect cases of febrile rash illness. Rubella cases reported through eJRF using a standard case definition were reviewed for this report (3). CRS cases, which are also reported through eJRF using a standard case definition, are detected through separate surveillance systems, often using sentinel sites that might not be nationally representative (3).

- ** Afghanistan, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Liberia, Madagascar, Mali, Niger, Nigeria, Somalia, South Africa, South Sudan, and Sudan.
- †† Immunization, Vaccines and Biologicals
- WHO Immunization Data portal Global
- 55 The World Bank publishes annual gross national income classification cutoffs per capita in U.S. dollars. The 2024 fiscal year provides classification data through 2023: high income ≥\$13,846; upper-middle income = \$4,466-\$13,845; lower-middle income = \$1,136-\$4,465; and low income ≤\$1,135. World Bank Country and Lending Groups World Bank Data Help Desk
- *** Developed by the World Bank, the Classification of Fragile and Conflict-Affected Situations is a framework to categorize countries based on their vulnerability to conflict, fragility, and weak governance. Two categories are used: 1) countries with high levels of institutional and social fragility, identified based on indicators that measure the quality of policy and institutions, and manifestations of fragility; and 2) countries affected by violent conflict, identified based on a threshold number of conflict-related deaths relative to the population. Classification of Fragile and Conflict-Affected Situations

Modeled Estimates of Current CRS Incidence

Because routine surveillance data underestimate CRS cases, estimates of CRS incidence (cases per 100,000 live births) and the number of annual CRS cases in 2019 for the 19 countries that had not yet introduced RCV by the end of 2023 (calculated as part of published estimates of the global and regional burden of CRS during 1996–2019) were used (5). These published estimates were calculated using 1) previously described catalytic models to estimate the age-specific prevaccination force of infection (the rate at which susceptible persons become infected) from seroprevalence data and 2) an age-structured dynamic rubella transmission model (5). For each dataset and catalytic model, 95% CIs for the force of infection, and when applicable, assay sensitivity, were derived. For each country, the transmission model was run using 1,000 values for the prevaccination force of infection, vaccine efficacy, vaccination coverage, and risk that an infant would be born with CRS if the mother was infected with rubella during pregnancy. These parameters were varied in the same range as that used previously (6). The base case value for vaccine efficacy was 95%, with a range of 85%-99%, and the assumed risk that a child born to a mother who was infected during pregnancy would have CRS was 65% (95% CI = 47%-88%), consistent with published estimates (5). The model used demographic data from United Nations population sources. ††† The 95% CIs for each outcome of interest were calculated from the outcome's range across the 1,000 model runs.

Modeled Estimates of Future CRS Incidence

To estimate the impact of RCV introduction on future CRS cases, the dynamic rubella transmission model (5) was adjusted to account for rubella virus importations and correlations between vaccine doses, and run for each of the 19 countries under three scenarios: 1) no RCV introduction in any country; 2) RCV introduction in 2025, beginning with a wide age-range catch-up MR SIA (for children aged 9 months-14 years) and continuing with follow-up MR SIAs (for children aged 9 months—4 years) every 4 years, with 90% MR vaccination coverage; and 3) RCV introduction in 2025, with a wide age-range catch-up and followup SIAs at the same intervals as the previous scenario, but with 60% (rather than 90%) MR vaccination coverage. For all three scenarios, the model was run 200 times (consistent with previous work for the Vaccine Impact Modeling Consortium and work on measles and rubella elimination), using the mean of 2018 and 2019 prepandemic MCV1 coverage as a proxy for future routine MR vaccination coverage and held constant over time.

To estimate the number of CRS cases averted by RCV introduction, the number of CRS cases under each of the

^{†††} United Nations Data Portal Population Division

vaccination scenarios was subtracted from the number in the no-vaccination scenario. As a sensitivity analysis, all scenarios were run using an independently developed University of Georgia (UGA) model. Although the two models varied in some of their assumptions, \$\sigma_{\infty}\sigma_{\infty}\$ the two models generated similar outputs about the 30-year percentage reduction in CRS cases. Therefore, modeling findings are included from only the United Kingdom Health Security Agency (UKHSA) dynamic rubella transmission model for simplicity. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy. \$\frac{45}{35}\$

Results

Immunization Activities and Eligibility to Introduce RCV

By the end of 2023, RCV had been introduced into the childhood immunization programs of all but 19 (10%) of

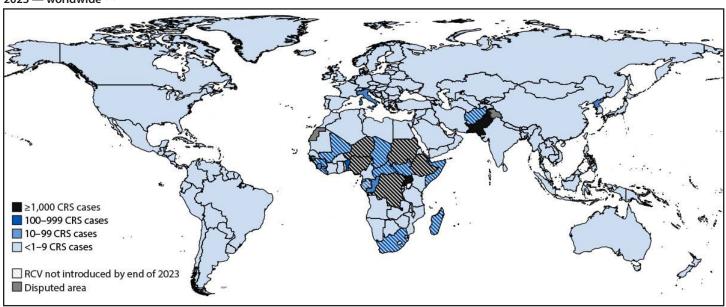
194 countries (Figure 1). Among these 19 countries, 15 are in the WHO African Region, and four are in the WHO Eastern Mediterranean Region; 13 are classified as low income and 12 are classified as either conflict-affected or having fragile institutions (Table).

In 2019, before the COVID-19 pandemic, estimated routine MCV1 coverage in all 19 countries ranged from 40% to 90%. During the pandemic period (2020–2022), 12 of these countries reported declines in MCV1 coverage, ranging from 2% to 33%. By 2023, MCV1 coverage had recovered to prepandemic levels in most countries (range = 41%–82%); however, only three (Liberia, Niger, and South Africa) achieved ≥80% MCV1 coverage through routine vaccination services. During 2017–2023, 18 countries conducted at least one nationwide SIA, eight (44%) of which achieved MCV coverage of ≥80% based on a validated postcampaign coverage survey. By the end of 2023, nine (47%) of the 19 countries reached the 80% MCV coverage threshold, either through routine vaccinations or SIAs, and thereby became eligible for RCV introduction.

Surveillance Activities and Reported Rubella Incidence

In 2023, these 19 countries reported 27,989 (78%) of the 35,714 reported rubella cases worldwide (Table). The countries with the highest annual reported incidences were Chad

FIGURE 1. Estimated number of congenital rubella syndrome cases, 2019* and introduction of rubella-containing vaccine, by country, 2023 — worldwide^{†,§,¶}



 $\textbf{Abbreviations:} \ CRS = congenital \ rubella \ syndrome; \ RCV = rubella-containing \ vaccine; \ WHO = World \ Health \ Organization.$

SSS To assess sensitivity model structure, all RCV introduction scenarios were run using a second model developed at UGA. The UGA model 1) allows for nonstable populations with changing birth and death rates, whereas the UKHSA model assumes stable population with fixed birth rates and then scales outputs to population projections; 2) incorporates transmission seasonality, whereas the UKHSA model does not; and 3) is not sex-structured, whereas the UKHSA model is sex-structured (i.e., considers population dynamics of males and females separately, in terms of their distinct biologic processes).

^{555 45} C.F.R. part 46.102(l)(2), 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.

^{*} Based on Estimates of the global burden of congenital rubella syndrome, 1996–2019.

[†] Introduction of RCV into the routine immunization program by December 31, 2023, as reported to WHO and UNICEF using the electronic Joint Reporting Form.

[§] By the end of 2023, 19 countries had not introduced RCV into their routine immunization program: Afghanistan, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Liberia, Madagascar, Mali, Niger, Nigeria, Somalia, South Africa, South Sudan, and Sudan. In 2019, when the estimates of CRS cases were made, Comoros, Pakistan, and Uganda had also not introduced RCV but did so by the end of 2023.

¹ Italy introduced RCV in 1972, initially only for girls aged 11–12 years, and RCV was introduced into routine immunization in 1990; because of historic coverage levels, CRS still poses a potential risk.

TABLE. Estimated measles-containing vaccine coverage, reported rubella incidence, and estimated congenital rubella syndrome incidence among countries that had not introduced rubella-containing vaccine by December 2023, by country and World Health Organization region — 19 countries, 2019 and 2023

	World Bank		MCV1 coverage, %§		Most recent measles SIA [§]		Met 80% MCV coverage required for	No. of reported rubella cases [§]		Rubella incidence**			Estimated CRS
Region/Country	income group,* 2023	FCV setting, [†] 2023		2023	Year	MCV SIA coverage, %¶¶	RCV	2019	2023	2019	2023	Estimated no. of CRS cases ^{††} (95% CI), 2019	incidence ^{§§} (95% CI), 2019
African Region													
Central African Republic	LIC	Conflict	41	41	2023	NR	No	182	121	368	235	172 (<1-603)	105 (<1-367)
Chad	LIC	Fragile	40	63	2023-24	NR	No	24	10,918	14	5,651	688 (<1-2,347)	105 (<1-357)
Democratic Republic of the Congo	LIC	Conflict	65	52	2023-24	95	Yes	561	650	60	61	2,771 (<1-8,828)	80 (<1-253)
Equatorial Guinea	UMIC	NA	51	61	2020	ND	No	3	3	18	16	44 (<1-159)	101 (<1-363)
Ethiopia	LIC	Conflict	57	61	2023	88	Yes	266	1,085	23	84	3,507 (<1-10,125)	99 (<1-283)
Gabon	UMIC	NA	62	66	2017	ND	No	0	7	0	28	81 (44-125)	121 (66-188)
Guinea	LMIC	NA	47	47	2022	ND	No	80	67	61	47	465 (<1-1,605)	102 (<1-352)
Guinea-Bissau	LIC	Fragile	79	72	2019	88	Yes	0	255	0	1,184	63 (<1-217)	96 (<1-330)
Liberia	LIC	NA	68	82	2018	89	Yes	140	NR	278	NR	164 (<1-577)	102 (<1-360)
Madagascar	LIC	NA	60	51	2022	65	No	122	390	43	125	697 (<1-1,945)	80 (<1-223)
Mali	LIC	Conflict	71	73	2019	84	Yes	19	15	9	6	824 (<1-2,856)	103 (<1-358)
Niger	LIC	Conflict	79	80	2022	92	Yes	7	88	3	34	1,102 (<1-3,786)	105 (<1-360)
Nigeria	LMIC	Conflict	58	60	2022-23	87	Yes	1,644	10,221	78	449	9,719 (<10-25,102)	130 (<1-337)
South Africa	UMIC	NA	83	80	2023	ND	Yes	1,370	870	230	138	422 (22-1,095)	36 (1.9-93)
South Sudan	LIC	Conflict	65	72	2023	ND	No	149	44	143	38	504 (<1-1,365)	79 (<1-214)
Eastern Mediterranean Region													
Afghanistan	LIC	Conflict	57	55	2022	NR	No	59	444	16	107	914 (<1-2,477)	77 (<1-207)
Djibouti	LMIC	NA	83	76	2020	ND	No	NR	5	NR	43	12 (<1-32)	59 (<1–157)
Somalia	LIC	Conflict	46	46	2022	NR	No	0	2,407	0	1,311	358 (<1–1,222)	94 (<1–321)
Sudan	LIC	Fragile	90	51	2019	98	Yes	281	399	62	80	1,230 (<1–2,727)	91 (<1–202)

Abbreviations: CRS = congenital rubella syndrome; FCV = fragile, conflict-affected, or vulnerable; LIC = low-income country; LMIC = lower-middle-income country; MCV1 = first dose of measles-containing vaccine; MCV2 = second dose of measles-containing vaccine; NA = not applicable; ND = not done; NR = not reported; RCV = rubella-containing vaccine; SIA = supplementary immunization activity; UMIC = upper-middle-income country; WHO = World Health Organization.

(5,651 cases per 1 million population), Guinea-Bissau (1,184), and Somalia (1,311).

Modeled Estimates of Current and Future CRS Cases

In 2019, an estimated 24,000 CRS cases occurred in the 19 countries that had not yet introduced RCV by 2023, accounting for 75% of an estimated 32,000 CRS cases worldwide. Approximately 1,000 CRS cases were estimated to have occurred in each of five countries (Democratic Republic of the Congo, Ethiopia, Niger, Nigeria, and Sudan) (Figure 1).

Modeling estimates indicated that in the absence of RCV introduction, a mean of 30,000–34,000 CRS cases would

occur each year during 2025–2055, with a cumulative mean of 1,025,286 cases across all 19 countries during this 30-year period (Figure 2). In contrast, with RCV introduction in the 19 countries in 2025, the estimated annual number of CRS cases would decline sharply during 2025–2027 in both vaccination scenarios (i.e., 60% and 90% MR coverage) and remain low through 2055. By 2055, the projected cumulative mean number of cases in both vaccination scenarios is estimated to be 40,000–60,000. During 2025–2055, compared with no RCV introduction, rubella vaccination would prevent an estimated 986,000 CRS cases in these 19 countries.

^{*} Gross national income per capita in U.S. dollars for fiscal year 2024: high income ≥\$13,846; UMIC = \$4,466-\$13,845; LMIC = \$1,136-\$4,465; and LIC ≤\$1,135. World Bank Country and Lending Groups – World Bank Data Help Desk

[†] Developed by the World Bank, the Classification of Fragile and Conflict-Affected Situations is a framework to categorize countries based on their risk for conflict, fragility, and weak governance. Two categories are used: 1) countries with high levels of institutional and social fragility, identified on the basis of indicators that measure the quality of policy and institutions, and manifestations of fragility; and 2) countries affected by violent conflict, identified on the basis of a threshold number of conflict-related deaths relative to the population. <u>Classification of Fragile and Conflict-Affected Situations</u>

[§] Measles vaccination coverage

In 2020, WHO confirmed its recommendation that countries achieve a coverage of ≥80% with MCV1 through routine vaccination or with a dose of MCV during SIAs before introducing RCV into the routine immunization schedule. Rubella vaccines: WHO position paper - July 2020

^{**} Rubella incidence is calculated on the basis of cases reported through the WHO and UNICEF electronic Joint Reporting Form and United Nations population data. Number of cases are calculated per 1 million population.

^{††} Based on a dynamic transmission model, developed at the United Kingdom Health Security Agency. <u>Estimates of the global burden of Congenital Rubella Syndrome</u>, 1996-2019 - ScienceDirect

^{§§} Cases per 100,000 live births.

[¶] MCV doses administered through SIAs are considered supplementary doses and are not counted toward MCV1 or MCV2 coverage. Coverage results are based on validated postcampaign coverage surveys, using the WHO coverage survey methodology. World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual

Baseline scenario: no RCV introduction 70,000 Scenario 1: RI constant, 90% MR coverage age group 9 mos-14 yrs, and 90% MR SIA coverage age group 9 mos-4 yrs Scenario 2: RI constant, 60% MR coverage age group 9 mos-14 yrs, and 90% MR SIA coverage age group 9 mos-4 yrs 60,000 50,000 Estimated no. of cases 40,000 30,000 20,000 10,000 0 2025 2027 2029 2031 2033 2035 2037 2039 2041 2055

FIGURE 2. Estimated number of annual congenital rubella syndrome cases with rubella vaccine introduction and in the absence of rubella vaccine introduction —19 countries, 2025–2055*,†,§

Abbreviations: CRS = congenital rubella syndrome; MCV1 = first dose of measles-containing vaccine; MR = measles and rubella; RCV = rubella-containing vaccine; RI = routine immunization; SIA = supplementary immunization activity; WHO = World Health Organization.

Year

Summary

What is already known about this topic?

Rubella infection during early pregnancy can result in miscarriage, fetal death, or a constellation of birth defects known as congenital rubella syndrome (CRS). By 2023, among 194 World Health Organization member countries, 175 (90%) had introduced a rubella-containing vaccine (RCV) into their routine immunization program.

What is added by this report?

In this modeling study of vaccination, in the 19 countries that have not introduced RCV and where an estimated 24,000 CRS cases occurred in 2019, universal RCV introduction during 2025–2055 would avert an estimated 986,000 CRS cases. In 2024, based on these estimates and other considerations, the World Health Organization recommended universal RCV introduction in these 19 countries.

What are the implications for public health practice?

Universal RCV introduction during the next 5 years could accelerate progress toward rubella and CRS elimination worldwide.

Discussion

The 19 countries that have not yet introduced RCV are home to some of the world's most vulnerable populations and communities and include approximately 25 million infants (3). These countries account for most of the current global rubella and CRS cases, with CRS incidences comparable to those found worldwide in the prevaccine era (5). RCV introduction in these countries could avert an estimated 30,000 CRS cases annually and approximately 986,000 cases during the next 30 years.

Other recent modeling studies have documented that RCV introduction into routine immunization programs in these and other countries has the immediate effect of decreasing rubella and CRS cases, resulting in a lower CRS incidence than would occur without vaccination for approximately 15 years even without introductory SIAs, and can achieve elimination of rubella transmission with improved routine coverage or moderate coverage SIAs (7–9). The projected rapid and sustained

^{*} With 95% CIs indicated by bars.

[†] In the two vaccination scenarios, rubella vaccine is introduced by combining with measles-containing vaccine, and annual RI coverage with MR vaccine remains at the mean of the 2018 and 2019 estimates for MCV1 for 2025–2055. In each scenario, MR introduction is preceded by a wide-age catch-up MR SIA for children aged 9 months–14 years as recommended by WHO, and then followed every 4 years by a follow-up MR SIA for children aged 9 months–4 years, which is needed for measles elimination. In the first scenario, coverage with both types of SIAs is 90%; in the second, 60%.

S CRS cases prevented by rubella vaccine introduction and vaccination are estimated by the area between the estimated cases with vaccination and those without vaccination. A cumulative total of 986,000 cases were estimated to have been prevented by rubella vaccination in either of the two scenarios during 2025–2055 in the 19 countries: Afghanistan, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Liberia, Madagascar, Mali, Niger, Nigeria, Somalia, South Africa, South Sudan, and Sudan.

reductions in CRS cases that would follow RCV introduction in these 19 countries supports universal RCV introduction.

To determine whether ≥80% MCV coverage should continue to be required before a country is eligible to introduce RCV, the findings from the two modeling groups underwent a methodologic review by the WHO Immunization and Vaccines-Related Research Advisory Committee in June 2024 (10). At the September 2024 SAGE meeting, the evidence on rubella epidemiology, routine and SIA coverage with MCV in countries currently not using RCV, the programmatic success of RCV introduction in other countries, and estimated future incidence from mathematical models were presented by the Measles and Rubella Partnership**** Rubella Task Team. Responding to these findings, SAGE recommended removing the 80% coverage threshold, called for universal introduction of RCV in the remaining 19 countries, and continued the recommendation to conduct wide age-range catch-up SIAs with MR vaccine before introduction to ensure that those persons who missed earlier vaccination opportunities are protected (4). The SAGE recommendations have set the stage to facilitate progress toward the Global Vaccine Action Plan 2011-2020 and Immunization Agenda 2030 rubella elimination goals.

To capitalize on this new opportunity, the remaining 19 countries will need support from global partners to facilitate vaccine introduction, with a particular focus on ensuring high-quality SIAs. Support from Gavi, the Vaccine Alliance, †††† for low- and lower-middle–income countries is crucial to ensure access to vaccines and to facilitate building the infrastructure necessary for effective delivery during these SIAs. Also critical is that countries not eligible for Gavi support receive support to introduce RCV, ensuring that global elimination can be achieved. In fragile and conflict-affected settings, robust monitoring and implementation strategies will be needed to ensure that SIAs reach all populations and reduce the incidence of rubella and CRS.

Limitations

The findings in this report are subject to at least three limitations. First, the quality of data on measles vaccination coverage, including SIA coverage, as well as on reported rubella cases, can vary and might lead to inaccurate estimates, making accuracy and reliability assessments challenging. Second, although the prospective modeling assumed that all 19 countries would

introduce RCV in 2025, the year of introduction will likely vary during the next ≥5 years for each country; thus, the impact over time will vary from these estimates. Finally, the modeled estimates depend on data inputs that can vary in quality and completeness, as well as the model assumptions, potentially influencing the accuracy of the projections.

Implications for Public Health Practice

The decision by SAGE to recommend universal RCV introduction in the remaining countries provides an opportunity to reduce the global incidence of CRS, a preventable and potentially fatal condition, and to eliminate barriers to vaccine introduction resulting from the current 80% MCV coverage threshold. RCV introduction in these 19 countries during 2025–2030 will rapidly accelerate progress toward rubella and CRS elimination worldwide.

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^{****} Measles & Rubella Partnership

^{†††††} Gavi is an international organization bringing together public and private sectors with the shared goal of saving lives and protecting health by increasing equitable and sustainable use of vaccines. Eligibility for Gavi's financial support is based on national income. In 2025, countries became eligible for Gavi support if their most recent gross national income per capita, as reported by the World Bank, was \$\$1,820 U.S. dollars. Since 2011, the eligibility threshold is adjusted for inflation on an annual basis.

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