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Serologic Immunity to Tetanus in the United States, National Health and Nutrition Examination Survey, 2015–2016

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Abstract

Background: Tetanus, a life-threatening infection, has become rare in the United States since introduction of tetanus toxoid-containing vaccines (TTCVs), recommended as a childhood series followed by decennial boosters beginning at age 11–12 years; vaccination uptake is high in children but suboptimal in adults. The objective of this study was to estimate the prevalence of sero-immunity to tetanus among persons aged ≥6 years in the United States and to identify factors associated with tetanus sero-immunity. Understanding population protection against tetanus informs current and future vaccine recommendations.

Methods: Anti-tetanus toxoid antibody concentrations were measured for participants of the 2015–2016 National Health and Nutrition Examination Survey (NHANES) aged ≥6 years for whom surplus serum samples were available using a microsphere-based multiplex antibody capture assay. Prevalence of sero-immunity, defined as ≥0.10 IU/mL, was estimated overall and by demographic characteristics. Factors associated with tetanus sero-immunity were examined using multivariable regression.

Results: Overall, 93.8% of the U.S. population aged ≥6 years had sero-protection against tetanus. Prevalence of sero-immunity was above 90% across racial/ethnic categories, sex, and poverty levels. By age, ≥90% had protective sero-immunity through age 69 years but prevalence of sero-immunity declined thereafter, with 75.8% of those aged ≥80 years having protective sero-immunity. Older age (adjusted prevalence ratio (aPR): 0.89, 95% CI: 0.85–0.92) and being

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born outside the United States (aPR: 0.96, 95% CI: 0.93–0.98) were significantly associated with lower prevalence of sero-immunity.

Conclusion: The majority of the U.S. population has vaccine-induced sero-immunity to tetanus, demonstrating the success of the vaccination program.

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Summary:

Overall, a higher proportion of the U.S. population had sero-protection against tetanus compared to previously reported estimates. Prevalence of tetanus sero-immunity was high across all race and ethnic groups. There were notable differences in prevalence of tetanus sero-immunity by age.

Keywords

Tetanus; sero-immunity; National Health and Nutrition and Examination Survey; NHANES; MMACA; ELISA; microsphere-based multiplex antibody capture assay

Introduction

Tetanus is a life-threatening, exotoxin-mediated infection caused by the spore-forming bacterium *Clostridium tetani*. *C. tetani* spores are abundant in soil and intestinal tracts of animals and humans. Infection occurs by the spores entering the body through breaks in the skin or mucous membranes; it is not transmitted from person to person [1]. Diagnosis of tetanus is based on clinical syndrome without laboratory confirmation. Tetanus is usually characterized by seizure-like muscle spasms that begin in the jaw (trismus) and progress to other muscle groups in a descending manner. Spasms can last several weeks and often require prolonged hospitalization with attendant risk of nosocomial infections. Other complications include laryngospasms, hypertension, pulmonary embolism, aspiration pneumonia, and death. Mechanical assistance with respiration may be needed in severe cases [2].

In the United States, tetanus toxoid-containing vaccines (TTCVs) were introduced into routine childhood vaccination in the mid-1940s; a decennial booster dose with tetanus toxoid and reduced diphtheria toxoid vaccine (Td) for all persons ≥6 years old was added in 1966 [1, 3]. Since then, tetanus has become a rare disease in the United States, with almost all reported U.S. cases occurring in persons who were unvaccinated or not up to date with vaccination [1].. Between 2000 and 2019, 579 tetanus cases were reported to the National Notifiable Diseases Surveillance System, with an average annual incidence of 0.01 cases per 100,000 population. The majority of cases occurred among adults: >55% in those aged 20–59 years and 30% in persons aged 60 years and older. However, reported incidence of tetanus is low across all ages. The overall case fatality ratio was 7.6%. Risk of death increased with age and was highest (41.7%) among persons aged ≥80 years [4].

The Advisory Committee on Immunization Practices recommends 5 doses of a diphtheria and tetanus toxoid and acellular pertussis (DTaP) vaccine by age 6 years, followed by a TTCV booster dose every 10 years beginning at age 11 or 12 years [5]. Childhood

vaccination coverage has been high and stable in the United States for decades. Since 2001, receipt of ≥3 doses of DTaP vaccine by age 35 months has exceeded 90% [6]. Booster vaccination among adolescents is similarly high, ranging from 85% to 90% since 2012 [7]. Vaccination coverage has remained consistently lower in adults, however, with only 60% of adults reporting receipt of a decennial TTCV booster since 2010. In 2019, self-reported coverage was 63% in adults aged ≥19 years and 57% in those aged ≥65 years [8].

A better understanding of population immunity to tetanus is important to evaluate current and inform future vaccination recommendations in the United States. We used sera from the National Health and Nutrition Examination Survey (NHANES) 2015–2016 to evaluate population sero-immunity to tetanus in the United States.

Methods

Survey Design & Population

The 2015–2016 NHANES was used to estimate the prevalence of tetanus sero-immunity among persons aged ≥6 years in the United States. NHANES is a complex, multi-stage probability survey that is representative of the civilian non-institutionalized U.S. population [9]. NHANES is administered by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC); since 1999, surveys are conducted in 2-year cycles. Demographic characteristics including age, race, ethnicity, income, education, military service, and country of birth are obtained from consenting participants during the household interview. Participants who complete the interview are asked to attend a mobile examination center (MEC) where serum samples are obtained as part of a physical examination [9]. MEC participants aged ≥6 years can consent (parent or guardian signs consent form for participants aged <18 years) to storing their serum specimens for use in future studies as part of the NHANES Biospecimen Program [10]. During 2015–2016, 15,327 persons were selected for the study, of whom 9,971 (65%) were interviewed and 9,544 (62.3%) completed a physical examination in the MEC [9]. Of those examined, 5,910 (62%) aged ≥6 years consented to storage of their sera for future testing. This study was reviewed and approved by the National Center for Health Statistics' Research Ethics Review Board.

Laboratory methods

Pristine serum samples collected from 5,910 participants aged ≥6 years as a part of the NHANES Biospecimen Program were analyzed and quantified for anti-tetanus antibody concentrations using a microsphere-based multiplex antibody capture assay (MMACA) with tetanus toxin (TT) developed by the Microbial Pathogenesis and Immune Response Laboratory at CDC [11], and calibrated to the World Health Organization (WHO) 1st International Standard (TE-3) for TT antibodies, purchased from the National Institute for Biological Standards and Control (NIBSC; UK).

Diluted serum was incubated with tetanus toxoid conjugated Luminex microspheres. Following a series of washes, bound antibody was detected with phycoerythrin (PE) coupled reporter antibody using the Luminex 100/200 and Magpix plate readers (Luminex Corp,

Houston, TX). Tetanus antibody concentrations were expressed as tetanus toxoid-specific IgG in international units per milliliter (IU/mL). The Lower Level of Quantification (LLOQ) for the MMACA assay was 0.007 IU/mL.

Data Analysis

Sero-immunity was defined as antibody concentrations ≥0.10 IU/mL using globally accepted thresholds [12]. We estimated the prevalence of sero-immunity overall and by demographic characteristics. Age in years was divided into the following age groups: 6–10, 11–19, 20–29, 30–39, 40–49, 50–59, 60–69, 70–79, and ≥80. Race and ethnicity were classified as non-Hispanic White, non-Hispanic Black, Hispanic, and Other. Data on years of education attained and military service were analyzed for respondents ≥20 years. The ratio of family income to poverty was calculated based on self-reported income, family size, and state-specific poverty guidelines for 2015 and 2016. A ratio less than 1 was classified as below the poverty level. We were unable to examine prevalence of sero-immunity by vaccination history because that information was not available.

Sampling weights were used for all analyses to obtain nationally representative estimates. Estimates that did not meet the NCHS proportion reporting rules were considered unstable [13, 14]. We estimated population distributions and 95% confidence intervals (CIs), overall and by demographic characteristics. Rao-Scott Chi-Square test was used to evaluate significant differences in sero-immunity among subgroups [15]. We used logistic regression to obtain marginal predicted probabilities expressed as bivariable prevalence ratios (PRs) with 95% CIs [16]. To evaluate independent associations between demographic characteristics and sero-immunity we developed a multivariable model with age categorized into two groups (<65 and ≥65 years) to estimate adjusted PRs and 95% CIs. Estimates with a 95% CI that did not include the null or with a 2-tailed significance level (P-value) <.05 were considered statistically significant.

To compare these results with published estimates from NHANES III (1988–1994), we also calculated sero-prevalence using a higher antibody concentration threshold of ≥ 0.15 IU/mL as was used as the cut-off in the previous study. SAS 9.4 (SAS Institute Inc., Cary, NC, USA) and SAS-callable SUDAAN 11.0.3 (RTI International) were used for data management and analysis.

Results

Immunity to tetanus

Overall, 93.8% of the U.S. population aged ≥6 years was protected against tetanus as measured by tetanus-toxoid antibody concentrations (Table 1). By age, 90.0% of children aged 6–10 years and 94.5% of those aged 11–19 years had sero-immunity. Prevalence of sero-immunity remained over 95% in all subsequent age groups through 50–59 years and was slightly lower in the 60–69-year age group (92.9%). There was a significant decrease thereafter, with only 84.1% of those aged 70–79-years, and 75.8% of those aged ≥ 80 years having sero-immunity against tetanus. Sero-immunity was similarly high in men and women across all age groups through the 60–69 age category and remained over 90% among older

men. However, a significantly lower proportion of women in the oldest two age groups had protection against tetanus (Figure 1).

Prevalence of sero-immunity to tetanus was high across all race/ethnic categories, highest among White persons (95.2%), followed by non-Hispanic Black persons (93.0%) and Hispanic persons (90.8%). A smaller proportion of persons born outside the United States had protection against tetanus compared to U.S. born persons (87.8% and 95.0%, respectively). Prevalence of sero-immunity was lowest among persons aged ≥20 years with less than a high school education and increased with increasing years of education (85.9% for high school graduates and 92.9% in those with >high school education). While a smaller proportion of persons living below poverty level had tetanus sero-immunity compared to those living at or above poverty (91.8% vs. 94.5%), sero-immunity was high in both groups. Among adults aged 17 years and older who reported ever serving in the military, nearly all had protection (99.6%).

In bivariable analysis, prevalence of tetanus sero-immunity was significantly lower in persons aged ≥65 years compared to those <65 years (PR: 0.89, 95% CI: 0.86–0.93). Prevalence of tetanus sero-immunity was significantly lower among Hispanic persons compared to non-Hispanic White persons (PR: 0.95, 95% CI: 0.93–0.98), non-U.S. born persons compared to those born in the United States (PR: 0.93, 95% CI: 0.90–0.95) and persons living below poverty level compared to those who live at or above poverty level (PR: 0.97, 95% CI: 0.96–0.99) (Table 2). However, in multivariable analysis, only older age (adjusted PR: 0.89, 95% CI: 0.85–0.92) and being born outside the United States (adjusted PR: 0.96, 95% CI: 0.93–0.98) remained significantly associated with lower prevalence of sero-immunity.

Tetanus sero-immunity estimates at the higher antibody concentration threshold of 0.15 IU/mL are summarized in the supplementary table. Compared to the lower cut-off used in the primary analysis (0.10 IU/mL), prevalence of sero-immunity was 1.9% lower overall. Differences were small across all categories except in the lowest and highest age groups. Prevalence of sero-immunity was 8% lower in the 6–10-year age group and 4% lower in persons older than age 70 years.

Discussion

In this nationally representative study conducted during 2015–2016, 94% of persons aged 6 years and older in the United States had protection against tetanus as measured by anti-tetanus antibody concentrations using a highly sensitive multiplex assay that detects antibodies across a wide dynamic range. Prevalence of protection was over 90% in males and females, across all racial and ethnic categories, and irrespective of poverty level. Percent protection was lower in persons born outside the United States compared to U.S.-born persons, and among adults aged 20 years and older with less than a high school education vs those with more years of education, though it remained above 85% in both groups. There were notable differences in prevalence of tetanus sero-immunity by age. Though not statistically significant, a lower proportion of children aged 6–11 years had tetanus sero-immunity compared to adolescents and young adults, and there was a sharp and significant

decrease in the proportion with sero-immunity among older adults, with about a quarter of U.S. adults aged ≥80 years not having sero-immunity against tetanus. The decrease in the older age groups appeared to be driven largely by decreased protection among women. Reasons for lower protective immunity in older females vs. males are not clear and may be due to sex differences in immune senescence or differences in vaccine uptake by are more likely because among study participants in the oldest age groups who were born before introduction of TTCVs into childhood vaccination, a higher proportion of men served in the military and were subject to mandatory vaccination. Despite the lower sero-immunity in older women, the annual incidence of tetanus has remained similarly low in older men and women in the past two decades. From 2011–2020, tetanus incidence was 0.02 cases per 100,000 population among both men and women aged ≥80 years [4, 17].

Results from the present study indicate that a higher proportion of the U.S. population has protection against tetanus compared to previously reported estimates, even when the same antibody thresholds were used in the analysis. Using NHANES data from 1988–1994, McQuillan et al. found that only 72% of persons aged ≥6 years in the United States had protection against tetanus overall whereas seroprevalence at the same antibody threshold was over 90% in this study. Notably, the McQuillan et al. study reported much lower prevalence of protection in older age groups, as low as 45% and 21% in older men and women, respectively [18]. The lower population protection against tetanus is also reflected in the incidence during that time compared to more recent estimates (average annual incidence from 1992–2000 was 0.09 cases and 0.06 per 100,000 population in men and women aged ≥80 years, respectively). This sharp contrast to our present findings likely reflects the fact that adults aged 50 years and older in the 1988–1994 study were born before childhood vaccination with a primary series of TTCVs was recommended, and those aged 30 years and older had not received a booster dose as that recommendation was made in 1966.

Booster vaccination with a TTCV, which is usually combined with a diphtheria toxoid, has been discontinued or is administered at extended intervals in many countries based on recent evidence suggesting longer duration of protection against tetanus and diphtheria from booster vaccination [19, 20]. However, decennial booster vaccination with a TTCV continues to be recommended in the United States given there is no natural immunity to the disease, duration of protection from booster vaccination is not well understood, and self-reported booster vaccination uptake declines in older adults [21]. Additionally, the TTCVs licensed and used in the United States are combination vaccines that also provide protection against diphtheria or diphtheria and pertussis. Thus, changes to the current booster recommendations must also consider population susceptibility to and impact on those diseases for which prevalence of sero-immunity has been shown to be lower compared to tetanus sero-immunity [18, 22–25], especially in the setting of COVID-19 disruptions to routine childhood vaccinations [26–29].

This study has some limitations. Although we used data from a nationally representative survey, the findings are generalized to the noninstitutionalized, civilian population, and the prevalence of sero-immunity may be different in populations not represented in the survey [30]. Additionally, given the small sample sizes, the analysis was likely not powered to detect differences in some sub-groups. The assay used in this analysis is not a neutralizing

assay and could have overestimated protection [12, 31]. Lastly, NHANES does not collect history of tetanus vaccination, thus we were unable to evaluate durability of protection from vaccination.

This study indicates that the majority of the U.S. population has vaccine-induced sero-immunity to tetanus, demonstrating the success of the vaccination program despite the suboptimal coverage of booster vaccination among older adults. While the findings are reassuring overall, the results suggest that some groups such as older persons and those who were not born in the United States may benefit from more targeted vaccination efforts. Importantly, this comprehensive assessment of population sero-immunity to tetanus will help inform national TTCV recommendations and policy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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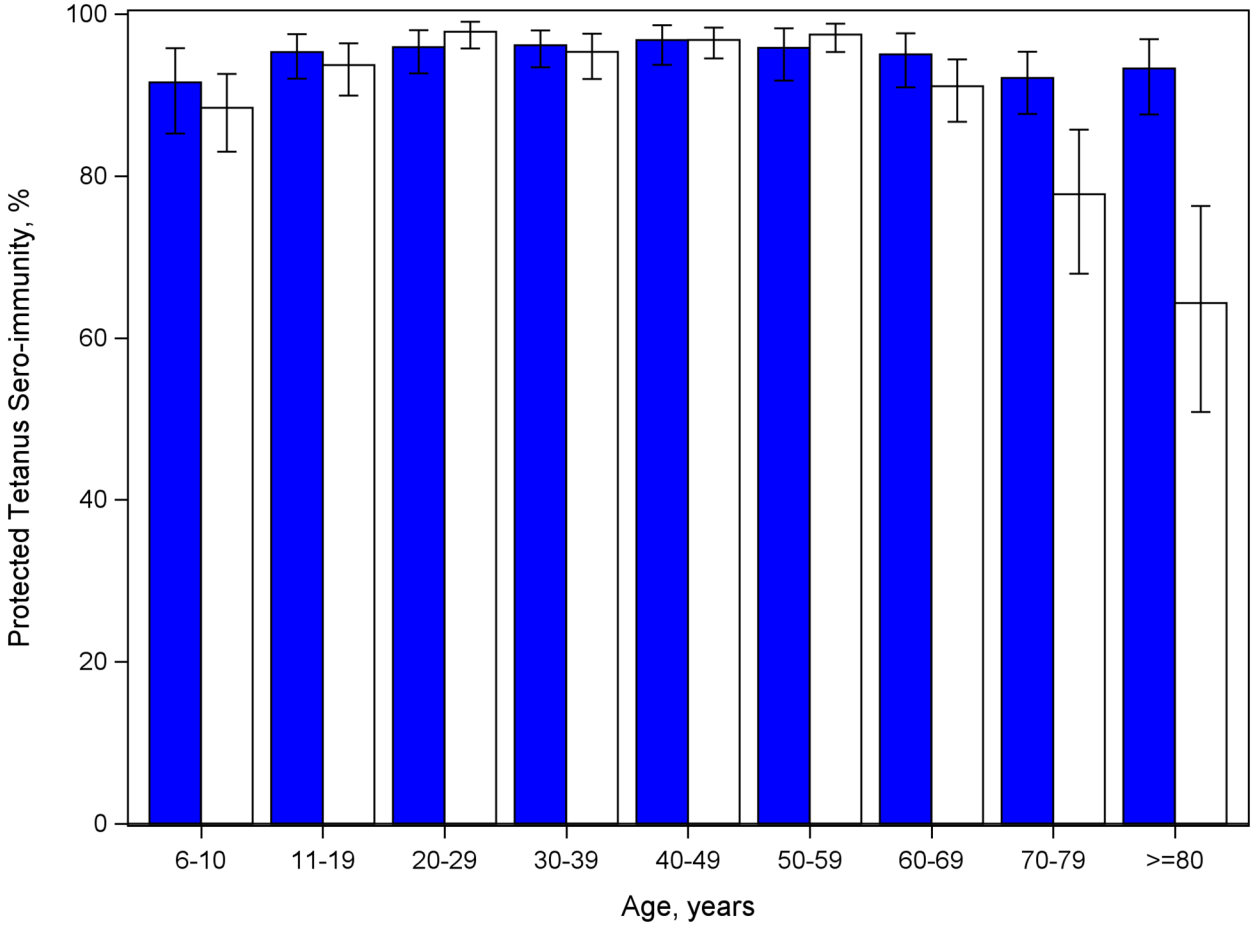

Figure 1:

Estimated prevalence of tetanus sero-immunity by sex and age group, National Health and Nutrition Examination Survey, 2015–2016

Legend: Sex ▪ Male ▫ Female

*Sero-immunity = ≥0.10 IU/mL by microsphere-based multiplex antibody capture assay

Table 1.

Estimated prevalence of tetanus sero-immunity among persons aged ≥6 years by selected characteristics, National Health and Nutrition Examination Survey, 2015–2016

Demographic Characteristic	Sample Size (Unweighted)	Weighted Prevalence of Sero-immunity* % (95% CI)	*P* †
Overall	5910	93.8 (92.9– 94.7)	
Sex			<.01
Male	2856	95.2 (94.2 – 96.1)	
Female	3054	92.5 (91.1 – 93.8)	
Age (years)			<.001
6–10	626	90.0 (85.9 – 93.2)	
11–19	990	94.5 (91.7 – 96.6)	
20–29	690	96.8 (95.2 – 98.0)	
30–39	694	95.7 (93.2 – 97.5)	
40–49	698	96.8 (94.7 – 98.2)	
50–59	706	96.7 (94.4 – 98.2)	
60–69	782	92.9 (90.4 – 94.3)	
70–79	453	84.1 (77.8 −89.4)	
≥ 80	271	75.8 (67.7 – 82.8)	
Race/Ethnicity			<.01
Non-Hispanic White	1965	95.2 (93.9 – 96.3)	
Non-Hispanic Black	1099	93.0 (90.6 – 94.9)	
Hispanic	1978	90.8 (89.1– 92.4)	
Other	868	91.4 (88.8 – 93.6)	
Country of Birth			<.001
United States	4310	95.0 (94.0 – 95.8)	
Other	1599	87.8 (85.0 – 90.3)	
Poverty level			<.01
Below poverty	1299	91.8 (90.2 – 93.3)	
At/above poverty	4076	94.5 (93.5 – 95.4)	
Education ‡			<.001
< High school	1015	85.9 (81.5 – 89.7)	
High school diploma	950	92.9 (90.9 – 94.6)	
> High school	2328	96.2 (95.2 – 97.0)	
Military Service ‡			<.001
Ever active	422	99.6 (98.4 – 100)	
Never active	3872	93.5 (92.3 – 94.6)	

*Sero-immunity = ≥0.10 IU/mL by microsphere-based multiplex antibody capture assay

†Rao-Scott Chi-square test

[≠]Among persons aged >20 years

Table 2.

Unadjusted and adjusted prevalence ratios (PRs) for tetanus seroimmunity among persons aged ≥ 6 years, National Health and Nutrition Examination Survey, 2015–2016

Demographic Characteristic	Sample Size (Unweighted)	PR % (95% CI)	aPR* % (95% CI)
Sex			
Male	2856	1.00	1.00
Female	3054	0.97 (0.96 – 1.00)	0.97 (0.96–1.00)
Age (years)			
<65	4839	1.00	1.00
≥65	1071	0.89 (0.86 – 0.93)	0.89 (0.85 – 0.93)
Race/Ethnicity			
Non-Hispanic White	1965	1.00	1.00
Non-Hispanic Black	1099	0.98 (0.96 – 1.00)	0.97 (0.95–1.00)
Hispanic	1978	0.95 (0.93 – 0.98)	0.96 (0.94–1.00)
Other	868	0.96 (0.93 – 1.00)	0.98 (0.95–1.00)
Country of Birth			
United States	4310	1.00	1.00
Other	1599	0.93 (0.90 – 0.95)	0.95 (0.93–0.98)
Poverty level			
At/above poverty level	4076	1.00	1.00
Below poverty	1299	0.97 (0.96 – 0.99)	1.00 (0.97–1.01)

*Model includes sex, age in years, race/ethnicity, country of birth, and poverty level