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Evaluation of Hepatitis B Virus Screening, Vaccination, and Linkage to Care Among Newly Arrived Refugees in Four States, 2009–2011

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Abstract

Many U.S.-bound refugees originate from countries with intermediate or high hepatitis B virus (HBV) infection prevalence and have risk for severe liver disease. We evaluated HBV screening and vaccination of newly arrived refugees in four states to identify program improvement opportunities. Data on HBV testing at domestic health assessments (1/1/2009-12/31/2011) were abstracted from state refugee health surveillance systems. Logistic regression identified correlates of infection. Over 95% of adults aged 19 years (N = 24,647) and 50% of children (N = 12,249) were tested. Among 32,107 refugees with valid results, the overall infection prevalence was 2.9% (0.76–9.25%); HBV prevalence reflected the burden in birth countries. Birth in the Western Pacific region carried the greatest infection risk (adjusted prevalence ratio = 4.8, CI 2.9, 7.9). Care linkage

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Compliance with Ethical Standards

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for infection was unconfirmed. Of 7409 susceptible persons, 38% received 3 doses of hepatitis B vaccine. Testing children, documenting care linkage, and completing 3-dose vaccine series were opportunities for improvement.

Keywords

Hepatitis B virus; Screening; Vaccination; Refugees

Introduction

Hepatitis B virus (HBV) infection is among the top ten causes of infectious disease-related mortality globally [1]. Without diagnosis and treatment, 15–25% of an estimated 240 million persons with chronic HBV infection (CHB) worldwide will die prematurely from long term sequelae of cirrhosis, liver failure, and hepatocellular carcinoma [2]. Approximately 85% of the world's population lives in countries with a high or intermediate prevalence of HBV infection (i.e., hepatitis B surface antigen [HBsAg] prevalence 8% and 2–7%, respectively). The United States has a low prevalence (< 2%) with up to an estimated 2 million chronically HBV-infected people and over 90% of new cases of CHB are imported [3–5].

Each year approximately 60,000–80,000 refugees are resettled to the United States [6]. Previous reports have documented HBsAg prevalence of 3–15% among U.S. refugees [7–13]. HBV infection prevalence is estimated to be higher among refugees than other immigrants [14], likely attributed not only to the burden in their birth country but also exposures in the transit country where refugee camps can be overcrowded, with limited access to care [12, 13]. Because CHB infection remains asymptomatic for years until liver complications develop, HBV screening, vaccination, and linkage to care of newly arriving refugees through states' refugee health services are crucial to reducing HBV-related morbidity and mortality in the United States.

The health department of each state provides oversight to federally-funded refugee health services, which can be rendered by local health departments, designated clinics, or private physicians. The Office of Refugee Resettlement (ORR) in the Department of Health and Human Services advises newly arriving refugees to report for a domestic health assessment within 90 days of arrival in the United States [15]. This recommended health assessment includes a comprehensive physical examination, review of overseas records, updating of vaccination per U.S. guidelines [16, 17], and screening for select communicable diseases, including HBV. CDC has developed guidelines to assist the state public health departments and clinicians in determining the best evidence-based screening tests to perform during the domestic health assessment [18, 19].

CDC guidelines for HBV screening and management recommend HBV testing of all refugees who were born or lived in countries with a prevalence of 2% (unless documented laboratory evidence of HBV screening is available), or who have risk factors for infection (e.g., HIV infection, injection drug use, hemodialysis, household contact of infected person, pregnancy) [18, 19]. Recommended tests for HBV serology are HBsAg, antibody to

hepatitis B core antigen (anti-HBc), and antibody to hepatitis B surface antigen (anti-HBs). Persons identified as infected should be linked to care for further evaluation, and those not infected, but who lack immunity should be offered the complete 3-dose hepatitis B vaccine series. Although CDC issues these recommendations for HBV testing, vaccination, and management, variability exists in local refugee health service practices depending on state health departments' policies and local resources.

We evaluated HBV screening, vaccination, and linkage to care of refugees presenting for domestic health assessment in four states to identify the prevalence of HBV infection and susceptibility, refugee sub-populations that require the greatest public health attention for screening, and potential opportunities for program improvement in HBV screening, vaccination, and management practices.

Methods

Participants and Data Collection

We conducted a cross-sectional, retrospective analysis of hepatitis B screening and management outcomes of domestic health assessments performed during 1/1/2009–12/31/2011 at 99 refugee health clinics in California (CA), Massachusetts (MA), Minnesota (MN), and Washington (WA). The selected clinics represented health assessment referral sites for 75–94% of refugees arriving in each of the four states (N=41,661), and approximately 22% of all refugees (N = 204,389) arriving in the United States during the review period [6]. The main data source for each state was its refugee health surveillance database. One state also used medical records because its surveillance system was under development at the time of the evaluation. Three states used the state immunization registry to complete data on vaccination. Data on demographics, HBV serologic test results, hepatitis B vaccination status, and linkage-to-care for HBV-infected persons were abstracted.

Definitions

A valid test result was defined as being either positive or negative for at least one hepatitis B serologic test. Table 1 shows the interpretation of serologic combinations of valid test results based on which refugees were categorized as being infected, susceptible, immune, and uninfected/immune status unknown. Some serologic combinations were not categorized (and excluded from all analyses) because of either missing HBsAg results, results that were difficult to interpret, or documented hepatitis B vaccination within 7 days prior to the blood draw for serologies, which could result in a false positive HBsAg result [20].

Analyses

To identify sub-populations requiring greater attention in screening, the proportion of all refugees presenting for a domestic health assessment tested for at least one of the three HBV serologic markers (HBsAg, anti-HBc, anti-HBs) was assessed by demographic characteristics; statistically significant differences in proportions were assessed by specifying linear contrasts. Among HBV-tested refugees who had a valid test result, the prevalence of HBV infection, susceptibility, and immunity was calculated. The proportions of persons linked to care among infected persons and with documented receipt of complete

3-dose hepatitis B vaccine series among susceptible persons were assessed. Multi-level multivariable modeling accounting for state and clinic level clustering using a log link function and Poisson distribution was used to calculate unadjusted and adjusted prevalence ratios (PR) and 95% confidence intervals (95% CIs) to determine the association of demographic factors (age, sex, World Health Organization region of birth [Africa, the Americas, Eastern Mediterranean, Europe, South East Asia, and Western Pacific] [21], and arrival state) with the outcome of HBV infection. An interaction term for sex and age was retained in the model to understand differences in infection prevalence between males and females by age group. SAS statistical software version 9.3 (SAS Institute Inc, Cary, NC, USA) was used for all analyses.

This public health program evaluation was determined not to be research involving human subjects and was exempt from review and approval by Institutional Review Boards (IRB) at CDC and three of the four participating states. The fourth state determined that review and approval from its IRB was not required since data were collected and analyzed as part of routine refugee health surveillance.

Results

During 1/1/2009–12/31/2011, a total 36,896 refugees presented for a domestic health assessment at the evaluated clinics, and of those, 32,205 (87.3%) received at least one of three HBV serologic tests and 32,107 (87.0%) had valid results. Among the four states, 20,456 (55.4%) refugees presented to CA clinics, 4905 (13.3%) to MA clinics, 4998 (13.5%) to MN clinics, and 6537 (17.7%) to WA clinics. Of the 32,205 refugees screened, 10,268 (31.9%) persons were tested with all three serologic tests, with the remaining having one or two tests. The median number of days between arrival and presentation for initial health assessment was 29 days (interquartile range [IQR]:19–47 days) among persons tested and 46 days (IQR: 29–76 days) for those not tested.

Similar proportions (~ 87%) of men and women were HBV-tested among 36,896 refugees presenting for a domestic health assessment. While 95.6% (N = 24,647) of adults aged 19 years were tested, 52.7% (N = 3830) children aged < 5 years, and 78.8% (8419) children and adolescents aged 6–18 years were tested (p < 0.0001); two of the four states accounted for the lower proportions of testing among persons aged < 19 years. Although 72.1% (N=2045) of persons born in the Europe region were tested (largely attributed to low proportion [25%] of testing in one state), over 87% of refugees born in the other WHO regions were tested (p < 0.0001). The majority (96.4%, N = 475) of pregnant women were tested for HBV serology.

Table 2 shows the characteristics of all refugees presenting for domestic health assessments and those with valid test results. Among 32,017 persons with valid test results, 16,551 (51.6%) were male, 13,990 (43.6%) were aged 19–39 years, 18,771 (58.5%) were born in the Eastern Mediterranean region, 8681 (27.0%) were born in the South-East Asia region. A total of 937 (2.9%) persons were infected, 16,481 (51.3%) were susceptible, 10,186 (31.7%) were immune, and 4269 (13.3%) were infected with unknown immune status; the test results of the remaining 234 (0.73%) persons were not categorized because of either missing

HBsAg test results (n = 171) or serologic combinations that were difficult to interpret (n = 35).

Table 3 shows the prevalence of HBV infection among 32,107 newly arrived refugees with valid test results by top birth countries, which had at least 100 refugees tested for HBV serology. The highest prevalence of HBV infection (8%) was identified among refugees born in Burma, Sudan, and Laos, representing 11.5, 0.4, and 0.3% of 32,107 refugees with valid results, respectively. Refugees from Iraq and Iran made up 51.8% (16,617) of refugees and had a low (< 2%) prevalence of infection.

Of 16,481 susceptible persons identified, data on receipt of the hepatitis B vaccine, either overseas or upon arrival in the United States, were available for 7409 (45.0%); the remaining 9072 (all from one state) were referred for vaccination, but documentation of vaccination was not available. Among the 7409 susceptible persons, 2839 (38.3%) received the complete 3-dose series of the vaccine, 2152 (29.0%) received two doses, 1450 (19.6%) received one dose, and 968 (13.1%) received no doses. Of the 2839 persons who received all three doses, 165 (5.8%) received > 3 doses. The majority (85%) of documented vaccine doses were administered in the United States upon arrival rather than overseas.

All 937 infected persons were referred to a provider for further assessment. However, data confirming linkage to care (e.g., attendance of follow-up medical appointment) were not available. In two states, documentation of having follow-up laboratory tests for liver function or HBV viral load was available for 328 (76%) of 431 infected persons, which could be indicative of their attendance of follow-up appointment.

Region of birth emerged as the strongest correlate of infection after adjustment for age, gender, and state of refugee health assessment in the multivariable analysis (Table 4). Compared with persons born in the Eastern Mediterranean region, those born in the Western Pacific, South-East Asia, or Africa regions had 4.8 (95% CI 2.9, 7.9), 3.3 (1.8, 6.1), and 3.1 (1.6, 6.0) times higher prevalence of HBV infection, respectively. Before the age of 5 years, males were 60% less likely than females to be infected. After age 5 years, males were 20–70% more likely to be infected depending on age, with children and adolescents aged 6–18 years having the greatest likelihood of infection.

Discussion

This evaluation of refugee health services for hepatitis B screening, vaccination, and linkage to care in four states showed that the majority (87%) of newly arrived refugees were tested for HBV at domestic health assessments during 2009–2011. The median time from refugees' arrival to the United States and presentation for health assessment was 29 days, which was within the 90-day ORR recommended timeframe [15]. The overall prevalence of HBsAg was 2.9% among refugees, representing an approximately 10 times higher burden of HBV infection than seen in the general U.S. population [3], confirming the need for early diagnosis and management of HBV infection among newly arriving refugees. Given the underdiagnosis of HBV infection by U.S. providers [22, 23], the refugee domestic health

assessment is a key opportunity for early detection and prevention of HBV-related morbidity and mortality.

While over 95% of refugees aged 19 years were tested for HBV at the evaluated clinics, only about half of children aged < 6 years, and three quarters of children and adolescents aged 6–18 years were tested. Improving HBV screening among children and adolescents is crucial because transmission during the perinatal and early childhood period contributes to the HBV burden in high and intermediate prevalence countries [2]. Further, the risk of progression from acute to chronic infection is inversely related to the age at the time of infection; > 90% of infected infants, 25–50% of infected children aged 1–5 years, and < 5% of infected older children and adults can progress to chronic infection, and potentially develop cirrhosis, liver failure, hepatocellular carcinoma [19]. As countries have gradually integrated hepatitis B vaccination into their national vaccination programs, hepatitis B vaccination coverage among U.S.-bound refugee children has improved [24]. However, because 3-dose coverage still remains below the U.S. target of 95%, CDC continues to recommend vigilance in HBsAg testing of refugee children aged < 18 years born in intermediate or high prevalence countries (regardless of vaccination history) unless a negative HBsAg test is documented in their overseas medical examination [18].

The prevalence of HBsAg among newly arriving refugees in this analysis varied between 0.8 and 15.7% based on the country of birth. Each year, the origin of refugees admitted to the United States can vary, depending on the geopolitical situation and governmental priorities [25]. For the states in this analysis, during 2009–2011, refugees from the Eastern Mediterranean region and South East Asia made up 58 and 27%, respectively, of all refugees. Iraq and Iran represented over half of the refugees tested (30.3 and 21.4%, respectively) and had a low prevalence of HBV infection, 0.76 and 1.72%, respectively, consistent with previously published estimates [12, 26]. Birth in the Western Pacific region (e.g., China, Korea, Vietnam,) had the highest likelihood of infection after adjustment for sex, age, and state of domestic refugee health assessment. However, refugees from this region and the Africa region, another high prevalence region, made up only 2.5 and 6.7%, respectively, of the total refugee population in this review, which likely explain our finding of an overall intermediate level of HBsAg prevalence of 2.9%. Previous studies have documented a higher risk of HBV infection among males versus females [8, 13]. Our analysis found disparities in HBV infection based on sex to be present among males between the ages of 6 and 60 years, with males aged 6-18 years having the greatest likelihood of infection. The evidence to explain these findings is lacking, requiring further investigation.

Although all HBV-infected refugees in this evaluation were referred to care, confirmation of actual care linkage through attendance of a follow-up appointment was not collected in the reviewed data sources. Treatment of HBV infection can suppress viral replication and halt the progression of liver disease, reducing the risk of cirrhosis, end stage liver disease, and HCC [27]. However, poor health-seeking behavior and low utilization of preventive care among refugees combined with potentially limited capacity of local programs to ensure linkage to care, may hinder timely treatment of hepatitis B infection among refugees [28–30]. In fact, delayed diagnosis of hepatitis B-related HCC among refugees has been

documented [9]. After our evaluation, with the availability of additional resources, one state demonstrated promising results in documenting linkage to care through bilingual care navigators who provided culturally appropriate education, made medical appointments, and arranged transportation to appointment for newly arrived refugees [28]. Ongoing effort and resources will be needed to further develop such strategies that ensure linkage to care and enable benefits of treatment.

Approximately 50% of assessed refugees were susceptible to HBV infection in this evaluation. However, hepatitis B vaccination records were available for less than half of susceptible refugees, among whom 38% had evidence of completing the 3-dose series. Children and adolescents (aged < 19 years) who are not fully vaccinated during the domestic health assessment would be captured again during adjustment of legal residency status in the United States, when nationally recommended age appropriate vaccinations, including hepatitis B vaccination, are required [18]. However, ACIP recommendations for hepatitis B vaccination in adults are primarily based on risk, which could be missed during follow-up care. Recently the United States has implemented overseas vaccination programs for U.S.-bound refugees, through which the series may be initiated but not completed before arrival [31]. Thus the domestic health assessment represents a key opportunity to ensure that refugees at risk for infection receive the complete 3-dose hepatitis B vaccine series to achieve optimal seroprotection against HBV infection [32, 33].

This analysis is subject to several limitations. First, the refugees in this review were not representative of the refugee population entering the United States during the evaluation period, with an over representation of refugees from Iraq (30.3%) and Iran (21.4%). Among all refugees entering the United States during 2009-2011, the highest proportion were from Burma (26.1%), Iraq (21.6%), Bhutan (20.5%) and Somalia (5.7%); refugees from Iran made up 5.2% of all refugees [6]. Nevertheless, the refugee population included in this review represented over 75% of refugees entering the four evaluated states and 22% of all refugees resettled in the United States during the study period. Second, 362 refugees in this review had an isolated positive anti-HBc result (i.e., HBsAg-/anti-HBc+/anti-HBs-) and were classified as immune (as they were predominantly from intermediate or high prevalence countries), but they could have had early HBV infection, which would be hard to determine without further testing. Third, HBV vaccination might have been underestimated because overseas and U.S. vaccination records in some states were incomplete, not capturing vaccinations performed outside the domestic health assessment (e.g., by private providers). Fourth, because we did not have information about the transit country, we were unable to adjust for associated infection risk. Fifth, approximately 70% of assessed refugees did not have documented results for all three serologic tests, likely attributable to state or local standard operating procedures, limiting complete interpretation of results for infection and immunity. Finally, state refugee screening surveillance systems did not capture follow up health information or track refugee referrals, which limited our ability to verify if refugees referred for further care did in fact link to care or completed vaccination series.

New Contribution to the Literature

This analysis demonstrated that the domestic refugee health assessment represents a key opportunity to test refugees for HBV if not already tested before arrival in the United States, link infected persons to care, and vaccinate susceptible persons to prevent transmission. Potential opportunities for refugee health program improvement were HBV screening with all three serologic tests, testing of children and adolescents from intermediate and high prevalence countries irrespective of hepatitis B vaccination status, documenting completion of 3-dose hepatitis B vaccination series in state immunization registries or surveillance systems, and developing interventions to confirm linkage to care of infected refugees to facilitate early care and treatment.

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Table 1

Classification of hepatitis B serologic screening results^{*a*} of newly arrived refugees presenting for domestic health assessment in four states, January 1, 2009–December 31, 2011

Infected
HBsAg+/anti-HBc+/anti-HBs-
HBsAg+/anti-HBc-/anti-HBs-
HBsAg+/anti-HBc+
HBsAg+/anti-HBs+
HBsAg+/anti-HBs-
HBsAg+/anti-HBc-
HBsAg + only
Susceptible
HBsAg-/anti-HBc-/anti-HBs-
HBsAg_/anti-HBc-
HBsAg_/anti-HBs-
Immune (previous infection or vaccination)
HBsAg-/anti-HBc+/anti-HBs+
HBsAg-/anti-HBc+/anti-HBs-
HBsAg-/anti-HBc-/anti-HBs+
HBsAg_/anti-HBc+
HBsAg_/anti-HBs+
Not infected, immune status unknown
HBsAg-/anti-HBc unknown/anti-HBs unknown
Excluded (unable to interpret)
HBsAg+/anti-HBc+/anti-HBs+
HBsAg+/anti-HBc-/anti-HBs+
Any person missing HBsAg results, regardless of other testing results
Any persons with a positive HBsAg result who received the hepa titis B vaccination within 7 days prior to the blood draw for serolo gies or on the same day as but before the blood draw

HBsAg hepatitis B surface antigen, anti-HBc antibody to hepatitis B core antigen, anti-HBs antibody to hepatitis B surface antigen, + positive result, - negative result

^aIncluded only valid test results (i.e., positive or negative result to at least one serologic marker, HBsAg, anti-HBc, anti-HBs)

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Characteristic of newly arrived refugees presenting for domestic health assessment at refugee health clinics in four states, January 1, 2009–December 31, 2011

	Number of persons presented for domestic health assessment	%	Number of persons with valid ^a HBV test results	%
Total	36,896		32,107	
Sex				
Male	18,971	51.4	16,551	51.6
Female	17,925	48.6	15,556	48.5
Age (years)				
0-5	3830	10.4	2013	6.3
6–18	8419	22.8	6604	20.6
19–39	14,643	39.7	13,990	43.6
40–59	6815	18.5	6464	20.1
60+	3189	8.6	3036	9.5
Region of birth country				
Americas	157	0.4	136	0.4
South-East Asia	9767	26.5	8681	27.0
Europe	2045	5.5	1466	4.6
Eastern Mediterranean	21,468	58.2	18,771	58.5
Western Pacific	903	2.5	793	2.5
Africa	2453	6.7	2169	6.8
Missing	103	0.3	91	0.3
Pregnancy status				
Not pregnant	17,274	46.8	14,997	46.7
Pregnant	475	1.3	458	1.4
Unknown pregnancy status	176	0.5	101	1.4
State				
CA	20,456	55.4	17,931	55.8
MA	4905	13.3	4850	15.1
MN	4998	13.6	4931	15.4

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	Number of persons presented for domestic health assessment	%	Number of persons with % valid ^a HBV test results	%
WA	6537	17.7	17.7 4395	13.7
^a Valid = positive or negative resu	a Valid = positive or negative result to at least one serologic marker (HBsAg, anti-HBc, anti-HBs)	HBsAg,	anti-HBc, anti-HBs)	

Table 3

Prevalence of hepatitis B infection by top birth countries^{*a*} among newly arrived refugees tested for hepatitis B virus at refugee health clinics in four states, January 1, 2009–December 31, 2011

Country of birth	Number of persons	Number	Prevalence
	with a valid test	of infected	of infection
	result	persons	
	n	n	%
Total	32,107	937	2.9
Laos	108	17	15.7
Sudan	119	13	10.9
Burma	3707	343	9.3
Vietnam	511	32	6.3
Somalia	1435	84	5.9
Eritrea	257	15	5.8
Moldova	425	24	5.7
Ethiopia	910	47	5.2
Democratic	175	9	5.1
Republic of			
Congo			
Thailand	1210	59	4.9
Iran	6878	118	1.7
Belarus	123	2	1.6
Russia	260	4	1.5
Bhutan	2807	32	1.1
Afghanistan	188	2	1.1
Ukraine	403	4	1.0
Kenya	384	4	1.0
Nepal	827	7	0.9
Iraq	9739	74	0.8
Cuba	122	0	0
Other ^b	1519	47	N/A

 a The prevalence of infection among countries that had at least 100 refugees tested shown (total 30,588 refugees)

^bOther = 88 countries with a total of 47 infected persons

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Table 4

Correlates of hepatitis B infection among newly arrived refugees presenting for domestic health assessment at refugee health clinics in four states, January 1, 2009–December 31, 2011

Characteristic	Number of per sons infected	Total with valid ^a HBsAg test	% persons infected	Crude prevalence ratio (PR) and Adjusted PR and CI confidence interval (95%CI)	Adjusted PR and CI
Total	934	$31,65 \mathrm{G}^{b}$	3.0		
Age (years)					
0-5	17	1977	0.9	Ref	N/A
6-18	180	6509	2.9	3.2 (1.6, 6.3)	N/A
19–39	452	13,796	3.3	3.8 (1.7, 8.7)	N/A
40–59	194	6371	3.1	3.5 (1.6, 8.0)	N/A
+09	91	2997	3.0	3.5 (1.8, 6.7)	N/A
Gender					
Male	570	16,303	3.5	1.5 (1.3, 1.7)	N/A
Female	364	15,347	2.4	Ref	N/A
Age/gender					
0–5 years					
Male	5	1039	0.5	0.4 (0.1, 1.3)	0.4 (0.1–1.3)
Female	12	938	1.3	Ref	Ref
6-18 years					
Male	116	3382	3.4	1.7 (1.3, 2.2)	1.7 (1.3–2.3)
Female	64	3127	2.1	Ref	Ref
19–39 years					
Male	284	7372	3.9	1.5 (1.2, 1.8)	1.4(1.1-1.8)
Female	168	6424	2.6	Ref	Ref
40–59 years					
Male	114	3026	3.8	1.6 (1.3, 2.0)	1.5 (1.2–1.9)
Female	80	3345	2.4	Ref	Ref
60 + years					
Male	51	1484	3.4	1.3 (1.0, 1.7)	1.2 (0.9–1.6)
Female	40	1513	2.6	Ref	Ref

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Characteristic	Number of per sons infected	Total with valid ^a % persons HBsAg test infected	% persons infected	Crude prevalence ratio (PR) and Adjusted PR and CI confidence interval (95%CI)	Adjusted PR and CI
WHO Region birth					
Africa	66	2157	4.6	2.9 (1.7, 4.8)	3.1 (1.6–6.0)
Eastern Mediterranean	293	18,625	1.6	Ref	Ref
Europe	39	1450	2.7	1.7 (1.1, 2.7)	1.8 (1.1–3.0)
South-East Asia	445	8631	5.2	3.3 (1.9, 5.4)	3.3 (1.8–6.1)
Western Pacific	58	787	7.4	4.7 (2.9, 7.6)	4.8 (2.9–7.9)
Site					
CA	387	17,681	2.2	Ref	Ref
MA	114	4807	2.4	$1.1\ (0.8, 1.5)$	0.7 (0.5–1.1)
MN	288	4815	6.0	2.7 (2.0, 3.7)	1.8 (1.2–2.5)
WA	145	4347	3.3	1.5 (1.2, 1.9)	0.8 (0.6–1.1)

b 457 persons were excluded from this analysis (234 results could not be categorized, 135 from America region with 0 infected persons, 88 with missing birth region). The comparison of infected group (n = 934) consisted of persons whose tests results were categorized as immune, susceptible, and non-infected (n = 30,936 persons)