HHS Public Access

Author manuscript

Vaccine. Author manuscript; available in PMC 2018 March 08.

Published in final edited form as:

Vaccine. 2018 January 25; 36(4): 467–472. doi:10.1016/j.vaccine.2017.12.014.

Burden of medically attended influenza infection and cases averted by vaccination — United States, 2013/14 through 2015/16 influenza seasons

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Abstract

Background—In addition to preventing hospitalizations and deaths due to influenza, influenza vaccination programs can reduce the burden of outpatient visits for influenza. We estimated the incidence of medically-attended influenza at three geographically diverse sites in the United States, and the cases averted by vaccination, for the 2013/14 through 2015/16 influenza seasons.

Methods—We defined surveillance populations at three sites from the United States Influenza Vaccine Effectiveness Network. Among these populations, we identified outpatient visits laboratory-confirmed influenza via active surveillance, and identified all outpatient visits for acute respiratory illness from healthcare databases. We extrapolated the total number of outpatient visits for influenza from the proportion of surveillance visits with a positive influenza test. We combined estimates of incidence, vaccine coverage, and vaccine effectiveness to estimate outpatient visits averted by vaccination.

Results—Across the three sites and seasons, incidence of medically attended influenza ranged from 14 to 54 per 1,000 population. Incidence was highest in children aged 6 months to 9 years (33 to 70 per 1,000) and lowest in adults aged 18-49 years (21 to 27 per 1,000). Cases averted ranged from 9 per 1,000 vaccinees (Washington, 2014/15) to 28 per 1,000 (Wisconsin, 2013/14).

Discussion—Seasonal influenza epidemics cause a considerable burden of outpatient medical visits. The United States influenza vaccination program has caused meaningful reductions in

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Conflicts of interest

Drs. M. Jackson and R. Zimmerman report research grants from Sanofi, unrelated to the present work. Dr. R. Zimmerman reports research grants from Merck, unrelated to the present work. The remaining authors report no conflicts of interest.

outpatient visits for influenza, even in years when the vaccine is not well-matched to the dominant circulating influenza strain.

Keywords

Influenza; human; Influenza; vaccines; Incidence

INTRODUCTION

Influenza is unique among vaccine-preventable diseases, in that maintaining immunity requires frequent re-vaccination due to the ongoing antigenic drift of influenza viruses.[1] In practice, this is accomplished through yearly influenza vaccination programs, which represent a multi-billion dollar investment of public health resources annually.[2] The effectiveness of seasonal influenza vaccines, and the impact of influenza vaccination on the burden of disease due to influenza, can vary considerably year to year.[3] A number of factors contribute to this variability, including the dominant virus types/subtypes and the antigenic match between the virus strains included in the vaccines and the circulating virus strains.[4, 5] Systems to monitor influenza vaccine effectiveness (VE) have been established in a number of countries (e.g. [6-9]), contributing to a growing understanding of sources of variability in influenza VE. These studies can also identify unexpected problems with influenza vaccines, such as reduced effectiveness of certain vaccine virus strains from specific vaccine products or due to egg adaptation.[4, 10]

Although annual VE estimates serve many scientific and public health purposes, of perhaps greater interest to policy makers are estimates of the impact of influenza vaccination programs on cases, deaths, or medical encounters averted by vaccination. These estimates have been more difficult to obtain due to under-diagnosis of influenza in most clinical settings.[11] Many systems for estimating influenza VE through test-negative sampling are not equipped to estimate the incidence of influenza, which is needed to assess vaccine impact. One exception is the United States Influenza Vaccine Effectiveness (US Flu VE) Network.[6] Several study sites within the US Flu VE Network are able to provide population-based estimates of influenza incidence as well as VE. We have previously used the US Flu VE Network to demonstrate that ambulatory care visits averted by influenza vaccination can vary even when VE is relatively consistent, due to differences in influenza attack rates.[12] In this paper, we report the impact of influenza vaccination in the US on ambulatory care visits for influenza for the 2013/14 through 2015/16 influenza seasons, during which influenza VE varied considerably.

METHODS

Details of the US Flu VE Network have been published previously.[5, 6, 10, 13] In brief, the US Flu VE Network consists of five geographically distinct sites in the United States: Kaiser Permanente Washington in western Washington State (KPW, formerly Group Health Cooperative); the Marshfield Clinic in Marshfield, Wisconsin (MC); Baylor Scott and White Health in Temple, Texas (BSW); the University of Michigan and the Henry Ford healthcare systems in Ann Arbor and Detroit, Michigan; and the University of Pittsburgh partnered

with the UPMC (aka, the University of Pittsburgh Medical Center) in Pittsburgh, Pennsylvania. These sites conducted active surveillance for medically attended influenza at ambulatory care clinics. For the present paper, estimates of influenza incidence were taken from the KPW, MC, and BSW sites, for which enumerated population cohorts could be defined and which have demographic and healthcare utilization data available through linked databases. The study was approved by institutional review boards at each participating site and the Centers for Disease Control and Prevention (CDC).

Source populations

We defined population cohorts as of September 1st of each study year (2013–2015). For KPW, the source population was drawn from enrollees in KPW's integrated group practice. These members receive healthcare coverage through KPW and receive medical care from KPW providers at KPW medical centers. Influenza surveillance was conducted at five (2013/14, 2015/16) or seven (2014/15) KPW medical centers. For estimating influenza incidence, we restricted the source population to KPW members whose primary healthcare provider was at one of the influenza surveillance clinics. The MC population consisted of a) persons with at least 12 months of residency (or since birth for those less than 12 months old) in the central Marshfield Epidemiology Study Area (MESA), a 14 zip code region centered around Marshfield, Wisconsin (all seasons), and b) non-MESA residents who have had ≥2 encounters within the 3 prior years at the main MC campus in Marshfield, affiliated hospital, or two adjacent satellite clinics (aged 6 months through 17 years in 2014/15 and all ages in 2015/16). MC captures at least 93% of all medical visits from MESA residents.[14] Influenza surveillance was conducted at primary care clinics located at the Main MC campus and one satellite clinic that serves MESA residents. The BSW population consisted of persons who had seen a BSW primary care provider for any reason within the 3 prior years and who lived in the Temple Population Research Area of East Bell County (defined by zip codes 765xx, excluding 7654x); BSW's market share among this population covers approximately 72% of all outpatient visits (MG, personal communication). Influenza surveillance was conducted at seven BSW primary care and urgent care clinics in East Bell County.

We defined covariates on all subjects in the source populations using administrative healthcare databases as previously described.[12] Subjects were classified according to age on September 1st of each season (6 months to 8 years; 9 to 17 years; 18 to 49 years, 50 to 64 years; and 65 years or older) and receipt of current season's influenza vaccine, as defined from administrative healthcare databases and state immunization registries.[15] We identified all ambulatory care visits for presumptive medically attended acute respiratory illness (ARI) based on International Classification of Diseases, Version 9, Clinical Modification (ICD-9, for encounters prior to 1 October 2014) and Version 10 (ICD-10, for encounters on or after 1 October 2014) codes (Supplemental Appendix).

Influenza surveillance and laboratory testing

At each surveillance clinic, trained staff reviewed appointment schedules and consulted with clinical staff, as needed, to identify patients seeking care for ARI, defined as respiratory illness with cough of less than eight days' duration.[13] Eligible patients were those with

ARI who were ≥6 months of age as of September 1st (and thus eligible for current season's influenza vaccination). Study staff collected combined nasal and oropharyngeal (nasal only on children <2 years of age) swabs from eligible and consenting patients. Swab specimens were tested for influenza A and B viruses using real-time reverse transcriptase polymerase chain reaction (RT-PCR), with probes and primers provided by CDC. Specimens testing positive were further tested for virus subtype (influenza A) or lineage (influenza B). For the present study, US Flu VE enrollees who were not members of the site's source population were excluded from the analyses. Influenza cases were defined as patients seeking outpatient care with a positive test for any influenza virus.

Analysis

We estimated the cumulative incidence of medically attended influenza in our study populations by extrapolating the total number of influenza cases in the populations from the number of influenza cases among the US Flu VE enrollees.[12] For this, we stratified the source populations into mutually exclusive groups based on study site *s*, age group *a*, vaccination status *v*, and number of medically attended acute respiratory illness (MAARI) visits *m*. Each US Flu VE enrollee was then assigned a sampling weight. US Flu VE enrollees with zero MAARI visits were assigned a sampling weight of 1.0; the weight for other enrollees was the total number of subjects in the enrollee's (*s, a, v, m*) stratum divided by the number of US Flu VE enrollees in that stratum. Using the sampling weights, we estimated the total number of medically attended influenza cases in each (*s, a, v, m*) stratum. Confidence limits were calculated by bootstrapping from the source populations and the US Flu VE enrollees. To account for the fact that some influenza cases occurred before or after active surveillance at each site, we up-weighted the number of influenza cases at each site by the inverse of the proportion of influenza cases detected by state surveillance (Texas, Washington, and Wisconsin) that occurred during enrollment periods.

After calculating the cumulative incidence of influenza, we estimated the number of outpatient influenza visits averted by vaccination as previously described.[12] Age-specific estimates of influenza VE were taken from the US Flu VE Network. For each year and within each age stratum, we assumed influenza VE to be constant across the study sites. All analyses were conducted using SAS version 9.4 (SAS Institute, Cary NC).

RESULTS

The source populations ranged in size from 47,211 persons (Wisconsin, 2013/14 season) to 162,633 persons (Washington, 2014/15 season) (Table 1). Averaged across sites and years, 21.8% of persons in the source populations were children aged 6 months to 17 years, while 18.6% were adults aged ≥65 years. Overall, 39.0% of source population members had documented receipt of influenza vaccine. Average annual influenza vaccine coverage was higher at the Washington and Wisconsin sites (49.6% and 45.3%, respectively) than at the Texas site (23.8%). The proportion of source population members with at least one MAARI visit ranged from 11.3% in 2013/14 to 14.4% in 2014/15.

Across the source populations, the proportion enrolled in US Flu VE Network surveillance ranged from 0.8% (Texas, 2013/14 season) to 2.8% (Wisconsin, 2014/15 season). The

proportion enrolled was highest for children aged <9 years (3.3%) and lowest for adults aged ≥65 years (1.1%). Although all US Flu VE Network enrollees by definition had an ambulatory care visit for ARI, not all of these visits were assigned a MAARI ICD code, so between 11.2% and 12.8% of US Flu VE Network enrollees had no MAARI visit as defined for this analysis (Table 1).

Incidence of outpatient visits due to influenza

Averaged across the three sites, the cumulative incidence of ambulatory visits for influenza ranged from 24.7 (95% confidence interval [CI], 21.7 to 27.7) per 1,000 in 2013/14 to 39.2 (95% CI, 35.9 to 42.7) per 1,000 in 2014/15. Incidence varied substantially by season, by age group, and by study site (Figure 1). The lowest incidence, 6.9 cases per 1,000 population, was observed in adults aged ≥65 years of age in Wisconsin during the 2015/16 season. The highest incidence, 76.8 cases per 1,000, was observed in children aged 6 months to 8 years in Texas during the 2014/15 season. The 2014/15 season, which was dominated by A(H3N2) viruses (Figure 1), had the highest burden of ambulatory visits for influenza of the three seasons.

Incidence tended to be highest among children aged 6 months to 8 years (Figure 1), with mean incidence of 48.9 (95% CI, 26.9 to 74.6) cases per 1,000. Incidence tended to be lowest in adults aged 18-49 years, with mean incidence of 23.9 (95% CI, 16.3 to 32.4) cases per 1,000. Incidence of ambulatory visits was not significantly different between adults aged 50-64 years (28.9 cases per 1,000, 95% CI 15.9 to 43.2) and adults aged ≥65 years (27.8 cases per 1,000, 95% CI 13.3 to 45.5).

Cases averted by vaccination

Overall, influenza vaccination averted an estimated 13.9 (95% CI, 3.7 to 25.9) ambulatory medical visits per 1,000 vaccinees. Despite having the greatest incidence of influenza, the 2014/15 season had the fewest cases averted by vaccination (10.4 per 1,000, not statistically significant) (Figure 2), owing to poor vaccine effectiveness that year (Figure 2). When the 2014/15 season was stratified by age, statistically significant cases averted were observed in 2014/15 for all age groups except adults 18-49 years of age (Figure 2).

Across all three seasons, estimated cases averted were highest for children aged 6 months to 8 years (21.4 cases averted per 1,000 vaccinees; 95% CI, 5.6 to 40.5) and lowest for adults aged 18 to 49 years (9.7 cases averted per 1,000 vaccinees; 95% CI, 4.0 to 15.6). The mean proportion of influenza ambulatory visits averted by vaccination was 14% (95% CI, 4 to 23%). The proportion averted ranged from 6% (95% CI, 0 to 12%) in Texas in 2014/15 to 40% (95% CI, 20 to 63%) in Washington in 2013/14.

Discussion

Seasonal influenza epidemics can cause substantial morbidity. In this study, we found that up to 5% of the population may seek outpatient care for influenza during a high severity influenza epidemic such as 2014/15. Extrapolated to the United States as a whole, this corresponds to approximately 16 million outpatient visits for influenza in a season of high severity. For comparison, by extrapolating from hospital-based surveillance, CDC estimated

that there were 16,184, 354 medical visits for influenza during the severe 2014/15 season.[16]

Although the United States influenza vaccination program is primarily aimed at preventing hospitalizations and deaths due to influenza,[1] reducing the burden of ambulatory visits for influenza is also a public health benefit of vaccination. Based on our study results, we found that, on average, vaccinating 1,000 people prevented 13.9 outpatient visits for influenza (or, one outpatient visit was prevented for every 72 persons vaccinated). In our study populations, with vaccine coverage ranging from 24 to 50%, vaccination prevented an estimated 14% of ambulatory visits for influenza.

A major challenge for influenza vaccination programs is that the virus strains included in seasonal vaccines must be chosen 9 months or more prior to the start of the next influenza season.[17] This lead time requires public health officials to predict which candidate vaccine viruses will best match the viruses that will circulate in the upcoming season.[18] This can lead to antigenic differences between the vaccine viruses and circulating viruses, as was seen in the 2014/15 influenza season, when the vaccine lacked effectiveness against the predominant A(H3N2) virus circulating in the United States that season.[5] However, despite the lower degree of similarity to circulating viruses, this study suggests that the 2014/15 influenza vaccine was still beneficial, with a statistically significant number of cases estimated to have been averted by vaccination for age groups at highest risk of complications following influenza infection. Even though the 2014/15 Northern Hemisphere vaccine was not effective against most circulating A(H3N2) viruses that season, the vaccine was still effective against circulating influenza B viruses, and vaccination reduced the number of ambulatory visits for influenza B virus infections.

Our estimate that influenza vaccination averted a mean of 14% of ambulatory influenza visits across three years is generally consistent with estimates from prior studies. We previously estimated cases averted in the US Flu VE Network for the 2011/12 and 2012/13 seasons.[12] In that study, the median estimate was that 14% of ambulatory influenza cases were averted, ranging from 9% to 35% across study sites and seasons. A CDC study that inferred the number of ambulatory influenza cases in the United States from the number of influenza hospitalizations estimated that a median of 16% of cases were averted by vaccination across non-pandemic years from 2005/06 to 2010/11.[19] Updates to that study estimated that vaccination averted between 7.5% and 31% of ambulatory influenza cases from 2010/11 through 2015/16.[16, 20, 21]

Several limitations of this study are worth noting. First, our estimates of cases averted only include the direct effects of the vaccine among vaccinated individuals, and do not account for indirect effects due to reduced transmission of influenza. Thus, the true impact of influenza vaccination may be greater than estimated in this study. Second, our study subjects were mainly sampled from insured populations, for which patterns of vaccination and healthcare utilization may differ from uninsured populations. This may limit the generalizability of our results to uninsured populations. However, the insured populations from which our subjects were drawn are largely representative of their geographic regions in terms of age, sex, and race/ethnicity.[22, 23] Third, our study populations were drawn from

three geographic regions in the United States and may not generalize to other regions. Fourth, our surveillance case definition required subjects to have an acute respiratory illness with cough. Although cough is a sensitive marker for identifying potential influenza cases, [24] this may have missed patients with influenza who did not report a cough at the time of presentation. Finally, when extrapolating from our US Flu VE Network enrollees to the entire source population, we assumed that patients who were not assigned a MAARI ICD code did not have influenza, unless they were enrolled and tested positive. This may underestimate the burden of medically-attended influenza.

Despite their limitations,[25] influenza vaccines remain the best available tool for reducing the risk of influenza disease. Our study suggest that the United States influenza vaccination program is leading to modest but meaningful reductions in ambulatory care visits for influenza, even in years when the vaccine is not well-matched to the dominant circulating influenza strain.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding

This project was supported by the Centers for Disease Control and Prevention (CDC) through cooperative agreements with Group Health Research Institute (U01 IP000466), University of Michigan (U01 IP000474), Marshfield Clinic Research Foundation (U01 IP000471), Baylor Scott & White Health (U01 IP000473), and University of Pittsburgh (U01 IP000467). University of Pittsburgh also received funding from the National Institutes of Health (grants UL1 RR024153 and UL1TR000005). CDC staff assisted in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; preparation, review and approval of the manuscript; and the decision to submit for publication.

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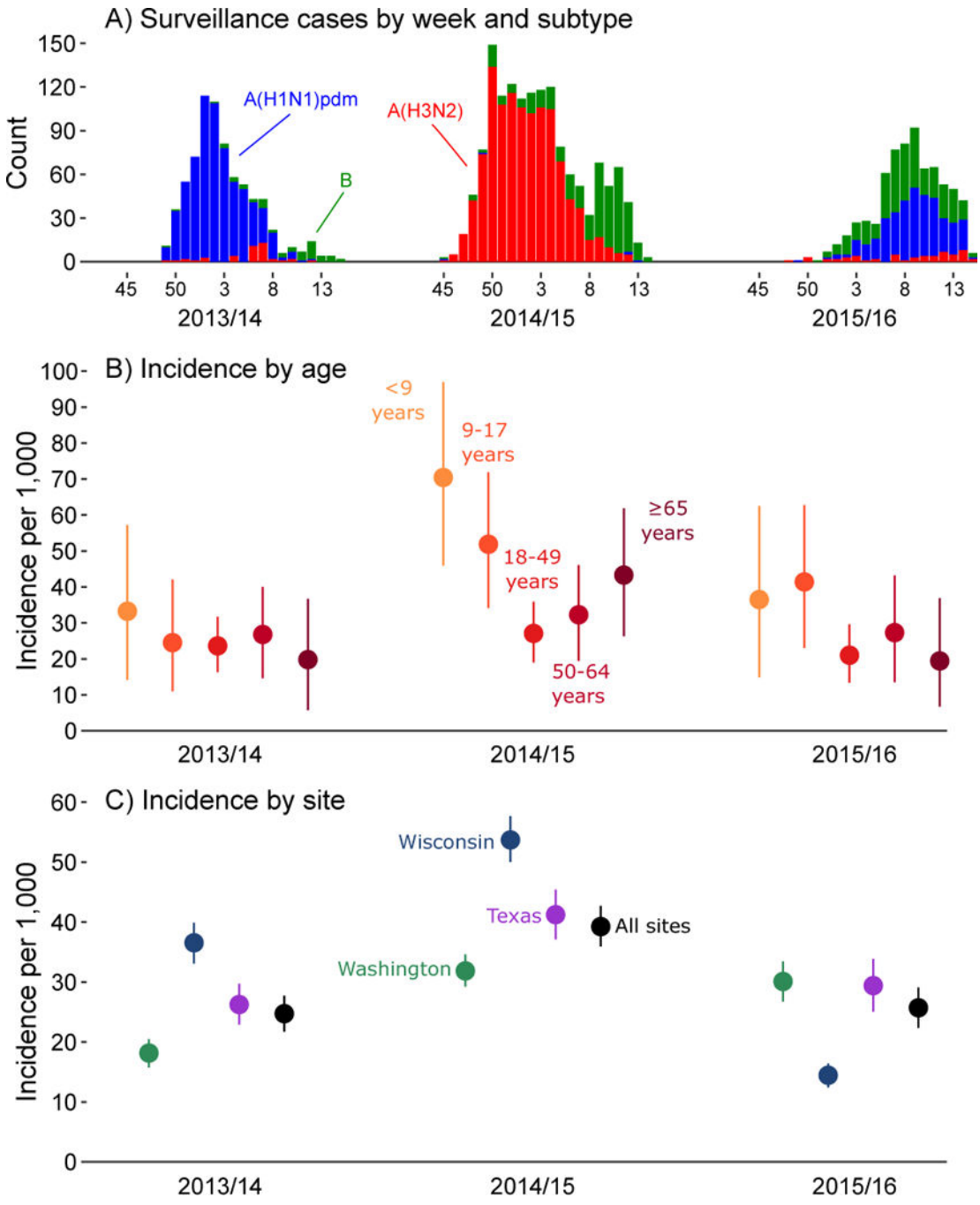

Figure 1.

A) Influenza cases identified by surveillance; B) Incidence of medically attended influenza by age group; C) Incidence of medically attended influenza by study site

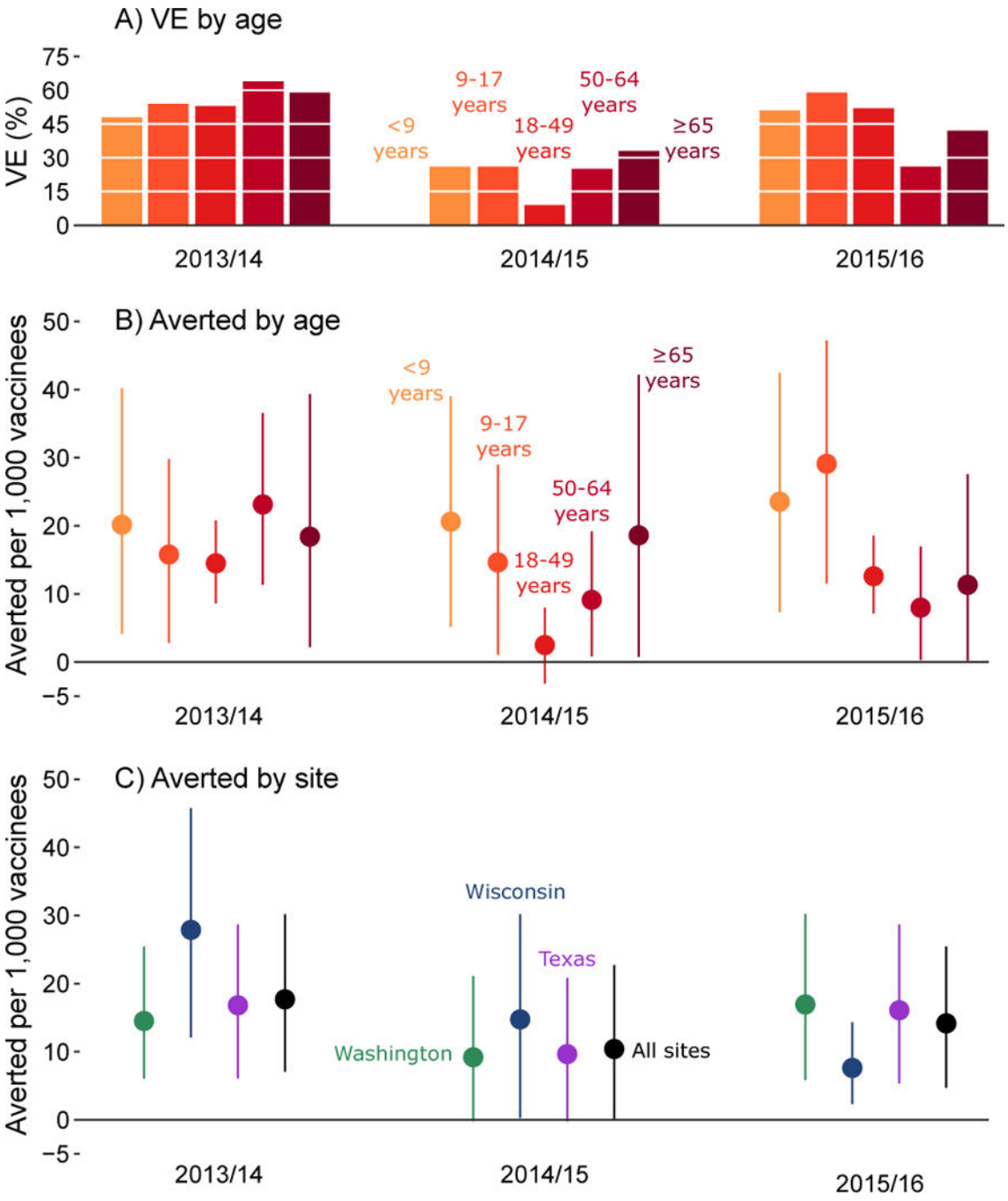

Figure 2.

A) Estimated influenza vaccine effectiveness (VE); B) Estimated cases averted per 1,000 vaccinees, by age group; C) Estimated cases averted per 1,000 vaccinees, by study site

Table 1

Characteristics of source populations and US Influenza Vaccine Effectiveness (US Flu VE) Network enrollees

	Source population			US Flu VE Network enrollees		
Characteristic	**2013/14**	**2014/15**	**2015/16**	**2013/14**	**2014/15**	**2015/16**
Total population	292,180	350,487	336,106	3,887	6,224	4,364
Age group						
0–8 years	29,913 (10%)	41,650 (12%)	34,170 (10%)	852 (22%)	1,643 (26%)	972 (22%)
9–17 years	30,095 (10%)	42,712 (12%)	34,611 (10%)	440 (11%)	906 (15%)	557 (13%)
18–49 years	121,246 (41%)	130,593 (37%)	126,202 (38%)	1,407 (36%)	1,854 (30%)	1,504 (34%)
50–64 years	61,686 (21%)	72,313 (21%)	71,799 (21%)	728 (19%)	960 (15%)	700 (16%)
65+ years	49,240 (17%)	63,219 (18%)	69,324 (21%)	460 (12%)	861 (14%)	631 (14%)
Study site						
Texas	129,842 (44%)	121,467 (35%)	118,128 (35%)	1,022 (26%)	1,542 (25%)	1,300 (30%)
Washington	115,127 (39%)	162,633 (46%)	128,884 (38%)	1,629 (42%)	2,841 (46%)	1,842 (42%)
Wisconsin	47,211 (16%)	66,387 (19%)	89,094 (27%)	1,236 (32%)	1,841 (30%)	1,222 (28%)
Vaccinated	108,052 (37%)	142,673 (41%)	130,977 (39%)	2,053 (53%)	3,392 (54%)	2,217 (51%)
MAARI visits						
0	259,286 (89%)	300,173 (86%)	288,164 (86%)	437 (11%)	797 (13%)	545 (12%)
1	24,600 (8%)	35,845 (10%)	32,438 (10%)	2,333 (60%)	3,396 (55%)	2,378 (54%)
2 or more	8,294 (3%)	14,469 (4%)	15,504 (5%)	1,117 (29%)	2,031 (33%)	1,441 (33%)