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Cost-Effectiveness and Impact of a Targeted Age- and Incidence-based West Nile Virus Vaccine Strategy

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Abstract

Background.—West Nile virus (WNV) is the leading cause of arboviral disease in the United States and is associated with significant morbidity and mortality. A previous analysis found that a vaccination program targeting persons aged ≥60 years was more cost-effective than universal vaccination, but costs remained high.

Methods.—We used a mathematical Markov model to evaluate cost-effectiveness of an age- and incidence-based WNV vaccination program. We grouped states and large counties (≥100 000 persons aged ≥60 years) by median annual WNV incidence rates from 2004 to 2017 for persons aged ≥60 years. We defined WNV incidence thresholds, in increments of 0.5 cases per 100 000 persons ≥60 years. We calculated potential cost per WNV vaccine-prevented case and per quality adjusted life-years (QALYs) saved.

Results.—Vaccinating persons aged ≥60 years in states with an annual incidence of WNV neuroinvasive disease of ≥0.5 per 100 000 resulted in approximately half the cost per health outcome averted compared to vaccinating persons aged ≥60 years in the contiguous United States. This approach could potentially prevent 37% of all neuroinvasive disease cases and 63% of WNV-related deaths nationally. Employing such a threshold at a county level further improved cost-effectiveness ratios while preventing 19% and 30% of WNV-related neuroinvasive disease cases and deaths, respectively.

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Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Conclusions.—An age- and incidence-based WNV vaccination program could be a more cost-effective strategy than an age-based program while still having a substantial impact on lowering WNV-related morbidity and mortality.

Keywords

West Nile virus; vaccination; cost-effectiveness; impact

West Nile virus (WNV) is the leading cause of mosquito-borne disease in the contiguous United States [1]. The virus is maintained in an enzootic cycle between birds and mosquitoes and is transmitted to humans primarily by *Culex* species mosquitoes [2]. This complex ecology results in high spatiotemporal variability in the incidence of human disease, with seasonal summer peaks that vary in size and location [3, 4]. Although some focal areas have consistently higher burden of disease, others have only sporadic cases or intermittent outbreaks.

Most WNV infections are asymptomatic or clinically inapparent [2, 5, 6]. Approximately 20%–30% of infections result in a systemic febrile illness, and <1% lead to neuroinvasive disease (eg, meningitis, encephalitis, acute flaccid myelitis). Among patients with neuroinvasive disease, the case-fatality is 10%, and residual neurologic deficits are common among survivors [7]. The risk of WNV encephalitis and death increases with age [8]. The average annual incidence of neuroinvasive disease cases reported to Centers for Disease Control and Prevention (CDC) from 1999 to 2018 increased with each decade of life, ranging from 0.03 per 100 000 in persons aged <10 years to 1.1 in persons aged ≥70 years [3].

Estimated healthcare costs associated with different WNV disease manifestations can be used to assess the cost-effectiveness of prevention interventions, including vaccination. A previous study extrapolating short- and long-term healthcare costs and lost productivity based on 80 patients hospitalized with WNV disease in Colorado in 2003 estimated a total cumulative cost of $778 million (adjusted to 2012 US dollars [USD], or $981 million, adjusted to 2020 USD) over a 14-year period nationally [9]. A more recent analysis of WNV-associated hospitalization charges in California, including 3109 patients hospitalized from 2004 to 2017, found substantially higher hospitalization costs totaling >$838 million over the 14-year period ($59.9 million/ year) [10]. In this analysis, the majority of patients hospitalized with WNV disease were aged ≥60 years and had at least one underlying condition.

There are no proven treatments for, or approved vaccines to prevent, WNV disease. Several candidate vaccines are under development, including 2 that have completed phase 2 clinical trials, but none is currently licensed for use in humans [11–14]. Two previous analyses examined the cost-effectiveness of WNV vaccination. The first analysis looked at administering vaccine to all individuals in the United States to prevent WNV infection [15]. Overall, the vaccine was not considered to be cost-effective, as many people who would be vaccinated would never be exposed or develop the disease if infected. The second analysis modeled the comparative cost and health outcomes of WNV vaccination among different age cohorts [9, 16]. The model found that a vaccination program targeting persons

aged ≥60 years was more cost-effective than universal vaccination, but costs to prevent most outcomes remained high. To assess an even more targeted vaccination approach, we added a geographic component and evaluated the costs and impact of a WNV vaccination program targeting persons aged ≥60 years in states and counties with consistently elevated disease incidence. Results of this analysis could help guide future vaccine development and implementation.

METHODS

We utilized the previously described mathematical Markov model [16] to estimate the costs and health outcomes of WNV vaccination compared to no vaccination among a cohort of persons aged ≥60 years in selected states and counties with successively higher thresholds of median annual incidence of WNV neuroinvasive disease (Supplementary Table 1). The model tracks, from cohorts' entry until age 90 years, the probability of a person becoming infected with WNV, developing clinical disease, and disability while adjusting the inputs (e.g., neuroinvasive disease incidence, baseline mortality) based on the cohorts' age. In order to assess the impact of adding the geographic disease incidence component to the previous model, we restricted the model to one scenario used previously, that 2 doses of vaccine administered 6 weeks apart provides lifelong protective immunity and assumed full coverage of the entire cohort. The use of a second dose was assumed as a conservative approach, given the need for booster dosing of some flavivirus chimeric vaccines and other vaccines (e.g., recombinant zoster vaccine) targeting older adults [14]. Because there are currently no licensed WNV vaccines, we used ChimeriVax-WN02 immunogenicity and adverse event data from phase II trials [12, 13] to populate the model and used seroconversion rates to estimate 90% vaccine efficacy (range, 85%–95%). We assumed the cost in 2012 USD for 2 doses of vaccine to be $230 and for administration to be $70, for a total of $300 (range, $100–$500). We used previously published direct and indirect cost estimates for hospitalization and 5-year follow-up costs for WNV disease by clinical syndrome and cost estimates for non-hospitalized cases of non-neuroinvasive WNV disease [9, 16, 17] (Supplementary Table 1).

We used age-specific WNV neuroinvasive disease case data reported to CDC's national arboviral disease reporting system, ArboNET, and Census Bureau data for 2004–2017 to calculate annual neuroinvasive disease incidence rates per 100 000 population in the ≥60-year-old age group for each state. As no WNV transmission has been reported in Alaska or Hawaii, we ranked and categorized the 48 contiguous states and Washington D.C. by their median annual WNV neuroinvasive disease incidence rate in this age group over the time period. We then grouped the states using median incidence rate thresholds from ≥0.0 to ≥2.5 per 100 000 in increments of 0.5 (Supplementary Table 2). For each threshold group, we calculated annual combined incidence rates (total annual WNV neuroinvasive disease case counts over total annual population in the ≥60-year-old age group) to generate distribution curves for the model. We applied the "fit distribution to data" function of @Risk 7.1 software (Palisade Corporation, Ithaca, New York) to the incidence rates to generate the incidence distribution for the model based on the Akaike information criterion (AIC) (Supplementary Table 1). We used previously established ratios of WNV neuroinvasive disease cases to infections based on blood donor data (1:300 for persons aged 10–64

years and 1:50 for persons aged ≥65 years) [18] to estimate the total number of WNV infections. To estimate the number of WNV disease cases, we assumed that 20%–30% of WNV-infected people develop clinical disease (Supplementary Table 1) [5]. To account for persons considered WNV-immune and therefore unlikely to benefit from vaccination, we extrapolated data from 10 states having the highest average annual incidence to estimate the proportion of the population previously infected [19].

We repeated these methods for counties with ≥100 000 persons aged ≥60 years using the same median incidence rate thresholds, except for the lowest incidence group which was >0.0 rather than ≥0.0 (Supplementary Table 3). For the countylevel analysis, because estimated annual age-specific county data were not available, we estimated numbers per age category using 2010 Census data.

Analysis

We calculated cost-effectiveness ratios, compared to the “no vaccination” scenario, per WNV disease case averted, per WNV-related quality-adjusted life-year (QALY) saved, per WNV neuroinvasive disease case averted, and per WNV-related death averted. We ran the model for 10 000 iterations and calculated mean costs per health outcome with 95% confidence intervals (CI) in 2012 US dollars, to allow for comparison to previous estimates. Both costs and health outcomes were discounted at an annual rate of 3% [20]. We conducted statistical analysis on the outputs derived from the model using Stata 15 IC (StataCorp, College Station, Texas). As the data were not normally distributed, we conducted the Kruskal-Wallis test to determine if there was a significant difference between median incidence thresholds for each output. We conducted post-test estimation for pairwise comparison using Dunn Test, similar to our previous analysis [16].

We calculated the percentages of all neuroinvasive disease cases and deaths potentially preventable by using the average annual numbers of cases reported in each group of states for persons aged ≥60 from 2004 to 2017. For simplicity and comparison with the previous model, we assumed 100% vaccine coverage for the targeted groups with 90% vaccine efficacy (Supplementary Table 1), without assuming any change in population immunity, and used cases reported for all ages nationally as the denominator.

RESULTS

State-Level Analysis

WNV vaccination of all persons aged ≥60 years in the 48 contiguous states and Washington D.C. (ie, median incidence rate ≥0.0) had the highest costs for all outcomes prevented. As the median threshold incidence of those states targeted for WNV vaccination increased, the costs per health outcome prevented decreased (Table 1). For example, for the 25 states with a median annual incidence of ≥0.5 (Table 1, Supplementary Table 2), the costs for all health outcomes prevented were reduced by approximately half when compared to those with an incidence ≥0.0 ($P < .001$, Supplementary Table 4). For the 25 states with WNV incidence ≥0.5, estimated mean costs of vaccination versus no vaccination (rounded to the nearest $1000) were $39,000 (95% CI: $12,000–$95,000) per WNV disease case prevented,

$665,000 (95% CI: $217,000–$1,467,000) per WNV neuroinvasive disease case prevented, $4,629,000 (95% CI: $1,519,000–$10,085,000) per WNV-related death prevented, and $350,000 (95% CI: $114,000–$773,000) per WNV-related QALY saved.

Vaccinating older adults in these 25 states would prevent an estimated 446 neuroinvasive disease cases annually, which is 37% of the average annual number of all neuroinvasive disease cases reported nationally in all age groups. In addition, vaccinating persons aged ≥60 years in these 25 states could prevent an estimated 72 deaths each year, or 63% of the average annual number of WNV-related deaths reported nationally in all age groups.

The proportion of neuroinvasive disease cases and deaths that could be prevented decreased with increasing incidence. For example, the costs for all outcomes were roughly half for states with a median incidence of ≥2.5 compared to states with a median incidence of ≥0.5. However, only 4 states had a median incidence of ≥2.5 with a combined total of 1.4 million persons aged ≥60 years. Therefore, although it would be more cost-effective to vaccinate older adults in these 4 states with the highest incidence of disease, such a program would prevent only 4% of all WNV neuroinvasive disease cases and 7% of all WNV-related deaths among persons of all ages in the United States (Table 1). The pairwise comparison for the states at different incidence thresholds found that the cohorts were statistically significantly different from one another for all outcomes except for the ≥0.5 and ≥1.0 pair for the 4 outcomes and the ≥1.5 and ≥2.0 for 3 of the 4 outcomes (Supplementary Table 4).

County-Level Analysis

Targeting counties with populations of ≥100 000 persons aged ≥60 years with elevated WNV neuroinvasive disease incidence (Supplementary Table 3) led to further reductions in cost compared to targeting states with the same thresholds (Table 2). Compared to states with a median incidence of ≥.5, targeting the 38 counties in 18 states meeting this incidence threshold, with a combined population of 10.5 million persons aged ≥60 years, would reduce the mean costs per health outcome prevented by 20–30%. For these 38 counties, estimated mean costs of vaccination versus no vaccination (rounded to the nearest $1000) were $28,000 (95% CI: $7,000–$71,000) per WNV disease case prevented, $512,000 (95% CI: $154,000–$1,148,000) per WNV neuroinvasive disease case prevented, $3,733,000 (95% CI: $1,180,000–$8,179,000) per WNV-related death prevented, and $271,000 (95% CI: $82,000–$612,000) per WNV-related QALY saved. Vaccinating older adults in these 38 counties would prevent an estimated 230 neuroinvasive disease cases annually, which is 19% of the average annual number of all neuroinvasive disease cases reported nationally in all age groups. In addition, vaccinating this group could prevent 34 deaths each year, or 30% of the average annual number of WNV-related deaths reported nationally in all age groups. The pairwise comparison for the counties at different incidence thresholds found that the cohorts were statistically significantly different from one another for all outcomes except for the ≥1.5 and ≥2.0 pair (Supplementary Table 5).

DISCUSSION

From this age- and incidence-based model of WNV vaccination, we found that it is more cost-effective to vaccinate an older cohort in states or counties with relatively higher WNV

neuroinvasive disease incidence compared to implementing a national age-based vaccine strategy. By limiting the vaccination strategy to states with an annual neuroinvasive disease incidence of ≥0.5 per 100 000 persons aged ≥60 years, we saw a reduction of approximately one-half of the costs per event prevented. Furthermore, even with such targeting, there was a substantial decrease in WNV-related neuroinvasive disease cases and deaths. Because of the geographically focal nature of WNV and the increased risk of severe disease in older adults, vaccinating persons aged ≥60 years in the 25 states with consistently higher disease incidence could result in a 37% reduction in WNV neuroinvasive disease cases and 63% reduction in WNV-related deaths among persons of all ages nationally. Focusing the vaccine campaign on older adults in states with even higher incidence provides additional benefit on cost-effectiveness but reduces the impact on the proportion of cases and deaths prevented. Further limiting this to counties meeting the 0.5 per 100 000 persons aged ≥60 years incidence threshold would lower the mean costs by one-fifth to one-third of that for states meeting this incidence threshold while preventing up to one-third of all WNV-related deaths annually.

Our findings of targeting vaccination to areas with highest incidence being more cost-effective for a vaccination program are not surprising or unprecedented. Hepatitis A vaccine was initially recommended in regions with high hepatitis A incidence rates because the healthcare system costs per QALY saved ranged from $500 in the highest incidence regions to $71,500 in the lowest-incidence regions [21]. Hepatitis A vaccination for children started with high-risk groups in areas with high rates of disease, followed by vaccination of children living in states, counties, and communities with hepatitis A rates consistently above the national average. The targeted vaccination strategy was highly effective at reducing disease and subsequently led to recommendations for nationwide childhood vaccination [22]. Our analysis provides support for targeting WNV vaccination to older age groups in areas with consistently high WNV disease incidence rates. However, such an approach would depend on the feasibility of implementing a targeted vaccination approach within local jurisdictions.

Although there are no defined thresholds of cost-effectiveness for vaccination programs, the cost-effectiveness ratios we found with a program targeting higher WNV incidence regions still exceed what might be considered favorable [23]. Comparisons across studies can be done using cost per QALY saved, although variations in measurement, populations at risk, and patient and societal preferences make it challenging to interpret differences between vaccine programs. For example, a CDC economic analysis of pneumococcal vaccination (PCV13) of persons aged ≥65 years versus no vaccination found a cost-effectiveness ratio of $562,000 (range, $112,000–$2.3 million) per QALY saved [24], which is higher than the ratios we found for a WNV program targeting higher-incidence states. In contrast, a CDC analysis of vaccination of persons aged ≥60 years with a recombinant zoster vaccine versus no vaccination found cost-effectiveness ratios of <$60,000 per QALY saved [25].

It is likely that a WNV vaccination program would be more effective than existing prevention recommendations. Current prevention strategies rely on community vector control measures and personal protective measures to reduce mosquito exposures (https://www.cdc.gov/westnile/resourcepages/pubs.html), as well as screening of blood donations. Although such interventions have been shown to decrease risk of WNV infection, variable

use of community and personal protective measures and limitations in efficacy remain challenges [26–28].

Similar to our previous model [16], the current model has several of the same limitations, including (1) indirectly estimating incidence of WNV infection from incidence of WNV neuroinvasive disease; (2) no available data for WNV vaccine costs, effectiveness, or duration of protection; (3) use of potential surrogates for QALY weights (e.g., influenza nonhospitalized QALY for WNV non-neuroinvasive disease); and (4) assuming 100% vaccine coverage to estimate impact on WNV-related outcomes. Vaccination coverage among older adults in the United States has been estimated to be 35%–69% [29], and if this were the case for a WNV vaccine, the number of cases prevented would be lower. In addition, our model continued to utilize the costs of WNV disease obtained from a cohort of patients in Colorado [9]; more recent estimates of WNV disease hospitalizations from California suggest that these costs might not be representative of other locations and could underestimate the cost-effectiveness ratios of the outcomes we examined [10].

CONCLUSION

An age- and incidence-based WNV vaccination program targeting those at higher risk for severe disease (persons aged ≥60 years) in areas with consistently high WNV disease burden is more cost-effective than an age-specific or complete national program. If a WNV vaccine were to become available, states with an annual incidence of WNV neuroinvasive disease of at least 0.5 per 100 000 persons aged ≥60 years could consider implementing a vaccination strategy targeting this population. Implementation at a county level using the same strategy in counties with a large population of persons aged ≥60 years is likely to improve cost-effectiveness ratios even further.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Maximum Impact and Costs (2012 US Dollars) of a West Nile Virus (WNV) Vaccination Program Targeting Persons Aged ≥60 Years in Groups of US States[a] and the District of Columbia With Varied Incidence of WNV Neuroinvasive Disease in This Age Group for 2004–2017 Compared With No Vaccination

	Median Annual WNV Neuroinvasive Disease Incidence per 100 000 Persons Aged ≥60 years			
	≥0.0	**≥0.5**	**≥1.5**	**≥2.5**
Number of states and D.C. [a]	49	25	11	4
Population aged ≥60 years	70 373 968	32 369 276	19 145 418	1 414 857
Estimated annual events prevented[b]				
Neuroinvasive disease cases prevented (%)	536 (44)	446 (37)	338 (28)	43 (4)
WNV-related deaths prevented (%)	88 (77)	72 (63)	54 (47)	8 (7)
Costs per event prevented (95% CI) (rounded to $1000)[c]				
WNV disease case prevented	$78 000 ($25 000–$173 000)	$39 000 ($12 000–$95 000)	$30 000 ($9 000–$74 000)	$20 000 ($4 000–$57 000)
WNV-related death prevented	$8 904 000 ($3 017 000–$18 713 000)	$4 629 000 ($1 519 000–$10 085 000)	$3 503 000 ($1 079 000–$7 617 000)	$2 091 000 ($477 000–$5 337 000)
WNV-related QALY saved	$687 000 ($238 000–$1 459 000)	$350 000 ($114 000–$773 000)	$266 000 ($83 000–$577 000)	$163 000 ($37 000–$419 000)

Abbreviations: CI, confidence interval; QALY, quality adjusted life-years; WNV, West Nile Virus.

[a] Excluding Alaska and Hawaii, because no WNV transmission has been reported in these states.

[b] Estimated annual number of neuroinvasive disease cases and WNV-related deaths that could be prevented by vaccinating persons aged ≥60 years in each set of states, and the proportion of neuroinvasive disease cases and deaths that would be prevented nationally among all age groups, assuming 100% vaccine coverage and 90% vaccine efficacy.

[c] There was a statistically significant difference in cost-effectiveness ratios for all outcomes across the incidence groups (Kruskal-Wallis test $P = .0001$).

Table 2.

Maximum Impact and Costs (2012 US dollars) of a West Nile Virus (WNV) Vaccination Program Targeting Persons Aged ≥60 years in Groups of US Counties With ≥100 000 Persons Aged ≥60 years With Varied Incidence of WNV Neuroinvasive Disease in This Age Group for 2004–2017 Compared With No Vaccination

	Median Annual WNV Neuroinvasive Disease Incidence per 100 000 Persons Aged ≥ 60 years			
	>0.0	**≥0.5**	**≥1.5**	**≥2.5**
Number of counties	51	38	18	5
Population aged ≥60 years	13 497 343	10 527 728	5 772 479	2 637 073
Estimated annual events prevented[a]				
Neuroinvasive disease cases prevented (%)	250 (21)	230 (19)	175 (14)	91 (7)
WNV-related deaths prevented (%)	38 (33)	34 (30)	26 (23)	14 (13)
Costs per event prevented (95% CI) (rounded to $1000)[b]				
WNV disease case prevented	$33 000 ($9 000–$79 000)	$28 000 ($7 000–$71 000)	$18 000 ($3 000–$68 000)	$16 000 ($2 000–$61 000)
WNV-related death prevented	$4 547 000 ($1 486 000–$9 554 000)	$3 733 000 ($1 180 000–$8 179 000)	$2 194 000 ($529 000–$5 881 000)	$1 876 000 ($389 000–$5 181 000)
WNV-related QALY saved	$329 000 ($104 000–$707 000)	$271 000 ($82 000–$612 000)	$160 000 ($36 000–$470 000)	$138 000 ($27 000–$416 000)

Abbreviations: CI, confidence interval; QALY, quality adjusted life-years; WNV, West Nile Virus.

[a]Estimated annual number of neuroinvasive disease cases and WNV-related deaths that could be prevented by vaccinating persons aged ≥60 years in each set of states, and the proportion of neuroinvasive disease cases and deaths that would be prevented nationally among all age groups, assuming 100% vaccine coverage and 90% vaccine efficacy.

[b]There was a statistically significant difference in cost-effectiveness ratios for all outcomes across the incidence groups (Kruskal-Wallis test $P = .0001$).