

RESEARCH PAPER



# Disparities in healthcare providers' interpretations and implementations of ACIP's meningococcal vaccine recommendations

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## ABSTRACT

Invasive meningococcal disease (IMD) caused by the bacteria *Neisseria meningitidis* is rare but potentially fatal. For healthy adolescents, the US Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with MenACWY and recommends MenB vaccination under shared clinical decision-making (previously "Category B"). The recommendation for MenB vaccination was the first category B recommendation in adolescents, and it is unclear how healthcare providers (HCPs) implement these guidelines. This 2017 web-based survey of US HCPs explored characteristics associated with prescribing or receiving MenB and MenACWY vaccines, HCP knowledge of vaccine recommendations, and real-world practice patterns. Of 529 respondents, 436 prescribed MenB vaccines to their eligible adolescent/young adult patients and 93 prescribed MenACWY vaccines only. MenB vaccine prescribers were more likely to be pediatricians compared with MenACWY vaccine only prescribers, and patients who received MenB vaccines were more likely to be non-Hispanic whites living in shared spaces (eg, college dormitories) than those not receiving the vaccine. Seventy-seven percent of HCPs indicated that they prescribe MenACWY vaccines consistently with ACIP recommendations (to all members of an age group), whereas only 7% indicated that they prescribe MenB vaccines consistently with ACIP recommendations (individual clinical decision making). Patient-related factors, disease-related factors, and guidelines all influenced HCP decisions to prescribe meningococcal vaccines. Providing HCPs with clear guidance on how to initiate discussion of MenB vaccines with patients and their caregivers may aid in fully protecting US adolescents against meningococcal disease caused by 5 of the disease-causing serogroups.

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## Introduction

Invasive meningococcal disease (IMD) is a rare but serious and unpredictable infection caused by the bacteria *Neisseria meningitidis*.<sup>1,2</sup> The disease is fatal in 10% to 20% of cases, with case fatality rates up to 40% in patients with septicemia; 20% of survivors may experience debilitating long-term sequelae, including hearing loss or cognitive impairment.<sup>1</sup>

Nearly 80% of cases of IMD in the United States are caused by meningococcal serogroups B, C, W, and Y.<sup>3</sup> Two quadrivalent meningococcal vaccines that provide coverage against serogroups A, C, W, and Y (MenACWY) are available in the United States.<sup>4,5</sup> In 2005, when a conjugated MenACWY vaccine became available, the Advisory Committee on Immunization Practices (ACIP) recommended routine MenACWY vaccination at age 11 to 12 years.<sup>6</sup> At the time, meningococcal disease incidence rates were 0.5 to 1.1 per 100,000 population, and individuals 11 years of age and older accounted for 62% of cases overall, with 75% of these cases attributed to serogroups C, W, and Y. In 2011, as the burden of the disease was still high in young adults aged 16 through 21 years, the ACIP recommended a booster MenACWY dose at age 16 years to protect adolescents through the entire period of increased risk.<sup>7</sup> These routine

recommendations apply to people within the specified age or risk group and were previously referred to as Category A, although the Centers for Disease Control and Prevention has transitioned to new nomenclature.<sup>8–10</sup>

The incidence of meningococcal disease has steadily declined in the United States over the last 2 decades, and the reduction in the incidence of meningococcal disease due to serogroups C, W, and Y among adolescents suggests an effect of the MenACWY vaccine program in this age group.<sup>11</sup> However, MenACWY vaccines do not protect against meningococcal serogroup B (MenB) disease, which has become the predominant serogroup causing meningococcal disease in recent years in the United States.<sup>3</sup> MenB-FHbp (Trumenba<sup>®</sup>, Pfizer Inc, Philadelphia, PA)<sup>12</sup> and MenB-4C (Bexsero<sup>®</sup>, GSK Vaccines, Srl, Sovicille, Italy)<sup>13</sup> are recombinant protein-based MenB vaccines available in the United States for use in persons aged 10 to 25 years. In 2015, although there were only 50 to 60 cases of MenB disease and 5 to 10 related deaths in adolescents and young adults aged 11 to 23 years, more than 80% of MenB cases occurred in individuals aged 16 to 23 years.<sup>14</sup> In addition, between 2009 and 2013, several MenB outbreaks had occurred at US colleges. Together with the availability of

MenB vaccines, this prompted the ACIP in June 2015 to make a non-routine recommendation for MenB vaccination of healthy 16- to 23-year-olds (16–18 years preferred) under shared clinical decision-making (ie, “Category B” recommendation).<sup>14,15</sup> These ACIP recommendations did not categorize college students as at increased risk for MenB disease as incidence estimates from 2009 to 2013, which were considered at that time, among college students aged 18 to 23 years (0.09 per 100,000) were lower than the incidence in all individuals (0.14 per 100,000) and among non-college individuals (0.21 per 100,000) of the same age.<sup>14</sup> Another factor in the ACIP decision was that data on breadth and duration of protective coverage with MenB vaccines were not yet available.<sup>16</sup>

Since the ACIP recommendation for MenB vaccination, further changes in MenB epidemiology have occurred. In 2017, MenB disease was responsible for 38.3% of cases among all age groups.<sup>3</sup> Moreover, the percentage of meningococcal disease caused by MenB among adolescents and young adults aged 16–23 years has increased from 58.3% in 2015 to 69.6% in 2017.<sup>3,17</sup> US college students have a 3.5 times greater relative risk for MenB disease versus adolescents not attending college,<sup>18</sup> and all college outbreaks since 2011 were caused by MenB.<sup>19</sup> In addition, adolescents are the most common carriers of *N meningitidis* and are more likely to transmit the causative bacteria to others because of age-specific environmental and social behavioral characteristics.<sup>20,21</sup>

To better understand the implementation of ACIP recommendations for MenB vaccines and their potential effects on vaccine uptake among adolescents, which is a subpopulation with unique immunization delivery challenges,<sup>22,23</sup> our study aimed to (1) examine healthcare provider (HCP) characteristics in relation to their prescribing patterns with meningococcal vaccines (MenACWY and MenB), (2) understand real-world decision processes of HCPs and their interpretation of ACIP recommendations, and (3) assess patient characteristics associated with the receipt of MenB vaccines.

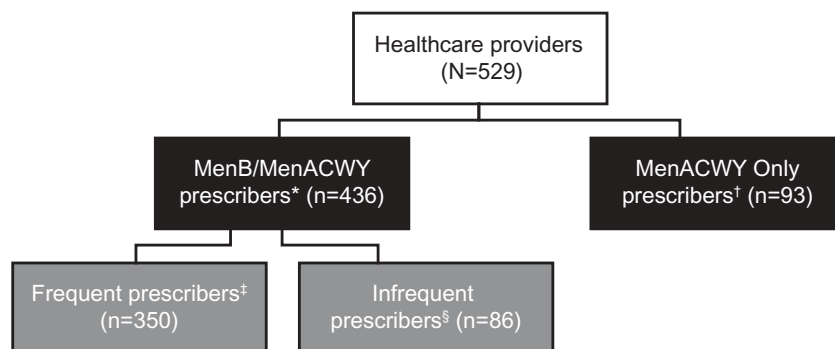
## Results

### Participants

A total of 529 HCPs met the study inclusion criteria and completed the web-based survey. These HCPs were among the 3630 of the 73,350 potential participants who responded to the survey invitation (4.9% response rate). Patient chart reviews of 2832 patients aged 16–23 years were conducted by 453/529 HCPs (85.6%). Of the 529 HCPs, 431 (81.5%) indicated that they prescribed both the MenB and MenACWY vaccines to eligible adolescent or young adult patients, 5 (0.9%) indicated that they prescribed only the MenB vaccine, and 93 (17.6%) indicated that they prescribed only the MenACWY vaccine. For the purpose of this analysis, prescribers of MenB only were combined with prescribers of both MenACWY and MenB to form the MenB/MenACWY prescriber analysis group (n = 436; Figure 1). Among MenB/MenACWY prescribers, 350/436 (80.3%) were identified as frequent prescribers (who indicated that they prescribed the MenB vaccine “almost always” or “usually”) and 86/436 (19.7%) were identified as infrequent prescribers (who indicated that they prescribed the MenB vaccine “sometimes,” “upon request,” or “rarely/never”). Of the 2832 patient chart reviews conducted, 2379 were included in the analysis because the patient had received either the MenB vaccine only (n = 349), both the MenB and MenACWY vaccine (n = 1172), or the MenACWY vaccine only (n = 858); 453 charts were excluded because the patients had not received either vaccine. Similar to the HCP analysis, those who received the MenB vaccine only were combined with those who received both MenACWY and MenB vaccines to form the MenB/MenACWY receiver analysis group (n = 1521).

### Characteristics of healthcare providers prescribing the meningococcal serogroup B vaccine

According to the bivariate analysis, factors significantly associated with HCP likelihood of prescribing MenB vaccine were sex, age, type of HCP, specialty, number of patients aged 16–23 years typically treated per month, interpretation of ACIP



**Figure 1.** Flow chart of respondents by prescribing patterns and provider type.

\*Recommended either the MenB vaccine only or recommended both the MenB and MenACWY vaccines. †Recommended the MenACWY vaccine only (n = 63 primary care physicians; n = 22 nurse practitioners; n = 8 physician assistants). ‡Indicated that they prescribed the MenB vaccine “almost always” or “usually” (n = 290 primary care physicians; n = 37 nurse practitioners; n = 23 physician assistants). §Indicated that they prescribed the MenB vaccine “sometimes,” “upon request,” or “rarely/never” (n = 73 primary care physicians; n = 9 nurse practitioners; n = 4 physician assistants). MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.

recommendations for MenB vaccines for adolescents, use of private/commercial insurance or Medicaid, and the percentage of their patients (according to the HCP) who understood the difference between the MenB and MenACWY vaccines (Table 1).

In the multivariable analysis adjusting for all model covariates (Table 2), HCPs with a higher likelihood of prescribing the MenB vaccine (based on a threshold of  $P < .10$ ) were more likely to be men, pediatricians, or to treat a higher number of patients aged 16–23 years each month compared with those who did not prescribe MenB vaccines. A higher likelihood of prescribing MenB was also associated with having spent more years in the practice, having more patients using student health insurance plans compared with no insurance, having fewer patients on Medicaid versus no insurance, or having a higher number of patients who the HCP perceived as understanding the difference between the MenB and MenACWY vaccines.

### Characteristics of patients receiving the meningococcal serogroup B vaccine

Factors that significantly varied between patients who had received the MenB vaccine versus those who had received

**Table 1.** HCP characteristics by whether they prescribe the MenB vaccine.

Characteristic	MenB/ MenACWY Prescribers (n = 436)	MenACWY Only Prescribers (n = 93)	P Value
Male n(%)	253 (58.0)	38 (40.9)	<b>0.003</b>
Age category, n (%), y			<b>0.002</b>
<35	50 (11.5)	19 (20.4)	
35–44	138 (31.7)	30 (32.3)	
45–54	136 (31.2)	24 (25.8)	
55–64	101 (23.2)	12 (12.9)	
>65	11 (2.5)	8 (8.6)	
Type of healthcare professional, n (%)			<b>0.001</b>
PCP	363 (83.3)	63 (67.7)	
Nurse practitioner	46 (10.6)	22 (23.7)	
Physician assistant	27 (6.2)	8 (8.6)	
Specialty (PCP only), n (%)			<b>0.017</b>
Internal medicine	57 (15.7)	9 (14.3)	
Family practice	56 (15.4)	19 (30.2)	
Pediatrics	250 (68.9)	35 (55.6)	
Primary practice location, n (%)			0.193
Urban	145 (33.3)	29 (31.2)	
Suburban	256 (58.7)	51 (54.8)	
Rural	35 (8.0)	13 (14.0)	
Number of years in practice, mean (SD)	16.37 (7.74)	15.12 (9.51)	0.174
Number of patients aged 16–23 y treated in a month, mean (SD)	160.28 (190.14)	115.81 (93.62)	<b>0.028</b>
Percentage of time spent in direct patient care, mean (SD)	95.72 (6.18)	94.61 (6.49)	0.121
Percentage of type of insurance coverage held by patients, mean (SD)			
Private/commercial	61.19 (24.90)	52.58 (26.66)	<b>0.003</b>
Student plan	6.39 (9.27)	4.40 (7.21)	0.052
Medicaid	22.15 (21.58)	28.91 (24.93)	<b>0.008</b>
Government/VA hospital	4.37 (11.38)	6.31 (15.17)	0.161
No insurance	5.18 (6.54)	6.37 (10.16)	0.155
Other	0.72 (4.04)	1.43 (4.96)	0.141
From HCP's perspective, percent of patients who understand the difference between MenB and MenACWY, mean (SD)	35.36 (27.62)	15.85 (19.83)	<b>&lt;0.001</b>

HCP = healthcare provider; MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B; PCP = primary care provider. P values <0.05 are indicated in bold font.

the MenACWY vaccine only were age, ethnicity, student status, living arrangement, insurance coverage, whether the patient had received other vaccines in the past, or whether the patient was treated by a frequent MenB vaccine prescriber (Table 3). In the multivariable analysis adjusting for all model covariates (Table 4), patients who received the MenB vaccine were more likely to be male, non-Hispanic white (compared with all other race/ethnicity categories), living in a campus dormitory or other shared space, or treated by a frequent MenB prescriber. Patients were more likely to receive the MenB vaccine if they received the human papilloma virus (HPV) vaccine but less likely to receive the MenB vaccine if they had ever received the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine.

### Interpretation of the advisory committee on immunization practices recommendations

Respondents were asked to indicate their interpretation of ACIP's recommendations by selecting the decision process they used to determine who should receive the MenACWY and/or the MenB vaccine (Figure 2). Regarding MenACWY, 77% of all survey respondents interpreted the recommendation as to prescribe to everyone in a particular age group regardless of risk factors, 18% interpreted the recommendation as to prescribe only to specific subgroups of patients based on risk factors, 4% interpreted the recommendation as to prescribe based on individual clinical decision not described by the previous 2 categories, and 1% indicated that they did not know how to interpret the recommendation. For MenB vaccines, the corresponding response rates were 48%, 41%, 7%, and 5%. The percentage of HCPs who interpreted recommendations as to prescribe MenB vaccination based on individualized clinical decision-making was higher among MenACWY only prescribers (12%) compared with MenB/MenACWY prescribers (6%). This difference was significant according to the multivariate analysis (Table 2), which showed that MenB/MenACWY prescribers were more likely than MenACWY only prescribers to recommend the MenB vaccine to everyone in a particular age group or subgroup, whereas MenACWY only prescribers were more likely than MenB/MenACWY prescribers to recommend the MenB vaccine based on individual clinical decision-making. In addition, 25% of MenACWY only prescribers indicated that they did not know how to interpret ACIP recommendations for the MenB vaccine, compared with only 0.5% of MenB/MenACWY prescribers.

### Factors affecting the decision by healthcare providers to prescribe or not to prescribe the meningococcal vaccines

Healthcare providers most frequently ranked guideline considerations and disease-related factors as the most influential reasons regarding their decision to prescribe the MenACWY and MenB vaccines, respectively. In contrast, when HCPs decided not to prescribe the MenACWY or MenB vaccine, they most frequently ranked patient-related factors and guideline considerations, respectively, as most influential (Figure 3). Compared with the most influential reasons listed above, vaccine-related

**Table 2.** HCP factors associated with likelihood of prescribing MenB vaccine\*.

Parameter		Estimate ± SE	P Value	Odds Ratio
Sex	Female	-0.88 ± 0.32	0.006	0.414
	Male	0		1.000
Type and specialty	Internal medicine	-0.97 ± 0.52	0.062	0.377
	Family practice/family medicine	-1.38 ± 0.47	0.003	0.250
	Nurse practitioner/physician assistant	-1.23 ± 0.38	0.001	0.292
	Pediatrician	0		1.000
Number of adolescent patients aged 16–23 y typically treated in a month		0.004 ± 0.001	0.010	1.004
Number of years in practice		-0.039 ± 0.019	0.036	0.961
Percentage of patients on student health insurance plans vs percentage of patients with no insurance		0.038 ± 0.020	0.064	1.038
Percentage of patients on Medicaid vs percentage of patients with no insurance		-0.024 ± 0.007	0.0005	0.976
Percentage of patients on other plans vs percentage of patients with no insurance		-0.067 ± 0.028	0.014	0.935
Interpretation of ACIP recommendations for MenB vaccine	Everyone	2.284 ± 0.507	< 0.0001	9.821
	Only specific subgroups	0.859 ± 0.469	0.067	2.361
	Don't know	-2.951 ± 0.923	0.001	0.052
	Individualized clinical decision	0		1.000
Percent of patients who understand the difference between MenB vs MenACWY vaccines		0.029 ± 0.007	< 0.0001	1.030

ACIP = Advisory Committee on Immunization Practices; HCP = healthcare provider; MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B; SE = standard error.

\*Based on the adjusted model using reference group = 0.

**Table 3.** Patient characteristics by whether they received the MenB vaccine\*.

Characteristic	Received MenB Only or Both MenB and MenACWY Vaccines <sup>†</sup> (n = 1521)	Received MenACWY Vaccine Only <sup>†</sup> (n = 858)	P Value
Age, mean (SD), y	17.72 (1.54)	17.47 (1.50)	< <b>0.001</b>
Male	828 (54.4)	443 (51.6)	0.188
Race			0.147
White/Caucasian	1022 (67.2)	539 (62.8)	
African American	248 (16.3)	163 (19.0)	
Asian	136 (8.9)	79 (9.2)	
Other	79 (5.2)	59 (6.9)	
Don't know/not available	36 (2.4)	18 (2.1)	
Ethnicity			<b>0.024</b>
Hispanic	187 (12.3)	135 (15.7)	
Non-Hispanic	1252 (82.3)	667 (77.7)	
Don't know/not available	82 (5.4)	56 (6.5)	
High school student	795 (52.3)	537 (62.6)	< <b>0.001</b>
College/graduate student	550 (36.2)	202 (23.5)	< <b>0.001</b>
Living arrangement			< <b>0.001</b>
Parents	979 (64.4)	671 (78.2)	
On-campus dorm	324 (21.3)	90 (10.5)	
Sharing with other students/friends/roommates	107 (7.0)	45 (5.2)	
Alone	43 (2.8)	31 (3.6)	
Other	8 (0.5)	0 (0.0)	
Don't know	60 (3.9)	21 (2.4)	
Insurance coverage			<b>0.008</b>
Private/commercial	1056 (69.4)	589 (68.6)	
Student healthcare plan	111 (7.3)	46 (5.4)	
Medicaid	274 (18.0)	187 (21.8)	
Government/VA hospital	36 (2.4)	11 (1.3)	
No insurance (cash payer)	22 (1.4)	20 (2.3)	
Other	5 (0.3)	0 (0.0)	
Don't know	17 (1.1)	5 (0.6)	
Ever received other vaccines			
MenACWY 1st dose	1144 (75.2)	826 (96.3)	< <b>0.001</b>
MenACWY booster dose	1002 (65.9)	685 (79.8)	< <b>0.001</b>
HPV	1045 (68.7)	540 (62.9)	<b>0.004</b>
Tdap	1252 (82.3)	787 (91.7)	< <b>0.001</b>
Treated by a frequent MenB prescriber	1250 (82.2)	639 (74.5)	< <b>0.001</b>

HCP = healthcare provider; HPV = human papilloma virus; MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B; Tdap = tetanus, diphtheria, and acellular pertussis; VA = Veterans Affairs.

P values < 0.05 are indicated in bold font.

\*According to chart review by HCP.

<sup>†</sup>Values are presented as n (%) unless otherwise noted.

factors, vaccine access, or patient finances/insurance were less impactful. For both vaccines, financial considerations were more likely to be a top consideration in the decision not to prescribe

(ranked highest by 7% for MenACWY and 8% for MenB vaccine) compared with the decision to prescribe (ranked highest by 1% for MenACWY and 2% for MenB vaccine) (Figure 3).

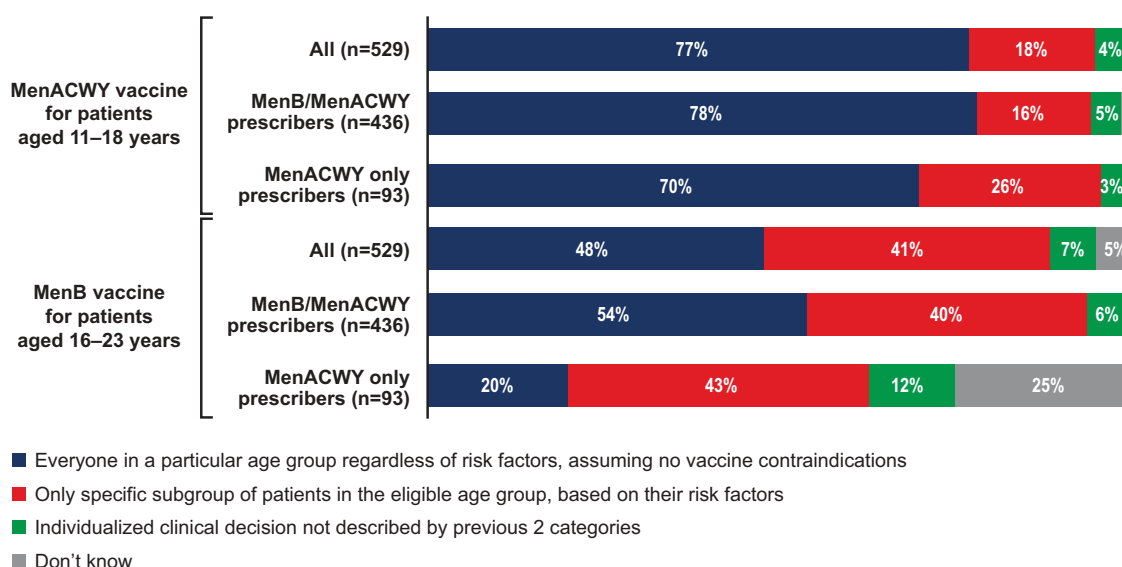


**Table 4.** Patient factors associated with likelihood of receiving MenB vaccine\*.

Parameter		Estimate ± SE	P Value	Odds Ratio
Sex	Female	-0.175 ± 0.089	0.051	0.840
	Male	0		1.000
Race/ethnicity	Non-Hispanic black	-0.281 ± 0.126	0.026	0.755
	Hispanic	-0.366 ± 0.132	0.006	0.694
	Asian	-0.255 ± 0.160	0.112	0.775
	Other/don't know/NA	-0.239 ± 0.175	0.173	0.788
	Non-Hispanic white	0		1.000
Living arrangement	On-campus dormitory/sharing with others	0.739 ± 0.113	< 0.0001	2.094
	Parents/alone/other/don't know	0		1.000
Ever received HPV vaccine	Yes	0.635 ± 0.103	< 0.0001	1.886
	No	0		1.000
Ever received Tdap vaccine	Yes	-1.246 ± 0.156	< 0.0001	0.288
	No	0		1.000
Treated by a frequent MenB prescriber	Almost always/usually	0.460 ± 0.107	< 0.0001	1.584
	Sometimes/upon request/rarely/never	0		1.000

HPV = human papilloma virus; MenB = meningococcal serogroup B; NA = not available; Tdap = tetanus, diphtheria, and acellular pertussis; SE = standard error.

\*Based on the adjusted model using reference group = 0.

**Figure 2.** Healthcare providers' interpretations of ACIP vaccine recommendations.

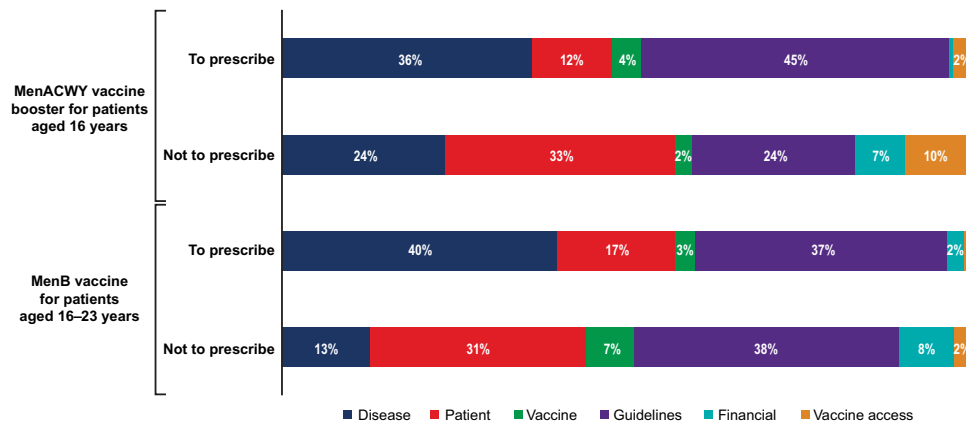
Survey respondents were asked, "ACIP has recommendations for each of the following vaccines. Based on your interpretation, please describe the choice that best describes how you recommend each of the vaccines. Please select one answer for each vaccine." Please note, provider interpretation of the recommendations does not necessarily reflect provider behavior. For example, many of the MenACWY only prescribers responded to the above question that they would prescribe MenB vaccines based on their interpretations; however, these providers also indicated they have not previously prescribed the MenB vaccine to their patients. Percentages were rounded to the nearest integer and may not exactly add up to 100; values ≤1% are shown but percentages are not labeled. ACIP = Advisory Committee on Immunization Practices; MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.

### Practice patterns for the meningococcal serogroup B vaccine

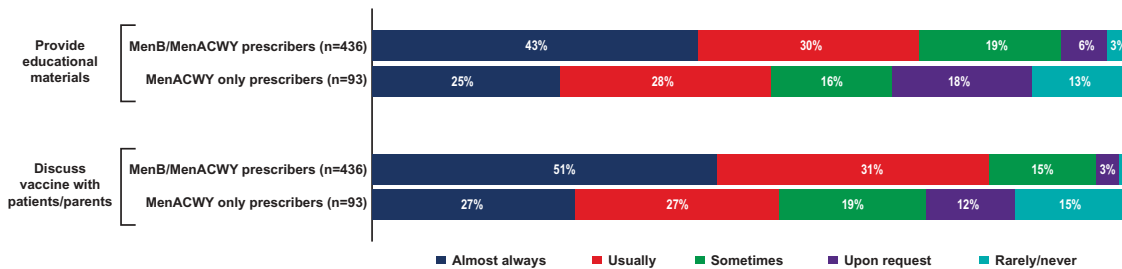
Survey participants were asked about their behavior surrounding discussions with their patients regarding MenB vaccines. Of MenB/MenACWY prescribers, 43% indicated that they almost always provided educational materials and 51% discussed the MenB vaccine with patients or caregivers, in contrast to the respective 25% and 27% of MenACWY only prescribers (Figure 4). MenB/MenACWY prescribers also typically spent more time discussing the MenB vaccine with patients compared with MenACWY only prescribers, with 81% of MenB/MenACWY prescribers and 57% of MenACWY only prescribers indicating that conversations lasted ≥1 minute (Figure 5).

The amount of time spent on discussions about the MenB vaccine was most frequently from 1–<2 minutes, as indicated by 41% of MenB/MenACWY prescribers and 33% of MenACWY only prescribers (Figure 5). During discussions about the MenB vaccine, the specific topics most frequently raised by all participants were meningococcal disease (discussed by 89% of MenB/MenACWY prescribers and 67% of MenACWY only prescribers) and associated risk factors (discussed by 75% of MenB/MenACWY prescribers and 58% of MenACWY only prescribers; Figure 6).

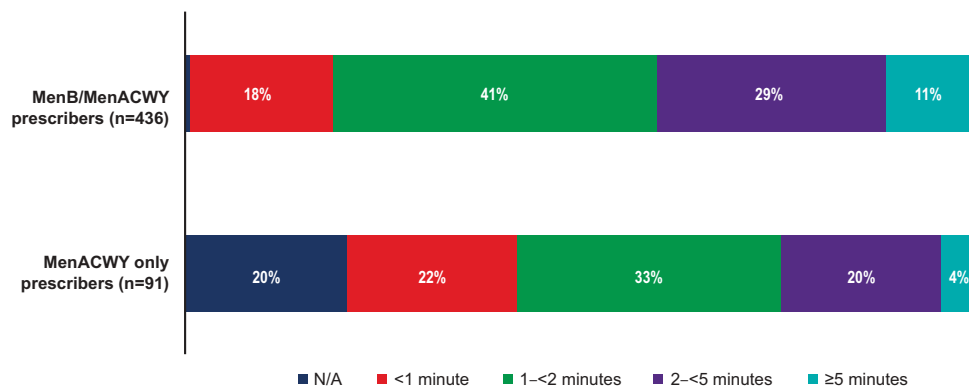
Other topics that were usually discussed were vaccine efficacy, vaccine safety, dosing schedule, ACIP recommendations, and school/college requirements (discussed by 54%–60% of MenB/MenACWY prescribers and 37%–52%



**Figure 3.** Most impactful considerations in healthcare providers' decisions to prescribe or not prescribe MenB and/or MenACWY booster to their adolescent patients. Survey respondents were asked, "As you prescribe/do not prescribe the Meningococcal B/Meningococcal ACWY vaccine to your adolescent patients, how impactful is each of the following parameters in your decision? Please rank each of the listed parameters below in order from the most impactful to the least impactful." Values indicate the percentages of respondents who ranked each factor as the #1 most impactful consideration out of the 6 options. Percentages were rounded to the nearest integer and may not exactly add up to 100; values ≤1% are shown but percentages are not labeled. MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.



**Figure 4.** MenB vaccine prescribing patterns among respondents. Percentages were rounded to the nearest integer and may not exactly add up to 100; values ≤1% are shown but percentages are not labeled. MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.

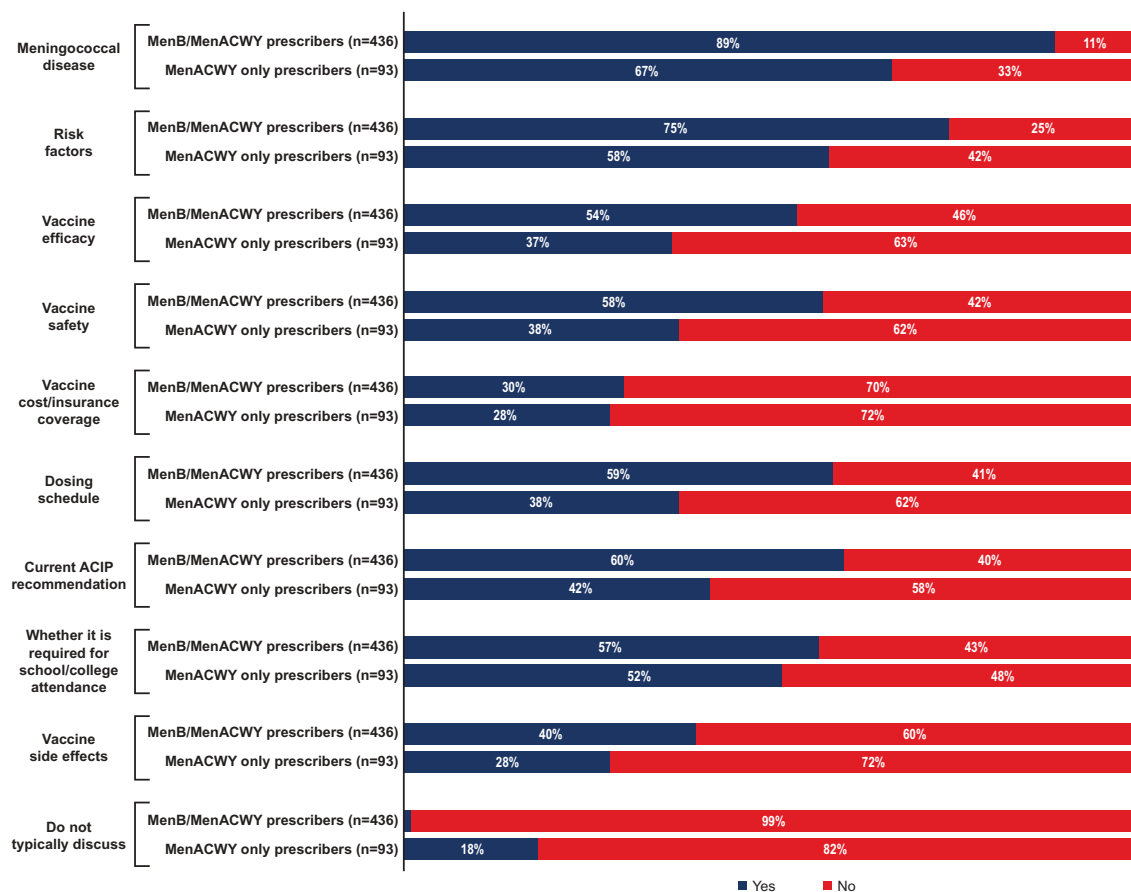


**Figure 5.** Time typically spent on discussing the MenB vaccine with patients or caregivers. Percentages were rounded to the nearest integer and may not exactly add up to 100; values ≤1% are shown but percentages are not labeled. MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.

of MenACWY only prescribers); vaccine costs/insurance and vaccine side effects were discussed less frequently. One percent of MenB/MenACWY prescribers and 18% of MenACWY only prescribers indicated that they do not typically discuss the MenB vaccine with patients or caregivers.

## Discussion

Two meningococcal vaccines, MenB and MenACWY, are needed to fully protect adolescents and young adults against the most common serogroups that cause meningococcal disease in the United States.<sup>3–5,12</sup> Based on recent surveillance



**Figure 6.** Topics discussed with patients or caregivers during MenB vaccine discussions.

Respondents were asked to indicate whether or not they discussed the listed topics. Percentages were rounded to the nearest integer and may not exactly add up to 100; values  $\leq 1\%$  are shown but percentages are not labeled. ACIP = Advisory Committee on Immunization Practices; MenACWY = meningococcal serogroups A, C, W, and Y; MenB = meningococcal serogroup B.

data, MenB is responsible for most cases – notably 69.6% in 2017 – among US adolescents and young adults aged 16–23 years.<sup>3</sup> The 2 vaccines have different ACIP recommendations: MenACWY vaccination is universally recommended for all individuals aged 11–18 years,<sup>11</sup> whereas MenB vaccination for healthy individuals is recommended in the context of shared clinical decision making.<sup>8,16</sup> Our survey of >500 practicing HCPs in the United States revealed challenges in implementing the shared clinical decision-making recommendation with the following 3 key findings: (1) HCPs interpreted the ACIP vaccine recommendations and implemented these recommendations in their clinical practices differently; (2) the characteristics of HCPs who prescribed the MenB vaccine versus those who only prescribed the MenACWY vaccine differed; and (3) the characteristics among the patients reviewed here who received the MenB vaccine versus those who did not varied. These findings may reflect differences in ACIP recommendations for the 2 vaccines<sup>8,11,14</sup> or disparate access to newer vaccines, given that MenB vaccines were licensed and recommended in 2014/2015, whereas MenACWY vaccines were first licensed in 2005.<sup>4,12,24</sup>

Overall, our findings add to the results from previous survey studies regarding MenB vaccine. In the first national survey of HCPs who treat adolescents, Kempe and colleagues<sup>25</sup> found that among those who discussed the

MenB vaccine with patients, 91% prescribed the vaccine. However, among HCPs who “rarely/never” discussed the vaccine with patients, only 11% prescribed the MenB vaccine. Similar to our study, this survey reported differences in HCP’s interpretation of ACIP vaccine recommendations. The authors provided 2 possible interpretations of the category B recommendation: either that the HCP should initiate discussion with patients or caregivers so that they can choose whether to receive the MenB vaccine or that the HCP should decide whether to initiate discussion based on their own understanding of the disease and individual patient risk. The data presented by Kempe and colleagues suggested that the latter interpretation is more common and that HCPs may regard the category B recommendation as “lesser” than the routine or category A recommendation.<sup>25</sup> Moreover, there was confusion among HCPs regarding which meningococcal vaccine (ie, MenACWY or MenB) to administer to 11- to 12-year-olds, as well as a misunderstanding about the category A recommendation for MenB vaccination in children aged  $\geq 10$  years who are at increased risk of IMD.

Our study suggests a lack of understanding of category B recommendations among HCPs. We show that HCPs who did not prescribe the MenB vaccine were less likely than those who prescribed the vaccine to be aware of MenB guidelines, with 25% of MenACWY only prescribers versus only 0.5% of

MenB/MenACWY prescribers responding that they did not know how to prescribe the vaccine based on ACIP recommendations. Moreover, when HCPs were asked to select their strategy for deciding when to prescribe meningococcal vaccines, 77% of respondents correctly interpreted the ACIP category A recommendation for MenACWY vaccine prescription, but only 7% correctly interpreted category B recommendations for MenB.<sup>8</sup> The percentage of respondents who thought MenB vaccination was recommended for everyone in a particular age group was similar to the percentage who thought it should be prescribed to specific subgroups based on risk factors.

In another study, Kempe and colleagues reported that 56% and 38% of pediatricians and family physicians surveyed, respectively, were able to correctly define the category B recommendation.<sup>26</sup> One reason that these percentages were higher than those reported here may be the difference in how the survey questions were worded. The Kempe study asked respondents to define the recommendation, whereas our study asked HCPs to indicate how they decide whether to prescribe the MenB vaccine in their practice based on ACIP recommendations. It is also possible that those who thought ACIP recommended to prescribe MenB vaccination for “only specific subgroups of patients in the eligible age group, based on their risk factors” may have interpreted college attendance as a risk factor related to individual clinical decision-making. Given this possibility, it is notable that the percentage of respondents who selected either the “at risk” or “individual clinical decision making” interpretation was 48%, similar to the values observed by Kempe and colleagues.<sup>26</sup>

Also similar to our survey results, factors associated with lower likelihood of prescribing in the Kempe survey included an inability to define the recommendations and the mistaken belief that ACIP category B recommended vaccines were not covered by insurance.<sup>26</sup> The most influential factors in HCP decisions to prescribe the MenB vaccine included disease incidence and the efficacy and safety of the MenB vaccine. An overall lack of knowledge about MenB disease or awareness of the MenB vaccine may be a primary reason for not initiating discussion. The authors suggested a need for additional guidance from national organizations (eg, American Academy of Pediatrics [AAP] and the American Academy of Family Physicians [AAFP]) on talking points and how to implement a successful discussion of the MenB vaccine.

In our study, the most important factors influencing HCPs in their decision to prescribe the MenB vaccine were disease-related factors and guideline considerations. This result is consistent with data from Kempe and colleagues,<sup>25</sup> indicating that disease outbreaks and disease incidence were the most influential considerations for HCPs. Both the present study and the report from Kempe and colleagues also identified guideline considerations as an important factor in HCP decision not to prescribe the MenB vaccine.<sup>25</sup> Identification of guideline considerations as influencing decisions both to prescribe and not to prescribe the vaccine may indicate confusion or disparate interpretations of ACIP's recommendations among HCPs.

Our results also imply that different providers have different interpretations of what is meant by individual clinical

decision making. Only about half of MenB/MenACWY prescribers and a quarter of MenACWY only prescribers in our study indicated that they “almost always” provide educational materials and/or discuss the MenB vaccine with patients or their caregivers. This inference is also supported by the finding that guideline considerations were an important consideration for decisions both to prescribe and not to prescribe. Some prescribers may decide they should always discuss the vaccine with patients, whereas some may choose whether or not to initiate discussion based on their own clinical assessment of the vaccine risk-benefit profile.<sup>25</sup> Providers might also choose not to discuss the MenB vaccine with their patients if they believe it will not be covered by insurance or that it will take a longer time to explain compared with a category A-recommended vaccine.<sup>26</sup>

Healthcare providers in our study who prescribed the MenB vaccine to their patients were more likely to be pediatricians and to have spent more time in their current practice. They were also more likely to treat a higher number of adolescent and young adult patients each month and to perceive their patients as understanding the difference between the MenACWY and MenB vaccines. These characteristics altogether suggest that MenB prescribing patterns may be associated with a greater understanding of the disease risks and vaccine benefit in this population through more experience practicing on this particular age cohort. This is consistent with previous evidence suggesting that the more years of practice a pediatrician has, the more likely their patients are to receive the MenB vaccine (although this effect declines with >30 years in practice).<sup>27</sup> Our results are also consistent with the survey performed by Kempe and colleagues, in which 73% of pediatricians versus 41% of family physicians surveyed administered the MenB vaccine to their adolescent and young adult patients.<sup>25</sup> In 1 study, investigators showed that MenB recipients (aged 16–18 y) were more likely to also be up-to-date on HPV and measles-containing vaccines, which suggests vaccine receipt may depend on the provider.<sup>28</sup>

Patients included in the chart review who received the MenB vaccine were more likely than those who had not received the vaccine to be non-Hispanic white males. Our study did not assess if these results may have been influenced by potential racial disparities in college enrollment. Although our study was not population-based, the results were consistent with a previous population-based survey of adolescent patients and their caregivers, in which non-Hispanic white patients were more likely to be aware of the MenB vaccine and Hispanic patients were less likely to be aware.<sup>29</sup> Another study reported similar findings for the HPV vaccine series, which is more likely to be completed by non-Hispanic white females compared with African American or Hispanic females (although a pooled analysis found that Hispanic females were more likely than non-Hispanic females to initiate the series).<sup>30</sup> Notably, more consistent HCP recommendations were identified as an important factor leading to reduced racial disparities in HPV vaccine coverage over time, suggesting that HCP recommendation may be able to play a similar role regarding the MenB vaccination. These factors can also depend on the facility in which patients receive care, with evidence suggesting that teenagers who receive care in



community or district health centres are significantly less likely to receive the MenB vaccine.<sup>28</sup>

Compared with patients who did not receive the MenB vaccine, vaccinated patients in our study were more likely to live in a college dormitory or other shared space, which may reflect an understanding by the HCP or the patient or caregiver that college students are at increased risk of MenB disease. An increased incidence of IMD has been identified among college freshmen living in dormitories,<sup>31</sup> and recent data suggest that all college students are at an increased risk of developing IMD compared with nonstudents; this increased risk is entirely driven by MenB disease.<sup>32</sup> MenB has been responsible for all college outbreaks since 2011<sup>19,33</sup> and is 3.5 times more likely to affect college students compared with nonstudents.<sup>18</sup>

Individuals in our study who received the MenB vaccine were also more likely to have received the HPV vaccine but less likely to have received the Tdap vaccine. These associations may be related to more complete vaccination records available for those who received the MenB vaccine, given that the MenB vaccine was associated with more HCP and patient familiarity in a previous survey.<sup>29</sup> It may also be the case that HCPs included in this survey had more complete records available for HPV compared with Tdap vaccination history. Although both vaccines are recommended by the AAP for administration at age 11–12 years, in practice adolescents often receive HPV vaccination much later, similarly to ages at which the MenB vaccine would be prescribed.<sup>34–36</sup>

Adolescent immunization delivery poses unique challenges such as infrequent medical appointments during which many important health topics including vaccination must be covered.<sup>23</sup> The estimated MenACWY vaccine coverage of individuals aged 13 to 17 years in 2018 was 86.6% for  $\geq 1$  dose and 50.8% for  $\geq 2$  doses.<sup>37</sup> In contrast, MenB vaccine uptake is much lower, with only an estimated 17.2% of individuals aged 17 years having received  $\geq 1$  dose of a multi-dose vaccine series in 2018<sup>37</sup> and an estimated <50% complete the series.<sup>38</sup> Patients and parents rely on their physicians to guide decisions about vaccination,<sup>23,30,39</sup> and pediatricians in turn rely on clear guidance and support from the ACIP regarding how vaccines should be prescribed to their patients.<sup>23</sup> Historically, when such guidance has been provided, pediatricians have been demonstrably effective advocates of vaccination and have contributed to achieving high vaccination coverage.<sup>23</sup> Our results, consistent with previous reports,<sup>25,26</sup> indicate that clarity and additional guidance are needed to help HCPs interpret and implement the category B recommendation for MenB vaccines.

One possible limitation of our study is that a total of 3630 HCPs from the Lightspeed/All Global panel responded to 73,350 e-mail invitations, representing a response rate of 4.9%. We did not have access to a membership list from a medical society (eg, AAP, AMA, AAFP) or their administrative support to remind members to complete the survey and help improve the response rate. Therefore, we used a large, vetted physician panel to obtain a number of responses that enabled reliable conclusions to be drawn. This approach has been used by other peer-reviewed studies,

including as an example a published chart review survey of physicians treating patients with plaque psoriasis who were recruited with the same panel used here.<sup>40</sup> We also minimized potential selection bias through the study design by directing HCPs to select the most recent patient charts that met the clearly outlined criteria. Additionally, analytical techniques such as using multiple regression were used to control for potential confounders and differences in baseline characteristics between MenB versus non-MenB groups. The outcomes from this chart review study were similar to outcomes observed in previous studies.<sup>40</sup> Another possible limitation is that HCPs may have based responses about whether or not they prescribed the MenB vaccine on recollection alone, which may have been subject to bias. Additionally, HCPs who did not prescribe any meningococcal vaccines were excluded from the survey; thus, the fraction of HCPs who prescribe MenB vaccines out of all US HCPs (including those who do not prescribe meningococcal vaccines) may be smaller than the fraction in this study. Lastly, inferences about characteristics associated with MenB vaccination could only be made regarding patients included in the study, rather than the adolescent population as a whole. The total number of patients treated by each HCP was unknown because charts were not randomly selected; rather, they were selected by the HCPs to meet specific quotas of patients who had or had not received the MenB vaccine.

## Conclusion

Our study adds to a growing body of evidence demonstrating a need to help HCPs better understand and implement the category B ACIP recommendation for individual clinical decision-making regarding MenB vaccination.<sup>25,26</sup> Providing clear guidance, including regarding how to initiate discussion of MenB vaccines with patients and their caregivers as suggested by the AAP and ACIP,<sup>41</sup> may help ensure that US adolescents are fully protected against meningococcal disease caused by all 5 serogroups.

## Methods

### Participants

A web-based survey was conducted between August and October of 2017 among HCPs, including primary care providers, nurse practitioners, and physician assistants. HCPs were recruited through the full, double opt-in Lightspeed/All Global panel<sup>42</sup> of >55,600 US HCPs with American Medical Association (AMA) membership. Each participant was expected to complete the survey in <50 minutes.

Eligible participants were primary care providers with confirmed certification and  $\geq 3$  years of experience as a pediatrician, family practitioner, or internal medicine specialist, as well as nurse practitioners and physician assistants who worked in 1 of the above specialties. Eligible HCPs also spent  $\geq 50\%$  of their time in direct patient care, treated  $\geq 30$  patients aged 16–23 years each month, recommended MenACWY and/or MenB vaccination to their adolescent or young adult patients (regardless of whether the vaccine was

administered in the office), and consented to study participation.

Healthcare providers who self-identified as prescribers of the MenB vaccine for their eligible patients were asked to review 4–8 charts of recently seen patients, of which up to 4 charts were for patients who had received a MenB vaccination within the previous 6 months and up to 4 charts were for patients who had not received a MenB vaccination within the previous 6 months. Eligible patients identified by chart review were aged 16–23 years during a wellness visit within the previous 6 months (at which time they were not pregnant or breastfeeding), had no severe or life-threatening vaccine allergies, and had received  $\geq 1$  childhood vaccination.

Healthcare providers who completed the survey and reviewed at least 4 patient charts received an honorarium of \$75 plus \$15 per additional patient chart. The study was reviewed and approved by the Pearl Institutional Review Board<sup>43</sup> (IRB Study No.: 17-KANT-153; 29 East McCarty St., Ste. 100, Indianapolis, IN 46225), an independent IRB registered with the Office for Human Research Protections and the US Food and Drug Administration that is fully accredited by the Association for the Accreditation of Human Research Protection Programs. Pearl IRB found that the research met the requirements for a waiver of documentation of consent under 45 CFR 46.101(b)(4).

### Survey and chart review

The survey collected information on HCP characteristics; interpretations of ACIP recommendations for adolescent vaccines including the HPV vaccine, the MenB and MenACWY vaccines, and the Tdap vaccine; vaccination practice patterns; and factors influencing their decision whether or not to prescribe a MenB and/or MenACWY vaccine. Requested HCP characteristics included sex, age, type of HCP, medical specialty, practice setting (office/clinic, hospital, university/medical school, government/VA, or other), practice location, years in practice, number of patients aged 16–23 years typically treated per month, types of healthcare coverage plans accepted, and time spent in direct patient care.

Healthcare providers were asked to interpret ACIP recommendations for MenB and MenACWY vaccines by selecting 1 of the following 4 choices regarding how the vaccine should be prescribed: (1) to everyone in a particular age group, regardless of risk factors, assuming no vaccine contraindications, (2) only to specific subgroups of patients in the eligible age group, based on their risk factors, (3) based on individualized clinical decision not described by the previous 2 categories, or (4) do not know. HCPs were also asked for their frequency of providing educational materials for, discussing, and recommending MenB and/or MenACWY vaccines, with answers ranging from “almost always” to “rarely/never.” Time spent discussing the vaccine with patients was requested, as well as the specific topics discussed (ie, meningococcal disease, risk factors, vaccine efficacy, vaccine safety, vaccine side effects, vaccine cost/insurance coverage, dosing schedule, ACIP recommendations, and school/college vaccination requirements).

Healthcare providers were asked to rank the following factors from the most impactful to the least impactful on

their decision to prescribe or not to prescribe each vaccine (MenB and MenACWY): disease-related factors (eg, level of risk to the community or patient, past experience), patient-related factors (eg, age eligibility, request or lack thereof by the patient or the patient’s school, living arrangements, travel plans), vaccine-related factors (eg, efficacy, side effects), guideline considerations (from ACIP or AAP), financial considerations (cost of vaccine or vaccination), or vaccine access considerations (availability at the practice or at local pharmacies).

For chart reviews, patient demographics (eg, age, sex, race/ethnicity), employment status, living arrangement, insurance coverage, and vaccination history were requested. If the patient received the MenB vaccine, HCPs were asked if they discussed the vaccine with the patient or received a request from the patient, and also to indicate the specific reasons that the patient received the vaccine (eg, increased risk, travel plans, school/college requirements).

### Analysis

On the basis of a survey question that asked HCPs whether they prescribed or recommended the MenB and/or MenACWY vaccine to their eligible adolescent or young adult patients (regardless of whether the vaccine was administered in the office or elsewhere), HCPs were divided into the following 2 groups: MenB/MenACWY prescribers (HCPs who recommended either the MenB vaccine only or who recommended both MenB and MenACWY vaccines) or MenACWY only prescribers (HCPs who recommended the MenACWY vaccine only). Bivariate analyses of HCP characteristics associated with being a MenB/MenACWY prescriber versus a MenACWY only prescriber were conducted to identify factors that differed significantly between the 2 groups. On the basis of which vaccines they had received within the past 6 months, patients included in chart reviews were separated into the following 3 groups: those who had received the MenB vaccine (whether or not they had also received the MenACWY vaccine), those who had received the MenACWY vaccine only, and those who had not received a meningococcal vaccine. Bivariate analyses were conducted to compare patient characteristics between those who had received the MenB vaccine and those who had received the MenACWY vaccine only.

Variables identified to be significant ( $P < .05$ ) in the bivariate analyses and other variables of theoretical importance were entered into multivariable logistic regression models. These models were designed to evaluate significance and relative associations among potential predictors of vaccination while simultaneously controlling for other potential predictors. Backward elimination was used to select variables significantly associated with each outcome; the threshold for inclusion in the models was an alpha level of 0.10. Because prescribers and nonprescribers of each vaccine responded to different sets of questions, the most impactful factors on the decision to prescribe or not to prescribe MenB or MenACWY vaccines were only analyzed descriptively.

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AS and LH are employees of Pfizer and may hold stock or stock options. AD serves on advisory boards for Merck, Pfizer, and Sanofi Pasteur and as a consultant to Pfizer related to MenB vaccination. AG, LL, and VL were employees of Kantar Health at the time the study was conducted, which was a paid contractor by Pfizer, and conducted the survey.

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