RESEARCH ARTICLE

Taylor & Francis

OPEN ACCESS Check for updates

Meningococcal serogroup B vaccination series initiation in the United States: A real-world claims data analysis

Elizabeth R. Packnett ^[], Nicole M. Zimmerman ^[], Patricia Novy ^[], Laura C. Morgan ^[], Nnenna Chime ^[], and Parinaz Ghaswalla ^[]

^aMerative (formerly IBM Watson Health), Cambridge, MA, USA; ^bGSK, Philadelphia, PA, USA; ^cGSK, Rockville, MD, USA

ABSTRACT

In the United States (US), meningococcal serogroup B (MenB) vaccination has been recommended for 16-23-year-olds (preferably 16-18 years) based on shared clinical decision-making since 2015. MenB vaccine coverage (≥1 dose) by age 17 years has been reported, but initiation at older ages and by insurance type is unknown. In this retrospective cohort study, MarketScan claims data were analyzed to assess MenB vaccine series initiation (i.e. receipt of a first dose) during 2017–2020 among US commercially insured and Medicaid-covered individuals aged 16–18 and 19–23 years. Kaplan-Meier curves were generated to estimate series initiation at various times from index (latest of 1/1/2017 or 16th/19th birthday, depending on the cohort). Multivariable analyses were conducted to identify factors associated with series initiation. Among 1,450,354 Commercial and 1,140,977 Medicaid 16-18-year-olds, MenB vaccine series initiation rates within 3 years of each person's first eligibility were estimated to be 33% and 20%, respectively; among 1,857,628 Commercial and 747,483 Medicaid 19-23-year-olds, 3% and 1%, respectively. Factors identified to be significantly associated with increased likelihood of initiating a MenB vaccine series included co-administration of meningococcal serogroups ACWY (MenACWY) vaccine, younger age, female sex, nonwhite race (Medicaid only), New England or Middle Atlantic location (Commercial only), urban residence, and previous influenza vaccination. MenB vaccine series initiation among the studied US adolescents and young adults was low. There is a need for continued efforts to better understand barriers to the uptake of vaccines that are recommended based on shared clinical decision-making.

Introduction

Invasive meningococcal disease (IMD) can result in meningitis and/or septic shock,¹ which can be fatal.² Although IMD has declined in the United States (US) since the 1990s,³ during 2019, there were 375 cases of IMD (0.11 per 100,000 population), of which meningococcal serogroup B (MenB) was the most common cause (26.4%).⁴ Among 16–23-year-olds, almost half (21/43) of the reported cases of meningococcal disease were caused by MenB.⁴

In the US, MenB vaccination has been recommended for healthy 16–23-year-olds (preferably 16–18 years) since 2015 based on shared clinical decision-making.^{5–7} This involves a joint decision between the health care provider and the patient/parent about whether MenB vaccination is beneficial.⁷ This decision should be based on the seriousness of IMD, the increased risk among college students, and the high efficacy of MenB vaccines, balanced against the low overall risk of infection and the relatively short duration of protection.⁷ In contrast to the shared clinical decision-making recommendation for MenB vaccination, meningococcal serogroups A, C, W, Y (MenACWY) vaccination is routinely recommended for all adolescents at ages 11–12 and 16 years.⁷

Based on data from the National Immunization Survey– Teen (NIS-Teen), the estimated MenB vaccine coverage (≥ 1 dose) among 17-year-olds increased from 14.5% in 2017 to 17.2% in 2018, 21.8% in 2019, 28.4% in 2020 (before the coronavirus disease 2019 [COVID-19] pandemic), and 31.4% in 2021.⁸⁻¹² However, coverage at ages other than 17 years has not been reported, nor has coverage by insurance type. We therefore conducted a real-world claims data analysis to estimate MenB vaccine series initiation rates among US individuals aged 16–18 and 19–23 years during 2017 to early 2020; describe MenB vaccination characteristics among initiators; and identify factors associated with MenB vaccine series initiation. Figure 1 provides an overview of the context, novelty, and impact of the study in a form that could be shared with patients.

CONTACT Parinaz Ghaswalla parinaz.ghaswalla@gmail.com Pealth Economics and Outcomes Research, Moderna, 200 Technology Square, Cambridge, MA 02139, USA.

*GSK, Philadelphia, PA, USA. [‡]Dynavax, Emeryville, CA, USA.

[§]IQVIA, Durham, NC, USA.

¹Moderna, Cambridge, MA, USA.

© 2023 GlaxoSmithKline Biologicals S.A. Published with license by Taylor & Francis Group, LLC.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License (http://creativecommons.org/licenses/by-nc-nd/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited, and is not altered, transformed, or built upon in any way.

ARTICLE HISTORY

Received 12 October 2022 Revised 16 December 2022 Accepted 31 December 2022

KEYWORDS

Meningococcal serogroup B; vaccination; MenB-4C; MenB-FHbp; adolescents

B Supplemental data for this article can be accessed on the publisher's website at https://doi.org/10.1080/21645515.2023.2165382



MENB VACCINE INITIATION AMONG ADOLESCENTS AND YOUNG ADULTS IN THE US WAS LOW

UNDERSTANDING FACTORS PREVENTING RECEIPT OF MENB VACCINATION COULD BE BENEFICIAL TO OPTIMIZE/FACILITATE VACCINE INITIATION AMONG ADOLESCENTS AND YOUNG ADULTS

DOI: 10.1080/21645515.2023.2165382

*During the 3 years following eligibility for MenB vaccination. *Coverage among Medicaid individuals may have been underestimated.

Figure 1. Plain Language Summary.

Methods

Study design

In this retrospective cohort study (GSK study identifier: VxHO-000048), claims data were analyzed to assess MenB vaccine series initiation (i.e. receipt of a first dose) among individuals aged 16–18 and 19–23 years during January 2017 through February 2020 (Commercial) or December 2019 (Medicaid). MenB vaccine series completion rates among initiators have been reported separately.¹³

Data source

De-identified health plan enrollment data and claims from the *MarketScan* Commercial Claims and Encounters, including Early View data and the *MarketScan* Multi-State Medicaid databases, were analyzed. The Commercial database contains demographic characteristics and health care experiences of several million employees and their dependents covered under various fee-for-service and capitated health plans. It covers all US Census regions and includes an indicator for region of residence. The Medicaid database reflects the health care service use of Medicaid enrollees in programs in geographically dispersed states. It contains demographic characteristics and pooled health care experience of Medicaid enrollees covered under fee-for-service and managed care plans.

All study data were obtained using the International Classification of Diseases, 9th and 10th Revisions, Clinical Modification codes, Current Procedural Terminology codes, Healthcare Common Procedure Coding System codes, and National Drug Codes. All study data were accessed with protocols compliant with US patient confidentiality requirements, including the 1996 Health Insurance Portability and Accountability Act (HIPAA) regulations. As all databases used in the study are fully de-identified and compliant with the HIPPA; this study is not human subjects research and was not submitted for Institutional Review Board approval.

Study population and dates

MenB vaccine series initiation was evaluated in two nonmutually exclusive groups of individuals aged 16-18 (preferred vaccination age)^{5,7} and 19-23 years in each insurance cohort (Commercial or Medicaid). The 19-23-year-old cohort could include individuals from the 16-18-year-old cohort who did not receive MenB vaccination before their 19th birthday. The index date was the latter of January 1, 2017 and the individual's 16th or 19th birthday (depending on the cohort) (Supplementary Figure S1). Individuals had to have ≥ 6 months of continuous enrollment before and after the index date, no history of MenB vaccination between October 1, 2014 and the index date, and no high-risk conditions (asplenia, persistent complement component deficiency, sickle cell disease, or eculizumab use) during 6-month baseline or follow-up. Patients with high-risk conditions were excluded as they are routinely recommended to receive MenB vaccination, rather than this being based on shared clinical decision-making.5-7 Commercial individuals

had to be the child of the employee to avoid double counting those who transitioned from their parent's insurance to their own and to help avoid including individuals who had previously received MenB vaccination in the 19–23-year-old cohort.

The patient identification period ended on August 31, 2019 (Commercial) or June 30, 2019 (Medicaid) to allow for \geq 6-month follow-up (Supplementary Figure S1). Individuals were followed until the earliest of the end of continuous enrollment, their 19th or 24th birthday (depending on the cohort), or the end of the study period (February 29, 2020 [Commercial] or December 31, 2019 [Medicaid]).

Outcomes

Outcomes are reported separately for four cohorts: Commercial 16–18-year-olds, Commercial 19–23-year-olds, Medicaid 16–18-year-olds, and Medicaid 19–23-year-olds. The main outcomes are the proportions who initiated a MenB vaccine series following the index date and the times to series initiation. Series initiation rates are described overall and by age, sex, residence density, race (only available for the Medicaid cohorts), and geographic region (only available for the Commercial cohorts). Other outcomes include baseline characteristics according to whether MenB vaccination was received; factors associated with MenB vaccine series initiation; and MenB vaccination characteristics.

Vaccinations

Receipt of either of the two licensed vaccines (MenB 4-component [MenB-4C] or MenB factor H binding protein [MenB-FHbp]) was identified using Current Procedural Terminology codes (MenB-4C: 90620; MenB-FHbp: 90621) and National Drug Codes (MenB-4C: 46028011401, 46028011402, 46028011411, 58160097602, 58160097606, 58160097620; MenB-FHbp: 00005010010, 00005010005, 00005010001, 00005010002). Of note, vaccines administered under the Vaccines For Children (VFC) program do not generate a vaccine-specific claim, so these could not be included. This would have mainly affected the Medicaid population.

Statistical analysis

Continuous data are presented as means and standard deviations (SDs) or medians and interquartile ranges (IQRs); categorical data are presented as numbers and percentages. The proportions of individuals who initiated a MenB vaccine series are those who received ≥ 1 MenB vaccine dose during variable follow-up divided by the study population. The differences between cohorts were not tested statistically.

Kaplan–Meier curves were generated to describe the time from the index date to MenB vaccine series initiation. Five Kaplan–Meier curves were generated in each of the Commercial and Medicaid cohorts for ages 16, 17, 18, 16–18, and 19–23 years. Individuals were censored when they were lost to follow-up (end of continuous enrollment, 19th or 24th birthday [depending on the cohort], or end of the study period). MenB vaccine series initiation rates were estimated at 3-month intervals up to 3 years. The proportions of individuals of each age (on the index date) and with receipt of other vaccinations (during 6-month baseline; or on the index date/during follow-up) were compared between those who initiated a MenB vaccine series and those who did not within each cohort using chi-squared tests. p < .001 was taken to be statistically significant.

Multivariable Cox proportional hazard regression models were fit to identify factors independently associated with likelihood of MenB vaccine series initiation in each cohort. When MenACWY vaccination at any time during the study period was included, the models became distorted as a high proportion of co-administered MenACWY vaccine dominated. Therefore, the final models were adjusted for age, sex, race (Medicaid only), region (Commercial only), urban vs. rural, index month, presence of human immunodeficiency virus infection, health care expenditures, number of preventive care and vaccine administration office visits, and receipt of MenACWY, influenza, or other vaccinations only during 6-month baseline. Adjusted hazard ratios and 95% confidence intervals were calculated.

Results

Populations

The eligible populations, studied during January 2017 through February 2020 (Commercial) or December 2019 (Medicaid), were as follows: Commercial 16–18-year-olds (n = 1,450,354), Commercial 19–23-year-olds (n = 1,857,628), Medicaid 16–18-year-olds (n = 1,140,977), and Medicaid 19–23-year-olds (n = 747,483) (Supplementary Table S1).

MenB vaccine initiation rates

In the Commercial cohorts, 16.6% of 16–18-year-olds and 2.3% of 19–23-year-olds initiated a MenB vaccine series (Figure 2a,b) during mean (SD) follow-up durations of 22.7 (8.7) and 26.0 (10.3) months, respectively. In the Medicaid cohorts, 11.6% of 16–18-year-olds and 0.5% of 19–23-year-olds initiated a MenB vaccine series (Figure 2c,d) during 22.0 (8.4) and 23.1 (9.8) months of follow-up. Among MenB vaccine series initiators, the median (IQR) times to initiation in the Commercial 16–18- and 19–23-year-old cohorts were 9.6 (4.9–17.8) and 7.8 (3.8–15.6) months, respectively. In the Medicaid cohorts, they were 8.0 (3.6–15.0) and 7.8 (3.7–14.7) months, respectively.

Using Kaplan–Meier analyses to account for variable follow-up, MenB vaccine series initiation during the 3 years following each person's first eligibility was estimated to reach 33% and 3% in the 16–18- and 19–23-year-old Commercial cohorts, respectively (Figure 3a); and 20% and 1%, respectively, in the Medicaid cohorts (Figure 3b).

Factors associated with MenB vaccine series initiation rates

In each cohort, MenB vaccine series initiation rates increased with decreasing age and were higher among females vs. males and in urban vs. rural locations (Figure 2). In the Medicaid cohorts, MenB vaccine series initiation rates were higher among nonwhite vs. White individuals (Figure 2c,d). In the Commercial cohorts, MenB vaccine series initiation rates were highest in the Middle Atlantic and New England regions (Supplementary Figure S2).

Individuals who initiated a MenB vaccine series were significantly younger than those who did not (Supplementary Table S2). They were generally significantly more likely (by 1.1–2.9-fold) to have received MenACWY, influenza, or other vaccines during baseline, apart from MenACWY in the Medicaid 16–18-year-old cohort. They were 2.5–35.9 times more likely to have received these other vaccines on the index date or during follow-up.

Initial multivariable models were built including the administration of MenACWY vaccine at any time during the study period as a covariate. However, this highly influential factor caused the models to become distorted due to the high correlation between MenB vaccine series initiation and MenACWY vaccine co-administration. Anv-time MenACWY vaccination therefore had to be removed from the final models to avoid distortion. In these models, factors that increased the likelihood of initiating a MenB vaccine series included younger age, female, nonwhite race (Medicaid only), New England (Commercial only) or Middle Atlantic (Commercial 16-18-year-old only) location, urban residence, and baseline influenza or non-MenACWY /non-influenza vaccinations, but not baseline MenACWY vaccination (Table 1).

MenB vaccination characteristics

Most MenB vaccine doses were MenB-4C (63.4-85.5% across the four cohorts) (Table 2). Most first MenB vaccinations were administered during June - August (32.9-48.9%), mainly in an office (75.7-97.8%) and at a preventive care/well-child visit (59.7-79.8%). In the Commercial 16-18- and 19-23-year-old cohorts, most vaccines were given by a pediatrician (72.2% and 51.2%, respectively), while in the Medicaid 16-18- and 19-23year-old cohorts, key providers were pediatricians (38.3% and 17.5%, respectively), "other" (29.6% and 21.1%), and unknown (26.0% and 51.3%). In the Commercial and Medicaid 16-18-year-old cohorts, MenB vaccine was most commonly co-administered with MenACWY vaccine (53.4% and 65.5%, respectively), while in the Commercial and Medicaid 19-23-year-old cohorts, it was most often given with other (non-MenACWY/non-influenza) vaccines (32.6% and 34.8%, respectively).

Discussion

This large retrospective cohort study used data from January 2017 through February 2020 (Commercial) or December 2019 (Medicaid). Using Kaplan–Meier analysis to account for variable follow-up, MenB vaccine series initiation by 3 years was estimated to reach 33% and 20% in the 16–18-year-old Commercial and Medicaid populations, respectively, and 3% and 1% in the 19–23-year-old Commercial and Medicaid populations, respectively. This aligns with the



a. Commercial 16–18 years

b. Commercial 19–23 years

Figure 2. MenB vaccine series initiation, overall and by age, sex, residence density, and race (only available in the Medicaid cohort) in the (a) commercial 16–18 years, (b) commercial 19–23 years, (c) Medicaid 16–18 years, and (d) Medicaid 19–23 years. MenB, meningococcal serogroup B.

preferred age for MenB vaccination being 16–18 years,^{5,7} and is not surprising given that many MenB vaccinations were given at preventive care/well-child visits by pediatricians, and 19–23-year-olds are less likely to attend such visits or see pediatricians.

According to NIS-Teen survey data from 2017 to 2020, 14.5-28.4% of 17-year-olds received ≥ 1 dose of MenB

vaccine.^{8–11} This aligns with our Kaplan–Meier analysis results among individuals aged 16 years at index, which indicate MenB vaccine initiation rates of 12–25% (Commercial) or 10–18% (Medicaid) after 1–2 years, i.e. when they would be age 17 years (just 17 to almost 18). Although the many differences in study designs make it hard to directly compare these results, this concordance is reassuring.



Figure 3. Time to MenB vaccine series initiation since the date of each person's first eligibility for the (a) commercial and (b) Medicaid populations^a. ^aIndividuals were censored after the earliest of the end of continuous enrollment, 19th (16–18-year-old age group) or 24th birthday (19–23-year-old age group), or end of study period. MenB, meningococcal serogroup B.

Most MenB vaccine doses were given during the summer, potentially before starting or going back to school or college, even though MenB vaccination is not preferentially recommended for college students.⁵ It is also possible that state mandates for vaccination before college/university entry could have impacted MenB vaccination even though these do not include MenB vaccine,¹⁴ as mandates for MenACWY vaccine have been found to increase MenB vaccine coverage.¹⁵ In addition, high rates of MenB vaccine series initiation and co-administered MenACWY vaccine was observed: 53.4% (Commercial) and 65.5% (Medicaid) in the 16-18-year-old cohorts. The high rates of co-administration of MenB and MenACWY vaccines in the 16-18-year-old cohorts indicate that the second MenACWY vaccine dose may provide a vaccination platform to increase MenB vaccination series initiation.

The association between MenB vaccination series initiation and co-administered MenACWY vaccine was so strong that it precluded the inclusion of any-time MenACWY vaccination as a covariate in the final multivariable models due to model convergence. In contrast, baseline MenACWY vaccination (i.e. during the 6 months before MenB vaccination) was significantly associated with reduced MenB vaccine series initiation in 2/4 cohorts, possibly because individuals who received a second dose of MenACWY vaccine (recommended at age 16 years)¹⁶ during baseline had already been offered and refused a MenB vaccination or the topic of meningococcal vaccination did not come up again, as they already received MenACWY vaccine. However, it should be noted that only 1.7-7.1% of individuals who received MenB vaccination had MenACWY vaccination during the previous 6 months, with 11.2-65.5% having co-administered MenACWY and MenB vaccines, and some individuals likely having MenACWY vaccine earlier than 6 months before MenB vaccination.

In multivariable analysis, baseline influenza or non-MenACWY/non-influenza vaccines were associated with significantly increased MenB vaccine series initiation, likely indicative of higher health-seeking behavior. This aligns with results from a multivariable analysis of 2017–2018 NIS-Teen data, which found that complete human papillomavirus (HPV) vaccination was significantly associated with an increased likelihood of MenB vaccination (\geq 1 vs. 0 dose) in 17year-olds.¹⁷

Other factors that were associated with increased likelihood of MenB vaccination series initiation in multivariable analysis included younger age, female, New England or Middle Atlantic (Commercial only), and urban location. These factors have also been associated with increased MenB vaccine series completion.^{13,18} However, while nonwhite race was associated with increased MenB vaccine series initiation in the Medicaid population (race information was not available for the Commercial population), previous studies have reported lower MenB vaccine completion among Black vs. White Medicaid individuals, but higher or similar MenB vaccine completion among Hispanic, Other, or Unknown vs. White Medicaid individuals.^{13,18} These findings would require further research to understand the potential interplay between race and series initiation vs. completion, and the potential impact of race in a commercial population.

We found higher MenB vaccination rates among Commercial vs. Medicaid individuals, although no statistical comparisons were made due to multiple confounders, particularly the inability to count vaccines administered through the VFC program. This is seemingly at odds with results from an NIS-Teen study, which found that private health insurance was significantly associated with a decreased likelihood of MenB vaccination.¹⁷ However, as discussed in the limitations, we may have underestimated vaccine uptake in the Medicaid cohorts.

Table 1. Cox regression models for probability of MenB vaccine series initiation^a.

	Commercial, HR (95% Cl)		Medicaid, HR (95% CI)	
	16–18 years	19–23 years	16–18 years	19–23 years
Age at index date (ref. 16 years)				
17 years	0.96* (0.95-0.98)	NA	0.57* (0.56–0.59)	NA
18 years	0.69* (0.68-0.71)	NA	0.31* (0.30-0.33)	NA
Age at index date (ref. 19 years)				
20 years	NA	0.56* (0.54–0.58)	NA	0.63* (0.56–0.70)
21 years	NA	0.28* (0.27-0.29)	NA	0.51* (0.44-0.58)
22 years	NA	0.13* (0.12-0.14)	NA	0.41* (0.35-0.48)
23 years	NA	0.06* (0.05-0.07)	NA	0.26* (0.20-0.35)
Female (ref. male)	1.11* (1.10–1.11)	1.20* (1.18–1.22)	1.12* (1.11–1.14)	1.07* (1.00-1.14)
Race (ref. White)				
Black	NA	NA	1.15* (1.14–1.17)	1.30* (1.21–1.40)
Hispanic	NA	NA	1.26* (1.23–1.28)	1.69* (1.50-1.90)
Other	NA	NA	1.53* (1.49–1.56)	1.50* (1.25–1.81)
Unknown	NA	NA	1.17* (1.14–1.20)	1.93* (1.74–2.13)
Region (ref. New England)				
Middle Atlantic	1.32* (1.30–1.35)	0.70* (0.68-0.73)	NA	NA
East North Central	0.95* (0.93-0.97)	0.49* (0.47-0.50)	NA	NA
West North Central	0.83* (0.81-0.85)	0.34* (0.32-0.36)	NA	NA
South Atlantic	0.92* (0.90-0.94)	0.34* (0.33-0.35)	NA	NA
East South Central	0.65* (0.64–0.67)	0.21* (0.20-0.22)	NA	NA
West South Central	0.65* (0.64–0.67)	0.16* (0.15–0.17)	NA	NA
Mountain	0.61* (0.59–0.62)	0.21* (0.20-0.22)	NA	NA
Pacific	0.67* (0.65–0.69)	0.41* (0.39–0.43)	NA	NA
Other	0.87* (0.82-0.92)	0.50* (0.44–0.57)	NA	NA
Rural (ref. urban/unknown)	0.65* (0.64–0.66)	0.57* (0.55–0.60)	0.74* (0.73–0.75)	0.47* (0.43–0.52)
Baseline ^b vaccination (ref. not)				
MenACWY	1.01 (0.99–1.02)	0.89* (0.83-0.95)	0.85* (0.83-0.88)	0.99 (0.77-1.28)
Influenza	1.67* (1.65–1.69)	1.94* (1.88–2.00)	1.82* (1.79–1.85)	2.86* (2.57-3.19)
Other ^c	1.09* (1.07–1.10)	1.23* (1.18–1.29)	1.04* (1.02–1.07)	1.35* (1.17–1.55)
Baseline ^b HIV infection (ref. not)	0.69 (0.52–0.91)	0.73 (0.49–1.08)	0.75 (0.53–1.06)	0.66 (0.25–1.75)

**p* < .001.

^aModel controlled for all covariates listed above plus index month and baseline health care expenditures, number of preventive care office visits, and number of vaccine administration office visits. Please note that MenACWY at any time during the study period was not included in the final model as earlier models became distorted due to the high proportion of MenACWY vaccine co-administrations on the date of MenB vaccination, which affected the other covariates.

^b6 months before index (excluding the index date).

^CIncluding adenovirus, anthrax, Bacillus Calmette–Guérin, cholera, hepatitis A, hepatitis B, HPV, pneumococcus, rabies, rotavirus, typhoid, DTP, measlesmumps-rubella, polio, varicella, yellow fever, plague, Japanese encephalitis, *Haemophilus influenzae* B, DTP/*Haemophilus influenzae* B, DTP/polio, MenCY/*Haemophilus influenzae* B vaccinations.

CI, confidence interval; DTP, diphtheria-tetanus-pertussis; HIV, human immunodeficiency virus; HPV, human papillomavirus; HR, hazard ratio; MenACWY, meningococcal serogroups A, C, W, Y; MenB, meningococcal serogroup B; MenCY, meningococcal serogroups C, Y; NA, not applicable (age) or not available (race for Commercial or region for Medicaid); ref., referent group.

To summarize, reduced MenB vaccine series initiation was associated with male sex, White race (only available for Medicaid), various geographic regions (only available for Commercial), and rural location, hence strategies to boost uptake could be focused to target these. For example, social media posts to inform teenagers about the consequences of IMD, or the provision of information about the benefits and safety of MenB vaccines in states with low uptake and higher rural concentration.

Lastly, we note that the low MenB vaccine series initiation rates are exacerbated by poor series completion rates, with only around half of the individuals who initiate a MenB vaccine series completing the series.^{13,18,19} Hence, the overall proportion of individuals who receive a full MenB vaccine series is very low. One of the factors that has been significantly associated with improved completion is receipt of MenB-4C vs. MenB-FHbp vaccines,^{13,18} likely due to their different dosing schedules. MenB-4C vaccine is recommended to be given as a two-dose series at 0 and \geq 1 month, whereas MenB-FHbp vaccine should be given at 0 and 6 months, but if the second dose is given early, a third dose should be given ≥ 4 months after the second dose.^{6,7}

Our study was conducted before the COVID-19 pandemic was recognized in the US, so the factors associated with MenB vaccine uptake during and after the pandemic may be different. Vaccine coverage was impacted by the pandemic - as reported for some vaccines in some age groups, although the impact on MenB has not yet been reported.¹² It is therefore important to review patient vaccination records - including during appointments for COVID-19 vaccination - to ensure that children and adolescents are up to date with other recommended vaccinations.¹² Estimating missed opportunities for MenB vaccine series initiation was not included in this study, but missed opportunities for MenB vaccine series completion have been reported elsewhere.¹³ Future research looking at patterns of primary care visits for older adolescents (e.g. well, preventative, or vaccination-only appointments at age 16–18 years), before, during and after the COVID-19 pandemic, could provide further insights into missed opportunities to educate and provide preventative care against MenB disease.

Table 2. MenB vaccination characteristics among those who received MenB vaccination.

	Commercial		Medicaid				
	Age 16–18 years	Age 19–23 years	Age 16–18 years	Age 19–23 years			
	n = 240,602	n = 42,141	n = 132,381	n = 3,804			
MenB vaccine type (all doses) ^a n (%	b)						
MenB-4C	152,646 (63.4)	27,197 (64.5)	104,725 (79.1)	3,252 (85.5)			
MenB-FHbp	89,700 (37.3)	15,301 (36.3)	28,590 (21.6)	560 (14.7)			
Age at first MenB vaccination, n (%))						
16 years	89,869 (37.4)	NA	65,816 (49.7)	NA			
17 years	83,946 (34.9)	NA	46,194 (34.9)	NA			
18 years	66,787 (27.8)	NA	20,371 (15.4)	NA			
19 years	NA	19,677 (46.7)	NA	1,849 (48.6)			
20 years	NA	11,376 (27.0)	NA	900 (23.7)			
21 years	NA	6,234 (14.8)	NA	452 (11.9)			
22 years	NA	3,227 (7.7)	NA	324 (8.5)			
25 years	INA	1,027 (3.9)	NA	279 (7.5)			
Month of first MenB vaccination, n	(%)	4 24 6 (4 0 0)	7 726 (5 0)				
January	13,/95 (5./)	4,216 (10.0)	7,726 (5.8)	286 (7.5)			
February	13,132 (3.3)	1,424 (3.4)	7,791 (5.9)	250 (0.0)			
March	11,000 (4.0)	2,230 (3.4)	7,995 (0.0) 8,557 (6.5)	238 (0.8)			
May	17,624 (4.9)	3 615 (8 6)	9,625 (7,3)	342 (9.0)			
lune	32 711 (13 6)	4 576 (10 9)	12 314 (9 3)	359 (9.4)			
VILL	41.258 (17.1)	6.066 (14.4)	16,159 (12,2)	417 (11.0)			
August	43,722 (18.2)	8,689 (20.6)	20,833 (15.7)	474 (12.5)			
September	15,370 (6.4)	2,074 (4.9)	12,467 (9.4)	307 (8.1)			
October	15,449 (6.4)	2,154 (5.1)	12,897 (9.7)	348 (9.1)			
November	13,537 (5.6)	2,617 (6.2)	9,227 (7.0)	302 (7.9)			
December	11,008 (4.6)	2,920 (6.9)	6,790 (5.1)	212 (5.6)			
Year of first MenB vaccination, n (%	b)						
2017	69,417 (28.9)	14,601 (34.6)	38,884 (29.4)	1,253 (32.9)			
2018	76,725 (31.9)	13,620 (32.3)	43,790 (33.1)	1,227 (32.3)			
2019	87,811 (36.5)	13,029 (30.9)	49,707 (37.5)	1,324 (34.8)			
2020	6,649 (2.8)	891 (2.1)	NA	NA			
Vaccination setting of first MenB vaccination, n (%)							
Office	235,364 (97.8)	39,588 (93.9)	100,184 (75.7)	3,102 (81.5)			
Pharmacy	1,576 (0.7)	1,616 (3.8)	187 (0.1)	86 (2.3)			
Emergency room	5 (0.0)	0 (0.0)	5 (0.0)	1 (0.0)			
Other outpatient	3,657 (1.5)	937 (2.2)	32,005 (24.2)	615 (16.2)			
Type of visit for first MenB vaccination, n (%)							
Preventive care/well-child	191,910 (79.8)	27,665 (65.6)	105,385 (79.6)	2,270 (59.7)			
Vaccine-only	27,702 (11.5)	7,000 (16.6)	12,487 (9.4)	324 (8.5)			
Other	20,990 (8.7)	7,476 (17.7)	14,509 (11.0)	1,210 (31.8)			
Provider type of first MenB vaccinat	tion, n (%)						
Pediatrician	173,673 (72.2)	21,594 (51.2)	50,651 (38.3)	667 (17.5)			
Family medicine	27,326 (11.4)	9,673 (23.0)	6,194 (4.7)	216 (5.7)			
Internal medicine	5,785 (2.4)	2,220 (5.3)	1,142 (0.9)	54 (1.4)			
Pharmacist	1,699 (0.7)	1,/38 (4.1)	188 (0.1)	86 (2.3)			
Obstetrician/gynecologist	258 (0.1)	79 (0.2)	655 (0.5) 20 124 (20 C)	24 (0.6)			
Unknown	21,377 (0.7) 10 167 (1 3)	4,330 (10.8) 2 200 (5 5)	37,134 (29.0) 31,117 (26.0)	004 (Z1.1) 1 053 (51 2)			
	10,402 (4.3)	2,233 (3.3)	עוד,ד(20.0)	(0.10)			
Co-administration of first MenB dos	e with other vaccinations,	, n (%)		460 (10 0)			
Menacw Y	128,480 (53.4)	4,/24 (11.2)	80,/50 (05.5)	409 (12.3) 916 (21.5)			
nnuenza Othor ^c	20,410 (12.1) 63 128 (26.2)	0,101 (14.5) 13 740 (32.6)	22,008 (17.1) 32,030 (24,0)	010 (21.3) 1 232 (24.9)			
other	05,120 (20.2)	13,740 (32.0)	52,550 (24.5)	(0.+0)			

^aData for MenB vaccine type are numbers of individuals who received any dose(s) of MenB-4C and any dose(s) of MenB-FHbp vaccines. The sums add to more than the numbers of individuals as some received both vaccines.

^blncluding nurse practitioner/physician assistant, other physician, or other professional (non-physician).

^CIncluding adenovirus, anthrax, Bacillus Calmette–Guérin, cholera, hepatitis A, hepatitis B, HPV, pneumococcus, rabies, rotavirus, typhoid, DTP, measles-mumps-rubella, polio, varicella, yellow fever, plague, Japanese encephalitis, *Haemophilus influenzae* B, DTP/*Haemophilus influenzae* B, DTP/polio, MenCY/*Haemophilus influenzae* B vaccinations.

DTP, diphtheria-tetanus-pertussis; HPV, human papillomavirus; MenACWY, meningococcal serogroups A, C, W, Y; MenB, meningococcal serogroup B; MenB-4C, meningococcal serogroup B 4-component; MenB-FHbp, meningococcal serogroup B factor H binding protein; MenCY, meningococcal serogroups C, Y; n, number of individuals; NA, not applicable.

Similarly to our MenB vaccine series completion study,¹³ the current retrospective study of MenB vaccine series initiation has various limitations related to the use of claims data. As individuals were identified via administrative claims, covariates or outcomes could have been misclassified and clinical details are subject to data coding limitations and data entry error. Further, claims data

do not include information on factors that could influence vaccination behavior. Also, vaccinations that did not generate a claim and those that occurred prior to the period of continuous enrollment would not have been captured, e.g. among those who were eligible to receive vaccinations under the VFC program.²⁰ Most such children are eligible for Medicaid, hence vaccine administration fees are billed to Medicaid, but these fees are not vaccine specific, so we could not determine which vaccine an individual with a VFC-sponsored vaccine received. We have, therefore, likely underestimated MenB vaccinations, particularly in the Medicaid population.

Our results may also have been confounded by MenB outbreaks. Any such outbreaks would have increased MenB vaccine uptake, but some of these may not have been captured in the claims data (e.g. if they were provided free of charge to university students). This could also have influenced some of the geographical findings.

Lastly, race data were only available for the Medicaid cohorts, while region data were only available for the Commercial cohorts. Hence, a full assessment of racial and geographic inequity of MenB vaccination across US populations cannot be inferred.

MenB vaccine series initiation among US adolescents and young adults was low, with a long median time to initiation, although most MenB vaccinations occurred during the preferred age range of 16-18 years. Even in this age cohort, only 33% of the Commercial and 20% of the Medicaid cohorts were estimated to have initiated a MenB vaccine series within 3 years. Co-administration of MenB and MenACWY vaccines was common in the 16-18-year-old cohorts, indicating that the second dose of MenACWY vaccine may provide a platform to increase MenB vaccination series initiation. Factors associated with reduced MenB vaccine series initiation in multivariable models included male sex, White race (Medicaid only), living in central US regions (Commercial only), and rural location; hence, initiatives to increase MenB vaccine uptake could be targeted toward such individuals. Lastly, there is a need for continued efforts to better understand additional barriers to the uptake of vaccines that are recommended based on shared clinical decision-making.

Acknowledgments

The authors would like to thank Gilwan Kim (IBM Watson Health at the time of the study conduct) for her contribution to the data collection and analysis, as well as Oscar Herrera-Restrepo (GSK) for his contribution to the manuscript content and development. The authors would also like to thank Business & Decision Life Sciences platform for editorial assistance and manuscript coordination, on behalf of GSK. Jenny Lloyd (Compass Healthcare Communications Ltd., on behalf of GSK) provided medical writing support.

Authors contributions

All authors participated in the design or implementation or analysis, and interpretation of the study, and in the development of this manuscript and in its critical review with important intellectual contributions. All authors had full access to the data and gave approval before submission. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The work described was carried out in accordance with the recommendations of the International Committee of Medical Journal Editors for conduct, reporting, editing, and publication of scholarly work in medical journals.

Disclosure statement

ERP is employed by Merative (IBM Watson Health at the time the study was conducted), and NMZ and LCM were employed by IBM Watson

Health at the time of the study conduct and/or manuscript development. Merative (IBM Watson Health at the time the study was conducted) received funding via a contractual agreement with GSK to perform the work contributing to this research. NMZ is now employed by GSK. PN and PG were employed by GSK at the time of the study conduct and hold shares in GSK. PN is now employed by and holds shares in Dynavax. PN was employed by Moderna in the meantime and holds shares in Moderna. PG is now employed by and holds shares in Moderna. NC is employed by and holds shares in GSK. The authors declare no other financial and nonfinancial relationships and activities.

Funding

GlaxoSmithKline Biologicals SA funded this study [GSK study identifier: VxHO-000048] and was involved in all stages of study conduct, including analysis of the data. GlaxoSmithKline Biologicals SA also paid all costs associated with the development and publication of this manuscript.

ORCID

Elizabeth R. Packnett i http://orcid.org/0000-0002-4731-6956 Nicole M. Zimmerman i http://orcid.org/0000-0001-5819-7844 Patricia Novy i http://orcid.org/0000-0003-0655-4672 Laura C. Morgan i http://orcid.org/0000-0003-1339-9746 Nnenna Chime i http://orcid.org/0000-0002-7380-2114 Parinaz Ghaswalla i http://orcid.org/0000-0002-2883-5590

Data sharing statement

GSK makes available anonymized individual participant data and associated documents from interventional clinical studies which evaluate medicines, upon approval of proposals submitted to www.clinicalstudyda tarequest.com. To access data for other types of GSK sponsored research, for study documents without patient-level data and for clinical studies not listed, please submit an enquiry via the website.

References

- Brandtzaeg P, van Deuren M. Classification and pathogenesis of meningococcal infections. Methods Mol Biol. 2012;799:21–35. doi:10.1007/978-1-61779-346-2_2. PMID: 21993637.
- Wang B, Santoreneos R, Giles L, Haji Ali Afzali H, Marshall H. Case fatality rates of invasive meningococcal disease by serogroup and age: a systematic review and meta-analysis. Vaccine. 2019;37(21):2768-82. doi:10.1016/j.vaccine.2019.04. 020. PMID: 30987851.
- 3. Centers for Disease Control and Prevention (CDC). Meningococcal disease. Surveillance. Atlanta (GA): National Center for Immunization and Respiratory Diseases; 2022 Feb 7. [accessed 2022 Mar 2]. https://www.cdc.gov/meningococcal/sur veillance/index.html.
- Centers for Disease Control and Prevention (CDC). Enhanced meningococcal disease surveillance report. Atlanta (GA): National Center for Immunization and Respiratory Diseases; 2019. [accessed 2021 Dec 15]. https://www.cdc.gov/meningococ cal/downloads/NCIRD-EMS-Report-2019.pdf.
- MacNeil JR, Rubin L, Folaranmi T, Ortega-Sanchez IR, Patel M, Martin SW. Use of serogroup B meningococcal vaccines in adolescents and young adults: recommendations of the Advisory Committee on Immunization Practices, 2015. MMWR Morb Mortal Wkly Rep. 2015;64(41):1171–76. doi:10.15585/mmwr. mm6441a3. PMID: 26492381.
- Patton ME, Stephens D, Moore K, MacNeil JR. Updated recommendations for use of MenB-FHbp serogroup B meningococcal vaccine — Advisory Committee on Immunization Practices, 2016.

MMWR Morb Mortal Wkly Rep. 2017;66(19):509–13. doi:10. 15585/mmwr.mm6619a6. PMID: 28520709.

- Mbaeyi SA, Bozio CH, Duffy J, Rubin LG, Hariri S, Stephens DS, MacNeil JR. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. MMWR Recomm Rep. 2020;69(9):1–41. doi:10.15585/ mmwr.rr6909a1. PMID: 33417592.
- Walker TY, Elam-Evans LD, Yankey D, Markowitz LE, Williams CL, Mbaeyi SA, Fredua B, Stokley S. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2017. MMWR Morb Mortal Wkly Rep. 2018;67(33):909–17. doi:10.15585/mmwr. mm6733a1. PMID: 30138305.
- Walker TY, Elam-Evans LD, Yankey D, Markowitz LE, Williams CL, Fredua B, Singleton JA, Stokley S. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2018. MMWR Morb Mortal Wkly Rep. 2019;68(33):718–23. doi:10.15585/mmwr. mm6833a2. PMID: 31437143.
- Elam-Evans LD, Yankey D, Singleton JA, Sterrett N, Markowitz LE, Williams CL, Fredua B, McNamara L, Stokley S. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2019. MMWR Morb Mortal Wkly Rep. 2020;69(33):1109–16. doi:10. 15585/mmwr.mm6933a1. PMID: 32817598.
- Pingali C, Yankey D, Elam-Evans LD, Markowitz LE, Williams CL, Fredua B, McNamara LA, Stokley S, Singleton JA. National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years — United States, 2020. MMWR Morb Mortal Wkly Rep. 2021;70(35):1183–90. doi:10.15585/ mmwr.mm7035a1. PMID: 34473682.
- Pingali C, Yankey D, Elam-Evans LD, Markowitz LE, Valier MR, Fredua B, Crowe SJ, Stokley S, Singleton JA. National vaccination coverage among adolescents aged 13–17 years — National Immunization Survey-Teen, United States, 2021. MMWR Morb Mortal Wkly Rep. 2022;71(35):1101–08. doi:10.15585/mmwr. mm7135a1. PMID: 36048724.

- Packnett ER, Zimmerman NM, Kim G, Novy P, Morgan LC, Chime N, Ghaswalla P. A real-world claims data analysis of meningococcal serogroup B vaccine series completion and potential missed opportunities in the United States. Pediatr Infect Dis J. 2022;41(4): e158–65. doi:10.1097/INF.000000000003455. PMID: 35086118.
- Immunization Action Coalition. State laws and mandates by vaccine. Minnestota (MN): Immunization Action Coalition; 2021 May 24. [accessed 2021 Nov 26]. https://www.immunize.org/laws/.
- Srivastava T, Emmer K, Feemster KA. Impact of school-entry vaccination requirement changes on clinical practice implementation and adolescent vaccination rates in metropolitan Philadelphia. Hum Vaccin Immunother. 2020;16(5):1155–65. doi:10.1080/21645515. 2020.1712934. PMID: 31977274.
- 16. Centers for Disease Control and Prevention (CDC). Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2021. Atlanta (GA): National Center for Immunization and Respiratory Diseases; 2022 Feb 17. [accessed 2022 Oct 5]. https://www. cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.
- Hansen CE, Niccolai LM. Factors associated with receipt of meningococcal B vaccine among United States adolescents, National Immunization Survey-Teen, 2017-2018. J Adolesc Health. 2021;69 (5):769–73. doi:10.1016/j.jadohealth.2021.04.029. PMID: 34148798.
- Packnett E, Irwin DE, Novy P, Watson PS, Whelan J, Moore-Schiltz L, Lucci M, Hogea C. Meningococcal-group B (MenB) vaccine series completion and adherence to dosing schedule in the United States: a retrospective analysis by vaccine and payer type. Vaccine. 2019;37(39):5899–908. doi:10.1016/j.vaccine.2019. 06.065. PMID: 31443990.
- La EM, Garbinsky D, Hunter S, Poston S, Novy P, Ghaswalla P. Meningococcal B vaccination coverage among older adolescents in the United States. Vaccine. 2021;39(19):2660–67. doi:10.1016/j. vaccine.2021.03.071. PMID: 33849722.
- Centers for Disease Control and Prevention (CDC). Vaccines for Children Program (VFC). Atlanta (GA): National Center for Immunization and Respiratory Diseases; 2016 Feb 18. [accessed 2021 Jun 17]. https://www.cdc.gov/vaccines/pro grams/vfc/index.html.