

A Real-world Claims Data Analysis of Meningococcal Serogroup B Vaccine Series Completion and Potential Missed Opportunities in the United States

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Background: In the United States, meningococcal serogroup B (MenB) vaccination is recommended for 16–23-year-olds based on shared clinical decision-making. We estimated series completion among individuals initiating MenB vaccination for the 2 available vaccines: MenB 4-component (MenB-4C, doses at 0 and ≥ 1 month) and MenB factor H binding protein (MenB-FHbp, doses at 0 and 6 months).

Methods: This retrospective health insurance claims data analysis included 16–23-year-olds who initiated MenB vaccination (index date) during January 2017 to November 2018 (MarketScan Commercial Claims and Encounters Database) or January 2017 to September 2018 (MarketScan Multi-State Medicaid Database) and had continuous enrollment for ≥ 6 months before and ≥ 15 months after index. The main outcome was MenB vaccine series completion within 15 months. Among noncompleters, preventive care/well-child and vaccine administrative office visits were identified as potential missed opportunities for series completion. Robust Poisson regression models identified independent predictors of series completion.

Results: In the Commercial ($n = 156,080$) and Medicaid ($n = 57,082$) populations, series completion was 56.7% and 44.7%, respectively, and was higher among those who initiated MenB-4C versus MenB-FHbp (61.1% versus 49.8% and 47.8% versus 33.9%, respectively; both $P < 0.001$). Among noncompleters, 40.2% and 34.7% of the Commercial and Medicaid populations, respectively, had ≥ 1 missed opportunity for

series completion. Receipt of MenB-4C and younger age were independently associated with a higher probability of series completion.

Conclusions: Series completion rates were suboptimal but were higher among those who initiated MenB-4C. To maximize the benefits of MenB vaccination, interventions to improve completion and reduce missed opportunities should be implemented.

Key Words: adolescents, MenB-4C, MenB-FHbp, meningococcal serogroup B, vaccination

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Invasive meningococcal disease (IMD), caused by *Neisseria meningitidis*, can result in meningitis and/or septic shock.¹ Globally, the case fatality rate for IMD is $\approx 8\%$,² and survivors can develop long-term sequelae, including skin scarring, hearing loss, limb amputations, and psychologic effects.³ There are various serogroups of *N. meningitidis*, of which A, B, C, W, X and Y cause IMD.⁴ In the United States during 2006 to 2015, among 7924 cases of IMD (0.26 per 100,000 population), meningococcal serogroup B (MenB) was the most common cause (35.8%), followed by serogroups Y (28.5%)

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and C (22.8%).⁵ Additionally, in 2018, 21 of the 34 reported cases of meningococcal disease among 16–23-year-olds in the United States were caused by MenB.⁶

Routine vaccination against meningococcal serogroups A, C, W and Y (MenACWY) was introduced for children 11–12 years of age in the United States in 2005,⁷ with recommendation for a booster dose at age 16 years added in 2010.⁸ However, MenB vaccination has only been recommended since 2015, for those 16–23 years of age (preferably 16–18 years) based on shared clinical decision-making.^{9–11} This involves the healthcare provider and patient/parent deciding whether MenB vaccination is beneficial, balancing the seriousness of invasive MenB disease, the increased risk among college students and the protection provided by MenB vaccines versus the low-risk of MenB infection and the estimated relatively short duration of protection.¹⁰ Routine MenACWY and MenB vaccines are also recommended for individuals [≥2 months of age (MenACWY) or ≥10 years (MenB)] at increased risk of meningococcal infection.¹⁰ Although uptake of MenACWY vaccination among adolescents is high (≥1 dose: ≈90%; ≥2 doses: ≈50%),¹² uptake of MenB vaccination is lower (≥1 dose: ≈20%–30%; ≥2 doses: no data).^{12,13}

There are 2 recommended MenB vaccines—MenB 4-component (MenB-4C, *Bexsero*, GSK, Belgium) and MenB factor H binding protein (MenB-FHbp, *Trumenba*, Pfizer, USA). MenB-4C has always been recommended as a 2-dose series at 0 and ≥1 month.^{9,10} In 2015, MenB-FHbp was recommended as a 3-dose series at months 0, 2 and 6.⁹ In 2017, this changed to a 2-dose series 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.^{10,14} For those at increased risk or during an outbreak, MenB-FHbp is recommended to be given at 0, 1–2 and 6 months.^{10,14}

A previous US study examined MenB series completion from 2015 to 2018, but as the dosing recommendations for MenB-FHbp changed during this time, the latest dosing recommendations were applied retroactively.¹⁵ Therefore, the current study estimated and compared series completion rates for MenB-4C and MenB-FHbp during 2017 to 2020 among US individuals 16–23 years of age using the current dosing recommendations for MenB-FHbp.¹⁰ Figure, Supplemental Digital Content 1, <http://links.lww.com/INF/E643> provides an overview of the context, novelty, and impact of the current study in a form that could be shared with patients. Video, Supplemental Digital Content 2, <http://links.lww.com/INF/E644> provides a voiced animation explaining the study design and results.

MATERIALS AND METHODS

Data Source and Study Design

This study (GSK study identifier: VxHO-000048) used deidentified data from the IBM MarketScan Commercial Claims and Encounters Multi-State Medicaid databases (see further details in the Text, Supplemental Digital Content 3, <http://links.lww.com/INF/E645>).

In this retrospective cohort study, individuals with a MenB vaccination were identified during January 2017 (ie, after the updated dosing recommendation for MenB-FHbp had been approved in October 2016^{14,16}) through either November 2018 (Commercial) or September 2018 (Medicaid) to allow for 15 months of follow-up before February 2020 (Commercial) or December 2019 (Medicaid) (see Figure, Supplemental Digital Content 4, <http://links.lww.com/INF/E646>). The date of first MenB vaccination during this time was the index date. The 6 months before this was the baseline period; 15 months after was the follow-up period. This length of follow-up was selected to allow for individuals who received their index vaccination in early summer to receive subsequent series vaccinations in late summer of

the next year. Data dating back to October 2014 were examined to exclude individuals at high risk of MenB infection. Codes used to identify MenB vaccination claims are detailed in Table, Supplemental Digital Content 5, <http://links.lww.com/INF/E647>.

Study Population

Inclusion criteria were ≥1 claim for a MenB vaccination during the identification period; 16–23 years of age on the index date and continuous enrollment with medical and pharmacy benefits for ≥6 months before and ≥15 months after the index date. Individuals with claims for both MenB-4C and MenB-FHbp during the follow-up period were excluded, as were those with a high-risk condition that would indicate MenB vaccination (asplenia, persistent complement component deficiency, sickle cell disease or eculizumab use), or MenB vaccination between October 2014 and December 2016. Characteristics such as age, sex, race/ethnicity (Medicaid only), geographic region (Commercial only), and month and year of index MenB vaccination were captured on the index date.

Outcomes

The main outcome was the proportion of individuals who completed a MenB vaccine series within 15 months of the first MenB vaccine dose, overall and separately for MenB-4C and MenB-FHbp. A MenB-4C series was considered complete if an individual had ≥1 additional claim indicating MenB-4C ≥28 days after the index dose. A MenB-FHbp series was considered complete if an individual had ≥1 additional claim indicating MenB-FHbp ≥168 days after the index dose.

Statistical Analyses

All analyses were completed separately in the Commercial and Medicaid populations. Index demographic and baseline clinical characteristics are reported descriptively, as are vaccination characteristics for the first and completion doses.

Series completion rates within 15 months were compared between the 2 MenB vaccine types, overall, and by age, sex, race/ethnicity (Medicaid only), vaccination month, urban/rural residence and census region (Commercial only). χ^2 tests were used to test for differences in nominal/categorical variables; t tests were used to test for differences in interval/continuous variables.

Kaplan–Meier curves were generated to describe the time from MenB vaccine initiation to series completion. Log-rank tests were used to assess statistical significance.

In an exploratory analysis, individuals who did not complete their series, but had preventive care/well-child or vaccine administration-related outpatient office visits (identified using the codes in Table, Supplemental Digital Content 6, <http://links.lww.com/INF/E648>) during months ≈1–15 (MenB-4C) or ≈5.5–15 (MenB-FHbp), were identified, and these visits were classified as potential missed opportunities for MenB series completion.

Multivariable analyses were conducted to identify factors independently associated with series completion within 15 months. Robust Poisson regression models were constructed to estimate the adjusted relative risks (aRRs) of series completion by vaccine type while controlling for baseline characteristics. The Commercial and Medicaid models were adjusted for: age at index, sex, race (Medicaid only), region (Commercial only), population density (urban/rural), index month and year, index provider type, co-administration of MenACWY, influenza or other vaccines at index MenB, number of preventive care/well-child and vaccine administration office visits, total expenditures during baseline and presence of HIV infection. HIV infection was included to adjust for underlying differences in the likelihood of series completion, as individuals with HIV are at increased risk of meningococcal infection,¹⁷ but routine MenB vaccination is not recommended.¹⁰

Associated 95% CIs were calculated for each of the covariates in both models. For all analyses, $P \leq 0.001$ was taken to be statistically significant.

RESULTS

Study Population

Among 305,161 Commercial individuals and 111,765 Medicaid individuals with ≥ 1 MenB vaccination claim during January 2017 through either November 2018 (Commercial) or September 2018 (Medicaid), 156,080 Commercial and 57,082 Medicaid individuals met the study inclusion criteria (see Table, Supplemental Digital Content 7, <http://links.lww.com/INF/E649>). In both populations, more individuals received a first dose of MenB-4C than MenB-FHbp (Commercial: 61.5% versus 38.5%; Medicaid: 78.0% versus 22.0%).

Most individuals were 16–18 years of age (Commercial: 83.9%; Medicaid: 97.0%), and $\approx 52\%$ of each population were female (see Table, Supplemental Digital Content 8, <http://links.lww.com/INF/E650>). Over half of the Commercial individuals initiated vaccination from June to August (52.9%), whereas a similar proportion of Medicaid individuals were vaccinated from June to September (53.7%).

MenB Completion Rates

For both vaccines combined, 56.7% and 44.7% of the Commercial and Medicaid populations received a completion dose within 15 months of a first dose. Individuals who received a first

dose of MenB-4C were significantly more likely than those who received a first dose of MenB-FHbp to receive a completion dose of the same vaccine within 15 months (Commercial: 61.1% versus 49.8%; Medicaid: 47.8% versus 33.9%; both $P < 0.001$; Fig. 1). Series completion rates were also higher for MenB-4C in each age group (apart from Medicaid age 23 years), sex, race/ethnicity, vaccination month and residence density (apart from Medicaid unknown), with most differences reaching statistical significance (Fig. 1). Series completion generally tended to decrease with increasing age and peaked when the first dose was given in June (Fig. 1). By region (Commercial population only), receipt of a completion dose was highest in New England (overall: 66.4%; MenB-4C: 68.7%; MenB-FHbp: 59.9%) and lowest in the Mountain (overall: 49.3%; MenB-FHbp: 41.0%) or West South Central (MenB-4C: 54.7%) regions (Figures, Supplemental Digital Content 9, <http://links.lww.com/INF/E651>).

Vaccination Characteristics

Most MenB vaccinations were administered at office visits ($\approx 80\%$ – 100% across doses and populations; see Table, Supplemental Digital Content 10, <http://links.lww.com/INF/E652>). However, although most first doses were given at preventive care/well-child visits ($\approx 80\%$), most completion doses were given at vaccine-only visits ($\approx 60\%$ – 70%). Pediatricians were the main provider type for both doses (Commercial: $\approx 70\%$; Medicaid: $\approx 40\%$), with other and unknown providers giving most of the remainder in the Medicaid population. First MenB vaccine doses were often co-administered with MenACWY (Commercial: 43.6%; Medicaid: 66.3%), but

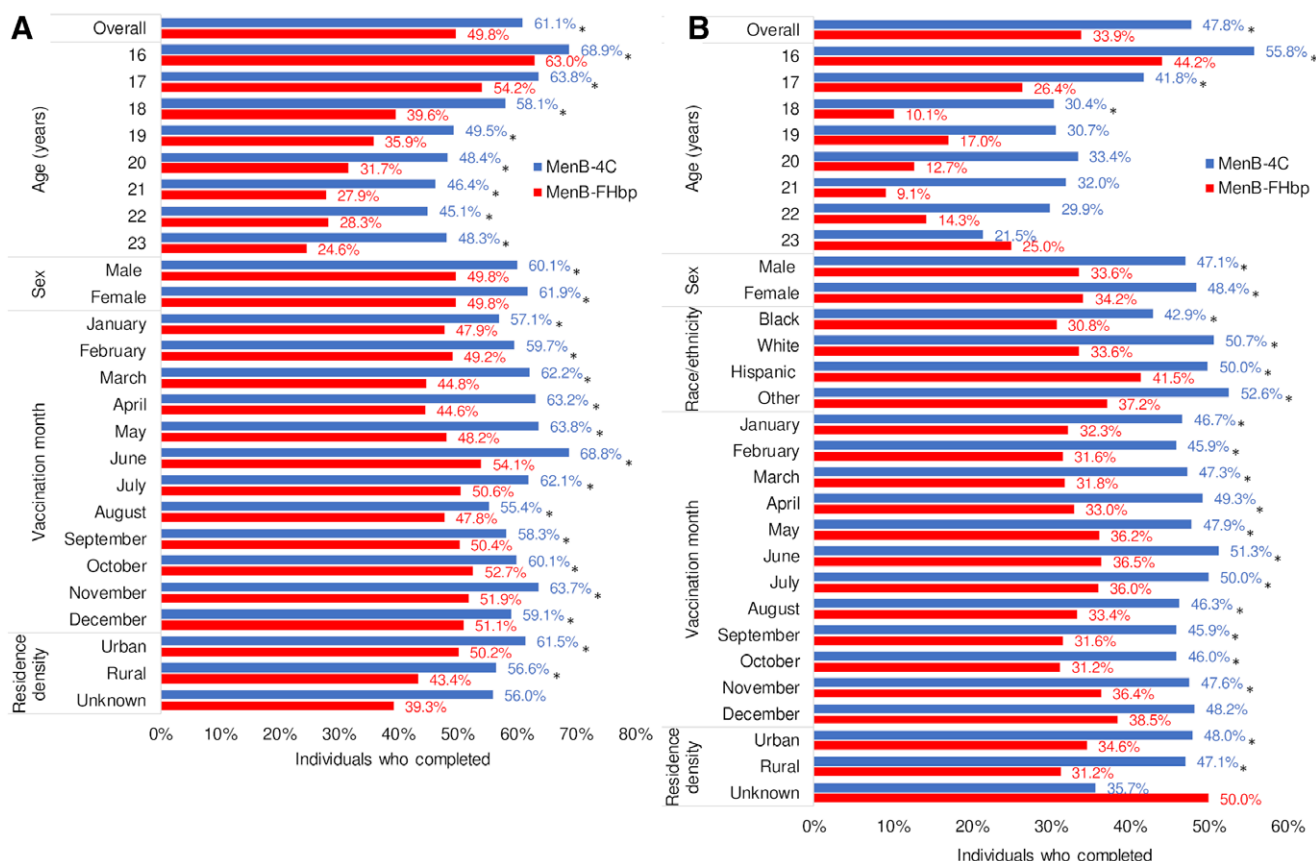


FIGURE 1. Series completion rates at 15 mo from series initiation in the (A) Commercial and (B) Medicaid populations.

*Significantly higher for MenB-4C vs. MenB-FHbp ($P \leq 0.001$).

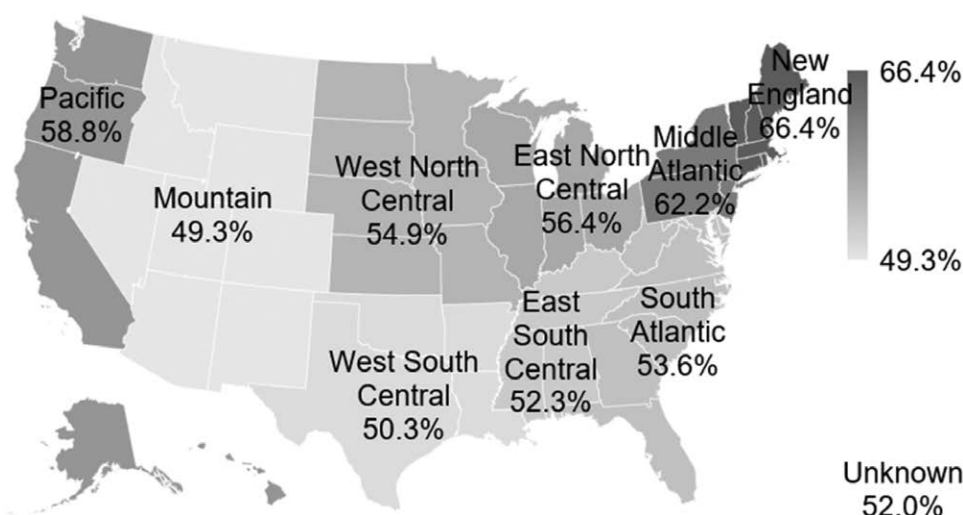


FIGURE 2. Regional variation in series completion rates of MenB vaccines in the Commercial population. *Regional data were not available in the Medicaid database.

this rarely occurred for completion doses (<5%). Approximately 12%–15% of either MenB vaccine doses in either population were administered with influenza vaccines; with 13%–28% being co-administered with other vaccines.

Time to Completion

By Kaplan–Meier analysis, series completion rates were significantly higher for MenB-4C than MenB-FHbp at all time points in both populations (Fig. 3). Among completers, the mean $\pm$ SD times to completion were significantly shorter for MenB-4C than MenB-FHbp (Commercial: 5.1 ± 4.6 versus 9.6 ± 2.8 months; Medicaid: 6.0 ± 4.9 versus 10.3 ± 2.8 months; $P < 0.001$).

Potential Missed Opportunities

In the Commercial population, 56.7% of individuals received a completion dose within 15 months. Among those who did not complete the series, 40.2% had a non-MenB vaccine administration or preventive care/well-child office visit during ≈ 1 –15 or ≈ 5.5 –15 months after receipt of the first dose of MenB-4C or MenB-FHbp, respectively. Had these individuals (17.4% of the total) received their completion MenB dose at this visit, the completion rate would have been 74.1% (Fig. 4A). Similarly, in the Medicaid population, the completion rate could have reached 63.9% instead of 44.7% (Fig. 4B).

Factors Associated With Completion

In Poisson regression models, factors that were strongly associated with completion of a MenB series in both populations included receipt of MenB-4C (versus MenB-FHbp) (Commercial: aRR, 1.25; 95% CI, 1.24–1.26; Medicaid: aRR, 1.43; 95% CI, 1.39–1.47; both $P < 0.001$), index administration during June or July, more pre-index vaccine administration office visits, and female sex (Fig. 5). Conversely, increasing age, receipt outside New England (Commercial only), Black race (Medicaid only), co-administration of vaccines other than MenACWY and influenza, and rural location (only significant for Commercial) were associated with reduced rates of series completion (Fig. 5). Pediatricians had higher completion rates than most other providers, although pharmacists (who gave very few vaccines; see Table, Supplemental Digital Content 10, <http://links.lww.com/INF/E652>) had the highest completion rate in the Commercial population, but the lowest rate in the Medicaid population.

DISCUSSION

In this retrospective database study, MenB series completion rates were suboptimal in the Commercial (56.7%) and Medicaid (44.7%) populations who initiated MenB vaccination. This is in line with results from a prior study of the IBM MarketScan Commercial Claims and Encounters Database and MarketScan Multi-State Medicaid Database,¹⁵ which examined individuals who initiated a MenB vaccine series during 2015 to 2016 (58% and 44% series completion, respectively) and those from a study that used 2017 to 2018 National Immunization Survey Teen data (47% series completion overall).¹⁸

In the current study, individuals who received the first dose of MenB-4C were significantly more likely to complete the series than those who received the first dose of MenB-FHbp (Commercial: 61.1% versus 49.8%; Medicaid: 47.8% versus 33.9%), and this relationship persisted after adjustment in Poisson regression models. Furthermore, due to the differences in schedule recommendations, time to series completion was significantly shorter with MenB-4C than MenB-FHbp, resulting in earlier maximum protection with MenB-4C. These results are in line with the prior IBM database study,¹⁵ in which completion rates were also significantly higher among individuals who initiated MenB-4C versus MenB-FHbp (Commercial: 62.9% versus 52.0%; Medicaid: 48.5% versus 31.2%). The current study, which used data from after the revised Advisory Committee on Immunization Practices guidelines for the MenB-FHbp dosing schedule,^{14,16} confirms the results of the earlier database study,¹⁵ in which the latest dosing recommendations were applied retroactively.

Besides receipt of MenB-4C (versus MenB-FHbp), factors associated with significantly higher completion rates—in both the current study and the prior study¹⁵—were female sex, younger age (likely due to parental oversight), non-Black race, vaccination by a pediatrician and residing in the Northeast. Both studies also found higher completion rates in the Commercial versus Medicaid populations,¹⁵ although neither study compared these statistically. Both studies highlight the important role of pediatricians in MenB vaccination, as those who initiated with a pediatrician were generally more likely to complete the series.¹⁵ Notably, $\approx 28\%$ of MenB vaccinations in the Medicaid population (versus $\approx 4\%$ for Commercial) were administered by providers with unknown specialty, including those in public health facilities and urgent care centers. Medicaid patients are less likely to be able to schedule appointments with

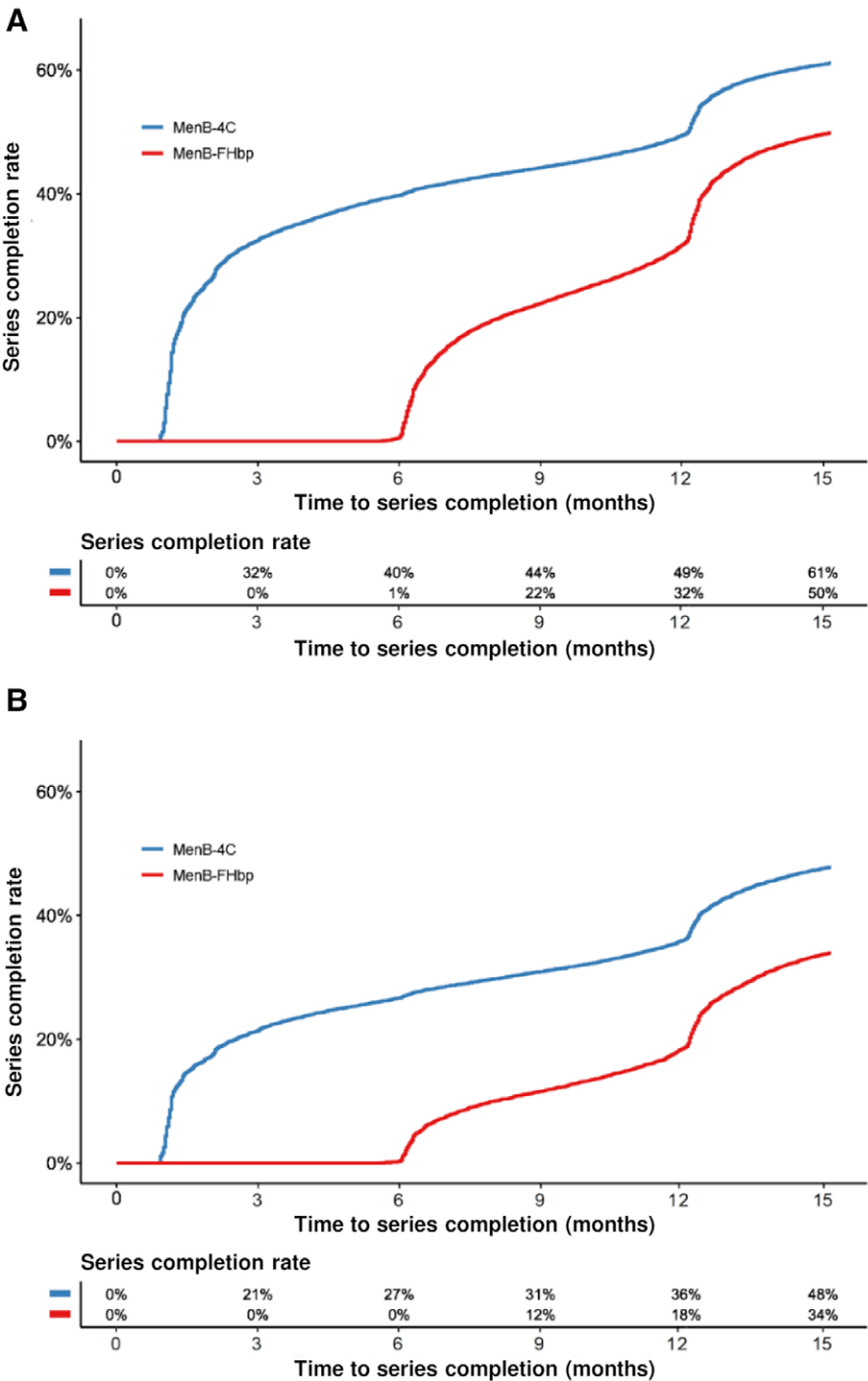


FIGURE 3. Kaplan–Meier analysis of time to series completion of MenB vaccine series in the (A) Commercial and (B) Medicaid populations. *Series completion rates were significantly higher for MenB-4C than MenB-FHbp at all time points (log-rank $P < 0.001$).

primary care providers and specialist physicians and more likely to use emergency facilities.^{19,20} These differences in provider types likely reflect barriers to access in the Medicaid population that, if addressed, may improve MenB vaccination uptake and series completion.

In the current study, most MenB vaccine first doses were given at preventive care/well-child visits, whereas completion doses

were generally given at vaccine-only visits. First MenB doses were often co-administered with MenACWY (presumably the booster dose of MenACWY vaccine recommended at age 16 years),¹⁰ especially in the Medicaid population. In addition, there were noticeable increases in completion rates 12 months after initiation in both populations, likely due to series completion during an annual preventive care/well-child visit. This suggests the recommendation for

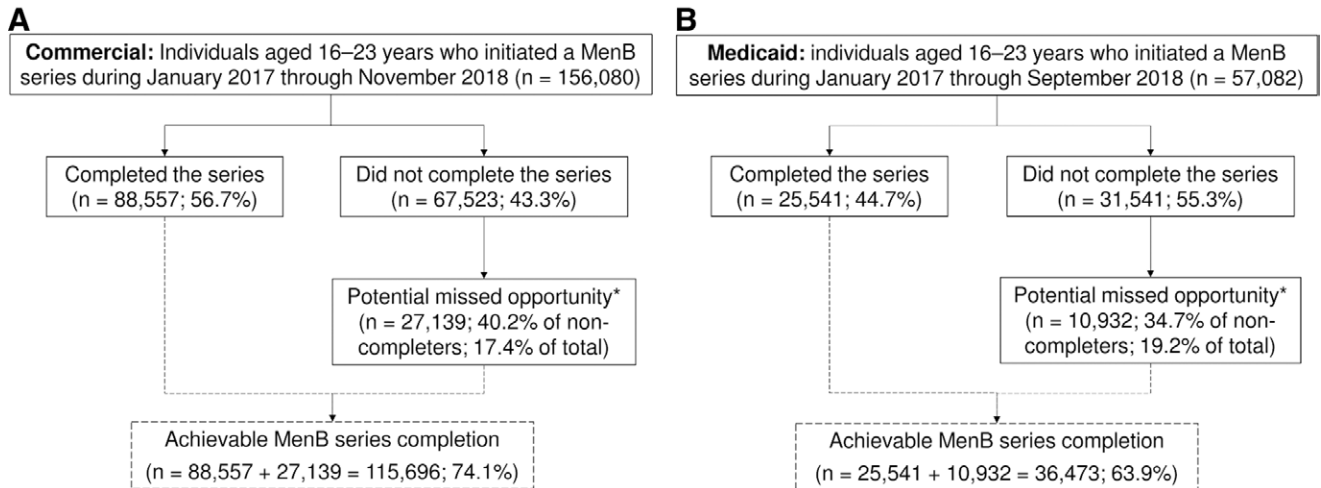


FIGURE 4. Potential missed opportunities and achievable series completion rates for MenB vaccine series in the (A) Commercial and (B) Medicaid populations. *Had a preventive care/well-child or non-MenB vaccine administration office visit during ~ 1 –15 months after MenB-4C or ~ 5.5 –15 months after MenB-FHbp.

administration of a MenACWY booster at age 16 years may serve as a platform to increase MenB vaccine uptake, particularly when part of an annual preventive care/well-child visit and that maintaining annual visits through early adulthood may improve completion rates for multidose vaccines.

Co-administration of MenB with vaccines other than MenACWY or influenza was associated with a significantly decreased likelihood of MenB vaccination series completion. During the study period, the only vaccines routinely recommended for the included age group (16–23 years) were MenACWY booster at age 16 years and annual influenza vaccination. Individuals receiving other vaccinations were likely receiving them as part of a ‘catch-up’ vaccination schedule and may, therefore, also be less likely to follow recommended schedules for MenB vaccination. Further research is necessary to understand the role of prior adherence to recommended vaccination schedules and completion of multidose vaccine series, particularly when vaccination is recommended based on shared clinical decision-making.

Many recent US studies have assessed factors that are associated with human papillomavirus (HPV) vaccination series completion rates among US adolescents/young adults that provide additional insight into the factors associated with increased adherence to multidose vaccine schedules in adolescents.^{21–30} Similar to the current study, various of these HPV studies reported significantly higher rates of completion in younger individuals,^{21–23,25} female sex,^{23,26,27} White race,^{22,27–29} Northeast location,^{23,25,30} non-Medicaid²⁹ and April to June administration.²⁵ Other factors associated with higher HPV completion rates include routine checkups,²¹ more office visits,^{23,27} receipt of other vaccines^{23,25} and administration by a pediatrician²² or obstetrician/gynecologist.²⁵ The current study provides additional evidence of the important role of pediatricians and annual preventive care visits in increasing completion of multidose vaccines, as well as demonstrating consistent regional variation in multidose series completion. Interventions to maintain routine preventive care through early adulthood, particularly those targeting regions with lower rates of multidose vaccine series completion, should be considered to improve completion of multidose vaccine series.

Many individuals who initiated MenB vaccination did not complete the series. In the current study, 40.2% of the Commercial

population and 34.7% of the Medicaid population who did not receive a completion MenB vaccine dose within the applied time limits attended a vaccine administration or preventive care/well-child office visit during these times. Had they received their completion dose at such a visit, completion rates could have been considerably higher. Other potential strategies to improve vaccine series completion include provider recommendation,³¹ patient/parent education,³² scheduling second dose appointments at the first dose appointment,³³ sending patient/parent reminders (eg, text messages),^{32–35} mobile health applications,³⁶ use of the Immunization Information System,³⁷ use of a prompt and reminder system for providers,³⁸ vaccination mandates³⁷ and use of school-based health centers.²⁶

Limitations

This retrospective study has several limitations related to the use of claims data. There was potential for misclassification of covariates or outcomes, as individuals were identified through administrative claims data rather than medical records. Also, claims data do not include information on social, cognitive, or institutional factors that may influence vaccination behavior. Furthermore, clinical details are subject to data coding limitations and data entry errors. Individuals who may have received three doses of MenB-FHbp due to their risk status cannot be identified using claims data, but these individuals would still be counted as complete in this analysis, so series completion for MenB-FHbp was not underestimated.

Office visits during follow-up were limited by the fact that some visits may occur after the outcome is observed and may be undercounted for some patients due to the use of Early View data. As claims adjudicate at different rates, the medical component of care for some patients was not complete in the Early View data. However, only a small proportion of patients with follow-up near the end of the Early View reporting were affected by this limitation.

Any vaccinations that did not generate a claim would not have been captured in the databases. Children who were uninsured, underinsured, Medicaid eligible or American Indian or Alaska Native are eligible to receive recommended childhood vaccines for free under the Vaccines For Children (VFC) program.³⁹ Most children who receive VFC vaccines are eligible for Medicaid, and

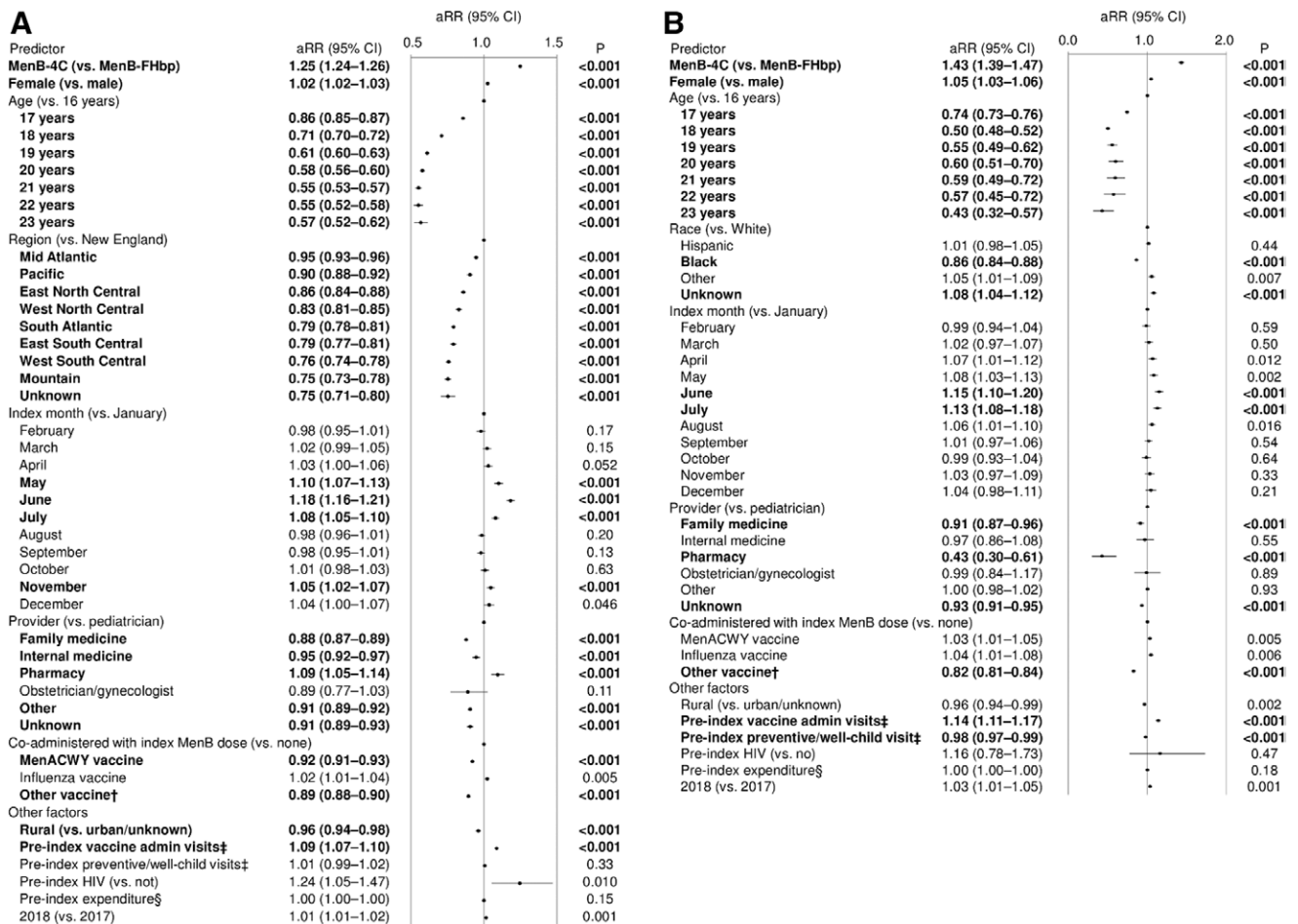


FIGURE 5. Poisson regression analysis of adjusted relative risks for series completion of MenB vaccine series in the (A) Commercial and (B) Medicaid populations. *Bold text indicates significance at $P \leq 0.001$. †Includes adenovirus, anthrax, *Bacillus Calmette–Guérin*, cholera, hepatitis A, hepatitis B, human papillomavirus, pneumococcus, rabies, rotavirus, typhoid, diphtheria-tetanus-pertussis, measles-mumps-rubella, polio, varicella, yellow fever, plague, Japanese encephalitis, *Haemophilus influenzae* type b, diphtheria-tetanus-pertussis/*Haemophilus influenzae* type b, diphtheria-tetanus-pertussis/polio, MenCY/*Haemophilus influenzae* type b vaccinations. ‡Per increase of 1 visit. §Per \$1 per person per month increase. MenCY indicates meningococcal serogroups C, Y.

as such, vaccine administration fees are billed to Medicaid. These vaccine administration fees are not vaccine-specific, which limited our ability to determine which vaccine an individual with a VFC-sponsored vaccine received, so we may have underestimated vaccinations in the Medicaid population.

CONCLUSIONS

Completion rates were suboptimal for both MenB vaccines. However, completion rates were significantly higher among individuals who initiated MenB-4C versus MenB-FHbp vaccines, and the time to series completion was shorter, reflecting the dosing schedule of MenB-4C, which allows for administration of the second dose at any interval ≥ 1 month after the first. This study also showed a substantial number of potential missed opportunities for completion in both the Commercial and Medicaid populations. To ensure optimal effectiveness of MenB vaccines, it is critical to implement interventions to improve completion rates and reduce potential missed opportunities.

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