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ORIGINAL PAPER

Outcomes from the Use of Targeted Interventions to Increase Meningococcal Vaccination Rates in a Pediatric Clinic

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Abstract

Background Meningococcal disease is a life-threatening illness that can cause sequelae such as neurological impairment, hearing loss, seizures, limb amputations, and scarring. Adolescents and young adults are at highest risk for contracting this disease which comes with a case-fatality ratio of 10–15%. Common serogroups in the United States are B, C, W, and Y, which are covered by two separate vaccines administered in a two-dose series. While MenACWY is routinely administered, the booster dose is often missed. Only 21.8% of teens reported receiving the MenB vaccine. While it is not currently part of routine care, recent outbreaks have been caused by serogroup B, prompting the need for increased vaccination rates.

Methods MenACWY and MenB vaccination rates and demographic information were collected for 16–19-year-old patients in a pediatric clinic. Interventions including staff education, call logs, EMR communications to parents/guardians, and careful chart review were employed.

Results At the time of baseline MenACWY data collection, there were N = 333 subjects between 16 and 19 years of age and N = 335 subjects between 16 and 19 years of age provided for MenB data. Upon completion, there were N = 319 subjects. Comparison of pre- and post-intervention data demonstrated a statistically significant increase in MenACWY series completion from 67.3 to 76.2% (p = 0.035) and a non-statistically significant increase in MenB completion from 6.9 to 10.3% (p = 0.197).

Conclusions There was a statistically significant improvement in MenACWY but not MenB vaccination rates, indicating a need for more effective measures in addressing low MenB coverage.

Keywords Meningococcal disease · Meningococcal vaccination · Adolescent vaccination · MenACWY · MenB

Introduction

Meningococcal disease is a rare but life-threatening illness caused by the bacteria *Neisseria meningitidis*. This disease can manifest as septicemia and/or meningitis and has the potential to cause devastating, lifelong sequelae. It also carries a frightening case-fatality ratio of 10–15% [1]. Adolescents and young adults are the primary carriers of this pathogen and are commonly the ones affected by this debilitating illness, which may ultimately result in death [1]. The most common meningococcal serogroups that cause disease in the United States are serogroups B, C, W, and Y [2]. Those affected by meningococcal disease may present first with non-specific symptoms such as pharyngitis, fever, nausea, vomiting, loss of appetite, headaches, and coryza. 30–60% of those with invasive meningococcal disease will develop meningitis, an inflammatory response within the subarachnoid space. This causes symptoms such as fever, neck stiffness, photophobia, headache, and vomiting. Some patients will also present with seizures or a rash. The other common presentation of invasive meningococcal disease is septicemia. Signs of septicemia include lower limb pain, skin pallor, and a petechial/purpuric rash, which is seen in

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40–80% of cases. If the disease progresses, affected individuals will develop hypotension and subsequent confusion due to hypoperfusion of the brain. 12% of affected patients will develop signs and symptoms of both meningitis and septicemia [1]. 10–15% of individuals with invasive disease die, while 10–20% of survivors suffer from long-term, disabling sequelae including neurological impairment, hearing loss, limb amputations, chronic pain, seizures, and skin scarring [1]. Amputations of digits and/or limbs may be necessary due to overwhelming necrosis of skin, muscle, and bone. Skin scarring secondary to necrotic purpura can be so severe that an individual may require skin grafting [1]. This disease has the potential to disable and disfigure individuals at a young age, thus causing profound, lifelong suffering.

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of all 11–12-year-olds with the meningococcal conjugate (MenACWY) vaccine. There are two options to choose from: Menactra and Menveo. Both come in a two-dose series. The first dose should be given at 11–12 years of age, with the second or the booster dose given at age 16 (up to 18). If a healthy individual got his or her first dose at age 16 or after, a second booster dose is not needed. This vaccine protects against serogroups A, C, W, and Y [3]. Although these vaccines are protective against meningococcal disease caused by these serogroups, immunity begins to wane approximately 5 years after the first vaccination, leaving individuals mostly unprotected at their most vulnerable age [4]. According to the Enhanced Meningococcal Disease Surveillance Report in 2017, Serogroups C, W, and Y caused 143/350 cases of meningococcal disease in the United States [5]. In 2018, 86.6% of teens ages 13–17 reported receiving 1 dose of the MenACWY vaccine. However, only 50.8% of those teens reported receiving the second booster dose [6]. There have been ten United States university outbreaks of serogroup B meningococcal disease since 2013 [7]. Unfortunately, the meningococcal vaccine that is routinely administered to adolescents ages 11–18 only covers serogroups A, C, W, and Y. Therefore, thousands of college students were vulnerable to developing meningococcal disease caused by serogroup B during these outbreaks, causing the FDA to expedite approval of the MenB-Fbp vaccine (Trumenba) in 2014 and MenB-4C vaccine (Bexsero) in 2015. However, current ACIP recommendations are to only provide routine MenB vaccination to high-risk groups, which include individuals with complement deficiencies (including those on eculizumab and ravulizumab-cwvz), hypo- or asplenia, microbiologists who are constantly exposed to *N. meningitidis*, and those in an area where there is an outbreak. ACIP provides a category B recommendation for healthy individuals who are not at increased risk, leaving the ultimate decision up to shared clinical decision making [3]. This poses significant obstacles to establishing adequate MenB vaccination coverage. Since this is not a routinely recommended vaccination series, clinicians may lack adequate knowledge on the vaccine itself, as well as its importance, and may subsequently feel uncomfortable recommending it to or discussing it with their patients. Many patients rely on their physicians to be up to date on all of the newly available vaccines and provide them with that information. If an adolescent contracts meningococcal disease of serogroup B and finds out at that time that there was a preventative vaccine for this disease, this may foster distrust in that provider and the care they have previously received.

The new ACIP recommendations are as follows:

- Persons aged ≥ 10 years at increased risk for serogroup B meningococcal disease (Category A recommendation): for persons at increased risk for meningococcal disease and for use during serogroup B meningococcal disease outbreaks, 3 doses of MenB-FHbp should be administered at 0, 1–2, and 6 months to provide earlier protection and maximize short-term immunogenicity. However, if the second dose of MenB-FHbp is administered at an interval of ≥ 6 months, a third dose does not need to be administered.
- Adolescents and young adults aged 16–23 years (Category B recommendation): when given to healthy adolescents who are not at increased risk for meningococcal disease, 2 doses of MenB-FHbp should be administered at 0 and 6 months. If the second dose of MenB-FHbp is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose.
- For persons at increased risk for meningococcal disease and for use during serogroup B meningococcal disease outbreaks, ACIP recommends that 3 doses of MenB-FHbp be administered at 0, 1–2, and 6 months.
- When given to healthy adolescents who are not at increased risk for meningococcal disease, ACIP recommends that 2 doses of MenB-FHbp should be administered at 0 and 6 months [3].

The preferred vaccination age is 16–18 because antibody titers are highest 24–48 months after vaccination, which covers patients when they are most vulnerable of contracting meningococcal disease [8]. While these ACIP recommendations apply to Trumenba, the two Bexsero doses can be given four weeks apart instead of the required 6-month dosing interval that Trumenba requires.

According to the CDC Enhanced Surveillance Report in 2017, there were 134 cases of meningococcal disease caused by serogroup B, 48 of which occurred in 16–23-year-olds. More specifically, in the 18–24-year-old age group, 39 cases occurred, 31 of which were in college students. 27/39 of those students had information on the MenACWY vaccines,

and 100% had received the series. On the other hand, only 17/39 of these students had information regarding the MenB vaccines, and of those, zero received the MenB series [5]. According to the National Immunization Survey-Teen (NIS-Teen) in 2019, only 21.8% of 17-year-olds in the United States reported receiving the MenB vaccine [6]. This is astonishingly low and addresses the need for targeted intervention to increase coverage due to the increasing number of recent outbreaks being caused by serogroup B.

A study by Kempe et al. in 2016 demonstrated that only 51% of pediatricians and 31% of family practitioners reported that they "always or often" bring up the MenB vaccine with patients and families. They also found that only 73% of pediatricians were currently administering the MenB vaccine to patients, and many reported not having adequate knowledge on factors contributing to a patient's need for the vaccine [9]. From a parent's perspective, lack of knowledge about the MenB vaccine may hinder their child's ability to receive the vaccine. In a study by Basta et al., the majority of parents had not heard of the MenACWY or B vaccines [10]. Thus, there are significant knowledge gaps on both the provider and patient/parent sides of the clinical relationship, and efforts to educate physicians, patients, and their families should be taken seriously in order to increase vaccination against meningococcal disease.

Methods

Baseline meningococcal vaccination data was collected from two pediatric providers' patient lists. Male and female patients aged 16–19 years old at the time of initial data collection (July 20, 2020) were included in the study if they had been seen by their provider within the last five years. Data included how many doses (0, 1, or 2) of the meningococcal ACWY and B vaccines had been received by each individual patient. After statistical analysis of the data, a summary of the data broken down by provider was presented to the providers and clinical staff to discuss areas of improvement and intervention strategies to increase rates of vaccination against meningococcal disease. A list of patients due for one or both of these vaccines was compiled. Agreed upon interventions were clinical staff education, appointment call logs, electronic informative mailings to parents/guardians of patients due for meningococcal vaccinations, and careful chart review during appointments (Table 1). Clinical staff implemented these interventions. Follow up vaccination coverage data was pulled at 3 months to assess progress, and finally at 5 months to analyze the overall effectiveness of the interventions employed. This data was compared to national and state data for MenACWY and MenB vaccination coverage.

Results

At baseline, there were N = 333 subjects between 16 and 19 years of age provided at the time of initial data collection for MenACWY vaccination coverage data, and N = 335 subjects between 16 and 19 years of age provided for MenB vaccination coverage data.

At the time of study completion, there were N = 319 subjects. Comparison of baseline data to post-intervention data demonstrated a statistically significant increase in completion of the MenACWY series from 67.3 to 76.2% (p = 0.035) after five months of the designed intervention strategies (Fig. 1). However, for MenB, there was a non-statistically significant increase in MenB vaccination rates from 6.9 to 10.3% (p = 0.197) (Fig. 1).

Demographic analysis showed the largest increase in MenACWY two-dose coverage occurring in patients on Medicaid, from 38.4% at baseline to 43.4% after intervention (Fig. 2). The increase of vaccination coverage in African American patients was largest, from 33.9% pre-intervention, to 38.9% post-intervention (Fig. 3). The MenB completion rate nearly doubled in the Medicaid group, increasing from 4.8 to 8.5% (Fig. 4). The Hispanic patient population had the greatest increase in MenB completion rates, from 2.1 to 3.5% (Fig. 5).

Table 1 Description of interventions

Interventions utilized
Clinical staff education: 2 lunch sponsored meetings were hosted in collaboration with GSK. Information about meningococcal disease and the vaccine was reviewed, and feedback was provided on the project's progress
Call logs: a list of patients due for one or both vaccines was provided to nurses of both providers. Three call attempts for appointment scheduling were made
Electronic communication to parents/guardians: informational letters about meningococcal disease and the vaccine urging parents/guardians to schedule an appointment were sent home to patients due for one or more vaccines. Letter was sent via Epic and was available in both English and Spanish
Careful chart review: staff were urged to do chart review for every 16–19-year-old patient coming to clinic for whatever reason to ensure that the patient was fully vaccinated with MenACWY and MenB vaccines

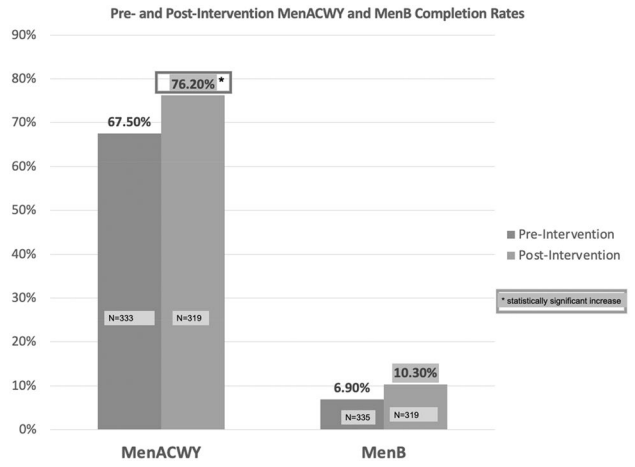

Fig. 1 Comparison of baseline data (N = 333) to post-intervention data (N = 319) demonstrated a statistically significant increase in completion of the MenACWY series from 67.3 to 76.2% (p = 0.035) after 5 months of the designed intervention strategies (in this Figure). However, for MenB, comparison of baseline data (N = 335) to post-intervention data (N = 319) demonstrated a non-statistically significant increase in vaccination rates from 6.9 to 10.3% (p = 0.197)

Discussion

According to the 2019 National Immunization Survey-Teen (NIS-Teen), 88.9% of adolescents surveyed across the nation had received ≥ 1 dose of MenACWY. However, of the 17-year-old population, only 53.7% reported receiving the booster dose of MenACWY. In Nebraska, 86.3% (CI ± 5.5) of 13–17-year-olds had received ≥ 1 MenACWY vaccine, falling below the national average [6]. A statistically significant finding was observed for MenACWY series completion (2 doses) in this study.

Nationally, 21.8% of 17-year-old adolescents received ≥ 1 dose of MenB, an increase from 17.2% in 2018 [6]. Data specific to Nebraska was not available at the time of this study. While there was a non-statistically significant increase in MenB vaccination rates from 6.0 to 10.3%, this rate is far below the national rate of 21.8%. Thus, much more work needs to be done in order to determine the most efficacious intervention strategies to increase coverage.

There were several limitations to this study, including the imbalance of patient populations between the two participating pediatric providers. One provider had a much larger cohort of patients in this age range due to starting her practice in this clinic approximately 16 years earlier than the other provider, and thus, has a larger adolescent population at this point in time. The provider that is newer to the clinic has a younger patient population. Additionally, these providers had differing levels of intervention participation by their clinical staff due to time restraints, leading to dramatic differences in vaccination coverage rates by the end of the study. For example, 3.3% of patients of the provider with a larger cohort (N = 273) had received two MenB vaccines at the beginning of the study, compared to 22.6% of the patients of the other provider with less patients (N = 62). By the end of the study, the provider with more patients demonstrated a MenB series completion rate of 6.1%, while the provider with less patients achieved a 29.8% series completion rate. Thus, the intervention strategy employed in this study may have been more effective for one provider team, and the average of these numbers does not adequately display the disparity in coverage rates. Another significant limitation to this study was the COVID-19 pandemic. Like many pediatric clinics during this time, in-person visits were significantly reduced. This posed a significant barrier in scheduling patients for vaccine appointments. Additionally, a small cohort of patients was lost by the end of the study, which was determined to be due to their age falling outside the limits of 16–19 years. Data was pulled by age, with that age being 16–19 each time. Thus, many patients who had turned 20 years old during the time of the study were left out by the last data collection. Of note, a majority of the

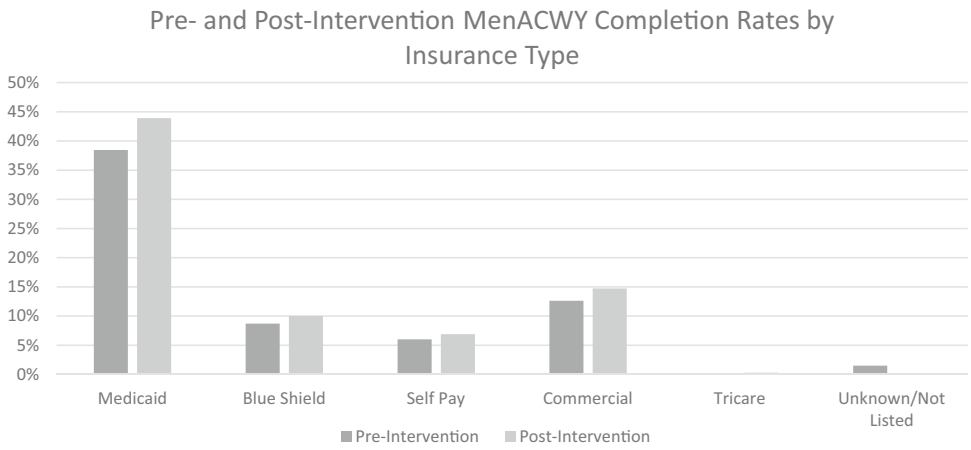

Fig. 2 Demographic analysis showed the largest increase in MenACWY two-dose coverage occurring in patients on Medicaid, from 38.4% at baseline (N = 174) to 43.4% after intervention (N = 174)

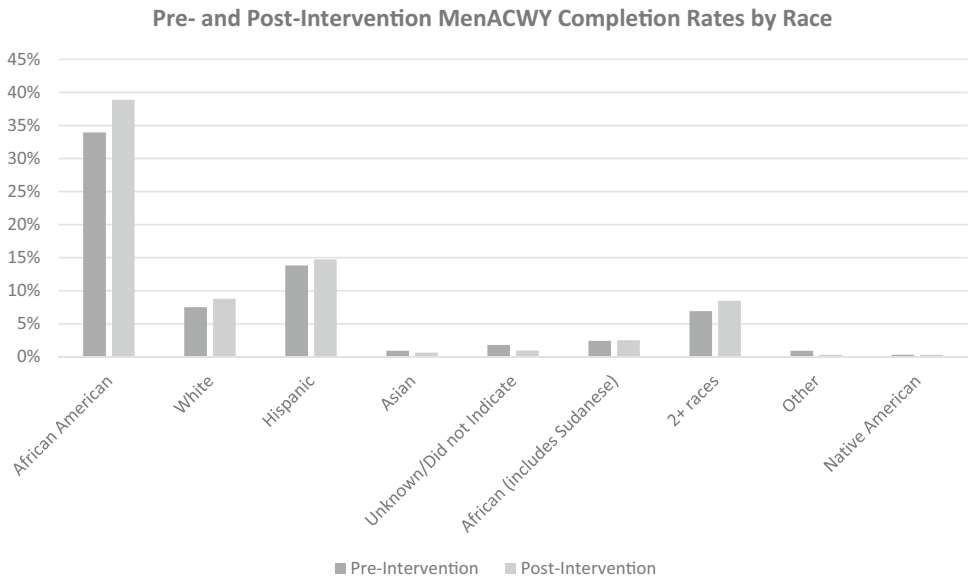

Fig. 3 Demographic analysis showed the largest increase of MenACWY vaccination coverage occurred in African American patients, from 33.9% pre-intervention (N = 168), to 38.9% post-intervention (N = 168)

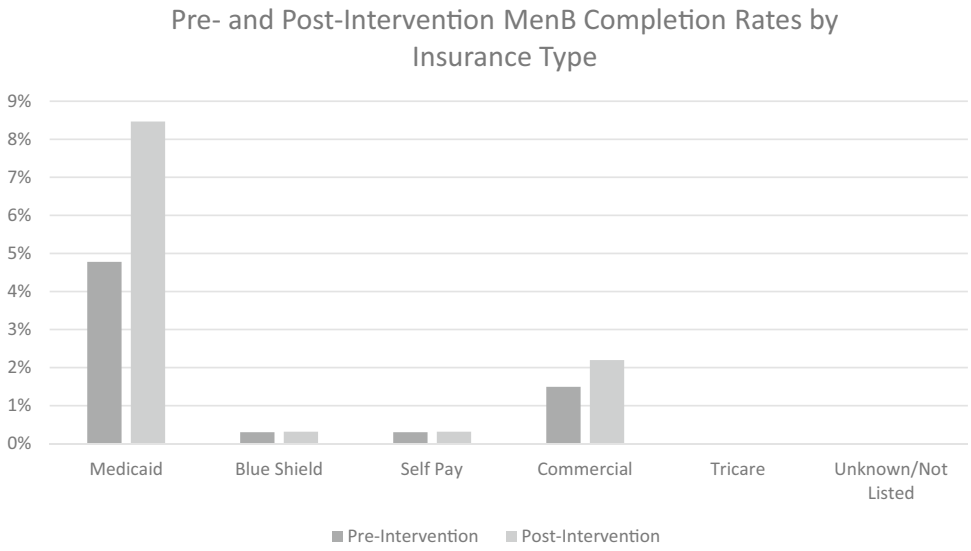

Fig. 4 Demographic analysis showed that the MenB completion rate nearly doubled in the Medicaid group, increasing from 4.8% pre-intervention (N = 174) to 8.5% post-intervention (N = 174)

patients at this clinic are from minority populations and are on Medicaid or lack any insurance coverage.

Discussions with providers and clinical staff demonstrated that full understanding of the MenB vaccine was lacking before the study began. A common misconception was that immunity from the MenB vaccine lasts only three years, when in fact, recent GSK data on the Bexsero vaccine shows that immunity can last up to 7.5 years. Operating on that misconception, providers were not motivated to vaccinate patients until they turned 18, as they were aiming to provide the greatest protection during their college years. While, theoretically, vaccinating patients at age 18 would provide the most protection, 18-year-old patients rarely show up for well child checks. Hence, the rates of MenB vaccination were very low. Operating with the new knowledge of antibody persistence up to 7-1/2 years, providers are now beginning the series with their 16-year-old patient population.

Future studies should address designing interventions that are sustainable and less time consuming for nurses and other clinical staff. A possible time conserving measure is flagging systems in the EMR to alert clinical staff to patients who are due for MenACWY or MenB vaccines. An expanded patient population should be used, encompassing patients 11–19 years of age to allow for a greater window of opportunity to administer the second MenACWY dose after the first dose is received at 11–12 years of age. Ideally, the future study would include patients with zero doses of the meningococcal vaccines to allow for greater understanding of how the interventions may influence vaccination rates. When patients who have already received one dose of the vaccine are included, it becomes unclear whether or not they

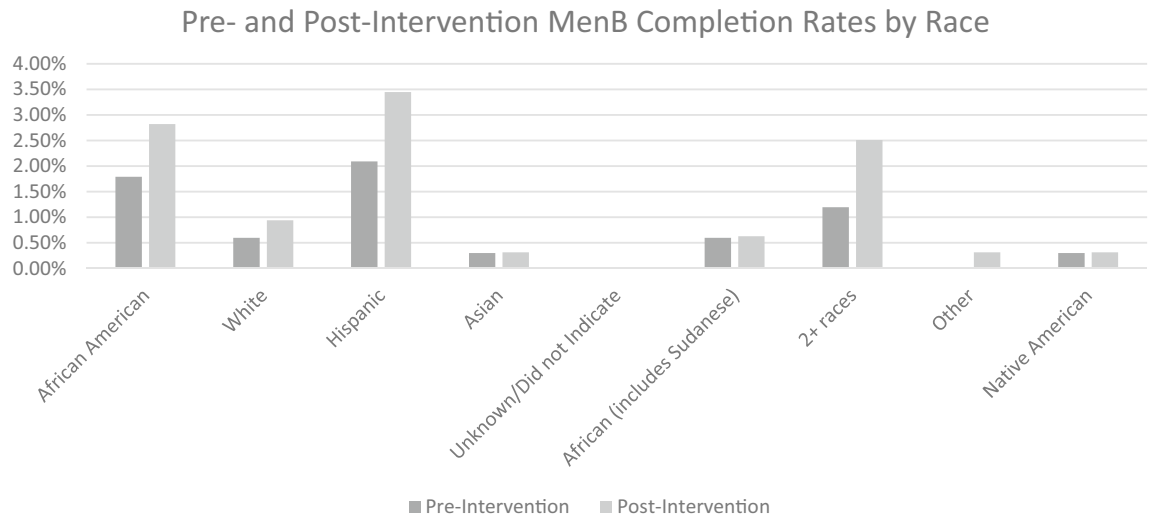

Fig. 5 Demographic analysis showed that the Hispanic patient population had the greatest increase in MenB completion rates, from 2.1% pre-internvention (N = 55) to 3.5% post-intervention (N = 55)

received the second dose due to the intervention or simply because they were due for their second dose after already receiving the first dose prior to the study.

Lastly, due to the recent college outbreaks being caused by serogroup B, it is increasingly important for universities to take action in order to prevent future deadly outbreaks. Guidelines should be addressed, emphasizing the importance of receiving the meningococcal vaccines (especially MenB) before college to provide the greatest amount of coverage during the students' most vulnerable times.

Conclusion

Overall, vaccination coverage for meningococcal disease in the United States is subpar. Although many adolescents are receiving their first dose of the MenACWY vaccine, the rates of booster dose vaccination are astonishingly low, along with the number of teens receiving the MenB vaccine since its introduction several years ago. Meningococcal disease has the potential to damage or even end the life of a young adult just entering into the world. Thus, it is critical to address the issue of meningococcal vaccination coverage in the United States as soon as possible. While current ACIP guidelines encourage shared clinical decision-making when it comes to the MenB vaccine, a trend in recent outbreaks suggests that protection against serogroup B has become increasingly important, especially for those living in close quarters, such as in college dormitories or military barracks. Both provider and parent knowledge about the importance of these vaccines is lacking, demonstrating the need for greater education about meningococcal disease and ways it can be prevented.

Author contributions Done collectively.

Declarations

Conflict of interest Drs. Vasudevan and Hudson were sub-investigators in vaccine studies sponsored by Merck & Co., Inc., GlaxoSmithKline, Pfizer, Sanofi Pasteur, and Novartis. Neither of these physicians received grants. Dr. Varman has clinical trial grants from Sanofi, Pfizer, Medimmune, Merck, and GSK. She also serves in an advisory committee for GSK and Seqirus. She did not have ay specific conflict of interests for this project.

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