Recommendations and Requirements

CHAPTER 5
Introduction

The Advisory Committee on Immunization Practices (ACIP) is responsible for creating policy recommendations on the use of vaccines and related agents for effective control of vaccine-preventable diseases. Immunization Programs are responsible for implementing new or revised ACIP recommendations in their jurisdictions. Implementing new or updated ACIP recommendations can permeate many facets of the Immunization Program, such as educating teens, parents and health care providers and updating the Immunization Information System (IIS), and Vaccines for Children (VFC) policy and procedures. Each of these items requires planning and coordination across the Immunization Program, with providers, schools, parents, and other community partners.

In addition to implementing ACIP recommendations, Immunization Programs must also implement state/local/territorial vaccination requirements. Many of the requirements are based around entry into childcare, elementary school, middle school or college, as well as participation in certain extracurricular activities like sports teams or clubs.

The activities highlighted in this chapter relate to implementation of recommendations and requirements:

- **Getting Started:** Getting a jump start on new or revised ACIP vaccine recommendations (North Dakota)
- **Moving Forward:** Implementing a new school requirement for meningococcal conjugate vaccine (New York State)
- **Taking It to the Next Level:** Updating VFC policy and school requirements for meningococcal B vaccine (Indiana)
National Resources for Immunization Recommendations and Requirements

- ACIP main website: www.cdc.gov/vaccines/acip/
- ACIP meetings: www.cdc.gov/vaccines/acip/meetings/meetings-info.html
- ACIP recommendations and guidelines: www.cdc.gov/vaccines/hcp/acip-recs/
- ACIP VFC resolutions: www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html

Child Care/School/College Vaccine Mandates

- Immunization Action Coalition (IAC) webpage on state mandates, including vaccine-specific mandates by state: www.immunize.org/laws/
- IAC webpage contains links to other resources, including state-specific exemption information and policy statements from various groups on vaccine exemptions: www.immunize.org/laws/#exempt
- National Conference of State Legislatures (NSCL) webpages on vaccines and immunizations and state legislation and statutes for HPV vaccine:
- Association of State and Territorial Health Officials (ASTHO) webpage on state legislative tracking, of which immunizations and vaccines are a subtopic: www.astho.org/state-legislative-tracking
In February 2017, the Centers for Disease Control and Prevention (CDC) updated the immunization schedule for children and adolescents, adding a separate column for age 16. The header of the “16 yrs” column is shaded similarly to the “4–6 yrs” and “11–12 yrs” column headers, and the words in the row for meningococcal conjugate vaccine (MCV4) now read “2nd dose” instead of “booster.” These changes draw attention to the need for a second dose of MCV4 vaccine at this age but also emphasize age 16 as an immunization platform.

Several groups have expressed support for an immunization platform at age 16 years, including AIM, the National Foundation for Infectious Diseases, the Society for Adolescent Health and Medicine, and the Adolescent Immunization Initiative. This platform will help establish age 16 as a milestone for receiving vaccinations, as well as, provide guidance and other elements of preventive care relevant for older teens.

The expected benefits of an age-16 platform from an immunization standpoint include:

+ administering an on-time second dose of MCV4;
+ providing an opportunity to discuss and/or administer meningococcal B (MenB) vaccine;
+ reviewing and addressing the need for seasonal influenza vaccine and catch-up doses of other vaccines (e.g., human papillomavirus (HPV), varicella, hepatitis A, and hepatitis B vaccines); and
+ ensuring that vaccines are given while adolescents are still VFC eligible or covered by parental insurance.

Immunization Programs play a critical role in supporting efforts to increase immunization rates in older adolescents, such as educating providers and families of the importance of immunization at this age, promoting use of reminder/recall, and implementing new school requirements.
AIM Adolescent Immunization Webinar

AIM hosted a webinar featuring the UNITY Consortium that focused on adolescent health and immunization beliefs, as well as resources for helping providers give a strong recommendation for adolescent vaccines.

www.immunizationmanagers.org/AdolZWebinarApr2017
Observations from an AIM Focus Group on Adolescent Immunization

This information is based on feedback from a focus group consisting of seven Immunization Program Managers. The group discussed opportunities and challenges in promoting adolescent vaccination, especially a 16-year-old platform, and the critical role for Immunization Programs. Additional information about the focus group is available in an issue brief published in the Journal of Public Health Management and Practice: https://aim.site-ym.com/resource/collection/89656EA4-3D74-4555-9458-87BA784AD961/Clark_et_al_JPHMP.pdf

Potential Strategies for Improvement:

**IMMUNIZATION PROGRAMS SUPPORTING PROVIDERS**

**ADOLESCENT WELL VISIT**

✚ Consider sending notices about school immunization requirements in early spring or throughout the year instead of the end of the school year. Sending adolescent reminder/recall notices throughout the year may increase awareness about the 16-year-old platform.

**IMMUNIZATIONS AND NON-TRADITIONAL PROVIDERS**

✚ Share materials with provider organizations for inclusion in their newsletters to educate providers about adolescent immunization and the new 16-year-old platform.

✚ Work with internal partners in dental health and STD prevention to expand the reach of adolescent immunization promotion beyond primary care providers.
Immunization Programs Tracking Adolescent Vaccination Rates

Potential Strategy for Improvement:

STATE-LEVEL ADOLESCENT IMMUNIZATION RECORDS

- Encourage CDC partners to expand NIS-Teen to measure MCV booster dose coverage at age 16 on a state by state basis.
- Share local coverage rate estimates to encourage reporting of adolescent data and heighten visibility of adolescent immunization, including the 16-year-old platform.

Immunization Programs Educating the Public

Potential Strategy for Improvement:

EDUCATIONAL MATERIALS FOR OLDER TEENS

- Develop information packets to address transition to early adulthood; emphasize adolescent responsibility for their own health care and the importance of receiving immunizations while still covered by VFC or parents’ insurance.
- Keep the audience in mind when creating information packets by using content and images relevant to older teens, eg, sports physicals, or driver licensing.

Potential Strategy for Improvement:

LIMITED BUDGETS

- Use digital advertisements at high school sporting events to promote immunization in this demographic.
- Create educational slide deck presentations on immunizations and on STDs for health education teachers to use in their classrooms.
- Encourage and work with national partners to produce adolescent immunization campaigns.

Immunization Programs Addressing School Requirements

Potential Strategy for Improvement:

EDUCATING PARENTS

- List all vaccines recommended for adolescents, not just those required for school, in communication to parents about school requirements.
- Have reminder/recall notices refer parents to providers or public health departments to identify needed vaccines, rather than listing specific vaccines.

Overview of activity
The North Dakota Department of Health Immunization Program Manager listens to ACIP meetings via the CDC webcast link (www.cdc.gov/vaccines/acip/meetings/webcast-instructions.html) to quickly disseminate to providers information related to new or revised immunization recommendations and begin planning programmatic adjustments.

Ages targeted
All adolescents (no specific ages)

Background/impetus for the activity
When the ACIP makes a new or revised vaccine recommendation, Immunization Programs must disseminate this information to their providers and make decisions about the adjustments needed in program processes (eg, IIS forecasting) and educational materials. North Dakota Immunization Program’s approach is described using two recently revised ACIP adolescent vaccine recommendations as examples:

- In June 2015, ACIP revised its recommendation for MenB vaccine, expanding from the existing recommendation for routine use in certain medically at-risk populations and outbreaks, to also include a “permissive” recommendation for individuals aged 16 to 23 years of age, with a preference for vaccination at 16 to 18 years.
- In October 2016, the ACIP lowered the recommended number of HPV vaccine doses from 3 to 2 doses for adolescents who initiate the vaccination series by aged 14 years.

Description of activity
When a new or revised vaccine recommendation is scheduled for discussion at an ACIP meeting (held three times per year), the Program Manager listens to the relevant portions of the live meeting webcast. After the meeting, the Program Manager writes a brief summary of the recommendation and related ACIP discussion. This summary is shared with program staff and is sent to the program’s public and private VFC providers.

The Immunization Program staff internally discusses what needs to be done in response to the recommendation, including revising or developing educational resources and making changes to the North Dakota Immunization Information System (NDIIS). The program also solicits feedback from the state Immunization Advisory Committee (NDIAC), especially from provider members regarding how they expect to implement the recommendation and any potential issues they foresee.

Changes to NDIIS may be needed to reflect new or updated ACIP recommendations such as revisions to the vaccine ordering system, forecasting algorithm, reminder/recall protocol, and algorithm for generating coverage rate reports. Changes to the forecasting algorithm take the longest to implement, as they are done by an outside vendor that supports IIS forecasting in several states. The program pays the vendor a flat annual maintenance fee.
for their services, so ACIP recommendation changes do not affect cost to the program for forecaster revisions.

Some of the decisions and issues specific to the new MenB permissive recommendation addressed by the Immunization Program include:

- The Immunization Program recommends to its providers that they keep some MenB vaccine in stock, even if they do not plan to routinely recommend the vaccine, in case of patient/parent request.
- The program sought feedback from the NDIAC on how to address MenB vaccine forecasting in the NDIIS, given that it is a permissive recommendation and NDIIS cannot forecast a permissive recommendation differently than a routine recommendation. The options were to forecast MenB vaccine either for all adolescents aged 16 to 23 years or only for those adolescents who received a first dose (ie, forecasting subsequent doses). The NDIAC decided to have NDIIS forecast the vaccine for all adolescents, in part to prompt providers to discuss the availability of the vaccine with patients and parents.
- The NDIIS forecaster had to take into account that the two available MenB vaccine products were not interchangeable and initially had different schedules. NDIIS forecasts the next dose as the same brand as the first dose received; if the other brand is used for the next dose, then the forecaster will show that additional dose(s) of that brand are needed.
- The program decided not to include MenB vaccine in its quarterly reminder/recall of adolescents aged 12 to 17 years, because nearly every adolescent aged 16 to 17 would be included. This would be costly, and because the vaccine is not routinely recommended for all adolescents, it could also be confusing to parents.

Some of the decisions and issues specific to the revised HPV recommendation addressed by the Immunization Program include:

- The Immunization Program decided to exclude HPV from its quarterly adolescent reminder/recall efforts until the forecaster is ready, because the program does not want to recall adolescents for a third dose who are no longer recommended to receive one.
- The program will change how it calculates and reports HPV coverage rates, which affects the coverage rate reports that it posts on its website as well as those that are generated for quarterly provider site rate report cards and AFIX visits.

Role of Immunization Program and other agencies/groups involved
The Immunization Program is responsible for implementing new or revised ACIP recommendations in the state and disseminating relevant information to public and private immunization providers. The North Dakota state chapters of the American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) are not as active as in other states, so the Immunization Program is the main resource for providers (other than for those in large health systems).
Dissemination
The Immunization Program uses its VFC provider listserv to communicate guidance on new and revised ACIP recommendations to its providers. Other dissemination tools include monthly “Lunch and Learn” webinars, a quarterly newsletter, and biennial immunization conferences. Non-VFC providers are more difficult to reach, but they also may attend the lunchtime programs and the state immunization conference. The program also reaches out to various associations (eg, Pharmacy Association, Long Term Care Association, NDAAP) to provide education at their conferences. The Immunization Program also notifies North Dakota Medicaid of changes/additions to ACIP recommendations to ensure rapid coverage on the Medicaid formulary.

Intersection with other program activities
New or revised ACIP recommendations must be integrated into all of the program’s activities relevant to the recommendation, including parent and provider education efforts, NDIIS, and VFC policy and procedures.

Funding
This activity is funded as part of the Immunization Program’s CDC cooperative agreement.

Staffing
All staff are involved in implementing new or revised ACIP recommendations as part of their normal duties. The Immunization Program Manager listens to and summarizes relevant ACIP meetings. All staff members are trained to address questions and answers/calls to the program’s toll-free number, and an increased amount of staff time is devoted to answering the increased volume in calls following a recommendation change. NDIIS staff test the vendor’s forecaster changes before putting it into production.

Implementation status
This activity occurs as needed, ie, whenever ACIP updates vaccine recommendations.

Successes
- Listening to the ACIP discussion related to new or revised recommendations can provide a deeper understanding of the issues and rationale, which is helpful for addressing provider questions.
- The program has a very small staff; training all staff to answer provider questions helps improve their own understanding of the recommendation and distributes the workload of responding to provider calls.
- The NDIIS uses CDC’s Clinical Decision Support for Immunization (https://www.cdc.gov/vaccines/programs/iis/cdsi.html), which has reduced the amount of staff time to provide cases for the immunization forecaster to the vendor. Additionally, all Immunization Program staff test forecaster changes in the NDIIS test environment, which ensures issues are identified prior to production.

Challenges
- Permissive recommendations, such as for MenB vaccine, generate a high volume of provider calls with questions and requests for guidance, which require extra communication and call response by the program. To help providers make their own decisions, the program explains the rationale for the recommendation being permissive rather than routine.
- Permissive recommendations can lead to differential implementation across providers.
For example, the largest health system in North Dakota has its own immunization advisory committee, which decided to routinely recommend MenB vaccine for all of its patients aged 16 to 23 years. Interpretation of MenB vaccine coverage data will need to take into account these differences.

- Addressing recommendations for vaccines with more than one brand that are not interchangeable is more challenging, such as for MenB vaccine. IIS forecasting must take into account that a person who receives two different brands will require additional doses. Also, providers do not want to stock multiple brands in their offices. In addition, availability was an issue for one of the MenB vaccine brands after its FDA approval and ACIP recommendation.

- Providers do not usually like to implement ACIP recommendations until they are published in Morbidity and Mortality Weekly Report (MMWR), but the CDC encouraged immediate implementation of the 2-dose HPV recommendation. This led to a lot of questions and confusion among providers.

- When changes to IIS forecasting algorithms are complicated, such as for the 2-dose HPV vaccine recommendation, it can take several months for the vendor to complete the revisions. Providers generally follow the NDIIS forecaster, so although the recommendations changed for HPV vaccine, since the forecaster wasn’t updated immediately, providers continued to administer three doses. The program develops guidance materials for providers in the interim, such as an HPV vaccine algorithm flowchart that it posted on its website.

**Other lessons learned/Advice to other programs**

- Participating in meetings at which new and revised recommendations are discussed (e.g., ACIP meetings and AIM calls that occur after ACIP meetings) helps programs to stay informed. Providers should not hear about ACIP updates before the Immunization Program. Also, it can take up to 90 days for ACIP meeting minutes to be published online, so listening to the webcasts is the fastest way to get the information.

- It is helpful to review ACIP meeting agendas beforehand to identify the specific items of interest. The meetings last two days and it is not usually feasible to listen to the entirety.

- IIS staff should be included in conversations about upcoming or recent ACIP recommendation changes so that the IIS can be updated in as timely a manner as possible.

**Relevant resources**


- North Dakota Lunch and Learns: [www.ndhealth.gov/Immunize/Providers/Education.aspx](http://www.ndhealth.gov/Immunize/Providers/Education.aspx)


**For more information**

North Dakota Department of Health
Immunization Program
(701) 328-3386
“One of our most successful strategies involving older adolescents (age 16–18 years) was revising school requirements to include the second dose MCV4 and the HepA vaccines for high school seniors—which in turn creates a platform for HPV and MenB administration.”

— David McCormick, Indiana Program Manager
Overview of activity
In response to a new school-entry requirement affecting adolescents, the New York State Department of Health Bureau of Immunization took a variety of steps to support its implementation.

Ages targeted
Public and private school students entering grades 7 and 12.

Background/impetus for the activity
In New York State, new school immunization requirements must be added by the state legislature; then regulations consistent with statutory requirements may be revised or promulgated. In June 2015, the state legislature passed a bill to require meningococcal vaccine for students entering grades 7 and 12, effective Sept. 1, 2016. The bill was signed into law in October 2015. The New York State Department of Health Bureau of Immunization was not involved in initiating the new law, but did support the bill. Once the bill passed, the Bureau took many steps to ensure smooth implementation of the new requirement.

Description of activity
Once the bill passed the legislature, the Immunization Bureau began drafting amendments to the public health regulations related to school immunization requirements. To amend the regulations, the Bureau referred to language used for prior school immunization requirements and to the ACIP recommendations. Although the law refers generally to “meningococcal vaccine,” the requirement is written specific to meningococcal conjugate vaccine (MCV4). For the 2016-2017 school year, one dose of MCV4 is required before grade 7 and a total of two doses are required before grade 12 (unless the first dose was received on or after a student’s 16th birthday). The one-dose MCV4 requirement steps up a grade each year (eg, for the 2017-2018 school year, one dose is required for entry into both grade 7 and 8).

Soon after the bill was passed, the Bureau sent a letter to health care providers and schools that included basic information on the new requirement, so they could prepare for its implementation. A second letter was sent as a notification of the 45-day public comment period for the proposed regulation and to provide more detail on the requirement.

The Bureau looked at MCV4 coverage rates in both NIS-Teen and the New York State IIS (NYSIIS). In 2014, NIS-Teen data, the New York State-specific rate for one dose at aged 13 to 17 years was comparable to the national average (75% vs 79%, respectively, with overlapping confidence intervals), while the rate for two or more doses at aged 17 (available at the national level only) was 29%; NYSIIS rates were similar. The Immunization Bureau also developed and ran various test scenarios (eg, unusual schedules) in NYSIIS to anticipate implementation issues. The Bureau used these data to create outreach materials designed to increase awareness of the second dose recommendation.
To educate health care providers, school staff with immunization-related responsibilities, and parents about the new requirement, the Immunization Bureau:

- Updated a chart prepared annually for schools that summarizes and explains school-entry requirements (April 2016)
- Developed frequently asked questions (FAQs) documents for both health care providers and schools (April 2016)
- Held a webinar for health care providers discussing the new school immunization requirement, the ACIP recommendations, and best practices for getting adolescents immunized (January 2016)
- Held a webinar for schools focused on the new school immunization requirements and how to implement them (March 2016)
- Created a flyer for parents (see image at left) that was posted on the Bureau’s website and made available to schools and health care providers as parent handouts; it was translated into five languages (January-February 2016)
- Developed a new website specifically focused on the meningococcal school requirement (January-February 2016)
- Conducted a media campaign (February-May 2016) with television, radio, digital, and social media messaging, as well as a smaller online campaign in Summer 2016 for a back-to-school reminder
- Distributed copies of the parent flyers to local health departments (LHDs) during an annual meeting (March 2016) and asked them to hand deliver them to health care providers

To monitor uptake and compliance with the new requirement, the Bureau monitors MCV4 coverage in NYSIIS and plans to look at data from its Annual School Survey.

Role of Immunization Program and other agencies/groups involved

The Bureau was responsible for amending the regulations, developing and sending materials to health care providers and schools, and setting up NYSIIS to monitor coverage rates. These regulations were adopted in accordance with the requirements in the New York State Administrative Procedure Act (SAPA).

Throughout the process the Immunization Bureau worked very closely with the State Education Department, especially on the language of the regulations. The Bureau also worked with the New York City Department of Health and Mental Hygiene, which is a separate CDC awardee but is covered by the same statewide school requirements, on the wording of the new regulations and supporting materials. Together the three parties held a number of calls with the state association representing private and parochial schools to inform and gather feedback from its members on the new requirement.

The Bureau also worked with its LHD partners, who have in-depth knowledge of their school populations. The LHDs worked closely with schools in their jurisdiction to support efforts to get adolescents immunized.
The media campaign was managed internally through the state’s Bureau of Marketing and Creative Communications, a division of the Public Affairs Group. They created the advertisements and contracted with a video production company to produce the video advertisement, and with a media buyer for advertising placement. Printing of materials was done in house. Bureau staff conducted the webinars.

**Dissemination**

The Bureau disseminates information about new school immunization requirements to providers and schools through existing listservs, by posting on its public web page, and through the state’s health commerce system (HCS); HCS accounts are required for all schools and medical professionals.

**Intersection with other program activities**

Addressing the new school immunization requirement overlapped with the regular duties of the Immunization Bureau’s NYSIIS and school assessment staff.

**Funding**

The media campaign was largely supported by state funds, with support for staff time and a small amount for the media campaign supported by the Bureau’s CDC cooperative agreement.

**Staffing**

Key staff members involved included the Immunization Program Manager, the Bureau’s Adult and Adolescent Immunization Coordinator and School Assessment Coordinator, NYSIIS staff, and the Division of Legal Affairs.

**Implementation status**

The media campaign has ended, although the Bureau will continue social media postings (e.g., Facebook, Twitter) during back-to-school time. The Bureau conducts an annual webinar on school requirements for the upcoming school year, which is usually held in March for the start of the school year in the fall. The Immunization Bureau also annually updates materials such as the immunization chart and FAQs documents.

**Successes**

- It was helpful for the Immunization Program to have nearly a year’s head start from the time when the bill initially passed the legislature to the date of implementation.
- Based on feedback from school nurses, the lead time gave them ample time to screen students’ records in NYSIIS and alert parents that doses were needed.
- The parent flyer has been well received by parents and schools. Also, several Immunization Programs have asked permission to adapt the flyer for their own school requirements. The Bureau also received positive feedback on the media campaign and webinars.
- The LHDs were an important partner. Many were very proactive in holding clinics in the schools, working closely with schools to promote clinics in other locations, and extending their usual immunization clinic hours. They vaccinated large numbers of adolescents in a short period of time to ensure that they met the new requirement.
- NYSIIS has been a great tool to monitor progress, and NYSIIS coverage data are encouraging. As of December 2016, coverage of one dose had improved 8 percentage points from the prior year. For students in grade 12, looking at either two doses or one dose at aged 16 years or older, coverage had increased by 28 percentage points, which far exceeded the Bureau’s expectations.
Challenges

- The Bureau was surprised by the number of calls it received regarding adolescents who had received two doses of MCV4 prior to aged 16 (which means they needed a third dose). The Bureau thought this would be a rare situation related to medical indications. The issue seems to be that some providers gave the first dose earlier than aged 11 to 12 years and then gave the second dose 5 years after that, prior to aged 16.

- Most public schools have school nurses, but private schools often do not have any medical personnel on staff. NYSIIS indicates whether doses are valid or invalid and whether the series is complete, but if a student’s information is incomplete in NYSIIS or the school does not use NYSIIS, nonmedical staff may have difficulty interpreting whether students meet the requirement.

- There were some concerns about students in grade 12 potentially not qualifying to graduate if they missed too many days of school due to noncompliance with the meningococcal vaccine requirement. The second MCV4 dose is challenging in part because students are not required to receive a physical for grade 12, and older adolescents often do not routinely visit a health care provider other than the subset requiring sports physicals. Anticipating this challenge, the Bureau sent information to providers specific to the second dose in February 2016, including the rationale for the second dose recommendation and helpful handouts from the Immunization Action Coalition’s Give2MCV4.org project. These materials were well received.

- The Tdap (grade 6) and MCV4 (grade 7) school-entry requirements are required at different grades. Therefore, guidance and clarification about this was provided to schools, providers, and parents.

- NYSIIS does not record a student’s grade level, so age is used as a proxy for calculating coverage rates in NYSIIS. For students in grade 7, the proxy is ages 12 years and 0 days to 12 years and 364 days, with a similar range for 17-year-olds representing 12th graders, understanding that some children in those groups are actually in the grade above or below.

- While the law refers to “meningococcal vaccine” generally, the Bureau specifies in its materials that the MenB vaccine may not be substituted in place of the required MCV4 vaccine.

Other lessons learned/Advice to other programs

- Engage partners (e.g., providers, schools, LHDs) as broadly and early as possible. The more time they are given to prepare for new school requirements, have their questions answered, and disseminate information to parents, the less chance that the requirements take anyone by surprise.

- When preparing for implementation of new school requirements, it is helpful to add more staff, if possible, to handle incoming calls. The Bureau experienced very high call volumes in the summer and fall, even with all the materials that were disseminated.

- Keep an eye on vaccine supply. The Bureau notified its VFC providers in early summer, to encourage them to have an ample supply of meningococcal vaccine in stock. With the recent emphasis on reducing wastage, providers are sometimes too conservative in their vaccine orders. There were occasional concerns about providers running out of vaccine, but for the most part, the Bureau believes this messaging was effective.

- IIS can be very helpful to support new school requirements, such as to explore potential implementation issues and monitor the impact on coverage rates.
Relevant resources

- School and provider materials related to the new school requirement:
  www.health.ny.gov/prevention/immunization/schools/school_vaccines/
- Flyer for parents on new requirement:

For more information
New York State Department of Health
Bureau of Immunization
(518) 473-4437

Program Practice Interviews
Dr. Elizabeth Rausch-Phung (NY) discussing the program’s implementation of a new school requirement for meningococcal vaccination for students entering 7th and 12th grades.

www.immunizationmanagers.org/PPInterviewNYS
Overview of activity
The Indiana State Department of Health Immunization Program implemented a requirement for VFC providers to stock MenB vaccine and planned to require or recommend the vaccine for incoming students in grade 12.

Ages targeted
Adolescents aged 16 to 18 years

Background/impetus for the activity
In June 2015, the ACIP revised its recommendation for MenB vaccine, expanding from the existing recommendation for routine use in certain medically at-risk populations and outbreaks, to also include a “permissive” or Category B recommendation for individuals aged 16 to 23 years, with a preference for vaccination at 16 to 18 years of age.

Description of activity
As with any change in vaccine recommendations, the Indiana Immunization Program responded to the MenB permissive recommendation by reviewing information about the vaccine and disease incidence in the state, the language of the ACIP recommendation, the state administrative code relevant to vaccines, and VFC program policies. Based on the VFC provider agreement, which states that providers must offer all ACIP recommended vaccines and makes no distinction between Category A versus Category B recommendations, the program’s interpretation was that VFC providers must stock MenB vaccine. In addition, the program wanted to minimize missed opportunities and felt that the ACIP language regarding “individual clinical decision” signified that a provider should administer the vaccine if they determine that a patient needs or wants the vaccine. The program also checked with the Indiana Department of Insurance and its Medicaid program to ensure that the MenB vaccine and an administration fee would be covered by insurance. Taking all of this information into account, the Immunization Program communicated to its VFC providers that they must stock the MenB vaccine and discuss MenB with all patients aged 16 to 18 years. The program communicated multiple times with providers about the new requirement and asked them to comply within 60 days.

The Immunization Program requires providers to stock at least one box of 10 doses, unless they can show proof that they would not see at least five patients aged 16 to 18 years in a 2-year span. A few providers with eligible patient populations that did not stock MenB vaccine were suspended from the VFC program. Due to the cost of MenB vaccine, the program asks providers to stock only one of the two brands. However, the program does require LHDs or other providers with documented patients to carry both products. For example, providers who are attempting to do catch up college students (up to aged 19 years) in their county.

With respect to school requirements, the program has a committee that discusses changes to school requirements. The committee was aware that the MenB vaccine was in the pipeline, and the program started informing schools that MenB vaccine could be required for school
The Immunization Program does not need legislative approval to update the list of vaccines required for school entry but must give 2 years’ notice of new requirements. The program is required to release the 2-year schedule every November, showing new requirements as recommended for the upcoming year, and as required for the following year. For example, MenB vaccine for incoming seniors is recommended for the 2017-2018 school year and required in the proposed 2018-2019 schedule (see image above). This requirement complements the existing grade 12 requirement for a second dose of MCV4 vaccine and a new requirement for Hepatitis A (HepA) vaccine in grades 6 and 12. The congruence of dose spacing between the HepA, HPV, and MenB vaccines enhances the program’s efforts to spur vaccine series completion among adolescents.

The program received significant provider pushback on the MenB school requirement. Providers felt the state was overriding “individual clinical decision” and going over and entry at some point in the near future. When the ACIP issued a permissive recommendation, the committee first decided to not include MenB as a school requirement. However, the committee then reviewed the relevant state administrative code, which is broadly written to say that all school-aged children shall be protected against “meningitis,” which would include MenB disease.

The Immunization Program does not need legislative approval to update the list of vaccines required for school entry but must give 2 years’ notice of new requirements. The program is required to release the 2-year schedule every November, showing new requirements as recommended for the upcoming year, and as required for the following year. For example, MenB vaccine for incoming seniors is recommended for the 2017-2018 school year and required in the proposed 2018-2019 schedule (see image above). This requirement complements the existing grade 12 requirement for a second dose of MCV4 vaccine and a new requirement for Hepatitis A (HepA) vaccine in grades 6 and 12. The congruence of dose spacing between the HepA, HPV, and MenB vaccines enhances the program’s efforts to spur vaccine series completion among adolescents.

The program received significant provider pushback on the MenB school requirement. Providers felt the state was overriding “individual clinical decision” and going over and
above the ACIP/CDC recommendation. The state chapter of the AAP also did not support the requirement. After substantial discussion, both parties agreed the program will change the 2018-2019 requirement to a recommendation with documentation of parent refusal after consulting with a physician.

**Role of Immunization Program and other agencies/groups involved**

The Immunization Program determines and implements changes to its VFC provider policies so they are consistent with new ACIP recommendations, and develops new school requirements in conjunction with its school requirements advisory committee. The committee usually meets in July to discuss current recommendations and then solicits comments. Participants on this committee include the Indiana Immunization Coalition, the Indiana Department of Education, the Indiana School Nurses Association, and one or two provider representatives (typically a LHD and a private provider). Based on the program’s discussions with the state chapter of the AAP on the MenB vaccine school requirement, a member of the AAP state chapter will now also sit on this committee.

**Dissemination**

The program communicated information about the MenB VFC policy and related educational materials to providers via the program’s monthly newsletter, email blasts, and mailed letters. School requirements are sent to each school corporation operating in the state via the superintendent and school nurse. School requirements are also sent to health care professionals through the Indiana Professional Licensing Agency.

**Intersection with other program activities**

The MenB VFC policy change occurred during influenza season, during which the program has frequent interactions with providers. The program used these opportunities to discuss the MenB vaccine, such as clearing up confusion between the MCV4 and MenB vaccines. The program also uses influenza vaccine orders as a compliance tool. The program has put a hold on providers’ influenza vaccine orders to ensure compliance with IIS reporting, dose-level accountability, and stocking of VFC vaccines, including MenB vaccine.

The Immunization Program added information on MenB vaccine into its vaccine training workshop (“Immunizations from A to Z”), which providers are encouraged to complete at least once every 2 years.

The Indiana system IIS, known as CHIRP (Children and Hoosier Immunization Registry Program), was updated for MenB ordering and forecasting. However, MenB vaccine is not yet included in the program’s centralized reminder recalls. The program is making changes to the IIS to accept parent refusal information via HL7 messaging, instead of via manual entry, in case the MenB school requirement is revised per the agreement with the state chapter of the AAP.

**Funding**

Program activities related to the VFC policy change and school requirements for MenB vaccine are funded through its CDC cooperative agreement.

**Staffing**

Program activities related to the VFC policy change and school requirements for MenB vaccine involve the Program Manager, VFC coordinator, and IIS staff. In addition, the chief nurse consultant acts as the program’s liaison with school nurses.
Implementation status
The VFC policy for MenB vaccine is in place. MenB is not a required vaccine for school, but it is still on the school vaccine chart as recommended.

Successes
- Between January and June 2016, the proportion of VFC providers stocking MenB vaccine increased from less than 10% to more than 90%, and the number of doses administered per month went from fewer than 500 to more than 2,500 doses.
- Using influenza vaccine orders as a compliance tool has been successful because providers are highly motivated to have influenza vaccine in stock. (Influenza vaccine orders have been held for 43 providers)
- Discussions with the state chapter of the AAP regarding their concerns with the MenB vaccine school requirement led to a unique compromise solution and strengthened this partnership going forward.

Challenges
- In its initial communications with providers about the requirement to stock MenB vaccine, the program did not take into account that some providers do not see patients aged 16 to 18 years. After pushback from these providers, the program adjusted the requirement to exclude providers who could provide evidence that they did not see the relevant patient population.
- The program experienced barriers in trying to communicate the updated VFC policy for MenB vaccine to its providers. For example, the program used its VFC listserv to email providers, but found that these emails often were not read, and that some email addresses were invalid or were for generic practice email accounts that were not regularly monitored. In addition, a practice’s VFC contact was often not the person making vaccine stocking decisions, so the information did not always reach the most appropriate person. The program determined that letters sent by postal mail, targeted to the medical director, were the most effective way to communicate this VFC policy change.
- From the Immunization Program’s perspective, federal guidance did not address whether Category B recommendations should be treated any differently under the VFC program. The program proceeded with its policy based on its interpretation of the VFC provider agreement. The program had put considerable effort into ensuring provider compliance with stocking all VFC vaccines (eg, rotavirus and HPV vaccines), and thought that having a different policy for MenB vaccine would be unfair and inconsistent.
- Many providers were confused about the difference between the MenB and MCV4 vaccines, which the program addressed via educational materials and discussions with providers.
- Many VFC providers called to express their disagreement with the requirement to stock a vaccine that had received a Category B recommendation from the ACIP. The program was able to resolve most of these calls by sharing data on MenB disease in the state (eg, most of the recent meningitis cases in the state were caused by MenB) and reminding providers that the recommendation states the vaccine should be offered if the patient wants it after discussing it with the provider.
- The program’s requirement to stock a box of 10 doses was challenging at first because the first few shipments of one of the available brands had a very short shelf life. To minimize vaccine wastage, the program worked with providers to move vaccine among neighboring providers, if necessary.
Medicaid initially declined some claims for MCV4 and MenB vaccines given in the same visit. The two vaccines have the same billing code. The program worked with Medicaid to create an identifier for providers to use in these situations, so that Medicaid could tell that it was two different vaccines given in the same visit, not the same vaccine being billed twice.

Other lessons learned/Advice to other programs

- Programs should review data on the types of meningitis disease circulating in their state. The Indiana Immunization Program was unaware that MenB was circulating in the state before looking at the data, but nearly 80% of the 15 meningitis cases seen in Indiana in 2014-2015 were caused by MenB. If a state finds that MenB is circulating in the state, these data can help support MenB vaccine policies.
- Based on the program’s experience establishing a MenB vaccine school requirement, the state chapter of the AAP will now be represented on the program’s school requirements committee to ensure that its perspective is taken into account, and that it can keep its membership informed.
- Programs should ensure that existing partners are sufficiently informed and involved with changes to program policies and requirements, especially in unique situations (eg, Category B vaccine recommendation).
- The program’s goal is to maintain an effective delivery system for viable vaccines to the eligible population. In doing so, it must balance broad provider participation against issues of provider compliance. Indiana is willing to lose some providers who are unwilling to comply in order to have an immunization system of greater integrity. To ensure that provider dropout does not contribute to decreased access to immunization providers, the program monitors access and potential pockets of need via program data (eg, from IIS) and communication with LHDs, which are on the frontlines.

Relevant resources

- Indiana Immunization Coalition MenB campaign: http://vaccinateindiana.org/beware-of-b/
- Letters to Indiana VFC providers regarding the MenB vaccine VFC policy change (January 2016, March 2016, and May 2016).

For more information

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REFERENCES


