



“The high mortality rates, frequency of serious sequelae, and rapid progression of invasive meningococcal disease all argue for prevention whenever possible.”

—Paul A. Offit, MD

Addressing the Challenges of Serogroup B Meningococcal Disease Outbreaks on Campuses:

A report by the National Foundation for Infectious Diseases

Overview

Recent outbreaks of serogroup B invasive meningococcal disease on US college campuses have heightened awareness about the gap in available vaccines to protect against this serious and sometimes fatal infection. Federal agencies, college health authorities, public health officials, and consumer advocates are in a heightened state of awareness about the challenges of facing this unpredictable disease and the need for an effective and timely public health response when outbreaks occur. Challenges in responding to the recent outbreaks provided a compelling reason for the National Foundation for Infectious Diseases (NFID) to assemble a panel of stakeholders/subject matter experts (See Page 9) to examine the public health response to the recent outbreaks and strategies for appropriate and streamlined public health responses to future outbreaks.

May 2014

Serogroup B meningococcal outbreaks are difficult to manage

Two recent, but very different outbreaks at Princeton University and the University of California Santa Barbara (UCSB) are challenging how public health officials define and respond to meningococcal disease outbreaks. While the outbreak at UCSB followed a more “typical” outbreak pattern, with four cases occurring in rapid succession over two weeks, the Princeton outbreak included nine cases over a longer period (about one year) with variable intervals between cases. Each outbreak was confined to students, with no cases reported in faculty, staff, or the surrounding community population. Also, the two outbreaks were genetically unrelated, each campus having a distinct genetic pattern.

As of the date of this report, public health officials cannot say with certainty whether either outbreak is over. Both outbreaks, along with three other college campus outbreaks in the last five years in which the Centers for Disease Control and Prevention (CDC) was consulted, were caused by meningococcal serogroup B bacteria. This serogroup is not included in the currently licensed meningococcal vaccines administered to US adolescents or to individuals of other ages with certain risk factors that make them susceptible to invasive meningococcal disease.¹

Managing any invasive meningococcal disease outbreak is demanding, but the lack of a licensed vaccine against serogroup B made public health decisions even more challenging in these recent circumstances.² Lack of a vaccine makes it harder to create a targeted outbreak containment strategy and makes attempts to develop a population-based prevention strategy more difficult.

Although most invasive meningococcal disease cases are isolated and do not signal an impending outbreak,³ even one case on campus can cause serious medical and social stress, including public concern about transmission into the general community. The public is highly attuned to the severity of invasive meningococcal disease, mandating a response from college and local public health officials. At a minimum, college or public health officials will identify close contacts for post-exposure antibiotic prophylaxis. Beyond that, as the two recent outbreaks demonstrate, the next steps are less clear.

When college outbreaks do occur, they often place a large burden on campus resources. Outbreak management requires coordination and cooperation among many groups, including campus health authorities, local and state public health departments, college staff, faculty, students, and parents, as well as significant financial and personnel resources. The CDC will often be consulted, as was the case in both the Princeton and UCSB outbreaks.

US adolescents are well vaccinated against meningococci, but not protected against serogroup B

The meningococcal vaccines currently approved for use in the US protect against serogroups A, C, W, and Y.¹ Because serogroup B bacteria differ structurally, a serogroup B vaccine has been more difficult to produce.^{4,5} The current meningococcal vaccines are recommended for routine vaccination of adolescents at 11-12 years of age with a booster dose at 16 years of age and roughly three-quarters of US teens are currently immunized.^{1,6}

While there is no US vaccine to protect against serogroup B, there is a serogroup B vaccine approved for use in Europe, Canada, and Australia.⁷ This vaccine, manufactured by Novartis Vaccines, was used under an investigational new drug (IND) agreement between the US Food and Drug Administration (FDA) and CDC to help control the outbreaks at Princeton and UCSB.

The Novartis vaccine and another serogroup B vaccine in development by Pfizer have been granted “breakthrough therapy” status by the FDA.^{8,9} Both vaccines will be reviewed on a new accelerated schedule to help meet US public health needs.¹⁰ While FDA has not provided a timetable for approval, both manufacturers are anticipated to apply for licensure by mid-2014.

The challenge of creating a serogroup B vaccine

Currently licensed meningococcal vaccines use a fragment of the polysaccharide outer coating of meningococcal bacteria to trigger the body’s immune response.⁴ While this has worked well for other serogroups, the outer coating (capsule) on serogroup B bacteria does not induce an immune response because it too closely resembles other human cells.^{4,5} Scientists have now isolated protein fragments on the outer surface of serogroup B bacteria that induce immunity and are present on a large enough percentage of B strains to make the vaccine effective for widespread use. These vaccines appear to be effective against many, but perhaps not all, serogroup B strains.

Invasive meningococcal disease is fast moving and deadly

Invasive meningococcal disease is characterized by rapid progression (typically hours but occasionally several days) from symptom onset to severe outcomes, even when it is diagnosed and treated quickly.¹¹⁻¹³ Although the most common clinical manifestations of invasive meningococcal disease are severe—meningitis with or without bacteremia, and pneumonia in adults—its earliest symptoms may be non-specific and “flu like.”^{11,14} These can quickly progress to more severe and specific symptoms including stiff neck, nausea, vomiting, confusion, and a telltale reddish pink/purplish rash (purpura fulminans), usually on the lower extremities or lower arms and hands.

Mortality from invasive meningococcal disease is 10 to 15 percent (death can occur within hours or days) and among survivors is associated with an 11 to 19 percent risk of serious long-term sequelae, such as hearing loss, skin scarring, brain damage, kidney failure, and limb amputations.^{1,11-13} The disease occurs mostly in previously healthy individuals.

College campuses are a focus of meningococcal disease prevention efforts because of the increased incidence of the disease during adolescence and young adulthood.^{15,16} This increased risk is likely due to enhanced person-to-person transmission from crowded living conditions and social behaviors common among college students including going to bars and parties, alcohol consumption, more than one kissing partner, and smoking.^{2,17,18} Meningococcal bacteria are not spread by casual contact or by simply breathing the air where a person with meningococcal disease has been.

Epidemiology and burden of serogroup B meningococcal disease

Invasive meningococcal serogroup B disease is similar to serogroups A, C, W, and Y in clinical presentation, morbidity, and mortality. The highest incidence of serogroup B disease is in infants younger than one year of age, but a second peak is seen in adolescents (Figure 1).^{14,19} In recent years, serogroup B has overtaken serogroups C and Y as the most common cause of disease in adolescents. This may be, in part, a result of high vaccination coverage against serogroups C and Y.

Meningococcal disease incidence has been declining in the US since the late 1990s (Figure 2). The decline began before high vaccine coverage was achieved and has been seen in all serogroups, including serogroup B.^{6,20}

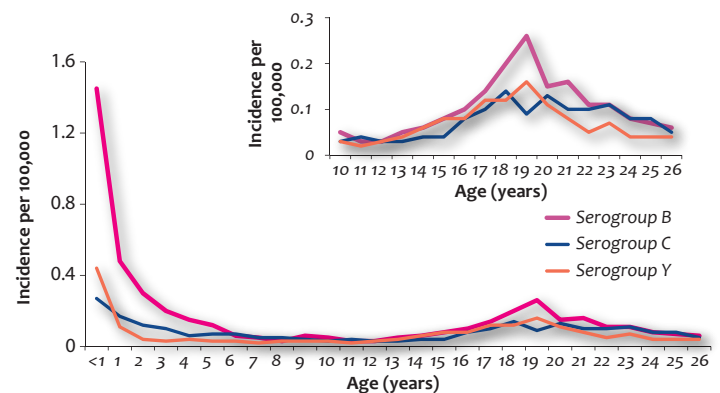
In higher incidence years (1997-1999), there were 780 meningococcal disease cases in individuals aged 11 to 24 years with 142 of them caused by serogroup B. In recent, lower incidence years (2010-2012), there were 106 cases in this age group with 29 caused by serogroup B.²⁰

But it is important to note that meningococcal disease is characterized by its volatile and irregular epidemiology. It has been described as having a cyclic nature with peaks and troughs and Cohn et al. discuss the “historical precedence for major shifts in meningococcal disease patterns.”¹⁴ These shifts may include changes in incidence, changes in the proportion of cases caused by each serogroup, peaks emerging in different age groups, and regional changes in epidemiology.^{14,21,22}

“We should not let down our guard because when the disease increases again, it has a striking capacity to kill and maim.”

—William Schaffner, MD

Figure 1: Incidence of meningococcal disease by age and serogroup, US 2005-2012



Source: Courtesy of the Centers for Disease Control and Prevention. Data on File: National Notifiable Diseases Surveillance System with additional serogroup data provided by state and local health departments.

Princeton University: Year-long outbreak with atypical clinical presentations

In March 2013, a Princeton University student was diagnosed with serogroup B invasive meningococcal disease while on break with her family in another state (Figure 3). A few weeks later, a prospective student who had visited the campus was diagnosed with the disease, but the cases were not immediately connected. The University instituted post-exposure antibiotic prophylaxis for close contacts of both cases and asked medical staff to be alert to other students presenting with meningococcal disease symptoms.

Within a few weeks another student was diagnosed with serogroup B invasive meningococcal disease. A look back at the second case revealed that it, too, was caused by serogroup B. The New Jersey Department of Health (NJDOH) declared the three cases a cluster and Princeton began a widespread hygiene campaign to educate students about ways to reduce transmission. Messages were delivered via posters in dormitories, table tent cards in

the dining halls, brochure distributions, meetings, emails, and a dedicated website.

A fourth case followed quickly and by this time, genetic testing of strains confirmed that all four cases were identical and the NJDOH declared an outbreak. While the educational campaign and targeted prophylaxis continued, the University prepared for the end of the school year, which raised major concern because some 20,000 people would be crowding the campus for reunion and commencement activities, increasing fears about further transmission. On the other hand, there was also hope that the summer recess to follow would halt transmission completely and stop the outbreak.

The semester concluded with no new cases, but in late June another case occurred, this time in a Princeton student traveling abroad in Greece with a group of about 15 other Princeton students. By early July 2013, Princeton, CDC, and NJDOH officials were discussing the possibility of a vaccination campaign, but because these cases were all caused by serogroup B, they needed FDA permission to use an investigational vaccine. Initial steps toward a vaccination program began in August 2013.

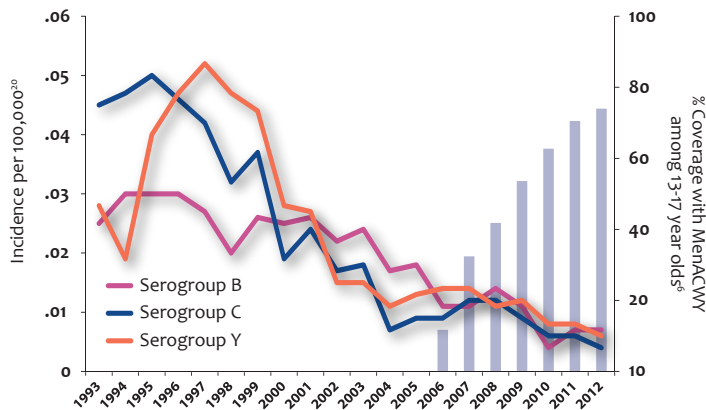
Princeton University continued its hygiene campaign in the fall and even engaged students to help develop new messages that would resonate with their peers. But three more cases occurred on campus in the fall, bringing the total to eight. With each new case came prophylaxis of contacts and increased stress on campus. With the initial steps toward getting an IND already in place by the CDC, Princeton was able to move forward quickly with vaccination plans.

The IND was approved just before the eighth case was diagnosed in late November and the first vaccine clinic was scheduled for early December 2013. Once Princeton officials were convinced that widespread immunization with the investigational serogroup B vaccine was the best course, they had to develop and implement a communication plan quickly and set up the first vaccination clinics, which they modeled on their influenza vaccination clinics.

Princeton delivered the two-dose vaccine series to 90 percent of its students. Though it was an enormous undertaking with extensive educational efforts, campus officials recognized that the high uptake rates were influenced by the perceived risk among students.

The last case had only been reported a few weeks before the first vaccine clinic, so student (and parent) fear and motivation were high. In addition, shortly before the first clinic, news of a student at UCSB suffering bilateral foot amputations from meningococemia was reported. Finally, the vaccine clinic followed the Thanksgiving break, during

Figure 2: Incidence by serogroup and vaccine coverage, US, 1993-2012



ABCs cases from 1993-2012 estimated to the U.S. population with 18% correction for under reporting¹⁰
National Immunization Survey – Teen; 2006-2012⁶

which campus officials believe parents urged their children to be vaccinated.

“No one expects to deal with a year-long outbreak and no one can ever be fully prepared for it. Navigating the outbreak and organizing a vaccination program took extensive collaboration between the University and state and federal public health officials.”

—Peter Johnsen, MD, Director of Medical Services, Princeton University

Unfortunately, the outbreak associated with Princeton still may not be over. In March 2014, a Drexel University student died from invasive meningococcal disease after close contact with a group of Princeton students who traveled to Drexel for a social event. Molecular typing confirmed the case was caused by the identical B strain at Princeton. Princeton has since decided to offer the serogroup B vaccine to all incoming freshmen in September 2014 in an effort to prevent additional cases.

University of California Santa Barbara: Four cases in two weeks

There were four meningococcal serogroup B cases on the UCSB campus in November 2013. Epidemiologic investigation later linked these cases to another that occurred seven months earlier. The five students appeared to have little in common. Four were male; one was a senior, two were freshmen, and two were sophomores. They lived at five different locations and in very different living environments including a 1,300-bed high-rise dormitory, a private apartment, and a sorority house (three were involved in Greek life).

Atypical clinical presentations worry Princeton medical staff

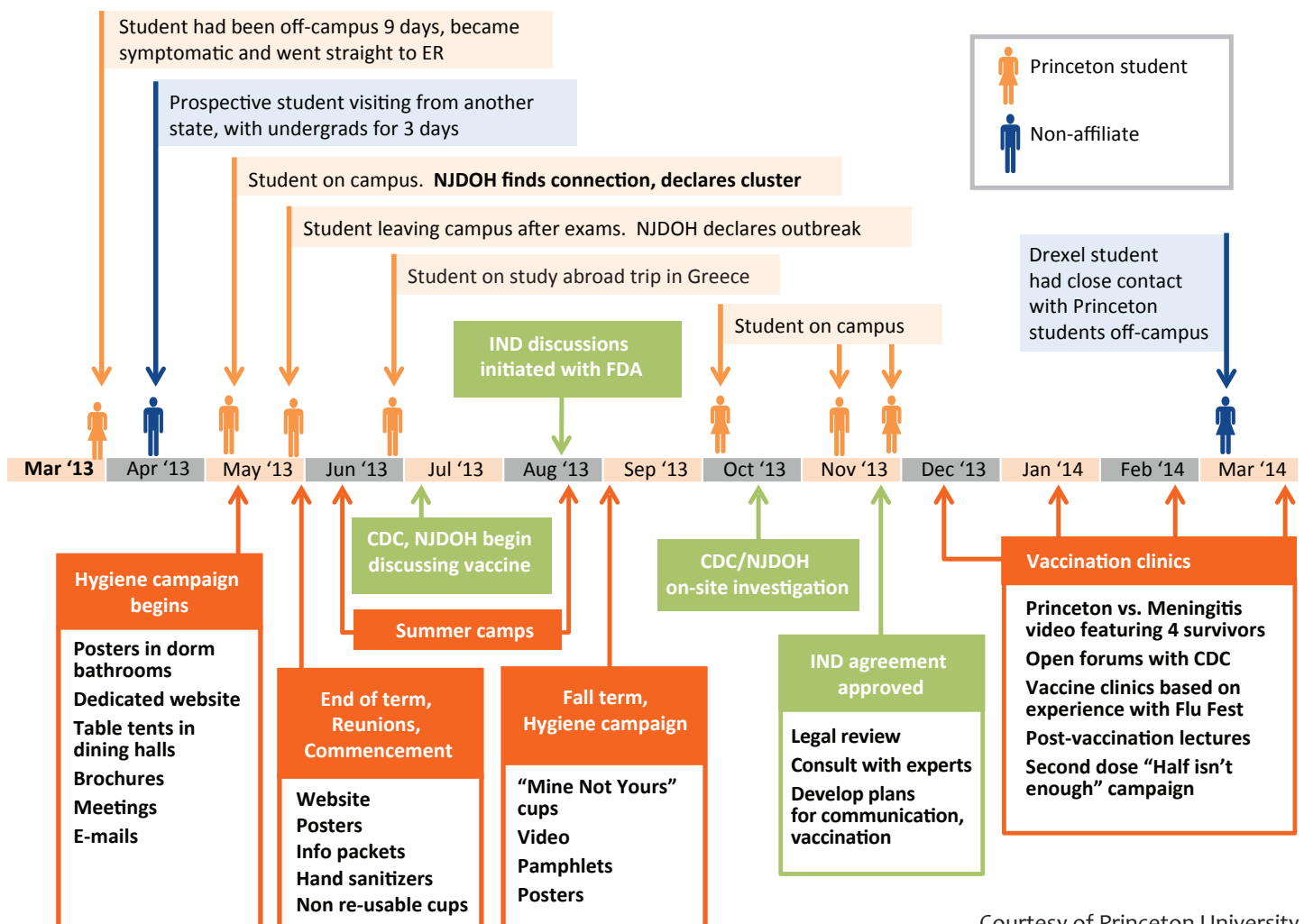
One of the biggest concerns for the Princeton medical staff was making a rapid diagnosis so students could be treated quickly. While some cases presented with clear clinical markers for invasive meningococcal disease (headache, high temperature, stiff neck, petechial rash), others did not.

One student reported a high fever the night before (103°F), but when she presented the next day at the infirmary she had a low-grade fever (<100°F), was alert and joking, and had no other symptoms consistent with an invasive meningococcal disease diagnosis. Nonetheless, physicians checked her white blood cell count (elevated at approximately 27,000), took blood cultures, and sent her to the hospital. The cultures later confirmed meningococemia and the patient continued to worsen in the hospital.

Another student presented in the infirmary with exudative tonsillitis. He had a fever of 103°F and a positive rapid strep test. He was diagnosed with group A streptococcal tonsillitis and kept overnight because of the fever. But in the middle of the night he developed the telltale petechial rash of meningococemia. He was promptly admitted to a local hospital where he developed multi-organ failure just a few hours later.

Immediate diagnosis was hindered in these cases by the lack of readily recognizable clinical markers. Milder and atypical presentations left the Princeton medical staff concerned and uneasy about making rapid, accurate diagnoses.

Figure 3: Timeline of the meningococcal outbreak at Princeton University



Courtesy of Princeton University

IND, Investigational New Drug
NJDOH, New Jersey Department of Health

Four had social interactions consistent with known risk factors for contracting meningococcal disease, but in the fifth case, only a remote connection could be identified—a roommate who was on a sports team with another case. The four cases in November all occurred shortly after a widely attended Halloween event in a densely populated community near campus. Students report that it is not uncommon for partygoers to share cups, glasses, and smoking materials, and to participate in kissing games.

Not only does UCSB have a large student population (19,000 undergraduates), but it also sits just five miles away from a similarly sized but non-residential community college. It is not unusual for students from both schools to socialize together on the campuses and in and around the neighboring town.

“The outbreak at UCSB has been costly. The safety of our students is our first priority, but the challenge of finding the funds to pay for this outbreak is also a reality we need to face.”

—Mary Ferris, MD, Student Health Executive Director, UCSB

The Santa Barbara Public Health Department was very involved in helping UCSB investigate the cases and define the target population for post-exposure antibiotic prophylaxis. But there were challenges. One of the students presented in septic shock, making it difficult to get a complete history. Investigators

Lack of clear clinical markers in UCSB meningococcal cases

Local doctors have become apprehensive about missing or delaying a meningococcal diagnosis. This has resulted in an increase in emergency department visits and blood cultures not just on campus, but across the local area.

While one case was diagnosed quickly, two of the invasive meningococcal disease cases at UCSB were not. One student was sent home from the emergency room and another who had rash and fever was diagnosed with chickenpox. The meningococcal diagnoses were made for these two students when blood cultures turned positive one and two-days later, respectively.

identified close contacts of this case on the lacrosse team for prophylaxis but only learned later of his involvement with several other sports teams when those teammates came to the infirmary asking to also be treated as close contacts.

Officials from UCSB, the Santa Barbara Public Health Department, and CDC debated how broadly to use post-exposure prophylaxis. In the end, the University administered nearly 1,200 prophylactic doses of ciprofloxacin. This broad-based approach was agreed to, in part, in response to unease on the campus as well as the difficulty in defining close contacts rigorously. In addition to prophylaxis, the University began a large educational campaign on ways to reduce transmission. This included directives to avoid risky social behaviors. University officials cannot say definitively whether the prevention messages had an impact on student behavior; anecdotally, students reported that the campaign influenced their choices.

Within 10 days of the fourth case, discussions began about seeking an IND for use of the unlicensed serogroup B vaccine to help control the outbreak. The discussions included University officials, the CDC, and county and state public health officials. The decision was made to pursue an IND, and CDC prepared the application with their epidemiologic analysis, including definition of the target population for vaccination as the entire undergraduate student body. Because the local public health department did not have the capacity to deliver vaccines to such a large target population, the responsibility fell solely on UCSB.

It took three months to get the necessary approvals from CDC and FDA, and set up the first vaccine clinic. During that time, campus officials worked closely with CDC to resolve issues related to the IND application process with FDA, as well as required contracts and procurement. They faced logistical and practical challenges. The University had to purchase and install five commercial refrigerators to maintain the vaccine cold chain and they transformed a hockey rink into a vaccine clinic, which required running new electrical lines, installing computers and internet service, bringing in medical equipment and privacy screens, etc. They supplemented UCSB staff with outside nurses and administrative personnel to staff the clinic.

University officials and public health experts believe the three-month gap between the last case and the vaccination clinic diminished the sense of urgency for vaccination among students. Still they achieved a first-dose coverage rate of 51 percent, with rates of 60 percent for dormitory residents and Greek life members. Thirty-seven percent of undergraduates received the full two-dose series, with higher completion rates among freshmen (50 percent) and sophomores (45 percent).

Challenges and Recommendations

Licensure of meningococcal serogroup B vaccines will have the single greatest impact on improving responses to future outbreaks.

Once the serogroup B vaccines are licensed, the CDC Advisory Committee on Immunization Practices (ACIP) will provide recommendations for their use in endemic and outbreak circumstances.

However, because of the extreme nature and epidemiology of meningococcal disease, the changing epidemiology, and the experience of recent outbreaks, the panel did advance some thoughts about the potential ways serogroup B meningococcal vaccines might be used.

The logic of adding serogroup B prevention to current routine immunization strategies was discussed. If invasive meningococcal disease is severe enough to warrant routine immunization with one of the currently available vaccines, and the current high vaccine coverage rates would argue that healthcare professionals (HCPs) and parents believe it is, then we must give equal weight to preventing disease caused by all serogroups, not just those in the current quadrivalent vaccines. The panel recognized the public health challenges of adding vaccine doses for adolescents. The panel concluded that a CDC recommendation that goes beyond outbreak control will provide a possible solution, vaccination. It may also facilitate insurance coverage for vaccinations.

Increased efforts needed to educate and raise awareness among HCPs about invasive meningococcal disease presentation.

There was a spectrum of clinical presentations in the two recent college outbreaks. Clinicians who were more alert to the possibility of invasive meningococcal disease appeared more likely to make a rapid diagnosis. Since this disease is rare, clinicians, especially younger ones, may have little to no personal experience in diagnosing it. We must, therefore, increase efforts to educate HCPs on all of the potential clinical markers for the disease.

Even in the setting of a known outbreak, clinicians failed to make diagnoses of disease, because of the absence of expected (or anticipated) clinical markers or failure to recognize markers. Situational awareness must be improved among HCPs so that they have invasive meningococcal disease in the differential diagnosis during campus outbreaks. Decision-making tools incorporated into the electronic medical record, along with electronic information flow between public health professionals and

clinicians that support these tools can provide powerful educational messages in real-time during an encounter.

Meningococcal disease incidence is well known to be cyclical. If US incidence increases again, our public health and healthcare systems need to be prepared. This includes making sure younger clinicians know how to recognize, diagnose, and treat cases, and report them promptly to public health authorities.

Educational resources need to be readily available for the public when outbreaks occur.

Educating affected populations about risk reduction and convincing college students to minimize risk may mean an undesirable change in lifestyle to many. Students are unlikely to alter their social behaviors except in cases where their fear is heightened (e.g., during an outbreak), so it is essential to reach them as quickly as possible after a case is reported.

It is extremely difficult to deliver definitive messages in the face of such an uncertain disease. An evidence-based social marketing campaign that addresses both vaccination and healthy behaviors can be developed for ready use during outbreaks to help universities provide reassurance and accurate information in a timely manner. These campaigns can also contain materials that can be used proactively before an outbreak occurs.

The FDA should communicate clearly about the new licensure pathway for meningococcal serogroup B vaccines.

A new “breakthrough therapy” pathway has been established by the FDA and serogroup B meningococcal vaccines are the first vaccines to be granted review under this new procedure. The FDA should communicate clearly about its process and licensure steps, as well as anticipated timing, so that the concerned public is informed.

In this case, data from geographical locations with much higher incidence of serogroup B disease may prove useful, facilitating rapid FDA assessment of vaccine safety and efficacy.

Media need to be engaged in a thoughtful and positive way by all stakeholders.

Media coverage can heighten public fear and may not always provide accurate and balanced information that communicates what public health officials know and

the realities of the US vaccine approval process. Every public health official and infectious disease specialist who has contact with media must increase efforts to help reporters present medically accurate information to the public utilizing risk communication skills. Resources should be dedicated to providing media with easy access to information on all aspects of meningococcal disease diagnosis, treatment, transmission, and prevention to inform future news coverage.

The capacity for rapid identification of meningococcal serogroups must be maintained.

As invasive meningococcal disease incidence has declined in the US, it has become cost prohibitive for some local laboratories to maintain their capacity to test isolates. This is particularly problematic in the case of serogroup B outbreaks because serogrouping is the first essential step in determining whether the strain causing the outbreak is covered by available vaccines.

One clinician at a large medical center reports that the change from the ability to serogroup inside the medical center to having to send the isolates out to the city or state health department means a delay of seven to 10 days in serogroup identification. Even though the incidence of invasive meningococcal disease is low, its severity and ability to cause public panic supports the need for public health laboratories to maintain the capacity for rapid serogrouping of meningococcal isolates.

Epidemiologic definitions of outbreaks should be reviewed and updated, as necessary.

The outbreaks at UCSB and Princeton showed that links are not always clear and yet outbreaks can flourish. Longer intervals between cases, and cases such as the one that occurred in a Princeton student traveling in Greece with classmates, show that this pathogen can be carried asymptotically in some individuals who can then pass it on to others who may become symptomatic. The characteristics that make some individuals carriers and others victims are not well enough defined to drive our definition of outbreaks. Studies in the UK have demonstrated widespread acquisition of the carrier state among college students shortly after arrival on campus.²¹ With widespread acquisition of the carrier state among students, searching for evidence of close connections between cases may not be needed before an outbreak is declared.

The ACIP Meningococcal Vaccine Work Group is addressing this challenge by reviewing the nature of the recent outbreaks to determine whether current outbreak

definitions need to be adjusted. Outbreak definition adjustments and more flexible definitions of connectivity between cases also could expand the scope of those who should receive post-exposure antibiotic prophylaxis.

Consider how resources influence when and how outbreaks are declared and managed.

Managing an outbreak is a challenging process for any campus, but it is even more difficult for those with fewer available resources. For instance, campuses without a student health center, such as community colleges, may not be able to respond directly. They will likely rely on the capacity of local public health departments. But this may not be a viable solution in all areas. As the outbreak at UCSB showed, local public health departments also have resource limitations and meningococcal outbreaks have the capacity to quickly overtake available resources. There is currently no clear schematic to follow that defines roles for universities and the various public health agencies (local, state, CDC) in outbreak declaration and control.

Once an outbreak is declared, prevention programs must be implemented as quickly as possible.

In recent outbreaks, campus and public health officials noted that both student and parent perception of risk was a major factor in participation in prevention measures. The longer the period from the last cases to the availability of the prevention program, the harder it will be to motivate participation. When fear is high, motivation is high.

At UCSB, teammates of a case self-identified and came to the infirmary asking for chemoprophylaxis. At Princeton, where the time from the last case to the first vaccine clinic was very short, vaccination rates exceeded 90 percent of the targeted 9,000 students. At UCSB, where the gap was three months between the last case and the first vaccine clinic, the rate was 51 percent of the targeted 19,000 students. Availability of a licensed vaccine should help to shorten the time between the decision to undertake a vaccination program and the actual implementation.

Universities should consider advanced planning about ways to cover costs of managing outbreaks.

Meningococcal outbreaks are extremely rare, but very costly. Universities faced with an outbreak are not likely to have the luxury of deciding whether to incur certain expenses.

Nor are they likely to have the time to find the most cost-efficient ways to deal with the outbreak. The cost of vaccine procurement is just a fraction of the total expenses involved in managing an outbreak. Examples

of costs unlikely to be covered by any type of insurance include developing and printing materials for education and awareness campaigns; increased communications with parents, the general public, the media, and others; greatly increased need for on-campus counseling—medical and psychological; purchasing refrigerators for vaccine storage and other required equipment; physical set up of clinics, including internet service and privacy screens; and hiring additional nursing or administrative support personnel for clinic staffing.

While this is a complicated issue and it is not possible to plan ahead for every eventuality, universities should examine their insurance policies and consider the feasibility of adding coverage that could help offset some of the costs associated with outbreaks. Declared public health emergencies may also help distribute costs.

Summary: Though rare, invasive meningococcal disease requires public health attention due to its severity.

Invasive meningococcal disease is fast moving and causes significant morbidity and mortality. Even one case on a college campus can induce a great deal of public anxiety. But it is not only the public that expresses concern and anxiety. HCPs worry about their ability to quickly recognize a potential case, confirm the diagnosis, begin treatment, and report it to public health authorities.

The impact on financial and personnel resources begins with just one case and expands greatly in the event of an outbreak. College campuses are often not equipped to deal with the repercussions on their own. Defining an outbreak, planning for control, and implementing containment procedures requires input and active participation of a range of experts.

While not every eventuality can be foreseen, advanced planning is essential for invasive meningococcal disease outbreaks, which can strike at any time and have a high likelihood of being severe and causing public panic. It is imperative that we give officials the tools they need when faced with such outbreaks. This includes safe and effective vaccines and antibiotics and clear direction on their use; ongoing education and laboratory capacity (e.g., rapid isolate testing) to ensure HCPs can make accurate and quick diagnoses; ready-made public education and awareness materials that can be easily customized; and finally, a roadmap that helps them navigate the difficult path from an isolated case to resolution of an invasive meningococcal disease outbreak.

Panel

William Schaffner, MD, Chair

Immediate Past-President, NFID
Professor of Preventive Medicine
Department of Health Policy
Professor of Medicine, Division of Infectious Diseases
Vanderbilt University School of Medicine
Nashville, TN

Carol J. Baker, MD

Professor of Pediatrics, Molecular Virology & Microbiology
Baylor College of Medicine
Executive Director
Center for Vaccine Awareness & Research
Texas Children's Hospital
Houston, TX

Lynn Bozof

President
National Meningitis Association
Atlanta, GA

Jeffrey Engel, MD

Executive Director
Council of State and Territorial Epidemiologists
Atlanta, GA

Paul A. Offit, MD

Chief, Division of Infectious Diseases
Director, Vaccine Education Center
Children's Hospital of Philadelphia
Maurice R. Hilleman Professor of Vaccinology
Professor of Pediatrics
University of Pennsylvania School of Medicine
Philadelphia, PA

James C. Turner, MD

Executive Director, National Social Norms Institute
Professor of Internal Medicine
University of Virginia School of Medicine
Charlottesville, VA

The authors gratefully acknowledge the following individuals who presented data during the April 8, 2014 roundtable that informed the ideas and recommendations presented in this report: Amanda Cohn, MD (CDC), Mary Ferris, MD (UCSB), Peter Johnsen, MD (Princeton University), Jessica MacNeil, MPH (CDC), and Wellington Sun, MD (FDA).

This activity is supported by an unrestricted educational grant from Novartis Vaccines and Diagnostics, Inc. [NFID policies](#) restrict funders from controlling program content.

References

1. Cohn AC, MacNeil JR, Clark Ta, et al. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2013;62(RR-2):1-28.
2. Mandal S, Wu HM, MacNeil JR, et al. Prolonged university outbreak of meningococcal disease associated with a serogroup B strain rarely seen in the United States. *Clin Infect Dis*. 2013;57(3):344-8.
3. Brooks R, Woods CW, Benjamin DK Jr, Rosenstein NE. Increased case-fatality rate associated with outbreaks of *Neisseria meningitidis* infection, compared with sporadic meningococcal disease, in the United States, 1994-2002. *Clin Infect Dis*. 2006;43:49-54.
4. Bell LM. A new vaccine against meningococcal serogroup B. *NEJM Journal Watch Pediatrics and Adolescent Medicine*. 2013; Feb 20.
5. Snape MD, Pollard AJ. The beginning of the end for serogroup B meningococcus? *Lancet*. 2013;381(9869):785-7.
6. Centers for Disease Control and Prevention. National and state vaccination coverage among adolescents aged 13-17 years—United States, 2012. *MMWR Morb Mortal Wkly Rep*. 2013;62(34):685-93.
7. Centers for Disease Control and Prevention. Serogroup B meningococcal vaccine and outbreaks (questions and answers). <http://www.cdc.gov/meningococcal/outbreaks/vaccine-serogroupB.html>. Accessed April 22, 2014.
8. Novartis meningitis B vaccine Bexsero® receives FDA Breakthrough Therapy designation in the US [news release]. Basel, Switzerland: Novartis, April 7, 2014. <http://www.novartis.com/newsroom/media-releases/en/2014/1774805.shtml>. Accessed April 16, 2014.
9. Pfizer's Investigational Vaccine Candidate Bivalent rLP2086 Receives U.S. Food and Drug Administration Breakthrough Therapy Designation for Potential Prevention of Meningococcal B Disease [news release]. New York, NY: Pfizer, Inc, March 20, 2014. <http://press.pfizer.com/press-release/pfizers-investigational-vaccine-candidate-bivalent-rfp2086-receives-us-food-and-drug-a>. Accessed April 16, 2014.
10. US Food and Drug Administration. Regulatory Information. Frequently asked questions: Breakthrough therapies. <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstotheact/fdasia/ucm341027.htm>. Accessed May 2, 2014.
11. Pace D, Pollard AJ. Meningococcal disease: clinical presentation and sequelae. *Vaccine*. 2012;30 Suppl 2:B3-9.
12. Edwards MS, Baker CJ. Complications and sequelae of meningococcal infections in children. *J Pediatr*. 1981;99:540-5.
13. Kirsch EA, Barton P, Kitchen L, Giroir BP. Pathophysiology, treatment, and outcome of meningococemia: A review and recent experience. *Pediatr Infect Dis J*. 1996;15:967-79.
14. Cohn AC, MacNeil JR, Harrison LH, et al. Changes in *Neisseria Meningitidis* disease epidemiology in the United States, 1998-2007: implications for prevention of meningococcal disease. *Clin Infect Dis*. 2010;50:184-91.
15. Froeschle JF. Meningococcal disease in college students. *Clin Infect Dis*. 1999;29(1):215-6.
16. Harrison LH, Dwyer DM, Maples CT, Billman L. Risk of meningococcal infection in college students. *JAMA*. 1999;281:1906-10.
17. Imrey PB, Jackson LA, Ludwinski PH, et al. Meningococcal carriage, alcohol consumption, and campus bar patronage in a serogroup C meningococcal disease outbreak. *J Clin Microbiol*. 1995;33(12):3133-7.
18. Imrey PB, Jackson LA, Ludwinski PH, et al. Outbreak of serogroup C meningococcal disease associated with campus bar patronage. *Am J Epidemiol*. 1996;143(6):624-30.
19. Centers for Disease Control and Prevention. Summary of notifiable diseases, 2011: meningococcal disease, invasive. *MMWR Morb Mortal Wkly Rep*. 2013;60(53):18.
20. Centers for Disease Control and Prevention. Active Bacterial Core Surveillance (ABCs) cases from 1993-2012. <http://www.cdc.gov/abcs/reports-findings/surv-reports.html>.
21. Neal KR, Nguyen-Van-Tam JS, Jeffrey N, et al. Changing carriage rate of *Neisseria meningitidis* among university students during the first week of term: cross sectional study. *BMJ*. 2000;320(7238):846-9.
22. Rosenstein NE, Perkins BA, Stephens DS, Popovic T, Hughes JM. Meningococcal disease. *N Engl J Med*. 2001;344:1378-88.
23. Rosenstein NE, Perkins BA, Stephens DS, et al. The changing epidemiology of meningococcal disease in the United States, 1992-1996. *J Infect Dis*. 1999;180:1894-1901.



**National
Foundation for
Infectious
Diseases**

www.nfid.org