

Ann & Robert H. Lurie Children's Hospital – Dr. T. Tan

Title: "Remember MenB": Impact of Healthcare Provider and Patient Education on Awareness and Understanding of Meningococcal B disease and Vaccine Recommendations and Impact on Increasing Vaccination Rates

Abstract:

There remains a lot of confusion surrounding clinical healthcare practitioners' understanding of the meaning of a Category B vaccine recommendation, especially with regards to the population for whom the vaccine should be given. This lack of understanding contributes to a lack of discussion with the patient about the vaccine and lack of a recommendation for the vaccine. It is also important that adolescents and young adults (16 to 23 years of age) have an awareness and understanding of meningococcal disease and the availability and importance of meningococcal vaccines. This is a group of individuals that are gaining independence and may seek medical care independently without their parents being present. Having an understanding of meningococcal disease and vaccines allows for these individuals to proactively seek to be vaccinated. However, the awareness and understanding of the population about meningococcal disease and availability of vaccine is unknown.

The objectives of this study will be to examine the impact of: 1) targeted healthcare provider education on improving the understanding of category B vaccine recommendations, 2) targeted education of adolescents and young adults on meningococcal disease and availability of preventative vaccines, and 3) the creation of a 2nd adolescent vaccine platform at 16 to 18 years of age for meningococcal vaccines on increasing meningococcal booster and MenB vaccination rate. Pre- and post- education information will be obtained by web-based anonymous surveys. For the adolescents and young adults, impact of education will be measured by increased willingness to receive preventative meningococcal vaccines. Interrupted time sequence analysis will be performed on adolescent vaccine records of patients in the Lurie Children's Hospital CIN and CCPA networks to trend the changes in meningococcal vaccination rates comparing the pre- and post-education periods to measure the impact of the education on increasing meningococcal vaccination rates in this age group.

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C. Responses to Reviewer’s Comments

1. In concept this idea is great, however, unfortunately in reality this is extremely difficult to implement since all the colleges and universities have very different rules for participating in research. The Northwestern Student health service had initially indicated that they were interested in participating, however, because the head of the student health service is retiring this summer and the new head of the service has not been appointed, when I approached them for a more formal commitment to the study they declined to participate. I am now working with DePaul University, which does not have a student health service (which is the norm for the vast majority of the colleges and universities in the Chicago area), however, the majority of the members of the DePaul University student body are from the Chicago area and see their private PCPs.

2. Response: The EMR system modification will be designed so that there is a meningococcal immunization reminder that “pops-up” on the charts of patients between 16 to 18 years of age when they come in to see a health-care provider for any type of visit. The reminder will include administering the booster dose of quadrivalent meningococcal ACWY vaccine and prompt the physician to discuss MenB vaccination with the patient and/or their parents. Dr. Lum and myself will function as the champions for this aspect of the study.

3. The Clinically integrated Network (CIN) is made up of 81 practices with 292 physicians and is a subset of the Lurie Children’s CCPA network. CCPA as a whole does not keep track of the information that is requested. The best information available comes from the CIN network. The following is visit data broken out by age group. You can see that for the 12-20 year old age group that CIN follows there are over 82, 000 patients who had over 180, 500 visits last year with an average of 2 visits per patient. The practices in the CIN provide care to a very ethnically and socioeconomically diverse population of patients across the Chicagoland area. This includes children that are insured, uninsured and Medicaid.

CIN Pediatrician Patients CY 2015

Age Range	Patients	Visits	vis/pt
< 1	36,678	258,410	7.0
1 - 4	66,024	243,170	3.7
5 - 11	103,283	252,777	2.4
12 - 20	82,508	180,603	2.2
totals	288,493	934,960	3.2

4. Thank you for pointing out this oversight. The terminology has been corrected to “Category B” in the protocol

D. Main Section of the proposal

I. Goal and Objectives:

1. Determine healthcare providers (HCPs) understanding of a Category B vaccination recommendation and create a targeted education program to clarify misconceptions surrounding this issue so that HCPs can better identify at risk patients in the 16 to 23 year old age group and use MenB vaccine which has a "Category B" recommendation.
2. Determine the baseline awareness and understanding of meningococcal disease among adolescents and young adults 18 to 23 years of age (high school and college students). Create educational web based video to provide information about this topic and determine impact of video on increasing awareness and understanding of disease and importance of vaccination in this patient population. This will be measured via anonymous survey tool. Create tools to measure impact of these interventions on increasing MenB vaccination rates and completion of meningococcal quadrivalent and MenB vaccine series.
3. Create a second adolescent vaccination platform for meningococcal vaccines at 16 to 18 years of age, when the booster dose of MenACWY is given and MenB vaccine could be given. Implement this change into the electronic medical record (EMR) so that MenB would appear as a recommended vaccination for at risk individuals to be given at time of the MenACWY booster dose.

II. Current Assessment of Need in Target Area

1. Healthcare providers are confused regarding the meaning of a Category B vaccination recommendation and how the recommendation should be implemented.¹ Questions that frequently arise center around which patients 16 to 23 years of age should be vaccinated and how to interpret the phrase that vaccination is "at the discretion of the clinician" based on clinical judgement. Helping clinicians understand the meaning of a Category B recommendation can result in a change in the mind set from a permissive recommendation to a recommendation for an at risk population. An example of a lag in vaccination implementation due to a permissive recommendation is human papilloma virus (HPV) vaccine use in males. When initially licensed for males, HPV vaccine had a permissive recommendation for certain age groups.² The confusion surrounding the meaning of "permissive" resulted in a significant delay in uptake of the vaccine in the pediatric and young adult male populations. The delay was further impacted by the confusion of healthcare providers on the meaning of a permissive recommendation. The vaccine was recommended for routine use in males in 2011.³ Dr. Tan has performed studies looking at the awareness and acceptance of HPV vaccine among parents of boys aged 9 to 18 years of age and among young men who have sex with men (MSM) aged 15 to 26 years of age using an anonymous survey tool.⁴⁻⁶ As has been shown in other studies, the parents looked to their healthcare providers to recommend a vaccine for their sons, however if the healthcare provider is confused by or unaware of the recommendations for the use of the vaccine, the vaccine will not be recommended.

In 2010, the CDC ACIP updated the recommendation for the use of meningococcal conjugate vaccines⁷ to include: 1) a 2 dose vaccine series for the routine immunization of adolescents, with the first dose preferable given at age 11 or 12 years, with a booster dose at age 16 years (catchup schedule also included) – see chart.

Initial Meningococcal Vaccine Dose	Booster Dose
11-12 years (preferred timing)	16 years
13-15 years	16-18 years
≥16 years	No booster

And, 2) a 2 dose primary series administered 2 months apart for adolescents with human immunodeficiency virus (HIV) infection, and persons aged 2 through 54 years with persistent complement component deficiency and functional or anatomic asplenia.

Since the updated recommendations were made, implementation and administration of the booster dose of conjugate meningococcal vaccine in the adolescent population has been slow. Data from the National Immunization Survey – Teen, United States 2014 showed that 79.3% of teens 13 to 17 years of age had received the first dose of conjugate meningococcal vaccine, however, only 28.5% of 17 year olds had received the booster dose.⁸ This leaves a very large portion of the adolescent population inadequately protected against meningococcal disease and demonstrates the need for the development of strategies to improve the vaccination rate of the booster dose of conjugate meningococcal vaccine. Several potential strategies would be 1) to develop educational programs on meningococcal disease and importance of vaccination targeted at the 16-23 year old population and 2) the development of an adolescent meningococcal vaccination platform for 16 to 18 year olds which would include the booster dose of meningococcal conjugate vaccine ACWY and discussion and administration of meningococcal serotype B vaccine.

2. Adolescents and young adults 16 to 23 years of age frequently are not seeing a physician or healthcare provider (HCP) on a regular basis and usually not in the presence of their parents, especially in the college setting. The understanding of 16 to 23 year olds about meningococcal disease and the availability of preventative vaccines is unknown. Creating targeted education material for this population about meningococcal disease and the importance of vaccine can result in students proactively seeking to be vaccinated. An informed patient allows for a vaccine discussion between the patient and the HCP. For example, in a study that Dr. Tan performed looking at the awareness of HPV disease and HPV vaccine among a young MSM population, a group that is at increased risk for HPV infection and disease, the majority had no awareness of HPV disease (66%) or the availability of the vaccine (66%). This lack of knowledge would have a significant impact on whether they would ask for or accept an HPV vaccine.⁶ Studies have shown that increasing knowledge about a certain disease can have an influence on vaccination rates. Collins and colleagues⁹ performed a nonrandomized controlled study that measured the impact of an education intervention on the number of college students who received quadrivalent polysaccharide meningococcal vaccine prior to arrival on a university campus over a 3 year period. The investigators found that educational material sent to the students prior to

arriving on campus increased the number of students who were vaccinated with meningococcal polysaccharide vaccine from 40% in the group that received no educational information up to 60% in those that had received information on the benefits of meningococcal vaccine prior to arriving on campus. Other studies have looked at identifying factors contributing to either being or not being vaccinated and educational tools for prevention of meningococcal disease¹⁰⁻¹² but none of the studies specifically looked at student awareness and understanding of disease and importance of vaccination.

III. Target Audience:

1. Healthcare providers that care for adolescents and young adults (pediatricians, adolescent medicine providers, college health providers, advanced practice nurses) 16 to 23 years of age that work in the various practices in the CIN and CCPA networks. The providers in the CIN and CCPA networks have expressed an interest in gaining a better understanding of the meaning of a category B vaccine recommendation so that they can provide the most appropriate recommendation and care for their adolescent and young adult patients.
2. Adolescent and young adult patients 16 to 23 years of age (high school and college students), the population for whom meningococcal vaccination is indicated. Providing information to this population on meningococcal disease and the importance of vaccination to protect themselves against disease is important. It informs this population on a condition for which they are at increased risk and can result in them proactively seeking vaccine to protect themselves. Both the healthcare providers and adolescents and young adult patients would benefit from the outcome of this project.

IV. Project Design and Methods – based on review of the literature, there were no studies that were found that looked at the objectives proposed for this study. Dr. Tan was a contributor to the online Medscape program “Meningococcal B vaccination: Implementing the ACIP Category B recommendations”. The proposed study is different in that we are interested in determining healthcare provider understanding of a Category B recommendation. The information obtained will be extremely helpful in developing targeted education to address the gaps in the understanding and will build upon the information provided in the Medscape program.

A. Healthcare provider education

- 1) An anonymous web based, prospective survey instrument will be created and administered to the healthcare providers in the Lurie Children's Hospital CIN and CCPA networks to gauge baseline understanding of a Category B vaccine recommendation. (See Sample Survey 1). The survey will examine basic practice demographics and awareness, understanding, and perceived barriers of a Category B vaccine recommendation.
- 2) Based on results of the healthcare provider survey, a very concise web-based educational module (10 mins duration) will be created to clarify the meaning of a Category B vaccine recommendation and improve understanding of the population to which the vaccine is recommended.

3) Healthcare providers will be notified of the availability of the educational module via email and can watch at their convenience.

4) A brief post-education anonymous web-based survey instrument will be created and administered to the healthcare providers in the Lurie Children's Hospital CIN and CCPA networks to determine impact of the education on understanding of a Category B vaccine recommendation.

B. Adolescent and Young Adult Education

1) An anonymous web based, prospective survey instrument will be created to determine adolescent and young adult awareness and understanding of meningococcal disease and availability and importance of meningococcal vaccination. (See Sample Survey 2). The anonymous survey will be sent out via email to high school students (≥ 18 years) in the various Lurie Children's Hospital CCPA/CIN practices in the Chicago area and to DePaul University undergraduate students via the Depaul University email system. Students in the various practices will be identified by the practitioners and given the link to participate in the survey and educational module. Because of Federal Laws and IRB regulations regarding the protection of children participating in research, surveying adolescents 16 and 17 years of age will not be possible. In order for individuals of this age group to participate, a signed assent and signed parental consent is required. The requirement of signed parental consent is not feasible given that most older adolescents are not seeing a healthcare provider with their parent(s) present, especially in the college setting.

2) A web based educational video will be created aimed at the 16 to 23 year old population to educate them on meningococcal disease and the importance of vaccination. The link to this video will be provided at the end of the initial pre-education survey.

3) Following completion of the video, several additional questions regarding meningococcal disease and willingness to receive meningococcal vaccine will be asked.

4) Each student who completes the pre- and post- video survey questions and views the educational video will receive a small monetary incentive (\$10) in the form of an e-gift card to a food establishment for participating. A web link will be provided for claiming the compensation.

5) Number of students participating in and completing the study will be monitored on a monthly basis based on the number of completed surveys obtained.

6) This phase of the project will go on for 1 year with the hope of having 4,000 adolescent and young adults participate in the project.

C. Creation of 2nd adolescent meningococcal vaccine platform

1) Working with EPIC team at Lurie Children's we will create a second adolescent vaccine platform for meningococcal vaccines for adolescents 16 to 18 years of age. This is when the booster dose of quadrivalent MenACWY vaccine should be given and when MenB vaccine should be discussed and administered.

2) The platform would appear under the immunization tab of the patient chart and a reminder for meningococcal vaccines would be triggered on the charts of patients 16 to 23 years of age who are being seen by a healthcare provider for any type of encounter.

3) Baseline booster dose meningococcal ACWY vaccination rates will be obtained from the vaccination records of adolescents and young adults 16-23 years of age who are being seen by the healthcare providers in the Lurie Children's Hospital CIN and CCPA networks for the 2 year period prior to implementation of education and the 2nd adolescent meningococcal vaccine platform.

4) To determine the impact of the education on a category B vaccine recommendation and implementation of a 2nd adolescent meningococcal vaccine platform, interrupted time sequence analysis will be performed on the vaccination records of the adolescents seen by the healthcare providers in the CIN and CCPA network to track the booster dose vaccination rates of quadrivalent meningococcal ACWY and MenB. This will be performed for a 1 year duration, on an every 3 month basis after completion of the education and implementation of the 2nd adolescent meningococcal vaccine platform.

V. Evaluation Design:

A. For the Lurie Children's Hospital CIN and CCPA network healthcare providers, to determine if the practice gap has been addressed, we will:

- 1) Administer a brief, anonymous, web-based survey to the healthcare providers to gauge the impact of the education on understanding of a Category B vaccine recommendation. And
- 2) Perform interrupted time sequence analysis on extracted data from the vaccine records of patients 16 to 23 years of age who are being seen by a healthcare provider for any type of encounter. This will be done on an every 3 month basis for a one year duration post-education to trend vaccination rates of the booster dose of quadrivalent meningococcal ACWY and Men B vaccines. This will be compared to baseline pre-education quadrivalent meningococcal ACWY vaccination rates – data will be obtained for the 2 year period prior to the education. This will also help to determine the impact of the creation and implementation in the EMR of a 2nd adolescent meningococcal vaccine platform. The desired outcome would be a modest 15%-20% increase in both booster quadrivalent meningococcal ACWY vaccine and MenB vaccination rates.

B. For the adolescents and young adults, to determine if the practice gap has been addressed, we will:

- 1) Compare the results of the pre-education survey results to the post-education survey results to gauge the impact of education on meningococcal disease and importance of vaccination on the improved understanding of meningococcal disease and vaccines and willingness of adolescents and young adults to be vaccinated. The desired outcome would be $\geq 20\%$ increase in the willingness of adolescents and young adults to receive meningococcal vaccine post-education.

C. The outcomes of the project can be broadly disseminated by presentation of the findings at National meetings (e.g. National Conference and Exhibit annual meeting of the American Academy of Pediatrics, Family Medicine Experience annual meeting of the American Academy of Family Physicians, American College Health Association Meeting), at Grand Rounds programs

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at different academic institutions, at Vaccine Education Programs through the Public Health Departments, and through publication of the results of the study in peer review journals (e.g. Pediatrics, Family Medicine, Journal of Public Health Management & Practice, Vaccine, Journal of American College Health, Archives of Pediatrics and Adolescent Medicine)

VI. Detailed Workplan and Deliverables Schedule – It is anticipated that the project will take 2.0 years to complete and generate meaningful data.

Creation of healthcare provider and adolescent and young adult web based pre-education surveys	Sept 1, 2016 to Dec 1, 2016 – 3 months
Creation of adolescent and young adult web based educational video on meningococcal disease and the importance of vaccine	Sept 1, 2016 to Jan 1, 2017 – 4 months
Work with EPIC operators and CIN/CCPA to develop monitoring system template for data extraction to obtain meningococcal booster vaccine information from EMR of charts of patients 16 to 23 years of age seen by healthcare provider for any type of visit over 2 year period	Sept 1, 2016 to Jan 1, 2017 – 4 months
Work with EPIC operators to create 2 nd adolescent meningococcal vaccine platform	Jan 1, 2017 to March 1, 2017 – 2 months
Administration of pre-education web-based healthcare provider survey	Dec 1, 2017 to Jan 31, 2017 - 2 months
Administration of pre-education web-based survey, educational video and post-education survey to adolescents and young adults	Jan 1, 2017 to Jan 1, 2018 – 12 months
Monitor on a monthly basis number of students completely surveys and viewing educational video	Feb 1, 2017 to Feb 1, 2018 – 12 months
Analyze pre-education web-based survey results from healthcare providers	Feb 1, 2017 to March 1, 2017 – 1 month
Create web based educational module on understanding of Category B vaccine recommendations for healthcare providers	March 1, 2017 to April 1, 2017 – 1 month
Administer educational module on understanding of Category B vaccine recommendations for healthcare providers and post-education survey	April 1, 2017 to May 1, 2017 – 1 month

Analyze results of healthcare providers post-education survey	May 1, 2017 to June 1, 2017 – 1 month
Implement 2 nd adolescent meningococcal vaccine platform in EMR	June 1, 2017 – July 1, 2017 – 1 month
Perform interrupted time sequence analysis on an every 3 month basis for 12 months and monitor vaccine timeliness and refusal results and patient demographic data. Based on the results, develop measures for improvement.	July 1, 2017 to July 1, 2018 – 12 months
Analyze results of adolescent and young adult post-education survey	Feb 1, 2018 to May 31, 2018 – 4 months
Analyze results of interrupted time sequence analysis of healthcare providers	Oct 1, 2017 to July 1, 2018 – 9 months
Prepare data for dissemination	July 1, 2018 to Sept 1, 2018 – 2 months

E. References:

1. CDC. Grading of recommendations assessment, development, and evaluation (GRADE): Use of Serogroup B meningococcal (MenB) vaccines in persons at increased risk for serogroup B meningococcal disease. www.cdc.gov/vaccines/acip/recs/grade/mening-serogroup-b.pdf
2. CDC. FDA licensure of quadrivalent human papillomavirus vaccine (HPV4, Gardasil) for use in males and guidance from the Advisory Committee on Immunization Practices (ACIP). MMWR. 2010;59:630-632.
3. CDC. Recommendations on the use of quadrivalent human papillomavirus vaccine in males – Advisory Committee on Immunization Practices (ACIP), 2011. MMWR. 2011;60:1705-1708.
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8. CDC. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents aged, 13-17 years – United States, 2014. *MMWR* 2015;64(29):784-792.
9. Collin L, Dupont L, Nagle D. The impact of education efforts on first-year university students' acceptance of meningococcal vaccine. *J Am Coll Health* 2003;52(1):41-43.
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Survey 1: Sample survey for health care providers on Category B vaccine recommendations

For each of the questions, please check the most appropriate answer.

1. Gender:
Male _____ Female _____

2. Ethnicity:
White _____ Black _____ Hispanic _____ Asian _____ Other _____

3. Age Group:
25-30 years _____ 51-55 years _____
31-35 years _____ 56-60 years _____
36-40 years _____ 61-65 years _____
41-45 years _____ 66-70 years _____
46-50 years _____ > 70 years _____

4. Years in Practice:
0-5 years _____ 26-30 years _____
6-10 years _____ 31-35 years _____
11-15 years _____ 36-40 years _____
16-20 years _____ 41-45 years _____
21-25 years _____ > 45 years _____

5. Practice Location:
Urban _____ Suburban _____ Rural _____

6. Portion of patients in your practice in the 12 to 23 year age group:
a. _____ <10%
b. _____ 10-20%
c. _____ 21-30%
d. _____ 31-40%
e. _____ 41-50%
f. _____ >50%

7. Are you aware that the CDC Advisory Committee for Immunization Practices (ACIP) now designates vaccine recommendations into either a Category A or Category B recommendation?
Yes _____
No _____
Not aware _____

8. Of the following, what is your understanding of a Category B meningococcal vaccine recommendation:
 - a. Vaccine is recommended for everyone in an age group or risk factor group
 - b. Vaccine is recommended only for those patient with underlying conditions
 - c. Vaccine is recommended only for patients 16 to 18 years of age
 - d. Vaccine is recommended based on healthcare provider clinical decision
 - e. Vaccine is recommended only in the event of a meningococcal outbreak
 - f. Don't know

9. Of the following, for whom is meningococcal B vaccine routinely recommended (Category A recommendation): (check all that apply)
 - a. Persons with functional or anatomic asplenia (including sickle cell disease)
 - b. Persons with complement component deficiencies
 - c. Persons traveling abroad
 - d. Persons with exposure to community outbreak due to a specific vaccine serogroup
 - e. Persons with cochlear implants/CSF leaks
 - f. Persons with chronic heart/lung disease
 - g. Persons with immunosuppressive conditions or on immunosuppressive medications

10. Of the following, which factors are barriers for you recommending a vaccine with a Category B recommendation: (Please check all that apply)
 - a. Concerned about adverse effects
 - b. Cost/Reimbursement
 - c. Multiple vaccine doses
 - d. Unaware of the recommendations for vaccine use
 - e. Unsure about how to discuss vaccine
 - f. Unsure about for whom the vaccine should be given
 - g. Unsure about when the vaccine should be given
 - h. Waiting for more information on long term vaccine efficacy
 - i. Other (please specify) _____

Survey 2: Sample pre-education survey for 16 to 23 year olds

For each of the questions, please check the most appropriate answer(s).

1. Gender:
Male _____ Female _____
2. Ethnicity:
White _____ Black _____ Hispanic _____ Asian _____ Other _____
3. Age:
18 years _____ 22 years _____
19 years _____ 23 years _____
20 years _____ > 23 years _____
21 years _____
4. Year in college:
Freshman _____ Sophomore _____ Junior _____ Senior _____ Other _____
5. Have you heard of meningococcal disease?
Yes _____ No _____
6. How is meningococcal disease transmitted?
 - a. Contact with infected respiratory secretions _____
 - b. Contact with infected blood _____
 - c. Handling/petting an infected animal _____
 - d. Ingestion of contaminated food and water _____
7. Which of the following are risk factors for transmission of meningococcal disease (please check all that apply):
 - a. _____ Active and passive smoking
 - b. _____ Attending sporting events/family gatherings/BBQ-picnic
 - c. _____ Attending a concert
 - d. _____ Bar/pub patronage
 - e. _____ Club/nightclub patronage
 - f. _____ Concurrent or recent upper respiratory infection (i.e. cold, influenza)
 - g. _____ ≥ 2 alcoholic drinks a week
 - h. _____ Eating in a restaurant
 - i. _____ Going to a movie theater
 - j. _____ Injectable drug use
 - k. _____ Living in a dormitory
 - l. _____ Marijuana use

- m. Mouth to mouth kissing
 - n. Sharing cigarettes/cigars/e-cigarettes
 - o. Sharing items of clothing or towels
 - p. Sharing utensils, drinks or water bottles
8. Are you aware if there are vaccines available to protect a person against meningococcal disease?
Yes No Don't Know
9. To your knowledge, have you received any doses of meningococcal vaccine?
Yes No (skip to Q11) Don't Know (skip to Q11)
10. If you **answered yes to question 9**, what was the reason(s) you received meningococcal vaccine (please check all that apply):
- a. Routine vaccine given by primary care physician
 - b. School entry requirement
 - c. Entry requirement for attending camp
 - d. Needed for travel abroad
 - e. Exposure to person(s) with meningococcal disease
 - f. Given during community outbreak of meningococcal disease
 - g. Parent requested that vaccine be given
11. Knowing what you currently know about meningococcal disease and vaccine, would you want to be vaccinated?
Yes No Don't know enough to make a decision
12. Please click on the link below to view an educational video on meningococcal disease and vaccine.