

A. Cover Page

Project Title

Enhancing MenB Administration in College Environments (EMBrACE)

Grant ID

27269125

Collaborators

- New York University
- Children's Research Institute at Children's National Health System

Abstract

The overarching goal of the ***Enhancing MenB Administration in College Environments (EMBrACE)*** project is to increase MenB vaccination coverage among a national sample of college students. The primary participants in the EMBrACE project will be college healthcare providers (HCPs) and the primary beneficiaries of the intervention (in terms of greater MenB coverage) will be college students aged 18-23 years.

A Baseline Needs Assessment Survey among 200 HCPs will be conducted to determine knowledge, attitudes, beliefs and practices regarding MenB vaccination, as well as perceived barriers to MenB vaccine delivery in the college setting. Formative data from the survey will inform the content focus of the QI intervention in Phase 2.

Adapted from the IHI Breakthrough Series Model, Phase 2 will enroll 50 participating institutions in a learning collaborative that will combine action-oriented training in QI, evidence-based practices in multi-vaccine delivery, and education in MenB vaccine recommendations. The intervention will include 6 Interactive Online Modules and 6 Expert-Led, Didactic Virtual Learning Sessions. Between Learning Sessions, participants will use the Model for Improvement to run small, rapid cycle tests of change and scale up successful system-level improvements quickly. Activities will be supported via an online resource center, listserv, archived sessions, and coaching. Evaluation of the Virtual QI Learning Collaborative will be done using an interrupted time series design over the six months of the intervention.

The interactive online modules and archived webinars developed in Phase 2 will be updated and repackaged based on key learnings into enduring materials for widespread distribution.

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C. Reviewer Comments

Thank you for the opportunity to submit a full proposal and for the comments regarding our letter of intent. Outlined below is how we addressed the reviewer comments.

Reviewer Comment #1: While all review panel members were interested by your program and look forward to reading your full proposal, a few request that you expand your description in some specific areas. The panel felt the LOI lacked some detail (as expected given the length of the LOI) that they would like provided in the full proposal.

Response #1: Significant detail has been added to the proposal in section *D4. Project Design and Methods* including an elaboration on the virtual QI learning collaborative intervention and additional description of the Institute for Healthcare's Improvement Breakthrough Series model on which our intervention will be based.

Reviewer Comment #2: One panel member noted that American College Health Association (ACHA) has not put in place formal MenB recommendations as they have for ACWY. Please provide details around ACHA's commitment to collaborate on this project as described?

Response #2: Actually, as described in the section, *D2b. Assessment of Need*, in April 2016, ACHA posted updated pre-matriculation immunization guidelines (http://www.acha.org/documents/resources/guidelines/ACHA_RIPI.pdf) that now include serogroup B meningococcal vaccine. Further, we will not rely exclusively on ACHA for participant recruitment. As described in section *D3. Target Audience*, we will recruit participants from the 3496 subscribers of the open-access SHS listserv and through targeted one-to-one outreach via personalized emails and phone calls. We have used these methods successfully for previous recruitment efforts of college healthcare professionals for similar immunization QI learning collaboratives. Since submitting the LOI, we have had conversations with directors of multiple offices of student health services all of whom were very excited about the prospects of participating in a MenB vaccination learning collaborative to improve the health of their institutions' study bodies while facilitating fulfillment of their benchmarking and performance improvement requirements for accreditation, from accrediting bodies such as the Accreditation Association for Ambulatory Health Care (AAHC). As a demonstration of interest in our proposed learning collaborative, we have included three letters of support from representatives of potentially eligible institutions.

Reviewer Comment #3: How would the investigators go about changing pre-matriculation requirements without support and policy change from ACHA?

Response #3: Because there is virtually no data about the knowledge, attitudes, beliefs, current practices and needs of college health professionals with regard to MenB, the first step to supporting potential policy change is to provide the ACHA with a summary of the current state of affairs. Therefore, to help inform future college health programming and policy, we have added an explicit objective to the proposed project:

Prepare and present a report of the findings from the Baseline Needs Assessment Survey to the ACHA Vaccine-Preventable Diseases Advisory Committee to improve the committee's understanding of members' needs regarding MenB education and resources.

D. Main Section

D1. Goal and Objectives

The overarching **goal** of the **Enhancing MenB Administration in College Environments (EMBrACE)** project is to increase MenB vaccination coverage among a national sample of college students. We will do so by achieving the following specific **objectives**:

1. Conduct a Baseline Needs Assessment Survey of 200 participants to determine college healthcare providers' (HCPs) knowledge, attitudes, beliefs and current practices regarding MenB vaccination, as well as perceived barriers and facilitators to improving MenB vaccine delivery within SHS settings.
2. Prepare and present a report of the findings from the Baseline Needs Assessment Survey to the Vaccine-Preventable Diseases Advisory Committee of the American College Health Association (ACHA) to improve the committee's understanding of members' needs regarding MenB education and resources.
3. Enroll HCPs representing 50 different colleges in a Virtual QI Learning Collaborative and evaluate for effect of participation on office of SHS' MenB vaccination delivery.
4. Create and disseminate enduring MenB QI Educational Materials so that other college HCPs continue to benefit after the project ends

D2. Current Assessment of Need in Target Area

D2a. Background

College students are at especially high risk of contracting and passing on meningococcal disease due to greater exposure to close habitation in dormitories, large social gatherings, alcohol consumption, multiple kissing partners and smoking.¹⁻³ It is therefore not unexpected that all seven outbreaks of serogroup B meningococcal disease in the United States between 2009-2013 have occurred on college campuses.⁴ High meningococcal B (MenB) vaccination coverage among college students is imperative to reduce the risk of future outbreaks. Nonetheless, significant barriers prevent many college students from receiving MenB vaccine from their regular primary care providers and medical homes. Among students attending colleges outside of their hometowns, geographic separation can prevent regular access to the medical home. In addition, gaps in identifying a medical home can occur when students transition care from pediatric to adult providers. As a result, individuals in their teens and early 20s make fewer medical visits than any other age group, and the majority fail to receive all recommended vaccines.^{5,6}

Student Health Services (SHS) within colleges are ideally poised to fill the temporary void in students' access to preventive health services including MenB vaccination. Nonetheless, college healthcare professionals (HCPs) have only recently begun focusing on adolescent vaccination with an emphasis on pre-matriculation immunization requirements (PIR) rather than comprehensive vaccine delivery.⁷ Further, there is significant variation in the methods and interventions used by colleges to ensure compliance with PIR and increase overall immunization coverage among their student bodies. A recently published paper by Jewett, et

al. found that among 308 colleges responding to a survey on immunization practices, 73% had any PIRs. Among colleges with PIRs, penalties to students for noncompliance included: preventing registration for the following semester (33%); preventing registration for the current semester (23%); restricting class attendance (16%); and preventing participation in organized sports (6%). Colleges also differed in terms of the vaccines administered within the health centers with 74% offering influenza vaccine, 37% varicella vaccine, and 55% the quadrivalent meningococcal vaccine (MenACWY). The figures reported in Jewett, et al. are likely an overestimate of national college immunization practices and rates since the majority of their survey respondents represented institutions that had health centers and performed health screenings which is often not the case for smaller, or lower resourced, colleges.

To decrease the spread of meningococcus and other vaccine-preventable diseases on college campuses, it is critical from a public health perspective to increase the role of college HCPs in adolescent/young adult vaccine delivery. We can do so by training college HCPs in established quality improvement (QI) methodology and providing them with the motivation and tools necessary to enhance their capacity to deliver adolescent/young adult vaccines including MenB effectively.

D2b. Assessment of Need

Leading infectious disease experts recommend that colleges be the focus of meningococcal disease prevention efforts.¹⁰ Reports from mass MenB immunization campaigns in response to college outbreaks demonstrate that students can be educated and motivated to receive MenB vaccine on campus, and that SHS have the capacity to administer MenB vaccine to a majority (89.1% and 94%) of students and track vaccination accurately.^{8,9} Because MenB vaccine was only recommended as of late last year,⁴ current rates of uptake are unknown. Nonetheless, comparison of two separate assessments of MenACWY vaccination rates among college students (65.1%)¹¹ versus children ages 13-17 years old (79.3%)¹² suggest that MenB vaccination coverage may also be lower among college students than younger adolescents. It is unknown how many college SHS currently offer MenB vaccine and what the knowledge, attitudes and beliefs are of college HCPs about MenB vaccine. We intend to explore these questions by conducting a Baseline Needs Assessment Survey as a first step in this proposed project.

In April 2016, ACHA posted updated pre-matriculation immunization guidelines (http://www.acha.org/documents/resources/guidelines/ACHA_RIPI.pdf) that now include serogroup B meningococcal vaccine. The ACHA guidelines regarding MenB vaccination are consistent with the recommendations of the Advisory Committee on Immunization Practices. Currently, the ACHA has very virtually no educational resources regarding the MenB vaccine for members. The ACHA maintains a Vaccine-Preventable Diseases Advisory Committee which provides guidance, education and resources to colleges and universities regarding vaccines, and vaccine-preventable disease outbreaks. Based on personal conversations with college health professionals, we believe there is a significant practice gap in MenB vaccine delivery among HCPs. We also believe there is an interest by college HCPs to participate in a MenB vaccination learning collaborative to improve the health of their institutions' study bodies while facilitating fulfillment of their benchmarking and performance improvement requirements for

accreditation, from accrediting bodies such as the Accreditation Association for Ambulatory Health Care (AAAHC); our letters of support provide evidence of this interest. We will seek input from college HCPs regarding items to include in our Baseline Needs Assessment Survey and then, after the survey is complete, submit a summary report of the findings to provide the ACHA Vaccine-Preventable Diseases Advisory Committee with a foundation for understanding the gaps in MenB vaccination knowledge base and delivery capacity among ACHA members and the field of college health.

D3. Target Audience

The *primary participants* in the EMBRACE project will be college HCPs, including physicians, physician assistants, administrators, nurses, and health educators. The *primary beneficiaries* of the intervention (in terms of greater MenB coverage) will be college students aged 18-23 years. We will recruit participants for the needs assessment survey from the 3496 subscribers of the open-access SHS listserv and through targeted one-to-one outreach via personalized emails and phone calls. Assessments of the respondents' colleges' characteristics (size, funding source, academic rigor/focus, models for supporting student health, and student body demographics) will be performed upon attainment of each quarter of the ultimate recruitment goal. Extra emails and phone calls will be directed to colleges with characteristics underrepresented in the survey at the time of each interim assessment so that the final sample reflects the diversity of national college characteristics as closely as possible. Participants in the Virtual QI Learning Collaborative will be recruited at the American College Health Association's Annual Meeting in May 2017, through the SHS listserv, and one-to-one outreach. In keeping with the methods employed in our prior successful recruitment of college HCPs for the New York State Higher Ed Immunization Collaborative, we believe it will be important to pitch the EMBRACE Learning Collaborative to potential participants as an opportunity to increase vaccination rates broadly on their campuses, and to advertise a nominal participation fee to increase the perceived value of the learning opportunity and thus increase commitment to and engagement in Collaborative activities. As such, there will be a fee of \$150 for colleges to participate. However for lower resourced colleges, a sliding fee and full waiver process will be available; no interested college will be turned away for inability to pay the fee. Factoring in scholarship requests, we anticipate raising ~\$3000, 100% of which will be applied toward enhancing the enduring QI materials we will create for dissemination to other college HCPs who do not participate in the Learning Collaborative.

Based on our enrollment in previous QI projects recruited from the same population, we anticipate being able to recruit at least 200 participants in the EmBRACE Needs Assessment Survey and improvement teams representing 50 colleges in the Learning Collaborative. Given that college enrollment ranges from <1000 to >50,000, our intervention has the potential to benefit over 300,000 college students directly. It is expected a greater number of college HCPs will utilize (and students will benefit from) the enduring education materials that will be distributed after the project ends.

D4. Project Design & Methods

We are proposing a 3-phase project involving:

Phase 1: Baseline Needs Assessment Survey

The survey will be used to determine HCPs' knowledge, attitudes and beliefs about MenB vaccine, and perceived barriers to MenB vaccine delivery in the college setting. Formative data from the survey will inform the content focus of the QI intervention in Phase 2. We will also prepare and present a report of the findings to the ACHA Vaccine-Preventable Diseases Advisory Committee to improve the committee's understanding of members' needs regarding MenB education and resources.

Phase 2: Virtual QI Learning Collaborative Intervention

Adapted from the Institute for Healthcare Improvement (IHI)'s Breakthrough Series Model, Phase 2 will use a collaborative learning approach and will combine training in QI, evidence-based practices in multi-vaccine delivery, and education in MenB vaccine recommendations.

The Breakthrough Series (BTS) Model is "an improvement method that relies on the rapid spread and adaptation of existing knowledge to multiple, similar sites to accomplish common aims... [BTS] seek to: 1) find, describe, and diffuse best practices throughout participating sites; 2) improve outcomes by facilitating participating organizations' understanding of their systems of care and changing them rapidly, yet safely; 3) develop expertise in the science of improvement; and 4) disseminate and deploy knowledge gained during the Collaborative as broadly as possible." The work of the BTS is organized around a "change package," which consists of a number of high-level outcomes supported by evidence-based concepts and specific change ideas that, when implemented, bring about quality improvement. This model is action-oriented and emphasizes an "all teach, all learn" approach to achieving breakthrough improvements over a defined period of time. The model includes Learning Sessions in which participants learn from each other and subject matter experts. Formal academic knowledge is bolstered by the practical voices of peers who can say, "I had the same problem; let me tell you how I solved it."

The work of the Learning Collaborative will be organized around the Care Model; this "change package" will drive the specific evidence-based changes necessary to address the factors that impact vaccination rates, including self-management support, delivery system design, decision support, clinical information systems, and community resources and policies. Together these components of care are essential to achieving a SHS system that facilitates the delivery of vaccinations to college students, a population that is generally not proactive about receiving routine care or preventive services. To apply changes in their local settings, institutions will form improvement leadership teams composed of professionals with different functions within their healthcare centers (e.g., physicians, nurses and administrators). Teams will learn The Model for Improvement, an approach for organizing and carrying out their improvement work. This model identifies four key elements of successful process improvement: specific and measurable aims, measures of improvement that are tracked over time, key changes that will result in the desired improvement, and a series of testing "cycles," (plan-do-study-act cycles) during which teams learn how to apply key change ideas to their unique SHS setting.

The intervention will include 6 Interactive Online Modules to guide participants in applying QI methodology to increasing MenB vaccination rates in a college setting and 6 Expert-Led, Didactic Webinar Learning Sessions. To maximize interactivity, collaboration and learning, the intervention will use a flipped classroom approach: the online modules will be completed

asynchronously before each Learning Session allowing greater opportunity for productive, interactive, action-oriented discussion between subject matter experts and participants at the Learning Sessions to address the local challenges with translating the evidence into practice. Module and Learning Session topics will be informed by the Baseline Needs Assessment Survey but most likely will include:

- Overview of Meningococcal Disease, MenB Vaccine, and Quality Improvement Basics
- Evidence-Based Strategies for Increasing Vaccination on College Campuses
- Model for Improvement & Plan-Do-Study-Act (PDSA) Cycles
- Getting Your QI Initiatives Started: Establish Your Team, Set an Aim, and Understand the Problem
- System Redesign: Integrating Vaccination Assessment and Delivery into Routine Care
- Faculty Facilitated PDSA Planning
- Rapid Cycle Testing for Implementing Vaccine Delivery Improvement Strategies
- Data Driven Methods for Assessing MenB Vaccination Practices on Campus
- Galvanizing Leadership and Staff to Support MenB Vaccine Delivery Improvements
- Leveraging Community Assets
- Spreading and Sustaining Gains
- Team Sharing of Vaccination Delivery Insights and Stories

During the Action Periods (between webinars), participants will complete 6 Interactive Online Modules (to be determined from topics noted above) and “In Action” assignments to use the Model for Improvement to run small, rapid cycle tests of change and scale up successful system-level improvements quickly. Activities will be supported via an online resource center, listserv, archived sessions, and monthly group conference calls facilitated by experienced QI coaches.

Participant engagement will be measured using the following methods:

- Using the learning management platform we will design to house our interactive Interactive Online Modules, we will track participants' progress, including percentage of the Interactive Online Modules completed, number of page clicks within modules and scores on quizzes embedded within modules.
- We will use the web conferencing software analytics to determine number of participants signed on and duration of participation in each conference.
- The QI Coach will track completion and quality of Action Period assignment submissions, engagement on the listserv/community platforms, and requests for individual coaching or advice.

Phase 3: Widespread dissemination of enduring MenB QI educational materials

During Phase 3, we will consolidate the learnings harvested during Phase 2 and use this new knowledge to update and repackage the Interactive Online Modules and archived webinars developed in Phase 2 into enduring materials. The materials will be hosted on the Network for Improvement and Innovation in College Health website, which is owned by New York University

and directed by Dr. Ciotoli and Ms. Smith. To supplement the enduring materials, the website functionality will be expanded to include a free, open-access, online learning community that will allow college health professionals to network, share resources, and provide peer support beyond the funding period. Widespread distribution of these enduring materials will occur by advertising their free access via the Network for Improvement and Innovation in College Health, open-access college health listservs, and presentations at regional and national college health meetings. We will also reach out to professional organizations such as ACHA and NASPA (Student Affairs Professionals in Higher Education) to request dissemination through their networks.

Innovation

Our study will be the first to determine college HCP's MenB knowledge, attitudes, beliefs, practices, and perceived barriers and facilitators of MenB delivery in the SHS setting. It will also be first to conduct a MenB QI learning collaborative for college HCPs. This project will build on the expertise of Dr. Carlo Ciotoli and Ms. Allison Smith in leading national college health QI initiatives including: the Network for Improvement and Innovation in College Health, the National College Depression Partnership (the first college health QI collaborative), the AHRQ-funded Project to Build Improvement Capacity in College Health, and the NYS Higher Ed Immunization Collaborative (the first immunization QI collaborative in the field of college health). The project will also benefit from the experience in immunization QI of Dr. Linda Fu who has directed multiple immunization delivery QI projects which have received local and national awards. Results of her projects have been disseminated via national and international presentations and publications in major pediatric journals.¹³⁻¹⁶

D5. Evaluation and Outcomes

D5a. Overview

Rigorous analyses are planned for this project's two scientific studies to evaluate outcomes regarding pursuit of Objectives 1 (conducting a Baseline Needs Assessment Survey to determine college HCPs' knowledge, attitudes, beliefs and current practices regarding MenB vaccination, as well as perceived barriers and facilitators to improving MenB vaccine delivery within SHS settings) and 2 (conducting and evaluating a Virtual QI Learning Collaborative to improve college HCPs' delivery of MenB vaccination).

Enrollment and eligibility

Our goal will be to enroll 200 participants in the EmBRACE Needs Assessment Survey and 50 project site leaders in the Learning Collaborative using the methods described in the section, *Target Audience*. While individuals will be able to elect to participate only in the survey, survey respondents will be encouraged to serve as site leaders for their SHS centers in the learning collaborative. Conversely, survey completion will be mandatory for those who participate in the learning collaborative so that we may tailor learning sessions to the group's particular needs. The online Baseline Needs Assessment survey will be housed on the REDCap data management platform. The program will use embedded stop-logic to assess potential participants for eligibility. To be eligible to participate in the baseline survey and learning collaborative,

individuals will need to be directly involved in SHS at 2- or 4-year institutions of higher education with practical knowledge about their institutions' vaccination practices, policies and procedures. Eligible participants will be college HCPs, including physicians, physician assistants, SHS administrators, nurses, and health educators. To participate in the learning collaborative, individuals will additionally need to attest to their institutions' commitment to improving their student bodies' immunization coverage and ability to form improvement teams consisting of at least one vaccination provider and an SHS administrator. Multiple college HCPs from a single institution may participate in the needs assessment survey since we anticipate perspectives will vary within institutions by respondents' professional roles. However, only one individual should serve as a site leader for each college's improvement team in the learning collaborative.

D5b. Procedures for evaluating Objective 1, the Baseline Needs Assessment Survey

Study design: The Baseline Needs Assessment Survey will be designed as a cross-sectional study.

Survey items

Once eligibility is confirmed, the REDCap system will automatically continue onto the content portion of the Needs Assessment survey. This 15-minute, online survey will include items to determine participants' baseline knowledge, attitudes, and beliefs with regard to all adolescent/young adult vaccines including MenB, vaccine safety, VPDs, and counseling students about vaccines in general and MenB specifically. It will determine current awareness and application of immunization delivery best practices and perceived barriers and facilitators to improving MenB vaccine delivery in the SHS setting. Finally, the survey will assess aspects about the institution including student body sociodemographic composition, geographic location, size and composition of the office of SHS. The survey will be designed such that participants will be able to stop and resume participation (via unique links to their incomplete surveys emailed to participants who exit the survey prior to completion) if they need time to gather accurate information. Whenever possible, items will be taken verbatim and/or adapted from existing surveys to allow for easy comparison of results to the existing literature (see Table). Upon completion of the survey, participants will be emailed an online Amazon gift card code for \$20.

Table 1. Examples of sources of items to be included either verbatim or modified for the EMBRACE Needs Assessment Survey

Concept to be measured	Potential items' source
Knowledge about of the dangers of MenB and other vaccine preventable diseases (VPDs) in college settings	Vaccine Policy Collaborative Initiative (Kempe 2015) ¹⁷
Attitudes and beliefs about MenB and other adolescent vaccines	Vaccine Health Belief Model (Liau 2012); ¹⁸ Parent Attitudes about Childhood Vaccines (PACV) survey (Opel 2011) ¹⁹
Awareness and current application of immunization delivery best practices	Standards for child and adolescent immunization practices (NVAC 2003); ²⁰ Suggestions to improve your immunization services (IAC 2014) ²¹

Perceived health system barriers to and facilitators of improved MenB delivery	Innovation Diffusion Theory (Rogers, 1995) ²²
Awareness of effective strategies for communicating with students about MenB and other vaccines	Vaccine Policy Collaborative Initiative (Kempe 2015) ¹⁷

Analytic plan

Survey data will be reviewed for completeness and errors. Variables will be examined for impossible or unusual values and will be checked for consistency with related variables. Descriptive analyses, including means with standard deviations and medians with interquartile ranges for continuous data, and percentages for categorical data, will be used to describe findings.

D5c. Procedures for evaluating Objective 2, the Virtual QI Learning Collaborative

Study Hypothesis: Offices of SHS with participants in a virtual QI learning collaborative will significantly improve their MenB vaccination delivery rates over baseline.

Study design: Evaluation of the Virtual QI Learning Collaborative will be done using an interrupted time series design over the six months of the intervention.

Outcomes to be assessed:

- 1) Individual student-level outcomes to be assessed include: **MenB vaccination rates over the course of the intervention (primary outcome** on which power calculation is based); rates of MenB vaccination missed opportunities; and rates of documentation of MenB vaccine refusal
- 2) Systems-level outcomes to be assessed include: MenB vaccine ordering availability; use of MenB standing orders; identification of a MenB immunization champion; use of student MenB vaccination reminders and recalls; inclusion of MenB vaccination history in pre-matriculation requirements; and use of MenB HCP decision-support/reminders

Data collection:

Participants will upload immunization data onto online surveys via the REDCap data system a total of 10 times over the course of the study: twice for each of the two months preceding the start of the learning collaborative, six times monthly over the six months of the learning collaborative period, and then once 5-months after the learning collaborative ends (as in Table 2). The first two data assessments will be used to establish baseline rates. The last two assessments will be used to determine impact of learning collaborative participation on vaccine delivery over time and sustainability of results, respectively.

Table 2. Participant immunization data collection in relation to the Learning Collaborative In Action period.

Learning Collaborative Activity Month	-1	0	1	2	3	4	5	6	7	8-11	12
Learning Collaborative In-Action Period			x	x	x	x	x	x			
Immunization Data uploaded by participants	x	x	x	x	x	x	x	x	x		x

For individual student-level data, participants will perform a retrospective chart review to record information from a consecutive sample of 15 health records of students who have had at least one SHS encounter immediately preceding the assessment date (working backwards). Exact assessment dates for each month of data collection will be predetermined by study staff and varied to ensure that each day of the week is equally represented over the course of the data collection period in case immunization practices differ according to office staffing variability by day of the week. Selected dates for data collection will only be shared with participants after the dates have passed to avoid knowledge of the data collection requirement temporarily changing practices. Participants will be instructed to include records from patients treated by all HCPs working on the assessment date.

Analytic plan:

Descriptive analyses, including means with standard deviations and medians with interquartile ranges for continuous data, and percentages for categorical data, will be used to describe findings from the baseline provider survey. A time series analysis using autoregressive error models will be conducted to evaluate whether MenB vaccination rates change over time from prior to the study start to 5 months following the study. Secondary analyses will consider vaccination rate pre and post-intervention using linear regression models adjusted for repeated measures by school to determine whether vaccination rates were significantly higher following completion of the learning collaborative. For both models, time-period vaccination rates at the school level will be considered as the outcome. Process control charts using estimates prior to initiation of the learning collaborative as a baseline measure may also be constructed to facilitate comparison with other QI initiatives. To evaluate factors associated with MenB vaccination, patient-level log-binomial regression models, clustered by college, will be created to assess willingness to receive vaccination among patients to whom the vaccine was offered. Variables associated with MenB vaccination on bivariate analyses at $p < 0.10$ will be considered for inclusion in multivariable models

Amount of expected change:

Based on our anecdotal knowledge of current practices, most participants will not offer on-campus MenB vaccination at baseline. Thus, we anticipate our intervention will increase MenB vaccination delivery by at least 15%--as much if not more than the amount of change seen in previous immunization QI projects conducted with pediatric practices.^{13,23} Using sample size formulas developed for trend assessment of repeated measures, it is estimated that enrollment of 20 improvement teams (i.e. colleges) will provide 90% power to detect an increase of 15% in vaccination rates over the course of the study at $\alpha = 0.05$. Although only 20 colleges are needed, since we will be instructing HCPs in proven immunization best practices, we believe that it is preferable to enroll more than 20 colleges in the EmBRACE Learning Collaborative if possible. Based on our enrollment in previous QI projects recruited from the same population, we anticipate being able to recruit 50 project site leaders representing 50 colleges in the Learning Collaborative. Therefore, we will aim to have 50 colleges participate in the learning collaborative, but will be satisfied with a recruitment of at least 24 colleges—a number that will allow for full data collection on 20 colleges given a 20% drop out rate.

To provide adequate estimates of vaccination rates with narrow 95% confidence intervals, institutions will be asked to evaluate 15 student records at each time-point, for a total of a minimum of 300 student records (if a minimum of 20 colleges fully report data) for each time-point across colleges. Because degree of correlation between measures and within colleges is unknown, the sample size calculation allows for a high degree of correlation (up to 0.7).

D5d. Dissemination plan:

See Project design, Phase 3 for plan to disseminate enduring MenB QI materials (created and empirically tested in Phase 2) to others at no charge by leveraging existing college health networks to which project investigators belong. In addition, project study results will be disseminated via presentations at relevant national conferences (such as the ACHA and PAS Annual Conferences), and publications in such journals as *Journal of Adolescent Health* and *Journal of American College Health*.

D6. Workplan and Deliverables Schedule

Year	Activity	Month of Study											
		1	2	3	4	5	6	7	8	9	10	11	12
1	• Finalize Collaborative Structure	x	x	x	x	x	x	x	x	x	x	x	x
	• Develop Survey, obtain IRB approvals	x	x	x									
	• Recruit & enroll for survey and collaborative				x	x	x	x	x	x	x		
	• Analyze results of survey											x	x
	• Prepare MenB needs assessment report							x	x	x	x		
	• Develop 6 Interactive Online Modules											x	x
	• Data collection tools for collaborative		x	x	x	x	x	x	x	x	x	x	x
2	• Data uploaded by collaborative participants	x	x	x	x	x	x	x				x	
	• Action period for collaborative participants									x	x	x	x
	• Develop & disseminate enduring MenB QI educational materials									x	x	x	x
	• Analyze results of collaborative intervention											x	x
	• Prepare final project report and manuscripts												

Year 1

- Finalize Collaborative Structure
 - Identify college health professionals to serve as faculty

- Identification and consolidation of relevant knowledge.
- Host 2 day faculty meeting to review the quality improvement project methodology, including the aims, measures, data collection tools, criteria for team participation selection and other project design related issues.
- Develop the learning session webinar topics, times and faculty.
- Develop Survey, obtain IRB approvals:
 - Literature review of existing instruments to assess provider knowledge, attitudes and beliefs with regard to all adolescent/young adult vaccines including MenB, vaccine safety, VPDs, and counseling about vaccines in general and MenB specifically
 - Pilot test the instrument
 - Program into REDCap data system
 - Prepare and submit IRB application
- Recruit & enroll for survey and collaborative:
 - A diversity of marketing materials will be developed including a web presence on collegehealthqi.nyu.edu, email blasts, and phone scripts.
 - We will recruit participants from open-access SHS listserv and through targeted one-to-one outreach via personalized emails and phone calls. We will also reach out to existing networks, such as higher education and college health professional associations to promote.
 - We will develop a brief application for colleges interested in joining the collaborative.
 - At the 2017 ACHA Annual Meeting, we will set-up targeted meetings with key college health leaders to obtain feedback to inform the Collaborative content and materials and to recruit participants.
 - An informational webinar about the Collaborative will be held after the Annual Meeting for those considering participation.
- Analyze results of survey & prepare MenB needs assessment report
 - Data will be cleaned and analyzed using the methods outlined in section D5. Findings will be shared with the EMBRACE faculty and project team to inform the Interactive Online Modules and Collaborative content. A formal report will be prepared for and distributed to higher education and college health stakeholders such as the American College Health Association.
- Develop 6 Interactive Online Modules:
 - Identify speakers for videos embedded within the modules.
 - Original content about quality improvement and vaccine delivery tailored to college HCPs will be produced, including multimedia content. Feedback will be obtained about content, and revisions will be made as necessary
 - Define technical requirements and scope. The online learning management platform will be developed and content will be loaded into the platform. Usability testing will be conducted with a small group of HCPs and revisions will be made as necessary.
 - Additional web development work will integrate the modules/online learning management platform into existing collegehealthqi.nyu.edu website to create a single user experience.
- Develop data collection tools for collaborative
 - Finalize measures & qualitative reporting forms

- Develop data collection tool and obtain feedback from college HCPs to ensure the proposed data is obtainable with minimal effort.
- Program into REDCap data system

Year 2

- Data uploaded by collaborative participants
- Action period for collaborative participants
 - Project Team will review Senior Leader reports due monthly, follow up with teams as needed, communicate with Senior Leaders, assess teams/collaborative progress, facilitate discussion on Listserv
 - Individual run charts of each participating team's monthly measures will be developed/updated by the project team each month and presented back to the team
- Develop & disseminate enduring MenB QI educational materials
 - Harvest key learnings, consolidate learnings into a package that can be widely spread, and developing a plan to support spread throughout the field of college health.
 - Based on learnings and feedback obtained about content, revisions to Interactive Online Modules and website will be made as necessary
 - Define technical requirements and scope to move Interactive Online Modules to NYU server and web development work to create an online learning community
 - Complete additional web development work to fully integrate the modules/online into existing collegehealthqi.nyu.edu website
- Analyze results of collaborative intervention
 - Data will be cleaned and analyzed using the methods outlined in section D5.
- Prepare final project report and manuscripts

E. References

1. 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):3133-3137.
2. 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):624-630.
3. 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):344-348.
4. MacNeil JR, Rubin L, Folaranmi T, Ortega-Sanchez IR, Patel M, Martin SW. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(41):1171-1176.
5. Humiston SG, Rosenthal SL. Challenges to vaccinating adolescents: vaccine implementation issues. *Pediatr Infect Dis J.* 2005;24(6 Suppl):S134-140.
6. National Foundation for Infectious Diseases. Call to action: Adolescent vaccination--Bridging from a strong childhood foundation to a healthy adulthood. Bethesda, MD, 2005.
7. Vaccine-Preventable Disease Advisory Committee. *Recommendations for institutional prematriculation immunizations.* Hanover, MD: American College Health Association;2014.
8. McNamara LA, Shumate AM, Johnsen P, et al. First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak. *Pediatrics.* 2015;135(5):798-804.
9. Soeters HM, McNamara LA, Whaley M, et al. Serogroup B Meningococcal Disease Outbreak and Carriage Evaluation at a College - Rhode Island, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(22):606-607.
10. Schaffner W, Baker CJ, Bozof L, Engel J, Offit PA, Turner JC. *Addressing the Challenges of Serogroup B Meningococcal Disease Outbreaks on Campuses.* Bethesda, MD: National Foundation for Infectious Diseases;2014.
11. American College Health Association. *National College Health Assessment, Spring 2015 Reference Group Data Report.* Hanover, MD 2015.
12. Reagan-Steiner S, Yankey D, Jeyarajah J, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years - United States, 2014. *MMWR Morb Mortal Wkly Rep.* 2015;64(29):784-792.
13. Fu LY, Weissman M, McLaren R, et al. Improving the quality of immunization delivery to an at-risk population: a comprehensive approach. *Pediatrics.* 2012;129(2):e496-503.
14. Fu LY, Zook K, Gingold J, et al. Frequent vaccination missed opportunities at primary care encounters contribute to underimmunization. *J Pediatr.* 2015;166(2):412-417.
15. Gingold JA, Briccetti C, Zook K, et al. Context matters: Practitioner perspectives on immunization delivery quality improvement efforts. *Clin Pediatr.* Jan 6, 2016-epub ahead of print.
16. Fu LY, Zook K, Gingold J, et al. Strategies for improving vaccine delivery: a cluster randomized trial. *Pediatrics.* In press March 11, 2016.
17. Kempe A, O'Leary ST, Kennedy A, et al. Physician response to parental requests to spread out the recommended vaccine schedule. *Pediatrics.* 2015;135(4):666-677.
18. Liao A, Stupiansky NW, Rosenthal SL, Zimet GD. Health beliefs and vaccine costs regarding

human papillomavirus (HPV) vaccination among a U.S. national sample of adult women. *Prev Med.* 2012;54(3-4):277-279.

19. Opel DJ, Mangione-Smith R, Taylor JA, et al. Development of a survey to identify vaccine-hesitant parents: the parent attitudes about childhood vaccines survey. *Hum Vaccin.* 2011;7(4):419-425.
20. Standards for child and adolescent immunization practices. National Vaccine Advisory Committee. *Pediatrics.* 2003;112(4):958-963.
21. Suggestions to improve your immunization services. Immunization Action Coalition. www.immunize.org/catg.d/p2045.pdf. Accessed June 2, 2016.
22. Rogers EM. *Diffusion of innovations*. Fourth ed. New York: Simon & Schuster; 1995.
23. Slora EJ, Steffes JM, Harris D, et al. Improving pediatric practice immunization rates through distance-based quality improvement: a feasibility trial from PROS. *Clin Pediatr.* 2008;47(1):25-36.