SYLLABUS & COURSE INFORMATION

SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF MINNESOTA

PUBH 6383

Vaccines
Spring 2019 (1st Half of Semester 1/23/19 – 3/11/19)

COURSE & CONTACT INFORMATION

Credits:	2
Meeting Day(s):	Monday and Wednesday
Meeting Time:	2:30pm-4:25pm
Meeting Place:	Moos Health Sciences Tower 2-118

Instructor:	Nicole E. Basta, PhD MPhil
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Office Hours:	By appointment
Office Location:	West Bank Office Building, Suite 300

COURSE DESCRIPTION

Vaccines are one of the most successful public health interventions ever developed. Yet, fundamental misconceptions about how and why vaccines work and about the scientific evidence for their efficacy and safety limit the ability of public health professionals to prevent and control the spread of vaccine-preventable diseases. Vaccinology is the branch of infectious disease epidemiology that addresses these issues, building upon core concepts in epidemiologic methods to explain both the individual- and population-level impact of vaccines. In this graduate level course, students will focus on critical concepts and methods in epidemiology, infectious diseases, vaccinology, and public health needed to:

1) Understand the principles of infectious disease transmission dynamics that determine how and why vaccines reduce the burden of disease

2) Utilize epidemiologic methods and study designs to assess vaccine efficacy/effectiveness

3) Develop and implement strategies to address the challenges of achieving and maintaining high vaccine coverage in diverse communities across the US and globally.

More than 25 human diseases can be prevented by vaccination and dozens of novel and next-generation vaccines are currently under development. From ongoing efforts to eradicate polio worldwide to measles outbreaks in the US where the disease had once been eliminated to the development of fast-tracked Ebola vaccines during the West African outbreak, vaccines have taken center stage in the field of infectious diseases over the past several decades because of the incredible impact vaccines have had on saving lives, preventing disease, and preserving health. However, despite the success of vaccination programs against many serious diseases, challenges to designing, delivering, and maintaining trust in vaccines persist. Communities in the US simultaneously express disinterest and distrust in routine vaccinations of children against once-common diseases such as polio and measles while at the same time demanding rapid development of vaccines for newly emergent diseases. Globally, vaccine-preventable diseases (pneumonia and diarrheal diseases including rotavirus) remain top causes of death in children under 5 years old. Yet

vaccine access continues to be a challenge. The field of vaccinology allows us to examine, from an epidemiologic methods perspective, how and why vaccines protect individuals and populations and how and why we face challenges to achieving and maintaining high vaccine uptake among at-risk populations worldwide. In doing so, we gain the knowledge needed to develop strategies that can successfully protect all individuals from vaccine-preventable diseases.

From the perspective of researchers, public health practitioners, and medical professionals, we will learn about numerous study designs to assess vaccine efficacy, effectiveness, and safety, and we will learn to apply communication skills critical to translating epidemiologic evidence about vaccines to the public. Specifically, we will draw upon the primary literature to understand concepts in infectious disease transmission dynamics, herd immunity, maternal immunity, and waning/boosting of immune responses. These concepts set the foundation for understanding how and why vaccines protect both individuals and populations and how individuals interact with populations in complex ways. Throughout this course, we will apply principles of epidemiology and epi methods to understand how vaccines have successfully reduced the burden of disease in many different settings across the globe and examine how the challenges of vaccine hesitancy, refusal, and lack of access threaten the advances that have been made in reducing the burden of infectious diseases. Students from many different disciplines who are interested in understanding why vaccines have been regarded as one of the greatest public health achievements of all time will gain a clear understanding of the essential role that they play in preventing disease and maintaining health populations.

COURSE PREREQUISITES

One graduate course in Epidemiology and one graduate course in Biostatistics or permission of the instructor. All individuals attending class must be registered.

COURSE GOALS & OBJECTIVES

At the end of this course, students will be able to:

1. Describe key concepts in immunology and population dynamics that underlie the principles by which vaccines protect individuals and populations.
2. Explain the stages of vaccine development from pre-clinical to licensure and the regulatory process for evaluating vaccine candidates in the US.
3. Understand and interpret key quantitative measures in infectious disease transmission dynamics including the concepts of herd immunity, R_0, and the critical vaccination fraction.
4. Calculate and interpret epidemiological measures including direct and indirect vaccine efficacy.
5. Describe the methods needed to implement specialized epidemiologic study designs including challenge studies, test-negative designs, and stepped-wedge designs to assess the direct of vaccines on individuals and indirect effects of vaccination programs in populations and understand when to implement such designs. Evaluate the quality of studies utilizing these designs.
6. Summarize the schedule of recommended vaccinations for pregnant women, infants, adolescents, and adults and understand how maternal immunity, waning and boosting of immunity and other concepts shape these recommended schedules.
7. Recognize the controversies surrounding vaccines that contribute to vaccine hesitancy and vaccine refusal in the US and globally.
8. Describe barriers to achieving and maintaining high vaccine uptake in diverse settings among diverse populations in the US and globally.
9. Characterize the health disparities that result in limited access to vaccines in low-income settings and how these disparities shape the global epidemiologic patterns of infectious disease morbidity and mortality.
10. Communicate evidence-based messages to the public to promote health and address misinformation and misconceptions.

COURSE WORKLOAD EXPECTATIONS

PubH 6383: Vaccines is a 2 credit, half-semester course held during the first half of Spring 2019 semester. The University expects that for each credit for a half-semester course, students will spend a minimum of 6 hours per week attending class and/or engaging in reading, studying, completing assignments, and furthering your knowledge of the course material over the half term. This amounts to approximately 12 hours per week devoted to this course, including 4 hours in-class time. The course will consist of a mixture of lectures, readings from the primary literature and textbooks, case studies, group discussions, and in-class and at-home exercises. Students will have the opportunity to learn about multiple topics under the themes of epidemiologic methods, infectious diseases transmission dynamics, study designs, how and why vaccines work, and barriers to reducing and eliminating vaccine-preventable diseases. Students will also be challenged to develop and demonstrate communication strategies to address controversies in vaccinology. In addition, students will learn to interpret epidemiologic studies relevant to infectious diseases. In this course, students will be expected to evaluate and draw upon sound epidemiologic evidence to develop well-reasoned arguments to address key topics in the field of vaccinology.

LEARNING COMMUNITY

School of Public Health courses ask students to discuss frameworks, theory, policy, and more, often in the context of past and current events and policy debates. This courses also asks students to work in teams or discussion groups. Students come from a diversity of backgrounds and have had varied experiences. Respectful and thoughtful exchanges are expected when collaborating, listening, and engaging with others in this course and are critical to successful professional, academic, and scientific engagement with topics.

Like other work in the course, all student-to-student communication is covered by the Student Conduct Code (https://z.umn.edu/studentconduct).

COURSE TEXT & READINGS

All readings should be completed before attending the session for which they are listed. For example, students should reach “A short history of vaccination” and the 2013 NEJM paper before attending the first class.

Note: All course readings (including textbooks) are available as PDFs or e-books through the UMN Library. The course Moodle site will include links to these readings. Students are NOT expected to purchase these books, (unless they prefer to). Students can access these texts online:

Vaccines 7th Edition. Plotkin, Stanley A.; Orenstein, Walter A.; Offit, Paul A.; Edwards, Kathryn M. 2018. Available to UMN students as an ebook by following the link to ClinicalKey in the UMN Library catalogue.

Design and Analysis of Vaccine Studies. Halloran, M. Elizabeth, Longini, Jr., Ira M., Struchiner, Claudio J. Springer New York. Statistics for Biology and Health Series. 2012. Available to UMN students as an ebook in the UMN Library catalogue.

Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Kroger A, Wolfe S, eds. Centers for Disease Control and Prevention.13th ed. Washington D.C. Public Health Foundation, 2015. Downloadable free online: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

The Vaccine Book. Ed. Bloom, Barry R.; Lambert, Paul-Henri. 2016.
Available to UMN students as an ebook by following the link in the UMN Library catalogue.

Additional readings from the primary scientific literature are listed in the tables below.

Course Outline/Weekly Schedule

Week	Topic	Readings	Assignments DUE 12 NOON
Week 1 **Wed Jan 23**	• Introduction to Vaccinology • History of Vaccination, Key Developments, and Ongoing Challenges	• Vaccines, 7th Edition, Section 1.1 A Short History of Vaccination • van Panhuis WG, et al. Contagious diseases in the United States from 1888 to the present. NEJM. 2013 Nov 28;369(22):2152-8.	
Week 2 **Mon Jan 28**	• Vaccine Design, Development, and Safety • Study Designs: Clinical Trials to Evaluate Vaccines	• The Vaccine Book. Chapter 6 "How are Vaccines Assessed in Clinical Trials?" • The Vaccine Book. Chapter 8 "How is Vaccine Safety Monitored?" • Review these interactive infographics to learn how vaccines are made and to become familiar with different types of vaccines: https://www.historyofvaccines.org/content/how-vaccines-are-made and https://www.historyofvaccines.org/content/types-vaccines	• **Reading Question DUE** • **Assignment 1 Distributed**
Week 2 **Wed Jan 30**	• Key Concepts in Vaccine Immunology (Guest Lecture with Kristina Burrack) • Quantitative Methods for Measuring Vaccine Efficacy (VE): How Vaccines Protect Individuals	• Epidemiology and Prevention of Vaccine-Preventable Diseases. Chapter 1: Principles of Vaccination • The Vaccine Book. Chapter 2: "How Vaccines Work" • Recommended to test your knowledge of immunology: https://www.historyofvaccines.org/content/how-vaccines-work • Design and Analysis of Vaccine Studies. Vaccine Effects. Chapter 2-2.6, pages 19-30	• **Reading Question DUE**
Week 3 **Mon Feb 4**	• Understanding Quantitative Concepts in Vaccinology: Susceptibility, R0, Contact Rate, Critical Vaccination Fraction: How Vaccines Protect Populations I • Infectious Disease Transmission Dynamics: How Vaccines Protect Populations II	• The Vaccine Book. Chapter 1 "Understanding Vaccine Impact at Population and Individual Levels"	• **Reading Question DUE** • **Assignment 1 DUE** • **Assignment 2 Distributed**
Week 3 **Wed Feb 6**	• Community (Herd) Immunity: How Vaccines Protect Populations III • Evaluating Indirect, Total, and Overall Effects: How Vaccines Protect Populations IV	• Fine P, et al. ''Herd Immunity'': A Rough Guide. Clinical Infectious Diseases. 2011;52(7):911–916. • Halloran ME & Struchiner CJ. Study Designs for Dependent Happenings. Epidemiology. 1991; 2(5): 331-338.	• **Reading Question DUE**

Week 4 **Mon Feb 11**	• Maternal, Infant, and Child Vaccination: Successes and challenges • Adolescent and Adult Vaccination: Successes and challenges	• The Vaccine Book. Chapter 10 "Maternal Immunization: Protecting Vulnerable Populations" • Birth - 6 yrs Vaccination Schedule CDC. http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html • Adolescent Vaccination Schedule. CDC. https://www.cdc.gov/vaccines/schedules/easy-to-read/preteen-teen.html • Adult Vaccination Schedule. CDC. https://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html	• **Reading Question DUE** • **Assignment 2 DUE** • **Presentation Topics/Partner DUE** • **Assignment 3 Distributed**
Week 4 **Wed Feb 13**	• Protecting Minnesotans: Immunization Recommendations in Action (Guest Lecture and Exercise with Miriam Muscoplat and Jennifer Heath)	• Barber A, et al. Coverage with Tetanus, Diphtheria, and Acellular Pertussis Vaccine and Influenza Vaccine Among Pregnant Women — Minnesota, March 2013–December 2014. MMWR. 2017;66(02):56–59 • Review Vaccines During Pregnancy - CDC. http://www.cdc.gov/vaccines/pregnancy/pregnant-women/index.html	
Week 5 **Mon Feb 18**	• Vaccine Hesitancy and Refusal in the US • Ethical Consideration for Vaccines: Private Choices and Public Goods – (Guest Lecture with Fareed Awan)	• The Vaccine Book. Chapter 26 "Vaccine Acceptance" • The Vaccine Book. Chapter 27 "Trust and Confidence in Vaccines" • Salmon DA et al. Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. The Lancet. 2006 Feb 4;367(9508):436-42	• **Reading Question DUE** • **Assignment 3 DUE** • **Assignment 4 Distributed**
Week 5 **Wed Feb 20**	• Communication Strategies for Public Health Controversies • In Class Exercise: Developing Public Health Messages to Address Vaccine Controversies	• Jarrett C et al. Strategies for addressing vaccine hesitancy – A systematic review. Vaccine. 2015 Aug 14;33(34):4180-90. • Phadke VK et al. Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis. JAMA. 2016 Mar 15;315(11):1149-58.	• **Reading Question DUE**
Week 6 **Mon Feb 25**	• Nova: Calling the Shots • Discussion led by Guest Lecturer Angie Ulrich	• TBA	• **Reading Question DUE** • **Assignment 4 DUE**

Week 6 **Wed Feb 27**	• Epi Study Designs for Assessing the Direct and Indirect Effect of Vaccines: Household-Based Study Designs and Cluster-Based Study Designs including Stepped-Wedge Designs, Test-Negative Designs and Challenges Studies • Epi Study Designs: Serological Surveys and Sero-Epidemiology	• Jackson ML, Nelson JC. The test-negative design for estimating influenza vaccine effectiveness. Vaccine. 2013 Apr 19;31(17):2165-8. doi: 10.1016/j.vaccine.2013.02.053. Epub 2013 Mar 13. • Darton T *et al*. Design, recruitment, and microbiological considerations in human challenge studies. Lancet Infect Dis. 2015 Jul;15(7):840-51. doi: 10.1016/S1473-3099(15)00068-7. • Cutts FT and Handon M. Seroepidemiology: an underused tool for designing and monitoring vaccination programmes in low- and middle-income countries. Trop Med Int Health. 2016; 21(9):1086-98. Epub 2016 Jul 1.	• **Reading Question DUE** **<u>REMINDER:</u>** • **UPLOAD PRESENTATION SLIDES TO MOODLE BY SUNDAY Mar 3 at 5pm**
Week 7 **Mon Mar 4**	• Student Presentations • Student Presentations		
Week 7 **Wed Mar 6**	• Student Presentations • Student Presentations		
Week 8 **Mon Mar 11**	• Global Challenges in Vaccine Delivery: Disparities in Access • Global Challenges in Vaccine Preventable Diseases: Future Outlook	• Vaccines 7th Edition. Section 76 Immunization in Developing Countries. pp 1486-1511.	• **Reading Question DUE**

SPH AND UNIVERSITY POLICIES & RESOURCES

The School of Public Health maintains up-to-date information about resources available to students, as well as formal course policies, on our website at www.sph.umn.edu/student-policies/. Students are expected to read and understand all policy information available at this link and are encouraged to make use of the resources available.

The University of Minnesota has official policies, including but not limited to the following:

- Grade definitions
- Scholastic dishonesty
- Makeup work for legitimate absences
- Student conduct code
- Sexual harassment, sexual assault, stalking and relationship violence
- Equity, diversity, equal employment opportunity, and affirmative action
- Disability services
- Academic freedom and responsibility

Resources available for students include:

- Confidential mental health services
- Disability accommodations
- Housing and financial instability resources
- Technology help
- Academic support

EVALUATION & GRADING

This course will be graded out of 500 points. Points will be allocated according to the grading rubric outlined below.

Attending and contributing to the discussion is key to success in this course. Students will be asked to sign in at the start of each class session. Students will be required to submit a question prior to the beginning of each class session listed in the above schedule based on the reading for that session through the course Moodle website. Students will be encouraged to ask questions throughout the lecture, including the question they submitted if it hasn't been answered. Students will also be encouraged to engage in discussion with the instructor, guest lecturers, and their peers.

Assignments 1-4 will be handed out one week prior to the due date. Each assignment will consist of a written response that addresses a topic covered in class or one of the readings. Through these assignments, students will gain critical skills in assessing the primary literature, evaluating epidemiologic study designs, interpreting results, and applying concepts from the epidemiology of vaccines to issues of local, national, and global importance.

For the final presentation, students will choose a specific vaccine that is not covered in the course from the list provided on the course Moodle site. Students will apply concepts covered in the course to their chosen vaccine and present the results of their research on this topic during a 15-minute presentation. Students will undertake the final project in pairs and will be graded according to the criteria below.

Students must identify a partner and choose a vaccine via email by Monday, Feb 11th, 12 noon (assignments made on a first come/first served basis) for approval prior to beginning research. Students may also ask to be assigned a partner, if they prefer. The aim of the presentation is to apply skills and methods covered in the course to reading and evaluating the primary literature and to demonstrate critical understanding of the key issues relevant to the epidemiology of a specific vaccine. Additional details will be presented in lecture.

GRADING RUBRIC

Assignments	Points	% of Grade	Due Date
In Class Engagement - 2.5 points per session for attendance and engagement (14 sessions; max 35 points) - 2.5 points per lecture for submitting a question about any of the readings prior to lecture (10 sessions, max 25 points)	**60 pts**	**12%**	- **Daily for all class sessions** - **Daily questions due at 12 noon before class** (not required on 1/23, 2/13, 3/4, or 3/6)
Assignment 1	**60 pts**	**12%**	**Due 2/4/19 at 12 noon**
Presentation Topics	**-**	**-**	**Due 2/11/19 at 12 noon**
Assignment 2	**60 pts**	**12%**	**Due 2/11/19 at 12 noon**
Assignment 3	**60 pts**	**12%**	**Due 2/18/19 at 12 noon**
Assignment 4	**60 pts**	**12%**	**Due 2/25/19 at 12 noon**
Final In-Class Presentation (15-minute presentation) - Content (max 100 pts) - Clarity and effective use of communication skills to convey complex concepts (max 50 pts) - Responding to questions (max 50 pts)	**200 pts**	**40%**	**UPLOAD TO MOODLE by SUNDAY, 3/3/19 at 5pm** **Presentations IN CLASS on 3/4/19 or 3/6/19**
Total	**500 pts**	**100%**	

GRADING SCALE

The University uses plus and minus grading on a 4.000 cumulative grade point scale in accordance with the following, and you can expect the grade lines to be drawn as follows:

% In Class	Grade	GPA	
93 - 100%	A	4.000	• A = achievement that is outstanding relative to the level necessary to meet course requirements. • B = achievement that is significantly above the level necessary to meet course requirements. • C = achievement that meets the course requirements in every respect. • D = achievement that is worthy of credit even though it fails to meet fully the course requirements. • F = failure because work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (Incomplete). • S = achievement that is satisfactory, which is equivalent to a C- or better • N = achievement that is not satisfactory and signifies that the work was either 1) completed but at a level that is not worthy of credit, or 2) not completed and there was no agreement between the instructor and student that the student would receive an I (Incomplete).
90 - 92%	A-	3.667	
87 - 89%	B+	3.333	
83 - 86%	B	3.000	
80 - 82%	B-	2.667	
77 - 79%	C+	2.333	
73 - 76%	C	2.000	
70 - 72%	C-	1.667	
67 - 69%	D+	1.333	
63 - 66%	D	1.000	
< 62%	F		

Evaluation/Grading Policy	Evaluation/Grading Policy Description
Scholastic Dishonesty, Plagiarism, Cheating, etc.	You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis (As defined in the Student Conduct Code). For additional information, please see https://z.umn.edu/dishonesty The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: https://z.umn.edu/integrity. If you have additional questions, please clarify with your instructor. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam. Indiana University offers a clear description of plagiarism and an online quiz to check your understanding (http://z.umn.edu/iuplagiarism).
Late Assignments	Failure to submit assignments by the due date without documentation of a legitimate reason will result in a 10% reduction in points for each 24-hour period that passes between the original due date and the submission date.
Attendance Requirements	Students are expected to attend class and actively participate in class lectures, discussions, and activities. Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Students should notify the instructor of such absences as soon as possible.
Other Policies	As noted above, please refer to www.sph.umn.edu/student-policies/ for a complete list of UMN SPH student policies.