

# Module 1 – Immunization

Vaccination is one of the public health interventions that has had the greatest impact on the world's health. A handful of vaccines prevent illness or death for millions of individuals every year. Smallpox has been eradicated, poliomyelitis has been eliminated from the Western Hemisphere, and measles cases in the U.S. have reached a record low. However, vaccines are under-utilized and there is still a long way to go to improve health nationally and globally. In the U.S., only 68% of children receive all recommended vaccines by the age of 35 months. The rates of influenza and pneumococcal immunization for eligible adults are even lower. Worldwide, almost 2 million children die each year from diseases for which vaccines are available. Over 90,000 children worldwide still fall victim to paralytic polio; most of these cases could be prevented by immunization. Better utilization of existing vaccines is one strategy to improve the health of the nation and the world.

New vaccines offering protection against other pathogens are continually being developed and tested. Two of the greatest challenges in vaccine science are the development of effective vaccines for HIV and malaria. Even if such vaccines become available, effective vaccination strategies will be necessary to achieve good compliance and fully realize their potential.

After this module, you should have a better understanding of your future role in this 'cornerstone' of preventive medicine. As a physician, you will need to be familiar with on-line references that will provide you with the current guidelines for immunization. You should also recognize the geographic and demographic variations in immunization rates, barriers to effective vaccination programs, and the public misconceptions about vaccine side effects. You should be capable of evaluating actual data about vaccine safety, and the efficacy of new vaccinations that will be developed in the future. These and other issues will be explored in this module.

## I. Learning Objectives for the Immunization Module

1. Recognize the impact vaccinations have had on mortality rates in the U.S.
2. Review the current guidelines for immunizing children, adolescents and adults.
3. Understand how immunization rates vary among different geographic, socioeconomic and ethnic groups.
4. Review the Healthy People 2020 objectives for immunization rates in the next decade.
5. Be aware of adverse events that are known to be associated with vaccination and the relative frequency of these events.
6. Recognize common misconceptions about adverse events of vaccination. Understand the current best scientific evidence about those misconceptions.
7. Discuss the legal and ethical issues of mandatory vaccination in order to attend school. Are there legal precedents?
8. Briefly review some important future challenges in vaccine development.

9. Convert questions about vaccine efficacy or concerns about vaccine safety into answerable questions and utilize the medical literature or evidence-based medicine repositories to answer them.
10. Identify case reports (or case series) studies, case control studies, cohort studies, and clinical trials. Recognize the relative value of evidence from each of these study types.

## II. Instructions for the First Small Group Forum

**Note: All students should bring their laptop computers to the initial session of this module. As a group you will need to review certain websites and begin a literature search. A librarian will join your group to discuss appropriate techniques for searching the literature related to your presentation, but you will each be asked to conduct a literature search (see section C below).**

### A. Review the following prior to the first small group session.

**Healthy People 2020 Topics and Objectives**

<http://healthypeople.gov/2020/topicsobjectives2020/default.aspx>

Read the overview of 'Immunization and Infectious Diseases' and briefly review the specific objectives related to childhood vaccination rates and HP2020 goals (objectives IID-7 and IID-8), adolescent vaccination rates and HP2020 goals (objective IID-11), influenza vaccination rates and HP2020 goals (objective IID-12), and pneumococcal vaccination rates and HP2020 goals (objective IID-13).

Be familiar with the **Centers for Disease Control** website on vaccines and immunization <http://www.cdc.gov/vaccines/> Know where to find currently recommended immunization schedules and guidelines. Know where to find information about common misconceptions and vaccine safety.

### B. Discuss the following 3 case vignettes during the forum (After this session, everyone in the group should be able to answer the questions at the end of each vignette.)

#### **Case 1**

A mother brings her 2-month old infant to your office for a well baby visit. He has not had any serious problems since his previous visit at 1-month. You discuss the infant's feeding, sleeping, and behavior with the mother. A general physical exam is normal. You mention that the baby should receive several vaccines today and mention that diphtheria, tetanus and Pertussis (DTaP) is one of them. The mother is visibly uncomfortable at this suggestion. You sense her unease and ask her what is wrong. She says that she heard the Pertussis vaccine causes seizures and brain damage.

1. Is there data about adverse effects of the DTaP vaccine?
2. What are some other common misconceptions about vaccines?
3. How are adverse effects of vaccines reported?
4. How are patients who suffer adverse effects from a vaccine compensated?
5. Specifically, what would you say to the mother?

*To answer these questions it may be helpful to consult the CDC's Vaccines and Immunization webpage <http://www.cdc.gov/vaccines/>. Look at Vaccine Safety section and the section on Reporting Side Effects. Additional information on how to handle problems like this may be found at the National Network for Immunization Information website <http://www.immunizationinfo.org/>. You may want to look at "Misinformation about Vaccines" from the Health Professionals page.*

### **Case 2**

A 50-year old man is planning to make the Hajj (a pilgrimage to Mecca, Saudi Arabia) in March of next year. He comes to your office asking about vaccinations and other prophylaxis that he should take for safe travel. He is your patient but it has been 18 months since you last saw him. He has been without complaints. He has a history of hypertension for which he takes a beta-blocker twice per day. He has had no major illnesses, no surgeries, and no hospitalizations. He has no allergies.

1. What other aspects of the history are important to obtain?
2. List the specific vaccines you will recommend.
3. When will you administer these vaccines and how will you advise him about side effects?
4. Are any laboratory tests required before he begins the vaccinations you advise?
5. Is there additional counseling you will provide to help ensure a safe trip?

*(To answer these questions it will be useful to consult the CDC website [www.CDC.gov](http://www.CDC.gov) and look in the Travelers' Health section and search by destination.)*

### **Case 3**

A 17-year old girl is preparing to go to college in the fall. She has no major medical illnesses and has never been hospitalized. She will be living in a dormitory. She read about a vaccine that prevents meningococcal meningitis. She is wondering whether or not she should get this vaccine.

1. How will you advise her?

2. Should all college freshmen receive meningococcal vaccine?
3. What is the evidence for or against widespread use of this vaccine?

*(To answer these questions it will be useful to consult the CDC's Vaccines and Immunization webpage <http://www.cdc.gov/vaccines/> and look at the vaccine schedules for adolescents to find the recommended vaccines. Also look at the ACIP (Advisory Committee on Immunization Practices) recommendations for the use of specific vaccines. Read parts of the 2010 MMWR Updated Recommendations for the Use of Meningococcal Vaccine.*

**C. Discuss the following multiple-choice questions (we will review these and provide answers in class)**

1. Investigators attempted to assess the efficacy of the pneumococcal vaccine in adults 65-years of age and older. They had access to a HMO database of 47,000 adults in this age group that dated back to 1995. At that time, 26,000 had received the 23 valent pneumococcal vaccine and 21,000 had not. They were able to track all cases of invasive pneumococcal disease in this population between 1995 and 1999 and correlated these cases with the patient's prior vaccination status. They calculated the relative risk of invasive pneumococcal disease in the vaccinated group to be .58.

This is an example of a

- A) Case-control study
  - B) Case series
  - C) Prevalence survey
  - D) Retrospective cohort study
2. Investigators studied the relationship between autistic disorders in children and prior immunization with MMR vaccine. They calculated the incidence of autism in vaccinated children and in unvaccinated children.

Which of the following results would suggest that vaccination with MMR is a risk factor for the development of autistic disorder?

- A) A relative risk of 0.92 in the vaccinated group.
- B) An attributable risk of minus 3 per 1,000 person-years in the vaccinated group
- C) A relative risk of 2.5 in the vaccinated group.
- D) An attributable risk of 0 per 1,000 person-years in the vaccinated group

3. Most people infected with West Nile virus (WNV) have only minor symptoms (or remain asymptomatic). Data from cross-sectional surveys in epidemic areas suggest that for every person hospitalized with serious illness (meningitis or encephalitis) approximately 150 people have been infected with the virus. In the first three years of the U.S. epidemic, 178 persons were hospitalized with serious illness and there were 18 deaths.

Your best estimate of the case fatality rate for WNV infection is

- A) Greater than 10 %
- B) 10%
- C) 0.66% (1 in 150)
- D) 0.066% (1 in 1500)

#### **D. Plan your group project and presentation**

Your group has been asked to research one of the following topics for a symposium to be held in 2 weeks. At that symposium, two members of the group will be expected to give a 15-minute presentation on this topic using PowerPoint. Each member of the group should help research the questions and provide information for the presentation. One person in your group should serve as a leader and ensure that each member of the group presents at least once during the year.

Look over your assigned topic and the guidelines that have been provided. A librarian will help you conduct a proper literature search. Begin to discuss how you will put this information together into a presentation and assign each member of the group a task to complete by next week. At that time, you may wish to meet again independently and work on your presentation.

*Contact Dr. DiCarlo via email if you have any questions about your presentation. Finally, email a copy of your PowerPoint presentation to Dr. DiCarlo ([rdicar@lsuhsc.edu](mailto:rdicar@lsuhsc.edu)) one day prior to your presentation.*

# Small Groups 1, 5, 9 and 13

## Study Topic #1: Childhood Immunization and Parental Concerns

*Instructions: Give a 15-minute PowerPoint presentation on the above topic. You should answer the following questions (and may want to consult the suggested resources). **At least one part of your presentation should involve the summary of one or more primary journal articles.** You may find a lot of information, so please try to limit the discussion to the essential statistics and arguments.*

1. Briefly review the current recommendations for childhood vaccinations in the U.S. from birth to age 7?  
*Consult the CDC's Vaccines and Immunization webpage <http://www.cdc.gov/vaccines/> and look at the vaccine schedules for children. You can show the schedule briefly or list the vaccines, but don't attempt to explain the schedule in any detail.*
2. Examine the current rates of childhood immunization. Are there differences based on socioeconomic status, ethnicity, and geography? Where is Louisiana rank?  
*Data from the National Immunization Survey shows rates of various vaccines by state, socioeconomic status, and ethnicity. From the CDC's Vaccines and Immunization webpage (above), go to Vaccination Coverage and Surveillance and look at the NIS data regarding vaccination rates in children. Are there differences by ethnicity and socioeconomic status? How does Louisiana compare to the nation as a whole?*
2. Cite some common misconceptions about the risks of childhood vaccinations (use the CDC website referenced above to start).  
*Consult the CDC's Vaccines and Immunization webpage and look at the common questions. Can you find examples of websites that provide misinformation about childhood vaccinations?*
4. Review a controversial area about vaccine safety for children. Suggested topics are: 1) is there a link between MMR vaccine and development of autism? 2) Has exposure to thimerosal (an ethyl mercury based preservative) containing vaccines been harmful to children? Choose one topic and briefly summarize the arguments or evidence suggesting a causal association.  
*Consult the CDC's Vaccines and Immunization webpage (above) and look at the section on vaccine safety. You may also want to look at the 2004 Institute of Medicine report on vaccines and autism (<http://www.iom.edu/>). Read the executive summary for an overview.*
5. Find and briefly discuss one primary study evaluating the controversy you chose to review. Describe the study design; was it appropriate to answer the question? Discuss the findings and the measures of risk that were used. **Please let Dr. DiCarlo know what article you will be reviewing prior to your presentation** (contact him if you have trouble finding an appropriate reference).  
*You may want to begin by searching comprehensive sites about autism and MMR with many links and citations of recent studies (below). Some recent studies may be referenced on these sites, so you may also want to try your own search using PubMed.*  
[http://www.cdc.gov/od/science/iso/mmr\\_autism.htm](http://www.cdc.gov/od/science/iso/mmr_autism.htm)

# Small Groups 2, 6, 10 and 14

## Study Topic #2: Vaccines in Adolescence and Ethical Aspects of Mandatory Vaccination

*Instructions: Give a 15-minute PowerPoint presentation on the above topic. You may want to answer the following questions and consult the suggested resources. **At least one part of your presentation should involve the summary of a primary journal article.***

1. Briefly review the current recommendations for “adolescent” vaccinations in the U.S. from ages 7 to 18? When was each vaccine recommended for use?  
*Consult the CDC’s Vaccines and Immunization webpage <http://www.cdc.gov/vaccines/> and look at the vaccine schedules for adolescence. You can show the schedule briefly or list the vaccines, but don’t attempt to explain the schedule in detail.*
3. Can you find any data showing the current rates of vaccination in this age group? Does the National Immunization Survey investigate immunizations in this age group? From the CDC’s Vaccines and Immunization webpage (above), go to Vaccination Coverage and Surveillance and look at the NIS data regarding vaccination rates in teens.
4. Discuss the rationale behind the recent recommendations for the Pertussis booster and the meningococcal vaccine in adolescents. Provide justification for their approval by discussing the benefits that are likely to occur from widespread use of each. What is the cost of each?  
*Consult the CDC’s Vaccines and Immunization webpage (above) and look at the ACIP recommendations for these vaccines.*
5. Discuss the evidence in support of widespread use of the HPV vaccine in adolescents using a primary study. Describe the study design; was it appropriate to answer the question posed? Discuss the findings *and the measures of risk that were used*. **Please let Dr. DiCarlo know what article you will be reviewing prior to your presentation.**
6. Briefly discuss the laws requiring vaccination in order to attend school. What vaccines are required in Louisiana? Are there exemptions to the laws? What are the ethical issues surrounding mandatory vaccination for school age children. Do similar arguments apply to the HPV vaccine for adolescents?  
*Consult the CDC’s Vaccines and Immunization webpage (above) and look at the section on laws and requirements. You may also want to look at some recent papers in the New England Journal of Medicine (May 10, 2007 issue) for thoughts and ideas.*

# Small Groups 3, 7, 11 and 15

## Study Topic #3: Problems and Successes in Adult Immunization

*Instructions: Give a 15-minute PowerPoint presentation on the above topic. You may want to answer the following questions and consult the suggested resources. **At least one part of your presentation should involve the summary of a primary journal article.***

1. Briefly review CDC guidelines for use of the following vaccines in adults: influenza, pneumococcal polysaccharide, hepatitis [A and B] vaccines, tetanus booster (Td and Tdap), and the new zoster vaccine. Do not discuss HPV, meningococcal, varicella, and MMR vaccines as these will have been discussed by previous groups.  
*Consult the CDC's Vaccines and Immunization webpage <http://www.cdc.gov/vaccines/> and look at the vaccine schedules for adults. You can show the schedule briefly or list the vaccines, but don't attempt to explain the schedule in great detail.*
2. Discuss recommendations for use of the adult pneumococcal vaccine. What percentage of eligible adults receives this vaccine? Are there socioeconomic, ethnic, or geographic areas of concern? What are the HP2020 objectives for pneumococcal vaccination rates?  
*Look at the CDC vaccine website (above) for information about the **adult** pneumococcal vaccine. There may be data on Pneumococcal vaccination rates among adults from the National Health Interview Survey: from the CDC's Vaccines and Immunization webpage (above), go to Vaccination Coverage and Surveillance and look at the NIS data regarding vaccination rates in adults. How is this data obtained? You may also review data from the HP2020 objectives.*
3. Discuss recommendations for use of the influenza vaccine. What percent of adults are immunized? Are there socioeconomic, ethnic, or geographic areas of concern? What are the HP2020 objectives for influenza vaccination rates?  
*Use same sources as #3 above.*
4. Briefly describe the consequences of influenza (morbidity and mortality). What is meant by a flu pandemic? List the typical hemagglutinin and neuraminidase antigens on seasonal influenza A and B virus? Are concerns about the H1N1 "swine-origin" flu virus warranted?  
*From the CDC's Vaccines and Immunizations site (above), you may want to go to Recommendations and look at ACIP recommendations for use of the influenza vaccine. The August 6, 2010 issue of MMWR has a nice short discussion of the biology and epidemiology of influenza. The following sites provide some information about influenza and its consequences. The Stanford site describes the great pandemic of 1918: <http://www.cdc.gov/flu/> <http://www.stanford.edu/group/virus/uda/>*
5. Do we have an effective vaccine against the H1N1 strain? Discuss the evidence using a primary study. Describe the study design; was it appropriate to answer the question posed? Discuss the findings *and the measures of risk that were used*. **Please let Dr. DiCarlo know what article you will be reviewing prior to your presentation.**

# Small Groups 4, 8, 12 and 16

## Study Topic #4: Future Directions for Vaccine Development

*Instructions: Give a 15-minute PowerPoint presentation on the above topic. You may want to answer the following questions and consult the suggested resources. **At least one part of your presentation should involve the summary of a primary journal article.***

1. In the coming decades, new challenges in immunization will continue to emerge. Problems with antibiotic resistance, emerging infections, increased international travel, and possible bioterrorism suggest that infectious diseases will remain a threat to population health. In this presentation, we would like you to briefly review two of the bigger vaccine challenges the world faces: vaccination to protect against malaria and vaccination against HIV.
2. Briefly review the need for a vaccine against HIV and the particular challenges to the development of such a vaccine. What biologic strategies are likely to be employed in the development of a preventive HIV vaccine? Some sources you might consult are:  
*The NIH resources on HIV/AIDS and vaccine development*  
<http://sis.nlm.nih.gov/hiv/vaccine.html>  
*The NIAID site "Challenges in Designing HIV Vaccines"*  
<http://www.niaid.nih.gov/topics/hivaids/understanding/prevention/pages/vaccinechallenges.aspx>  
*International AIDS vaccine initiative website also provides an orientation to the history of HIV vaccine development, challenges and current strategies.* <http://www.iavi.org/>
3. Briefly review the need for a vaccine against malaria and the particular challenges to the development of such a vaccine. What biologic strategies are likely to be employed in the development of a preventive malaria vaccine? Some sources you might consult are:  
*The NIAID site on malaria research (look at the NIAID research agenda).*  
<http://www.niaid.nih.gov/topics/malaria/Pages/default.aspx>  
*PATH Malaria vaccine initiative website provides an orientation to the problem and vaccine strategies.* <http://www.malariavaccine.org/>
4. Summarize a primary study about the safety or efficacy of a candidate vaccine against HIV or malaria. Describe the study design; was it appropriate to answer the question posed? Discuss the findings *and the measures of risk that were used*. **Please let Dr. DiCarlo know what article you will be reviewing prior to your presentation.**