

WOMEN'S HEALTH

A realistic vaccination program for all patients, including gravidas

'Delegate' is the key to success for this simple screening and vaccination protocol, which uses free forms available online. A detailed chart covers vaccination during pregnancy.

Because of our unique access to women at all stages of life—who often consult no other physician—Ob/Gyns are well positioned to proclaim and bestow the benefits of vaccination.

For women who are pregnant or planning to conceive, benefits extend to the neonate through the first 4 to 6 months of life. For all women, especially those with coexisting chronic diseases, immunization stands to reduce mortality and serious morbidity.

This article details a simple 6-step plan for an immunization program in a typical practice. A key success factor is to minimize disruption by delegating authority for the program to a specific person or persons.

'Success' leaves adults at greater risk than children

Few doctors in any specialty pay regular attention to immunization. Over the past 20 years in particular, the United States has lacked a comprehensive adult vaccination program. As a result, many gynecologic patients today are underimmunized.

The tremendous success of childhood

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immunization has rendered diseases such as polio and measles "invisible" and fostered the perception that vaccination beyond childhood is no longer necessary. As a result, adults, not children, are now at greater risk of death due to vaccine-preventable disease (TABLE 1).

Another reason behind underimmunization is disproportionate media attention to adverse reactions, which discourages people from getting vaccinated.

Ob/Gyns and other clinicians face these challenges:

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KEY POINTS

- Adults, not children, incur a greater risk of death due to vaccine-preventable diseases.
- During flu season, almost half of the hospitalizations and deaths for cardiopulmonary conditions in healthy pregnant women are due to influenza.
- Screening all gravidas for hepatitis B surface antigen would prevent chronic hepatitis B viral infection in 6,000 neonates every year.
- Only 54% of community-dwelling elderly persons are immunized against *Streptococcus pneumoniae*, which has a 55% to 60% mortality rate in persons aged 70 or older.
- Influenza is more likely to cause death in middle-aged persons with multiple medical conditions than in healthy elderly persons.

TABLE 1

Estimated preventable deaths with complete vaccination of targeted adult populations

DISEASE	ESTIMATED ANNUAL DEATHS AMONG ADULTS (n)	ESTIMATED VACCINE EFFICACY* (%)	CURRENT USE† (%)	ADDITIONAL PREVENTABLE DEATHS PER YEAR (n)
Pneumococcal infection	40,000	60	14	20,640
Influenza	20,000	70	30	9,800
Hepatitis B	5,000	90	10‡	4,050
Hepatitis A	100	95	10	86
Measles, mumps, rubella	<30	95	Variable	<30
Tetanus/diphtheria	<25	99	40§	<15
Varicella	≥9	NA	53-90	≥9

*Indicates efficacy in immunocompetent adults. Among elderly and immunocompromised patients, efficacy is estimated to be lower.

†The percentage of targeted groups who have been immunized according to current recommendations. Rates vary among different targeted groups.

‡Highly variable (range, 1% to 60%) among different targeted groups.

§Estimate based on seroprevalence data.

||Among children 19 to 35 months of age.

Adapted from the Centers for Disease Control and Prevention^{10,17} and from Gardner P, Schaffer W¹⁸ with permission of the Massachusetts Medical Society (copyright 1993, Massachusetts Medical Society. All rights reserved).

- Establishing an office routine for screening all patients and giving vaccinations.
- Informing ourselves and our patients of the benefits of vaccination in specific groups.
- Providing reliable information about possible adverse effects.

TABLE 2 details targeted populations, dosing, and safety in pregnancy for vaccines recommended for adults.

The sobering facts: Morbidity and mortality rates of vaccine-preventable diseases

Streptococcus pneumoniae causes roughly 3,000 to 6,000 cases of meningitis, 50,000 cases of bacteremia, and 500,000 cases of pneumonia each year in the United States.¹ In people over age 70, the mortality rate is 55% to 60%.² Compounding the risk is the increase in penicillin-resistant pneumococci. Still, only 54% of elderly patients get immunized against pneumonia—well below the

goal of 90% set by Healthy People 2010³ for noninstitutionalized elderly.

Influenza causes approximately 20,000 deaths each year, but that figure can reach 40,000 or more in some epidemics.⁴ The death rate begins to rise in midlife and is greatest in persons with chronic medical conditions such as cardiovascular disease, chronic obstructive lung disease, asthma, and diabetes. In fact, influenza has a higher fatality rate in middle-aged persons with multiple medical conditions than in healthy persons 65 years of age or older.

Only a fraction of persons aged 50 to 65 with a high-risk condition are immunized against influenza.

Influenza and pneumonia together are the seventh leading cause of death nationally and the fifth leading cause in older adults.⁵ A study of working adults aged 18 to 64 showed that flu vaccination decreased episodes of upper-respiratory ill-

FluMist intranasal vaccine approved for ages 5 to 49—but not for gravidas

Although it is roughly 7 times more expensive than a flu shot (at approximately \$46 per dose), the new intranasal vaccine, FluMist, has appealing qualities—especially for people who spurn vaccination to avoid the needle. FluMist (MedImmune Inc, Gaithersburg, Md) is a cold-adapted, live, trivalent vaccine approved June 17, 2003, by the US Food and Drug Administration for ages 5 to 49 years. It is available for the 2003–2004 influenza season.

Easy to administer. Each prefilled sprayer contains a 0.5-mL dose, which clinicians administer by placing the Teflon tip into the patient's nose and depressing the plunger. (A dose separator ensures that 0.25 mL is delivered into each nostril.) Because of its simplicity, the vaccine ultimately could be available in nonclinical settings such as shopping malls, boosting the number of persons who get immunized each year.

FluMist induces intranasal immunoglobulin A that is specific for each of the 3 influenza strains targeted this season by the US Public Health Service. This is important because influenza virus enters the body through the nose. (The shots do not induce intranasal immunoglobulin.)

How effective is FluMist? The estimated efficacy of live-attenuated vaccine in healthy adults exposed to wild-type influenza A and B viruses was 85% in 1 study, but ranged as high as 100% in a meta-analysis.^{19,20}

When FluMist was tested in a randomized, double-blind, placebo-controlled trial, recipients were as likely as controls to experience 1 or more febrile illnesses during peak outbreak periods. However, they had significantly fewer severe febrile illnesses and febrile upper respira-



To administer FluMist, place the tip of the sprayer in the nostril and depress the plunger. Then remove the dose separator and repeat the process in the other nostril. Ease of use may lead to wider availability in nonclinical settings such as shopping malls.

tory tract illnesses. They also missed fewer work days and required fewer visits to a health-care provider.²¹

Contraindications include pregnancy. Because its effects during pregnancy are unknown, FluMist should not be given to gravidas.

Further, persons with a history of Guillain-Barré syndrome or hypersensitivity to eggs or egg products should not receive the vaccine. Nor should FluMist be given to those with known or suspected immune deficiency diseases or immunosuppression, or whose immune status may be depressed due to therapies such as systemic corticosteroids, antimetabolites, alkylating drugs, and radiation.²²

Precautions. Vaccinated persons may shed live virus and should avoid close contact with immunocompromised people for 21 days or more.

The effects of administering FluMist at the same time as other vaccines have not been studied. For this reason, it is best given alone.

Adverse reactions include cough, runny nose, sore throat, chills, tiredness or weakness, nasal congestion, rhinitis, and sinusitis.

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▪ A realistic vaccination program

ness by 25% and reduced doctor visits for such illness by 44%.⁶

Ample quantities of flu vaccine are available this flu season. The past 3 seasons, shortages compelled the Centers for Disease Control and Prevention (CDC) to recommend a graduated vaccination schedule to ensure that the neediest individuals were immunized first, while supplies were adequate.

Each year the CDC, the US Food and Drug Administration (FDA), and vaccine manufacturers review the vaccine supply and notify physicians of projected shortages.

Hepatitis B virus (HBV) infects between 128,000 and 320,000 people each year in the United States. Approximately 1.25 million Americans have chronic infection. The lifetime risk of acquiring the disease is estimated at 5%.⁷ More than 5,000 people die of HBV-related liver disease annually, and HBV infection is the second leading cause of cancer worldwide.

Measles, mumps, and rubella (MMR) cases declined greatly in the 20th century, thanks to widespread vaccination. By 2001, the number of cases reported annually had declined to 116 for measles (from an all-time high of more than 500,000), to 266 for mumps, and to 23 for rubella.^{8,9} Although the vaccines for these 3 viruses are extremely effective, occasional outbreaks of all 3 illnesses are still reported in the United States. Measles outbreaks occur because the disease is highly contagious, with an attack rate of 90% or higher among unvaccinated household contacts.

Varicella. Before vaccination became available, roughly 4 million cases of varicella zoster virus infection occurred each year in the United States. Although the virus usually causes relatively benign chickenpox, death is a possibility. From 1990 to 1994, for example, before the varicella vaccination program, 11,000 hospitalizations and 100 deaths were attributed to varicella disease each year.¹⁰ Most

of those who died were previously healthy.

During 2002, 9 fatal cases of varicella in adults and children were reported.¹⁰ That figure likely represents only a partial accounting of varicella-related deaths. According to National Center for Health Statistics data for 2000, varicella was listed as the primary cause of death on 44 death certificates in 23 states and the District of Columbia, although only 9 (20%) varicella-related deaths were reported to the CDC.¹⁰

Vaccination during pregnancy: Benefits versus risks

As the American College of Obstetricians and Gynecologists (ACOG) notes in a committee opinion,¹¹ preconception vaccination “to prevent disease in the offspring, when practical, is preferred to vaccination of pregnant women.” However, in pregnancy, the benefits of immunization usually outweigh the risk of adverse events when:

- the likelihood of exposure to disease is high,
- infection would pose a risk to the mother or fetus, and
- the vaccine is unlikely to cause illness or injury.¹²

Rubella vaccine is of particular concern for pregnant women. Thus, it is reasonable to ask any premenopausal patient if she is pregnant. If she is pregnant and has no antibodies to rubella, she should receive the MMR vaccine postpartum at the time of hospital discharge.

If she is not pregnant, she should be vaccinated and advised to postpone pregnancy for 4 weeks. In addition, when indicated, the patient’s children and other household contacts should be immunized against MMR and varicella.

Influenza is a significant concern for the pregnant patient. A retrospective cohort study found that, during flu season, almost half of the hospitalizations and deaths for cardiopulmonary conditions in healthy pregnant women are attributable to influenza.¹³ Thus, inactivated influenza vaccine is rec-

ommended for gravidas who are in the second or third trimester of pregnancy during flu season.

Hepatitis B. According to ACOG, the Advisory Committee on Immunization Practices, and other organizations, all pregnant women should be screened for hepatitis B surface antigen (HBsAg), preferably at an early prenatal visit.

Screening all pregnant women in the United States would detect about 22,000 HBsAg-positive women and prevent chronic HBV infection in 6,000 neonates each year.¹⁴ Gravidas whose initial test is negative but who are at high risk for infection should be tested again late in pregnancy.

TABLE 2 gives specifics on immunization in pregnancy.

STEP 1

Assign an advocate in charge of vaccination

Any office-based vaccination program requires an enthusiastic advocate—a nurse, physician, or, better yet, several health professionals who understand that an immunization program is key to improved medical care. The advocate's job is to promote the benefits of vaccination among both staff and patients.

In a pediatric setting, physicians and nurses cite lack of time as the main reason they do not communicate with patients about the importance of immunization¹⁵—and that time shortage is likely a barrier when adult vaccination is at issue, as well. For example, 57% of medical patients interviewed gave the same reason for their failure to get immunized against pneumonia: No one told them it was recommended for their age group.¹⁶ By assigning this responsibility to one individual or several persons as a team, it becomes more likely that the issue will be addressed.

Each office visit presents an opportunity. Women with chronic illnesses are most likely to benefit from pneumonia and influenza vac-

cines, and women who are planning to conceive should be up to date on MMR, tetanus-diphtheria, and varicella (TABLE 2).

STEP 2

Use free questionnaires for history-taking, records

Both new and established patients should have their immunization history reviewed. Unfortunately, an accurate history may be difficult to obtain, since patients receive their vaccinations from different providers and often do not keep adequate records. The most reliable sources of information are the patient, her previous physician and, sometimes, her parents.

Necessary information includes the type of immunization received, when it was administered, whether there were adverse reactions and, if so, what they entailed.

History of allergies to eggs, neomycin, or streptomycin should be determined, as these contraindicate certain vaccines (TABLE 2).

One way to help determine whether further immunization is needed is to have the patient complete an immunization questionnaire for review by a nurse or medical assistant.

Adult screening forms are available free of charge from the CDC online at www.cdc.gov/nip/recs/adult_vac_scrn_hcp.pdf. **Forms for recording immunizations** also are available through the CDC (at www.cdc.gov/nip) and the Immunization Action Coalition (at www.immunize.org).

STEP 3

Develop policies for the fundamentals

Immunization will be simplified if the office has protocols for both general administration and specific vaccines.

- Before administering a vaccine, take precautions to prevent the spread of disease. These include washing hands carefully with soap and water before the vaccination is given. Although gloves are not routinely

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TABLE 2**Guide to adult vaccination, including vaccination during pregnancy**

VACCINE AND TYPE	ADMINISTRATION	INDICATIONS	USE IN PREGNANCY	CONTRAINDICATIONS AND PRECAUTIONS
Hepatitis A Inactivated whole virus	2 doses (interdose interval: 6-12 months)	<ul style="list-style-type: none"> • Adults who travel outside the US and Canada • Patients with chronic liver disease or clotting disorders • Drug users • Food handlers • Day-care workers 	<ul style="list-style-type: none"> • Safety in pregnancy not determined, but this is a killed whole virus vaccine 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine • Severe acute illness
Measles, mumps, rubella (MMR) Live attenuated virus; contains gelatin and neomycin	2 doses (interdose interval: 1 month)	<ul style="list-style-type: none"> • All adults born in 1957 or later • Recipients of killed measles virus vaccine (1963-1967) • Second dose necessary in health-care workers, college students, and international travelers 	<ul style="list-style-type: none"> • Contraindicated • Pregnancy should be delayed for 30 days after administration • MMR should be administered postpartum upon discharge from the hospital if the patient is rubella nonimmune 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine • Severe acute illness • Immunocompromised status • Allergy to neomycin • Delay 30 days if purified protein derivative of tuberculin given
Tetanus/diphtheria Absorbed toxoids	<ul style="list-style-type: none"> • Primary: 3 doses (week 0, week 4, and 6-12 months later) • Booster: every 10 years • The American College of Physicians recommends a single booster at age 50 at the time of general evaluation 	<ul style="list-style-type: none"> • All adults 	<ul style="list-style-type: none"> • Safe to administer • If booster was given more than 10 years earlier or the date cannot be remembered, gravida should receive a booster at the time of examination 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to toxoid or component • Severe acute illness
Varicella (chickenpox) Live attenuated virus	<ul style="list-style-type: none"> • Two 0.5-mL doses (interdose interval: 4-8 weeks) • Keep vaccine frozen at or below 5°F • Use within 30 minutes of reconstitution • Postexposure prophylaxis²³⁻²⁵: Vaccine can prevent or reduce severity of disease after exposure to wild varicella if given within 3 days 	<ul style="list-style-type: none"> • All susceptible adults (approximately 95% of adults have immunoglobulin G antibodies to varicella) 	<ul style="list-style-type: none"> • Contraindicated, although many pregnant women have received the vaccine without adverse outcome • All gravidas should be asked about their history of varicella and, if uncertain, a varicella immunoglobulin G serum level should be obtained • The patient should be given the first dose of varicella upon postpartum discharge from the hospital and a second dose at 6-week visit • Varicella zoster immune globulin is indicated for exposed immunosuppressed patients, during early pregnancy for susceptible exposed mothers, and for infants of women who develop chickenpox 5 days before to 2 days after delivery at 125 U/10 kg (maximum 625 U; minimum 125 U). Ideally, it should be given intramuscularly within 96 hours of exposure 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine or component • Immunocompromised status • If not given at the same time as MMR, separate injections by 30 days

Guide to adult vaccination ... continued

VACCINE AND TYPE	ADMINISTRATION	INDICATIONS	USE IN PREGNANCY	CONTRAINDICATIONS AND PRECAUTIONS
Pneumococcal infection 23 purified capsular polysaccharide antigens	One 0.5-mL dose intramuscularly or subcutaneously. May be repeated in 5-6 years in persons with high-risk conditions	<ul style="list-style-type: none"> • All adults ≥65 years • Persons <65 years with chronic illnesses (eg, cardiopulmonary disease, chronic liver disease, anatomic or functional asplenia, alcoholism, diabetes mellitus), cerebrospinal fluid leaks, or immunocompromised status • Smokers • Persons with cochlear implants • Persons receiving chemotherapy, corticosteroids, or organ or bone marrow transplants 	<ul style="list-style-type: none"> • Safe in any trimester • Recommended in gravidas with chronic illnesses 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine or component • Severe acute illness • Do not give by intradermal route
Influenza Trivalent inactivated virus (TIV) (2 A influenza strains and 1 B influenza strain)	1 dose annually during flu season (October 1 through March 31)	Generally recommended for everyone, and particularly: <ul style="list-style-type: none"> • Persons 6 months to 2 years or ≥50 years with cardiopulmonary disease, diabetes, chronic liver disease, renal disease, or immunosuppressed status • Residents of chronic-care facilities • Pregnant women in the 2nd or 3rd trimester during flu season • Women with medical problems (vaccinate before flu season) 	<ul style="list-style-type: none"> • Safe in any trimester, but specifically recommended in 2nd and 3rd trimester during flu season 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine or component • Allergy to eggs • Severe acute illness
Influenza Live attenuated influenza vaccine	1 dose annually during flu season	<ul style="list-style-type: none"> • Anyone who wishes to reduce the risk of becoming ill with influenza. • Persons 5-9 years of age require 2 doses if no history of TIV administration • Persons 9 to 49 require 1 dose annually 	<ul style="list-style-type: none"> • Contraindicated 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine or component • Severe acute illness • Pregnancy (give TIV instead) • Allergy to eggs
Hepatitis B Recombinant hepatitis B surface antigen produced from yeast	<ul style="list-style-type: none"> • 3 doses (months 0, 1, and 6) • Inject into the deltoid muscle 	<ul style="list-style-type: none"> • Household contacts and sexual partners of hepatitis B virus carriers • Women with more than 1 sexual partner in 6 months • Patients with chronic liver disease • Patients and workers in dialysis units • All health-care and public-safety workers • Patients and staff members of institutions for the disabled • Patients with other sexually transmitted infections • Inmates of correctional facilities • International travelers 	<ul style="list-style-type: none"> • Safe in any trimester • Screening for hepatitis B surface antigen vaccine recommended in all pregnancies 	<ul style="list-style-type: none"> • Previous anaphylactic reaction to vaccine • Severe acute illness

required, they are advisable if there are open lesions on the hands or there is a chance of coming into contact with infectious body fluids.

- Syringes and needles should be sterile, disposable, and used for only 1 injection.
- Never mix different vaccines in the same syringe unless they are specifically licensed for such use.
- For the specifics of administering each agent, consult the manufacturer's package insert. The recommended dose varies among different vaccines and, sometimes, for the same vaccine produced by different manufacturers.

Follow the manufacturer's recommendations on administration route (intramuscular, subcutaneous, intradermal) and injection site. In adults, always give injections into the deltoid muscle, never the gluteus muscle.

Deviation from the recommended route and site can result in inadequate protection. For example, the immunogenicity of HBV is significantly lower when it is injected into the gluteal rather than the deltoid muscle.

- There is no advantage to splitting the dose into 2 injections. Data suggest that splitting the dose may decrease antibody production.

Most widely used vaccines are safe and effective when given on the same day at separate sites. These include inactivated vaccines, toxoids, and live virus vaccines.

The antibody response to simultaneously administered live virus vaccines results in appropriate titers for each vaccine without an increase in adverse effects.

- Finally, draw the vaccine into the syringe only at the time of administration. Since most vaccines look the same once they are in a syringe, this policy helps avoid confusion.

STEP 4

Ensure essential tasks are completed

The vaccination program advocate can be charged with these responsibilities:

- Order and reorder vaccines, inspect them upon delivery, and follow the manufacturer's specifications for storage. These are not tasks to be taken lightly. Failure to meet the requirements for storage and handling can reduce a vaccine's potency.
- Provide every patient with a vaccine information statement (VIS) for each drug. The VIS is a 1-page information sheet produced by the CDC to inform patients of the benefits and risks of specific vaccines.

The information sheets are available free of charge from the CDC's National Immunization Program Web site, at www.cdc.gov/nip. The VIS should be given to the patient before the vaccine is administered..

- Record the following information in the patient's chart:
 - VIS edition and date it was given
 - Name of the person who gave the vaccine
 - Date vaccine was given
 - Vaccine manufacturer
 - Vaccine lot number

STEP 5

Identify contraindications

A number of conditions preclude the use of a vaccine, and should be elicited in the history. They include:

- **Anaphylaxis** with a previous vaccination.
- **Egg allergy** (for influenza, measles, mumps, and yellow-*fever* vaccines).
- **Neomycin or streptomycin allergy** (for MMR vaccine).
- **Immunosuppression** (for live virus vaccine).
- **Temperature elevation exceeding 40.5°C** after a previous vaccination.

Contraindications do NOT include mild, acute upper-respiratory or gastrointestinal illness with a fever of 38°C or less; current antimicrobial therapy or convalescence from a recent illness; pregnancy in another household contact; breastfeeding; personal history of "allergies" to penicillin; or family history of allergies, adverse reactions to vaccination, or seizures.

STEP 6**Be prepared for adverse reactions**

Proper screening is the key to preventing most adverse reactions.

Anaphylaxis. Asking the patient about contraindications and taking precautions greatly reduces the risk of anaphylaxis and other serious reactions. Nevertheless, the clinician administering the vaccine should have the necessary procedures in place to manage anaphylactic reactions, and should be certified in cardiopulmonary resuscitation.

Syncope is most common in adolescents and young adults. Between 1990 and August 2001, the Vaccine Adverse Event Reporting system recorded 2,269 instances of syncope; 40% occurred in 10- to 18-year-olds.¹¹

Most cases of vaccine-related syncope occur within 15 minutes of administration. Although syncope is uncommon, some authorities recommend that patients be observed for 15 to 20 minutes after administration. If syncope develops, observation can be continued until the symptoms resolve. ■

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Free resources for physicians**For general information**• **National Immunization Hotline**

English: (800) 232-2522

Spanish: (800) 232-0233

• **Immunization Action Coalition**

www.immunize.org

From the Centers for Disease Control and Prevention, National Immunization Program• **Immunization history forms**

www.immunize.org/catg.d/p2023b.pdf

• **Adult vaccination screening forms**

www.cdc.gov/nip/recs/adult_vac_scrn_hcp.pdf

• **6 common misconceptions about vaccination and how to respond to them**

www.cdc.gov/nip/publications/6mishome.htm

• **Vaccine information statements**

www.cdc.gov/nip/publications/VIS/default.htm

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