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GENERAL RECOMMENDATIONS ON IMMUNIZATION

The General Recommendations on Immunization statement¹ has recently been updated by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). The guideline can be found in its entirety at <http://www.cdc.gov/mmwr/preview/mmwrhtml/r5515a1.htm>. This article will summarize key vaccination guidelines including timing and spacing of vaccines, simultaneous administration of multiple vaccines, lapsed vaccination schedule, altered immunocompetence, concurrent administration of antimicrobial agents, breast feeding, and vaccinating persons with bleeding disorders or receiving anticoagulant therapy. Also included are several tables that summarize general vaccine dosing and administration information.

Timing and Spacing of Vaccines

The optimal response to a vaccine depends on multiple factors, including the nature of the vaccine and the age and immune status of the recipient. Vaccines are recommended for members of the youngest age group at risk for experiencing the disease for whom efficacy and safety of the vaccine have been demonstrated.

Approximately 90% to 95% of recipients of a single dose of certain live vaccines administered by injection at the recommended age (i.e., measles, rubella, and yellow fever) have protective antibody (generally within two weeks of the dose). For varicella and mumps vaccines, 80% to 85% of vaccinees are protected after a single dose. However, because a limited proportion of recipients (5% to 15%) of measles-mumps-rubella (MMR) or varicella vaccines fail to respond to a single dose, a second dose is recommended to provide another opportunity to develop immunity. The majority of persons who fail to respond to the first dose of MMR or varicella vaccine respond to a second dose.

The Recommended Childhood and Adolescent Immunization Schedule and the Recommended Adult Immunization Schedule are revised annually (see the CDC's website at <http://www.cdc.gov/nip>).

Spacing of Multiple Doses of the Same Vaccine

Vaccination providers should adhere as closely as possible to recommended vaccination schedules. Recommended ages and intervals between doses of multidose antigens provide optimal protection and have the best evidence of efficacy. Recommended intervals between doses of commonly used vaccines are provided in Table 1. In certain circumstances, administering doses of a vaccine at shorter than the recommended intervals might be necessary. This can occur when a person is behind schedule and needs to be brought up-to-date as quickly as possible or when international travel is impending. In these situations, an accelerated schedule can be implemented. The accelerated or minimum intervals and ages that can be used for scheduling catch-up vaccinations are also provided in Table 1. **Vaccine doses should not be administered at intervals less than these minimum intervals or earlier than the minimum age.**

In clinical practice, vaccine doses occasionally are administered at intervals less than the minimum interval or at ages younger than the minimum age. Doses

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administered too close together or at too young of an age can lead to a suboptimal immune response. However, administering a dose a limited number of days earlier than the minimum interval or age is unlikely to have a substantially negative effect on the immune response to that dose. **Therefore, ACIP recommends that vaccine doses administered 4 or fewer days before the minimum interval or age be counted as valid.** However, because of its unique schedule, this recommendation does not apply to the rabies vaccine. **Doses administered 5 or more days earlier than the minimum interval or age of any vaccine should not be counted as valid doses and should be repeated as age-appropriate.** The repeat dose should be spaced after the invalid dose by the recommended minimum interval. Doses administered 5 or more days before the minimum age should be repeated on or after the child reaches the minimum age and 4 or more weeks after the invalid dose.

Simultaneous Administration of Vaccines

Simultaneously administering all vaccines for which a person is eligible is critical because simultaneous administration increases the probability that a patient will be fully vaccinated at the appropriate age. Simultaneous administration also is critical when preparing for foreign travel and/or if uncertainty exists that a person will return for further doses of vaccine. Simultaneously administering the most widely used live and inactivated vaccines has produced seroconversion rates and adverse reactions rates similar to those observed when the vaccines are administered separately. Routinely administering all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the visit.

Combination vaccines can reduce the number of injections required at an office visit. **Use of licensed combination vaccines is preferred to separate injection of their equivalent component vaccines to reduce the number of injections and missed opportunities to protect through vaccination.** Only combination vaccines licensed by FDA should be used. **Individual vaccines should never be mixed in the same syringe unless they are approved specifically for mixing by FDA.**

If multiple vaccines are administered at a single visit, administration of each preparation at a different anatomic site is desirable. For infants and younger children, if more than two vaccines must be injected in a single limb, the thigh is the preferred site because of the greater muscle mass; the injections should be sufficiently separated (i.e., 1 inch or more if possible) so that any local reactions can be differentiated. For older children and adults, the deltoid muscle can be used for more than one intramuscular injection.

Non-simultaneous Administration of Vaccines

No evidence exists that inactivated vaccines interfere with the immune response to other inactivated vaccines or to live vaccines. **An inactivated vaccine can be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine.** Data are limited about interference between live vaccines. **The immune response to one live-virus vaccine might be impaired if administered within 30 days of another live-virus vaccine.** Persons who received varicella vaccine less than 30 days after MMR vaccination had an increased risk for varicella vaccine failure of 2.5-fold compared with persons who received varicella vaccine before or greater than 30 days after MMR. In comparison, another study determined that the response to yellow fever vaccine is not affected by monovalent measles vaccine administered 1 to 27 days earlier. The effect of non-simultaneously administering rubella, mumps, varicella, and yellow fever vaccines is unknown.

To minimize the potential risk for interference, injectable or nasally administered live vaccines not administered on the same day should be administered at least four weeks apart whenever possible (see Table 3). If injectable or nasally administered live vaccines are separated by less than four weeks, the vaccine administered second should not be counted as a valid dose and should be repeated. The repeat dose should be administered greater than four weeks after the last invalid dose. Yellow fever vaccine can be administered at any time after single-antigen measles vaccine. Oral live vaccines (typhoid vaccine and rotavirus vaccine) can be administered simultaneously or at any interval before or after other live vaccines (injectable or intranasal), if indicated. Table 2 lists the routine vaccines and if they are live or inactivated.

Table 3: Guidelines for Spacing of Live and Inactivated Vaccines

Vaccine Combination	Recommended Minimum Interval Between Doses
Two or more inactivated vaccines	Can be administered simultaneously or at any interval between doses.
Inactivated and Live Vaccine	Can be administered simultaneously or at any interval between doses.
Two or more live injectable or intranasal vaccines	Can be administered simultaneously or at 4-week minimum interval.
Live oral vaccine with live injectable or intranasal vaccine	Can be administered simultaneously or at any interval between doses.

Lapsed Vaccination Schedule

Vaccines should be administered as close to the recommended intervals as possible. **However, longer-than-recommended intervals between doses do not reduce final antibody concentrations, although protection might not be attained until the recommended number of doses has been administered.** With the exception of oral typhoid vaccine, an interruption in the vaccination schedule does not require restarting the entire series of a vaccine or toxoid or the addition of extra doses.

Contraindications and Precautions to Vaccination

Healthcare providers may inappropriately consider certain conditions or circumstances to be true contraindications or precautions to vaccination. Among the most common conditions often inappropriately considered contraindications are diarrhea, minor upper-respiratory tract illnesses (including otitis media) with or without fever, mild-to-moderate local reactions to a previous dose of vaccine, current antimicrobial therapy, and the convalescent phase of an acute illness. True contraindications and precautions to different vaccination can be found at the CDC website at www.cdc.gov/nip and in the prescribing information of individual vaccines.

The decision to administer or delay vaccination because of a current or recent acute illness depends on severity of symptoms and etiology of the disease. All vaccines can be administered to persons with minor acute illness (e.g., diarrhea or mild upper-respiratory tract infection with or without fever). Vaccination should not be delayed because of the presence of mild respiratory tract illness or other mild acute illness with or without fever. Persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

Altered Immunocompetence

Determination of altered immunocompetence is important because the incidence and severity of certain vaccine-preventable diseases are higher in persons with altered immunocompetence; therefore, certain vaccines (e.g., inactivated influenza and pneumococcal vaccines) are recommended specifically for persons with these diseases. Vaccines might be less effective during the period of altered immunocompetence. Live vaccines generally should be deferred until immune function has improved. Inactivated vaccines administered during the period of altered immunocompetence might need to be repeated after immune function has improved. Finally, persons with altered immunocompetence might be at increased risk for an adverse reaction after administration of live-attenuated vaccines because of reduced ability to mount an effective immune response.

All inactivated vaccines can be administered safely to persons with altered immunocompetence; the usual doses and schedules are recommended. However, the effectiveness of such vaccinations might be suboptimal. Except for influenza vaccine, which should be administered annually, vaccination during chemotherapy or radiation therapy should be avoided if possible because antibody response might be suboptimal. However, administration of inactivated vaccines during chemotherapy or radiation is not contraindicated. Patients vaccinated within two weeks of starting immunosuppressive therapy or while receiving immunosuppressive therapy should be considered unvaccinated and should be revaccinated at least three months after therapy is discontinued if immune competence has been restored. Severe complications have followed vaccination with live vaccines among persons with altered immunocompetence. **Persons with most forms of altered immunocompetence should not receive live vaccines** (e.g., MMR, varicella vaccine, live-attenuated influenza [LAIV], yellow fever vaccine, oral typhoid, BCG, and rotavirus) except in certain circumstances.

Corticosteroids used in greater than physiologic doses can reduce the immune response to vaccines. The immunosuppressive effects of steroid treatment vary, but the majority of clinicians consider a dose equivalent to either greater than 2 mg/kg of body weight or 20 mg/day of prednisone or equivalent for persons who weigh more than 10 kg when administered for two weeks or greater as sufficiently immunosuppressive to raise concern about the safety of vaccination with live-virus vaccines. **Vaccination providers should wait at least one month after discontinuation of high-dose systemically absorbed corticosteroid therapy administered for more than two weeks before administering a live-virus vaccine.** The safety and efficacy of live-attenuated vaccines administered concurrently with recombinant human immune mediators and immune modulators is unknown. Therapeutic monoclonal antibodies, especially the antitumor necrosis factor agents (e.g., adalimumab, infliximab, and etanercept), should be used cautiously with live vaccines. **Avoidance of live attenuated vaccines during intermittent or low-dose chemotherapy or other immunosuppressive therapy is prudent,** unless the benefit of vaccination outweighs the hypothetical increased risk for an adverse reaction after vaccination.

Vaccination of Contacts of Persons with Altered Immunocompetence

Household and other close contacts of persons with altered immunocompetence should receive all age-appropriate vaccines. MMR, varicella, and rotavirus vaccines should be administered to susceptible household and other close contacts of immunocompromised patients when indicated. MMR vaccine viruses are not transmitted to contacts, and transmission of varicella vaccine is rare. No special precautions are needed unless the varicella vaccine recipient has a rash after vaccination, in which case direct contact with susceptible household contacts should be avoided until the rash resolves. To minimize potential rotavirus transmission, all members of the household should employ hand hygiene measures after contact with feces of a rotavirus-vaccinated infant for at least 1 week. Household and other close contacts of persons with altered immunocompetence should receive annual influenza vaccination. LAIV can be administered to otherwise eligible household contacts.

Concurrently Administering Antimicrobial Agents and Vaccines

The use of an antimicrobial agent is not a contraindication to vaccination. Antimicrobial agents have no effect on the response to live-attenuated vaccines (e.g., measles, mumps, rubella, varicella vaccines, etc.). The one exception is the live oral Ty21a typhoid vaccine which should not be administered to persons receiving antimicrobial agents until 24 hours after any dose of antimicrobial agent. Antimicrobial agents have no effect on inactivated, recombinant subunit, or polysaccharide vaccines or toxoids.

Antiviral drugs used for treatment or prophylaxis of influenza virus infections have no effect on the response to inactivated influenza vaccine (injection). **However, live-attenuated influenza vaccine (LAIV) (intranasal) should not be administered until 48 hours after cessation of therapy using antiviral influenza drugs.** If feasible, antiviral medication should not be administered for two weeks after LAIV administration. Antiviral drugs active against herpesviruses (e.g., acyclovir or valacyclovir) might reduce the efficacy of live-attenuated varicella vaccine. These drugs should be discontinued at least 24 hours before administration of varicella-containing vaccines, if possible.

The antimalarial drug mefloquine could affect the immune response to oral Ty21a typhoid vaccine if taken simultaneously. To minimize this effect, it is prudent to administer **Ty21a typhoid vaccine at least 24 hours before or after a dose of mefloquine.**

Breast Feeding and Vaccination

Neither inactivated nor live vaccines administered to a lactating woman affect the safety of breast feeding for women or their infants. Breast feeding does not adversely affect immunization and is not a contraindication for any vaccine, with the exception of smallpox vaccine. Limited data indicate that breast feeding can enhance the response to certain vaccine antigens. Breast-fed infants should be vaccinated according to recommended schedules.

Although live vaccines multiply within the mother's body, the majority have not been demonstrated to be excreted in human milk. Although rubella vaccine virus might be excreted in human milk, the virus usually does not infect the infant. If infection does occur, it is well-tolerated because the virus is attenuated. Inactivated, recombinant, subunit, polysaccharide, conjugate vaccines and toxoids pose no risk for mothers who are breast feeding or for their infants.

Vaccinating Persons with Bleeding Disorders and Persons Receiving Anticoagulant Therapy

Because of the risk for hematoma formation after injections, intramuscular injections are often avoided among persons with bleeding disorders by using the subcutaneous routes for vaccines that are administered normally by the intramuscular route. When any intramuscular vaccine is indicated for a patient with a bleeding disorder or a person receiving anticoagulant therapy, the vaccine should be administered intramuscularly if, in the opinion of a physician familiar with the patient's bleeding risk, the vaccine can be administered with reasonable safety by this route. If the patient receives antihemophilia or similar therapy, intramuscular vaccinations can be scheduled shortly after such therapy is administered. A fine needle (23 gauge or smaller) should be used for the vaccination and firm pressure applied to the site, without rubbing, for at least 2 minutes. The patient or family should be instructed concerning the risk for hematoma from the injection.

Resources

Additional resources for vaccine information can be found on the following websites:

- Centers for Disease Prevention and Control (CDC) National Immunization Program
www.cdc.gov/nip
- Immunization Action Coalition
www.immunize.org
- American Academy of Pediatrics
www.aap.org
- National Network for Immunization Information (NNII)
www.immunizationinfo.org
- World Health Organization (WHO) Immunization Safety & Global Advisory Committee on Vaccine Safety
www.who.int/immunization_safety/en/
www.who.int/vaccine_safety/en/
- American Academy of Family Physicians (AAFP)
www.familydoctor.org

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2. Merck. Gardasil package insert. Whitehouse Station, NJ: 2006 October.
3. Merck. ProQuad package insert. Whitehouse Station, NJ: 2006 July.
4. Merck. Rotateq package insert. Whitehouse Station, NJ: 2006 February.
5. Merck. Zostavax package insert. Whitehouse Station, NJ: 2006 June.
6. Sanofi Pasteur. ActHIB package insert. Swiftwater, PA: 2005 December.
7. Sanofi Pasteur. Decavac package insert. Swiftwater, PA: 2005 December.
8. Sanofi Pasteur. Fluzone package insert. Swiftwater, PA: 2005 July.
9. Sanofi Pasteur. IPOL package insert. Swiftwater, PA: 2005 December.
10. Sanofi Pasteur. Menomune package insert. Swiftwater, PA: 2005 December.
11. Physicians' Desk Reference (electronic version), Thomson Micromedex, Greenwood Village, Colorado (Edition expires 3/2007).

Summarized by Joan M. Murhammer, R.Ph., Drug Information Clinical Pharmacist, Department of Pharmaceutical Care

Table 1: Recommended and Minimum Ages/Intervals between Vaccine Doses of Routinely Recommended Vaccines^{1*}

Vaccine (UHC Formulary Brand)	Dose	Recommended Age for this Dose	Minimum Age for this Dose	Recommended Interval to next Dose	Minimum Interval to Next Dose
Diphtheria, Tetanus, & Acellular Pertussis (DTaP) (Infanrix®)	Dose 1	2 months	6 weeks	2 months	4 weeks
	Dose 2	4 months	10 weeks	2 months	4 weeks
	Dose 3	6 months	14 weeks	6 to 12 months	6 months [‡]
	Dose 4	15 to 18 months	12 months	3 years	6 months
	Dose 5	4-6 years	4 years	--	--
Haemophilus B conjugate (ActiHIB®, HibTITER®) [†]	Dose 1	2 months	6 weeks	2 months	4 weeks
	Dose 2	4 months	10 weeks	2 months	4 weeks
	Dose 3	6 months	14 weeks	6 to 9 months	8 weeks
	Dose 4	12 to 15 months	12 months	--	--
Hepatitis A (Havrix®)	Dose 1	12 to 23 months	12 months	6 to 18 months	6 months
	Dose 2	18 to 41 months	18 months	--	--
Hepatitis B (Recombivax-HB®)	Dose 1	Birth	Birth	1 to 4 months	4 weeks
	Dose 2	1 to 2 months	4 weeks	2 to 17 months	8 weeks [†]
	Dose 3	6 to 18 months	24 weeks	--	--
Human Papillomavirus (Gardasil®)	Dose 1	11 to 12 years	9 years	2 months	4 weeks
	Dose 2	11-12 yrs (+ 2 mos)	109 months	4 months	12 weeks
	Dose 3	11-12 yrs (+ 6 mos)	112 months	--	--
Influenza, Inactivated (TIV) (Fluzone®, FluArix®)	Dose 1	6 to 59 months	6 months	1 month ^{††}	4 weeks
	Dose 1	--	5 years	6 to 10 weeks ^{††}	6 weeks
Measle, Mumps, & Rubella (M-M-R II®)	Dose 1	12 to 15 months	12 months	3 to 5 years	4 weeks
	Dose 2	4 to 6 years	13 months	--	--
Meningococcal, Conjugate (Menactra®)	Dose 1	11 to 12 years	11 years	--	--
Meningococcal, Polysaccharide (Menomune®)	Dose 1	--	2 years	5 years	5 years
	Dose 2 ^{¶¶}	--	7 years	--	--
Pneumococcal, Conjugate (PCV) (Prevnar®) [†]	Dose 1	2 months	6 weeks	2 months	4 weeks
	Dose 2	4 months	10 weeks	2 months	4 weeks
	Dose 3	6 months	14 weeks	6 months	8 weeks
	Dose 4	12 to 15 months	12 months	--	--
Pneumococcal, Polysaccharide (PPV) (Pneumovax 23®)	Dose 1	--	2 years	5 years	5 years
	Dose 2 ^{¶¶}	--	7 years	--	--
Poliovirus (IPV) (IPOL®)	Dose 1	2 months	6 weeks	2 months	4 weeks
	Dose 2	4 months	10 weeks	2 to 14 months	4 weeks
	Dose 3	6 to 18 months	14 weeks	3 to 5 years	4 weeks
	Dose 4	4 to 6 years	18 weeks	--	--
Rotavirus (RotaTeq®) ^{§§}	Dose 1	2 months	6 weeks	2 months	4 weeks
	Dose 2	4 months	10 weeks	2 months	4 weeks
	Dose 3	6 months	14 weeks	--	--
Tetanus & Diphtheria Toxoids (Td) (Decavac®)	Dose 1	11 to 12 years	7 years	10 years	5 years
Tetanus, Reduced Diphtheria, & Acellular Pertussis (Tdap) (Adacel®)	Dose 1	≥ 11 years	10 years	--	--
Varicella (Varivax®)	Dose 1	12 to 15 months	12 months	3 to 5 years	12 weeks ^{**}
	Dose 2	4 to 6 years	15 months	--	--
Zoster (Zostavax®)	Dose 1	60 years	60 years	--	--

* When administering combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components.

† The third dose of hepatitis b should be administered at least 8 weeks after the second dose and at least 16 weeks after the first dose.

‡ The minimum recommended interval between the third and fourth dose of DTaP is 6 months, but the fourth dose does not need to be repeated if administered at least 4 months after the third dose.

¶ Haemophilus b conjugate (Hib) and pneumococcal conjugate (PCV) – require fewer doses when series started ≥ 7 months.

** The minimum interval to the second dose of varicella vaccine is 4 weeks if first dose given ≥ 13 years of age.

†† Two doses of influenza are recommended for patient < 9 years old receiving the vaccine for the first time. Persons ≥ 9 years or who have received previously do not require a second dose.

§§ The first dose of rotavirus must be administered at age 6 to 12 weeks. Rotavirus vaccine should not be administered to children ≥ 33 weeks old regardless of the number of doses given.

¶¶ Dose 2 is only indicated for certain high-risk patients

Table 2: Dose, Route, Recommended Age Range and Frequency of Commonly Prescribed Vaccines²⁻¹¹

Vaccine (UHC Formulary Brand)	Live	Approved Age Range	Dose	Route	Recommended Frequency
Diphtheria, Tetanus, & Acellular Pertussis (DTaP) (Infanrix®)	No	6 weeks to < 7 years	0.5 ml	IM	2, 4, 6, 15-18 months, & 4-6 years (5 doses)
Diphtheria, Tetanus, Acellular Pertussis, Hepatitis B, & Poliovirus (Pediarix®)	No	6 weeks to < 7 years	0.5 ml	IM	2, 4, & 6 months (3 doses); additional doses of IPV and DTaP are needed to complete series.
Haemophilus B conjugate (ActHIB®, HibTITER®)	No	≥ 6 weeks	0.5 ml	IM	2, 4, 6, & 12-18 months (4 doses); fewer doses needed if series started ≥ 7 months old
Hepatitis A & B (Twinrix®)	No	≥ 18 years	1 ml (≥ 18 years)	IM	0, 1, & 6 months (3-doses)
Hepatitis A (Havrix®)	No	≥ 12 months	0.5 ml (≤ 18 years) 1 ml (≥ 19 years)	IM	0 & 6-12 months (2 doses)
Hepatitis B (Recombivax-HB®)	No	≥ birth	0.5 ml (≤ 19 years) 1 ml (≥ 20 years)	IM	0, 1, & 6 months (3 doses) Alternative: 0, 4-6 months (2 x 1 ml dose) for 11-15 year olds
Human Papillomavirus (Gardasil®)	No	9 to 26 years	0.5 ml	IM	0, 2, & 6 months (3 doses)
Influenza, Inactivated (TIV) (Fluzone®, Fluarix®)	No	≥ 6 months	0.25 ml (6-35 months) 0.5 ml (≥ 3 years)	IM	2 doses (4 weeks apart) first season receive vaccine if <9 years; then single-dose annually
Influenza, Live (LAIV) (FluMist®)	Live	5 to 49 years	0.5 ml	Intranasal	2 doses (≥ 6 weeks apart) first season receive flu vaccine if <9 years; then annually
Measle, Mumps, & Rubella (M-M-R II®)	Live	≥ 12 months	0.5 ml	SQ	12-15 months & 4-6 years (2 doses; can separate doses by 4 weeks)
Measles, Mumps, Rubella, & Varicella (MMRV) (ProQuad®)	Live	12 months to 12 years	0.5 ml	SQ	12-15 months (1 dose); can separate doses by 3 months if a second dose is given
Meningococcal, Conjugate (Menactra®)	No	11 to 55 years	0.5 ml	IM	Single-dose; preferred product for 11 to 55 year olds
Meningococcal, Polysaccharide (Menomune®)	No	≥ 2 years	0.5 ml	SQ	Single-dose; revaccination may be given in certain high-risk groups within 3 to 5 years
Pneumococcal, 7-valent Conjugate (PCV) (Prevnar®)	No	6 weeks to 59 months (CDC) or 9 years (FDA)	0.5 ml	IM	2, 4, 6, & 12-15 months (4 doses); the number of doses is decreased if the series is started ≥ 7 months old
Pneumococcal, 23-valent Polysaccharide (PPV) (Pneumovax 23®)	No	≥ 2 years	0.5 ml	IM or SQ	Single-dose; booster given in certain high-risk groups or when turn 65 years (if ≥ 5 years since last dose)
Poliovirus (IPV) (IPOL®)	No	≥ 6 weeks	0.5 ml	IM or SQ	2, 4, 6-18 months, & 4-6 years (4 doses)
Rotavirus (RotaTeq®)	Live	6 to 32 weeks	2 ml	PO	2, 4, & 6 months (3 doses)
Tetanus & Diphtheria Toxoids (adult) (Td) (Decavac®)	No	≥ 7 years	0.5 ml	IM	Booster every 10 years
Tetanus, Reduced Diphtheria, & Acellular Pertussis (Tdap) (Adacel®)	No	11 through 64 years	0.5 ml	IM	Single-dose; then Td booster every 10 years
Varicella (Varivax®)	Live	≥ 12 months	0.5 ml	SQ	2 doses; Interval 4 weeks apart if first dose ≥ 13 years old and 12 weeks apart if ≤ 12 years old
Zoster (Zostavax®)	Live	≥ 60 years	0.65 ml	SQ	Single-dose

Hospital Practice Protocol

ANTICOAGULATION CASE MANAGEMENT SERVICE

Effective October 1, 2006, the Iowa Board of Medical Examiners and the Iowa Board of Pharmacy Examiners established criteria for collaborative drug therapy management between physicians and pharmacists. In the hospital setting, the Pharmacy and Therapeutics Subcommittee is responsible for authorizing the protocols for hospital pharmacists to perform drug therapy management for inpatients or patients in the hospital's clinics. The Pharmacy and Therapeutics Subcommittee has authorized the following protocol for the Anticoagulation Case Management Service.

The Anticoagulation Case Management Service (ACMS) is a service provided by pharmacists in conjunction with licensed independent practitioners (LIPs) that involves coordinated care in a structured and systematic process for monitoring adult patients on anticoagulation. This coordinated care results in improved patient outcomes and reduced healthcare expenses, as evidenced by a reduction of bleeding episodes and thromboembolic events.

Physicians and Pharmacists authorized to participate in collaborative drug therapy management:

- Physicians from UIHC Internal Medicine, Family Medicine, and Primary Care Clinic North may refer patients to the Anticoagulation Case Management Service in their respective areas using an ACMS consult form.
- UIHC pharmacists and pharmacy residents may provide care to patients pursuant to this agreement when working in the ACMS clinic.

Initiation of collaborative drug therapy management for anticoagulation:

- By signing the consult form, the referring physician allows pharmacists to monitor and adjust warfarin therapy in all patients referred to the service. Patients will remain under the care of the primary physician for all medical problems.

Protocol development, administration, quality assurance and pharmacist training:

- The pharmacist actions described below as being authorized in this protocol shall be administered under the Policies and Procedures for the Anticoagulation Case Management Service.
- A data collection process will be utilized at each patient encounter to capture information regarding adverse effects and INR values. This information will be assessed on an annual basis. The findings will be compared to national averages as part of an evaluation of the service.
- Each new pharmacist who participates in the anticoagulation service will be trained and evaluated during an orientation period. Therapeutic plans and electronic notes will be reviewed during this time for a period consisting of no less than eight half-days in the clinic. Additionally, an anticoagulation competency will be required to be completed when a pharmacist starts working in the clinic.

Actions authorized under the protocol and medications covered:

- Modification of anticoagulation-related drug dosages based on symptoms, laboratory results, physical findings, or changes in pertinent assessment parameters that would affect anticoagulation therapy.
- Refill authorizations on existing prescriptions relating to anticoagulation.

- Generation and interpretation of laboratory tests as needed to appropriately assess anticoagulation therapy. These may include fingerstick and venipuncture pt/INR, CBC, and TSH.
- Medications included in the protocol include anticoagulants and vitamin K derivatives.

Drug-drug interactions, changes in diet, changes in alcohol intake, patient's previous response to warfarin dose changes, non-adherence, and other appropriate assessment parameters will be addressed before dosing adjustments are made. All final dosing and follow-up decisions are left to the clinical pharmacist's professional judgment.

Procedures followed to communicate therapy monitoring and/or modification to the patient and patient's physician:

- Recommend follow-up in no more than four weeks depending on dose adjustment and clinical evaluation. If a dosage change is made, the patient will receive written instructions confirming the new dosing and follow-up instructions.
- If adjustments are made over the phone, the pharmacist will verify the instructions by having the patient repeat the new dose.
- Following a patient encounter, the ACMS pharmacist will complete a progress note to be included in the electronic medical record. The ACMS pharmacist will be the final reviewer on anticoagulation progress notes. Med List on IPR will also be updated to reflect therapy modifications.

Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician:

- If the patient reports symptoms consistent with thromboembolism.
- If initiation of enoxaparin therapy may be indicated.
- If the patient is dismissed from the service due to not following the respective clinic's policies and procedures as outlined in the signed patient-provider agreement.
- If the INR value is elevated to a dangerous level or the patient is experiencing significant bleeding (INR value dependent on patient age and medical condition).
- If the patient has any other acute anticoagulation-related issues as deemed by the clinical pharmacist.
- If a new medication order is needed.

For information regarding newly marketed drugs, drug-drug interactions, foreign drug identification, adverse drug reactions, alternative medications or other medication-related questions, contact the **DRUG INFORMATION CENTER**. The Center is open Monday through Friday from 8:00 a.m. - 12:30 p.m. and 1:00 p.m. - 4:30 p.m. (except holidays).

**ADVERSE DRUG
REACTION?

CALL THE DRUG
INFORMATION
CENTER**