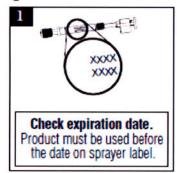
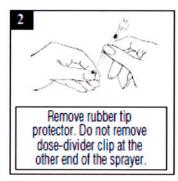
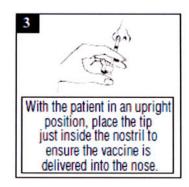
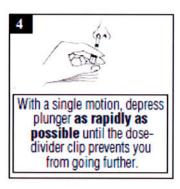
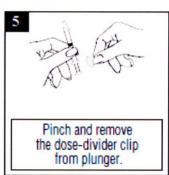
Figure 1

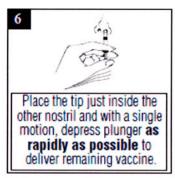














Note: Active inhalation (i.e., sniffing) is not required by the patient during vaccine administration

3 DOSAGE FORMS AND STRENGTHS

Pre-filled, single-dose intranasal sprayer containing 0.2 mL suspension [See Description (11)].

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is contraindicated in individuals with a history of hypersensitivity, especially anaphylactic reactions, to eggs, egg proteins, gentamicin, gelatin, or arginine or with life-threatening reactions to previous influenza vaccinations.

Needle Length and Injection Site for Inactivated Influenza Vaccine

Inactivated influenza vaccine must be administered by the intramuscular route only

Birth through 18 years of age		
Age	Needle Length	Injection Site
Infant 6 – 12 months	1" (25 mm)	Anterolateral thigh
Toddler 1 - 2 years	1" - 1 1/4" (25-32 mm) 5/8"* - 1" (16-25 mm)	Anterolateral thigh ⁺ Deltoid muscle of the arm
Child/adolescent 3 through 18 years	5/8"* - 1" (16-25 mm) 1" - 1 ¼" (25-32 mm)	Deltoid muscle of the arm ⁺ Anterolateral thigh
	19 years of age ar	nd older
Sex/weight	Needle Length	Injection Site
Male and female less than 130 lbs (60 kg)	1" (25 mm)	Deltoid muscle of the arm
Female 130 - 200 lbs (60-90 kg)	1" - 1½" (25-38 mm)	Deltoid muscle of the arm
Male 130 – 260 lbs (60- 118 kg)	1½" (38 mm)	Deltoid muscle of the arm
Female more than 200 lbs (90 kg)	1½" (38 mm)	Deltoid muscle of the arm
Male more than 260 lbs (118 kg)	1½" (38 mm)	Deltoid muscle of the arm

^{*}A 5/8" needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

Adapted from General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2006;55(RR-15). September 2009.

^{*}Preferred site.

Appendix D

Muscle Tissue

Ons are tissue cutaneous

Fatty (Subcutaneous) Tissue

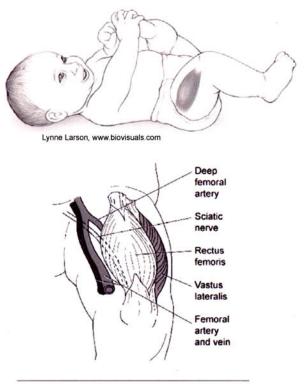
90° Angle

Lynne Larson, www.biovisuals.com

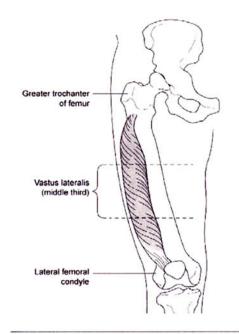
 Intramuscular (IM) injections are administered into muscle tissue below the dermis and subcutaneous tissue.

 Site - Although there are several IM injection sites on the body, the recommended IM sites for vaccine administration are the vastus

lateralis muscle (anterolateral thigh) and the deltoid muscle (upper arm). The site depends on the age of the individual and the degree of muscle development.

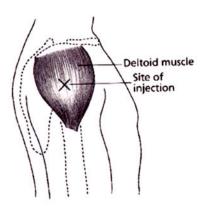


The vastus lateralis muscle of the upper thigh used for intramuscular injections.



The vastus lateralis site of the right thigh, used for an intramuscular injection.





- Needle Gauge 22- to 25-gauge needle
- Needle Length For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone. The vaccinator should be familiar with the anatomy of the area into which the vaccine will be injected.

Decision on needle size and site of injection must be made for each person on the basis of the size of the muscle, the thickness of adipose tissue at the injection site, the volume of the material to be administered, injection technique, and the depth below the muscle surface into which the material is to be injected

- Infants (Younger Than 12 Months)
For the majority of infants, the anterolateral aspect of the thigh is the recommended site for injection because it provides a large muscle mass. The muscles of the buttock have not been used for administration of vaccines in infants and children because of concern about potential injury to the sciatic nerve, which is well documented after injection of antimicrobial agents into the buttock. If the gluteal muscle must be used, care should be taken to define the anatomic landmarks.*

^{*}If the gluteal muscle is chosen, injection should be administered lateral and superior to a line between the posterior superior iliac spine and the greater trochanter or in the ventrogluteal site, the center of a triangle bounded by the anterior superior iliac spine, the tubercle of the iliac crest, and the upper border of the greater trochanter.

Appendix D

Injection technique is the most important factor to ensure efficient intramuscular vaccine delivery. If the subcutaneous and muscle tissue are bunched to minimize the chance of striking bone, a 1-inch needle is required to ensure intramuscular administration in infants. For the majority of infants, a 1-inch, 22-25-gauge needle is sufficient to penetrate muscle in an infant's thigh. For new born (first 28 days of life) and premature infants, a 5/8 inch needle usually is adequate if the skin is stretched flat between thumb and forefinger and the needle inserted at a 90-degree angle to the skin.

- Toddlers and Older Children (12 Months through 10 Years)
 The deltoid muscle should be used if the muscle mass is adequate. The needle size for deltoid site injections can range from 22 to 25 gauge and from 5/8 to 1 inch on the basis of the size of the muscle and the thickness of adipose tissue at the injection site. A 5/8-inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger and the needle inserted at a 90° angle to the skin. For toddlers, the anterolateral thigh can be used, but the needle should be at least 1 inch in length.
- Adolescents and Adults (11 Years or Older)
 For adults and adolescents, the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh also can be used. For men and women weighing less than 130 lbs (60 kg) a 5/8-1-inch needle is sufficient to ensure intramuscular injection. For women weighing 130-200 lbs (60-90 kg) and men 130-260 lbs (60-118kg), a 1-1½-inch needle is needed. For women weighing more than 200 lbs (90 kg) or men weighing more than 260 lbs (118 kg), a 1½-inch needle is required.

- Technique

- Follow standard medication administration guidelines for site assessment/selection and site preparation.
- To avoid injection into subcutaneous tissue, spread the skin of the selected vaccine administration site taut between the thumb and forefinger, isolating the muscle. Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle.
- Insert the needle fully into the muscle at a 90° angle and inject the vaccine into the tissue.
- Withdraw the needle and apply light pressure to the injection site for several seconds with a dry cotton ball or gauze.
- Aspiration Aspiration is the process of pulling back on the plunger of the syringe prior to injection
 to ensure that the medication is not injected into a blood vessel. Although this practice is advocated
 by some experts, the procedure is not required because no large blood vessels exist at the recomended injection sites.