THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

#8: Administration of Immunizing Agents

- Competency: Prepares and administers immunization agents correctly.

1.0 PREPARATION FOR ADMINISTRATION OF BIOLOGICAL PRODUCTS

1.1 Client Health Assessment

Each time the client presents for immunization, they must be screened to ensure that they are well and can safely receive the recommended vaccines. Refer to SIM, Chapter 6, *Contraindications and Precautions* for more information.

1.1.1 General Screening Questions

1. Is your child/are you feeling sick today? Does your child/do you have diarrhea, vomiting or a high fever today?
2. Does your child/do you have allergies to medications, vaccine components, latex or foods?
3. Has your child/have you ever had a life-threatening allergic (anaphylactic) reaction after receiving a vaccine in the past?
4. Has your child/have you had any reactions to vaccines that you were concerned about?
5. Has your child/have you received any vaccines from other providers such as a family physician, Nurse Practitioner, pharmacist or from a travel clinic?
6. Has your child/have you received any vaccines in the past 4 weeks?
7. In the past year, has your child/have you received any blood products or a transfusion, immune globulins (antibodies) or antiviral drugs?
8. Has your infant had an episode of intussusception? Does your infant have an uncorrected congenital gastrointestinal malformation (e.g. Meckel's diverticulum)?
9. Is there a history of severe combined immunodeficiency (SCID) or a history of recurrent, unexplained early deaths in the family?
10. Does your child/do you have any diagnosed medical conditions such as:
    a. Kidney, liver (hepatitis A, B or C), heart or lung diseases (e.g., asthma)?
    b. An abnormal or absent spleen?
    c. Bone marrow problems or a blood disorders (e.g. sickle cell disease or anemia)?
    d. A bleeding disorder or are on long-term aspirin therapy?
    e. Any metabolic diseases (e.g., diabetes mellitus)?
    f. A chronic cerebrospinal fluid leak or a shunt for hydrocephaly?
    g. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine?
    h. Uncontrolled seizures, progressive encephalopathy or other progressive or neurological disorder that is not stabilized with treatment?
11. Does your child/do you have any form of immune system problems or suppression related to cancer, leukemia, lymphoma, HIV infection or AIDS, or a congenital immune system problem (e.g. severe combined immunodeficiency disorder [SCID], B-lymphocyte [humoral] immunity, T-lymphocyte [cell- mediated] immunity, complement system [properdin, or factor D deficiencies] or phagocytic functions)?
12. Is your child/are you currently taking cortisone, prednisone, and other corticosteroids or immune-suppressing drugs, receiving anticancer drugs (chemotherapy) or having radiation (X-ray) treatments?
    a. Examples of immune suppressing drugs may include anti-rheumatic drugs, and drugs used for the management of inflammatory bowel disease.
13. Has the mother taken any monoclonal antibody medications during her pregnancy with this child? (Refer to Appendix 8.2: Monoclonal Antibody Medications for list).
14. Has your child/have you ever had a cochlear, solid organ, islet cell or stem cell transplant, or are recommended to have a transplant in the future?
15. Has your child/have you ever had a nervous system disorder (e.g. Guillain-Barré syndrome)?
16. Is your child/are you pregnant or is there chance she/you could become pregnant during the next month?
17. Has your child/have you ever had a positive TB skin test?

1.2 Standard Precautions

- Biological products, syringes and needles are considered sterile once manufactured. Therefore, aseptic technique must be practiced when preparing these products.
- Wash hands well using soap and water, or a waterless hand cleanser prior to preparing biological products and between clients.
- The use of non-sterile or sterile gloves during immunization is not recommended and unnecessary unless the immunizer is concerned about contact with a client's body fluids or the immunizer's skin on their hands is not intact. Gloves must be changed between clients.
- Use a separate, sterile safety engineered sharp device (SESD) for each injection.
- Engage the safety mechanism on needles immediately following administration of the biological product.
- Immediately discard the syringe/needle into a sharps container that is placed safely away from clients (and children).
- Never recap needles or empty used needles/syringes from one sharps container to another.
- Immediately report needle stick injuries to a supervisor for consideration of possible post-exposure immunoprophylaxis. Follow worksite occupational health and safety protocol.

1.3 Product Preparation

If the protective cap on a single-dose vial is removed, or if a manufacturer's pre-filled syringe is opened (e.g., syringe cap removed), the vaccine should be used on that clinic day or discarded CIG).

1.3.1 Pre-Preparation: Pre-Loading of Syringes

Pre-preparation of prefilled syringes and pre-loading of syringes with biological products that come in vial or ampoule presentations is discouraged because of the uncertainty of product stability in syringes, risk of contamination, increased potential for administration errors, and biological product wastage.

1.3.1.1 Filter Needles

Filtration needles are not recommended for vaccine preparation or administration as they may filter out active ingredients such as adjuvants (CIG). In 2010, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a review titled *Filtered Needles for Withdrawing Medication from Glass Ampoules: A Review of the Cost-Effectiveness and Incidence of Complications*. Regarding the use of filtered needles in public health nursing practice, the Ministry of Health endorses the following conclusion statement in this report: "*Due to the lack of recent published literature, no conclusions can be drawn on the incidence of complications from glass particle administration, or the cost-effectiveness of using a filtered needle when withdrawing medication from a glass ampoule*". This includes diluents in ampoule presentations as well.

1.3.1.2 Combination of Contents of Multi-Dose Vials

Withdrawing contents from multiple multidose vials to make a vaccine dose and prevent wastage is not recommended by the Ministry of Health because of potential contamination risks and lot number discrepancies.

1.3.2 Preparation Instructions

1. When preparing any biological product, consider the "10 Rights" of immunization:
   1. Right client
   2. Right assessment
   3. Right client education
   4. Right to refuse
   5. Right product
   6. Right dose
   7. Right route
   8. Right time
   9. Right documentation
   10. Right evaluation
2. Thoroughly wash hands with soap and water or cleanse with a sanitizer.
3. Prepare necessary materials (e.g., single use, disposable sterile syringe/needle, vaccine, diluent if required, 70% isopropyl alcohol, sharps container, supplies for the management of anaphylaxis).
4. Different vaccines must never be combined in the same syringe.
5. Check the characteristics of the product to be administered:
   - Correct product, form of presentation and expiry date.
   - Check three times that it is the correct product: when removing from fridge/biological cooler, when drawing up and/or reconstituting, and prior to administration.
   - Expected appearance: are there any irregularities (e.g., particulate matter, damage)?
   - Expiry date. If only the month and year are provided for the expiry date, the biological product can be used to the end of that month.
6. If a previously opened multi-dose vial is available, check the date that the vial was opened (as recorded on the label). Most multi-dose vials must be used within 30 days of opening, unless the manufacturer specifies another time period (i.e., once punctured, some influenza vaccine MDVs are stable to the expiry date noted on the vial).

If there is discoloration, extraneous particulate matter, or obvious lack of re-suspension, mark the vial as "DO NOT USE," return it to proper storage conditions, complete a *Vaccine Problem Supply* report form, and contact the Ministry of Health for direction.

1.3.3 Vials

1. Wash hands or cleanse with a sanitizer.
2. Remove the plastic cap covering the vial.
3. Cleanse the surface of the rubber stopper using a cotton pad/swab moistened with 70% isopropyl alcohol. Allow to air dry.
4. Gently swirl the vial immediately before removing each dose to ensure that the contents are fully dispersed.
   - For a product in a "ready to go" liquid presentation, draw into the syringe a volume of air equal to the quantity of biological product to be removed.
   - For lyophilized, or freeze-dried products (e.g., MMR) requiring reconstitution, the diluent acts as the air in the syringe so there is no need to draw air into the diluent syringe.
5. Hold/place the vial right side up and insert the needle through the centre of the rubber stopper. Do not insert blunt needles with or without a filter into vials because of coring risk.
6. Slowly inject the air or diluent from the syringe.
7. If the biological product was reconstituted, gently swirl the vial to ensure the contents are fully dispersed.
   - Single dose vial - withdraw all contents to ensure client receives full concentration of antigens.
   - Multidose vial - withdraw the required quantity of biological product into the syringe.
8. Remove the needle from the vial and expel any air bubbles from the syringe.
9. It is not necessary to change needles between drawing up the biological product into the syringe and immunizing the client. Change the needle only if it is damaged, or becomes contaminated.
10. Discard the empty vial into a sharps container.
11. If it is the first entry into a multi-dose vial, record the date (include day, month and year) on the label of the vial.
12. Immediately return multi-dose vials to the refrigerator/biological cooler.

1.3.4 Vaccines with Diluents

1. Before reconstituting, check labels on both the vaccine vial and the diluent vial to verify:
   - That they are the correct products to mix together.
   - That both are within their expiration dates.
2. Reconstitute vaccines just prior to use by:
   - Removing the protective caps and wiping each stopper with an alcohol swab;
   - Inserting needle of syringe into diluent vial and withdrawing entire contents. Do not insert blunt needles with or without a filter into vials because of coring risk;
   - Inject diluent into vaccine vial and gently agitating to thoroughly dissolve the lyophilized powder. Draw up all contents to ensure client receives full concentration of antigens.
   - If reconstituted vaccine is not used immediately or comes in a multi-dose vial:
     - Clearly mark the vial with the date and time that the vaccine was reconstituted.
     - Protect vaccines from light.
3. Changing the needle after the reconstitution is unnecessary unless the needle has been damaged or contaminated.
4. Check the colour and appearance of the reconstituted vaccine to ensure it matches the description on the package insert.

1.3.5 Ampoules

1. Gently swirl the ampoule immediately before removing the contents to ensure that the contents are fully dispersed.
2. Tap the ampoule lightly to ensure that the contents are in the lower part of the ampoule.
3. Using a swab moistened with isopropyl alcohol, wipe the neck area of the ampoule prior to opening to prevent bacterial contamination of ampoule contents.
4. Break the neck of the ampoule using the alcohol swab, cotton ball or cotton gauze. If you cut yourself in breaking the ampoule, discard the ampoule, since the product may be contaminated. Wash your hands and cover the cut before continuing.
5. Draw up all contents to ensure client receives full concentration of antigens using a sterile syringe and needle. It is not necessary to change needles between drawing up the biological product into the syringe and administering it to the client.
6. Discard the ampoule into a sharps container.
7. Expel the air bubbles from the syringe.

1.3.6 Multidose Vials

1. Refer to section 1.3.3 Vials for details.
2. Hold/place the vial right side up and insert the needle through the centre of the rubber stopper. Do not insert blunt needles with or without a filter into multidose vials because of coring risk.

1.3.7 Prefilled Syringe-Vaccine Vial Format

1. Do not remove any air that is present in the prefilled vaccine- or diluent-containing syringe prior to inserting it into the vaccine-containing vial. This air is required to ensure that all of the liquid is inserted into the vial to attain the correct volume of reconstituted vaccine. If no air is noted, a little amount of air should be withdrawn into the syringe prior to inserting its contents into the vial.
2. Ensure that the vial is sitting on the counter so that the stopper cap is facing upright. Remove the plastic cap and wipe the stopper with an alcohol pad and let dry. Hold the vial steady on the counter. Hold the syringe so that the needle is pointing down and the air bubble (point 1 above) is present under the syringe stopper. Insert the needle straight down into the centre of the vial stopper and then inject this vaccine into the vaccine vial. This will ensure that the air bubble in the syringe will clear all vaccine into the vial. There should be no remaining vaccine in the syringe or needle. (The question and answer below was recently published in the *Immunization Action Coalition* newsletter Volume 17 Issue 1 and is available at: http://www.immunize.org/va/va38.pdf.
   - **Q**: Some single-dose pre-loaded vaccines come with an air pocket in the syringe chamber. Do we need to expel the air pocket before vaccinating?
   - **A:** No. You do not need to get rid of the air pocket. The air will be absorbed. This is not true for syringes that you fill yourself; you should expel air bubbles from these syringes prior to vaccination to the extent that you can readily do so).
3. Remove the syringe and gently shake the vial contents for reconstitution. Draw into the syringe a small volume of air. With the vial sitting flat on the counter (stopper facing up), insert the air from the syringe into the vial; this added pressure ensures that all vial content can be withdrawn.
4. Pick up and invert the vial upside down. Pull the needle back until the tip is in the liquid. Pull back on the plunger until you remove the entire liquid contents of the vial; a bit of air from within the vial can also be withdrawn into the syringe to ensure the needle is cleared of vaccine.
5. With the syringe upright so that the needle is at the top, remove the needle from the vial and if there are air bubbles in the syringe, tap them gently so that they move under the needle and then gently push them out of the needle, being very careful not to expel any vaccine. This action primes the needle.
6. Recap the needle and the vaccine is ready to administer.

1.4 Scheduling and Administration of Multiple Injections

There are no contraindications to receiving multiple injections of vaccines at the same clinic visit. There is no increase in side effects or reduced vaccine effectiveness. Guideline 7 in CIG (2006, p. 25) states, *"providers should administer all vaccine doses for which a recipient is eligible at the time of each visit"*. Adherence to this standard of practice will avoid missed immunization opportunities and the possibility of susceptible individuals contracting vaccine-preventable diseases.

1.4.1 Practice Considerations

- When two or more injectable biological products are to be administered, they may be administered in the same limb (except for rabies vaccine and rabies immune globulin), providing the distance between injection sites is a minimum of 2.5 cm (1 inch,) apart so that local reactions can be distinguished for each product administered.
- Give biological products that are known to cause more stinging and/or pain last (e.g., give DTaP-IPV-Hib first, followed by MMRV and then Pneu-C-13).
- If multiple injections are to be given, and two health care providers are available, ask the client if they would prefer to have the biological products administered simultaneously in different limbs. The premise is that this procedure allows the client more control in the immunization experience and may decrease anxiety from anticipation of next injection(s).

1.5 Publicly Funded Immunizations Following Non-Conforming Situations

- Publicly funded vaccine doses administered any time before the eligible minimum age or eligible minimum interval as recommended in the Saskatchewan Immunization Manual are medication administration errors.

4-Day Grace Period Principles

- The US Advisory Committee on Immunization Practices (ACIP) established the "4-day grace period" that may be applied when assessing the validity of historic documented vaccine doses that were administered up to four days before the minimum age or minimum interval.
- The 4-day grace period **may be applied by RHAs and FNJs** when reviewing **historical** client immunization records (such as childhood records for school entry).
- The 4-day grace period **should not** be applied by RHAs and FNJs:
    - To schedule future immunization visits for **publicly funded** vaccines.
    - To allow for the administration of publicly funded vaccines **at the discretion of the PHN** when they encounter a client before the minimum ages and/or intervals for a vaccine have been met.
- In certain situations, like accelerated schedules for travel or other situations such as during communicable disease investigations or when immunizing hard to reach populations, a regional **MHO may discretionarily** determine that doses of selected vaccines administered before the recommended minimum age or minimum intervals supersede the 4-day grace period and are valid doses. This is a regional decision **and** written regional policies (to address such instances should exist regarding the 4 day grace period (for publicly or non-publicly funded vaccines). Where a policy doesn't exist, the MHO recommendation must be documented in Panorama.
    - PHNs must document in Panorama the rationale regarding the application of the 4-day grace period (outside of historical immunizations) in a client's immunization record.
- **The 4-day grace period does not apply to post-exposure rabies vaccine, or to accelerated vaccine schedules (e.g., HB, HAHB).**

A. Administration of a vaccine 4 or fewer days before the minimum age or minimum interval.

Inactivated vaccines

- Inactivated vaccine doses administered up to 4 days before the minimum age or minimum interval for a vaccine antigen(s) may be assessed as valid.

Live vaccines

- Live injectable and oral vaccine doses administered up to 4 days before the minimum age for a vaccine antigen(s) may be assessed **as valid**.
- Live injectable and oral vaccine doses administered up to 4 days before the minimum interval for a vaccine antigen(s) **are invalid** regardless of circumstances.
    - This applies whether the same or different injectable antigens have been administered (e.g., MMRV and MMRV, or MMR and Var). Invalid doses need to be repeated at the appropriate minimum interval from the invalid dose.
- NOTE: Because live oral and intranasal vaccines do not interfere with viral antibody production from other live (oral, intranasal or injectable) vaccines, they can be given regardless of the interval in relation to other vaccines.

B. Administration of a vaccine 5 or more days before the minimum age or minimum interval.

- Live or inactivated vaccine doses administered 5 days or more before the minimum age or minimum interval **are invalid** and need to be repeated at the appropriate minimum interval from the invalid dose.

1.5.1 Vaccines Given at Less than the Recommended Minimum Interval

- Refer to SIM, Chapter 5, Section 2.1, *Minimum Intervals between Vaccine Series Doses*.
- Generally, a vaccine dose that was given 5 days or more before the minimum interval is an invalid dose and must be repeated at the correct minimum interval.
- If two live injectable vaccines are not given on the same day and are given at less than the recommended minimum intervals, the second vaccine given is invalid and must be repeated at the correct minimum interval from administration.

1.5.2 Vaccines Given at Less than the Recommended Minimum Age

- Refer to SIM, Chapter 5, Section 2.1, *Minimum Intervals between Vaccine Series Doses*.
- Generally, a vaccine given at less than the acceptable minimum age is an invalid dose must be repeated once the client is of acceptable age. Refer to section 1.5 above.

1.5.3 Vaccines Given by Incorrect Route

- Refer to SIM, Chapter 5, Section 4.3, *Individuals Who Received a Vaccine by a Route Other than that Recommended* for information.

1.5.4 Reduced Doses of Vaccine

- Refer to SIM, Chapter 5, Section 4.4, *Individuals Who Received an Inappropriate Vaccine Dose* for information.

1.5.5 Expired Vaccines

A. **If there is no urgency to repeat the expired dose and the client is agreeable**, the immunizer may contact the manufacturer's medical information department (do online search for contact information) to request if they have data to support the potency of the administered expired vaccine dose.
    a. The inquirer **must** request to receive printed confirmation of these data from the manufacturer for inclusion/uploading in the client's medical/immunization record.
    b. **NOTE: If A is not feasible by the immunizer, refer to B.**

B. If an **expired live or non-live dose** was inadvertently given; and the client is not agreeable to having the manufacturer contacted; **or** the manufacturer does not have potency data as in **A**, or time is a factor, it is **an invalid dose and** should be repeated.
NOTE: Document a client's refusal for a repeat dose in their record.
    a. If the error **is detected on the same day** that administration occurred, repeat the dose that same day at a different injection site. The repeat dose is a valid dose.
    b. If the error **is not detected** on the same day:
        I. For a **non-live vaccine**, a repeat dose should be given as soon as possible.
            i. However, recombinant zoster vaccine (RZV; SHINGRIX™) should be administered 28 days after the invalid dose, to reduce the burden of adverse reactions which occurs with this vaccine.
        II. For a **live vaccine**, a 28-day interval is required, because circulating interferon may interfere with the replication of the second live vaccine.
            ii. For rotavirus vaccine doses, the repeat dose should be administered after a 28-day interval from the invalid dose or at the maximum age for the vaccine dose (whichever is earlier).

2.0 ADMINISTRATION ROUTES, SITES AND TECHNIQUES

Providers must ensure that biological products are correctly administered using the recommended dose, route, site and schedule to optimize product effectiveness and reduce the risks of local reactions and adverse events. **Always read the product monograph thoroughly for comprehensive administration instructions.**

2.1 Special Considerations

- Most live, attenuated and inactivated vaccines are to be administered by one specific route as stated in the product monograph. However, specific vaccine product monographs indicate two acceptable routes for administration.
- Some vaccines that are indicated only for intranasal or oral administration routes are packaged in devices that resemble injection syringes.
- Immune globulins must be administered in sites distanced from vaccine sites.

2.1.1 Limb Integrity

Injection of a vaccine into an area where lymphatic circulation may be impaired (e.g., local lymphedema, lymphangioma, axillary lymph node dissection, arteriovenous (A-V) fistula, upper limb amputation) could theoretically result in an impaired immune response due to impaired vaccine absorption, although there are no data to support this. Consider an alternative injection site if possible. There is no evidence or theoretical rationale for avoiding injection through a tattoo or superficial birthmark (CIG, 2017). Vastus lateralis may be used as an alternative site for all ages.

2.1.2 Persons with Bleeding Disorders

Haematoma formation and excessive bruising post IM injection may occur among clients with bleeding disorders or those that are on anticoagulant therapy. The MHO and/or client's physician is best positioned to assess an individual client's ability to safely receive IM injections. A fine gauge needle (23, 25, or 27 G) should be used. Z-track technique may be used to prevent bleeding. Do NOT aspiration. Apply direct pressure (without rubbing) to the injection site for 2 minutes or longer (CIG). The client or caregiver should receive information on the risk of developing, and managing a haematoma.

2.2 Injection Guidelines

- Before administering any biological products, visually inspect the skin's surface over the injection site for bruises, scars, or inflammation. Sites with established tattoos are safe to use.
- Palpate the site as biological products should not be injected where there is poor muscle mass, and existing inflammation, itching, scars, nodules, sensitivity, induration, or pain.
- For those 4 years and older, moderately rub or stroke the injection site prior to injection.
- Cleanse the site for 5 seconds with isopropyl alcohol and allow for drying before administering the injection.
- Coach the client to relax the limb muscles prior to injection.
- Administer the least painful or stinging products first.
- For IM and SC injections, insert the needle quickly and firmly into the injection site, and stabilize the syringe to prevent it from moving.
- Do not aspirate the syringe for any injections. Aspiration is painful, may traumatize tissues, and affect absorption.
- Rapid injection of vaccines (not immunoglobulins or PPD) reduces pain during injection.
- Withdraw IM and SC needles quickly, at the same angle that it was inserted. Promptly activate the safety engineered sharps device.
- All needles and sharps must be immediately disposed of as a single unit into a sharps container.
- Apply gentle pressure with a cotton ball to the injection site for 10 seconds after the injection.
- If the dose leaked out during administration, immediately administer another dose to ensure complete immunization status of the client.
- Adhesive bandages are not recommended for use because they may:
    - Contain latex;
    - Irritate the injection site; or
    - Become a choking hazard for infants and young children.

2.3 Anatomical Guidelines and Sites

Longer needle lengths reduce the incidence of localized side effects. If the needle strikes bone during insertion, withdraw it slightly before injection of the product into the muscle. Use clinical judgment in selecting appropriate injection sites and needle sizes for IM injections based upon the:

- Client's age;
- Injection site muscle mass;
- Thickness of adipose tissue over the injection site;
- Volume of the product to be administered;
- Number of products to be administered; and
- Viscosity of the biological product.

Table 1: Vaccine Intramuscular Injection Site, Needle Length and Total Daily Site Volume per Age Group

Age group	Injection site (90° angle)	Needle length (22-25 gauge)	Total site volume
Children			
• Birth to less than 12 months	Vastus lateralis	1"	1 mL
• 12 months up to and including 4 years	Deltoid * Vastus lateralis	1" 1"	1 mL 2 mL
• 5 years up to and including 17 years	Deltoid Vastus lateralis	1" (1½"inches for heavier children)	1 mL 2 mL
Adults			
• 18 years and older	Deltoid Vastus lateralis	1" – 1½" 1" – 1½"	2 mL 3 mL

(Adapted from BCCDC Immunization Manual, 2009)

* When the deltoid muscle is considered for use in young children 12 months of age or over, assesses the adequacy of the muscle size prior to administration.

Table 2: Immune Globulin Preparation Injection Site, Needle Length and Total Daily Site Volume per Age Group

CLIENT AGE	SITE ▲ (90° IM)	NEEDLE LENGTH	SIZE (Gauge)	MAX. VOLUME
Children				
• Birth to less than 12 months	Vastus lateralis	1"	23	1 mL
• 12 months up to and including 4 years	Deltoid * Vastus lateralis	1" 1"	22-23 22-23	1 mL 2 mL
• 5 years up to and including 17 years	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1" – 1½" 1" – 1½" 1" – 1½" 1" – 1½"	20-23 22-23 20-23 20-23	1 mL 3 mL 3 mL 3 mL
Adults				
• 18 years and older	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1" – 1½" 1" – 1½" 1" – 1½" 1" – 1½"	20-22 20-22 20-22 20-22	2 mL 5 mL 4 mL 5 mL

(Adapted from BCCDC Immunization Manual, 2009)

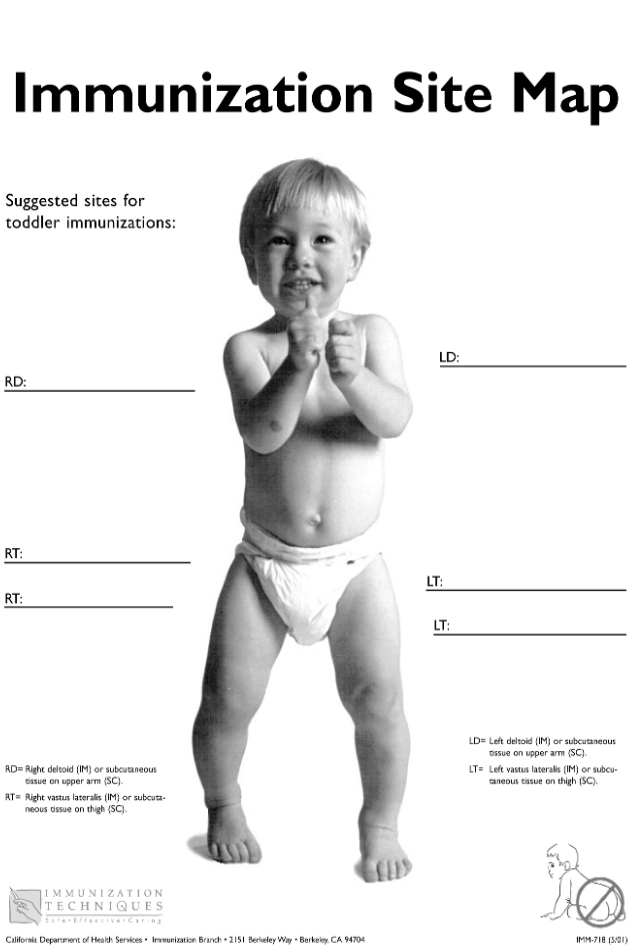
* When the deltoid muscle is considered for use in young children 12 months of age or over, assesses the adequacy of the muscle size prior to administration.

▲ Different immune globulin preparations **must be** separated by minimum 2.5 cm if given in the same limb (e.g., TIg and RabIg in adult deltoid). **It is recommended to administer in different sites if possible.**

[1] One deltoid should be reserved for the administration of rabies vaccine **on day 0** of rabies post-exposure immunoprophylaxis.

[2] Use of the dorsogluteal site is **only recommended in adolescents and adults** when the deltoid, vastus lateralis and ventrogluteal sites have had maximum volumes of an immune globulin preparation injected and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is done in the dorsogluteal site.

Figure 1: Infant and Child Immunization Site Maps



(Source retrieved April 2, 2011 from: http://www.immunize.org/clinic/administering-vaccines)

2.4 Intramuscular (IM)

The IM route is used to deposit a biological product deep into a muscle at a 90° angle, where it can elicit the best immune response (see figure 1). If such a product is erroneously injected into the dermis or adipose tissue, irritation, induration, inflammation, or an abscess may form at the injection site.

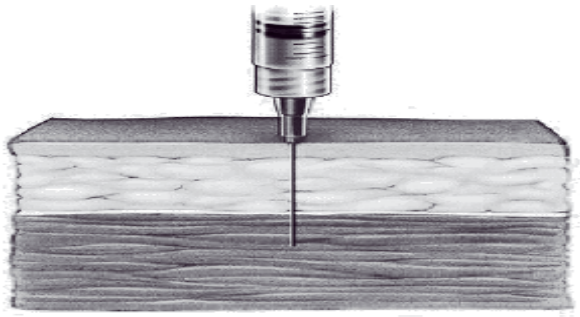


Figure 1

Three techniques are acceptable to administer IM injections:

1. Use the thumb and index finger to gently stretch the skin over the site while inserting the needle at a 90° angle to the skin;
2. Use the free hand to gently bunch the muscle while inserting the needle at a 90° angle to the skin; or
3. Use the Z-track method. **Z-tracking is appropriate to administer IM injections to all age groups, except for infants**. Z-tracking involves using the free hand to displace the skin and adipose tissue at least one inch laterally in relation to the underlying muscle, prior to 90° insertion of the needle into the muscle. The Z-tracking must be kept in place until after the biological product is deposited into muscle and the needle is withdrawn, therefore preventing reflux of the medication into the subcutaneous tissue (see figure 2). This technique seals off the puncture tract and traps the product within the muscle, minimising pain, irritation and bleeding at the site.

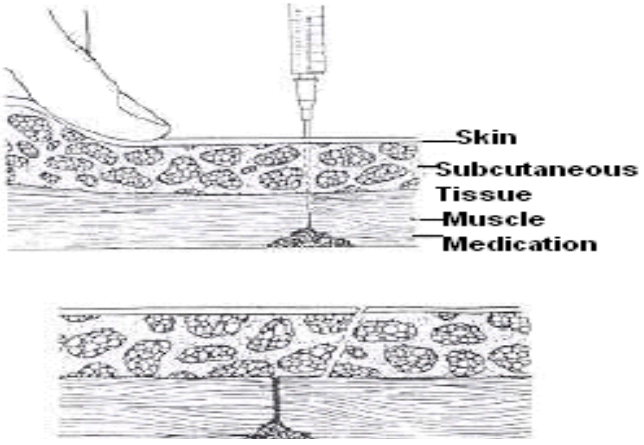


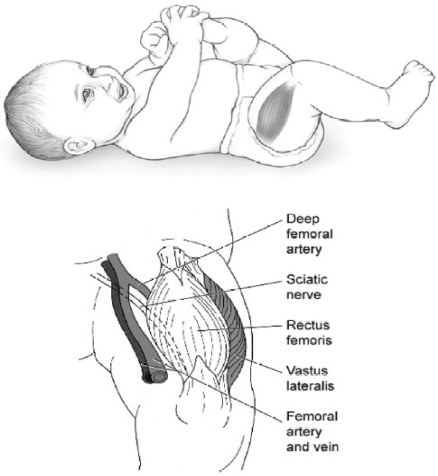
Figure 2

2.4.1 Vastus lateralis

These are the preferred sites for IM injections in infants less than 12 months of age because they are well developed at birth and are safely distanced from any nerves or major blood vessels. Using these sites can temporarily affect the movement of the child's leg.

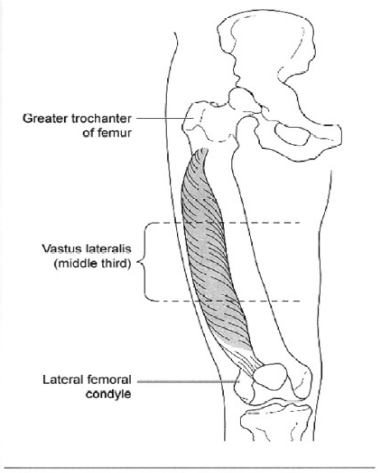
To landmark the site:

1. Visually divide the length of the muscle that originates on the greater trochanter of the femur and the lateral border of the kneecap into thirds.
2. The anterolateral aspect of the middle third is where the belly of the vastus lateralis muscle lies, and the injection site is in the middle of this area.
3. In width, the site extends from the midline of the top of the thigh to the midline of the outer side of the thigh. (see figures 3 and 4)



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

Figure 3



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

Figure 4

2.4.2 Deltoid

The deltoid muscles are the preferred IM injection sites for adults and children 12 months of age or older. The deltoid muscle is insufficiently developed in younger infants.

To landmark the site:

1. Visualize an inverted triangle with its base at the acromion process and its peak just below the axilla.
2. The injection site is in the center of the triangle (see figures 5 and 6 below).

Figure 5

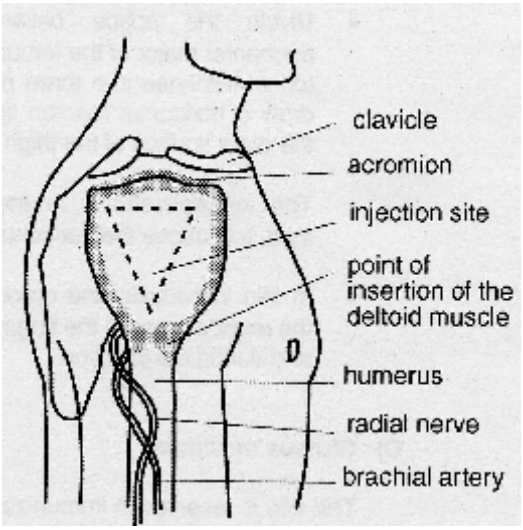


Figure 6

(Figure 5 retrieved April 3, 2011 from www.cdc.gov; Figure 6 retrieved April 2, 2011 from BCCDC at http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf)

2.4.3 Ventrogluteal (For Immunoglobulin Administration Only)

Do not use this site for vaccine administration. Active immunizing agents should not be administered into the gluteal muscle.

The ventrogluteal site is the preferred site for the IM injection of large volumes of immune globulin preparations (i.e., Ig, HBIg, RabIg, TIg, VarIg). Appropriate site selection of the gluteal muscle is necessary to avoid injury to the sciatic nerve.

This site can be used in those over 7 months of age.
This muscle is accessible in the supine, prone, and side lying position.

To landmark this site:

1. Use the right hand to locate the site on the left hip, and the left hand to locate the site on the right hip.
2. Place heel of the hand over the greater trochanter of the client's hip with wrist almost perpendicular to the femur.
3. Point the thumb toward the client's groin and the fingers toward the client's head.
4. Point index finger to the anterior superior iliac spine, and extend the middle finger back along the iliac crest toward the buttock. The index finger, the middle finger, and the iliac crest form a V-shaped triangle.
5. The injection site is the centre of the triangle (see figure 7).

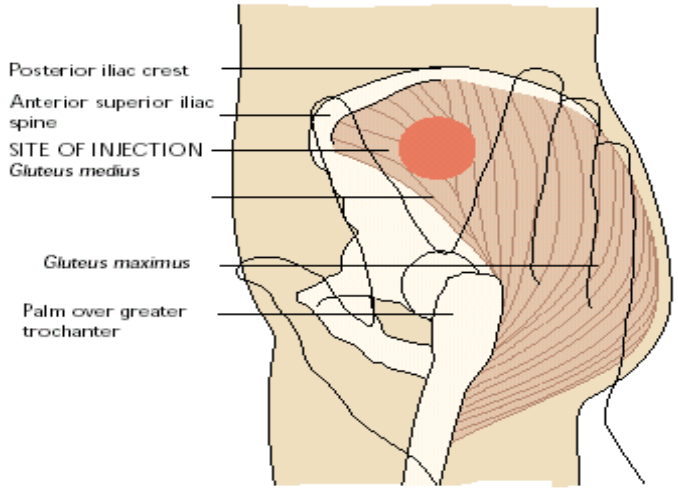


Figure 7

(Figure 7 retrieved April 2, 2011 from BCCDC at: http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf).

2.4.4 Dorsogluteal (For Immunoglobulin Administration Only)

Do not use this site for vaccine administration. Active immunizing agents should not be administered into the gluteal muscle.

The dorsogluteal site is only to be used for the IM injection of large volumes of immune globulin preparations when the ventrogluteal and vastus lateralis sites have had maximum volumes of an immune globulin preparation injected and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is done in the dorsogluteal site.

This site should only be used in individuals over 5 years of age.

Place client in a prone, side lying, or standing position.
To landmark this site:

1. Divide the buttock into 4 quadrants.
2. The injection site is the centre of the upper outer quadrant (see figure 8).

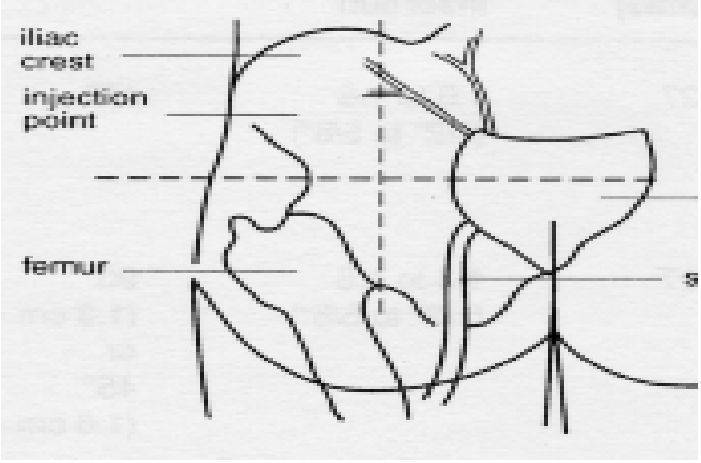


Figure 8

(Figure 8 retrieved April 2, 2011 from BCCDC at: http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf).

2.5 Subcutaneous (SC)

This route is used when less rapid absorption is indicated. Use a 25 – 27 gauge ⅝ inch needle at **45°** angle for subcutaneous injections (see figure 9). The upper outer triceps area is recommended for all individuals 12 months and older because the thickness of adipose tissue is greater than the adipose tissue over the deltoid muscle. **The area over the deltoid muscle is not recommended for SC injections**. The area over the anterolateral thigh is recommended for infants less than 12 months of age. To landmark sites, see figure 10A and 10B.

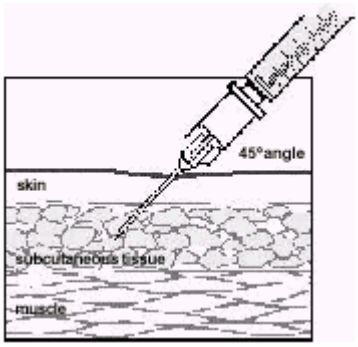


Figure 9 (Source BCCDC)

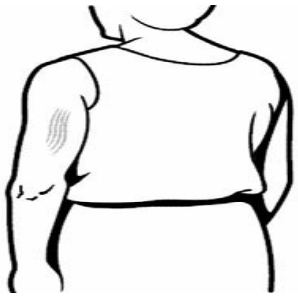


Figure 10A: ≥ 12 months SC

Figure 10B: infant SC

(Figure 9 and 10B retrieved April 2, 2011 from BCCDC at: http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf). Figure 10A retrieved April 2, 2011 from www.CDC.gov).

2.6 Intradermal Vaccines (ID)

This route is used when slow absorption into the circulation is desired. Care must be taken to administer ID injections properly, as a suboptimal immune response may occur if the vaccine is administered subcutaneously. BCG is administered ID over the deltoid muscle. Rabies vaccine may also be administered ID in some situations.

Some injectable vaccines are formulated for ID injection over the deltoid muscle at a 90° degree angle. They are pre-filled syringe with micro-needles and administered over the deltoid muscle (see figure A below).

Figure A: Intradermal vaccine administration site.

(Figure A retrieved April 2, 2011 from www.cdc.gov).

2.7 Intradermal Tuberculosis Skin Test (TST) (to screen for latent TB infection)

- **Schedule TST before, on same day as, or 4 weeks after a live vaccine has been received**.

1. The usual site for a TST is the flexor (anterior) surface of the forearm. Avoid red or swollen areas and visible veins.
2. Use a 1 mL tuberculin syringe and a 26 or 27 gauge ¼-½ inch needle.
3. Clean the vial with an alcohol swab and let dry before withdrawing 0.1 mL (5 tuberculin units) of purified protein derivative (PPD).
4. Clean the injection site with an alcohol swab and let area dry before insertion.
   - Ensure that a topical anesthetic cream was not used prior to TST, as localized edema can occur at the injection site and may be confused with a positive TST.
5. Gently stretch the skin to ensure that it is taut.
6. Insert the needle at a 5° to 15° degree angle intradermally with the bevel up, until the needle tip is visible under the skin (see figure 11).

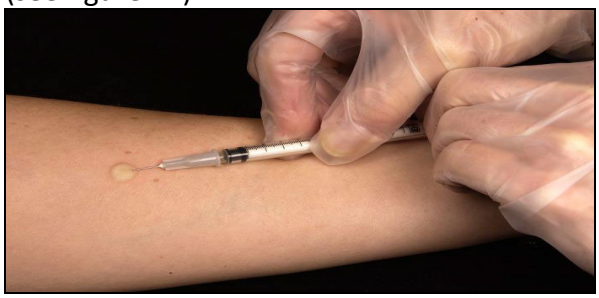


Figure 11

(Figure 11; Source: Photo credit: Greg Knoblock. Content provider(s): CDC/Gabrielle Benenson. Retrieved July 18, 2012 from http://phil.cdc.gov/Phil/details.asp

   - Do not aspirate before injecting PPD. Inject the PPD slowly. A defined bleb (wheal) approximately 6-10 mm in diameter should appear , then disappear within 15 minutes after injection (see figure 12).
   - Some PPD or blood may leak out of the site, but this is not cause for concern.
   - Do not cover the site with a bandage or dressing.
   - Tell client not to scratch or massage the injection site.

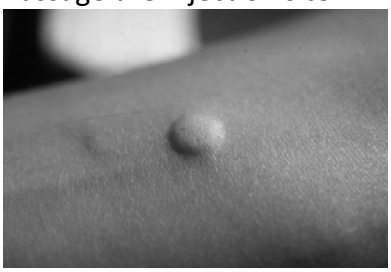


Figure 12

(Figure 12; Source Québec Immunization Manual, retrieved April 2, 2011 from http://publications.msss.gouv.qc.ca/acrobat/f/documentation/piq/09-283-02.pdf)

7. If a bleb has not formed, the TST must be repeated on another appropriate site, at least 2 inches from the first site, and the second site must be circled to identify that this site result must be read
8. Read the TST results in 48 - 72 hours.
   - Palpate for induration and mark the transverse edges with a pen.

- Measure the widest transverse diameter between the induration edges only, NOT the redness.
- Always measure the TST result using a flexible calibrated ruler and **record measurement in millimetres only.**
- If the result is between whole numbers (e.g., 5.6 mm) **round down to smallest whole** number (e.g., 5 mm). Negative TST results must be recorded as 0 mm.
- Refer to Table 2: *TB Skin Test Result Interpretations* below.

9. Two-Step TB Skin Testing
   a) Two-step testing to detect a boosting response may be indicated for certain clients (e.g., HCWs or those ≥ 50 years). Refer to the *Saskatchewan TB Program Manual* for more information.
      - Two step testing can identify booster responders who have an anamnestic immune response from the TST. Individuals whose 1st TST is less than 10 mm are retested in 1 to 3 weeks to check for this response.
   b) Two-step testing can also identify newly infected case contacts whose initial test was negative. They are retested up to 8 weeks later to assess if they have converted to being infected.
10. All TST results shall be document on the appropriate client health record/document and forwarded to TB Control Saskatchewan with the exception of tests performed off-reserve for the purpose of general occupational screening, travel screening and post-secondary education requirements.

Table 2: TB Skin Test Result Interpretations (Source: Canadian Tuberculosis Standards, 7th Edition 2013)

TST result	Situation in which reaction is considered positive*
0-4 mm	In general this is considered negative, and no treatment is indicated.
	Child under 5 years of age and high risk of TB infection
≥5 mm	HIV infection
	Contact with infectious TB case within the past 2 years
	Presence of fibronodular disease on chest x-ray (healed TB, and not previously treated)
	Organ transplantation (related to immune suppressant therapy)
	TNF alpha inhibitors
	Other immunosuppressive drugs, e.g. corticosteroids (equivalent of ≥15 mg/day of prednisone for 1 month or more; risk of TB disease increases with higher dose and longer duration)
	End-stage renal disease
≥10 mm	All others, including the following specific situations: – TST conversion (within 2 years) – Diabetes, malnutrition (<90% ideal body weight), cigarette smoking, daily alcohol consumption (>3 drinks/day) – Silicosis – Hematologic malignancies (leukemia, lymphoma) and certain carcinomas (e.g. head and neck)

- All adverse events related to the administration of PPD must be documented in the patient's health record and recorded on the Health Canada, *Canada Vigilance Adverse Reaction Reporting Form*, available online at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/ar-ei_form-eng.pdf. These forms must also be forwarded to the regional MHO for review.

2.8 Infiltration of Rabies Immune Globulin (RabIg)

Infiltration of RabIg into a wound incurred by an animal bite protects individuals that have not been previously immunized with rabies vaccine. Two important goals of RabIg infiltration are:

1. To neutralize the rabies virus at the wound site as soon as possible after exposure; and
2. To prevent the migration of the rabies virus from peripheral nerves to the central nervous system.

These regimens are applicable for persons in all age groups, including children.

- Administer 20 IU/kg body weight.
- Because RabIg might partially suppress active production of rabies virus antibodies, no more than the calculated dose should be administered.
- If anatomically feasible, the full calculated dose of RabIg should be infiltrated around and into the depth of the wound(s).
- When the calculated dose is insufficient to infiltrate all the wounds, RabIg can be diluted with saline to obtain the necessary quantity up to a 3:1 dilution (e.g., 30 ml of physiological saline for 10 ml of RabIg for a total of 40 ml).
- Any remaining RabIg (including diluted) should be injected IM in the deltoid or vastus lateralis sites.
- Do not administer RabIg in the same syringe as rabies vaccine.
- Do not administer RabIg in the same anatomical site on the same day that rabies vaccine is given.

2.9 Intranasal (IN)

Always read the product monograph thoroughly for comprehensive administration instructions. Live attenuated influenza vaccine (LAIV) is the only vaccine to be administered by the intranasal route. The administration device is an AccuSpray™ nasal spray syringe that has a dose divider clip that allows for measured 0.1 mL spray into each nostril.

1. With the patient in an upright position, the sprayer tip is inserted slightly into the nostril. Instruct the patient not to inhale the vaccine as it is being administered.

(Image retrieved February 7, 2012 from: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/D/vacc_admin.pdf)

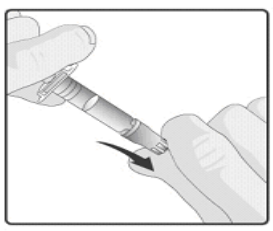
2. The plunger is depressed as quickly as possible until the divider clip prevents further administration.
3. Remove the dose divider from the sprayer and administer the second dose into the second nostril.
4. The vaccine does not need to be repeated if the client coughs or sneezes after administration of the LAIV.

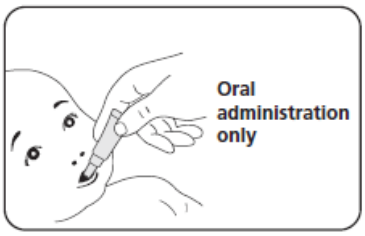
2.10 Oral (PO)

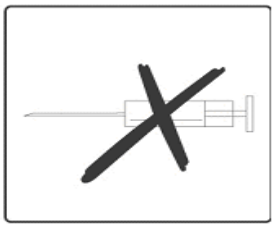
Always read the product monograph thoroughly for comprehensive administration instructions. For most oral vaccines, the complete dose must be swallowed and retained.

Oral Solutions: Never inject oral solutions into body tissues.

1. Remove the protective tip cap from the oral applicator.
2. The infant should be seated in a reclining position.
3. Administer orally (i.e. into the infant's mouth towards the inner cheek) the entire content of the oral applicator. Do not mix with other medicinal liquids. (All images 2017 ROTARIX product monograph).







Ready for Use Liquids: Re-administration of another dose of the liquid pentavalent rotavirus vaccine RotaTeq is not recommended if dose is spat out or regurgitated by the infant.

1. Tear open the pouch and remove the dosing tube.
2. Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.
3. Open the dosing tube in 2 easy motions:
   a) Puncture the dispensing tip by screwing cap clockwise until it becomes tight.
   b) Remove cap by turning it counter clockwise.
4. Administer dose by gently squeezing liquid into infant's mouth toward the inner cheek until dosing tube is empty. A residual drop may remain in the tip of the tube.

Capsules: Vaccine capsules should not be chewed but swallowed as soon as possible after placing in the mouth. Capsules should be taken with at least 4 oz of cool or lukewarm water as per the recommended schedule.

Sachet and Vaccine Vial Combinations: Medicines, food and drink need to be avoided for 1 hour before and after ingesting the vaccine. Do not use milk, juice or a carbonated beverage to mix the vaccine/sachet in.

1. The effervescent sachet needs to be mixed into a cup of 5 oz. cool water.
2. The vial must be shaken well and then poured into the cup.
3. Stir contents gently for 5 to 10 seconds.
4. The vaccine should be swallowed as soon after mixing as possible.

Double Sachet Combinations: Medicines, food and drink need to be avoided for 1 hour before and after ingesting the vaccine. Do not use milk, juice or a carbonated beverage to mix the sachets in.

1. The sachets must be folded along the solid black line and cut along the dotted line after insuring that the contents have been displaced to the bottom to prevent spillage.
2. The contents of both chambers are to be emptied simultaneously into 100 mL of cold or lukewarm water.
3. Gently mix the sachet contents for 5 to 10 seconds.
4. The vaccine should be swallowed as soon after mixing as possible.

3.0 MANAGEMENT OF PAIN AND ANXIETY

3.1 Positioning Infants and Children

The *Comforting Restraint* methods as presented below, actively involve the caregiver in embracing the child and controlling all four limbs. It avoids "holding down" or overpowering the child, but it helps the immunizer to steady and control the limb of the injection site.

3.1.1 Infants and Toddlers

3.1.1.1 Vastus lateralis

Verbally instruct and physically guide the caregiver to hold the child so that the vastus lateralis site is clearly visible and the child is firmly restrained to prevent movement during the immunization.

1. Ask the caregiver to fully uncover/unclothe the child's leg and hold the child in a seated or semi-recumbent position on their lap as in the figures 13 and 14 below.

Figure 13

Figure 14

(Figures 13 and 14 retrieved February 7, 2012 from BCCDC at: http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf)

2. Ensure the child's arm that is positioned closest to the caregiver, is tucked into the caregiver's side or placed behind the caregiver's back. The child's other arm is controlled with the caregiver's arm and hand placed over it. In the case of children under 1 year of age, the caregiver can control both arms with one hand.
3. Instruct and guide the caregiver to firmly hold the child's legs and feet between his or her thighs, and control them with their free hand. The caregiver's hand may be placed over the child's knee to prevent the leg from being raised by the child during the immunization below in figure 15.

Figure 15 (Figure retrieved February 7, 2012 from: http://www.health.gov.nl.ca/health/publichealth/cdc/im_section4.pdf)

3.1.1.2 Deltoid

Verbally instruct and physically guide the caregiver to hold the child so that the deltoid site is clearly visible and the child is firmly restrained to prevent movement during the immunization.

1. Ask the caregiver to fully uncover/unclothe the child's arm and hold the child in a seated or semi-recumbent position on their lap as in the figures 16 and 17 below.

Figure 16

Figure 17

(Figures 16 and 17 retrieved February 7, 2012 from BCCDC at: http://www.bccdc.ca/NR/rdonlyres/D8264FFC-445B-439E-A3E7-763374383206/0/SectionIV_AdministrationofBiologicalProducts_November.pdf)

2. Ensure the child's arm that is positioned closest to the caregiver is tucked into the caregiver's side or placed behind the caregiver's back. The child's other arm is controlled with the caregiver's arm and hand placed over it as pictured above.
3. Instruct and guide the caregiver to firmly hold the child's legs and feet between his or her thighs, and control them with their free hand, if necessary.

3.1.2 Kindergarten-Aged and Older Children

3.1.2.1 Deltoid

Verbally instruct and physically guide the caregiver to hold the child so that the deltoid site is clearly visible and the child is firmly restrained to prevent movement during the immunization.

1. Ask the caregiver to fully uncover/unclothe the child's arm and seat the child on parent's lap (figures 18 and 19) or have the child stand in front of the seated caregiver.

Figure 18

Figure 19

(Figures 18 and 19 retrieved April 3, 2011 from www.cdc.gov)

2. Ensure the child's arm that is positioned closest to the caregiver is placed behind the caregiver's back. The child's other arm is held close to the child's body with the caregiver's arm and hand placed over it as pictured above.

3.2 Recommendations for a More Successful Immunization Experience

3.2.1 Foster a Culture of Empathy and Respect

- Ask about the child's previous experiences with needles. Individual responses to stress are influenced by temperament, environment and past experience.
- Acknowledge the child's feelings. Give permission to cry.
- Do not give false reassurance (i.e., "it won't hurt"). Honest reassurance is "it may hurt a bit, but I think you can handle it."
- Do not tolerate threats, shaming, or manipulation from the child's caregiver. When a caregiver threatens a child, the most helpful response is to offer empathy to the caregiver, state a neutral fact or principle and offer hope (e.g., "This must be frustrating for you. Immunizations are never emergencies. I think we can work out something we can all live with").
- Discourage the use of bribes, and encourage effort – no matter how small.
- Remain firm as you manage the process. At the same time, show respect for the child.

3.2.2 Structure the Clinical Environment

- When a caregiver presents with more than one child, immunize the most anxious one first (usually the eldest), even if the caregiver thinks otherwise. The needle is the focus of the child's fear and watching while someone else is immunized may increase fear and anxiety.
- Provide privacy and prepare the immunization ahead, if possible, always out of sight of the child. If the child asks to see the needle, explain you will show it after the procedure.
- Describe what you plan to do, thereby displaying respect for a child's right to know, confidence in their ability to manage, and interest in addressing concerns. The child may wonder how long the needle will be in their arm or how quickly it will go in. Threatened loss of control is a factor in needle fear.
- Consider the use of practice dolls with children under 6. Offer to immunize a stuffed toy or doll, and invite the child to hold the "patient". Use a syringe without a needle and go through all the steps, explaining each one as your proceed.
- Provide limited, realistic choices and let the child decide (e.g., "Would you like to use your right or left arm?" "Would you prefer to sit or stand?"). Offering realistic choices creates a setting where the child can maintain some personal control and contributes to an atmosphere of mutual respect. Supportive, secure positioning can be achieved with a child (depending upon age) either standing or sitting.
- Do not have the caregiver restrain the child before you are ready to administer the vaccine. The longer the child is restrained the greater the loss of personal control and hence increased anxiety. The goal of restraint is not to overpower the child, but to assist the child to remain as still as possible for the procedure.
- Manage the time and set limits. If the child cannot calm him or herself, acknowledge their effort and offer a rest period. If there is no other alternative, reschedule the immunization.

3.3 Evidence-Based Interventions for Pain and Anxiety

The physical discomfort associated with injections is short-lasting, but may cause anxiety and a life-long fear of needles, medical procedures and health care providers. Evidence-based management interventions enable caregiver and immunizers to comfort and reassure children, and may reduce potential psychological effects (e.g., trauma) of such procedures. It is recommended that PHNs:

a) Refer to CIG Vaccine Administration Practices Table 4: Immunization pain management strategies for children, by age groups (as Appendix 8.3 in this chapter).
b) Watch the *Reduce the Pain of Vaccination in Babies* video at: http://www.youtube.com/watch?v=dZcBc9UnMtw;
c) Read *Reducing pain during vaccine injections: clinical practice guidelines* (Taddio et al, 2015) http://www.cmaj.ca/content/early/2015/08/24/cmaj.150391; and
d) Read *Pain Management during Vaccine Injections A Clinician's Guide: Children < 3 years* (http://immunize.ca/uploads/pain/5p_lessthan3_web_e.pdf)

3.3.1 Infants and Toddlers

- A child, who is dry, fed, and emotionally content, may react less strongly to pain during immunization.
- Ask caregivers to position and cuddle their baby on their lap during the immunization. Allow the baby to suck before, during and after the immunization:
  - If mothers are breastfeeding, encourage them to nurse their baby before, during and after the immunizations. Breastfeeding calms and comforts both the baby and mother and can reduce baby's pain.
  - There is some evidence that giving a sweet tasting solution to non-breastfeeding infants just prior to injections may provide analgesia. Honey is not to be given to infants under 12 months of age.
  - Encourage non-breastfeeding mothers and other care providers to use a pacifier or formula to comfort and calm the baby.

3.3.2 Older Toddlers and Children

Children may "pick up" on their caregiver's anxiety. By coaching caregivers to adopt a calm affect, caregivers and children may have a better immunization experience. Distraction techniques and behaviour modification measures are effective in decreasing pain response during and following immunization. Regardless of the type of distraction, the more the child is involved in the distraction, the lower their pain.

- Coach children to count or squeeze hard on the hand of the caregiver.
- Work with the caregiver to use distraction techniques such as singing, reading, blowing soap bubbles or using toys.
- Slow, deep breathing has a physiologic calming effect and can, at minimum, limit anxiety escalation. Coach children to engage in slow deep breathing or blowing (away the pain) during the each immunization.
- Briefly describe to the child what will happen during each immunization and how it will feel. Do not say that it won't hurt. Instead say the pain lasts a short time and feels like a "sting", "poke" or "squeeze".
- Answer children's questions:
  - Why do I need a needle? ("To help you stay healthy.")
  - What will happen? ("The medicine will be put in your arm with a needle.")
  - How will it feel? ("You may feel a poke or small sting that will last a few seconds.")

3.4 Topical Anaesthetics

Clients who are concerned about the pain associated with immunization may be interested in using topical anaesthetics. Children and adults may feel a sense of control when using these products, and distress and anxiety may be prevented or lessened. This is preferable, instead of delaying or avoiding immunization because of a fear of needles. When used correctly, they cause superficial localized anaesthesia at the injection site. Pain relief occurs at the insertion point of the needle, but pressure felt within the muscle upon injection of the product is generally unaffected. Topical anaesthetics should be applied to intact skin over a suitable injection site for the minimum duration of time required (see Table 3)

Non-prescription topical anaesthetics are available at pharmacies and clients are encouraged to consult a pharmacist for further product information. It is the responsibility of parents/clients who wish to use these products to follow the manufacturer's instructions and check the contraindications, precautions, and possible side effects prior to use. Some products have been studied prior to specific vaccine administration; while the effect of topical anaesthetics on the immunologic response to certain vaccines is unknown, they are not thought to interfere.

Health Canada released an advisory statement March 2, 2009 regarding topical anaesthetics. It is available for review at http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/14544a-eng.php or in Appendix 8.1: EXCERPT: Health Canada Endorsed Important Safety Information on Topical Anaesthetics.

3.4.1 Cream and Gel Formulations Refer to Table 3: Non-Prescription Topical Anaesthetics Available in Canada.

3.4.1.1

Maxilene™ (RGR Pharma) is the brand name of a topical anaesthetic consisting of liposomal lidocaine 4% or 5% and is indicated to relieve the pain and/or itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations in individuals 2 years of age and older. A physician must be consulted prior to use in children under the age of 2 years.

3.4.1.2

EMLA® (AstraZeneca Canada Inc.) is the brand name for a topical anaesthetic consisting of 2.5% lidocaine and 2.5% prilocaine. It comes in a multidose cream and a single dose patch. It does not appear to affect the antibody response to MMR, DTaP-IPV, Hib or hepatitis B vaccines in infants and children. The product needs to be applied for a minimum of one hour to provide effective anaesthesia. EMLA is contraindicated in anyone sensitive to any of the components. EMLA is also contraindicated in individuals with congenital or idiopathic methemoglobinemia; in pre-term infants (gestation less than 37 weeks); and in infants less than 3 months of age (young infants have a higher risk of developing methemoglobinemia). Refer to the product monograph for detailed information (in references).

3.4.1.3

Ametop Gel® (smith&nephew) is the brand name for a topical anaesthetic consisting of 4% tetracaine that is indicated for use in individuals one month of age and older. It has been demonstrated that application of Ametop® prior to MMR vaccination does not interfere with the immunologic response. Ametop Gel achieves anaesthesia within 30 to 45 minutes and may last for four to six hours after removal. When compared to EMLA, Ametop has been found to provide better anaesthesia when used before needle insertion in children. It is contraindicated in premature babies or full-term infants less than one month of age, in whom the metabolic pathway for tetracaine may not be fully developed; and individuals with known hypersensitivity to local anaesthetics of the ester type.

Table 3: Non-Prescription Topical Anaesthetics Available in Canada

Active Ingredient	**Liposomal Lidocaine**	**Lidocaine/Prilocaine**	**Tetracaine**
Brand	Maxilene	EMLA	Ametop
Time to effect	30+ min	60+ min	30+ min
Occlusion recommended?	No*	Yes (for the cream)	Yes
Duration of effect after removal	1-2 hours	≥ 2 hours	4-6 hours
Concentration/ Dosage Form	4% cream	2.5% cream	4% gel
	5% cream	2.5% patch	
Availability and Comments	5 g, 30 g	No dressing 30 g, w/ dressings 5 g	1.5 g The manufacturer does not advise use of this product for immunizations.
	15 g, 30 g	1 g	

*Unless area needs to be covered to prevent child from ingesting anaesthetic
Source: 2011 Saskatchewan Drug Information Services; updated 2015, medSask

3.4.2 Vapocoolants

Evidence has been equivocal, though a systematic review has concluded vapocoolants are no more effective than placebo and are associated with some pain from application. Currently in Canada, Omniderm Pharma distributes two vapocoolants indicated for pre-injection anesthesia, from an American manufacturer, Gebauer (Ethyl chloride), and Pain Ease.

3.5 Post-Immunization Client Care

1. Provide current information about the management of common vaccine side effects.
2. Prophylactic administration of acetaminophen prior to or immediately post-immunization for pain management is ineffective and is not recommended because of interference with vaccine induced immune responses. The March 2018 *Peadiatrics and Child Health* article **Fever prophylaxis can reduce vaccine responses: A caution** states:

   "Prophylactic use of antipyretic/analgesic drugs can reduce immune responses to some infant vaccines, warranting judicious use. The clinical significance of such reduced responses is uncertain but stronger responses are obtained in the absence of prophylaxis. In contrast, using these drugs to treat symptoms once they appear is unlikely to interfere with immune responses and would reduce the number of asymptomatic children exposed to other potential drug adverse effects. The above observations that anti-inflammatory drugs only interfere with antibody responses if present during the first 6 to 8 hours after immunization serve as a reminder that injection site inflammation is an essential first step in initiating responses to vaccines, activating dendritic cells and recruiting macrophages that rapidly transport vaccine antigens to regional lymph nodes where antibody responses begin. Acetaminophen and ibuprophen target different parts of the inflammatory response cascade, likely explaining their differing effects on immune responses."
3. As of this date, there is no supporting evidence for effective prophylactic use of acetaminophen in children prone to febrile seizures.
4. When fever occurs, acetaminophen (e.g., Tylenol™, Tempra™) is recommended for infants and young children because it controls fevers better than other anti-pyretics. Always counsel caregivers to provide anti-pyretic doses based on their child's weight, not age. Provide caregivers a copy of the *Caring for Your Child's Fever* fact sheet, available at: http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets
5. Ibuprofen (e.g., Motrin™, Advil™ or other brands) can be used for children over 6 months if acetaminophen does not relieve the fever and the child is drinking well. Read the Ibuprofen box for the correct dose. Do not alternate acetaminophen and ibuprofen, as there is a risk of overdose.
   - **Acetylsalicylic acid (Aspirin) is not recommended for children with fever because of its association with a neurological condition known as Reye's syndrome.**
6. Review expected side effect with caregivers or clients, and counsel them when to seek medical attention post-immunization
7. It is recommended that all immunized clients remain in the clinic for 15 minutes post-immunization. This may facilitate the management of any adverse reactions.
   - Those with a previous adverse event should remain at the clinic site for 30 minutes or longer, or according to MHO recommendations.

4.0 REFERENCES

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5.0 APPENDICES

Appendix 8.1: EXCERPT: Health Canada Endorsed Important Safety Information on Topical Anesthetics

Subject: Association of Topical Anesthetics with Serious Side Effects
Date: 2009-03-05

Health Canada, in collaboration with AstraZeneca Canada Inc. and Smith & Nephew Inc., wishes to alert Canadians to the potential hazards of topical anesthetics (e.g., EMLA®, AMETOP Gel™ and locally compounded products). Topical anesthetics are generally approved for numbing the skin before procedures like vaccinations and minor skin surgery. Topical anesthetics are also being used, often without direct medical supervision, to numb large areas of skin before cosmetic procedures such as laser removal of body hair.

Serious side effects of topical anesthetics have been reported, including seizures, irregular heartbeat and difficulty breathing. In rare instances these side effects have resulted in death. Adults who have experienced these serious side effects used very large amounts of topical anesthetics. After applying the product to their skin, they usually covered the area with plastic wrap to increase the effectiveness of the topical anesthetic. Some infants and children have experienced serious side effects after receiving amounts of topical anesthetics close to the recommended dose.

- Serious side effects have occurred with application of topical anesthetics over large areas of skin often before laser removal of body hair.
- You are more likely to have serious side effects if you apply large amounts of these products to irritated or broken skin or if you apply large amounts of these products and cover the treated area with plastic wrap or other dressing.
- Children should be closely observed during and after use of topical anesthetics, as they are at greater risk than adults for serious side effects.
- If someone using a topical anesthetic shows signs such as weakness, confusion, headache, difficulty breathing, discoloured skin, or any other sign of being unwell, they should receive immediate medical attention.

If you plan to use a topical anesthetic, you should carefully read and follow the product label and/or package insert. An air-tight dressing can be used with some topical anesthetics. If you are not sure about the amount to use or how to apply the product, ask your doctor or pharmacist or other knowledgeable health care professional for guidance.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported postmarketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving topical anesthetics should be reported to the manufacturer or to Health Canada at the following address:

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345 or Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in The Canadian Compendium of Pharmaceuticals and Specialties.
For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca, or Tel: (613) 954-6522 or Fax: (613) 952-7738

Source: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/advisories-avis/public/2009/emla_ametop_pc-cp-eng.pdf, retrieved

Appendix 8.2 Potentially Immunosuppressive Biologic Agents (not an exhaustive list):

- Infants are exempt from receiving any rotavirus vaccines if their mothers took monoclonal antibody medications during pregnancy.
- Though not monoclonal antibodies, it is advised that live vaccines be avoided prior to 1 year of age in infants exposed to these biologics in utero [1].
- Cancer agent [2].

Immunosuppressive Agent	Brand Name(s) (Reference biologic agent listed first, followed by biosimilars in alphabetical order)
Abatacept[1]	Orencia®
Adalimumab	Humira®; Abrilada®; Amgevita™; Hadlima®; Hulio®; Hyrimoz®; Idacio®; Simlandi™; Yuflyma™
Alemtuzumab	Lemtrada®; MabCampath®*
Anakinra [1]	Kineret®
Anifrolumab	Saphnelo
Basiliximab	Simulect®
Belimumab	Benlysta™
Bimekizumab	Bimzelex®
Brodalumab	Siliq™
Canakinumab	Ilaris®
Certolizumab pegol	Cimzia®
Daratumumab [2]	Darzalex®
Dinutuximab	Unituxin®
Eculizumab	Solaris®
Etanercept [1]	Enbrel®; Erelzi®; Brenzys®
Gemtuzumab ozogamicin [2]	Mylotarg®
Golimumab	Simponi®
Guselkumab	Tremfya®
Infliximab	Inflectra®; Remicade®; Remsima™; Avsola®; Ixifi®; Omvyence™; Renflexis®
Inotuzumab ozogamicin [2]	Besponsa™
Ixekizumab	Taltz®
Natalizumab	Tysabri®
Obinutuzumab [2]	Gazyva®
Ocrelizumab	Ocrevus®
Ofatumumab	Kesimpta™
Polatuzumab [2]	Polivy®
Risankizumab	Skyrizi®
Rituximab	Rituxan®; Riximyo®; Ruxience™; Truxima™; Riabni™
Sarilumab	Kevzara®
Secukinumab	Cosentyx®
Siltuximab	Sylvant®
Tildrakizumab	Ilumya™
Tocilizumab	Actemra®
Ustekinumab	Stelara®
Vedolizumab	Entyvio®

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Appendix 8.3: Immunization pain management strategies, by age group (CIG)

Age Group	Pain management strategies
All ages	• Injection of vaccines without aspiration • Injecting vaccines that cause the most injection site pain after other vaccines

Infants and young children (3 years of age and under) [2]	• Education of parent/caregiver about pain management before and on the day of immunization
	• Topical anesthetics prior to vaccine injection
	• Presence of parent/caregiver during vaccine injection
	• Breastfeeding during vaccine injection (≤ 2 years of age)
	• If the infant/young child is not breastfed during vaccine injection a combination of other strategies may be used, such as:
	  ◦ Skin-to-skin contact during vaccine injection (≤1 month of age)
	  ◦ Holding during vaccine injection or holding and rocking/patting after vaccine injection
	  ◦ Administration of a sweet-tasting (sucrose or glucose) solution prior to vaccine injection (≤ 2 years of age) [3]

Children (3-12 yr) [2]	• Education of parent/caregiver about pain management before and on the day of immunization • Education of individual about pain management for vaccine injection on the day of immunization [4] • Topical anesthetics prior to vaccine injection • Presence of parent/caregiver during vaccine injection (≤ 10 years of age) • Sitting up during vaccine injection
Adolescents (12-17 yr) [2]	• Education of parent/caregiver about pain management before and on the day of immunization • Education of individual about pain management for vaccine injection on the day of immunization [4] • Sitting up during vaccine injection
Adults (≥ 18 yr)	• Education of individual about pain management for vaccine injection on the day of immunization [4] • Sitting up during vaccine injection

1 The strategies noted in the table are strong recommendations for reducing pain during vaccine injections from Taddio A, McMurtry CM, Shah V et al. (HELPinKIDS&Adults Team) Reducing pain during vaccine injections: clinical practice guideline. CMAJ 2015; 187(13): 975-982. For additional recommendations on pain management strategies refer to the article.

2 There is some overlap in ages across these categories (i.e., children aged 3 and 12 years are included in two separate categories) owing to the need to balance over-simplification in creating age categories with appropriate guidance, overlap in the underlying literature base as well as substantial differences in developmental trajectories of individual children.

3 If an infant is scheduled to receive a dose of rotavirus vaccine, provide it first as it is sweet-tasting. In this scenario, no additional sweet-tasting solution is required prior to vaccine administration.

4 For example, give information on what to expect (the procedure and how it will feel) as well as suggestions on how to cope.

Source: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-8-vaccine-administration-practices.html#t4

Appendix 8.4 – Oral Vaccine Administration via Enteral Tube

Saskatchewan Immunization Manual STANDARD WORK	**Name of Activity**: Procedure – Oral Vaccine Administration via Enteral Tube Role performing Activity: Public Health Nurse		
	Location: Saskatchewan Immunization Manual		**Department:** Chapter 8
	Date Prepared: 2019-04-16	**Last Revision:**	**Date Approved**:

Standard Work Summary: Steps to administer oral vaccines to infants who are unable to take vaccines by mouth and who have an enteral feeding tube.

Anatomical location of enteral feeding tube	A. Nasogastric (NG) B. Orogastric (OG) C. Nasojejunal (NJ) D. Gastrostomy (G-tube) E. Jejunostomy (J-tube) F. Gastro-jejunostomy (G-J tube) G. Percutaneous enterogastrostomy (PEG) H. Percutaneous gastrojejunostomy (PGJ or PEJ)

Sequence	Task Definition
1.	Check with the parent/ guardian to ensure that they have the necessary supplies for the procedure (e.g., two appropriate syringes at the immunization appointment). • NOTE - If the parent/guardian presents without the necessary supplies, provide the other vaccine(s) that are due. Follow up with a home visit or a clinic visit to administer the oral vaccine. Med cups do not need to be supplied by parents as they will be available at clinics. • Two appropriate syringes (3 mL syringe or larger) **NOTE largest amount of volume need to prime a NG line is 1.8 mL so a 3 mL syringe is adequate. • One appropriate 3 mL syringe for placement confirmation & flushing. • One appropriate 3 mL syringe for administering medication. • Sterile water is recommended for enteral tube flushing when oral vaccines are being administered. Sterile water ampoules can be on hand at clinics and therefore not needed for parents to provide.
2.	Perform hand hygiene. Maintain clean technique when accessing tube& administering medication.

3.	**Check placement and patency of the enteral tube.** • **Do not proceed with vaccine administration by enteral feeding tube unless tube placement and patency has been confirmed.** **Nasogastric or Orogastric** **A.** Confirm placement of gastric tube in nares or mouth with 2 step process: 1. Confirm with parent that the centimeter marking visible at a nare or the mouth is correct. 2. Confirm by visualizing stomach content. i. Kink off gastric tube, remove end cap of enteral tube port. Attach empty appropriate syringe to gastric tube. ii. Gently aspirate 0.5-1.0 mL of stomach content into syringe and then return visualized gastric contents with push pause technique back into stomach. iii. Kink off gastric tube, remove syringe and recap enteral tube port **B. Nasojejunal** • Confirm with parent the external baseline length of tube measurement. **C. Gastrostomy (button/balloon enteral tube)** • Confirm correct placement by ensuring the flange is flush to the skin. **D. Jejunostomy** • Confirm correct placement by ensuring the flange is flush to the skin. **E. Gastro-jejunostomy** • Confirm correct placement by ensuring the flange is flush to the skin. **F. Percutaneous enterogastrostomy** • Confirm correct placement by ensuring the flange is flush to the skin. **G. Percutaneous gastrojejunostomy (PGJ or PEJ)** • Confirm with parent the external baseline length of tube measurement.
4.	**Flushing of gastric tube pre-vaccine administration:** 1. Using same appropriate syringe for placement check, draw up 3mL of sterile water for the flush. a. The reason to use the same syringe is to help remove the acidic stomach content residual from sticking to the inside of the syringe. 2. Clamp off gastric tube, remove cap and attach appropriate syringe with sterile water. 3. Gently flush with a pause-push technique. 4. Kink off gastric tube,by folding the tube over on itself, remove the syringe and re capthe enteral tube port.
5.	**Administration of vaccine:** 1. Squirt the oral vaccine content into a medicine cup. 2. Using the second 3 mL syringe, draw up all vaccine from the medicine cup. Once medication drawn up, ensure all air is removed from the syringe prior to connecting to the gastric tube. 3. Kink off the gastric tube, uncap the enteral tube port and attach it to medication syringe. 4. Release the kink and use a push-pause technique to administer the medication through the tube. 5. Kink off tube, remove the medication syringe and recap the enteral tube port. 6. Dispose of syringe if syringe does not belong to clien,t or have family rinse syringe if syringe belongs to client and they do not want to dispose of it.
6.	**Flushing of gastric tube post-vaccine administration:** 1. Draw up 3 mL of sterile water into the designated “flush” syringe. 2. Kink the tube and uncap the tube port and attach flush syringe 3. Unkink tube and gently flush with a pause-push technique. 4. Kink off tube, remove syringe, and recap tube port 5. Dispose of remaining water.
7.	Perform hand hygiene.
8.	Ensure client has all appropriate syringes if provided by family. If syringes provided by health care, dispose of syringes in garbage.
9.	Documentation: • Document vaccine as administered orally (PO). • Add a note in comments section stating the oral vaccine was administered via enteral tube.