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1.0 DEFINITIONS

Infant	Birth up to the age of 12 months
Toddler	Age 12 months up to the age of 3 years
Preschooler	Age 3 years to the age of 5 years
Subcutaneous injection	Injection of a biological product into the layer of fatty tissue between the skin and muscle
Intramuscular injection	Injection of a biological product into muscular tissue
Intradermal injection	Injection of a minimal quantity (0.01 ml to 0.1 ml) of a biological product just under the dermis

2.0 PREPARATION FOR ADMINISTRATION OF BIOLOGICAL PRODUCTS

2.1 Product Preparation

For the administration of particular products, review guidelines in the Communicable Disease Control Manual, Chapter 2, Section VII: Biological Products, available at: <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm>.

Prepare necessary materials (e.g. sterile syringe/needle, 70% isopropyl alcohol, sharps container, **supplies for the management of anaphylaxis**).

When administering any biological product, consider the 7 “Rights” of medication administration (i.e. right product, right client, right dose, right time, right route, right reason, and right documentation).

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/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.
- If a previously opened multi-dose vial, check the date that the vial was opened (as recorded on the label). Multi-dose vials must be used within 30 days of opening, unless the manufacturer specifies a shorter period.



2.2 Informed Consent

Informed consent is an essential pre-condition to providing immunization. It is the professional and legal responsibility of the provider to obtain informed consent prior to immunization.

Refer to the Communicable Disease Control Manual, Chapter 2, Section IB: Informed Consent available at http://www.bccdc.ca/NR/rdonlyres/E3262CF8-ACBB-4A6F-B425-0DEE1C282405/0/SectionIB_InformedConsent_May09.pdf.

Also refer to the informed consent policy specific to your worksite and the College of Registered Nurses of British Columbia Standard of Practice, *Consent* available at <https://www.crnbc.ca/Standards/Lists/StandardResources/359ConsentPracStd.pdf>

Note the following are elements of informed consent:

- specific to immunization service
- client-centered
- voluntary
- obtained without fraud or misrepresentation
- assesses client's capability
- provides standard information
- provides client time to ask questions and receive answers
- gives client the right to refuse or revoke consent

2.3 Client Assessment

Review client's record to determine which biological products client is eligible for at this visit.

Ask client or parent / guardian about all relevant contraindications and precautions to receiving the biological product, including history of anaphylaxis and history of fainting. Note that the only contraindications to all vaccines approved in Canada are: anaphylaxis to a component of the vaccine; significant immunosuppression (live vaccines only); and pregnancy (live vaccines only). Review precautions for each biological product in the Communicable Disease Control Manual, Chapter 2, Section VII: Biological Products, available at http://www.bccdc.ca/NR/rdonlyres/CD9F6894-8373-469C-9F8A-6B27F76418D9/0/SectionVII_BiologicalProducts_June.pdf.

To reduce the likelihood of fainting (and the possibility of injuries), consider the following measures to lower stress in those awaiting immunization:

- Seat every client prior to immunization
- Maintain a comfortably cool room temperature and if possible, plenty of fresh air
- Avoid long line ups in mass immunization clinics
- Prepare biological product(s) out of view of recipients
- Provide privacy during immunization
- If client is anxious and pale, have them lie down with legs elevated
- Apply cold wet cloth to face.



2.4 Vaccination Following Vaccine Administration Errors

2.4.1 Vaccine Given at Less than the Minimum Interval

Consider a vaccine dose given at less than the minimum interval to be an **invalid** dose and repeat the dose.

- The repeat dose should be spaced after the invalid dose by the recommended minimum interval for the specific dose of that vaccine.
- Refer to BC Communicable Disease Manual, Immunization Program, Section IIA, Minimum Intervals Between Vaccine Doses Table at http://www.bccdc.ca/NR/rdonlyres/8CBF9E71-D186-4549-91CC-239E94D326F8/0/SectionIIA_June.pdf

2.4.2 Vaccine Given at Less than the Minimum Age

Consider a vaccine dose given at less than the minimum age to be an **invalid** dose and repeat the dose.

- Live vaccine (e.g., MMR or varicella): Repeat the dose when the child reaches the minimum age **and** at least 4 weeks after the dose that was given too early.
- Inactivated vaccine (e.g., INFANRIX hexa™): Repeat the dose when the child reaches the minimum age.

2.4.3 Live Vaccines Given Less than 4 Weeks Apart

If two live parenteral vaccines are not given on the same day and are given less than four weeks apart, consider the vaccine that was given second to be invalid.

- Repeat the vaccine that was given second a minimum of 28 days after it was given.

2.4.4 Expired vaccine

If an expired product is given inadvertently, the dose must be repeated.

- If it is a live vaccine, give on the same day the expired vaccine was given. If the error is discovered after that, repeat the dose of live vaccine 28 days later.
- If an expired dose of an inactivated product is given, give another dose as soon as possible.



3.0 CONSIDERATIONS FOR THE SCHEDULING AND ADMINISTRATION OF MULTIPLE INJECTIONS

“Administer all vaccine doses for which a recipient is eligible at the time of each visit.” This is Guideline 7 of the National Guidelines for Immunization Practices (Canadian Immunization Guide, 2006). Adherence to this standard of practice will avoid a missed opportunity for immunization and the inherent possibility of the individual contracting a vaccine preventable disease in the intervening period of time. Individuals should be fully immunized at the appropriate age. The practice also results in fewer periods of discomfort for the client and fewer office visits with decreased time and cost factors for both clients and health care providers.

There are no contraindications to giving multiple injections of vaccines at the same clinic visit. There is no increase in side effects, reduced vaccine effectiveness, or reduced parental compliance.

When two or more biological products are to be administered, it is preferable, but not necessary, to use different limbs. Use of different limbs assists in differentiation of local adverse events following immunization.

If multiple injections are to be given, and two health care providers are available, ask client if they would like 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).

Give biological products that are known to cause more stinging and/or pain last (e.g., give INFANRIX hexa™ first, followed by Prevnar™). Give MMRII™ last. Published pain-related data are not available for other vaccines.

When administering two or more biological products in the same limb, separate the injections by as much distance as possible. A separation of 2.5 cm (1”) is preferable so that local reactions are unlikely to overlap.

When administering multiple vaccines intramuscularly, the vastus lateralis or deltoid muscle may be used.

- For infants less than 12 months of age, the thigh (vastus lateralis) is the preferred site for more than one IM injection because of its greater muscle mass. The thigh may also be used at any other age.
- For infants ≥ 12 months, older children and adults, the deltoid is the preferred site for more than one IM injection, providing there is adequate muscle mass.



The literature contains varying recommendations regarding the maximum number of injections and maximum total volume of all the injections to be given into one IM injection site (i.e., the vastus lateralis or the deltoid). The decision regarding number of injections and maximum volume to be administered should be based on the age and assessed muscle mass of the individual. In general:

- Vastus lateralis: 1.0 ml in infants; 2 ml in children \geq 12 months to 5 years; 3 ml in children 5 years to 18 years, 5.0 ml in adults
- Deltoid: 1.0 ml in children \geq 12 months to 18 years; 2.0 ml in adults

4.0 DRAWING UP MULTIPLE DOSES OF A BIOLOGICAL PRODUCT

A biological product should be withdrawn from the vial by the provider administering the product. The College of Registered Nurses of British Columbia Practice Standard *Medications* states “Nurses only administer medications they themselves or a pharmacist have prepared, except in an emergency.” The Practice Standard is available at: <https://www.crnbc.ca/Standards/Pages/Default.aspx>

Pre-loading syringes with a biological product is discouraged because of the uncertainty of product stability in syringes, risk of contamination, increased potential for administration errors, and biological product wastage.

If the decision is made to draw up multiple doses of a biological product for programmatic reasons, such as a mass influenza or disease outbreak immunization clinic, follow these guidelines:

- Check product insert. Some biological products should **not** be pre-drawn as they must be used immediately (e.g., varicella vaccine).
- Keep pre-drawn biological product in an insulated biological cooler at a temperature of 2° - 8° C. Avoid direct contact between the syringes and the ice pack.
- Securely attach needle caps over the needles, when possible.
- If the needle cap becomes loose or dislodged, discard the needle and biological product-containing syringe.
- To ensure there is no tampering with pre-drawn biological product do not leave biological coolers unattended at any time.
- Unless otherwise specified by the biological product manufacturer, or Epidemiology Services, BCCDC, discard unused pre-drawn biological products at the end of the clinic.

Clearly record the date of opening on the labels of any leftover, opened multi-dose vaccine vials



5.0 DRAWING UP BIOLOGICAL PRODUCTS IN VIAL PRESENTATION

Wash hands or cleanse with a sanitizer.

Remove the plastic cap covering the vial.

Cleanse the surface of the rubber stopper using a cotton pad/swab moistened with 70% isopropyl alcohol. Allow to air dry.

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) having to be reconstituted, the diluent acts as the air in the syringe so there is no need to draw air into the diluent syringe.

Hold/place the vial right side up and insert the needle through the centre of the rubber stopper.

Slowly inject the air or diluent from the syringe.

If the biological product was reconstituted, gently swirl the vial to ensure the contents are fully dispersed.

Hold the vial upside down and withdraw the required quantity of biological product into the syringe.

Remove the needle from the vial and expel the air bubble(s).

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.

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.

Immediately return multi-dose vials to the refrigerator/biological cooler.



6.0 DRAWING UP BIOLOGICAL PRODUCTS IN AMPULE PRESENTATION

Gently swirl the ampule immediately before removing the contents to ensure that the contents are fully dispersed.

Tap the ampule lightly to ensure that the contents are in the lower part of the ampule.

Using a swab moistened with isopropyl alcohol, wipe the neck area of the ampule prior to opening to prevent bacterial contamination of ampule contents.

Break the neck of the ampule using the alcohol swab, a clean cotton ball or a clean cotton gauze. If you cut yourself in breaking the ampule, discard the ampule, since the product may be contaminated. Wash your hands and cover the cut before continuing.

Withdraw the contents of the ampule using a sterile syringe and 25-gauge needle. It is not necessary to change needles between drawing up the biological product into the syringe and administering it to the client.

Discard the ampule into a hard sided, labeled sharps container.

Expel the air bubble(s) from the syringe.

The literature suggests there is a potential for introduction of microscopic glass shards into the contents of an ampule when it is opened. The clinical significance of intramuscular or subcutaneous administration of glass shards is not clear. There is a theoretical association between the injection of glass shards and transient local reactions. Filter needles are recommended in the literature when a medication in ampule presentation is delivered intravenously, and when a patient is receiving ongoing IM injections of a medication from an ampule.

Filter needles are **not** indicated for the routine administration of biological products or epinephrine. The reasons are as follows:

- There are fewer glass shards introduced to ampule contents on opening of a smaller ampule (e.g., Varilrix® diluent), compared to a larger size ampule.
- Fewer shards will potentially be drawn into an unfiltered needle when the needle bore is smaller (i.e., higher gauge needles used for vaccination).
- The practice standard of using a cotton pad when opening the ampule will reduce the risk of glass shards entering the ampule contents.
- Filter needles could potentially filter out particulate matter such as adjuvants or other active ingredients, making a vaccine less effective.



7.0 STANDARD PRECAUTIONS

Gloves are not required when administering biological products unless the vaccinator has open hand lesions or will come into contact with potentially infectious body fluids.

Wash hands well or use a sanitizer between clients.

To prevent accidental needle stick injury, do not recap standard needles.

When safety needles are used, engage safety mechanism immediately following administration of the biological product.

Immediately discard needle and attached syringe in hard sided, labeled sharps container. Place sharps container so as to avoid reaching or having to reach in front of the client. Caution should also be taken so that the sharps container cannot be reached by children in the clinic setting.

Do not empty used needles and syringes from one sharps container to another.

Report percutaneous (needle stick) injuries immediately to supervisor for consideration of possible post-exposure immunoprophylaxis. Follow worksite health and safety protocol. All immunization providers should have completed a full series of hepatitis B vaccine.

8.0 INJECTION SITES, NEEDLE SIZE AND POSITIONING

Use clinical judgment to select appropriate injection site and needle size. This assessment is based upon:

- client's age
- volume of biological product to be administered
- viscosity of biological product
- adequacy of muscle mass
- recommended route of administration for the biological
- number of products to be administered.

After selecting the appropriate injection site, inspect the skin's surface over the site for bruises, scars, or inflammation. Palpate site for masses, edema, or tenderness. If any of these are found at the injection site, do not use the site, as there might be interference with absorption of the biological.

Correct positioning of the client is a critical step in ensuring the biological product is administered in the correct site. Instruct the parent /guardian to hold the child such that the immunization site is clearly visible to the immunizer and the child is sufficiently restrained to prevent as much movement as possible during the immunization. See the following website for photos of "comforting restraint" of infants, toddlers and older children. <http://www.immunize.org/news.d/comfrten.pdf>

Examples of positioning for injection in the vastus lateralis:



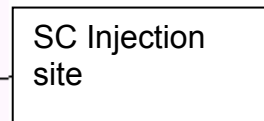
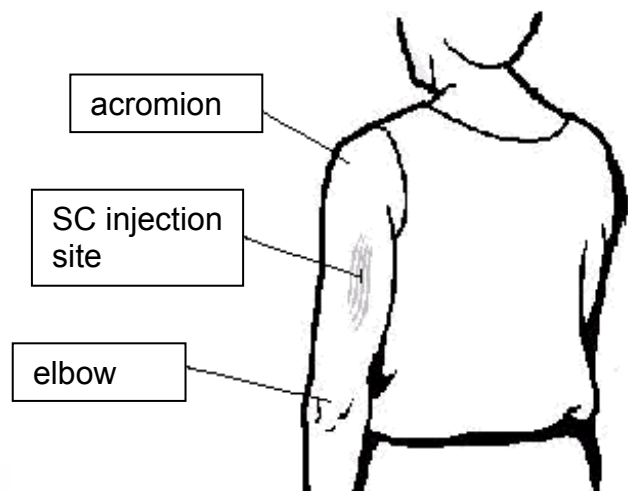
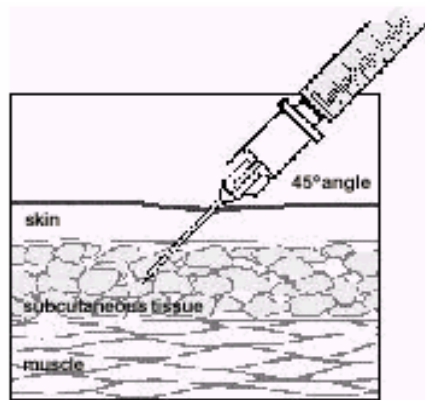
Examples of positioning for injection in the deltoid:



8.1 Needle size and sites for subcutaneous (SC) injection

Use a 25 – 27 gauge 5/8" – 7/8" needle for subcutaneous injections.

Sites for subcutaneous injection are the lateral aspect of the upper arm and the fatty area of the anterolateral thigh. The thigh is the site of choice for infants <12 months of age and the upper outer triceps area is recommended for all individuals ≥12 months.





8.2 Needle size and sites for intramuscular (IM) injection

Use a needle length sufficient to reach the largest part of the muscle. This is to prevent the biological being deposited in subcutaneous tissue and to decrease or prevent abscess formation. The use of longer needles has also been associated with less redness and swelling at the immunization site than occurs with shorter needles.

For infants, toddlers, and older children a 7/8" - 1" needle is recommended, depending on the muscle size and the amount of subcutaneous tissue.

For adolescents and adults, a 1 – 1^{1/2}" needle is usually used.

Use a 22 to 25 gauge needle depending on the viscosity of the biological product. A larger bore needle (e.g., 22 gauge) may be required when administering viscous products such as immune globulin preparations.

The IM site of choice for infants less than 12 months of age is the vastus lateralis (anterolateral thigh). It should also be considered for older children with a small deltoid muscle mass. For children ≥ 12 months of age and for adults, the preferred site is the deltoid muscle. When the deltoid muscle is used for children ≥ 12 months of age, first assess the adequacy of the muscle mass.

Assess the depth of the muscle mass to determine the needle length to be used. One way of doing this is as follows: before injecting the deltoid muscle or vastus lateralis, grasp the muscle between thumb and index finger. One half the distance between thumb and index finger will be the approximate length of the needle required to penetrate that muscle.

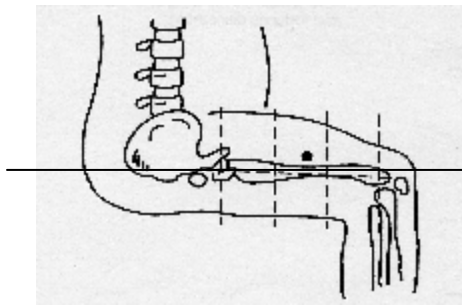
Assessing the ventrogluteal muscle or dorsogluteal muscle requires more calculation because the muscle mass cannot be easily grasped. However, the amount of subcutaneous fat at the site can be assessed. Using thumb and index finger pick up the layer of fat and skin above the muscle. This layer of tissue moves easily over the underlying muscle. One half of the distance between thumb and index finger will be the approximate length of the needle required to **reach** the muscle. The client's overall size will need to be assessed in order to decide on the length to add in order to **penetrate** the muscle mass. For example, frail adults may need a needle length of 1 inch; well-developed, muscular adults or obese adults will need a longer needle length.

8.2.1 Vastus lateralis (anterolateral thigh) site

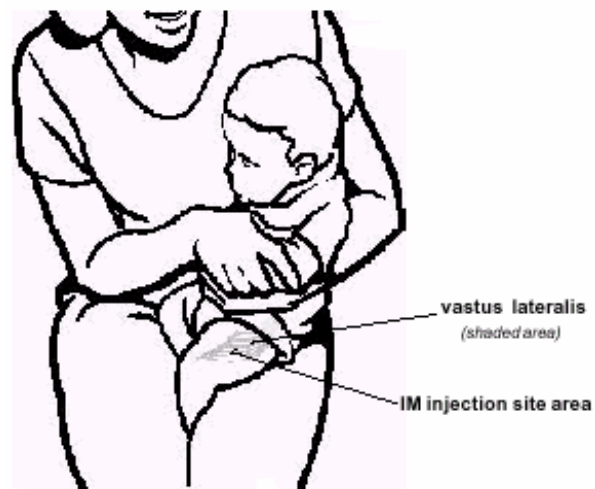
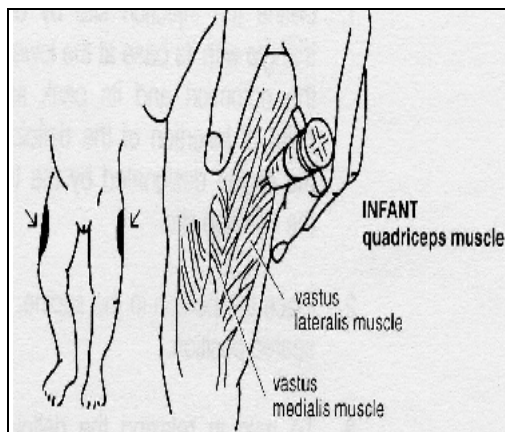
This site is used for both IM and SC injections.

When immunizing an older child or adult, position client in a supine, side lying, or seated position.

When immunizing an infant, have the parent/caregiver hold the infant in a "cuddle" or semi-recumbent position on their lap.



- Define the site by dividing the space between the trochanter major of the femur and the top of the knee into three parts; draw a horizontal median line along the outer surface of the thigh.
- The injection site is in the middle third, just above the horizontal line.



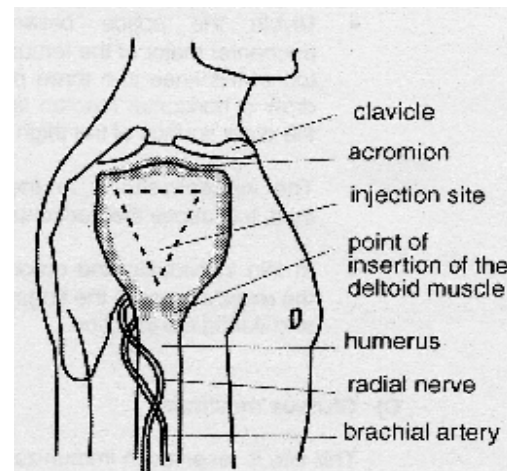
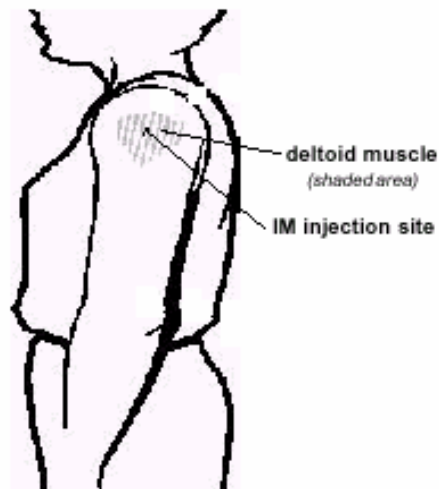
8.2.2 Deltoid site

This site is used for IM injections only.

Have the child sit sideways on the lap of the parent/caregiver. The injection arm should be held close to the infant's body while the other arm is tucked behind the parent's/caregiver's back.

To help in relaxing the muscle during the injection, the older client may be seated with their elbow bent and their forearm resting on the arm of a chair and internally rotated.

Define the site by drawing a triangle with its base at the lower edge of the acromion and its peak above the insertion of the deltoid muscle. The injection site is in the center of the triangle.



8.2.3 Ventrogluteal site

Do **not** use this site for vaccine administration.

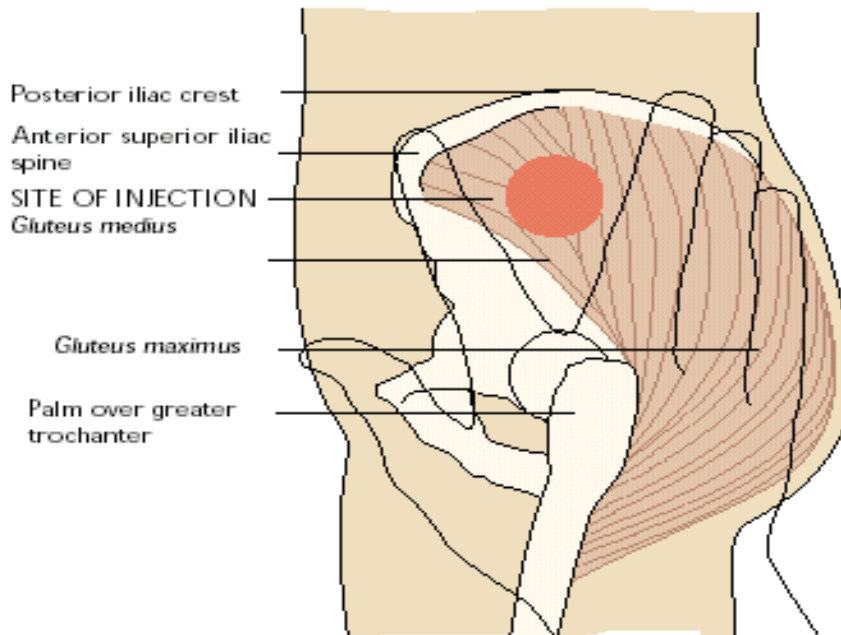
The ventrogluteal site is the preferred site for the IM injection of large volumes of immune globulin preparations (e.g. Ig, HBIg, TIg, RabIg).

This site can be used in those over 7 months of age.

This muscle is accessible in the supine, prone, and side lying position.

The right hand is used for locating the site on the left hip; the left hand is used for locating the site on the right hip.

Place heel of the hand over the greater trochanter of the client's hip with wrist almost perpendicular to the femur. Point the thumb toward the client's groin and the fingers toward the client's head. 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. The injection site is the center of the triangle.



8.2.4 Dorsogluteal site

Do **not** use this site for vaccine administration, as it is less immunogenic for a number of vaccines, including hepatitis B and rabies vaccines.

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.

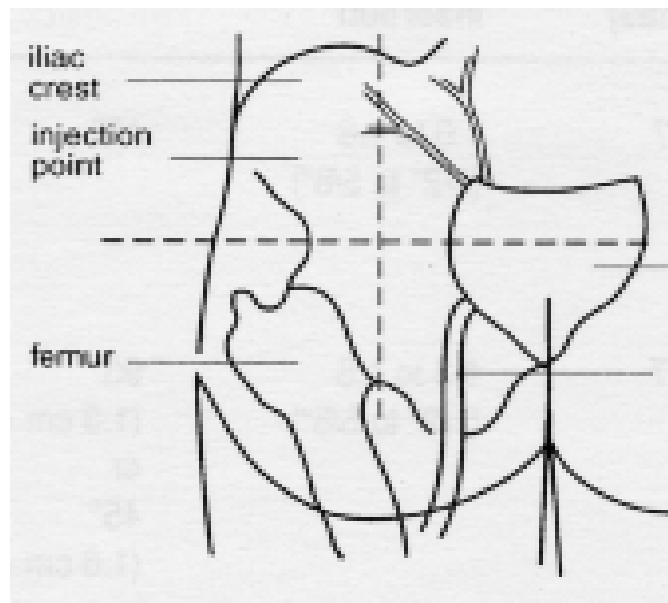
This site should **only** be used in individuals over five years of age.

Place client in a prone, side lying, or standing position.

Encourage a posture that will provide muscular relaxation and reduce discomfort (i.e. turning toes inward when prone, flexing the upper leg at hip and knee when lying on the side, flexing knees and leaning upper body against a support when standing).

Define the site by dividing the buttock into 4 quadrants. The injection site is the centre of the upper outer quadrant.

Direct the needle anteriorly (i.e., if the client is lying prone, direct the needle perpendicular to the table's surface, not perpendicular to the skin plane).





8.3 Site and needle size for intradermal injection

Use a 1 ml TB syringe and 27 gauge needle of 1/2" length.

The usual site for intradermal injections is the flexor (anterior) surface of the forearm.

Have client rest their arm on a firm surface, forearm turned up.

Because of the decreased antigenic mass administered with ID injections, attention to technique is essential to ensure that the material is not injected subcutaneously.

9.0 INJECTION ROUTES

Routes of administration of each biological product are recommended by the manufacturer. Deviation from the recommended route of administration may reduce vaccine efficacy or increase local adverse events. Report any administration of a biological by a route other than that recommended by the manufacturer to the appropriate person in your health care setting.



9.1 Injection Routes for Biological Products

Intramuscular (IM)	Subcutaneous (SC)	IM or SC	Intradermal (ID)	Oral
<i>DaPT</i>	IPV	Pneumococcal (polysaccharide)	Pre-exposure rabies vaccine	Rotavirus
DaPT-IPV	MMR		TB skin test	
DaPT-IPV-Hib	Meningococcal (polysaccharide)		INTANZA™	
DaPT-HB-IPV-Hib				
Hepatitis A	Varicella			
Hepatitis B	Zoster			
Hib				
HPV				
Immune Globulin (Ig) Preparations				
Influenza				
Meningococcal C Conjugate				Intranasal
Meningococcal Quadrivalent Conjugate				FLUMIST®
Pneumococcal (conjugate)				
Rabies				
Td				
Td-IPV				
Tdap				
Typhoid				

9.2 Subcutaneous (SC) injection route

PROCEDURE	IMPORTANT POINTS
<ul style="list-style-type: none"> • Use correct length and size of needle. Grasp a skin fold of fatty tissue at site with thumb and forefinger. Measure skin fold from top to bottom; be sure needle is approximately one half this length. • Clean the site with a cotton pad/swab/ball moistened with 70% isopropyl alcohol. 	<ul style="list-style-type: none"> • Pinching skin elevates SC tissue and ensures that needle will be injected into SC tissue. • Allow the skin to air dry prior to injection to avoid a burning sensation on insertion of the needle.
<ul style="list-style-type: none"> • Insert the needle quickly and firmly, with the bevel facing upwards, at a constant angle of 45°. • For an obese client, use a longer needle and inject at a 90° angle to reach SC tissue. 	<ul style="list-style-type: none"> • Quick, firm insertion minimizes discomfort.
<ul style="list-style-type: none"> • Release the skin. 	<ul style="list-style-type: none"> • Injecting into compressed tissue irritates nerve fibers.
<ul style="list-style-type: none"> • Rapidly inject the biological product. ❶ 	<ul style="list-style-type: none"> • Rapid injection reduces pain.
<ul style="list-style-type: none"> • Remove the needle in one swift motion, immediately applying pressure to the injection site with a dry cotton pad/swab/ball. • Do not massage the injection site. 	<ul style="list-style-type: none"> • Minimizes discomfort during needle withdrawal. Alcohol on a cotton pad/swab can irritate non-intact skin. • Massage can damage underlying tissue.

NOTE: Aspiration is not recommended as there are no data to document its necessity prior to the SC injection of biological products.

❶ Rapid injection is recommended for all vaccines injected subcutaneously or intramuscularly. It is not recommended for more viscous biological products such as immune globulin preparations or those for which the manufacturer recommends a slower administration.

9.3 Intramuscular (IM) injection route

PROCEDURE	IMPORTANT POINTS
<ul style="list-style-type: none"> • Use correct length and size of needle. • Clean the site with a cotton pad/swab/ball moistened with 70% isopropyl alcohol. 	<ul style="list-style-type: none"> • Allow skin to air dry to avoid a burning sensation on insertion of the needle.
<ul style="list-style-type: none"> • Insert needle quickly at a 90° angle into muscle. 	
<ul style="list-style-type: none"> • If client's muscle mass is small, grasp body of muscle between thumb and fingers before and during the injection. 	<ul style="list-style-type: none"> • Ensures that biological product reaches the muscle mass.
<ul style="list-style-type: none"> • Rapidly inject the biological product ❶ 	<ul style="list-style-type: none"> • Rapid injection reduces pain.
<ul style="list-style-type: none"> • Remove the needle in one swift motion, immediately applying pressure to the injection site with a dry cotton pad/swab/ball. • Continue to apply pressure for 30 seconds. • Do not massage injection site. 	<ul style="list-style-type: none"> • Minimizes discomfort during needle withdrawal. Alcohol on a cotton pad/swab can irritate non-intact skin. • Minimize bruising. • Massage can damage underlying tissue.

NOTE: Aspiration is not recommended as there are no data to document its necessity prior to IM injection of biological products. There are no large blood vessels at the recommended immunization sites. Aspiration may increase the time it takes to immunize and is more painful for the client. To view video clips of slow (including aspiration) immunization techniques and rapid immunization techniques see:

http://www.msss.gouv.qc.ca/sujets/santepub/vaccination/index.php?professionnels_de_la_sante Scroll down page to section titled ***Aspirer ou non avant d'injecter un vaccin?***

There are 5 videos demonstrating immunization technique.

❶ Rapid injection is recommended for all vaccines injected subcutaneously or intramuscularly. It is not recommended for more viscous biological products such as immune globulin preparations or those for which the manufacturer recommends a slower administration.

9.4 Intradermal (ID) injection route

PROCEDURE:	IMPORTANT POINTS:
<ul style="list-style-type: none"> • Use correct length and size of needle. • Clean the site with a cotton pad/swab moistened with 70% isopropyl alcohol. 	<ul style="list-style-type: none"> • Allow skin to air dry to avoid a burning sensation on insertion of the needle.
<ul style="list-style-type: none"> • Gently stretch the skin in the selected region between the thumb and index finger. 	
<ul style="list-style-type: none"> • Insert the needle with the bevel facing upwards, at a constant angle of 15° until the bevel disappears. 	<ul style="list-style-type: none"> • The needle should be clearly visible beneath the skin.
<ul style="list-style-type: none"> • Inject the biological product slowly with controlled pressure. • A white elevated wheal (bleb) 6-8 mm in size should appear. • If an elevated wheal does not appear, repeat the procedure, (use the other arm). • Remove the needle quickly and sponge the injection point with a dry cotton pad/swab/ball. • Do not apply a Band-Aid after a TB skin test. 	<ul style="list-style-type: none"> • Injection of the solution in the dermis may cause a burning and prickling sensation. • This indicates the product was not administered intradermally. • Use of dry cotton pad/swab will minimize discomfort associated with alcohol on non-intact skin. • A Band-Aid can mark the skin and confuse skin test readings.



10.0 CLIENT OBSERVATION FOLLOWING IMMUNIZATION

Advise recipients of any biological product (i.e., vaccine, immune globulin, TB skin test) to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously. **Thirty (30) minutes is a safer duration when the person has had a prior allergic reaction to the biological product or a component of the biological product. If an individual has such an allergic history, immunization should occur in an emergency room setting.** See Communicable Disease Control Manual, Chapter 2, Section IX: Vaccine Associated Adverse Events available at: http://www.bccdc.ca/NR/rdonlyres/74D83EE6-B735-48C5-8F8B-300A55E1E4C9/0/CD_Manual_Chap2_SectionIX_AdverseEvents.pdf. The risk of fainting is the more common reason to keep biological product recipients under observation.

In a school-based or mass immunization setting, the clinic site would be the ideal location for client observation. However, it can be problematic in terms of flow of people. Directly observe any client with symptoms such as pallor or sweating (possibly pre-syncope) in the clinic setting. Enable these clients to sit or lie down until symptoms resolve.

Where recipients of a biological product choose not to remain under supervision after immunization, inform them (or their parent/guardian) of the signs and symptoms of anaphylaxis and instruct them to obtain immediate medical attention should symptoms occur.

If a band-aid is applied to an infant or toddler, advise its removal before leaving the clinic. This is to avoid the risk of the child choking on the band-aid.

11.0 MANAGEMENT OF PAIN AND ANXIETY BEFORE AND DURING ADMINISTRATION OF A BIOLOGICAL PRODUCT

Pain associated with immunization is generally described as mild and short lived. However, the need for multiple injections and conflicting information about vaccines in the media has increased public concern and anxiety associated with immunizations. Health care providers must establish an environment that promotes trust and mutual respect. A useful reference for parents is HealthLink BC File 50e “Getting Ready for Your Child’s Shots” available at: <http://www.healthlinkbc.ca/healthfiles/index.stm>.

Refer to subsections [2.2 Informed Consent](#) and [2.3 Client Assessment](#) for techniques to decrease anxiety and the risk of fainting prior to administration of biological products.

As the discomfort associated with immunization is generally mild and transient, it can usually be managed with measures such as those described in [11.1.3 Calming and distraction techniques](#). Some individuals who are particularly concerned about pain associated with immunization may be interested in the use of topical anesthetics.



11.1 Recommendations for a more successful immunization experience

11.1.1 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 parent/guardian or caregiver. When a parent threatens a child, the most helpful response is to offer empathy to the parent, 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.

11.1.2 Structure the environment

If a parent presents with more than one child, immunize the most anxious one first (usually the eldest), even if the parent 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 you 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 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. Referral to a family physician may also be an option.

11.1.3 Calming and distraction techniques

Distraction techniques are effective in decreasing pain response in infants, toddlers, and children during and following immunization. Regardless of the type of distraction, the more the child is involved in the distraction, the lower their pain.

Work with the parent to use distraction techniques such as reading, music, use of pinwheels or soap bubbles, and instructing children to “blow the pain away.” Slow, deep breathing has a physiologic calming effect and can, at minimum, limit anxiety escalation.

Consider the following techniques to minimize child and parent distress following immunization:

- Suggest swaddling, cuddling and rocking the infant to the parents
- Suggest parents try breastfeeding, bottle-feeding, or using a pacifier

12.0 USE OF TOPICAL ANESTHETICS

Topical anesthetics that may be used to decrease the mild and short-lived pain associated with immunization include: EMLA (eutectic mixture of local anesthesia consisting of 2.5% lidocaine and 2.5% prilocaine), Ametop® gel (4% amethocaine) and vapocoolants (e.g., Fluori-Methane).

Studies have demonstrated that EMLA does not affect the immunologic response to MMR, DTaP-IPV-Hib (Pentacel®), or hepatitis B (Recombivax®). However, it is difficult for parents to use EMLA as it needs to be applied at the correct injection site approximately 60 minutes before the injection.

Ametop® gel produces anesthesia within 30 to 40 minutes and has been shown not to interfere with the immunologic response to MMR vaccine.

Vapocoolants are effective immediately after application but as their effect is very short lived, their efficacy in decreasing immunization pain is uncertain.



13.0 MANAGEMENT OF FEVER AND PAIN FOLLOWING IMMUNIZATION

Inform client (or parent / guardian) about expected reactions to each biological product administered.

Advise parents that child may experience fever, injection site pain and cry or be fussy following immunization. For the alleviation of fever and pain, suggest parents:

- Give acetaminophen (see [13.1 Fever management](#) for appropriate dosages)
- Apply a clean, cool wet washcloth for 15 to 20 minutes over the immunization site(s)
- Refer to:

<http://www.cdph.ca.gov/programs/immunize/Pages/ComfortMeasuresforInfants.aspx> for more information regarding comforting their child after immunization.

Instruct client (or parent / guardian) to contact health care provider if concerned about reaction or about any adverse event that occurs following receipt of the biological product. See Communicable Disease Control Manual, Chapter 2, Section IX: Vaccine Associated Adverse Events available at: http://www.bccdc.ca/NR/rdonlyres/74D83EE6-B735-48C5-8F8B-300A55E1E4C9/0/CD_Manual_Chap2_SectionIX_AdverseEvents.pdf for more information regarding adverse events.

Local and systemic reactions may follow use of biological products. Common reactions to biological products are usually mild, self-limited, and without permanent sequelae. They are intrinsic to the immunizing antigen or some component of the biological product. These reactions can safely be managed with symptomatic treatment.

Local reactions include pain, redness and swelling at the injection site. These reactions tend to occur within a few hours of the injection, and are common with inactivated vaccines that contain adjuvants (e.g., DaPT/IPV/Hib). Crying and irritability in infants and young children are likely responses to pain at the site of injection.

The body's response to injected proteins can also affect heat regulation and produce fever within a few hours of vaccination.

Systemic reactions are more generalized events and include fever, rash, malaise, myalgia, and headache. These reactions are more common following the administration of live attenuated vaccines (e.g., measles, mumps and rubella vaccines) that must replicate in order to produce immunity. The systemic reactions represent symptoms produced from that replication, and are similar to a mild form of the natural disease.

When the immunizing agent is a live attenuated vaccine, inform parents that systemic adverse events tend to occur later than those following the administration of inactivated vaccines. For example, for a measles-mumps-rubella-containing vaccine, fever may occur 5 – 30 days after vaccination, most commonly within 7 –14 days. With a varicella vaccine, fever may occur within 0 – 42 days, most commonly between 14 and 27 days after immunization.



13.1 Fever Management

When fever is suspected, it is preferable to use a thermometer to measure temperature accurately.

Recommend acetaminophen for use in managing fever and pain. Its use is preferred to that of ibuprofen. Acetaminophen has an overall safer drug interaction and precaution profile as compared to ibuprofen.

Acetylsalicylic acid (ASA) is not recommended for children because of its associated risk of Reye syndrome.

It appears unlikely that a serious risk such as the link between ASA and Reye syndrome will surface for acetaminophen. However, the same cannot yet be said with an equivalent degree of certainty for ibuprofen. Until adverse event data collected over a period of years prove conclusively that rare serious events are not associated with ibuprofen, acetaminophen must remain the drug of first choice. While likely to be safe and efficacious, ibuprofen should be reserved for second-line therapy, and then used on an episode by episode basis on the advice of a physician.

There are no supporting clinical studies for the prophylactic use of acetaminophen in children prone to febrile seizures. In fact prophylaxis in high risk children has been shown to be ineffective.

Acetaminophen may be given at a dosage of 10 - 15 mg/kg, four to five times daily, not to exceed five doses or 65 mg/kg in 24 hours. Advise parents not to continue use beyond 48 hours unless specified to do so by a physician. Advise parents to initiate this dosage regimen when there are symptoms of fever and/or pain shortly after immunization. For prophylactic use, the first dose may be given prior to or at the time of the biological product administration.

The dosage guidelines in the following table will provide an effective but non-toxic serum concentration level based on average child weight. The single dose is calculated to provide 10 -15 mg of acetaminophen per kilogram of body weight. Advise parents to read the label on the product they are using and be aware of the concentration of medication. When it is not possible to determine the weight of the child, dosage may be approximated according to age.



Acetaminophen Dosage Guidelines			
Age	Weight		Single Dose Acetaminophen^❶
	(kilograms)	(pounds)	
0 – 3 months	2.7 – 5.4	6 - 11	40 mg
4 – 11 months	5.5 – 7.9	12 - 17	80 mg
12 – 23 months	8.0 – 10.9	18 - 23	120 mg
2 – 3 years	11.0 – 15.9	24 - 35	160 mg
4 – 5 years	16.0 – 21.9	36 - 48	240 mg
6 – 8 years	22.0 – 26.9	49 - 60	320 mg

❶ This dosage may be repeated up to five times daily, at minimum intervals of four hours, not to exceed five doses or 65 mg/kg in 24 hours and not to continue beyond 48 hours unless specified by a physician.

14.0 DOCUMENTATION

Promptly record the administration of all biological products using the documentation system in place at your worksite. For each biological product administered the minimum data to be recorded in the client's record should include:

- name of the biological product
- date
- route of administration
- anatomical site
- name of the biological product manufacturer
- lot number
- name and title of the person administering the biological product
- any reactions following immunization.
- any recommended biological products that were not given (i.e., declined, deferred, or contraindicated)
- informed consent for immunization obtained (see [BC Communicable Disease Control Manual, Chapter 2, Section 1B](#)).



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