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Communicable Disease Control Manual

Chapter 2: Immunization

Appendix B - Administration of Biological Products

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1. Definitions

Infant: birth to less than 1 year of age

Toddler: 1 to 2 years of age (inclusive)

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. Preparation for Administration of Biological Products

2.1 Product Preparation

For the administration of particular products, review guidelines in [Part 4 – Biological Products](#).

Prepare necessary materials (e.g., sterile syringe/needle, 70% isopropyl alcohol, sharps container, **supplies for the management of anaphylaxis**). For information on supplies needed to manage anaphylaxis, refer to [Part 3 – Management of Anaphylaxis in a Non-Hospital Setting](#). Check the expiration date on the needle/syringe, if present (1).

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) (2).

2.2 Product Inspection

Check the characteristics of the product to be administered:

- Correct product - Check **three times** that it is the correct product: when removing from refrigerator/biological cooler, when drawing up/reconstituting and prior to administration.
- Correct formulation and presentation - Ensure product being administered is correct formulation (e.g., hepatitis B vaccine is available in pediatric or adult formulation) and correct presentation (e.g., influenza vaccine is available in injectable and intranasal presentations).
- Expected appearance - Inspect product for 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 the month.
- If a previously opened multi-dose vial, check the date that the vial was opened (as recorded on the label). Once entered, multi-dose vials must be used within the time period specified by the manufacturer as indicated within the respective product pages in [Part 4 – Biological Products](#).

2.3 Client Assessment

Verify the client using two identifiers (e.g., name and date of birth) (3,4). Ensure client identifiers match client information on immunization record.

Assess each client to determine which biological products the client is eligible for at this visit. Consider client's previous immunizations, age, relevant health status, and occupational or lifestyle risk factors.

Ask client or parent/guardian about all relevant contraindications and precautions to receiving each biological product being administered at that visit, including previous adverse events following immunization. **Vaccine providers should recommend deferral or withholding of vaccines for true precautions and contraindications only** (5). Review the contraindications and precautions for each biological product in [Part 4 – Biological Products](#).

Seat every client prior to immunization (6). If client appears anxious pre-immunization or describes a history of fainting with previous immunization, have them lie down for the immunization if possible. If client appears pale and displays signs of fainting pre-immunization, advise them to lie down and apply a cold wet cloth to their face. Refer to [Appendix D - Reducing Immunization Injection Pain](#) for other strategies to mitigate anxiety.

2.4 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. For more information, refer to [Appendix A – Informed Consent for Immunization](#).

For details regarding informed consent, refer to the informed consent policies specific to your worksite and your professional body.

3. Considerations for the Scheduling and Administration of Multiple Injections

“Vaccine providers should use all clinical opportunities to screen for needed vaccines and to administer all vaccine doses for which a vaccine recipient is eligible at the time of each visit.”(7).

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.

Most vaccines can be safely and effectively administered at the same visit (7). There is no increase in side effects, reduced vaccine effectiveness, or reduced parental compliance. For recommendations on concomitant administration of specific vaccines, refer to [Part 2 – Immunization of Special Populations](#) and [Part 4 - Biological Products](#).

Vaccines that are intended for separate administration should never be combined by vaccine providers. The safety, immunogenicity, and effectiveness of unlicensed combinations are unknown.

Give biological products that are known to cause more stinging and/or pain last (e.g., PREVNAR® 13 and MMR II®) (6,8). Published pain-related data are not available for other vaccines.

When more than one vaccine is to be administered, it is preferable, but not necessary, to use different limbs (9). Use of different limbs assists in differentiation of local adverse events following immunization.

When a vaccine and immune globulin product are being administered, separate limbs must be used.

When administering two or more vaccines in the same limb, separate the injections by as much distance as possible. A separation of 2.5 cm (1 inch) is preferable so that local reactions are unlikely to overlap. When selecting a site for multiple injections, consider available muscle mass to allow for adequate spacing between injections.

When administering multiple vaccines intramuscularly, the vastus lateralis or deltoid muscle may be used. Intramuscular injections of vaccine are administered into the vastus lateralis in infants less than 12 months of age. The vastus lateralis or the deltoid muscle can be used for toddlers and older children. The deltoid is often selected as the injection site in these age groups as temporary muscle pain in the vastus lateralis muscle post-vaccination may affect ambulation. However, when selecting a site, it is important to consider available muscle mass.

For more detailed information, refer to [Section 14.1.1 Recommended Needle Sizes, Sites and Maximum Volumes for Intramuscular Injection](#).

When more than one product will be administered to an individual, each product should be labelled or placed on a tray that clearly names each vaccine. For information on simultaneous injections, refer to [Appendix D – Reducing Immunization Injection Pain](#).

4. Drawing Up Multiple Doses of a Biological Product

Drawing up multiple doses of a vaccine prior to administration is not best practice and is strongly discouraged.

It is best practice to draw up vaccine immediately before administering the product to the client.

Pre-drawing vaccines into syringes is discouraged for a number of reasons (9):

- Uncertainty regarding product stability in syringes
- Risk of contamination (the syringe will not contain a bacteriostatic agent)
- Increased potential for administration errors
- Biological product wastage
- Risk of needlestick injury when recapping needle after pre-drawing

If the decision is made to draw up multiple doses of a biological product at a mass 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). Other products may have limited stability once drawn up.
- Only pre-draw vaccine into syringes when **one** biological product is being administered at the clinic.

- Draw up a maximum of 10 doses or the contents of one multi-dose vial (whichever is greater). Do not draw up additional doses until the 10 doses have been administered.
- Withdraw each dose from a multi-dose vial in a sterile needle and syringe. Do not leave a needle in a multi-dose vial (10-13).
- 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 icepack.
- Ensure each immunizer has their own biological cooler.
- Securely attach needle caps over the needles. 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.
- Discard unused pre-drawn biological products at the end of the clinic.

A biological product should be withdrawn from the vial by the provider administering the product. The [British Columbia College of Nurses and Midwives Practice Standard: Medication](#) states “Nurses administer only medications they themselves or a pharmacist have prepared, except in an emergency.” (2).

5. Drawing Up a Large Quantity of Biological Product for Individual Use

In some instances, a product will need to be withdrawn from more than one vial. This may occur when drawing up immune globulin products or when more than one vial of hepatitis B vaccine is required for the individual’s dose.

In these instances, the biological product may be withdrawn from more than one vial into the same syringe provided the vials are the same lot number and expiry date. To combine the product into one syringe (14):

- Aspirate a volume of air equivalent to the amount of product to be withdrawn from vial A and inject the air into vial A, ensuring the needle does not come into contact with product in the vial.
- Holding onto the plunger, withdraw the needle and syringe from vial A.
- Aspirate a volume of air equivalent to the amount of product to be withdrawn from vial B and inject the air into vial B.
- Immediately withdraw the quantity of product needed from vial B and withdraw the needle and syringe.
- Insert needle into vial A and withdraw quantity of product needed from vial A to obtain the full dose.
- Discard vials immediately after use, regardless of any remaining product in the vial.

In rare instances, more than one individual may be present at the same appointment and require administration of an immune globulin product supplied in vial format (e.g., Ig, HBIg, Rablg, Varlg). To avoid wastage of the product, immune globulin may be withdrawn from a single vial for more than one individual provided a new, sterile needle and syringe is used for each individual. Any immune globulin product remaining in the vial(s) following administration of the appropriate dose(s) must be discarded immediately.

Refer to [Section 14.1.1 Recommended Needle Sizes, Sites and Maximum Volumes for Intramuscular Injection](#) for information regarding maximum volume per immunization site.

6. Drawing Up Biological Products in Vial Presentation

Wash hands or cleanse with a sanitizer.

Remove the plastic cap covering the vial. To avoid vaccine wastage, confirm it is the correct product before removing the plastic cap (15). In the event that the plastic cap is removed and the vial is not subsequently punctured, maintain the cold chain and use or discard the contents of the vial by the end of the clinic day (16,17).

Cleanse the surface of the rubber stopper using a cotton pad/swab moistened with 70% isopropyl alcohol. Allow to air dry (11,12).

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 (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. For detailed reconstitution guidelines, refer to [Section 7 Product Reconstitution](#).

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, unless a different size needle is required for administration (per [Section 14.1.1 Recommended Needle Sizes, Sites and Maximum Volumes for Intramuscular Injection](#)) or the needle 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. Partial doses from separate vials should not be combined to obtain a full dose (18).

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

7. Product Reconstitution (1,9,19)

Reconstitute vaccine according to manufacturer's instructions, using only the diluent provided by the manufacturer for reconstitution purposes.

- Diluent may be provided in a single dose vial, single dose ampule, or preloaded syringe.
- Store diluent according to manufacturer specifications.
- Ensure the diluent and the vaccine are the correct products to be mixed together and that neither product is expired.
- Reconstitute vaccine just prior to use.
- Swab both rubber seals with isopropyl alcohol and allow alcohol to dry (13).
- Introduce the diluent into the lyophilized vaccine product vial by inserting the needle at a 45 degree angle and injecting the diluent slowly toward the side of the vial and not directly into the vaccine powder. This will prevent foaming or potential denaturing of the vaccine protein.
- Swirl or rotate the vial gently until all the powder is dissolved and solution has a consistent appearance.
- Check the appearance of the reconstituted vaccine. Ensure the colour, appearance, and consistency are consistent with the product description on the product insert or product monograph.
- Best practice is to withdraw the entire volume of the reconstituted product from the vial and administer immediately.

8. Drawing Up Biological Products in Ampule Presentation

Wash hands or cleanse with a sanitizer.

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 (13).

Break the neck of the ampule using the alcohol swab, a clean cotton ball, a clean cotton gauze or an ampule breaker.

Note: When there is a painted dot on the ampule bulb head, this is indicating the ampule has a One Point Cut (OPC) system. An OPC system has a thinned breakage point on the neck of the ampule directly below the dot only, the OPC ampule can only be broken in one direction. This differs from a non-OPC ampule which has a 360° pre-scored breakage line around the neck of the ampule.

When breaking an OPC ampule, have the dot facing you, and place your thumb on the dot to ensure the thinned breaking point on the ampule neck is facing you. Your other hand will be holding the body of the ampule.

Holding the ampule at a 45° angle (to avoid spillage) apply light, even pressure to break the ampule at the neck with the upper part of the ampule (i.e., tip of the ampule head) detaching in the direction away from you. The initial breakage point will be facing you, therefore hold the ampule at a sufficient distance away from you to protect from any potential shattering glass. See image demonstrating opening an OPC ampule below. Note the image is indicating the left and right hand positions for those who are right hand dominant.

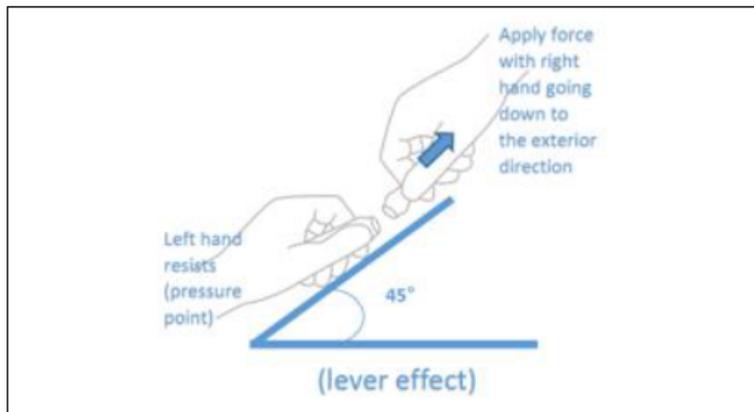


Image: GSK

Do not twist or rotate the ampule neck to open. If the ampule is very difficult to open, readjust the positioning of your hands as described above and try again. Do not try to force it open as too much force can lead to the ampule shattering.

If the ampule breaks into pieces, do not use and discard appropriately. If you cut yourself in breaking the ampule, discard the ampule, since the product may be contaminated. Wash your hands, seek first aid as needed, and follow the infection prevention and control protocols for your worksite 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, unless a different size needle is required for administration or the needle is damaged or becomes contaminated.

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 (20,21).

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., high 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 (9).

9. Syringes Pre-Filled by the Manufacturer (11,22)

Wash hands or cleanse with a sanitizer.

Inspect packaging to ensure protective barrier is intact.

Review lot number on box and on syringe. If packaging includes liquid vaccine as diluent for lyophilized vaccine, the lot number on the box will be used for recording purposes.

Shake or rotate syringe according to biological product monograph instructions.

Grasp needle-cap firmly near end where needle attaches to syringe.

For syringes with needle attached, rotate needle-cap slowly until loosened. Slowly slide off the cap.

For separate needles and syringes, firmly attach the needle onto the syringe with a push and clockwise twist. Use only safety-engineered needles. If the product comes with a needle without a safety-engineered shield, discard the needle in a sharps disposal container and replace with a safety-engineered needle prior to use.

Slowly eject the air bubble. If plunger is hard to push, hold syringe in one hand, and slowly rotate plunger clockwise (looking down on end of plunger) while pushing it into the barrel. (NOTE: Rotating plunger counter-clockwise may cause plunger to detach).

If the syringe has been activated (i.e., needle-cap removed or needle attached) but unused, discard at end of clinic day (23).

10. Standard Precautions

Glove use during immunization is not routinely recommended unless the skin on the vaccine provider's hands is not intact or when administering Bacille Calmette-Guérin (BCG) or smallpox vaccine. If gloves are worn, they should be changed between vaccine recipients. Hand hygiene should be performed after removing gloves.

Wash hands or cleanse with a sanitizer between clients.

To prevent accidental needle stick injury, do not recap needles after vaccine administration.

Safety-engineered needles must be used for biological product administration. WorkSafeBC states that a safety-engineered needle “includes a self-sheathing needle device and a retractable needle system.” (24).

Engage safety mechanism on needle 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 into another.

Report percutaneous (needle stick) injuries immediately to supervisor for consideration of possible post-exposure immunoprophylaxis. Follow the health and safety protocols for your worksite and see the [BCCDC Blood and Body Fluid Exposure Management guidelines](#). All immunization providers should have completed a full series of hepatitis B vaccine and have one documented laboratory test that shows they have developed sufficient antibodies per [Part 2 – Immunization of Special Populations, Health Care Workers](#).

11. Administration Routes

Ensure each biological product is administered according to the route recommended by the manufacturer. Refer to detailed information for each product in [Part 4 - Biological Products](#).

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

There are only two recommended intramuscular sites for administration of vaccines, the vastus lateralis muscle and the deltoid muscle. Injection at these sites reduces the chance of involving neural or vascular structures (1). For more information, refer to [14 Intramuscular, Subcutaneous, and Intradermal Injections](#).

Table 1: Administration Routes for Immunizing Agents

Intramuscular (IM)	Subcutaneous (SC)	IM or SC	Oral	Intranasal	Intradermal (ID)
DTaP-HB-IPV-Hib	IPV	Pneumococcal Polysaccharide	Rotavirus	Influenza (LAIV)	Rabies vaccine*
DTaP-IPV-Hib	MMR				
Hepatitis A	MMRV				
Hepatitis B	Varicella				
Hib	Zoster (Live)				
HPV					
Immune Globulin (Ig) Preparations					
Influenza (TIIV and QIIV)					
Meningococcal B					
Meningococcal C Conjugate					
Meningococcal Quadrivalent Conjugate					
Pneumococcal Conjugate					
Rabies					
Td					
Td/IPV					
Tdap					
Tdap-IPV					
Zoster (Recombinant)					

* In the event of a rabies vaccine shortage, consideration may be given to using the ID route for pre- and post-exposure immunization. For more information, refer to [Part 4 - Biological Products, Rabies Vaccines](#).

12. Oral Administration

Wash hands or cleanse with a sanitizer.

Ensure the lot number on the applicator and the box match as the applicator will be discarded immediately after administration.

Administer the liquid slowly down one side of the inside of the cheek (between the cheek and gum) toward the back of the mouth. Care should be taken not to go far enough back to initiate the gag reflex. Never administer or spray (squirt) the vaccine directly into the throat (1). Refer to manufacturer's instructions for detailed information on administration.

13. Intranasal Administration

Wash hands or cleanse with a sanitizer.

Ensure the lot number on the applicator and the box match as the applicator will be discarded immediately after administration.

The client should be seated in an upright position with their head tilted back. Instruct the client to breathe normally, and insert the tip of the nasal sprayer slightly into the nostril (1). Refer to manufacturer's instructions for detailed information on administration.

For information on the administration of FLUMIST® QUADRIVALENT, see Part 4 – Biological Products, Influenza Vaccines, [Flumist® Quadrivalent](#).

14. Intramuscular, Subcutaneous, and Intradermal Injections

Use clinical judgment to select the 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 product
- 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. There is no evidence to support avoidance of injection through a tattoo or superficial birthmark (9).

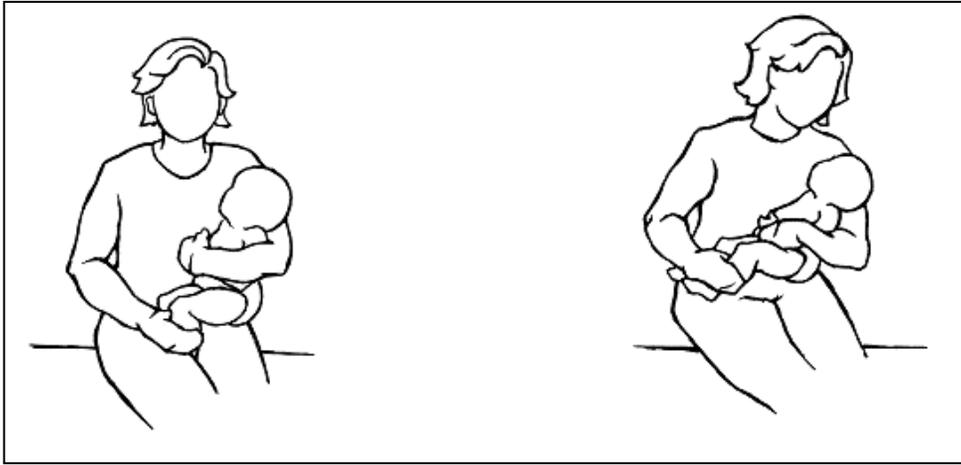
When possible, avoid injection in a site where lymphatic circulation may be impaired. Theoretically, there may be a lower immune response due to impaired vaccine absorption. Lymphatic circulation may be impaired in individuals with local lymphedema, lymphangioma, axillary lymph node dissection, A-V fistula, or upper limb amputation (9). If both arms are affected, consider using the vastus lateralis site.

Correct positioning of the client is a critical step in ensuring the biological product is administered in the correct site.

- Advise older children and adults to sit in a straight-backed chair with deltoid area exposed. Encourage client to keep forearms and hands in a relaxed position on upper thigh (25).
- 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. Refer to the following page for illustrations of positioning for infants and young children.

Examples of correct positioning for immunization of infants and children in the vastus lateralis and deltoid are shown on the next page.

Examples of positioning for injection in the vastus lateralis:



Examples of positioning for injection in the deltoid:



14.1 Intramuscular (IM) Injection Route (3,6,8,26,27)

Procedure	Important Points
Use correct length and gauge of needle.	See Section 14.1.1 Recommended Needles Sizes, Sites and Maximum Volumes for Intramuscular Injection .
Clean the site with a cotton pad/swab/ball moistened with 70% isopropyl alcohol.	Allow skin to air dry to avoid a burning sensation on insertion of the needle.
If client's muscle mass is small, grasp body of muscle between thumb and fingers before and during the injection.	Ensures that biological product reaches the muscle mass.
Insert needle quickly at a 90° angle into muscle.	
Do not aspirate.	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.
Inject biological product.	Rapid injection is no longer recommended as there is a lack of evidence supporting the effect of rapid injection on reduction of immunization pain (6).
Remove the needle in one swift motion, immediately applying pressure to the injection site with a dry cotton pad/swab/ball.	Minimizes discomfort during needle withdrawal. Alcohol on a cotton pad/swab/ball can irritate non-intact skin
Continue to apply pressure for 30 seconds.	Minimizes bruising.
Do not massage injection site.	Massage can damage underlying tissue.

14.1.1 Recommended Needle Sizes, Sites and Maximum Volumes for Intramuscular Injection (1,9,28-31)

Age	Site	Needle Length	Max Volume
< 28 days	Vastus lateralis	5/8"	1 mL
1 to < 12 months	Vastus lateralis	1"	1 mL
≥ 12 months to ≤ 2 years	Deltoid	5/8" - 1"	1 mL
	Vastus lateralis	1"	2 mL
> 2 years to < 5 years	Deltoid	5/8" - 1"	1 mL
	Vastus lateralis	1"	2 mL
5 years to 18 years	Deltoid	5/8" - 1"	1 mL ^A
	Vastus lateralis	1"	3 mL ^A
≥ 19 years	Deltoid	1 – 1 ½"	2 mL
	Vastus lateralis	1 – 1 ½"	5 mL

The 2 primary IM sites for immunization are the vastus lateralis (anterolateral thigh) and the deltoid muscles. The ventrogluteal and dorsogluteal sites may be used for immune globulin products only.

Intramuscular injections of vaccine are administered into the vastus lateralis in infants less than 12 months of age. The vastus lateralis or the deltoid muscle can be used for toddlers and older children. The deltoid is often selected as the injection site in these age groups as temporary muscle pain in the vastus lateralis muscle post-vaccination may affect ambulation. However, when selecting a site, it is important to consider available muscle mass.

Use a needle length sufficient to reach the largest part of the muscle. This is to prevent the biological product 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.

When selecting needle length, consider individual's age, muscle mass, and amount of subcutaneous tissue (adolescents and adults only).

- For infants, toddlers, and older children a 5/8"-1" needle is recommended, depending on the muscle size and the amount of subcutaneous tissue. A 5/8" needle is adequate only for the deltoid muscle

^A Based on clinical judgement, a greater volume (per guidelines indicated for those ≥ 19 years of age) may be considered based on the individual's muscle mass.

and only if the skin is stretched flat between thumb and forefinger and the needle inserted at a 90° angle to the skin (1).

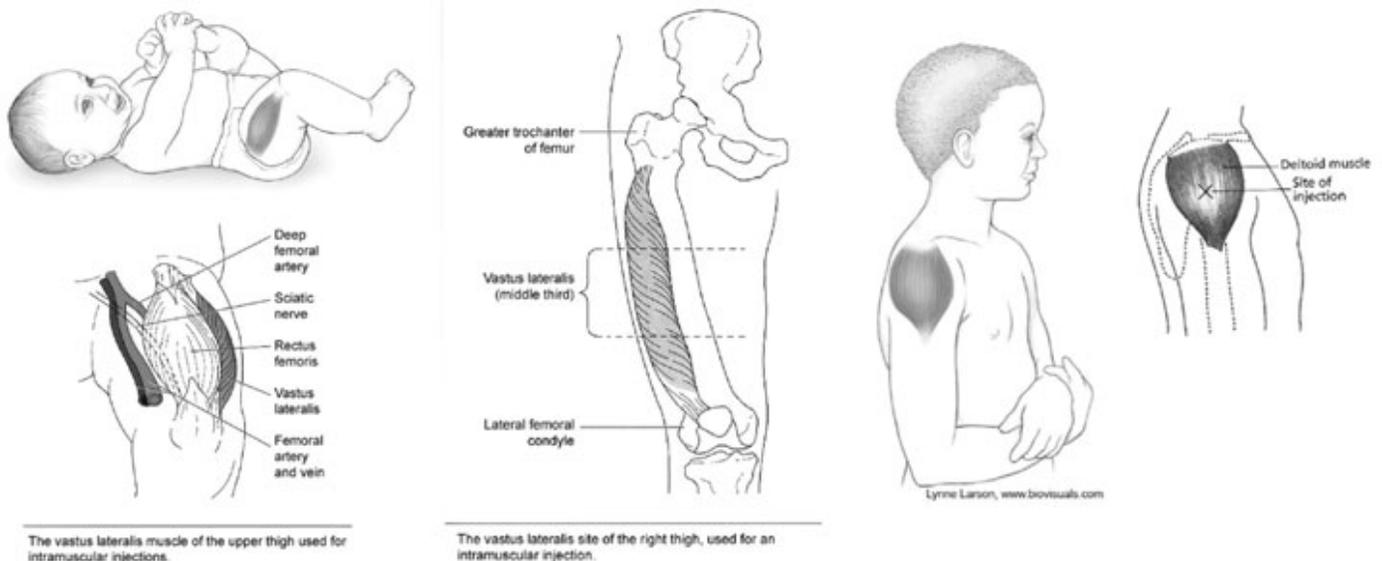
- For adolescents and adults, a 1"-1½" needle is usually used.

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 needle required to penetrate that muscle (32).

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 off the underlying muscle. One half of the distance between thumb and index finger will be the approximate length of the needle 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.

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.

14.2 Intramuscular Injection Sites



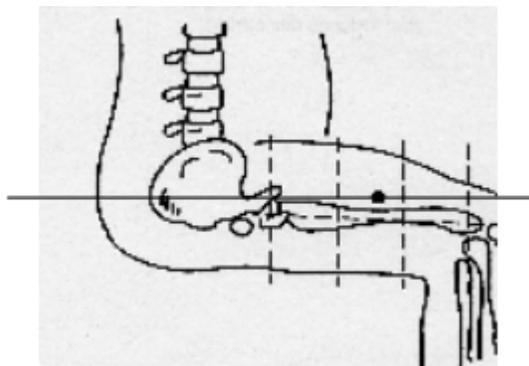
All images: Lynne Larson, Biovisual Communications

14.3 Vastus Lateralis (Anterolateral Thigh) Site

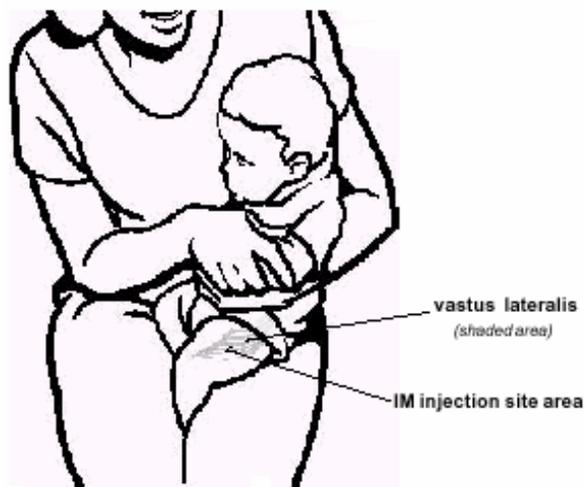
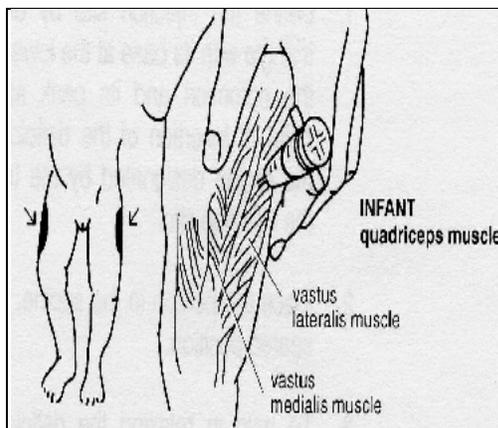
This site is used for both IM and SC injections.

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

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



- 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.



14.4 Deltoid Site (28,30,33,34)

This site is used for IM injections only.

Ensure all clients are seated prior to immunization.

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

Advise older children and adults to position their arm in a manner that exposes the deltoid muscle and relaxes the arm. Instruct the client to:

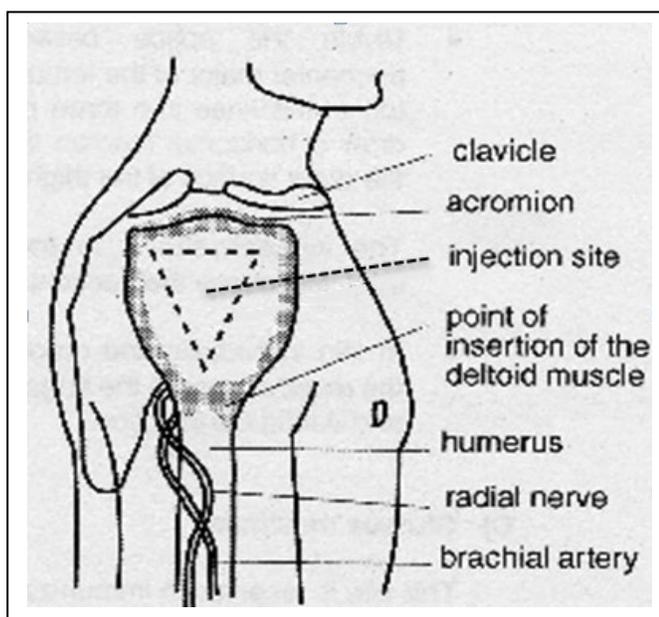
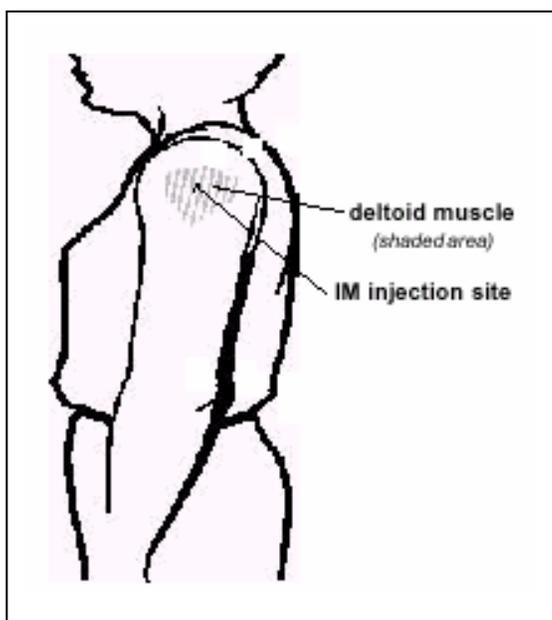
- Bend the elbow and place their forearm on the arm of the chair with the arm internally rotated; or
- Place both hands on their thighs; or
- Place their hand on their hip (abducting the shoulder approximately 60°) (30).

Expose the shoulder completely.

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.

The upper border of the deltoid muscle is located one to two finger widths below the acromion process. The bottom point of the deltoid muscle can be located by drawing an imaginary line across the arm from the crease of the axilla at the front to the crease of the armpit in the back (28).

The target zone for injection is 4 cm below the acromion for adults. In children 3-18 years of age, injections should be given 3-5 cm below the acromion (29).



14.5 Ventrogluteal Site

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

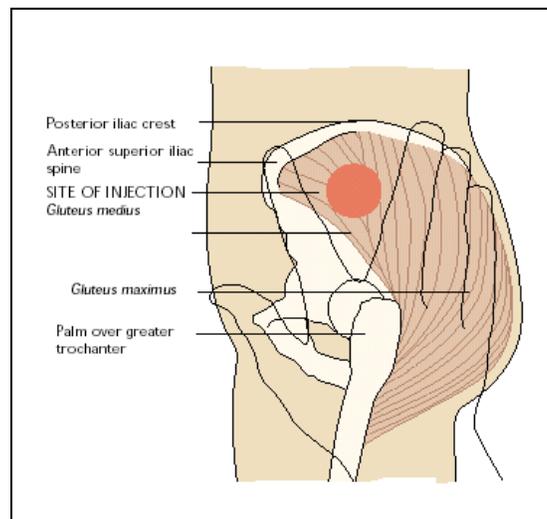
The ventrogluteal site is the preferred site for the IM injection of large volumes of immune globulin preparations (i.e., Ig, HBIg, RabIg, TIg, VarIg). For information regarding maximum volume of immune globulin by age group, refer to [Part 4 – Biological Products, Immune Globulin Preparations \(HBIg, Ig, TIg, VarIg, RabIg\)](#).

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.



14.6 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 vaccine.

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.

For information regarding maximum volume of immune globulin by age group, refer to [Part 4 – Biological Products, Immune Globulin Preparations \(HBIG, Ig, TIG, VarIG, RabIG\)](#).

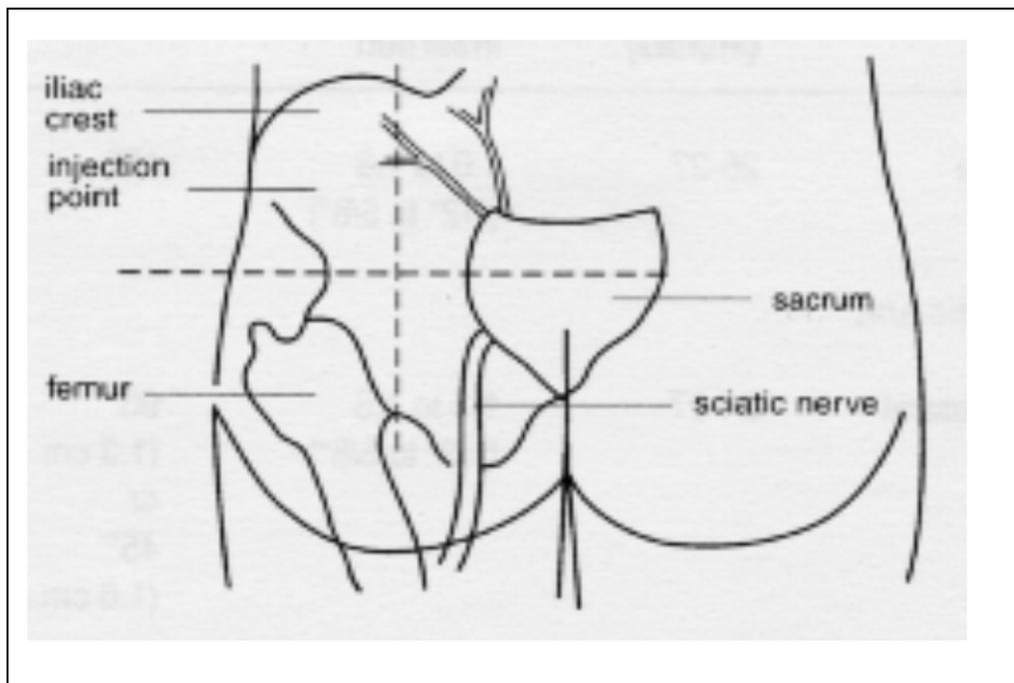
This site should **only** be used in individuals over 5 years of age.

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).



14.7 Subcutaneous Injections

14.7.1 Subcutaneous (SC) Injection Route (3,35,36)

Procedure	Important Points
Use correct length and gauge of needle. Grasp a skin fold or fatty tissue at the site with thumb and forefinger. Measure skin fold from top to bottom; be sure needle is approximately one half this length.	Pinching skin elevates SC tissue and ensures that needle will be injected into SC tissue.
Clean the site with a cotton pad/swab/ball moistened with 70% isopropyl alcohol.	Allow the skin to air dry prior to injection to avoid a burning sensation on insertion of the needle.
Insert the needle quickly and firmly at a constant angle of 45°. For an obese client, use a longer needle and inject at a 90° angle to reach SC tissue.	Quick, firm insertion minimizes discomfort.
Release the skin.	Injecting into compressed tissue irritates nerve fibers.
Do not aspirate.	Aspiration is not recommended as there are no data to document its necessity prior to the SC injection of biological products.
Inject the vaccine.	Rapid injection is no longer recommended as there is a lack of evidence supporting the effect of rapid injection on reduction of immunization pain (6).
Remove the needle in one swift motion, immediately applying pressure to the injection site with a dry cotton pad/swab/ball.	Minimizes discomfort during needle withdrawal. Alcohol on a cotton pad/swab/ball can irritate non-intact skin.
Do not massage the injection site.	Massage can damage underlying tissue.

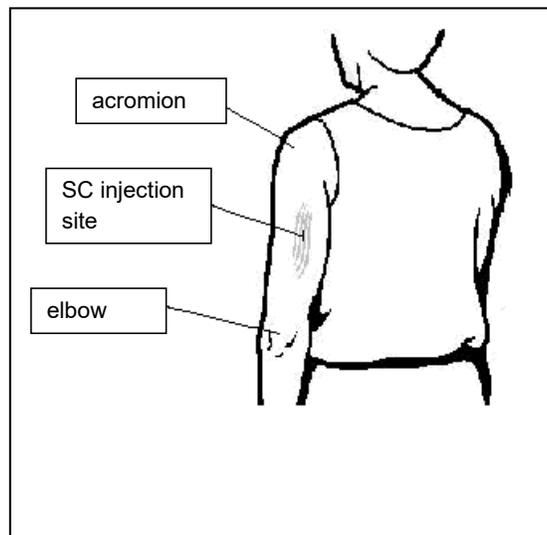
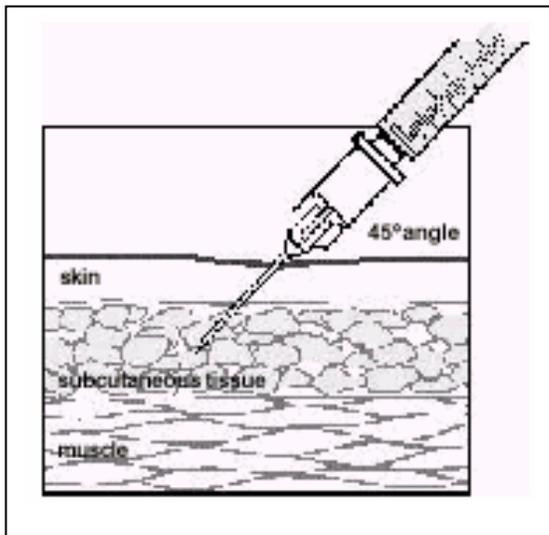
14.7.2 Needle Size and Sites for Subcutaneous (SC) Injection (1,3,35,36)

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.

Insert the needle at a 45 degree angle.



SC Injection site

14.8 Intradermal Injections

14.8.1 Needle Size and Site for Intradermal (ID) Injection

Use a 1 mL tuberculin syringe with a 26 or 27 gauge ¼" to ½" needle (37).

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

14.8.2 Intradermal (ID) Injection Route

Procedure	Important Points
Use correct length and gauge of needle.	
Clean the site with a cotton pad/swab/ball moistened with 70% isopropyl alcohol.	Allow to air dry to avoid a burning sensation on insertion of the needle.
Gently stretch the skin in the selected region between thumb and index finger.	
Insert the needle with the bevel facing upwards, at a constant angle of 15° until the bevel disappears.	The needle should be clearly visible beneath the skin.
Inject the biological product slowly with controlled pressure.	Injection of the solution in the dermis may cause a burning and prickling sensation.
A white elevated wheal (bleb) 6-8 mm in size should appear.	This indicates product was administered correctly (i.e., intradermally).
If an elevated wheal does not appear, repeat the procedure using an alternate site.	This indicates the product was <i>not</i> administered intradermally. If leakage occurs at the injection site, the needle bevel may not have been inserted far enough for it to be covered by the skin.
Remove the needle quickly and sponge the injection point with a dry cotton pad/swab/ball.	Use of dry cotton pad/swab/ball will minimize discomfort associated with alcohol on non-intact skin.

Step 1



Step 2



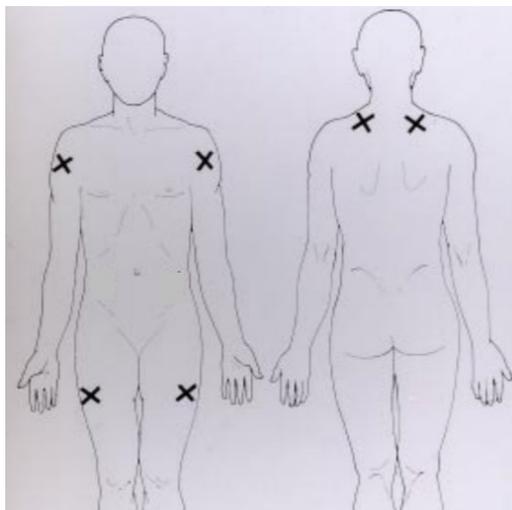
Step 3



For a demonstration of ID administration, see the following video: <https://www.youtube.com/watch?v=f3w-MIDAdg0>.

ID administration of rabies vaccine: The preferred site for ID administration of rabies vaccine is the deltoid area of the arms; alternatively the anterolateral area of the thighs and suprascapular areas can be used as well (see Figure 1 below). When 2 or more doses of vaccine are administered at the same visit, different sites/limbs should be used for each dose.

Figure 1: Intradermal administration sites for rabies vaccine



Source: World Health Organization

15. Client Observation Following Immunization

Advise recipients of any biological product (i.e., vaccine or immune globulin) to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously. **Thirty minutes is a safer duration when there is a specific concern about a possible vaccine reaction to the biological product or a component of the biological product.** The risk of fainting is the more common reason to keep biological product recipients under observation. If an individual reports an Adverse Event Following Immunization, refer to [Part 5 – Adverse Events Following Immunization](#).

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. For information regarding symptoms of fainting compared to anaphylaxis, refer to [Part 3 – Management of Anaphylaxis in a Non-Hospital Setting](#).

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 bandage 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 bandage.

16. Management of Fever and Pain Following Immunization

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

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

- Apply a clean, cool wet washcloth for 15-20 minutes over the immunization site(s).
- Give acetaminophen (see [16.1 Fever Management](#) for appropriate dosages). Alternatively, ibuprofen can be given, however it should not be given to children less than 6 months of age without first speaking to their health care provider.
- Refer to [Appendix D – Reducing Immunization Injection Pain](#) for more information regarding strategies to increase child comfort before and during the administration of a biological product.

Instruct the client (or parent/guardian) to contact their health care provider if concerned about a reaction or about any adverse event that occurs following receipt of the biological product. See [Part 5 – Adverse Events Following Immunization](#) for more information regarding adverse events.

Local and systemic reactions may follow the administration 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. 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 (e.g., commonly 5-14 days after MMR or varicella vaccines).

For detailed information on common reactions associated with each biological product, refer to [Part 4 – Biological Products](#).

16.1 Fever Management (38)

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

Recommend acetaminophen for use in managing fever and pain. Acetaminophen may be given at a dosage of 10-15 mg/kg, 4 to 5 times daily, not to exceed 5 doses or 65 mg/kg in 24 hours (39). Advise parents not to continue use beyond 48 hours unless specified to do so by their health care provider.

Alternatively, ibuprofen may be given, however it should not be given to children under 6 months of age without first speaking to a health care provider (40). Instruct the client (or parent/guardian) to follow the directions and dosage recommendations on the package. Ibuprofen can be given every 6-8 hours, up to 4 times in a 24-hour period (41), and should only be given if the child is well hydrated to reduce the risk of renal adverse events.

Acetylsalicylic acid (ASA) is not recommended for anyone under 18 years of age due to the risk of Reye syndrome.

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 (42). Advise parents to initiate this dosage regimen when there are symptoms of fever and/or pain shortly after immunization that are not well tolerated by the child.

Follow-up with a healthcare provider (or 8-1-1) is advised in the following scenarios to ensure that the infant/child's fever is not a sign of an unrelated serious illness:

- an infant < 3 months of age has a fever
- infants 3-12 months of age have a fever $\geq 39^{\circ}\text{C}$
- a child < 2 years has a fever lasting longer than 24-48 hours
- an older child has a fever lasting more than 72 hours, or
- there are signs of dehydration, refusal to eat food or drink, irritability, listlessness, unresponsiveness or any other worrisome signs or symptoms.

The dosage guidelines in the following tables for acetaminophen and ibuprofen will provide an effective but non-toxic serum concentration level based on the child's weight. The tables are intended to provide support to health care providers when advising parents or caregivers regarding appropriate dosage based on child's current weight. Advise parents to follow the instructions on the label of the product they are using and to be aware of the concentration of medication.

Acetaminophen Dosage Guidelines ^A		
Weight		Single Dose Acetaminophen
Kilograms (kg)	Pounds (lb)	
2-5.4 kg	6-11 lb	40 mg
5.5-7.9 kg	12-17 lb	80 mg
8-10.9 kg	18-23 lb	120 mg
11-15.9 kg	24-35 lb	160 mg
16-21.9 kg	36-47 lb	240 mg
22-26.9 kg	48-59 lb	320 mg
27-31.9 kg	60-71 lb	400 mg
32-43.9 kg	72-95 lb	480 mg

Source: Acetaminophen Labelling Standard (Health Canada, 2016) (39)

Ibuprofen Dosage Guidelines ^{B, C}		
Weight		Dose in milligrams (mg)
Kilograms (kg)	Pounds (lb)	
Less than 6 kg	Less than 12 lb	Ask a health care provider
5.5-7.9 kg	12-17 lb	50 mg
8-10.9 kg	18-23 lb	75 mg
11-15.9 kg	24-35 lb	100 mg
16-21.9 kg	36-47 lb	150 mg
22-26.9 kg	48-59 lb	200 mg
27-31.9 kg	60-71 lb	250 mg
32-43.9 kg	72-95 lb	300 mg
44 kg and above	96 lb and above	Adult dose

Source: American Academy of Pediatrics (2016) (43)

^A Do not exceed 5 doses in a 24 hour period.

^B Ibuprofen should not be given to children under 6 months of age without first speaking to a health care provider.

^C Do not exceed 4 doses in a 24 hour period.

17. 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 [Appendix A – Informed Consent for Immunization](#))

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