Nova Scotia Provincial Blood Coordinating Program

Atlantic Guidelines for Subcutaneous Immune Globulin Home Administration Programs

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Prepared by the Atlantic SCIG Working Group

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1 Background

Prior to January 2009, the distribution of SCIG was limited to patients with urgent medical requirements. As a result of a comprehensive review through a joint evaluation process between Canadian Blood Services (CBS) and the Canadian Agency for Drugs and Technologies in Health, the Provinces and Territories approved the inclusion of subcutaneous immune globulin (SCIG) as a regular product within CBS’s plasma protein products portfolio. The National Advisory Committee on Blood and Blood Products (NAC) provides medical and technical advice on the utilization management of blood and blood products to the provincial and territorial Ministries of Health and CBS. In May 2008, NAC provided the following recommendations on the utilization of SCIG:

1) The use of SCIG should be restricted to immunodeficiency patients, which is the patient group in which the product has been evaluated and deemed eligible for funding
2) There should be prospective tracking of use of the product both to ensure it is being used in appropriate patients at recommended doses
3) Adverse safety outcomes should be reported
4) The use of SCIG should be administered through a provincial program or specialty clinic for the purposes of education, tracking, monitoring outcomes, and optimizing dosing.

Since 2003, the four Atlantic Provinces have participated in an Atlantic Blood Utilization Strategy (ABUS) with the Nova Scotia Provincial Blood Coordinating Program (NSPBPCP) functioning as the secretariat. Intravenous Immune Globulin (IVIG) has been the focus of the Strategy with standardized data elements being developed, collected and submitted to the NSPBPCP where analysis occurred. The analyses have lead to the recommendation, development and implementation of strategies to facilitate appropriate ordering for the most common indications for the use of IVIG. To date, the strategies include the development of Atlantic guidelines and supplementary tools for Adult Neurologic and Hematologic conditions and Pediatric Indications and incorporation of a UL-N list to the preprinted order forms.

In September 2008 the Atlantic Collaborative IVIG Utilization Working Group expanded the mandate of ABUS to include SCIG. The expansion involved the collection of SCIG utilization data and the development of an Atlantic guideline for SCIG. In response to the expanded mandate, the NSPBPCP added SCIG data elements to the existing Atlantic IVIG data collection system and an Atlantic SCIG Working Group was convened to develop Atlantic guidelines for the implementation of SCIG home administration programs in hospitals across the Atlantic Provinces. A list of the members of the Working Group can be found in Appendix A.

These guidelines were distributed in November 2009 as a one year pilot. Feedback from the working group was obtained as well as recommendations from the Atlantic Clinical Expert Working Group on Primary Immune Deficiency and guided the revision of this document. Atlantic guidelines for the use of IVIG and SCIG were developed by the Atlantic Clinical Expert Working Group–Primary Immune Deficiency in December 2010 and are contained in Appendix C.
2 Introduction

The Canadian Standards Association (CSA) Standards for Blood and Blood Components Z902-10 specifically address home transfusion (Section 17) and state home transfusion should take place under a formalized program with documented operating procedures. Even though the subcutaneous self-administration of SCIG may not be considered to be a typical home “transfusion” it was still thought the clauses from this section of the Standards should be applied to an SCIG administration program and as such, forms many of the sections of this document. Where relevant, the text of the CSA Standards has been included.

This document contains information on SCIG but it should be noted that reading this document is not a substitute for reading the full monograph of any SCIG product.

At the end of this document there are several appendices. Appendix A, as previously mentioned is a list of the Atlantic SCIG Working Group members. Appendix B is a list of all the acronyms and abbreviations used in this document. The remaining appendices are the supplemental documents and templates referred to in the text of this document that are required for the implementation of a home administration program. Electronic versions of these documents as well as the present documents are provided on a CD-ROM.

3 Eligibility Criteria

3.1 Clinical Criteria

SCIG is indicated for the treatment of adult and pediatric patients with primary immune deficiencies who require immune globulin replacement therapy.

The subcutaneous route of administration is especially beneficial for patients who:
- Require a more stable or higher trough IgG level (for example, for those patients who feel fatigued prior to the next IVIG infusion).
- Require a different mode of administration of immune globulins in order to potentially decrease systemic adverse reactions with their current IVIG preparations or who have venous access issues.

With proper instruction, patients can self-administer SCIG at home. This also makes it an attractive option for patients who:
- Have a busy schedule and cannot afford the time/money to go to the hospital for their infusions.
- Prefer to self-infuse in the comfort of their home or while traveling.
- Live far away from the infusion centers.
- Want increased flexibility in scheduling their therapy.

According to clause 17.2.1 of the CSA Standards only patients who have previously received an infusion and who have not had an adverse reaction should be eligible for home infusion. This requires a patient to receive at least one SCIG infusion in the hospital.
3.2 Contraindications

There are several licensed SCIG products. Please consult the most recent product monograph for current and complete contraindications relevant to the specific SCIG product.

The general contraindications to SCIG include the following:

- Individuals with a history of anaphylactic or severe systemic response to immunoglobulin preparations
- Individuals with selective IgA deficiency (serum IgA less than 0.05 g/L) who have known antibody against IgA
- Individuals with Hypersensitivity to SCIG or any ingredient in the formulation or any component of the container. Refer to the product monograph for the ingredients in the formulation
- Young Children less than 1-2 years of age
- Pregnant Women
- Nursing Women

3.3 Mode of Administration of SCIG

Although SCIG is typically administered weekly by infusion pump, administration by a push technique may provide a greater degree of convenience. The push method of administration is now offered as an option in addition to the infusion by an electronic pump device.

4 Clinical Guidelines

4.1 Dosing Guidelines

SCIG should be administered at a dose of 400 to 600 mg/kg every 4 weeks in adult patients and 600 to 700 mg/kg every 3 to 4 weeks in pediatric patients. SCIG is given in weekly divided doses.

Over time it may be necessary to adjust the dose based on serum IgG levels and clinical response. The weight-based dosing is the same for pediatric patients; however, the safety and efficacy of SCIG has not been studied in young children.

For patients who are switching from IVIG to SCIG an initial dose can be calculated based on the previous IVIG dose. Patients will require the same amount as IVIG, but divided into weekly doses.
NOTE: administering the infusion requires the amount of product be measured in ml.

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{\text{Vial contents in g/ml}}
\]

For example if SCIG vial contents are 0.160 g/ml. The following equation can be used to calculate the total volume required for a single daily dose:

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{0.160 \text{ g/ml}}
\]

Sample Calculation: A patient needs to infuse a 17.4 g daily dose each week. The volume in ml of SCIG that is needed for each dose would be:

\[
\text{SCIG dose (ml)} = \frac{17.4 \text{ g of SCIG}}{0.160 \text{ g/ml}} = 109 \text{ ml of SCIG}
\]

The weekly dose may be divided in daily, biweekly or tri-weekly doses and rounded off to minimize the wastage when Push method is chosen for SCIG administration. For patients switching from IVIG to SCIG, the first dose should be given within one week after the last IVIG dose.

Vials are available in different sizes and doses should be rounded to the nearest vial size.

Some dose adjustments may be required over time to achieve the intended clinical response and serum IgG level.

A Pre-printed order form for SCIG products has been developed and is available in Appendix C. A Microsoft Word version of this order form is available on the included CD-ROM. The form has space for in-hospital and home infusion orders on the front and dosing and IgG monitoring guidelines on the back.

### 4.2 Monitoring of IgG Levels

A target serum IgG trough level of at least 7 g/L should be maintained. IgG levels should be measured monthly at the beginning of the treatment with SCIG, but as IgG levels are found to be stable, monitoring can be less frequent, every 3 to 6 months.

### 4.3 Monitoring of patient outcomes

Patients must use the Patient Infusion Log Sheet, Appendix D2 for pump method and E2 for Push method to document each infusion as well as any infections and adverse reactions.
Blood bank staff should coordinate with clinic staff to ensure both parties obtain copies of the Log Sheets in a suitable and timely manner. It is recommended that the clinic receive the Log Sheets from the patient, verify the contents, and then forward a copy to blood bank. Log Sheets that are resubmitted by the patient with revisions or corrections should follow the same process.

In the case of severe adverse reactions, such as anaphylaxis, the clinic and blood bank must be notified immediately.

### 5 Funding of Home Administration

All hospitals in the Atlantic Region obtain their blood and blood products from the national blood operator, CBS. The blood and blood products used in the provinces are paid for by the provincial governments. As a result, patients will not be required to pay for the SCIG.

Each province should follow its own policy for the provision of supplies to patients for use in home administration. In cases where supplies are not funded, patients will be expected to pay for their own supplies. Private insurance may cover some items such as an epinephrine device. In the event that the supplies are not provided by the facility it is important to consider this in your planning as this may cause delays in transitioning patients to SCIG.

Supplies for the Pump Method of administration:
One of the more costly items required for the infusion is the syringe driver pump. Inquiries can be made to CSL Behring regarding their pump donation program. Call Customer Service at 1-866-773-7721 for the name and contact information for your local area manager. More information about pumps can be found in the section on supplies.

Supplies for the Push Method of administration:
- SCIG vial(s) (at room temperature)
- Infusion Log Sheet
- Chlorohexidine swabs and alcohol swabs
- 18 gauge blunt fill needle(s)
- 10 ml syringe(s)
- 25G X ½” butterfly needle
- Sharps disposal container
- Gloves (if recommended)
- 2X2 gauze
- Band-Aid
6 Patient Education

6.1 Qualified Patient Educators

To implement a home infusion program, a facility must have qualified personnel to provide the necessary patient education. It is estimated that each patient will require two to four sessions of about one to three hours each to become skilled at everything required for safe and effective self-administration in the home. Prior to delivering the initial teaching sessions, patient educators should also have time to familiarize themselves with all teaching materials and other information such as the product monograph and pump/push instruction manual.

6.2 Training for Patient Educators

As of February 1, 2011 only the manufacturer of Vivaglobin®, CSL Behring, has a training program for patient educators. Sessions can be arranged by contacting your CSL Behring local area manager. Call Customer Service at 1-866-773-7721 for the name and contact information for your local area manager. This is focused on the pump method.

Training material for patient educators on the Push and Pump methods are included within this document.

6.3 Patient Learning

It is estimated that each patient will require two to four sessions of about one to three hours each to learn all that is required for safe and effective self-administration in the home. To complement the instructions provided by a health care professional, a set of detailed instructions for patient/family use has been created as separate documents, one for the pump method and one for the Rapid Push. Patients and families should use the instructions during education sessions and as a resource when at home. This document is available on the included CD-ROM.

To assist with patient education sessions, a skills checklist is provided. This checklist can be found in Appendix D3 for pump method and Appendix E3 for push method. Microsoft Word versions of these forms are available on the included CD-ROM.

6.4 Patient Quick Reference Sheet

The patient instructions have spaces in which information specific to a single patient’s administration can be written (e.g. total vials required for a single dose, etc.). These are located in various sections of the education package. When a patient becomes more comfortable with self administration and less reliant on the details of the education package, it may be helpful to have all the patient-specific information in one place to eliminate the need to flip through the many pages of the education package. A quick reference page is provided for this purpose. Educators should fill in the required information for patients/families.
Also on the quick reference page is a table that lists contact names and information in the event that issues arise related to the handling and administration of SCIG. This should be completed according to local contact information. This page is shown in Appendix D4 for pump method and Appendix E4 for push method. A Microsoft Word version is available on the included CD-ROM.

# 7 Roles and Responsibilities

The following is a list of the roles and responsibilities of the patient/family and principle health care professionals involved in an SCIG home infusion program. Further details of the individual listed items can be found in the relevant sections of this document.

## 7.1 Physician Roles and Responsibilities:

- In compliance with CSA standard clause 17.1.4, SCIG intended for home transfusion shall be prescribed by a licensed physician
- Determine patient eligibility for SCIG home infusion program based on the clinical criteria, contraindications, and the patient’s ability to comply with guidelines for administration
- Obtain the consent for home administration of SCIG
- Discuss with patients/families potential adverse reactions and how to manage them
- Prepare all necessary prescriptions (e.g. epinephrine device)
- Monitor patient progress through regular follow-up assessments
- Be available for telephone consultation to address adverse reactions occurring in the home. An alternate on-call physician can be made available for evenings, weekends, and/or holidays

## 7.2 Nursing Roles and Responsibilities:

Note: The following may be the responsibility of a single person or may be divided between a nurse educator and a clinic nurse.

- Educate patients on safe and effective self administration of SCIG. Topics include:

<table>
<thead>
<tr>
<th>Pump Method</th>
<th>Push Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic technique and infection control</td>
<td>Aseptic technique and infection control</td>
</tr>
<tr>
<td>Pump care and use</td>
<td></td>
</tr>
<tr>
<td>Priming infusion set</td>
<td>Removing air from the tubing</td>
</tr>
<tr>
<td>Site selection/catheter choice</td>
<td>Site selection/catheter choice</td>
</tr>
</tbody>
</table>
### Subcutaneous needle/catheter insertion

- Proper storage and disposal of supplies
- Expected adverse reactions and how to address them
- Use of the patient log sheets
- Important contacts and when to use them

### Proper storage and disposal of supplies

- Proper storage and disposal of supplies

### Expected adverse reactions and how to address them

- Expected adverse reactions and how to address them

### Use of the patient log sheets

- Use of the patient log sheets

### Important contacts and when to use them

- Important contacts and when to use them

- Review and complete the patient agreement with the patient/family
- Follow up technique observation (suggest one month after initial education sessions and scheduled periodically thereafter)
- Organize the provision of infusion pumps and ancillary products (tubing, syringes, swabs, etc.)
- Organize clinic follow-up visits (synchronization with pick up of SCIG at blood bank is desirable)
- Organization of all necessary prescriptions (e.g. epinephrine device)
- Document and notify the physician and blood bank of any adverse events
- Review and complete with the patient the responsibility agreement and maintain a record of the completed agreement

#### 7.3 Blood Bank Roles and Responsibilities:

- Issue SCIG to patient/family
- Document issuing of SCIG
- If the patient/family will be storing SCIG in the fridge, pack SCIG in the transport cooler according to the recommended packing protocols. Home fridge storage is only necessary if there is a chance the product will be kept in the home for more than 5 months or the storage temperature may be less than 2° C/exceed 25° C
- If necessary, validate a thermometer for patient/family use in monitoring the temperature of the fridge used to store SCIG
- Advise patient/family on proper transportation and home storage of SCIG
- Document infusions of SCIG
- Ensure traceability of SCIG in the lab information system
- Report any adverse events according to the provincial reporting standard
- Report utilization of SCIG in the same manner as for IVIG, using the IVIG reporting tool currently in use

#### 7.4 Patient Roles and Responsibilities:

- Complete home infusion training and demonstrate self-administration until competency is established
• Undergo periodic reassessment regarding the infusion technique as per an established review schedule or based on needs during subsequent follow up
• Follow the instructions for home infusion as per the patient education materials or the written modified program provided by the nurse educator
• Contact the nurse educator when questions regarding supplies or the home infusion process arise
• Maintain and dispose of equipment as instructed
• Perform home infusion in a safe and clean environment
• Administer doses on the schedule determined by the physician
• Ensure an adult who is not undergoing the infusion is present for the duration of the infusion and for 60 minutes following the completion of the infusion
• Complete a Patient Infusion Log Sheet for each infusion and submit a copy as instructed
• Document all adverse reactions on the Patient Infusion Log Sheet. Any adverse reaction that requires emergency medical attention should be reported to the patient’s physician before administering any further doses. Do not call a nurse educator to report or seek advice concerning clinical symptoms or reactions to infusions
• Order, transport, and store SCIG according to the instructions provided
• Attend all scheduled clinic appointments
• Have a clear understanding of the risks associated with administration of SCIG outside the hospital environment
• Bring in the cooler and ice packs when picking up additional product

8 Consent for Home Infusion

The consent for treatment with SCIG should be obtained by the patient’s physician and shall cover the items from the CSA Standards listed below in Table 1.

Table 1: Clauses from the CSA Standards Related to Consent for Home Transfusion

<table>
<thead>
<tr>
<th>Clause</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.2.1</td>
<td>There shall be an operating procedure for obtaining informed consent of the recipient prior to the transfusion of blood and blood components. Information given to the recipient shall include: a) a description of the blood or blood components; b) the associated risks and benefits, including life-threatening risks; and c) alternatives, if appropriate, to clinical circumstances, including benefits and risks.</td>
</tr>
<tr>
<td>17.3.1</td>
<td>Written informed consent shall be obtained before starting home transfusion. This shall be the responsibility of the recipient’s attending physician</td>
</tr>
<tr>
<td>17.3.2</td>
<td>Recipients shall be made aware that transfusion in the home is associated with additional risk.</td>
</tr>
</tbody>
</table>
Facilities should use a consent form that has been approved by legal counsel in the respective health district or region. The consent form does not need to be specific to SCIG or home infusion as long as the points listed in Table 2 below are addressed in the conversation between patient/family and physician. A sample transfusion consent form is provided in Appendix D5 for pump method and E5 for push method. This sample has been developed by the NSPBCP with advice from legal counsel at the Nova Scotia Department of Health. A Microsoft Word version of this form is available on the included CD-ROM.

The discussion points in Table 2 are available on a quick reference sheet and can be found as a PDF file on the included CD-ROM.

In addition to consent, the patient responsibility agreement described in the Safety and Adverse Events section below should also be completed.

### Table 2: Points to be Addressed When Obtaining Consent for Treatment with SCIG

- **SCIG is derived from human plasma and, even though all donors are carefully screened by medical history and sensitive laboratory tests, and the manufacturing process includes viral removal and inactivation steps, these measures cannot completely eliminate the risk of infection or other adverse reactions including serious injury and/or death.**

- **Post-marketing surveillance of SCIG use has shown rare cases of the following adverse events:**
  - Allergic reactions including a fall in blood pressure, dyspnea, cutaneous reactions, in isolated cases reaching as far as anaphylactic shock, even when patients have shown no hypersensitivity to previous administration
  - Generalized reactions such as chills, fever, headache, malaise, nausea, vomiting, arthralgia, and moderate back pain
  - Cardiovascular reactions particularly if the product is inadvertently infused intravascularly
  - Local reactions at the injection site or infusion site: swelling, soreness, redness, induration, local heat, itching, bruising or rash.

- **Administration of SCIG in the home is associated with additional risk related to the absence of health care professionals along with the absence of the assessments and treatments they provide related to adverse reactions.**

### 9 Supplies Required for Administration

For the Pump Method, one of the more costly items required for the infusion is the pump. Effective February 1, 2011 CSL Behring is the only SCIG manufacturer with a pump donation program. Inquiries can be made to CSL Behring regarding their pump donation program. Call Customer Service at 1-866-773-7721 for the name and contact information for your local area manager. The patient instructions that accompany these guidelines are based around the use of the Smiths Medical Graseby MS 16A Hourly Rate Syringe Driver. This pump is covered by a one
year warranty. After the warranty period, it is up to the patient and/or health care facility to cover the cost of any servicing or repairs. Provinces can decide if the Graseby syringe driver or a different type of pump should be used based on their particular needs.

The following should be considered when selecting a pump:

- Capable of accommodating a rate of delivery in milliliters per hour (approx. 20 ml/hr required). A syringe driver style pump may have the rate of delivery in mm/hr but can be converted from ml/hr based on the ml per mm of the syringe to be used
- Capable of delivering a large enough dose (15 ml per injection site is recommended and multiple sites can be infused simultaneously when multi-needle infusion tubing is used)
- Easy for patients to set up and operate
- Lightweight and portable
- Suitable for use in the home setting

Facilities should consider having one or more spare syringe drivers or pumps available to lend to patients in the event there is a problem with a patient-owned device.

Several other items are required for infusion of SCIG. Following is the list of the suggested supplies required for both Pump and Push Methods:

- Transportation container (for carrying SCIG from hospital to the home)
- Epinephrine device (for possible anaphylactic reactions)
- Syringes (for syringe driver)
- Alcohol swabs (for disinfecting the rubber stoppers of the vials)
- Antiseptic-treated wipe (for preparing administration sites)
- Adhesive tape (for holding tubing in place during administration)
- Transparent dressings (for topical anesthetic and subcutaneous needle)
- Transfer (fill) needles, 18 gauge, 1 inch, blunt (for drawing SCIG from the vials into syringes)
- Topical anesthetic (for preparing administration sites)
- Biohazard sharps container (large size) (for disposal of items after administration) – check local drugstores for sharps exchange programs
- Multi-needle subcutaneous infusion set (e.g. Trifurcated 36” MCT1360924G 9mm needle 24 gauge, wing set) (for administration)
  - Needle gauges of less than or equal to 25 are recommended to minimize resistance when product travels through the bore of the needle
  - Choice of needle length will depend on the subcutaneous tissue available:
    - For children, lengths of 6–9 mm are recommended
    - For adults, lengths of 9–12 mm are recommended

The storage details of the SCIG products must be followed from their respective product monograph. In general SCIG products can be stored at room temperature for up to 5 months. If there is chance patients may store SCIG products for longer than 5 months or cannot maintain the
product within its approved temperature range, a cold chain must be maintained and the following additional items are required:

- Cooler and packing materials (for transport of product from hospital to patient’s home):
  - Igloo Cool 16 Quart cooler
  - One 24 oz Blue Gel Pack
  - One 96 oz Blue Gel Pack
  - One or two (depending on the outdoor temperature) 36 oz Blue Gel Pack(s)
  - Five to seven (depending on the outdoor temperature) 12 ml/cell 12 x 4 flexible insulating blankets

- Certified or validated thermometer (for patient monitoring of storage temperatures)

More information can be found in the Transportation and Storage section.

10 Safety and Adverse Events

The section of the CSA Standards related to home transfusion addresses adverse events\(^1\). The specific items are listed in Table 3. Health care providers should ensure all requirements are met for each patient before home infusion of SCIG can take place. Where appropriate, these items are also addressed in the relevant supplemental documents and patient materials that are provided.

### Table 3: Clauses from the CSA Standards Related to Home Transfusion and Adverse Events\(^1\)

<table>
<thead>
<tr>
<th>Clause</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.2.1</td>
<td>Only recipients who have previously received a blood transfusion* and who have not had an adverse reaction should be eligible to receive home transfusion.</td>
</tr>
<tr>
<td>17.2.3</td>
<td>The home environment shall be evaluated and deemed safe for transfusion.</td>
</tr>
<tr>
<td>17.2.4</td>
<td>The recipient home shall have a working telephone, and should have access to emergency services that can provide a rapid response at the recipient’s location.</td>
</tr>
<tr>
<td>17.2.5</td>
<td>Another competent adult shall be available to assist the transfusionist** for the entire period of the infusion and remain available to the recipient for at least 60 min. thereafter.</td>
</tr>
<tr>
<td>17.6.2</td>
<td>A physician shall be available by telephone for immediate consultation should urgent medical care be required.</td>
</tr>
<tr>
<td>17.6.3</td>
<td>An operating procedure for handling potential complications shall be available.</td>
</tr>
<tr>
<td>17.6.4</td>
<td>There shall be a written protocol for administration of medications to treat adverse reactions. The medications shall be available throughout the transfusion and should only be administered as specified by a physician’s prescription.</td>
</tr>
</tbody>
</table>

* “blood transfusion” in the case of SCIG home administration refers to the subcutaneous infusion of SCIG.
** “transfusionist” in the case of SCIG home administration refers to the person administering the SCIG
An additional clause of the CSA Standards, clause 17.6.1, states the recipient’s vital signs shall be monitored and documented. Based on current practice with other self-administered blood products such as clotting factors, it was decided self-monitoring of vital signs by the patient or family is not required. However, patients should be closely monitored during the first infusion in the hospital in case there is anaphylaxis and patients must have an epinephrine device with them during all infusions administered outside the hospital.

Please refer to the SCIG product monograph for current and complete safety and adverse events information.

10.1 Responsibility Agreement

To reinforce the importance of safety, patients shall complete the responsibility agreement. This provides a list of the expectations of the patient/family for self-administering SCIG in a safe and effective manner. Also included on this agreement is a waiver of responsibility for the hospital and staff in the event there is an adverse outcome related to administration. The responsibility agreement can be found in Appendix D6 for pump method and E6 for pump method. An electronic version is available on the included CD-ROM.

10.2 Reaction Documentation and Reporting

Patients are to document all reactions, regardless of the severity, that occur related to the infusion of SCIG using the Patient Infusion Log Sheets. The log sheet can be found in Appendix D2 for pump method and appendix E2 for the push method. PDF versions can be found on the included CD-ROM which can be printed for patient use. The PDF version can also be given to patients so they may print more copies if required.

In the case of a severe reaction such as anaphylaxis, the reaction is to be reported immediately to the patient’s physician or the on-call immunologist and the blood bank. Blood bank staff are to report all reactions according to their provincial reporting standard.

Blood bank staff should coordinate with clinic staff to ensure both parties obtain copies of the Log Sheets in a suitable and timely manner. It is recommended the clinic receive the Log Sheets from the patient, verify the contents, and then forward a copy to blood bank. Log Sheets that are resubmitted by the patient with revisions or corrections should follow the same path.

10.3 Safe Disposal of Waste

Patients should use a large biohazard sharps container to dispose of all items that have come into contact with SCIG during the preparation and administration of the infusion. This includes syringes, needles, administration sets, and vials. All opened vials must be discarded even if they contain residual product.
Patients should check with local drugstores for sharps containers exchange programs. During transportation, care must be taken to ensure the lid is securely sealed on filled containers. Containers must not be filled beyond the manufacturer’s full line mark.

The items for disposal should only be placed in a biohazard sharps container. The items must not be placed in garbage or recycling bags and must not be flushed down the toilet or burned.

If an exchange program is not available, patients may purchase their own biohazard sharps containers. The local municipality or public health units should be contacted to determine the proper method for disposal.

11 Product Issuing and Tracking

It is suggested patients call the blood bank to make arrangements for issuing of each batch of SCIG. A time frame should be agreed upon to ensure enough lead time between the date of the call and the date the product is required for infusion. It may be convenient to arrange for issuing to coincide with clinic appointments.

To simplify transportation and storage of SCIG for patients, issuing of product to patients should occur only once or twice a month at the outset. The issuing interval may later be increased according to the comfort level of both the issuing blood bank and the patient/family.

Traceability of product is very important and can be maintained using an issuing form along with the Patient Infusion Log Sheet. A sample issuing form for blood bank use can be found in Appendix D7 for pump method and Appendix E7 for push method; and the Patient Infusion Log Sheet can be found in Appendix D2 for pump method and E2 for push method. Electronic versions of these forms can be found on the included CD-ROM.

As described above in the section, “Reaction Documentation and Reporting,” blood bank staff should coordinate with clinic staff to ensure both parties obtain copies of the Log Sheets in a suitable and timely manner. It is recommended that the clinic receive the Log Sheets from the patient, verify the contents, and then forward a copy to blood bank. Log Sheets that are resubmitted by the patient with revisions or corrections should follow the same path.

Each time product is dispensed, an issuing form should be completed and copies of the patient log sheets for the infusions since the previous dispense should be collected. Log Sheets may be collected on a more frequent basis if desired in which case patients can be asked to fax their Log Sheets. Copies of the Log Sheets should be retained in the blood bank and the relevant information should be entered into the blood bank information system. Infusion dates should be documented for utilization reporting purposes (see the SCIG Utilization Reporting section). Blood bank staff should coordinate with clinic staff to ensure both parties obtain copies of the Log Sheets in a suitable and timely manner.

It is important patients record the SCIG lot numbers from each vial used in the space provided on the log sheet. Home fridge temperature log sheets should also be verified for completion and required temperatures before dispensing additional product (see the Cold Chain Maintenance
section. A copy of the physician’s order for SCIG should be kept in the blood bank and patients should only be provided with the prescribed amount. Expired, broken, or spoiled product should only be replaced if the original vials are returned. Any discards should be documented on the same issuing form which documents the issue of the discarded vial(s).

12 Transportation and Storage

Clause 17.5 of the CSA Standards states the transportation procedure shall ensure product will remain at the required conditions until the time of transfusion1.

SCIG can be stored for 36 months in the refrigerator at +2 to +8 °C (+36 to +46 °F)2. It may be stored at room temperature (not exceeding +25 °C) for a period of up to five months (only within the overall storage period of 36 months). With this allowance for room temperature storage, patients/families may transport and store SCIG without the use of refrigeration, as long as there is no chance the home storage time will exceed five months for any vials.

For room temperature storage, the date of removal from refrigeration and the new expiry date must be noted on the product carton in the space provided before issuing. The new expiry date should be five months from the date the product is removed from the refrigerator. If, on the date the product is removed from refrigeration, the original, stamped expiry date is closer than five months, the expiry date should not be altered. Once product is removed from refrigeration, it cannot be returned2.

Care must be taken to protect the vials of SCIG during transportation and storage. A puncture-proof plastic container such as a hard-sided cooler or plastic storage bin is recommended. The transport container should not be used for any other purpose than for transporting SCIG.

Care must be taken to ensure storage temperature does not exceed +25 °C. Vials must be kept away from direct sunlight, heaters, and any other heat sources.

If there is a chance patients will be storing vials of SCIG in their homes for longer than five months, cold chain maintenance procedures must be followed for transportation of product from the hospital to the home as well as for home storage. Details of a cold chain maintenance protocol for SCIG can be found in Appendix D8 for pump method and Appendix E8 for push method.

13 SCIG Utilization Reporting

Utilization of SCIG is to be reported by blood bank staff using the existing IVIG data collection tools. Data is to be entered in the same manner as for IVIG except “Sub-Q” should be selected for “Type of Ig.” Doses should be reported based on dates of infusion and not the dates of issue. Any SCIG discards should also be reported in the discards section of the IVIG data collection tool.
14 Patient Relocation

Description

Situations when a patient may receive his or her teaching and first doses at one hospital (referring facility), then move to another location (target facility) for the remainder of the course of treatment and follow up require coordination between the health care professionals in each jurisdiction (province, territory).

Other situations include:
- Patients moving from one province or territory to another, for a vacation or other purpose, possibly long term in nature
- Patients visiting a province or territory from another country

Definitions

Referring physician: physician taking care of the patient at origin (home) location
Target physician: physician taking over care of the patient in new location

Principle

Early identification and communication are the important elements of such a transition.

Process

<table>
<thead>
<tr>
<th>Step</th>
<th>Most Responsible Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate contact with the target facility through the target physician who will be taking over the care of the patient.</td>
<td>Referring Physician</td>
</tr>
<tr>
<td>Notify nursing and laboratory Transfusion Service staff at the target facility; identify status of facility regarding use of the product.</td>
<td>Target Physician</td>
</tr>
<tr>
<td>Facilities unfamiliar with the product need additional support and documentation in order to establish protocols.</td>
<td>Target Physician and Referring Physician</td>
</tr>
<tr>
<td>Prepare for receiving patient by obtaining and reviewing specific information on the treatment and follow up, and patient’s training status for using product.</td>
<td>Referring facility nursing staff and Target facility nursing staff</td>
</tr>
<tr>
<td>Prepare for receiving patient by reviewing procedures for product ordering, issuing, storage and any other relevant details specific to the patient.</td>
<td>Laboratory transfusion service staff</td>
</tr>
<tr>
<td>Relevant documents should also be obtained and transferred. Consent documents and infusion logs are examples of relevant documents.</td>
<td>Referring physician and Target physician</td>
</tr>
<tr>
<td>Staff at the target facility may also wish to consider arranging an education session provided by the manufacturer of the SCIG product.</td>
<td>Target facility nursing and laboratory staff</td>
</tr>
</tbody>
</table>
15 References


2. CSL Behring Canada I. Vivaglobin - Product Monograph. 2009.


4. Eleni Galanis, Cheryl McIntyre, Joan Rousseau, Don Easterbrook. British Columbia Mass Immunization Clinic Cold Chain Project 2005-06; A collaboration between the BC Centre for Disease Control, BC Health Authorities, Cryopak Industries and sanofi pasteur. 2006 Nov 1.
Appendix A  Atlantic SCIG Working Group Membership

Membership of the Atlantic SCIG Home Infusion Program Working Group (Last updated January 25, 2011)

New Brunswick

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Clinical Coordinator Transfusion  
Medicine, Restigouche Health Authority

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Dr. Jennifer Fesser  
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Appendix B  Guide to Acronyms and Abbreviations

The following is a list of the acronyms and abbreviations used in the text of this document:

- **ABUS**  Atlantic Blood Utilization Strategy
- **CBS**  Canadian Blood Services
- **CSA**  Canadian Standards Association
- **IVIG**  Intravenous Immunoglobulin
- **NAC**  National Advisory Committee on Blood and Blood Products
- **NIST**  National Institute of Standards and Technology
- **NSPBCP**  Nova Scotia Provincial Blood Coordinating Program
- **SCIG**  Subcutaneous Immunoglobulin
- **PID**  Primary Immune Deficiency
Appendix C  Atlantic Guidelines for the Use of IVIG/SCIG in Primary Immune Deficiencies

The guidelines presented in this document are based on those authored by the NAC in 2010 and were modified and ratified for use in the Atlantic Provinces by the Atlantic IVIG Clinical Expert Working Group-Primary Immune Deficiency in December 2010.

1. Start IVIG at a dose of 400 to 600 mg/kg every 4 weeks in adult patients and 600 to 700 mg/kg every 3 to 4 weeks in pediatric patients. SCIG is given in weekly divided doses.
   Note: With respect to clinical efficacy for reducing infections, IVIG and SCIG preparations should be considered equivalent. For patients previously receiving IVIG, the SCIG dose should normally be equivalent to the IVIG dose the patient was receiving i.e. 1:1
   **Clinical considerations:** If there is bronchiectasis, dose and frequency of IG may be increased. Dosage of IG should be adjusted to prevent unnecessary wastage.

2. Patients with primary immune deficiency should be monitored by an expert in the treatment of patients with primary immune deficiency at least annually.

3. Aim to achieve a minimum IgG trough level of 7g/L in most patients.

4. Monitor IgG trough levels every 3 to 6 months in growing and in adult patients.
   **Clinical considerations:** The IgG trough generally stabilizes after 3 to 4 months of treatment with IVIG. After this time, regular monitoring of IgG trough levels allows adjustment of immunoglobulin dosage. Measurement of IgG trough levels may be necessary between regularly scheduled monitoring if the clinical situation changes.

5. The following conditions should prompt reevaluation of the IG dosage regimen before the annual visit:
   A. Any severe infection
   B. Lack of expected reduction in frequency or severity of infection
   C. Continued failure to thrive in pediatric patients
   D. Development of autoimmune complications
   **Clinical considerations:** Clinical judgment should be used as there may be other situations that would prompt reevaluation.

6. To minimize rate-related reactions, follow product specifications.
   **Clinical considerations:** As patients tolerate different rates of IG administration, adjust rates individually to optimize the rate of infusion. Reducing the rate of infusion often ameliorates rate-related reactions.
Appendix D

Subcutaneous Immunoglobulin (SCIG)

Patient Teaching Guide for Self Administration Using Syringe Driver (Pump)
Acknowledgements

CSL Behring Canada
Medical Day Unit Staff of CDHA
Medical Day Unit Staff of IWK

Note:
This document only covers the relevant information about SCIG. It does not cover all the details of the product. To get the best possible results from treatment, follow your Doctor’s instructions about dose and treatment schedule.
What is SCIG?

SCIG is a blood product used to treat adults and children with primary immune deficiency.
What is Primary Immune Deficiency?

Primary immune deficiency (PID) means a person’s immune system does not work properly. People with PID are unable to make certain antibodies - special infection - fighting proteins called immunoglobulin G (IgG). Without these antibodies, there is an increased chance of getting an infection.

- SCIG product replaces the IgG antibodies that are missing. It is called antibody replacement therapy.
- This treatment supports the prevention and treatment of infections.
SCIG Contraindications:

**Allergic Reactions**
SCIG should be avoided in persons with a history of severe allergic reactions to immunoglobulin treatment.

**IgA Deficiency**
SCIG should be avoided in persons with selective IgA deficiency who are known to have antibodies against IgA.
The Ingredients of the Product:

SCIG is made from human plasma and is a highly purified product. It contains immunoglobulin G (IgG), an antibody normally found in the blood of healthy people.

IgG helps the body fight disease and infections.

The other ingredients in SCIG products may include glycine, sodium chloride and water for injection.
Serious Warnings and Precautions:

• SCIG is a product made from donated plasma which is treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease.

• Human Immune Globulin products have been associated with the following:
  • aseptic meningitis syndrome
  • renal dysfunction
  • anemia (hemolysis, hemolytic)
  • TRALI (transfusion-related acute lung injury)
  • thrombo-embolism NOTE: Risk factors in thrombotic event are pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter, immobility, hyperviscosity from any cause including dehydration, hypercoagulable disorders, and multiple cardiac risk factors. Inform your physician if you have any such risk factor.

• Interactions: SCIG should not be mixed with any other products.
What Happens If I Miss A Dose?

– Use the missed dose as soon as you remember, and dose weekly from there. If a certain daily schedule is more convenient, then you can modify the schedule to dose every 6 or 8 days to get you back on schedule.

– Skip the missed dose if it is 48h from your next scheduled dose.
What Should I Avoid While Using SCIG?

• When you are on SCIG and receive a “live” vaccine the vaccine may not work as well during this time, and may not fully protect you from disease.
• Live vaccines include measles, mumps, rubella (MMR), oral polio, chickenpox (varicella), BCG (Bacillus Calmette and Guérin), and nasal flu vaccine.
• Inform the doctor who is giving you the vaccine of recent treatment with SCIG so that appropriate precautions can be taken.
**Transporting SCIG for short term storage**

Storing any vials in your home for less than 5 months is considered short term storage:

- For short term storage SCIG can be transported and stored at room temperature

- Care must be taken to protect the vials of SCIG during transportation
  - A puncture-proof plastic container such as a hard-sided cooler or plastic storage bin is recommended
  - The transport container should not be used for any other purpose than for transporting SCIG
  - During transport, the container should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk
  - Care must be taken to ensure temperature does not exceed the range of +2 °C to +25 °C. Vials must be kept away from direct sunlight, heaters and any other heat sources

- Proceed directly home with the transportation container containing SCIG
Storing SCIG for short term (less than 5 months)

- SCIG must be stored at a temperature of between +2 and +25°C (36 and 77 °F). The product cannot be stored at room temperature then placed back into the fridge.

- Do not allow the vials to be exposed to direct sunlight and do not store near any source of heat. Temperature may exceed 25°C by direct exposure to sunlight and heat source.

- Do not use SCIG after the expiry date. Report it as discarded.

- Keep the vials of SCIG in the boxes during storage.

- Keep SCIG out of the reach of children.
Transporting SCIG for long term storage

Storing any vials in your home for more than 5 months is considered long term storage:

- This set of additional instructions is to be used only if there is a chance any vials of SCIG will be stored in your home for more than five months.
Transporting SCIG for long term storage (continued)

• All vials must be kept cold from the time they leave the fridge at the hospital to the time they are administered. The temperature of the vials must be kept between $+2^\circ \text{C}$ to $+8^\circ \text{C}$ ($+36^\circ \text{F}$ to $+46^\circ \text{F}$), even during transport to your home.

• To maintain the temperature of the product during transportation, SCIG must be carried in a cooler
  – The recommended cooler is the Igloo Cool 16 Quart Cooler.
    • available at Home Hardware; Item # 6450-770
  – When SCIG is packed properly (with cold packs) in this cooler, the proper temperature will be maintained until you get home.
  – The hospital staff providing your SCIG will pack it properly in your cooler. You will need the following (check with hospital staff about acquiring these items):
    • One 24 oz Blue Gel Pak
    • One 96 oz Blue Gel Pak
    • One or two (depending on outdoor temp.) 36 oz Blue Gel Pack(s)
    • Five to seven (depending on outdoor temp.) 12 ml/cell 12 x 4 flexible insulating blankets
Transporting SCIG for **long term** storage (continued)

- Proceed directly home with the packed cooler and place the boxes of vials in the fridge within ten minutes of arriving home

- During transport, the cooler should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk

- Avoid opening the lid of the cooler during transport

- Your transport cooler should not be used for any purpose other than transporting SCIG
**Storing SCIG for long term (more than 5 months)**

- Keep SCIG in the refrigerator between +2°C to +8°C (+36°F to +46°F).
  - It is safe to store SCIG in the regular food fridge, but keep the boxes away from anything that may spill. A thermometer must be used to monitor the fridge temperature.
  - Once a day, check the fridge temperature and record it on the temperature log sheet. Use a thermometer verified by staff in the blood bank. Bring the log sheet with you when you go to pick up more product.
  - Do not freeze SCIG and keep the boxes away from the rear of the fridge to avoid the risk of freezing.
  - Keeping the boxes of vials in a plastic storage container with a lid will help protect the product from freezing and food spills.

- Do not use SCIG after the expiry date. Report it as discarded.

- Store vials in the boxes.

- Keep SCIG and all medications out of the reach of children.
Loss of Refrigeration

• If the fridge temperature goes outside the recommended range (for example, during a power outage), the product should be moved to another location where the proper temperature can be maintained. Some options include:
  – Moving the product to the transport cooler with cold packs. Frozen cold packs should not come in direct contact with the product boxes
  – Using the transport cooler to transport product to a working fridge (for example, in a neighbor’s or friend’s home). Ensure the fridge temperature is within the recommended range
  – Using the transport cooler to transport product to the hospital. In this case, please call the blood bank ahead of time

• In each situation, place the fridge thermometer alongside the product to monitor the temperature. The thermometer should not be in contact with any cold packs
Preparation for Use:

- When SCIG is stored in the fridge, it is important to let the vials reach room temperature before using.

- Do this by taking them out of the fridge for 45 – 75 minutes before the infusion.
How to Infuse SCIG

- SCIG is given as an injection under the skin (subcutaneously)

- SCIG must not be given into a blood vessel (vein or artery) as it is not known if this is safe

- If you experience a serious allergic reaction at any time, STOP the infusion of SCIG and contact your doctor or an emergency health care professional immediately
Safety requirements related to self-administering SCIG are as follows:

- The home (or any administration location) must be clean and safe.
- The home (or any administration location) must have a working telephone, and there must be access to rapidly available emergency assistance, e.g. 911.
- A competent adult should be available to assist the recipient for the entire period of the administration and should remain available to the recipient for at least 60 minutes after administration has been completed.
- An epinephrine device must be available during all infusions administered outside the hospital.
Instructions for Administering SCIG:

Patient name: ________________________________

Your monthly dose of SCIG is: _____ml every _____

You will use _____ vials for each dose

Each dose is given over _____ minutes

You will use _____ injection sites for each dose

The maximum volume for each injection site is _____ ml as directed by your health care provider
Step 1: Gather your supplies

On a clean table, gather all the supplies:

- SCIG vial(s) (at room temperature)
- Infusion Log Sheet
- Syringe driver
- Administration set _____
- Alcohol swabs
- Antiseptic skin preps
- _____ syringe(s), size _____
- _____ needles(s), size _____
- Transparent or gauze dressing(s)
- Tape
- Sharps disposal container
- Gloves (if recommended)
Step 2: The following instructions are specifically for the Graesby Syringe Driver (pump). Please refer to the brochure if using Freedom 60 or any other syringe driver.

- Prepare the pump by inserting the battery. Listen for the alarm
- Do a safety check:
  Press and hold the start/test button. The motor should start and then stop after 5 seconds. The alarm should sound
- Do not use the syringe driver if the motor doesn’t stop or the alarm doesn’t sound. Refer to the instruction manual
- Release the start/test button. The pump will start.
- The light will flash and the motor will sound off and on
- Check the rate of infusion on the pump

*Your rate is ______ mm/hr*

*Do not change your rate unless advised to do so*
Step 3: Wash and Dry Your Hands

Wash and dry your hands thoroughly prior to preparing your SCIG infusion.
Step 4: Inspect Each Vial of SCIG

Check each vial of SCIG for any discoloration or presence of particles in the solution by gently turning the vial (do not shake).

If the solution is cloudy, has particles in it, or if the cap is missing, do not use it. Keep it and return it to the hospital when you go to pick up more product.

Check the expiry date on each vial. Do not use past the expiry date. Call _____________ for a replacement.
Step 5: Prepare the Vial

Remove the cap from the vial(s). Disinfect the rubber stopper by wiping it with an alcohol swab.

Let it dry.
Be careful not to shake the vial(s).
Step 6: Prepare the Syringe and Needle

• You will need ___ size ___ syringe(s)
• You will need ___ needle(s)
• Open the syringe and needle packages. Do not touch the ends where they will connect
• Attach the needle to the syringe by pushing them together and turning until snug
• Repeat these steps if you need to fill more than one syringe
Step 7: Inject Air into the Vials

- Pull the syringe plunger back to draw ____ ml of air into the syringe
- Remove the cap from the needle. Do not touch the needle
- Insert the needle into the center of the stopper of SCIG vial, but not all the way into the solution
- Inject the air into the vial by pushing down on the plunger but avoid injecting any air into the solution. (Holding the vial horizontally may help). Keep pressure on the plunger so air stays in the vial
Step 8: Fill the Syringe

- Leaving the needle in the vial, carefully turn the vial upside down
- Draw the solution into the syringe and remove the needle from the vial
- Draw the solution from each of your other vials into the syringe as directed
Step 8 (continued): Fill the Syringe

• Remove any large air bubbles by tapping the syringe and pushing on the plunger. Be careful not to waste any solution.

• When you have finished filling this syringe, carefully recap your needle and put the filled syringe on your clean table.

• If you use more than one syringe, follow the same steps to fill the next syringe.

• Remove the capped needle from the first syringe and discard into a sharps disposal container.
Step 9a: Prime the Administration Set

Prime the administration set to remove air from the tubing and needle.

To Prime:

- Remove the plastic cap from the end of the tubing. Do not touch the end of your tubing or the tip of the syringe.
- Connect the syringe filled with SCIG to the administration set and slowly push on the syringe plunger to fill the tubing with solution.
- Stop when you see the solution approaching the inner end of the needle. Do not prime to the very tip of the needle.
- Close the clamp.
Step 9b: Priming a Multi-Site Set

If you are using an administration set with more than one tubing (lumen) for use with multiple sites:

- Attach the filled syringe to the end of the administration set.
- Close the clamps on all lumens, except the one you want to prime.
- Gently push on the syringe plunger until you see the solution approaching the inner part of the first needle. Close the clamp.
- Open the clamp on the 2nd lumen. Prime with solution. Close the clamp.

Repeat these steps for all other lumens.
Step 10: Select Injection Site(s)

- You will need to use ____ injection sites
- Select injection site(s) from these areas:
  - Abdomen
  - Thighs (outer or inner)
  - Upper arms
  - Hip

Follow your healthcare providers advice on how often you should change or rotate your sites.
Step 11: Prepare Injection Site(s)

- Clean the site(s) with antiseptic skin prep(s)
- Start cleaning at the center of the site and work outward to cover a circle of about 4 inches
- Let the sites dry
- If using more than one site, make sure each site is at least two inches apart
Step 12: Insert the Needle(s)

- Pinch the skin where you plan to put the needle in
- Insert the needle into the fatty tissue under the skin as directed
Step 13: Check for Correct Placement

After you insert a needle, you must check that the needle has not gone into a blood vessel:

- Open the clamp
- Gently pull back on the syringe plunger
- Look to see if any blood is flowing back into the administration set

If you do not see blood, go to step 14.

If you see any blood, remove the needle and discard the administration set.

Then, repeat steps 9-13 using a new administration set and a new injection site.

If you are using a multi-site set, follow your healthcare provider’s instructions.
Step 14: Securing Each Needle to the Skin

Cover the needle with transparent dressing or gauze and tape it in place.
Step 15: Attach the Syringe to the Pump

• Place the syringe in the V-shaped holder on the top of the pump
• Place the finger grip of the syringe in the first slot on top of the pump.
• Press the white button on the back of the pump to line up the second slot with the end of the plunger
• Sit the end of the plunger in the second slot
• Draw the rubber strap over the syringe and press it into the groove at the front of the pump
• Open clamp(s)

Remember: the pump was already turned on during the Safety Check (step 2) and will now start to deliver your SCIG.
Step 16: Infusing the SCIG

Your syringe of SCIG will take _____ minutes to infuse.
Your total dose will take _____ minutes.

While Infusing, check that:
- The light on the pump is flashing (about once a second)
- The solution appears to be going at the right rate
- The pump motor sounds (off and on)

When the syringe is empty:
- The pump will alarm and stop
- Close clamp(s)
- Remove the syringe from the pump
- Connect the next filled syringe to your administration set
  OR
- Prepare a new administration set (follow your directions)
- Press the start button to restart the pump
Step 17: Stopping the Pump

• The syringe driver will automatically stop when the syringe is empty.

• The pump does not have an OFF switch. If you need to stop the pump before the dose is finished:
  – Move the rate to “00” or take the battery out
  – Then close the clamp(s) on the set or remove the needle from the injection site before removing the syringe from the pump to avoid pushing more solution into the infusion site
  – Press the start button to restart
Step 18a: Following the Infusion

- When your treatment has finished, leave the needle(s) in place for about 1 minute before removing.
- Apply pressure to site with gauze.
- Cover your injection site(s) with gauze or ________.
Step 18b: Following the Infusion

- Discard all preparation and administration equipment in a large biohazard sharps disposal container.
- Once opened even by mistake SCIG cannot be saved. Discard it in the biohazard sharps disposal container.
- Report the discard (if any) in patient infusion log sheet appendix D2 for pump.
- Sharps containers are available from various sharps exchange programs. Your health care provider will tell you about the options in your area.
- Remove the battery from the pump and store pump as directed.
Notes on Sharps Containers

- Items for disposal should only be placed in a biohazard sharps container. The items must not be placed in garbage or recycling bags and must not be flushed down the toilet or burned.

- Use a LARGE size sharps container and do not fill beyond the manufacturer’s full line.

- During transportation, care must be taken to ensure the lid is securely sealed on filled containers.
Step 19: Record the Infusion

On your Infusion Log Sheet you must:

- Record the date and time of the infusion
- Record the exact dose of your infusion
- Record the lot number and expiration date from the vials used
- Record any reactions that occurred as a result of the SCIG infusion
- Record discards if any
- Fill in all the other sections according to the instructions from your healthcare provider

Provide ALL your completed log sheets to your physician at your following visit or you may choose to fax your log sheets after each infusion.
Managing the Side Effects of SCIG
Anaphylaxis

• Although rare in occurrence, anaphylaxis is the most severe potential reaction that can occur as a result of infusing SCIG.

• It is a life-threatening allergic reaction that affects many areas of the body. Anaphylaxis can lead to death in a matter of minutes if left untreated.

• Symptoms of an anaphylactic reaction, as well as instructions for when to give epinephrine, are listed in the following table.

• Note that during an anaphylactic reaction, not all symptoms may occur.

• Always have an epinephrine injection device with you when infusing SCIG and ensure the device has not expired.
  – Expiry date of current injection device: ______________

• Early recognition of symptoms and immediate treatment could save a person’s life. Delay in treatment could cause a more severe anaphylaxis episode. When in doubt, treat with epinephrine.
## Symptoms of an Anaphylactic Reaction

<table>
<thead>
<tr>
<th>Body Region</th>
<th>Symptoms [Note that during a reaction not all symptoms may occur]</th>
<th>Should You Give Epinephrine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face/Head</td>
<td>Redness, itchy eyes/nose, swelling of eyes, runny nose, sneezing</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td></td>
<td>Swelling of lips and tongue, itchy mouth or tongue</td>
<td>Yes</td>
</tr>
<tr>
<td>Skin</td>
<td>Itching, redness, warmth, hives, rash or swelling in areas other than infusion sites.</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>Throat</td>
<td>Itching, tightness, hoarse voice, hacking cough, trouble swallowing, trouble speaking, choking</td>
<td>Yes</td>
</tr>
<tr>
<td>Lungs</td>
<td>Trouble breathing, shortness of breath, repeating cough, wheezing</td>
<td>Yes</td>
</tr>
<tr>
<td>Stomach</td>
<td>Nausea, vomiting, stomach pain or cramps, diarrhea</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>General</td>
<td>Dizziness, unsteadiness, drowsiness, sense of doom, feeling faint or fainting</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Epinephrine Devices

- Epinephrine is a life-saving treatment and is the antidote for anaphylaxis

- There are two types of epinephrine devices:
  - Epi Pen®
  - Twinject®

- Techniques on using these devices should be reviewed regularly. Instructions are available on DVDs and websites. Instructions are also found directly on the devices themselves.

- These devices can be used through clothing.
How to Use Epi Pen®

- Remove the device from its carrying case

- Grasp the Epi Pen® with the black tip pointing downward

- Pull off the grey safety cap

- Place the BLACK tip against the mid-outer thigh and press firmly until the Epi Pen® activates
  - This device can be used through clothing

- Hold while counting for 10 seconds, then remove
How to Use Twinject®

• The Twinject® device contains 2 doses. The second dose is rarely needed

• Pull off the GREEN caps from both ends

• Place the RED tip against the mid-outer thigh and press firmly until the Twinject® activates
  – This device can be used through clothing

• Hold while counting for 10 seconds, then remove
Twinject®- 2nd Dose

- The second dose is rarely needed but should be given if:
  - There is no improvement in symptoms 10 minutes after the first dose is given
  OR
  - There is initial improvement, but then symptoms rebound or return

- Unscrew and remove the RED tip
  - Beware of the exposed needle

- Holding the BLUE hub at the needle base, remove the syringe from the barrel

- Slide the YELLOW collar off the plunger

- Insert the needle into mid-thigh (at least 5 cm (2 inches) from the first injection site) and push the plunger down completely
After Epinephrine is Given

- Call 911 and tell them someone is having a life-threatening allergic reaction. Ask them to send an ambulance immediately.
- You must have medical attention and monitoring if epinephrine is given, even if symptoms have improved.

How to Dispose of Epinephrine Device

- Carefully place the used auto-injector (needle end first) into the storage tube.
- Screw the cap of the carrying case on completely.
  - This automatically bends the needle back and secures the pen so it won’t fall out of the tube.
- Give any used auto-injectors to emergency responders or emergency room personnel.
# Trouble Shooting Subcutaneous Administration of Immunoglobin

| Leaking | • Check connections between tubing and syringe  
• Is the butterfly needle inserted properly  
• Volume administered too quickly therefore leaking at the site |
| --- | --- |
| Insertion site: reaction  
Redness  
Swelling  
Itchiness | • Volume administered too quickly  
• Decrease the volume and spread over a longer period of time  
• Apply cold compress or ice cube to the area before administering subcutaneous immunoglobin  
• Apply warm compress to the area before administering subcutaneous immunoglobin  
• If taping the needle down, you could be getting a reaction to the tape  
• Did any immunoglobin get on the needle while flushing the tubing? (Use 2X2 gauze to wipe off the needle)  
• After cleaning the skin wait a min or two then administer the immunoglobin. The area should be dry prior to puncturing the site  
• Rotate the sites regularly |
| Needle Discomfort | • Needle length too long  
• Rotate sites regularly  
• Apply warm compress to the area before administering subcutaneous immunoglobin  
• Apply cold compress or ice cube to the area before administering subcutaneous immunoglobin |
| Blood in tubing | • Discard butterfly needle and start over |
## Other Reactions to SCIG Signs and Symptoms

<table>
<thead>
<tr>
<th>Site Reaction</th>
<th>Non-pharmacological interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itching</td>
<td>• Slow down on the infusion &lt;br&gt;• Needle in correctly &lt;br&gt;• Apply cold compress &lt;br&gt;• Ensure you are rotating the sites &lt;br&gt;• When priming the needle, do not allow excess SCIG droplets on outside of the needle</td>
</tr>
<tr>
<td>Redness</td>
<td>• Slow down the infusion &lt;br&gt;• Apply cold compress</td>
</tr>
<tr>
<td>Burning</td>
<td>• Stop infusion for 5–10 minutes then restart &lt;br&gt;• Slow the infusion down &lt;br&gt;• Cold compress &lt;br&gt;• Gentle massage &lt;br&gt;• Change site</td>
</tr>
<tr>
<td>Swelling</td>
<td>• Warm compress for 5-10 minutes</td>
</tr>
<tr>
<td>Urticaria (hives)</td>
<td>• Stop SCIG &lt;br&gt;• Seek medical attention &lt;br&gt;• Determine with physician if treatment should continue</td>
</tr>
<tr>
<td>Discomfort</td>
<td>• Slow infusion &lt;br&gt;• If intolerable pain – may be in muscle, remove catheter &lt;br&gt;• Once needle removed, warm compress and gentle message</td>
</tr>
</tbody>
</table>
Injection Site Reaction

Mild

Moderate
Injection Site Reaction

- Injection site reactions can be identified by what is usually mild to moderate redness, swelling, discomfort, and itching
- This is a normal and common reaction which should fade over 24 – 48 hours
- Keep a record of any injection site reactions on your Infusion Log Sheet
- Your physician can recommend ways to lessen discomfort related to injection site reactions
- Use of ice during administration or dividing dose between abdomen and thighs can lessen the discomfort
- If the injection site reactions are severe or if you are concerned about them, call your doctor or nurse using the contact information provided
- If itchiness persists you can consult your physician
Other Common Reactions

- There are some other common reactions that can occur related to the administration of SCIG. If any of these occur, make a note on your log sheet:
  - **Headache:** Some patients get headaches in the beginning, but they decreased after some time. You could take Tylenol 1-2 tablets orally every 4-6 hours, may last two to three days. The headache could also be triggered by stress or stressors. (I.e. anxiety, tension)
  - If your headache is prolonged contact the clinic
  - **Fever and/or Chills** (for a fever - note on the log sheet your temperature and how long after the infusion it began)
  - **Nausea**
  - **Mild or Moderate Rash**

- Any other reactions that are felt to be a result of the administration of SCIG should also be noted on the log sheet

For more information on side effects see the SCIG product insert
Uncommon Side Effects

- Diarrhea
- Gastrointestinal
- Allergic
- Increased Cough
- Pain
- Sore Throat

If, at any time, you are concerned about anything related to the administration of SCIG, or if you have any unusual reactions call your doctor or nurse.

You should also call the clinic if any of the following occur post infusion:
- Shortness of breath
- Chest discomfort
- Pain to shoulder, arm or leg
- Injection site continues to bleed
- Fever lasting > 24 hours
Traveling with SCIG

When planning your trip you should:
• Get a travel letter from your clinic, it will have:
  A. Your name and diagnosis
  B. Name of the drug
  C. Dosage
  D. The reason you are to carry gel/ice packs.
  E. Contact information
• Make a list of the supplies you will need
• Always carry an extra week in case of unexpected delays. Outside Canada advance notice will be needed so arrangements can be made with the nearest clinic and/or hospital
Packing SCIG:

A. The product must be kept in its original box
B. Use a container that can hold freezer/ice packs
C. When using ice packs:
   – SCIG should not be placed in direct contact with the ice
   – Use towel or something to separate the two
   – If there is a chance of the box getting wet place in a zip lock bag to keep it dry

• Your product must be kept with you at all times. It is considered a “carry on bag”
• Always consider travel insurance

When traveling with SCIG outside of Canada and USA:
• Check with your travel agent for restrictions on traveling with liquids at points of departure
• Check Customs requirements
• You will need stickers from the hospital to put on every box you are taking
Appendix D1: Pre-Printed Order Form for Pump Method

The following shows the pre-printed order form for SCIG. For actual use, see the order form file on the CD-ROM provided with these guidelines. Note how the second page is designed to be printed on the back of the order form for reference.
Dosing Guidelines

Start SCIG at a dose of 400 to 600 mg/kg every 4 weeks in adult patients and 600 to 700 mg/kg every 3 to 4 weeks in pediatric patients. SCIG is given in weekly divided doses. Over time it may be necessary to adjust the dose based on serum IgG levels and clinical response. The weight-based dosing is the same for pediatric patients; however, the safety and efficacy of SCIG has not been studied in children less than two years old.

For patients who are switching from IVIG to SCIG an initial SCIG dose can be calculated based on the previous IVIG dose. Patients will require an equal amount of SCIG, but divided weekly doses. The following can be used as a conversion equation:

Initial SCIG dose (g/week) = \( \frac{\text{previous IVIG dose (g)}}{\text{previous IVIG treatment interval (weeks)}} \)

**Sample Calculation:** A patient was receiving 38 g of IVIG every 3 weeks. The new dose for SCIG would be:

Initial SCIG dose = \( \frac{38 \text{ g of IVIG}}{3 \text{ weeks}} = 12.66 \text{ g of SCIG per week} \)

**NOTE:** Administering the infusion requires the amount of product to be measured in ml. For example, if SCIG vial contents are 0.160 g/ml (vial concentrations may vary with different products as SCIG comes in different concentrations e.g. 16%, 20%, 10% and this is how you would do the calculation). Please check and use the specific vial concentration of the product that you are using. The following equations may serve as a sample to calculate the total volume required for a single daily dose.

**Sample Calculation:** A patient needs to infuse a 12.66 g daily dose each week. The volume in ml of SCIG that is needed for each dose would be:

SCIG dose (ml) = \( \frac{12.66 \text{ g of SCIG}}{0.160 \text{ g/ml}} \) (If you are using a SCIG product with 16% concentration)

\[ \Rightarrow \text{SCIG dose (ml)} = \frac{12.66 \text{ g of SCIG}}{0.160 \text{ g/ml}} = 79 \text{ ml of SCIG} \]

**OR**

SCIG dose (ml) = \( \frac{12.66 \text{ g of SCIG}}{0.10 \text{ g/ml}} \) (If you are using a SCIG product with 10% concentration)

\[ \Rightarrow \text{SCIG dose (ml)} = \frac{12.66 \text{ g of SCIG}}{0.10 \text{ g/ml}} = 126 \text{ ml of SCIG} \]

For patients switching from IVIG to SCIG, the first dose should be given within one week after the last IVIG dose.

Vials are available in different sizes and doses and should be rounded to the nearest vial size. Sample rounding: A calculated dose of 50 ml can be left as is (using eight 10 ml vials). A calculated dose of 79 ml should be rounded up to 80 ml (using eight 10 ml vials). A calculated dose of 81 ml should be rounded down to 80 ml (using eight 10 ml vials). A calculated dose of 82 ml should be rounded up to 83 ml (using eight 10 ml vials and one 3 ml vial).

Some dose adjustments may be required over time to achieve the intended clinical response and serum IgG level.

Monitoring of IgG Levels

A target serum IgG trough level of at least 7 g/L should be maintained. IgG levels should be measured monthly at the beginning of the treatment with SCIG, but as IgG levels are found to be stable, monitoring can be less frequent every 3 to 6 months.
Appendix D2: Patient Infusion Log Sheet for Pump Method

The following shows the Patient Infusion Log Sheet. For actual use, see the file on the CD-ROM provided with these guidelines. Electronic versions may be given to patients to allow them to print their own copies at home.

### Appendix D2: Patient Infusion Log Sheet

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Physician Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID:</td>
<td>Hospital Name:</td>
</tr>
<tr>
<td>Nurse Name:</td>
<td>Fax/email:</td>
</tr>
</tbody>
</table>

#### Infusion Details
- Infusion Date:
- Infusion start time:
- Infusion end time:
- Total dose: ml
- Rate per site: ml
- Rate per hour:
- Record the lot number of all medications used in this dose:
- Discard any unused:
- Side effects related to this dose:

#### Patient Feedback
- I have had an infection during the past week (explain):
- Fever associated with the infection: °C
- After my SCIG therapy last week, I felt:
  - Better
  - Same
  - Not as well

#### Infusion Sites
- Sites Infused (mark each site with an X along with the infusion date):

#### Questions to Ask
- Questions to ask my doctor or nurse:

#### Signatures
- Patient Signature:
- Witness Signature:

#### Log Verification (for Hospital Use Only)
- Name:
- Title:
- Hospital:
- Date:
Appendix D3: Skills Checklist for Pump Method

The following shows the Skills Checklist. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

**Subcutaneous Immunoglobulin Home Infusion Skills Checklist**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Name &amp; Role of Person Responsible for Infusions (if different from patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The educator should enter the date & his/her initials to document when each skill is introduced, reinforced, & mastered.

<table>
<thead>
<tr>
<th>Patient Skills</th>
<th>Introduced</th>
<th>Reinforced</th>
<th>Mastered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date</td>
<td>Initials</td>
<td>Date</td>
</tr>
</tbody>
</table>

- Transportation and storage requirements for SCIG
- Define subcutaneous administration and location of tissue
- Describe appropriate sites for catheter placement.
- Describe appropriate care of infusion site.
- Describe signs/symptoms of subcutaneous needle complications.
- Gather appropriate supplies for procedures.
- Drawing up SCIG and priming tubing
- Insert subcutaneous catheter and check for blood return.
- Insert syringe on pump and setting rate
- Accurately administer SCIG
- Discontinuing subcutaneous infusion.
- Identify appropriate interventions for complications. **Scenarios to be discussed:**
  - A) Blood return in tubing upon pull back
  - B) Pump malfunction
  - C) Site issues
- Disposal of biological waste
- Post-infusion site care.
- Care and maintenance of infusion pump
- Use of epinephrine device.
- Additional patient-specific tasks (if applicable):

<table>
<thead>
<tr>
<th>Comments:</th>
</tr>
</thead>
</table>

**To be completed after the final education session:**
I have been instructed on subcutaneous infusion and I understand and feel competent in all the above skills above. I accept the responsibility for using proper and safe techniques to carry out the prescribed home infusion therapy.

_________________________  ________________________
Signature of Patient/Parent/Trainee       Date

_________________________  ________________________
Signature of Patient Educator      Date
Appendix D4: Patient Quick Reference Sheet for Pump Method

The following shows the Patient Quick Reference Page. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

**Subcutaneous Immunoglobulin Home Infusion**

**Patient Quick Reference Sheet**

**Patient name:** ________________________________.

**Product name:** ________________________________.

**My dose of SCIG is:** _______ ml every _______

**My vial size is** _______ ml and I will use _______ vials for each dose.

**Each dose is given over** _______ minutes or hours. I will use _______ injection sites for each dose.

**I need** _______ size _______ syringes. I will need _______ needles.

**The pump speed should be set to** _______ mm per hour.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Who to Call</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic Reaction</td>
<td>911</td>
<td>911</td>
</tr>
<tr>
<td>Concerned about a possible reaction to SCIG</td>
<td>Immunologist on call</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Questions Regarding supplies or the infusion process</td>
<td>Patient Educator: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Appointment Times</td>
<td>Immunology Clinic</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Submitting Log sheets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions regarding treatment</td>
<td>Immunologist: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Ordering and pick up of SCIG</td>
<td>Blood Bank</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Ordering and Pick up of Infusion Supplies</td>
<td>[name and location]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Other medications</td>
<td>Local drug store</td>
<td></td>
</tr>
<tr>
<td>Problem with syringe pump</td>
<td>Patient Educator: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Only applicable for Vivaglobin</td>
<td>Manufacturer: Smiths Medical</td>
<td>(905) 477-2000</td>
</tr>
<tr>
<td>Other?</td>
<td></td>
<td>[insert phone number]</td>
</tr>
</tbody>
</table>

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Appendix D5: Sample Consent Form for Pump Method

The following shows the sample consent form. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

Consent for Transfusion of Blood, Blood Components And/or Plasma Derivatives

I _____________________________ have been informed by my physician, __________________________, that in the course of my medical/surgical treatment I may need a transfusion of blood, blood components or plasma derivatives (i.e. red blood cells, plasma, platelets, factor concentrate or cryoprecipitate). Autologous blood and other appropriate alternatives to the use of human blood have also been discussed.

I have been informed of and understand the benefits and risks associated with this therapy. I understand that risks exist even though the blood and/or blood components or plasma derivatives have been tested. I understand that all blood donors are volunteers and are carefully screened by medical history and sensitive laboratory tests in order to minimize the risk of infectious disease transmission, however these measures cannot completely eliminate these risks or the risks of other adverse reactions including serious injury and/or death.

I have been given information, including a pamphlet (“Benefits and Risks of a Transfusion”) on blood, blood components and plasma derivatives and the chance to ask questions about the benefits and risks. My physician has answered all my questions to my satisfaction.

I have read (or has been read to me) and understand all the above. I consent to the transfusion of blood, blood components and/or plasma derivatives if it becomes necessary during the course of treatment.

____________________________________________________  ___________________
Signature of patient        Date

Or

____________________________________________________ ___________________
Signature of Substitute Decision Maker    Date

____________________________________________________
Substitute Decision Maker (Print Name)

STATEMENT OF TREATING PHYSICIAN:
I confirm that I have explained the nature, associated benefits, potential risks, and likely consequences of consenting to or refusing the transfusion of blood, blood components or plasma derivatives and alternative therapies and provided an opportunity to ask questions and answered all questions that were asked.

____________________________________________________  ___________________
Signature of Physician        Practice Registration #

____________________________________________________
Print Name        Date
Appendix D6: Responsibility Agreement for Pump Method

The following shows the Responsibility Agreement. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

Subcutaneous Immunoglobulin Home Infusion Responsibility Agreement

Patient Name: ____________________________________________________________

The following is a list of responsibilities required of a patient to participate in the SCIG home infusion program:

• Complete home infusion training and demonstrate self-administration until competency is established
• Undergo periodic reassessment regarding the infusion technique as per an established review schedule or based on needs during subsequent follow up.
• Follow the instructions for home infusion as per the patient education materials or the written modified program provided by the nurse educator
• Contact the nurse educator when questions regarding supplies or the home infusion process arise
• Maintain and dispose of equipment as instructed
• Perform home infusion in a safe and clean environment
• Administer doses on the schedule determined by the physician
• Ensure an adult who is not undergoing the infusion is present for the duration of the infusion and for 60 minutes following the completion of the infusion.
• Complete a Patient Infusion Log Sheet for each infusion and submit a copy as instructed
• Document all adverse reactions on the Patient Infusion Log Sheet. Any adverse reaction that requires emergency medical attention should be reported to the patient’s physician before administering any further doses. Do not call a nurse educator to report or seek advice concerning clinical symptoms or reactions to infusions.
• Order, transport, and store SCIG according to the instructions provided
• Attend all scheduled clinic appointments
• Have a clear understanding of the risks associated with administration of SCIG outside the hospital environment.

I understand that failure to comply with the above responsibilities may pose a threat to my safety and may result in termination of home infusion therapy and reversion to in-hospital treatment with intravenous immunoglobulin.

I understand that I am participating in the SCIG home infusion program at my own risk and I hereby waive any and all claims and release from all liability and agree not to sue any hospital staff or representatives for any and all personal injury, death, or loss sustained by me as a result of preparing, infusing, handling, or storing SCIG in my home or at any location outside of the hospital due to any cause whatsoever.

I declare that I have read and understood these conditions.

___________________________________________    _______________________
Signature of Patient        Date

___________________________________________    _______________________
Signature of Parent or Legal Guardian     Date
Appendix D7: Sample Issuing Form for Pump Method

The following shows the sample issuing form. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines. Changes can be made to this sample to suit local processes. This form stays in the blood bank and is not meant to be issued to patients.

Subcutaneous Immunoglobulin Home Infusion
SCIG product Issuing Form
Department of Laboratory Medicine - Transfusion Medicine Service

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Health Card or Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering Physician:</td>
<td>Ordered Dose:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Number of Boxes:</th>
<th>ml per box:</th>
<th>Expiry Date (dd/mm/yy):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Issued:

Computer Numbers:

Pool Numbers:

Issuing Technologist’s Name:

Issued to (signature):

Issued/Transfused in Computer:  ☐ Yes  ☐ No

Discards Returned:

<table>
<thead>
<tr>
<th>Lot #:</th>
<th>Amount Discarded:</th>
<th>Reason for Discard:</th>
<th>Received by (initials):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tracking of Corresponding Patient Log Sheets:

<table>
<thead>
<tr>
<th>Issuing Tech</th>
<th>Received</th>
<th>Forwarded to MLT II</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLT II</td>
<td>Reviewed</td>
<td>Forwarded to Clinic</td>
</tr>
</tbody>
</table>
Appendix D8: Cold Chain Maintenance for Pump Method

The information in this appendix applies to situations where there is a chance SCIG may be stored at a patient’s home for more than five months. This is because room temperature storage time is limited to five months and once SCIG is removed from refrigeration, it cannot be returned. Storage for longer than five months requires the product be kept at a temperature of between +2 and +8 °C both during transport and storage.

To maintain the temperature of the product during transportation from the hospital to the patient’s home, product must be transported in a cooler. It is recommended patients use the Igloo Cool 16 Quart cooler. This cooler, along with specific seasonal packing configurations (summer and winter), has been validated as having the capability to maintain the contents within the required temperature range for eight hours using the summer configuration and even longer with the winter configuration. The following items are required for the packing protocol:

- Igloo Cool 16 Quart cooler (available at Home Hardware; Item # 6450-770)
- One 24 oz Blue Gel Pack (Cryopak Item # 80501)
- One 96 oz Blue Gel Pack (Cryopak Item # 80503)
- One or two (depending on the outdoor temperature) 36 oz Blue Gel Pack(s) (Cryopak Item # 80502)
- Five to seven (depending on the outdoor temperature) 12 ml/cell 12 x 4 flexible insulating blankets (Cryopak Item # 85000)

All packing items, with the exception of the cooler, can be obtained from Cryopak. Call 1-888-423-7251 for the name of your local Cryopak sales representative.

The packing configurations for summer and winter are shown in Figures J1 and J2. The validation study supporting the packing configuration can be found on the included CD-ROM (see “British Columbia Mass Immunization Clinic Cold Chain Project 2005-06”). Blood bank staff should pack the product into the cooler for the patient to ensure the proper configuration is used. Note that patient coolers should not be used for any other purpose other than transporting SCIG.

Patients should be advised to proceed directly home with the product and to place the product in the fridge within ten minutes of arriving. During transport, the cooler should be kept in the passenger compartment of the car to avoid temperature extremes that can occur in the trunk.

In the home, product must be kept in the fridge within a temperature range of +2 to +8 °C. Ideally, a National Institute of Standards and Technology (NIST) certified thermometer should be used to monitor the fridge temperature. Considering the expense of such a thermometer, a reasonable option would be to use a thermometer verified against a calibrated, NIST-certified thermometer in the blood bank.

SCIG may be stored in the regular food fridge or in a separate designated fridge. If stored in the food fridge care must be taken to keep SCIG away from any items that could spill. Regardless of the type of fridge, the boxes of vials must be kept away from the back of the fridge to prevent freezing that...
can occur when contact is made with the back inside wall of the fridge. SCIG vials must be kept in their boxes during storage.

The fridge temperature should be recorded daily. A template temperature log sheet can be found in Appendix K. An electronic version of this template is included on the included CD-ROM. Patients should bring the temperature log sheets when picking up product so that adherence to daily temperature logging and temperature requirements can be verified. Copies of the logging sheets should be retained in the blood bank.

Patients/families should have a plan in place to deal with a power failure and associated loss of refrigeration. A variety of options are available as long as the temperature is maintained in the range of 2–8 °C. Options include:

- Moving the product to the transport cooler with cold packs
- Using the transport cooler to transport product to a fridge in a home not affected by the power failure
- Using the transport cooler to transport product to the hospital blood bank. The blood bank should be notified in advance of this transfer.

In each situation, a certified or verified thermometer as described above should be used to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs.
Figure D8a: *Summer* (April 2–Nov 14) Packing Configuration

- **Lid**
- **1 x 36 oz Blue Gel Pack (Item #80502)** preconditioned at -16.5 °C. For temperatures over +38 °C add 1 additional gel pack.
- **2 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; fan folded to fit.**
- **SCIG vials in boxes; pre-conditioned at +5 °C.**
- **1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; wrapped around vials.**
- **1 x 96 oz Blue Gel Pack (Item #80503); pre-conditioned at +5 °C; placed in bottom of cooler.**
- **Igloo Cool 16 Quart cooler; pre-conditioned at +22 °C (Home Hardware Item #6450-770).**

All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
Figure D8b: Winter (Nov 15 – April 1) Packing Configuration for the Igloo Cool 16 Cooler

- 1 x 24 oz Blue Gel Pack (Item #80501); pre-conditioned at -16.5 °C.
- 1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000) pre-conditioned at +22 °C; fan folded to fit; add 1 additional 12 x 4 flexible insulating blanket layer at +22 °C for every 5 °C below -15 °C.
- 2 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000) pre-conditioned at +5 °C; fan folded to fit.
- SCIG vials in boxes; pre-conditioned at +5 °C.
- 96 oz Blue Gel Pack (Item #80503); pre-conditioned at +5 °C; placed in bottom of cooler.
- Cooler; pre-conditioned at +22 °C (Home Hardware Item #6450-770).

All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
## Appendix D9: Home Fridge Temperature Log Sheet for Pump Method

The following shows the Home Refrigerator Temperature Log Sheet. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

### Subcutaneous Immunoglobulin Home Infusion
#### Home Refrigerator Temperature Log Sheet

<table>
<thead>
<tr>
<th>Date</th>
<th>Temp.</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Note: the temperature in the refrigerator used to store SCIG must be in the range of +2 to +8 °C, the fridge temperature goes outside the recommended range, the product should be moved to another location where the proper temperature can be maintained. Options include:

- Moving the product to the transport cooler with cold packs.
- Using the transport cooler to transport product to a working fridge (for example, in a neighbor’s or friend’s home). Ensure the fridge temperature is within the recommended range.
- Using the transport cooler to transport product to the hospital. In this case, please call the blood bank ahead of time.

In each situation, place the fridge thermometer with the product to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs. Frozen cold packs should not come in contact with the product boxes.

Log Verification - Name: ________________________________    Title: ______________________

Hospital: ___________________________________________    Date: ______________________
Appendix E

Subcutaneous Immunoglobulin (SCIG)

Patient Teaching Guide for Self Administration Using Push Method

PROMOTING EXCELLENCE IN TRANSFUSION MEDICINE
Acknowledgements

Alberta Health Services
CSL Behring Canada
Medical Day Unit Staff of CDHA
Medical Day Unit Staff of IWK

Note:
This document only covers the relevant information about SCIG. It does not cover all the details of the product. To get the best possible results from treatment, follow your Doctor’s instructions about dose and treatment schedule.
What is SCIG?

SCIG is a blood product used to treat adults and children with primary immune deficiency.
What is Primary Immune Deficiency?

Primary immune deficiency (PID) means a person’s immune system does not work properly. People with PID are unable to make certain antibodies - special infection - fighting proteins called immunoglobulin G (IgG). Without these antibodies, there is an increased chance of getting an infection.

- SCIG product replaces the IgG antibodies that are missing. It is called antibody replacement therapy.
- This treatment supports the prevention and treatment of infections.
SCIG Contraindications:

**Allergic Reactions**
SCIG should be avoided in persons with a history of severe allergic reactions to immunoglobulin treatment.

**IgA Deficiency**
SCIG should be avoided in persons with selective IgA deficiency who are known to have antibodies against IgA.
The Ingredients of the Product:

SCIG is made from human plasma and is a highly purified product. It contains immunoglobulin G (IgG), an antibody normally found in the blood of healthy people.

IgG helps the body fight disease and infections.

The other ingredients in SCIG products may include glycine, sodium chloride and water for injection.
Serious Warnings and Precautions:

• SCIG is made from donated human plasma which is tested and treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease

• Human Immune Globulin products have been associated with the following:
  • aseptic meningitis syndrome
  • renal dysfunction
  • anemia (hemolysis, hemolytic)
  • TRALI (transfusion-related acute lung injury)
  • thrombo-embolism NOTE: Risk factors in thrombotic event are pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter, immobility, hyperviscosity from any cause including dehydration, hypercoagulable disorders, and multiple cardiac risk factors. Inform your physician if you have any such risk factor.

Interactions: SCIG should not be mixed with any other products
What Happens If I Miss A Dose?

- Use the missed dose as soon as you remember, and dose weekly from there. If a certain daily schedule is more convenient, then you can modify the schedule to dose every 6 or 8 days to get you back on schedule.
- Skip the missed dose if it is 48h from your next scheduled dose.
What Should I Avoid While Using SCIG?

- When you are on SCIG and receive a “live” vaccine the vaccine may not work as well during this time, and may not fully protect you from disease.
- Live vaccines include measles, mumps, rubella (MMR), oral polio, chickenpox (varicella), BCG (Bacillus Calmette and Guérin), and nasal flu vaccine.
- Inform the doctor who is giving you the vaccine of recent treatment with SCIG so that appropriate precautions can be taken.
Transporting SCIG for Short Term Storage

Storing any vials in your home for less than 5 months is considered short term storage:

- For short term storage SCIG can be transported and stored at room temperature

- Care must be taken to protect the vials of SCIG during transportation
  - A puncture-proof plastic container such as a hard-sided cooler or plastic storage bin is recommended
  - The transport container should not be used for any other purpose than for transporting SCIG
  - During transport, the container should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk
  - Care must be taken to ensure temperature does not exceed the range of +2 °C to +25 °C. Vials must be kept away from direct sunlight, heaters and any other heat sources

- Proceed directly home with the transportation container containing SCIG
Storing SCIG for **Short Term** (less than 5 months)

- SCIG must be stored at a temperature of between +2 and +25°C (36 and 77 °F). The product cannot be at room temperature then placed back into the fridge.

- Do not allow the vials to be exposed to direct sunlight and do not store near any source of heat. Temperature may exceed 25°C by direct exposure to sunlight and heat source.

- Do not use SCIG after the expiry date. Report it as discard.

- Keep the vials of SCIG in the boxes during storage.

- Keep SCIG out of the reach of children.
Transporting SCIG for Long Term Storage

Storing any vials in your home for more than 5 months is considered long term storage:

- This set of additional instructions is to be used only if there is a chance any vials of SCIG will be stored in your home for more than five months.
Transporting SCIG for Long Term Storage (continued)

- All vials must be kept cold from the time they leave the fridge at the hospital to the time they are administered. The temperature of the vials must be kept between +2° to +8°C (+36° to +46°F), even during transport to your home.

- To maintain the temperature of the product during transportation, SCIG must be carried in a cooler.
  - The recommended cooler is the Igloo Cool 16 Quart Cooler
    - available at Home Hardware; Item # 6450-770
  - When SCIG is packed properly (with cold packs) in this cooler, the proper temperature will be maintained until you get home.
  - The hospital staff providing your SCIG will pack it properly in your cooler. You will need the following (check with hospital staff about acquiring these items):
    - One 24 oz Blue Gel Pak
    - One 96 oz Blue Gel Pak
    - One or two (depending on outdoor temp.) 36 oz Blue Gel Pack(s)
    - Five to seven (depending on outdoor temp.) 12 ml/cell 12 x 4 flexible insulating blankets.
Transporting SCIG for Long Term Storage (continued)

• Proceed directly home with the packed cooler and place the boxes of vials in the fridge within ten minutes of arriving home.

• During transport, the cooler should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk.

• Avoid opening the lid of the cooler during transport.

• Your transport cooler should not be used for any purpose other than transporting SCIG.
Storing SCIG for **Long Term** (more than 5 months)

- Keep SCIG in the refrigerator between +2° to +8°C (+36° to +46°F)
  - It is safe to store SCIG in the regular food fridge, but keep the boxes away from anything that may spill. A thermometer must be used to monitor the fridge temperature
  - Once a day, check the fridge temperature and record it on the temperature log sheet. Use a thermometer verified by staff in the blood bank. Bring the log sheet with you when you go to pick up more product
  - Do not freeze SCIG and keep the boxes away from the rear of the fridge to avoid the risk of freezing
  - Keeping the boxes of vials in a plastic storage container with a lid will help protect the product from freezing and food spills

- Do not use SCIG after the expiry date. Report it as discard
- Store vials in the boxes
- Keep SCIG and all medications out of the reach of children
Loss of Refrigeration

- If the fridge temperature goes outside the recommended range (for example, during a power outage), the product should be moved to another location where the proper temperature can be maintained. Some options include:
  - Moving the product to the transport cooler with cold packs. Frozen cold packs should not come in direct contact with the product boxes
  - Using the transport cooler to transport product to a working fridge (for example, in a neighbor’s or friend’s home). Ensure the fridge temperature is within the recommended range
  - Using the transport cooler to transport product to the hospital. In this case, please call the blood bank ahead of time

- In each situation, place the fridge thermometer alongside the product to monitor the temperature. The thermometer should not be in contact with any cold packs
Preparation for Use:

- When SCIG is stored in the fridge, it is important to let the vials reach room temperature before using.

- Do this by taking them out of the fridge for 45 – 75 minutes before the infusion.
How to Infuse SCIG

• SCIG is given as an injection under the skin (subcutaneously)

• SCIG must not be given into a blood vessel (vein or artery) as it is not known if this is safe

• If you experience a serious allergic reaction at any time, STOP the infusion of SCIG and contact your doctor or an emergency health care professional immediately
Safety Requirements

Safety requirements related to self-administering SCIG are as follows:

- The home (or any administration location) must be clean and safe.
- The home (or any administration location) must have a working telephone, and there must be access to rapidly available emergency assistance, e.g. 911.
- A competent adult should be available to assist the recipient for the entire period of the administration and should remain available to the recipient for at least 60 minutes after administration has been completed.
- An epinephrine device must be available during all infusions administered outside the hospital.
Instructions for Administering SCIG:

Patient name: ___________________________

Your monthly dose of SCIG is: _____ml

You will give _____ injections a week

You will use _____ vials for each dose

Each dose is given slowly over _____ minutes

You will use _____ injection sites for each dose

You will need:
___ 10 cc syringe ___18 gauge needle ___ 25 gauge butterfly needle
Step 1: Gather Your Supplies

On a clean table, gather all the supplies:

- SCIG vial(s) (at room temperature)
- Infusion Log Sheet
- Chlorohexidine swabs and alcohol swabs
- 18 gauge blunt fill needle(s)
- 10 ml syringe(s)
- 25G X ½” butterfly needle
- Sharps disposal container
- Gloves (if recommended)
- 2X2 gauze
- Band-Aid
Step 2: Wash and Dry Your Hands

Wash and dry your hands thoroughly prior to preparing your SCIG infusion.
Step 3: Inspect Each Vial of SCIG

Check each vial of SCIG for any discoloration or presence of particles in the solution by gently turning the vial (do not shake).

If the solution is cloudy, has particles in it, or if the cap is missing, do not use it. Keep it and return it to the hospital when you go to pick up more product.

Check the expiry date on each vial. Do not use past the expiry date. Call ____________ for a replacement.
Step 4: Prepare the Vial

Remove the cap from the vial(s).

Disinfect the rubber stopper by wiping it with an alcohol swab.

Let it dry.
Be careful not to shake the vial(s).
Step 5: Prepare the Syringe and Needle

- You will need 10 ml syringe
- You will need 18 gauge blunt fill needle
- Open the syringe and needle packages. Do not touch the ends where they will connect
- Attach the needle to the syringe by pushing them together and turning clockwise until snug
Step 6: Inject Air into the Vials

- Pull the syringe plunger back to draw ____ ml of air into the syringe
Step 7: Injecting air into the vial

• Remove the cap from the needle. Do not touch the needle.

• Insert the needle into the center of the stopper of SCIG vial but not all the way into the solution.

• Inject the air into the vial by pushing down on the plunger but avoid injecting any air into the solution. (Holding the vial horizontally may help). Keep pressure on the plunger so air stays in the vial.
Step 8: Fill the Syringe

- Turn the vial upside down making sure the tip of the needle is in the liquid and pull back on the plunger to draw the product into the syringe.

- Draw up ______ ml into the syringe.

- Remove any large air bubbles by tapping the syringe and pushing on the plunger. Be careful not to waste any solution. Pull back slightly on the plunger to get the fluid from the needle.

- When you have finished filling this syringe, carefully recap your needle and put the filled syringe on your clean table.

- Repeat these steps if you need to fill more than one syringe.
Step 9: Connecting the Butterfly Needle

- Straighten the tubing attached to your butterfly needle
- Twist off 18 gauge needle from the syringe and discard into a sharps disposal container
- Remove the plastic cap from the end of the butterfly tubing
- Connect the butterfly tubing to the syringe
Step 10: removing air from the tubing

- Remove the air from the butterfly tubing by pushing on the syringe plunger until the solution reaches the bottom of the wings on the butterfly.

- If fluid reaches the tip of the butterfly needle, wipe the tip of the needle with your 2X2 gauze.

- Avoid getting product on the tip of the butterfly needle as it causes skin irritation.
Step 11: Select Injection Site(s)

- Select an area approved for subcutaneous injection (see diagram)
- The best area is the abdomen. Stay approximately two inches away from the umbilicus (belly button) in any direction
- Do not inject into an area that is scarred, bruised or there is a large blood vessel under the skin
Step 12: Prepare Injection Site(s)

- Wipe the area with a chlorohexidine swab in a circular motion, avoid going over the already cleaned area.
- Start cleaning at the center of the site and work outward to cover a circle of about 4 inches.
- Let the skin dry.
- If using more than one site, make sure each site is at least two inches apart.
Step 13: Insert the Needle

- Insert the butterfly needle at either a 45° or 90° angle
- Insert the needle using “pinch an inch” technique, as directed
Make sure you are not in a blood vessel:

When the needle is in, pull back slightly on the plunger to make sure you are not in a blood vessel.

If you pull back on the plunger and see blood in the butterfly tubing, pull out the butterfly needle and apply pressure to the site. Discard the butterfly needle and start over at Step 9.
Injecting SCIG:

If you do not see blood, secure the needle and inject the SCIG at a slow rate of approximately 0.3 ml/min.
Step 14: Applying Pressure

• Once the SCIG has been given, keep pressure on the syringe plunger for 30 seconds before removing butterfly needle (You may choose to slowly count “1 Mississippi- 2 Mississippi- ……29 Mississippi” for timing)

• Place 2X2 gauze over the insertion site and pull out the butterfly while applying pressure

• This may be uncomfortable but this helps seal the tissue and prevent leakage
Step 15: Following the Infusion

- It is not uncommon to notice blood coming from the insertion site. Do not worry as you may have nicked a small blood vessel either on insertion or removal of the butterfly needle.

- Apply pressure to the site with the 2X2 gauze.

- A small amount of clear fluid (product) may appear via insertion site. This could be some of the product that has followed the needle track to the surface.

- Clean the area with chlorohexidine swab and apply pressure with 2X2 gauze.
Step 16: Following the Infusion

- Discard all preparation and administration equipment in a large biohazard sharps disposal container.
- Once opened even by mistake SCIG cannot be saved. Discard it in the biohazard sharps disposal container.
- Report the discards (if any) in patient infusion log sheet appendix E2.
- Sharps containers are available from various sharps exchange program. Your health care provider will tell you about the options in your area.
Notes on Sharps Containers

• Items for disposal should only be placed in a biohazard sharps container. The items must not be placed in garbage or recycling bags and must not be flushed down the toilet or burned.

• Use a LARGE size sharps container and do not fill beyond the manufacturer’s full line.

• During transportation, care must be taken to ensure the lid is securely sealed on filled containers.
Step 17: Record the Infusion

On your Infusion Log Sheet you must:
- Record the date and time of the infusion
- Record the exact dose of your infusion
- Record the lot number and expiration date from the vials used
- Record the discards if any
- Record any reactions that occurred as a result of the SCIG infusion
- Fill in all the other sections according to the instructions from your healthcare provider

Provide ALL your completed log sheets to your physician at your following visit or you may choose to fax your log sheets after each infusion.
Managing the Side Effects of SCIG
Anaphylaxis

- Although rare in occurrence, anaphylaxis is the most severe potential reaction that can occur as a result of infusing SCIG.
- It is a life-threatening allergic reaction that affects many areas of the body. Anaphylaxis can lead to death in a matter of minutes if left untreated.
- Symptoms of an anaphylactic reaction, as well as instructions for when to give epinephrine, are listed in the following table.
- Note that during an anaphylactic reaction, not all symptoms may occur.
- Always have an epinephrine injection device with you when infusing SCIG and ensure the device has not expired.
  - Expiry date of current injection device: ____________
- Early recognition of symptoms and immediate treatment could save a person’s life. Delay in treatment could cause a more severe anaphylaxis episode. When in doubt, treat with epinephrine.
# Symptoms of an Anaphylactic Reaction

<table>
<thead>
<tr>
<th>Body Region</th>
<th>Symptoms [Note that during a reaction not all symptoms may occur]</th>
<th>Should You Give Epinephrine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face/Head</td>
<td>Redness, itchy eyes/nose, swelling of eyes, runny nose, sneezing</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td></td>
<td>Swelling of lips and tongue, itchy mouth or tongue</td>
<td>Yes</td>
</tr>
<tr>
<td>Skin</td>
<td>Itching, redness, warmth, hives, rash or swelling in areas other than infusion sites.</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>Throat</td>
<td>Itching, tightness, hoarse voice, hacking cough, trouble swallowing, trouble speaking, choking</td>
<td>Yes</td>
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<tr>
<td>Lungs</td>
<td>Trouble breathing, shortness of breath, repeating cough, wheezing</td>
<td>Yes</td>
</tr>
<tr>
<td>Stomach</td>
<td>Nausea, vomiting, stomach pain or cramps, diarrhea</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>General</td>
<td>Dizziness, unsteadiness, drowsiness, sense of doom, feeling faint or fainting</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Epinephrine Devices

- Epinephrine is a life-saving treatment and is the antidote for anaphylaxis

- There are two types of epinephrine devices:
  - Epi Pen®
  - Twinject®

- Techniques on using these devices should be reviewed regularly. Instructions are available on DVDs and websites. Instructions are also found directly on the devices themselves

- These devices can be used through clothing
How to Use Epi Pen®

• Remove the device from its carrying case

• Grasp the Epi Pen® with the black tip pointing downward

• Pull off the grey safety cap

• Place the BLACK tip against the mid-outer thigh and press firmly until the Epi Pen® activates
  – This device can be used through clothing

• Hold while counting for 10 seconds, then remove
How to Use Twinject®

• The Twinject® device contains 2 doses. The second dose is rarely needed

• Pull off the GREEN caps from both ends

• Place the RED tip against the mid-outer thigh and press firmly until the Twinject® activates
  – This device can be used through clothing

• Hold while counting for 10 seconds, then remove
Twinject®- 2nd Dose

• The second dose is rarely needed but should be given if:
  – There is no improvement in symptoms 10 minutes after the first dose is given
  OR
  – There is initial improvement, but then symptoms rebound or return

• Unscrew and remove the RED tip
  – Beware of the exposed needle

• Holding the BLUE hub at the needle base, remove the syringe from the barrel

• Slide the YELLOW collar off the plunger

• Insert the needle into mid-thigh (at least 5 cm (2 inches) from the first injection site) and push the plunger down completely
After Epinephrine is Given

• Call 911 and tell them someone is having a life-threatening allergic reaction. Ask them to send an ambulance immediately
• You must have medical attention and monitoring if epinephrine is given, even if symptoms have improved

How to Dispose of Epinephrine Device

• Carefully place the used auto-injector (needle end first) into the storage tube
• Screw the cap of the carrying case on completely
  – This automatically bends the needle back and secures the pen so it won’t fall out of the tube
• Give any used auto-injectors to emergency responders or emergency room personnel
# Trouble Shooting Subcutaneous Administration of Immunoglobulin

| Leaking                                      | • Check connections between tubing and syringe  
|                                             | • Is the butterfly needle inserted properly  
|                                             | • Volume administered too quickly therefore leaking at the site |
| Insertion site: reaction                    | • Volume administered too quickly  
| Redness                                     | • Decrease the volume and spread over a longer period of time  
| Swelling                                    | • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin  
| Itchiness                                   | • Apply warm compress to the area before administering subcutaneous immunoglobulin  
|                                             | • If taping the needle down, you could be getting a reaction to the tape  
|                                             | • Did any immunoglobulin get on the needle while flushing the tubing? (Use 2X2 gauze to wipe off the needle)  
|                                             | • After cleaning the skin wait a min or two then administer the immunoglobulin. The area should be dry prior to puncturing the site.  
|                                             | • Rotate the sites regularly |
| Needle Discomfort                           | • Needle length too long  
|                                             | • Rotate sites regularly  
|                                             | • Apply warm compress to the area before administering subcutaneous immunoglobulin  
|                                             | • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin |
| Blood in tubing                             | • Discard butterfly needle and start over |
## Other Reactions to SCIG Signs and Symptoms

<table>
<thead>
<tr>
<th>Site Reaction</th>
<th>Non-pharmacological interventions</th>
</tr>
</thead>
</table>
| Itching         | • Slow down on the infusion  
                  • Needle in correctly  
                  • Apply cold compress  
                  • Ensure you are rotating the sites  
                  • When priming the needle, do not allow excess SCIG droplets on outside of the needle                                                                 |
| Redness         | • Slow down the infusion  
                  • Apply cold compress                                                                                                                                             |
| Burning         | • Stop infusion for 5–10 minutes then restart  
                  • Slow the infusion down  
                  • Cold compress  
                  • Gentle massage  
                  • Change site                                                                                                                                                    |
| Swelling        | • Warm compress for 5-10 minutes                                                                                                                                            |
| Urticaria (hives) | • Stop SCIG  
                  • Seek medical attention  
                  • Determine with physician if treatment should continue                                                                                                           |
| Discomfort      | • Slow infusion  
                  • If intolerable pain – may be in muscle, remove catheter  
                  • Once needle removed, warm compress and gentle massage                                                                                                           |
Injection Site Reaction

Mild

Moderate
Injection Site Reaction

- Injection site reactions can be identified by what is usually mild to moderate redness, swelling, discomfort, and itching.
- This is a normal and common reaction which should fade over 24 – 48 hours.
- Keep a record of any injection site reactions on your Infusion Log Sheet. Your physician can recommend ways to lessen discomfort related to injection site reactions.
- Use of ice during administration or dividing dose between abdomen and thighs can lessen the discomfort.
- If the injection site reactions are severe or if you are concerned about them, call your doctor or nurse using the contact information provided.
- If itchiness persists you can consult your physician.
Other Common Reactions

- There are some other common reactions that can occur related to the administration of SCIG. If any of these occur, make a note on your log sheet:
  - **Headache:** Some patients get headaches in the beginning, but they decreased after some time. You could take Tylenol 1-2 tablets orally every 4-6 hours, may last two to three days. The headache could also be triggered by stress or stressors. (I.e. anxiety, tension)
  - If your headache is prolonged contact the clinic
  - **Fever and/or Chills** (for a fever - note on the log sheet your temperature and how long after the infusion it began)
  - **Nausea**
  - **Mild or Moderate Rash**

- Any other reactions that are felt to be a result of the administration of SCIG should also be noted on the log sheet

For more information on side effects see the SCIG product insert.
Uncommon Side Effects

- Diarrhea
- Gastrointestinal
- Allergic
- Increased Cough
- Pain
- Sore Throat

If, at any time, you are concerned about anything related to the administration of SCIG, or if you have any unusual reactions call your doctor or nurse.

You should also call the clinic if any of the following occur post infusion:
- Shortness of breath
- Chest discomfort
- Pain to shoulder, arm or leg
- Injection site continues to bleed
- Fever lasting > 24 hours
Traveling with SCIG

When planning your trip you should:
• Get a travel letter from your clinic, it will have:
  A. Your name and diagnosis
  B. Name of the drug
  C. Dosage
  D. The reason you are to carrying gel/ice packs.
  E. Contact information
• Make a list of the supplies you will need
• Always carry an extra week in case of unexpected delays
• Outside Canada advance notice will be needed so arrangements can be made with the nearest clinic and/or hospital
Packing SCIG:

A. The product must be kept in its original box
B. Use a container that can hold freezer/ice packs
C. When using ice packs:
   – SCIG should not be placed in direct contact with the ice
   – Use towel or something to separate the two
   – If there is a chance of the box getting wet place in a zip lock bag to keep it dry.

• Your product must be kept with you at all times. It is considered a “carry on bag”
• Always consider travel insurance

When traveling with SCIG outside of Canada and USA:
• Check with your travel agent for restrictions on traveling with liquids at points of departure
• Check Customs requirements
• You will need stickers from the hospital to put on every box you are taking
Appendix E1: Pre-Printed Order Form for Push Method

The following shows the pre-printed order form for SCIG. For actual use, see the order form file on the CD-ROM provided with these guidelines. Note how the second page is designed to be printed on the back of the order form for reference.

PRE-PRINTED ORDER FORM FOR PUSH METHOD
Blood Transfusion Service
Request for Subcutaneous Immunoglobulin
Name of the product---------------------

Patient: _____________________ Weight _______ kg Allergies: __________________________

- The following orders may be used in any patient care area and will be carried out by a qualified health professional only on the authority of a physician.
- All orders to be carried out must be checked and/or completed as appropriate. An order preceded by a checkbox is only to be carried out if checked. Missing information will result in delays.
- All dates must be written yyyy/mm/dd. All times must be on the 24-hour clock (hh:mm)

**Indication:**

☐ Primary Immune Deficiency (Use for any other indication is not recommended at this time.)

**In-Hospital Administration Orders (see reverse for dosing guidelines):**

☐ Infuse _______ grams (_______mL) starting on __________(yyyy/mm/dd). Repeat every _______ days for a total of _______ treatments.

**Home Infusion Orders (see reverse for dosing guidelines):**

☐ Patient: Infuse _______ grams (_______ mL) every _______ days for a total of _____ months.

☐ Transfusion Services: Dispense _______ grams (_______ mL) to patient every _______ weeks for a total of _______ months. Based on the comfort level of both the patient and transfusion services, dispense may occur less frequently (i.e. every 8 to 12 weeks) with the amount dispensed at each visit increased to provide the amount required until the next dispense.

Physician’s Signature: ___________________________ Date (yyyy/mm/dd): __________
Physician’s Name: ___________________________ Reg. No. __________

<table>
<thead>
<tr>
<th>For Lab Use Only</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>Date (yyyy/mm/dd)</td>
<td>Dose</td>
</tr>
<tr>
<td>☐ 1</td>
<td></td>
<td>☐ 5</td>
</tr>
<tr>
<td>☐ 2</td>
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<td>☐ 6</td>
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<tr>
<td>☐ 3</td>
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<td>☐ 7</td>
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<tr>
<td>☐ 4</td>
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<td>☐ 8</td>
</tr>
</tbody>
</table>

Bar Code ___________________________
Dosing Guidelines

Start SCIG at a dose of 400 to 600 mg/kg every 4 weeks in adult patients and 600 to 700 mg/kg every 3 to 4 weeks in pediatric patients. SCIG is given in weekly divided doses. Over time it may be necessary to adjust the dose based on serum IgG levels and clinical response. Weight-based dosing is the same for pediatric patients; however, the safety and efficacy of SCIG has not been studied in children less than two years old.

For patients who are switching from IVIG to SCIG an initial SCIG dose can be calculated based on the previous IVIG dose. Patients will require an equal amount of SCIG, but divided weekly doses. The following can be used as a conversion equation:

\[
\text{Initial SCIG dose (g/week)} = \frac{\text{previous IVIG dose (g)}}{\text{previous IVIG treatment interval (weeks)}}
\]

Sample Calculation: A patient was receiving 38 g of IVIG every 3 weeks.
The new dose for SCIG would be:

\[
\text{Initial SCIG dose} = \frac{38 \text{ g of IVIG}}{3 \text{ weeks}} = 12.66 \text{ g of SCIG per week}
\]

NOTE: administering the infusion requires the amount of product be measured in ml. For example if SCIG is 16% w/v then 100 g of product is 62.5 ml of infusion. Different products may have different concentrations, e.g. 16%, 20%, 10% and this is how you would do the calculation. Please check and use the specific w/v concentration of the product that you are using. The following equation may serve as a sample to calculate the total volume required for an once a week dose:

Sample Calculation: A patient needs to infuse a 12.66 g dose once a week. Each dose would be:

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{0.160 \text{ g/ml}} \quad \text{(If you are using a SCIG product with 16% concentration)}
\]

\[
\Rightarrow \text{SCIG dose (ml)} = \frac{12.66 \text{ g of SCIG}}{0.160 \text{ g/ml}} = 79 \text{ ml of SCIG}
\]

OR

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{0.10 \text{ g/ml}} \quad \text{(If you are using a SCIG product with 10% concentration)}
\]

\[
\Rightarrow \text{SCIG dose (ml)} = \frac{12.66 \text{ g of SCIG}}{0.10 \text{ g/ml}} = 126 \text{ ml of SCIG}
\]

The weekly dose is divided into daily, biweekly or tri-weekly doses and rounded off to minimize the wastage when the push method is chosen for SCIG administration.

For patients switching from IVIG to SCIG, the first dose should be given within one week after the last IVIG dose.

Vials are available in different sizes and the dose should be rounded to the nearest vial size. Sample rounding: A calculated dose of 80 ml can be left as is (using eight 10 ml vials). A calculated dose of 79 ml should be rounded up to 80 ml (using eight 10 ml vials). A calculated dose of 81 ml should be rounded down to 80 ml (using eight 10 ml vials). A calculated dose of 82 ml should be rounded up to 83 ml (using eight 10 ml vials and one 3 ml vial). Some dose adjustments may be required over time to achieve the intended clinical response and serum IgG level.

Monitoring of IgG Levels

A target serum IgG trough level of at least 7 g/L should be maintained. IgG levels should be measured monthly at the beginning of the treatment with SCIG, but as IgG levels are found to be stable, monitoring can be less frequent every 3 to 6 months.
## Appendix E2: Subcutaneous Home Infusion Log for Push Method

<table>
<thead>
<tr>
<th>Date of Infusion</th>
<th>Infection present? Yes/No detailed description</th>
<th>Infection treated Yes/No</th>
<th>Which antibiotic was used?</th>
<th>Site used R/L/U/Lo/F Abd/ Leg</th>
<th>Lot Number</th>
<th>Wasted Product: in grams with Reason</th>
<th>Comments/Problems/Reactions/ Blood tests</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

### Symbols:
- **R**: right
- **L**: left
- **U**: upper
- **Lo**: lower
- **Abd**: abdomen
- **F**: love handles
Appendix E3: Skills Checklist for Push Method

The following shows the Skills Checklist. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

**Subcutaneous Immunoglobulin Home Infusion Skills Checklist**

<table>
<thead>
<tr>
<th>Patient Skills</th>
<th>Introduced</th>
<th>Reinforced</th>
<th>Mastered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation and storage requirements for SCIG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Define subcutaneous administration and location of tissue</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Describe appropriate sites for catheter placement.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe appropriate care of infusion site.</td>
<td></td>
<td></td>
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<tr>
<td>Describe signs/symptoms of subcutaneous needle complications.</td>
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<tr>
<td>Gather appropriate supplies for procedures.</td>
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</tr>
<tr>
<td>Drawing up SCIG and priming tubing.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Insert subcutaneous catheter and check for blood return.</td>
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<tr>
<td>Accurately administer SCIG</td>
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<td></td>
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<tr>
<td>Discontinuing subcutaneous infusion.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Identify appropriate interventions for complications. Scenarios to be discussed:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A) Blood return in tubing upon pull back</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B) Site issues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposal of biological waste</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Post-infusion site care.</td>
<td></td>
<td></td>
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<tr>
<td>Use of epinephrine device.</td>
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<tr>
<td>Additional patient-specific tasks (if applicable):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

To be completed after the final education session:

I have been instructed on subcutaneous infusion and I understand and feel competent in all the above skills above. I accept the responsibility for using proper and safe techniques to carry out the prescribed home infusion therapy.

__________________________________________________________  ________________________
Signature of Patient/Parent/Trainee      Date

__________________________________________________________  ________________________
Signature of Patient Educator      Date
Appendix E4: Patient Quick Reference Sheet for Push Method

The following shows the Patient Quick Reference Page. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

Subcutaneous Immunoglobulin Home Infusion
Patient Quick Reference Sheet

Patient name: _______________________________________.
Product name: _______________________________________.
My dose of SCIG is: __________ ml every week.
Divide in _________ ml every day/every second day/every third day.

My vial size is ________ ml and I will use ________ vials for each dose.

Each dose is given over _______ minutes or hours. I will use ______ injection sites for each dose.

I need ______ size ________ syringes. I will need ________ needles.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Who to Call</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic Reaction</td>
<td>911</td>
<td>911</td>
</tr>
<tr>
<td>Concerned about a possible reaction to SCIG</td>
<td>Immunologist on call</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Questions Regarding supplies or the infusion process</td>
<td>Patient Educator: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Appointment Times</td>
<td>Immunology Clinic</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Submitting Log sheets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions regarding treatment</td>
<td>Immunologist: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Ordering and pick up of SCIG</td>
<td>Blood Bank</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Ordering and Pick up of Infusion Supplies</td>
<td>[name and location]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Other medications</td>
<td>Local drug store</td>
<td></td>
</tr>
<tr>
<td>Other?</td>
<td></td>
<td>[insert phone number]</td>
</tr>
</tbody>
</table>
Appendix E5: Sample Consent Form for Push Method

The following shows the sample consent form. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

**Consent for Transfusion of Blood, Blood Components And/or Plasma Derivatives**

I _____________________________ have been informed by my physician, __________________________, that in the course of my medical/ surgical treatment I may need a transfusion of blood, blood components or plasma derivatives (i.e. red blood cells, plasma, platelets, factor concentrate or cryoprecipitate). Autologous blood and other appropriate alternatives to the use of human blood have also been discussed.

I have been informed of and understand the benefits and risks associated with this therapy. I understand that risks exist even though the blood and/or blood components or plasma derivatives have been tested. I understand that all blood donors are volunteers and are carefully screened by medical history and sensitive laboratory tests in order to minimize the risk of infectious disease transmission, however these measures cannot completely eliminate these risks or the risks of other adverse reactions including serious injury and/or death.

I have been given information, including a pamphlet (“Benefits and Risks of a Transfusion”) on blood, blood components and plasma derivatives and the chance to ask questions about the benefits and risks. My physician has answered all my questions to my satisfaction.

I have read (or has been read to me) and understand all the above. I consent to the transfusion of blood, blood components and/or plasma derivatives if it becomes necessary during the course of treatment.

____________________________________________________  ___________________
Signature of patient        Date
Or

____________________________________________________ ___________________
Signature of Substitute Decision Maker    Date

__________
Substitute Decision Maker (Print Name)

**STATEMENT OF TREATING PHYSICIAN:**
I confirm that I have explained the nature, associated benefits, potential risks, and likely consequences of consenting to or refusing the transfusion of blood, blood components or plasma derivatives and alternative therapies and provided an opportunity to ask questions and answered all questions that were asked.

____________________________________________________ __________________
Signature of Physician        Practice Registration #

__________
Print Name

__________
Date
Appendix E6: Responsibility Agreement for Push Method

The following shows the Responsibility Agreement. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

Subcutaneous Immunoglobulin Home Infusion Responsibility Agreement

Patient Name: ____________________________________________________________

The following is a list of responsibilities required of a patient to participate in the SCIG home infusion program:

- Complete home infusion training and demonstrate self-administration until competency is established
- Undergo periodic reassessment regarding the infusion technique as per an established review schedule or based on needs during subsequent follow up.
- Follow the instructions for home infusion as per the patient education materials or the written modified program provided by the nurse educator
- Contact the nurse educator when questions regarding supplies or the home infusion process arise
- Maintain and dispose of equipment as instructed
- Perform home infusion in a safe and clean environment
- Administer doses on the schedule determined by the physician
- Ensure an adult who is not undergoing the infusion is present for the duration of the infusion and for 60 minutes following the completion of the infusion.
- Complete a Patient Infusion Log Sheet for each infusion and submit a copy as instructed
- Document all adverse reactions on the Patient Infusion Log Sheet. Any adverse reaction that requires emergency medical attention should be reported to the patient’s physician before administering any further doses. Do not call a nurse educator to report or seek advice concerning clinical symptoms or reactions to infusions.
- Order, transport, and store SCIG according to the instructions provided
- Attend all scheduled clinic appointments
- Have a clear understanding of the risks associated with administration of SCIG outside the hospital environment.

I understand that failure to comply with the above responsibilities may pose a threat to my safety and may result in termination of home infusion therapy and reversion to in-hospital treatment with intravenous immunoglobulin.

I understand that I am participating in the SCIG home infusion program at my own risk and I hereby waive any and all claims and release from all liability and agree not to sue any hospital staff or representatives for any and all personal injury, death, or loss sustained by me as a result of preparing, infusing, handling, or storing SCIG in my home or at any location outside of the hospital due to any cause whatsoever.

I declare that I have read and understood these conditions.

___________________________________________    _______________________
Signature of Patient        Date

___________________________________________    _______________________
Signature of Parent or Legal Guardian     Date
Appendix E7: Sample Issuing Form for Push Method

The following shows the sample issuing form. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines. Changes can be made to this sample to suit local processes. This form stays in the blood bank and is not meant to be issued to patients.

Subcutaneous Immunoglobulin Home Infusion
SCIG product Issuing Form
Department of Laboratory Medicine - Transfusion Medicine Service

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Health Card or Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering Physician:</td>
<td>Ordered Dose:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Number of Boxes:</th>
<th>ml per box:</th>
<th>Expiry Date (dd/mm/yy):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot #</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date (dd/mm/yy):</td>
</tr>
<tr>
<td>Lot #</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date (dd/mm/yy):</td>
</tr>
<tr>
<td>Lot #</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date (dd/mm/yy):</td>
</tr>
</tbody>
</table>

Date Issued:

Computer Numbers:

Pool Numbers:

Issuing Technologist’s Name:

Issued to (signature):

Issued/Transfused in Computer: □ Yes □ No

Discards Returned:

<table>
<thead>
<tr>
<th>Lot #:</th>
<th>Amount Discarded:</th>
<th>Reason for Discard:</th>
<th>Received by (initials):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot #:</td>
<td>Amount Discarded:</td>
<td>Reason for Discard:</td>
<td>Received by (initials):</td>
</tr>
</tbody>
</table>

Tracking of Corresponding Patient Log Sheets:

<table>
<thead>
<tr>
<th>Issuing Tech</th>
<th>MLT II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Received</td>
<td>□ Reviewed</td>
<td>□ Forwarded to MLT II</td>
</tr>
<tr>
<td>□ Forwarded to Clinic</td>
<td>□ Forwarded to Clinic</td>
<td></td>
</tr>
</tbody>
</table>
Appendix E8: Cold Chain Maintenance for Push Method

The information in this appendix applies to situations where there is a chance SCIG may be stored at a patient’s home for more than five months. This is because room temperature storage time is limited to five months and once SCIG is removed from refrigeration, it cannot be returned. Storage for longer than five months requires the product be kept at a temperature of between +2 and +8 °C both during transport and storage².

To maintain the temperature of the product during transportation from the hospital to the patient’s home, product must be transported in a cooler. It is recommended patients use the Igloo Cool 16 Quart cooler. This cooler, along with specific seasonal packing configurations (summer and winter), has been validated as having the capability to maintain the contents within the required temperature range for eight hours using the summer configuration and even longer with the winter configuration⁴. The following items are required for the packing protocol:

- Igloo Cool 16 Quart cooler (available at Home Hardware; Item # 6450-770)
- One 24 oz Blue Gel Pack (Cryopak Item # 80501)
- One 96 oz Blue Gel Pack (Cryopak Item # 80503)
- One or two (depending on the outdoor temperature) 36 oz Blue Gel Pack(s) (Cryopak Item # 80502)
- Five to seven (depending on the outdoor temperature) 12 ml/cell 12 x 4 flexible insulating blankets (Cryopak Item # 85000)

All packing items, with the exception of the cooler, can be obtained from Cryopak. Call 1-888-423-7251 for the name of your local Cryopak sales representative.

The packing configurations for summer and winter are shown in Figures J1 and J2. The validation study supporting the packing configuration can be found on the included CD-ROM (see “British Columbia Mass Immunization Clinic Cold Chain Project 2005-06”). Blood bank staff should pack the product into the cooler for the patient to ensure the proper configuration is used. Note that patient coolers should not be used for any other purpose other than transporting SCIG.

Patients should be advised to proceed directly home with the product and to place the product in the fridge within ten minutes of arriving. During transport, the cooler should be kept in the passenger compartment of the car to avoid temperature extremes that can occur in the trunk.

In the home, product must be kept in the fridge within a temperature range of +2 to +8 °C. Ideally, a National Institute of Standards and Technology (NIST) certified thermometer should be used to monitor the fridge temperature. Considering the expense of such a thermometer, a reasonable option would be to use a thermometer verified against a calibrated, NIST-certified thermometer in the blood bank.

SCIG may be stored in the regular food fridge or in a separate designated fridge. If stored in the food fridge care must be taken to keep SCIG away from any items that could spill. Regardless of the type of fridge, the boxes of vials must be kept away from the back of the fridge to prevent freezing that can
occur when contact is made with the back inside wall of the fridge. SCIG vials must be kept in their boxes during storage.

The fridge temperature should be recorded daily. A template temperature log sheet can be found in Appendix K. An electronic version of this template is included on the included CD-ROM. Patients should bring the temperature log sheets when picking up product so that adherence to daily temperature logging and temperature requirements can be verified. Copies of the logging sheets should be retained in the blood bank.

Patients/families should have a plan in place to deal with a power failure and associated loss of refrigeration. A variety of options are available as long as the temperature is maintained in the range of 2–8 °C. Options include:

- Moving the product to the transport cooler with cold packs
- Using the transport cooler to transport product to a fridge in a home not affected by the power failure
- Using the transport cooler to transport product to the hospital blood bank. The blood bank should be notified in advance of this transfer.

In each situation, a certified or verified thermometer as described above should be used to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs.
Figure E8a: *Summer (April 2–Nov 14) Packing Configuration*

- **Lid**
- **1 x 36 oz Blue Gel Pack (Item #80502)** preconditioned at -16.5 °C. For temperatures over +38 °C add 1 additional gel pack.
- **2 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; fan folded to fit.**
- **SCIG vials in boxes; pre-conditioned at +5 °C.**
- **1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; wrapped around vials.**
- **1 x 96 oz Blue Gel Pack (Item #80503); pre-conditioned at +5 °C; placed in bottom of cooler.**
- **Igloo Cool 16 Quart cooler; pre-conditioned at +22 °C (Home Hardware Item #6450-770).**

All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
Figure E8b: *Winter* (Nov 15 – April 1) Packing Configuration for the Igloo Cool 16 Cooler

Cooler lid

1 x 24 oz Blue Gel Pack (Item #80501); pre-conditioned at -16.5 °C.

1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item # 85000) pre-conditioned at +22 °C; fan folded to fit; add 1 additional 12 x 4 flexible insulating blanket layer at +22 °C for every 5 °C below -15 °C.

2 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000) pre-conditioned at +5 °C; fan folded to fit.

SCIG vials in boxes; pre-conditioned at +5 °C.

1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000) pre-conditioned at +22°C; fan folded to fit; add 1 additional 12 x 4 flexible insulating blanket layer pre-conditioned at +22 °C for every 5°C below -15 °C.

96 oz Blue Gel Pack (Item #80503); pre-conditioned at +5 °C; placed in bottom of cooler.

Cooler; pre-conditioned at +22 °C (Home Hardware Item #6450-770).

All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
Appendix E9: Home Fridge Temperature Log Sheet for Push Method

The following shows the Home Refrigerator Temperature Log Sheet. For a printable version, see the Microsoft Word file on the CD-ROM provided with these guidelines.

Subcutaneous Immunoglobulin Home Infusion
Home Refrigerator Temperature Log Sheet

Patient Name: ____________________________________________

Note: the temperature in the refrigerator used to store SCIG must be in the range of +2 to +8 °C, the fridge temperature goes outside the recommended range, the product should be moved to another location where the proper temperature can be maintained. Options include:

- Moving the product to the transport cooler with cold packs.
- Using the transport cooler to transport product to a working fridge (for example, in a neighbor’s or friend’s home). Ensure the fridge temperature is within the recommended range.
- Using the transport cooler to transport product to the hospital. In this case, please call the blood bank ahead of time.

In each situation, place the fridge thermometer with the product to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs. Frozen cold packs should not come in contact with the product boxes.

<table>
<thead>
<tr>
<th>Date</th>
<th>Temp.</th>
<th>Date</th>
<th>Temp.</th>
<th>Date</th>
<th>Temp.</th>
<th>Date</th>
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<tbody>
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</table>

Log Verification - Name: ___________________________________   Title: ______________________

Hospital: _________________________________________ Date: ______________________