Home Infusion Toolkit

Intended for use by Transfusion Medicine Services
that issue products for home infusion

ORBCoN

Ontario Regional Blood Coordinating Network

Inspiring and facilitating best transfusion practices in Ontario.

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DISCLAIMER

The content and templates provided in *The Home Infusion Toolkit* are not intended to replace any program, processes, policies or procedures already implemented at a hospital. This resource is provided solely as an example of the various standards and responsibilities for home infusion within a Hospital Transfusion Service (with a focus on the Transfusion Medicine Laboratory) and examples of documents to support the capture of key information. These documents may be edited to suit the purposes of individual hospitals and programs. Furthermore, although the advice and information contained in this document is believed to be true and accurate at the time of publication, neither the authors nor the publishers can accept any legal responsibility for any errors or omissions that may have occurred.

BACKGROUND

This toolkit is intended to assist hospital Transfusion Medicine Laboratories (TML) with the provision of blood products for home self-infusion.

With the licensure and availability of certain blood products, patients can be trained to self-infuse and manage their treatment at home, resulting in improvement to their quality of life. Because these products are manufactured from human blood, there are requirements for monitoring and tracking use, storage and handling. Issuing these products for home use requires an established process for hospital Transfusion Services (TS) to ensure that required standards are met.

INTRODUCTION

The provision of blood products for home self-infusion by a hospital TS is regulated by the following national standards and provincial laboratory accreditation requirements:

- Canadian Standards Association (CSA) Standards for Blood and Blood Components (CSA Z902)
- Canadian Society for Transfusion Medicine (CSTM) Standards for Hospital Transfusion Services
- Institute for Quality Management in Healthcare (IQMH) Medical Laboratory Accreditation Requirements

Management of a home infusion program involves the collaborative effort by an interprofessional team of health care providers involved in the various steps in the process. The TML plays a key role in the provision of the product to the patient. While the TML may not be directly responsible for some of the activities that are required to meet the required standards, they should understand who is assuming responsibility within the referral home infusion program. Evidence of compliance for all required activities associated with a home infusion program should be available for audit and assessment purposes.

SCOPE OF THIS RESOURCE

This resource was created to provide hospitals that issue home infusion products to patients in Ontario with a resource that outlines the requirements for such a service and also provides some sample documents to support it. Sample documents provided in this toolkit are to be used as a model only in creating your own organizational documents to support your hospital's home infusion program. Those documents provided in WORD format can be edited into hospital templates. Home infusion programs currently vary in their scope and staff responsibilities. Hospitals across Ontario vary in the levels of services they provide to these patients and in the staff members who provide them. For example, a large teaching hospital may provide a comprehensive patient service from clinical diagnosis and support, to patient training for home infusion, issuing and monitoring products for home use. They may also liaise with their surrounding community hospitals and share responsibilities with other community home infusion programs. Some community hospitals' main responsibilities may only lie in the issuing and tracking of patient product. However, these hospitals must have assurances and proof that all elements of a home infusion program have been performed and completed satisfactorily in order to comply with accreditation requirements.

Provision of patient training may vary. Some large hospitals train their own patients while other programs use a third-party provider.

This resource, therefore, was designed to be flexible to ensure all hospitals will be able to use it, no matter what the scope of their program or how their patient services are delivered. The responsibility for performing required tasks in this document may vary from hospital to hospital, therefore, staff members (e.g. nurse, medical laboratory technologist-MLT, physician) performing some of these tasks have been defined as the "most responsible person-MRP.

This resource does not define a homogeneous home infusion program for Ontario. It is designed to assist and support TSs with home infusion programs. The forms found in this toolkit can be used to document the process at various steps along the way and provide the TS with relevant information to demonstrate compliance with the regulations.

ELEMENTS OF A HOME INFUSION PROGRAM

1. Home infusion programs must adhere to relevant standards for the administration of human blood products. These standards are reflected in this document.

2. Managing patients on home infusion should take place under a physician led program. Often portions of these programs are located at larger hospitals in major cities. Patients may prefer to pick up their product at their local community hospital. Hospitals that provide the product to the patient should establish policies and procedures to ensure the product is managed in compliance with the standards. Each hospital will have to determine the scope of their program in order to meet the needs of the patients they are serving.

3. The program should monitor patient safety elements as well as treatment efficacy.

4. Approved patients should have access to home infusion products.

5. These blood products are expensive and considered to be a limited resource. Patients are expected to use these products appropriately and to submit timely, accurate records of product use and document and report any adverse events. Failure to comply with these conditions is grounds for withdrawal from the home infusion program.

WHAT IS SUBCUTANEOUS IMMUNE GLOBULIN (SCIG)?

Subcutaneous Immune Globulin (SCIG) is a human plasma derived preparation of immunoglobulins. The manufacturing process is the same as that used to prepare intravenous immune globulin (IVIG). It is most commonly used to treat primary immune deficiency (PID) and secondary immune deficiency (SID).

ADVANTAGES OF SUBCUTANEOUS IMMUNE GLOBULIN HOME INFUSION

- No venous access required
- Slow administration and gradual absorption reduce severe headaches and other adverse events[1]
- Maintains more consistent IgG levels; eliminates low trough levels[1]
- Facilitates self-infusion, increasing patient autonomy – may improve patient's self-image and sense of control[1]
- Quality of life may be improved by facilitating the ability to travel and reduce absenteeism from work

WHAT IS C1 ESTERASE INHIBITOR (C1-INH)?

C1 esterase inhibitor (C1-INH) is also derived from human plasma. C1-INH has an important inhibiting potential on several of the major cascade systems of the human body, including the complement system, the intrinsic coagulation (contact) system, the fibrinolytic system, and the coagulation cascade[2].

It is used to treat or prevent attacks and symptoms resulting from hereditary angioedema (HAE). HAE is a rare disease caused by low levels of C1-INH or malfunctioning C1-INH. This condition causes swelling of the face, hands, feet, throat, stomach, and bowels. It can be life-threatening, as laryngeal edema may cause complete airway obstruction[3].

ADVANTAGES OF C1 ESTERASE INHIBITOR HOME INFUSION

- Improved patient safety and comfort as a result of quick administration at home to address an oncoming severe attack
- Enables home prophylaxis to prevent attacks from known triggers (e.g. dental procedures, menstruation) and ongoing prevention of severe, regular attacks
- Cost efficiencies because of the reduction in need for emergency services
- Improved patient autonomy and quality of life

PRODUCT STORAGE/TRANSPORTATION OF HOME INFUSION PRODUCTS

SCIG	**Hizentra®**	Can be stored either in the refrigerator or at room temperature (at +2°C to +25°C). Hizentra® is stable for the period indicated by the expiration date printed on the outer carton and vial/pre-filled syringe label. Do not freeze. Do not use product that has been frozen. Do not shake. Keep Hizentra® in its original carton to protect it from light.[4]
	Gamunex®	May be stored for 36 months at +2°C to +8°C (36-46°F), AND product may be stored at temperatures not to exceed +25°C (77°F) for up to 6 months anytime during the 36-month shelf life, after which the product must be immediately used or discarded. Do not freeze.[5]
	Cuvitru®	Store at refrigeration temperature: +2 °C to +8°C for up to 36 months or room temperature: not to exceed +25°C for up to 24 months from the date of manufacture.[6]
C1 Esterase	**Berinert®**	When stored at temperatures of +2°C to +25°C, Berinert® 500 is stable for the period indicated by the expiration date on the carton and vial label (up to **30** months).[2] When stored in the refrigerator or at room temperature (at +2 °C to +25 °C), Berinert® 1500 is stable for the period indicated by the expiration date on the carton and vial label (up to **36** months).[2] Keep Berinert® in its original carton until ready to use. Do not freeze. Protect from light [2]
	Cinryze®	This product is stable in its original container between +2°C to +25°C. Do not freeze. Store in the original package in order to protect from light.[7]

RESPONSIBILITIES WITHIN A HOME INFUSION PROGRAM

This chart is meant to be a guide for hospitals. The roles and duties may vary to meet the needs of individual sites and staffing requirements. All participants within the home infusion program must be aware of their responsibilities.

	RESPONSIBILITIES	RELATED FORMS
Issuing Hospital TML	Order product for home infusion from CBS as per directions received from the Most Responsible Person. Note: it may be beneficial to keep a limited amount of extra product on hand in case of urgent need.	SCIG Product Request Form C1-INH Product Request Form
	Enter home infusion products into the TML inventory system. The products must be documented in a way that ensures traceability in the event of a recall or lookback/traceback.	See storage/transportation section (refer to manufacturer's product insert)
	Package and label the product for the patient as per your facility's policy/procedure.	
	Provide product to patient. Patient should bring government issued identification with a minimum of two unique patient identifiers (Minimum requirements are a name and DOB). If a designate is assigned to pick up product, the designate must bring government issued identification and documented authorization for product pickup for that patient.	Letter of authorization for product pickup
	In the event of a recall, lookback or traceback, notify the patient's physician (and patient if appropriate) as per your facility's policy/procedure.	
	Report any severe adverse reactions to the product manufacturer, Health Canada and Ontario Transfusion Transmitted Injuries Surveillance System (TTISS).	
Documentation Required	• Doctor's order • Patient Participant agreement • Proof of training • Product request form-- new order should be obtained at least once a year • Product pick up notification	Patient Participant Agreement Patient Skills Assessment (SCIG) SCIG Product Request Form C1-INH Product Request Form Product Pick up Notification
Most Responsible Person(s) (MRP) or Designate (e.g. Physician, RN, senior laboratory staff or Transfusion Safety	Manage program policies and procedures for Home Infusion.	
	Ensure that everyone (e.g. TML, Patient, Physician, Program Nurse etc.) involved in the program is aware of their responsibilities.	
	Maintain a file for each patient that includes Consent Forms, Participant Agreement Forms, product orders and reports of any adverse reactions.	

	RESPONSIBILITIES	RELATED FORMS
Officer) This individual/individuals may be different at each organization due to staffing requirements and availability of transfusion safety officers, physicians or other staff.	Maintain information about where patient has chosen to pick up their product.	
	Ensure the hospital TML is contacted and made aware that the patient has identified their facility of choice for product pick up. Ensure the TML is able to accommodate the request and ensure they are aware of their responsibilities.	
	C1 ESTERASE: Inform/ in-service to hospital emergency department of potential C1 Esterase Inhibitor users in the area and the potential need for urgent treatment.	
	Review the Patient Infusion Log from the patient every 3 months to ensure product is being appropriately used, there are no side effects / reactions noted and that documentation is complete. The patient log sheets should be filed as part of the patient's medical record, transfusion record or as per the facility policy.	
	Ensure information about any severe adverse reactions reported by the patient is forwarded to the TML that issued the product to ensure appropriate reporting to Health Canada, TTISS and the product manufacturer. Documentation of serious adverse events must be kept as per current standards.	
	Contact the internal or external program nurse if there are any concerns or adverse reactions identified on the Patient Infusion Log or if there is lack of compliance or high wastage of product.	
	SCIG ONLY-IF MRP is not the ordering physician, request that the patient contact the ordering physician if there is more than 1 NEW infection noted on the Patient Infusion Log, increased symptoms or adverse reactions.	Infection Log (SCIG)
Internal or External Program Registered Nurse (adult patients)	Ensure required documents are on the patient's chart.	Home Infusion Patient Consent and Participation Agreement (SCIG) Home Infusion Patient Consent and Participation Agreement (C1-INH) Patient Participation Agreement Nursing policy for SCIG Home Infusion
	Training for self-administration must meet all relevant requirements from the standards. This involves initial demonstration of technique and observation of patient during self- administration. Patients accessing home infusion products must have access to a home infusion program, with qualified personnel (according to facility policy) to assess the patient, order product and provide patient education.	Patient Skills Assessment (SCIG) CSA standard on home infusion

	RESPONSIBILITIES	RELATED FORMS
	Review the management of potential side effects / reactions and ensure the patient has had their questions answered by the responsible physician.	
	After enrollment, review the 1-month Patient Infusion Log with patient to ensure compliance with both appropriate dose, frequency of infusions and complete documentation on Patient Infusion log. Reinforce the need for compliance.	Patient Infusion Log SCIG Patient Infusion Log C1-INH
	Discuss with patient the preferred hospital TML where product will be picked up in the future.	
Most Responsible Physician (i.e Immunologist, patients' primary physician)	Patient discussion and documentation of informed consent for blood products. This discussion and documentation should occur at least annually, or in accordance with the hospital policy. Send completed Informed Consent forms to the internal or external training program nurse.	
	Discuss with patient potential side effects / reactions and the management of any side effect / reaction. **Please refer to the product monograph for current and complete safety and adverse events information**	
	Complete Patient Product Request Form upon initial request and annually thereafter. Send completed Product Request Forms to contacts as indicated on the bottom of the Request Form.	SCIG Product Request form C1-INH Product Request form
	Complete the travel letter to be provided to patient as required.	Travel letter SCIG Travel Letter C1-INH
	Complete Emergency letter/card for C1-INH.	Emergency Card/letter Template (C1-INH)
	Monitor significant laboratory data to determine efficacy or possible adverse effects.	NAC Guidelines for IG therapy for PID
	Review any health concerns including tracking and monitoring frequency and severity of infection (SCIG)/attacks (C1-INH.)	Infection log (SCIG)
Patient Roles and Responsibilities	Complete participant agreement and consent documents.	Home Infusion Patient Consent and Participation Agreement (SCIG)
	Complete home infusion training with program nurse and demonstrate competence in self-infusion.	Patient Skills Assessment (SCIG)
	Describe potential side effects / reactions and explain their management.	
	Agree to 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.	SCIG Patient Brochure SCIG Patient Handbook
	Contact the internal or external program nurse when questions regarding supplies or the home infusion process arise.	
	Maintain and dispose of equipment as instructed.	

	RESPONSIBILITIES	RELATED FORMS
	Perform home infusion in a safe and clean environment.	
	Administer doses on the schedule determined by the physician.	
	Order product when home supply is less than 14 days.	
	Pickup product as instructed from the TML.	Patient skills Assessment (SCIG) (first pick up)
	Ensure any wasted or expired product is documented on tracking log sheet and disposed of following the instructions provided.	
	Attend all scheduled clinic appointments.	
	Recognize the risks associated with home administration of product and ensure product is stored correctly.	

REFERENCES

1. Berger M. Clin Immunol. 2004;112:1-7
2. Berinert product monograph, CSL Behring Canada Inc, September 12th 2017
3. Ugochukwu C.; Nzeako,MD,MPH; Evangelo Frigus, MD; Willian J. Tremaine MD. *Hereditary Angioedema: A Broad Review for Clinicians.* Arch Inter Med, 2001;161:2417-2429.
4. Hizentra product monograph , CSL Behring Canada Inc, July 11th 2018
5. Gamunex product monograph, Grifols Canada Ltd. January 29 2013
6. Cuvitru product monograph,Shire PharmaCanada ULC, July 17th 2018
7. Cinryze product monograph, ViroPharma Biologic, Inc, August 17th 2015

SOURCES OF INFORMATION AND USEFUL RESOURCES

1. Canadian Standards Association. CSA Standard - Blood and blood components Z902-15
2. NSPBCP Atlantic Guidelines for SCIG Home Administration Programs, September 2016
3. British Columbia PBCO Guidelines for Home Infusion, 2009

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APPENDIX A: DOCUMENTS

These sample documents are to be used as a model only in creating your own organizational documents to support your hospital's home infusion program. Those documents provided in WORD can be edited into hospital templates.

SCIG Forms

SCIG Product Request Form

Patient skills assessment (SCIG)

Infection Log (SCIG)

Home Infusion Patient Consent and Participation Agreement (SCIG)

Nursing policy for SCIG Home Infusion

Patient Infusion Log SCIG

Travel letter SCIG

SCIG Patient Handbook

SCIG Patient Brochure

C1 Esterase Forms

C1-INH Product Request Form

Home Infusion Patient Consent and Participation Agreement (C1-INH)

Patient Infusion Log C1-INH

Travel Letter C1-INH

Emergency Card/Letter Template (C1-INH)

Other Useful Forms

Product Pick up Notification

Patient Participant agreement

Letter of authorization for product pickup