Subcutaneous immunoglobulin (SCIg) ‘Getting started’

November 2023

VICTORIA State Government

Australian Red Cross Lifeblood

Blood Matters

Acknowledgement of Country

We acknowledge and pay our respects to the past, present and future Traditional Custodians and Elders of this land and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

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What is SCIg?

Subcutaneous immunoglobulin

- Immunoglobulins (also known as antibodies), are glycoprotein molecules produced by plasma cells (white blood cells). They act as a critical part of the immune response by specifically recognising and binding to particular antigens, such as bacteria or viruses, and aiding in their destruction.
    - Normal IgG level 7 – 12 g/L (this may vary slightly between laboratories)
- Produced by fractionation of donated human plasma
- The main immunoglobulin in SCIg is IgG (approx 98%)
- Human immunoglobulins have been used to treat hypogammaglobulinaemia since the 1950s
- SCIg has been available since the 1980s in USA and Europe but with limited acceptance initially, now widely used in USA, Europe and UK
- Licenced by NBA in Australia in 2013

Approved indications for SCIg in Australia

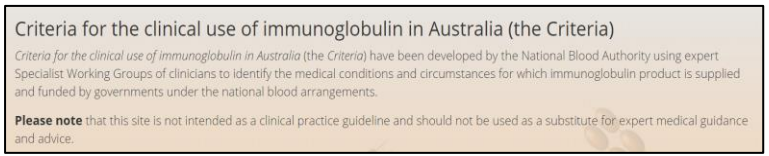
Primary immunodeficiency diseases with antibody deficiency

Specific antibody deficiency

Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)

Secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)

Chronic inflammatory demyelinating polyneuropathy CIDP



https://www.criteria.blood.gov.au/

Comparison table between SCIg and IVIg

Issue	SCIg	IVIg
Who can have it?	Meet SCIg criteria	Meet IVIg criteria
Where	Patient's home – self or carer administered	Hospital – health professional administered
Route	Subcutaneous; abdomen, thigh, upper arm	Intravenous
Lifestyle	Can be administered at a convenient time Gives more flexibility and independence Fewer hospital visits, less expensive	Required to attend hospital every month Arranged by hospital staff
Education	Must learn to insert subcutaneous needle, draw up product, use pump, document event	Report any reactions
Duration of infusion	Approx. 1 hour per infusion – varies depending on dose, number of sites and product	2 – 5 hours per infusion
Frequency	Daily, weekly, fortnightly – varies depending on dose	1 per month (4 weeks)/as prescribed
Health effect	Consistent, steady Ig levels, no wear off effect	Peaks and troughs, wear off effect can start up to 1 week prior to next infusion
Side effects	Local side effects; site swelling, redness and itching at the injection site(s), Can last 1 – 2 days Lower risk of systemic side effects	Systemic side effects; during and post infusion Headache, nausea, flushing shivers, itch and fatigue Can last up to 3 days post infusion
Travel	Can administer SCIg while travelling	Can be difficult to arrange treatment especially overseas

Pro and cons

Type	Pros	Cons
IVIg	• Less frequent infusion (monthly) • Rapid increase in serum IgG • Does not require patient training	• Usually hospital based • IV access required • Risk of immediate and systemic adverse effects • Adverse effects from high IgG levels in 12-48 hours post infusion • Symptoms related to wear off effects of IgG trough levels
SCIg	• Home based therapy • IV access not needed • Few systemic side effects • Can be used for patients with previous systemic reactions to IVIg or IV access difficulties - SCIg therapy may be the preferred treatment in these patients • Shorter infusion duration • More consistent IgG levels with no wearing off effects related to IgG trough levels • Improved QOL for patient and family with flexibility, independence and empowerment • Reduced hospital costs • Reduced patient travel time and associated costs and inconveniences (e.g. time off school/ work, parking costs). • Patient can take treatment with them when travelling (e.g. on holiday)	• Frequent administration (1-3 times per week) • Local side effects (swelling, induration, local inflammation, itch), which are usually mild and transient • Some patients may require battery or spring driven pumps, although some patients may use the rapid push method which does not require a pump. • Requires treatment plan compliance

Australasian Society of Clinical Immunology and Allergy (ASCIA) SCIg Position Statement

- SCIg treatment for immunodeficiency is efficacious, well tolerated, has a favourable safety profile and should be available to all patients where clinically appropriate, with relevant education and follow up care.

- Studies have demonstrated:
  - Immune Replacement Therapy using SCIg has equivalent efficacy to IVIg in preventing bacterial infections in patients with antibody deficiencies.
  - Results suggest that maintaining higher steady state IgG levels results in fewer infections.
  - Incidence of infection is inversely related to the steady state IgG level and maintaining higher IgG levels are beneficial, although no given level is necessarily adequate for all patients.
  - Studies indicate that SCIg infusions result in more stable serum immunoglobulin concentrations with little fluctuation in IgG levels compared to the peaks and troughs of IgG levels associated with monthly IVIg administration.
  - More stable IgG levels reduce the risk of immediate and systemic adverse effects due to high IgG levels post-infusion and symptoms related to wearing off effects of IgG trough levels.

- SCIg therapy has been shown to be well tolerated with a low risk of systemic side effects.

- Whilst local tissue reactions are frequent with SCIg therapy, they are often mild and tend to improve over time. Provision of adrenaline autoinjectors is not considered to be necessary, given the demonstrated safety of SCIg infusions.

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Based on Recommendation 5 ASCIA Position statement - subcutaneous immunoglobulin (SCIg)
ASCIA_HP_Position_Statement_SCIg_2018.pdf (allergy.org.au)

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Why use SCIg?

- Patients have greater control of their own care
- Stable immunoglobulin levels
- Fewer infections
- Reduced hospital admissions
- Improved compliance with treatment
- Do not need IV access
- Systemic side effects are rare

What do patients want?

- Improved outcomes reported on health-related quality of life (HRQoL) scores in patients with PID (Home therapy with subcutaneous immunoglobulins for patients with primary immunodeficiency diseases; Elle Haddad et. al. Transfusion and Apheresis Science, 46 (2012) 315 – 321)

- Most patients prefer SCIg and studies in PID patients have reported improved HRQoL when switching from IVIg to SCIg therapy. (T.M.Windegger et al. / Transfusion Medicine Reviews 31 (2017) 45–50)

- Similar result found for patients with SID although very few studies found (T.M.Windegger et al. / Transfusion Medicine Reviews 31 (2017) 45–50)

- AusPIPs – [Primary immunodeficiency support group] are engaged and a number using SCIg

Patient eligibility/criteria

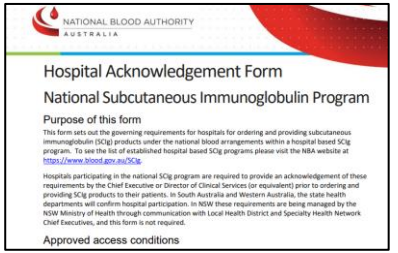
- Patient must meet approved clinical indication as set out in the Criteria
- The patient must be treated by a clinical specialist within a hospital based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the SCIg product, at no additional cost to patients
- Patient-specific SCIg request must be submitted to, and authorised by, the Australian Red Cross Lifeblood (Lifeblood) via BloodSTAR

Health service eligibility criteria

- The hospital must be approved by the NBA to commence a hospital based SCIg program

  The NBA - Hospital Acknowledgement Form National Subcutaneous Immunoglobulin Program must be completed and includes governance requirements for the program.

  SCIg-hospital-acknowledgment-form-2021.pdf (blood.gov.au)


NATIONAL BLOOD AUTHORITY
AUSTRALIA

Hospital Acknowledgement Form

National Subcutaneous Immunoglobulin Program

Purpose of this form

This form sets out the governing requirements for hospitals for ordering and providing subcutaneous immunoglobulin (SCIg) products under the national blood arrangements within a hospital based SCIg program. To see the list of established hospital based SCIg programs please visit the NBA website at https://www.blood.gov.au/SCIg.

Hospitals participating in the national SCIg program are required to provide an acknowledgement of these requirements by the Chief Executive or Director of Clinical Services (or equivalent) prior to ordering and providing SCIg products to their patients. In South Australia and Western Australia, the state health departments will confirm hospital participation. In NSW these requirements are being managed by the NSW Ministry of Health through communication with Local Health District and Specialty Health Network Chief Executives, and this form is not required.

Approved access conditions

  Completed form must be returned to the to the National Blood Authority –

  Email: iggovernance@blood.gov.au
  Fax: (02) 6151 5235 (Attention: Ig Governance)

  Governance Requirements:

  - Quality Assurance
  - Clinical oversight
  - Equipment and facilities
  - Education and training
  - Regular review
  - Supply of product
  - Reporting unused, discarded, spoilt/broken product

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Governance – quality assurance & clinical oversight

Quality assurance

- *Policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards, particularly Clinical Governance Standard (1) and Blood Management Standard (7).*
  - Who will write the policies/procedures?
  - Who will monitor compliance?

Clinical oversight

- *A recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist*
- *Must provide ongoing clinical oversight and support for participating patients*
- *The responsible clinician must consider patient suitability for the self-management and administration of SCIg to ensure appropriate management and use of SCIg product*

Governance – equipment, facilities, education & training

Equipment and facilities

- *Must ensure that patients have access to all necessary equipment and consumables to administer the product,* ***at no additional cost to patients***
  - What equipment will be used?
  - Where will the patient education take place?
  - Where will the patient get the necessary consumables from?
  - Who will ensure the patient has everything they need?

Education and training

- *Must provide education and training for staff and patients*
  - Who will provide the staff education?
  - Who will be responsible for patient education?
  - Will education be one on one, or can it be a group session?

Governance – review and product supply

Regular review

- *Assessing clinical benefit of treatment for ongoing therapy should be conducted at periods specified by the responsible clinician in line with the Criteria*
- *Patients should be encouraged to maintain a diary to record SCIg product use and any adverse reactions, as well as collection and management of product as an aid for the clinician at the assessment*

Supply of product

- *Orders for SCIg for authorised patients must be managed via BloodSTAR, or alternative arrangements if necessary.*
- *The amount of SCIg supplied to a patient should not exceed more than is required for treatment for two months*
- *Supply and dispensing of SCIg product to patients must be in accordance with relevant state/territory legal requirements*
    - SCIg is an S4 medication and must be dispensed by a pharmacist
    - Requires a medication prescription; must provide a copy to the pharmacy
    - BloodSTAR and BloodNET for traceability

Governance – reporting unused, discarded, spoilt/broken product

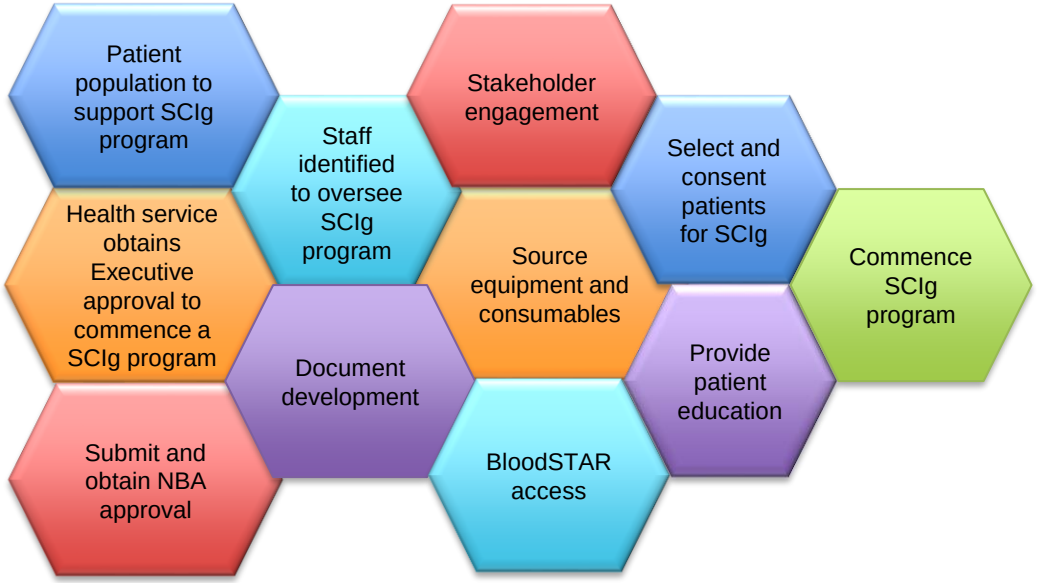
Reporting unused, discarded, spoilt/broken product

- *Patients supplied with SCIg will be expected to report details of unused, discarded or spoilt/broken product to the hospital, to be reported by the hospital through BloodNet*
  - Who will the patient report this to?

Other considerations

- Cost benefit analysis – business case to support the decision (template available on Blood Matters SCIg program, tools and resources webpage [SCIg program, tools and resources (health.vic.gov.au)]
- Clinical engagement – medical, nursing and pharmacy staff
- Space – is there a suitable ward/location for patient education?
- BloodSTAR registration, education

Putting the SCIg pieces together



Patient selection

- Willingness to participate in the program
- Patient or carer with the dexterity and ability to administer SCIg
- Patients with difficult IV access
- Patients who have significant or frequent reactions to IVIg
- Those who travel a long way to get treatment
- Patients who are time poor for any reason and find it difficult to attend for IVIg
- Patients who may be more compliant with SCIg than IVIg – assess reason for non-compliance

Contraindications to SCIg*

- Anaphylactic or severe systemic reactions to immunoglobulin (Ig)
- Extensive skin conditions- psoriasis, eczema
- Cognitive impairment
- Poor manual dexterity, decreased hand grip, tremors, poor eyesight
- IgA deficiency – discuss with immunologist
- Hizentra® AU - patients with known hyperprolinemia (type I or II)
- Hizentra® - patients with known hyperprolinemia (type I or II)
- Cuvitru® - patients with known reactions to glycine and patients with IgA deficiency
- Xembify®° - patients with known reactions to glycine and patients with IgA deficiency

* Refer to product information

° Xembify® will be available from January 2024

Products and vials

Issue	Hizentra® AU*	Hizentra® *	Cuvitru®*	Xembify®*°
Plasma source	Local	Imported	Imported	Imported
Stabilizer	Proline	Proline	Glycine	Glycine
Concentration	20%	20%	20%	20%
Storage	<25°C (do not freeze)	<25°C (do not freeze)	2 – 8°C (do not freeze)	2 – 8°C (do not freeze) May be stored ≤25°C for up to 6 months any time prior to expiry date
Vial sizes	1g (5mL), 2g (10mL), 4g (20mL)	1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL)	1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL), 10g (50mL)	1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL)
Rate	1st infusion - 20 mL/hr/site 2nd & 3rd infusions - 35mL/hr/site Subsequent infusions based on patient comfort & tolerability	1st infusion - 20 mL/hr/site 2nd & 3rd infusions - 35mL/hr/site Subsequent infusions based on patient comfort & tolerability	1st & 2nd infusions - 10mL/hr/site if tolerated increase every 10 min to a max of 20mL/hr/site Subsequent infusions based on patient comfort & tolerability	1st & 2nd infusions - 25mL/hr/site Subsequent infusions – gradually increase to 35mL/hr/site based on patient comfort & tolerability
Frequency	Individualised	Individualised	Individualised	Individualised

- * Refer to Product information
- ° Xembify® will be available from January 2024

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Ordering SCIg - BloodSTAR

- Patient needs to meet criteria for SCIg and MO needs authorisation from Lifeblood via BloodSTAR
- Nursing (or delegated) staff order the product using a planning sheet in BloodSTAR. *This is how the blood bank or pharmacy in the health service are notified of the order*
- Pharmacy or blood bank order the product from Lifeblood via BloodNET
- Product is delivered to pharmacy or blood bank
- For inpatient care, the product can be issued to the ward by blood bank (or pharmacy)
- For home-care the product must be dispensed by pharmacy *(S4 medication)*
- In some cases, the product can be ordered by treating facility and delivered to a rural hospital/pharmacy *(by agreement)*
- Need to advise the blood bank/pharmacy what vial sizes are needed for the patient, so the right dose can be given on a weekly basis

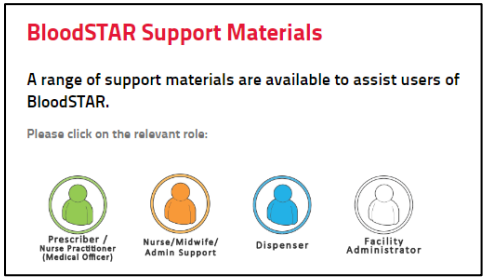
BloodSTAR

Two part process

1. BLOODportal user registration – create username and password for all NBA systems
2. BloodSTAR role request – requesting a role and location for access to your facility
3. BloodSTAR support materials

https://www.blood.gov.au/bloodportal

BloodSTAR-User-Tip-Sheet-Registration-and-Role-Request-Dec2018.pdf



https://www.blood.gov.au/bloodstar-support-materials

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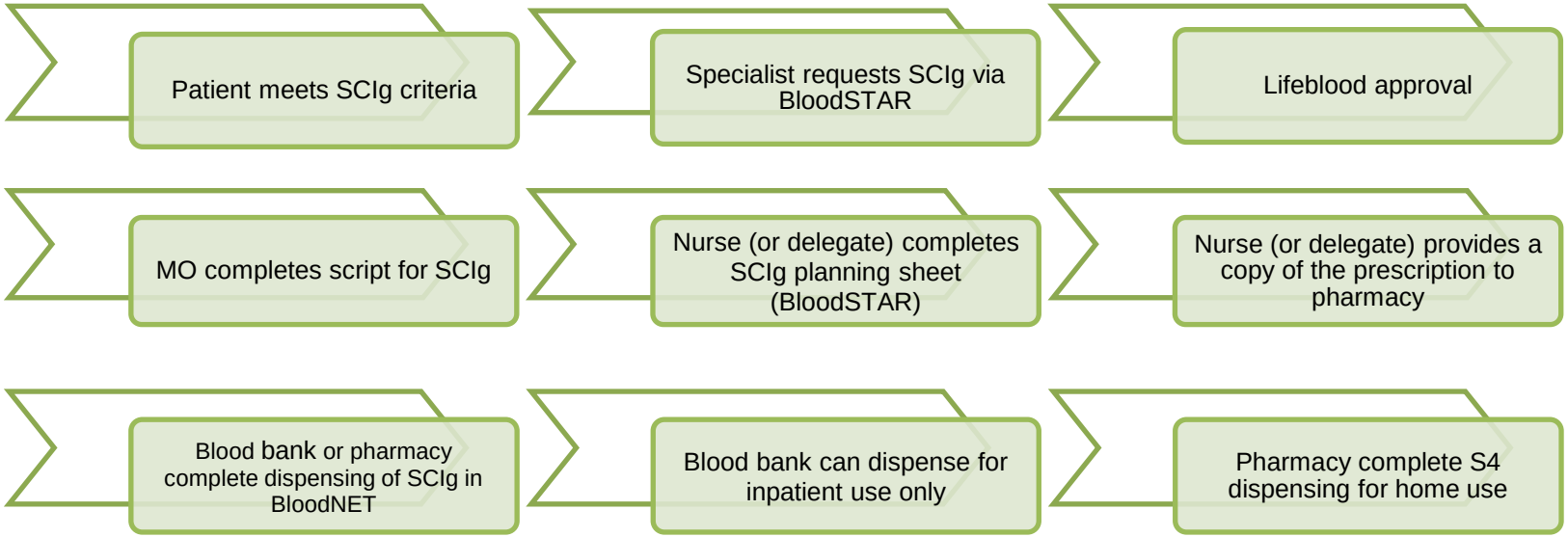
Ordering SCIg flow



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Patient education

- Hand washing & aseptic technique
- Pumps & consumables
- Injection site selection & care
- Ordering & collection of product & consumables
- Transport & storage of product
- Checking, preparing and drawing up the product
- Priming infusion set & needle insertion technique
- Dose and rate calculations (+/- VersaRate – when using the EMED system)
- Adverse reaction management
- Documentation of infusion & report wastage

Equipment: pumps & consumables

- Cooler bag/esky for transport (ice brick)
- Infusion pump
- Subcutaneous infusion set
- Sharps container
- Antibacterial wipes or soapy water (to clean a work surface or infusion mat)
- Alcohol swabs
- Luer lock syringe(s)
- Drawing up needle(s)/vented dispensing pin
- Adhesive dressing
- Small band aid/gauze/cotton ball
- Infusion diary/Infusion App

Subcutaneous infusion sets

Item	EMED	HIgH-Flo	Neria
Needle gauge	24G & 27G	24G & 26G	27G
Needle length	4mm, 6mm, 9mm, 12mm	4mm, 6mm 9mm,12mm,14mm	Steel: 8mm, 10mm, Soft: 9mm
Tubing	36 inch / 70cm	20 inch extension set available	Single lumen: 80cm Multiple lumens: 90cm Soft cannula: 110cm
Needle sets	1, 2, 3, 4 lumens	1, 2, 3, 4, 5, & 6 lumens	Steel: 1, 2, 4 lumens Soft cannula: single lumen
Wings	Y	Y	Y
Adhesive dressing	Dressing included	Dressing included	Integrated dressing

Subcutaneous infusion sets cont…

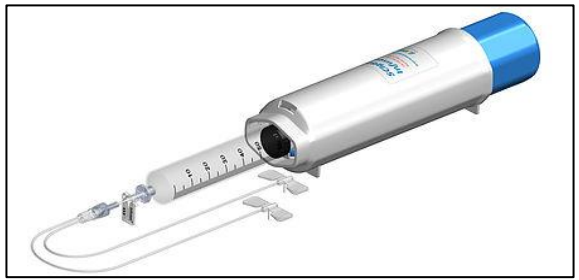
Item	Butterfly needle Terumo	BD Saf-T-Intima
Needle gauge	21G, 23G, 25G	20G, 22G, 24G
Needle length	19mm	19mm
Tubing	30cm, 9cm	Short
Needle sets	Single lumen	Single lumen
Wings	Y	Y
Adhesive dressing	Dressing not included	Dressing not included

Pumps

Emed - SCIg 60 infusion system

https://www.emedtc.com/products

- Spring driven
- 50/60mL BD syringe
- Rate controller - VersaRate Plus | EMED Technologies (emedtc.com)



Springfuser ® syringe infusion pump - 10,30 or 50

Go Medical Industries Pty Ltd - Springfusor & FCT

- Spring driven
- 10ml, 30ml or 50ml Syringe (syringe size varies with pump size)
- Flow rate control tubing and syringe (purchased separately)
- Can be used with any needle system

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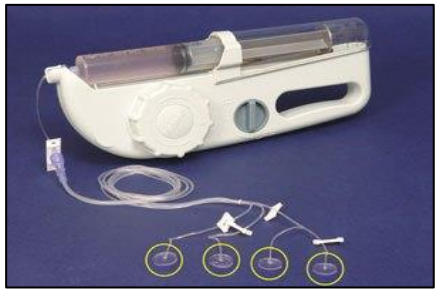
Other pumps

Niki T34™
- Battery powered
- Programmable – rate control
- Up to 50mL options

FREEDOM60®
- Spring driven
- Uses flow control tubing
- 60mL BD syringe



FreedomEdge®
- Spring driven
- Uses flow control tubing
- 20-30 mL syringe

Documentation

Record in the patient infusion diary/infusion App/medical record:

- Product name
- Batch number
- Dose
- Volume
- Infusion time
- Infusion site
- Infusion rate
- Symptoms/side effects

Questions to you

- What support/assistance do you need?
- Business case
- Policy/procedure
- Staff education and checklist
- Patient education and checklist
- FAQs

Further information:

Contact: Anne Graham

Blood Matters Project Nurse

Phone: 03 9694 0126

Blood Matters SCIg information, tools and resources:

https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-access-program

Acknowledgement

Australian governments fund the Australian Red Cross Lifeblood to provide blood, blood products and services to the Australian community.

Accessibility

To receive this presentation in another format phone 03 9694 0102, using the National Relay Service 13 36 77 if required, or email Blood Matters <bloodmatters@redcrossblood.org.au>.

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