Subcutaneous Immunoglobulin Program Patient Training Checklist

Patient Skills	The below skills are to be discussed and assessed at each patient training session
Competent (C) **Not yet competent (NYC)**	At each training session record the patient competency level on the Training Competency form
What are Immunoglobulins	• Immunoglobulins are antibodies that are found in blood. • Produced by the body's immune system to fight infections caused by bacteria and viruses. • If the patient is low in these immunoglobulins, they may not be able to fight infection. • SCIg is an immunoglobulin therapy that is used to increase and correct low levels of immunoglobulins in the blood. • By injecting SCIg products at regular weekly intervals the patient's immunoglobulin levels should remain stable and infection rates should be reduced.
Blood Tests	IgG levels to be taken at a minimum: • baseline then • monthly for 3 months then • 6 monthly for the duration of the treatment
Transportation and storage requirements (product specific)	• Patient to supply: 12 pack sized foam esky and ice bricks (to cover bottom of the esky) when collecting product (monthly). • Protect from light. • Do not use after expiry date. • Do not freeze. • SCIg products must be taken home immediately and placed in a plastic container in the centre of the fridge (2-8^{o}C). • If SCIg product is removed from refrigerated conditions, it must be stored at below 25^{o}C and used within: Evogam – 2 weeks Hizentra – 2 years Cuvitru – 12 months • The date of removal from refrigeration and the new expiry date must be recorded on the outer carton. • In the event of a power failure place the SCIg product in a foam esky with ice bricks (this should keep the temperature below 8 degrees for 4 hours). Locate a working refrigerator as soon as possible.
Location of infusion site	• Administration of the Immunoglobulin into the subcutaneous tissue at: - Abdomen - Thighs - Upper arms • It is recommended that the same infusion site be used each infusion episode. • Initial mild 'flare' reactions may be experienced but these will diminish over time. • Infusion volume may be divided between infusion sites and it is recommended each site should not exceed 30mLs, but variations may be acceptable based on patient tolerability. • Infusion sites should be at least 5cm apart.

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Equipment Checklist	**Patient to supply:** • 6 pack sized foam esky • Ice bricks to cover bottom of foam esky • Plastic container to store products in refrigerator • Small band aid or gauze **Staff to supply for each infusion:** • Subcutaneous needles or thumb needles (number will depend on number of infusion sites) • Alcohol swab x 2 • Luer lock syringes (number and size will depend on number of infusion sites) • Drawing up needle (if required) • Surgical tape (required if using subcutaneous needles without fixing device) • SCIg product – check dose and expiry • Sharps container – when full return to the hospital and exchange it for a new one • Infusion Diary • Have everything within easy reach for preparation and infusion. • Ensure the infusion is prepared on a clean working area / surface.
Checking the product – type, dose, expiry, discolouration	• Check product type – is the product the same as what the MO has ordered. • Check dose – ensure patient is aware of total monthly and weekly dose. Ensure patient aware of location of dose on product packaging. • Check expiry – ensure Pt is aware of expiry date on bottle – do not administer if after expiry date. • Discolouration – check solution. Solution must be clear. Do not use if cloudy or contains particles / sediment / deposits. • Remove product from refrigerator 15-30 minutes and bring to room temperature prior to injecting.
Preparing the infusion site	• Select appropriate infusion site. • Collect all equipment from the equipment checklist and place on a clean work surface.
Preparing the product	• Wash and dry hands to prevent cross infection. • Remove cap from the vial and wipe the rubber stopper with an alcohol swab; allow to dry. • Prepare the syringe (draw back plunger to fill the syringe with air. • Attach the drawing up needle (Hizentra)/ transfer adaptor (Evogam). • Insert the needle/transfer adapter into the rubber stopper on the bottle. • Inject the air from the syringe into the vial and invert the vial, draw back the immunoglobulin into the syringe. • Repeat as required for multiple vials using a new vial adapter for each.
Prime tubing	• Connect the syringe filled with the Immunoglobulin to the infusion tubing/needle. • Gently push the syringe plunger until the solution fills the tube but leave 2mm to 5mm un-primed prior to the needle. This ensures there is no solution at the needle tip for insertion to reduce risk of irritation during insertion.

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Insert of the SC Needle / Thumb needle **(no touch technique)**	Clean the injection site with an alcohol swab Pinch the skin around the injection site If using a butterfly needle insert on a 45^{o} angle under the skin – place gauze or cotton wool under the needle to maintain angle and secure with surgical tape. If using thumb needles inject at a 90^{o} angle and secure with attached dressing. **SAFE-T-CHECK** **Check the needle placement – ensure no blood return and the needle is not in a blood vessel. Pull plunger back gently, if no blood return, disconnect the syringe and watch for blood return in the tubing for approximately 5 seconds. If no blood return progress with the infusion.** **If blood return is noted the needle may be inserted in a blood vessel – do not administer but remove and discard the needle and tubing. Repeat the needle insertion as above 2-5 cm from original puncture site.**
Administer the product	Slowly infuse product at approximately 210 mL/hour and gradually increase with each infusion up to 430-40mL/hour. Variations may be acceptable based on patient tolerability. The infusion site may be changed if patient comfort becomes an issue.
Removal and disposal of needles and vials	At completion of the infusion leave the syringe attached to the needle/ infusion line. Remove the needle by taking off the dressing and pull the needle out of the skin. Cover injection with a dressing/gauze and apply light pressure to the injection site. The needle, attached tubing, syringes and empty vials must be discarded in a sharps container. Once the sharps container is full, return it to the hospital for disposal. Do not dispose of the immunoglobulin equipment in general, household waste.
Record infusion in the treatment diary	Record product name, batch number, dose, volume, infusion time, infusion site, symptoms/side effects.
Reporting waste/unused	Expired or unused SCIg products/bottles must be returned to the hospital and not discarded in household waste. Unused or expired product that is returned is to be reported and/or returned to blood bank/transfusion service in the hospital by the nursing staff. Record all waste/unused SCIg products on the Treatment Record Sheet.

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<table>
<tr><td rowspan="4">Adverse events and reactions</td><td colspan="3">Redness and swelling at the injection site are common particularly in the first 4-8 weeks of commencing on SCIg treatment. Swelling and redness should gradually dissipate over the initial 24-48 hours.</td></tr>
<tr><td>Reaction</td><td>Treatment</td><td>Options</td></tr>
<tr><td>Normal

Swelling, redness and inflammation at the injection site</td><td>Cold pack (optional)</td><td>May consider paracetamol or antihistamine if ordered by a medical officer</td></tr>
<tr><td>Mild

Headache, flushing, feeling sick, shivering, itchiness, muscle aches, anxiety, dizziness</td><td>Stop the infusion for 30 minutes</td><td>Restart when symptoms have subsided/ceased. May consider paracetamol or antihistamine if ordered by a medical officer</td></tr>
<tr><td>Moderate

Chest pain, wheezing, severe itchiness or worsening mild symptoms</td><td>Stop the infusion and seek medical attention</td><td>Follow medical advice. Alert the Blood Bank and CNC Blood Management</td></tr>
<tr><td>Rebooking treatment and product collection</td><td colspan="3">SCIg Clinic:
• SCUH - Adem Crosby Centre
- DUIT Clinic 6
• Nambour – Cancer Care Centre
• Gympie – Chemotherapy Service

Patient training (weekly for two - four weeks or as long as patient requires)
- 1st training will require a three-hour booking depending on volume
- Subsequent bookings may require two-hour sessions

Once training is complete the patient must be booked monthly for 15-30 minutes in an appropriate SCIg Infusion Clinic for collection of the immunoglobulin product and disposables, documentation of previous infusions and completion of treatment record sheet.</td></tr>
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Ordering of SCIg products	• SCIg products must be approved for use through Lifeblood • The prescribing medical officer must complete the online authorisation on BloodSTAR on the National Blood Authority website • Once approved, nursing staff are to order the SCIg products on BloodSTAR. • Ensure preferred vial sizes are written in the comments section. Orders must be placed at least one week prior to the date of collection by the patient.

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	• Once a patient is assessed as stable (nil adverse reactions, and after three months of treatment) ordering and collection of SCIg can occur on a two monthly basis. • SCIg products will be supplied from Lifeblood to the hospital Blood Bank. • Nursing staff are to collect the blood product on date and time of patient collection and pack in esky with ice bricks for transportation home.

Understanding of Niki pump usage and troubleshooting	• The nurse will pre-set the infusion time with the patient (approx. 30-40 mL/hour depending on patient comfort and tolerability) during the training sessions.
	• To turn the NIKIT34, press and hold the ON/OFF button until it 'beeps'.
	• The version of software will flash on the screen. The NIKI T34 will then flash 'pre-loading'. Allow the NIKI T34 to pre-load, it calibrates itself during this process.
	• During this pre-loading phase the actuator will move to the position of the last infusion.
	• Measure drawn up syringe against NIKI T34 and press either FF or Back to align actuator to syringe plunger. The actuator will re-set to the previous syringe size.
	• The actuator can only be moved as described. DO NOT use force to try and move the actuator manually as this could damage the device.
	• Raise the barrel arm clamp and place the syringe in, then lower the barrel arm clamp. If the syringe is not placed correctly then the screen will flash at which sensor the placement is incorrect. Check the 3 sensors.
	• The 3 point syringe detection for correct placement are:
	  ○ A – Barrel clamp arm. This detects size/width of barrel and secures it
	  ○ B – Syringe ear/collar sensor small metal switch. Detects secure loading of syringe collar
	  ○ C – Plunger sensor. Detects secure loading of syringe plunger.
	• Once the syringe is correctly loaded the next screen display will ask for identification of the syringe brand.
	  ○ Use a luer lock syringe (10ml or 20ml Terumo, 10ml or 30ml BD Plastik syringe). Ensure that the NIKI T34 has recognized the syringe you are using correctly - to confirm press "yes"
	  ○ Check and review data on screen, Volume, Duration, Rate - to confirm press "yes"
	  ○ Start Infusion - to confirm press "yes"