Document Name: **SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) – ADMINISTRATION**

Restrictions:

Description

What are immunoglobulins

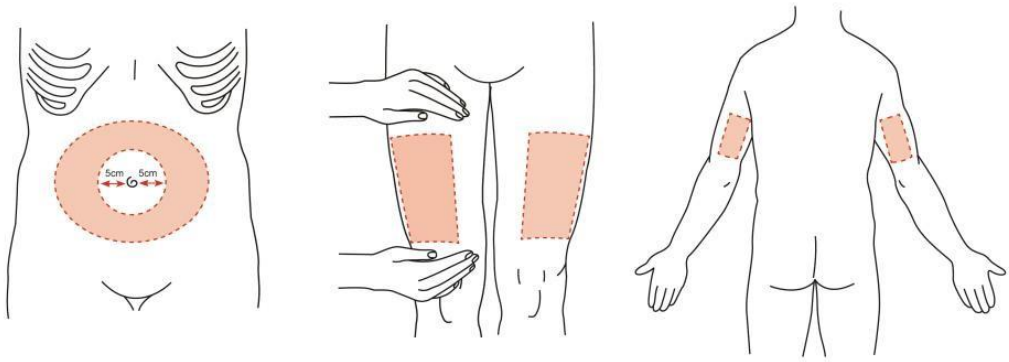
- Immunoglobulins are antibodies that are found in blood.
- Produced by the body's immune system to fight infections caused by bacteria and viruses.
- If the patient is low in these immunoglobulins they may not be able to fight infection.
- SCIg is an immunoglobulin therapy that is used to increase and 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

Equipment

Refer Appendix 3 for consumables lists

- SCIg infusions can be easily performed in the home setting. The patients can use a pump device or manually deliver the infusion via a slow push. The latter is likely to more effective after several months use of the pump.
- The most cost-effective pump is the EMED SCIg 60 infuser, which is a non-electronic TGA-registered pump that is sturdy, robust and accurate without the need for yearly calibration.
- The pump is used with a SAF-Q needle and a initially Versa-rate flow plus control tubing to deliver the infusion at an appropriate rate (start at open and use control dial to slow rate if not tolerated).
- The EMED pump should be cleaned according to work cleaning instructions for the SCIg 60 infuser.

Infusion sites



SCIg may be administered at a number of possible sites according to patient preference. Usually the lower abdomen will be used. Ensure selected site is at least 5cms from umbilicus "belly button". The outer edge of the thigh or back of the upper arm can also be used. The shaded areas can be used for insertion of the needle.

NB: Rotation of infusion sites is not recommended. Using the same site for infusion can help to reduce the amount of swelling and redness that may occur post infusion. Avoid areas of rash, bruising, irritation.

Infusion process:

In the health service

Prior to commencing the infusion check:

- SCIg has been prescribed
- The correct SCIg presentation has been issued (check that the dose for administration matches the dose authorised and matches the authorised product)
- **SCIg has reached room temperature prior to infusion**
- The correct corresponding technique for the patient has been identified (manual push or via infusion device/pump). The choice of administration technique and equipment is at the discretion of the treating healthcare professional and the patient, based on availability of devices and personal preference.
- Baseline observations have been taken and recorded
- Any pre-infusion symptom which may be confused with an adverse reaction has been noted.

Checking the infusion:

- Check patient identity as per **PATIENT AND PROCEDURAL SITE IDENTIFICATION and MEDICATION Administration**
- Check you have the right rate of infusion. Different SCIg products are given according to different infusion schedules and patient clinical need.
- **Infusion: subcutaneous**
- **Please be aware that infusion volumes vary between products /presentations** (see Table 1 **SUBCUTANEOUS IMMUNOGLOBULIN (SCIG)- patient selection and management**
- Products/preparations are not interchangeable
- Administration techniques and equipment – may be via manual push infusion device/pump refer. **SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion**
- Infusion site selection – most common is lower abdomen - ensure site is at least 5cms from umbilicus
- Site rotation is **not** recommended - using the same site for infusion can help to reduce the amount of swelling and redness that can occur post infusion

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Observations

Perform and document the patient's temperature, pulse, respiration rate and blood pressure at the following points as a minimum:

- prior to commencing
- on completion
- observe patient for 20 minutes post completion.

If a patient experiences an adverse reaction to SCIg infusion more frequent observations may be required.

Subcutaneous Immunoglobulin (SCIg) Program Treatment Flowchart

Selection of Patients:

- Primary immunodeficiency with antibody deficiency
- Specific antibody deficiency
- Acquired hypogammaglobulinaemia secondary to haematological malignancy
- Secondary hypogammaglobulinaemia

Treating Consultant:

- Patient identified & accepted into program by Haematologist.
- Initial Authorisation Request submitted in BloodSTAR including Privacy Consent (www.blood.gov.au)
- Blood and Blood Product Prescription form completed (4weekly training sessions & 1 month supply).
- Pathology Request form for baseline IgG.
- Complete section 2 of **SCIg - CSL Cares Nurse Care Patient Enrolment form**

Blood Tests – IgG ·

- Baseline *then* ·
- monthly for 3 months *then* ·
- 6 monthly for the duration of the treatment

Treatment co-ordination:

Notification to SCIg program co-ordinator (Day stay ward)

- Communication with patient re: SCIg program, products, infusion methods, training timeframe.
- Asess: hand strength and dexterity, ability to retain information, willingness to self infuse and any other limiting factors. ·
- **Patient must agree to progress with inclusion in the SCIg Program.**

Patient Booking:

- **Training booking**: weekly for 4 weeks (duration of 3-4 hours). ·
- Consider availability of SCIg trained staff.

Ordering of Product: (1 week prior to treatment)·

- Order via BloodSTAR Pharmacy to order product in Blood Net. ·
- Once Pt is stable ordering can be undertaken each 2 months.
- Pt. to notify pharmacy 1 week in advance of need for new supplies

Patient training

- Weekly training sessions until the patient is confident and competent to self manage infusions – nurse and patient assessment.
- Minimum 1 week – 4 weeks approx.
- Assess infusion method required for each patient – push, EMED pump, other
- Pt training to be undertaken by a SCIg trained nurse following **Doing your own Subcutaneous immunoglobulin infusion.**
- **SCIg Training Competency** form must be completed each training session and signed by patient once deemed competent (then file in Medical record).
- Complete **Treatment Record/ care plan** and **Product and Consumable Supply List** at first training session file in infusion folder on ward.
- Complete **Patient Assessment** form at end of each training session (file in pts medical record)·
- Document in patient clinical record.

Collection Bookings appointment.

- Once patient is stable (nil adverse effects/issues) collection 2 monthly
- Nurse collect supplies as required for next 8 weeks on the **Consumable Supply List** and gives to patient at their appointment.
- Undertake a patient assessment and complete **Patient Assessment** form at each collection booking.
- Address all identified issues and if required discuss with MO or Transfusion Trainer.
- Make next collection booking with patient.
- Update **Treatment Record/ care plan** and **Consumable Supply List if required.**

- **Prescription** required for each 8 week supply of product
- Patient collects SCIg product from Pharmacy (pre ordered).*Pt. to notify pharmacy 1 week in advance of need for new supplies*
- Product Packed in patient supplied esky with ice bricks and instruct patient to place in fridge as soon as they get home.
- Hizentra must be stored below 25 degrees Celsius (fridge):

Home treatment: Patient education requirements

Patients to receive a personalised education program in day procedure by a clinical nurse specialist trained in how to administer SCIg therapy at home.

Patients must:

- Receive appropriate training and education prior to self-administering at home
- Understand transportation & storage requirements of specific product
- Describe SCIg administration and appropriate sites for infusion
- Understand and demonstrate care of infusion site
- Describe appropriate supplies necessary to complete procedure
- Understand how to use infusion device/pump, and what to do when not working or if alarm sounds
- Understand "push" method as an alternative or when infusion device/pump is unavailable
- Understand how to check and prepare product, how to report wastage and return unused product
- Demonstrate ability to prepare infusion site and draw up product from single or multiple vials and prime tubing
- Demonstrate insertion of subcutaneous needle/catheter /checking for blood/what actions to take if blood is present
- Demonstrate appropriate aseptic technique
- Demonstrate accurate administration of treatment, and removal and safe disposal of needle
- Demonstrate ability to accurately record infusion treatment information in diary
- Understand potential situations/reactions which could result from the infusion
- Understand correct management of any reactions to treatment

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Initial training for self-administration at home

Specific steps to be assessed prior to patient/carer considered competent to self-administer medication in a home setting.

The number of training sessions should be individualised according to patient's/carer's needs, as a guide patient training weekly 2-4 weeks.

- The first education session is usually a minimum of 2hrs but can be up to 3hrs to be undertaken in Day Procedure.
- The subsequent sessions tend to be shorter 1 – 2hrs in Day procedure
  - Demonstrate at first visit
  - Support and assist at second visit
- Patient information utilised
  - **SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion** https://www.youtube.com/watch?v=LOEQz165jtU emed
  - https://www.youtube.com/watch?v=nP4LGk-I5Ds Hizentre CSL
  - CSL Patient packs and support program brochure.
  - Patient Education competency record is completed (Appendix 2).
- Future Visits are booked in Day Procedure.
- Patients to be enrolled in CSL support program 'CSL Behring Cares Program' by Nurse who first discusses the appropriate support offering with the patient receiving SCIg therapy.
  - Assess level of support required - at a minimum all patients to be enrolled in Level 3 so they can access phone support. Most patients would benefit from Level 1, with a coaching visit when first administering at home.
  - Complete Enrolment form **SCIg - CSL Cares Nurse Care Patient Enrolment form** (prescriber to completer section 2)
  - Email form to support@cslbehringcares.com.au or fax the form to 1800 734 989

Documentation / responsibilities

Patient / carer	Treatment must be documented /recorded in patient treatment diary (booklet / sheets (Appendix 4) /My Hizentra app, SWH only code for setup 4949 https://www.hizentra.com/patient-infusion-app. Patient to notify pharmacy 1 week in advance of need for new supplies
Specialist	BloodSTAR authorization & Annual blood product consent Medication order on medication chart for training sessions Prescriptions for each 1 or 2 month supply of product for home administration. Complete section 2 of **SCIg - CSL Cares Nurse Care Patient Enrolment form**
Nurse	Education competency (Appendix 2) Consumables supplied. (Appendix 3) Treatment record / care plan (Appendix 5) Patient assessment form (Appendix 6) at each review / or entry in clinical notes Complete **SCIg - CSL Cares Nurse Care Patient Enrolment form**
Pharmacy	BloodSTAR/ BloodNet request dose etc.
CSL support program	Reports From CSL support program forward to Day procedure and to be include in Patients medical record.

Patient reviews

Once patient is independent for administration of SCIg they will required regular review and supply of product and equipment.

- Monthly for the first 3 months of treatment approx. 30 min – 1hour depending if there are any issues that need to be addressed, unless deemed independent enough to have 8 weekly reviews Or 8 weekly with CSL support visit would be acceptable.
- Once patient is stable (nil adverse effects/issues) collection may be extended to 2 monthly.
- During these reviews the Nurse will review
  - the adequacy of replacement, resulting in serum IgG level > 7 g/L,
  - the Patient Treatment Diary,
  - Clinical indicators of effective IgG replacement that include, but are not limited to, clinical infections or antibiotic prescriptions and
  - Reinforce what to do in case of adverse effects.
- As a guide IgG blood test is to be undertaken Pre, 2nd monthly for first 6mths then as directed by Medical Officer.
- Complete **Patient Assessment** form (Appendix 6) at each collection booking. Address all identified issues and if required discuss with MO.
- **Supply** the patient with the required consumables as required on the Consumable Supply List (Appendix 3) and document consumables given (file in Infusion folder).
- **Document** in patient clinical record on patient assessment form /clinical notes
- Review treatment record / care plan (Appendix 5) and update if needed (file in Infusion folder, if updated old form filed in medical record with date superseded).
- Make next review booking with patient every 8 weeks,
- The Nurse may consider ceasing the SCIg and returning the patient to IVIg if there are concerns regarding patient ability to safely administer or the patient is unable to meet the required schedule.
- If patient has any further questions, they can also contact the 'CSL support program' outside review appointments.

Pharmacy

- Medication order on medication chart required for dispensing for training sessions.
- **Prescription** required for each 1 or 2 month supply of product for home administration.
- **Patient to Collect** SCIg product from pharmacy. Hizentra must be stored below 25 degrees Celsius (fridge) Evogam refer product info.
- Pack product in patient supplied esky with ice bricks and instruct patient to go directly home and place in fridge
- Follow-up that authorisation (BloodSTAR) and prescriptions are organised for next review.
- Reminder to specialist if more paperwork required.

Adverse effects

Adverse effects tend to most commonly be infusion site related.
Table 2 and 3 outline possible effects and management.
Consideration should be given to patients who receive SCIg:

- for the first time
- when there has been a long interval since the previous infusion (8 weeks).

Table 2: Possible side effects

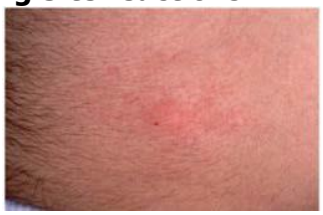
Very Common	**Common**	**Rare**
• Infusion site related • Fever • Nausea • Vomiting • Diarrhoea	• Chills • Back pain • Arthralgia • Hypotension	• Allergic reactions • Anaphylactic shock • Thrombotic reactions • Urticaria

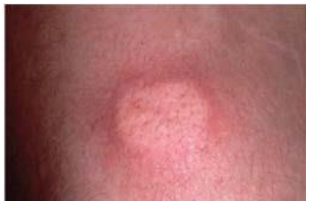
Table 3: Adverse effect management at home by patient or carer
(Ensure to record all adverse effects in patient diary)

Reaction	**Action 1**	**Action 2**
Mild (common skin reaction) Large swelling and redness at insertion site	Apply cold pack to the area	Take paracetamol or antihistamine if instructed/ordered. Swelling should resolve over next 24-48hrs
Moderate Headache, flushing, nausea, shivering, itching, muscle aches, anxiety, dizziness, irritability	**STOP** infusion for 30 minutes	Restart when symptoms have gone, Take paracetamol / antihistamine if instructed /ordered
Severe Chest pain, wheezing severe itching or any mild or moderate symptoms as above become worse	**STOP infusion** **Call 000 to get urgent medical help** Patient to Lie or sit down as comfortable	Tell your doctor or nurse specialist as soon as able.

Troubleshooting Site reactions

Mild





Moderate

Injection site reactions - Blanching - Redness/Rash - Itching - Discomfort - Swelling	Assess for tape allergy – change to paper/ hypoallergenic tape Assess needle size- choose needle that is consistent with volume to be infused Assess length of needle – may be too short and infusing into the intradermal layer Assess site location – may be too close to muscle layer Decrease rate of infusion or volume per site Avoid tracking of Ig through the intradermal layer check needle tip is dry prior to insertion Consider appropriateness of rotating infusion site Consider use of topical anaesthetic cream
Leaking at insertion site	Assess needle - ensure fully inserted and fixed securely Assess placement – is it in area of movement, consider alternative site Assess length of needle – may be too short, change to longer needle Assess infusion volume – decrease amount per site Assess rate of infusion – slowing rate may help
Extreme discomfort with needle	Assess needle length ensure no too long and irritating abdominal wall Assess needle is being inserted "dry" to prevent tracking through intradermal layer Consider using needless indwelling subcutaneous catheter device Consider using ice or topical anaesthetic cream prior to insertion
Long infusion time	Ensure SCIg ready to use at room temperature Assess volume per site, rate of infusion, number of sites or adjust infusion regime Check equipment for clamps/kinks, correct selection of needle size, tubing. If using a pump check function, battery not low.
Blood return observed	Remove and discard needle with blood return and reinsert with new insertion needle and site

Troubleshooting further info

https://www.slideshare.net/DallasAllergyImmunology/immunoglobulin-replacement-therapy

Adverse effect reporting

Adverse effects should be reported using Riskman and following SWH **ADVERSE DRUG REACTION** and also reported to both the supplier and the Blood Service.

Supplier adverse event forms are available directly from the supplier or contact the Blood Service transfusion nurses (TN) who will forward a copy. Blood Service TN email: vtatn@redcrossblood.org.au CSL Behring email: adverse.events.global@cslbehring.com

Where a change of product is required, this is done via BloodSTAR using a dose change request / initial authorisation request by the treating Medical Officer. There is also the option of creating an alert on Blood STAR to prevent dispensing of the offending product. The alert can be added by the treating Medical Officer

Key align policies

MEDICATION Administration

Key align documents

SCIg - CSL Cares Nurse Care Patient Enrolment form
SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion
SUBCUTANEOUS IMMUNOGLOBULIN (SCIG)- patient selection and management
SCIg EMED Versarate Plus flow calculator

Legislation, standards & best practice

POISONS CONTROL PLAN (PCP)

References

- https://www.transfusion.com.au/blood_products/fractionated_plasma/SCIg
- https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/evogam-au-pi-800.pdf?la=en-us&hash=2FECE8E47F85B328F10996442028EC8F31F833DD Evogam®
- https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/hizentra-au-product-information-800.pdf?la=en-us&hash=852F1A8C1BA08F755B6BE1FE7209193EF0489F40 Hizentra®
- https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf

Contributors

	Name **First initial. Surname**	**Position** **I.e. AUM Intensive care**	**Involved in**			
			Development / review	**Ratification**	**Implementation**	**Compliance**
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Contributors:						
Committee/s:	Clinical policy, procedure and pathways committee			X		
Consumer input						
Executive sponsor	J Clift	Director of Nursing				

Implementation & communication

Clinical policy, procedure and pathways committee monthly memo
Staff education and training program

Compliance

Riskman

Appendix 1: Patient information - How to administer *refer*

SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion

Appendix 2: Patient education competency

Affix Patient identification label here

Steps must be assessed by the clinician prior to patient/carer being competent to self-administer SCIg. The number of training sessions required are individualised for each patient.

Patient Skills	**Session 1** Date: / / Clinician Name: Signature:	**Session 2** Date: / / Clinician Name: Signature:	**Session 3** Date: / / Clinician Name: Signature:	**Session 4** Date: / / Clinician Name: Signature:
Competent (C) Not yet competent (NYC) (Please circle)	**C NYC**	**C NYC**	**C NYC**	**C NYC**
Describe transportation & storage of SCIg product.				
Define SCIg administration & location of infusion site/s				
Demonstrates appropriate selection of infusion sites				
Understands appropriate equipment required				
Demonstrates understanding of infusion device/pump (*only required if infusion device/pump used)*				
Demonstrates understanding of "push" method. *(pt. must be aware even if infusion device pump is used)*				
Demonstrates understanding of SCIg checking – type, dose, expiry, discolouration.				
Demonstrates understanding of how to draw up SCIg from single or multiple vials				
Demonstrates ability to prime tubing and set up pump (where pump used)				
Demonstrate ability to: • prepare skin for infusion site • insert s/c needle/catheter using no touch (aseptic) technique • secure needle/catheter check for blood return				
Demonstrate ability to remove and safely discard needle				
Demonstrates ability to accurately record treatment in infusion diary and understands how to report waste and return unused SCIg				
Demonstrates understanding of adverse effects and how to manage.				
Changes or problems (record in clinical notes)	☐	☐	☐	☐
Satisfactory to self-administer Yes /No				
Patient acknowledgment.				
Rebook to Day Procedure if more education needed	☐	☐	☐	☐

Created using NBA, Sunshine Health Service, Barwon Health documents, Younger et. al. 2015

Appendix 3: Consumable supply list

South West Healthcare

Affix patient identification label here

Use as a guide to equipment required by patient to home administer SCIg

Product and supplies		**Number supplied each review**								
Patient supply										
Small Esky & ice brick/s frozen if required *Make sure patient knows to bring to each review.*										
Preparation area mat *Supplied by CSL with startup kit*										
Infusion pump – *EMED SCIg 60* if required Supplied on setup										
Band-Aids to apply post infusion										
Hospital supply	Supply No	E.g. Per week								
Leur lock syringes BD 50mL if using EMED syringe driver ☐ Other if using different method_____ ☐		1								
Drawing up needle - Micropin for Hizentra		2								
Infusion needle/s – *SAF Q* _____		1								
Infusion extension set if required		?1								
Rate controller if using EMED syringe driver may only be required initially		1								
Occlusive dressing i.e. Tegaderm to anchor needle while infusion in progress *comes with EMED needles*		?2								
Pressure pad (if on blood thinners) otherwise pt. supplies own Band-Aid		?2								
Alcohol prep swabs.		3								
Sharps container (exchange when full)		? 1								
Infusion diary / sheets / using app https://www.hizentra.com/patient-infusion-app	Pg. 11									
SCIg Product Number to be supplied each month Hizentra® – vial size 1g (5mL) ☐ 2g (10mL) ☐ 4g (20mL) ☐, 10g (50mL)☐ Evogam®– vial size 0.8g (5mL) ☐ 3.2g (20mL) ☐ **NB:** Dose approved and frequency of infusion needs to be considered when requesting SCIg. Ensure vials requested match dose required to ensure no waste.	Pharmacy									
Staff initials										
Date supplied										

Created using Sunshine Health Service, Duff et.. al. 2015, Younger et.. al. 2013.

Appendix 4: Patient treatment diary

NB: CSL Behring have patient record booklets available for both Evogam® and Hizentra® which can be used instead.
or My Hizentra app https://www.hizentra.com/patient-infusion-app
____ SWH set up code 4949

Affix Patient identification label here

Healthcare team contact details

Hospital /Clinic name:_____

Specialist name:_____

Phone:_____email: (if applicable)_____

Nurse name:_____

Phone:_____email: (if applicable)_____

General Practitioner name:_____phone:_____

Product: (circle) Evogam®Hizentra® Dose:_____g /_____mL Frequency:_____

Infusion Record

	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Date and Time								
Volume								
Site/s used								
Side effects								
Medications used								
Batch numbers (affix label/s)								
Notes								

Next appointment date:_____

Created using CSL Behring 'Hizentra® ' , Sunshine Health Service, Duff et.. al. 2015, Younger et.. al. 2013.

Appendix 5 Subcutaneous immunoglobulin program

Treatment record / care plan

Affix Patient identification label here

Commence new treatment record sheet if changes to dose, treatment hospital or unit.

Please keep as a record in unit based infusion folders for reference by nursing staff

Patient Weight _____(kg)

Product Name: (please circle) Evogam Hizentra

Total Dose: Monthly _____(g) Weekly _____(g)

Total Volume: Monthly _____(mL) Weekly_____(mL)

Number of Infusions each week: (please circle) 1 Other (please state)**:** _____

Number of Injection Sites: 1 2 3 4 **Volume Infused each site:** _____

Vial Size each weekly dose:

Evogam: 5mL (0.8g) no. of vials _____ 20mL (3.2g) no. of vials _____

Hizentra: 5mL (1g) no. of vials _____ 10mL (2.g) no. of vials _____

20mL (4g) no. of vials _____ 50mL (10g) no. of vials _____

S/C Needle

EMED Size ___G x ___mm number of lumens_____

Other _____

Luer Lock Syringe Size and number:

50 mL BD Luer Lock Number _____

Other _____

Comments: _____

Nurse signature **Date** **Time**

Date superseded

File in Medical record once superseded

Appendix 6 SUBCUTANEOUS IMMUNOGLOBULIN PROGRAM

Patient Assessment form

Affix Patient identification label here

Assessment to be undertaken at each training session / product collection booking/ review

IgG blood test is to be undertaken Pre, 2nd monthly for first 6mths then as directed by Medical officer

Date Infused / product collected Date range --/-- /--- to --/-- /--- Assessor	**Patient Assessment** **IgG result** _____Date of collection_____ Lab **Site reaction**: no yes size (cm) *(please circle)* redness swelling itchy other Other reactions: _____ _____ _____ *Since the last patient review / assessment:* **Has the patient had any recent infections** No…..Yes.. If yes: Type _____Duration_____ _____ _____ Did the infection require the patient to attend a GP No Yes Did the patient commence on antibiotics No Yes If yes, Name _____Dose_____ Duration_____ Did the patient require admission into hospital No Yes If yes, how many days Hospital Name **Other issues** (please comment): _____ _____ _____ _____ _____ _____