7. SCIG self-administration at home – in children

Every country and institution may have different regulations regarding immunoglobulin therapy administration. Some of the steps/measures given below may not be necessary. Please follow your local and national guidelines.

The suitability of each patient for subcutaneous IgG therapy (SCIG) at home needs to be assessed before starting training. The attending doctor, the nurse and the patient, all have to agree to start the training.

Plan the training sessions in a schedule with the patient; advise them that learning the technique might take several sessions.

In children, home-based treatment should always be performed in presence of a parent or legal representative. In the following guideline "the patient" refers to the child and their legal representative.

Criteria for inclusion in a home therapy program

(Please see competency assessment document in Appendix 3 and refer your patients to Appendix 5 for adverse event management at home)

- Patient motivation is important, some patients may never wish to undertake home therapy
- Compliance
- Dexterity, mental capacity and appropriate support should be considered
- A telephone must be available at the place of infusion
- It is advisable that the family doctor is informed of the home therapy
- It is strongly advised that an infusion partner is present at the time of infusion; the infusion partner must also be educated
- The patient and infusion partner should be assessed on a regular basis to verify their knowledge about their condition, their treatment, potential adverse events, and infusion technique. The patient's compliance with the therapy should also be checked

SCIG is well tolerated by the majority of the patients, but it is important to note that each patient may react differently to different immunoglobulin products. Each patient may also require an individualized infusion regimen in order to minimise adverse events and to achieve the desired therapeutic response (1). SCIG can be given at a frequency varying from daily to every 3–4 weeks (2-4). Once a successful regimen has been established, it should be adhered to at every infusion. Every follow-up visit should include a review of the administration route, premedication and patient treatment satisfaction. A change of route or product may be required; the geographical location of therapy administration may also be changed (hospital or home-therapy).

Local reactions are seen in about 80% of the patients starting with SCIG. The most common are swelling, redness and induration (5). However, these reactions usually subside over time (6). For further information, please refer to the section on adverse event management (Appendix 5).

SCIG can be administered via a pump or manual push (4, 7, 8).

The patient/legal representative(s) should:
- Be aware of the possible adverse events (including delayed and late adverse event)
- Know what to do in case of adverse event
- Have a telephone contact to call for advice

Knowledge crucial for home therapy

All patients trained for home therapy should have the following knowledge (9):

- "Know-that" knowledge, which relates to the understanding of the disease, such as diagnosis, prognosis and therapy
- "Know-why" knowledge, which relates to understanding how the patient's behaviour affects their disease, therapy and daily life
- "Know-how" knowledge, which related to the skills needed to infuse safely

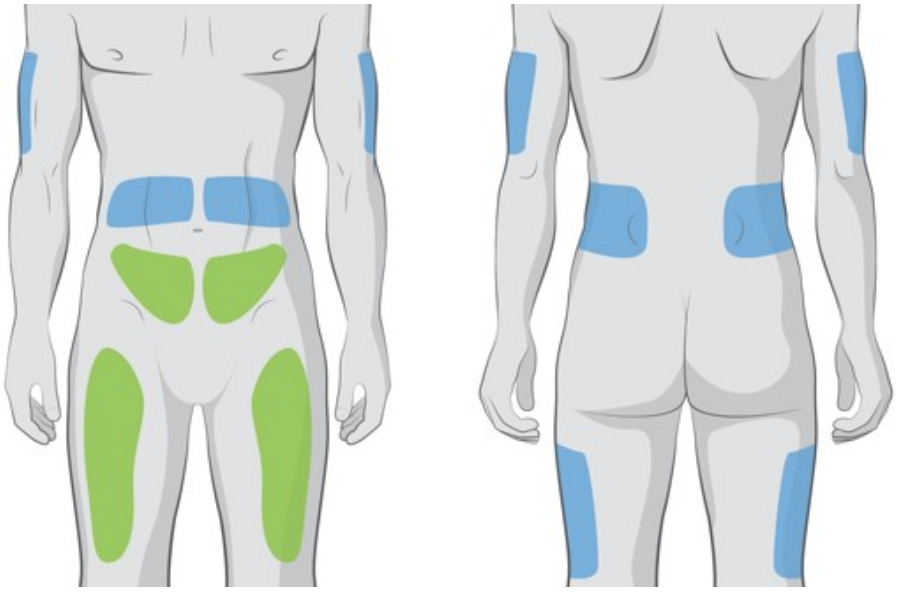
SCIG – self-infusion *via* pump administration at home for children

For detailed rationales, please see explanations below the list

Patients should have received immunoglobulin and the dose should be firmly established before starting the training. They should fit the inclusion criteria for home therapy.
Before the first training session • Assess the level of understanding of disease, treatment, and technique with the child and its legal representative(s) • Describe possible adverse events and assess the patient/legal representative's knowledge and understanding • Complete pre-treatment blood tests (according to local protocol/agreement) (Rationale 1) • Immunoglobulin trough levels should be checked regularly, and the patient should know why this is done (Rationale 2)
Pre-infusion assessment • Teach the patient/legal representative to assess the patient's well-being, by teaching them not to infuse when there is an infection, flu-like symptoms, or a temperature • The patient/legal representative has to assess that the immunoglobulin product ordered is the product prescribed, check the product name, dose, and expiry date • Show the patient/legal representative how to inspect the product's clarity and colour (Rationale 3) • Remind the patient/legal representative to verify that the product is at room temperature before the infusion (Rationale 4) • Teach the patient/legal representative how to inspect skin and choose infusion site(s)

(see Figure)

Figure: SCIG infusion sites



Green areas show preferred infusion sites; other alternatives are shown in blue.

- Advise the patient/legal representative to have nearby any medication prescribed for use in case of adverse events (NOTE: it is not standard practice in every country to prescribe medication for emergency situations)

Equipment

- Local anaesthetic cream/spray or cryogenic spray may be applied to the SC site (10)
- Immunoglobulin product for subcutaneous use. Please note: doses should be rounded to the nearest whole bottle size, to prevent wastage
- SC infusion pump, able to give adequate infusion rate and pressure
- Needles or mini-spikes and syringes for drawing up the immunoglobulin solution
- Infusion set
- Needle for subcutaneous use, 45° to 90° angle, gauge size 24G to 27G, 6–14 mm length
- Disinfectant
- Gauze
- Adhesive tape
- Sharps container

Infusion – the patient/legal representative is educated and trained to (11):

- Wash hands, prepare a clean area before infusion, and use aseptic technique (Rationale 5)
- Assess their well-being and not to infuse if they have an infection, flu-like symptoms, or a temperature
- When required, complete pre-treatment blood tests and investigations
- Draw the immunoglobulin into a syringe
- Prime the SC infusion set with immunoglobulin up to 1 cm before the tip of the needle (Rationale 6)
- Clean infusion sites with alcohol wipes and allow to dry (not standard practice in all countries)
- Create a skin fold and insert needle for subcutaneous use into the subcutaneous tissue (at an angle of 45° to 90°, depending on the needle)
- When the needle is placed (and connected to the infusion set), gently pull back the

plunger of the syringe to see if any blood flows back into the line. If blood is observed, change infusion set and insert a new needle in another location (Rationale 7)
- Secure the needle with adhesive dressing or use the dressing provided with the needle
- Attach the infusion set to the pump
- Do not leave the child unattended during infusion
- At the end of the infusion, remove the needles and dispose of used equipment safely
- Apply post infusion dressing if required
- Assess for adverse events
- Contact emergency services in case of severe adverse events, or the local clinician for milder adverse events
- Complete their infusion log and assess their comfort levels and satisfaction

(Please see troubleshooting in Appendix 6)

Careful documentation of every SCIG infusion should include

- Current health status, medications and any changes in this status in the period between infusions
- The product name, dose and batch numbers of the products used (Rationale 8)
- Any pre-medications taken
- Duration of infusion
- Any problems experienced by the patient during infusion and what was done to address them
- Patient treatment/infusion satisfaction
- The patient should bring their infusion diary to the next appointment with their prescribing clinician

Rationale 1

Patients should be tested for exposure to known blood borne pathogens **before** starting SCIG therapy. Once immunoglobulin therapy has been started, serologic tests may become positive because of the passively transferred antibodies and not be informative of the patient's infection status. Normally, health centres test for HIV and hepatitis A, B, and C, and measure complete blood count, hepatic transaminases and renal function before initiating immunoglobulin therapy by any route. In hematologic disease, Coombs' testing should be done prior to SCIG therapy (www.uptodate.com/contents/general-principles-in-the-use-of-immuneglobulin?source=search_result&search=intravenous+immunoglobulin&selectedTitle). In immunodeficient patients, serologic tests are frequently not informative because patients are not able to form antibodies specific for these pathogens. A negative serologic test in a patient with immune deficiency does not mean that the patient has not been exposed to the pathogens. PCR tests are used to detect active infection with Epstein-Barr virus, CMV and Hepatitis B.

Rationale 2

To monitor the effectiveness of treatment.

Rational 3

The liquid should be clear and transparent; if it is cloudy or has deposits, the product should not be used.

Rationale 4
Systemic adverse events are very rare in SC administration, however, they are more likely to occur with cold immunoglobulin solutions (fridge temperature), with the first infusion, a fast infusion, a large infusion, a long interval since the prior infusion, a switch to a new product or batch number, or the presence of a current infection (12). The most common immediate reactions are headache, cold sweat, light dizziness, chills, fever, and muscular pain. These are usually mild and occur within an hour of starting an infusion and disappear within 6 hours. Both pharmacologic and non-pharmacologic interventions (supplying blankets or pillows, heating pads and encouraging the use of relaxation techniques) may be indicated.
Although local reactions are very common with SC administration (local itchiness, swelling and redness) they are deemed normal and are not considered worrisome.

Rationale 5
Good hygiene is an important aspect in infection prevention.

Rationale 6
When in direct contact with the skin, immunoglobulins can cause local reaction.

Rationale 7
Accidental IgG infusion in a blood vessel increases the risk of systemic adverse events.

Rationale 8
Although the risk of transmission of blood-borne infections with currently licensed SCIG products is minimal, it is still present. The dose, brand, batch number, expiration date, and manufacturer of any immune globulin product infused into any patient should be carefully recorded in the medical record, as is done for all blood products. In addition, patients should be trained to keep their own logs of this information, as it is often required by law to have donor-to-recipient traceability.

SCIG – self-infusion *via* manual push at home for children

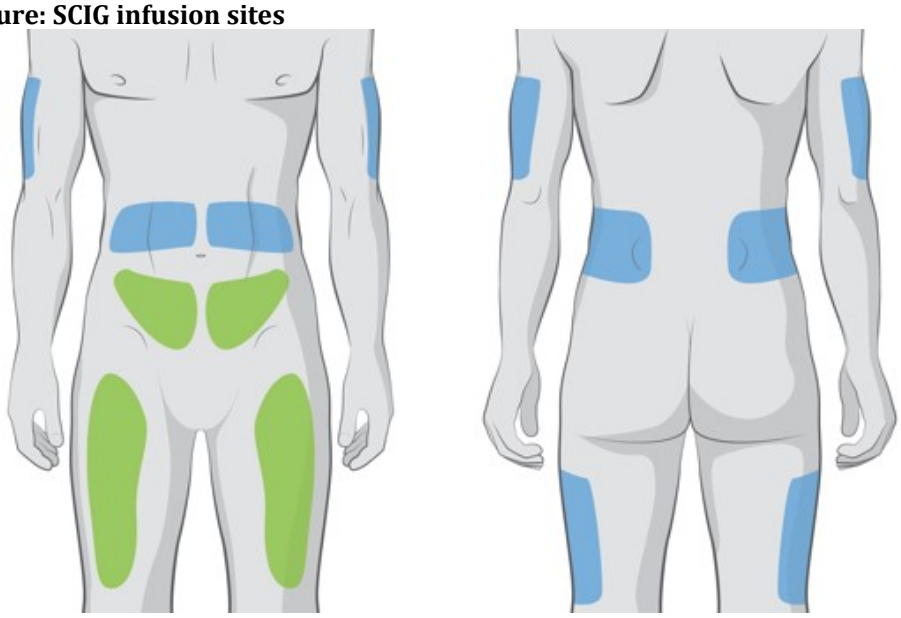
For detailed rationales, please see explanations below the list

Patients should have received immunoglobulin therapy and the dose should be firmly established before starting the training. They should fit the inclusion criteria for home therapy.
Before the first training session • Assess the level of understanding of disease, treatment, and technique with the child and their legal representative(s) • Describe possible adverse events and assess the patient/legal representative's knowledge and understanding • Complete pre-treatment blood tests (according to local protocol/agreement) (Rationale 1) • Immunoglobulin trough levels should be checked regularly, and the patient should know why this is done (Rationale 2)

Pre-infusion assessment

- Teach the patient/legal representative to assess the patient's well-being, by teaching them not to infuse when there is an infection, flu-like symptoms, or a temperature
- The patient/legal representative has to assess that the immunoglobulin product ordered is the product prescribed, check the product name, dose, and expiry date
- Show the patient/legal representative how to inspect the product's clarity and colour (Rationale 3)
- Remind the patient/legal representative to verify that the product is at room temperature before the infusion (Rationale 4)
- Teach the patient/legal representative how to inspect skin and choose infusion site(s) (see Figure)

Figure: SCIG infusion sites



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- Immunoglobulin product for subcutaneous use. Please note: doses should be rounded to the nearest whole bottle size, to prevent wastage
- Needles or mini-spikes and syringes for drawing up the immunoglobulin solution
- Butterfly needle 23G (blue), approx. 45° insertion angle
- Disinfectant
- Gauze
- Adhesive tape
- Sharps container

Infusion – the patient/legal representative is educated and trained to (11):

- Wash hands, prepare a clean area before infusion, and use aseptic technique (Rationale 5)
- Assess their well-being and not to infuse if they have an infection, flu-like symptoms, or a temperature
- When required, complete pre-treatment blood tests and investigations

- Draw the immunoglobulin into a syringe
- Not to prime the needle with the immunoglobulin solution (Rationale 6)
- Clean infusion sites with alcohol wipes and allow to dry (not standard practice in all countries)
- Create a skin fold and insert needle into the subcutaneous tissue in the area that was anesthetized (at an angle of approx. 45°)
- Gently pull back the plunger of the syringe when the infusion needle is placed, to see if any blood flows back. If blood is observed, start over in another location with a new needle (Rationale 7)
- Inject the immunoglobulin gently, with a rate of 1-2 mL per minute per site
- At the end of the infusion, remove the needles and dispose of used equipment safely
- Apply post infusion dressing if required
- Assess for adverse events
- Contact emergency services in case of severe adverse events, or the local clinician for milder adverse events
- Complete their infusion log and assess their comfort levels and satisfaction

(Please see troubleshooting in Appendix 6)

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