3. IVIG self-administration at home

This option is not available in every country. Please check your local guidelines to see if patients can be trained to receive intravenous IgG therapy (IVIG) at home.

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 home therapy needs to be assessed before starting any patient on home therapy. The attending doctor, the nurse and the patient, all have to agree to start the education and training.

IVIG home-therapy is usually offered to adults only.

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

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

Criteria for inclusion in a home therapy program

(Please see competency assessment document in Appendix 2 and refer your patients to Appendix 5 for adverse event management at home)

- Patient motivation is important, some patients may never want to undertake home therapy
- Dexterity, mental capacity and appropriate support should be considered
- Good veins are essential to be able to train a patient for home-based IVIG
- No adverse events should have been observed during the last several infusions at the hospital
- 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

Knowledge crucial for home therapy

All patients trained for home therapy should have the following knowledge (1):

- "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

IVIG self-administration – education and training

For detailed rationales, please see explanations below the list. **Patients should have received immunoglobulins and the dose should be firmly established before starting the training. Patients should fit the inclusion criteria for home therapy. An infusion partner needs to be educated to recognise symptoms of adverse events during infusion. It is recommended that the patient and the infusion partner complete a written informed consent after finishing the education.**

Before the first education and training session

- Assess the patient's level of understanding of disease, treatment, and technique
- Describe possible adverse events, including possible flu-like symptoms after the first 2 to 3 infusions, and assess the patient'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 to assess their well-being, by teaching them not to infuse when they have an infection, flu-like symptoms, or a temperature
- Advise the patient to drink water before, during and after the infusion (Rationale 3)
- The patient has to assess that the immunoglobulin product ordered is the product prescribed, check the product name, dose, and expiry date
- Show the patient how to inspect the product's clarity and colour (Rationale 4)
- Remind the patient to verify that the product is at room temperature before the infusion (Rationale 5)
- Advise the patient to have at hand any medication prescribed for use in case of adverse events close at hand

Equipment

- Immunoglobulin product for intravenous use
- Sterile towel
- Tourniquet
- IV infusion set
- Butterfly needle: gauge size 21G to 24G
- Disinfectant
- Adhesive tape
- Blood sampling equipment if indicated
- Adrenaline auto-injector (discontinued as a routine for all patients in the UK and Sweden as a meta-analysis showed that anaphylaxis has not occurred in home therapy, that auto-injection devices are often out of date and that their use can cause more harm than benefits)
- Sharps container

Infusion – the patient and/or the infusion partner is educated and trained to (2):

- Wash hands, prepare a clean area before infusion, and use aseptic technique (Rationale 6)
- Prepare for cannulation with a butterfly
- 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
- Check the prescription and the medication
- Prime the administration set with immunoglobulin

- Calculate the drop rate and adjust the flow set accordingly (20 drops equal 1 mL, confirm with the local administration set)
- Infuse the immunoglobulin according to the prescribed rate, starting slowly and increasing to the maximum prescribed rate as directed
- Assess if the rate can be increased
- Check the peripheral infusion site half-hourly for inflammation (tenderness, swelling, redness) and leakage. STOP the infusion if there are any signs of inflammation, extravasation or adverse events (Rationale 5)
- Contact emergency services in case of severe adverse events, or the local clinician for milder adverse events
- At the end of the infusion, remove the butterfly, make sure that the access site has completely stopped bleeding
- Dispose of used equipment safely, and complete the infusion log

(Please see troubleshooting in Appendix 6)

Careful documentation of every IVIG infusion must 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 7)
- Any pre-medications taken
- Duration of infusion and any rate titrations made
- 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 IVIG 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 IVIG 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.

Rationale 3

Patients receiving IVIG should be well hydrated prior to the infusion. This is particularly important for patients with risk factors for thrombosis and/or renal complications of IVIG therapy, such as pre-existing renal insufficiency, diabetes mellitus, who are greater than 65 years of age, suffer from paraproteinaemia,

heart disease, and/or concomitant use of nephrotoxic agents. In patients who are not able to drink, and if their condition permits, additional IV hydration may be considered. Good hydration reduces the risk of adverse events.

Rational 4
The liquid should be clear and transparent; if it is cloudy or has deposits, the product should not be used.

Rationale 5
Systemic adverse events 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 (3, 4). 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.

Rationale 6
Good hygiene is an important aspect in infection prevention.

Rationale 7
Although the risk of transmission of blood-borne infections with currently licensed IVIG 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.

References

1 Gardulf, A., Hansen, S., Johansson, K. & Linden, M. (2005) Rapid subcutaneous IgG replacement therapy in children and adults-20 years of clinical experience. *Inmunología,* **24**, 50-3.

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3 Orbach, H., Katz, U., Sherer, Y. & Shoenfeld, Y. (2005) Intravenous immunoglobulin. *Clinical reviews in allergy & immunology,* **29**(3), 173-184.

4 Stiehm, E.R. (2013) Adverse effects of human immunoglobulin therapy. *Transfus Med Rev,* **27**(3), 171-8.