Mary Elizabeth M. Younger, PhD, CRNP
Loris Aro, RN
William Blouin, MSN, ARNP, CPNP
Carla Duff, MSN, CPNP, CCRP
Kristin B. Epland, MSN, FNP
Elyse Murphy, BSN, RN
Debra Sedlak, CPNP
Nurse Advisory Committee Immune Deficiency Foundation

Nursing Guidelines for Administration of Immunoglobulin Replacement Therapy

ABSTRACT

Immunoglobulin (Ig) replacement therapy, given as regular infusions of pooled human Ig, is the recognized treatment of humoral immunodeficiencies characterized by hypogammaglobulinemia and impaired antibody responses. It is a safe, effective therapy when delivered by nurses who have been educated to oversee and/or provide these infusions. Guidelines for administration have been developed by the Immune Deficiency Foundation Nurse Advisory Committee to provide a framework and guidance to those nurses administering this therapy.

Key words: IG (immunoglobulin), immunoglobulin replacement therapy (Ig therapy), intravenous immunoglobulin (IVIG), nursing guidelines, primary immunodeficiency disease (PIDD), subcutaneous immunoglobulin (SCIG)

Immunoglobulin (Ig) therapy has evolved to encompass a multitude of uses across many medical specialties. This biologic therapy is used for replacement in antibody-deficient patients as well as an immunomodulatory treatment for many autoimmune and neurologic diseases. Research is ongoing regarding future applications of this therapy, with its use likely to expand.

Author Affiliations: Johns Hopkins, Baltimore, Maryland (Dr Younger); Sussman and Associates Immunology, Toronto, Ontario, Canada (Ms Aro); Miami Children's Hospital, Miami, Florida (Mr Blouin); All Children's Hospital/University of South Florida, St. Petersburg, Florida (Ms Duff); Midwest Immunology Clinic, Plymouth, Minnesota (Ms Epland); CSL Behring, King of Prussia, Pennsylvania (Ms Murphy); and Duke University, Durham, North Carolina (Ms Sedlak).

Mary Elizabeth M. Younger, PhD, CRNP, is a pediatric nurse practitioner in the Division of Pediatric Immunology at Johns Hopkins in Baltimore, Maryland. She has extensive experience with managing immunoglobulin therapy for hundreds of antibody-deficient patients.

Loris Aro, RN, is employed as a patient nurse educator and clinical research coordinator at Sussman and Associates Immunology in Toronto, Ontario, Canada.

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William Blouin, MSN, ARNP, CPNP, works in allergy/immunology at Miami Children's Hospital. With more than 35 years of experience in pediatrics, his interests and expertise are in the areas of allergy, HIV, immunology, infusion, and transplantation.

Carla Duff, MSN, CPNP, CCRP, is a pediatric nurse practitioner in the Division of Pediatric Allergy and Immunology at the University of South Florida/All Children's Hospital in St. Petersburg, Florida. She has many years of experience with clinical immunology and managing immunoglobulin replacement therapy for primary immunodeficient patients.

Kristin B. Epland, MSN, FNP, is a family nurse practitioner specializing in the care and diagnosis of primary immunodeficiencies and autoimmune diseases. She has worked with immune-deficient children and adults through home infusion nursing and now at the Midwest Immunology Clinic and Infusion Center in Plymouth, Minnesota.

Elyse Murphy, BSN, RN, is a medical science liaison with CSL Behring with expertise in immunoglobulin therapies and more than 30 years of experience in the disease state areas of immunology, hematology-oncology, neurology, and transplant.

Debra Sedlak, CPNP, has more than 25 years of experience in clinical immunology with the division of Pediatric Allergy and Immunology at Duke University Medical Center, Durham, North Carolina.

The Immune Deficiency Foundation (IDF) was founded in 1980 to improve the diagnosis, treatment, and quality of life of persons with primary immunodeficiency through advocacy, education, and research. The IDF Nurse Advisory Committee is composed of 11 nurses who together have hundreds of years of nursing experience in meeting the needs of this patient population and facilitating the mission of the IDF (www.primaryimmune.org).

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Corresponding Author: Mary Elizabeth M. Younger, PhD, CRNP (myounge2@jhmi.edu).

Currently, Ig therapy is delivered at various sites of care and administered by personnel with equally varied levels of training. Standard curricula for nursing baccalaureate and postgraduate programs do not provide the level of detailed infusion therapy training necessary for administering and managing Ig therapies, nor has a standardized set of guidelines been developed. It is well recognized that overall nursing competency contributes to safe and better patient care as well as improved outcomes. The goal of infusion nursing practice should be to deliver therapy safely and effectively. Its delivery should be facilitated by professionals who are familiar with the rationale for the therapy and have been educated appropriately. As the need to establish guidelines has been identified, the Immune Deficiency Foundation Nurse Advisory Committee has developed guidelines to bridge the gap and provide a resource for nurses involved with Ig infusion therapy.

Ig REPLACEMENT THERAPY FOR PRIMARY IMMUNE DEFICIENCY

Ig replacement therapy is prescribed for those patients with primary immunodeficiencies characterized by hypogammaglobulinemia and/or the inability to make protective levels of antibody in response to exposure to an antigen. Examples of these conditions include, but are not limited to, severe combined immunodeficiency, common variable immunodeficiency, Wiskott-Aldrich syndrome, and Bruton's agammaglobulinemia. Regular infusions of pooled human Ig are the standard of care for treatment of these conditions.[1-11] Infusions can be given equally efficaciously via an intravenous (IV) or subcutaneous route.[12-14] Initially, they can be administered in a hospital or outpatient infusion suite. Once tolerability has been established, infusions can also be given safely in the home.[15-17] Dosing is based on the patient's weight, serum Ig, and antibody levels and on the clinical response to therapy.[18-20]

Nursing qualifications for those nurses administering infusions or teaching self-administration to patients must comply with each state's nurse practice act and the governing state's board of nursing. The nurse providing Ig replacement therapy should have knowledge of its clinical indications and implications and should demonstrate competency in clinical judgment and practice. These competencies include adherence to established infection control practices and maintenance of aseptic technique; venipuncture and establishment of venous access, if necessary; provision of therapy-related patient education; knowledge of appropriate nursing interventions for therapy-related adverse events or complications; collaboration and communication with the multidisciplinary care team; and appropriate documentation practices. The goal for care is to provide Ig replacement therapy safely and effectively. To attain this goal, a plan of care for the patient receiving Ig therapy, including assessment, planning, implementation, and evaluation steps, is shown in Figure 1.

Ig PRODUCT MANUFACTURING

Ig products for infusion contain a broad spectrum of IgG antibodies against bacterial and viral agents that are capable of opsonization and neutralization of microbes and toxins.[21-23] Intravenous immunoglobulin (IVIG) preparations are obtained, purified, and manufactured from human plasma and contain at least 90% IgG and minute amounts of IgA, IgM, and IgE.[24-28] Plasma is collected from thousands of donors and pooled to make an individual lot of immunoglobulin. Different manufacturers use various methods to ensure product safety by removing or inactivating viruses and bacteria.[29] These methods include solvent/detergent treatment, a combination of process chemistry, partitioning, ultrafiltration, and/or inactivation during cold ethanol fractionation, low pH, or nanofiltration.

IVIG THERAPY

IVIG therapy has been widely available in the United States since the 1980s. It is Food and Drug Administration (FDA) approved for treatment of some neurologic and autoimmune diseases, in addition to use as replacement therapy in primary immunodeficiency.[22] Generally, IVIG is given every 3 to 4 weeks. It is possible to give the large volumes (ie, 1-2 g/kg) that are recommended to treat such illnesses as Kawasaki disease or autoimmune cytopenias. There are currently multiple products available. All products are equally efficacious, but they have differences in concentration, stabilizing agents, and the form in which they are available (ie, lyophilized products versus liquid products). The vast majority of patients tolerate IVIG well, but it is important to remember that 1 size does not necessarily fit all. Each patient needs an individualized regimen of product, rate, and, if necessary, premedications.[18,19,21]

PRACTICE CRITERIA FOR ADMINISTRATION OF IVIG

Storage of IVIG

Specific reconstitution and storage requirements of each brand of IVIG are discussed in the package insert of that particular product. Most products include instructions for storage in the original packaging to protect the product from light and temperature variability. Nurses/pharmacists must review this information before mixing and administering IVIG. Ig product that has been frozen should never be used.

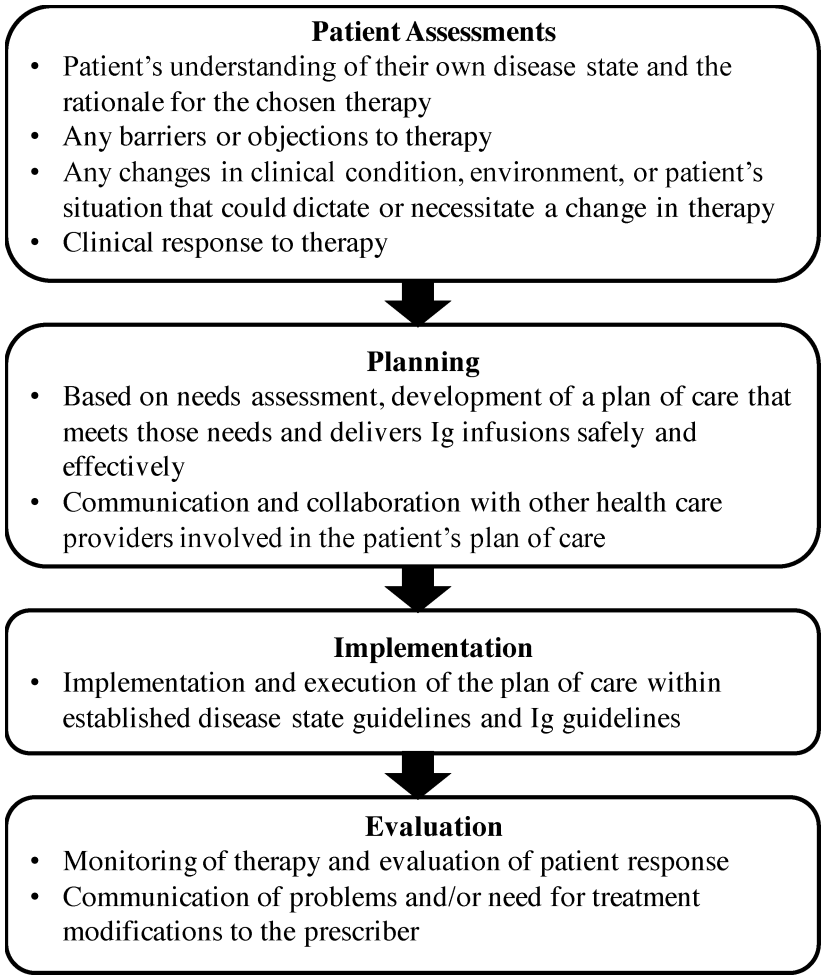

Figure 1. Plan of care for the patient receiving Ig therapy to be executed by the nurse providing therapy. *Abbreviation: Ig, immunoglobulin.*

Handling of IVIG

Expiration dates should be checked, and expired solutions should not be used. The product should be inspected for turbidity, particulate matter, and/or clumped material. If any of these are present, the product should not be used. If IVIG was not reconstituted or pooled under a hood, it should be administered as soon as possible. IVIG products do not contain any preservatives. The manufacturer's information about stability should be noted, and guidelines regarding how long the solution is stable after reconstituting or pooling should be followed.

Preparation of Liquid IVIG Products

Preparation should occur in a clean environment.[30] When preparing a liquid IVIG product for infusion, allow the product to come to room temperature before administration. Depending on institutional policy, a sterile IV administration set can be directly attached to the vial. Pooling of multiple vials into a single, empty IV solution container is also acceptable; however, every attempt should be made to avoid using multiple lot numbers of the same-sized vial when pooling product. For example, when using multiple vials of the same Ig product, all the vials should be from the same lot number. Lot numbers and expiration dates should be recorded in the documentation of the infusion.

Preparation of Lyophilized IVIG Products

The manufacturer's recommended diluents should be used to reconstitute lyophilized products. These diluents include sterile water, normal saline, and D5W (5% dextrose in water). It is important to note that the diluent can significantly affect the physical property, such as the osmolality, of the final product. The product and the diluent should both be at room temperature before reconstitution because cold product or diluent significantly increases the time required for the product to dissolve and for the solution to be ready for infusion. Most manufacturers provide step-by-step instructions for reconstitution; the product inserts should be read for these specifics. Dilution and flushing should be in accordance with recommended instructions from the manufacturer. For example, some Ig products are not compatible with normal saline.

Administration of IVIG

The specifications of the product should be reviewed for potential contraindications. Individual product characteristics should be considered in relation to patients with comorbidities and potential risk factors of adverse reactions or events.[31-34] For example, the volume and osmolality of the product should be considered before use in infants, elderly patients, or patients with congestive heart failure or renal disease. It is important to note that potential renal or thrombotic complications are exponential, not additive.[35-38]

Patients with documented IgA deficiency, who require Ig therapy, should be monitored closely during their infusions. It should be noted that Ig is not necessarily contraindicated in patients with undetectable levels of IgA.[39-41] Therapy should be dispensed and administered with 1 consistent product because products are not interchangeable; for example, lyophilized and liquid forms of the same product are not the same. Patients are at greater risk for adverse events if they are naive to Ig therapy, if they have not received their therapy for more than 8 weeks, or when switching brands of product.

Orders for Ig replacement therapy should be reviewed for dosing and infusion rates. The usual dose of IVIG for treatment of primary immunodeficiency is 400 to 800 mg/kg given every 3 to 4 weeks. Higher doses may be indicated if trough IgG levels are determined to be too low or the clinical response is inadequate. In these cases, the dose and/or the dosing interval may require adjustment. The package inserts should be consulted for infusion rates, but infusion rates should always be based on patient tolerability with deference to identified potential risk factors. Generally, the first 2 infusions should be given at the lowest recommended rate. If the infusion is well tolerated, without adverse reactions, the rate can be gradually increased over subsequent infusions to the maximum rate as listed by the product manufacturers. For all infusions, a gradual (every 15 or 30 minutes) ramp-up approach until the maximum rate of infusion is reached is recommended.[42] Infusion rates for patients with identified risk factors (such as those with renal insufficiency or with a history of thromboembolic events [TEEs]) should not exceed the manufacturer's highest recommended rate of infusion, even if they tolerate infusions well. It should be noted that thrombotic events or renal complications associated with IVIG are silent—that is, they can occur without warning.

The nurse should assess any changes in the patient's health status prior to infusion. Changes that may have an impact on or the potential to affect therapy (eg, weight change, acute illness or infection, diarrhea) should be communicated to the prescriber before proceeding with the infusion. A complete set of vital signs should be taken before beginning the infusion and as indicated during the infusion. Premedications including acetaminophen, ibuprofen, hydrocortisone or another systemic steroid, diphenhydramine, and/or ondansetron may be prescribed. These drugs should not routinely be given before the first infusion because the majority of patients tolerate IVIG without problems. But, if it is determined by a reaction to an infusion that premedication is necessary, it should be given before every infusion as prescribed, and the continued need for premedication should be reassessed periodically. The initial infusion of Ig, as well as the first dose of a new product, should be given in a controlled or monitored setting. If the clinician determines that the patient's ongoing response to therapy warrants continued monitoring, subsequent infusions should be administered in a controlled setting as well. Home infusions are recommended when the patient is stable on a dosing regimen of product, rate, and, if warranted, premedication. IVIG cannot be mixed with any other IV medications. Rates of infusion should be closely monitored and controlled; the use of an infusion pump is recommended. American Academy of Allergy, Asthma & Immunology guidelines for Ig replacement therapy strongly discourage the use of implanted ports for this therapy in immunodeficient patients because of the increased risk for infection and TEEs.[43] If IV access is problematic, the nurse should discuss the difficulty with the prescriber and consider alternate routes of administration for therapy.

Adverse Reactions to IVIG

Adverse reactions are rare and, in most patients, directly related to the flow rate and/or temperature of the solution.[43-45] A nursing policy should be in place for treatment and management of all adverse reactions. Drugs for treatment of all adverse reactions, including anaphylaxis, must be available in the treatment setting. Mild to moderate reactions include headache, nausea and vomiting, chills, rigors, flushing, and/or dizziness. Management of these reactions includes slowing or stopping the infusion, medicating the patient for the reaction as prescribed, and/or restarting the infusion at a slower rate once the symptoms have subsided. Once the infusion has been restarted, attempts may once again be made to increase the rate of the infusion. These increases must be done slowly and incrementally as indicated by the patient's reactions and tolerance. After the patient experiences an infusion-related reaction, the prescriber may consider routine premedication for all future infusions. If reactions persist despite premedication, a product or route change may be considered. All Ig products carry warnings about rare complications that are associated with this class of product. These potential complications are discussed in each product's package insert under "Warnings and Precautions."[46] The nurse should adhere to individual manufacturer's recommendations in patients with identified risk factors.

All Ig products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death.[47,48] The renal function of patients at risk

should be monitored by obtaining periodic measurements of blood urea nitrogen and serum creatinine. Patients should also be instructed to notify their providers of decreased urine output. Risk factors for patients predisposed to renal complications include, but are not limited to, preexisting renal insufficiency, diabetes mellitus, age greater than 65 years, volume depletion, sepsis, paraproteinemia, and treatment with known nephrotoxic drugs.

All Ig products have been reported to be associated with TEEs.[49] Risk factors for patients predisposed to TEEs include, but are not limited to, any history of cardiovascular disease or previous thrombotic events, advanced age, hypertension, cerebrovascular disease, diabetes mellitus, high serum levels of monoclonal proteins, and any history of prolonged immobilization.

Aseptic meningitis has been reported in association with Ig therapy and may occur with high doses and/or rapid infusion rates.[50] Hemolysis has been reported with all Ig products, particularly with high-dose therapy.[51] Patients should be monitored for signs of hemolysis after infusion and instructed with regard to symptoms that should be immediately reported to the prescriber. Transfusion-related acute lung injury has been reported rarely with all Ig products. Patients should be monitored for adverse pulmonary effects.

It should be noted that true IgE-mediated anaphylaxis is extremely rare in antibody-deficient patients; however, the possibility for such a reaction does exist. If the patient exhibits signs of anaphylaxis or an acute allergic reaction, the infusion should be stopped immediately and the patency of the IV line should be maintained with normal saline or D5W. Immediate emergency response procedures should be performed, including administering an appropriate dose of epinephrine and calling 911. The prescriber should be notified immediately. If epinephrine has been administered,

TABLE 1

Troubleshooting IVIG Infusion Problems

Infusion Problem	Assessment/Cause	Nursing Response
Fever, chills, rigors	Solution is not at room temperature; infusion rate may be too fast	• Stop infusion
		• Administer prescribed medications
		• When symptoms resolve, restart the infusion at the previously tolerated rate
Intrainfusion headache	Solution is not at room temperature; infusion rate may be too fast; patient may not be adequately hydrated	• Administer analgesia as prescribed
		• Slow the rate
		• Nonpharmacologic comfort measures
		• Instruct the patient about the importance of adequate hydration before the next infusion
Postinfusion headache, malaise, arthralgias, myalgias	May be an inflammatory response indicating intolerance to specific product or IVIG in general	• Symptomatic pharmacologic (analgesias and nonpharmacologic measures [rest, heating pad, etc])
		• Consult prescriber; a short course of steroids may be necessary; premedication before the next infusion is indicated
		• If problems persist, consider change in product or route of administration
Urticaria	May indicate intolerance to product or a specific lot number of a product	• Stop the infusion and contact prescriber
		• Administer prescribed antihistamines and/or steroids
		• Observe for signs of true anaphylaxis and, if they occur, initiate emergency interventions (administer epinephrine and activate emergency response system)
Vasomotor symptoms (blood pressure changes, flushing, increased heart rate)	Product is not at room temperature; infusion rate may be too fast; may indicate intolerance to product	• Stop infusion
		• Consult prescriber and follow orders for fluid bolus and diuretics as prescribed
Nausea, vomiting	Infusion rate may be too fast; product is not at room temperature; may indicate intolerance to product	• Stop infusion and consult prescriber
		• Administer prescribed antiemetics
		• Provide symptomatic comfort measures

Abbreviation: IVIG, intravenous immunoglobulin.

the patient must be transported to the nearest emergency facility by first responders. Subsequent infusions should be given with a different product, in a hospital or infusion center, until it is determined that the patient can tolerate IVIG without complications. The lot number of the drug involved in the reaction should be carefully documented, and the reaction should be reported to the FDA via Medwatch (www.fda.gov/safety/Medwatch.htm) as well as to the manufacturer. The appropriate responses to these issues are presented in Table 1.

SUBCUTANEOUS IMMUNOGLOBULIN THERAPY

Subcutaneous immunoglobulin (SCIG) therapy[52,53] has been widely available in the United States since January 2006 when the FDA first approved a 16% product manufactured specifically for subcutaneous use and it became commercially available.[54,55] Since then, several other Ig products have been approved for subcutaneous use in the United States.[56-58] These products vary in their concentrations and amino acid bases. Because SCIG does not require IV access, the therapy is typically self-administered by the patient or by a family member/caregiver of the patient. SCIG therapy is generally very well tolerated; a high degree of patient satisfaction has been reported.[59-64] SCIG therapy is administered weekly or as a combination of multiple weekly infusions or injections as dictated by the patient's wishes and mode of delivery. It provides the benefit of physiologically stable IgG levels as opposed to the peaks and troughs associated with IVIG therapy administered every 3 to 4 weeks.[65] Unlike IVIG, which is approved for other medical uses in addition to replacement therapy, subcutaneous products are FDA approved only for replacement therapy.[66]

Practice Criteria for Administration of SCIG

Storage of SCIG

The manufacturer's specification should be used for storage. Some products require refrigeration; others do not. Refrigerated products should be brought to room temperature before use. Solutions that have been frozen should never be used. If there has been a temperature excursion that exceeds the manufacturer's recommendation, the product should not be used. The product should be stored in the original carton to protect it from light and temperature variability.

Handling of SCIG

Expiration dates should be checked, and expired solutions should not be used. The product should be inspected for turbidity, particulate matter, and/or clumped material. If any of these are present, the product should not be used. The product should always be handled using aseptic technique. If the product has been drawn up by the specialty pharmacist under a hood, it should be used within 24 hours.

Administration of SCIG

Patients should keep logs of their infusions that include dates, total time of infusion, lot numbers of products, location and number of sites, and reactions. Dosage is based on weight, consideration of comorbidities, and clinical response. The usual dose of SCIG is 100 to 200 mg/kg given every week. SCIG allows flexibility for infusion regimens,[67] and multiple dosing regimens are possible. This flexibility and the various possibilities for infusion should be fully explained to the patient so that a collaborative agreement between the patient and prescriber can be reached. For example, a weekly dose of 6 g could be given at 1 time or split into 2, 3, or 6 infusions per week. Patients should be given the option to design a regimen with which they can achieve full compliance.

Infusions can be given into a single site or split and infused into multiple sites simultaneously. Decisions about the number of sites should be made with the patient. Generally, most adults can tolerate 30 mL in a single site, but it may be necessary to work up to this volume over a period of time. Manufacturers' recommendations for volumes per site and infusion rates are included in the package inserts and prescribers' guidelines.

The length of needles for infusion should be chosen and selected according to the amount of subcutaneous tissue the patient has. Average-sized patients usually do well with 9-mm needles. Children and very thin people may require a 6-mm needle; similarly, larger patients may need 12-mm or 14-mm needles. The goal is to infuse the drug into subcutaneous tissue, avoiding the dermal layer and the muscle. Subcutaneous needles for infusion range from 24 to 27 gauge. Standard steel-winged needles can also be used if the patient chooses to deliver the infusion via push rather than pump. Decisions regarding gauge may be influenced by the desired rate for the infusion. This decision, too, should be made in conjunction with patient input. Infusions can be given via a syringe driver pump or via self-push, as desired. Rapid infusion rates have been shown to be safe and well tolerated.[68-71]

Subcutaneous needles should be inserted into the skin at an appropriate angle to ensure solid implantation into the subcutaneous tissue. Skin may be held taut or plumped up for insertion, according to the patient's preference. The skin can be pretreated with topical anesthetics, such as lidocaine/prilocaine cream, ethyl chloride, or ice, if the patient desires. Because SCIG products can be irritating to the dermis, it is important to ensure that no

medication gets into the dermis. When priming the tubing, patients should be instructed *not* to prime all the way to the needles and to use a dry insertion technique. After the needles are inserted, the plunger of the syringe should be pulled back to check for a blood return. If blood is seen, then the needle may be in the intravascular compartment. The needle should be removed and discarded. A new needle set should be primed and inserted as instructed.

Reactions to SCIG Therapy

Local site reactions including redness, pruritus, and swelling are the most commonly reported side effects from SCIG. Injection site reactions are generally worst with the first infusions and should decrease with every subsequent infusion. If local reactions have not resolved within 3 to 4 days after the infusion, adjustments to the infusion regimen should be considered. These adjustments may include changing the brand of the needle set, the length or gauge of the needle, the number and location of sites, the volume per site, and the rate of infusion. Systemic side effects have been reported from SCIG, though rarely. The most common systemic effects are headache, back/joint pain, and gastrointestinal disturbances, including diarrhea and nausea. These side effects can be treated with analgesics, anti-inflammatory drugs, or antidiarrheals as ordered by the prescriber. A change in product can also be considered if these side effects persist or are intolerable for the patient.

As with IVIG, true anaphylaxis associated with SCIG in patients with antibody deficiencies is very rare, but patients must be taught about the possibility of such a reaction, how to recognize the signs and symptoms of anaphylaxis, and what their response should be. If symptoms of anaphylaxis occur, the infusion must be stopped immediately. Emergency medical services and the prescriber should be notified immediately, and appropriate treatment and supportive therapy should be administered. Subsequent infusions should be given in a hospital or other controlled setting until it is determined that the patient can tolerate infusions without complications. The lot

TABLE 2

Troubleshooting SCIG Infusion Problems

Infusion Problem	Assessment/Cause	Nursing Response
Site swelling	Reaction should be consistent with the volume infused and the amount of subcutaneous tissue a patient has (eg, thinner patients may have larger areas of swelling)	• Increase the number of infusion sites
		• Decrease volume per site
		• Change infusion site location
		• Slow infusion rate
Site erythema	Very red and irritated reactions may indicate that the drug has been infused intradermally or leaked back into the dermis	• Reassess needle insertion technique
		• Change length of needle/use longer needle
		• Assess for tape/adhesive sensitivity
		• Change brand of immunoglobulin
Pain with infusions	May indicate that needle is in a muscle	• Reassess needle insertion technique
		• Use shorter needle
Site itching/burning	May indicate misplacement of needle into dermis, a response to drug itself, or irritation from alcohol, tape, or transparent adhesive dressings	• Assess site location
		• Evaluate needle length; longer needles may be required to reach subcutaneous tissue
		• Apply cold compresses
		• Consider decreasing volume per site
		• Consider alternative methods to secure needles if adhesive reaction is suspected
Leaking from infusion site	May indicate problems with depth of needle or volume infused per site	• Modify infusion regimen, ie, consider change(s) to volume per site, needle length, rate of infusion
Assess site reactions for duration and intensity	Reactions should decrease as drug is absorbed across 24-48 h and diminish over time with every subsequent infusion	• Patient teaching regarding expectations for local reactions
		• Symptomatic treatment including warm compresses

Abbreviation: SCIG, subcutaneous immunoglobulin.

TABLE 3

Important Points of Emphasis in Immunoglobulin Replacement Therapy Instruction

1. The preparation of infusions should always be done in a clean environment and initiated after the person preparing the infusion has washed his or her hands.
2. Both IVIG and SCIG products should always be administered at room temperature.
3. The patient should keep a diary or infusion log that documents specifics about each infusion, including product lot numbers and expiration dates.
4. All patients need clear, understandable written instructions regarding their therapy. These instructions should include product name and dose, normal and abnormal expectations/symptoms associated with therapy, and emergency responses including contact information by which prescribers can be notified or consulted.
5. Infusions can be given at rates as tolerated by the patient.

Abbreviations: IVIG, intravenous immunoglobulin; SCIG, subcutaneous immunoglobulin.

number of the drug involved in the reaction should be carefully documented, and the reaction should be reported to the FDA via Medwatch as well as to the manufacturer.

It is important for nurses to adequately assess and address any infusion site problems that occur during SCIG administration. Local site reactions should be assessed for duration and intensity. These reactions should decrease as the drug is absorbed across 24 to 48 hours and should also diminish over time with every subsequent infusion. Nurses should educate patients regarding expectations for local reactions and symptomatic treatment of these reactions, including warm compresses or cool compresses (whichever the patient prefers). Some of the local site reactions that patients may experience include swelling, erythema, pain, itching, or burning at the infusion site. In addition, leakage at the infusion site may take place. The appropriate responses to these issues are presented in Table 2.

RESPONSIBILITIES FOR NURSES FOR MANAGEMENT OF IVIG AND SCIG THERAPY

Ig replacement therapy has evolved in its safety and tolerability since primary immunodeficiency disease was first described in the 1950s, and now it is the recognized therapy for treatment of humoral antibody defects. Patients generally do extraordinarily well once therapy is initiated. With the variety of products and the multiple modes of infusion available, an individualized replacement therapy regimen can be designed for each patient. Like most therapies of this nature, however,

TABLE 4

Key Teaching Points for IVIG and SCIG Therapy

For IVIG Therapy	For SCIG Therapy
1. The critical need for compliance with the timing of infusions	1. The critical need for compliance and establishing a regular routine for timing of infusions
2. Identification of potential risk factors and appropriate overall management	2. Identification of possible subcutaneous infusion sites including areas of subcutaneous tissue on the abdomen, thigh, upper arm, or the flanks, upper, or outer quadrant of the buttocks
3. Rates of infusion are individualized according to the manufacturer's recommendations, identified risk factors, and patient tolerability	3. Subcutaneous sites do not need to be rotated unless a problem occurs at a particular site
4. Expectations regarding potential reactions and/or adverse events	4. Skin that is bruised, tender, red, or hard should not be used; similarly, scars and/or stretch marks should be avoided
	5. If a blood return is noted when checking the needle for placement, the needle should be removed and the entire needle set discarded and replaced

Abbreviations: IVIG, intravenous immunoglobulin; SCIG, subcutaneous immunoglobulin.

treatment success or failure depends largely on the scope and quality of the delivery of the therapy and the associated patient teaching.

The nurse's responsibilities in ensuring the success of Ig replacement therapy lie in patient education, advocacy, and therapy management. Some key points that should be emphasized as nurses instruct patients in the administration or self-administration process are presented in Table 3.

Patients should be provided with the information that will allow them to take ownership of their therapy. Decisions regarding therapy should be made collaboratively between the patient and the prescriber. Although the prescriber will make recommendations regarding therapy, the ultimate decision about the number of infusions per week, the number of sites used, the rate of infusion, when the infusions are carried out, and the mode of performing infusions belongs to the patient and should be made after the patient has received all the information necessary to make an informed decision regarding these issues. A number of key teaching points for IVIG and SCIG therapy are important to ensure successful patient outcomes and are shown in Table 4.

In conclusion, these guidelines have been developed to help nurses administer Ig replacement therapy in the safest and most effective way. Ig replacement therapy is medically indicated for a variety of patients, including primary immunodeficiency diseases, hematological disorders, and specific neuromuscular disease. Patients are treated with Ig infusions either in the hospital, in the physician's office/infusion suite, or in the home. Because most of these infusions are either administered by nursing professionals or self-administered (as taught by nursing professionals), infusion nurses are in a unique position to improve the treatment experience and provide improved quality of life for patients receiving Ig therapy.

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