

CONSIDERATIONS:

1. The RN administering IgG shall be knowledgeable of indications of use, appropriate dosage, administration, monitoring parameters, side effects, toxicities, and potential complications.
2. Immunoglobulins, or antibodies, are complex Y-shaped molecules that coordinate the immune response to infection and regulate the immune system.
3. There are five classes of Immunoglobulins: IgG, IgA, IgE, IgM, and IgD.
4. The immune system recognizes and attacks foreign substances, called "antigens":
 - a. Antigens are molecules on the surface of viruses, fungi, or bacteria
 - b. Some non-living substances such as toxins, chemicals, and drugs are classified as antigens
 - c. For each new antigen encountered, the immune system forms a defense that is specific to that antigen, allowing the body to destroy it
 - d. Immunoglobulins are an important part of that defense, as they attach to their specific, matching antigen, which enables phagocytes (a type of white blood cell) to engulf, digest and destroy the antigen
 - e. Binding of the immunoglobulin to an antigen also activates a set of proteins called the "complement" system", which ruptures bacteria and viruses
 - f. Consequently, immune globulin therapy provides passive immunity through antibodies present in carefully pooled donor plasma
5. FDA-approved Immune Globulin therapy (IVIG) is given for the following immunodeficiency and autoimmune conditions:
 - a. Primary Immune Deficiency (PID)
 - b. Chronic Variable Immune Deficiency (CVID)
 - c. Graft vs. Host Disease
 - d. Kawasaki Disease
 - e. Idiopathic Thrombocytopenia Purpura (ITP)
 - f. Neurologic conditions treated with IVIG include:
 - i. Multiple Sclerosis (MS)
 - ii. Chronic inflammatory demyelinating polyneuropathies (CIDP, Polymyositis)
 - iii. Guillian-Barré Syndrome
 - iv. Multifocal motor neuropathies
 - v. Infections in low birth weight, premature infants
 - vi. Dermatomyositis
6. Off label use of IVIG is widely used by an estimated 70% of patients for other indications
7. Before IVIG administration home visit:
 - a. First dose of IVIG must be administered in an acute care facility where emergency equipment is available.
 - b. Obtain and review physician orders for patient diagnosis, specific IVIG product, infusion rate, and reaction protocol
 - c. Obtain the following information from prescribing physician:
 - i. Patient allergies
 - ii. History of headaches or migraine headaches
 - iii. Baseline serum IgA level
 - iv. Any other baseline lab results
 - v. History of previous reaction to blood or blood product administration
 - d. Ensure ordering physician has read/signed home health agency Immune Globulin Standing Orders that includes, but is not limited to the following information:
 - i. Premedication protocol
 - ii. Therapy administration parameters
 - iii. Anaphylaxis treatment
 - iv. Ordered labs
 - e. Obtain orders to draw IgA prior to initiation of therapy if lab results are unavailable:
 - i. Individuals with severe IgA deficiency will not receive IVIG in the home setting
 - ii. Risk of severe hypersensitivity reactions including anaphylaxis exist
8. Prior to IVIG therapy:
 - a. If patient has a current infection or one in the past 3 - 4 days Immune Globulin therapy should be infused at a slower rate throughout the entire infusion
 - b. Dosing of immune globulin therapy is based on a patient weight, obtained prior to each therapy administration
 - c. DO NOT infuse other medications during or concurrently during IVIG therapy unless ordered by the prescribing physician due to incompatibility
 - d. D5W must be infused as a pre, during, and post main IV line flushes to IVIG and not 0.9% Normal Saline. Immune globulin products are not compatible with Normal Saline
 - e. Titration rate and maximum rate of infusion must be included in the physician's orders.
 - f. Instruct patient/caregiver of the potential for adverse reactions and symptoms to immediately report during and after the infusion
9. Adverse/Anaphylactic reactions during IVIG therapy:
 - a. Even though IVIG is well tolerated by patients, reactions can occur

- b. To decrease this potential, consider the following:
 - i. Infusion rate should be decreased or stopped at the first sign of any patient report of reaction or complication
 - ii. During IVIG infusions, RN should continually assess/monitor for the following potential side effects:
 1. Elevated blood pressure
 2. Flushing or fever
 3. Headache
 4. Fatigue
 5. Chills
 6. Tachycardia
 7. Diaphoresis
 8. Low back pain
 9. Chest discomfort, pressure or pain
 10. Nausea or vomiting
 11. Sneezing
 12. Muscle cramps
 13. Localized skin irritation (urticaria, redness, wheals) may be from tape. Large area may be medication reaction
 14. Appearance, condition, and patient response or complaint of IV catheter site
 - c. Localized Allergic Response-Mild Reaction Management:
 - i. Stop infusion immediately
 - ii. Notify nursing supervisor
 - iii. Continue to closely monitor patient vital signs/response every 15 minutes X's one hour or until symptoms stop
 - iv. Administer 25 - 50 mg Diphenhydramine PO, or Tylenol PO as ordered for symptom specific reactions
 - v. When side effect(s) subside, may begin to slowly titrate infusion rate back up to previous rate as patient tolerates
 - vi. If adverse reaction persists, or anaphylaxis occurs, stop the infusion. Run D5W at 20 - 30 mL/hr. Notify physician, nursing supervisor, administer anaphylaxis protocol as ordered
 - d. Generalized Allergic Response:
 - i. Anaphylaxis is suspected if the following signs and symptoms occur
 - ii. Subjective:
 1. Generalized itching
 2. Chest tightness
 3. Difficulty speaking
 4. Agitation
 5. Uneasiness
 6. Sense of impending doom
 7. Dizziness
 8. Nausea
 - 9. Crampy abdominal pain
 - 10. Desire to urinate/defecate
 - 11. Chills
- a. Objective:
 - i. Flushed appearance
 - ii. Edema of face, neck, eyelids, hands, feet
 - iii. Localized or generalized urticaria
 - iv. Respiratory distress with or without wheezing
 - v. Hypotension
 - vi. Cyanosis
 - b. Stop infusion immediately:
 - i. Disconnect medication and tubing
 - ii. Hang with new tubing for D5W or normal saline 0.9% at 20cc/hr
 - iii. Evaluate signs and symptoms rapidly
 - iv. Initiate Adverse Reaction Protocol as ordered by physician:
 - v. Have family member or care giver call 911 (if no other person available RN to call EMS)
 - vi. Assist patient to supine position and elevate legs
 - vii. Administer Diphenhydramine IV or IM
 - viii. Administer IV Solu-Medrol slow IV push if ordered
 - ix. Administer Epinephrine 1:1000, 0.2 - 0.5 mg (0.2-0.5 mL) SQ every 20 minutes up to 4-hours (with a maximum of 1 mg total dose or Epi Pen (patient must be seen in ER following administration of Epinephrine or Epi Pen)
 - x. Maintain patency of airway: observe for signs of laryngeal edema including hoarseness and dyspnea
 - xi. If cardiopulmonary arrest occurs, begin CPR
 - xii. Notify patient's physician for further orders
 - xiii. Notify pharmacist of reaction
 - xiv. RN to remain with patient until EMS arrives
- EQUIPMENT:**
- Gloves (non-sterile) or Sterile gloves with central line access
 - Antimicrobial hand scrub
 - Alcohol prep pads/wipes
 - IV administration tubing (gravity or pump)
 - Safety peripheral IV needle and IV start kit if peripheral IV access, or safety Huber needle and sterile dressing change kit for port access
 - Appropriate securement devices for specific IV site considering patient allergy to adhesives
 - Needleless connector/IV extension tubing
 - Ordered Immune Globulin product
 - Pre hydration fluids if ordered

OSHA approved sharps container
Red biohazard trash bag
2 x 2 sterile gauze
Band-Aid
10 cc syringes as need
Prefilled preservative-free Sodium Chloride (0.9%)
pre/post infusion flush as ordered by physician
5 - 10 mL prefilled heparin flush (as ordered by physician) to heparinize a central line or keep a peripheral line patent for an extended IVIG infusion
Dedicated patient
Sphygmomanometer/stethoscope/thermometer

PROCEDURE:

1. Initial patient assessment and explanation of IVIG infusion procedure to patient.
2. Adhere to Standard Precautions.
Refer to *Infusion Therapy – Peripheral Line: Insertion and Maintenance* for peripheral access or *Infusion Therapy – Central Line*
3. Verify and ensure physician's order for immune globulin therapy:
 - a. Verify patient identify with current history and diagnosis, allergies, previous reactions to blood or blood products
 - b. Document expiration date, lot #, and brand of immune globulin product
 - c. Obtain patient's weight during each visit
4. Prepare work area with antiseptic wipe allowing area to dry.
5. Obtain/document base line vital signs including blood pressure, heart rate, respiratory rate and temperature.
6. Once IG infusion has begun, vital signs should be taken every 15 minutes X one hour, every 30 minutes X one hour, then hourly thereafter throughout infusion and with assessed need.
7. Place poly back towel over area to place supplies for IV access.
8. Wash hands thoroughly with antimicrobial soap and don gloves.
9. Immune Globulin Infusion:
 - a. Check medication label for accuracy and inspect all medications and fluid containers for leaks, cracks, discoloration, and particulate matter
 - b. Do not spike IV vial until initial vital signs documented and applicable venous access is achieved. Immune Globulin products remain stable for 3 hours after spiking
 - c. Following successful IV access, flush line with 10 mL Sodium Chloride, then infuse the ordered pre-hydration fluid
 - d. If ordered pre-hydration fluid is Normal Saline, prime and flush the primary line following normal saline prehydration fluid with about half

- e. of the ordered D5W prior to connecting the secondary tubing containing the IG product
- e. Administer all IV pre medications and prehydration fluids through mainline. Keep mainline ready in the event of an adverse reaction. Use secondary tubing for IG product
- f. Apply gloves before handling IG vials
- g. Check expiration date of IG product
- h. Do not shake immune Globulin product vial
- i. To spike vial, disinfect the top of the IG vial with an alcohol prep pad, swiping several times over the top and around the neck of the vial, then with IG vial on a stable surface, insert tubing spike straight into IG vial
- j. Clamp tubing, turn bottle upside down and half fill drip chamber with fluid
- k. Hang bottle to IV pole and slowly prime secondary tubing with ordered IG product
- l. Thoroughly cleanse access site in D5W main line with alcohol and piggy back IG product to main line
- m. Begin IVIG at ordered rate. Ensure main line of D5W is clamped before starting IVIG
- n. Observe for immediate or delayed signs or symptoms of infiltration/extravasation
- o. Slowly titrate infusion rate up every 30 minutes to reach pre-determined max infusion rate
- p. Once IG infusion is completed, infuse remaining ordered post flush solution of D5W, then flush catheter with 10 mL of 0.9% Sodium Chloride
- q. Remove safety needle and discard in biohazard container
- r. Immediately apply pressure to the site for a minimum of 3 - 5 minutes
- s. Apply bandage to cover site once hemostasis is achieved

AFTER CARE:

1. Observe for any infusion related reaction such as urticaria, abnormal breathing/breath sounds, chest tightness/heaviness, or low back pain.
2. Documentation of IVIG infusion in patient record:
 - a. Date/time of infusion/dose/route/rate/frequency
 - b. Immune Globulin product name
 - c. Lot number/expiration of each vial used
 - d. Gauge/length of safety needle to access VAD
 - e. Number of IV access attempts
 - f. Complete vital sign record (BP, HR, RR, temp) Titration rates
 - g. How patient tolerated infusion process
 - h. Patient report of improvement of symptoms
 - i. Documentation of all patient education and their understanding of information.
 - j. Documentation of any emergency care provided

3. Notify/communicate with ordering physician of outcome of infusion including response to therapy, management of experienced side effects, vital sign range, if applicable, and patient tolerability of infusion process.
4. Communicate with patient within 24 hours following infusion to monitor for post infusion symptoms and how IVIG has benefitted condition symptoms.
5. Post infusion patient education includes continued non-caffeinated beverage intake X 3 days following infusion and three days prior to next IVIG infusion, medication profile review, signs and symptoms of infusion related reaction, when to call physician and home health agency.

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