HEALTH SERVICES

TITLE: INTRAVENOUS IMMUNOGLOBULIN (IVIG) / CMV IVIG (Cytogam®)
A. Prior to Obtaining IVIG
B. Obtaining IVIG
C. Administering IVIG
D. Following Administration
E. Transfusion Reaction (Actual or Suspected)

CATEGORY:  RN – General
RPN – General
LPN – General

PURPOSE

- To provide information on the description, preparation, setup, administration, monitoring, documentation and potential adverse reactions of IVIG.

NURSING ALERT:

- As with any blood product acute anaphylactic reaction is a potential side effect. The nursing procedure should be followed carefully and equipment for resuscitation available.
- IVIG has caused hypotension and signs of anaphylaxis. This usually occurs in patients with severe IgA deficiency.
- IVIG should be administered in the concentration it is supplied in. In the very rare situation, i.e. neonatal transfusions, dilution may be required. **Refer to Appendix A for Neonatal Administration Guidelines.**
- IVIG should be administered promptly after opening container and infused within 4 hours. Partially used vials should be discarded. Turbid vials must be sent back to lab.
- Subsequent bottles with different lot numbers require rate and vital signs to be restarted.
- CMV IVIG (Cytogam®) is unique in that it is an immunoglobulin IgG containing a standardized concentration of antibody to CMV (Cytomegalovirus).
- CMV IVIG (Cytogam®) is administered the same as IVIG.

EQUIPMENT

1. Available at all times for treatment of an acute anaphylactic reaction:
   - Epinephrine
   - Diphenhydramine
   - Resuscitation equipment (including Code Blue Cart and medications)
2. Personal protective equipment (PPE) – gloves and protective eyewear
3. Equipment for initiating intravenous (IV), if not already in progress
4. IVIG
5. Infusion pump
6. Infusion pump tubing primary
7. Vented tubing with filter (if applicable and supplied by lab)
8. Y site extension set (in case of adverse reaction) SPD # 313436 for adults
   Pediatrics: Use 7 inch microbore extension tubing (SPD #313402)
9. D5W IV solution
10. IV tubing and D5W solution available for potential adverse effects

**NOTE:** Vented filtered tubing will be sent by lab for IVIG product as required. Not all IVIG requires a filter. IVIG will infuse on secondary setting if filtered tubing supplied.

**PROCEDURE**

**A. Prior to Obtaining IVIG**

1. Ensure “SK Immune Globulin Optimization Program IVIG – ADULT” (PPO #561) or “SK Immune Globulin Optimization Program IVIG – PEDIATRIC” (PPO #562) Practitioner Pre-Printed Orders (PPO) are completed and signed by physician. Upon completion, phone and fax form to local Laboratory/Transfusion service to order product.

2. Verify physician has obtained consent for transfusion of IVIG.
   Consent Link: [http://rhdintranet/Transfusions/public/Forms/Consent%20Refusal%20release%20of%20unmatched%20blood%20for%20RQHR.pdf](http://rhdintranet/Transfusions/public/Forms/Consent%20Refusal%20release%20of%20unmatched%20blood%20for%20RQHR.pdf)

3. Ensure adequate venous access.

4. Obtain and document baseline vital signs (BP, HR, RR, SpO2, and T) within 1 hour of initiation of administration. Document all vital signs related to infusion on unit specific vital signs record. All other documentation related to infusion should be documented in Nursing Notes.

5. Provide adult patients with CEAC Document #1216 and pediatric patients/caregivers with CEAC Document #1273.

   **NOTE:** If patient will be having repeated IVIG infusions, provide CEAC Document #1277 “Intravenous Immune Globulin (IVIG) Patient Logbook” for their tracking at home on discharge.

**B. Obtaining IVIG**

1. Stamp blood requisition with addressograph and indicate required blood product on requisition.

   **NOTE:** Any RQHR employee certified to transport blood and blood products may obtain product from Transfusion Department. Volunteers are not regarded as employees of RQHR.

2. Present requisition to lab staff to obtain IVIG.

   **NOTE:** A check is performed with lab personnel. Patient name, MRN#, date of birth, lot #, expiry date, correct dosage of product.
3. Obtain Notification of Administration of Blood and/or Blood Products (Appendix C) form from lab. Ensure it is signed by patient and a copy sent home on discharge.

4. Resolve any discrepancies prior to leaving lab.

C. Administering IVIG

**NURSING ALERT:**

- An administration which is too rapid may cause flushing, severe headache and changes in vital signs. Slowing or stopping the infusion usually allows symptoms to disappear promptly.
- Ensure patient is aware of signs and symptoms of potential reaction and has ability to call nursing staff.
- Pre-medication with Diphenhydramine, Methylprednisolone and/or Ibuprofen may be ordered by physician as per PPO to reduce risk of transfusion reaction.
- Avoid simultaneous administration of any other blood products or medications linked to hypersensitive reactions.
- Never add or piggyback any medication to IVIG infusion.
- IVIG must be administered using an IV Pump.

1. Don PPE – gloves and protective eyewear.

2. Explain procedure to patient.

3. Perform verification check:
   - Patient Identification (Name, MRN#, Date of birth) utilizing RQHR Policy 0612
   - Correct concentration of product
   - Lot#
   - Expiry date
   - Do not use if turbid, cloudy, or has particulate matter

**NURSING ALERT:**

- All blood products must be CHECKED AT THE BEDSIDE BY TWO INDIVIDUALS from following designations:
  - registered nurse (RN)
  - registered psychiatric nurse (RPN)
  - licensed practical nurse (LPN)
  - nurse practitioner (NP)
  - medical doctor (MD)
  - perfusionist
NURSING ALERT (Cont.)

- A grad nurse (GN) may check blood products only if checking with an RN, RPN or LPN. (See Policy #4.2.4 – Administration of blood products, in the RQHR Policy Manual on the intranet.)
- Student nurses may administer if under direct supervision of instructor or RN, RPN or LPN.

4. Prime IV pump tubing with IVIG on primary line with vent open (unless vented filtered tubing supplied by lab).

   NOTE: If vented filtered tubing supplied by lab, prime infusion pump tubing with D5W on primary line and prime secondary vented filtered tubing with IVIG.

   NOTE: Neonatal administration refer to Appendix A.

NURSING ALERT:

- There is approximately 15 mL of fluid from pump cassette to distal end of tubing without extension tubing. This 15 mL will contain D5W if infusing via secondary setting with vented filtered tubing from lab. Take this information into account with commencement of vital signs monitoring.

5. Initiate infusion at rate indicated below unless otherwise ordered by physician.

   NOTE: **ADULTS** – IVIG DOSAGE RECOMMENDED:
   Refer to SK IVIG Optimization Program Guidelines

   The following is infusion rate for adults unless otherwise ordered by physician. If patient experiences discomfort at infusion site, a larger vein may be required.

   **Adults: Initial Infusion Rate (Day 1):**

   1) 20 mL/hr for 10 min.
   2) Increase to 50 mL/hr for 10 min.
   3) Infuse remainder at 150 mL/hr until complete, if well tolerated.

   **After Initial Infusion for Adults (Day 2 to last day of physician’s orders):**

   1) Administer at 60 mL/hr for first 15 minutes.
   2) Infuse remainder at 150 mL/hr if tolerated well.
NOTE: **PEDIATRICS - IVIG DOSAGE RECOMMENDED:**
Dose and rate of infusion to be ordered by Hematologist or Pediatrician.

If rate not ordered: Infuse IVIG (by itself) as follows:

1) 0.6 mL/kg/hr for first 20 minutes, then
2) 1.2 mL/kg/hr for the next 20 minutes, then
3) 2.4 mL/kg/hr for the remainder of infusion

NOTE: For pediatric dosing, regardless of weight in kg, DO NOT exceed adult rate of 150mL/hr.

NOTE: **NEONATAL ADMINISTRATION GUIDELINES REFER TO APPENDIX A.**

**CMV IVIG (Cytogam®)**

**Initial Dose:** Administer intravenously at 15 mg/kg/hr. If no adverse reactions occur after 30 minutes, the rate may be increased to 30 mg/kg/hr; if no adverse reactions occur after a subsequent 30 minutes, then the infusion may be increase to 60 mg/kg/hr (volume not to exceed 75 mL/hr). **DO NOT EXCEED THIS RATE OF ADMINISTRATION.** The patient should be monitored closely during and after each rate change.

**Subsequent Doses:** Administer at 15mg/kg/hr for 15 minutes. If no adverse reactions occur, increase to 30mg/kg/hr for 15 minutes and then increase to a maximum rate of 60 mg/kg/hr (volume not to exceed 75 mL/hr). **DO NOT EXCEED THIS RATE OF ADMINISTRATION.** The patient should be monitored closely during each rate change.

NOTE: CMV IVIG (Cytogam®) maximum rate infusion of 60 mg/kg/hr (volume not to exceed 75 mL/hr).

6. Monitor vital signs Q15min x 1 after IVIG infusion has reached the patient, then Qhourly, and at end of infusion.

NOTE: For pediatrics, T, HR, BP, RR, and SpO2 prior to infusion initiation, prior to each rate increase and prior to each lot change q30 minutes times 2, then q1h until completion of infusion.

NOTE: For neonatal see Appendix A.

NOTE: Subsequent bottles/lot #’s can be infused at same rate as tolerated by patient on previous bottles (i.e. new bottles with same lot numbers do not have to be restarted at initial rate). Different lot numbers require a restart of rate and vital signs.
7. Observe for adverse reaction as listed in Nursing Alert Section E:

NOTE: If adverse reaction suspected, stop infusion and refer to Section E – Transfusion Reaction (Actual or Suspected).

Reactions are often reduced by avoiding rapid infusion rates.

D. Following Administration of IVIG:

1. Remove completed IVIG and flush tubing with D_{5}W IV solution using final rate of infusion to flush line.

2. Discard glass bottle(s) in biohazard or sharps container on unit.

3. File fraction product slip in patients chart. See Appendix B.

4. Place White Transfusion Record Tag into shredding bin on unit. See Appendix B.

5. Document in the Nursing Notes only and include the following:
   a. date and time of commencement
   b. lot # and product
   c. site of infusion
   d. vital signs – to be documented on unit specific vital signs record
   e. volume transfused
   f. patients reaction to transfusion
   g. signature with designation or initials (as per area standard)

E. Transfusion Reaction (Actual or Suspected)

NURSING ALERT:

- Common signs and symptoms of IVIG reaction:
  Early (first 1-2 hours):
     o Headache
     o Flushing
     o Itching, rash
     o Nausea, vomiting
     o Myalgia
     o Malaise
     o Tachycardia
     o Temperature elevation > 1°C
     o Hypo or hypertension
     o Chills
     o Dyspnea, wheezing, chest tightness
  Later symptoms of reaction (3-7 days post infusion):
    ▪ Dark or red urine
    ▪ Jaundice
1. STOP TRANSFUSION IMMEDIATELY if reaction is suspected leaving IVIG and administration set intact until further instruction.

2. Attach NEW D5W PRIMARY LINE on port closest to patient to keep vein open.

3. Obtain vital signs (T, HR, BP, RR, SpO2).

4. Apply supplemental oxygen if required.

5. Re-check patient identification and IVIG product.

6. Notify physician and Transfusion Department for further instructions regarding transfusion.

7. Return residual IVIG and tubing (clamped and capped) to transfusion department if transfusion is discontinued.

8. Complete Saskatchewan Hospital Transfusion Adverse Event Report Form whenever patient experiences a transfusion reaction or suspected reaction and document in Nursing Notes in patient chart.

Adverse Events Form Link:
REFERENCES


Cytogam product insert: Cytomegalovirus Immune Globulin Intravenous (Human) CSL Behring Canada, Inc. March 2, 2015.


Saskatchewan IVIG Optimization Program Guidelines. (September 2015).


Revised by: Teresa Smith, CNE-3E, Paula Van Vliet, Transfusion Safety Manager RQHR, Jana Lowey, CNE-4F, Sarah Harder, CNE-5F
Date: June 2016

Revised by: Jana Lowey, CNE-4F, Juliann BlaserLindenbach, CNE-Ambulatory Care, Jo Nelson Clinic Coordinator-Ambulatory Care, Paula Van Vliet, Transfusion Safety Manager, Sarah Harder, CNE-5A
Date: February 2017
(New Appendix A added – 20Feb18)

Approved by: Date:

Approved: April 5, 2017
**NEONATAL MEDICATION DILUTION GUIDELINES**

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<th>Drug</th>
<th>Dose and Rate Calculations on Preprinted Order form to be completed by Prescriber.</th>
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| Immune Globulin Intravenous (human) (10% solution) Manufacturer may vary | **Dosage recommendations:**
* Fetal neonatal alloimmune thrombocytopenia (F/NAIT) as adjunctive therapy to platelet transfusion: 1g/kg/dose every day for 2 doses if required, depending on response
* Hemolytic disease of the fetus and newborn, in presence of hyperbilirubinemia (HDFN) despite intensive phototherapy (continued increase in bilirubin greater than 8 micromol/L/hr or total bilirubin within 34 to 51 micromol/L of the exchange level).
* Neonatal thrombocytopenia due to maternal idiopathic thrombocytopenia purpura (ITP)/Systemic lupus erythematosus, as adjunctive therapy to platelet transfusion: 1g/kg/dose

| Calculation of dose: | Desired dose (g/kg) x weight (kg) = dose (g) to be given
|----------------------|------------------------------------------------|
|                      | Eg: If targeting 0.5g/kg/ dose for a 3kg baby, then 0.5 g/kg x 3 kg = 1.5g
|                      | Dose to give is 1.5g.

| Calculation of volume of 10% IVIG to provide for that dose: | Grams of IVIG ordered = volume (mL) of 10% IVIG required for the dose
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| Solution Dilution: | Eg: 1.5g dose ordered = 15mL of 10% IVIG is required for the dose
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| Administration: | Dilution is not required if the Privigen product is utilized as is considered iso-tonic (320 mosmol/L). Other IVIG products may have higher osmolalities and require dilution. No other product to be administered without confirmation with neonatologist and assessment for need for dilution.
|-----------------|-------------------------------------------------------|
|                 | Prime through microbore tubing, then prime through 0.22 micron filter
|                 | Attach to separate IV site and infuse with medication infusion pump.

| Calculation of infusion rates: | For all infusions, start at step 1 and advance to next step as outlined if tolerating infusion:
|-------------------------------|---------------------------------------------------------------|
| 1) Infuse at 0.005mL/kg/min x 30 minutes = mL over 30 minutes | Eg: for a 3kg baby: 0.005mL/kg/min x 30 min
|                  | = 0.0005mL x 3 kg x 30 min = 0.45mL given over 30 minutes |
| 2) Infuse at 0.01mL/kg/min x 30 minutes = mL over 30 minutes | Eg: for a 3kg baby: 0.01mL/kg/min x 30 minutes
|                  | = 0.01mL x 3 kg x 30 min = 0.9 mL given over 30 minutes |
| 3) Infuse at 0.02mL/kg/min x 30 minutes = mL over 30 minutes |
| 4) Infuse at 0.04mL/kg/min x 30 minutes = mL over 30 minutes |
NEONATAL MEDICATION DILUTION GUIDELINES

5) For doses of 0.5g/kg, continue at this rate until complete dose provided
6) For doses greater than 0.5g/kg, continue to increase rate as follows:
   Infuse at 0.06mL/kg/min x 30 minutes = _____mL over 30 minutes
   Infuse at 0.08mL/kg/min x 60 minutes = _____mL over 60 minutes and
   continue this rate until complete dose provided.

Monitoring
During infusion:
Vitals (heart rate, respiratory rate, & BP q15min x 2, then q30min for remainder of
infusion (can record vital signs from the cardiorespiratory monitor, to minimize handling)
Temperature prior to beginning transfusion, 15 min after and then q1h during infusion

Potential adverse reactions
Increased temperature, deterioration of ventilation status requiring increased support,
hypotension, tachycardia, increased flushing.
Risk of necrotizing enterocolitis may be increased in term and late preterm infants treated
for isoimmune hemolytic jaundice
Intravascular hemolysis reported in HDFN post infusion

Black box warning
Intravenous Immune Globulin products (IVIG) have been reported to be associated with
renal dysfunction, acute renal failure, osmotic nephrosis, and death. Use caution in
patients predisposed to acute renal failure and administer at the minimum rate of infusion
practical in such patients. Higher rates of renal failure are associated with IVIG products
containing sucrose. (Privigen® does not contain sucrose.)

Anaphylaxis and recommended treatments
- Manifested as autonomic dysregulation, bronchospasm and/or laryngospasm,
  severe dyspnea, laryngeal and/or pulmonary edema may occur in rare instances.
- Epinephrine 0.1mg/mL (1:10,000) 0.1mL/Kg/dose IV push, repeated every 3 – 5
  minutes as needed (on order of neonatologist, NCA, NNP)

If reaction occurs during infusion:
- Stop infusion immediately, but leave IVIG solution and administration set intact.
- Saline lock IV site to maintain unless alternate maintenance solution directions
  received.
- Obtain vital signs (temperature, HR, BP, RR, Oxygen saturation)
- Cardiopulmonary support to be provided as needed.
- Re-check patient identification and IVIG product.
- Notify neonatologist, NCA, or NNP and Transfusion Department for further
  instructions regarding the transfusion.
- Return residual IVIG and tubing (clamped and capped) to Transfusion
  Department if transfusion is discontinued.
- Complete Saskatchewan Hospital Transfusion Adverse Report Form (see
  Saskatchewan Provincial IVIG Nursing Procedure)

Refer to Saskatchewan Provincial Nursing Procedure for IVIG.

References:
2. Privigen® Product Monograph; Immune Globulin Intravenous (Human) 10% Solution for infusion; Submission control number
183354; Date of approval July 8, 2015
4. Navarro, M et al; Necrotising enterocolitis as a consequence of the use of intravenous immune globulin for newborn
5. Figueras-ely J et al; Intravenous Immunoglobulin and necrotizing enterocolitis in newborns with hemolytic disease; Pediatrics
2010; 125: 139-144.
IF TRANSFUSION
REACTION IS
SUSPECTED, COMPLETE
SASKATCHEWAN
HOSPITALS ADVERSE
EVENT REPORT FORM.
Notification of Administration of Blood and/or Blood Products

Name: ____________________________

MRN: ____________________________

During your stay in the Regina Qu'Appelle Health Region you were given a human blood product.

If you have any questions regarding this product please contact your physician.

Discharge/Transfer

(Signature of person or substitute decision maker) ____________________________
(Data ____________) ____________________________

(Health Care Professional providing discharge or transfer documentation)

White - Health Records    Canary - Patient