Immune Globulin Therapies—How the Appropriate Selection and Use of Immune Globulin Products Can Impact Patient Care

Post-test and Rationale

1. Which of the following is the primary source of plasma for production of intravenous immune globulin (IVIG) therapy:

   A. Whole blood donation
   B. Pooled plasma from whole blood donation
   C. Plasmapheresis from screened donors***

Correct Answer: C
The major manufacturers of IVIG products, which include Baxter, CSL Behring, and Grifols, primarily use source plasma donated at certified plasma collection centers.

2. Which of the following would be the MOST beneficial holding period for plasma donations in the IVIG production pipeline:

   A. 15 days
   B. 30 days
   C. 60 days***
   D. 120 days

Correct Answer: C
Inventory hold, one of the Quality Standards of Excellence, Assurance and Leadership (QSEAL) standards, requires all source plasma to be held in inventory for at least 60 days from the time of collection. Used as an added source of protection prior to preparing pools of plasma, inventory hold allows manufacturers to retrieve units of plasma from disqualified donors because of information received
postdonation (i.e., delayed admission of high-risk behavior or international travel, becoming reactive for HIV, HBV, or HCV). Under the inventory hold standard, manufacturers are required to document and verify that each unit of source plasma was not released for further manufacture until after the 60-day hold period expired.

3. **Which of the following standards recommends the hold period for donated plasma prior to manufacturing:**

   A. Quality Standards of Excellence, Assurance and Leadership (QSEAL)***
   
   B. National Donor Deferral Registry (NDDR)
   
   C. Plasma Protein Therapeutics Association (PTTA)
   
   D. Code of Federal Regulations (CFR)

**Correct Answer: A**

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4. **Which one of the processes listed below leads to immunoglobulin A (IgA) separation from the immunoglobulin G (IgG) fraction:**

   A. Cohn-Oncley process***
   
   B. Kistler-Nitschmann method
   
   C. Pasteurization
   
   D. Solvent/Detergent (S/D) treatment
The following 2 types of cold ethanol fractionation exist: the Cohn-Oncley process and the Kistler-Nitschmann method, which is a variation of the former. For each of these fractionation methods, plasma proteins are selectively precipitated into several fractions based on their solubility in solutions of different alcohol concentrations, pH values, ionic strengths, and temperatures. An important difference between these 2 methods is that the Cohn-Oncley process removes IgA, while the Kistler-Nitschmann method does not.

5. Which of the following stabilizers is NOT associated with renal complications with IVIG therapy:
   A. Glycine***
   B. Mannitol
   C. Sucrose
   D. Sorbitol

The sugars that are used to stabilize IVIGs include the following: sucrose, glucose, maltose, or D-sorbitol. As an alternative, the amino-acids that can be used for IVIG stabilization are glycine, L-proline, or L-isoleucine. For patients with renal impairment, if available, select a nonsugar stabilizing agent, avoiding sucrose in particular.

6. For which of the following patients would it be advantageous to avoid an IVIG product with a high sodium content and larger volume preparation:
A. Patient with immune thrombocytopenic purpura (ITP)
B. Patient with chronic inflammatory demyelinating polyneuropathy (CIDP)
C. Patient with chronic heart failure (CHF)***
D. Patient with history of psychiatric disorder

**Correct Answer: C**
Patients with known cardiovascular disease or an elevated risk of thromboembolic events should avoid high-dose IVIG products containing high sodium levels, high osmolality/osmolarity, and high volume load.

7. **When starting a patient on IVIG therapy, which of the following adverse events would be the MOST likely to occur:**

A. Anaphylaxis caused by IgA deficiency
B. Renal failure
C. Thromboembolism
D. Infusion-related reactions***

**Correct Answer: D**
These local reactions may include pain, bleeding, or bruising at the infusion site. Mild adverse events that are commonly observed in patients include headaches, nausea, malaise, myalgia, arthralgia, chills, anxiety, flushing, abdominal cramps, rash, low-grade fever, and leukopenia.
8. A patient 45 years of age presents with newly diagnosed CIDP at a local neurologist’s office. The treatment plan is to start IVIG therapy. Which of the following treatment doses of IVIG therapy is MOST appropriate:

A. 400 mg/kg
B. 500 mg/kg
C. 2000 mg/kg/cycle***
D. 1500 mg/kg

Correct Answer: C
To treat many autoimmune and inflammatory disorders, high dose IVIG therapy is used, typically a 2 g/kg/cycle. These autoimmune diseases include the following: idiopathic thrombocytopenic purpura (ITP), Kawasaki disease, multifocal motor neuropathy (MMN), and chronic inflammatory demyelinating polyneuropathy (CIPD).

9. Which of the following products would be an appropriate option for subcutaneous administration for a patient with primary humoral immunodeficiency?

A. Gammagard
B. GamaSTAN
C. HyQvia***
D. Privigen

Correct Answer: C
There are only 2 immunoglobulin products on the market that are administered via subcutaneous infusions. The first is Hizentra, which is indicated for the treatment of primary humoral immunodeficiency in adults and pediatric patients 2 years of age and older. HyQvia is another subcutaneous immunoglobulin product indicated for primary humoral immunodeficiency treatment in adults.

10. Which of the following is an approved U.S. Food and Drug Administration (FDA) indication for IVIG therapy:

   A. Myasthenia gravis
   B. Guillain-Barré syndrome
   C. Systemic lupus erythematosus
   D. Multifocal motor neuropathy***

Correct Answer: D

IVIGs are approved for a number of immunodeficiency and autoimmune disorders, including Primary humoral immunodeficiency (PID), B-cell chronic lymphocytic leukemia (CLL), idiopathic thrombocytopenic purpura (ITP), Kawasaki disease, multifocal motor neuropathy (MMN), and chronic inflammatory demyelinating polyneuropathy (CIPD).