Self-Assessment Test
Botulinum Toxin: Update on Emerging Therapeutic Uses and Potential Safety Considerations

This program is located at www.ashpmedia.org/symposia/neurotoxin

There are 20 questions associated with this self-assessment test.

1. Which of the following statements best characterizes the mechanism of action of botulinum neurotoxins?
   a. They temporarily induce the synthesis of acetylcholine.
   b. They temporarily promote the storage of acetylcholine in synaptic vesicles.
   c. They temporarily inhibit acetylcholine release into the synapse.
   d. They temporarily induce the breakdown of acetylcholine in the synapse.

2. Botulinum toxin type A and type B products available in the United States differ with respect to which of the following characteristics?
   a. Formulation.
   b. Formulation and protein content.
   c. Formulation, protein content, and excipients.
   d. Formulation, protein content, excipients, and dosage.

3. Reduction in chronic pain from botulinum toxin type A in patients with cervical dystonia has been attributed to:
   a. Inhibition of substance P and calcitonin gene-related peptide in nociceptive nerves.
   b. Inhibition of substance P and calcitonin gene-related peptide in motor nerves.
   c. Inhibition of acetylcholine in nociceptive nerves.
   d. Inhibition of acetylcholine in motor nerves.
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4. Which of the following mechanisms mediate the beneficial effects of botulinum toxin type A in patients with spasticity?
   a. Inhibition of atrophy in extrafusal/intrafusal muscle and increased acetylcholine release.
   b. Induction of atrophy in extrafusal/intrafusal muscle and increased acetylcholine release.
   c. Inhibition of atrophy in extrafusal/intrafusal muscle and reversible blockade of acetylcholine release.
   d. Induction of atrophy in extrafusal/intrafusal muscle and reversible blockade of acetylcholine release.

5. Botox and Dysport are interchangeable because both are botulinum neurotoxin type A products, but neither is interchangeable with Myobloc because it botulinum neurotoxin type B.
   a. True.
   b. False.

6. The neurotoxin protein exposure in patients treated with botulinum neurotoxin products is a concern because:
   a. A high exposure can increase vesicle-mediated exocytosis and reduce the therapeutic effect.
   b. A high exposure can decrease vesicle-mediated exocytosis and reduce the therapeutic effect.
   c. A low exposure can increase neutralizing antibody formation and reduce the therapeutic effect.
   d. A high exposure can increase neutralizing antibody formation and reduce the therapeutic effect.

7. For which of the following indications is botulinum toxin type A approved by the Food and Drug Administration (FDA)?
   a. Adult spasticity.
   b. Hyperhidrosis.
   c. Low back pain.
   d. Migraine headache.
8. In its evidence-based review, the American Academy of Neurology Therapeutics and Technology Assessment Committee determined that botulinum neurotoxin
   a. Is effective and should be offered as a treatment option for migraine headache.
   b. Is effective and should be offered as a treatment option for cervical dystonia.
   c. Is probably ineffective for adult spasticity.
   d. Is probably ineffective for blepharospasm.

9. In its evidence-based review of botulinum neurotoxin for pediatric spastic equinus, the American Academy of Neurology Therapeutics and Technology Assessment Committee recommended that the drug is established as safe and effective and should be offered.
   a. True.
   b. False.

10. Which of the following presents a challenge in obtaining FDA approval for botulinum toxin in patients with spasticity?
    a. A lack of understanding of the etiology of spastic disorders.
    b. The reluctance of patients to participate in clinical trials.
    c. The lack of a definition of meaningful function.
    d. The small number of patients affected by the disorder.

11. Which of the following adverse effects is most commonly associated with the use of botulinum toxin type A for the treatment of cervical dystonia?
    a. Compensatory sweating.
    b. Dysphagia.
    c. Limb tremor.
    d. Ptosis.
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12. Which of the following statements about the status of biosimilars guideline development by the European Union (EU) and FDA is correct?
   a. Neither the EU nor the FDA has addressed the issue, but the EU probably will take a leadership role that the FDA will follow.
   b. Neither the EU nor the FDA has addressed the issue, but the FDA probably will take a leadership role that the EU will follow.
   c. The EU has addressed the issue and FDA probably will use the EU guidelines as a model.
   d. The FDA has addressed the issue and the EU probably will use the FDA guidelines as a model.

13. Which of the following was among the earliest uses of botulinum toxin evaluated in clinical research?
   a. Headache.
   b. Hyperhidrosis.
   c. Ocular disorders.
   d. Spasticity.

14. Which of the following terms is appropriate to use for Dysport and Botox?
   a. Follow-on biologics.
   b. Generic biopharmaceuticals.
   c. Generic equivalents.
   d. None of the above.

15. The biological activity of botulinum toxin type A is standardized so that one unit of one product is equivalent to one unit of another product.
   a. True.
   b. False.

16. The EU guidelines on comparability of biotechnology products require that the new and original/reference product have similar profiles in terms of:
   a. Chemical composition, safety, and cost.
   b. Cost, safety, and efficacy.
   c. Impurities, safety, and efficacy.
   d. Quality, safety, and efficacy.
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17. Which of the following is an economical means for comparing biosimilars?
   a. Comparing products based on their summary of product characteristics information.
   b. Conducting comparative randomized clinical trials.
   c. Compiling a comparative database of clinical experience with the products.
   d. Establishing registries for patients receiving the products.

18. Which of the following is a distinction between biopharmaceuticals and conventional chemical drugs?
   a. Biopharmaceuticals are less foreign to the human body.
   b. Biopharmaceuticals are less hazardous to the environment.
   c. Biopharmaceuticals are more fully characterized.
   d. Biopharmaceuticals have a larger molecular size.

19. Which of the following statements about erythropoietic agents is correct?
   a. The two commercially available epoetin alfa products are nearly identical in carbohydrate composition, amino acid sequence, and pharmacologic actions.
   b. Epoetin alfa and erythropoietin are identical in carbohydrate composition, amino acid sequence, and pharmacological actions.
   c. Darbepoetin alfa and erythropoietin are identical in carbohydrate composition, amino acid sequence, and pharmacological actions.
   d. Epoetin alfa and darbepoetin alfa are identical in carbohydrate composition, amino acid sequence, and pharmacologic actions.

20. Which of the following characteristics of biologics often does not become apparent in clinical trials, creating an opportunity for pharmacist involvement in post-marketing monitoring?
   a. Bioavailability.
   b. Efficacy.
   c. Immunogenicity.
   d. Lipophilicity.