Assessment

1. The World Health Organization has developed guidelines for cancer pain relief that recommend using an analgesic "ladder" to sequentially treat cancer pain.

2. Cancer pain patients with persistent pain are typically treated only with short-acting opioids.
   a. True
   b. False

3. Patients with breakthrough cancer pain (BTCP) present with mild to severe transient flares of pain.
   a. True
   b. False

4. Rapid-onset opioids (ROO) are also known as transmucosal immediate release fentanyl (TIRF).
   a. True
   b. False

5. Schedule I (CI) drugs are considered less likely to be abused than Schedule V (CV) drugs?
   a. True
   b. False

6. Schedule II (CII) drug prescriptions may be phoned into pharmacies.
   a. True
   b. False
7. Opioids are generally agonists at the **μ** receptor, producing analgesia by stimulating this receptor.

8. One disadvantage of treating BTCP with only an increased dose of long-acting opioids is over medicating, thus leading to increased adverse events.
   a. True
   b. False

9. Fentanyl is available in a long-acting formulation.
   a. True
   b. False

10. **Actiq** is the fentanyl buccal tab.

11. **FentaR** is the fentanyl lozenge.

12. Describe the differences of treating BTCP with a short-acting opioid versus TIRFS.
    
    Takes longer for medication to begin working - causing possible "pain gaps"

13. **Lazanda** is the fentanyl nasal spray.

14. **Abstral** is the fentanyl sublingual tablet.

15. **Onsolis** is the fentanyl buccal soluble film.

16. **Actiq** fentanyl lozenge has an onset of 15 minutes.

17. **Actiq** fentanyl lozenge has a bioavailability of 50 percent.
18. **FENTORA** fentanyl buccal tab has an onset of 15 minutes.

19. **FENTORA** fentanyl buccal tab has a bioavailability of 65 percent.

20. All competitive TIRFS contain a citrate component.
   a. True
   b. False

21. Provide any attributes, as related to Safety and Tolerability, when using fentanyl nasal spray.
    \[**IRRITATION**, NO GI EXPOSURE\]

22. Provide any attributes, as related to Safety and Tolerability, when using fentanyl buccal tablet.
    \[**APPLICATION SITE IRRITATION**, 507, GI EXPOSURE\]

23. Provide any attributes, as related to Safety and Tolerability, when using fentanyl buccal soluble film.
    \[**MINIMAL IRRITATION**, 507, GI EXPOSURE\]

24. Provide any attributes, as related to Safety and Tolerability, when using fentanyl lozenge.
    \[**APPLICATION SITE IRRITATION, CAVITIES**, 75, GI EXPOSURE\]

25. Provide any attributes, as related to Safety and Tolerability, when using fentanyl sublingual tablet.
    \[**MINIMAL IRRITATION**, 75, GI EXPOSURE\]

26. List the brand name and the onset for the fentanyl nasal spray.
    \[**LAZANDA - 10 MINUTES**\]
27. List the brand name and the bioavailability percentage for the fentanyl nasal spray.
   Lazanda - 100%

28. List the brand name and the onset for the fentanyl sublingual tablet.
   Abstral - 10 min

29. List the brand name and the bioavailability percentage for the fentanyl sublingual tablet.
   Abstral - 54.7%

30. List the brand name and the onset for the fentanyl buccal soluble film.
   Onsolis - 15 min

31. List the brand name and the bioavailability percentage for the fentanyl buccal soluble film.
   Onsolis - 71.1%

32. List the available strengths for the fentanyl nasal spray.
   Lazanda
   100, 200, 400, 800 mcg

33. List the available strengths for the fentanyl sublingual tablet.
   Abstral
   100, 200, 300, 400, 600, 800 mcg

34. List the available strengths for the fentanyl buccal soluble film.
   Onsolis
   200, 400, 600, 800, 1200

35. List the available strengths for the fentanyl buccal tablet.
   Fentora
   100, 200, 300, 400, 600, 800

36. List the available strengths for the fentanyl lozenge.
   Actiq
   300, 400, 600, 800, 1200, 1600
Assessment

(PLEASE NOTE: First 15 questions derive from Module 5-A.)

1. SSPs always need to be prepared to recite the basic facts of a paper (title, authors, publication information, number of patients, design, and key results) if needed.
   a. True
   b. False

2. It is okay to present information from clinical papers out of context.
   a. True
   b. False

3. As an effective SSP, you should try to lead physicians with conclusions about a study and its results.
   a. True
   b. False

4. It is your job to know and stay within regulatory guidelines when talking about clinical papers.
   a. True
   b. False

5. P values are expressed as P=.xxx or P<.xxx.
   a. True
   b. False
6. The lower P value, the less likely it is that the observed results are due to chance.
   a. True
   b. False

7. The Abstract is like a "road-map" for the clinical paper; it shows you where you are going before you start reading.
   a. True
   b. False

8. What section of the clinical study presents the basic findings of a study?
   RESULTS

9. The Discussion answers the question, "How was this study performed?" and will answer nearly every question you or a physician might have about how the study was conducted.
   a. True
   b. False

10. The Introduction section presents key efficacy and safety data without interpretation.
    a. True
    b. False

11. The Methods or Conclusions section presents the authors' conclusions about the study results and their clinical relevance.
    a. True
    b. False
12. Retrospective studies are most useful for evaluating long-term risks of a particular intervention or exposure to a risk factor.
   a. True
   b. False

13. Review articles are original articles about a particular subject such as a disease state that is usually written by experts in that particular field.
   a. True
   b. False

   a. True
   b. False

15. Study endpoints should be clinically meaningful.
   a. True
   b. False

16. Due to the risk of fatal respiratory depression, SUBSYS™ is contraindicated in opioid non-tolerant patients and in management of acute or postoperative pain, including headache/migraines.

17. SUBSYS is available only through a restricted program called the TIRF REMS Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors are required to enroll in the program.
   a. True
   b. False
18. SUBSYS™ is the branded name, whereas fentanyl sublingual spray would be considered the generic name.

19. What is the Indication for SUBSYS? Management of Breakthrough pain in adult cancer pts who are already receiving and tolerant to around-the-clock opioid therapy.

20. What are the dosage strengths of SUBSYS? 100, 200, 400, 600, 800, 1200, 1600

21. What would be the most common adverse reactions during treatment (frequency ≥5%) with SUBSYS? Nausea, vomiting, constipation, dyspnea and somnolence

22. Administer SUBSYS with caution to patients with liver or kidney dysfunction.
   a. True
   b. False

23. Safety and effectiveness of SUBSYS in pediatric patients below 18 years of age has been established.
   a. True
   b. False

24. When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to SUBSYS.
   a. True
   b. False

25. Because of the risk for misuse, abuse, addiction, and overdose, SUBSYS is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS).
26. SUBSYS contains fentanyl, a(n) **Opioid Analgesic** and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics and it can be abused in a manner similar to other opioid agonists, legal or illegal.

27. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least:
   a. 60 mg of oral morphine daily for at least one week
   b. at least 100 mg of hydrocodone for at least one week
   c. at least 25 mcg of transdermal fentanyl/hour for at least one week
   d. at least 30 mg of oral oxycodone daily for at least one week
   e. at least 8 mg of oral hydromorphone daily for at least one week
   f. an equianalgesic dose of another opioid daily for a week or longer
   g. at least 25 mg of oral oxymorphone daily
   h. All the above except for f
   i. All the above except for b
   j. All the above

28. Patients must remain on around-the-clock opioids when taking SUBSYS.
   a. True
   b. False

29. The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is always 100 mcg.

30. For each breakthrough pain episode treated, if pain is not relieved after 20 minutes, patients may take **one** additional dose of the same strength for that episode. Thus patients should take a maximum of **two** doses of SUBSYS for any breakthrough pain episode.
31. Patients MUST wait at least 2 hours before treating another episode of breakthrough pain with SUBSYS.
   
   a. True
   
   b. False

32. The safety of SUBSYS has been evaluated in a total of 3 patients with breakthrough cancer pain.

33. The dose range studied in the safety trial ranged from 100 mcg per dose to 1600 mcg per dose.

34. The most common adverse reaction leading to discontinuation of SUBSYS was constipation.
   
   a. True
   
   b. False

35. SUBSYS is rated as a Pregnancy Category C.

36. What are the inactive ingredients in SUBSYS?
   
   DEHYDRATED ALCOHOL, PURIFIED WATER, PROPYLENE GLYCOL, XYLITOL, L-METHIONINE

37. Following the single dose administration of SUBSYS, 400 mcg, the mean absolute bioavailability of fentanyl is 76% as measured by AUC.

38. In a study that compared the relative bioavailability of SUBSYS and ORAL TRANSMUCOSAL FENTANYL CITRATE, in 21 healthy adult subjects, the rate and extent of fentanyl absorption were considerably greater with SUBSYS: 34% greater maximum plasma concentration (Cmax) and 92% greater systemic exposure (AUCinf).
39. The median time of maximum plasma concentration (Tmax) across these five doses of SUBSYS varied from 0.67 - 1.25 hours (range of 0.08 - 4.00 hours) as measured after the start of administration.

   a. True
   b. False

40. SUBSYS should be avoided in patients with Grade 1 and more severe mucositis unless the benefits are expected to outweigh the risk of respiratory depression.

   a. True
   b. False

41. The efficacy of SUBSYS was demonstrated in a **controlled crossover** study in opioid tolerant adult patients with cancer and breakthrough pain.

42. Out of 130 patients who entered the titration phase of the efficacy study, ____ patients and ____% were able to titrate to a dose that adequately reduced pain with tolerable side effects and entered into the double-blind period.

   a. 86/66%
   b. 77/59%
   c. 113/87%
   d. 98/75%
   e. 127/98%

43. SUBSYS produced a statistically significantly greater reduction in pain intensity compared to placebo as measured by the Summed Pain Intensity Differences scale (SPID) at ____ minutes.
44. SUBSYS is supplied in individually sealed blister packages. Store at 20-25°C (68-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.

a. True
b. False

45. Patients and caregivers must be advised to dispose of used unit doses systems immediately after use and any unneeded unit dose systems remaining from a prescription as soon as they are no longer needed. Consumed units represent a special risk because they are no longer protected by the blister package, yet may contain enough medicine to be fatal to a child.

a. True
b. False

46. A disposal bottle is not provided with every SUBSYS carton dispensed, thus patients should devise their own safety disposable protocol.

a. True
b. False

47. Each SUBSYS carton contains individual blister packages containing single spray units of SUBSYS, a supply of small white disposable bags for disposing of used SUBSYS units, a medication guide and a package insert.

48. Match the dosage strength (fentanyl base) with the correct carton/blister package color:

a. 100 mcg
b. 200 mcg
c. 400 mcg
d. 600 mcg
e. 800 mcg

- Blue
- Green
- Orange
- Purple
- Magenta (Pink)
49. Patient must sign the Patient-Prescriber Agreement Form (PPAF) to acknowledge that they understand the risks of SUBSYS.
   
   a. True
   b. False

50. As a component of the TIRF REMS Access program, prescribers must review the contents of the SUBSYS Medication Guide with every patient before initiating treatment with SUBSYS.

51. SUBSYS is available only from Pharmacies that are enrolled in the TIRF REMS Access program.

52. Patients and their caregivers can purchase a Child Safety Kit at their local pharmacy. The kit should consist of a safe interim storage bag, a lock for the bag and contain a package of cabinet and drawer child safety latches for securing the storage space at home to help patients store SUBSYS and other medicines out of the reach of children.

   a. True
   b. False
Assessment

1. Which is not considered to be a function of managed care?
   a. Measure the performance of providers
   b. Influence the cost of healthcare services
   c. Influence the utilization of healthcare services
   d. Provide access to healthcare for all consumers

2. What are the dual goals of managed care?
   a. Enroll members and prevent disease
   b. Reduce costs and limit access to services
   c. Maximize utilization of services and reduce drug spending
   d. Provide quality care and effectively manage the costs of care

3. Match each managed care event or trend with the appropriate time period:
   a. 1920s [D] Congress passes HMO Act
   b. 1930s [A] doctors launch plans in Oklahoma and California
   c. 1940s-1960s [E] managed care becomes dominant
   d. 1970s [A] challenges posed by aging population, reduced benefit
   e. 1980s [C] slow, steady growth
   f. 1990s [E] rapid growth, many plan models emerge
   g. 2000s [B] birth of the Kaiser Permanente Health System
4. Which two types of plans require payment for a healthcare service after the service is provided?
   a. Staff-model HMO
   b. Fee-for-service
   c. PPO
   d. IPA-model HMO

5. In a PPO, provider fees are discounted when members remain within the provider network.
   a. True
   b. False

6. When a physician group contracts with an HMO, fees are provided before the HMO’s members require services.
   a. True
   b. False

7. What type of plan gives members the option to access care through an HMO, PPO, or indemnity plan at the time a service is required?
   a. POS

8. What type of system coordinates healthcare services across the continuum of care?
   a. Employer-provider coalition
   b. Network-model HMO
   c. Health reimbursement system
   d. Integrated delivery system
9. A health reimbursement arrangement (HRA) or health savings account (HSA) is usually a component of a
   a. Group-model HMO
   b. Consumer-directed health plan
   c. POS plan
   d. Indemnity plan

10. Which statement best describes the purpose of a managed care formulary?
   a. Clamp the lid on costs that pharmaceutical companies charge
   b. Limit physician prescribing to the lowest-cost prescription drugs
   c. Encourage physicians to prescribe cost-effective medications
   d. Help patients make informed choices about prescription drugs

11. Which phrase describes an open formulary?
   a. Loosely managed
   b. Limited number of drugs
   c. Physicians must prescribe from the list
   d. Requires special procedures for unlisted drugs

12. In a three-tier formulary, which formulary tier usually lists preferred brands?
   a. Tier 1
   b. Tier 2
   c. Tier 3
   d. Tier 4
13. Which formulary enforcement procedure involves potential bonuses paid to physicians as a reward for cost-effective prescribing?
   a. Risk pool
   b. Counter-detailing
   c. "Dear Doctor" letter
   d. Prior authorization

14. Match each patient cost-sharing method with its definition:
   a. Out-of-pocket payment before coverage applies
   b. Fixed fee paid when a prescription is dispensed
   c. Percentage of the retail cost of a prescription
   d. Coinsurance
   e. Deductible
   f. Copayment

15. Which is not a function of drug utilization review?
   a. Minimize inappropriate drug use
   b. Force physicians to follow formulary guidelines
   c. Encourage pharmaceutical companies to reduce prices
   d. Minimize the number of prescriptions that are not indicated

16. Prior authorization is the formal process that MCOs use to require providers to __________________ before performing particular services or procedures.
   a. Check with the patient
   b. Obtain approval
   c. Use a less expensive option
   d. Follow a clinical practice guideline
17. Step therapy requires physicians to prescribe more expensive drugs only after trying less costly products first.

a. True
b. False

18. Match each key player with his/her key professional responsibility:

a. Negotiates with pharmaceutical manufacturers
b. Serves as primary drug information contact for physicians and nurses
c. Manages pharmacy department and its operations

C. Pharmacy Director
B. Director of Clinical Pharmacy Services
A. Pharmacy Contracts Specialist