FINAL YEAR UNIVERSITY EXAMINATION 2019-2020
Final Year B.Pharm. Semester VIII
SUBJECT-BPH_E_808_T-Pharmacovigilance
MULTIPLE CHOICE QUESTIONS: PRACTICE QUESTION BANK

SET 1

Q.1. Pharmacovigilance continue throughout:-
a) Post marketing surveillance
b) Pre and post marketing surveillance
c) Pre marketing surveillance
d) None of the above

Q.2 Process of pharmacovigilance is-
a) Case processing-signal management-risk management -submission to umc
b) Case processing-risk management -signal management-submission to umc
c) Submission to umc- case processing-signal management-risk management
d) Risk management- submission to umc- case processing-signal management

Q.3 Adverse event is due to –
a) Life threatening
b) Due to drug/treatment
c) May have causal relationship with treatment
d) May not have causal relationship with treatment

Q.4 Serious adverse event
a) Result in death
b) Cover within 1 month
c) Result in defects of body
d) Result in mental illness

Q.5 Pharmacovigilance
a) Increase economic burden on healthcare system
b) Improve public health
c) Neglects patient safety
d) Discourage effective drug use

Q.**6** What Is an Adverse Drug Reaction

a. Mechanism of drug
b. Unwanted effect of drug
c. Wanted effect of drug
d. Efficacy of drug

Q.7 NDA stands for –
a) New drug applicant
b) Novel drug application
c) New device application
d) New drug application

Q.8 Phase I clinical trial involved
a. 20 -100 patients
b. 100- 300 patients

c. 100-200 patients
d. 200-500 patients

Q.9 What role does Pharmacovigilance play in Medical Affairs?
a) The Robin Hoods of the Pharma world.
b) Dealing with negligent behaviour during clinical drug trials.
c) Dealing with the enforcement of restrictions by the FDA during clinical trials.
d) Dealing with reports of adverse events in patients during clinical trials.

Q.10 What is the role of Medical Affairs in Preclinical Research?
a) Medical Affairs controls all Preclinical Research
b) Medical Affairs provides value perspective/vision based on its understanding of alternative products and unmet medical needs
c) Medical Affairs acts as the liaison between the Regulatory Department and the Discovery team to ensure that the two divisions are working together to meet the strategic needs of the company.
d) Medical Affairs plays no role in Preclinical Research.

Q.11 Which of the following patients are most at risk of suffering from an adverse drug reaction?
a) An 8 month year old infant receiving a prescription for an antibiotic.
b) A 22 year old patient with asthma receiving prescriptions for inhalers to relieve and prevent their asthma.
c) A 48 year old patient who has hypertension and receives a prescription for an ACE inhibitor.
d) A 68 year old patient who has oedema receiving a prescription for a diuretic. A 68 year old patient who has oedema receiving a prescription for a diuretic.

Q.12 To begin clinical research study it is mandatory to get approval from?
a. Sponsor
b. Regulator
c. Regulators and ethics committee
d. ethics committee

Q.13 Which of the following adverse drug reactions would you report to the Medicines and Healthcare Products regulatory Agency (MHRA) via the yellow card system for reporting?
a) A patient reports a skin rash after starting a course on amoxicillin capsules.
b) A patient reports experiencing dyspepsia when they take their indomethacin capsules.
c) A patient complains of a dry irritating cough since they have started taking ramipril.
d) A patient complains they have experienced diarrhoea since taking azilsartan

Q.14 Website of WHO for Pharmacovigilance is
a. Vigimed
b. Viginex
c. Vigimel
d. Viginac

Q. 15 Signal Detection is
a. The act of looking for and/or identifying signals using data from any source
b. To identify information regarding drug
c. To identify information about any vaccine
d. detection of bioavailability of drug

Q. 16 The Uppasala Monitoring Center is located in which of the following country?

A. China
B. Japan
C. Sweden
D. India

Q 17 The WHO International Drug Monitoring Programme was established in the year

A. 1986
B. 1990
C. 1996
D. 1968

Q 18 Type A pharmacological class of Adverse Drug Reaction stands for

A. Bizzare
B. Augmented
C. Delayed
D. Continuous drug use

Q 19 This observational study of pharmacovigilance includes a group of individuals who share a common characteristic and may be chosen based on a population definition, or based on a particular exposure

A. Case control study
B. Cohort study
C. Cross sectional study
D. Spontaneous reporting

Q 20 The Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopeia Commission, is situated at

A. Calcutta
B. Mumbai
C. Ghaziabad
D. Jaipur

Q 21 It is a list of patients with the same characteristics useful in the active surveillance of Pharmacovigilance

A. Sentinel sites
B. Registries
C. Drug event monitoring
D. Case series

Q 22 In this type of classification of ADR the frequency of ADR calculated on the basis of number of events(numerator) occurring in a particular number of population (denominator) is termed as.

A. Severity classification
B. Mechanism classification
C. Frequency classification
D. Pharmacological classification

Q 23 Which of the following is the definition of **Unexpected Adverse Drug Reaction**?

A. Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.
B. A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.
C. An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational medicinal product).
D. Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Q 24 What is the frequency of PBRER submission for a newly developed medicinal product?

A. 6 months
B. 12 months
C. 3 months
D. 1 month

Q 25 Individual safety case report (ICSR) should summarize all the following information except:

A. Post-mortem/ autopsy findings
B. Medical reviewer’s evaluation and comment
C. Pre-approval expedited reports
D. Information in the chronology of patient experience

Q 26 CIOMS VI deals with:

A. Benefit–Risk Balance for Marketed Drugs: Evaluating Safety Signals
B. Current Challenges in Pharmacovigilance
C. Development Safety Update Report

D. Management of Safety Information from Clinical Trials

Q 27 What are the minimum criteria for expedited reporting?

A. An identifiable patient; a suspect medicinal product; an identifiable reporting source; and an event or outcome that can be identified as serious and unexpected
B. An identifiable patient and an event or outcome that can be identified as serious and unexpected
C. An identifiable patient; a suspect medicinal product; an identifiable reporting source; an event or outcome that can be identified as serious and unexpected; and follow-up information of the patient
D. An identifiable patient; a suspect medicinal product; and an identifiable reporting source.

Q 28 Which is the primary source of reference product information for a PBRER?

A. Company Core Data Sheet (CCDS)
B. US Package Insert (USPI)
C. Summary of Product Characteristics (SmPC)
D. Japanese package inserts

Q 29 According to WHO-ART, thrombophlebitis arm and thrombophlebitis leg are which terms?

A. High level term
B. Preferred term
C. Included term
D. System organ class

Q 30 MedDRA includes all of the following except:

A. Medical and surgical procedures
B. Patient demographic terms
C. Product quality issues
D. Toxicologic issues

Q 31 Which one of the following comprise primary drug information resource?

A. Review and research articles
B. Major compendia
C. EMBASE and MEDLINE
D. Clinical research study reports

Q 32 Which of the following database is maintained by UMC on behalf of World Health Organization?

A. EudraVigilance
B. Motherisk
C. Vigibase
D. General Practice Research Database (GPRD)

Q 33 Why a special focus on post-marketing safety reporting is necessary for paediatrics? Choose the wrong statement.

A. Relatively small number of pediatric patients are often involved in pediatric trials.
B. Children are frequently involved in early phase 1 pharmacokinetic and safety and phase 2 dose-finding and safety studies.
C. There are differences in absorption, metabolism, distribution, and elimination in the various pediatric age groups.
D. There is extensive off-label use of products within the pediatric population.

Q 34 Which one of the following could serve as a premarketing source of data regarding reproductive and developmental safety of prenatal drug exposures?

A. Clinician case reports
B. Centralized adverse event reporting systems (AERSs)
C. Clinical study data
D. Pregnancy drug exposure registries

Q 35 A man started medications before his partner became pregnant. But she has a miscarriage now. Which of the following statement is wrong with respect to this event?

A. The ADR is miscarriage.
B. The patient is the man who took the medicine.
C. The patient is the partner who experienced miscarriage.
D. The patient is the foetus.

FINAL Year B.Pharm. Semester VIII
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SET 2

1) What is Pharmacovigilance
A) Effects of drugs and mechanism of action
B) Biochemical and physiological effect of drug
C) Analyze the risk, safety of medicine
D) Role of the drug of Genome Response

2) Who is responsible for WHO international drug monitoring Programme?
A) Uppsala monitoring centre
B) WHO drug dictionary
C) PVPI
D) Contract research Organization

3) The functions of UMC are
A) Development of adverse reaction signals
B) Exchange information
C) Analyse data
D) Collecting, assessing and communicating information from member countries

4) The no of volunteers involved in phase I are -
A) <10
B) 20-80.
C) 200 -300
D) 1000-3000

5) CROs stand for
A) Contract research organizations
B) Controlled research organizations
C) Contract risk organizations
D) Controlled risk organizations

6) Pharmacovigilance programme of India was started by Govt of India on -
A) 14th July 2012.
B) 14th July 2010
C) 10 June 2012.
D) 10 July 2010

7) The objectives of PVPI includes
A) Adverse drug reaction
B) Monitoring the Patients.
C) Patient counselling
D) Create national wide system for patient safety reporting

8) Adverse drug reactions are
A) Only side effects

B) Noxious and unintended response of drug at normal therapeutic dose
C) 1st leading cause of death
D) Pharmacogenomic effect

9) Type A adverse reactions are -
A) Dose dependent. B) Unpredictable
C) Dose independent. D) Idiosyncratic

10) Type B adverse reactions are -
A) Dose independent B) predictable. C) Dose dependent
D) Idiosyncratic

11) Delayed adverse reactions -
A) Adverse drug reaction
B) Adverse event occurs after some time
C) Drug interaction
D) Drug-Drug reaction

12) Continuous drug use adverse reactions may be -
A) Irreversible, unexpected
B) Reversible, expected
C) Irreversible, expected
D) Reversible, unexpected

13) The most commonly adopted method for reporting of ADR is -
A) Expedited reporting. B) Longitudinal electronic patient records
C) Spontaneous reporting. D) Suspected reporting

14) What is the first step in management of ADR -
A) Treatment of ADR. B) Detection of ADR
C) Withdrawal of suspected drug
D) Dose reduction of drug causing ADR

15) Management of ADR involves
A) Symptomatic and specific treatment of suspected reaction
B) Unwanted reaction
C) Drug Management
D) Dose reduction

16) Naranjio scale method of causality assessment is -
A) Algorithmic method B) probabilistic method
C) Global introspection. D) Algebraic Method

17) What is the meaning of highly probable ADR?
A) If frequencies of ADR are medium
B) If frequencies of ADR are more
C) If frequencies of ADR are less

D) If frequencies of ADR are 1.1000 or rare.

18. Which one of the following in not true in infants, that may influence safety of drugs?
    A. Glucuronidation does not reach adult levels for at least 3 years of age
    B. Higher volume of distribution for hydrophilic drugs
    C. Less volume of distribution for hydrophilic drugs
    D. Less volume of distribution for hydrophilic drugs

19. Infants have lower renal clearance because:
    A. They have Higher free fraction of drugs
    B. GFR reaches adult levels by 2 years of age
    C. Nephrogenesis is not complete till 2 years of age
    D. They have delayed absorption

20. A known limitation of spontaneous ADR reporting is:
    A. Under reporting
    B. False reporting
    C. Excess reporting
    D. Spontaneous ADR reporting has no limitations

21. Which of the following is special aspects of drugs in the elderly?
    A. Higher distribution of lipid soluble drugs
    B. Increased hepatic metabolism capacity
    C. Decreased circulatory response (postural control, thermoregulation, cognitive function)
    D. Progressive deterioration of renal function not reflected by serum creatinine

22. Which of the following is not a possible pregnancy outcome?
    A. Spontaneous abortion
    B. Ectopic pregnancy
    C. Stillbirth
    D. Leukaemia

23. What is pre-term birth?
    A. less than 37 completed weeks of gestation.
    B. less than 34 completed weeks of gestation.
    C. less than 38 completed weeks of gestation.
    D. less than 32 completed weeks of gestation.

24) Following is the method of Pharmacovigilance
A) Induced reporting
B) Active surveillance
C) Online reporting
D) Sentinel site

25) This is Passive Surveillance method -
A) Spontaneous reports. B) Sentinel site
C) Drug event monitoring. D) Registries

26) Aims of spontaneous reporting are -
A) To keep watch on event
B) Benefit risk analysis
C) Adverse drug event
D) Case studies

27) Following is not a method of stimulated reposting
A) Online reporting. B) Sponsor encouragement reporting
C) Offline reporting. D) Prompt / induced reporting

28) Sentinel meaning -
A) Adverse drug reaction. B) To keep watch for an event
C) Adverse drug event. D) Sponsor reporting

29) Sentinel system was launched by FDA in -
A) May 2010. B) May 2008. C) April 2010. D) April 2008

30) Type of comparative observational studies is
A) Randomized controlled trials
B) Qualitative studies
C) Cohort studies
D) Test controlled studies

31) Targeted clinical investigations required -
A) IRB approval B) FDA approval.
C) IEC approval. D) IRB /ICE approval

32) This is the type of registry -
A) Disease registry B) Case registry
C) Case series D) ADR registry

33) Which of the following is false about prescription event monitoring (PEM) -
A) PEM actively encourages prescribers to report
B) PEM is expensive to set up
C) Allows surveillance of deaths
D) PEM is not interventional

34. WHO-ART has:
   A. 4 levels hierarchical structure
   B. 10 levels hierarchical structure
   C. 5 levels hierarchical structure
   D. 6 levels hierarchical structure

35. Which one is proper description of term “Benefit-risk analysis”?
   A. Studies that compare cases with a disease to controls without the disease, looking for differences in antecedent exposure
   B. Examination of the favourable and unfavourable results of undertaking a specific course of action.

C. Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product
D. A plan to conduct activities relating to the detection, assessment, understanding, reporting and prevention of adverse effects of medicines during clinical trials

36. What is an Attributable risk?
A. The probability of an event affecting members of a particular population
B. description or assessment of both positive and negative effects of a medicine
C. Any negative or harmful occurrence that takes place during treatment, that may or may not be associated with a medicine.
D. Difference between the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk)

37. What is full form of MedDRA
A. Medical Dictionary for Regulatory Activities
B. Medical Directory for Regulatory Affairs
C. Medical Dictionary for Regulations and Actions
D. Medical Directory for Regulations of Affairs

38. PV tools not used by UMC are
A. VigiFlow™
B. VigiSearch™
C. VigiMine™
D. VigiPass™

39. Which one of the following is High level term?
A. Peptic ulcer
B. Gastric ulcer
C. Stomach ulcer
D. Pyloric ulcer

40. Which of the following define Cohort studies?
A. Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product
B. Studies that identify defined populations and follow them forward in time, examining their rates of disease.
C. These examine exposures and outcomes in populations at one point in time; they have no time sense
D. Studies that do not have control groups, namely case reports, case series, and analyses of secular trends. They contrast with analytic studies

41. Define Solicited reports
A. Those derived from organized data collection systems, which include clinical trials, registries, post-approval named patient use programs, other patient support and disease management programs, surveys of patients or healthcare providers, or information gathering on efficacy or patient compliance

B. An unsolicited communication to a company, regulatory authority, or other organization that describes an adverse drug reaction in a patient given one or more medicinal products and which does not derive from a study or any organized data collection scheme.
C. Can occur in certain situations, such as after a direct healthcare professional communication (DHPC), a publication in the press or questioning of healthcare professionals by company representatives
D. Part of the marketing authorisation of a medicinal product setting out the agreed position of the product as distilled during the course of the assessment process which includes the information described in Article 11 of Directive 2001/83/EC.

42. Type C adverse drug reaction are
A. A dose-related reaction
B. A non-dose-related reaction
C. A dose- and time-related reaction
D. A time-related reaction

43. Type E adverse drug reaction is
A. A withdrawal reaction
B. An unexpected failure of therapy reaction
C. A dose-related reaction
D. An expected failure of therapy reaction

44) ICH stands for –
A) The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
B) International council on harmonization
C) Internal conference on harmonization
D) Indian committee on harmonization

45) ICH guidelines E6 is for -
A) Good Clinical Practice
B) Studies in support of special population
C) General considerations for clinical trials.
D) The extent of Population

46) CIOMS is based in –
A) Uppsalla Sweden B) California
C) Geneva D) England

47) To date, there are ___CIOMS working groups
A) 6. B) 8. C) 10. D) 15

48) CDSCO is located in __

A) Kolkata B) New Delhi C) Chennai D) Mumbai

49) D&C act was passed in -
A) 1947. B) 1980. C) 1951. D) 1940

50) Indian Pharmacovigilance system is regulated by -
A) USFDA B) CDSCO. C) IPC. D) DRDO