

HANGONA M. JIMMY
Clerk Rep
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CLINICAL PHARMACOLOGY EXERCISE 3

CARDIOVASCULAR DISORDERS, HYPERLIPIDAEMIAS AND ANTICOAGULANTS

- ✓ 1. Concerning hypertensive emergencies:
 - ✓ A. List advantages and disadvantages of oral versus parenteral drug therapy for a patient with severely elevated blood pressure
 - B. Compare and contrast the intravenous anti-hypertensives used for treating hypertensive emergencies with regard to: mechanism of action, efficacy, onset and duration of action, safety and special indications
 - ✓ C. What are the treatment goals for a patient with a hypertensive emergency?
- ✓ 2. Concerning management of chronic hypertension:
 - A. What are the goals for the treatment of hypertension?
 - ✓ B. Describe (with suitable examples) how you would select an appropriate anti-hypertensive regimen based on patient-specific characteristics and concurrent disease states. In each example you give, what lifestyle modification would you advise?
 - C. Compare and contrast the drugs used in the long-term treatment of hypertension (i.e. non-emergency setting) with regard to: mechanism of action, efficacy, safety, special indications and contra-indications
 - D. Design an appropriate monitoring plan for each group of anti-hypertensive drugs
- ✓ 3. Concerning the drug management of heart failure:
 - A. What are the goals for the pharmacologic management of heart failure?
 - B. Describe the medications used in the short- and long-term management of heart failure and give the rationale for the use of each drug you mention
 - ✓ C. What clinical and laboratory parameters are needed to evaluate the therapy for achievement of the desired therapeutic outcome and to detect and prevent adverse events?
 - D. What is the role of beta-adrenergic blockers in the management of heart failure?
- ✓ 4. Ischaemic heart disease (IHD) and acute coronary syndromes (ACS)
 - A. List the goals for pharmacotherapy in IHD and describe the pharmacotherapeutic options available for treating IHD. How does each drug you mention meet the therapeutic goals?
 - B. Describe how you would optimise medical therapy in a patient with persistent angina (with consideration of co-morbidities). How would you assess the clinical response to anti-anginal therapy for efficacy and adverse effects?
 - C. Compare and contrast the anti-platelet drugs used in the management of acute coronary syndromes with regard to mechanism of action, efficacy, safety, special indications and role played in the management of ACS
 - D. Describe how you would design an optimal therapeutic plan for management of acute myocardial infarction and describe how the drugs you would select achieve the therapeutic goals
 - E. What is the role of low-molecular-weight heparins in the management of acute coronary syndromes?
 - F. List the modifiable risk factors for IHD and describe the potential benefit to be derived by their modification in an individual patient

5. Arrhythmias

- A. Describe how treatment for lone atrial fibrillation differs from that associated with identifiable underlying causes
- B. What pharmacotherapeutic regimens would you recommend to achieve and maintain ventricular rate control in patients with atrial fibrillation? List the benefits and risks of the drugs you mention.
- C. What therapies are available to convert atrial fibrillation to normal sinus rhythm?
- D. How would you treat acute-onset ventricular tachycardia and what are your goals for treatment? How would you monitor the patient to evaluate the therapy for achievement of the desired therapeutic outcome and to prevent toxicity?
- E. What prophylactic interventions against ventricular tachycardia/ventricular fibrillation after a myocardial infarction are available?

6. Anticoagulants

- A. What are the advantages and limitations of the therapeutic options for deep vein thrombosis in the outpatient setting?
- B. Describe how you would develop an individualised therapeutic plan for a patient presenting with a deep vein thrombosis. What are your acute and chronic goals? Explain how you would titrate warfarin doses in both the initiation and maintenance phases of therapy.
- C. What information would you give to a patient receiving anticoagulation therapy to enhance compliance, minimise adverse effects and ensure successful therapy?
- D. Compare and contrast warfarin and heparin with regard to: mechanism of action, onset and duration of effect, safety, monitoring and indications
- E. Briefly discuss low-molecular weight heparins (LMWH)
- F. Vitamin K can be given to patients with excessive anticoagulation to lower INR values. When is it appropriate to consider vitamin K administration? Which route of administration would you recommend?
- G. There are several mechanisms by which drugs may interact with warfarin. What are the major mechanisms of these interactions? Give examples of drugs that interact by each mechanism
- H. Antibiotics are a common cause of drug-drug interactions with warfarin. Which antibiotics are likely to interact with warfarin? Which antibiotics are reasonable alternatives to these drugs?

7. Hyperlipidaemias

- A. List the factors you would consider when deciding which patients with hyperlipidaemia are candidates for therapeutic interventions
- B. What pharmacotherapeutic options are available for the management of hyperlipidaemias? Explain the mechanism of action for each drug you mention. For each regimen you give, design an appropriate monitoring plan including laboratory parameters and time intervals for follow-up.
- C. Describe the factors that you would consider when planning a pharmacotherapeutic regimen for a patient you have decided needs to be treated for hyperlipidaemia. What considerations would you make in patients with the following features: (1) Alcohol abuse (2) Young pregnant woman (3) Diabetes mellitus (4) Chronic hepatitis C (5) End-stage renal disease on haemodialysis three days per week
- D. What lifestyle modifications would you advise in a patient with hyperlipidaemia?
- E. In what circumstances would you discontinue therapy with HMG-CoA reductase inhibitors?

CLINICAL PHARMACOLOGY EXERCISE 4

DIABETES MELLITUS, HYPERTHYROIDISM & HYPOTHYROIDISM

1. Diabetes mellitus (DM)
 - A. Compare and contrast the pharmacotherapeutic options in the management of type 2 DM including mechanisms of action, indications, contraindications and side effects
 - B. What are the desired goals in the management of a patient with DM?
 - C. Describe the factors that would affect your choice of initial therapy in a patient newly diagnosed with type 2 DM and explain how each factor would influence your selection of drugs
 - D. What parameters should be monitored to evaluate the efficacy and possible adverse effects associated with a regimen selected for a patient with DM?
 - E. Which over-the-counter products should be recommended for patients to use in treating hypoglycaemic episodes?
 - F. What information should be provided to a patient about diabetes and its treatment to enhance compliance, ensure successful therapy, minimise adverse effects and prevent future complications?
 - G. Describe the therapies available to correct the metabolic derangements of diabetic ketoacidosis (DKA).
 - H. What are the therapeutic decision points in DKA treatment and list the parameters for altering therapy at these points?
 - I. Outline a treatment plan for DKA
 - J. When is DKA considered to be resolved, and when can intravenous insulin therapy be converted to subcutaneous therapy?
 - K. Outline a plan for converting a patient from IV to subcutaneous insulin after resolution of DKA
2. Hyperthyroidism
 - A. What treatment options are available for the management of hyperthyroidism? What are the indications of each treatment modality?
 - B. Describe how you would select and justify patient-specific initial and follow-up pharmacotherapy for a patient with hyperthyroidism. What are your therapeutic goals? How would you monitor the patient?
 - C. Design a systematic approach for a patient education technique for the drug therapy of hyperthyroidism
 - D. Describe how you would treat hyperthyroidism in a pregnant woman.
 - E. Suppose a patient becomes hypothyroid on treatment but still has Grave's disease, what would be your treatment plan?
3. Hypothyroidism
 - A. What are the goals of therapy for hypothyroidism?
 - B. Describe how you would develop an appropriate treatment plan for thyroid replacement in a patient with hypothyroidism based on individual patient characteristics
 - C. What clinical and laboratory parameters are needed to evaluate thyroid replacement therapy to achieve euthyroidism and prevent adverse effects
 - D. Outline your patient education to a patient on thyroid replacement therapy
 - E. What are the potential cardiovascular effects of thyroid replacement therapy in patients with coronary artery disease? How should these effects be managed or minimised?

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CLINICAL PHARMACOLOGY EXERCISE 5

SEIZURE DISORDERS & PARKINSONISM

1. Seizure disorders
 - A. There are several drug interactions with phenytoin and other anti-epileptic drugs. Describe the effects that these drugs have on one another. What, if anything, should be done to compensate for these drug interactions?
 - B. Briefly describe the haematological effects of all the anti-epileptic drugs
 - C. Women with epilepsy who take anti-epileptic drugs may consider self-discontinuing their medication when they become or want to become pregnant. Describe the potential risks to the mother and baby from anti-epileptic drugs and from uncontrolled seizures. What can be done to minimise these risks?
 - D. Outline the drug treatment for status epilepticus
 - E. A patient taking sodium valproate has poorly controlled seizures and a decision is made to add lamotrigine. What precautions should be taken? How should you initiate lamotrigine therapy?
 - F. Seizure medications can be withdrawn after a certain seizure-free interval. Comment on this statement. How should the withdrawal be done?
 - G. What is the effect of smoking on anti-convulsants? What is the basis of this effect?
 - H. What patient- and disease-specific data should you collect for patients with complex partial seizures? How would you use the information to design an appropriate therapeutic package for a patient with complex partial seizures? What are the desired therapeutic outcomes for patients with complex partial seizures?
 - I. Outline a plan for assessing a patient's compliance with anti-epileptic drug regime
 - J. Develop a plan for educating a patient with seizure disorder to enhance compliance, minimise adverse effects and ensure successful therapy
 - K. What are the different types of seizures based on clinical presentation? List the recommended drugs of choice and alternative therapies for different types of seizures. List the most common adverse effects and monitoring parameters for each drug you mention.
2. Parkinson's disease (PD)
 - A. What are the goals of therapy for PD?
 - B. Describe how you would develop an optimal pharmacotherapeutic plan for a patient with PD. What treatment options are available?
 - C. Describe how you would make alterations in therapy for a patient who experiences adverse drug effects on your initial drug regimen
 - D. Comment on the use of apomorphine in the treatment of PD
 - E. What information would you give to a patient with PD about the disease and drug therapy?

CLINICAL PHARMACOLOGY EXERCISE 6

INFECTIONS

1. Differentiate common bacterial pathogens associated with bacterial meningitis in newborns versus older children. Recommend appropriate empiric antimicrobial therapy for bacterial meningitis.
2. Describe the properties of antimicrobial agents that allow them to penetrate the CNS during meningitis
3. What pathogens are commonly associated with community-acquired pneumonia (CAP)? Recommend an effective and economical empiric antimicrobial regimen for CAP in adults (include doses and routes of administration). What patient parameters are associated with clinical stability in order to convert from IV to oral therapy?
4. What bacterial organisms typically cause acute otitis media (AOM)? What drug treatment options are available for AOM? Describe a scenario in which it would be appropriate to use azithromycin to treat AOM.
5. Compare commonly prescribed antibacterial agents with regard to spectrum, efficacy, and appropriateness of selection for Group A beta-haemolytic streptococcal (GABHS) pharyngitis.
6. List common causes of anti-infective treatment failure in GABHS pharyngitis and recommend appropriate management strategies
7. What conditions or risk factors predispose individuals to pressure ulceration (decubitus ulcers)? What are the different options available for treatment of decubitus ulcers? Describe interventions for prevention of decubitus ulcers
8. What are the most likely pathogens associated with diabetic foot infections? Recommend appropriate antimicrobial regimens for diabetic foot infections.
9. Determine a potential dosing regimen for a patient with no drug allergy who has staphylococcus endocarditis and is on haemodialysis
10. Describe the drug management of prosthetic valve infective endocarditis
11. List the antibiotics that are commonly associated with the development of Clostridium difficile associated diarrhoea (CDAD) and give the proposed mechanisms of this effect. Recommend pharmacotherapy regimens for the treatment of initial and recurrent cases of CDAD and describe how you would monitor the efficacy of these treatments.
12. Recommend appropriate empiric therapy for primary bacterial peritonitis
13. Recommend appropriate empiric antimicrobial and symptomatic pharmacotherapy for a patient with suspected pyelonephritis. What are the principles of antimicrobial drug selection for pyelonephritis?
14. Give the antimicrobial drug regimens of choice for these sexually transmitted infections: (1) chlamydial urethritis (2) gonococcal urethritis (3) lymphogranuloma venereum (4) chancroid (5) syphilis (6) genital herpes. What alternative regimens are available?
15. Construct a prudent empiric antibiotic regimen for a febrile neutropenic patient
16. Explain the role of various antifungal agents in the treatment of neutropenic patients with fever
17. How do the different types of lipid-based amphotericin B (liposomal, lipid-complex, colloidal dispersion) formulations and amphotericin B deoxycholate compare in terms of efficacy and safety?
18. Discuss the suspected pathogens in gram-negative sepsis and outline an initial empiric treatment strategy
19. Outline a treatment plan for empiric therapy of acute osteomyelitis and septic arthritis

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CLINICAL PHARMACOLOGY EXERCISE 7

REPRODUCTIVE SYSTEM

1. Compare and contrast the various marketed hormonal contraceptives. Describe the factors you would consider when selecting the best product for an individual patient.
2. Discuss the potential for drug interactions in a patient taking a hormonal oral contraceptive
3. What information should be provided to a patient taking a hormonal oral contraceptive to enhance compliance, ensure successful therapy and minimise adverse effects?
4. List the risks and benefits associated with hormone replacement therapy (HRT). Which candidates are appropriate for HRT?
5. Design a comprehensive pharmacotherapeutic plan for a patient on HRT including treatment options and monitoring. What is the optimum time for a patient to continue on HRT?
6. Describe the drug treatment options available for erectile dysfunction. Compare the potential advantages and disadvantages of each treatment.

CLINICAL PHARMACOLOGY EXERCISE 8

HAEMATO-ONCOLOGY DISORDERS

1. Describe appropriate iron therapy for the treatment of iron deficiency anaemia.
List all potential medications that should be avoided within close proximity of iron administration.
2. Describe appropriate dosage regimen for treatment of vitamin B12 deficiency anaemia.
List the monitoring parameters for the initial and subsequent evaluation of patients with Vitamin B12 deficiency anaemia.
How would antibiotic treatment of a patient with *Helicobacter pylori* affect concurrent cobalamin deficiency?
3. Describe appropriate treatment regimen to rectify anaemia resulting from folic acid deficiency
List the monitoring parameters for the initial and subsequent evaluation of patients with folic acid deficiency anaemia.
What is the dual interaction between phenytoin and folic acid, and how should this interaction be managed?
Why is folic acid supplementation necessary in pregnancy?
4. Describe how you would optimise analgesic therapy in a patient with sickle cell disease.
What are the optimal endpoints of pharmacotherapy in sickle cell disease patients?
What treatment would you recommend that may reduce the frequency of sickle cell crises?
Discuss the role of prophylactic antibiotics in the management of sickle cell anaemia.
5. List the treatment options available for breast carcinoma and briefly discuss their advantages and limitations.
What chemotherapy regimens are used for breast carcinoma? Design appropriate monitoring parameters to detect and prevent adverse effects associated with the chemotherapy regimens.
Develop a treatment plan for chemotherapy-associated anaemia.
6. What chemotherapeutic regimens may be considered for non-small cell lung carcinoma (NSCLC)?
Describe appropriate treatment strategies for brain metastases due to NSCLC.
What is the role of anti-epileptic agents in management of brain metastases?
7. Compare and contrast the hormone therapy options for first-line treatment of metastatic prostate cancer.
Recommend a pharmacotherapeutic plan for patients with hormone-refractory metastatic prostatic cancer
Recommend an appropriate pain management plan for a patient with bony metastatic disease.

8. Describe the pharmacotherapeutic treatment of choice and the alternative available for the treatment of non-Hodgkin's lymphoma (NHL).
What are the acute and chronic toxicities associated with the drugs used to treat NHL? What measures are used to prevent or treat these toxicities?
List the monitoring parameters for response to treatment and toxicity in patients with NHL
If a patient on treatment for NHL experienced tumour lysis syndrome, what options are there for treating the hyperuricaemia?
What therapeutic options are available for patients with relapsed diffuse large B-cell lymphoma?
9. Describe the pharmacotherapeutic treatment of choice and the alternative available for the treatment of Hodgkin's disease (HD).
What are the acute and chronic toxicities associated with the drugs used to treat HD? What measures are used to prevent or treat these toxicities?
List the monitoring parameters for response to treatment and toxicity in patients with HD
What are the salvage therapy options for patients with relapsing HD?
What is the anti-emetic regimen of choice to prevent acute nausea and vomiting for highly emetogenic chemotherapy?
10. What are the treatment options for chronic myelocytic leukaemia (CML)?
What are the important prognostic indicators for CML?
List the appropriate parameters to monitor efficacy and potential adverse effects for treatment for CML.
11. What are the initial and long-term treatment goals of pharmacotherapy in a patient with acute lymphocytic leukaemia (ALL)?
Give an example of a drug treatment regimen for acute lymphocytic leukaemia.
What are the common drug-induced diseases in children with ALL? Describe how you would design an effective prophylactic and treatment strategy for drug-induced diseases in children with ALL.
What key information should be presented to a child's family when educating them about the chemotherapy agents used for ALL.
Describe the ancillary medications and supportive care measures that are necessary when administering intermediate-dose methotrexate.

CLINICAL PHARMACOLOGY EXERCISE 9

RESPIRATORY AND GASTRO-INTESTINAL DISORDERS

1. Describe the treatment of acute severe asthma.
What clinical and laboratory parameters should you monitor to assess the efficacy and side effects drug therapy of acute severe asthma?
2. Describe a rational and comprehensive approach to management of chronic asthma.
3. Describe how you would develop a complete outpatient regimen for the treatment of chronic obstructive lung disease in a patient.
4. Describe how you would develop an individualised treatment plan for a patient with gastro-esophageal reflux disease taking into consideration the efficacy and safety of drugs available.
5. Describe an appropriate regimen for the management of a patient with peptic ulcer disease.
6. Describe treatment options for (1) chronic Crohn's disease (2) acute episode of ulcerative colitis
7. Compare the use of oral versus intravenous anti-emetic agents.
Design an appropriate anti-emetic drug regimen for nausea and vomiting associated with cancer chemotherapeutic agents.
8. Explain the place of drug therapy in the treatment of diarrhoea and recommend appropriate products. What are the contra-indications to the use of anti-motility drugs in acute diarrhoeal diseases?
9. Recommend appropriate analgesic, nutritional and enzyme therapy for patients with acute pancreatitis.

CLINICAL PHARMACOLOGY EXERCISE 10

RENAL, PSYCHIATRIC & DERMATOLOGIC DISORDERS

1. Provide recommendations to prevent development of drug-induced acute renal failure.
2. Discuss the efficacy of diuretics and dopamine in acute renal failure. Recommend pharmacological interventions that may alter the rate of progression of renal disease.
3. Develop a treatment plan for alcohol withdrawal.
4. Describe how you would manage the adverse effects of anti-psychotic drugs. Discuss the role of atypical anti-psychotics in the treatment of schizophrenia.
5. Develop a pharmacotherapy plan for a patient with depression. Compare the side effect profiles of various antidepressant drugs.
6. Describe the treatment strategies for acne including appropriate situations for the use of each drug.
7. Explain the indications for topical, photochemical and systemic treatment modalities for psoriasis. Compare the efficacy and adverse effects of systemic therapies for psoriasis including standard therapies (methotrexate, acitretin, cyclosporine, azathioprine, hydroxyurea and sulfasalazine); newer agents (efalizumab and alefacept); and investigational agents (infliximab and gentanercept).
8. Give examples of drugs that are associated with each of the following cutaneous reactions: (1) Fixed drug reactions (2) Photoallergic and phototoxic reactions (3) Bullous reactions (4) Morbilliform and urticarial reactions (5) Pigmentation (6) Lichenoid eruptions (7) Stevens-Johnson syndrome and toxic epidermal necrolysis, (8) Hypersensitivity syndrome (9) Vasculitis

CLINICAL PHARMACOLOGY EXERCISE 11

MISCELLANEOUS

1. Discuss the role of ticlopidine, clopidogrel, and the combination of extended-release dipyridamole 200mg plus immediate-release aspirin 25mg in the secondary prevention of ischaemic stroke
2. Discuss the safety and efficacy of thrombolytics for treatment of acute ischaemic stroke
3. Discuss the role of statins for the primary and secondary prevention of acute ischaemic stroke
4. Compare the efficacy of salbutamol via nebulisation versus multi-dose inhaler in acute asthma
5. If a patient with chronic asthma continues to take inhaled corticosteroids when she is postmenopausal, can anything be done to minimise the problem of osteoporosis?
6. Discuss the efficacy of various agents in the secondary prevention of NSAID-induced peptic ulcer disease
7. Recommend therapies for treatment of pain and inflammation in patients with peptic ulcer disease
8. Discuss the administration of sucralfate to renally-compromised patients
9. Recommend pharmacologic therapy to treat or prevent complications of ascites and portal hypertension
10. Compare the pharmacokinetics and pharmacodynamics of the diuretics used in the treatment of cirrhotic ascites. Explain the rationale for using furosemide and spironolactone in combination.
11. Discuss the pros and cons of using antibiotics as prophylaxis against recurrent spontaneous bacterial peritonitis in liver cirrhosis ascites and identify high-risk patients who would benefit from this therapy
12. Recommend appropriate pharmacologic therapy for the control of bleeding oesophageal varices
13. Design a plan for monitoring the efficacy and adverse effects of recommended treatments for hepatic encephalopathy
14. Discuss the efficacy and potential role of flumazenil and bromocriptine in the treatment of hepatic encephalopathy
15. List the potential advantages and disadvantages of using antibiotics for the treatment of hepatic encephalopathy

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CLINICAL PHARMACOLOGY EXERCISE 12

MISCELLANEOUS

1. Discuss the various intravenous agents that are used for aborting migraine headaches
2. Prepare a report highlighting anti-epileptic drugs used for the prophylaxis of migraine
3. Discuss the different strategies used in the treatment of migraine
4. Compose a list of drugs thought to aggravate or give rise to drug-induced pancreatitis
5. Recommend appropriate analgesic, nutritional and enzyme therapy for patients with acute pancreatitis
6. Recommend appropriate enzyme therapy for management of steatorrhea in a patient with chronic pancreatitis
7. Discuss therapeutic alternatives and outline a plan for pain management during an acute exacerbation in a patient with chronic pancreatitis
8. Determine the clinical and laboratory endpoints for treatment of chronic hepatitis B
9. Discuss the efficacy and adverse effects of chronic hepatitis B treatment with interferon, lamivudine and adefovir dipivoxil
10. Outline a pharmacologic and nonpharmacologic regimen for patients with chronic hepatitis B
11. Develop a pharmacologic plan for the treatment of complications associated with acute renal failure
12. Outline a treatment plan for a pregnant patient with allergic rhinitis. Justify your selection of pharmacologic agents based on their efficacy and safety profiles
13. Discuss the risks and benefits of the therapeutic alternatives available for the treatment of tinea pedis and onychomycosis
14. Develop a therapeutic plan for the management of bacterial vaginosis
15. Describe the best therapeutic approach for a woman diagnosed with bacterial vaginosis who is breastfeeding her infant
16. Review mechanisms of antimicrobial resistance by organism and drug class. Create a list of antimicrobial agents to which organisms are more likely to develop resistance

CLINICAL PHARMACOLOGY EXERCISE 14

HIV/AIDS AND TUBERCULOSIS

1. Describe situations in which you would consider stopping antiretroviral drugs in a patient
2. Describe recommended first-line and second-line antiretroviral (ARV) regimens for children. What special considerations would you have for ARV treatment of adolescents?
3. Pregnancy and HIV
 - A. Describe the considerations that you would make in planning treatment for an HIV positive pregnant woman diagnosed with tuberculosis who is to be initiated on antiretroviral drugs
 - B. With suitable examples, describe what you would do if a woman becomes pregnant while on antiretroviral therapy. What precautions should be taken?
 - C. Describe the drug regimens for the prevention of mother to child transmission in Zambia
4. Give the drug regimens for treatment of tuberculosis in the following cases
 - A. Sputum positive pulmonary tuberculosis in an adult
 - B. Tuberculous meningitis in a six-year old boy
 - C. Abdominal tuberculosis in an adult
 - D. Sputum positive pulmonary tuberculosis relapse in a male adult. How would treatment be different if the patient was a pregnant woman? A child below 12 years of age?
5. What treatment options are available for patients with multidrug resistant tuberculosis?
6. List the recommended antiretroviral regimens in HIV patients co-infected with tuberculosis
7. A 24-year old lady who was diagnosed with HIV one year ago when she was hospitalised for pneumocystis carinii pneumonia tells you that she is ready to start antiretroviral drugs. Her CD4 count is 156 cells/microL. Currently she has no symptoms. Her full blood count, renal and hepatic functions are normal.
 - A. Is it rational to begin antiretroviral therapy in this patient?
 - B. Is prophylactic therapy for any HIV-associated opportunistic pathogen indicated in this patient?
 - C. Suggest an antiretroviral regimen
 - D. What parameters would you select to monitor the clinical efficacy and toxicity of the regimen?
 - E. What important information would you provide to this patient about her therapy?
 - F. Suppose the patient tells you she has difficult swallowing large pills, what antiretroviral regimen would you suggest?
 - G. Describe situations in which antiretroviral therapy should be initiated in patients with HIV infection and determine the desired outcome of such therapy

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CLINICAL PHARMACOLOGY EXERCISE 13

OPPORTUNISTIC INFECTIONS

1. A 49-year old HIV positive man has been diagnosed with hepatitis C virus (genotype 3a). He has been taking stavudine, lamivudine and efavirenz for three years. His liver function tests are ALT: 85 IU/L and AST: 46 IU/L and serum creatinine is 95 micromol/L.
 - A. Suggest a treatment plan for the patient.
 - B. What laboratory and clinical parameters are necessary to evaluate the patient's drug regimens for achievement of the desired therapeutic outcomes and to detect or prevent adverse effects?
 - C. What pharmacological interactions would occur between the drugs you mention and anti-retroviral drugs?

2. A 32-year old HIV infected man has been diagnosed with advanced AIDS, relapse of cytomegalovirus (CMV) retinitis and has a serum creatinine of 180 micromol/L. His liver function is normal. His CD4 count is 43/ microL. He is antiretroviral-naïve.
 - A. What are the goals of therapy for this patient?
 - B. Recommend an appropriate treatment regimen for the patient.
 - C. Discuss the risks and benefits of the therapeutic options available for the treatment of cytomegalovirus (CMV) retinitis.
 - D. What factors would you consider when planning the treatment for CMV retinitis in a patient?
 - E. Discuss the mechanism of resistance of CMV to ganciclovir, foscarnet and cidofovir.

3. What are the current guidelines for discontinuing prophylactic therapy for AIDs-associated opportunistic infections?

4. Suggest drug treatment regimens (preferred and alternative) for the following opportunistic conditions in HIV. In each case mention any precautions that should be taken and any adjunctive treatment that might have to be given
 - A. Mycobacterium avium complex
 - B. Microsporidiosis
 - C. Cryptosporidiosis
 - D. Isospora belli
 - E. Toxoplasmosis
 - F. Cryptococcus neoformans meningitis
 - G. Oro-pharyngeal candidiasis
 - H. histoplasmosis
 - I. Herpes zoster
 - J. Kaposi's disease
 - K. Non-hodgkin's lymphoma
 - L. Cervical carcinoma

CLINICAL PHARMACOLOGY EXERCISE 15

MALARIA

Question 1

Discuss the following anti-malaria drugs with respect to: mechanism of action and anti-malarial effect, clinical uses, safety profile, drug resistance and cost:

- A. Quinine
- B. Chloroquine
- C. Amodiaquine
- D. Artemisinin derivatives
- E. Artemether-lumefantrine
- F. Atovaquone-proguanil
- G. Sulfadoxine-pyrimethamine
- H. Chlorproguanil-dapsone
- I. Halofantrine
- J. Tetracyclines

Question 2

- A. Explain the rationale for anti-malaria drug combinations in the treatment of malaria.
- B. Give three examples of rational anti-malaria drug combinations and state one major advantage and disadvantage of each

Question 3

List four desirable characteristics of an anti-malarial drug regimen that would make it suitable for first-line treatment of malaria in a resource-poor and malaria-endemic country.

Question 4

Discuss the National Malaria Treatment Policy in Zambia

Question 5

Discuss chemoprophylaxis of malaria

CLINICAL PHARMACOLOGY EXERCISE 16

PHARMACOVIGILANCE

Definitions

Define the following terms and concepts as they are used in Pharmacovigilance:

- A. Pharmacovigilance
- B. Drug or Medicine
- C. Adverse Drug Reaction
- D. Side Effect
- E. Unexpected adverse reaction
- F. Adverse Event or Experience
- G. Serious Adverse Event
- H. Adverse Event following Immunisation
- I. Signal

Post marketing surveillance

- A. What is post marketing surveillance?
- B. Discuss the importance of post marketing surveillance.
- C. What are the major aims of pharmacovigilance?
- D. Explain why there is need for having a pharmacovigilance system in Zambia.

Adverse Drug Event Reporting

- A. What is spontaneous reporting? List the advantages and disadvantages of spontaneous reporting schemes.
- B. What is a case report? List the characteristics of a good case report.
- C. Describe what events should be reported to the national pharmacovigilance unit.
- D. What are the benefits of reporting adverse events?

Adverse Drug Effects

- A. With suitable examples, describe the three types of adverse drug effects (Types A, B and C drug reactions).
- B. Explain why Type B adverse effects are usually not detected during the pre-marketing phases of clinical trials.
- C. Explain the steps you would take to make a diagnosis of an adverse drug event
- D. What measures would you take to reduce the risks of adverse drug events?

Drug interactions

- A. What is a drug interaction?
- B. What factors have contributed to the increased incidence of adverse drug reactions due to drug interactions?
- C. What types of patients are most at risk of significant drug interactions?
- D. With suitable examples, describe the types of drugs that are associated with greatest risk of drug interactions
- E. Describe how you would minimize the risk of harmful drug interactions