

2009 Oncology Pharmacy Preparatory Review Course Learning Objectives

Acute Leukemia/Tumor Lysis Syndrome

John M. Valgus, Pharm.D., BCOP

Hematology/Oncology Specialist

University of North Carolina Hospitals and Clinics

Clinical Assistant Professor

University of North Carolina School of Pharmacy

Chapel Hill, North Carolina

1. Describe the epidemiology, etiology, pathophysiology and prognostic factors of acute myeloid leukemia (AML) and acute lymphocytic leukemia (ALL) in adults.
2. Identify and discuss the signs and symptoms of AML and ALL in adults.
3. Outline appropriate patient-specific treatment for AML and ALL in adults including:
 - a. pharmacotherapy of leukemia
 - b. monitoring of drug-related toxicities
 - c. management of drug- and disease-related complications

Adult Sarcomas

R. Donald Harvey, III, Pharm.D., BCPS, BCOP

Assistant Professor of Hematology and Oncology

Director, Phase I Unit

Winship Cancer Institute

Emory University School of Medicine

Atlanta, Georgia

1. Outline the epidemiology, etiology, pathophysiology and clinical presentation for soft tissue sarcomas (STS) and osteosarcomas (OS).
2. Describe the currently accepted standard treatments and monitoring parameters for STS and OS.
3. Apply the clinical data underlying therapeutic treatment recommendations for STS and OS.
4. Explain expected outcomes to a given therapeutic modality in terms of response and toxicity or other endpoints for state of the arts treatments for STS and OS.
5. Devise and communicate appropriate plans for preventing, monitoring, and treating toxicities associated with therapeutic interventions for STS and OS.

Bone Marrow Transplantation I & II

*Ashley Morris, Pharm.D., BCOP
Clinical Associate
Division of Cellular therapy
Duke University Medical Center
Durham, North Carolina*

1. List the immunologic and anatomic sources of hematopoietic stem cells and indications for HSCT with expected outcomes.
2. Describe the ideal properties of HSCT conditioning regimens based on indication for and type of transplant; be able to give examples of common myeloablative and nonmyeloablative HSCT conditioning regimens.
3. List those diseases for which hematopoietic stem cell transplantation is the preferred treatment modality.
4. List the clinical manifestations, risk factors, preventive strategies and first line treatment (acute and chronic) strategies for acute and chronic graft-versus-host disease.
5. Understand common complications following HSCT and how to manage them e.g., veno-occlusive disease, infectious complications, graft versus host disease.
6. List the common infectious pathogens during HSCT according to time frame following HSCT and transplant type with associated frequencies, life-threatening potential, and treatment and/or prevention strategies.

Breast Cancer, Part I & II

*Chad Barnett, Pharm.D., BCOP
Breast Cancer Specialist
The University of Texas,
MD Anderson Cancer Center
Houston, Texas*

1. Outline the most appropriate screening and prevention strategy for breast cancer.
2. Describe the most appropriate patient-specific therapy and monitoring for a stage of disease.
3. Apply the clinical data underlying therapeutic treatment recommendations.
4. Explain expected outcomes to given therapeutic modality in terms of response and toxicity or other endpoints (e.g., survival, clinical benefit, etc.).
5. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with treatment of breast cancers.

Chronic Leukemias

*Christopher A. Fausel, Pharm. D., BCPS, BCOP
Clinical Pharmacist
Hematology/Oncology/BMT
Indiana University Cancer Center
Indiana University
Indianapolis, Indiana*

1. Outline the epidemiology, etiology, pathophysiology and clinical presentation for chronic myeloid leukemia (CML), chronic lymphocytic leukemia (CLL) and myelodysplastic syndrome (MDS).
2. Describe the currently accepted standard treatments and monitoring parameters for CML, CLL and MDS.
3. Apply the clinical data underlying therapeutic treatment recommendations for chronic myeloid leukemia (CML), chronic lymphocytic leukemia (CLL) and myelodysplastic syndrome (MDS).
4. Explain expected outcomes to a given therapeutic modality in terms of response (remission, hematologic/cytogenetic/molecular) and toxicity for state of the art treatments for CML, CLL and MDS.
5. Devise and communicate appropriate plans for preventing, monitoring, and treating toxicities associated with therapeutic interventions for CML, CLL, and MDS.

Colon Cancer

*Patrick Medina, Pharm.D., BCPS
Assistant Professor of Pharmacy
College of Pharmacy
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma*

1. Identify the risk factors for colon cancer.
2. Outline preventive and screening strategies for both individuals at high-risk for colon cancer as well as those at average risk.
3. Describe the treatment options for colon cancer based on patient-specific factors, such as stage of disease, age of patient and previous treatment received.
4. Recommend pre- and postmedications to prevent or treat potential toxicities for common regimens used in colon cancer.
5. Outline the pharmacological principles for agents used to treat colon cancer.
6. List adverse effects of the chemotherapy that require specific patient counseling.

Disease Related Symptoms: Hypercalcemia, SVC, Malignant Effusions

Val Adams, Pharm.D., FCCP., BCOP

Associate Professor

College of Pharmacy

University of Kentucky

Lexington, Kentucky

1. Outline the most appropriate screening and prevention strategy for a patient presenting with disease related symptoms.
2. Describe the most appropriate patient-specific therapy and monitoring for a patient presenting with disease related symptoms.
3. Apply the clinical data underlying therapeutic treatment recommendations.
4. Explain expected outcomes to a given therapeutic modality in terms of response, and toxicity.
5. Devise and communicate appropriate plans for preventing, monitoring, and treating adverse reactions associated with treatment of cancer.

Drug Information and Guidelines

Linda S. Tyler, Pharm.D.

Director of Pharmacy

University of Utah Hospital and Clinics

Salt Lake City, Utah

1. Outline the key features of the Health Insurance Portability and Accountability Act (HIPAA).
2. Describe how HIPAA impacts patient care.
3. List ways in which HIPAA impacts research.
4. Describe ways to search PubMed more effectively.
5. Describe sources of clinical guidelines.
6. Compare and contrast the types of guidelines available.

Genitourinary Cancers, Renal, Testicular, Bladder

Patrick Medina, Pharm.D., BCPS

Assistant Professor of Pharmacy

College of Pharmacy

University of Oklahoma Health Sciences Center

Oklahoma City, Oklahoma

1. Outline the most appropriate screening and prevention strategies for bladder, renal cell, and testicular cancers.
2. Know the prognostic factors for bladder, renal cell, and testicular cancers.
3. List the most appropriate patient-specific therapy and monitoring for the standard regimens for adjuvant and advanced disease in bladder, renal cell, and testicular cancers.
4. State the anticipated outcomes for the treatment of bladder, renal cell, and testicular cancers.
5. Devise and communicate appropriate plans for preventing, monitoring, and treating adverse reactions associated with the treatment of bladder, renal, and testicular cancers.
6. Define the role of tumor markers in the management of testicular cancer.

GI Cancers, Esophageal, Liver, and Stomach

Dina K. Patel, Pharm. D., BCOP

Clinical Pharmacy Specialist

GI Medical Oncology

The University of Texas

M.D. Anderson Cancer Center

Houston, Texas

1. Describe the pathogenesis and pathophysiology of pancreatic, stomach, and liver tumors.
2. Explain the risk factors, clinical symptoms, and staging for pancreatic, stomach, and liver tumors.
3. Describe the role of screening and prevention in pancreatic, stomach, and liver tumors.
4. Outline the appropriate pharmacologic and non-pharmacologic treatment of pancreatic, stomach, and liver tumors.
5. Describe the pharmacology and toxicities associated with each chemotherapeutic agent used to treat pancreatic, stomach, and liver tumors.

Head and Neck and Brain Cancer

*John M. Valgus, Pharm.D., BCOP
Hematology/Oncology Specialist
University of North Carolina Hospitals and Clinics
Clinical Assistant Professor
University of North Carolina School of Pharmacy
Chapel Hill, North Carolina*

1. Describe the pathogenesis and pathophysiology of head and neck and adult CNS tumors.
2. Explain the risk factors, clinical symptoms, and staging of head and neck and adult CNS tumors.
3. Describe the role of screening and prevention in head and neck and adult CNS tumors.
4. Outline the appropriate pharmacologic and non-pharmacologic treatment of head and neck and adult CNS tumors.
5. Describe the pharmacology and toxicities associated with each chemotherapeutic agent used to treat head and neck and adult CNS tumors.

Lung Cancer

*R. Donald Harvey, III, Pharm.D., BCPS, BCOP
Assistant Professor of Hematology and Oncology
Director, Phase I Unit
Winship Cancer Institute
Emory University School of Medicine
Atlanta, Georgia*

1. Outline the most appropriate screening and prevention strategy for lung cancer.
2. Describe the most appropriate patient-specific therapy and monitoring for a small cell and non-small cell lung cancer.
3. Apply the clinical data underlying therapeutic treatment recommendations.
4. Explain expected outcomes to a given therapeutic modality in terms of response, survival, and toxicity.
5. Devise and communicate appropriate plans for preventing, monitoring, and treating adverse reactions associated with treatment of cancer.

Lymphomas/Multiple Myeloma

*Christopher A. Fausel, Pharm. D., BCPS, BCOP
Clinical Pharmacist
Hematology/Oncology/BMT
Indiana University Cancer Center
Indiana University
Indianapolis, Indiana*

1. Outline the most appropriate screening and prevention strategy for non-Hodgkin's lymphoma, Hodgkin's Disease, and multiple myeloma.
2. Know the difference between the Working Formulation and the REAL classification of non-Hodgkin's lymphomas.
3. State the Goldie-Coldman hypothesis and dose intensity principle and examine their influence on the development of chemotherapy regimens in the management of lymphomas.
4. List the prognostic factors non-Hodgkin's lymphoma, Hodgkin's Disease, and multiple myeloma and their influence on survival and therapy.
5. Know the "gold" standard regimens for advanced aggressive non-Hodgkin's lymphomas and advanced Hodgkin's Disease.
6. For indolent lymphomas and multiple myeloma, list potential chemotherapy, immunotherapy, and antiangiogenesis regimens along with their response rates, toxicities, and how to monitor for response and toxicity.
7. State the role of autologous bone marrow/stem cell transplantation in non-Hodgkin's lymphoma, Hodgkin's Disease, and multiple myeloma.
8. State the dose adjustments of liver and renal dysfunction for doxorubicin, vincristine, bleomycin, and melphalan.

Melanoma and Skin Cancer

*Val Adams, Pharm.D., FCCP., BCOP
Associate Professor
College of Pharmacy
University of Kentucky
Lexington, Kentucky*

1. Discuss the epidemiology, etiology, and prognosis of melanoma, basal cell cancer and squamous cell cancer of the skin.
2. List the risk factors for melanoma and nonmelanoma skin cancers.
3. Given a patient case, list the treatment options for basal cell cancer of the skin, squamous cell cancer of the skin and melanoma.
4. Outline the role of adjuvant therapy with interferon- α for cutaneous melanoma.

5. Identify the toxicities and appropriate monitoring parameters for aldesleukin therapy for metastatic melanoma.

Ovarian and Gynecologic Malignancies

Dayna L. McCauley, Pharm.D., BCOP

Practice Manager

Long Island Gynecologic Oncologists, PC

State University of New York at Stony Brook and Winthrop-University Hospital

Smithtown, New York

1. Outline the most appropriate screening and prevention strategy for ovarian cancer.
2. Describe the most appropriate patient-specific first-line therapy and monitoring for low-risk and high-risk early stage, and advanced stage ovarian cancer.
3. Apply patient-specific clinical data to your therapeutic treatment recommendations.
4. Explain the expected outcome for a patient with low-risk and high-risk early stage ovarian cancer, and advanced stage ovarian cancer in terms of initial response rate and five-year survival.
5. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with the medical treatment of ovarian cancer.

Oncology Drug Literature, Biostatistics and Study Design

Linda S. Tyler, Pharm.D.

Director of Pharmacy

University of Utah Hospital and Clinics

Salt Lake City, Utah

1. Given a study from the literature:
 - a. Describe the study design used in a study
 - b. Discuss the strength and weaknesses of the study design
 - c. Interpret the statistical information reported in a clinical study.
 - d. Assess the appropriateness of the study endpoints and the statistical analyses used.
 - e. Identify sources of bias
2. Differentiate between clinical significance and statistical significance

Pain Management, Bone Metastes and Spinal Cord Compression

*Dina K. Patel, Pharm. D., BCOP
Clinical Pharmacy Specialist
GI Medical Oncology
The University of Texas
M.D. Anderson Cancer Center
Houston, Texas*

1. Outline the most appropriate screening and prevention strategies for cancer pain.
2. Describe the etiology and significance of cancer pain, spinal cord compression and bone metastases in the cancer population.
3. Explain the processes for patient assessment, management and follow-up of patients with pain, spinal cord compression and bone metastases.
4. Explain the expected outcomes to a given therapeutic modality in terms of response and toxicity or other endpoints (e.g., regaining functional capacity, prevention of skeletal events, etc.)
5. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with treatment of pain, spinal cord compressions, and bone metastases.

Pediatric Malignancies

*Mark T. Holdsworth, Pharm.D., BCOP
Associate Professor of Pharmacy and Pediatrics
College of Pharmacy
University of New Mexico
Albuquerque, New Mexico*

1. Summarize the pathogenesis, pathophysiology, and signs and symptoms of the various pediatric malignancies.
2. Identify the prognostic factors associated with the pediatric malignancies.
3. Define the appropriate pharmacologic and non-pharmacologic treatment plan and monitoring for the pediatric malignancies (including the various stages, where appropriate).
4. Apply the clinical data underlying therapeutic treatment recommendations for pediatric malignancies.
5. Explain expected outcomes to a given therapeutic modality employed in common pediatric malignancies in terms of response, toxicity and survival.
6. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with the treatment of pediatric malignancies.
7. Calculate appropriate chemotherapy doses for children receiving standard chemotherapy for various pediatric malignancies.

Pharmacology

*Patrick Medina, Pharm.D., BCPS
Assistant Professor of Pharmacy
College of Pharmacy
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma*

1. Identify the mechanism of action of the major classes of chemotherapy and targeted agents.
2. Apply the dose modifications for antineoplastics in patients with renal and hepatic dysfunction.
3. Summarize the mechanisms of resistance associated with antineoplastics and targeted agents. Describe the strategies utilized to overcome these resistance mechanisms.
4. List the dose limiting toxicities as well as any unique toxicities of each antineoplastic agent or targeted agent.
5. Summarize the tumor growth hypotheses that have been used to model cancer cell death from antineoplastic therapy.

Prostate Cancer

*Jill M. Kolesar, Pharm.D., FCCP, BCPS
Associate Professor of Pharmacy
School of Pharmacy
University of Wisconsin – Madison
Director, Analytical Instrumentation Laboratory for Pharmacokinetics, Pharmacodynamics and Pharmacogenetics (3P)
University of Wisconsin Comprehensive Cancer Center
Madison, Wisconsin*

1. Outline the most appropriate screening and prevention strategy for prostate cancer.
2. Describe the most appropriate patient-specific therapy and monitoring for a stage of disease.
3. Apply the clinical data underlying therapeutic treatment recommendations.
4. Explain expected outcomes to a given therapeutic modality in terms of response and toxicity or other endpoints (e.g., survival, clinical benefit, etc.).
5. Develop and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with the treatment of cancers.

Symptom Management, Part I, II & III

Teresa A. Mays, Pharm D., BCOP

Director, Investigational Drug Department

San Antonio, Texas

1. Describe the most appropriate patient-specific therapy and monitoring for a stage of disease.
2. Apply the clinical data underlying therapeutic treatment recommendations.
3. Explain expected outcomes to a given therapeutic modality in terms of response and toxicity or other endpoints (e.g., survival, clinical benefit, etc.).
4. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with treatment of breast cancers.
5. Outline the most appropriate screening and prevention strategy for secondary malignancies.
6. Describe the most appropriate patient-specific therapy and monitoring for each major chemotherapy toxicity.
7. Apply the clinical data underlying therapeutic treatment recommendations for symptom management.
8. Explain expected outcomes to a give therapeutic modality in terms of response and toxicity or other endpoints (e.g. clinical benefit, etc.).
9. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with treatment of cancers.
10. Describe the most appropriate patient-specific therapy and monitoring for each major chemotherapy toxicity.
11. Apply the clinical data underlying therapeutic treatment recommendations for symptom management.
12. Explain expected outcomes to a given therapeutic modality in terms of response and toxicity or other endpoints (e.g., clinical benefit, etc.).
13. Devise and communicate appropriate plans for preventing, monitoring and treating adverse reactions associated with treatment of cancers.

The Anticancer Drug Development Process

Jill M. Kolesar, Pharm.D., FCCP, BCPS

Associate Professor of Pharmacy

School of Pharmacy

University of Wisconsin – Madison

Director, Analytical Instrumentation Laboratory for Pharmacokinetics, Pharmacodynamics and Pharmacogenetics (3P)

University of Wisconsin Comprehensive Cancer Center

Madison, Wisconsin

1. Describe the activities in each phase of the investigational anticancer drug development process.
2. Design an anticancer investigational protocol using appropriate study methodology.
3. Identify the required components of an informed consent.
4. Design an investigational pharmacy according to federal and state laws and utilizing appropriate governmental resources and guidelines.
5. Differentiate between an IND, NDA, ANDA, group C drug, and emergency use drug.