

| Policy #: | 03.49.000 | | |
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| Section: | Clinical Care/Patient Rights | | |

Ordering and Administering of Anti-Neoplastic Agents/Chemotherapy

Purpose:

To ensure that antineoplastic therapy is safely ordered, prepared, and administered to patients with malignancies.

Definition:

Antineoplastic agents can be administered through an oral, subcutenaous, intramuscular, intra-arterial, intravesical, intrathecal or parenteral routes and are drugs administered with the intent of treating malignant neoplasms. Antineoplastic agents include but are not limited to cytotoxic chemotherapy, small molecule inhibitors, monoclonal antibodies, and drug conjugates. Hormonal agents are not included in the definition of antineoplastic therapy for the purposes of this policy. Some drugs used as antineoplastics may also be used for non-neoplastic indications; when used for other indications they are not covered by this policy.

Anti-neoplastics maybe classified as a Hazardous medication per the National Institute for Occupational Safety and Health (NIOSH) and United States Pharmacopeia 800 (USP 800) guidelines, please refer to Policy #13.03.013 *Hazardous Drug Handling* (Appendix A) for appropriate handling of these agents.

Application:

All orders for antineoplastic therapy at Boston Medical Center

Privileged practitioners to order antineoplastic therapy

- a. Practitioners must be privileged during the credentialing process to order antineoplastic therapy. Privileged practitioners may include MDs and DO's. Nurse practitioners and physician assistants may also be privileged to order antineoplastic therapy, with the following exceptions:
 - 1) Nurse practitioners and physician assistants may not order antineoplastic therapy for stem cell transplantation.
- b. Fellows in approved training programs may write chemotherapy orders but orders must be signed by a credentialed physician before they are available to nursing and pharmacy.
- c. In emergent situations, a single dose of tretinoin or hydroxyurea may be ordered by a house officer or fellow without attending co-signature.
- d. Interns, residents, pharmacists, and others may not write orders for antineoplastic therapy with the following exceptions:
 - 1) Pharmacists may re-order antineoplastic therapy for densitization protocols and when a dose of antineoplastic therapy requires separation into multiple bags, syringes, etc.
 - 2) Pharmacists may place antineoplastic orders on hold with consent of the ordering provider.

Exceptions:

None

Procedure:

1. ANTINEOPLASTIC ORDERS:

- 1.1. Antineoplastic orders must be written within the computerized order entry system (EPIC) as part of an approved treatment plan. Treatment plans must be approved by designated representatives from pharmacy, nursing, and physician leadership.
- 1.2. Specific directions, including dose guidelines for both intravenous and oral antineoplastics will be included in the treatment plan.
- 1.3. Doses for antineoplastics that are based on weight or body surface area must be calculated based on a weight obtained within 24 hours.
- 1.4. Treatment parameters must be based on laboratory values obtained within 24 hours of administration.
- 1.5. Orders for oral neoplastics will be referred to the specialty pharmacy upon signature of the treatment plan. Pharmacy will draft specific oral antineoplastic orders based on the directions in the treatment plan. Oral antineoplastic orders drafted by pharmacy will then be sent back to the ordering provider for signature prior to oral chemotherapy being dispensed. Oral antineoplastics will not be dispensed without final provider signature.
- 1.6. Initial antineoplastic orders for any given regimen must be accompanied by a treatment note. The treatment note must contain the following elements:
 - 1.6.1. Names of the drugs being administered
 - 1.6.2. Dosing guidelines for the drugs being administered (i.e the doses described in mg/m2 or mg/kg) and the associated dose schedule of the drugs. Specific dose calcluations based on body surface area or weight are not required in the treatment note
 - 1.6.3. Indication for treatment
 - 1.6.4. Description and reason for any dose adjustments from the standard regimen made in the treatment plan.
- 1.7. A subsequent treatment note describing dose modifications and reason for modifications must be written for patients undergoing dose modifications,
- 1.8. A new treatment note must be written and signed for any inpatient receiving antineoplastic therapy during each inpatient admission.
- 1.9. All treatment notes must be signed by a credentialed attending physician. Nurse practitioners and physician assistants may not sign treatment notes.
- 1.10. For inpatients, if the provider signing the antineoplastic orders and treatment note is not the inpatient attending of record, the inpatient attending of record must document concurrence with administering chemotherapy in the patient chart prior to the administration of antineoplastic therapy.
- 1.11. Nursing and pharmacy will not dispense antineoplastics if there is not a valid order by a credentialed provider, an initial treatment note for the regimen signed by an attending physician, and a subsequent treatment note for patients requiring dose modifications on subsequent cycles or for inpatients during a new admission, as described above.

2. SPECIAL CONSIDERATIONS FOR ORAL ANTINEOPLASTICS

2.1. Prior to dispensing oral antineoplastics, the pharmacist will provide counseling to the patient confirming handling/dispending, directions of use, clinically relevant side effects, and contact information for their health care provider in the event of questions.

2.2. Patients receiving oral antineoplastics should be evaluated by their provider at a minimum of 3 month intervals. Oral antineoplastics will not be refilled for patients who have not seen their provider in more than 6 months.

3. SPECIAL CONSIDERATIONS FOR INTRA-ARTERIAL AND INTRAVESICAL ANTINEOPLASTICS

- 3.1. Intra-arterial chemotherapy must be administered under the direction of an interventional radiologist. All safety checks as described for other routes of administration must be performed. following the same safety checks described for chemotherapy administered via other routes.
- 3.2. Intravesicle chemotherapy can be prescribed and administered under the direction of an urology physician in an appropriate setting (i.e., staffing, equipment, etc.). All safety checks as described for other routes of administration must be performed. following the same safety checks described for chemotherapy administered via other routes.

4. SPECIAL CONSIDERATIONS FOR INTRATHECAL ANTINEOPLASTICS

4.1. Intrathecal antineoplastics can only be administered by a properly privileged LIP, or by a hematology/oncology fellow under the supervision of an attending physician. All safety checks as described for other routes of administration must be performed. In addition, a Universal Protocol (Time Out) is required before this procedure. (see *Policy #03.60.000 – Universal Protocol (Time Out)*)

5. CONSENT:

- 5.1. Written informed consent must be obtained in accordance with *Policy #03.02.000 Patient Consent* prior to **administration of drugs for antineoplastic indications**. Informed consent is required for each regimen, even if the drugs have been used earlier in the course of disease in a different combination. Desensitization protocols for drugs that have been administered previously are considered a new regimen. Consent is required for all routes of administration. The signed copy of the consent (either ink-signed paper consent or electronic signature) should be stored in the medical record, and a copy of the consent given to the patient. If paper, a copy must be sent to HIM for scanning into the patient's EHR. The original consent can be used for patients who are subsequently admitted to the inpatient setting but either the original consent or a copy should be available in the patient's medical record. If the consent is not available, a new consent for the current treatment plan must be obtained prior to antineoplastic administration. This policy applies for both standard regimens and for investigational drugs and research protocols.
- 5.2. **Hormonal Agents:** Hormonal agents used in the treatment of cancer do not require a written informed consent.

5.3. Hydroxyurea:

- 5.3.1. When Hydroxyurea is administered for treatment of malignant conditions (i.e. cytoreduction for leukemia), the same policies and procedures used for other antineoplastics apply, with the exception of a single dose which may be ordered in emergent situations (i.e hyperleukocytosis).
- 5.3.2. When Hydroxyurea is administered for treatment of non-malignant conditions (i.e. sickle cell disease, myelofibrosis), informed consent is not required.
- 5.4. **All-trans retinoic acid (ATRA):** When ATRA is administered for the treatment of acute promyelocyctic leukemia (APL), the same policies and procedures for chemotherapy apply, with the exception of a single dose which may be ordered by a licensed independent provider (LIP) in emergent situations.

6. NURSING PROCEDURES:

- 6.1. Refer to *Nursing Policy #10.03.010 Medication Administration*. And Hazardous Drugs and Chemotherapy waste and spill Policy #06.17.000.
- 6.2. Only RNs who have demonstrated competence (per BMC standards) in antineoplastic drug administration will administer antineoplastics.
- 6.3. Nurses in Urology may administer intravesical chemotherapy after requird competency obtained.
- 6.4. Oral anti-neoplastic agents) may not be be split or crushed; capsules may not be opened by RN at bedside/medication room for administration. If a patient is unable to swallow, the ordering provider and the Hematology Oncology Pharmacy Specialist should be informed for extemporaneous compounding of oral liquid dosage formulation or alternative drug delivery method for the anti-neoplastic agent.
- 6.5. Prior to administration, the following assessments and checks will be made by RN:
 - 6.5.1. Review the antineoplastic treatment plan; assess the patient's understanding of treatment goals, the antineoplastic regimen prescribed, potential side effects, and patient self-care measures. The RN should provide and document the appropriate individualized teaching.
 - 6.5.2. Complete pre-chemotherapy administration assessment:
 - 6.5.2.1. Confirm that the signed consent is in the medical record (see section 3.1 for applicability).
 - 6.5.2.2. Where appropriate, check all drug dosage and weight calculations and validate with an independent double check performed by a second RN, LIP, or pharmacist.The calculated dose must be within 10% of the ordered dose.
 - 6.5.2.3. Check that a signed treatment note is in the chart. As noted above, a new treatment note is required for any new inpatient admission and for any dose modifications from the standard regimen.
 - 6.5.2.4. Check that the orders contain all the components listed in Clinical Policy.
 - 6.5.2.5. Confirm that lab results are within the parameters for administering treatment, as documented in the antineoplastic orders and treatment plan. Lab results must be from labs drawn within 24 hours of antineoplastic administration.
 - 6.5.2.6. For antineoplastic orders based on weight or BSA, confirm that weight has been obtained within 24 hours.
 - 6.5.3. Verify route and determine patency of intravenous ACCESS. For patients receiving intravesical chemotherapy, insert Foley as ordered.
 - 6.5.4. Verify that the prepared antineoplastic label is independently double-checked by the administering RN and another RN, pharmacist or LIP against the written order. Both verifiers enter their signatures in EHR.
 - 6.5.5. Compare patient name or name/medical record number (inpatient) or name/date of birth (outpatient) on name band with medical label on chemotherapy bag, syringe, or tablet/capsule packet.

7. **PHARMACY PROCEDURES:**

7.1.1. Only pharmacy technicians trained to compound chemotherapy may do so (exceptions include leucovorin and mesna or other non-hazardous compounds). If no chemotherapy

trained pharmacy technician is available, for planned inpatient chemotherapy, arrangements will be made by the inpatient pharmacy clinical specialist for preparation and delivery.

- 7.1.2. Patients continuing oral antineoplastics on the inpatient service may use their own home supply which will be stored on the respective floor's Pyxis machine. See Policy #13.16.030
 Patient-Supplied Medication/Alternative Therapies for procedure. Only nurses with demonstrated competency in antineoplastic procedures and policy may administer oral antineoplastics.
- 7.1.3. Clinical pharmacy specialists reserve the right to withhold dispensing treatment in situations where patients are not monitored in accordance with standard guidelines.
- 7.1.4. Antineoplastic doses , whenever applicable, will be rounded to the nearest vial size or concentration in order to ensure accurate measurement or minimize drug waste. The verifying pharmacist should ensure that the difference between the originally ordered and the rounded dose is within 10%.
- 7.1.5. All antineoplastic orders require two independent checks for verification prior to dispensing. The first check must be completed by a chemotherapy trained pharmacist.
- 7.1.6. Second verification may be completed by a chemotherapy trained pharmacist or a pharmacy resident that has completed a previous oncology learning experience (e.g. rotation).Order verification includes checking the medication name, dose, route and indication against the approved treatment plan or approved oral regimen. The pharmacists will also review laboratory parameters to ensure they are met, appropriateness for the disease state, and potential drug-drug interactions.

8. ADMINISTRATION PROCEDURE:

- 8.1. Handling Guide: All medications have been assessed for the risk of exposure as low, moderate or high risk. This list is continually reviewed and updated by the pharmacy department. See PPE section for link to BMC Hazardous Drug Handling Guide Chart.
- 8.2. Patients receving antineoplastic/High Risk Hazardous drugs are placed on Hazardous Drug Excreta Precautions. Staff must don Personal Protective Equipment (PPE) when handling drugs and/or patient excreta during and for 48 hours after IV drug administration. PPE consists of front closed, non-permeable, lint-free disposable gown with tight fitting cuffs, gloves, and a face shield if splashing is anticipated. Gowns are single use and should not be reused. The used gown and gloves should be disposed of in a yellow chemotherapy precaution trash bag or yellow bucket located in patient's room. Patients receiving oral or injectable anti-neoplastic agents excretions are continuously hazardous, based on the half-life of the agent.
 - 8.2.1. Excreta from urinals/commodes shall be discarded in regular toilet facilities on the unit, with the lid down to prevent splash. For toilets with no lid, a disposable chuck can be placed over the opening to contain any splashes. Pour the waste gently to minimize splashing, and dispose of the chuck and all PPE in the yellow chemotherapy bucket. There is no evidence that double flushing is necessary. When yellow bucket is full, place in dirty utility room on the unit and call Environmental Health and Safety (EHS) at 617-638-8830 for pick up.
 - 8.2.2. USP 800 Hazardous Drug Safety guidelines have classified some chemotherapy/targeted agents as hazardous. Refer to the alert on medication administration record, or on the <u>BMC</u> <u>Nursing Department website</u>, for the appropriate personal protective equipment (PPE) that must be worn when administering or handling hazardous agents.

- 8.2.3. Closed system transfer device (CSTD) must be used when preparing or administering high risk hazardous agents. Please refer to BMC website's inpatient pharmacy link to <u>hazardous</u> <u>drug handling</u> chart.
- 8.3. In the event of exposure to chemotherapy agents, refer to the Safety Data Sheet (SDS) for immediate treatment recommendations. Obtain the SDS for the chemotherapy drug that caused contamination through Lexicomp for possible decontamination procedures. To access Lexicomp from BMC intranet > click on Clinical > under CLINICAL RESOURCES, click on Drug Information (Lexicomp) > From menu at top of page, click on "Toxicology" > Under "Explore by General Category:", click on MSDS > search Drug Trade Name for SDS. Report event to the department supervisor and complete Accident Report Form (ART) as soon as possible (see *Policy #07.27.000 Work Related Injuries*).
- 8.4. A RN/Pharmacist may take verbal orders from the hematology-oncology attending to hold the chemotherapy treatment only.
- 8.5. The RN, LIP and/or pharmacist will ensure that all appropriate protectants and possible rescue agents have been ordered and are available before administration of any anti-neoplastic agent.
- 8.6. Vesicant drugs will be administered as the first agent when more than one drug is being administered. It will be administered using a side-arm Intra Venous Push (IVP) and or bolus into a compatible running intravenous solution.
- 8.7. Continuous infusion vesicants or Irritants can only be administered via a central line.
- 8.8. Only antineoplastic drugs prepared by BMC Pharmacy that are properly labeled with the date, patient's name, medical record number, generic drug names, dose, expiration and pharmacist verification initials will be administered by the RN. <u>Antineoplastics prepared by an outside pharmacy cannot be administered</u>. Inpatients that bring in oral antineoplastics when difficult to obtain by pharmacy, will be kept in PYXIS, and administered from there.
- 8.9. If an antineoplastic is known to have an increased risk of allergic reaction, a LIP will be immediately available. Emergency medications and equipment will be available.
- 8.10. During intravenous push administration of vesicant drug, the RN will continually assess for signs and symptoms of infiltration and confirm a blood return after each 3cc of administered drug.
- 8.11. Continuous infusions of vesicants (which may be administered via a central line only) will be administered piggybacked into a compatible flush line. A blood return will be checked and documented every 4 hours. The central access site will also be checked and documented every 4 hours or as needed for signs or symptoms of infiltration. All nurses at BMC, even those not IV chemotherapy competent are responsible to assess central line site, patency and presence of blood return every 4 hours while patient is receiving continuous IV infusion of chemotherapy agent.
- 8.12. When administering intravenous bolus infusions of antineoplastics the tubing must be preprimed with a compatible solution. This chemotherapy or targeted therapy infusion is then piggybacked into a compatible main line at the port closest to the IV site, unless otherwise indicated.
- 8.13. When an antineoplastic agent requires non-PVC tubing, the chemotherapy line becomes the main line and the compatible flush line is piggybacked into the non-PVC tubing.
- 8.14. Complete an Adverse Drug Event (ADE) form A) only if antineoplastic toxicity is unexpected or the toxicity manifestation requires intervention and/or a change in the treatment plan; and B) when giving biotherapy, for any adverse event.

- 8.15. When RNs are administering an oral or injectable antineoplastic agent they must wear gloves, and dispose of empty syringe in sharps' container. Please see *Policy* #06.17.000 *Chemotherapy Waste and Spill Response* if you have any questions, and the Drug handling chart on the medication administration record.
- 8.16. All IV tubing luer lock injection ports must have an alcohol impreganated cap applied when not in use.
- 8.17. The travel of Inpatients with hazardous drugs infusing is prohibited. Stop infusion of hazardous drug if patient has to travel for emergency scan/procedure. If patients must travel to another area within the hospital with a hazardous medication infusing, a spill kit should accompany the patient. Otherwise, if a spill occurs, the transport worker will restrict the area and call the charge nurse of the sending unit, who will send nursing personnel with a spill kit to manage the spill, if spill is large and call x4-6666 for chemical spill safety assistance.

9. SPECIAL CONSIDERATIONS FOR BROCKTON

- 9.1. All oral anti-neoplastic taken by a Brockton patient will be verified by admitting provider with the prescribing oncologist, Drug/dose/route/frequency and administration instructions will be documented in electronic medical record in a Treatment note by the Oncologist. Consent will be in the electronic medical record.
- 9.2. Pharmacy will verify patient's supply and follow medication policy to secure oral medications.
- 9.3. A nurse will administer oral anti-neoplastic agents practicing safe handling (PPE) and an independent double check with another nurse confirming correct patient/drug/dose/route and frequency, then administer to patient practicing the "five rights" (i.e., right medication, right dose, right time, right route, and right patient), and document administration on the Medication Administration record in the electronic medical record.
 - 9.3.1. Brockton nurses must be competent to administer oral chemo. The nuse will:
 - 9.3.1.1. Complete the oral chemotherapy competency
 - 9.3.1.2. Read and follow this policy, as well as Policy #06.17.000- Hazardous Drugs and Chemotherapy Waste and Spill.
 - 9.3.1.3. Use the appropriate PPE (personnel protective equipment) when administering oral anti-neoplastic agents and handling hazardous excreta.
 - 9.3.1.4. Review and understand resources available to administer oral anti-neoplastic.
 - 9.3.1.5. Safely administer oral anti-neoplastic agents.

Responsibility:

Physicians, Nurse Practitioners, Physician Assistants, Pharmacists, RNs

Other Related Policies:

03.00.700 - Methotrexate for Early Ectopic Pregnancy
03.02.000 - Patient Consent
03.49.000a - Credentialing/ Privileging for Chemotherapy and Targeted Therapy for Non-Malignancy
03.60.000 - Universal Protocol (Time Out)
05.03.030 - Protective/Neutropenic Care
06.17.000 - Hazardous drugs and Chemotherapy Waste and Spill Response
07.27.000 - Work Related Injuries
10.03.010 - Medication Administration

10.03.110 - Management of IV Infiltrations and Extravasations10.03.11a - Extravasation Addendum13.03.013 - Hazardous Drug Handling

13.14.020 - Non-Formulary Medications

13.16.030 - Patient-Supplied Medication/Alternative Therapies

References:

Kienle, P. C. (2020) The Chapter <800> Answer Book. American Society of Health-System Pharmacists. Goldspiel BR, DeChristoforo R and Daniels CE (2000) A continuous-improvement approach for reducing the number of chemotherapy-related medication errors <u>Am J Health-Syst Pharm</u> 57 (Suppl 4): S4-S9

Olsen M, LeFebvre K. B., Brassil K.J. (Eds)(2019) Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice, Pittsburgh, PA: ONS.

Neuss, M.N, et al(2016) 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for Pediatric Oncology. *Oncology Nursing Forum*, 44(1)):January 2017, A1-A13..

Initiated by: Nursing

Contributing Departments: Pharmacy Hematology/Oncology



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| Section: | Clinical Care |

Credentialing/Privileging for Anti-neoplastic or Benign Disease Therapy

Purpose:

To delineate the Boston Medical Center (BMC) policy for the credentialing and privileging of Licensed Independent Practitioners (LIPs) to use anti-neoplastic or benign disease therapy in the treatment of specific conditions.

Policy Statement:

BMC is committed to maintaining safety in the care of patients while providing efficacy in the treatment of certain conditions with the use of anti-neoplastic and benign disease therapy. LIPs must be privileged to use anti-neoplastic and benign disease therapy.

Application:

- 1. All attending physicians who are not trained and privileged in anti-neoplastic therapy.
- 2. Nurse practitioners (NPs) and physician assistants (PAs) only as noted below. Otherwise, physician assistants and nurse practitioners are not authorized to use, administer, or prescribe systemic chemotherapy.

Exceptions:

Physicians with privileges in Hematology, Medical Oncology, or Gynecologic Oncology.

Definitions:

Anti-neoplastic Therapy/Chemotherapy: used specifically, but not exclusively, to treat malignancy including cytostatic, cytotoxic, and certain biologic response modifiers or targeted biologicals, all of which share common toxicities, especially those of immune and/or bone marrow suppression.

Benign Disease Therapy: Certain drugs typically referred to as anti-neoplastic Therapy/chemotherapy may be used for indications other than cancer. Reasonable therapeutic applications of such drugs must be established in the medical literature and sanctioned by the appropriate Medical Staff and Chief of Service.

Procedure:

- 1. Departments that wish to have LIPs use anti-neoplastic or benign disease therapy must have the specific privilege(s) listed on a Delineation of Privileges. The addition of anti-neoplastic or benign disease therapy privileges to a Department's Delineation of Privileges must be approved by the Credentials Committee and Medical Executive Committee, with input from the Medication Safety and Quality Committee.
- 2. LIPs must be privileged to use anti-neoplastic or benign disease therapy.
- 3. The request for privileges to use anti-neoplastic or benign disease therapy is usually made as part

of an initial or renewal credentialing application but may be made by any currently privileged member of the Medical- Dental staff at any time. Regardless of when they are obtained, privileges to use anti-neoplastic or benign disease therapy expire simultaneously with a LIP's current appointment and privileges period.

4. The requirements for obtaining privileges varies based on the training and type of the applicant.

4.1. Credentialing and Privileging for Anti-neoplastic Therapy/Chemotherapy

- 4.1.1. All attending physicians who are formally trained in anti-neoplastic therapy (Hematology or Oncology) may request privileges to use anti-neoplastic therapy /chemotherapy without further documentation
- 4.1.2. NPs and PAs in the Department of Hematology-Oncology may be privileged to use anti-neoplastic therapy /chemotherapy and must:
 - 4.1.2.1 Review and follow *Policy* #03.49.000 Ordering of Anti-Neoplastic Agents/Chemotherapy.
 - 4.1.2.2 Review Appendix I Competency for the Use and Prescription of Anti-Neoplastic Agents/Chemotherapy, and pass (with at least a 90% score) the Systemic Chemotherapy Credentialing Test (Appendix II) and submit it to the Medical Staff Office.
- 4.2. Physicians trained and privileged in the following may request privileges to use antineoplastic or benign disease therapy without further documentation:
 - 4.2.2. Dermatology, in doses usually recommended for the treatment of Psoriasis/Eczema, Immunobullous Disorders, and Connective Tissue Disorders
 - 4.2.3. Gastroenterology, at doses generally recommended for the treatment of Inflammatory Bowel Disease or Autoimmune Hepatitis.
 - 4.2.4. Nephrology, at doses generally recommended to treat Glomerulonephritis, vasculitis, lupus, and transplantation
 - 4.2.5. Obstetrics or Family Medicine, at doses generally recommended for the termination of tubal or ectopic pregnancy.
 - 4.2.6. Pulmonary Medicine, at doses used to treat sarcoidosis, immunologic and inflammatory lung disease, or lung disease associated with Connective Tissue Disease
 - 4.2.7. Rheumatology, at doses generally recommended for the treatment of Connective Tissue Disorders
- 4.3. All other LIPs seeking privileges to use anti-neoplastic or benign disease therapy must review Appendix I *Competency for the Use and Prescription of Systemic Chemotherapy for Non-Malignant Conditions*, and pass (with at least a 90% score) the *Systemic Chemotherapy Credentialing Test* (Appendix II) and submit it to the Medical Staff Office.
 - 4.3.2. The Medical Staff Office will review the submitted test, and assign a score to each based on the number of questions answered properly.
 - 4.3.3. Requests with non-passing scores:
 - 4.3.3.1 Will be offered the opportunity to retake the exam a second time.
 - 4.3.3.2 Subsequent non-passing scores will be compiled by the Medical Staff Office, and submitted, along with the scored test, to the Section Chief or Department Chair, who will arrange for appropriate education and remediation. The applicant will then be allowed to take the exam again.
 - 4.3.4. Requests with passing scores will be compiled by the Medical Staff Office, and will then be processed for approval according to the procedures described in the Medical Dental Staff Bylaws.
- 4.4. Additionally, NPs and PAs may only be privileged to use anti-neoplastic or benign disease therapy as follows:
 - 4.4.2. In Departments where physicians are approved to use anti-neoplastic or benign

disease therapy (see Section 4.2), to write **outpatient** maintenance orders. The initial prescription, and any subsequent dose adjustments, must be ordered and signed by an attending physician who is privileged to use anti-neoplastic or benign disease therapy.

- 4.4.3. NPs who do not have independent practice authority and PAs must obtain the recommendation of their Supervising Physician, or other applicably privileged attending in that Department.
- 5. Professional Practice Evaluation
 - 5.1. Each Department must participate in regular Professional Practice Evaluation activities.

Responsibility:

Medical Staff Office

Attachments:

APPENDIX I - Competency for the Use and Prescription of Systemic Chemotherapy for Non-Malignant Conditions

APPENDIX II - Systemic Chemotherapy Credentialing Test

Forms:

None

Other Related Policies/Protocols/Guidelines:

03.00.700 – Methotrexate for Early Ectopic Pregnancy
03.49.000 - Ordering and Administering of Anti-Neoplastic Agents/Chemotherapy
26.24.010 - Suspected Fever and Neutropenia Guideline
34.03.000 - Care of the Obstetric Patient Receiving Chemotherapy in the Outpatient Cancer Center

Initiated by:

Medical Staff Office

Contributing Departments:

Hematology/Oncology

BOSTON MEDICAL CENTER COMPETENCY FOR THE USE AND PRESCRIPTION OF SYSTEMIC CHEMOTHERAPY FOR NON-MALIGNANT CONDITIONS

Purpose: Various chemotherapeutic agents have shown efficacy in the treatment of specific nonmalignant conditions, as shown in Figure 1. Antineoplastic drugs differ from those normally prescribed for medical conditions in that systemic chemotherapy has a very narrow therapeutic window between clinical benefit and severe toxicity. Although this will be a low volume group of patients treated, it is high risk in terms of potential toxicity. Successful completion of this competency packet documents the attending level physician's knowledge of principles of systemic chemotherapy administration and prevention/management of toxicity, and it will lead to the credentialing of the attending physician to prescribe specific systemic chemotherapy agent(s) for specific conditions. All systemic chemotherapy orders must be written or co-signed by a credentialed attending physician within the appropriate service. All reasonable therapeutic applications of such drugs must be established in the medical literature and sanctioned by the appropriate Medical Staff Chief of Service. The Pharmacy and Therapeutics Committee will be responsible for monitoring therapeutic advances.

Objectives:

- 1. State the mechanism of action of selected systemic chemotherapy drug(s)
- 2. Describe 4 general toxicities of systemic chemotherapy agent(s) and measures to prevent or minimize their occurrence
- 3. Describe 4 organ specific toxicities of selected systemic chemotherapy drug(s) and measures to prevent or minimize their occurrence
- 4. Develop a plan of care for the patient receiving systemic chemotherapy drug(s) that includes informed consent, patient/family teaching, nursing orders to minimize or prevent toxicity, and patient follow-up
- 5. Demonstrate the correct prescription of selected systemic chemotherapy drugs

Method:

- 1. Self learning module
 - a. Competency packet
 - b. BMC Policy # 03.49.000
 - c. Optional articles from reference list
 - d. Clinical skills check off
- 2. Post-test

Evaluation:

1. Achieve a score of 90% on the 10 item post-test

References:

- 1. Chabner B and Longo DL (2006) *Cancer chemotherapy and Biotherapy: Principles and Practice* 4th Ed. Philadelphia PA: Lippincott Williams and Wilkins
- DeVita Jr VT., Lawrence TS, Rosenberg SA (2008) DeVita, Hellman, and Rosenberg's Cancer: Principles and Practice of Oncology 8th Ed. Philadelphia PA: Wolters Kluwer/Lippincott Williams & Wilkins
- 3. Wilkes GM, Barton-Burke M (2020) Oncology Nursing Drug Handbook, 13th Ed. Sudbury MA: Jones and Bartlett Publishers
- 4. UpToDate (2020) Prevention and treatment of chemotherapy-induced nausea and vomiting.
- 5. BMC Pharmacy Medication Guidelines for Nausea and Vomiting-Chemotherapy (June 2019)

Prescription of Systemic chemotherapy for Non-Malignant Conditions

Antineoplastic chemotherapy agents have shown great promise in the treatment of a number of nonmalignant conditions, as shown in Figure 1, and it is anticipated that this list of agents will grow. Unlike the prescription of medicines for treatment of disease in general, the prescription of systemic chemotherapy is targeted at a very narrow therapeutic window where benefit exceeds toxicity (1). In order to assure consistency in baseline knowledge about the fundamentals of systemic chemotherapy, a brief discussion of principles and practice are presented, with specific attention to toxicity prevention and management.

Collaboration with Medical Oncology

The purpose of the credentialing process is to allow the treating physician to order chemotherapeutic agents as appropriate for the diseases which fall within the scope of their specialty. It is helpful to the patient, because both the risks and benefits of a drug can be discussed by a single physician. However, questions regarding management of toxicities which occur after administration can be discussed with a member of the Medical Oncology service.

Credentialing for New Drugs

There is significant overlap in toxicity between many of the chemotherapeutic agents. Much of the information in this packet is general with this fact in mind. Toxicities that are specific to the agents that are currently in use are also included. However, it is likely that new drugs will be added in the future, and a physician's credentials can be expanded by a simple process including written material relevant to the drug and an oral discussion with the clinical director of Medical Oncology or designee.

PRINCIPLES OF CHEMOTHERAPY

Antineoplastic chemotherapy is intended to prevent malignant cells from reproducing, causing cell death, with the goal of reducing the number of cancer cells to zero (2). This would then prevent tumor expansion, invasion, and metastases. Chemotherapeutic agents are selected based on their ability to interfere with cell cycle function in any number of ways, from causing breaks in DNA strands, intercalation of base pairs, centromere stabilization, to alterations in cell membrane synthesis function. Cells die from the direct effect of chemotherapy, or indirectly, when Chemotherapy triggers apoptosis (3). Because these agents are administered systemically, normal cell populations that divide frequently are equally affected. For example, the dose limiting toxicity for many agents relates to bone marrow suppression. Fortunately, normal cells are better able to repair than malignant cells, so the injury to normal cells is usually temporary in renewing cell populations such as the bone marrow. In addition, there are colony stimulating growth factors for neutrophils and red blood cells available if full dose therapy is desired for cure.

Chemotherapy drugs are generally classified based on how they disrupt the cell cycle during cell division, and whether they are most active when the cell is dividing (cell cycle specific), or most active during specific parts of the cell cycle (phase) specific, or their activity doesn't depend upon whether the cell is

dividing or not (cell cycle nonspecific). Most agents however, cannot be assigned to one category alone (3). Cells in the resting phase (Go) are not vulnerable to phase or cell cycle specific drugs; however, they are responsive to alkylating agents such as mechlorethamine or the nitrosureas. When phase specific drugs are given, the exposure of cells in cycle may be quite brief, so that the number of cells killed is limited with a single exposure (3).

Figure 1 shows the phases of the cell cycle, and Table 2 shows a listing of common agents and their mechanism(s) of action.

The cell cycle is an ordered, predictable series of events, leading to cell growth and division into 2 daughter cells (5). Cells that are not dividing are in the Go stage, and usually immune to the effects of chemotherapy. The G1 stage stands for "GAP 1". During this phase, RNA and protein synthesis occur, and it lasts around 18-30 hours. The S stage stands for "Synthesis" when DNA is synthesized and DNA replication occurs. This phase lasts 16-20 hours. The G2 stage stands for "GAP 2" and this is when the structures necessary for mitosis are made (RNA and protein synthesis occurs). This phase lasts 2-10 hours. The M stage stands for "mitosis", and is when the chromosomes separate and the 2 daughter cells formed. This phase lasts 30 minutes to 1 hour. In humans, most cells are in the Go

phase at any one time.

Figure 1 See http://www.cellsalive.com/cell_cycle.htm for picture of cell cycle

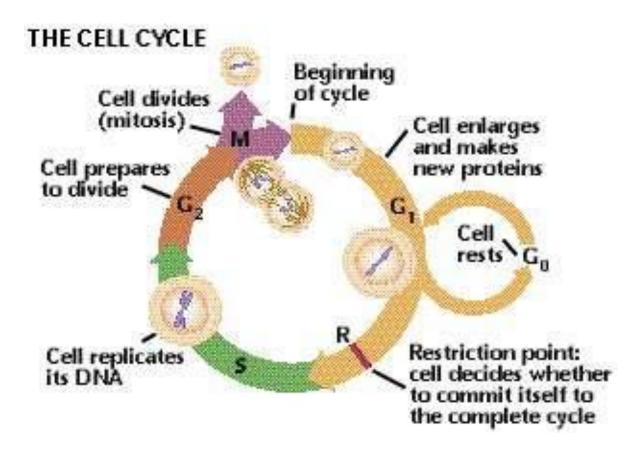


Table 2. Examples of Chemotherapy Agents, Mechanism of Action and Cell Cycle Specificity (3, 4)

| Phase | Class | Туре | Drug(s) | |
|------------------|--------------------|---|--|--|
| G1 | Natural Product | Enzyme | l-asparaginase | |
| | Hormone | Corticosteroid | Prednisone | |
| G1/S junction | Antimetabolite | Purine analogue | Cladrabine | |
| DNA Synthesis | Antimetabolite | Pyrimidine analogue | Cytarabine Gemcitabine 5-fluorouracil | |
| | | Folic acid analogue | Methotrexate Trimetrexate | |
| | | Purine analogue | 6-thioguanine fludarabine | |
| | Natural Product | Topoisomerase-I inhibitor | Topotecan Irinotecan | |
| | Miscellaneous | Substituted urea | Hydroxyurea | |
| G2 | Natural Product | Antibiotic | Bleomycin | |
| | | Topoisomerase II inhibitor | Etoposide | |
| | | Microtubule polymerization and stabilization | Paclitaxel | |
| | | Microtubular stabilization | Docetaxel | |
| М | Natural Product | Mitotic Inhibitor | Vincristine Vinblastine Vinorelbine | |
| Cell Cycle | Specific Drugs | (Active throughout the cell cycle | | |
| | Alkylating Agents | Nitrogen Mustard | Cyclophosphamide Melphalan Chlorambucil | |
| | | Alkyl sulfonate | Busulfan | |
| | | Triazene | Dacarbazine | |
| | | Metal salt | Cisplatin Carboplatin Oxaliplatin | |
| | Natural Products | Antibiotic *also topoisomerase II inhibitor | Doxorubicin* Daunorubicin Idarubicin Dactinomycin Epirubicin | |
| | | Antibiotic Anthracenediones | Mitoxantrone | |
| Cell Cycle | Non-Specific Drugs | (Work whether cell dividing or not) | | |
| Cen Cycle | Alkylating Agent | Nitrogen Mustard | Nitrogen Mustard | |
| | | Nitrosureas | Carmustine Lomustine | |

Cell Cycle Phase Specific Drugs

POTENTIAL DRUG TOXICITIES

Toxicities depend upon the specific agent, dose, schedule, route of administration, and underlying patient characteristics that increase the patient's risk for toxicity. Patients must be monitored closely to determine tolerance, toxicity, and self-care ability so that future treatment toxicity can be minimized by dose reduction or other measure.

Unfortunately, drugs cannot discriminate between frequently dividing cells that are normal and those that are malignant or which mediate autoimmune or inflammatory conditions. Consequently, normal cells as well as malignant cells are injured. Thus, anticipated acute side effects are found in normal cell populations that divide frequently, i.e., bone marrow, gastrointestinal (GI) mucosa, gonads, and hair follicles. Since normal cells are better able to repair themselves, these side effects are usually reversible. Depending on drug properties, delayed, longer-term toxicities may occur, which may be irreversible. Properties to be aware of include route of administration, dose, excretion, and predilection for uptake by specific organ cells. Examples of toxicities are:

- Lung toxicity from bleomycin, busulfan, and the nitrosureas (BCNU, CCNU)
- Cardiomyopathy from doxorubicin, daunorubicin, and mitoxantrone
- Renal dysfunction from cisplatin and high-dose methotrexate
- Hemorrhagic cystitis (bladder) from ifosfamide and cyclophosphamide
- Neurotoxicity from the platinum compounds, taxanes, and vinca alkaloids
- Development of secondary malignancies from melphalan, cyclophosphamide, and other drugs combined with radiotherapy
- Viral reactivation (especially Hepatitis B) from B-cell depleting targeted therapy such as Rituximab or Obinutuzumab or anthracylcines such as Doxorubicin and Daunorubicin

Bone Marrow Suppression

Normal bone marrow cells turn over frequently. Few chemotherapy drugs damage the stem cells, but those that do include cyclophosphamide. Over time this can reduce bone marrow reserve. Drugs that are myelosuppressive have a predictable nadir when blood counts (neutrophil, platelet) will be at their lowest. Antimetabolites usually have a nadir (lowest blood count values after chemotherapy) 10-14 days after the drug is given, as do many antibiotics, with recovery by day 21. Alkylating agents, such as cyclophosphamide have nadir at 7-14 days, with recovery by day 21-28. Certain alkylating agents such as oral melphalan and IV mitomycin C have a delayed nadir occurring at day 42 and 56, respectively. Patients at risk for severe bone marrow suppression are patients with reduced bone marrow reserve (due to prior chemo, radiation, or alcohol abuse), receiving drugs that may be sequestered in an effusion and slowly released, (e.g., methotrexate), receiving other bone marrow suppressive drugs concomitantly, or having end organ dysfunction in an organ responsible for drug metabolism/excretion. Degree of myelosuppression is also a function of dose, so that as the dose of myelosuppressive drugs such as cyclophosphamide is increased, the nadir in terms of absolute neutrophil count decreases. The risk of infection is inversely proportional to the absolute neutrophil count, so that risk of infection is moderately increased when ANC is 500-1000/mm3, is high risk when the ANC is < 500/mm3, and severe when the ANC is <200/mm3. In addition, the duration of neutropenia also influences the risk of developing a life-threatening infection. Exogenous neutrophil growth factors can be prescribed to minimize the risk of febrile neutropenia, and the oncologists would be very glad to consult with you about this if needed.

Measures to minimize toxicity: assess baseline CBC, diff, and administer chemotherapy when absolute neutrophil count is at least 1000/mm3. Check nadir counts at least the first cycle, and dose reduce as

necessary. Teach patient self-assessment for signs/symptoms of infection, including taking temperature, and to call prescribing MD or service covering MD who must have CBC/ANC assessed. If neutropenic with fever, this is a medical emergency and requires (usually) inpatient antibiotic/antimicrobial coverage depending upon causative organism. If difficulty contacting the provider, the patient should be instructed to go to the ED if temp>100.5F and/or s/s infection. In addition, patients should be instructed to avoid crowds, other individuals with colds or overt infection, especially at the time of the drug nadir, and to use effective hand washing techniques.

Platelets live approximately 10 days, are temporarily reduced following chemotherapy, usually with a similar nadir time as neutrophils. Chemotherapy is usually held or dose reduced for count <100K. Patient teaching includes calling prescribing MD if signs/symptoms of bleeding occur, to avoid aspirin containing meds and NSAIDs.

Mucositis

Stomatitis is caused by chemotherapy injury to the underlying mucosal stem cells, and the inability to replace mucosal cells as they are destroyed by the usual wear and tear of eating. Mucosal erythema occurs first, followed by tissue breakdown and ulcer formation. Fungal overgrowth can also occur. Stomatitis is usually related to drug (antimetabolites are most *stomatoxic*) and dose. Stomatitis usually precedes the nadir, so if it is seen, it is likely the nadir counts will be quite low. In the setting of non-malignant chemotherapy administration, this may not be a common side effect. Mucosal injury to stem cells is mirrored along the GI tract, and depending upon the drug, can result in diarrhea (eg, 5FU, methotrexate).

Measures to minimize toxicity: patient sucking ice during the drug infusion may cause vasoconstriction and protect the mouth from drug exposure, especially with antimetabolite drugs and HD melphalan. Patients should be taught to systematically cleanse their mouth (normal saline gargles after meals and at bedtime) along with usual mouth care. If secretions are thick, then 1/4 strength peroxide solution may be used. If stomatitis develops, mucosal protectants such as diphenhydramine/kaopectate: viscous xylocaine swish and spit (or swallow if patient has esophagitis as well), or GelClair will help increase comfort and ability to eat and drink fluids. It is important to teach patients self-assessment, and to call if local symptomatic care is ineffective, or they can't eat or drink fluids.

Nausea and Vomiting

Nausea and vomiting are related to stimulation of the chemotherapy receptor trigger zone on the floor of the fourth ventricle in the brain, which then stimulates the Vomiting Center. The vomiting center is stimulated by blood borne chemotherapy, as is well as by vagal efferents in the gut. The enterochromaffin cells in the gut are stimulated to release serotonin, which stimulates the vagus nerve, leading to direct stimulation of the vomiting center as well as the chemotherapy trigger zone. Substance P and neurokinin-1 receptors are now known to be mediators in a final pathway of nausea and vomiting. Great strides have been made in the prevention and control of nausea and vomiting related to chemotherapy. Drugs such as the serotonin antagonists help to block the release of serotonin in the gut so that stimulation of the vagus nerve does not occur. Examples of serotonin-antagonists are granisetron (Kytril), ondansetron (Zofran) and palonestron (Aloxi). Risk factors for nausea and vomiting include prior history of nausea/vomiting (seasickness, carsickness, pregnancy-related emesis), drug type and dose, age (younger have more trouble) and sex (females have more trouble). If the patient is anxious, giving lorazepam is helpful in preventing anticipatory nausea/vomiting from developing due to its amnesic effect. The addition of dexamethasone significantly increases the antiemetic potential of the antiemetic regimen by at least 10%, so is customarily added to the serotonin-antagonist. The Oncology Pharmacist is a great resource for appropriate anti-emetic therapy.

Measures to minimize toxicity: use aggressive antiemesis appropriate to the drug. Ensure that the antiemetic regimen includes coverage for the duration of the drug's effect. For most drugs, this is for the first 24 hours, but for some drugs, this may be up to 3 (cyclophosphamide, doxorubicin) -5 days (cisplatin) depending upon dose. Some patients will have nausea and/or vomiting, sometimes severe, despite what appears to be an appropriate antiemetic regimen. This may require outpatient (or inpatient) hydration to correct fluid and electrolyte loss, as well as more aggressive antiemesis. Please contact Medical Oncology or the Oncology Pharmacist to prescribe aprepitant, a Substance P Neurokinin-1 receptor antagonist, to prevent delayed nausea and vomiting prior to the patient's next cycle of chemotherapy. Please feel free to consult oncology and/or oncology pharmacist for challenging patients, or refractory nausea and/or vomiting.

*BMC Medication Guidelines: Nausea and Vomiting – Chemotherapy (June 2019)

Injury to Hair Follicles

Hair loss can be a very traumatic side-effect, and if the drug causes alopecia, hair loss can range from thinning to total alopecia, depending upon the drug. Drugs which cause alopecia are alkylating agents, most antimetabolites, and antineoplastic antibiotics. Hair preservation techniques such as scalp tourniquet create a sanctuary for malignant cells so are not usually used for patients receiving chemotherapy for cancer. If the drug causes total alopecia, then the patient should be encouraged to get a wig before actual hair loss to decrease body image trauma. The prescription should be written for a scalp prosthesis, and is usually covered by most health insurance plans. Hair loss is patchy at first, and then within 4-6 weeks all hair will be lost if the drug causes complete alopecia. Otherwise, if the drug causes only thinning, a person with thick hair may have little change in appearance in winter, since 25% of body heat is lost through the scalp, it is important to teach the patient to wear scarves, hats, etc. If body image distortion is significant, social service supportive counseling is often helpful.

Gonadal Dysfunction

The reproductive tissues are composed of rapidly dividing gonadal cells in men, whereas women are born with their full complement of ovarian follicles. Damage from systemic chemotherapy may cause temporary or permanent sterility, irregular menses, amenorrhea, premature menopause, and alterations in libido. Which if any of these reproductive changes occur depends on the age of the patient when treated, the drug and dose intensity. Young men may be interested in sperm banking, and in some centers egg banking may be possible for women. Patients should use birth control measures while receiving chemotherapy because of the mutagenic and teratogenic effects of most agents. Encouraging patients to discuss their concerns, as well as those of their partners is very helpful. If counseling is necessary, seek resources within the social services department.

DRUG ADMINISTRATION

Patient Consent

As systemic chemotherapy differs from most medications prescribed in terms of the acceptable toxicity, it is important to carefully explain potential drug side-effects and necessary self-care measures. The patient needs to be aware of these facts as well as the potential benefits so that he or she can make an informed judgement as to whether they wish to proceed with systemic chemotherapy. The fact that a discussion of risks and benefits of systemic chemotherapy has occurred between the physician and patient should be documented in the chart prior to administration as well as a signed systemic chemotherapy consent form. There may be instances, such as in Obstetrics and Gynecology, when a separate consent form needs to be created. If you wish to modify this form, or use a similar form, please discuss this with the Clinical Director of Hematology/Oncology.

Complications of Drug Administration

All drugs can cause hypersensitivity reactions, but only a few drugs cause severe problems. Some examples are:

- L-asparaginase
- Taxol
- Cisplatin
- Bleomycin (less common; 2% incidence in lymphoma patients)
- Rituximab

Systemic chemotherapy should be administered ideally by the systemic chemotherapy qualified nurses in the Moakley 3 Cancer Center or inpatient 6 East Menino. An anaphylaxis kit and code cart should be readily available.

Extravasation

Specific chemotherapeutic drugs called *vesicants* may cause severe tissue necrosis if extravasated. Some of these drugs have antidotes that will minimize or prevent local tissue damage.

When vesicants are administered as a continuous infusion, a central line is required. In addition, it is imperative that the IV insertion site is checked for signs/symptoms of extravasation at least hourly, and that the patient is instructed to tell the nurse immediately if stinging or burning is felt. As many continuous infusions of vesicant chemotherapy occur when the patient is at home, it is again imperative to instruct the patient to pay attention to any changes in sensation at the site, and to call the nurse if any discomfort, stinging, or burning is felt. A number of patients have had extravasation of drug from a dislodged needle onto the surrounding skin, which then caused a necrotic ulcer and necessitated explantation of the subcutaneous port.

• BMC Nursing Extravasation Policy & procedure 10.03.110, Extravasation Addendum (list of vesicants, irritants and antidotes) 10.03.11A

Safe Handling of Chemotherapy

Antineoplastic agents are effective because they interfere with cellular metabolism and replication, resulting in cell death. However, it is critical that all Health care providers protect themselves when handling these drugs so that they are not exposed to the potential drug hazards. These drugs can be:

- *Mutagenic:* capable of causing a change in the genetic material within a cell that can be passed on to future cell generations;
- *Teratogenic:* capable of causing damage to a developing fetus exposed to the drug; the greatest risk is during the first trimester of pregnancy when the fetal organ systems are developing;
- *Carcinogenic:* capable of causing malignant change in a cell.

In 1985 the Occupational Safety and Health Administration (OSHA) developed guidelines for the safe handling of antineoplastic agents. These guidelines were revised in 1995 to include all hazardous drugs.

• BMC Safety Policy& procedure Chemotherapy Waste Handling and Spills 06.17.000

Drug Errors

Within the last 5 years, oncology teams across the country have been humbled by the reports of significant and lethal errors that have occurred during the systemic chemotherapy prescription, admixing, and administration processes. BMC has taken steps to prevent the occurrence of these errors and tragic consequences through competent checks and balances. Fortunately, the series of well publicized errors has been a "wake-up" call, and together oncology nurses, pharmacists and physicians have worked together to develop safe environments for clinical practice. The Association of Clinical Oncologists specifies the steps an oncologist should take to minimize opportunities for error, including avoiding use of abbreviations for chemotherapy agents. The Oncology Nursing Society position paper "Regarding the Preparation of the Professional Registered Nurse who Administers and Cares for the Individual Receiving Chemotherapy" states the nurse administering chemotherapy and caring for patients receiving chemotherapy should complete a chemotherapy course and clinical practicum to safely and competently deliver chemotherapy. Thus, only nurses qualified to administer chemotherapy should give the drug. Also, integral to this is the patient teaching and close follow-up that is critical to good patient outcomes.

 2016 ASCO/ONS Chemotherapy Safety Standards, "Oncology Nursing forum" January 2017, Vol. 44, No. 1. pp 1-13

Name:

Please circle the answer that *best* answers the question.

1. Before a patient receives systemic chemotherapy, the physician must:

- 1) Discuss risks and benefits of therapy with the patient
- 2) Document the discussion of risks and benefits in the chart
- 3) Obtain a written consent
- 4) Merely inform the patient they will be receiving systemic chemotherapy

Please circle the correct response:

- a) 1 only
- b) 1, 2
- c) 1, 2, 3
- d) 1,2,3,4

2. The most appropriate time(s) to consult with a medical oncologist is/are:

- a) Prior to administration of drug to obtain indications for non-malignant conditions
- b) To obtain recommendations for standard anti-emetics
- c) To obtain recommendations for alternative antiemetic regimens when standard anti-emetics are ineffective
- d) To discuss predictable symptom(s)

3. When a new drug is shown to be effective for a non-malignant condition, specialty physicians MUST:

- a) Begin therapy with new agent as long as there is published literature
- b) Update professional credential to include prescription of new drug
- c) Discuss new literature indication with Oncology Pharmacist
- d) Consult medical oncology to see the patient and prescribe drug

4. A patient receiving cyclophosphamide for a non-malignant condition calls 10 days after receiving the drug to complain of sore throat and fever of 101F. It is 7p on Sunday night. The best action would be to:

- a) Tell the patient to come to your clinic to see the Fellow at 8a Monday morning
- b) Ask the patient if s/he has had shaking chills, and if so, to come to the ED
- c) Tell the patient to come to the ED, and call the ED to alert them
- d) Tell the patient to take acetaminophen 650 mg and to call if the fever doesn't resolve in 1 hour

5. Toxicities that occur commonly with antimetabolite and alkylating agents are:

- a) Bone marrow suppression, alopecia, neurotoxcitity, and hemorrhagic cystitis
- b) Gonadal dysfunction, mucositis, alopecia, cardiomyopathy
- c) Bone marrow suppression, alopecia, gonadal dysfunction, mucositis
- d) Renal dysfunction, sterility, alopecia, thrombocytopenia

APPENDIX II SYSTEMIC CHEMOTHERAPY CREDENTIALING TEST

6. You would discuss the following points with your patient about self-care after receiving cyclophosphamide systemic chemotherapy:

- a) Drink at least 1 glass of non-alcoholic fluid every hour to stimulate voiding, and to flush the bladder, the day of treatment, and for 2 days afterwards
- b) Take his temperature if he feels warm or flushed, or has signs/symptoms of an infection
- c) Call you if he develops a fever >100.5F, productive cough, burning on urination
- d) All of the above

7. You are prescribing cyclophosphamide for a sexually active woman aged 45 years old. It is important to tell her to use birth control measures because chemotherapy:

- 1) Causes DNA damage and is mutagenic
- 2) Can cause cancer in the fetus
- 3) Is teratogenic
- 4) Will cause cardiotoxicity if she becomes pregnant

Please circle the correct response:

- a) 1 only
- b) 1, 2
- c) 1, 2, 3
- d) 1,2,3,4

8. Of the combinations listed below, please select the most appropriate, as it relates to antineoplastic agent, class, and cell cycle specificity:

- a) Methotrexate: antimetabolite; G1 phase,
- b) Cyclophosphamide: alkylating agent; M phase
- c) Methotrexate: antimetabolite; S phase
- d) Mitoxantrone: alkylating agent; S phase

9. Administration of systemic chemotherapy can result in varying degrees of organ toxicity. All of the following sequelae may dictate a dosage modification except:

- a) Esophagitis
- b) Nausea and Vomiting
- c) Febrile Neutropenia
- d) Diarrhea

10. The most effective regimen for preventing acute chemotherapy-induced nausea and vomiting due to highly emetogenic chemotherapy is:

- a) serotonin- antagonist
- b) Dopamine antagonist + corticosteroid
- c) Butyrophenone + corticosteroid
- d) serotonin-antagonist + corticosteroid

*Once completed, return this test to the Medical Staff Office at fax: 617-414-6031, or credentialing@bmc.org