Chimeric Antigen Receptor T-Cell Therapy: Overview

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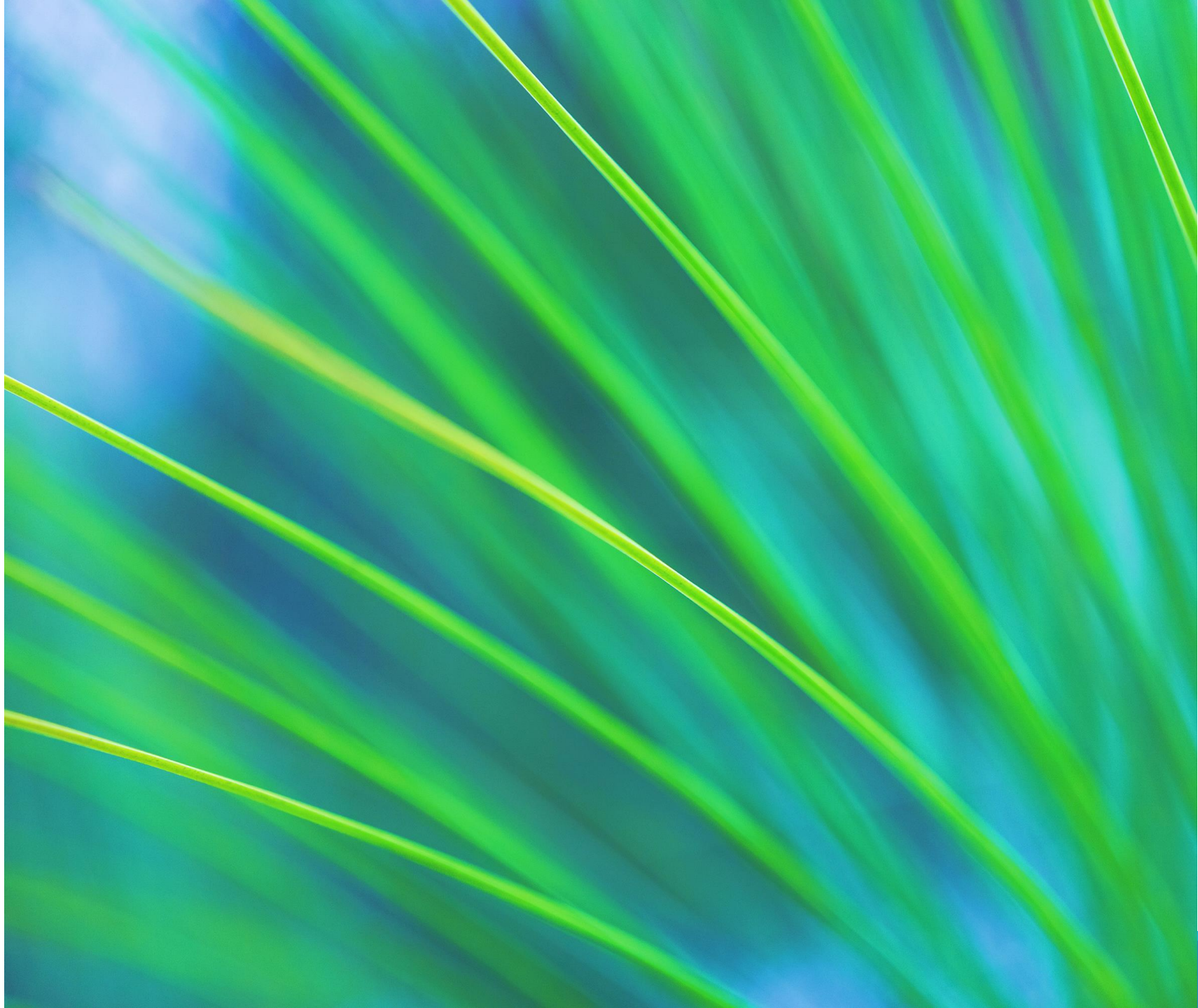


Objectives

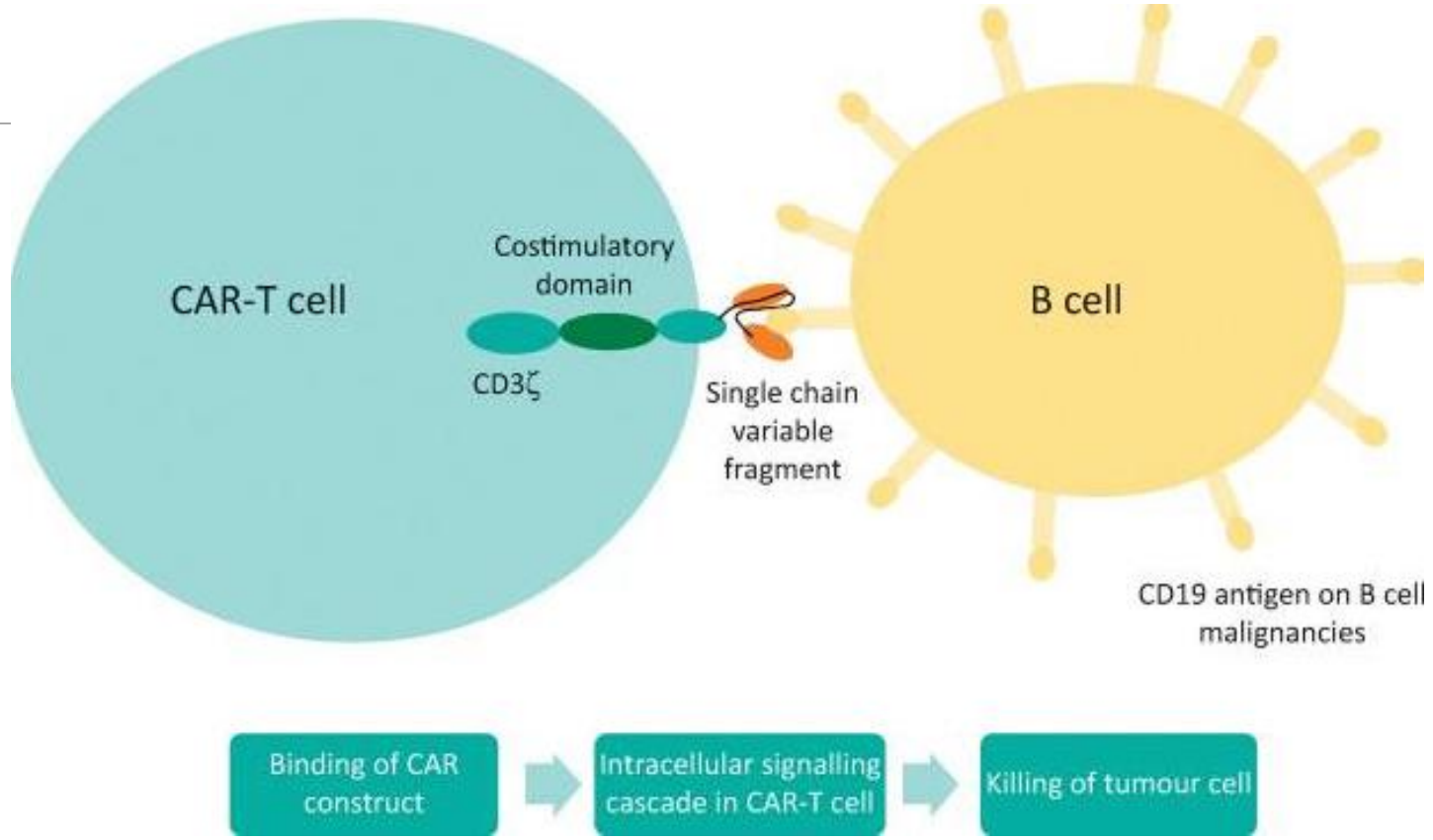
Apply	Apply evidence-based supportive care guidelines for management of CAR-T Cell therapy adverse events
Demonstrate	Demonstrate an understanding of nursing workflow updates for CAR-T
Pass	At the completion of this module the learner will pass the post test and understand the indications for CAR-T Cell Therapy and how to care for the patient

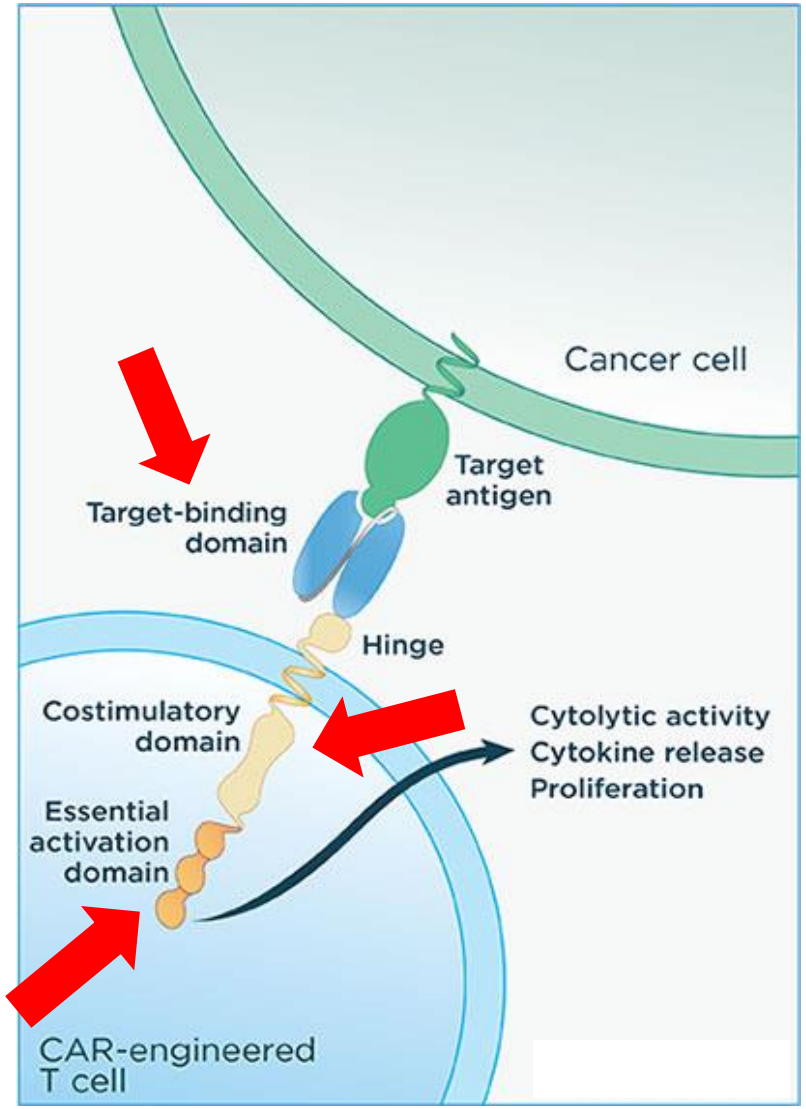
CAR-T Cell Pathophysiology

Immune cells called T cells (a type of white blood cell) are genetically modified in the lab by adding a man-made receptor (called a chimeric antigen receptor or CAR) which then allows them to target and destroy cancer cells

CARs allow T cells to recognize and attach to a specific protein or antigen, CD19, on tumor cells

CD19 is a protein expressed on the surface of almost all B-cell leukemias and lymphomas





CAR-T Cell Mechanism of Action

CAR-T cell technology genetically modifies a patient's T-cells to express CAR and enables T-cells to proliferate, recognize and target cells

CARs have 3 domains:

1. Target-binding domain
   - Allows CAR-T cells to recognize target molecules
2. Costimulatory domain
   - Enhances growth and survival of CAR-T cells
3. Activation domain
   - Activates CAR-T cells in sequence with costimulatory domain

CAR-T Cell Timeline

Step 1

The patient’s own blood is collected, and leukocytes are separated and removed

Step 2

CAR-T cells undergo a special manufacturing process in which they are engineered to recognize and eliminate cancer cells that contain the desired antigen

Step 3

The patient receives lymphodepleting chemotherapy to prepare for CAR-T cell infusion

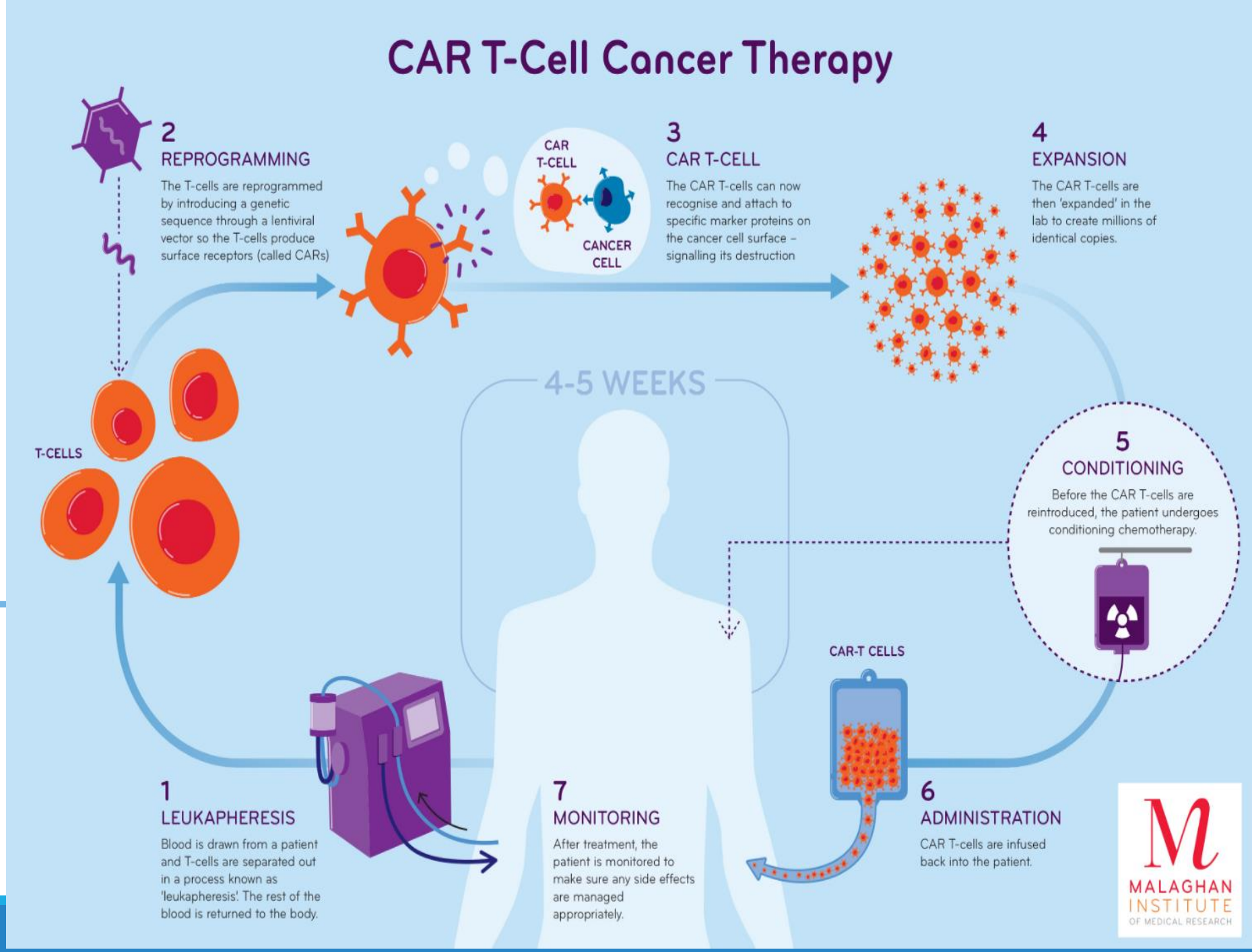
Step 4

The patient receives their infusion of CAR-T cells

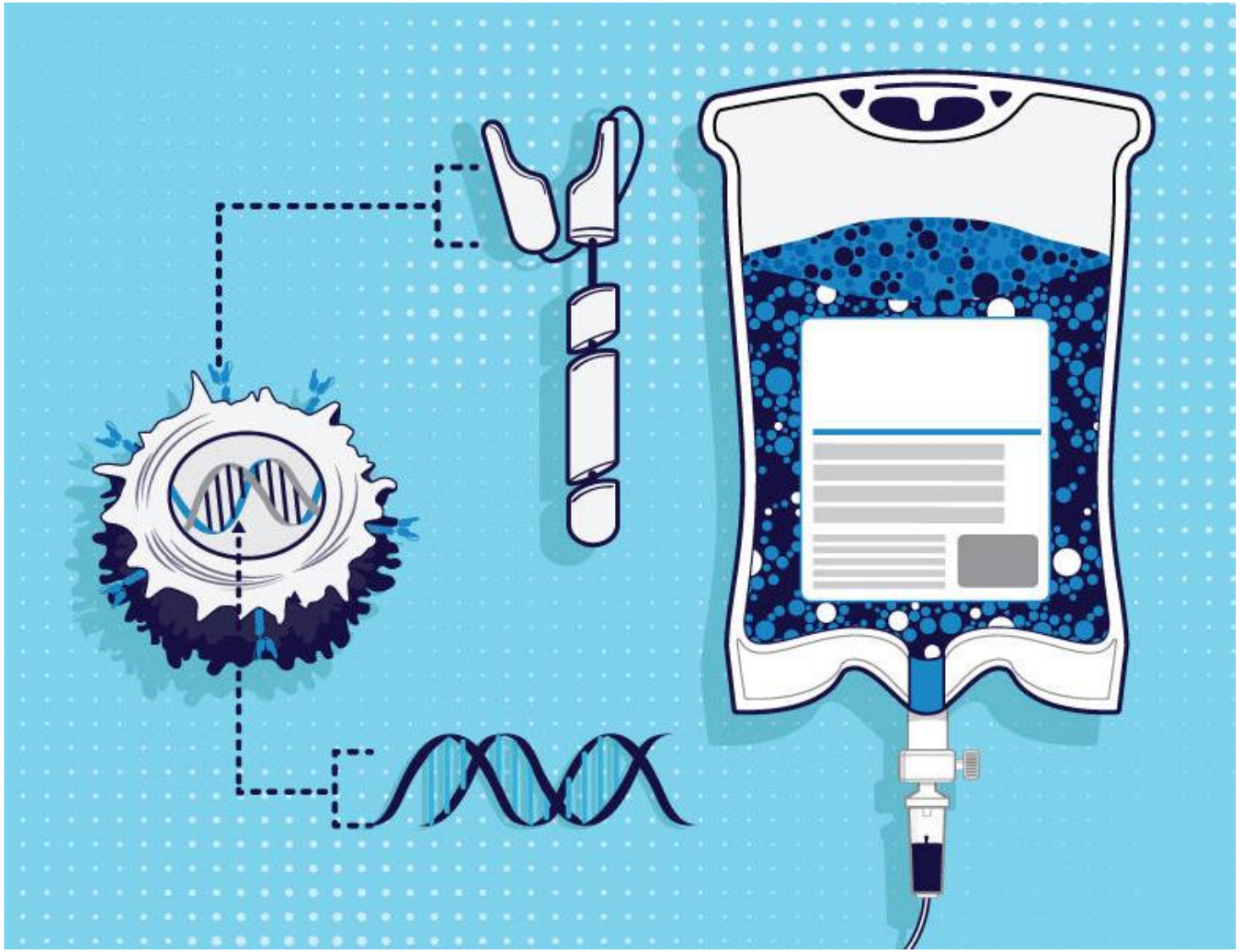
Step 5

The patient will remain inpatient to monitor for adverse effects

CAR-T Cell Therapy Treatment Process



CAR T-cell therapy (malaghan.org.nz) 2023



Leukapheresis Process

White blood cells that include T-cells are extracted through a process called apheresis

After apheresis, the T-cells are then sent to the manufacturer for modification

Average turnaround time:
17 to 22 days

Pre-Treatment

- Lymphodepleting chemotherapy is administered over 3-4 days
- Helps the body prepare for the modified CAR-T Cells
- In most circumstances it will be administered outpatient

CAR-T Therapy	Pre-Treatment: Lymphodepleting Chemotherapy
Yescarta (Axicabtagene ciloleucel)	• Cyclophosphamide 500mg/m^2 IV & Fludarabine 30mg/m^2 IV on the 5^{th}, 4^{th}, and 3^{rd} day before the infusion of Yescarta
Tecartus (Brexucabtagene autoleuce)	• Cyclophosphamide 500mg/m^2 IV & Fludarabine 30mg/m^2 IV on the 5^{th}, 4^{th}, and 3^{rd} day before the infusion of Tecartus
Kymriah (Tisagenlecleucel)	• Cyclophosphamide 250mg/m^2 IV + Fludarabine 25 mg/m^2 IV daily for 3 days • Alternative: Bendamustine 90 mg/m^2 IV daily for 2 days if patient experienced previous Grade 4 hemorrhagic cystitis with cyclophosphamide or demonstrates resistance to a previous cyclophosphamide containing regimen
Breyanzi (Lisocabtageene maraleucel)	• Cyclophosphamide 300mg/m^2 IV & Fludarabine 30mg/m^2 IV for 3 days
Abecma (Idecabtagene vicleucel)	• Cyclophosphamide 300mg/m^2 IV & Fludarabine 30mg/m^2 IV for 3 days
CARVYKTI (Ciltacabtagene autoleucel)	• Cyclophosphamide 300mg/m^2 IV & Fludarabine 30mg/m^2 IV for 3 days

CAR-T Cell Administration

Patient needs to be assessed by provider the morning of infusion for the following:

- Worsening leukemia burden (patients do not need to be in remission)
- Active, uncontrolled infection
- Active Graft Versus Host Disease
- Unresolved Significant Adverse Events from preceding chemotherapy

If any of these conditions exist, the infusion will be delayed!

CAR-T Cell Administration

Administration-Closely mirrors stem cell transplant administration

- After physician signs the order, nursing will communicate with stem cell lab and decide on infusion time (infusion time may be determined the day prior)
- Nursing will communicate predetermined time to pharmacy
- Pharmacist will arrive to BMTU with the medication label
- RN and Pharmacist will perform verification checks against MAR with product before and again after thaw, pharmacy then affixes label(s) to the product
- Please see unit specific Standard of Practice (SOP) 2200 for detailed instructions (on unit).

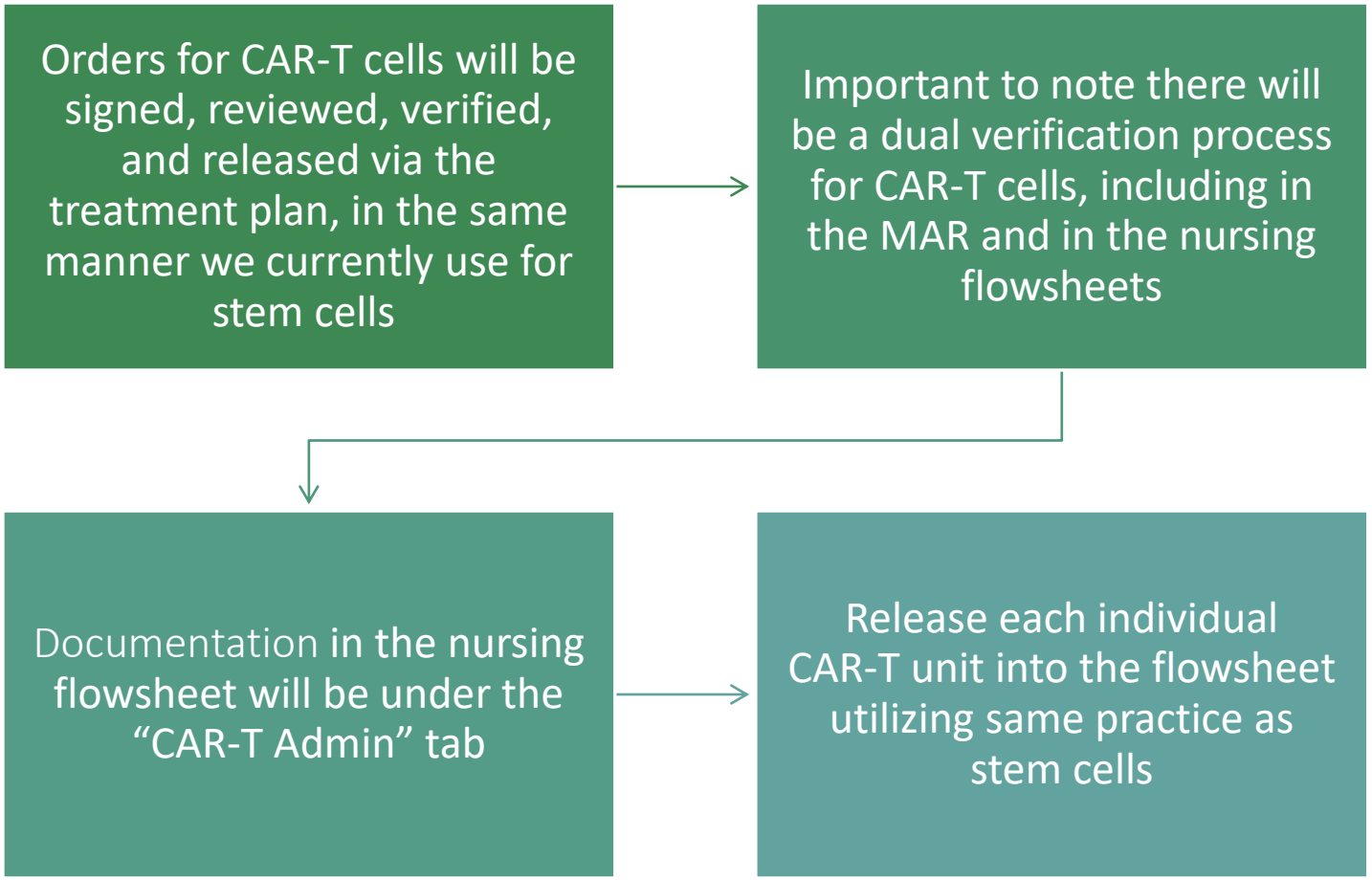
Do not use a leukocyte-depleting filter

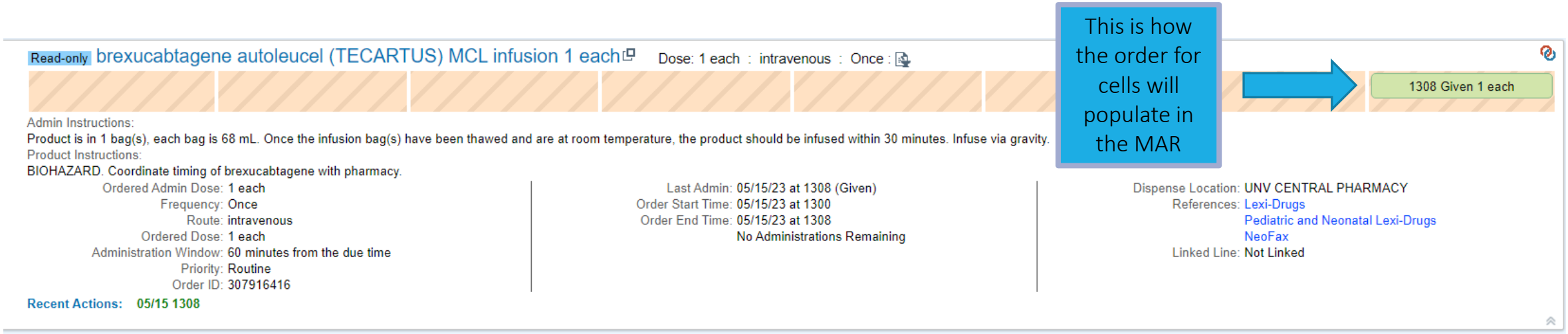
- Unless administering CARVYTKI

Product bag volume will range from 10mL-68mLs

Backflush to ensure all cells are given to the patient

CAR-T Cell Administration





This is how the order for cells will populate in the MAR

CAR-T Cell Administration

Administration is required in the MAR & allows for scanning of electronic RX label, however, full capabilities are limited, and nursing will have to manually enter the Donor Identification Numbers (DIN) or (JOIN) Number in the comment section.

- The DIN & JOIN Numbers are a unique identification code that is assigned to the patient's specific cellular material and is the link between the patient and their cells throughout the manufacturing process.

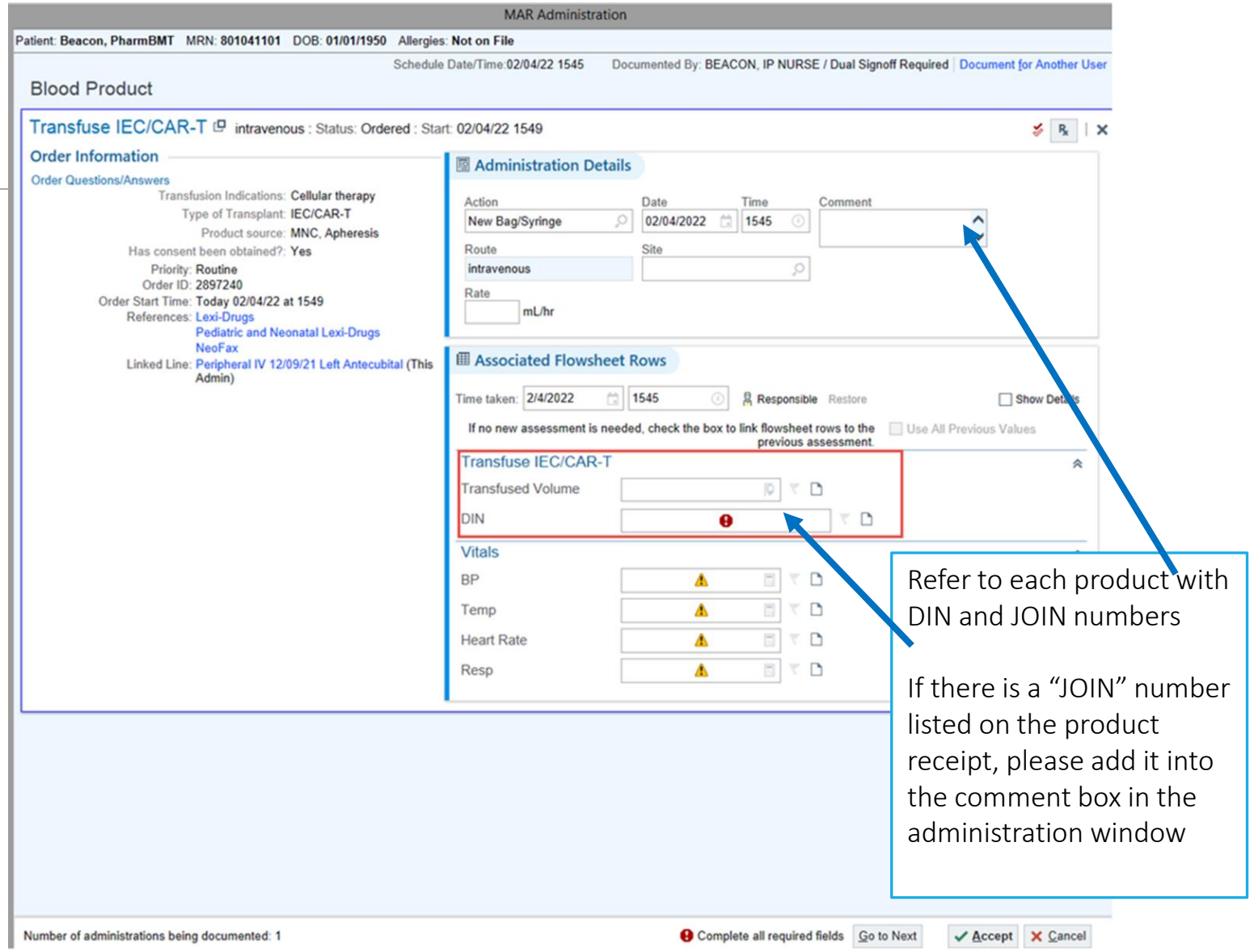
The administration instructions under the MAR will state the quantity of bags/syringes for infusion: There will only be one label to scan for all bags or syringes

Dual signoff by two cellular therapy trained RNs is required in both the MAR and flowsheet

Please see SOP #2200 for further administration guidelines

CAR-T Cell Administration

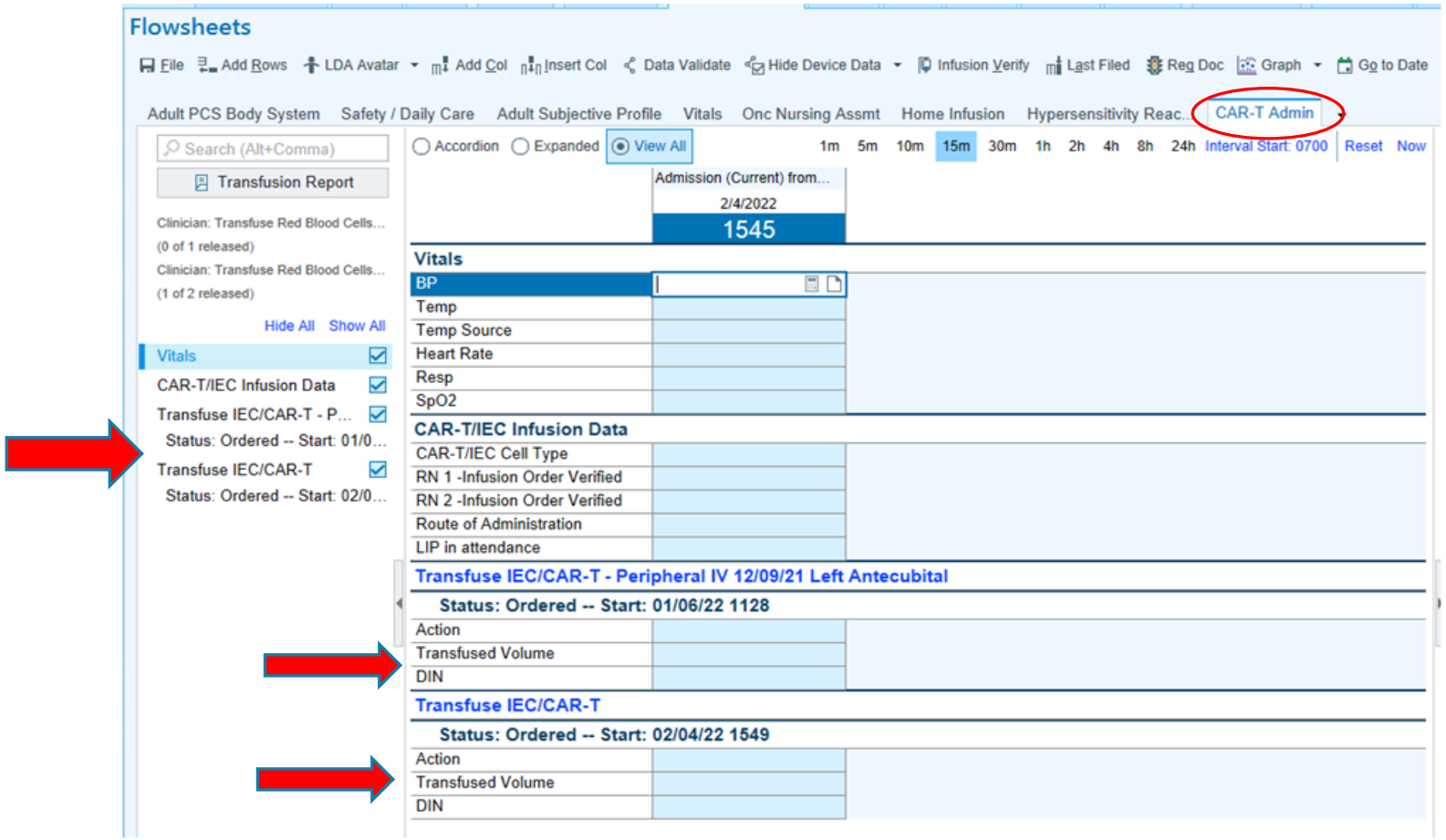
When you click on the Action Row, you will get the MAR Administration documentation screen, as seen here



CAR-T Cell Administration

Using the *CAR-T Admin* flowsheet:

The transfused volume and the DIN flowsheet rows cascade for each individual unit.



Nursing Responsibility in CAR T therapy

The patient's genetically modified cells are infused back into the patient. This requires close monitoring of vital signs and any other signs of infusion reaction. Refer to SOP 2200

Nursing interventions:

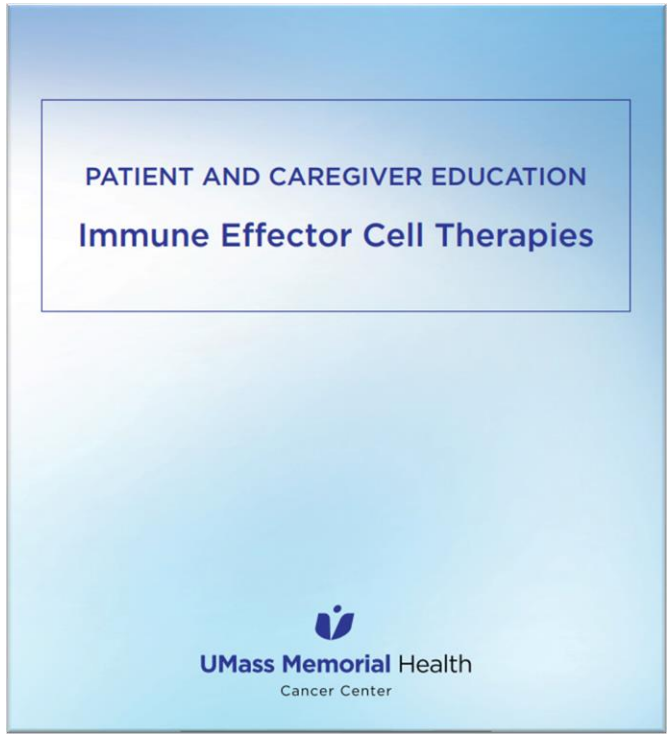
- Administer pre-medications as ordered
- Monitor for signs of infusion reaction and neurological changes

It is imperative to complete a neurologic assessment at baseline as neurotoxicity is a serious complication of this therapy

At discharge ensure patient has several frequent follow up visits scheduled with provider for close monitoring of complications

Patient education on potential side effects is extremely important in diagnosing early status changes that could prevent more serious complications

- Ensure education booklet has been provided to patient and family



What is the Risk Evaluation and Mitigation Strategy (REMS)

A program to manage known or potential serious risks associated with a specific drug product.

- BMTU Nurses follow their Standard of Practice (SOPs) of the unit which include Cytokine Release Syndrome (CRS) & Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) management along with the CAR-T Cell e-learning for oncology module for annual education on CRS & ICANs management
- 8 North Nurses only complete the CAR-T Cell e-learning for oncology module for annual education on CRS & ICANs management

REMS Training per the FDA is no longer required for each individual CAR-T product, as new products continue to be developed, training per institution is required to maintain competency on the risks of all CAR-T products

Annual training and competency in CRS & ICANS will continue to be required according to UMass SOPs using the UMass program guidelines regarding the assessment and management of CRS & ICANS

FDA Approved CAR-T Therapies

FDA Approved CAR-T Therapies & Clinical Indications:

- **Kymriah:** Relapsed/Refractory Large B-Cell Lymphomas, Follicular Lymphoma, B-Cell Acute Lymphoblastic Leukemia
- **Yescarta:** Relapsed/Refractory Large B-Cell Lymphomas
- **Tecartus:** Relapsed/Refractory Mantle Cell Lymphomas & B-Cell Acute Lymphoblastic Leukemia
- **Abecma:** Relapsed/Refractory Multiple Myeloma
- **Breyanzi:** Relapsed/Refractory Large B-Cell Lymphomas, Follicular Lymphoma, Mantle Cell Lymphomas , Chronic Lymphocytic Leukemia or Small Lymphocytic Leukemia
- **Carvykti:** Relapsed/Refractory Multiple Myeloma

Bi-Specific T-cell Engager Therapies (BiTE)

FDA Approved BiTE Therapies & Clinical Indications :

- **Blincyto:** R/R Philadelphia + B cell ALL
- **Tecvayli:** R/R Multiple Myeloma
- **Epkinly:** R/R DLBCL
- **Talvey:** R/R Multiple Myeloma who have received at least 4 lines of therapy
- **Glofitamab:** R/R DLBCL

These are Immuno-Oncology therapies that engage the immune system to treat cancer

BiTE therapies are a targeted immuno-oncology platform that connects the patient's own T cells to malignant cells

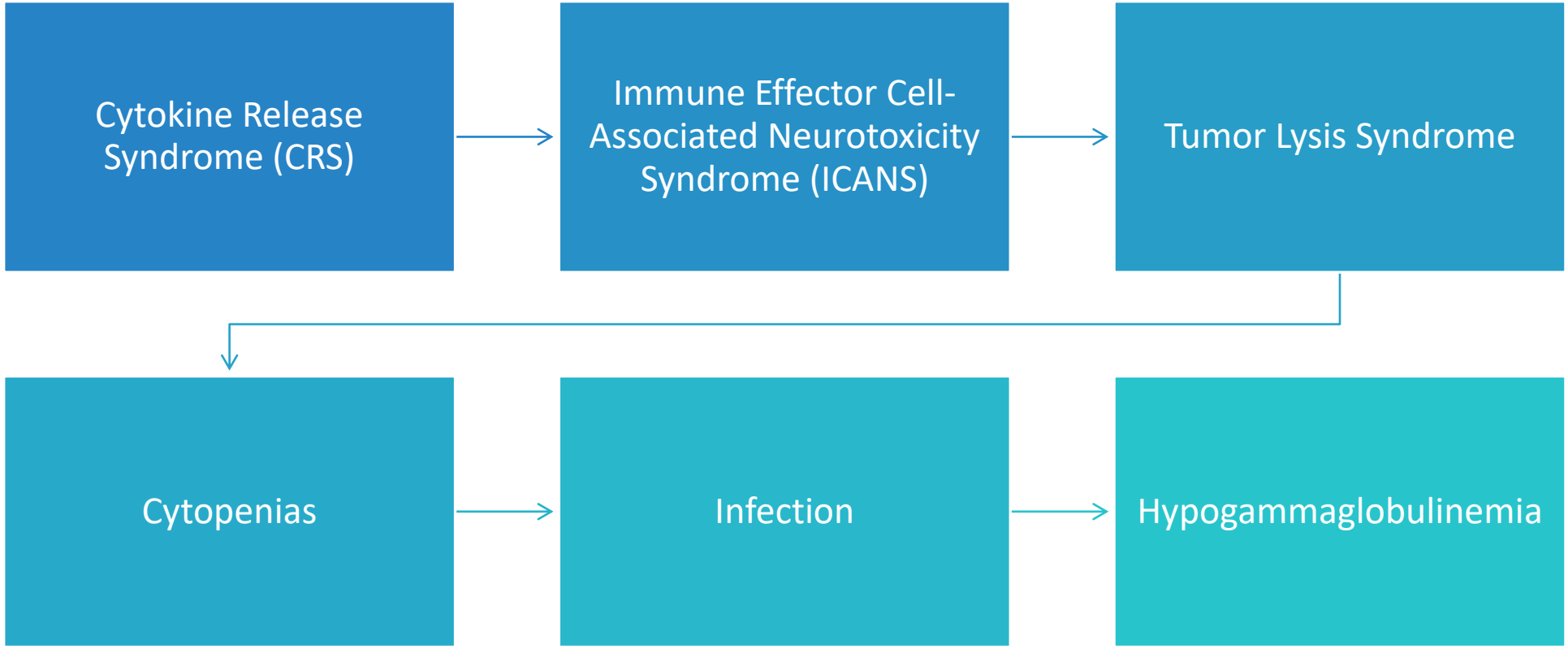
Non-Oncologic Indications for CAR-T Therapy

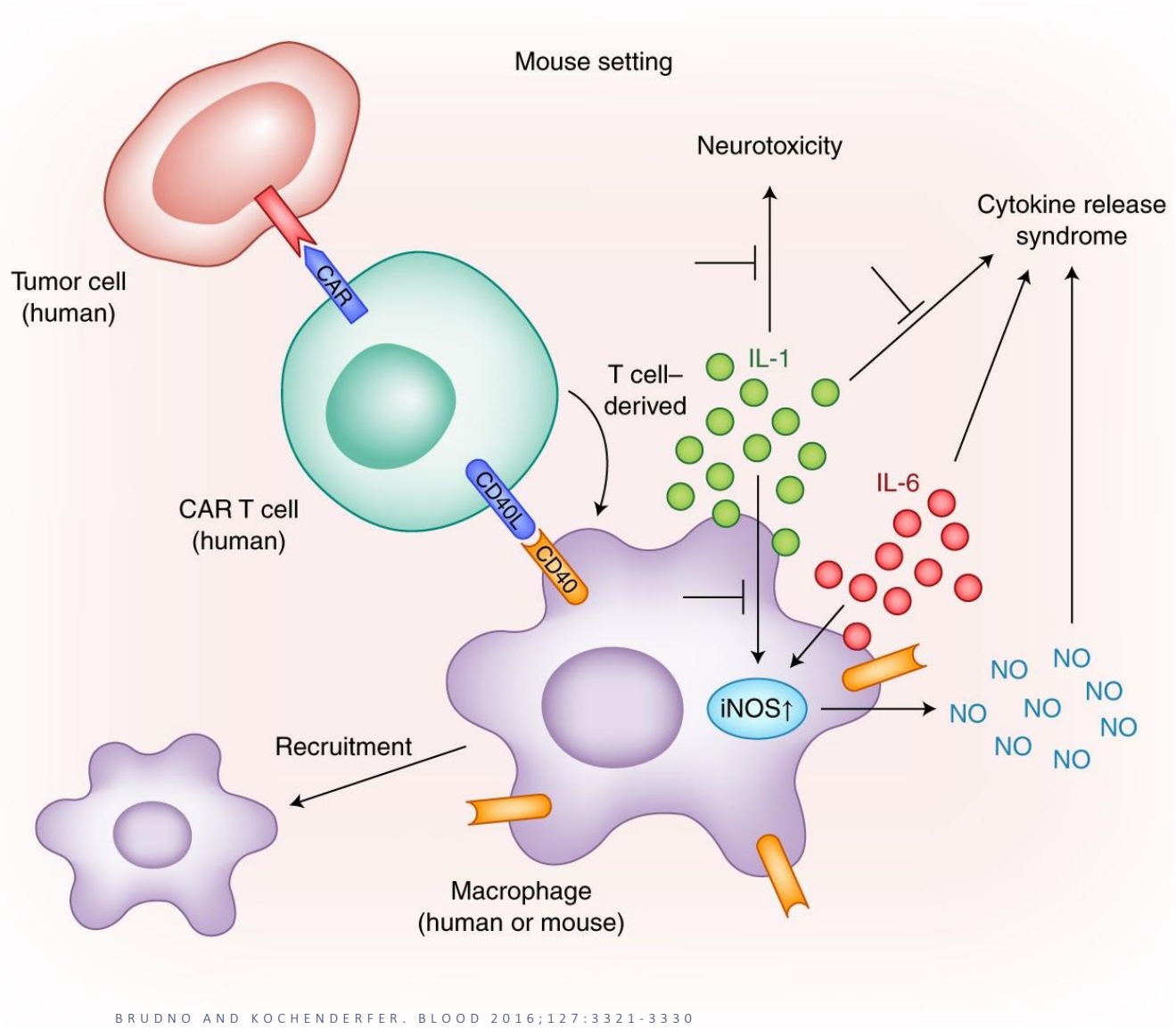
An Example of a Current Trial offered at UMass:

Phase 1 Open Label Multicenter Study of KYV-101 Autologous Fully Human Anti-CD19

- Designed to change the paradigm in the treatment of patients with B-cell driven autoimmune diseases. Trials have shown KYV-101 to induce deep and complete B-cell depletion
- Current existing approaches to address B-cell driven autoimmune diseases are often limited by modest effects leading to resistant and uncontrolled disease and or treatment related morbidity and mortality
- KYV-101works by attacking B cells including unhealthy B cells with the goal of helping to control reduce or reverse the disease
    - The aim is for the body to replenish with its own healthy B cells

CAR-T Cell Therapy Associated Toxicities:





BRUDNO AND KOCHENDERFER. BLOOD 2016;127:3321-3330

THE PATHOPHYSIOLOGY BEHIND:

CYTOKINE RELEASE SYNDROME (CRS)

Cytokine Release Syndrome (CRS)

Cytokine release syndrome is a response following any immune therapy that results in the activation or engagement of endogenous or infused T cells and/or other immune effector cells

Symptoms can be progressive, and include

Signs & Symptoms of CRS

Fever
Arthralgia/myalgias
Malaise
Rigors
Hypotension
Respiratory failure
Capillary leak
Tachycardia
Organ dysfunction (renal/liver failure)
Elevated CRP
Hypoxia

CRS Associated Events and Organ Dysfunction

Liver-Hepatic Dysfunction: Elevated ALT, AST and hyperbilirubinemia

Renal-Renal insufficiency

Respiratory-Respiratory failure, pulmonary edema

Cardiac-Transient cardiac insufficiency, transient arrhythmia

Cytopenia's-Last > 28 days. NO granulocyte macrophage colony-stimulating factor (GM-CSF) during the first 3 weeks following infusion as it may exacerbate CRS

Coagulopathy with hypofibrinogenemia-May accompany severe CRS

Characterized by prolonged PT/PTT, low fibrinogen, and may result in bleeding

CRS Assessment

Nursing will complete assessments for both CRS and ICANS starting on the day of infusion, twice daily or more frequently as indicated by patient's clinical status

- Flowsheets will be found under "Neurotoxicity/CRS Assessment"
- **CRS/ICANS UMASS Guidelines**
- Please refer to **SOP 2108-Immune Effector Cell Assessment and Management**

Immediately contact physician for any changes

Management based on clinical presentation

CRS mostly occurs within 2 weeks of the infusion

Can happen up to 4 weeks after infusion

Educate patients to seek immediate medical attention with any signs or symptoms of CRS

Evaluate and treat for other causes of fever or hypoxia

- Other causes of systemic inflammatory response should be ruled out including infection and malignancy progression
- Empiric treatment for infection is warranted in the neutropenic patient

CRS Grading

CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever[2]	Temperature ≥ 38°C	Temperature ≥ 38°C	Temperature ≥ 38°C	Temperature ≥ 38°C
with				
Hypotension[3]	None	Not requiring vasopressors	Requiring a vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
and/or[4]				
Hypoxia	None	Requiring low-flow[5] nasal cannula or blow-by	Requiring high-flow[6] nasal cannula, facemask, nonrebreather mask, or Venturi mask	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)

[1]Organ toxicity associated with CRS may be graded according to CTCAE v5.0 but they do not influence CRS grading
[2]Fever is defined as temperature ≥ 38°C not attributable to any other cause. In patients who have CRS then receive antipyretics or anti-cytokine therapy such as tocilizumab or steroids, fever is no longer required to grade subsequent CRS severity. In this case, CRS grading is driven by hypotension and/or hypoxia.
[3]CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause. For example, a patient with temperature of 39.5°C, hypotension requiring one vasopressor and hypoxia requiring low-flow nasal cannula is classified as having Grade 3 CRS.
[4]CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause.
[5]Low-flow nasal cannula is defined as oxygen delivered at <6 L/minute. Low-flow also includes blow-by oxygen delivery, sometimes used in pediatrics.
[6]High-flow nasal cannula is defined as oxygen delivered at >6 L/minute.

ASTCT = American Society for Transplantation and Cellular Therapy
CPAP = continuous positive airway pressure
BiPAP = bilevel positive airway pressure

CRS Management

- Onset average is 2-3 days after infusion with a typical duration of 7-8 days.
- Most common adverse event reported in clinical trials.
- CRS can be effectively managed when care based on CRS guidelines, including assessment, grading and interventions

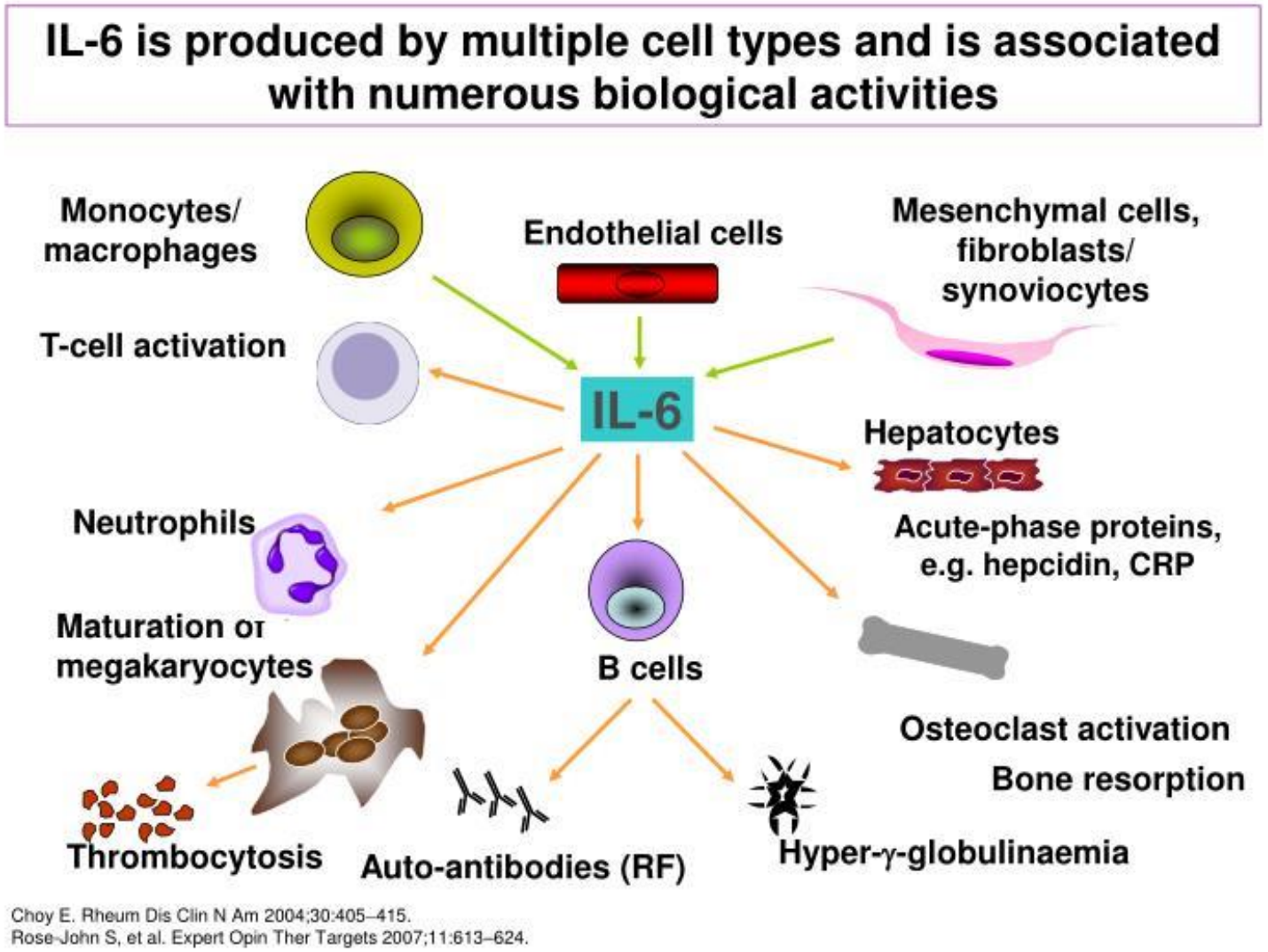
- Risk factors for severe CRS for the ALL indication (not identified for DLBCL indication)
  - Pre-infusion tumor burden
  - Infection
  - Early onset of Fever
  - Active Inflammatory processes

- Early symptoms include *fever, hypoxia, and headache.*
- Worsening symptoms include need for oxygen support, pressors, intubation.

CRS Management:

Medication Interventions

- **Tocilizumab 8 mg/kg IV**
- **Anakinra 100 mg daily or q12h IV/SQ (high dose) 8mg/kg/day IV-**Recommended in patients with suboptimal response to tocilizumab
- **Corticosteroids:** All Steroids must be approved or authorized by an attending physician before administration
  - Dosing is dependent on severity: Dosing may include Dexamethasone 10-20mg & Methylprednisone 1000 mg/day in divided doses IV for 3 days



Tocilizumab

Tocilizumab is used as the frontline treatment for Cytokine Release Syndrome

Interleukin-6 (IL-6) receptor antagonist

Indication: Adults and pediatric patients 2 years of age and older with CAR-T Cell induced grade 1 –grade 4 cytokine release syndrome

Typical IV dosage:

Patients less than 30 kg: 12 mg/kg

Patients at or above 30 kg: 8 mg/kg

Maximum dose: 800 mg per dose

Tocilizumab

Clinical response usually seen within 4 hours

Dose may be repeated every 8 hours for up to three doses in a 24 hour period

Maximum of 4 doses total over the entire course of CRS

Can be given alone or in combination with corticosteroids

Centers that administer CAR-T Cell are **required** to have at least 2 doses available per patient (this is verified prior to CAR-T administration)

Most common adverse reactions (incidence of at least 5%): upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, injection site reactions

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

Immune effector cell associated neurotoxicity syndrome is a disorder characterized by a pathologic process involving the central nervous system following any immune therapy that results in activation or engagement of endogenous or infused T cells and/or other immune effector cells.

Symptoms or signs can be progressive and may include

Signs & Symptoms of ICANS

Headache
Delirium
Altered Mental Status
Encephalopathy
Aphasia
Lethargy
Difficulty concentrating
Agitation
Tremor
Seizures
Cerebral edema (rare)

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

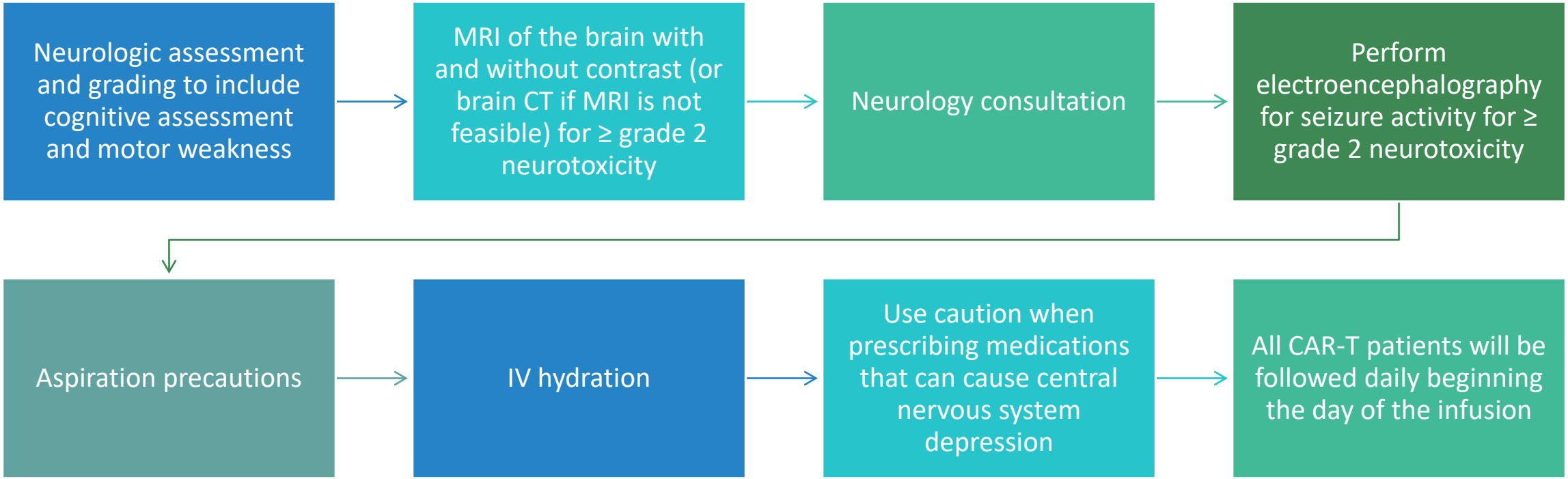
- Not well understood, but may be due to CAR-T cells in the CSF
- Onset average is 4-10 days post infusion
- Typical duration is 14-17 days
- Early toxicity can occur concurrently with CRS and high fevers, encephalopathy
- Affects up to 50% of patients
- Typically presents with delayed onset as CRS is resolving
- Majority occurred within 8 weeks following infusion, majority of events were transient

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

Clinical Presentation: Anxiety, dizziness, headache, peripheral neuropathy, aphasia, seizures, mutism, encephalopathy, delirium, impaired handwriting, agitation, somnolence

Interventions: Follow ICANS guidelines for assessment, grading and interventions, including steroids as ordered, and supportive care

Example of Neurologic Toxicity



ICANS Assessment and Management

ICANS Grading

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE Score[2]	7-9	3-6	0-2[3]	0[3] (patient is unarousable and unable to perform ICE)
Depressed level of consciousness[4]	Awakes spontaneously	Awakes to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse. Stupor or coma.
Seizure	N/A	N/A	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizure on EEG that resolve with intervention	Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between
Motor findings[5]	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Elevated intracranial pressure[6] **/ cerebral edema**	N/A	N/A	Focal/local edema on neuroimaging[7]	Diffuse cerebral edema on neuroimaging; Decerebrate or decorticate posturing; or Cranial nerve VI palsy; or Papilledema; or Cushing's triad

[1]ICANS grade is determined by the most severe event (ICE score, level of consciousness, seizure, motor findings, raised ICP/cerebral edema) not attributable to any other cause; for example, a patient with ICE score of 3 who has a generalized seizure is classified as grade 3 ICANS.
[2]See Chart 3 for ICE Scoring
[3]A patient with an ICE score of 0 may be classified as grade 3 ICANS if awake with global aphasia, but a patient with an ICE score of 0 may be classified as grade 4 ICANS if unarousable.
[4]Depressed level of consciousness should be attributable to no other cause (eg, no sedating medication).
[5]Tremors and myoclonus associated with immune effector cell therapies may be graded according to CTCAE v5.0, but they do not influence ICANS grading.
[6]Opthamology may be consulted to assess for papilledema if concern for elevated ICP, but otherwise not needed for all patients
[7]Intracranial hemorrhage with or without associated edema is not considered a neurotoxicity feature and is excluded from ICANS grading. It may be graded according to CTCAE v5.0.

Documenting Nursing Assessment for CRS & ICANS

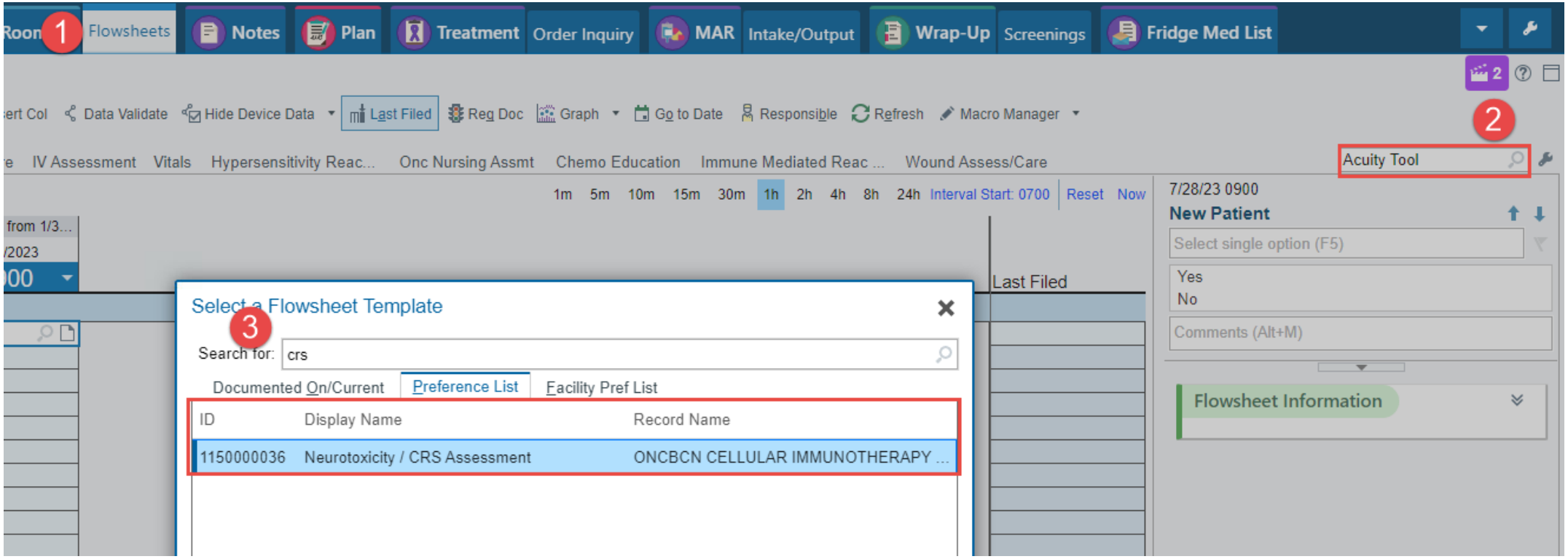
The RN is responsible for documenting each individual assessment twice daily, or once per shift

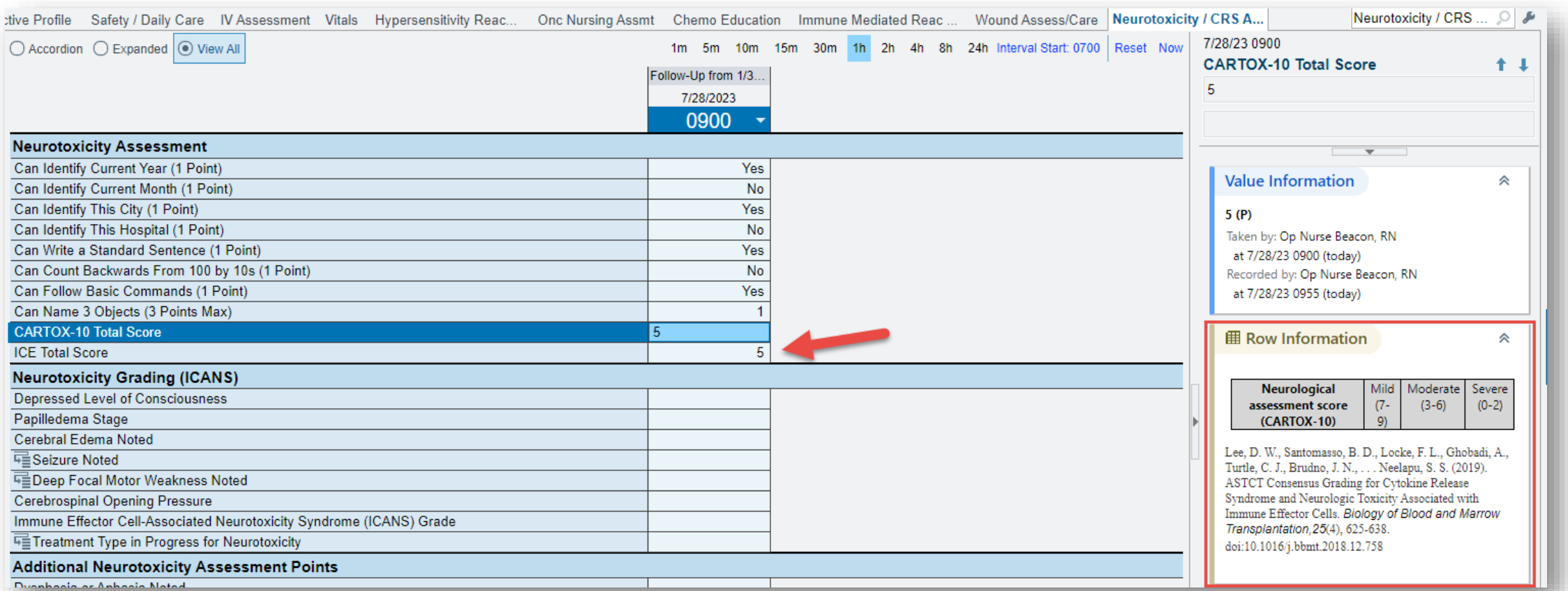
If change in clinical status, the RN will reassess and document more frequently

Each flowsheet has a cascading list of assessment questions

Documenting Nursing Assessment for CRS & ICANS

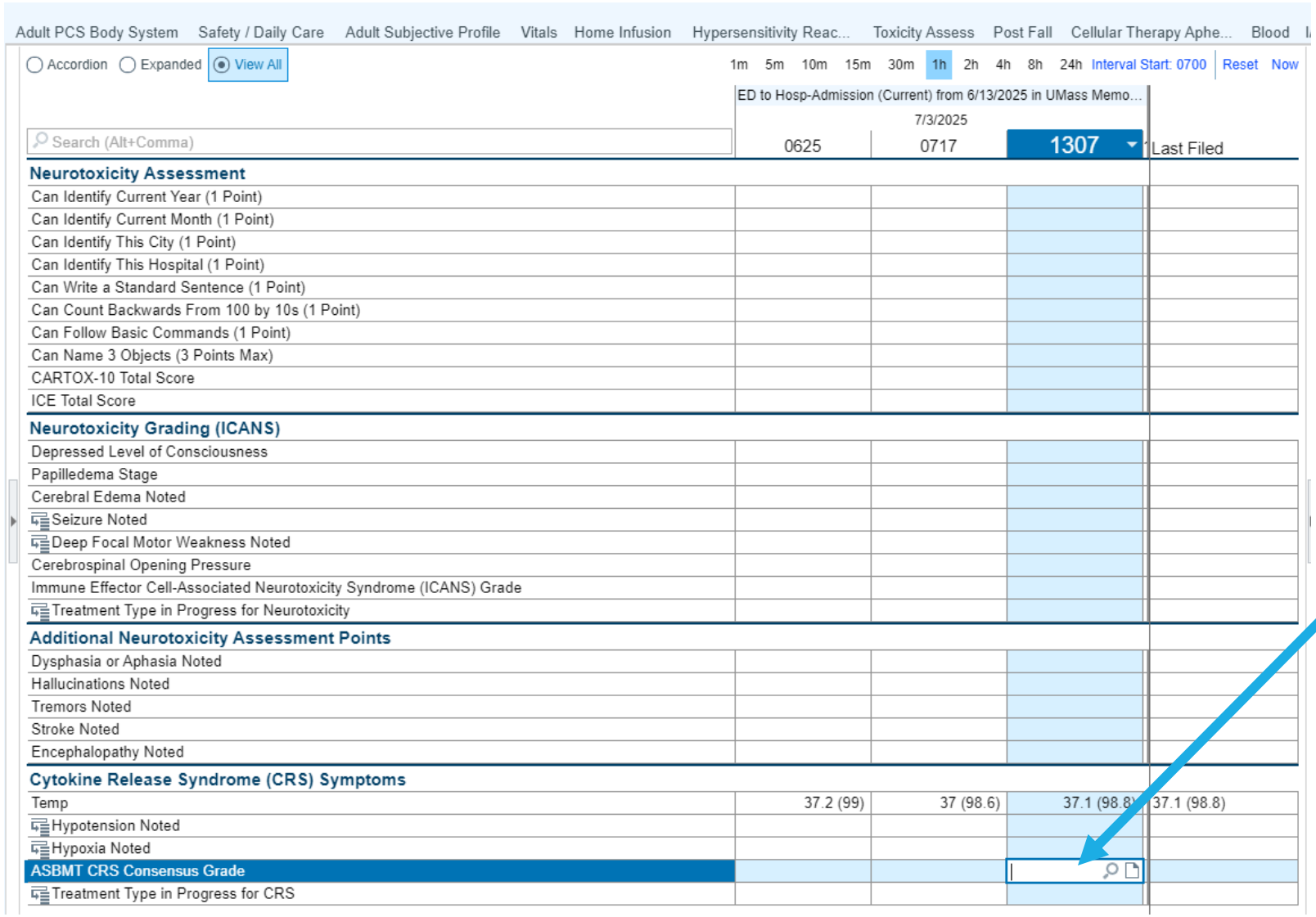
CRS & ICANS nursing assessments are found in the Flowsheet tab – type in “CRS”





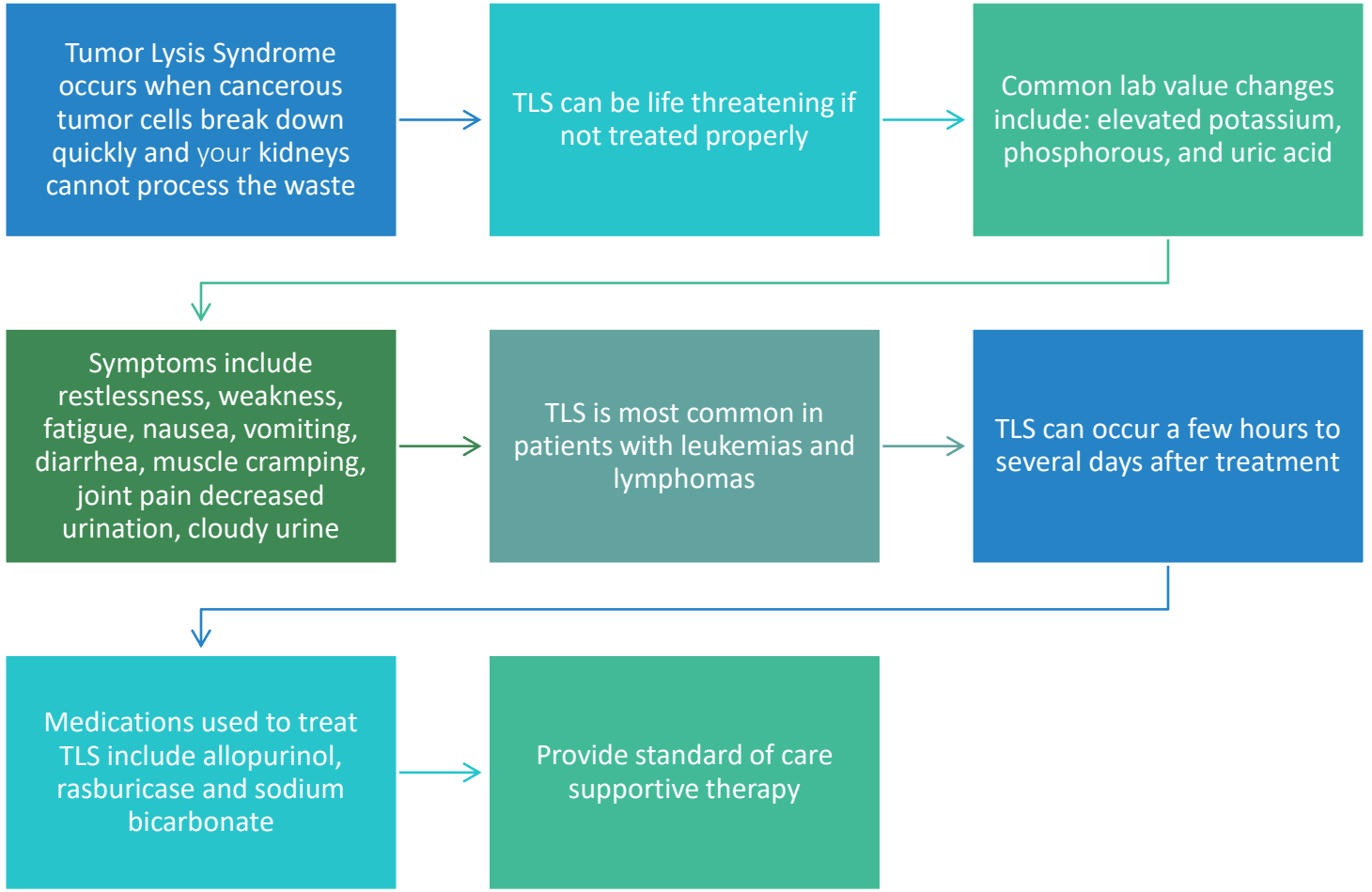
ICANS Documentation

- Assessment and grading of ICANS should be completed twice daily and with any change in condition
- If patient develops ICANS, notify provider and withhold oral intake of food, fluids, and medicine



CRS Documentation

Assessment and grading of CRS should be twice daily and *whenever* there is a change in patient status



Tumor Lysis Syndrome (TLS)

Cytopenias

May persist several weeks following therapy

Neutropenia is most common, leaving patients vulnerable to opportunistic infections

Monitor blood counts after infusion

Caused by:

- Conditioning chemo regimen
- CRS
- Prior exposure to multiple lines of therapy

Maintain neutropenic precautions

Supportive transfusions as needed

Examples of cytopenias:

- White Blood cells (WBC) < 3.8 (10*3uL)
  - Neutropenic < 1000 mm3
- Red Blood cells (RBC) < 4.20 (10*6/uL)
- Platelets (PLT) < 140 (10*3uL)

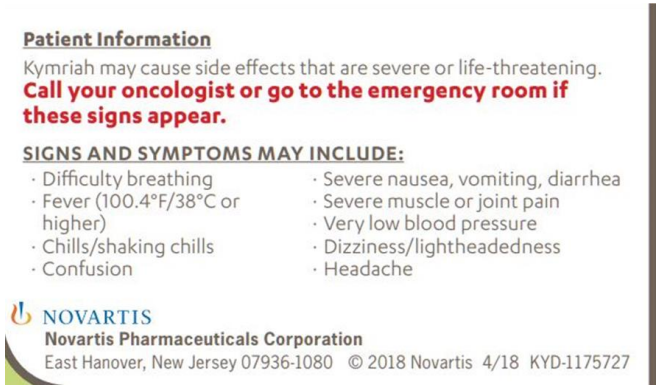
Key Take-Aways

- Assess for and identify toxicities
- Be familiar with best practices for management and recognize that best practices for management continue to change as new evidence emerges
- Educate patient and family about signs and symptoms of toxicities
- Reinforce patient and family members 24-hour triage process and when to seek medical attention
  - Wallet cards – The coordinators will provide the wallet cards to the patient prior to admission
  - Patient education book

PATIENT WALLET CARD

Have This Card With You At All Times
Show It To Any Doctor That Sees You And When You Go To The Hospital

You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting Kymriah. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.



Patient Information

Kymriah may cause side effects that are severe or life-threatening.
Call your oncologist or go to the emergency room if these signs appear.

SIGNS AND SYMPTOMS MAY INCLUDE:

- Difficulty breathing
- Fever (100.4°F/38°C or higher)
- Chills/shaking chills
- Confusion
- Severe nausea, vomiting, diarrhea
- Severe muscle or joint pain
- Very low blood pressure
- Dizziness/lightheadedness
- Headache

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References

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UMass Memorial Medical Center
Department of Nursing

PROCEDURE

Procedure Name: Care of the Neutropenic Oncology Patient **Approved: Sept 2024**
Effective: Sept 2024

I. PURPOSE:
To provide guidance to safely care for neutropenic oncology patients.

II. SCOPE:
This procedure applies to all nursing staff caring for neutropenic oncology patients

III. RELATED DOCUMENTS:
Policy 5009 Hand Hygiene
Policy 5003 Isolation Program
Policy 5001 Cleaning, Disinfection, Sterilization and Storage of Reusable Patient Care Equipment
Medication Administration
BMTU-SOP 0305 Infection Control

IV. PROCEDURE:
- Neutropenic precautions are instituted when the ANC (absolute neutrophil count) is 1000/mm³ or less, or by provider order.
- Any new temperature of 38°C or 100.4°F in a neutropenic oncology patient is to be reported promptly to the Physician/Advanced Practice Provider (APP) and is treated as a neutropenic fever.
- Patients/families are educated about neutropenia and neutropenic precautions and are provided with education materials.
- **Neutropenic Precautions:**

Inpatient/admitted patients:

A) Private room with neutropenic precautions door sign.

B) All hematopoietic stem cell transplant/Immune Effector Cell Therapies patients shall be placed in a positive pressure room on the Oncology/BMT unit.

C) Patients should be placed on Neutropenic/Immunocompromised diet per provider discretion.

C) No fresh or dried flowers or plants in patient rooms.

All patient care areas:

A) Meticulous hand hygiene by all (Refer to Hand Hygiene).

B) Avoid crowded areas, avoid sitting in waiting rooms, avoid contact with potentially infectious individuals or those that have received any "live" vaccinations in the past 30 days.

C) Monitor vital signs as ordered, with each ambulatory care visit, and PRN.
D) Assess and document each body system and any venous access device sites or other devices present for signs/symptoms of infection every shift/ambulatory visit and PRN.
E) Notify Independent Provider or Advanced Practice Provider (IP/APP) of any significant changes in blood pressure or a temperature elevation above 38°C (100.4°F).
F) Avoid activities that may compromise skin integrity.
G) Encourage frequent oral care (3-4 times/day) and inspect oral mucosa, and document.
H) Encourage maintenance of meticulous personal hygiene and perineal care.
I) Avoid patient use of rectal medications, temperatures, examinations and/or enemas.
J) Avoid IM/Deep SC injections when possible.
K) Instruct patient to avoid:
- Use of female internal hygiene products
- Sexual intercourse until ANC greater than 1500/mm³ or platelet count greater than 50,000

L) Provide ongoing patient/family education:
- Neutropenia.
- Risk of infection.
- Use of antibiotics and granulocyte stimulating colony factor (G-CSF) as appropriate.
- Discussion of positive patient outcomes/goals of treatment.
- Avoid/limit direct care of animals and animal feces.

- Antibiotics for neutropenic patients are time critical medications. (Refer to Medication Administration
  - Blood cultures should be discussed prior to antibiotic administration when patient is febrile (38 or higher)

6. Do NOT administer live vaccinations.

V. RESCISSION:

Care of the Neutropenic Oncology Patient Procedure September 2021

VI. REFERENCE:

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VII. MONITORING:

The Nursing Policy Committee is responsible for monitoring this procedure

Keywords: neutropenia, neutropenic, precautions, fever, oncology, ANC

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UMass Memorial Medical Center
Department of Nursing

PROCEDURE

Procedure Name: Chemotherapy/Immunotherapy Administration Procedure

Approved: June 2024
Effective: June 2024

I. PURPOSE:

To define the standard procedure for the safe administration of chemotherapeutic/immunotherapeutic agents to all adult and pediatric patients at UMMMC.

II. SCOPE:

This procedure applies to all chemotherapy competent Registered Nurses (chemo RN) who administer chemotherapy/immunotherapy and to all Registered Nurses (RN) who care for these patients during or after administration.

III. RELATED DOCUMENTS:

Policy 2003 – Safe Handling of Hazardous Drugs
Policy 2004 – Chemotherapy Biotherapy Management
Patient Education Documentation Policy
Policy 2226 – Management of High Risk-High Alert Medications
Chemotherapy/Hazardous Drug Spill Clean Up Procedure
Chemo Extravasation Nursing Procedure
Intravesicular Administration of Hazardous Drugs Procedure
Hazardous Drug (HD) Instillation and Disposal in the Operating Room
Medication Administration
Universal Protocol
Policy 2218 Triage and treatment of Medical Emergencies
Informed Consent
Treatment and Procedure Consent Form
Independent Verification with Double Signature for High-Risk High Alert Medication Procedure
pgs. 370-397 Chemotherapy/Immunotherapy Guidelines, ONS, 2023

IV. PROCEDURE:

A. Critical Elements

1. Intravenous infusions of Chemotherapy/Immunotherapy are administered via a peripheral intravenous catheter (PIV) or central venous access device (VAD) which has brisk blood preferred no signs or symptoms of phlebitis or infection and is of an adequate gauge for administration of the ordered medications.
2. Central Venous Access Device (Central VAD) (Port-a-Cath, Peripherally Inserted Central Catheter or similar) are:
    a. Required for all continuous chemotherapy/immunotherapy infusions equal to or greater than 12 hours in duration.
    b. Recommended for all irritant infusions.
3. Blood return is verified and documented prior to and following all intravenous chemotherapy/immunotherapy infusions and during infusions greater than two (2) hours in duration.
4. Peripheral intravenous access sites (IV sites):
    a. Are less than 24 hours old for administration of non-vesicant chemotherapy/immunotherapy.
    i. If no blood return is noted with no signs and symptoms of phlebitis, obtain MD order - ok to utilize IV for non-vesicant administration.
    b. A new peripheral IV is placed for administration of vesicants.
    c. Use of the following sites is not recommended for vesicant administration:
        i. Ventral surface of hand
        ii. Joints and areas near joints
        iii. Antecubital fossa
        iv. Lower extremities
        v. Areas distal to a recent venipuncture, including laboratory draws.
        vi. Areas of impaired circulation or lymph node drainage
        vii. Areas with decreased sensation (e.g. peripheral neuropathy)
    d. Midlines:
        i. No chemotherapy administration via midlines.
    ii. Midlines can be utilized for Immunotherapy administration.
5. Intravenous chemotherapy/immunotherapy infusions are run on IV pumps using the pre-programmed medication library, when available, except for peripheral vesicant infusions less than 30 minutes in duration.
6. The nurse is aware of the drug specific safety considerations for chemotherapy/ immunotherapy they are administering.
7. The Chemo RN assesses and documents comprehension of education to the patient about infusion related complications, prior to administration of the medication.
8. Chemotherapy/immunotherapy treatment plans are verified, released, and administered by a Chemo RN.
9. Oral chemotherapy administration requires independent verification and dual sign off.
    a. Standard (non-chemotherapy competent) RNs are allowed to administer.
    and cosign - refer to policy 2004.
10. Patients receiving infusions of chemotherapy/immunotherapy across shift changes have RN hand-off that includes chairside/bedside verification by both RNs of medication, IV access, rate, and remaining volume.

11. Closed system transfer devices (CSTD) are used wherever available.
    a. When making luer lock connections without a CSTD, a 2x2 sterile gauze is used around the connection and a plastic backed pad is placed under the connection point to minimize exposure.

B. Prior to IV Administration

1. The chemo RN reviews the most recent clinic or progress note by the Oncology provider to understand diagnosis, staging and treatment plan.
2. Complete and document an appropriate patient assessment.
3. Review vital signs.
4. Open treatment plan and:
    a. Review the signed consent form, ensuring all required elements are present per Policy 2004: Chemotherapy, Immunotherapy, and Biotherapy Management
        i) Refer to Policy 2004 Appendix A: 2004 Appendix A – Chemotherapy Cosignature and Consent Requirements
    b. Review the treatment plan against a validated source document (protocol builder template, COG protocol, NCCN template, research protocol) or published reference to:
        i) Confirm regimen/protocol is appropriate regimen for disease.
            1. When regimens are combined or adapted, review note from attending provider for rationale.
        ii) Confirm dosing and interval are appropriate and evidence based.
    c. Review the height/weight/BSA/Area Under the Curve (AUC) values, as appropriate; the **initial height/weight for treatment is performed with a chemo RN present, per the Independent Verification with Double Signature for High Risk High Alert Medication Procedure**
        i) Compare the values assigned to the treatment plan against the current day values.
        ii) When there is a greater than 5% difference in BSA calculation or a greater than 10% difference in weight (based on what is being used to calculate the dose) between the treatment plan height/weight and the current day measurements-the chemo RN notifies the ordering provider.
        iii) The provider can modify the dose using the current, up to date height and weight, or the provider or nurse **using an verbal order mode of cosign required**) can enter a nursing communication order into the medical record indicating "Okay to treat using prior height/weight from date"

        iv. For any parameters the patient does not meet, a nursing communication order needs to be placed by the provider or nurse with a verbal order from provider.
    d. Medication dosages based on AUC calculations are based on creatinine values up to fourteen (14) days old and weight up to five (5) weeks old.
    e. If updated labs are ordered, wait for the Creatinine to result before releasing the Treatment Plan – this will allow the dose to recalculate with the most up to date lab values.

f. If the updated values result in greater than a 10% dose change, the medication will be flagged in the treatment plan and the Chemo RN will notify the provider. The provider can update the dosage or notify the RN to enter a Nursing Communication order to proceed with the originally calculated dose.
g. Compare dosing to prior cycles, if applicable
    i) Verify drug name, dose, and calculations.
    ii) Verify route and rate of administration
    iii) Confirm appropriate intravenous access is in place, if required
    iv) Confirm treatment day and cycle number are accurate

5. Complete documentation of pre-chemo checklist in medical record.
6. Upon completion of above steps, the administering chemo RN releases the treatment plan: this serves as notification to pharmacy of nursing approval to proceed with verification and preparation of medications.
    a. Per Oncology Pharmacy Chemotherapy Compounding Times and Deadlines
        i. Nursing notification cutoff is 2:00 pm.
        ii. Inpatient chemotherapy signed, and release cutoff is 4:00 pm.
        iii. Chemotherapy orders for inpatient need to be compounded by 4:30 pm.
        iv. Any chemotherapy given off hours are to be for emergent circumstances.
7. Ensure appropriate equipment/PPE is accessible, see Policy 2003: Safe Handling of Hazardous Drugs (HD's) for further clarification.
    a. Chemotherapy spill kit
        i) Impervious gown, chemotherapy appropriate gloves, mask and/or face shield, as appropriate
        ii) Yellow hazardous waste disposal bin
8. Provide education to the patient and assess comprehension of learning of:
    a. Medications ordered
    b. Potential short- and long-term side effects
    c. Potential infusion related complications
    d. Toxicities
    e. Toxicities management
    f. When to call the provider/nurse
    g. Hazardous drug waste precautions for patient and family
    h. Follow up care and schedule
    i. Discharge instructions
    j. Line care, if applicable
9. Administer pre-medications and/or hydration, as ordered in the treatment plan

C. IV Administration

1. Perform hand hygiene
2. Don appropriate personal protective equipment (PPE) when administering medications declared as **hazardous**, see Policy 2003: Safe Handling of Hazardous Drugs (HD's) for additional details
3. Policy 2226: Management of High-Risk Alert Medications applies here. Just prior to administration of the chemotherapy/immunotherapy medications, **two (2) Chemo RN's independently, without involvement of one another, verify the prepared medication label against the medical record to confirm the following:**

a. Patient identified correctly, using two (2) hospital approved identifiers and participation of the patient or proxy, wherever possible.
b. Drug name and dose are correct
c. Diluent is correct and in line filters applied to tubing as appropriate
d. Volume is stated and appears correct (verified in syringe form)
e. Rate (as applicable) and route of administration is stated and correct
f. Expiration date and time are stated (administration must be completed within this time frame)
g. Appearance and physical integrity of medications and infusion set is appropriate
h. Two pharmacy initials present on the medication label
i. Visually verify the infusion pump rate is set correctly, per the orders

4. The workflow used will be:
    a. The administering RN brings the medication into the room
    b. Scan the patient's wristband barcode and verify information is correct
    c. Scan the medication barcode, verifying information is correct
    d. Hang the medication bag and set the pump rate (when applicable), but do not connect the infusion to the patient and leave pump on "hold" mode
    e. After verifying all components listed above, the RN SIGNS the medication and leaves it up for the second RN to check and sign
    f. The second RN will then come into the room and review the medication administration record on the screen, independently verifying all necessary components and then click COSIGN on the medication administration record and enter username and password
    g. The second RN then notifies the administering RN that the medication is ready to be given.
    h. The administering RN verifies and documents blood return of the venous access device (VAD), connects the medication to the patient and starts the pump from the "hold" status.
5. Verify and document blood return and patency on any venous access device immediately prior to administration of chemotherapy/immunotherapy.
6. Administer medications in order prescribed, if multiple medications are ordered
7. Closed system transfer devices (CSTD) are used whenever possible
8. Observe patient closely for signs/symptoms of infusion reaction, extravasation, infiltration and/or adverse effects of infusion.

D. Documentation Requirements

1. The MAR contains the documentation related to administration time, rate, device, and volume
2. The chemo RN documents:
    a. The education provided to the patient as above and their comprehension of the teaching
    b. The patient response to and tolerance of the treatment
    c. Any pertinent conversations between the RN and patient/family

E. Special Considerations for Vesicant Infusions

1. IV Push (acceptable through either PICC, VAD, peripheral access)
2. When administering a vesicant IV push or short infusion via a peripheral IV:

a. Remain with the patient for the duration of administration
b. Verify and document blood return prior to initiation, every 2-5 mL and at the completion of administration.
c. Infusions are administered via gravity; infusion pumps are not to be used to minimize the pressure on the vein
d. IV push preferred administration is the side-arm technique via a free-flowing compatible IV solution
e. Closely monitor IV site for signs and symptoms of infiltration, irritation, or extravasation; educate patient to immediately report any sensation of discomfort, burning or pain at IV site.
f. Gently flush the IV line with compatible solution at the completion of administration as ordered.
g. Discontinue administration at the first sign of extravasation and follow the Chemotherapy Extravasation Nursing Procedure

3. Mini-bag Vesicant Infusions/Short Infusions (ex: Vincristine)
    a. Remain with the patient for the duration of administration
    b. Verify and document blood return prior to initiation, every 2-5 mL , every 5-10 minutes for short infusions, and at the completion of administration.
    c. Vinca-alkaloid mini-bag infusions are given via gravity for adult patients
    d. Pediatric patients with a central VAD receive Vinca-alkaloid infusions via a syringe pump or IV pump, with continuous RN presence throughout the administration.
4. Continuous Infusion via central VAD only
    a. Verify and document blood return prior to initiation, every 4 hours during infusion and at completion of infusion.
    b. If the access is a Peripherally Inserted Central Catheter (PICC) which has multiple lumens, blood return may be checked on another lumen to minimize hazardous drug exposure.
    c. If the access is a dual lumen Implanted Port-A-Cath blood return must be checked on the same lumen utilizing a CSTD.
    d. Closely monitor VAD site for signs and symptoms of infiltration, irritation, or extravasation; educate patient to immediately report any sensation of discomfort, burning or pain.
    e. Flush the line with a compatible IV solution at completion of administration as ordered.
    f. Discontinue administration at first sign of extravasation and follow the Chemotherapy Extravasation Nursing Procedure.

F. Special Considerations for Intraperitoneal Administration

1. Access the Intraperitoneal Port-A-Cath (IP PAC) using standard aseptic technique, *there will not be a blood return.*

Refer to Section C-IV Administration for dual verification process.

2. Administer the chemotherapy/immunotherapy agent into the peritoneal cavity via the IP PAC by gravity administration, using standard safe handling technique.
3. Remain with the patient for the duration of administration.
4. Reposition patient per orders, if applicable.

5. Slow the rate and/or hold the infusion if patient expresses pain or burning and notify provider.
6. Leave medication in place for ordered dwell time and then, if ordered, allow the medication to flow, by gravity, out of the peritoneal cavity and back into the IV bag.
7. Disconnect tubing and safely return to Pharmacy for safe disposal in the black hazardous waste container

G. Special Considerations for Intrathecal Administration

1. The provider is responsible for the release of the treatment plan for IT chemotherapy.
2. Intrathecal (IT) chemotherapy/immunotherapy is dispensed from pharmacy *separately* from all other medications and is distinctly labeled "Intrathecal Administration Only"
3. The RN double checks the medication per section C with the administering provider, and both sign the MAR.
4. The RN and Provider participate in a "time-out" per UMMMC Policy Universal Protocol
5. The chemo RN assists with the procedure as needed.
6. Ensure the patient remains lying flat for 1 hour after completion of the procedure
7. Re-assess and document the lumbar puncture site and dressing1 hour post procedure
8. Educate the patient about post lumbar puncture care.

H. Special Considerations for Intravesicular Administration

1. Please refer to Intravesicular Administration of Hazardous Drugs Procedure

I. Special Considerations for Subcutaneous (SC) Chemotherapy/Immunotherapy Injections

1. Refer to age appropriate administration guidelines for specific injection sites.
2. Be sure to rotate injection sites if multiple injections are required and document the site of injection on the MAR
3. Use the smallest gauge needle possible, follow medication specific instructions

J. Special Considerations for Intramuscular (IM) Chemotherapy/Immunotherapy Injections

1. Evaluate the platelet count prior to administration, notify provider if count is if outside treatment parameters
2. Refer to age appropriate administration guidelines for specific injection sites. After insertion of the needle into the muscle at a 90-degree angle, attempt to aspirate to ensure the needle is not near a blood vessel
3. Avoid massaging the site, apply pressure as needed.

K. Special Considerations for Intra-Arterial Chemotherapy Embolization

1. This procedure is performed only in Interventional Radiology (IR)
2. All HD safe handling regulations are followed, per Policy 2003: Safe Handling of Hazardous Drugs
3. The radiologist and the IR RN follow the verification steps listed in Section C: Administration and then co-sign the MAR to document administration
4. The RN and Provider participate in a "time-out" as noted in UMMMC Policy Universal Protocol
5. The arterial access site requires monitoring, per provider order, after the procedure

L. Special Considerations for Intra-Operative Chemotherapy/Immunotherapy Administration

1. This procedure is performed only in the Operating Room (OR)
2. All HD safe handling regulations are followed, per Policy 2003: Safe Handling of Hazardous Drugs
3. The surgeon and the OR RN follow the verification steps listed in Section C: Administration and then co-sign the MAR to document administration
4. The RN and surgeon participate in a "time-out" as noted in UMMMC Policy Universal Protocol

M. Prevention and Management of Hypersensitivity, Anaphylaxis, or Cytokine Release Syndrome Reactions during/following Chemotherapy or Immunotherapy Administration

1. Assess the patient's history of allergies and previous exposure to the chemotherapy/immunotherapy medication ordered
2. Educate and instruct the patient to report any changes from their baseline, including but not limited to:
    a. Difficulty breathing
    b. Tongue or throat swelling
    c. Rapid heartbeat (tachycardia)
    d. Headache
    e. Dizziness
    f. Fever or chills
    g. Nausea
    h. Pruritis and/or rash
    i. Asthenia (loss of strength, new weakness)
    j. Neurologic changes (confusion, agitation, loss of consciousness)
3. When administering medications that are known to have a high risk of this type of reaction (pgs. 370-397 Chemotherapy/Immunotherapy Guidelines, ONS, 2023), stay with the patient for the first 15 minutes of the first and second doses
    a. If high risk or hypersensitivity/allergic reactions, there is a reaction kit available in pyxis.
4. If signs of reaction develop, immediately stop the infusion
5. Stay with the patient and have a coworker notify the provider/infusion APP immediately.
6. Maintain patent IV access and administer a bolus of IV fluids, if ordered.
7. Monitor vital signs and airway frequently.
8. Administer and document oxygen therapy as needed per provider order.
9. *Outpatient*: Apply the therapy plan-Emergency Medications Orders once
10. *Inpatient:* Utilize the emergency medications orders on the MAR
11. Administer rescue medications, per instructions provided in the MAR and per provider
12. If patient's condition deteriorates, escalate response per policy 2218-Triage and Treatment of Medical Emergencies
    a. ACC building or Hahnemann Campus – Call "9-911"from an internal phone and request ambulance transport to the emergency department

b. University or Memorial campus hospital buildings – Dial "12345" from an internal phone

13. Have a coworker provide emotional support to any family members present; Chaplaincy can be paged for additional support
14. If patient's reaction resolves, the provider may order the original medication infusion to resume.
    a. Obtain orders for new rate and duration via a chemotherapy/therapy plan rate change communication (if the provider edits the medication in the treatment plan, it nullifies the medication labels, so only a rate change communication order as noted above is needed)
15. Document the event completely, including time of reaction, what treatment was required, if the patient was able to complete the infusion, overall response, and condition.

a. Submit a Safety Intelligent Report (SI) promptly after the event.

V. RECISSION:

Chemotherapy/Immunotherapy Administration Procedure April 2021

VI. REFERENCE:

ASCO/ONS Chemotherapy Administration Safety Standards, American Society of Clinical Oncology, 2016.

Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice, Second Edition (2023) Oncology Nursing Society, Pittsburgh, PA

Safe Handling of Hazardous Drugs, Fourth Edition, (2024), Oncology Nursing Society, Pittsburgh, PA

The Pediatric Chemotherapy and Biotherapy Curriculum, Fourth Edition (2019) Association of PEDIATRIC Hematology/Oncology Nurses, Glenview, IL

VII. MONITORING:

The Nursing Policy Committee is responsible for monitoring this procedure

Keywords:
Chemotherapy, Chemo, Immunotherapy, Administration

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Approved By: Linda Scoble MS RN NPD-BC June 20, 2024
Authorized Signature Chair, Nursing Policy Committee Date

Approved By: Michelle O'Rourke June 21, 2024
Authorized Signature Chief Nursing Officer Date

UMass Memorial Health
UMASS MEMORIAL MEDICAL CENTER

Policy	
2003 Safe Handling of Hazardous Drugs (HD's)	
Effective Date: 2/10/2026	**Policy Owner:** Medication Safety Specialist
Rescission: Supersedes policy dated: 8/21/2024	**Approved by:** _____ Justin Precourt, DNP, RN President, UMass Memorial Medical Center
Applicability: All medical center staff who administer, prepare, transport or care for patients who have received HD's	
Keywords: chemotherapy, biotherapy, Hazardous Drugs, HD's, Safe Handling	

Policy

a. UMMMC will follow national best practice standards related to Hazardous Drug handling by healthcare workers.

b. Occupational exposure to these medications has been shown to have potential adverse effects; this policy is in place to ensure that hazard controls are utilized to minimize exposure.

Definitions

National Institute for Occupational Safety and Health (NIOSH) Hazardous Drugs (HD's): As defined by NIOSH, a hazardous drug is a drug that is (A) Approved for use in humans by the FDA CDER; (B) not otherwise regulated by the US Nuclear Regulatory Commission; and (C) either:

- Is accompanied by prescribing information in the "package insert" that includes a manufacturer's special handling information (MSHI), or
- Is determined to be a carcinogenic hazard, developmental hazard, reproductive hazard, genotoxic hazard, or other health hazard by exhibiting one or more of the following toxicity criteria in humans, animal models, or in vitro studies:
  - Carcinogenicity
  - Developmental toxicity (including teratogenicity)
  - Reproductive toxicity
  - Genotoxicity
  - Organ toxicity at low doses, or a
  - Structure and toxicity profile that mimics exiting drugs determined hazardous by exhibiting any one of the previous five toxicity types

Hazardous Drugs (HDs): Products which meet the NIOSH definition for a hazardous drug and agents which pose risk when handling, such as in the case of biologic agents and viral vectors. For the purposes of UMass Memorial Medical Center and all HD related policies and procedures, HDs will refer to this definition.

Personal Protective Equipment (PPE): The layer(s) of protection between the employee and the HD or contaminated waste; consisting of protective equipment and garments designed for worker protection.

The primary responsibility for protection is on the worker. PPE includes nitrile gloves; disposable, HD-permeability resistant gowns; eye and face protection and respirators. UMMMC will ensure that PPE is available to all staff to minimize exposure.

General Procedure

a. Identification and assessment of risk associated with hazardous drugs
   i. HDs will be assessed for their exposure risk to caregivers who may handle the medications or bodily fluid of patients who have received these medications through a formal Assessment of Risk (AOR)
   ii. Hazardous agents will be assessed by their formulation, unit of procurement, and unit of administration. Each AOR will review exposure risk in each stage of the medication use process (such as receiving, storage, dispensing, preparation, transport, administration, spill management, bodily fluid handling) vs the 5 routes of exposure (ingestion, dermal absorption, injection, eye absorption, and inhalation) on a risk matrix assessing likelihood and impact.
   iii. Based on the scores of the risk assessment, minimum containment and protection strategies are assigned for each hazardous drug formulation.
   iv. The hazardous drug list is reviewed annually and posted on the organization's intranet for reference which includes the overall risk by formulation and associated containment and protection strategies
   v. Hazardous exposure risk designations are also available within the Electronic Health Record (EHR)
   vi. Whenever possible, medications which are dispensed by the pharmacy for direct patient use, will be labeled as an HD

b. Hazardous risk designations
   i. Hazardous medications will be grouped into three designations based on the AOR: Low risk, intermediate risk, and high risk
   ii. The hazard designation may differ for each medication, route/formulation, and caregiver based on the AOR
   iii. Low risk for exposure: drugs which have minimal potential to expose or harm the caregiver due to its hazard classification, formulation, and point in the medication use process.
   iv. Intermediate risk: drugs which have a higher potential to expose or harm the caregiver than low risk drugs due to its hazard classification, formulation, and point in the medication use process.
   v. High risk for exposure: drugs which have the highest potential to expose or harm the caregiver due to its hazard classification, formulation, and point in the medication use process. Full PPE and full containment strategies are required when handling these agents.
   vi. A caregiver may increase the PPE or containment strategies when handling an HD based on personal assessment or if the caregiver expects to be exposed such as in the case of a patient vomiting or spitting the medication during administration.
   vii. Medication Administration PPE and containment requirements by classification

	Minimum PPE Requirements	**Additional PPE**	**Notes**
Low Risk	Single set of gloves	Gown, head, shoe, and face covers may be added if needed based on assessed exposure risk.	Medication manipulation such as crushing and splitting allowed on patient care areas

Low Risk – No Manipulation	Single set of gloves, manipulation not allowed in patient care areas	Respiratory protection needed if risk of aerosolization.	Medication manipulation such as crushing and splitting allowed in Pharmacy only.
Intermediate risk	Double glove		
High Risk	"Full PPE" – HD rated gown, double gloves.		

viii. Medication preparation PPE and containment strategies by classification

	PPE/Containment Requirements	**Notes**
Low Risk	Single set of gloves, no hood	
Low Risk – IV	Non-hazardous compounding room - standard compounded sterile product PPE	If batching product, may be done in an HD room based on assessment
Intermediate Risk	Full PPE (as defined above), regular room, no hood	Particle generating activities must be completed in an HD room in a biologic safety cabinet (BSC)
High Risk	Full PPE, HD room, BSC	

c. Notification to staff and education on exposure to hazardous drugs

i. Initial education and annual review of the policy and related procedures are required prior to handling of or exposure to HD's at UMMMC.

ii. UMMMC will provide education and training specific to each caregiver's role for all staff that have the potential for exposure to HD's or HD contaminated waste products. Training will include the risks of exposure, including the potential for reproductive and developmental effects, the recommended precautions for specific handling activities, safe handling of contaminated bodily fluids, proper disposal of contaminated wastes and how to handle acute exposure.

iii. Staff who are actively trying to conceive, are currently pregnant, or are breastfeeding may request to be engaged in duties that do not require HD handling.

iv. Patients and their caregivers will receive education about safe handling to minimize unintended exposures. Caregivers will be required to attest they have received this education which includes but is not limited to information on how to handle hazardous drugs with reproductive risk. It is the responsibility of caregivers to review and utilize the minimum containment and protection strategies when handling hazardous drug or contaminated bodily fluids.

v. Admitted patients who are receiving high exposure risk HD's shall have visible signage posted to notify all Caregiver's of the presence of HD's in the room and/or the patient's bodily fluids, dated and timed with a 48-hour timeframe post administration of HD, unless otherwise noted on the sign.

d. Containment and protection strategies

i. Engineering controls will be used whenever possible and appropriate to minimize contamination of hazardous drug to the environment or personnel handling these products. Engineering controls include negative pressure, externally vented, containment rooms for pharmacy compounding and medication storage and use biologic safety cabinets for sterile

and non-sterile pharmacy compounding

ii. Closed system transfer devices (CSTD) will be used whenever possible during preparation and administration of hazardous medication. For certain high risk routes of administration, such as intrathecal, or when the formulation does not remain closed, due to the presence of an open bore needle such as in the case of intramuscular or subcutaneous administration, risk assessments will specifically address the overall exposure risk with and without a CSTD

iii. Intravenous infusion medications considered high risk for exposure will be primed by the pharmacy with the diluent the medication is compounded, unless the medication itself or type of administration (ex: desensitization, titratable continuous infusion, high risk for reaction) requires the line to be primed with active drug. Lines primed with drug will be labelled as such. A complete list of medications which are primed is included on the HD list.

iv. Personal Protective Equipment is the final level of protection, consisting of protective equipment and garments designed for worker protection from HD's. . As part of the HD list and information contained with the EHR, activities requiring PPE will be listed with the minimum PPE requirements and it is the primary responsibility of the caregiver to utilize recommended PPE which is made available

a. Activities requiring PPE include, but are not limited to receiving, preparation, dispensing, administration, disconnecting infusions, handling of bodily fluids of patients who have received HDs within the last 48 hours (or other time as determined by the medication indicated in the HD list), when cleaning areas contaminated by HDs, and transport. PPE requirements are included in more detail in associated policies and procedures.
b. Gloves: meet the American Society for Testing and Materials (ASTM) standard D6978 or its successor and are powder free. Gloves are made available in two cuff lengths: standard and extended cuff. Extended cuff gloves should be used when donning "full PPE" and must be used around an HD appropriate gown. Special attention must be paid to breakthrough times of HDs through the gloves used, especially for carmustine and thiotepa, to ensure gloves are replaced at appropriate intervals. Breakthrough times are listed on the glove container packaging.
c. Gowns: Disposable, lint-free, HD-permeability resistant gowns (herein after referred to as "gown") with a solid front, long sleeves, tight cuffs and back closure. Gowns are single use only.
d. Respirators: NIOSH approved respirators (N-95 or PAPR) should be worn when inhalation exposure is possible (when cleaning a spill or administering an aerosolized HD medication). Consult the safety data sheet (SDS) for the respirator appropriate to the situation.
e. Eye and face protection: Wear a face shield or combination mask-face shield in any situation where splash of HD is possible.
f. Shoe covers: wear shoe covers when cleaning a spill.
g. Hands must always be washed with soap and water after any contact with potential HD, even when PPE is used. Hand sanitizing foam will not remove HD residue.

e. Donning and Doffing PPE

i. Donning:
a. Don PPE in the following order as needed based on exposure risk: gown, mask/respirator, head/shoe/face cover, gloves, second pair of gloves
b. If donning two pairs of gloves with a gown, the inner pair of gloves should be put under the cuff of the gown, and the outer gloves over the cuff of the gown

ii. Doffing:
a. Doff PPE in the following order as needed based on exposure risk: outer gloves, head/shoe/face cover, gown, mask, inner gloves
b. Remove outer gloves, turning them inside out as removed, discard into appropriate HD disposal bin. Then remove gown, peel away from neck and shoulder, turn contaminated outside toward the inside, fold or roll into a bundle with exposed

surfaces covered and discard into appropriate HD disposal bin. Lastly, remove the inner gloves turning them inside out as removed and discard into appropriate HD disposal bin.

c. Hands must be washed with soap and water to remove any potential contaminants.

f. Receiving and storage of HDs
   i. HDs are received and unpacked according to Pharmacy procedure 7.3.1 Receiving of medications from authorized trading partners
   ii. All HDs in their final dosage form may be stored with non-HDs in the pharmacy or on patient care units, as instructed on the HD medication list
   iii. HDs not in their final dosage form are stored according to the pharmacy policy 2.2.0 Storage and Transport of Medications by the Pharmacy
   iv. Areas where HDs not in their final dosage form are handled or stored will be designated as HD handling areas and is restricted to pharmacy personnel
   v. Spill kits are readily available where HDs are stored and handled

g. Pharmacy Compounding Requirements
   i. HDs compounded by the pharmacy will follow all applicable pharmacy policies and procedures as they relate to hazardous drugs with the appropriate containment strategies as identified in the AOR and risk designation.

h. Transporting
   i. Transportation of HDs
   ii. All HD's are capped securely and transported in accordance with Pharmacy policy 2.2.0 Storage and Transport of Medications by the Pharmacy
   iii. All personnel involved in the transport of HD's are knowledgeable in potential hazards and safe spill cleanup procedure.
   iv. HDs are packaged in such a way to minimize any breakage, spilling, or contamination of the immediate environment. In addition, HDs at risk of spilling or high risk for environmental contamination may not sent in a pneumatic tub, as detailed in Department of Pharmacy Procedure 2.2.1 Pneumatic tube drug delivery.
   v. Transportation of patients on HDs
   vi. Patient transport to other departments should be avoided during the infusion of high exposure risk HD's. If patient transport during infusion is necessary:
      a. Notify the receiving department of the presence of infusing HD's and resulting precautions
      b. An RN qualified to the give the medication in question will travel with the patient, until a safe hand-off can be achieved to another properly trained RN
      c. An HD spill kit must travel with the patient
      d. If the patient is incontinent; a spare gown and extra nitrile gloves must travel with the patient

i. Administration:
   i. Medication formulation specific procedures for administration can be found in the Administration and management of patients on Hazardous Drugs Procedure
   ii. Medications requiring chemo competence as defined in Policy 2004 Chemotherapy, Immunotherapy, and Biotherapy Management can be found in the Procedure for Management of High-Risk High-Alert Medications
   iii. Policy 2004 Chemotherapy, Immunotherapy, and Biotherapy Management applies, with all related procedures
   iv. An HD Spill kit is available in all areas administering HDs

j. Disposal
   i. UMMMC will ensure that HD waste is disposed of in accordance with regulatory guidelines; done in a manner that protects staff and the environment per policy 6029 Chemical and

Pharmaceutical Disposal and Spill

ii. All contaminated items must be disposed of safely in an appropriate HD waste container.
iii. Administration tubing that was connected to HD tubing is considered contaminated
iv. Trace HD waste should be collected in a yellow HD waste container. This includes all HD tubing, empty (less than 3%) HD containers and contaminated PPE.
    a. Any item that came into contact with the HD packaging or tubing or the patient's bodily fluid is considered contaminated
    b. All PPE worn during administration of or personal care of a patient receiving HD is considered contaminated
a. Bulk chemo waste should be collected in the Black Bulk HD Waste Containers
    a. Bulk waste includes:
        i. Non-empty containers
        ii. All materials used and PPE worn while cleaning up an HD spill
vi. HD waste containers are labeled as such and must remain closed except when waste is being placed in the container.

k. Body Fluid Handling
    i. Precautions are maintained in handling body fluids of patients during administration of HD's and for at least 48 hours following administration of high exposure risk HDs.
    ii. Gown and gloves are worn when in contact with bodily fluids
    iii. Masks are worn when splashing is a risk
    iv. Men are encouraged to sit while urinating to minimize aerosolization of HD particles
    v. Use disposable ostomy pouches where available
    vi. Housekeeping follows OSHA guidelines when performing responsibilities where HD administration has occurred
    vii. Use disposable linens if possible when contamination is a risk
    viii. Contaminated, non-disposable linens are laundered following current OSHA and NIOSH guidelines

l. Spills
    i. Employee Health provides medical surveillance for employees with occupational exposure
    ii. Refer to:
        a. Policy 6029 Chemical & Pharmaceutical Waste Disposal & Spill
        b. Chemotherapy/HD Spill Clean up
    iii. Full PPE, including a gown, gloves, shoe covers, and a hospital issued, fit tested N95 must be worn to clean up spills

m. Deactivation, decontamination, cleaning, and disinfection
    i. Any contaminated environments are cleaned in such a way to deactivate and decontaminate the HD. Pharmacy compounding areas are cleaned according to Pharmacy Policies and Procedures applicable to HDs.
    ii. Cleaning agents are chosen to meet the requirements of deactivation and decontamination. As there is no single agent known to chemically deactivate all types of HDs, UMMMC uses an agent known to be an oxidizing agent which is approved to decontaminate areas contaminated with HD residue.

No changes to this policy may be made in isolation or independently.

Clinical/Department Specific Procedures

2004 Chemotherapy Biotherapy Management

Pharmacy Policy 8.3.0 Preparation, Labeling, and assignment of beyond-use dates of compounded sterile preparations

Procedure for Management of High-Risk High-Alert Medications

Supplemental Materials

1. Chemical Spill Response Procedure
2. Collection, Storage, Transport and Disposal of Chemical Waste Procedure
3. Collection, Storage, Transport and Disposal of Pharmaceutical Waste Procedure
4. Hazardous Materials Spill Algorithm
5. UMMH Policy Automated Dispensing Machines (ADM)
6. Chemotherapy/HD Spill Clean-Up
7. Spill Clean-Up Guidelines - Formalin

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UMass Memorial Health
UMASS MEMORIAL MEDICAL CENTER

Policy	
2004 Chemotherapy, Immunotherapy, and Biotherapy Management	
Effective Date: 9/17/2025	**Policy Owner:** Oncology Nurse Educator
Rescission: Supersedes policy dated: 5/22/2025	**Approved by:** Justin Precourt, DNP, RN President, UMass Memorial Medical Center
Applicability: Qualified clinical staff including independent practitioners and advanced practice providers, pharmacists, registered nurses excluding the Marlborough Campus.	
Keywords: Chemotherapy, Immunotherapy, Biotherapy, Antineoplastic, Targeted, Vesicant, Safe Handling, Independent Double Check	

Policy

UMass Memorial Medical Center (UMMMC) administers chemotherapy, immunotherapy, and biotherapy medications for oncological purposes. UMMMC follows the processes documented below. The educational requirements of the clinical staff who will obtain consent, order, verify, prepare, and administer these medications and the minimum required documentation of the diagnosis, staging, history and plan are documented below.

Definitions

For the purposes of this policy, these definitions are used for oncological purposes only.

A. **Antineoplastic Therapy/Antineoplastic regimen**: All antineoplastic agents used to treat cancer, regardless of the route. Types include targeted agents (e.g., small-molecule inhibitors), chemotherapy, and immunotherapy (e.g., monoclonal antibodies, checkpoint inhibitors, biologics, cellular therapies).
    a. **Immunotherapy**: A type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases. Some types of immunotherapy only target certain cells of the immune system. Others affect the immune system in a general way. Types of immunotherapy include cytokines, vaccines, bacillus Calmette-Guerin (BCG), and some monoclonal antibodies
    b. **Biotherapy**: A type of treatment that uses substances made from living organisms to treat disease. These substances may occur naturally in the body or may be made in the laboratory. Some biotherapies stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases.
B. **Antineoplastic Treatment Plan**: A treatment plan specific to the patient developed before the initiation of antineoplastic therapy
C. **Combination of Antineoplastic Therapy/Regimen**: One or more antineoplastic agents used alone or in combination in a well-defined protocol or course of treatment, generally administered cyclically

D. **"Non-Standard" Regimen:** A treatment plan that has been modified from a UMMMC prebuilt treatment plan template/protocol beyond dose reductions or removal of medications due to tolerance concerns.
E. **Exception Order**: A request for antineoplastics or doses of antineoplastics that differs from the standardly available institutional treatments for a given condition (e.g. using an order set for a disease not assigned, adding a medication not included in the standard regimen, and escalation of dose or schedule beyond that defined in a standard regimen).
F. **Consent:** The process by which a patient is provided with sufficient information about the disease diagnosis and treatment options so that the individual can make a reasonable decision about treatment based on an understanding of the potential risks and anticipated benefits of the treatment (per Informed Consent Policy)
G. Qualified Clinical Staff:
    a. **Licensed Practitioner:** Any individual permitted by law and by the medical staff and board to provide care and services without direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges (e.g. medical oncologist doctors (MD), nurse practitioner/physician assistant (NP/PA), Advanced Practice Provider (APP), and/or fellows) who have been granted chemotherapy privileges by UMMMC. UMMMC does not consider residents to be qualified or competent in antineoplastic treatment/therapy.
    b. **Qualified Pharmacists**: Completion of national certification as a Board-Certified Oncology Pharmacist (BCOP), completion of a PGY2 Hematology/Oncology Pharmacy Residency, previous experience as an oncology pharmacist, or completion of a minimum three (3) month training period at UMMMC Oncology Pharmacy.
    c. **Qualified Registered Nurses/Chemo RNs**: UMMMC deems RNs as antineoplastic therapy competent (Chemo RN) by one or more of the following: (1) Possesses a current Oncology Nursing Society (ONS) Chemotherapy/immunotherapy/Biotherapy Provider Card; (2) Successful completion of a chemotherapy course accepted by UMMMC, and/or; (3) Has been administering chemotherapy/immunotherapy /biotherapy at UMMMC for at least 5 years. Chemotherapy Competent RNs complete and pass the annual required oncological education and performance validations to maintain competence.
H. Independent Verification: The procedure in which two licensed health care providers independently review the five (5) rights of medication administration which are then used together to ensure safe medication administration of a high-risk/high-alert medication.
I. Refer to Appendix A: Definition List for further/additional terms and definitions

General Procedure

1. Staffing and General Procedure:
    a. Credentialing of Qualified Providers will be recorded and logged for review on Echonet
    b. Chemo RNs maintain antineoplastic therapy competency. Competency is annually assessed per best practice standards via completion of an annual oncological educational update.
    c. A Qualified Provider is on site and immediately available in the inpatient and ambulatory setting at all times while treatments are being administered.
    d. Before the first administration of a new antineoplastic therapy regimen, the electronic health record is reviewed to confirm completion/documentation of the following nine (9) elements:
        i. Pathologic confirmation or verification of initial diagnosis
            1. If pathologic confirmation is unavailable, the Qualified Provider will document rationale for diagnosis
        ii. Initial cancer stage or current cancer status
        iii. Complete medical history and physical examination, including fertility status/preservation and pregnancy status, as applicable
        iv. Presence or absence of allergies and history of hypersensitivity and anaphylactoid reactions

v. Assessment of patient and/or caregiver's comprehension of information regarding the disease and the treatment plan including an initial psychosocial assessment, with action taken when indicated and agreeable to the patient
vi. The antineoplastic therapy/treatment plan, includes at minimum:
    1. Patent diagnosis
    2. Drugs
    3. Doses
    4. Route of administration
    5. Duration of treatment
    6. Goals of therapy (e.g. palliative versus curative)
vii. Planned frequency of office patient assessments and monitoring that is appropriate for the individual antineoplastic agent(s).
viii. Initial and ongoing assessments of social drivers of health and barriers to care including financial and logistical constraints and supports needed to provide access to required medications (if applicable)
ix. Informed consent and assent (if applicable) for the antineoplastic therapy

e. On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following six (6) elements and takes appropriate action:
    i. Functional status and/or performance status
    ii. Vital signs
    iii. Patient Identifiers (per Policy 2018: Patient Identification (for Select Interventions)
    iv. Allergies and previous treatment-related reactions
    v. Treatment toxicities
    vi. Pain assessment
f. Height and/or weight are measured, in metric units (cm and kg), and documented in the electronic health record.
    i. Dual-verified (at least one of whom is a qualified RN) height and weight measurement/documentation is required prior to preparation and administration of a newly prescribed antineoplastic treatment plan (i.e. cycle 1 day 1)
    ii. An accurate weight is required on day of treatment (or within at least 3 days prior to anticipated/planned treatment encounter)
g. Staff screens for and documents the patient's psychosocial concerns and need for support with each cycle or more frequently as indicated, with action taken when indicated and agreeable to the patient
h. The patient's medication list inclusive of prescribed and over-the-counter medications, herbal products, and supplements is updated and documented in the medical record at every encounter and reviewed by a licensed practitioner when a change occurs (in accordance with the Medication and Allergy Reconciliation Policy)
i. Providers are available to patients for triage purposes twenty-four (24) hours a day, 7 days a week through the clinic, on-call system, or Emergency Department (ED) for management of treatment related toxicities and emergencies, per Triage of Oncology Patient Telephone Calls Nursing Procedure
    i. The ED staff have continuous access to a Qualified Oncology Provider at all times, through the on-call system.
j. UMMMC utilizes a standardized tool, per the Handoff Communication policy, to ensure that accurate information is relayed from provider to provider regarding the patient's diagnosis, treatment, administration of antineoplastic therapy, critical lab values, recent or anticipated changes and current condition.
k. UMMMC utilizes the occurrence reporting system per Safety Event Reporting (Patient and Visitor)- System Policy the reporting/documentation, data collection, and evaluation of adverse events (e.g. infusion reactions and toxicities), medication errors, and near misses. UMMMC intervenes when determined appropriate following evaluation of collected data
l. UMMMC utilizes the Common Terminology Criteria for Adverse Events (CTCAE) Version 5 to implement a set of criteria for the standardized classification of adverse events of drugs and treatment used in cancer therapy

2. **Treatment Planning, Consent, and Education**
    a. A specific, written, informed consent guided by the Informed Consent policy is required prior to administration of antineoplastic therapy regardless of the route of administration.
    b. Consent is obtained once at the outset of an antineoplastic treatment or protocol without limit of duration, as long as there are no changes in the treatment plan or protocol in accordance with the Informed Consent Policy and Treatment And Procedure Consent Form)
        i. Abbreviations of treatment regimens can only be included IF each agent composing the abbreviation is explicitly written down/identified
        ii. As long as there is no change in the nature of recommended therapy, informed consent need only be obtained once at the outset of the course of treatment (in accordance with completion instructions detailed in Treatment and Procedure Consent Form
        iii. Informed consent and assent (if applicable) for antineoplastic therapy, as appropriate to the treatment population, is documented before initiation of the regimen
        iv. A new consent is required for each new treatment plan, medication, and/or investigational protocol
    c. A patient/caregiver learning assessment is performed by qualified clinical staff prior to the first antineoplastic therapy administration to target/individualize educational resources/content/materials and the delivery method of education provided before the first antineoplastic therapy administration (in accordance with the Patient Education Documentation Policy)
    d. Patients/caregiver(s) are provided with verbal, written, and/or electronic information as part of an education process before the first administration of antineoplastic agents in each treatment plan and is ongoing throughout the course of treatment. The content of this educational material will be documented and should be administered in the patient's preferred language in accordance with the Patient Education Documentation Policy.
3. **Ordering of Antineoplastic Treatment Plans**
    a. Antineoplastic therapy/treatment plans and research/investigational therapy/treatment plans (for all routes of administration) are created and made available in the electronic medical record as templates and contain hyperlinks to their evidence.
        i. An electronic health record (EHR) therapy/treatment plan validation team, which consists of an oncology pharmacist, chemo-competent RN, oncology attending physician and member of the EHR IS build team jointly meets to review each template for initial approval in addition to regular reviews/updates every 3 years
    b. Orders for antineoplastic therapy, regardless of route, are signed manually or by using the electronic health record by licensed practitioners
    c. Exception orders/non-standard regimens require a supporting reference and/or documentation of approval by a second licensed practitioner prior to ordering, signing, or administration in addition to the rationale documented in the electronic health record
    d. New orders or changes to orders for antineoplastics, regardless of route, including dose and schedule changes communicated directly to patients, are documented in the electronic health record
    e. Antineoplastics orders within therapy/treatment plans/regimens must include the patient's name and date of birth. In addition to the standard requirements outlined in Policy 2029: Medication Ordering, the following elements must be included in the treatment plan:
        i. A third unique patient identifier
        ii. Regimen name or protocol name and/or number
        iii. Cycle number and day number, when applicable
        iv. All medications within the treatment plan are listed by using full generic names (abbreviations are **not** acceptable or allowed)
        v. The dose calculation, including
            1. The calculation methodology
            2. The variables used to calculate the dose
            3. The changes in the values that prompt confirmation or recalculation of doses
        vi. Rate of drug administration for parenteral medications, when applicable
        vii. Sequencing of oral and/or parenteral drug administration, when applicable

viii. Supportive care medications appropriate for the regimen including premedication, hydration, growth f actors, and hypersensitivity and anaphylactoid medications are included in the preprinted or electronic order forms
    1. Explicit and specific criteria detailing when and why relevant supportive care medications should be released and administered
ix. Parameters that would require holding or modifying a dose (e.g. laboratory values, diagnostic test results, or change in patient's clinical status)

f. Treatment Plans f or oral chemotherapy, whether to be dispensed by UMMMC or another facility, also include the patient's name and date of birth in addition to the number of ref ills (with zero ref ills being the preferred default value f or all oral antineoplastics)

g. Signature Requirements

i. The first administration (i.e. C1D1) for an agent(s) of a treatment plan for new antineoplastic are signed by an attending licensed practitioner

ii. Subsequent cycles of treatment may be signed by licensed practitioners
    1. Dose **decreases** by NP/PA are allowed, with a documented rationale
    2. Dose **increases** (based on mg/m^2 and/or AUC or mg/kg dosing) must be signed by attending oncologists

iii. Any addition of new chemotherapy medications to an existing treatment plan needs to be signed by an attending oncologist or hematologist

iv. Treatment Plans written by oncology fellows are co-signed by attending oncologists

v. Hydroxyurea may be signed by qualified ordering providers

h. Rationale is documented in the EHR f or the following:
    i. Any dose changes f rom baseline
    ii. Any removal of an antineoplastic medication f rom a standard protocol
    iii. Any addition of an antineoplastic medication to a standard protocol
    iv. Any change in rate or frequency that is not already defined in the established protocol

i. If a Treatment Plan is designated as a "Non-Standard" Regimen and there are no references that can be provided, a second attending must document a note in the EHR affirming the safe and effective use of this regimen for the intended purpose (this will serve in lieu of proper reference f or all appropriate procedures)
    i. This note documents the regimen being used, the rationale f or use, and a reference.

j. Chemo RNs can accept verbal orders with co-signature (subject to the UMMMC Computerized Provider Order Entry (CPOE) and Order Modes Policy) regarding antineoplastics f or the following:
    i. Rate changes
    ii. Hold therapy
    iii. Delay therapy
    iv. Okay to treat outside of ordered treatment interval
    v. Okay to treat with current adverse events
    vi. Okay to treat outside of treatment parameters
    vii. Okay to treat with height/weight/BSA change

k. Qualified Pharmacists can take verbal or written communication orders with co-signature (subject to the UMMMC CPOE and Order Modes Policy) f or the following with appropriate iVent documentation:
    i. Updated treatment plan height/weight/BSA with corresponding dose adjustments of medications
    ii. Continuation of dose adjustment f rom a prior cycle

4. Verification of Biotherapy Antineoplastic Treatment Plans

a. Chemo RN verification is completed per the Chemotherapy Immunotherapy Administration Procedure and Pharmacy Policy 5.1.0: Oncology Service Standards

b. Treatment Parameters:
    i. Laboratory results within the treatment parameters must be resulted within 3 days of the date of treatment, unless otherwise stated within the plan.
    ii. Provider may give okay to proceed ("Okay to Treat") without current labs or to follow the treatment parameters based on laboratory results >3 days old.

1. This "Okay to Treat" must be documented as a Nurse Communication within or outside the treatment plan by either the provider or Chemo RN (co-signature required if entered by Chemo RN) in addition to containing reference to particular/relevant/applicable treatment parameters

c. Height/Weight/BSA Changes:
   i. For Adults and Pediatrics:
      1. Greater than a 5% +/- difference (or as specified in the treatment plan) between the assigned treatment plan BSA and current day measurements on a BSA dosed medication
      2. Greater than a 10% +/- difference (or as specified in the treatment plan) between assigned treatment plan weight and the current day measurements on a weight dosed medication
   ii. Chemo RN notifies the ordering Qualified Provider of height/weight/BSA discrepancy
   iii. Qualified Provider has four (4) options
      1. Modify the dose with the current, up-to-date height and weight
         a. If the order has already been released: Copy and paste the impacted order(s) in the treatment plan. Update the Treatment Plan weight/BSA. Re-sign the updated order
      2. Qualified Pharmacist can adjust to the most recent height and weight as a verbal order as communicated by the ordering Qualified Provider via verbal or written communication (co-signature required)
      3. Enter a Nursing Communication Order into the EHR indicating "Okay to treat with prior height/weight"
      4. Nurses can enter a Nursing Communication Order (order mode of verbal or telephone order with readback required) on the Qualified Providers behalf indicating "Okay to treat with prior height/weight" (per UMMMC CPOE and Order Modes Policy)
   iv. See Chemotherapy/Immunotherapy Administration procedure for more information

d. Checks and verification are performed by the Qualified Pharmacists prior to dispensing of the chemotherapy//immunotherapy biotherapy as per verification process, Policy 5.1.0 Oncology Service Standards

5. Dispensing

a. Dispensing is performed by the Qualified Pharmacist as per dispensing process outlined in Policy 5.1.0 Oncology Service Standards.
b. The preparer applies the chemotherapy label to each chemotherapy drug upon preparation.
   i. The label includes the data elements needed to complete the required comparison of the medication delivered with the original order.
   ii. It is labeled in accordance with regulatory requirements and Policy 2206 Medication and Solution Labeling
c. Chemotherapy is packaged, transported, and handled consistent with Policy 2003 Safe Handling of Hazardous Drugs
d. Qualified Pharmacists and/or technicians prepare the antineoplastic, in accordance with Policy 2003 Safe Handling of Hazardous Drugs

6. Administration of Antineoplastic Treatment/Therapy

a. Administration of chemotherapy, immunotherapy, and biotherapy is completed by a Chemo RN per Chemotherapy Immunotherapy Administration Procedure
b. Precautions will be followed for patients receiving intrathecal chemotherapy and vincristine per Institute for Safe Medication Practices (ISMP) Targeted Medication Safety Best Practices for Hospitals
c. Licensed practitioners, Chemo RNs, and/or Qualified Pharmacists are responsible for monitoring cumulative dosing of agents associated with cumulative toxicity
d. The current Chemotherapy and Biotherapy Guidelines (ONS) and The Pediatric Chemotherapy and Biotherapy Curriculum (APON) guidelines guide nursing practice.

e. The current National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE)- Version 5- is the standard definition of disease-specific toxicities for planning, evaluation, monitoring, and documentation of treatment-related toxicities

7. Adverse Events

a. Life-threatening emergencies follow Policy 2218 – Triage and Treatment of Medical Emergencies
b. Infiltration and extravasation events will be managed according to the Chemotherapy Extravasation Nursing Procedure
c. Hypersensitivity and anaphylactoid reaction management per Chemotherapy/Immunotherapy Administration Procedure
d. Hypersensitivity order sets and medications are accessible within the appropriate time frame for optimal treatment
e. CRS/ICANS management per UMass Memorial Health Guidelines for Treatment of Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and UMass Memorial Medical Center Clinical Practice Guideline for Immune Effector Cells-CAR T Therapy Management of CRS/ICANS
f. Report adverse events and /or unexpected outcomes of care per Safety Event Reporting (Patient and Visitor)- System Policy and Policy 1081 Adverse Reaction Drug Reporting.

8. Special Circumstances

a. If a patient is admitted to an inpatient unit within UMMMC and is known to be taking an oral chemotherapy agent, the admitting provider:
    i. Confirms with the prescribing provider that they would like the medication to be administered during admission
    ii. Orders the medication to be administered.
        1. Orders may be verified by any UMMMC pharmacist.
        2. If the medication is not routinely stocked by the inpatient pharmacy, the patient's own medication workflow must be followed per Policy 2201 Medications and Medication Devices Obtained From Sources Other Than the Hospital (Patient's Own Medication)
b. Dual RN verification, when required on the MAR, with independent double check per Policy 2226 Management of High-Risk, High-Alert Medications
    i. Standard (nonchemotherapy competent) RNs are allowed to administer and co-sign, following the Independent Verification with Double Signature for High Risk/High Alert Medications Nursing Procedure
    ii. When administering, the two RNs independently verify the following:
        1. Correct patient name on medication container and on patient bracelet
        2. Correct patient identifier from medication container (date of birth, home address, MRN)
        3. Correct dose is being administered (correct count of pills)
        4. Correct administration time
        5. Follow established guidelines in Policy 2206 Medication and Solution Preparation and Labeling
c. If a patient is admitted and/or transferred to a non-oncologic inpatient unit, with an infusion of chemotherapy currently running or urgently needed, the Oncology Attending or Qualified NP/PA will notify the Nursing Supervisor on-duty and they will follow the Off-Unit Chemotherapy Process.
    i. Attempts should be made to transfer the patient to the oncology, hematology, or BMT floor if possible.
d. Oncological Emergencies – if a patient presents to the Emergency Department and is diagnosed with a life-threatening oncological diagnosis which requires emergent chemotherapy:
    i. The Attending Oncologist will follow the Off-Unit Chemotherapy Process

No changes to this policy may be made in isolation or independently.

Entity/Department Specific Procedures

Departmental Policies/Procedures:

1. Nursing Procedure: Chemo Extravasation
2. Nursing Procedure: Chemotherapy Immunotherapy Administration Procedure
3. Nursing Procedure: Independent Verification with Double Signature for High Risk/High Alert Medications
4. Nursing Procedure: Telephone Triage of Oncology Patient Telephone Calls
5. Pharmacy Policy 5.1.0: Oncology Service Standards
6. UMass Memorial Health Guidelines for Treatment of Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
7. Clinical Practice Guideline for Immune Effector Cells-CAR T Therapy Management of CRS/ICANS

Medical Center Policies:

1. Patient Education Documentation Policy
2. Medication and Allergy Reconciliation Policy
3. Handoff Communication Policy
4. Policy 1081: Adverse Reaction Drug Reporting
5. Policy 2003: Safe Handling of Hazardous Drugs
6. Policy 2018: Patient Identification (for Select Interventions)
7. Policy 2201: Medication and Medication Devices Obtained from Sources other than the Hospital (Patient's Own Medication)
8. Policy 2206: Medication and Solution Preparation and Labeling
9. Policy 2029: Medication Ordering
10. Policy 2215: Handoff Communication
11. Policy 2218: Triage and Treatment of Medical Emergencies including Code Blue
12. Policy 2226: Management of High-Risk/High-Alert Medication

UMMH Policies

1. Policy Computerized Provider Order Entry (CPOE) and Order Modes
2. Informed Consent Policy
3. Universal Protocol Policy
4. Safety Event Reporting (Patient and Visitor)- System Policy

Supplemental Materials

- UMass Memorial Health Care Treatment and Procedure Consent Form
- Appendix A: Definition List
- Appendix B: Carboplatin Dosed by AUC

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Appendix A: Terms and Definitions List

A. **Cancer Stage**: A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging but should be specific to the tissue of tumor origin.
B. **Cancer Status**: Description of the patient's disease from the time of diagnosis, if relevant (e.g., recurrence, metastases)
C. **Functional Status**: A narrative description of an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being
D. **Performance Status**: The level of normal daily activity that patients can sustain to care for themselves (including their physical ability such as walking and working); expressed numerically (e.g. ECOG and/or Karnofsky Performance Status Scale) using standard criteria for measuring how the disease impacts the patient's daily living abilities.
E. **Onsite and immediately available**: Physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure.
F. **Identifier (patient identification)**: A set of parameters which, when taken, are unique to the individual. These can include but are not limited to: last name, first name, date of birth, unique identification number (i.e. medical record number). This must exactly match the information on the identity band, order, or drug label (or equivalent).
G. **Hypersensitivity/anaphylactoid Reaction**: A symptomatic interaction between antibodies and allergens that causes an exaggerated and harmful response in the body.
H. **Assent**: Expresses a willingness to participate in a proposed treatment by persons who, by definition, are too young to give informed consent, but who are old enough to understand the diagnosis and proposed treatment in general, its expected risks, and possible benefits; however, assent, by itself, is not sufficient. If assent is given, informed consent must still be obtained from the patient's parents or guardian, both of which must be done according to all applicable state and federal laws.

Appendix B. Carboplatin Dosed by AUC

1. Carboplatin dosed by AUC
    a. Carboplatin dosed by AUC does not follow the same procedure as above regarding changes in height, weight, and BSA. The dose of Carboplatin will automatically adjust based on the most recent height, weight, and serum creatinine.
    b. If the current dose of Carboplatin (as determined by the most recent height, weight, and serum creatinine) differs by >10% from the dose originally signed by the provider, the order will prompt an acknowledgement of this difference.
    c. The Chemo RN will clarify with the provider if they would like to proceed with dosing Carboplatin based on the most recent values (and thus be >10% different than the original dose) or if they would like a different dose.
    d. If the provider agrees to the updated dose using the most recent values, the Chemo RN will click the associated button and document the provider they discussed with.
    e. If the provider does not want to proceed with the updated dose, then they must edit the order and manually type in the dose desired.

2026 Annual Oncology Education

Lauren Steiner, MSN, RN.

Jessica Fields, BSN, RN.

Objectives

- Explain understanding of critical elements of Chemotherapy/Biotherapy policy and procedure
- Verbalize understanding of safe chemotherapy handling
- Demonstrate understanding of Closed System Transfer Devices
- Identify the different types of infusion reactions
- Discuss infusion reaction management
- Identify common side effects of anti-neoplastic therapy

Chemo Cheat Sheet

All of this information is generalized and may not pertain to your specific patient

***It is your responsibility to check treatment plan and orders

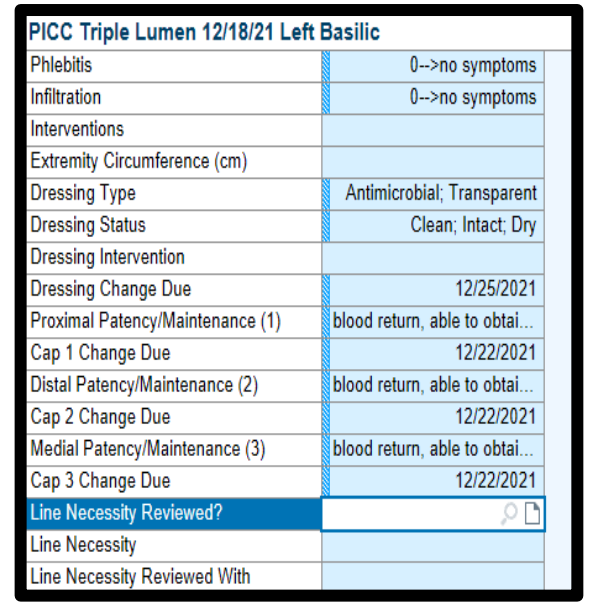
Chemotherapy Pharmacy: 32915 **BMT pharmacist:** Lauren Brothers
Chemotherapy Pharmacy After Hours: Hub – On Call Schedules – Pharmacy-Chemotherapy
Hem/Onc and BMT Fellows: Hub- On Call Schedules – Medicine Department – Hem/Onc
Cut off times: Nursing notification cutoff is 2:00 PM - Inpatient chemotherapy signed and released cutoff of 4:00 PM- Chemotherapy compounding cutoff of 5:00 PM
Oral chemo: Does not need chemo RN to administer, only need consent if for oncological intent-Jakafi for GVHD does not need consent. Oral chemo continued from home does not need new consent
Arsenic: "P listed substance". Must be disposed of in black bin in med room, not in yellow chemo bin
EPOCH: Chemo is orange/red in color. Continuous infusion over 24 hours x 4 days-Cytoxan after final bag-May receive Rituxan before/after
Rituxan: Follow Rituxan administration chart in MAR-Vitals with rate change-many patients receive APAP/Benadryl premedication
Cytarabine: Neurotoxicity Assessment dose before each dose-Document in EPIC -Have patient sign on paper sheet- Hold chemo and notify provider if any changes on score
Vincristine: Vincristine mini bags comes spiked on secondary tubing and primed with NS-The total volume should be less than 30ml-Vincristine is to run via gravity; no pump on the primary tubing- Use free flowing NS only; minimum 250ml bag
Doxorubicin: IV push via syringe, chemo is orange. IVP 1-2ml/min with free flowing NS
Mitoxantrone: Chemo is blue, will turn urine blue/greenish
Methotrexate: Chemo is yellow. Sodium Bicarb bolus followed by continuous sodium bicarb infusion. Cannot start MTX until urine pH >7. Check urine pH with each void until MTX level is less than 0.1. Leucovorin starts 12 hours after MTX completion and continues Q6H until MTX less than 0.1
IT Chemotherapy: LIPs are responsible for releasing IT chemotherapy in the treatment plan-LIPs will release IT chemotherapy during the day shift that it is due. RNs are NOT responsible for releasing IT chemo

Preparing for Chemo: Draw labs per treatment plan-Review labs-Double height and weight-Review treatment plan-Place Chemo Precautions sign on door-Consent in EPIC-Spill kit in room-2 Chemo RNs check orders and document pre-chemo checklist-Verify appropriate access
Chemotherapy Monitoring: Accurate I&Os-Check blood return every 4 hours and document -Ongoing patient education-Urine pH as ordered-Labs as ordered-Daily weight bedside shift report with treatment plan review and line check-Document rate verification in MAR at change of shift-Central Venous Access Device is required for all continuous chemo infusions equal to or greater than 12 hours in duration
After Chemo: Check blood return after completion and document -"Stop" infusion in MAR and document volume-Place chemo in chemo bag and into chemo bin-Complete Treatment Plan Day--Accurate I&O
Chemotherapy safe handling: PPE for chemotherapy/immunotherapy includes: Double glove with gloves that have been tested for use with HD's-Permeability resistant gown-Mask-Face shield-Eye protection
Closed System Transfer Device (CSTD) is a system that is specially designed to provide a secure luer lock connection when administering HDs- Injector-Connector-Infusion Clamp
Infusion Reactions: reactions occur with many oncological treatments-Infusion reactions can happen at ANY TIME! -Clinical presentation of reactions can vary in severity from mild to life-threatening. Many treatment plans include pre-medications prior to administration and all treatment plans should include PRN emergency medications
Types of Infusion Reactions: Cytokine Release Syndrome-Hypersensitivity Reaction-Anaphylaxis
Reaction Management: Stop the infusion immediately-Remain with the patient-Have another staff member notify the appropriate provider or initiate an emergency response-Dial 12345 to activate Rapid Response or Code Blue-Maintain a patent IV with Normal Saline or other appropriate IV fluid
DO NOT Y-SITE chemo with other chemo/medications/fluids unless you have no other choice for access and you have verified that they are compatible. Placing a peripheral IV is preferrable to Y-siting chemo

Chemotherapy Policy & Procedure Reminders

- Intravenous infusions of Chemotherapy/Immunotherapy are administered via a peripheral intravenous catheter (PIV) or central venous access device (VAD) which has brisk blood return, no signs or symptoms of phlebitis or infection and is of an adequate gauge for administration of the ordered medications
- Central Venous Access Device is required for all continuous chemotherapy/immunotherapy infusions equal to or greater than 12 hours in duration
- Blood return is verified prior to and following all intravenous chemotherapy/immunotherapy infusions and during infusions greater than two hours in duration

Chemotherapy/Immunotherapy Administration Procedure



PICC Triple Lumen 12/18/21 Left Basilic	
Phlebitis	0-->no symptoms
Infiltration	0-->no symptoms
Interventions	
Extremity Circumference (cm)	
Dressing Type	Antimicrobial; Transparent
Dressing Status	Clean; Intact; Dry
Dressing Intervention	
Dressing Change Due	12/25/2021
Proximal Patency/Maintenance (1)	blood return, able to obtai...
Cap 1 Change Due	12/22/2021
Distal Patency/Maintenance (2)	blood return, able to obtai...
Cap 2 Change Due	12/22/2021
Medial Patency/Maintenance (3)	blood return, able to obtai...
Cap 3 Change Due	12/22/2021
Line Necessity Reviewed?	
Line Necessity	
Line Necessity Reviewed With	

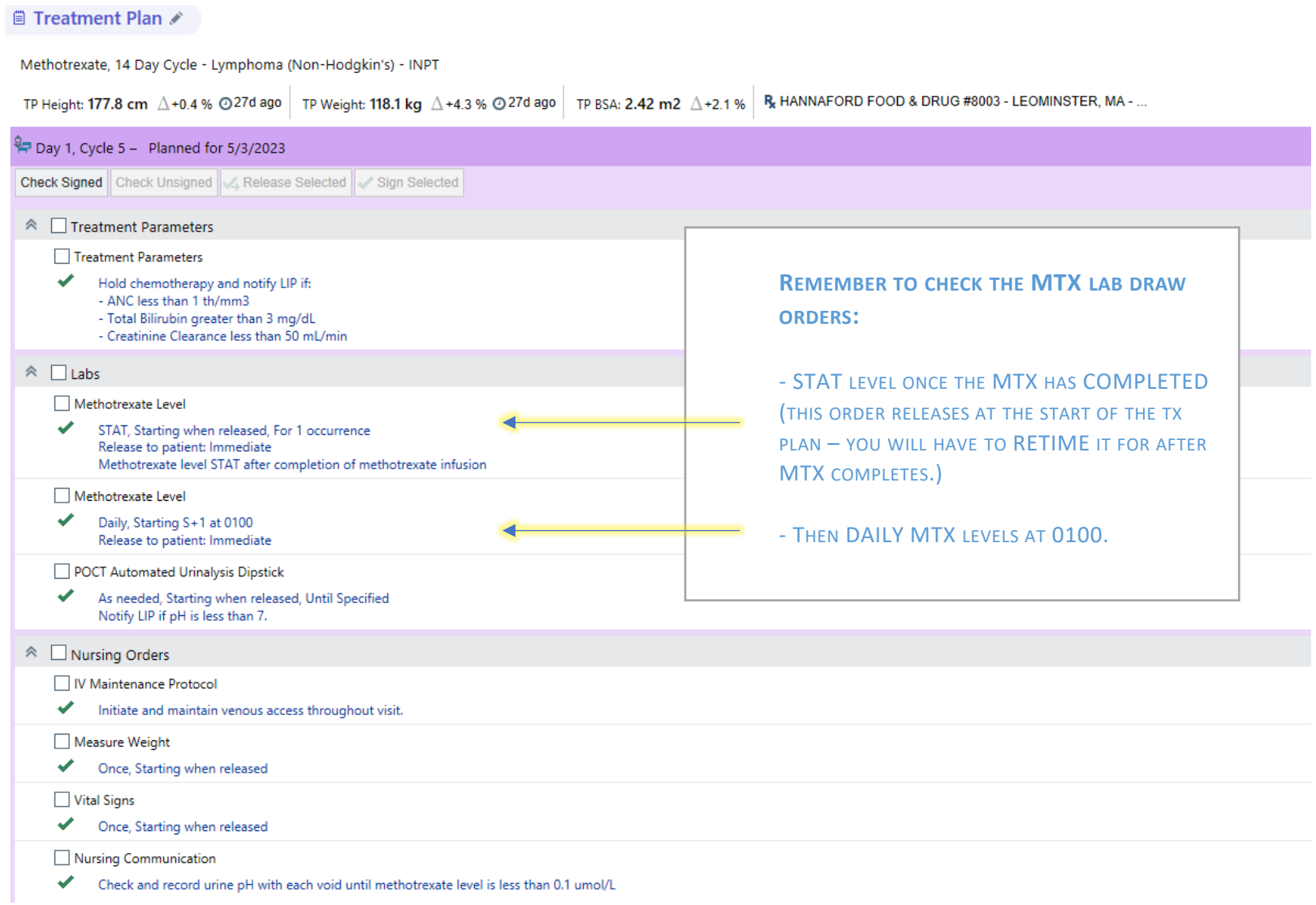
Chemotherapy Policy & Procedure Reminders

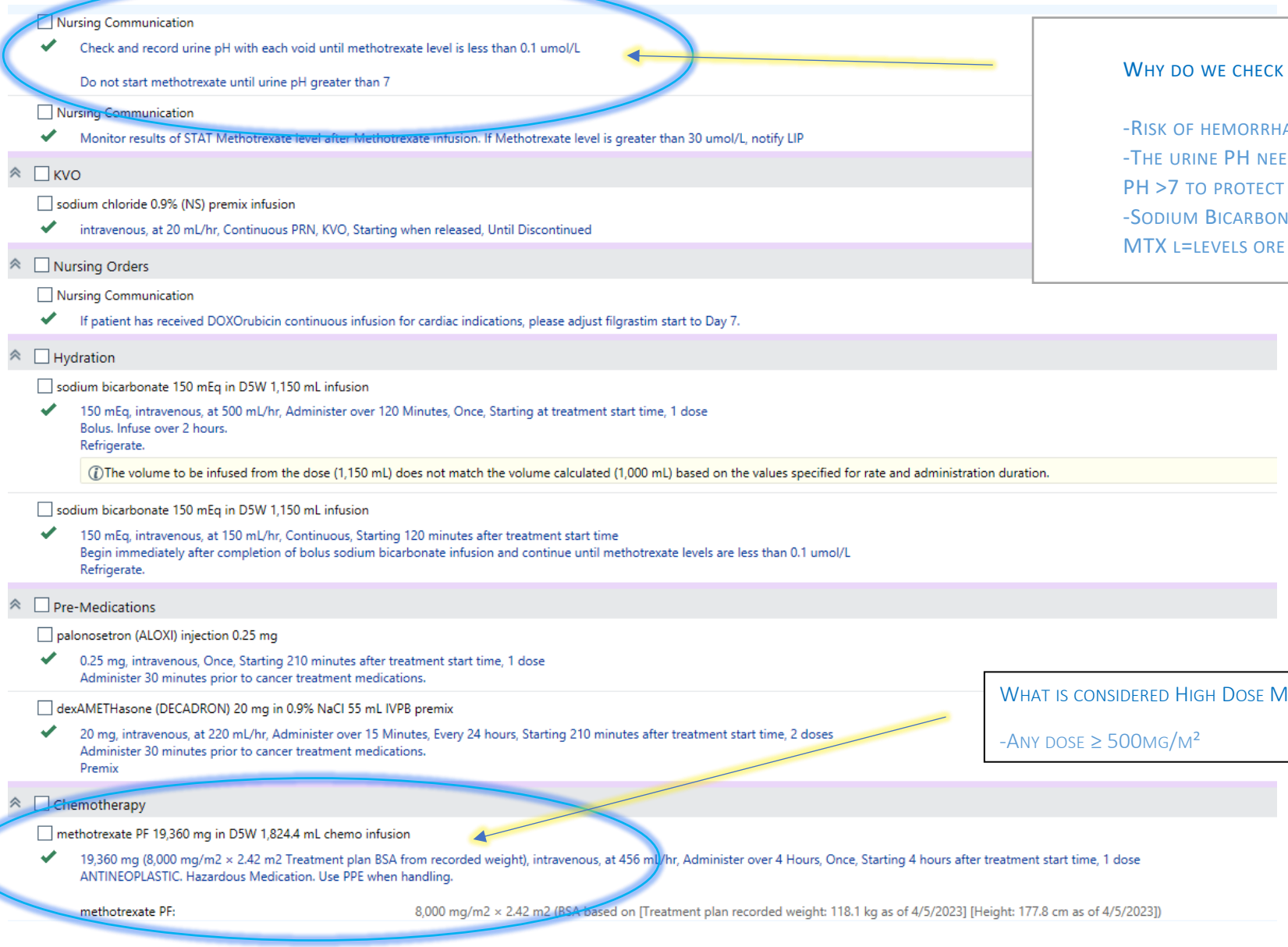
Patients receiving infusions of chemotherapy/immunotherapy across shift changes complete RN hand-off that includes bedside verification with 2 RNs for medication, IV access, rate, and remaining volume. Both RNs will also review the chemotherapy treatment plan to ensure that all pertinent chemotherapy orders have been released

THIS DUAL VERIFICATION WILL BE DOCUMENTED IN THE MAR

High Dose Methotrexate

***Gyn/Onc regimens may have different monitoring, refer to Physicians orders.*





Why do we check urine PH with HD MTX?

-Risk of hemorrhagic cystitis
-The urine PH needs to be kept alkaline with a PH >7 to protect the lining of the bladder
-Sodium Bicarbonate infuses continuously until MTX l=levels ore <0.1 umol/L

What is considered High Dose MTX?

-Any dose ≥ 500mg/m^2

Chemotherapy

- [ ] methotrexate PF 19,360 mg in D5W 1,824.4 mL chemo infusion

✔ 19,360 mg (8,000 mg/m2 × 2.42 m2 Treatment plan BSA from recorded weight), intravenous, at 456 mL/hr, Administer over 4 Hours, Once, Starting 4 hours after treatment start time, 1 dose
ANTINEOPLASTIC. Hazardous Medication. Use PPE when handling.

methotrexate PF:	8,000 mg/m2 × 2.42 m2 (BSA based on [Treatment plan recorded weight: 118.1 kg as of 4/5/2023] [Height: 177.8 cm as of 4/5/2023]) = 19,360 mg × 1 mL/25 mg = 774.4 mL × 25 mg/mL = 19,360 mg

- [ ] leucovorin 50 mg in D5W 112.5 mL IVPB

✔ 50 mg, intravenous, at 450 mL/hr, Administer over 15 Minutes, Every 6 hours, Starting 20 hours after treatment start time
Begin 12 hours after methotrexate completion and continue until MTX level is less than 0.1 umol/L

Hypersensitivity Reaction Medications

- [ ] Hypersensitivity Reaction Instructions

✔ If symptoms of hypersensitivity occur, initiate Emergency Medication protocol and contact provider.

- [ ] hydrocortisone sodium succinate (Solu-CORTEF) injection 100 mg

✔ 100 mg, intravenous, at 60 mL/hr, Administer over 2 Minutes, Once as needed, Itching, flushing, rash, chest tightness, back pain, rigors, Starting when released, Until Discontinued

- [ ] diphenhydrAMINE (BENADRYL) injection 50 mg

✔ 50 mg, intravenous, at 30 mL/hr, Administer over 2 Minutes, Once as needed, Itching, flushing, rash, chest tightness, back pain, rigors, Starting when released, Until Discontinued

- [ ] famotidine (PEPCID) injection 20 mg

✔ 20 mg, intravenous, Once as needed, Itching, flushing, rash, chest tightness, back pain, rigors, Starting when released, Until Discontinued
IV Push over at least 2 minutes
IV Push over at least 2 minutes.

- [ ] sodium chloride 0.9% (NS) premix infusion 500 mL

✔ 500 mL, intravenous, Administer over 15 Minutes, Once as needed, Systolic BP less than 90, Starting when released, Until Discontinued

- [ ] albuterol 2.5 mg/3 mL (0.083%) nebulizer solution 2.5 mg

✔ 2.5 mg, inhalation, Once as needed, wheezing, shortness of breath, chest tightness, Starting when released, Until Discontinued
Neb to be administered by: Nursing

Anaphylactic Reaction Medications

- [ ] EPINEPHrine (ADRENALIN) 1:1,000 (1 mg/mL) injection 0.3 mg

✔ 0.3 mg, intramuscular, Once as needed, anaphylaxis, Starting when released, Until Discontinued

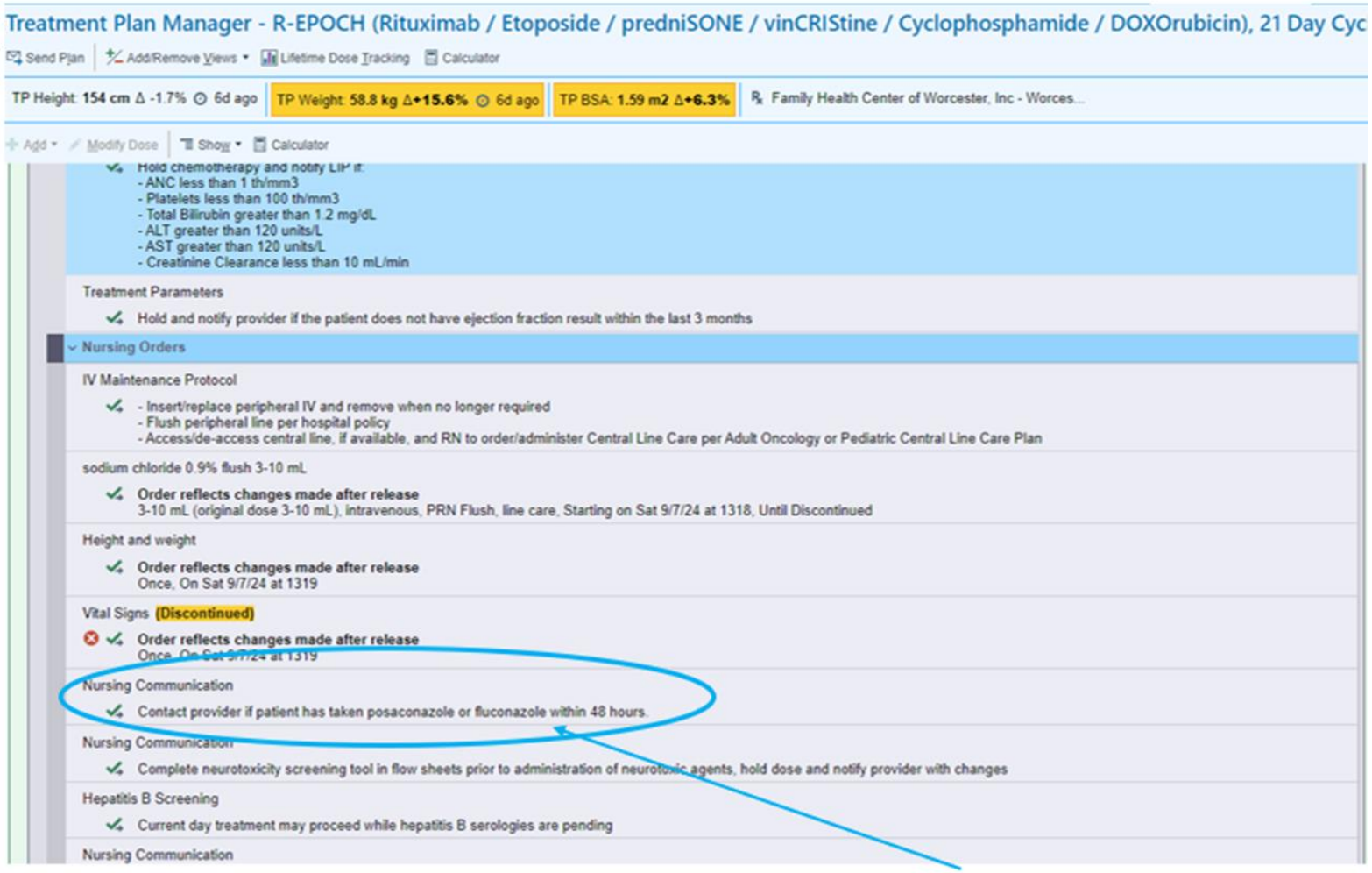
WHY DO WE GIVE LEUCOVORIN RESCUE WITH HD MTX?

-MTX HAS LITTLE SELECTIVITY FOR TUMOR CELLS AND ITS EFFECTIVENESS IS LIMITED BY TOXICITY TO NORMAL TISSUE

-TO IMPROVE THE THERAPEUTIC INDEX OF MTX THE CONCEPT OF RESCUING NORMAL CELLS FROM TOXICITY BY PROVIDING REDUCE FOLATES (LEUCOVORIN) TO BYPASS THE METABOLIC BLOCK INFUSED MY MTX-WHICH IN TERN HELPED PREVENT MTX-INDUCED TOXICITY WITHOUT DIMINISHING ANTITUMOR ACTIVITY

Carefully read through the treatment plan for specific orders such as antifungals

-drug interactions such as metabolization



Pt needs to hold Posaconazole, Fluconazole & Cresemba at least 48 hrs prior to admitting for EPOCH

Vincristine toxicity is significantly increased when combined w/ Azole treatment and can be life threatening d/t its interference w/ the metabolism of Vincristine

Guideline for Chemotherapy Releasing

This guideline has been developed to provide a standard for important deadlines for ordering and releasing inpatient chemotherapy

4. **Inpatient Chemotherapy Signed and Release Cutoff:**
   A. Inpatient chemotherapy signed and released cutoff of 4:00 PM
      i. The following need to be completed prior to release of chemotherapy:
         a) Attending or fellow reaches out to nursing and pharmacy to make them aware of patient. Nursing notification cutoff is 2:00 PM.
         b) Patient consented for chemotherapy and readily available to view in EMR
         c) Patient double height and weight documented in the chart and updated in the treatment plan, if needed
         d) Attending or fellow has pharmacy check orders for any needed edits prior to signing
         e) Nursing contacted to ensure a chemotherapy competent nurse is available to give chemotherapy (especially if off-unit chemo)
         f) Labs ordered and resulted
         g) Any testing (e.g. ECHO) completed
         h) Orders signed by appropriate clinician and nursing notified that plan is signed.

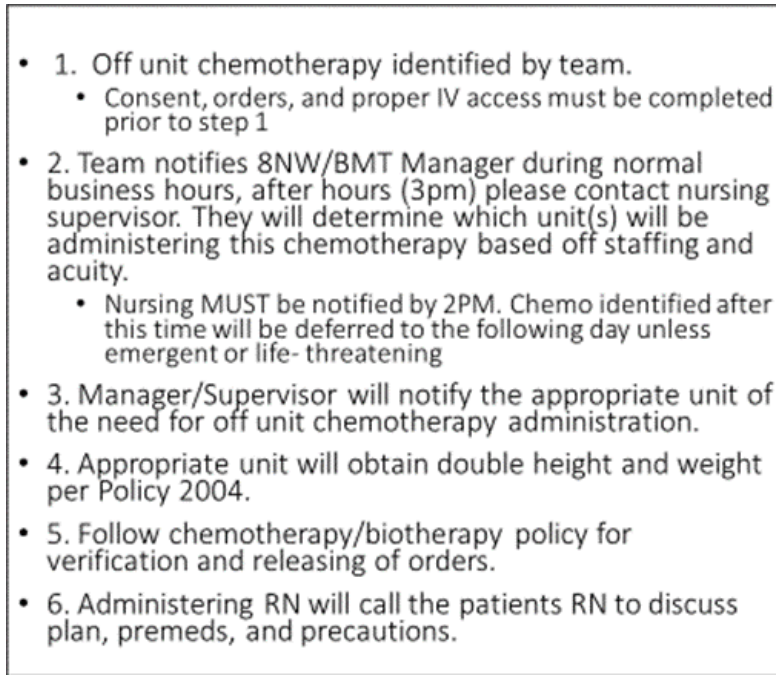
Guideline for Chemotherapy Releasing

This policy serves as a general parameter, but there may be cases in which chemotherapy administration is needed urgently off hours

Off hours chemotherapy may be indicated for: acute promyelocytic leukemia, new urgent acute leukemia, Burkitt's lymphoma, very aggressive lymphomas, or other clinically significant situations

If a patient presents with a life-threatening oncological diagnosis which requires emergent chemotherapy the attending oncologist will follow the Off-Unit Chemotherapy Process

Off Unit Chemo Process



- 1. Off unit chemotherapy identified by team.
  - Consent, orders, and proper IV access must be completed prior to step 1
- 2. Team notifies 8NW/BMT Manager during normal business hours, after hours (3pm) please contact nursing supervisor. They will determine which unit(s) will be administering this chemotherapy based off staffing and acuity.
  - Nursing MUST be notified by 2PM. Chemo identified after this time will be deferred to the following day unless emergent or life- threatening
- 3. Manager/Supervisor will notify the appropriate unit of the need for off unit chemotherapy administration.
- 4. Appropriate unit will obtain double height and weight per Policy 2004.
- 5. Follow chemotherapy/biotherapy policy for verification and releasing of orders.
- 6. Administering RN will call the patients RN to discuss plan, premeds, and precautions.

- If the patient is clinically appropriate, patient should be transferred to 8NW or BMTU. This process will be reserved for patients requiring emergent chemotherapy/immunotherapy in critical care areas

- Chemotherapy RN will give report to patient's RN pertaining to rate, side effects, and phone number of the chemotherapy RN

- If a patient is transferred from 8NW or BMTU to another patient care area, every attempt will be made to administer chemotherapy to the patient by the transferring unit

Chemotherapy safe handling

UMMC has guidelines for the handling of hazardous drugs (HDs), including chemotherapy

- These are derived from USP 800
- Provides practice and quality standards for handling of HDs

Hazardous Drugs (HD's): Drugs are hazardous if they demonstrate one or more of the following characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity
- Reproductive toxicity
- Organ toxicity at low dose
- Genotoxicity
- Newer drugs with similar structural profiles to known HD's

For additional information please refer to UMMC Policy 2003 Safe Handling of Hazardous Drugs (HD's)

Safe Handling of Hazardous Drugs

Chemotherapy safe handling

- PPE for chemotherapy/immunotherapy includes:
  - Double glove with gloves that have been tested for use with hazardous drugs (HD)
  - Permeability resistant gown (wrist cuffed gowns)
  - Mask
  - Face shield
- Eye protection: Most HDs have been shown to be irritating and damaging to mucous membranes
- Face and eye protection is necessary when there is a risk for spills or splashes
- Protect yourself from unnecessary exposure by using appropriate PPE whenever you are in contact with chemo, tubing or contaminated body fluids

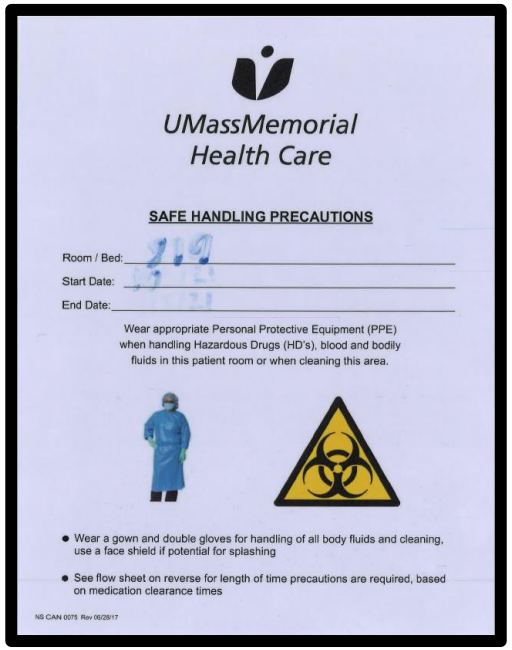
Chemotherapy safe handling

Patients who are receiving HD's will have visible signage outside their room from start of chemotherapy until 48 hours after the completion of final chemo infusion

Safety takes all of us!

When caring for a patient receiving HD's please educate PCAs, housekeeping, students, and other members of the care team to use appropriate PPE when exposure is possible!

<u>Please place signage prior to administering HDs</u>



UMassMemorial Health Care

SAFE HANDLING PRECAUTIONS

Room / Bed: 219

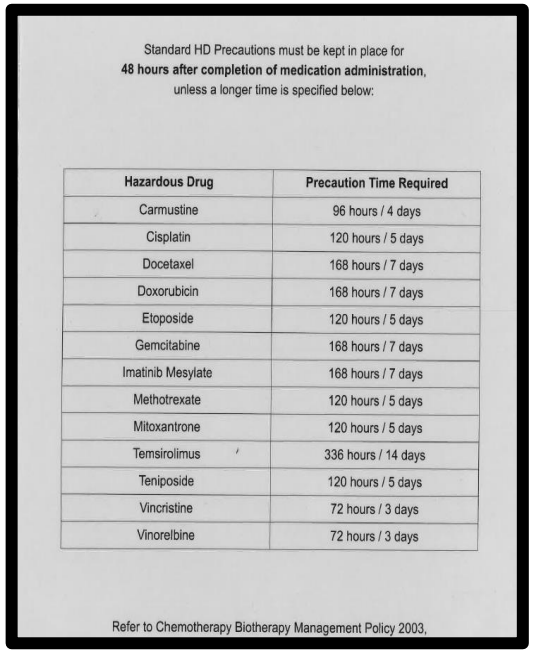
Start Date:

End Date:

Wear appropriate Personal Protective Equipment (PPE) when handling Hazardous Drugs (HD's), blood and bodily fluids in this patient room or when cleaning this area.

- Wear a gown and double gloves for handling of all body fluids and cleaning, use a face shield if potential for splashing
- See flow sheet on reverse for length of time precautions are required, based on medication clearance times

NS CAN 0075 Rev 06/28/17



Standard HD Precautions must be kept in place for **48 hours after completion of medication administration,** unless a longer time is specified below:

Hazardous Drug	Precaution Time Required
Carmustine	96 hours / 4 days
Cisplatin	120 hours / 5 days
Docetaxel	168 hours / 7 days
Doxorubicin	168 hours / 7 days
Etoposide	120 hours / 5 days
Gemcitabine	168 hours / 7 days
Imatinib Mesylate	168 hours / 7 days
Methotrexate	120 hours / 5 days
Mitoxantrone	120 hours / 5 days
Temsirolimus	336 hours / 14 days
Teniposide	120 hours / 5 days
Vincristine	72 hours / 3 days
Vinorelbine	72 hours / 3 days

Refer to Chemotherapy Biotherapy Management Policy 2003,

Chemotherapy Disposal

- Chemotherapy Waste
  - Must be collected in a yellow chemo container located in the dirty utility room on BMTU, 8 North, and 8 West
  - Includes all non-empty drug containers
  - All empty (less than 3%) chemotherapy drug containers
  - Any materials from spill cleanup
  - Contaminated and non-contaminated PPE
  - Please do not dispose of sharps in the yellow containers
    - *Sharps connected to a chemo syringe are to be placed in sharps bin still connected.*
  - Please do not dispose of other medication, hazardous waste, or blood products in the yellow chemo container

If a patient is being treated with Arsenic, please notify Environmental Health and Safety. Arsenic is considered P-Listed (Acutely Hazardous) Waste and requires specific disposal (black bin)

Agents that Aerosolize

Please make sure bag has been sealed prior to discarding in bins!

Hazardous Drugs administered at the medical center that vaporize at room temperature and are a risk of aerosolization include:

a) Carmustine

b) Cisplatin

c) Cyclophosphamide

d) Etoposide

e) 5-fluorouracil

f) Ifosfamide

g) Nitrogen Mustard

h) Thiotepa

Chemo spill kit

- Contec brand
- Check expiration date on kit
  - Use kit with earliest expiration first!
  - Return to Secretary or NESS if expired
- Extra kits in med rooms – or back room on 8North
- Must travel with patient actively receiving chemotherapy/hazardous medication – *place in belonging bag to keep clean.*
- Review items in kit – QR code on bag

- (Product)
- Review Hazardous Spill procedure

- Chemotherapy/HD Spill Clean-Up

Radiation Exposure

- Radiation Safety Office
  - 508-856-3208
- Radiation team rounds on patients who have received any radioactive material and will remove any contaminated waste/linen from the room.
  - Do not remove anything from the room!
- The time may vary, but a minimum of 24 hours after patient exposure. Always call the office to discuss.
- Patients room door may remain open.
- No routine cleaning during exposure time.
  - If room needs cleaning – Radiation Safety Office must be notified so they can check the room for radiation contamination and determine if cleaning can be done by EVS.

Knowledge ☑

True or False

You enter the room of a patient receiving HDs and notice that their IV pump is alarming. You do not need to don gloves before touching the patient's IV tubing

TRUE

FALSE

Knowledge ☑

When working with HDs, Personal Protective Equipment:

- Only needs to be worn by the registered nurse
- Is suggested, but not required
- Is designed to protect healthcare workers from exposure to HD's
- Must be purchased by the healthcare worker

Knowledge ☑

True or False

Your patient has completed their chemotherapy infusion and the bag appears empty. This chemotherapy bag is considered chemo waste and must be disposed of in a yellow chemotherapy container

TRUE

FALSE

Knowledge ☑

True or False

Your patient had radioactive dye 12 hours ago. The trash and linen bin are full. You can safely remove the trash and linen and bring them to the dirty utility room yourself.

TRUE FALSE

Equashield: Closed System Transfer Device (CSTD)

- A Closed System Transfer Device (CSTD) is a system that is specially designed to provide a secure luer lock connection when administering HDs
  - CSTDs are to be used whenever possible when administering HDs
  - Reduces the risk of accidental disconnection
  - Reduces drug leaks and spills
  - Are recommended by the Oncology Nursing Society and OSHA
  - Reduces caregivers chronic exposure to HDs
  - Improves patient and caregiver safety
  - Does not replace the need for proper PPE
  - Can use for up to 10 accesses (may leave on the IV line and alcohol in between use with longer regimens)

Closed System Transfer Device: Equashield

Luer Lock Adaptors & Connectors

EQUASHIELD®'s luer lock adaptors and connectors are designed to convert any standard luer lock port into a closed system connection for leak-free and dry connection.

EQUASHIELD®'s Luer Lock Adaptors, LL-2 and LL-2S are secured onto a patient line for safe injection via an EQUASHIELD® Syringe Unit (SU) or safe infusion via an FC-1 or FC-1S. While LL-2 and LL-2S safely and securely attach to any standard luer lock access port, the LL-2 remains stationary, and the LL-2S spins freely when attached; both are designed for safe and secure administration of hazardous drugs.

EQUASHIELD®'s Female Luer Lock Connectors, FC-1 and FC-1S provide a connection at the end of an IV line ensuring compliance during administration and reducing the risk of accidental disconnections. FC-1 is a standard connector, while FC-1S is a free swiveling connector; both are designed safe and secure administration of hazardous drugs.

LL-2
Luer Lock Adaptor 2

LL-2S
Luer Lock Adaptor 2 Swivel

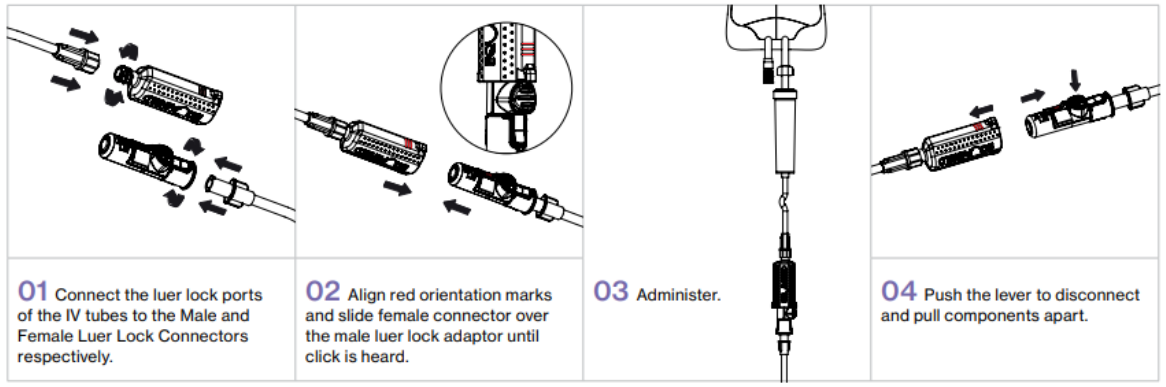
FC-1
Female Luer Lock Connector

FC-1S
Female Luer Lock Connector Swivel

Instructions for Use

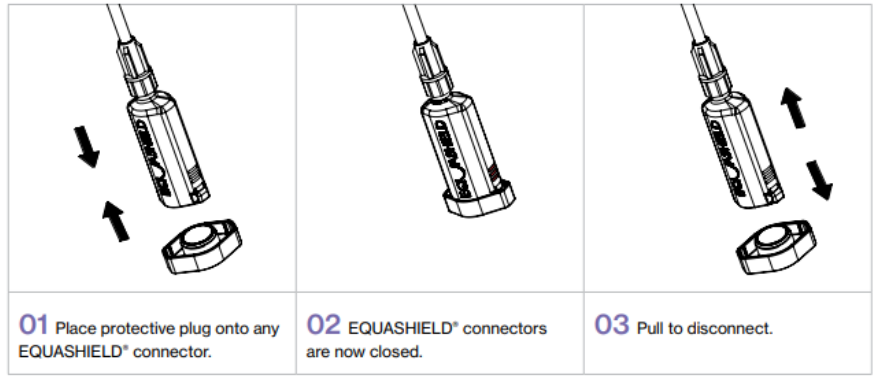
Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

Connection of two IV tubing segments



01	02	03	04
Connect the luer lock ports of the IV tubes to the Male and Female Luer Lock Connectors respectively.	Align red orientation marks and slide female connector over the male luer lock adaptor until click is heard.	Administer.	Push the lever to disconnect and pull components apart.

Connection of the Protective Plug



01	02	03
Place protective plug onto any EQUASHIELD® connector.	EQUASHIELD® connectors are now closed.	Pull to disconnect.

Equashield

<u>To Connect</u>

- Clean line site with alcohol.
- Apply “Luer Lock port” to line using aseptic technique.
- The “Luer Lock” is sterile out of package.
- Clean end of “Injector” with alcohol prior to connecting.
- To Connect: Line up the red marks on the luer lock port until it clicks into place (sometimes you will not hear a click just pull and ensure it is locked).

<u>To Disconnect</u>

- Apply pressure to level to disconnect.
- When disconnecting from an IV line DO NOT remove as a single unit.
- ALWAYS disconnect the “Luer lock port” from each other FIRST, then disconnect the connector from the IV line.

Knowledge ☑

True or False

Using a Closed System Transfer Device means that you do not need a don PPE to administer chemotherapy

TRUE

FALSE

Infusion Reactions

- Infusion reactions occur with many different types of oncological treatments
- Infusion reactions can happen at ANY TIME!
- They can occur just minutes into an infusion, during an infusion, or even after the infusion has been completed
- Clinical presentation of reactions can vary in severity from mild to life-threatening
- Infusion reactions can be scary for both patient and nurse, so it is crucial to know what steps to take
- Many treatment plans include pre-medications prior to drug administration and all treatment plans should include PRN emergency medications

Types of Infusion Reactions

Cytokine Release Syndrome

Hypersensitivity Reaction

Anaphylaxis

Cytokine Release Syndrome

Cytokine Release Syndrome (CRS), which is commonly referred to as an infusion reaction, is a symptom complex that occurs frequently when Monolclonal Antibodies (MoAbs) are administered. This reaction is related to the release of cytokines such as IL-2, IFN, and TPN from the targeted cells and other recruited immune cells, such as lymphocytes

Signs and Symptoms of Cytokine Release Syndrome

Fever	Chills
Nausea	Hypotension
Tachycardia	Headache
Weakness	Rash
Tongue or throat swelling	Dyspnea

Hypersensitivity Reaction

A Hypersensitivity reaction is triggered by an allergic rection to a medication, the metabolites of the medication, or the drug diluent. The allergen causes direct or IgE mediated mast cell degranulation with a histamine release

Signs and Symptoms of Hypersensitivity Reaction

Unease or agitation	Hives or rash
Chest tightness	Itching
Shortness of breath	Periorbital or facial edema
Wheezing	Lightheadedness or dizziness
Hypotension	Abdominal cramping, diarrhea, nausea, vomiting

Anaphylaxis

Anaphylaxis is an acute and life-threatening reaction where the airway and circulatory systems become severely compromised

Anaphylaxis can range in severity from mild breathing problems (such as mild wheezing) to complete circulatory collapse

<u>Recognition and action is essential!</u>

If your patient begins to experience any of these symptoms,

Do not panic!

Here's what to do…

Reaction Management

- Stop the infusion immediately and disconnect.
- Remain with the patient
- Have another staff member notify the appropriate provider or initiate an emergency response
  - Dial 12345 to activate Rapid Response or Code Blue
- Maintain airway, administer oxygen as needed
- Maintain a patent IV with Normal Saline or other appropriate IV fluid
- Position the patient appropriately
  - Sit upright if short of breath or vomiting
  - If hypotensive have patient laying as flat as possible
- Monitor vital signs frequently
- Obtain an EKG for serious reactions
- Be prepared for cardiopulmonary resuscitation
- Administer medications based on symptoms per treatment plan/provider order
- Provide emotional support to patient and family
- Document all treatments and response

Common Interventions for Reaction Management

Indication	Drug	Dose	Comments
Bronchial constriction (dyspnea, wheezing, stridor)	Epinephrine	0.1-0.5 mg IM into thigh (0.1-0.5ml of 1:1000 solution)	IM administration preferred over IV to minimize adverse cardiac effects
Shortness of breath, tachypnea (rate >20) or decreased oxygen saturation	Oxygen	6-10 L/min by face mask	Patients who are hemodynamically unstable may also benefit from oxygen
	Albuterol	2.5 mg of inhalation (3ml of 0.083% inhalation solution) by nebulizer	Hold in heart rate is > 110
Hypotension (>30% decrease in systolic blood pressure from baseline)	Epinephrine	0.1-0.5 mg IM into thigh (0.1-0.5 ml of 1:1,000 solution) or 5-10 mcg IV bolus (0.2 mcg/Kg) for hypotension	IM administration preferred over IV to minimize adverse cardiac effects, except in the presence of cardiovascular collapse. Cardiac monitoring is recommended
	Normal Saline IV	500 ml fluid bolus	Multiple fluid boluses may be required if patient remains hypotensive despite epinephrine
Hives, itching, flushing, swollen lips or tongue	Diphenhydramine	25-50 mg IVP	Both H1 and H2 blockers should be administered to counteract the multiple effects of histamine release
	Famotidine	20 mg IV	
	Ranitidine	50 mg IV	

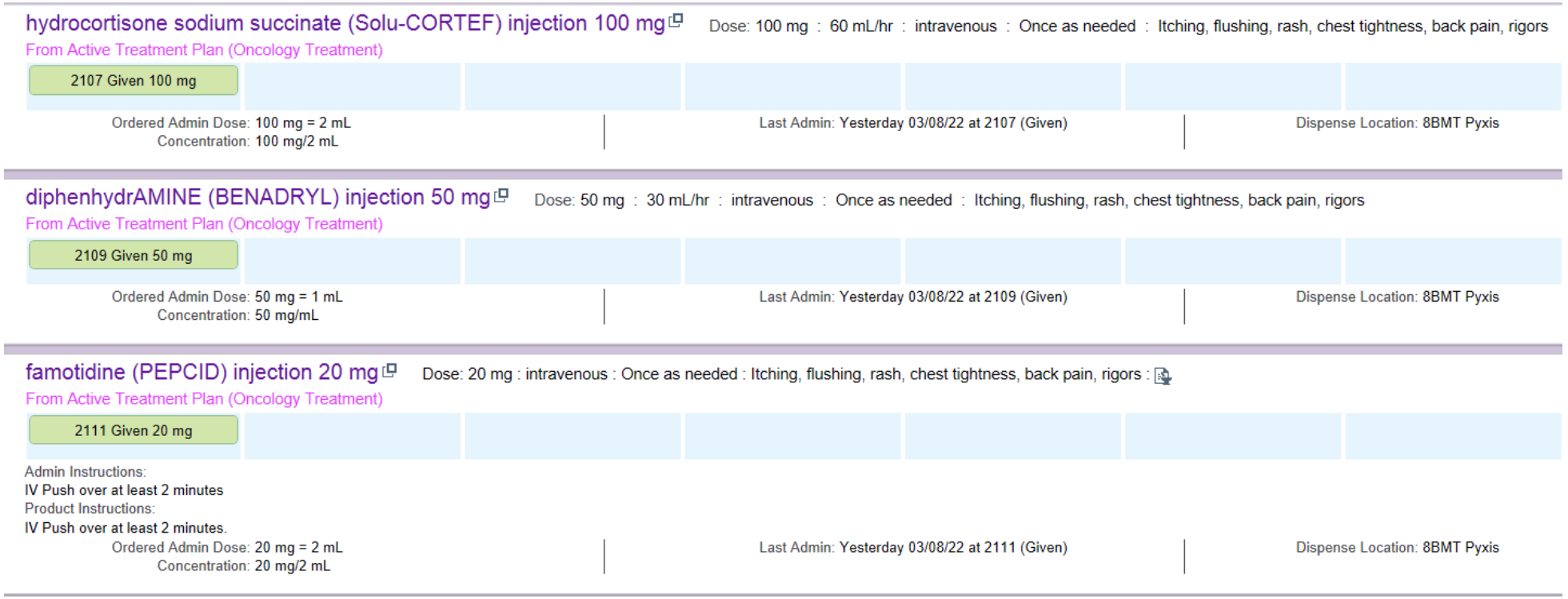
Reaction Medications in Treatment Plan

Reaction Medications should be released at the same time as chemotherapy so they can be verified by pharmacy and are ready to be administered if needed

Reactions kits are available in the pyxis, but *Pepcid is not in the kits* as the vials may be in the refrigerator.

MAR Documentation

Rescue medications should be documented in the MAR real time as they are being administered



Reaction Management – Final Steps

- After the patient has been treated and all interventions have been documented, please enter a safety event report
- Safety Event Reporting can be found on the Hub
- For additional information, please reference UMMC Policy 1081 Adverse Drug Reaction Reporting
- A Significant Event note should be filed in Epic regarding reaction. Be sure to include patient's symptoms and nursing interventions

Oncologic Emergencies

The following are emergent situations that you may see when treating and managing oncology patients:

- TACO & TRALI-When Administering blood products
- Cardiac Tamponade
- Disseminated Intravascular Coagulation (DIC)
- Super Vena Cava Syndrome
- SIADH
- Tumor Lysis Syndrome (TLS)
- Spinal Cord Compression

Blood Administration Complication Pearls: TRALI & TACO
What to look for and what to do next

Transfusion-Related Acute Lung Injury **(TRALI)**

- **What does the patient look like?**
  - Acute respiratory distress or failure during or within
    6 hours after transfusion; often dramatic onset
  - Bilateral pulmonary infiltrates on chest x-ray
  - Hypoxemia (O2 sat ≤ 90% on room air)
  - Hypotension or, in some cases, hypertension
  - Fever
  - Tachycardia
  - Dyspnea
  - Cyanosis

Transfusion-Associated Circulatory Overload (TACO)

- **What does the patient look like?**
  - Dyspnea
  - Cough
  - Rales on auscultation
  - Cyanosis
  - Tachycardia
  - Hypertension
  - Congestive heart failure
  - Bilateral pulmonary edema on CXR

- **What to do if either of these complications occur in your patient?**
  - **Stop** the infusion immediately
  - Obtain **vital signs**
  - **Call** the provider
  - **Refer** to policy #2070 for further actions regarding documentation and reporting.

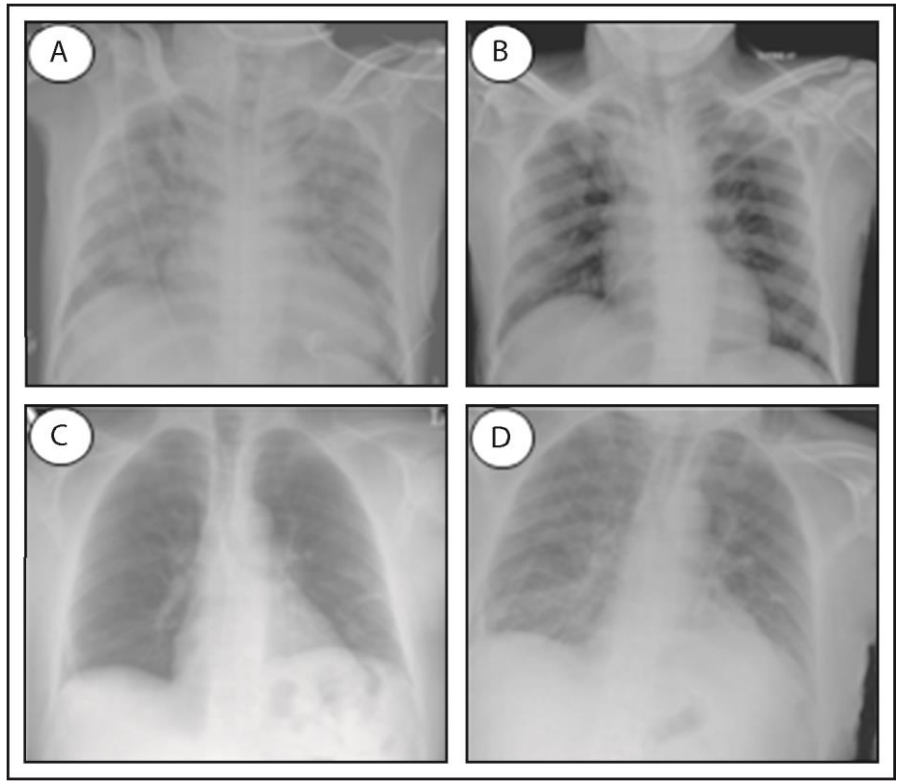
TRALI & TACO differ from an anaphylactic reaction, but can be an equally serious complication. Always be alert for **all** kinds of transfusion reactions

Transfusion-associated circulatory overload and transfusion-related acute lung injury

Chest radiographs of a TACO and TRALI patient

Patient at time of TACO occurrence (A), and the same patient after resolution of TACO (B).

Pretransfusion patient (C), and the same patient at time of TRALI occurrence (D)



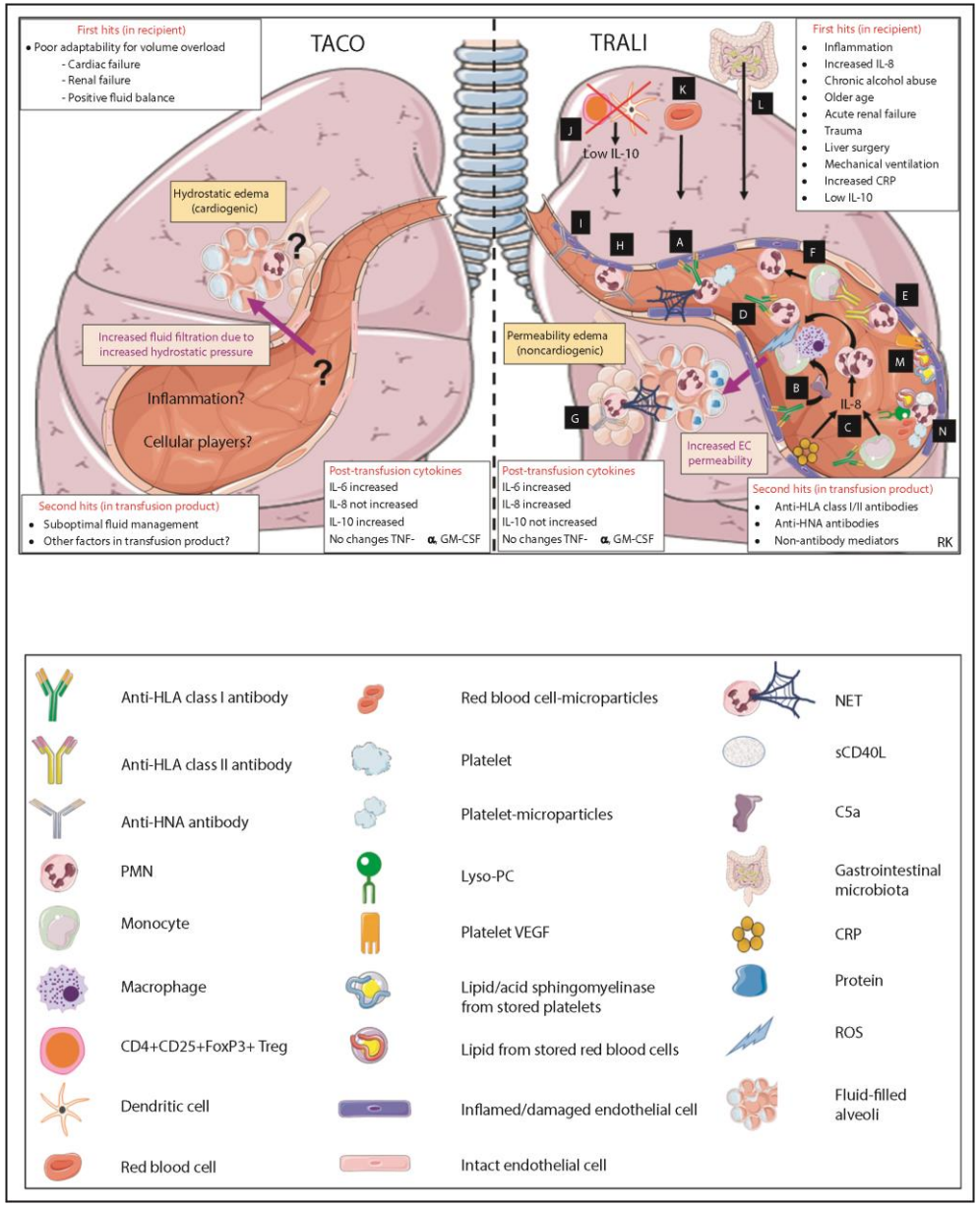
Normal chest radiographs without signs of pulmonary edema (B-C)

Infiltrative changes indicative of pulmonary edema (A,D)

John W. Semple,Johan Rebetz,Rick Kapur, Transfusion-associated circulatory overload and transfusion-related acute lung injury, Blood, 2019, Figure 1.

TACO & TRALI

Pathophysiological mechanisms of TACO and TRALI in the lungs



John W. Semple,Johan Rebetz,Rick Kapur, Transfusion-associated circulatory overload and transfusion-related acute lung injury, Blood, 2019, Figure 2.

Cardiac Tamponade (CT)

What is Cardiac Tamponade?

It occurs when there is excessive fluid that accumulates in the pericardium. The result is a constrictive event that places pressure on the heart and compresses the cardiac chambers which leads to:

- Decreased cardiac output & circulatory failure

Risk Factors:

- Metastatic involvement of the pericardium
- Incidence is highest among patients with lung cancer, breast cancer, leukemia, lymphoma and melanoma

Clinical Manifestations:

- Dyspnea
- Tachycardia and chest discomfort
- Jugular venous distension

How is it diagnosed?

- Echocardiogram
- Chest X-Ray

Nursing Considerations:

- Assess for respiratory, cardiovascular or neurologic compromise
- Treat the underlying cause with radiation, chemotherapy or surgery as appropriate
- Pericardiocentesis is used to treat symptoms and improve cardiac hemodynamics
- CT is typically associated with late-stage disease and limited survival

Disseminated Intravascular Coagulation (DIC)

What is DIC?

A condition in which clotting and bleeding occur simultaneously. There is widespread intravascular thrombosis which can lead to organ damage and failure. While simultaneous consumption of platelets and coagulation factors lead to hemorrhage.

Risk Factors:

- Sepsis with gram positive or negative organisms, or hemorrhagic fevers
- Solid tumor patients due to thrombotic consequences/VTE
- New diagnosis leukemia due to severe thrombocytopenia and factor deficiency
- Severe immunologic reactions such as transfusion reactions
- Trauma

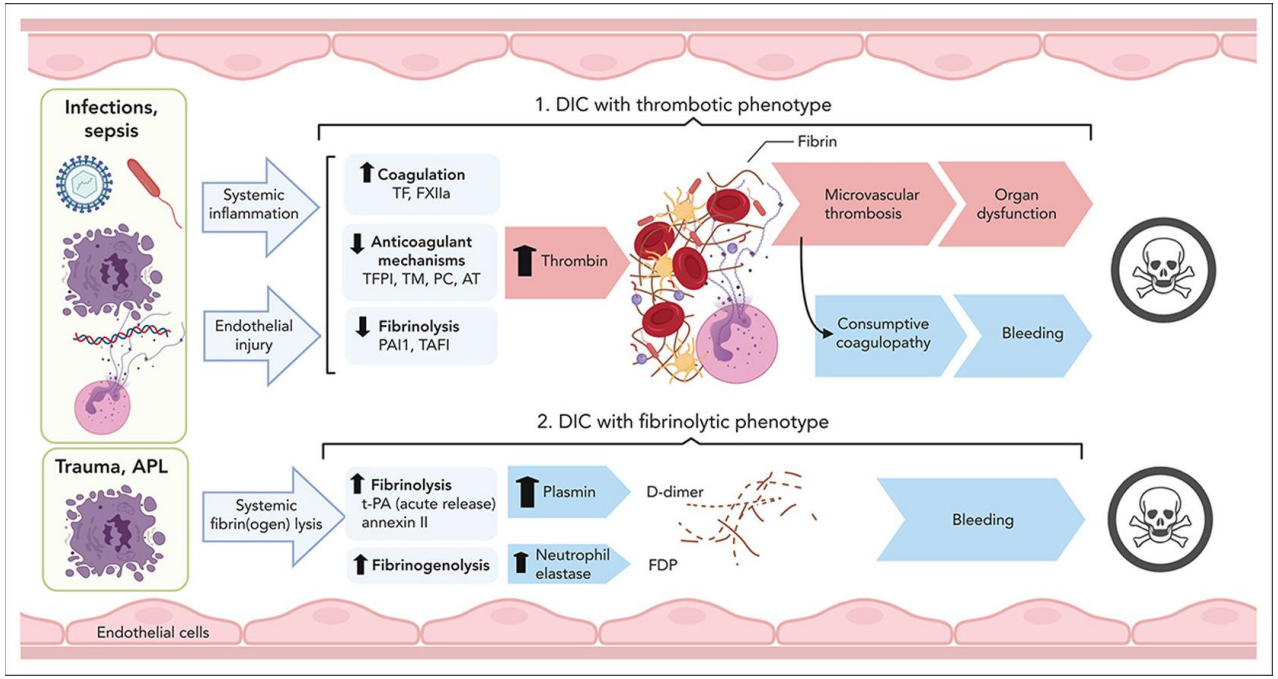
Clinical Manifestations:

- Visible can range from oozing to uncontrolled hemorrhage
- S/sx internal bleeding will cart deepening on anatomical location
- Clotting can present as hypoperfusion, ischemia, peripheral acrocyanosis, infarction, and organ failure

How is it diagnosed?

- No single lab test can diagnose the condition
- Assess for a clinical condition associated with DIC, clinical evidence, and lab findings that include:
  - Low or decreasing platelets
  - Low plasma level of coagulation factors and inhibitors
  - Prolonged coagulation tests
  - Increased markers of fibrin formation and degradation

Disseminated intravascular coagulation. *Nat Rev Dis Primers* **2**, 16038 (2016). https://doi.org/10.1038/nrdp.2016.38



Nursing Interventions:

- Treat the underlying cause
- Supportive care based upon the severity and clinical presentation
- Management may include anticoagulant medications, plasma transfusions to reduce bleeding, and transfusions of red blood cells/platelets in active bleeding

Superior Vena Cava Syndrome (SVC)

What is SVC Syndrome?

It is a group of symptoms that result from a mechanical obstruction or compression of the SVC, or veins emptying into the SVC

- It affects 3%-4% of patients with a cancer that involves the chest

Risk Factors:

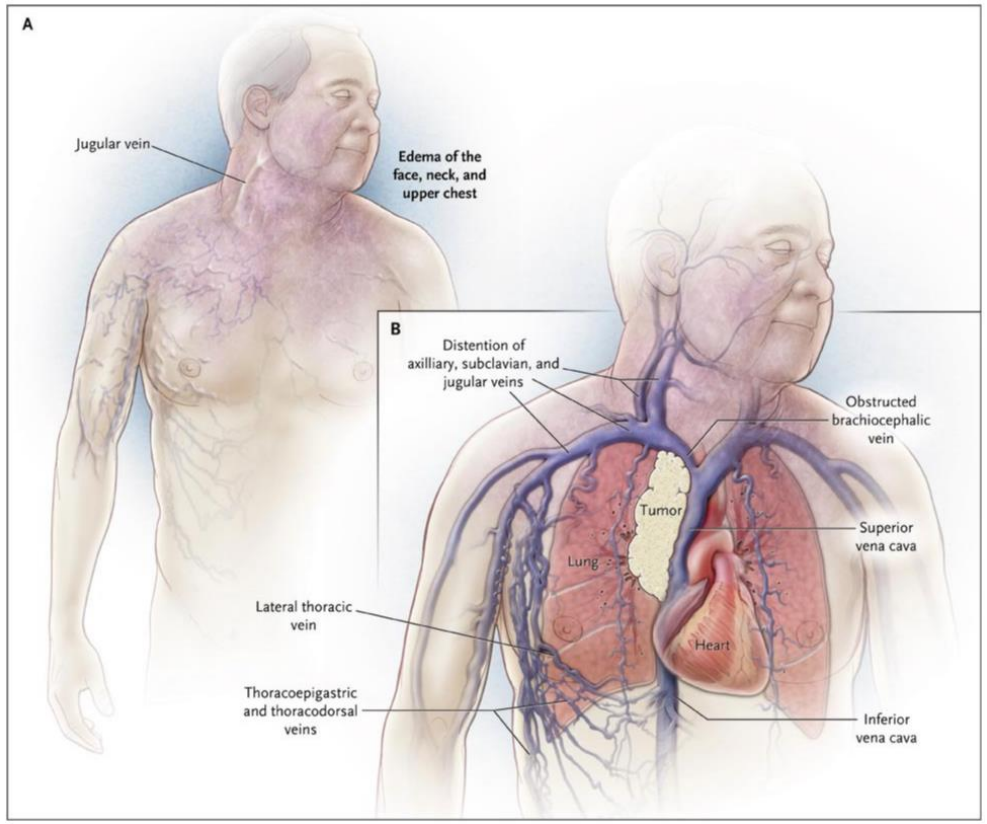
- Diagnosis of lung cancer or non-Hodgkin lymphoma
- Catheter or pacemaker wire associated thrombosis

Clinical Manifestations:

- Facial swelling or head fullness
- Facial, chest, neck and upper-extremity edema
- Dyspnea and nonproductive cough
- Distended veins in the chest

How is it diagnosed?

- Chest computed tomography with contrast
- Chest X-Ray



Nursing Interventions:

- Treat the underlying cause with radiation, chemotherapy or surgery
- Assess for respiratory, cardiovascular or neurologic compromise
- Supportive care with oxygen, bronchodilators, elevating the head od the bed and anxiety management

Syndrome of Inappropriate antidiuretic hormone secretion (SIADH)

What is SIADH?

It consists of hyponatremia, inappropriately elevated urine osmolality (greater than 100 mosm/kg) and decreased serum osmolality in an euvolemic patient. It is the leading cause of hyponatremia in patients with cancer, occurring in as many as 30% of all cases

- It is defined as a serum sodium level of <135 mmol/L
- Classification is defined as:
  - Mild 130-134 mmol/L
  - Moderate 125-129 mmol/L
  - Severe < 125 mmol/L

Clinical Manifestations:

- Weakness, Lethargy
- Headache, Mental status changes, Cerebral edema, Cerebral hemorrhage
- Anorexia
- Weight gain
- Excessive thirst
- Low urine output
- Low sodium level < 135 meq/L
- Increased Urine Specific Gravity > 1.02
- Nausea/Vomitting
- Pulmonary edema

TABLE 1.
CARDINAL SYMPTOMS OF SIADH

SYMPTOM	NORMAL LABORATORY VALUE
Hyponatremia with serum hypo-osmolality	135–145 meq/L, 280–295 mosm/L
Urine osmolality inappropriately high for serum osmolality	50 meq/kg
Urine less than maximally dilute	500–800 mosm/kg
Normal renal and adrenal function (reflected in cortisol level)	■ 0.6–1.2 mg/dl ■ 10–20 mcg/dl in the morning ■ 3–10 mcg/dl at 4 pm ■ Less than 5 mcg/dl at bedtime

SIADH—syndrome of inappropriate antidiuretic hormone
Note. Based on information from Raftopoulos, 2007; Zomp & Alexander, 2012.

Nursing Interventions:

- Slowly normalizing the patient's sodium level during 24-48 hours by utilizing hypertonic 3% saline
- Fluid restriction of 500 mLs less than the daily output
- Many patients will require loop diuretics such as Bumex, Lasix and Torsemide
- Strict I & O`s
- Neurologic checks
- Frequent sodium level checks

Tumor Lysis Syndrome (TLS)

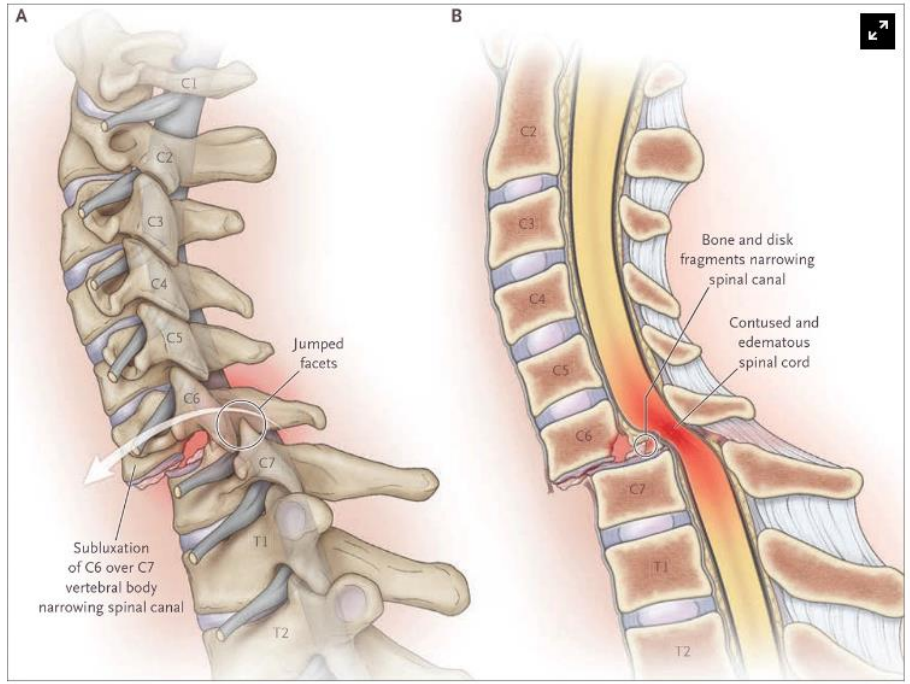
- TLS is an oncologic emergency in which large amounts of tumor cells are destroyed. Their contents are released into the bloodstream resulting in electrolyte disturbances
- TLS can be life threatening if not treated properly
- Common lab value changes include elevated potassium, phosphorous, blood urea nitrogen (BUN), creatinine, and uric acid
- Symptoms include restlessness, weakness, fatigue, nausea, vomiting, diarrhea, muscle cramping, joint pain, decreased urination, cloudy urine, EKG changes, and dysrhythmias
- TLS is most common in patients with types of cancer that have high potential for tumor lysis
  - High grade lymphomas
  - Acute leukemia
  - Any cancer with large bulky tumor mass
- TLS Treatment – Prevention is always the best treatment!
  - Medications used to treat TLS include Allopurinol, Rasburicase and Sodium Bicarbonate
  - Manage electrolyte imbalances
  - Provide standard of care supportive therapy

Spinal Cord Compression

What is Spinal Cord Compression?

Spinal cord compression involves tumor invasion or extension into the epidural space or pathologically collapsed vertebral bone fragments impinging on the spinal cord

- Up to 15% of patients with cancer experience malignant spinal cord compression throughout the course of their disease



Risk Factors:

- Solid organ malignancies with high incidence of vertebral metastasis
- Patients with lung cancer, prostate cancer, breast cancer, or multiple myeloma

Clinical Manifestations:

- Back pain that is aggravated in the supine and is alleviated upon sitting or standing
- Pain may be localized, radiating or referred
- Pain aggravated by activities that increase intra-abdominal pressure such as coughing or sneezing

How is it diagnosed?

- MRI or CT scan id the patient is unable to tolerated an MRI

Nursing Interventions:

- Corticosteroids and pain management
- Spinal decompression with radiation therapy and or surgery

Knowledge ☑

Patient JK is approximately 5 minutes into their first dose of Carboplatin when they report shortness of breath and feeling itchy. What is the first step you take?

- Page the provider
- Stop the Carboplatin infusion
- Obtain a set of vital signs
- Administer rescue medications per treatment plan
- Nothing, this is a normal reaction

Knowledge ☑

After stopping the Carboplatin infusion, JK continues to report shortness of breath and appears tachypneic. You are alone with the patient. What is the most appropriate next step?

- Leave JK to find another staff member to help you
- Provide reassurance to patient
- Press the “staff assist” button to call for help
- Start IV fluids

Side Effects of Antineoplastic Therapy

- Antineoplastic therapy is crucial to treating our oncology patients. While therapy offers a way to cure or control disease, it does not come without expected side effects

- Common side effects from chemotherapy/biotherapy that we see in our patients include
  - Myelosuppression
  - Neutropenic Fever
  - Tumor Lysis Syndrome

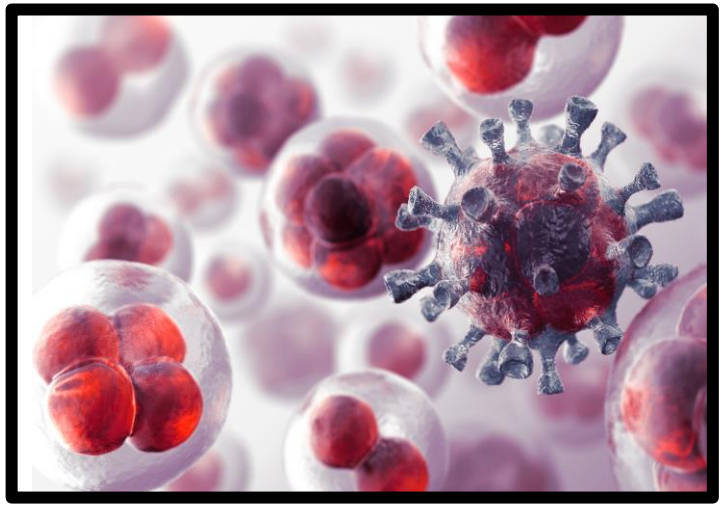
Myelosuppression

- Myelosuppression is a condition where there is a significant decrease in neutrophils, megakaryocytes, and erythrocytes within the bone marrow

- Myelosuppression includes:
  - Neutropenia
  - Anemia
  - Thrombocytopenia

Neutropenia

- Neutropenia is a marked decrease in circulating neutrophils
- Defined as an absolute neutrophil count (ANC) of <1,500 cells/mm3
- Chemotherapy induced neutropenia is the primary dose limiting toxicity associated with systemic chemotherapy
- Neutropenia has significant consequences for patients, including:
  - Infection (neutropenic fever)
  - Prolonged hospital stays
  - Chemotherapy/Immunotherapy dose reductions
  - Missed doses/Dose delays
- Neutropenia Interventions
  - Monitor blood counts
  - Maintain neutropenic precautions
  - Encourage meticulous hygiene for caregivers and patient
  - Provide patient education
  - Treatment with colony-stimulating factors (CSFs) per provider order



Neutropenic Precautions

- What are neutropenic precautions?
  - Neutropenic precautions are in place to keep our oncology patients safe. Their immune systems are very weak due to disease and/or treatment, and they are at high risk for infection
- When we use neutropenic precautions?
  - Neutropenic precautions are instituted when the absolute neutrophil count (ANC) is 500/mm^3 or less, or by provider order

Care of the Neutropenic Oncology Patient

Maintaining Neutropenic Precautions

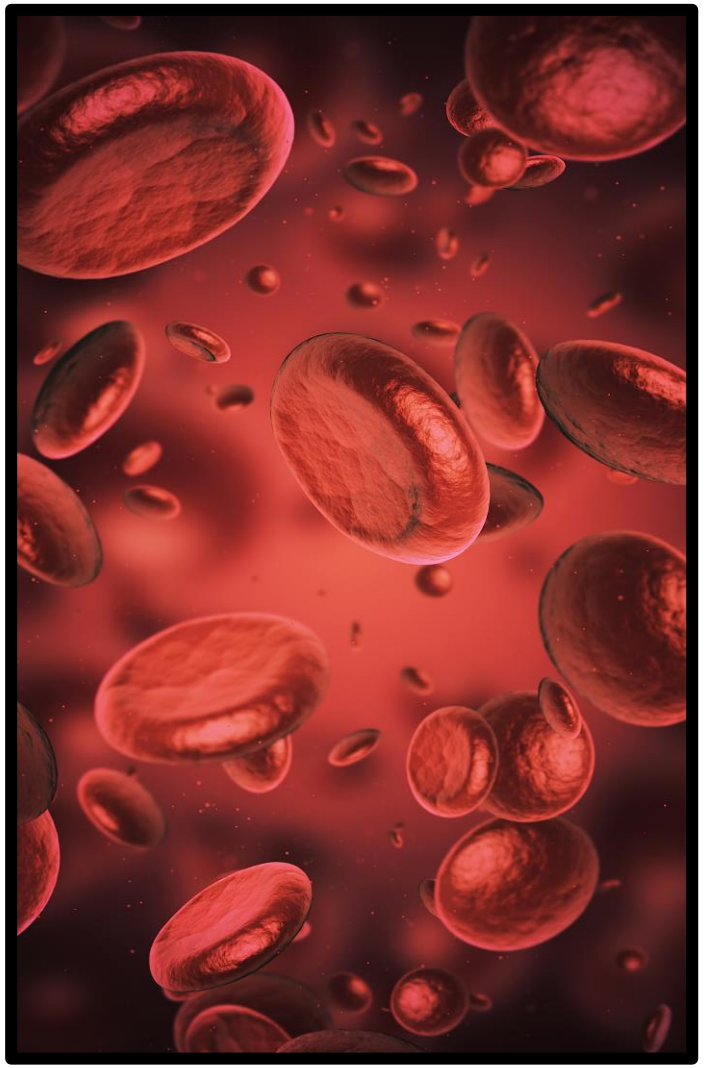
- Admitted patients should be placed in a private room
- Place “neutropenic precautions” sign outside room
- Meticulous hand hygiene by patients, staff, and visitors
- Educate patients to avoid crowded areas, sitting in waiting rooms, and contact with potentially infectious individuals
- Assess and document each body system and any venous access device sites or other devices present for signs/symptoms of infection every shift
- Avoid activities that may compromise skin integrity
- Avoid IM/Deep SC injections
- Encourage frequent oral care and inspect oral mucosa
- Encourage maintenance of meticulous personal hygiene and perineal care
- Avoid use of rectal medications, temperatures, examinations and enemas
- Educate patient to avoid direct care of pets or farm animals
- Avoid contact with animal waste and refrain from direct/indirect contact with reptiles, birds and fish

Neutropenic Fever

- A fever of **38.0 or greater** Celsius is the most reliable sign of infection in a neutropenic patient
- Report any fever in a neutropenic fever to the provider **immediately!**
- A neutropenic patient may not show any other signs of infection besides fever
- If your patient becomes febrile, notify provider as soon as possible
- Standard of care interventions for neutropenic fever:
  - Peripheral blood cultures within one hour of fever
  - Intravenous antibiotics – If patient is not already on antibiotics, blood cultures must be drawn before antibiotics can be started
  - Chest x-ray if respiratory symptoms present
  - Consider urine/sputum culture based on symptoms
  - Administer antipyretics as ordered

IV Antibiotics must be started as soon as possible

Anemia



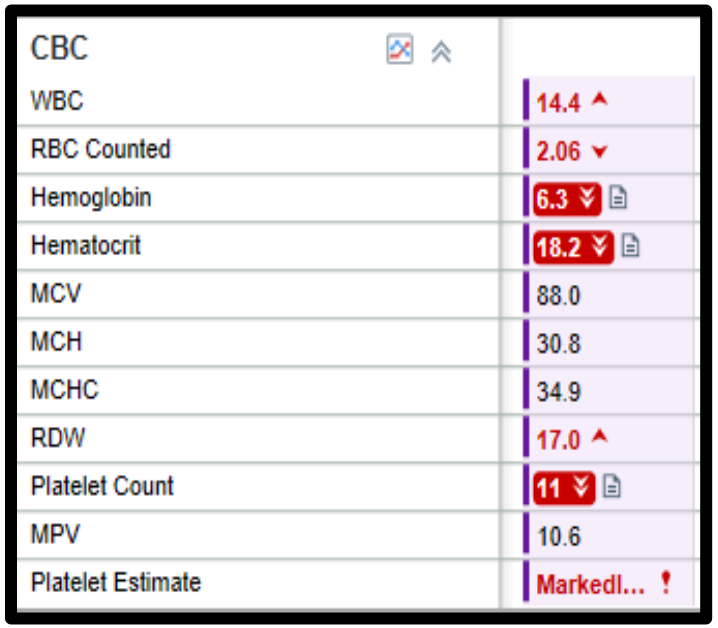
- Anemia is a decrease of red blood cells (RBCs) in the blood
- Anemia is generally considered a Hemoglobin (Hgb) of <12 g/dl
- Anemia is associated with shortness of breath, reduced exercise capacity and reduced energy
- Anemia Interventions
  - Monitor blood counts
  - Monitor patient for bleeding
  - Supportive transfusions of red blood cells as needed - Refer to provider order for transfusion parameters
  - Encourage patient to conserve energy when preforming ADLs

Thrombocytopenia

- Thrombocytopenia is a decrease in circulating platelet count below 100,000/mm3
- Platelets <10,000 mm3 is associated with serious, life-threatening hemorrhage
- Clinical presentation:
  - Petechiae
  - Overt bleeding
  - Enlarged and tender liver or spleen
  - Occult or overt blood in stool or urine
- Thrombocytopenia interventions
  - Maintain bleeding precautions
  - Monitor labs
  - Maintain a safe environment to prevent falls or bumping into objects
  - Maintain skin and mucous membrane integrity
  - Supportive transfusions of platelets as needed – Refer to provider order for transfusion parameters

Recurring Blood Instructions	Notify on call provider to order applicable blood product. All blood products to be filtered and irradiated. For platelet count less than 20 K - 1 unit single donor platelets, filtered and irradiated For hemoglobin less than 8 g/dL - 1 unit Packed Red Blood Cells filtered and irradiated For fibrinogen is less than 125 mg/dL - 2 units of Cryoprecipitate For INR greater than 1.5 - 3 units of Fresh Frozen Plasma

Knowledge ☑



CBC	
WBC	14.4 ▲
RBC Counted	2.06 ▼
Hemoglobin	6.3 ⩔
Hematocrit	18.2 ⩔
MCV	88.0
MCH	30.8
MCHC	34.9
RDW	17.0 ▲
Platelet Count	11 ⩔
MPV	10.6
Platelet Estimate	Markedl... !

You are caring for a 71-year-old patient with a new diagnosis of acute myeloid leukemia (AML) who is receiving induction chemotherapy. What provider orders would you anticipate based on the labs and recurring blood instructions?

Select all that apply

- Red Blood Cell transfusion
- Nothing; continue to monitor labs
- IV iron infusion
- Normal Saline bolus
- Platelet transfusion

Recurring Blood Instructions	Notify on call provider to order applicable blood product. All blood products to be filtered and irradiated. For platelet count less than 20 K - 1 unit single donor platelets, filtered and irradiated For hemoglobin less than 8 g/dL - 1 unit Packed Red Blood Cells filtered and irradiated For fibrinogen is less than 125 mg/dL - 2 units of Cryoprecipitate For INR greater than 1.5 - 3 units of Fresh Frozen Plasma

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