Advanced Oncology Certified Nurse Practitioner

REVIEW COURSE 2024

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Hematopoietic Stem Cell Transplantation

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Conflicts of Interest

- No conflicts of interest to report

Objectives

- Describe the types of hematopoietic stem cell transplantation (HSCT)
- Understand different stem cell sources
- Learn about HSCT conditioning regimens
- Recognize serious complications associated with HSCT and when they typically occur
- Identify the role of the APRN within an HSCT team

What is a Hematopoietic Stem Cell Transplant (HSCT)?

The process by which patients receive healthy hematopoietic stem cells via infusion to replace their own unhealthy bone marrow, which has been damaged due to high dose chemotherapy and their underlying disease

Types of HSCT

Autologous = stem cells come from the recipient

Allogeneic = stem cells come from another individual

(Bazinet & Popradi, 2019; Boley, C.L., et al., 2023)

Autologous HSCT

- Stem cells come from the recipient – most common!
- Mobilized stem cells collected from patient via apheresis > cryopreserved for future use > reinfused as a stem cell rescue
- Cancer Types: Hematologic malignancies (Multiple Myeloma, Hodgkin Disease, Non-Hodgkin Lymphoma), Solid tumors (Germ Cell Tumors [tandem], neuroblastoma, etc.), autoimmune diseases (i.e. multiple sclerosis)
- Advantages: No risk of graft-versus-host disease, more readily available stem cells
- Disadvantages: Lack of graft-versus-tumor effect, potential for contamination by residual tumor

(Bazinet & Popradi, 2019; Boley, C.L., et al., 2023)

Allogeneic HSCT

- Stem cells come from another individual
- Cancer types: Hematologic malignancies (Acute lymphocytic leukemia [ALL], Acute myelogenous leukemia [AML], Myelodysplastic syndrome [MDS], Non-Hodgkin Lymphoma [NHL]) and non-malignant hematologic conditions (severe aplastic anemia, sickle cell disease)

(Bazinet & Popradi, 2019; Boley, C.L., et al., 2023)

Allogeneic HSCT

- Types: Donor is determined based on Human Leukocyte Antigen (HLA) typing, which is closely correlated with transplant-related morbidity and mortality (full match is best!)
  - Matched related/sibling donor (MSD, 10/10)
  - Mismatched unrelated donor (MMUD, <10/10)
  - Cord
  - Matched unrelated donor (MUD, 10/10)
  - Haploidentical (half-match, parent/sibling/child)
  - Syngeneic (identical twin, acts more like an Auto)
- Advantages: Graft-versus-tumor effect (donor T-lymphocytes react against host antigens/residual cancer)
- Disadvantages: Graft-versus-host disease, greater post-HSCT complications, more difficult treatment course

(Bazinet & Popradi, 2019; Boley, C.L., et al., 2023)

HSCT Donor Sources

Bone Marrow – obtained via multiple bone marrow aspirations under general anesthesia in an OR

Peripheral Blood – obtained via apheresis

Umbilical Cord Blood – obtained via the combination of multiple umbilical cords (usually one to two)

Advantages and Disadvantages by Source Type

Source	Advantages	Disadvantages

Bone Marrow	• Donor:
	  • Collection in one day
	  • Does not require gCSF (growth factor) prior to collection
	• Recipient:
	  • **Lower risk of GVHD**
		• Donor:
		  • General anesthesia
		  • Greater discomfort
		• Recipient:
		  • **Slower engraftment**

Peripheral Blood	• Donor:
	  • Less discomfort
	• Recipient:
	  • **Quicker engraftment**
		• Donor:
		  • Collection can take multiple days
		  • Potential placement of pheresis catheter
		  • Requires gCSF (growth factor)
		• Recipient:
		  • **Higher risk of GVHD**

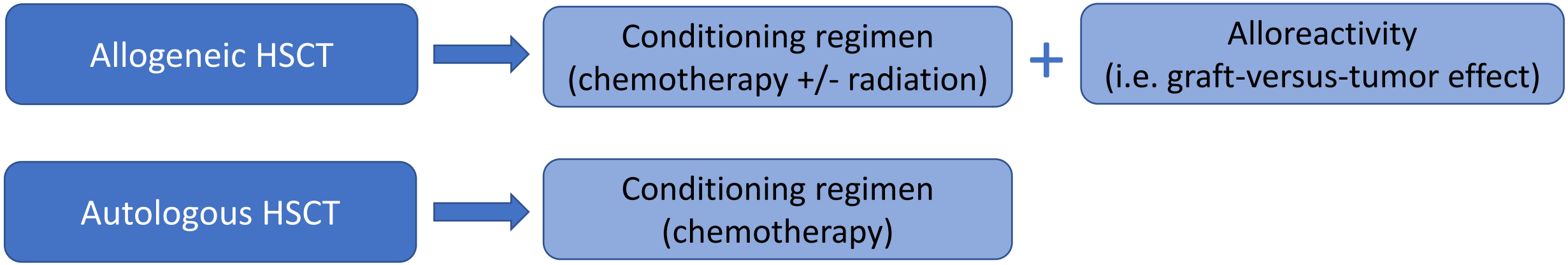
Cord Blood	• Donors:
	  • Abundant source, often discarded
	  • Safe, easy to collect
	  • Strict HLA matching not required
	• Recipient:
	  • **Lower risk of GVHD**
		• Donor:
		  • Smallest number of stem cells collected per donor cord (need multiple cords for adult recipients)
		  • Potential for maternal T-cell contamination
		• Recipient:
		  • **Lessened graft-versus-tumor effect**
		  • **Slowest engraftment**
		  • **Higher rates of graft failure and disease relapse**

(Boley, C.L., et al., 2023; Zack, 2018)

Mechanisms of Disease Control

All conditioning regimens include high-dose chemotherapy +/- radiation to:

1. Kill remaining cancerous cells
2. Create space for stem cells in the bone marrow



Transplant Process

PRE-HSCT EVALUATION

CONDITIONING REGIMEN

HSCT INFUSION DAY "0"

ENGRAFTMENT

SERIOUS COMPLICATIONS OF HSCT

Pre-HSCT Patient Evaluation

Disease Status:
Bone Marrow Biopsy
Imaging (CT, MRI, PET/CT)
Disease markers

Cardiac:
ECHO & EKG
Cardiology clearance

Pulmonary:
Pulmonary Function Test
Pulmonary clearance

Hepatic:
Hepatic Function/LFTs
Hepatology clearance

Renal:
Kidney function
Nephrology clearance

Infectious Disease:
Active infection &
history ID clearance

Dental:
Dental source of infection Dental clearance

Psychosocial:
Social Worker meeting and clearance

(Boley, C.L., et al., 2023; Loren, et al., 2023; Sorror, 2005)

Patient Factors Impacting Outcomes

- **HCT-SCI: Hematopoietic Cell Transplantation – Specific Comorbidity Index:** a numerical value to evaluate risk of non-relapse mortality based on 17 comorbidities >> higher number indicates higher risk
- **Age:** older patients carry increased risk for complications
- **Tumor burden:** low tumor burden (CR/MRD negative) and chemo sensitive disease associated with better outcomes and survival

(Sorror, et al., 2005; Sorror, 2013)

HCT – Specific Comorbidity Index

Comorbidity	Definition	Score
Cardiac	Coronary artery disease, congestive heart failure with ejection fraction <50%	1
Arrhythmia	Atrial fibrillation, sick sinus syndrome, ventricular arrhythmias	1
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	1
Diabetes	Requiring treatment (either insulin or oral hypoglycemic)	1
Cerebrovascular accident	Cerebrovascular accident or transient ischemic attack	1
Psychiatric	Depression/anxiety requiring treatment (including psychotherapy)	1
Mild hepatic	Chronic hepatitis, bilirubin 1–1.5 × ULN, or AST/ALT 1–2.5 × ULN	1
Obesity	Body mass index >35 kg/m^2	1
Infection	Documented infection or fever of unknown origin requiring antimicrobial treatment	1
Rheumatologic	Systemic lupus erythematosus, rheumatoid arthritis, polymyositis, mixed connective tissue disease, polymyalgia rheumatic	2
Peptic ulcer	Peptic ulcer disease requiring treatment	2
Moderate/severe renal	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	2
Moderate pulmonary	DLCO and/or FEV_1 > 65–80%, or dyspnea on slight activity	2
Prior solid tumor	Treated at any time in the past (excluding non-melanomatous skin cancer)	3
Heart valve	Any valvular disease (excluding mitral valve prolapse)	3
Severe pulmonary	DLCO and/or FEV_1 < 65%, or dyspnea at rest, or requiring supplemental oxygen	3
Moderate/severe hepatic	Cirrhosis, bilirubin > 1.5 × ULN, or AST/ALT > 2.5 × ULN	3

ALT, alanine transaminase; AST, aspartate transaminase; DLCO, diffusing capacity of the lung for carbon monoxide; FEV_1, forced expiratory volume in 1 s; ULN, upper limit of normal.

Conditioning Regimen Intensity: Definitions

Myeloablative (MAC) = Regimen causes irreversible pancytopenia and HSCT is required to rescue bone marrow function and prevent aplasia-related death

- Associated with highest risk of treatment-related mortality (TRM)
- Examples include:
  - Alkylating agents (i.e. Busulfan >6.4 mg/kg/day IV or AUC 16,000 µm*min, Melphalan ≥140 mg/m^2/course, Thiotepa ≥10 mg/kg/course)
  - Total body irradiation (TBI) ≥5 Gy single fraction or ≥ 8Gy fractionated

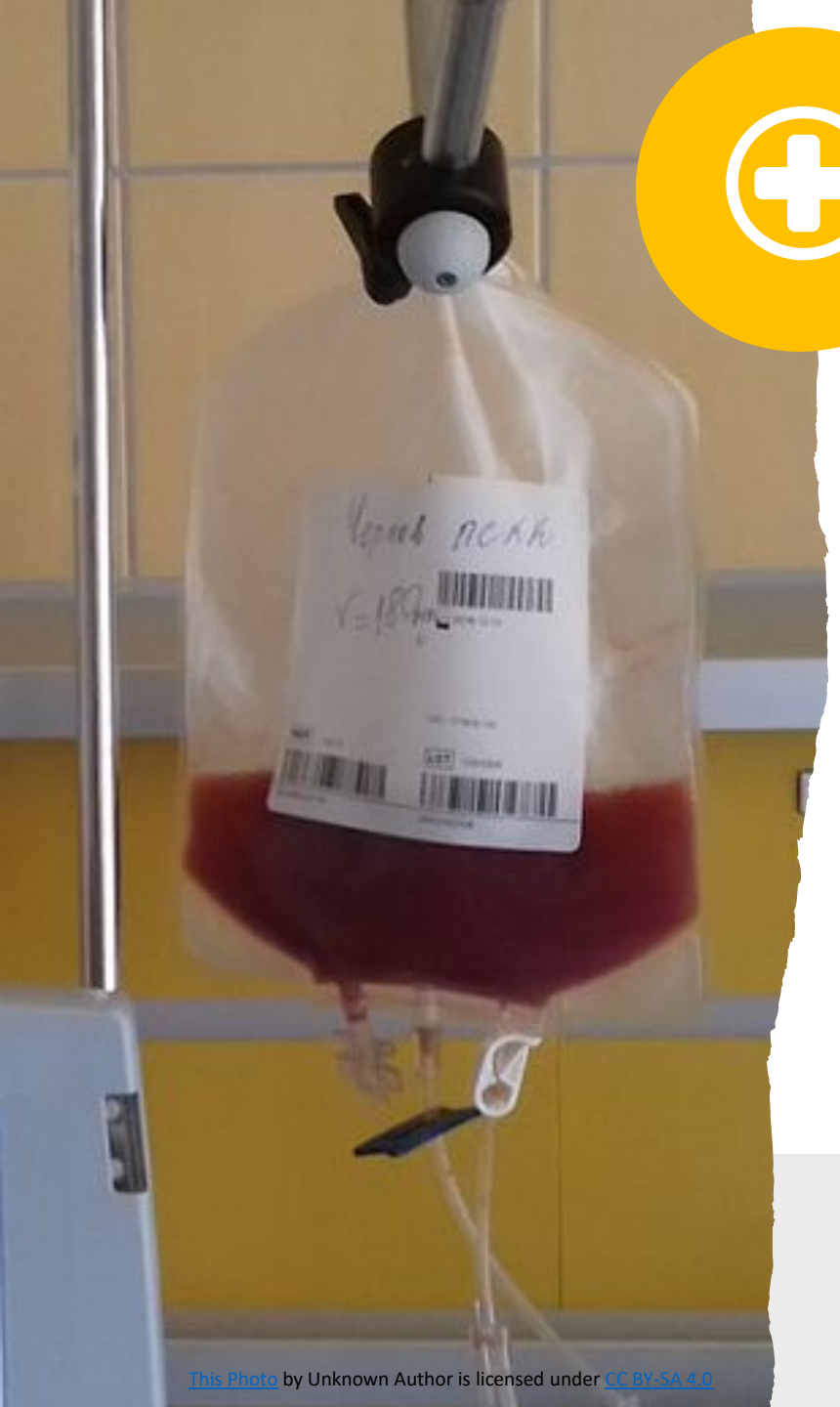
Non-myeloablative (NMA) = Regimen produces minimal cytopenias and no need for HSCT

- Results in initial state of mixed donor-host chimerism and relies heavily on graft-versus-tumor effect
- Examples include: Fludarabine + Cytarabine

Reduced-intensity (RIC) = Regimens that do not fulfill MAC or NMA criteria

- Commonly used in patients who cannot tolerate MAC
- Examples include: Fludarabine + Melphalan (100-140 mg/m^2/course) or Fludarabine + Busulfan

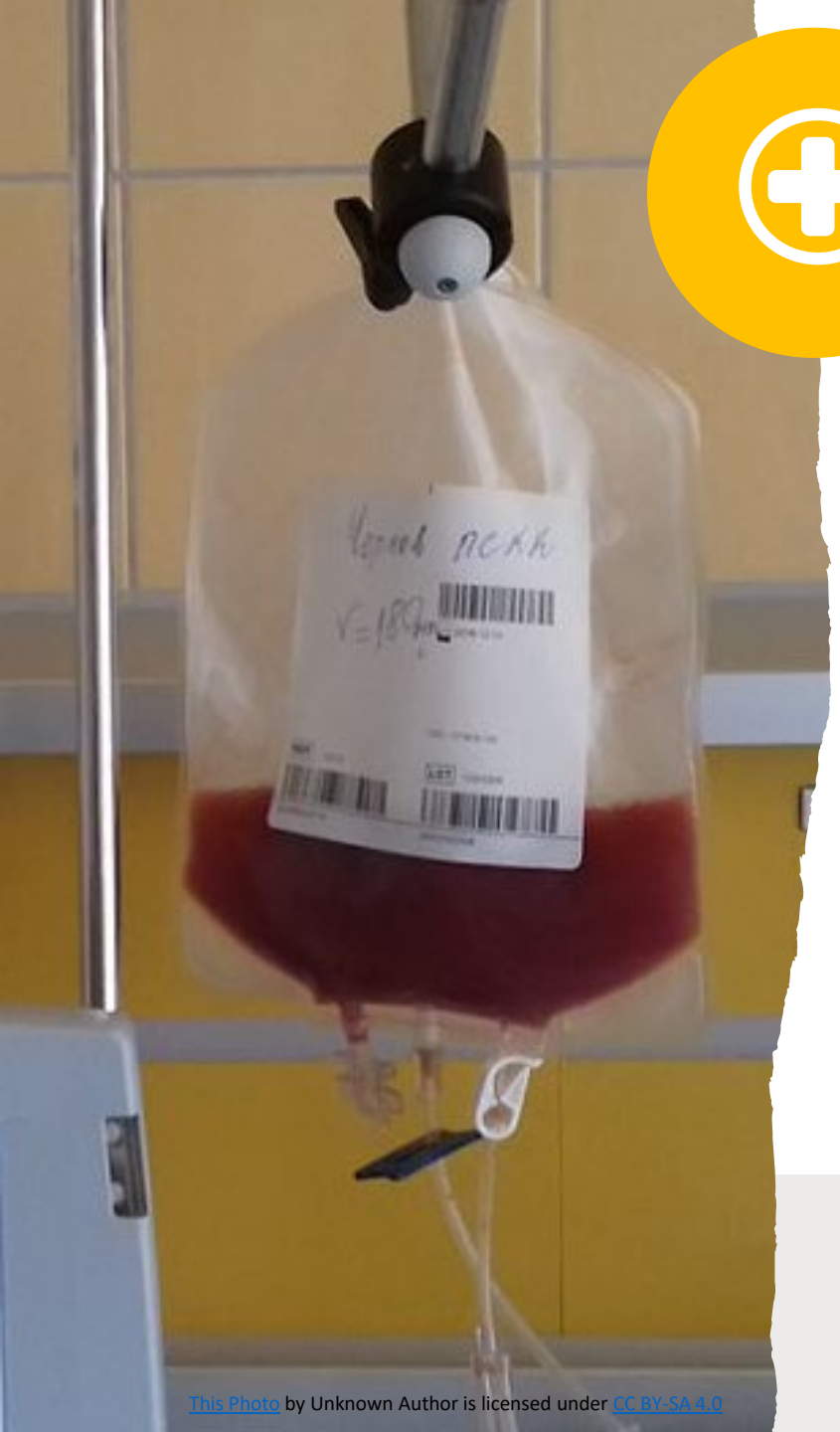
(Boley, C.L., et al., 2023; Loren, et al., 2023)



Day of HSCT Infusion = Day 0

- Transplant timeline is based on date of HSCT infusion, called Day 0
- Patients are typically premedicated to minimize risk of infusion reaction

(Boley, C.L., et al., 2023)



Day of HSCT Infusion = Day 0

- Fresh: Marrow source collected within hours or days of the infusion and not requiring cryopreservation
- Frozen/Cryopreserved: source collected weeks to years before infusion, requiring a cryopreservative (dimethyl sulfoxide [DMSO])
  - DMSO can cause a histamine release during/shortly after infusion, resulting in cardiopulmonary reactions, flushing, and abdominal cramping

(Boley, C.L., et al., 2023)

Engraftment

- Engraftment: the process by which hematopoietic stem cells migrate to the recipient bone marrow and proliferate
  - Date of Engraftment is the first date of three consecutive days with Absolute Neutrophil Count > 500/mm^3
- Primary Graft Failure: no signs of engraftment by approximately D+30, resulting in an urgent 2nd HSCT
  - Associated with a very high mortality rate

(Bazinet & Popradi, 2019)

Complications of HSCT: Pre-engraftment

Timing: Start of conditioning through neutrophil recovery

Complications

- Infection secondary to neutropenia → antimicrobial prophylaxis
- GI toxicities (nausea, vomiting, diarrhea) → supportive care
- Mucositis/esophagitis → cryotherapy
- Sinusoidal Obstruction Syndrome (SOS) → ursodiol prophylaxis through D+90 and close monitoring
- Other toxicities: fluid/electrolyte imbalances, malnutrition, deconditioning, bone marrow suppression (pancytopenia)
- Graft Failure

Complications of HSCT: Early Post-engraftment

Timing: Neutrophil recovery through D+100

Complications

- Infection secondary to immunocompromised state → antimicrobial prophylaxis
- SOS → ursodiol prophylaxis through D+90 and close monitoring
- Acute Graft-versus-Host Disease (aGVHD): primarily affecting GI tract, Liver, and Skin
- Relapse

Complications of HSCT: Late Post-engraftment

Timing: After D+100

Complications

- Infection secondary to immunocompromised state → antimicrobials
- Chronic Graft-versus-Host Disease (cGVHD) can affect any organ system
- Side effects of long-term steroid use: diabetes, avascular necrosis, osteoporosis
- Delayed toxicities from conditioning regimen: secondary cancers, hypothyroidism, etc.

Complications of HSCT: Blueprint Focus

- Sinusoidal Obstruction Syndrome (SOS)
- Graft-versus-host-disease (GVHD)
- Infection

Sinusoidal Obstruction Syndrome (SOS)

- Associated with high-dose chemotherapy or radiation
- Occurrence: 10-15% of patients
- MOA: Endothelial injury of sinusoids and venules triggers cytokine and tumor necrosis factor activation > results in coagulation, thrombosis, impaired blood flow ***
- Onset: Classical (by Day +21) and Late (after Day +21)
- Risk Factors: HLA-mismatch or unrelated donor, MAC, high-dose TBI during conditioning, older age, poor performance status, advanced disease, metabolic syndrome, hepatotoxic drugs, underlying liver conditions

(Boley, C.L., et al., 2023; Mohty et al., 2020)

Sinusoidal Obstruction Syndrome (SOS)

- Prophylaxis: Ursodeoxycholic acid (ursodiol) through Day +90 and occasionally defibrotide if high risk for SOS.
- Symptoms: fluid retention, weight gain, ascites, hepatomegaly, jaundice, hyperbilirubinemia; severe cases may have encephalopathy and multiorgan dysfunction
  - Severe cases have a high mortality rate
- Treatment: Defibrotide. Supportive care and nutritional support.

(Boley, C.L., et al., 2023; Mohty et al., 2020)

Graft-Versus-Host-Disease (GVHD)

- Complication after Allogeneic HSCT
- Immune reaction between recipient cells and donor T-lymphocytes, where donor T-lymphocytes identify healthy recipient cells/tissues as foreign and attack them.
- Incidence: up to 80% in mismatched donors
- Can cause significant morbidity and mortality
- Donor Risk factors
  - Mismatched or not fully-matched donor
  - Unrelated donor
  - Increasing donor age
  - SCT source: peripheral blood > bone marrow > cord blood
  - Cumulative blood transfusions (more antibodies)
  - Multiparous donor
  - If patients experience acute GVHD, higher risk of chronic GVHD

(Boley, C.L., et al., 2023; Jagasia et al., 2015; Przepiorka et al., 1994)

GVHD: Acute vs Chronic

Acute GVHD (aGVHD)

- Timing: usually within first 100 days post-SCT
- Organ Systems: Skin, upper and lower GI tract, liver
- Staging (individual organ systems): 1-4
- Severity Grading (total combined): I (skin <25% BSA) and II-IV

Chronic GVHD (cGVHD)

- Timing: usually within 1st year post-SCT, but may occur at anytime
- Any organ system, however most often skin, GI, liver, mouth, eyes, lungs, muscle, fascia, joints
- Grading: Score 0-3 based on extent of involvement (2014 National Institutes of Health criteria is the most widely accepted)
- cGVHD overlap with aGVHD symptoms – poor prognosis

(Jagasia et al., 2015; Przepiorka et al., 1994)

GVHD: Prophylaxis, Diagnosis, and Management

- Prophylaxis:
  - Calcineurin inhibitors (such as tacrolimus and cyclosporin)
  - Mycophenolate mofetil
  - Sirolimus
  - Post-Cytoxan: chemotherapy given Days 3 & 4 after SCT
- Diagnosis: based on clinical evaluation (biopsy can confirm diagnosis)
- Management:
  - Continue or restart original immunosuppressive agent (tacrolimus or sirolimus)
  - 1st line: Systemic corticosteroids (dosing based on organ system/severity)
  - 2nd+ line: Start if steroid refractory (next slide)
  - Clinical Trials

(Jagasia et al., 2015; Loren, et al., 2023; Przepiorka et al., 1994)

GVHD: Steroid-Refractory Management

- Acute GVHD: Ruxolitinib, Alemtuzumab, Alpha-1 antitrypsin, ATG, Basiliximab, Calcineurin Inhibitors (i.e. tacrolimus, cellcept), Etanercept, Extracorporeal, Photopheresis (ECP), Infliximab, mTOR inhibitors (i.e. sirolimus), Mycophenolate mofetil, , Pentostatin, Tociluzumab, Vedolizumab

- Chronic GVHD: Ruxolitinib, Ibrutinib, Belumosudil, Axatilimab-csfr, Abatacept, Alemtuzumab, Calcineurin Inhibitors (i.e. tacrolimus, cellcept), Etanercept, Extracorporeal photopheresis (ECP), Hydroxychloroquine, , Imatinib, Interleukin-2, Low-dose Methotrexate, mTOR inhibitors (i.e. sirolimus), Mycophenolate mofetil, Pentostatin, Rituximab

(Loren, et al., 2023)

Infection:

Opportunistic infections are one of the main causes of non-relapse mortality in the first two years after transplant

	Pre-engraftment	Early post-engraftment	Late post-engraftment
Risk Factors	• Treatment-related neutropenia • Mucosal/barrier breakdown (mucositis) • Central venous catheter access	• Treatment-related neutropenia • Impaired immunity • Acute GVHD	• Impaired immunity, • cGVHD and associated immunosuppressive treatment
Bacterial	• Gram negative bacilli • Gram positive organism • GI Streptococci species	• Gram negative bacilli • Gram positive organism • GI Streptococci species	• Primarily encapsulated bacteria
Viral	• Herpes Simplex Virus (HSV) • Respiratory and enteric viruses	• HSV • Respiratory and enteric viruses • **Cytomegalovirus reactivation (CMV)** • Epstein Barr Virus (BSV) • Human Herpes Virus 6 (HHV6) • Adenovirus	• HSV • Respiratory and enteric viruses • **CMV reactivation** • EBV • HHV6 • Adenovirus • **Varicella Zoster virus**
Fungal	• Candida • Aspergillus	• **Candida** • **Aspergillus** • **Pneumocystis jirovecii pneumonia (PJP)**	• Candida • PJP

(Wingard, J.R., 2024; Yeshurun, M. et al., 2023)

Common Opportunistic Infections + Prophylaxis

Bacterial infections

- Prophylaxis with Fluoroquinolone through engraftment

Pneumocystis Jirovecii Pneumonia (PJP)

- Prophylaxis with sulfamethoxazole-trimethoprim, pentamidine, atovaquone, or dapsone

Invasive Fungal: Candida & Aspergillus species

- Prophylaxis debated, however can use fluconazole, voriconazole, or caspofungin

(Wingard, J.R., 2024)

Common Opportunistic Infections + Prophylaxis

Cytomegalovirus (CMV) reactivation

- Check seropositivity of donor and recipient prior to HSCT
- If seropositive, consider prophylaxis with letermovir
- PCR surveillance regularly through Day +100 (early detection/treatment)
- CMV infection can lead to end-organ damage

Varicella Zoster Virus (VZV)

- Prophylaxis through the first year or longer if remaining on immunosuppressive medications
- Acyclovir, Valacyclovir, or Famciclovir

(Wingard, J.R., 2024)

Re-Immunization

- Start first round 6-12 months post-HSCT
- No live vaccines until 24 months post-HSCT

(Wingard, J.R., 2024)

Implications/Role of the Advance Practice Nurse

- Evaluate potential HSCT donors and recipients
- Perform procedures (bone marrow biopsies/harvest, lumbar punctures, skin biopsies)
- Care for HSCT patients across the continuum (pre-, peri-, post-HSCT)
- Educators and Advocates
- Champion the implementation of evidence-based practice changes
- Advance the field through participation in research

Practice Question 1

A.L. is a 46 year old male patient with history of acute myeloid leukemia, now day +42 post-allogeneic HSCT. He presents to your clinic with new-onset skin rash which started yesterday. The rash initially appeared on his forearms and later spread to his back and chest. It is described as erythematous with maculopapular lesions and associated pruritis. He is afebrile without other signs or symptoms of infection. His medication list includes prophylactic antimicrobials and immunosuppression, and no new medications have been introduced since hospital discharge two weeks ago.

Which of the following diagnosis is most likely?

a) Viral exanthem

b) Drug hypersensitivity reaction

c) Acute skin graft-versus-host-disease (GVHD)

d) Bacterial cellulitis

Practice Question 1: Answer/Rationale

Answer: c) Acute skin graft-versus-host-disease (GVHD)

Rationale:

- Acute skin GVHD usually occurs within the first 100 days after an Allogeneic HSCT and day +42 post HSCT falls within this window.
- Erythematous maculopapular lesions and associated pruritis are typical of acute skin GVHD presentation
- Patient's medications have not recently changed

Practice Question 2

M.T. is a 52 year old male patient Day +20 post-allogeneic HSCT who presents with 10kg weight gain since admission, abdominal distention and pain. Laboratory tests show elevated bilirubin levels and physical examination reveals hepatomegaly and ascites. His conditioning regimen included high-dose busulfan and cyclophosphamide.

What is the most likely diagnosis?

a) **Hepatic sinusoidal obstruction syndrome (SOS)**
b) **Acute graft-versus-host-disease (GVHD)**
c) **Drug-induced liver injury**
d) **Portal vein thrombosis**

Practice Question 2: Answer/Rationale

Answer: a) Hepatic sinusoidal obstruction syndrome (SOS)

Rationale:

- Timing: SOS typically occurs within 21 days post-transplant
- Signs/Symptoms: Key symptoms include weight gain due to fluid retention, abdominal pain, hepatomegaly, indicating liver dysfunction
- Conditioning regimen: high-dose busulfan is a known risk factor of SOS
- Laboratory findings: Elevated bilirubin and liver function tests support SOS
- Differential exclusion: other conditions like GVHD or drug-induced liver injury have different timelines or findings that do not align as closely with SOS

Practice Question 3

K.B. is a 62 year old female currently Day +19 post-autologous HSCT for non-Hodgkin Lymphoma. She presents with fever, malaise, and mild cough. Laboratory testing reveals WBC 1.1, ANC 0.8, Hgb 8.3, Platelets 22k, kidney and liver function are WNL. She is on prophylactic antivirals and antifungals. Chest X-ray and blood cultures are pending. Vital signs: Temp 102°F, BP 101/64, HR 110, RR 21, SpO2 92%.

Which of the following infections should be considered in the differential diagnoses for this patient?

a) **Bacteremia**
b) **Pneumocystis jirovecii pneumonia (PJP)**
c) **Respiratory viral infection**
d) **All of the above**

Practice Question 3: Answer/Rationale

Answer: d) All of the above

Rationale: Opportunistic bacterial, viral, and fungal/atypical infections are common in the early post-engraftment period

	Early post-engraftment
Risk Factors	• Treatment-related neutropenia • Impaired immunity • Acute GVHD
Bacterial	• Gram negative bacilli • Gram positive organism • GI Streptococci species
Viral	• HSV • Respiratory and enteric viruses • **Cytomegalovirus reactivation (CMV)** • Epstein Barr Virus (BSV) • Human Herpes Virus 6 (HHV6) • Adenovirus
Fungal	• **Candida** • **Aspergillus** • **Pneumocystis jirovecii pneumonia (PJP)**

Resources

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Thank you!

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