

SITT WORKSHEET 27

TOXICITY AND NON-NEUROLOGIC OUTCOMES CRITERIA

A. GENERAL		0	1	2	3	4
		WNL	(mild)	(moderate)	(severe)	(unacceptable)
COMPLETE BLOOD COUNT	LEUKOCYTES (total WBC)	WNL	<LLN - $3.0 \times 10^9/L$ <LLN - 3000/mm ³	$\geq 2.0 - <3.0 \times 10^9/L$ $\geq 2000 - 3000/mm^3$	$\geq 1.0 - 2.0 \times 10^9/L$ $\geq 1000 - <2000/mm^3$	$<1.0 \times 10^9/L$ <1000/mm ³
	ANC/AGC	WNL	$\geq 1.5 - <2.0 \times 10^9/L$ 1500 <2000/mm ³	$\geq 1.0 - <1.5 \times 10^9/L$ 1000 - <1500/mm ³	$\geq 0.5 - <1.0 \times 10^9/L$ $\leq 500 - <1000/mm^3$	$<0.5 \times 10^9/L$ <500mm ³
	LYMPHOPENIA	WNL	<LLN - $1.0 \times 10^9/L$ <LLN - 1000/mm ³	$\geq 0.5 - <1.0 \times 10^9/L$ $\geq 500 - <1000/mm^3$	$<0.5 \times 10^9/L$ <500/mm ³	NA
	PLT/ml	WNL	<LLN - $75.0 \times 10^9/L$ <LLN - 75,000/mm ³	$\geq 50.0 - <75.0 \times 10^9/L$ $\geq 50,000 - <75,000/mm^3$	$\geq 10.0 - <50.0 \times 10^9/L$ $\geq 10,000 - <50,000/mm^3$	$<10.0 \times 10^9/L$ <10,000/mm ³
	HGB	Patient's baseline normal	10-25% Decrease from patient's baseline	25-50% Decrease from patient's baseline	50 <75% decrease in patient's baseline or > 13 g/dl post transfusion	>75% decrease in patient's baseline or >15g/dl post transfusion
CARDIOVASCULAR	SINUS TACHYCARDIA	None	Asymptomatic, Not requiring treatment	Symptomatic, Not requiring treatment	Symptomatic, and requiring treatment of underlying cause	NA
	*HYPERTENSION	None	Asymptomatic, Transient increase (diastolic) If previously WNL: not requiring treatment	Symptomatic Recurrent, persistent increase (diastolic) If previously WNL: not requiring treatment	Requiring therapy or more intensive therapy than previously	Hypertensive Crisis
	+HYPOTENSION	None	Changes, not requiring therapy (Including transient orthostatic hypotension)	Requiring brief Fluid replacement Or other therapy, no hospitalization, no physiologic consequences	Requiring therapy And sustained medical attention, but resolves without persisting physiologic consequences	Shock (Associated with acidemia and impairing vital organ function due to tissue hyperfusion)
	* For Peds Use age and sex appropriate NL values > 95 th tile ULN +For Peds systolic BP 70 mmHg or less if > 1year of age, use two successive or three measurements in 24 hours.					
GASTROINTESTINAL	DIARRHEA	None	Increase of <4 stools/day over pretreatment	Increase of 4-6 stools/day, or nocturnal stools	Increase of ≥ 7 Stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
	CONSTIPATION	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon

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A. GENERAL		0 WNL	1 (mild)	2 (moderate)	3 (severe)	4 (unacceptable)
SENSORY	HEARING/INNER EAR	Normal	Hearing loss on audiometry only	Tinnitus or hearing loss, not requiring hearing aid or treatment	Tinnitus or hearing loss correctable with hearing aid or treatment	Severe unilateral or bilateral hearing loss (deafness), not correctable
	VISUAL (Blurring)	Normal	NA	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	NA
	VISUAL (night-blindness)	Normal	Abnormal electroretinography but asymptomatic	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	NA
	VISUAL (Other)	Normal	Mild	Moderate	Severe	Unilateral or bilateral loss of vision (blindness)
NEUROLOGY	DIZZINESS/ LIGHTHEADEDNESS/ HEADACHE	None	Not interfering with function	Interfering with function, but not interfering with activities	Interfering with activities of daily living	Bedridden or disabling
	SEIZURE (CONVULSION)	None	NA	Self-limited and consciousness is preserved	Consciousness is altered	Any type which is prolonged, repetitive, or difficult to control (e.g., status epilepticus, intractable epilepsy)
	ISCHEMIC STROKE	0 score on PSOM	0.5 – 2.5 score on PSOM	3.0 – 5.0 score on PSOM	5.5 – 10 score on PSOM	Permanent severe disability
	HEMORRHAGIC STROKE	0 score on PSOM	0.5 – 2.5 score on PSOM	3.0 – 5.0 score on PSOM	5.5 – 10 score on PSOM	Permanent severe disability
	HEAD INJURY	none	mild	moderate	severe	Life threatening
	CNS INFECTION/ ADEM	See	infection complication CRF 26			
INFECTION	INFECTION See Infection Complication CRF 26	None	Mild	Moderate	Severe	Life-threatening

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A. GENERAL		0 WNL	1 (mild)	2 (moderate)	3 (severe)	4 (unacceptable)
RENAL	RENAL FAILURE		NA	NA	Requiring dialysis, but reversible	Requiring dialysis, irreversible
	CREATININE	WNL	> ULN – 1.5 x ULN	> 1.5 – 3.0 x ULN	> 3.0 – 6.0 x ULN	> 6.0 x ULN
	DYSURIA	None	Mild symptoms, no intervention	Symptoms relieved with therapy	Symptoms not relieved despite therapy	
PULMONARY	ACUTE CHEST SYNDROME (Fever with new radiodensity on CXR)	None	NA	NA	Decreased O ₂ saturation from baseline > 5% at rest, requiring oxygen	Decreased O ₂ saturation requiring pressure support or assisted ventilation
	DYSPNEA (shortness of breath)	Normal	NA	Upon exertion	At normal level of activity	At rest or requiring ventilation
ALLERGIC REACTION	FEVER (Drug related)	None	Transient rash, drug fever < 38 ⁰ C (<100.4 ⁰ F)	Urticaria ≥ 38 ⁰ C (≥100.4 ⁰ F) and/or asymptomatic bronchospasm	Symptomatic bronchospasm requiring parental medication(s) with or without urticaria; Allergy-related edema	Anaphylaxis
	RASH/ DESQUAMATION	None	Macular or papular eruption or erythema without associated symptoms	Same as grd 1 with associated symptoms and covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Same as grd 2 but covering ≥ 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
	FLUSHING	Absent	Present	N/A	NA	NA
PAIN	VASOOCCLUSIVE EPISODES	None	NA	NA	Pain requiring visit to physician or ER	Pain requiring hospitalization
	ABDOMINAL	None	Mild not interfering with function	Moderate pain or analgesics interfering with activities of daily life	Severe pain or analgesics severely interfering with activities of daily living.	Disabling
	CHEST PAIN (non-cardiac, non-pleuritic)	None	Mild not interfering with function	Moderate pain or analgesics interfering with activities of daily life	Severe pain or analgesics severely interfering with activities of daily living	Disabling

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GENERAL	0 WNL	1 (mild)	2 (moderate)	3 (severe)	4 (unacceptable)	
LIVER	BILIRBIN	WNL	>ULN – 1.5 x ULN	>1.5 - 3.0 x ULN	>3.0 - 10.0 x ULN	> 10.0 x ULN
	SGOT, SGPT	WNL	ULN – 2.5 x ULN	>2.5 – 5.0 x ULN	5.0 – 20.0 x ULN	>20.0 x ULN
	ALK PHOS	WNL	ULN – 2.5 x ULN	>2.5 – 5.0 x ULN	5.0 – 20.0 x ULN	>20.0 x ULN
	HYPOALBUMINEMIA	WNL	<LLN – 3.0 g/dl	≥ 2.0 - <3.0 g/dl	<2.0 g/dl	NA
	FERRITIN	WNL	WNL – 1,000	> 1,000 - ≤ 3,000	>3,000 - <10,000 mg/dl	≥ 10,000 mg/dl
BLOOD TRANSFUSION	TRANSFUSION REACTION (See Appendix VII for Guidelines)	None	Urticaria	Fever or Chills	*Delayed hemolytic transfusion reaction (DHTR) See below	Shock, oliguria, hemoglobinuria
	BLOOD BORNE INFECTION	None	NA	NA	Hepatitis B Hepatitis C Hepatitis Non A Hepatitis Non B	Human Immune Deficiency Virus (HIV)
SICKLE CELL DISEASE RELATED EVENTS Complete Non-CVA Clinical Event Form	AVASCULAR NECROSIS	None	Present ambulatory without assistance	Present ambulatory with assistance for < 1 month	Present ambulatory with assistance for > 1 month or placed on blood transfusion for >2 months	Surgical procedure for joint stabilization
	PRIAPISM	None	Episode lasting < 4 hours	Episode lasting > 4 hours and requiring analgesics	Episode lasting > 4 hours, requiring aspiration from corpus cavernosum and administration of epinephrine or simple blood transfusion	Episode lasting > 4 hours requiring exchange transfusion

*Delayed hemolytic transfusion reaction (DHTR) – defined as a new immunogenic antibody associated with pain and/or an unexpected rate of decline in patients receiving blood.

CXR = Chest X-ray

CVA = Cerebral Vascular Event

N = Normal

LLN = Lower limit of Normal

ULN = Upper limit of Normal

WNL = Within Normal Limits