Immunotherapy patient assessment tool

Early detection and intervention are important in managing the side effects of immunotherapy treatment and preventing the development of severe toxicity. It is recommended that assessment is undertaken by the health care professional prior to each treatment, and as clinically indicated.

Hospital ID: MRN:

Surname:

Given names:

Date of birth: Sex: AMO:

Pronouns:

Preferred names:

Treatment protocol: Date: Cycle: Day:

Immunotherapy patient assessment	Yes	No	N/A
Previous infusion reaction	☐	☐	☐
Details:			
Allergies	☐	☐	☐
Details:			
Is the patient on steroids?	☐	☐	☐
Drug: Frequency:			
Dose: Date commenced/ceased:			
Is the patient on any other medications? E.g. thyroxine	☐	☐	☐
Details:			
Hepatitis screening attended?	☐	☐	☐

Pre-administration assessment

IMPORTANT: When performing a review of vital signs and blood results it is important to assess for trends. Increasing or decreasing levels should be noted in the assessment notes and documented as per local policy or procedure.							
Weight (kg)							
Vital signs checked	☐	☐	☐	☐	☐	☐	☐
Psychosocial assessment	☐	☐	☐	☐	☐	☐	☐
Rate the patient's ECOG Score: 0 - Fully active, able to carry on all pre-disease performance without restriction 1 - Self-care light activities 2 - Self-care unable to work 3 - Limited self-care confined to bed/chair 50% of waking hours 4 - Completely dependent							
ECOG Score							
Blood results assessed for trends from baseline - Indicate increase (I) decrease (D) stable (S) or not checked (N)							
LFT (AST, ALT, Bilirubin)							
WBC	_	_	_	_	_	_	_
Hb							
Neutrophils							
Platelets							
EUC							
TSH, T3, T4							
Cortisol							
LDH							
BSL (perform in clinic)							
Other	_	_	_	_	_	_	_
Assess the patient's venous access, note any complications: Erythema (E) Exudate (Ex) Pain (P) Swelling (S) Occlusion (O)							
Venous access device							
Comments							

Clinical assessment

Assess the patient for treatment related side effects and grade the following toxicities according to the CTCAE grading: 0 – nil, 1 – mild, 2 – moderate, 3 – severe, 4 – life-threatening. *See page 5-8 for more information.*							
Date							
Gastrointestinal and hepatotoxicity							
Mucositis oral (mouth ulcers)							
Diarrhoea							
Abdominal pain							
Mucous and/or blood present in stools							
Jaundice							
Nausea							
Vomiting							
Changes to urine colour							
Bruising (more often than normal)							
Anorexia (loss of appetite)							
Skin							
Pruritus							
Rash (note location/size/description)							
Peeling							
Blistering							
Pulmonary and cardiac toxicity - N.B. presence of fatigue and nausea may indicate cardiac toxicity							
Progressive or acute dyspnoea (difficult or laboured breathing)							
New or worsening cough							
Chest pain – cardiac/non-cardiac							
Palpitations							
Arrhythmias							
Syncope, dizziness							
Peripheral oedema							
Renal toxicity – N.B. Presence of peripheral oedema, may indicate renal toxicity							
Haematuria							
Reduced urine output (oliguria)							
Back pain							
Change in urine frequency, colour or clarity							

Assess the patient for treatment related side effects and grade the following toxicities according to the CTCAE grading: 0 – nil, 1 –mild, 2 – moderate, 3 – severe, 4 – life-threatening. *See page 5-8 for more information*							
Neurological							
Paraesthesia (tingling or numb feet and hands)							
Facial weakness							
Left and/or right sided weakness (arms, legs etc.)							
Headache							
Photophobia (eye sensitivity to light)							
Ataxia (balance and gait changes)							
Cognitive changes (mood, judgement, perception)							
Memory impairment							
Endocrine – N.B. Presence of headache or dizziness, may also indicate endocrine toxicity							
Chills							
Fever							
Fatigue							
Increased sensitivity to heat or cold							
Blurred vision							
Excessive thirst							
Excessive urination							
Musculoskeletal toxicity							
Arthritis, joint pain, swelling or inflammation							
Myalgia (muscle pain)							
Muscle weakness							
Where toxicity is suspected, urgent medical review should be organised and appropriate escalation procedures undertaken as per local policy							
Assessor's signature							

Sign/Symptom	Grade 1	Grade 2	Grade 3	Grade 4
Gastrointestinal and hepatotoxicity *LFT results should be analysed as part of the assessment for hepatotoxicity*				
Blood bilirubin increase	>ULN-1.5 x ULN if baseline was normal; >1.0-1.5 x baseline if baseline was abnormal	>1.5-3.0 x ULN if baseline was normal; >1.5-3.0 x baseline if baseline was abnormal	>3.0-10.0 x ULN if baseline was normal; >3.0-10.0 x baseline if baseline was abnormal	>10.0 x ULN if baseline was normal; >10.0 x baseline if baseline was abnormal
Aspartate aminotransferase increased	>ULN-3.0 x ULN if baseline was normal; 1.5-3.0 x baseline if baseline was abnormal	>3.0-5.0 x ULN if baseline was normal; >3.0-5.0 x baseline if baseline was abnormal	>5.0-20.0 x ULN if baseline was normal; >5.0-20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Alanine aminotransferase increased	>ULN-3.0 x ULN if baseline was normal; 1.5-3.0 x baseline if baseline was abnormal	>3.0-5.0 x ULN if baseline was normal; >3.0-5.0 x baseline if baseline was abnormal	>5.0-20.0 x ULN if baseline was normal; >5.0-20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Mucositis oral	Asymptomatic or mild symptoms	Moderate pain or ulcer that does not interfere with oral intake	Severe pain interfering with oral intake	Life-threatening consequences. Urgent intervention indicated
Diarrhoea	Increase of <4 stools per day over baseline. Mild increase in ostomy output compared to baseline	Increase of 4-6 stools per day over baseline. Moderate increase in ostomy output compared to baseline	Increase of ≥7 stools per day over baseline, incontinence, severe increase in ostomy output compared to baseline. Limiting self-care ADL. Hospitalisation indicated	Life-threatening consequences. Urgent intervention indicated
Abdominal pain	Mild pain	Moderate pain limiting instrumental ADL. Mucous or blood in stool	Severe pain limiting self-care ADL	No criteria
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake	No criteria
Vomiting	Mild, intervention not indicated	Moderate, outpatient IV hydration. Medication intervention indicated	Severe, tube feeding TPN or hospitalisation indicated	Life-threatening consequences. Urgent intervention indicated
Bruising	Localised or in a dependent area	Generalised	No criteria	No criteria
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition	Associated with significant weight loss of malnutrition (e.g. inadequate oral caloric and/or fluid intake)	Life-threatening consequences. Urgent intervention indicated
Skin toxicity				
Pruritus	Mild or localised	Intense or widespread intermittent, limiting instrumental ADL	Intense or widespread, constant, limiting self-care ADL or sleep	No criteria
Rash	Covering ≤10% of skin surface	Covering 10-30% of skin surface	Covering >30% of skin surface	Life-threatening Steven-Johnson syndrome, toxic epidermal necrolysis or rash complicated by full thickness dermal ulceration or necrotic, bullous, haemorrhagic manifestations

Sign/Symptom	Grade 1	Grade 2	Grade 3	Grade 4
Pulmonary and cardiac toxicity N.B. presence of fatigue and nausea may indicate cardiac toxicity				
Dyspnoea	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion limiting instrumental ADL	Shortness of breath at rest limiting self-care ADL	Life-threatening consequences. Urgent intervention needed
Cough	Mild symptoms	Moderate symptoms limiting instrumental ADL	Severe symptoms limiting self-care ADL	No criteria
Chest pain (non-cardiac)	Mild pain	Moderate pain limiting instrumental ADL	Severe pain limiting self-care ADL	No criteria
Chest pain (cardiac)	Mild pain	Moderate pain; pain on exertion; limiting instrumental ADL; haemodynamically stable	Pain at rest; limiting self-care ADL; cardiac catheterisation; new onset cardiac chest pain; unstable angina	No criteria
Palpitations	Mild symptoms; intervention not indicated	Intervention indicated	No criteria	No criteria
Arrhythmias	Asymptomatic; intervention not indicated	Non-urgent medical intervention indicated	Urgent intervention indicated	Life-threatening consequences; haemodynamic compromise
Syncope	No criteria	No criteria	Fainting; orthostatic collapse	No criteria
Dizziness	Mild unsteadiness or sensation of movement	Moderate unsteadiness or sensation of movement; limiting instrumental ADL	Severe unsteadiness or sensation of movement; limiting self-care ADL	
Peripheral oedema	5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self-care ADL	No criteria
Renal toxicity N.B. Presence of peripheral oedema, may indicate renal toxicity				
Creatinine increase	Creatinine >ULN to 1.5 x ULN or >1-1.5 x baseline	Creatinine >1.5 to 3.0 x ULN or >1.5 to 3.0 x baseline	Grade 3: >3.0 to 6.0 x ULN or >3.0 x baseline	Grade 4: Creatinine >6 x ULN
Haematuria	Asymptomatic, clinical or diagnostic observations only. Intervention not indicated	Symptomatic limiting instrumental ADL. Urinary catheter or bladder irrigation indicated	Gross haematuria limiting self-care ADL transfusion. IV medications, hospitalisation indicated or elective invasive intervention indicated.	Life-threatening consequences. Urgent invasive intervention indicated
Urine output decreased (finding based on test results that indicate urine production is less relative to previous output.)	No criteria	No criteria	Adult: Oliguria (<80 mL in 8 hours)	Adult: Anuria (<240 ml in 24 hours)
Back pain	Mild pain	Moderate pain limiting instrumental ADL	Severe pain limiting self-care ADL	No criteria

Sign/Symptom	Grade 1	Grade 2	Grade 3	Grade 4
Neurological toxicity				
Paresthesia	Mild symptoms	Moderate symptoms limiting instrumental ADL	Severe symptoms limiting self-care ADL	No criteria
Facial muscle weakness	Asymptomatic, clinical or diagnostic observations only. Intervention not indicated	Moderate symptoms limiting instrumental ADL	Severe symptoms limiting self-care ADL	No criteria
Muscle weakness (left-sided) (right-sided)	Symptomatic. Perceived by patient but not evident on physical exam	Symptomatic. Evident on physical exam, limiting instrumental ADL	Limiting self-care ADL	No criteria
Headache	Mild pain	Moderate pain limiting instrumental ADL	Severe pain limiting self-care ADL	No criteria
Photophobia	Symptomatic but not limiting ADL	Limiting instrumental ADL	Limiting self-care ADL	No criteria
Ataxia	Asymptomatic clinical or diagnostic observations only. Intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms limiting self-care ADL. Mechanical assistance indicate	No criteria
Cognitive disturbance	Mild cognitive disability not interfering with work/school/ life performance. Specialised educational services/devices not indicated	Moderate cognitive disability interfering with work/school/ life performance but capable of independent living. Specialised resources on part time basis indicated	Severe cognitive disability, significant impairment of work/ school/life performance	No criteria
Memory impairment	Mild memory impairment	Moderate memory impairment limiting instrumental ADL	Severe memory impairment limiting self-care ADL	No criteria
Endocrinopathies NB: Presence of headache or dizziness, may indicate endocrine toxicity				
Chills	Mild sensation of cold, shivering, chattering of teeth	Moderate tremor of the entire body. Narcotics indicated	Severe or prolonged, not responsive to narcotics	No criteria
Fever	38.0-39.0 degrees C (100.4-102.2 degrees F)	>39.0-40.0 degrees C (102.3-104.0 degrees F)	>40.0 degrees C (>104.0 degrees F) for ≤24 hrs	>40.0 degrees C (>104.0
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest limiting instrumental ADL	Fatigue not relieved by rest limiting self-care ADL	No criteria
Blurred vision	Intervention not indicated	Symptomatic, moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline). Limiting instrumental ADL	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200). Limiting self-care ADL	Best corrected visual acuity of 20/200 or worse in the affected eye

Sign/Symptom	Grade 1	Grade 2	Grade 3	Grade 4
Musculoskeletal toxicity				
Arthritis	Mild pain with inflammation, erythema, or joint swelling	Moderate pain associated with signs of inflammation, erythema, or joint swelling; limiting instrumental ADL	Severe pain associated with signs of inflammation, erythema, or joint swelling; irreversible joint damage; limiting self care ADL	No criteria
Myalgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain limiting self-care ADL	No criteria
Muscle weakness	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL	No criteria

References:

1. Antineoplastic drug patient assessment tool 2017 V.2, eviQ Cancer Treatments Online, Cancer Institute NSW, viewed, 20th June 2018, https://www.eviq.org.au/clinical-resources/assessment-tools/4-anti-cancer-drug-patient-assessment-tool
2. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 DCTD, NCI, NIH, DHHS November 27, 2017
3. Wood, L. S., N. P. Moldawer and C. Lewis. 2019. "Immune Checkpoint Inhibitor Therapy: Key Principles When Educating Patients." Clin J Oncol Nurs 23(3):271-280.
4. Management of immune-related adverse events (irAEs) 2020, eviQ Cancer Treatments Online, Cancer Institute, viewed 2nd March 2022,.eviq.org.au/clinical-resources/side-effect-and-toxicity-management/immunological/1993-management-of-immune-related-adverse-events#
5. Thompson, J. A., B.J. Schneider, J. Brahmer, et al. (2020). "NCCN Guidelines Insights: Management of Immunotherapy-Related Toxicities, Version 1.2020." J Natl Compr Canc Netw 18(3): 230-241.
6. Haanen, J. B., F. Carbonnel, C. Robert, et al. 2017. "Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up." Ann Oncol 28(suppl_4):iv119-iv142.

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