

# Variable guide: ART adverse events



Please refer to the below table when reporting any adverse events related to ART in **PART 4: ART ADVERSE EVENTS** on CHARS paediatric follow-up forms.

Adverse events include but are not limited to the following:

Event	Grade 2: Moderate	Grade 3: Severe	Grade 4: Life-threatening
<b>Abacavir hyper-sensitivity reaction</b>	One or more of the following: fever, gastro-intestinal symptoms (nausea, vomiting, diarrhoea), rash (erythema that may be macular, maculopapular, urticarial or pruritic), and malaise and/or constitutional flu-like symptoms including myalgia. Grade as Symptoms.		
<b>Alkaline phosphatase</b>	2.5 - <5.0 x ULN	5.0 - <10.0 x ULN	≥10.0 x ULN
<b>ALT</b>	2.5 - <5.0 x ULN	5.0 - <10.0 x ULN	≥10.0 x ULN
<b>Amylase (Pancreatic) or Amylase (Total), High</b>	1.5 - <3.0 x ULN	3.0 - <5.0 x ULN	≥ 5.0 x ULN
<b>AST</b>	2.5 - <5.0 x ULN	5.0 - <10.0 x ULN	≥10.0 x ULN
<b>Bilirubin</b>	1.6 - <2.6 x ULN	2.6 - <5.0 x ULN	≥5.0 x ULN
<b>Calcium (low)</b> (mg/dL (mmol/L)) ≥7 days old <7 days old	7.0 - <7.8 (1.75 - <1.95) 6.0 - <6.5 (1.50 - <1.63)	6.1 - <7.0 (1.53 - <1.75) 5.5 - <6.0 (1.38 - <1.50)	<6.1 (<1.53) <5.5 (<1.38)
<b>Cholesterol</b> (fasting, high)	5.15 - <7.77 mmol/L	≥7.77 mmol/L	
<b>Creatinine (high)</b>	>1.3 - 1.8 x ULN <u>OR</u> increase of >0.3mg/dL (26.5µmol/L) above baseline	>1.8 - <3.5 x ULN <u>OR</u> increase of 1.5 to <2.0x above baseline	≥3.5 x ULN <u>OR</u> increase of ≥2.0x above baseline
<b>Glucose</b> High, fasting High, non-fasting Low	6.95 - <13.89 mmol/L 8.89 - <13.89 mmol/L 2.22 - <3.05 mmol/L	13.89 - <27.75 mmol/L 13.89 - <27.75 mmol/L 1.67 - <2.22 mmol/L	≥27.75 mmol/L ≥27.75 mmol/L <1.67 mmol/L
<b>Haemoglobin (low)</b> Female, age ≥13yrs Male, age ≥13yrs Age 57 days - <13 yrs (for infants <57 days old, refer to DAIDS tables)	85 - <95 g/L 90 - <100 g/L 85 - <95 g/L	65 - <85 g/L 70 - <90 g/L 65 - <85 g/L	<65 g/L <70 g/L <65 g/L
<b>LDL (fasting, high)</b> Age >2yrs to 18yrs	3.34 - <4.9 mmol/L	≥4.9 mmol/L	
<b>Lipase (high)</b>	1.5 - <3.0 x ULN	3.0 - <5.0 x ULN	≥5.0 x ULN
<b>Lipodystrophy</b>	<u>Definitions of body fat changes</u> <i>Mild (grade 1):</i> Noticeable only if specifically looked for. No change in clothes fitting (other than expected by normal increase in height due to normal growth). <i>Moderate (grade 2):</i> Easily noted by patient or clinician. Clothing has become tight or loose (other than expected by normal increase in height due to normal growth). <i>Severe (grade 3):</i> Obvious to the casual observer. Has required a change in clothing, due to change in body shape not due to increase in height.		

Event	Grade 2: Moderate	Grade 3: Severe	Grade 4: Life-threatening
<b>Neuropathy/ Lower Motor Neuronopathy</b>	Mild transient Paraesthesia only.	Persistent or progressive paraesthesias, burning sensation in feet, or mild dysaesthesia; no weakness; mild to moderate deep tendon reflex changes; no sensory loss.	Onset of significant weakness, decrease or loss of DTRs, sensory loss in "stocking glove" distribution, radicular sensory loss, multiple cranial nerve involvement; bladder or bowel dysfunction, fasciculations, respiratory embarrassment from chest wall weakness. Grade 3 symptoms which do not resolve with dose reduction.
<b>Neutrophil Count (low)</b> <i>(for infants &lt;8 days old refer to DAIDS tables)</i>	0.600x10 <sup>9</sup> - 0.799x10 <sup>9</sup> /L	0.400x10 <sup>9</sup> - 0.599x10 <sup>9</sup> /L	<0.400x10 <sup>9</sup> /L
<b>Phosphate (low)</b> (mg/dL (mmol/L)) >14 yrs 1-14 yrs <1yr	1.4 - <2 (0.65 - <0.81) 2.5 - <3 (0.81 - <0.97) 2.5 - <3.5 (0.81 - <1.13)	1.0 - <1.4 (0.32 to <0.65) 1.5 - <2.5 (0.48 to <0.81) 1.5 - <2.5 (0.48 to <0.81)	<1.0 (< 0.32) <1.5 (< 0.48) <1.5 (< 0.48)
<b>Platelets, Decreased</b> (cells/mm <sup>3</sup> (cells/L))	50,000 - <100,000 (50.000x10 <sup>9</sup> - 100.000x10 <sup>9</sup> )	25,000 - <50,000 (25.000x10 <sup>9</sup> - <50.000x10 <sup>9</sup> )	< 25,000 (<25.000x10 <sup>9</sup> )
<b>Rash</b>	Diffuse rash OR Target lesions	Diffuse rash AND Vesicles or limited number of bullae or superficial ulcerations of mucous membrane limited to one site	Extensive or generalized bullous lesions OR Ulceration of mucous membrane involving two or more distinct mucosal sites OR Stevens-Johnson syndrome OR Toxic epidermal necrolysis
<b>Triglycerides</b> (fasting, high)	>3.42 - 5.7 mmol/L	>5.7 - 11.4 mmol/L	>11.4 mmol/L
<b>Other clinical symptoms</b> (not specified above)	May require minimal intervention and monitoring.	Requires medical care and possible hospitalisation.	Requires active medical intervention, hospitalisation, or hospice care.
<b>Other laboratory values</b> (not specified above)	Sufficiently abnormal to require evaluation as to casualty and perhaps mild therapeutic intervention. Not of sufficient severity to warrant immediate changes in drugs.	Sufficiently severe to require evaluation and treatment, including at least temporary suspension of drugs.	Life-threatening severity. Requires immediate evaluation, treatment, and usually hospitalisation.

Note: ULN = Upper limit of normal range

This table was adapted from NIH/DAIDS toxicity tables for grading severity of paediatric adverse events, November 2014. See [http://rsc.tech-res.com/Document/safetyandpharmacovigilance/DAIDS\\_AE\\_GRADING\\_TABLE\\_v2\\_NOV2014.pdf](http://rsc.tech-res.com/Document/safetyandpharmacovigilance/DAIDS_AE_GRADING_TABLE_v2_NOV2014.pdf) for further information/other events.

Please contact the CHARs team at [chars@ucl.ac.uk](mailto:chars@ucl.ac.uk) if you have any queries.