



GENERAL INSTRUCTIONS

The Physical Assessment form captures physical measurements performed on the patient from up to 7 days prior to enrollment, during the hospitalization for the episode of ALF, and at the follow-up visits.

The assessment is performed **daily** when the patient meets the following INR and encephalopathy criteria:

INR ≥ 1.5 and INR < 2.0 with encephalopathy or
INR ≥ 2.0 with or without encephalopathy

One PA form is to be completed per day on the days required according to the INR/encephalopathy criteria. Refer to page 2 of the Data Collection Timeline or Flowsheet for detailed information on the INR and encephalopathy criteria.

The assessment is to be performed as close as possible to the time of the routine blood draw when research samples are obtained. If a specific test is performed more than once in a given day, record the result from the assessment performed closest to the time the research samples were obtained, or if no research samples were obtained, use the first assessment of the day.

If an assessment is not performed at the same time as other assessment on that day, record the time that assessment was performed under the "Time if different from above" column. If any part of the time is unknown, enter -3 for the unknown part of the time and enter the other parts of the time that are known. If the entire time is unknown, check "Unknown".

When possible the physical exam should be performed by the same person performing the Global Assessment and at the same time as the Global Assessment.

Record the timepoint for an assessment performed at one of the follow-up evaluations. A timepoint is not required for assessments performed during the in-hospital period. The default timepoint in the data system will be "In-hospital".

Record results according to the units specified. Refer to the lab conversion sheet for site-specific differences.

Check "Not Done" when an assessment is not performed. The default value in the data system will be "Not Done" for all assessments.

SPECIFIC INSTRUCTIONS

Patient ID: Record the Patient ID

Date of Evaluation: Record the date that the assessments were performed. using a 2-digit month, day, year format.

Time of Evaluation: Record the time that the majority of the assessments for a given date were performed in 24-hour/military time (e.g. 00:00 = midnight, 06:00 = 6 A.M., 12:00 = noon, and 20:00 = 8 P.M.). If any part of the time is unknown, enter -3 for the unknown part of the time and enter the other parts of the time that are known. If the entire time is unknown, check "Unknown".

Height/Length: Record the patient's height/length in centimeters (1 inch = 2.54 cm). Check "actual" or "estimate" to indicate how the measure was obtained. Actual measurements include a standing measure of height, a bed measure of length, or a measurement documented in the chart that was obtained in a similar way. Estimates include measurements reported by the patient or parent/guardian, or documented in the chart as approximate measures.



Physical Assessment

Height/Length measurements should be performed at enrollment. Any additional measurements obtained during the hospitalization should be recorded on the date performed.

Weight: Record the patient's weight in kilograms (1 lb = 0.45 kg). Weight measurements should be performed at enrollment. Any additional measurements obtained during the hospitalization should be recorded on the date performed.

Vitals: Pulse/heart rate, blood pressure, and respiratory rate should be performed according to the INR/encephalopathy criteria and as close as possible to the collection of the research sample.

Vital signs taken while the patient is under general anesthesia should not be recorded. If the patient is placed under general anesthesia to be taken to the operating room or for any other reason, vital signs taken while the patient is under general anesthesia should not be reported on this form. Time under general anesthesia is defined as the time when the patient leaves the floor/PICU/NICU to be taken to the operating room (or other location) until the child returns to the floor/PICU/NICU.

FiO₂: FiO₂ must be collected in %.

| Estimating FiO ₂ from a given O ₂ flow: | | |
|---------------------------------------------------------------|-----------------------------|------------------------------|
| Method | O ₂ flow (l/min) | Estimated FiO ₂ % |
| Nasal cannula | Room air (RA) | 21 |
| | 1 | 24 |
| | 2 | 28 |
| | 3 | 32 |
| | 4 | 36 |
| | 5 | 40 |
| | 6 | 44 |
| Nasopharyngeal catheter | 4 | 40 |
| | 5 | 50 |
| | 6 | 60 |
| Face mask | 5 | 40 |
| | 6-7 | 50 |
| | 7-8 | 60 |
| Face mask with reservoir | 6 | 60 |
| | 7 | 70 |
| | 8 | 80 |
| | 9 | 90 |
| | 10 | 95 |

Temperature: Today: Temperature should be measured according to the INR/encephalopathy criteria and as close as possible to the collection of the research sample.

Previous date: Record the minimum and maximum temperature from the day before the date of the evaluation, and the corresponding time of the measurements (using 24-hour time). If the same minimum or maximum temperature occurs more than once on a date, record the first time the minimum or maximum is occurs on that day. If any part of the time is unknown, enter -3 for the unknown part of the time and enter the other part of the time that is known. If there is not a minimum or maximum measurement available from that date check "NA" (not available) for that measure.



Physical Assessment

Temperature measurements taken while the patient is under general anesthesia should not be recorded. If the patient is placed under general anesthesia to be taken to the operating room or for any other reason, temperatures taken while the patient is under general anesthesia should not be reported on this form. Time under general anesthesia is defined as the time when the patient leaves the floor/PICU/NICU to be taken to the operating room (or other location) until the child returns to the floor/PICU/NICU.

Fluids:

Total fluids: Record the total fluid intake in milliliters (same as cc's) since the last assessment. The first time the daily assessment is performed use the total fluid intake from the previous 24 hours based on the hospital chart standard (e.g. midnight to midnight, 7am to 7am, etc). If assessments are not performed daily, calculate the total fluid volume from the time of the last assessment.

Total output: Record the total fluid output in milliliters (same as cc's) since the last assessment. The first time the daily assessment is performed use the total fluid output from the previous 24 hours based on the hospital chart standard (e.g. midnight to midnight, 7am to 7am, etc). If assessments are not performed daily, calculate the total fluid volume from the time of the last assessment.

Glasgow Coma Scale:

Use one of the tables below to assess the patient's Glasgow coma scale. Record each of the sub-scores in the appropriate field and then calculate the sum of the three sub-scores and enter this as the Total score. If any of the sub-scores are not assessed, check "Not Done" for that sub-score. Record the total score if it is available in a source document, but do not calculate it from incomplete sub-scores.

If a component of the scale cannot be assessed or the total cannot be calculated because the components could not be assessed, check "Not assessable".

The lowest possible total score is 3 (deep coma or death) while the highest score is 15 (fully awake and aware). Any combined score of < 8 represents a significant risk of mortality. Scores are interpreted as: ≤ 8=severe, 9 – 12=moderate, ≥ 13=mild

| Glasgow Coma Scale | | | | | | |
|---------------------------|--------------------|-----------------------------------------------------|------------------------------------------------------------|-----------------------------------------|------------------------------|----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| Eyes | Does not open eyes | Opens eyes in response to painful stimuli | Opens eyes in response to voice | Opens eyes spontaneously | N/A | N/A |
| Verbal | Makes no sounds | Incomprehensible sounds | Utters inappropriate words | Confused, disoriented | Oriented, converses normally | N/A |
| Motor | Makes no movements | Extension to painful stimuli (decerebrate response) | Abnormal flexion to painful stimuli (decorticate response) | Flexion / Withdrawal to painful stimuli | Localizes painful stimuli | Obeys commands |

| Pediatric (birth to 36 months of age) Glasgow Coma Scale | | | | | | |
|-----------------------------------------------------------------|--------------------|-------------------------------------------|---------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------|--------------------------------------------|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| Eyes | Does not open eyes | Opens eyes in response to painful stimuli | Opens eyes in response to speech | Opens eyes spontaneously | N/A | N/A |
| Verbal | No verbal response | Inconsolable, agitated | Inconsistently inconsolable, moaning | Cries but consolable, inappropriate interactions | Smiles, orients to sounds, follows objects, interacts | N/A |
| Motor | No motor response | Extension to pain (decerebrate response) | Abnormal flexion to pain for an infant (decorticate response) | Infant withdraws from pain | Infant withdraws from touch | Infant moves spontaneously or purposefully |

Encephalopathy: Using the appropriate scale, record the level of encephalopathy.

Standard Clinical Scales (3 to 10 years of age)

| Stage | Clinical | Asterixis/Reflexes | Neurological signs | EEG changes |
|-------|--------------------------------------------------------------------------------------|------------------------------------------------|---------------------------------------|------------------------------------------------------------|
| 0 | None | None/normal | Psych testing only | Normal |
| I | Confused, mood changes, altered sleep habits, loss of spatial orientation, forgetful | None/normal | Tremor, apraxia, impaired handwriting | Normal or diffuse slowing to theta rhythm, triphasic waves |
| II | Drowsy, inappropriate behavior, decreased inhibitions | None/ hyperreflexic | Dysarthria, ataxia | Abnormal generalized slowing, triphasic waves |
| III | Stuporous, obeys simple commands | None/hyperreflexia, up-going toes (+ Babinski) | Rigidity | Abnormal generalized slowing, triphasic waves |
| IV | Comatose, arouses with painful stimuli (IVa), or no response (IVb) | Absent | Decerebrate or decorticate | Abnormal, very slow delta activity |

Peter Whittington scale (< 3 years of age)

| Stage | Clinical | Asterixis/Reflexes | Neurological signs |
|------------------|-------------------------------------------------------------------|-------------------------------------|----------------------------|
| Early (I and II) | Inconsolable crying, sleep reversal, inattention to task | Unreliable/ normal or hyperreflexic | Untestable |
| Mid (III) | Somnolence, stupor, combativeness | Unreliable/hyperreflexic | Most likely untestable |
| Late (IV) | Comatose, arouses with painful stimuli (IVa) or no response (IVb) | Absent | Decerebrate or decorticate |

If the level of encephalopathy recorded in the hospital chart indicates a range rather than an individual score, for example, a grade of 2-3, record the lower value.

If the encephalopathy cannot be assessed (e.g., patient is sedated), check "Not assessable".

If the encephalopathy is assessable but is not assessed (e.g., doctor did not choose to assess, encephalopathy not recorded in the chart), check "Not done".

Physical Exam General Guidelines:

Ascites, Jaundice, Splenomegaly, Hepatomegaly and Pupillary reactions are to be assessed daily based on information since the last assessment (or if it is the first assessment, within the past 24 hours). At each assessment, indicate whether or not the item is present since the last assessment.

Digital clubbing, Spider angioma, and Kayser-Fleischer rings are to be assessed at the time of enrollment into the PALF cohort study and then the assessment should be recorded when done clinically.

Ascites: Ascites is defined as excess fluid in the peritoneal cavity (space between the tissues lining the abdomen and abdominal organs). If the presence of ascites cannot be assessed because the abdomen is too edematous (or a similar physiological reason) then check "Not assessable."

Jaundice: Jaundice is characterized by hyperbilirubinemia (higher than normal levels of bilirubin in the blood) and deposition of bile pigment in the skin, mucous membranes and sclera with resulting yellow appearance of the patient.



Physical Assessment

- Splenomegaly:** Splenomegaly is defined as the enlargement of the spleen beyond its normal size. If the spleen is palpable or is >2 cm below the left costal margin then the patient is considered to have splenomegaly. If the spleen is not palpable or is ≤ 2 cm below the left costal margin then the patient is not considered to have splenomegaly. If splenomegaly cannot be assessed because the abdomen is too edematous (or a similar physiological reason) then check 'Not assessable.'
- Hepatomegaly:** Hepatomegaly is defined as the enlargement of the liver beyond its normal size. If hepatomegaly cannot be assessed because the abdomen is too edematous (or similar physiological reason) then check "Not assessable."
- ≤ 1 year of age: If the distance is >2 cm below the right costal margin then the patient is considered to have hepatomegaly. If the distance of the liver is ≤ 2 cm below the right costal margin then the patient is not considered to have hepatomegaly.
- >1 year of age: If the liver is palpable below the right costal margin then the patient is considered to have hepatomegaly. If the liver is not palpable then the patient is not considered to have hepatomegaly.
- Digital clubbing:** Digital clubbing is defined as a condition affecting the fingers and toes in which the extremities are broadened and the nails are shiny and abnormally curved. Record whether or not the patient has the presence of digital clubbing on the date of the assessment.
- Spider angioma:** Spider angioma (also known as a nevus araneus, spider nevus, vascular spider, and spider telangiectasia) is defined as a type of telangiectasis found slightly beneath the skin surface, often containing a central red spot and reddish extensions which radiate outwards like a spider's web. Record whether or not the patient has the presence of spider angioma on the date of the assessment.
- Kayser-Fleischer rings:** Kayser-Fleischer rings (KF rings) are defined as dark rings that appear to encircle the iris of the eye. Record whether or not the patient has the presence of KF rings on the date of the assessment
- Pupillary reactions:** Check all that apply to record the pupillary reaction on the date of the assessment.