HALT-C Trial Q X Q

CTP Score

Form # 15 Version A: 06/15/2000

Purpose of Form #15: The CTP Score form is used to calculate a patient's Child-Turcotte-Pugh Score, which grades the severity of liver disease.

When to complete Form #15: Form #15 should be completed at the following study visits:
- Screening (S00)
- Lead-in phase: Baseline (W00), Week 12 (W12), and Week 20 (W20),
- Randomization phase: All randomization phase study visits,
- Responder phase: Week 36 (W36), Week 48 (W48) and Week 72 (W72).

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit.

A4. Record the date of this visit using MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: CHILD-TURCOTTE-PUGH SCORING FOR GRADING SEVERITY OF LIVER DISEASE

B1. Serum albumin (g/dL)
Obtain the serum albumin result from your local lab.

- Enter a score of 1 if the serum albumin result was greater than 3.5.
- Enter a score of 2 if the serum albumin result was exactly 2.8, exactly 3.5, or between 2.8 and 3.5.
- Enter a score of 3 if the serum albumin result was less than 2.8.

If the serum albumin was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

B2. Serum total bilirubin (mg/dL)

Obtain the serum total bilirubin result from your local lab.

Use the first row of bilirubin scores for any patient who (a) does not have Gilbert's Syndrome, (b) does not have a hemolytic disorder, or (c) is not taking ribavirin.

- For these patients, enter a score of 1 if the serum total bilirubin result was less than 2.0.
- For these patients, enter a score of 2 if the serum total bilirubin result was exactly 2.0, exactly 3.0, or between 2.0 and 3.0
- For these patients, enter a score of 3 if the serum total bilirubin result was greater than 3.0.

Use the second row of bilirubin scores for any patient who (a) has Gilbert's Syndrome, (b) has a hemolytic disorder, or (c) is taking ribavirin. Any patient with Gilbert's syndrome should have this fact documented on Form # 3, Screening Medical History.

- For these patients, enter a score of 1 if the serum total bilirubin result was less than 4.0.
- For these patients, enter a score of 2 if the serum total bilirubin result was exactly 4.0, exactly 7.0, or between 4.0 and 7.0
- For these patients, enter a score of 3 if the serum total bilirubin result was greater than 7.0.

If the serum total bilirubin was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

B3. Prothrombin time (INR)

Obtain the prothrombin time result from your local lab. Prothrombin time results should be reported and used for calculations only as International Normalized Ratios (INR) because of variations in methods used and reference ranges for controls.

- Enter a score of 1 if the PT-INR result was less than 1.7.
- Enter a score of 2 if the PT-INR result was exactly 1.7, exactly 2.3, or between 1.7 and 2.3.
- Enter a score of 3 if the PT-INR result was greater than 2.3.

If the patient was taking coumadin at the time of the test, score the PT-INR according to the points indicated, even though the patient will receive a higher score than if s/he were not taking coumadin. Put a field level comment stating: "Patient on coumadin".

If the PT-INR was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

General Instructions for Items B4 and B5.

When a physical exam has not been performed, the CTP ascites and encephalopathy fields should be completed according to a conservative scoring method. The Steering Committee approved the following method on 04/16/2004:

- If the physical exam was not completed, coordinators should refer to values from the most recent previous CTP form to complete Form #15. Coordinators must consult with the PI to determine whether these "default" values are appropriate.
- If the PI determines that the "default" values are appropriate, the CTP fields can be completed. If all five CTP fields are complete, the total CTP score can be calculated.
- If uncertainty remains after consultation with the PI, one option is not to complete the CTP fields. A -9 should be entered in the DMS for those fields and for the total CTP score. The override explanation should be brief: "PE not performed, PI consulted, cannot use past score", or a similar clear succinct explanation.
- However, if it is suspected that the patient may have experienced clinical worsening of liver disease, s/he should be brought back to the clinic promptly for a physical examination. The CTP score should be determined on the basis of that physical exam.

B4. Ascites

Obtain the results of clinical assessment of ascites from the physical exam at this visit. If a physical exam is not done at this visit, see the general instructions above.

- Enter 1 if there was no evidence of ascites.
- Enter 2 if the patient had mild ascites (readily controlled by standard medical therapies).
- Enter 3 if the patient had severe ascites (difficult to control or uncontrollable by optimal, maximally tolerated medical therapies).

If the patient has ascites, complete Form #60 (Adverse Event Report) and Form #63 (Clinical Outcome), if applicable. Note that the definition of ascites for this assessment and an outcome of ascites are not the same.

Treatment may need to be discontinued permanently. Please refer to Section L of the HALT-C protocol in the Manual of Operations.

B5. Encephalopathy

Obtain the results of clinical assessment of encephalopathy from the physical exam at this visit. If a physical exam is not done at this visit, see the general instructions above.

- Enter 1 if the patient has no encephalopathy.
- Enter 2 if the patient has mild encephalopathy (easily controlled by standard medical therapies).
- Enter 3 if the patient has severe encephalopathy (difficult to control or uncontrollable by optimal, maximally tolerated medical therapies).

If the patient has hepatic encephalopathy, complete Form #60 (Adverse Event Report) and Form #63 (Clinical Outcome), if applicable. Note that the definition of encephalopathy for this assessment and an outcome of encephalopathy are not the same.

Treatment may need to be discontinued permanently. Please refer to Section L of the HALT-C protocol in the Manual of Operations.

B6. Total CTP Score

- Enter the sum of the scores for items B1 – B5. The possible range is 5 to 15.
- If there is a –9 entered for any score on items B1 – B5, the Total CTP score cannot be calculated. Record a –9 for the Total CTP score.

If the CTP score is 7 or higher on 2 consecutive study visits that occur three months apart, complete Form #60 (Adverse Event Report) and Form #63 (Clinical Outcome), if applicable.

If the CTP score is 10 or higher, treatment must be discontinued permanently. Please refer to Section L of the HALT-C protocol in the Manual of Operations. Complete Form #60 (Adverse Event Report) and Form # 63 (Clinical Outcome), if applicable.

If the CTP score is 7 or higher and accompanied by any of the following diagnoses, treatment must be discontinued permanently. Please refer to Section L of the HALT-C protocol in the Manual of Operations. Complete Form #60 (Adverse Event Report) and Form # 63 (Clinical Outcome), if applicable. The diagnoses are:

- Documented unresponsive variceal hemorrhage;
- Hepatorenal syndrome;
- Occurrence of one episode of spontaneous bacterial peritonitis;
- Refractory ascites or hepatohydrothorax unresponsive to treatment.

Child-Turcotte-Pugh Score for Grading Severity of Liver Disease

Modified Child-Turcotte-Pugh Score				
		#	ts	
Variable	**Units**	**1**	**2**	**3**
Serum albumin	(g/dL)	>3.5	2.8-3.5	<2.8
Serum total bilirubin (No Gilbert's Syndrome; No hemolytic diseases; Not receiving ribavirin)	(mg/dL)	<2.0	2.0-3.0	>3.0
Serum total bilirubin (In presence of Gilbert's Syndrome, a hemolytic disorder [e.g., patients receiving ribavirin]) ‡	(mg/dL)	<4.0	4.0-7.0	>7.0
Prothrombin Time	(INR)	<1.7	1.7-2.3	>2.3
Ascites		None	mild*	severe+
Encephalopathy		None	mild*	severe+

albumin score 3.5 = 2

NO ribavirin NO Gilbert's

Pt is on ribavirin or has Gilbert's

Definition of Ascites from Protocol:

Abdominal fluid which is:
a. mild, moderate or marked on U/S
b. progressive on serial PE
c. requires diuretic therapy

Mild, barely detectable on PE needs U/S confirmation of mild, moderate or marked.

Minimal fluid around liver on Ultrasound

Is the ascites or encephalopathy mild or severe? The PI will make a clinical judgment.

*Mild means readily controlled by standard medical therapies.

+Severe means difficult to control or uncontrollable by optimal, maximally tolerated medical therapies.

Prothrombin time results should be reported and used for calculations only as International Normalized Ratios (INR), because of variations in methods used and reference ranges for controls (expressed in seconds).

‡ Note that if, in the opinion of the investigator, the patient has Gilbert's syndrome or a hemolytic disorder (e.g., patients receiving ribavirin) the level of the serum total bilirubin may be increased to as high as 3.99 mg/dL without considering the total bilirubin to be sufficiently elevated for the patient to receive a score of 2 in the CTP scoring system.

The score is calculated as the sum of the scores for albumin, bilirubin, prothrombin time, ascites and encephalopathy (range 5-15). Class A is defined as 5-6, class B 7-9 and class C 10-15.