Date: October 15, 2008

Topic: CTCAE v3.0 Help Desk Tickets WG #5 SOC: Gastrointestinal

From: Ann Setser

Issue: AE Term - Constipation

 Comment: I would like to make a suggestion regarding CTCAE Version 3.0.  When looking up constipation, I noticed that the grading is based on interventions.  To stay consistent with flow of CTCAE I would suggest changing the grading to be based on symptoms.  I have attached a document which outlines my idea for grading constipation based on symptoms.

CTEP Response: Thank you for your thoughtful comments.  We are adding your suggestions to the file we are compiling that includes comments from many other CTCAE users.  When CTEP begins working on the next revision of CTCAE v3.0 (as yet unscheduled for at least 1 year), we will review your suggestions.  We are also keeping a list of health care professionals who might be interested in helping with that next revision and will add your name if you like.

The Remark listed with **Mucositis/stomatitis** (functional/symptomatic) needs to be added to Mucositis/stomatitis (clinical exam)

V3.0 Mucositis/stomatitis (clinical exam) grade descriptions are based on the clinical assessment made by what the clinician observes when examining a patient. They closely resemble the grade descriptions in the CTC v2.0 AE 'Muscositis due to radiation.'

V3.0 Mucositis/stomatitis (functional/symptomatic) grade descriptions are based on what the clinician learns when the patient is asked how the AE has influenced his/her ability to function (e.g., eat, drink, swallow, etc.). Grading Mucositis/stomatitis (functional/symptomatic) is  determined by obtaining medical history and eliciting symptoms described by the patient, not by clinician physical examination.

V3.0 Mucositis/stomatitis (functional/symptomatic) is accompanied by the REMARK:

*'Mucositis/stomatitis (functional/symptomatic) may be used for mucositis of the upper aero-digestive tract caused by radiation, agents, or GVHD.*

**However, either Mucositis/stomatitis can be used for the AE caused by radiation, agents, or GVHD.**

**----------------------------------------------------------------------------------------------------------------**

Dermatology/Skin - 'Chelitis' should this be **Cheilitis**?

CTEP Response: YES, THIS IS A TYPO AND SHOULD BE CHEILITIS.

Mucositis (functional/symptomatic) - Select Grade 2 - Lower GI Sites 'inicated', should this be 'indicated'?

CTEP Response: YES THIS IS A TYPO AND SHOULD BE INDICATED

Dear CTEP,

NCI CTC is a great grading tool for cancer treatment related toxicities.  It is important to promote its use in all clinical studies for accurate reporting of safety profiles and the comparability among publications.  We observed inconsistencies of reporting among international investigators.  To better follow CTCAE, I would like to confirm with you several common AE reporting practices and post some questions.

1. Subsequent events or complications of the initial event should be collected if they are not typically associated the event.  For example, dehydration, hypotension, acidosis, renal failure, etc. result from diarrhea.  Question: Can diarrhea Grade 4 cover these complications in reporting?  In case of G4 diarrhea, should all events (dehydration, acidosis, hypotension, renal failure (if exist)) be reported and graded OR covered by one or two terms (G4 diarrhea and dehydration)?  It seems overlapping in event terms and grade system which may affect the AE counts.

In my view, CTC is grading system, but not a dictionary.  CTC should be carefully followed when reporting cancer-treatment related toxicities.  Other events should be reported and coded by MedDra.  Training on CTC should be given to promote good reporting

Requests for inclusion in CTCAE v4.0:

* Anal fissure - MedDRA LLT
* GI perforation – not a MedDRA term. Option: MedDRA LLT & PT Gastrointestinal perforation
* Intestinal necrosis – MedDRA LLT for PT Gastrointestinal necrosis
* Caecitis – MedDRA LLT & PT
* Typhlitis – MedDRA LLT for PT Caecitis
* Proctitis – MedDRA LLT & PT
* aphtoses/aphtae
  + Oral aphthae MedDRA LLT for PT Aphthous stomatitis
* Epigastralgia
  + Epigastralgia is LLT for PT Abdominal pain upper
* Hepatalgia – not in MedDRA
  + MedDRA LLT Liver pain for PT Hepatic pain

Date: October 15, 2008

Topic: CTEP Help Desk CTCAE Tickets -- SOC: Hepatobiliary disorders

From: Ann Setser

Consider for addition to CTCAE v4.0:

* MedDRA LLT & PT Jaundice
* MedDRA LLT & PT Hepatitis