

As a result of the important feedback provided by our research sites over the last year, we have implemented some enhancements to the electronic data capture (EDC) system and updated our tools/forms found on criticalcarenutrition.com. They are outlined below. These enhancements will be available online as of 5 Dec 2008. These changes will not have any impact on data already entered into the system.

If you have any questions please do not hesitate to contact Janet Overvelde, Project Leader.

Electronic Reference Tools

Child's Class C Liver Disease Classification

As per the November REDOXS© Circular, the Child's Class C Liver Disease Classification has been updated. The updated table can be found on the Screening Form (page 2), Exclusion Criteria:

- Cirrhosis- child's class C liver disease [Click here for details](#)

Protocol Violation Form

The Protocol Violation (PV) Form is now available in a rewritable pdf format. As a result, you may now complete the form electronically and submit it to the Project Leader electronically via email. Please note the fields in the form have not changed. The PV Form is found on the Welcome, Home Page (see below).

[Screen New Patient](#)

[Protocol Violation Form](#) [SAE Form - Initial](#) [SAE Form - Follow-up](#)

SAE Report Forms

The Initial and Follow-up SAE Report Forms have had some formatting changes, to remove the shaded sections. There have been no content changes to these forms. The forms are accessible on the EDC system on the Welcome, Home Page (see below).

[Screen New Patient](#)

[Protocol Violation Form](#) [SAE Form - Initial](#) [SAE Form - Follow-up](#)

NOTE: The updated documents can also be found on [criticalcarenutrition.com/ REDOXS© Resources / Study Procedures Manual](http://criticalcarenutrition.com/REDOXS%20Resources/StudyProceduresManual). All versions of tools found on the website correspond to the version found on the EDC system.

Study Supplement Compliance Page

The table which appears at the top of the form has been updated to include 2 new columns: one to flag a protocol violation/deviation and another to note signs of phlebitis.

Study Supplement Compliance (daily data)

Day #	Date	EN Received	PV/PD	PN Received	PV/PD	Phlebitis Signs
1	15/Jul/2008	0.0		0.0		
2	16/Jul/2008	240.0		240.0		
3	17/Jul/2008	480.0		240.0		No
4	18/Jul/2008	480.0		240.0		No
5	19/Jul/2008	480.0		240.0		No
6	20/Jul/2008	480.0		240.0		No
7	21/Jul/2008	440.0	✓	240.0		No
8	22/Jul/2008	480.0		210.0		No
9	23/Jul/2008	20.0		160.0		Yes
10	24/Jul/2008	0.0		0.0		

Daily Nutrition Page

The table which appears at the top of the Daily Nutrition form has been updated to include the Formulas which is entered in the enteral nutrition section of the form.

In the parenteral nutrition section, the 'type of lipids' options found in the drop-down menu have been updated to include 'none received.' Now you do not need to choose 'other' and write "none received." This change applies to new patients going forward, previously entered data does not need to be adjusted.

Day #	Date	Enteral received	Enteral energy	Enteral protein	Formula	Parenteral received	Parenteral energy	Parenteral protein
1	15/Jul/2008	No						
2	16/Jul/2008	Yes	422.0	7.0	ROSS: Nepro	No		
3	17/Jul/2008	Yes	1298.5	62.2	ROSS: Promote	No		
4	18/Jul/2008	Yes	2112.6	105.8	ROSS: Promote	No		

Microbiology Page

Instructions detailing the rules for microbiology data entry will pop up when the 'click here for more details' link is selected.

The quantitative results field has been modified. A drop-down menu option of 'None' has been added for when the following sample types are selected: BAL, urine or cath tip. You are no longer required to select the 'other' option to enter this data. This change applies to new patients going forward, previously entered data does not need to be adjusted.

Sample

Record all positive cultures within the period 7 days prior to ICU admission until day 30, death or ICU discharge, whatever comes first. [Click here for more details](#)

Accession Number: 08:FL0000154R
 Date Culture taken: 07 Aug 2008, Time: 12:00 (24 hrs)
 Sample Type: Other chest tube

Accession Number: M36183
 Date Culture taken: 19 Apr 2008, Time: 00:30 (24 hrs)
 Sample Type: BAL or PBC Specimen

Organisms

Organism: Bacteria
 species: Staph sp.
 sub-species: Methicillin Resistant Staph Aureus (MRSA)
 Quantitative Results:
 >10⁴ cfu/ml or >10⁷ cfu/L
 <10⁴ cfu/ml or <10⁷ cfu/L
 None

Antibiotic Page

Instructions detailing the rules for antibiotic data entry will pop up when the 'click here for more details' link is selected.

Antibiotic

Record all antibiotics started within the period of 7 days prior to ICU admission and those started in ICU until day 30, death or ICU discharge, whatever comes first. Stop dates may extend beyond ICU discharge. [Click here for more details](#)

Antibiotic: Metronidazole
 Dose: 500.0 mg
 Route: IV PO/NG

Infection Adjudication

Following the notice in the October Circular, we have uploaded the revised changes to Infection Categories on the EDC system. These changes are also found on criticalcarenutrition.com / REDOXS© Resources / Study Procedures Manual.

Also, you will notice that definitions for 'probable and possible NO' are now available on the adjudication form. Click on 'details' to see the definitions.

This is a newly acquired infection
 This is NOT a newly acquired infection
 This is a previously adjudicated infection

Possible NO [Details ..](#)

Hospital Outcomes & 3, 6-Month Follow-up

We have added the status dot functionality to the Hospital Outcome and 3, 6-Month Follow-up forms. Many hospital outcome forms were left blank and the patient eCRF could be finalized. The status dot will provide a reminder to ensure the data is complete prior to finalizing a patient eCRF.

Also, you will notice the word 'edit' has been removed from the SF-36 section.

Outcomes and Follow Up

[ICU Outcome information](#)

[ADJUDICATION Form](#) ↓

[Hospital Outcome information](#) ↓ ✖

[3 month follow up information](#) ↓

[6 month follow up information](#) ↓ ✖

[Edit SF36 Page 1](#)

SF 36 - 3 Month survey [Edit SF36 Page 2](#)

[Edit SF36 Page 3](#)

[Edit SF36 Page 1](#)

SF 36 - 6 Month survey [Edit SF36 Page 2](#)

[Edit SF36 Page 3](#)