

## Clinical Evaluation Research Unit



The REDOXS<sup>®</sup> Study

REducing DEaths due to OXidative Stress

November was an amazing month for enrolments (21 patients!) and we are happy to bring you an update in this issue of the REDOXS<sup>®</sup> Circular. Please read along for important reminders and revisions on corrections to the web based data entry (page 2).

## Enrolment Update

# patients enrolled	Site
21	Kingston General
3	St. Joseph's Hamilton
21	Ottawa General
8	Ottawa Civic
2	Vancouver General
16	Sacre Coeur, Montreal
7	Maisonneuve-Rosemont, Montreal
6	Royal Victoria, Montreal
3	Royal Alexandra, Edmonton
<b>87 + 80 (from pilot) = TOTAL 167</b>	

### Monthly Enrolment

October: 9 patients

November : 21 patients

**1033**  
patients  
to go

### Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

Daphne Mayer

Suzanne Biro

### New Project Leader

Daphne Mayer has joined CERU as a co-Project Leader for REDOXS<sup>®</sup>

Please help us welcome her to this exciting study!

## Site Reports

We have generated site reports that will illustrate how well the study is being conducted at your site. These reports include an update on recruitment, reasons for exclusion, compliance with the supplements (time to start of supplements, volumes received), adequacy of enteral nutrition, completion of case report forms and Serious Adverse Events (SAEs). Please ensure that you report all the reported SAEs to your REB. We strongly encourage the research coordinators to review these reports in conjunction with the site investigator and other research staff. Please see emails sent November 30th and December 3rd.

## Trying to Optimize the Delivery of Enteral Study Supplements?

We have noticed that many sites are still struggling with delivering the prescribed volume of enteral study supplements. After carefully reviewing the patients that receive less than 80% prescribed supplements, it is evident that small bowel feeding (only 8% patients) is not being maximized. There is emerging data that combination Maxeran and Erythromycin may be effective in these patients. We have generated a memo that can be shared with your surgeons and GI staff/others that have concerns about feeding REDOXS patients via the enteral route. Refer to memo sent by email November 27th.

## Not caught up with data entry?

After reviewing the activity on our website, we have noticed that many enrolling sites have not entered data yet and as a result many patients are still not locked ("locked" means first stage of data entry is complete). Please see that at least two of your patients are locked so that we can start to schedule source verification visits. These visits are very important to identify errors in data entry earlier on and we appreciate your cooperation in entering the data. **Congratulations to Carole Sirois of Sacre Coeur, Montreal for locking the charts on 13 out of 16 patients!**

### REMINDER: Serious Adverse Events

When reporting SAEs there **MUST** be documentation by the Site Investigator/Delegate verifying that the event is unexpected, i.e. **not** related to the progression of the underlying disease.

### Reminder

Please remember to complete and submit the Delegation of Authority Logs. Also include current CVs of Site Investigators and Study Coordinators.

[www.criticalcarenutrition.com](http://www.criticalcarenutrition.com)  
click on The REDOXS<sup>®</sup> Study

### New Resources on website coming

Revised Study Procedures  
Manuals

(version September 21st 2007)

Training Presentations

## Web based data entry: check, correct & note



### Daily Data: gastric residual volumes and volumes discarded

The total volume of gastric residual volumes is equal to the total volume **measured** regardless of whether you discard it or re-feed it.

Volumes discarded means the amount of the residual volume measured that you **throw away**. **Hint:** gastric residual volume discarded can be equal to but can never be less than the total gastric residual volume (= volume measured).

**Date of stop of antibiotics:** if the antibiotic is started in ICU and continues after ICU d/c, you will need to follow the patient to get this date. When you enter this online, you will need to do the 3 (and 6) month data manually and then enter it online later as you will not be able to access outcomes until stop date of antibiotics has been entered.

**Blood Sugars: closest to 8:00am:** please interpret this as a blood sugar closest to 8:00 am  $\pm$  6 hours. If there is no blood sugar available from 8:00 am or  $\pm$  6 hours (i.e. 2:00 am-2:00 pm), please choose n/a. You do NOT need to correct data already entered but please follow this rule from now on.



## New Tools: contact us

**PF ratio table:** figure out the worst P/F ratio quickly

**Enteral calories/protein calculator:** email J. Korol at korolj@kgh.kari.net

**New Pharmacy worksheets:** dated November 2007

**Inclusion/Exclusion cards:** email S. Biro at biros@kgh.kari.net

## Use of Lipids: question missing on web!

Oops....we forgot to ask the following question:

Did the patient receive lipids today? Yes or No. Instead you are asked directly to enter the type of lipids used.

**What to do now?**

1. Check all patients that received parenteral nutrition
2. If they did not receive lipids, choose OTHER from type of lipid taxonomy and write in NONE RECEIVED. See below.



## Pharmacy News

### Clarification for receiving orders

We have made improvements to the Product Order Form to help eliminate confusion around the ordering/receipt of the products. When the pharmacist receives the shipment, he/she is to fill out the text box at the bottom of the Product Order Form and fax/email it back to us.

If you have any feedback regarding the ordering and shipment process please let Suzanne Biro know at biros@kgh.kari.net

## Good Questions !!

### Concomitant Medications: What about other steroids such as Decadron and Solumedrol? How do I record these?

We are only interested in hydrocortisone (=Solu-cortef) and the other medications listed, i.e. activated protein C, insulin and motility agents. You do not need to record Solumedrol or Decadron.

Thanks to Tracy McCardle for asking this question

### Eligibility: Is a patient who has cancer eligible?

Yes, a patient who has cancer is eligible as long as it is not metastatic cancer or stage 4 lymphoma.

Thanks to Pia Ganz for asking this question

### Eligibility: For a patient with Chronic Lung Disease that may have a chronic low PF ratio, do we need to pick 2 other organ failures?

No, for the patient with Chronic Lung Disease, a PF ratio of  $\leq$  300 can be chosen as one of the organ failures.

Thanks to Teresa Morrison for asking this question

### Infusion of Parenteral study supplements: Can the central line that is used for the parenteral study supplements be used for emergency drug use?

Yes, in the event of an emergency drug, the infusion of the parenteral study supplements can be stopped for a couple of hours as long as the infusion of the supplements is resumed and doubled up to make up the volumes (after proper flushing).

Thanks to Pam Pstuka for asking this question

### Duration of the study supplements: is it 28 days from the time that the first supplement is started?

Yes. In the event that the parenteral study supplements get started days before the enteral study supplements, the 28 days is from the start of the parenteral supplements.

Thanks to Helen Ferens for asking this question

