The REDOXS© Circular

June 2008 Issue # 11

Clinical Evaluation Research Unit

The *REDOXS*© Study
REducing Deaths due to OXidative Stress

Patient Enrolments in 2008	
January	16 pts
February	17 pts
March	17 pts
April:	17 pts
May	18 pts.
June	**17 pts**

923 Patients to go

June was a slow enrolment month with 17 patients; however it was a busy REDOXS© month with reports, trainings, conference calls and other communications. We would like to thank you for your continued support and for the enthusiasm and receptiveness you bring to the study. Your feedback is valued and therefore please do not hesitate to contact the Project Leaders if you have any questions or concerns about the study.

Congratulations to Joelle Lefrancq, Research Coordinator and the REDOXS© team at University Hospital of Liege, Belgium for enrolling their first patient.

The top enrolling sites in June were Sacre-Coeur with 4 enrolments, and St. Joseph's and London HSC with 2 enrolments each. WELL DONE!!!

Total energy intake
Are you adding calories from Propofol?

During source verification we have observed that calories from propofol have not consistently been added to total calories. In previous communications (REDOXS© Circular Issue #7 and in a clarifying email on March 11, 2008), we outlined how and when to add calories from propofol. Please have your site Dietitian check that these calculations are being done for all REDOXS patients. If you require additional information, please contact Daphne Mayer, Project Leader, mayerd@kgh.kari.net

Please note that propofol is not considered a type of lipid and therefore should not be entered in the "Type of Lipid" field on the PN nutrition screen of the eCRF.

Don't worry

For those Research Coordinators who missed the June 26th conference call training, we will provide you with an opportunity to get all the updates. We will be in touch.

Enrolment Update as of June 30, 2008

Sites Currently Enrolling	Total Enrolments	June Enrolments
Kingston General	36	1
St. Joseph's Hamilton	9	2
Ottawa General	41	1
Ottawa Civic	20	0
Vancouver General	5	1
Sacre Coeur, Montreal	27	4
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	9	1
Grey Nun's, Edmonton	6	1
Victoria General	1	0
London Health Science Centre	7	2
Health Science Centre, Winnipeg	4	1
Queen Elizabeth II HCS (Halifax)	2	1
Montreal General	7	0
L'Enfant Jesus (Quebec City)	2	1
Leige, Belgium	1	1
CHUV, Switzerland	3	0
Royal Jubilee Hospital, Victoria, BC	1	0
197 + 80 (from pilot) = 277 total		

Organ Failures - Hypoperfusion

Hyperperfusion is one of the organ failures that is an inclusion criterion for the study. This inclusion criterion is met when **any** of the following vasopressors are given:

- Norepinephrine (any dose) for ≥ 2 hrs
- Epinephrine (any dose) for ≥ 2 hrs
- Vasopressin (any dose) for ≥ 2 hrs
- Dopamine (≥ 5 µg/kg/min) for ≥ 2 hrs
- Phenylephrine (≥ 50 µg/min) ≥ 2 hrs

REDOXS© Study Contact Information

Daphne Mayer, Project Leader, 613 549 6666 ext 2834; mayerd@kgh.kari.net
Rupinder Dhaliwal, Project Leader, 613 549 6666 ext 3830; 613-484-3830 cell phone; dhaliwar@kgh.kari.net

Periodic Report

We hope the conference call on June 26th provided you with a clear explanation of how to interpret your site's Periodic Report. We've heard feedback from some of you and we welcome others to make comments or suggestions. Send Daphne Mayer, Project Leader an email at mayerd@kgh.kari.net.

Prophylaxis Antibiotics vs Empiric Antibiotics for suspicion of ICU acquired infection.

For all antibiotics started 72 hours after ICU admission, the Research Coordinator and Site Investigator must ask "Is this antibiotic prescribed for prophylaxis?" If an antibiotic is prescribed to prevent an infection, the response to the question is yes....this is a prophylaxis antibiotic. If an antibiotic is prescribed when there is a suspicion of an infection, there is no available culture and a broad spectrum antibiotic is given, the answer to the question is no.....this is an empiric antibiotic.

Infection Adjudication

As a result of recent central adjudication done at the Methods Centre, we need to make a few changes to the Categories of Infection outlined in Appendix 10 of the Implementation Manual (Pg 73-85). In general, we have clarified that fever is when core temperature >38 ºC. More specific changes have been made to the definitions of the following categories of infections:

- Category 4
- Category 6
- Category 7
- Category 8
- Category 11
- Category 12

We will be sending out the updated Categories of Infection shortly. The Site Investigator and Research Coordinator should discuss these changes and if they impact previously adjudicated infections. The updated Appendix will also be posted on the REDOXS© Study web page at www.criticalcarenutrition.com.

We have observed fewer suspicions of infections than anticipated. We ask that you err on the side of suspecting an infection. The updated categories will provide more guidance during this process.

SAE Reporting

As discussed in the June 26th Research Coordinators conference call, by September 2008 all SAEs must be reported to the Methods Centre within 24 hours. Effectively immediately, for new SAEs we ask that you please submit all concomitant medications given 48 hours before the onset of the SAE and all lab values relevant to the reported SAE.

Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

Daphne Mayer

Suzanne Biro

Daily Data

When asked to record the highest bilirubin, please note this is highest TOTAL bilirubin

Daily Worksheets and Checklists

We've made improvements to the Daily worksheets and Checklists found in your REDOXS© Study Procedures Binder. We will be sending these updates to the Research Coordinators very soon, and we will also post the updates on the website.

Stay Tuned!

Absolute Contraindication to Enteral Nutrition

One of the most commonly met exclusion criteria for the REDOXS© Study is absolute contraindication to enteral nutrition (e.g. GI perforation, obstruction or no GI tract access). A frequently asked question is whether a patient who has a GI perforation and is undergoing surgery, is eligible for enrolment in the study.

Yes, such a patient is eligible for enrolment as he/she will likely undergo GI surgery shortly after admission to ICU. In either case the enteral supplements can be started early even if there is a hesitancy to feed enteral nutrition. Remember, the enteral supplements are infused at a low rate (20 cc/hr), and if there are concerns in the first day or so, the enteral supplements could be infused at a lower rate, perhaps 10 cc/hr. Parenteral supplements can be started right away.

Good Questions !!

What temperature should I be collecting on the daily data page? Record the patient's temperature that is most aberrant from midline 37 C. For example, if you have readings of 36.2 C and 37.5 C, choose 36.2 C

Thanks to Frederik Delodder, CHUV for the question

What hospital discharge date should I capture if the patient is going to a rehabilitation facility? Enter the date the patient was transferred from the acute care facility to the rehabilitation facility as the discharge date. If it is an internal transfer (e.g. the rehabilitation facility is part of the hospital), please enter this transfer date as the discharge date.

Thanks to Ellen Macdonald, St. Joseph's for the question