The REDOXS© Circular

October 2008 Issue # 15

Clinical Evaluation Research Unit

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

October was our BEST month! 849 patients to go!

October was the *best* enrolment month to date with a total of 27 patients. This exceeds the highest enrolling month thus far in the study, which was 23 patients in July.

Well done everyone!!!

Congratulations to Ottawa General with 6 enrolments, and Grey Nun's Hospital, Ottawa Civic & St. Joseph's Hospital each with 3 enrolments each this month.

Enrolment Update as of October 31, 2008

Sites Currently Enrolling	*Total*	*October*
Kingston General	42	0
St. Joseph's Hamilton	14	3
Ottawa General	55	6
Ottawa Civic	26	3
Vancouver General	11	2
Sacre Coeur, Montreal	31	0
Maisonneuve-Rosemont, Montreal	11	2
Royal Victoria, Montreal	8	0
Royal Alexandra	12	0
Grey Nun's, Edmonton	9	3
Victoria General	2	1
London Health Science Centre	10	1
Health Science Centre, Winnipeg	7	1
Queen Elizabeth II HCS (Halifax)	3	0
St. Paul's, Vancouver	4	2
Montreal General	7	0
L'Enfant Jesus (Quebec City)	10	2
Leige, Belgium	1	0
CHUV, Switzerland	5	0
Royal Jubilee Hospital, Victoria, BC	3	1
271 + 80 (from pilot) = 351 total		

CERU Staffing Changes

As many of you know, Daphne Mayer has moved on from her position as REDOXS© Project Leader.

We would like to introduce you to Janet Overvelde. Many of you already know Janet in her capacity as the ABATE Project Leader. Janet will take on co-Project Leader responsibilities on REDOXS© effective November 24th and will continue to work on ABATE.

In the interim, please direct all your questions about the REDOXS© Study to Rupinder Dhaliwal.

After November 24, 2008, Janet will be available to field your REDOXS© questions and comments. Her contact information is 613 549 6666 x6241 or overvelj@kgh.kari.net

Energy Intake and the Dietitian Daily Checklist: Clarification

On August 8, 2008 we sent out the revised checklists and worksheets (Version: July 2008). Please note that the revised Dietitian checklist is a tool to assist the dietitian in collecting data *and* also optimizing the patient's intake from enteral nutrition, hence the checklists do not look exactly like the eCRF. One of the improvements made was the breakdown of energy and protein received into enteral and parenteral calories and a separate row for the calories from propofol. However, for the eCRF, you MUST add the calories from propofol into the calories received from enteral or parenteral nutrition as outlined in previous communications. If you need clarification, please do not hesitate to contact Rupinder Dhaliwal.

REDOXS© Study Contact Information
Rupinder Dhaliwal, Project Leader, 613 549 6666 ext 3830; 613-484-3830 cell phone; dhaliwar@kgh.kari.net
Effective Nov 24th 2008: Janet Overvelde, Project Leader, 613 549 6666 ext 6241; overvelj@kgh.kari.net

IMPORTANT CHANGE: Revised Appendices Version November 3rd 2008

Based on feedback from the Site Investigators during the conference call on September 5th 2008 and from face-to-face meetings, the Appendix 8.2 Categories of Infection has been revised. Given this recent revision and other previous updates to the antibiotics and micro-biology taxonomies, we have updated the eCRF and also the appendices section of the Implementation Manual. **Research Coordinators:** Please make sure that you replace the existing version in your study manual with this most recent version (Nov 5th 2008), which is also available on our website (www.criticalcarenutrition.com > REDOXS > RESOURCES >Implementation Manual Part) and is attached.

CERU RESEARCH TEAM

Daren Heyland
Rupinder Dhaliwal
John Muscedere
Janet Overvelde
Suzanne Biro
Jennifer Korol

Pharmacy: Please send in the Labeling Accountability Logs as soon as possible.

3 and 6 month follow-up update

Back in June 2008 at the Research Coordinators conference call, we proposed some changes to the 3 and 6 month questions. We were going to increase the options to the question "Were you able to conduct the follow-up interview?", from 4 to 6 options. Upon review of the current dataset, we have determined that the change is not warranted. As such, the 4 options remain as:

- Yes
- Patient died
- Patient refused or withdrew. Select this option if the patient or the substitute refused to participate in the interview at the time of contact (i.e. too ill) or withdraws consent to participate. Provide the date of refusal or withdrawal.
- Patient lost to follow-up. Select this option if you are unable to contact the patient and/or the substitute is unable to provide contact information. Provide the date the patient was last known to be alive.

Attention Pharmacy and Research Coordinators

Have you updated the Delegation of Authority Log or the Pharmacy Delegation of Authority Log lately?

If there have been changes in the list of people at your site/pharmacy who have a material effect on the REDOXS study, please update and fax/email your log to Suzanne Biro, Project Assistant 613 548 2428; biros@kgh.kari.net

Monthly Site Report

We will not be sending out the REDOXS monthly reports for October. Stay tuned for your November report.

Good Questions !!

Regarding the "sample type" of a micro culture, is ETT aspirate considered the same as bronchial wash? If the sample is from a simple bronchial wash then it should be considered the same as a ETT aspirate. This is different than bronchoalveoar lavage with quantitative cultures. Thank you to Michael Krause, Grey Nun's Hospital for the question.

I have a potential REDOXS patient with severe dementia and has come from a care home. I am hesitant to enrol due to concerns about the patient's ability to participate in long-term follow-up. Should I enrol the patient? If a substitute respondent is available to answer the SF36 questions and the patient is eligible then you can move ahead with enrolment. A substitute respondent should be an individual who would best knows the patient's condition. This may be a family member or a health care professional (i.e. assigned bedside nurse). Thank you to Dara Davies, Vancouver General for the question.

Are there any interactions between REDOXS supplements and monoclonal antibodies that used as immunosuppressives? There is no known mechanism by which the REDOXS© nutrients would interfere with monoclonal antibodies. Thank you to Sheilgah Mans, St. Paul's Hospital for the question.

Has there been an "insulin resistance" noted in patients receiving the REDOXS supplements? No, in fact there is evidence that glutamine enhances insulin sensitivity. Refer to Bakalar B et al, Crit Care Med 2006:381-6. Thank you to Dr. Dorscheid, St. Paul's Hospital for the question.