The REDOXS© Circular

April 2008 Issue # 9

Clinical Evaluation Research Unit

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

Enrolment Update as of April 30

Sites Currently Enrolling	Total Enrolments	April Enrolments
Kingston General	31	2
St. Joseph's Hamilton	5	1
Ottawa General	36	3
Ottawa Civic	20	1
Vancouver General	4	1
Sacre Coeur, Montreal	20	2
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	7	0
Grey Nun's, Edmonton	4	1
London Health Science Centre	4	1
Health Science Centre, Winnipeg	3	0
Queen Elizabeth II HCS (Halifax)	1	1
Montreal General	7	2
L'Enfant Jesus (Quebec City)	1	1
CHUV, Switzerland	3	1
162 + 80 (from pilot) = 242 total		

Patient Enrolments
March: 17 pts.
April: 17 pts.

Site Payments

Individual sites are paid quarterly (quarter end dates: March 31, June 30, September 30 and December 31). We have revised our payment schedule to include both finalized and locked patients along with any completed SF-36s. Every attempt will be made to ensure that copies of invoices and payment data (number of finalized/locked patients etc.) will be forwarded to site investigators as well as study coordinators electronically at the time of cheque requisition. If there are any questions or concerns, please contact Jennifer Korol (korolj@kgh.kari.net) or Suzanne Biro (biros@kgh.kari.net) at (613) 549-6666 x 6051 and 6686 respectively.

958 patients to go

WE NEED YOU!!

In the first three months of 2008 we have enrolled approximately 16-17 patients per month, and April has been very similar with 17 enrolments. With 18 sites actively screening, we should have enrolled close to 36 patients this month. WE NEED YOU to help us meet our goal!

Congratulations go out to L'Enfant Jesus & Queen Elizabeth II Health Science Centre for enrolling their first patients.

Attention Pharmacy

Some pharmacies may have **Enteral REDOXS formulas** that will expire in **May 2008**. **Please check if your current stocks expire next month**. If replacement stocks are required, please fill out a Monthly Site Inventory Log and email/fax to the attention of Suzanne Biro, Project Assistant (biros@kgh.kari.net; 613 548 2428).

Expired products should be recorded on the appropriate Nutrient Accountability Log and should be disposed of according to your pharmacy's drug destruction policy. Empty vials do not need to be kept for monitoring purposes and can also be disposed of according to your pharmacy policies.

Also, please remember to forward us your monthly inventory logs and your monthly temperature logs **every month** (including sites that currently have no or low enrolments).

REDOXS© Study Contact Information
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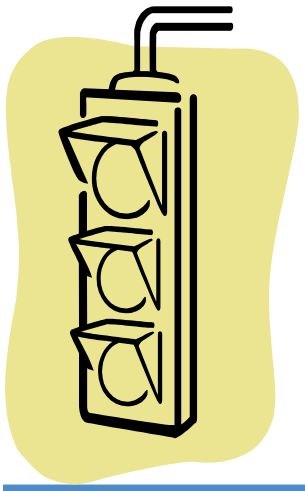

Antibiotic data collection - When do you start and stop?

Antibiotic data need only be collected for antibiotics started prior to day 30 in the ICU. The period of data collection for Antibiotics starts 7 days prior to ICU admission and may extend beyond ICU discharge (Refer to pg 45 in the Implementation Manual). Antibiotic data must be collected for:

- All antibiotics started 7 days prior to ICU admission, even if stopped prior to ICU admission.
- All antibiotics started prior to ICU admission and continued in ICU.
- All antibiotics started in ICU and continued beyond ICU discharge.

Please make a note of the following in your Implementation Manual: For REDOXS© patients that are in the ICU beyond 30 days,

- If an antibiotic is started in ICU before day 30 and continues after day 30, you need to collect the stop date/time.
- If the antibiotic is started after 30 days, you do **NOT** need to collect data.

Research Coordinators, Long Term Follow-up & the SF36

The Research Coordinator is responsible for conducting the SF-36 survey at 3 months and 6 months from ICU admission date as part of the long term follow-up for REDOXS©. The SF-36 Survey must be administered ± 2 weeks from the designated time points. Every attempt should be made to complete the interview within the given timeframe. To facilitate timely survey administration, please schedule yourself reminders for the 3 and 6 month long term follow-up for each REDOXS© patient.

Ideally, the SF36 should be administered to the patient; however if the patient is not able to participate a substitute may respond on their behalf. A substitute respondent should be an individual who knows the patient's condition the best. This may be a family member or a health care professional (i.e. assigned bedside nurse).

Please note in the SF-36 for questions 3(g) - 3(i), the questions reference miles or yards. Please substitute kilometres or metres as needed.

STAY TUNED FOR NEW TRAINING TOOLS TO HELP YOU CONDUCT THE SF36 QUESTIONNAIRE

Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

Daphne Mayer

Suzanne Biro

Microbiology Data Collection

Record all data starting 7 days prior to ICU admission until day 30, unless ICU discharge (actual) or

New Addition to the microbiology taxonomy:

A new bacterium - *Porphyromonas sp.* -has been added to the eCRF

Good Questions !!

I enrolled a REDOXS© patient 2 days ago, but the patient has unexpectedly improved and has just been extubated. What do I do?

1. Enteral study supplements: If the feeding tube has been removed during extubation, the enteral study supplements will stop. If the feeding tube remains in place, enteral supplements should continue. If the patient is re-ventilated and/or a feeding tube re-introduced, the enteral supplements should be re-started. ***NOTE****: It is encouraged that the clinical team leave the feeding tube in place for 24 hrs or more after extubation until it is certain that the patient will be transferred to the ward and/or that the patient is able to take in adequate PO intake.*
2. Parenteral study supplements: If the enteral study supplements have been stopped, you should continue with the parenteral study supplements.

If on the day of extubation the patient receives <80% of the enteral supplements, do I need to submit a protocol violation (PV)?

- If the patient is extubated and remains in the ICU, you must submit a PV for that day only. Indicate on the PV that re-insertion of the tube was not clinically indicated.
- If the patient is extubated and discharged from the ICU on the same day, you do not need to submit a PV.

Could you clarify the duration of study supplements for a patient that is discharged from ICU to the ward at < 5 days from ICU admission?

If the patient gets discharged from ICU at < 5 days from ICU admission, the supplements must continue on the ward until the patient receives a total of 120 hrs from the time supplements are started. That is, if IV access **and/or** GI access is available, the supplements must continue until the patient has received 120 hours of the study supplements.

Thanks to Frederic Morin, Frederik Delodder, Audrey-Anne Gosselin & Stephanie Dolle for these questions