



Clinical Evaluation Research Unit

Enrolment Update as of July 31, 2008



We reached a major milestone with time to spare. Teresa Morrison at London Health Sciences Centre enrolled the 300th patient and she is the winner of the REDOXS[®] Summer Challenge. Thank you to ALL for rising to the challenge. We enrolled 23 patients this month and we haven't seen numbers like these since November 2007. We hope you will continue to strive towards the enrolment goal of at least 2 patients/month/site.

900 patients to go.

Congratulations to Frederic Morin and the REDOXS[®] Team at L'Enfant Jesus for enrolling 4 patients in July.

STUDY ENROLMENT GUIDELINE

An on-going enrolment is patients that are randomized to the study who are extubated and/or discharged from ICU within 5 days from ICU admission. While we've communicated personally with many of you and have addressed this matter in previous newsletters, we think the following guideline may assist you during your assessment of the patient for the study: **To better judge the suitability of a potentially eligible patient, make sure there is no plan to wake and wean the next day, thus the patient will likely be in the ICU for 5 days.**

REDOXS[®] Project Leader Availability in August

Rupinder Dhaliwal will be away August 18 - 22, 2008 inclusive. If you require immediate assistance please contact Daphne Mayer 613 549 6666 x2834. Rupinder can be reached by cell phone after hours. Daphne Mayer will be away August 28 - September 4 inclusive. If you require immediate assistance, please contact Rupinder Dhaliwal during regular office hours (x 3830); and after hours (613-484-3830).

Sites Currently Enrolling	Total Enrolments	July Enrolments
Kingston General	38	2
St. Joseph's Hamilton	9	0
Ottawa General	44	3
Ottawa Civic	21	1
Vancouver General	8	3
Sacre Coeur, Montreal	28	1
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	11	2
Grey Nun's, Edmonton	6	0
Victoria General	1	0
London Health Science Centre	9	2
Health Science Centre, Winnipeg	5	1
Queen Elizabeth II HCS (Halifax)	2	0
St. Paul's, Vancouver	2	2
Montreal General	7	0
L'Enfant Jesus (Quebec City)	6	4
Leige, Belgium	1	0
CHUV, Switzerland	5	2
Royal Jubilee Hospital, Victoria, BC	1	0
220 + 80 (from pilot) = 300 total		

Training - Ethical Conduct for Research

A good complement to formal GCP training is a review of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). Go to <http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm>. There you will find the TCPS Tutorial. Once you complete the tutorial you will be provided a training certificate for your records.

DATA QUERY PROCESS

We have finalized the process for when inconsistencies are found in data entered in the eCRF. The data query process involves the Methods Centre formally seeking clarification from the sites. In early August, Jennifer Korol, Database Manager, will contact all Research Coordinators on this query process and will provide instructions on how to complete the Data Clarification form.

CENTRAL INFECTION ADJUDICATION

August also marks the start of central adjudication of all finalized patients at each site. This process involves queries at different stages. If there are ambiguities in microbiology or antibiotics entries, a Data Clarification form will be sent to the Research Coordinator. Once resolved and the adjudication form updated (if applicable), the central adjudicator will review the adjudications for the finalized patients. If there is disagreement, queries will be sent to the research coordinator to be discussed with the Site Investigator. Responses are then forwarded back to the Method Centre for resolution.

Stay tuned for more details.

UNUSED DISPENSED PRODUCT

Any unused dispensed product returned to pharmacy should be disposed of....do not re-dispense. As such, to minimize unnecessary dispensing or disposal of REDOXS® study supplements, please ensure there is good communication between the bedside nurse, pharmacist, technicians, and the Research Coordinator regarding a REDOXS® patient's status. Particularly, when a patient is not on the supplements for a period of time.

Investigator Confirmation Forms

In order to facilitate the Central Adjudication process, please send in the Investigator Confirmation Forms for finalized patients.

Thank you!

Research Team at CERU

Daren Heyland
Rupinder Dhaliwal
John Muscedere
Jennifer Korol
Daphne Mayer
Suzanne Biro

REMINDER

To determine if there is a suspicion of ICU acquired infection, you are prompted to answer two questions for positive cultures, after 72 hours from ICU admission. One of which is:

Is this a routine surveillance swab?

Remember that Cath tips/line swabs are not surveillance swabs. Examples of routine surveillance cultures include nasal swabs for MRSA, rectal swabs for VRE etc.

NEW AND IMPROVED!

As mentioned in the last newsletter, the daily worksheets and checklists have been improved. The Research Coordinators will receive the new versions in early August.

Micro - Data Entry

If a quantitative value is not available for a positive culture, you will need to enter this micro data as follows: Click on <Sample type>, and select <Other>. In the empty field that appears, type in the sample type (ie urinary etc). This will remove the quantitative results field and you will be able to continue progressing through the eCRF.

PERIODIC REPORTS - USING THE INFORMATION

At the Research Coordinator Conference call in June, there was discussion about the usefulness of the information provided in the site periodic reports. As a result, there will likely be some changes to the presentation of data in the next report.

To shed some light on the quality control points at Kingston General Hospital, Dr. Heyland, Principal Investigator and the Project Leaders, met with the KGH REDOXS® team to facilitate discussions around areas of improvement. The site team identified the issues as being educational improvements or system improvements. The Research Coordinators suggested improvements to study supplement compliance could be addressed through continuous communication with the bed side nurses and physicians around supplement start-up and the nature of the supplements versus nutrition. Additionally, the double-up guidelines need to be addressed with the bedside nurses regularly. A system improvement the team agreed upon, is the addition of the target start time of supplements on the orders; this time will be filled out by the Research Coordinator. This time will be communicated to pharmacy, who will then attach a bright label with this target time on the first bags of supplements. The goal here is to improve timing of study supplement start.

If you develop strategies that helps to make improvements on the quality control measures outlined in the periodic report at your site, we would love to hear about them. Please send ideas to Daphne Mayer, Project Leader @ mayerd@kgh.kari.net.

ANOTHER ENROLMENT GUIDELINE

Do not recruit patients when long term follow-up will be difficult. For example, patients who are tourists from Europe or do not have a fixed address should not be enrolled. If these types of patients meet inclusion criteria and do not meet an exclusion criterion, they are eligible but not randomized and should be entered into the eCRF accordingly.

Good Questions !!

I have a REDOXS® patient who received parenteral supplements for 28 days but did not receive enteral supplements for all of the 28 days. Should the patient continue to receiving enteral supplements until they have received 28 days in total?

No, the time period for administering the study supplements is until 28 days post randomization. Don't forget, data collection continues until day 30 if the patient remains in the ICU. (Thanks to Frederic Morin, L'Enfant Jesus, for the question) .

If patients are being fed via kaofeed, and the supplements are infusing via NG/OG, do we record post pyloric (for example) for feeding tube in the CRF and then make a comment that the supplements are infusing via NG (gastric)?

Yes. But remember that you are recording the location of the feeding tube (confirmed/presumed) rather than the type of feeding tube used. Record the location of the feeding tube according to the location of the tip of the tube. For example, you may be using a small bowel feeding tube but the actual location of the tip of the tube may be coiled in the stomach and hence the location should be recorded as gastric. (Thanks to Pat Thompson, RAH, for the question.)

Do we record NG drainage as gastric residual volumes?

For NG drainage (to low gomco/drainage tube), please do not record as gastric residual volumes. Gastric residual volumes are recorded when you are actually aspirating and checking to see how much residual is left in the stomach. (Thanks to Michael Krause, and Jennifer Barchard, Grey Nun's, for the question).