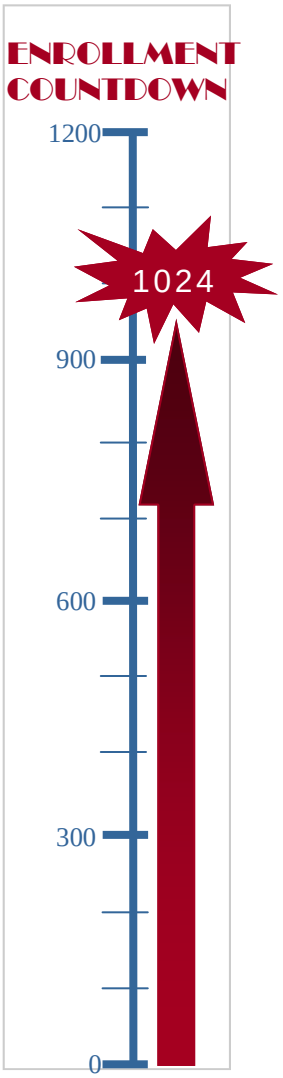
THE REDOXS© CIRCULAR

Data current to 28-Feb-2011

Site #	Institution	Feb	Cumulative
1	Kingston General	2	88
2	St. Joseph Healthcare	4	66
3	Ottawa General	4	192
4	Ottawa Civic	-	59
5	Vancouver General	-	20
6	Sacre-Coeur	1	80
7	Maisonneuve-Rosemont	-	17
8	Royal Victoria	-	15
9	Royal Alexandra	-	29
11	Grey Nun's	2	22
13	Victoria General	-	8
14	London HSC	-	18
16	Capital Health, QEII	-	19
19	Montreal General	2	26
20	L'Enfant Jesus	4	32
21	Liege, Belgium	-	8
22	CHUV, Switzerland	-	12
23	Royal Jubilee	-	12
25	Mount Sinai	2	44
26	U of Colorado	-	21

Site #	Institution	Feb	Cumulative
27	Miami Valley, Ohio	-	14
28	Fletcher Allen, Vermont	-	11
30	U of Louisville	-	22
31	U of Texas	1	12
32	University Hospital, London	-	12
33	Laval	4	15
34	Emory University	-	-
35	Kiel, Germany	-	5
37	Greifswald, Germany	-	8
38	Hamburg-Altona, Germany	-	5
39	Jewish Hospital	1	8
40	Atlanticare	-	5
41	Hershey Medical Center	-	1
42	Intermountain Healthcare	1	5
43	Mayo Clinic, Arizona	2	15
	*number patients from closed sites		18
	number patients enrolled in pilot		80
TOTALS		**30**	**1024**



What a Spectacular Month!!!

The definitive REDOXS study has been running since May 2007. In February we reached a significant study milestone with the enrollment of our 1000th patient. This could not have been accomplished without the efforts of many individuals.

We would like to take a moment to appreciate how many people have contributed or continue to contribute towards the REDOXS study at the research sites. Since 2007:

- 43 sites have been involved
- 100 Research Coordinators†
- 60 Dietitians†
- 200 Pharmacists and technicians†

The number of individuals required to make our most recent study milestone possible is truly astounding!

† Approximate number based on participation of 43 sites

- ***Bravo Chantal et Marie!*** Not only did the Team at Enfant-Jésus enroll the 1000th patient, they were one of the top recruiters this month with 4 patients enrolled.
- ***Way to go!*** There was a four-way tie for top enroller of this month. The Teams at St. Joseph's, Ottawa General and Hôpital Laval also enrolled 4 patients.
- ***Wonderful!*** It was 2 patients each for Kingston General, Grey Nun's, Montreal General, Mt Sinai and Mayo Clinic.
- **Great work!** Thanks to Sacre-Coeur, U of Texas, Jewish Hospital and Intermountain Healthcare for each enrolling a patient.
- Did you know that Hopital Sacre-Coeur enrolled their 80th patient in February? ***Formidable Patrice et Huber!***

TheREDOXS® Study
Reducing Deaths due to OXidative Stress

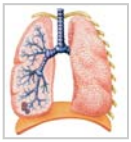
Did you know...

Did you know that patients can drink the enter study supplements?

It's true! For patients that have had their feeding tubes removed, as long as they can tolerate an oral diet, the study supplements can be administered by drinking. It is recommended that the daily prescribed volume of 480mL is divided into several smaller volumes to make it easier for the patient to drink.

This is an excellent strategy to ensure all study patients get the required 5 days of study supplements.

High Frequency Oscillation (HFO)



The following data conventions should be followed when collecting data on a patient receiving HFO:

- **Demographics: APACHE II**—When a patient is receiving HFO, the APACHE score may be falsely elevated from the respiratory rate (RR). Therefore if the patient is on HFO within the first 24 hours of ICU admission, the lowest and highest RR used to score the APACHE II should be pre-HFO RRs.
- **Daily Data: Respiratory Rate (RR)** - When a patient is receiving HFO, the respiratory rate (RR) should be entered as N/A. On the EDCS select the NA checkbox.

Latex Content of Parenteral Study Supplements

We have documentation from the manufacturers of Dipeptiven (Fresenius-Kabi) and Selenium† (Baxter Canada) that the rubber stoppers are latex free. If you require this documentation please contact Maureen Dansereau, Project Assistant.

†This documentation concerns Selenium used by Canadian sites only.

We enrolled our 900th patient at the beginning of October 2010. We must still run the corresponding interim analysis. Please enter your outstanding data as soon as possible, we require an additional 50 patients locked to conduct this analysis.

The Data Management Team has been issuing another round of data queries. Please respond to these in a timely manner.

$$$ Remember, the next round of quarterly payments will be processed at the end of March.

Commonly Asked Questions

Are standard amounts of vitamins and minerals that are present in enteral and parenteral nutrition allowed?

Standard amounts of selenium (up to a maximum of 60mcg/day) and zinc (up to a maximum of 5mg/day) that are already present in the parenteral solutions are allowed. Enteral or parenteral supplements/preparations that contain amounts of zinc (or selenium) higher than those above should not be allowed (e.g. maternal supplements).

Can parenteral supplements be piggybacked in through the same IV line that is infusing PN containing heparin or insulin or through the same line that is infusing heparin or insulin?

No. Currently there is no stability data for the study supplements administered via a conventional Y-set with PN admixtures, heparin/insulin infusions or other medications. As such, piggybacking the study supplements with heparin or insulin should be avoided. In this case you must use a separate line for the parenteral supplements.

We are approaching day 28 of the study, the patient had a disruption in study supplements of 2 days. Should we add an extra 2 days of study supplements to make up for this lost time, so the patient would continue to receive study supplements until day 30?

The study supplements should be administered for a maximum of 28 days from the time of randomization. If the patient experienced interruptions in study supplement administration during the course of the study, the site should NOT add extra days of study supplement administration to correct for this. Sites should focus on minimizing interruptions in study supplements as much as possible on an ongoing basis. Refer to pg. 4 & 7 of the Administration

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