June 2009 Issue #24

The REDOXS© Circular

The REDOXS® Study
REducing Deaths due to OXidative Stress

658 Patients to go...

Enrolment as of June 30, 2009

Site	June	Cumulative Total	Site	June	Cumulative Total
Kingston General	6	62	Sunnybrook, Toronto	-	2
St. Joseph's Healthcare	3	33	St. Paul's, Vancouver	-	6
Ottawa General	6	92	L'Enfant Jesus, Quebec City	1	19
Ottawa Civic	2	38	Liege, Belgium	-	3
Vancouver General	1	19	CHUV, Switzerland	-	8
Sacre Coeur, Montreal	4	48	Royal Jubilee, Victoria	-	5
Royal Alexandria, Edmonton	1	16	UZ Brussels	-	2
Maisonneuve—Rosemount	1	13	Mount Sinai, Toronto	2	16
Grey Nun's, Edmonton	1	12	University of Colorado	1	9
Victoria General	-	3	Miami Valley, Ohio	-	2
London Health Sciences Centre	-	10	University of Louisville	1	8
Health Sciences Centre, Winnipeg	-	8	Fletcher Allen, U of Vermont	1	4
Queen Elizabeth II, Halifax	-	7	St. Boniface, Winnipeg	-	-
**Montreal General*	-	7	University Hospital, London	2	2
**Royal Victoria*	-	8			

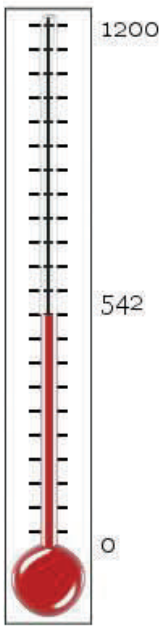
* Sites status = on hold due to staffing issues

Total = 542 *(includes 80 from pilot)*

33 patients were enrolled in the month of June, a new record!!

Keep up the great work ☺

Congratulations to the team at the University Hospital in London for enrolling their 1st two patients this month.



REDOXS© Goes to Germany

The REDOXS© Team welcomes our new colleagues from Germany. Start-up training was conducted in Kiel, Germany on 12-Jun-09.

We look forward to seeing our German sites begin to enroll patients very soon!

Begrüßen Sie deutsche Kollegen!

Methods Centre Staff Updates

Please note that beginning Jun 29th, Suzanne Biro, Project Assistant will be in the office on Tuesdays, Thursdays and Fridays.

Join me in welcoming Susan Campbell, Project Assistant to the REDOXS© Project Team. Susan will be working with Suzanne managing the product inventory and supporting other operational aspects of the study.

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Patients Transferred from External ICUs - Determining the Window of Eligibility

We have encountered several questions regarding the window of eligibility (exclusion criteria #1) for patients who are transferred from an ICU outside of the site's institution. Referring ICUs offer varying levels of care (e.g. urban centers vs. rural community settings) and hence patients arriving from these institutions vary in their acuity of illness.

In instances when sites have received patients from an external ICU the following can be found in the Study Implementation Manual concerning the time window for exclusion criteria #1:

> *"For patients that have been transferred from another ICU, the 24 hours for determining eligibility pertains to the TOTAL time in the intensive care unit setting."*

These queries have highlighted the need for further description as to what defines the intensive care setting in reference to our study criteria. The table below outlines two different scenarios to illustrate these definitions.

When in doubt call the Project Leader.

	SCENARIO 1	**SCENARIO 2**
Example	Patient is admitted to the ICU in a small community hospital that does not have the capacity to care for mechanically ventilated (MV) patients. After 16 hours in the ICU the patient was intubated and (MV) was initiated. Immediately following the initiation of MV, the patient was transferred to the research site. At the research site the patient was started on pressors/inotropes, etc…The external ICU and research site have differing levels of care.	Patient is admitted to ICU that routinely cares for patients requiring MV and pressors/inotropes. The patient is intubated and started on dopamine shortly after their arrival. Due to bed shortages, the patient is transferred to the research site. Both ICUs provide the same level of care.
Level of Care Provided in External ICU	NO intubation/mechanical ventilation (patients may be intubated then transferred shortly after) NO inotropes/pressors	Intubation/mechanical ventilation Inotropes/pressors
Time used to Determine Eligibility Window	Time of initiation of mechanical ventilation should be used to start the eligibility clock	Time of admission to external ICU should be used to start the eligibility clock

Exclusion Criteria #8—Primary Diagnosis of Burns

A patient is admitted to the ICU with 52% BSA burn which occurred in February. The burn is no longer considered "active". Can this type of patient be included in REDOXS©?

The exclusion criteria *"Patients with a primary diagnosis of burns ≥ 30%"* refers to "active" burns, therefore this patient would be considered eligible for the study if other eligibility criteria are met.

Thank you Dr. Fowler at Sunnybrook for the question

Enteral Nutrition Formulas—EDCS Additions

The following enteral nutrition formulas have been added to the taxonomy options on the EDCS:

- NESTLE: Fibersource
- NESTLE: Fibersource HN
- NESTLE: Isosource Protein Fibre
- NUTRICIA: Nutrison (Nutrison Standard)
- NUTRICIA: Nutrison Multi Fibre
- ROSS: Jevity 1.5 kcal

Remember to call CERU if you need to enter an enteral formula not currently found on the taxonomy.

What to do with Residual Volumes of Study Supplements Left in Bags

We would like to remind sites that every effort should be made to ensure patients receive the fully prescribed amount of enteral (480 mL) and parenteral (240 mL) study supplements per each 24 hour period.

Recently we have been made aware, that for various reasons (e.g. timing of bag changes and infusion pump issues) patients are not receiving the fully prescribed amounts of study supplements. We strongly encourage sites to advocate that any residual volume left in the study supplement bags at the end of a 24 hour period (or before the bag change) should be delivered to the patient. We anticipate this practice will enhance study supplement compliance rates and reduce those protocol violations!