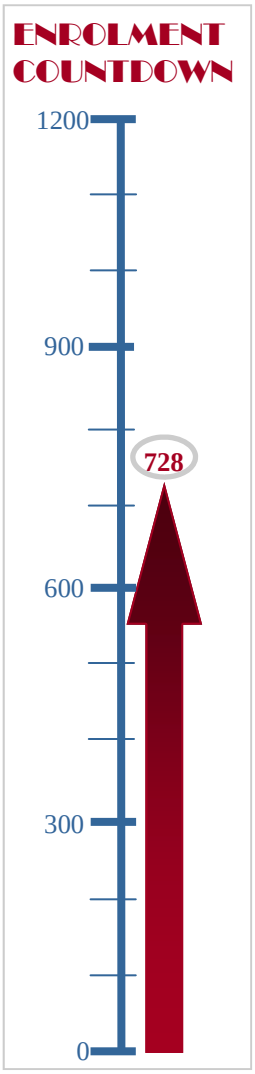
THE REDOXS© CIRCULAR

Data current to 28-Feb-2010

Site #	Institution	Feb	Cumulative
1	Kingston General	1	72
2	St. Joseph Healthcare	1	48
3	Ottawa General	6	123
4	Ottawa Civic	2	48
5	Vancouver General	-	19
6	Sacre-Coeur	2	62
7	Maisonneuve-Rosemont	-	15
8	Royal Victoria	-	10
9	Royal Alexandra	-	21
11	Grey Nun's	-	15
13	Victoria General	-	6
14	London HSC	-	14
16	Capital Health, QEII	2	13
19	Montreal General	2	16
20	L'Enfant Jesus	-	23
21	Liege, Belgium	-	6
22	CHUV, Switzerland	-	10
23	Royal Jubilee	-	8
25	Mount Sinai	2	30
26	U of Colorado	1	18
27	Miami Valley, Ohio	2	6
28	Fletcher Allen, Vermont	-	7
30	U of Louisville	-	10
31	U of Texas	1	5
32	University Hospital	-	6
33	Laval	1	8
34	Emory University	*Ready to start*	
35	Kiel, Germany	-	2
36	Lubeck, Germany	-	-
37	Greifswald, Germany	-	6
38	Hamburg-Altona, Germany	-	3
39	Jewish Hospital	*Ready to start*	
40	Atlanticare	*Starting Mar 2010*	
	Hershey Medical Center	*Starting Q1 2010*	
	Intermountain Healthcare	*Starting Q1 2010*	
	Mayo Clinic, Arizona	*Starting Q1 2010*	
	*number patients from closed sites		18
	number patients enrolled in pilot		80
	TOTALS	**23**	**728**

Patient recruitment has been discontinued at the following sites:
10—Hopital Charles Lemoyne
12—U of Alberta
15—HSC Winnipeg
17—Sunnybrook HSC
18—St. Paul's Hospital
24—UZ Brussels, Belgium
29—St. Boniface General Hospital



2 pts/site/month

Target Enrollment for March is **64** patients!

The highest enroller of the month is the Ottawa General with 6 patients! Way to go Tracy & Irene!

Welcome We will be activating several new US sites in the coming weeks. Welcome to the REDOXS© Team!

- Emory University Hospital, Atlanta, GA
- Hershey Medical Center, Hershey, PA
- Atlanticare Regional Medical Center, Atlantic City, NJ
- Intermountain Healthcare, Murray, UT
- Jewish Hospital, Louisville, KY
- Mayo Clinic, Phoenix, AZ

Elevated Urea in Patients with Renal Disease

Remember for REDOXS© patients with renal disease experiencing elevated urea levels, please refer to the Algorithm for Elevated Urea in Patients with Renal Disease (Appendix II, Administration of Study Supplements Manual).

We are relatively certain that the disproportionately elevated urea in the setting of a study patient with renal dysfunction (acute or chronic) does not represent a safety hazard and we encourage the use of study nutrients in patients with a high urea. **Remember, all serious adverse events in study patients will be reviewed by a third party data safety monitoring committee. For questions related to this topic contact the Project Leader.**

Interim Analysis

We are pleased to announce that we now have 600 locked patient CRFs!

Thank you to all sites for entering your data. The Data Management team is now working on generating data queries on these patients. Sites should expect to receive this in the next 1-2 weeks. Please respond to these queries as soon as possible following receipt as we are not able to run the analysis until the data is cleaned.

Thanks for your continued efforts towards meeting these timelines.

Pharmacy Notices

Attention Canadian Pharmacies: Calea Ltd, the Canadian distribution centre for REDOXS© products, is changing their storage facility. As a result, you will note a change in the Product Order form. Suzanne Biro will forward further information in this regard via email soon.

Dipeptiven Stock: All sites, please check your Dipeptiven stock for product due to expire at the end of April 2010. Please send requests for replenishment stock as soon as possible so we may fill the order a timely manner.

For any questions regarding REDOXS© products please contact Suzanne Biro (biros@kgh.kari.net).

Tips from the Data Management Team

Collecting Propofol Data

If propofol is running < 6 consecutive hours (within a study day) those propofol calories are NOT included in the total energy recorded on the Daily Nutrition Form.

If propofol is running ≥ 6 consecutive hours (within a study day) there are four possible scenarios:

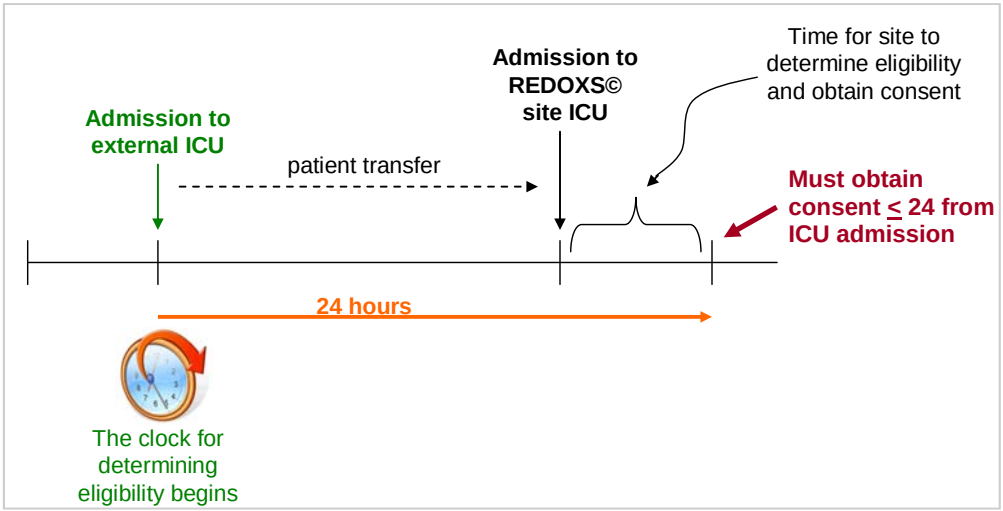
1. If pt is receiving both PN & EN, then propofol calories are added to PN total energy
2. If pt is receiving only PN, then propofol calories are added to PN total energy
3. If pt is receiving only EN, the propofol calories are added to EN total energy
4. If pt is not receiving any nutrition (no EN, no PN), then do not record calories from propofol.

Frequently Asked Questions

Exclusion #1: > 24 hours from admission to ICU to time of consent

One of the most commonly asked questions concerns defining the 24 hour period noted in Exclusion Criteria #1, specifically for those situations where a patient is transferred from another ICU.

Exclusion Criteria #1 "*>24 hours from admission to ICU to time of consent*" refers to the **TOTAL** time spent in the ICU setting. For patients that are transferred from another ICU, this includes the time spent in that ICU. The diagram to the right illustrates this situation. The orange arrow includes the **TOTAL** time spent in an ICU setting. The red arrow marks the 24 hour point noted in Exclusion Criteria #1.



Contact the Project Leader if you have any further questions.

Refer to Circular Issue # 24 (June 2009) for other information regarding patients transferred from outside ICUs.

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