

The REDOX[®] Circular

Enrolment as of April 30, 2009

Site	April	Cumulative Total	Site	April	Cumulative Total
Kingston General	1	53	Sunnybrook, Toronto	-	2
St. Joseph's Healthcare	5	29	St. Paul's, Vancouver	-	6
Ottawa General	3	80	L'Enfant Jesus, Quebec City	2	17
Ottawa Civic	-	34	Liege, Belgium	1	3
Vancouver General	-	17	CHUV, Switzerland	-	8
Sacre Coeur, Montreal	2	41	Royal Jubilee, Victoria	1	5
Royal Alexandria, Edmonton	-	15	UZ Brussels	-	2
Maisonneuve—Rosemount	-	12	Mount Sinai, Toronto	4	12
Grey Nun's, Edmonton	1	11	University of Colorado	2	6
Victoria General	-	3	Miami Valley, Ohio	1	2
London Health Sciences Centre	-	10	University of Louisville	1	6
Health Sciences Centre, Winnipeg	-	8	Fletcher Allen, U of Vermont	2	3
Queen Elizabeth II, Halifax	2	7	St. Boniface, Winnipeg	-	-
*Montreal General	-	7	*Royal Victoria	-	8

Total = 487 (includes 80 from pilot)

* Sites status = on hold due to staffing issues

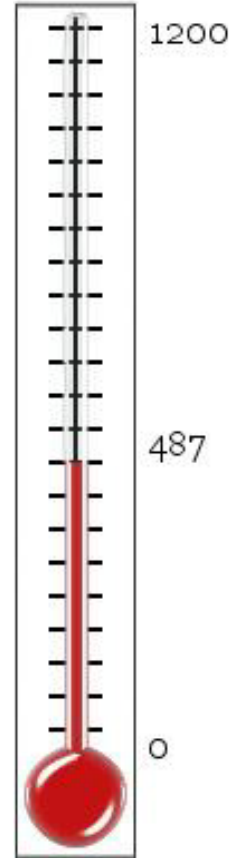
A total of 28 patients were enrolled in the month of April, a new record!!! We would like to acknowledge the following sites for enrolling patients this month:

St. Joseph's, Hamilton, ON
 Ottawa General
 Queen Elizabeth II, Halifax, NS
 University of Colorado, USA
 Kingston General
 Liege, Belgium
 Miami Valley, Ohio, USA

Mount Sinai, Toronto, ON
 Sacre Coeur, Montreal QC
 Enfant Jesus, Quebec, QC
 University of Vermont, USA
 Grey Nun's, Edmonton, AB
 Royal Jubilee, Victoria, BC
 University of Louisville, USA



**The competition for the 500th Patient Challenge is heating up!
 Who will win? 12 patients until we find out...**



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Pharmacy—Enteral Supplements Re-labeling Coming Soon



The enteral study supplements expiration date is being updated. To prevent pharmacies from having to re-label twice, we are suggesting that we wait for the stability test results confirming a second extension to the expiration date. These results will be available on 15-May-09. We will forward the re-labeling instructions and corresponding labels once the latest stability testing results are available. Refer to the email from Suzanne Biro on 4-May-09 for more information.

Data Entry Tips and Reminders

The data query process has revealed several common data queries. The following is a list of useful tips and reminders to keep in mind when collecting and entering data.

Antibiotics

Order time—If an antibiotic order time is documented in the medical chart after the time the first dose is given, check “no time available” for the order time in the EDC system.

Units—The following are acceptable entries for antibiotic units: milligrams (mg), grams (g) and units. If an antibiotic is administered as a tablet, please enter the dose associated with the tablet formulation (e.g. 2 tablets at 25 mg per tablet should be entered at 50 mg).

Combination antibiotics— for Trimethoprim Sulfamethoxazole enter the number of milligrams (mg) of Trimethoprim in the dose field. In the comments field, enter the corresponding dose of Sulfamethoxazole.

Microbiology

Culture Results—When 2 different accessions #s report the same results, it is necessary to enter the results in the EDC system for each accession # separately. Indicating a culture result as “same as accession # X” is not an acceptable entry.

Daily Data

Withdrawing life-sustaining treatments—For patients where life-sustaining treatments are being withdrawn, we request that daily data continue to be collected until the patient expires. Given these circumstances, some data will not be available (e.g. laboratory data), please use the “N/A” options.

Location of feeding tube—If the feeding tube is confirmed to be located in the esophagus, and the patient was fed, use the “gastric presumed” option to enter the data. If the feeding tube is confirmed to be located in the esophagus, and the patient was not fed, use the “no tube in place” option to enter the data.

Comments

General Instructions—Please ensure any entries you make in the comments fields are clear. We have noted that some sites use the comments fields to make notes to themselves. We support the use the comments fields for this purpose however there are instances when we may question the data based on these comments. For example, if “pending report” is entered, we may question whether the data entered is complete. Another example, for daily nutrition, if “540 calories from propofol” is entered into the comments, we wonder whether these 540 calories are included to the data entered or whether they should be added to the already entered data. Please ensure you delete any comments related to incomplete data once the data has been entered, or ensure comments do not lead to queries.

Frequently Asked Question

Many times our ICU patients receive discharge status and declassification but are still physically located in the ICU because there are no beds available on the ward. In these cases, how long do we collect data?

As long as the patient is physically located in the ICU, data collection should continue until the patient is discharged from the ICU, or study day 30 (study supplements until 28 days from randomization), whichever comes first. The ICU discharge date/time should be the “actual” date/time of discharge, not the time when the would have been discharged if bed was available.