



The REDOX[®] Study
REducing Deaths due to OXidative Stress

The REDOX[®] Study

REducing Deaths from OXidative Stress

Study Chair

Dr. Daren Heyland, MD, FRCPC

Project Leaders

Rupinder Dhaliwal, RD and Janet Overvelde



Research Questions

In critically ill patients with severe organ dysfunction, what is the effect of:

- 1) Glutamine supplementation compared to placebo on 28-day mortality?
- 2) Antioxidant supplementation compared to placebo on 28-day mortality?

Special Interest

The following article is one of two articles offered for continuing education credit in this issue. Please see page 382 for details.

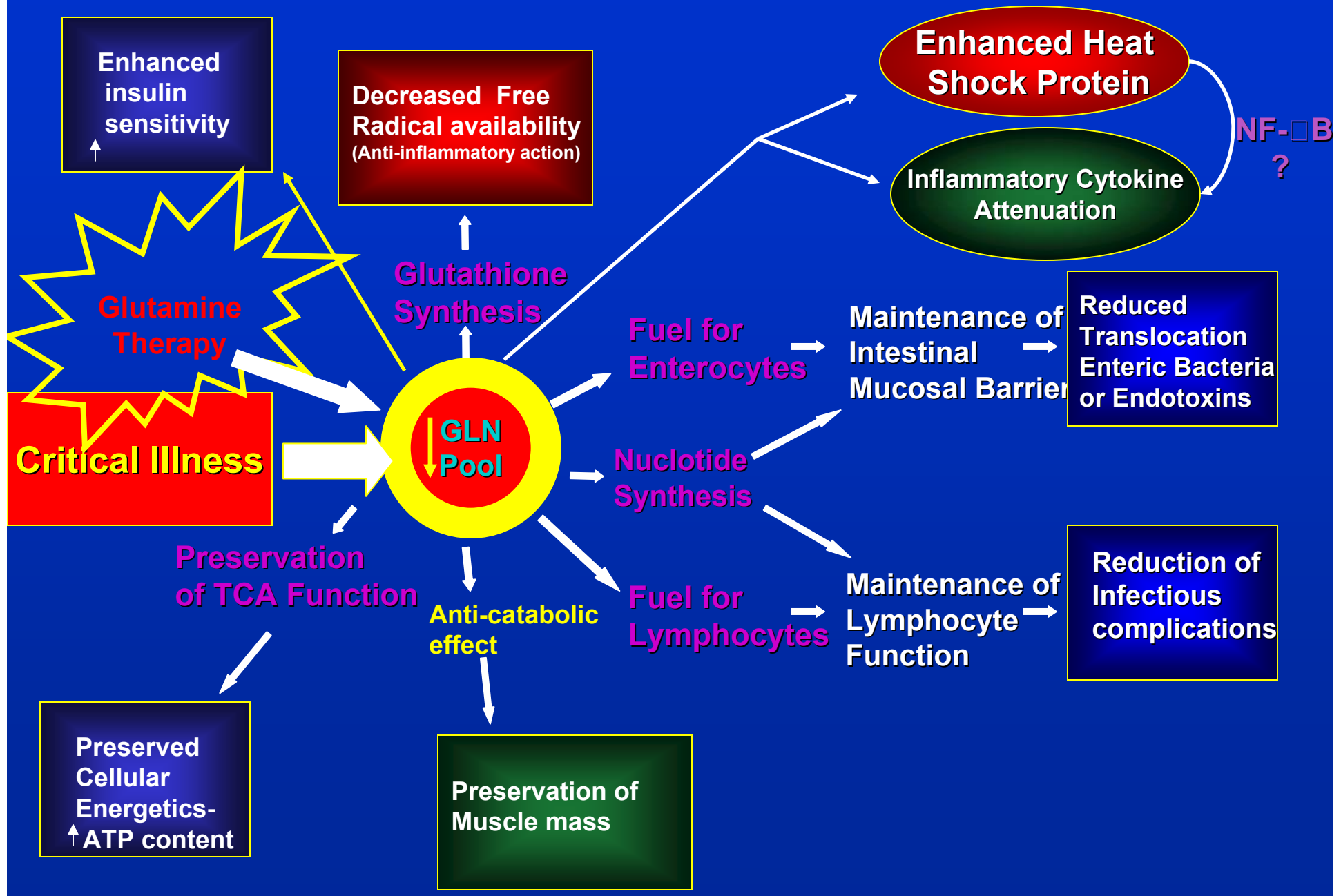
Canadian Clinical Practice Guidelines for Nutrition Support in Mechanically Ventilated, Critically Ill Adult Patients*

Daren K. Heyland, MD, FRCPC, MSc*; Rupinder Dhaliwal, RD*; John W. Drover, MD, FRCSC, FACS†; Leah Gramlich, MD, FRCPC‡; Peter Dodek, MD, MHSc§; and the Canadian Critical Care Clinical Practice Guidelines Committee

*From the *Department of Medicine and the †Department of Surgery, Queen's University, Kingston, Ontario; ‡Department of Medicine, Division of Gastroenterology, University of Alberta, Edmonton; and §St. Paul's Hospital, Center for Health Evaluation and Outcome Sciences, Vancouver, British Columbia, Canada*

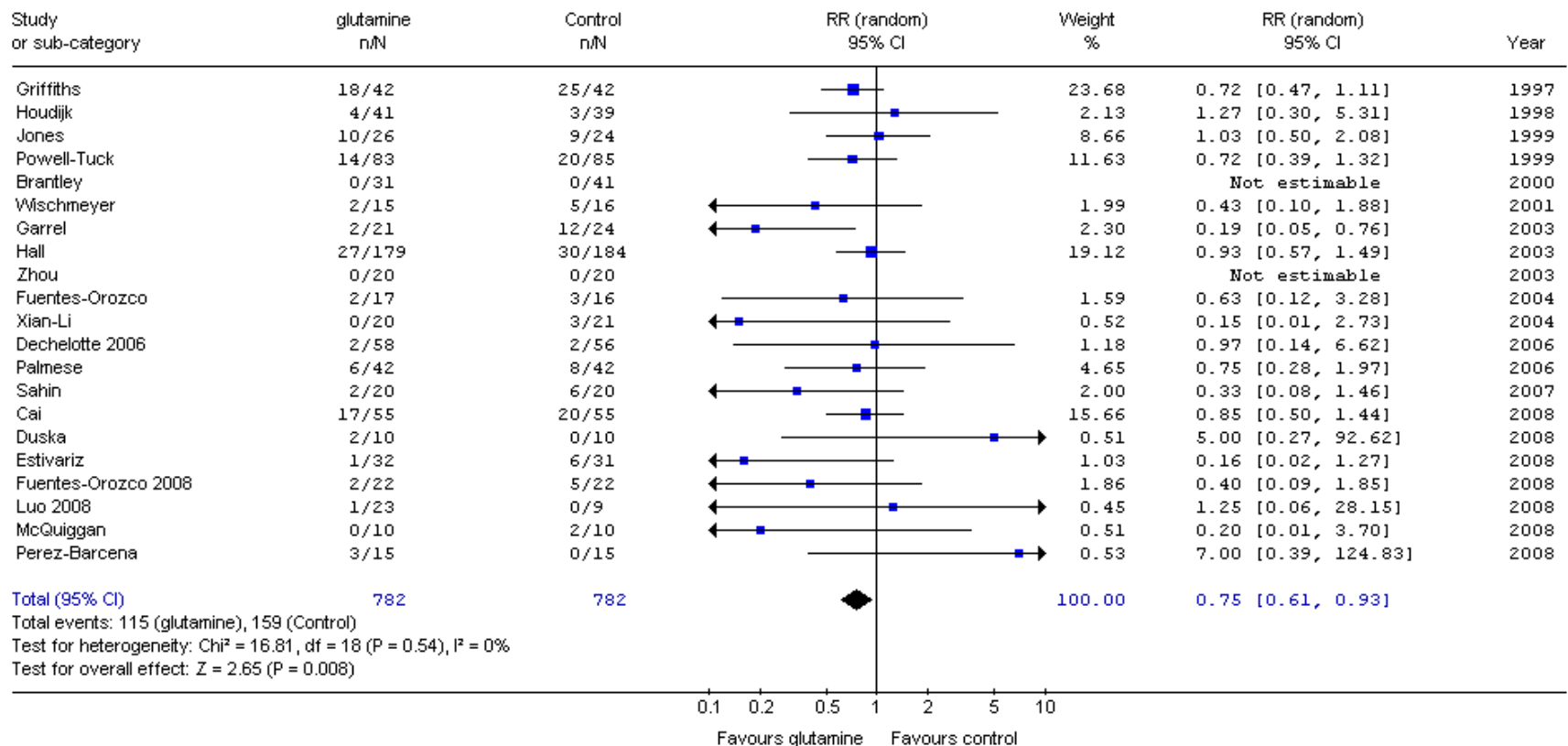
Heyland et al JPEN 2003

Potential Beneficial Effects of Glutamine



Effect of Glutamine: A Systematic Review of the Literature

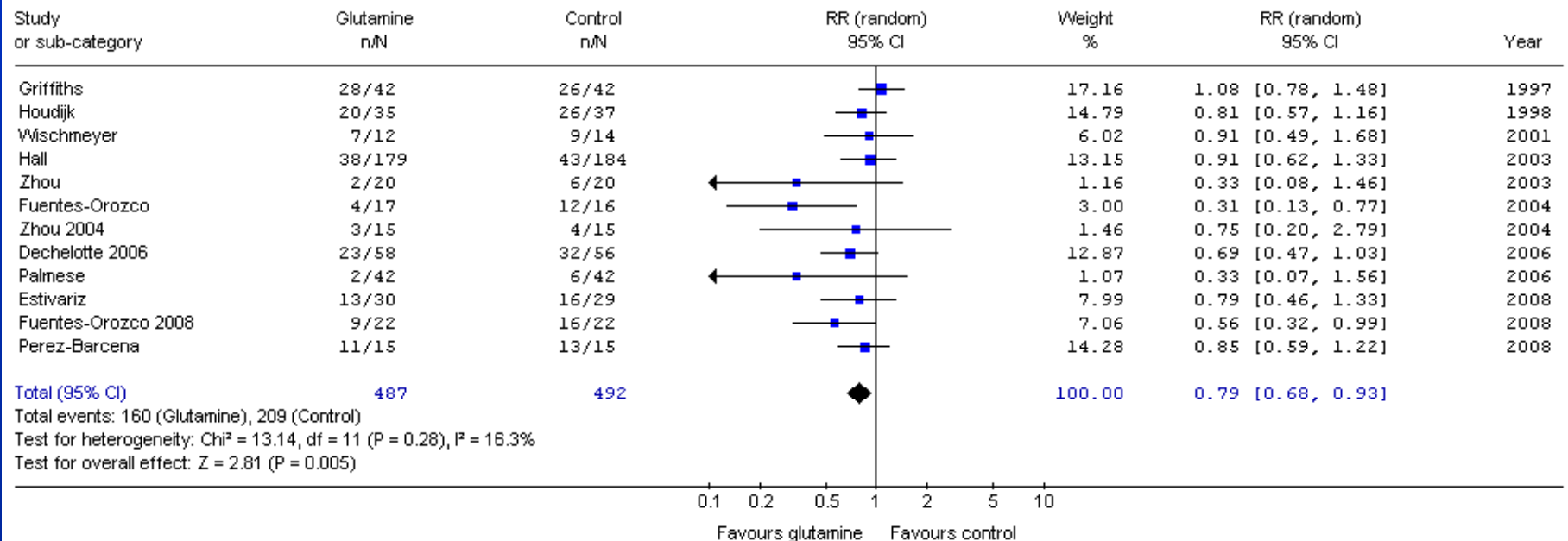
Review: glutamine New review (Version 01)
Comparison: 03 Glutamine vs Control
Outcome: 01 mortality



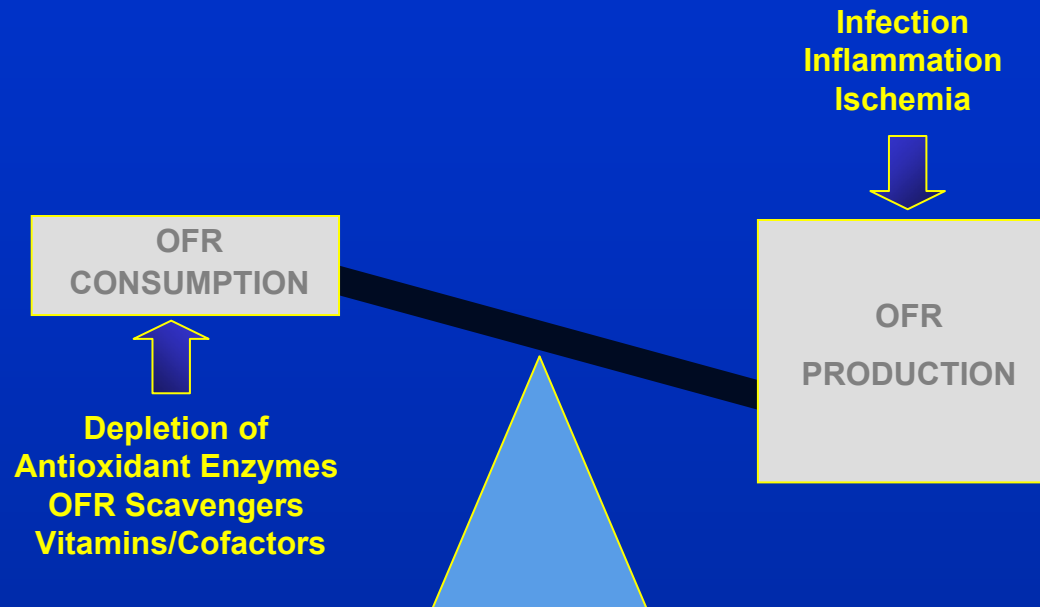
Effect of Glutamine: A Systematic Review of the Literature

Infectious Complications

Review: glutamine New review (Version 01)
 Comparison: 03 Glutamine vs Control
 Outcome: 02 Infectious Complications



Rationale for Antioxidants



OFR production > OFR consumption = OXIDATIVE STRESS

Impaired

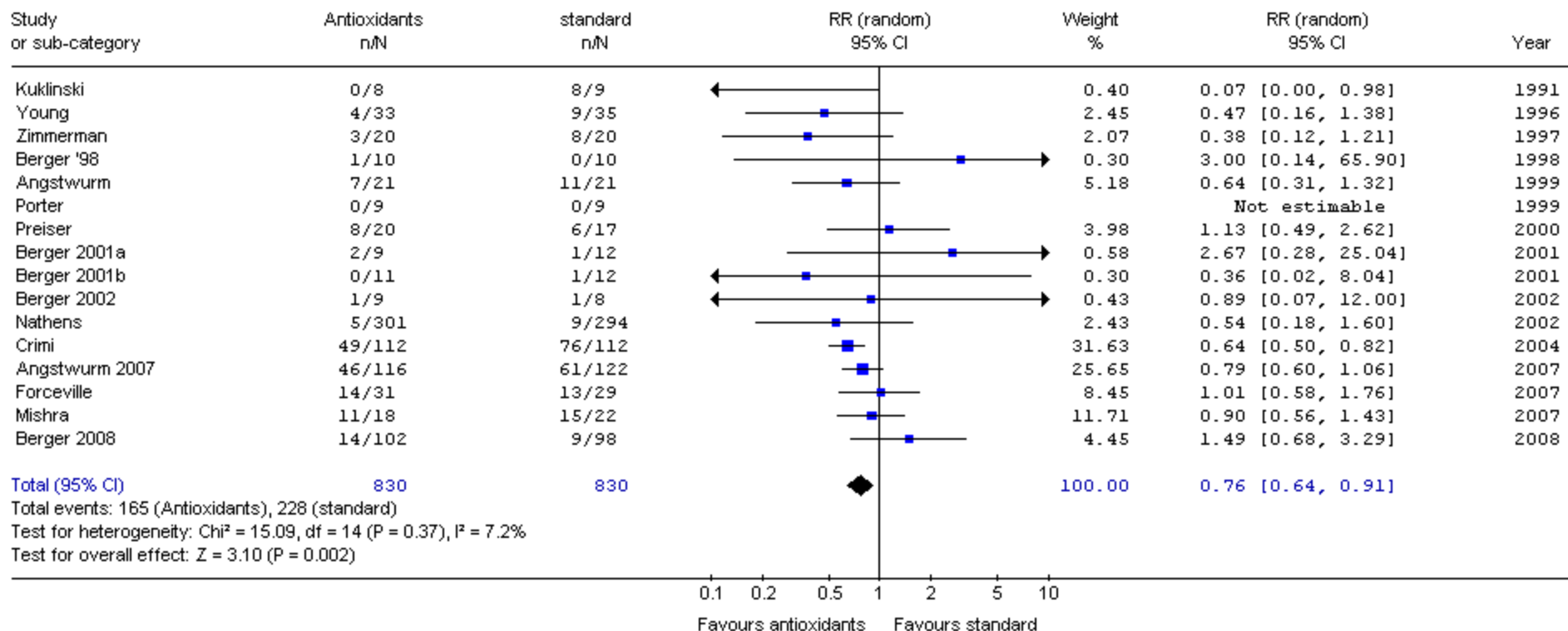
- organ function
- immune function
- mucosal barrier function

Complications and Death

Effect of Combined Antioxidant Strategies in the Critically Ill

Effect on Mortality

Review: Antioxidants (Version 01)
 Comparison: 01 Antioxidants (single + combined) vs standard
 Outcome: 01 Mortality



Pharmaconutrition A New Emerging Paradigm

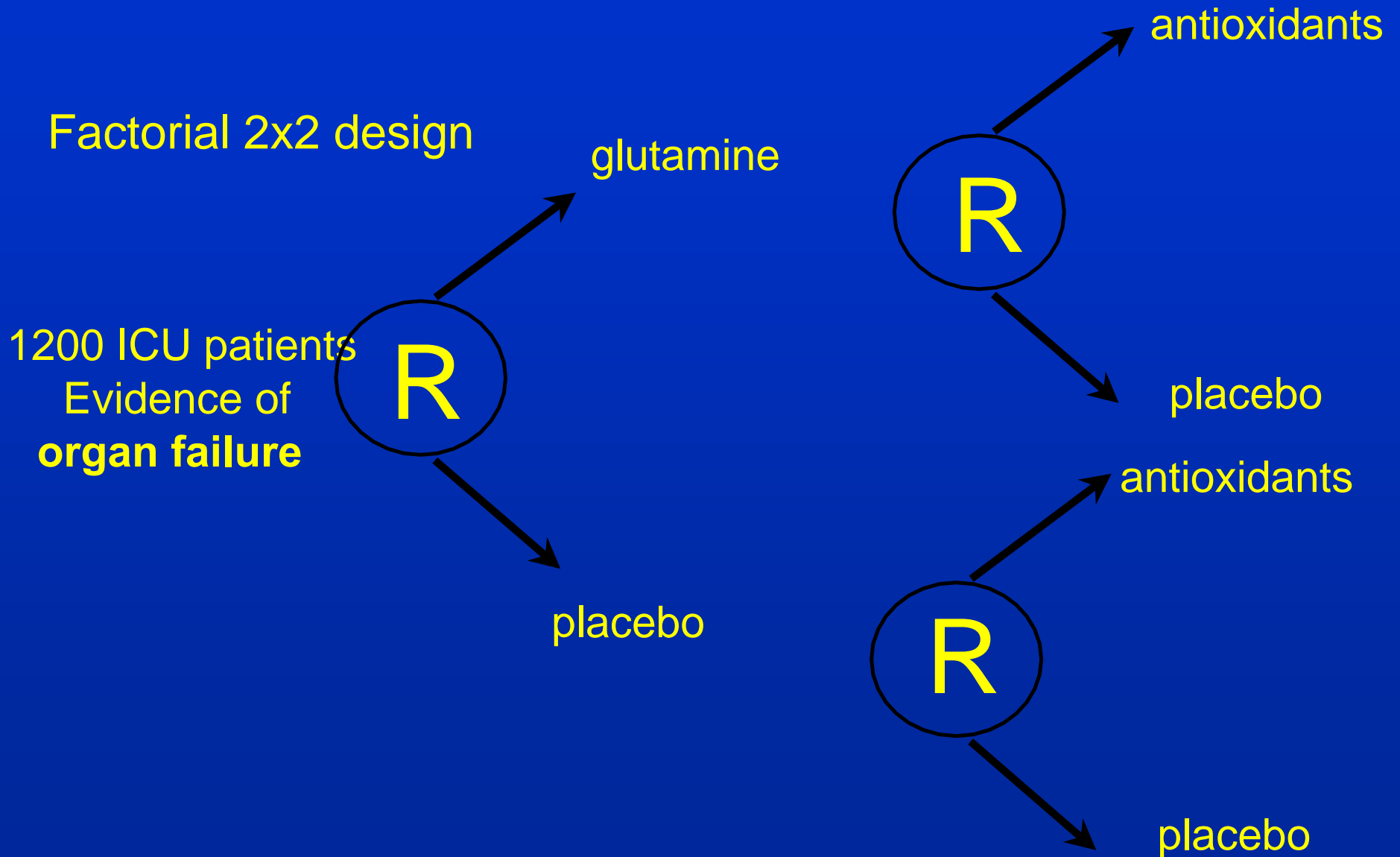
<u>Old</u>	<u>New</u>
Immunonutrition	Pharmaconutrients
Nutrition	Nutrients
Combined nutrients	Single nutrients
Heterogeneous populations	Homogenous Patients
Weak methods	Rigorous
Small single center	Large multicenter

Inferences

	Parenterally	Enterally
Glutamine/day	0.35 gms/kg	30 gms
Antioxidants per day	500 mcg Selenium	Vit C 1500 mg Vit E 500 mg B carotene 10 mg Zinc 20 mg Se 300 ug

- High dose appears safe
- High dose associated with
 - no worsening of SOFA Scores
 - greater resolution of oxidative stress
 - greater preservation of glutathione
 - Improved mitochondrial function

REDOXS[®] Study Design



Study Groups

	Enteral Supplement	Parenteral Supplement
GLN +AOX	Glutamine + AOX	Dipeptiven + Selenium
AOX	AOX only	Placebo + Selenium
GLN	Glutamine only	Dipeptiven + Placebo
Placebo	Placebo	Placebo + Placebo

Research Coordinator/Investigator blinded

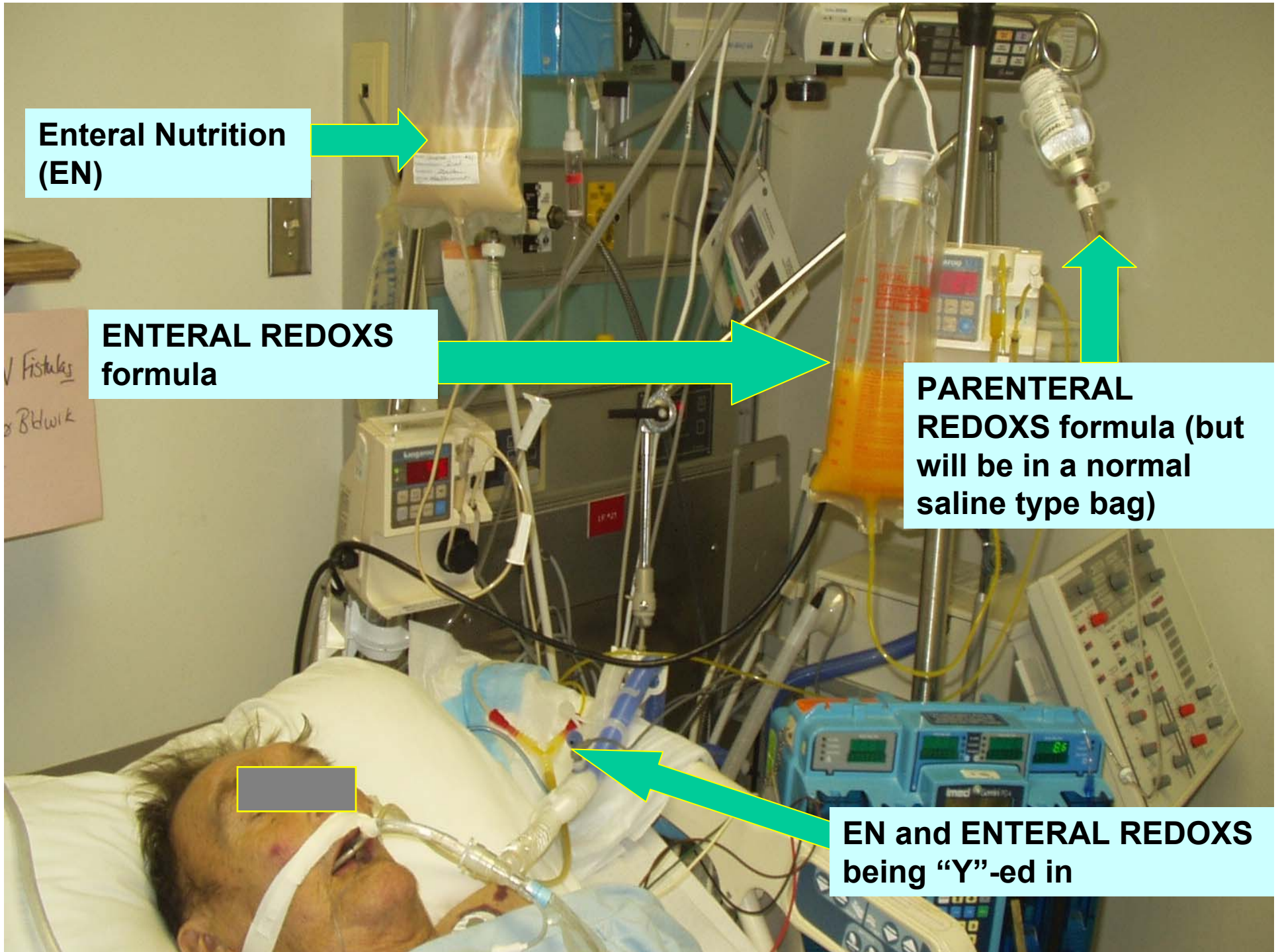
Pharmacist unblinded

**Enteral Nutrition
(EN)**

**ENTERAL REDOXS
formula**

**PARENTERAL
REDOXS formula (but
will be in a normal
saline type bag)**

**EN and ENTERAL REDOXS
being "Y"-ed in**



REDOXS[©] Teamwork



Site Investigator

Delegation of Authority

Patient Eligibility

SAE identification/assessment

ICU Infection adjudication

Investigator Confirmation

Refer to Site Investigator Training Package
available on www.criticalcarenutrition.com

Inclusion Criteria

Imp Manual p 13-15

Tools

Inclusion criteria: both criteria 1 and 2 must be met for patient to be eligible

- 1) Mechanically ventilated adult patients (≥ 18 years old) admitted to your ICU
- 2) Must have 2 or more of the following organ failures related to their acute illness*:
 - I. A PaO₂/FiO₂ ratio of ≤ 300
 - II. Clinical evidence of hypoperfusion defined as need for vasopressor agents (norepinephrine, epinephrine, vasopressin, or $\geq 5 \mu\text{g}/\text{kg}/\text{min}$ of dopamine or $\geq 50 \mu\text{g}/\text{min}$ phenylephrine) for ≥ 2 hours.
 - III. In patients without known renal disease, renal dysfunction defined as a serum creatinine $\geq 1.93 \text{ mg}/\text{dl}$ ($171 \mu\text{mol}/\text{L}$) or a urine output of less than 500 ml/last 24 hours (or 80 ml/last 4 hours if a 24 hour period of observation not available). In patients with acute or chronic renal failure (pre-dialysis), an absolute increase of $\geq 0.9 \text{ mg}/\text{dl}$ ($80 \mu\text{mol}/\text{L}$) from baseline or pre-admission creatinine or a urine output of less than 500 ml/last 24 hours (or 80 ml/last 4 hours) will be required.
 - IV. A platelet count of $\leq 50 \text{ mm}^3$.

Organ failures may have started before ICU admission but have to be present in the ICU

Organ failures may have resolved at the time of screening

Exclusion Criteria

Imp Manual p 13-15

Tools

Exclusion criteria: patient is ineligible if any one of the following is met

1. >24 hours from admission to ICU to time of consent . Refers to TOTAL time in any ICU
2. Patients who are moribund (not expected to be in ICU for more than 48 hours due to imminent death)
3. A lack of commitment to full aggressive care (anticipated withholding or withdrawal of care in the first week).
4. Absolute contraindication to enteral nutrients (e.g., GI perforation or obstruction, or lack of access for any reason).
5. Patients with severe acquired brain injury
 - a. Significant head trauma (defined as an injury resulting in a severe, disabling or fatal brain injury)
 - b. Grade 4 or 5 subarachnoid hemorrhage
 - c. Stroke resulting in a severe, disabling or fatal brain injury
 - d. Post-cardiac arrest related significant anoxic brain injury
6. Routine electrophysiology (patients with complicated peri-operative course requiring pressors, IABP, ECMO, or other devices can be included)
7. Seizures requiring anticonvulsant medication (pre-existing history)
8. Patients with primary admission diagnosis of burns ($\geq 30\%$ BSA)
9. Weight less than 50 kg or greater than 200 kg
10. Pregnant patients or lactating with the intent to breastfeed
11. Previous randomization in this study
12. Enrollment in a related ICU interventional study
13. Cirrhosis - Child's class C liver disease
14. Metastatic cancer or Stage IV Lymphoma with life expectancy <6 months

Need minimum 5 days of supplements, so do not enrol patients that are expected to get better and leave within 5 days

Eligibility confirmation by MD

Document in the medical chart

OR

Sign worksheet by SI and keep as source


FAQs

- Patient had 2 organ failures in ICU but only has 1 now....still eligible?
- Patient has a distended abdomen and high GRVs and may not start on enteral nutrition right away.....still eligible?
- Patient meets criteria but is getting better and is to be extubated soon. Do I enrol such a patient?

Delegation of Authority Logs

“The Investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties (ICH section 4.1.5)”

Completed Log to be sent to CERU before start of trial



Delegation of Authority Log

This log is used by the Qualified Investigator (i.e. Site Investigator) to indicate the Site Staff that have a material effect on the conduct of the Study and to whom the Investigator has delegated significant Study related duties/tasks. The signatures and details on this log will also facilitate tracking of edits/changes of the Site records. This log is to be kept by the Qualified Investigator and the Sponsor.

Name of Qualified Investigator: _____ Signature of Qualified Investigator: _____

Print Name	Signature	Initials	Study Role (Qualified Investigator*, sub-QI*, Research Coordinator (RC), Pharmacist, Technician, Dietitian)	Key Delegated Tasks (see next page)	Dates	
					Start	End

*Qualified Investigator: the Site Investigator responsible for the conduct of the REDOXs® study at your site.
*Sub QI: Investigator other than the Qualified Investigator that is responsible for tasks related to the REDOXs® study at your site.

ICU Infection Adjudication

Site Investigator to make determination of ICU acquired infection based on antibiotic and microbiology data entered

Microbiology

Collect all positive cultures within the period 7 days prior to ICU admission.

If culture date > 72 hrs ICU admission, 2 questions will be asked to help determine suspicion of ICU acquired infection.

The screenshot shows a web browser window titled "Critical Care Nutrition Survey Microbiology - Microsoft Internet Explorer". The address bar shows the URL: <https://ceru.hpcvl.queensu.ca/REDOXS/newMicro.do?id=53>. The page content includes a header for "The REDOXS Study" with the tagline "REducing Deaths due to OXidative Stress". Below the header, the page is titled "Microbiology" and includes a "Help" link. A navigation menu on the left contains links for "Home", "Patient Status", "Site Status", "Contact Us", and "Logout". The main form area is divided into sections: "Sample", "Organisms", and "Susceptibilities". The "Sample" section contains fields for "Accession Number", "Date Culture Sent" (with a dropdown for month and year, and a "Time (24 hrs)" field), and "Sample Type". The "Organisms" section features a list of organisms on the left and a list of susceptibilities on the right. The "Susceptibilities" section includes buttons for "Sensitive >", "Intermediate >", "Resistant >", and "< DELETE". At the bottom of the form, there are two questions: "Is this culture a manifestation of a previously diagnosed infection?" and "Is this culture from a routine surveillance?", each with "Yes" and "No" radio buttons. The form concludes with "Save Microbiology" and "Reset Form" buttons.

Screening #: 119
Enrolment #: 16

Site name: KGH

Home
Patient Status
Site Status
Contact Us
Logout

Sample
Record all positive cultures within 7 days prior to ICU admission

Accession Number:

Date Culture Sent: Time (24 hrs):

Sample Type:

Organisms

Organism	Susceptibilities
Adenovirus	S. Amantadine
Aerogenes	S. Amoxicillin
Aeruginosa	<input type="button" value="Sensitive >"/>
Agalactiae (Group B Strep)	<input type="button" value="Intermediate >"/>
Albicans	<input type="button" value="Resistant >"/>
Anginosus	<input type="button" value="DELETE"/>

Quantitative Results:

Is this culture a manifestation of a previously diagnosed infection? Yes No

Is this culture from a routine surveillance? Yes No

Suspicion of ICU Infection

- Is this culture a manifestation of a previously diagnosed infection?
- Is this a routine surveillance swab?

NEED TO ASK SITE INVESTIGATOR

- If NO to both.....automatically flagged for adjudication.

The REDOXS[®] Study

REducing DEaths due to OXidative Stress

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Screening #:5
Enrolment #:4

Microbiology

[Help](#)

Accession #	Date
GN-07-13369	28/Jun/2007
GN-07-13370	28/Jun/2007
07-195-0971	07/Jul/2007
07-196-0941	15/Jul/2007
07-169-0941	15/Jul/2007
07-196-0941	15/Jul/2007
07-199-2596	18/Jul/2007
07-199-2708	18/Jul/2007
07-199-2708	18/Jul/2007
07-199-2708	18/Jul/2007

Sample

Record ALL positive cultures from 7 days prior to ICU admission until ICU discharge

Accession Number

Date Culture taken Time (24 hrs)

Sample Type

Organisms

Pseudomonas sp. / Aeruginosa , Results: Sensitive: Ceftazidime, Ciprofloxacin, Meropenem, Piperacillin, Tobramycin

Add Organism

Is this culture a manifestation of a previously diagnosed infection? Yes No

Is this a routine surveillance swab? Yes No

Antibiotics

Period of data collection starts 7 days prior to ICU admission and may extend beyond ICU discharge.

If abx started > 72 hr ICU admission, 2 questions will be asked to help determine suspicion of ICU acquired infection.

The screenshot shows a web browser window displaying the 'Antibiotics' form for the REDOX Study. The browser's address bar shows the URL: <https://ceru.hpcvl.queensu.ca/REDOXS/newAntibiotic.do?id=53>. The page header includes the REDOX Study logo and the text 'REducing Deaths due to OXidative Stress'. The form is titled 'Antibiotics' and includes a 'Help' link. A navigation menu on the left contains links for Home, Patient Status, Site Status, Contact Us, and Logout. The form content includes a table with the following data:

Antibiotic	Date first dose received	Date last dose received
Acyclovir	02/Mar/2007	02/Feb/2007

Below the table, there is a form for adding a new antibiotic entry. It includes a dropdown menu for 'Antibiotic', a 'Dose' field, a 'Route' selection (IV or PO/NG), a 'Frequency' field, and three date-time pairs for 'Date antibiotics ordered', 'Date first dose received', and 'Date last dose received'. Each date-time pair consists of a date selector (month, day, year) and a time selector (24 hrs). There are three radio button questions: 'Is this antibiotic prescribed for prophylaxis?', 'Is this a dose adjustment of an antibiotic previously ordered for an infection?', and 'Is this antibiotic a substitute for an antibiotic previously ordered for an infection?'. At the bottom of the form are three buttons: 'Save Antibiotic', 'Reset Form', and 'New Antibiotic'. The footer of the page reads 'Copyright © Critical Care Connections Inc. All rights Reserved.'.

Suspicion of ICU Infection

- Is this antibiotic prescribed for prophylaxis?
- Is this a substitute for an antibiotic ordered for a previous infection?

NEED TO ASK SITE INVESTIGATOR

- If NO to ALL.....automatically flagged for adjudication.

The REDOX^S Study

REducing DEaths due to OXidative Stress

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Screening #:13
Enrolment #:11

Antibiotics

[Help](#)

Antibiotic	Date first dose received	Date last dose received
Piperacillin/Tazobactem	13/Aug/2007	18/Aug/2007
Ciprofloxacin	18/Aug/2007	24/Aug/2007
Cloxacillin	20/Aug/2007	22/Aug/2007
Vancomycin	20/Aug/2007	20/Aug/2007

Antibiotic

Record all antibiotics started 7 days prior to ICU admission and those during ICU stay.

Antibiotic:

Dose:

Route: IV PO/NG

Frequency:

Date antibiotics ordered: Time (24 hrs): No Time available

Date first dose received: Time (24 hrs):

Date last dose received: Time (24 hrs):

Is this antibiotic prescribed for prophylaxis? Yes No

Is this a dose adjustment of an antibiotic previously ordered for an infection? Yes No

Is this antibiotic a substitute for an antibiotic previously ordered for an infection? Yes No

Comments:

Infection Adjudication

After ICU outcomes AND all input warnings must be resolved

The screenshot shows a web browser window titled "Patient View - Windows Internet Explorer" with the URL "https://ceru.hpcvl.queensu.ca/REDOXS/patientMain.do?id=64". The page content includes a table of dates from 18/Apr/2007 to 21/Apr/2007, each with a yellow warning icon and an "Add" button. Below this are three main sections:

- Microbiology**: A table with columns "Accession #" and "Date".

Accession #	Date
123	10/Apr/2007
234	14/Apr/2007
1145	12/Apr/2007
1459	15/Apr/2007
	26/Feb/2007

An "Add Microbiology" button is located below the table.
- Antibiotics**: A table with columns "Antibiotic", "Date first received", and "Date last received".

Antibiotic	Date first received	Date last received
Bacitracin	15/Apr/2007	20/Apr/2007
Cefazolin	15/Apr/2007	16/Apr/2007
Erythromycin	14/Apr/2007	18/Apr/2007
Ampicillin	16/Apr/2007	22/Apr/2007

An "Add Antibiotic" button is located below the table.
- Outcomes and Follow Up**: A section containing several links: "ICU Outcome information", "ADJUDICATION Form", "Hospital Outcome information", "3 month follow up information", and "6 month follow up information". Below these are links for "SF 36 - 3 Month survey" (with sub-links for "Edit SF36 Page 1", "Edit SF36 Page 2", and "Edit SF36 Page 3") and "Click here to enter SF36 (6 month)", followed by "Investigator's Confirmation form". A red arrow points to the "ADJUDICATION Form" link.

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Automatic listing of relevant clinical data (microbiology, antibiotics, daily data) that will enable the Site Investigator to adjudicate newly acquired ICU infections.

REDOXS Study - Microsoft Internet Explorer

Address: <https://ceru.hpcvl.queensu.ca/REDOXS/loadAdjudication.do?id=95>

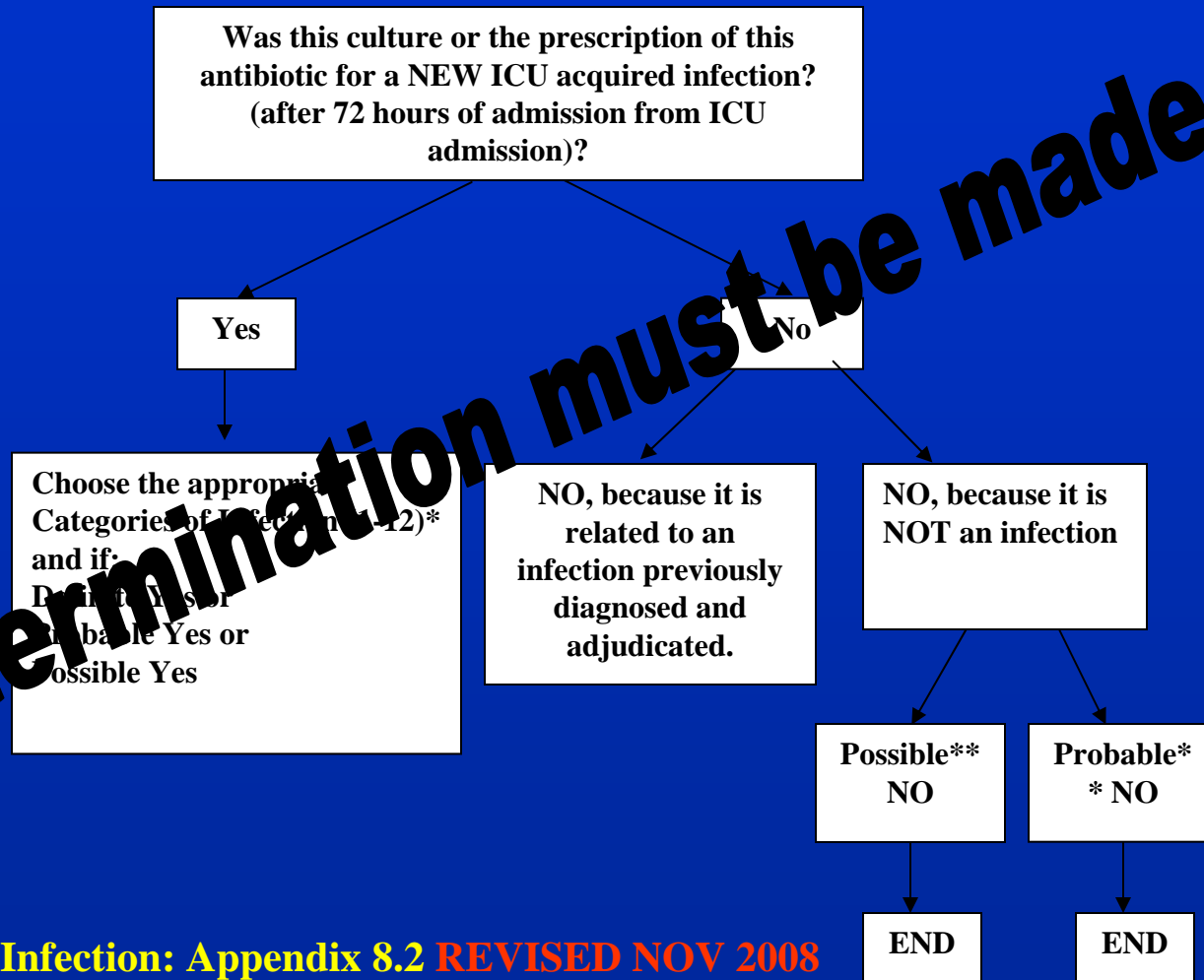
The **REDOXS**® Study
REducing Deaths due to OXidative Stress

Infection Adjudication
 Patient: 4
 Admission Diagnosis: Valvular heart surgery/CABG
 ICU admission date: 08/May/2007 16:39

Date	Temp	Worst PF ratio	WBC	Microbiology		Antibiotic				Newly Acquired Infection								
				Pressors	Vented	Sample	Organism	Antibiotic	Dose		Unit	Frequency	Route					
08 May 2007	38.5	77.0	High=11.2 Low=6.3	YES	YES													
08 May 2007	38.5	77.0	High=11.2 Low=6.3	YES	YES													
09 May 2007	38.7	147.0	High=16.3 Low=9.9	YES	YES			Ceftazidime	1.0	g	q12 hrs	IV						
10 May 2007	38.2	130.0	High=17.5 Low=14.0	YES	YES			Ceftazidime	1.0	g	q12 hrs	IV						
11 May 2007	38.0	105.0	High=18.2 Low=18.2	NO	YES													
12 May 2007	38.6	104.0	High=16.4 Low=16.4	NO	YES													
13 May 2007	37.8	128.0	High=19.7 Low=18.9	NO	YES	Other	30a Pylori											<input type="radio"/> This is a newly acquired infection <input type="radio"/> This is NOT a newly acquired infection <input type="radio"/> This is a previously adjudicated infection

Done

Determination of ICU Infection



*Categories of Infection: Appendix 8.2 REVISED NOV 2008

**Definition of No: Appendix 8.3

SAE Reporting: version Sep 15th 2008

- **Serious and Unexpected events**
 - regardless of relationships to supplements
- Initial report faxed to CERU within 24 hrs
- Follow up report within 10 days from becoming aware of SAE, plus meds and labs
- Record the event, not the outcome (death)

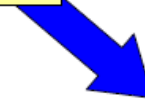
SAE Reporting by REDOXS® sites to the Clinical Evaluation Research Unit (CERU)

*Serious if:

- Results in death
- Is life threatening
- Requires or prolongs in-patient hospitalization
- Results in persistent or significant disability/incapacity
- May require medical or surgical intervention to prevent one of the other outcomes to defining serious

To be reported, the event needs to be both **Serious* and Unexpected****
Study Coordinator (SC) or Site Investigator (SI) identifies SAE

** Unexpected if:
not expected due to the progression of the underlying disease or co-morbid illnesses.



SC faxes the SAE **initial** report to the Project Leader **within 24 hours** of becoming aware of the event (# 613 548 2428) **plus**

- **concomitant medications**
(given within the 48 hours preceding the SAE)
- **lab values**
(related to the SAE)

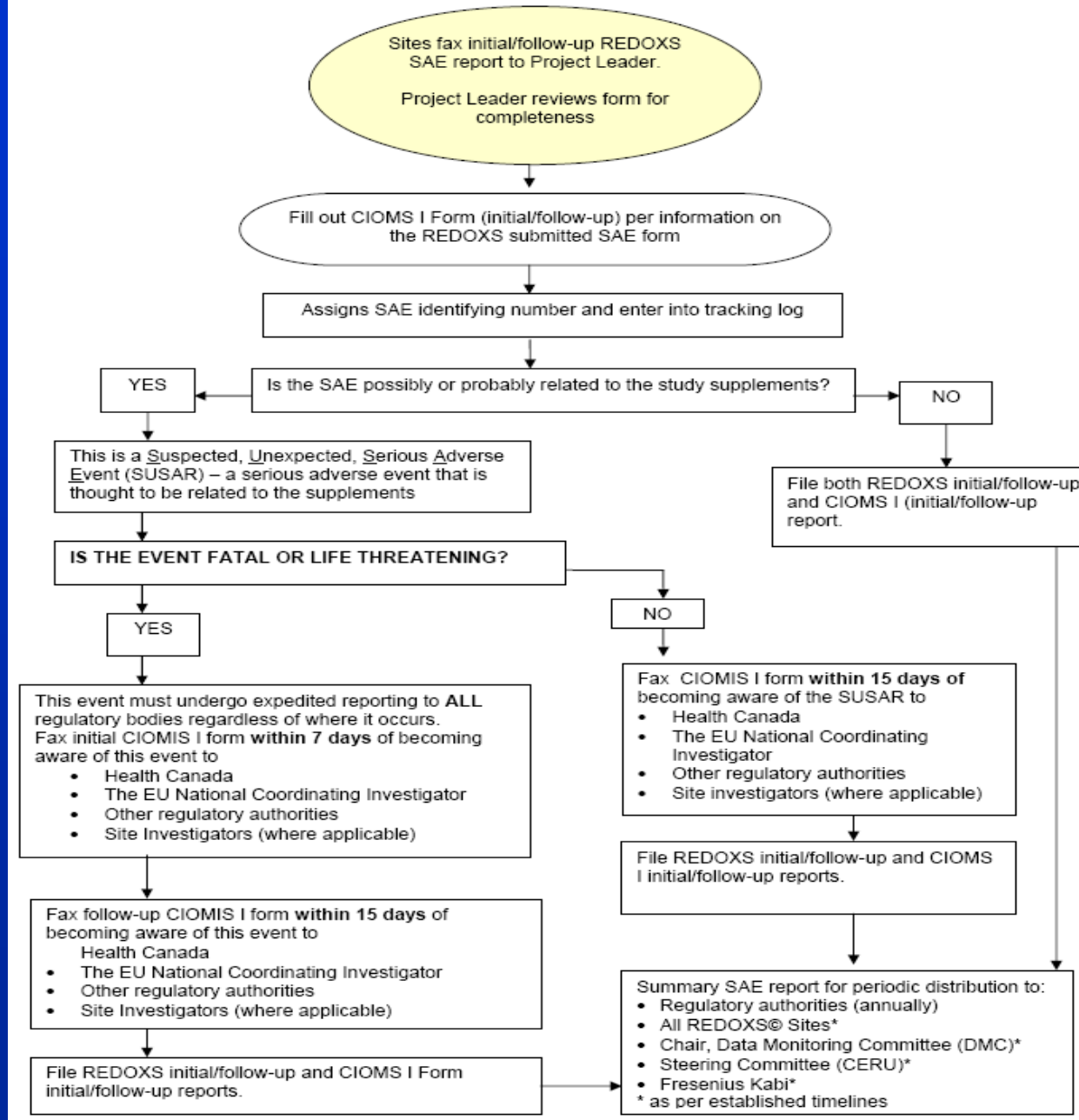
SC reports SAE to local Ethics Board as per required timelines



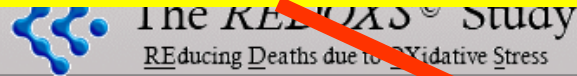
SC faxes the SAE **follow-up** report to the Project Leader **within 10 days** from becoming aware of the event (fax # 613 548 2428).

The Project Leader will collaborate with the Study Coordinator to assess the need for additional details and further follow-up reporting.

SAE Reporting by Clinical Evaluation Research Unit (CERU)



SAE forms available online



Welcome, Rupinder Bhaliwal

Site name: Kingston General [Edit](#)

- Home
- Edit User Profile
- Change Password
- Contact Us
- Logout

Screen New Patient

[Protocol Violation Form](#) [SAE Form - Initial](#) [SAE Form - Follow up](#)

Screened patients

Enrolled patients (You have 60 patients enrolled in this study)

In progress

To review or edit patient data, click on the row corresponding to the appropriate patient.

Screening #	Enrolment #	Status	Age	Gender	Height
163	60	in progress	78	F	145.0
162	59	in progress	57	M	165.0
161	58	in progress	34	F	152.0
160	57	in progress	74	M	182.0
159	56	in progress	72	M	177.0
158	55	in progress	67	M	170.0
157	54	in progress	85	M	170.0
156	53	in progress	81	F	165.0
155	52	locked	47	M	193.0
154	51	locked	52	M	165.0
153	50	in progress	79	M	175.0
152	49	in progress	61	M	185.0
151	48	in progress	70	M	162.6
150	47	in progress	59	M	192.0
149	46	in progress	77	M	173.0
119	41	in progress	52	M	175.0
109	35	locked	63	F	152.4
104	31	locked	40	F	142.0

Finalized patients

SAE Initial Report

Revised Sept 2008

The REDOXSM Study

Serious Adverse Events (SAE) - Initial Report

Complete and fax the INITIAL report to CERU at 613 548 2428 attention: Project Leader within **24 hours** of becoming aware of the event.
Complete one form for **EVERY** adverse event that is Serious and Unexpected. Report only those SAEs that occur from the time of randomization to the end of the study period (30 days from admission to ICU or until ICU d/c or death, whatever comes first)

Patient Information

Site number Initials Male Height (cm) Name of Site Investigator
Enrolment # DOB Female Weight

SAE #

Record the sequential SAE # for the patient i.e. for 1st SAE for this patient, write 01; For 2nd SAE for this patient, write 02.

Cardiac arrest

Serious Adverse Event Reported (only one per form)

Date SAE reported

Date became aware of SAE

Seriousness (select all that apply)

- Patient died --> please document date in Outcomes
- Life threatening
- Requires or prolongs hospitalization
- Results in persistent or significant disability/incapacity
- May require medical or surgical intervention to prevent one of other outcomes.

Outcomes (at the time of initial report) - select only one

- Complete recovery/return to baseline - Date of recovery
- Alive with sequelae
- Death - death date
- SAE persisting
- Unknown/lost to follow-up

Site investigator to

1. Identify SAE (serious and unexpected)
2. Unexpected nature of the event
3. Relationship to supplements

with Study supplements (select only one)

(select only one) in study supplements)

Accepted

Stopped
SAE

SAE to Study Supplements

- Possibly related
- Probably related

Print Form

Onset of SAE
ICU admission
Start of study supplement
Stop of study supplement
Signature of Site Investigator
Date

Complete Follow up report within required timelines

SAE Follow up Report

available on web

The REDOXS® Study

Serious Adverse Events (SAE) - Follow-up Report

No.

Complete and fax the Follow-up report to CERU at 613 548 2428 attention: Project Leader within **10 days of becoming aware of SAE**. The Project Leader and Study Coordinator to assess the need for additional details and further follow-up reporting. To be completed by the Site Investigator for **EVERY** initial SAE that was reported to CERU.

Patient Identification

Site #	Enrol. #	Initials	SAE #
<input type="text" value="01"/>	<input type="text" value="12"/>	<input type="text" value="CL"/>	<input type="text" value="01"/>

Chronological events preceding SAE until time of this report

OR 27/07/07, enrolled 28/07/07, cardiac arrest, pacemaker wires non functioning, no cardiac output

Past medical history, comorbid illness and reason for admission to hospital

DM II, COPD, Hiatus Hernia

Admitting diagnosis to ICU and chronological events leading to the SAE

CABG x 3 July 27th 2007, IABP, pressor support, cardiac arrest, resuscitation

Confirmation of unexpected nature of SAE (not due to progression of underlying disease)

Pt was improving overall. Less inotropic support needed. Onset of asystole/cardiac arrest was unexpected

Relationship of SAE to study supplements vs. progression of underlying illness (based on timing of supplements, SAE)

No relationship

Outcomes (at time of final report)

- Complete recovery/return to baseline - Date or recovery
- Alive with sequelae
- Death - death date
- SAE persisting
- Unknown/lost to follow-up

Relationship of SAE to study supplements

- Not related Possibly related
- Unlikely related Probably related

Action taken with Study supplements

- None (including not on study supplements)
- Dose reduced, interrupted or therapy delayed
- Study Supplements stopped permanently due to SAE

Action taken

- None Hospitalization
- Uncertain IV fluids
- Procedure or physical therapy Other, specify
- Blood or blood products
- Prescription drug therapy
- Non-prescription drug therapy

Summary

Patient suffered terminal cardiac arrest following salvage cardiac bypass grafting

Signature of Site Investigator

Date

Print Form

Investigator Confirmation

6	23/Apr/2008	✓	✓	✓	✓	✓
7	24/Apr/2008	✓	✓	✓	✓	✓
8	25/Apr/2008	✓	✓	✓	✓	✓
9	26/Apr/2008					

Microbiology

Accession #	Date	Status
M36183	19/Apr/2008	✓
M36192	19/Apr/2008	✓
M36211	19/Apr/2008	✓

Antibiotics

Antibiotic	Date first received	Date last received	Status
Ceftriaxone	19/Apr/2008	22/Apr/2008	✓
Vancomycin	19/Apr/2008	25/Apr/2008	✓
Metronidazole	19/Apr/2008		
Fluconazole	19/Apr/2008		

Outcomes and Follow Up

[ICU Outcome information](#)

[Hospital Outcome information](#)

[3 month follow up information](#)

[6 month follow up information](#)

SF 36 - 3 Month survey

[Edit SF36 Page 1](#)

[Edit SF36 Page 2](#)

[Edit SF36 Page 3](#)

[Click here to enter SF36 \(6 month\) Investigator's Confirmation form](#)

Investigator Confirmation
(on Patient Status Page)

Investigator Confirmation

Site _____
Enrolment # _____
Enrollment Date: _____

Site Name _____



The REDOX[®] Study
REducing Deaths due to OXidative Stress

Investigator's Confirmation

The electronic data collection was conducted under my supervision according to the protocol during the entire study.

The data and statements, including ICU acquired infection adjudication are complete and accurate to the best of my knowledge.

Full Name of Investigator

Signature of the Investigator

dd	mmm	yyyy

	: _
	24 hr clock

Update of Study

The REDOXS© Circular

691
patients to go...

Enrolment as of May 31, 2009

Site	May	Cumulative Total	Site	May	Cumulative Total
Kingston General	3	56	Sunnybrook, Toronto	-	2
St. Joseph's Healthcare	1	30	St. Paul's, Vancouver	-	6
Ottawa General	6	86	L'Enfant Jesus, Quebec City	1	18
Ottawa Civic	2	36	Liege, Belgium	-	3
Vancouver General	1	18	CHUV, Switzerland	-	8
Sacre Coeur, Montreal	3	44	Royal Jubilee, Victoria	-	5
Royal Alexandria, Edmonton	-	15	UZ Brussels	-	2
Maisonneuve—Rosemount	-	12	Mount Sinai, Toronto	2	14
Grey Nun's, Edmonton	-	11	University of Colorado	2	8
Victoria General	-	3	Miami Valley, Ohio	-	2
London Health Sciences Centre	-	10	University of Louisville	1	7
Health Sciences Centre, Winnipeg	-	8	Fletcher Allen, U of Vermont	-	3
Queen Elizabeth II, Halifax	-	7	St. Boniface, Winnipeg	-	-
<i>*Montreal General</i>	-	7	<i>*Royal Victoria</i>	-	8

