The*REDOXS*® Study

REducing Deaths due to OXidative Stress

Daily Worksheets and Checklists

July 31, 2008

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

Pt Name _____ CR# _____

Screening Date _____ Screening Time _____ Age _____

REDOXS© Screening Worksheet

Inclusion Criteria

1. ☐ Mechanically ventilated adult patients (≥18 years old) admitted to your ICU.
   AND
   Must have **2** or **more** of the following organ failures related to their acute illness:
   RECORD ALL ORGAN FAILURES
   Reminder:
2. - **Organ Failures may have started before ICU admission but have to be present**
   - **Organ failures may have resolved at time of screening**

☐ i. A Pa02/Fi02 ratio of <=300
Date of onset of respiratory failure:

dd	**mmm**	**yyyy**		**Time (24 hr)**

☐ ii. Clinical evidence of hypoperfusion defined as the need for vasopressor agents (norepinephrine, epinephrine, vasopressin, or ≥5 µg/kg/min of dopamine, or ≥ 50 µg/min phenylephrine) for **≥ 2 hours**.
Date of onset of hypoperfusion failure:

dd	**mmm**	**yyyy**	**Time (24 hr)**

☐ iii. In patients without known renal disease, renal dysfunction defined as a serum Creatinine ≥ 171 umol/L **or** a urine output of ≤ 500ml/last 24 hours (or 80 ml/last 4 hours if a 24 hr period observation not available).
In patients with acute on chronic renal failure (pre-dialysis), an absolute increase of ≥ 80 umol/L from baseline or pre-admission creatinine **or** a urine output of ≤500ml/last 24 hours (or 80ml/last 4 hours) will be required.
Date of onset of renal dysfunction:

dd	**mmm**	**yyyy**	**Time (24 hr)**

☐ iv. A platelet count of ≤ 50 mm3.
Date of onset of low platelet count

dd	**mmm**	**yyyy**	**Time (24 hr)**

Pt Name _____ CR# _____

Screening Date _____ Screening Time _____ Age _____

Exclusion Criteria [Choose only 1 (most pertinent)]

- ☐ > 24 hours from admission to ICU to time of consent
- ☐ Patients who are moribund (not expected to be in ICU for more than 48 hours due to imminent death.
- ☐ A lack of commitment to full aggressive care (anticipated withholding or withdrawing treatments in the first week).
- ☐ Absolute contraindication to enteral nutrients (e.g.: GI perforation, obstruction or no gastric access for any reason).
- ☐ Patients with severe acquired brain injury:
  - i. Significant head trauma (defined as an injury in the opinion of the investigator to represent a severe, disabling or fatal brain injury).
  - ii. Grade 4 or 5 subarachnoid hemorrhage.
  - iii. Stroke resulting in coma and intubation.
  - iv. Post cardiac arrest with suspected significant anoxic brain injury.
- ☐ Routine elective cardiac surgery (patients with complicated peri-operative course requiring IABP, ventricular assist devices can be included).
- ☐ Seizure disorder requiring anticonvulsant (=previous hx of seizure d/o).
- ☐ Patient with primary admission diagnosis of burns (>=30%BSA).
- ☐ Weight less than 50 Kgs or greater than 200 Kgs.
- ☐ Pregnant patients or lactating with the intent to breastfeed.
- ☐ Previous randomization in this study.
- ☐ Enrolment in a related ICU interventional study.
- ☐ Cirrhosis- child's class C liver disease
- ☐ Cancer-metastatic cancer or Stage IV Lymphomas with an expected life expectancy of less than 6 months
- ☐ None of the above

Eligibility confirmed by Dr. _____

Patients Height _____ cms

Date & time Pharmacy Contacted _____

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PATIENT CONTACT INFORMATION

ID#/CR# _____ Enrol. # _____ Date _____

Do not complete this form for patients/SDM not giving consent or patients who are not eligible for participation.

PATIENT

_____ _____
Last Name Given Names

_____ _____ _____
Apt. No. Street Postal Code

_____ _____ _____
Town/City Province/State Country

_____ – _____ _____ – _____
Home Phone # Work Phone #

ALTERNATIVE CONTACT #1

_____ _____ _____
Last Name Given Names Relationship

_____ _____ _____
Apt. No. Street Postal Code

_____ _____ _____
Town/City Province/State Country

_____ – _____ _____ – _____
Home Phone # Work Phone #

ALTERNATIVE CONTACT #2

_____ _____ _____
Last Name Given Names Relationship

_____ _____ _____
Apt. No. Street Postal Code

_____ _____ _____
Town/City Province/State Country

_____ – _____ _____ – _____
Home Phone # Work Phone #

ALTERNATIVE CONTACT #3

_____ _____ _____
Last Name Given Names Relationship

_____ _____ _____
Apt. No. Street Postal Code

_____ _____ _____
Town/City Province/State Country

_____ – _____ _____ – _____
Home Phone # Work Phone #

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Baseline Form

Patient name_____ CR_____ Study #_____

Patient Baseline

		DD	MMM	YYYY	
Hospital admission	Date:	_____	_____	_____	Time _____
ICU admission	Date:	_____	_____	_____	Time _____
Mechanical Vent.	Date:	_____	_____	_____	Time _____

Primary ICU Admission Diagnosis: _____
Medical ☐ Surgical ☐ Elective OR ☐ Emergent OR (see taxonomy)

Comorbids (see taxonomy)_____
_____

APACHE II score_____

Sex: F M

Weight: _____

Age: _____

Ethnicity _____

Diabetic Y N Type I II

Etiology of Shock

Cardiogenic	☐	Septic	☐	Neurogenic	☐
Anaphylactic	☐	Other	☐	Origin Uncertain	☐

Nutrition Baseline

Prescribed Kcals: _____ Protein grams _____

		dd	mmm	yyyy	
Parenteral Study Supplement start	Date	_____	_____	____	Time _____
Parenteral Study Supplement stop	Date	_____	_____	____	Time _____
Enteral Study Supplement start	Date	_____	_____	____	Time _____
Enteral Study Supplement stop	Date	_____	_____	____	Time _____
Enteral Feeds start	Date	_____	_____	____	Time _____
Enteral Feeds stop	Date	_____	_____	____	Time _____
Parenteral Feeds start	Date	_____	_____	____	Time _____
Parenteral Feeds stop	Date	_____	_____	____	Time _____

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Pt Name_____ID#_____
Enrolment#_____

Daily Data Collection

	Study Day	Day	Day	Day	Day	Day	Day	Day
Daily Data	DD/MMM/YYYY							
	HR ↑							
	BP ↓ (lowest systolic & corresponding diastolic)							
	Temp (most aberrant from midline 37 °C)							
	U/O 0-199, 200-499 or ≥500							
	Resp R ↑							
	P/F ↓							
	Dialysis Y/N (If yes, Acute or Chronic)	Y N	Y N	Y N	Y N	Y N	Y N	Y N
	Mech. ventilated Y/N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
	WBC ↑ and ↓							
	Platelets ↓							
	BS (closest to 8 am; measured between 02:00-14:00)							
	Urea ↑							
	Creatinine ↑							
	Albumin ↑							
	Bilirubin ↑ (total)							
	Total gastric residual volumes							
	Vol. of gastric residuals discarded							
	Feeding tube location Gastric confirmed Gastric presumed Post-pyloric duodenal confirmed Post-pyloric duodenal presumed Post-pyloric jejunal confirmed Post-pyloric jejunal presumed No tube in place on that day							
	Diarrhea Y/N (>750ml/day or > 5/day)	Y N	Y N	Y N	Y N	Y N	Y N	Y N
Concomitant meds.	Inotropes today record ↑ (highest hourly dose)							
	Hydrocortisone Y//N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
	APC Y/N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
	Motility agents [None, Motilium, Erythromycin, or Metoclopromide (Maxeran)]							
	Insulin units/day (total)							

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Pt Name_____ID#_____
Enrolment#_____

MICROBIOLOGY

Record ALL positive cultures from 7 days prior to ICU admission (from current admission to your hospital) until ICU discharge (maximum Day 30).
ICU admission date_____

Consult with the Site Investigator for the following questions:
Question #1: Is this culture a routine surveillance swab? **Question #2: Is this culture from a previously diagnosed infection?**

Date/time culture collected	Accession #	Sample Type	CFU/ml or CFU/L	Organism (s)	Sub-species	Susceptibilities	Ques. #1	Ques. #2
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N
							Y....N	Y....N

*If the answer for both Questions #1 & 2 are no, and >72 hrs from ICU admission, flag for infection adjudication.

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Pt Name_____ID#_____
Enrolment#_____

ANTIBIOTICS

The period of data collection starts 7 days prior to ICU admission and stop dates for antibiotics may extend beyond ICU discharge. Record:

- all antibiotics started within the period of 7 days prior to ICU admission (from current admission to your hospital) even if stopped prior to ICU admission
- all antibiotics started 7 days prior to ICU admission (from current admission to your hospital) and continued in ICU
- all antibiotics started in ICU and continued beyond ICU discharge. For an ICU stay beyond 30 days where an antibiotic is started before day 30 and continues after day 30, follow the patient to collect the actual stop date/time. Do not record antibiotics started after day 30.

Consult with the Site Investigator for the following questions:
Question #1: Is this antibiotic for prophylaxis? Question #2: Is this antibiotic a substitute for an antibiotic previously ordered for an infection?

Antibiotic	Dose	Route	Frequency	Order date/time	Start date/time	Stop date/time	Ques. #1	Ques. #2
		IV.....PO					Y.....N	Y.....N

*If the answer for both Questions #1 & 2 are no, and >72 hrs from ICU admission, flag for infection adjudication.

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Dietitian Daily Checklist

ICU Admission Date: _____
Record only once (max. kcals & protein prescribed)
Prescribed Energy Intake _____Kcals
Prescribed Protein Intake _____grams

Patient Enrollment No # _____
Date EN started in ICU_____ Time_____
Date EN stopped in ICU_____ Time_____
Date PN started in ICU_____ Time_____
Date PN stopped in ICU_____ Time_____

Study Day*	**1 (ICU admit)**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
ENTERAL NUTRITION															
Received today? Y/N															
Energy (kcal)															
Propofol (kcal) **															
Total EN energy (kcal)															
Total EN protein (g)															
Type of Formula (select up to 3)															
Interrupted for ↑ GRV or emesis? Y/N															
Interrupted for ↑ urea or fluid concerns? Y/N															
PARENTERAL NUTRITION															
Received today? Y/N															
Energy (kcal)															
Propofol (kcal) **															
Total PN energy (kcal)															
Total PN protein (g)															
Lipids received today? Y/N If yes, type?															
Interrupted for ↑ urea or fluid concerns? Y/N															
ENTERAL NUTRITION OPTIMIZATION															
Energy or protein from EN <80% prescribed? Y/N															
If yes, motility agents used? Y/N															
If yes, small bowel feeding tube used? Y/N															
If EN interrupted, RD review requested? Y/N															
Comments															

*Study Day 1 is from ICU admission to the end of your 24 hr flowsheet. Study Day 2 and subsequent days are the 24 hr period according to your flowsheet.
**If propofol is running <6 continuous hours (within a study day) those propofol calories are NOT included in total energy. If propofol is running >= 6 continuous 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, then 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.

Version: 17-Dec-09
Replaces version: July 31, 2008

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Dietitian Daily Checklist

ICU Admission Date: _____ Patient Enrollment No # _____

Study Day*	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
ENTERAL NUTRITION															
Received today? Y/N															
Energy (kcal)															
Propofol (kcal) **															
Total EN energy (kcal)															
Total EN protein (g)															
Type of Formula (select up to 3)															
Interrupted for ↑ GRV or emesis? Y/N															
Interrupted for ↑ urea or fluid concerns? Y/N															
PARENTERAL NUTRITION															
Received today? Y/N															
Energy (kcal)															
Propofol (kcal) **															
Total PN energy (kcal)															
Total PN protein (g)															
Lipids received today? Y/N If yes, type?															
Interrupted for ↑ urea or fluid concerns? Y/N															
ENTERAL NUTRITION OPTIMIZATION															
Energy or protein from EN <80% prescribed? Y/N															
If yes, motility agents used? Y/N															
If yes, small bowel feeding tube used? Y/N															
If EN interrupted, RD review requested? Y/N															
Comments															

*Study Day 1 is from ICU admission to the end of your 24 hr flowsheet. Study Day 2 and subsequent days are the 24 hr period according to your flowsheet.
**If propofol is running <6 continuous hours (within a study day) those propofol calories are NOT included in total energy. If propofol is running >= 6 continuous 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, then 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.

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OUTCOMES AND LONG-TERM FOLLOW-UP

Patient name_____ CR #_____ Study #_____

(date format: dd/mmm/yyyy; time format hh:mm)

OUTCOMES		
ICU admission	_____ date	_____ time
ICU discharge **Alive** **Dead**	_____ date	_____ time
Final MV Discontinued	_____ date	_____ time
Hospital discharge **Alive** **Dead**	_____ date	_____ time
Patient on dialysis upon hospital discharge?	Yes	No

LONG TERM FOLLOW-UP		
Patient consented?	Yes	No

3 month SF36		6 month SF36	
Projected date: _____±2wks		Projected date: _____±2wks	
Completion date: _____		Completion date: _____	
☐ Died	_____ date of death	☐ Died	_____ date of death
☐ Refused	_____ date of refusal	☐ Refused	_____ date of refusal
☐ Withdrew	_____ date of withdrawal	☐ Withdrew	_____ date of withdrawal
☐ Lost to follow up	_____ date - last known alive	☐ Lost to follow-up	_____ date - last known alive
☐ Missed time line	_____ date – next attempt	☐ Missed time line	_____ date – next attempt
Comments:		Comments	