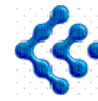


REDOXS[®] Study Bulletin

Pharmacy Procedure Amendment



The REDOX[®] Study
Reducing Deaths due to Oxidative Stress

The Issue

As some of you may be aware, over the past several months we have turned our attention to our current practices concerning the preparation and administration of parenteral study supplements. Specifically, we have conducted an intensive review of the impact the inherent overfill found in 250 mL normal saline bags has on the dose of parenteral study supplements administered to REDOX[®] study patients. Based on the results of a survey we conducted in February with REDOX[®] pharmacists, it was revealed that an average of 10% of the daily dose of parenteral study supplements may be lost through ignoring overfill of the 250 mL normal saline bag. This is due to the discarding of the remaining volume of parenteral supplements at the end of the 24 hour infusion.

The Solution

In collaboration with the study Sponsor, pharmacists, research coordinators and study stakeholders we have conducted a rigorous analysis of this issue including all possible strategies to remedy any potential dose losses. As a result, the decision has been made to tighten up our the current dispensing practice to ensure REDOX[®] patients are receiving the total prescribed dose of parenteral study supplements in each (bag) 24 hour period. As a result of this, pharmacists are now to make bags containing exactly 250 mls normal saline, using empty sterile bags (e.g. Viaflex).

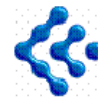
Pharmacy Procedures (pgs 15, 16) and related Parenteral Study Supplement Worksheets (Appendix F) have been amended to reflect these changes (version: 3-Jul-09).

Action Items for Pharmacists

Effective July 24, 2009, we are officially amending the pharmacy procedures to ensure that pharmacists are accounting for when preparing parenteral study supplements.

We are sensitive that this change in practice will take time to implement. We ask that pharmacists work towards implementing these procedures as soon as possible, with a target date of 24-Jul-09.

Once training has been completed and these procedures have been completed please fax the attached Confirmation Fax to the Project Leader.



The REDOX[®] Study
Reducing Deaths due to Oxidative Stress

Confirmation Fax

Attn: Janet Overvelde, Project Leader

Fax: 1-613-548-2428

RE: Amendment to Pharmacy Procedures (v. 3-Jul-09)

Following implementation of the updated Pharmacy Procedures, please complete this form and fax to the Project Leader (by 24-Jul-09).

Institution: _____

Completed by: _____
Print Name

I confirm that the following changes have been implemented at the above named institution:

- Pharmacy Manual has been replaced with version 3-Jul-09.
- Pharmacy Manual Appendix: Parenteral Study Supplement Worksheets have been replaced with version 3-Jul-09.
- Training has been conducted for all Pharmacy staff involved with the REDOX[®] Study OR Training has commenced and is ongoing for all Pharmacy staff involved with the REDOX[®] Study.

The updated Pharmacy Procedures have been implemented at our institution as of _____.
date

Signature

Date