



## AMBER STUDY TIPS AND UPDATES FEB 2015



### EMAILING THE AMBER STUDY OFFICE

Please get in touch with us in the AMBER office by emailing [AMBER@gcu.ac.uk](mailto:AMBER@gcu.ac.uk).



### MESSAGE TRAINING DVDs

When we started recruiting in Jan 2015, we gave sites version 1 of the DVD – This contained a video to show how the carer could do the massage and also a video to show how to do self-massage (either lying down or sitting). Feedback on the carer massage video was that the language used is quite clinical and not easily understood by a patient. We have edited the video with a voice over and now have version 2 of the DVD. The AMBER study office will post sites who have version 1, a new batch of version 2 DVDs.

- **PLEASE SEND ALL VERSION 1 DVDs BACK TO THE STUDY OFFICE**
- **ADD IN DVD 02 INTO THE FOLLOW UP PACKS INSERTS**
- **PLEASE REMEMBER** that there are 2 videos on the DVD and remember to show the correct one to the patient depending on if the patients are having a carer doing the massage or are doing self-massage.



### HINTS ON COMPLETING QUESTIONNAIRE AND NURSE ASSESMENT CRFs

#### 1. QoL of Life Questionnaire – Q 11

**Do you get autonomic dysreflexia because of your bowels?**

**(a)**

onever

- 1rarely
- 2some of the time
- 3most of the time
- 4always

**(b) How much does this bother you?**

(please ring one number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

Not at all a great deal

**DEFINITION:** Autonomic Dysreflexia, also known as Hyperreflexia occurs due to an exaggerated autonomic response to pain below the level of spinal cord injury resulting in the blood pressure becoming excessively high. The most common symptoms of autonomic dysreflexia are sweating, pounding headache, tingling sensation on the face and neck, blotchy skin around the neck and goose bumps.

**HOW TO ANSWER THIS QUESTION:**

**This condition is only applicable if a person has a spinal cord injury. If the patient does not have a spinal cord injury please ANSWER for (a) NEVER and (b) 0.**

**2. Baseline Nurse Assessment form**

In section 3, qu 2 (Bowel Symptoms Page 7) the following questions refer to the Bristol Stool chart.

Please make sure all questions are answered – if patient does not ever have a specific type (1-7) then always tick 0%

Description of Stool (see Bristol Stool Chart at end of the form) What percentage of time is your stool:	_____				
	100%	75%	50%	25%	0%
1. Like pellets/hard lumps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Sausage shaped, but lumpy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Like a sausage but with cracks at its surface	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Like a sausage or snake, smooth on its surface	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Soft blobs with clear cup edge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. Fluffy pieces with ragged edges, a mushy stool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Watery, no solid pieces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



## PAPERWORK TO SEND TO AMBER STUDY OFFICE

To enable timely data entry and to enable us to spot any issues with the study data early we would like to amend when all our centres send us the study paperwork. Please find details below:

**Baseline Data:** After the baseline appointment please send:

1. Consent
2. Bowel Diary (completed for 7 days before baseline appointment)
3. Nurse assessment form (up to page 11)
4. Cone med form (if applicable)
5. Baseline Questionnaire.

**Follow up calls (weeks 1-6):** After each follow up call please send:

1. The telephone record CRF
2. Update on con-med (if applicable)
3. AE CRF (if applicable)

You can scan and email or fax or post (if posting send photocopies and keep original at site) . Patient Identifiable information should be FAXED.

**The AMBER Nurse Visit guide will be updated and circulated to sites.**



## DATABASE TRAINING

We now have a LIVE Database for the study.

The Trial Manager will be sending sites who are already up and running or who had a site initiation a username and a password for a test system for you to practice on and a user guide. Sites ONLY have to add the participant to the database and enter the screening data.

The Trial Manager will be in touch to arrange a training session. Once you have practiced and entered the 3 screening forms (we will provide this data) and completed a training session you will be provided with a username and login for the LIVE system.

For some sites, there may be a backlog of screening forms to enter. This should be done as so as possible so the AMBER study office can start entering the rest of the data.