September 2013

OVATION Observer

Recruitment & Status Update

Institution	# Randomized
CHUS (Screening initiated May-2013)	20 (enrollment capped)
Kingston General (Screening initiated Jun-2013)	4
Mt Sinai (Screening initiated Jul-2013)	6
Ottawa General (Ready to begin recruitment)	--
Ottawa Civic (Ready to begin recruitment)	--

We now have 2 sites actively recruiting patients, with another expected to start within the next week. The lead site in Sherbrooke (CHUS) has capped enrollment because they have reached 20 patients. We expect the team at Enfant-Jesus to being recruiting within the next month with Toronto General and Toronto Western soon thereafter.

As the summer holiday season comes to an end we anticipate the following sites will begin activities to up regulate: University of Alberta, Queen Elizabeth II and Sunnybrook.

We are also exploring the addition of a US site to join the pilot.

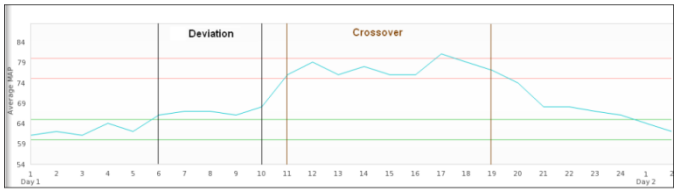
OBSERVATIONAL TUDY

Earlier in August we forwarded out the Observational study protocol to interested sites to review and confirm their participation. We will be following up with each of the sites invited to determine timelines and the go forward strategy.

With preparations for the definitive grant (to CIHR) and the horizon we will be conducting a face-to-face meeting in the Hamilton area on Oct 30th. Given the objectives of this meeting we will be inviting investigators, current collaborators and future collaborators to participate. Invitees should refer to the registration link in the previously circulated email to note your attendance.

New Collaboration

We are pleased to communicate to the group that we have established a new collaboration with the Institute For Safe Medication Practices (ISMP). ISMP is devoted to medication error prevention and safe medication use (http://www.ismp.org). We anticipate this relationship to include their involvement in the dissemination/uptake of our results.



Protocol Adherence Audit Tool

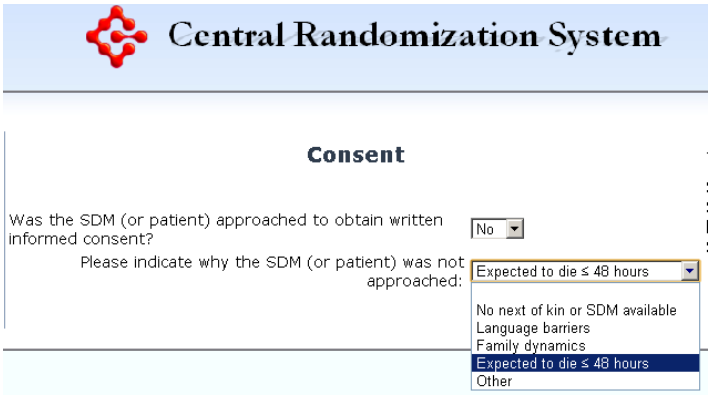
After several iterations and comprehensive testing, we are ready to roll out the Protocol Adherence audit tool we have developed and incorporated into the electronic data capture system (REDCap). Instructions on using the tools will be circulated in the next couple of weeks.

Moribund Patients: An Additional Reason to Exclude

Though not part of the formal exclusion criteria for the study, it has been determined that it is acceptable to not enroll patients who are otherwise eligible but, in the opinion of the clinical team, they are likely to die within 48 hours. **It is important for the site to document this reason for not enrolling a patient in the CRS.**

Entering an otherwise eligible patient who is expected to die into the CRS

1) Proceed to enter the presence of all inclusion criteria. SAVE form.
2) Enter the absence of any exclusion criteria. SAVE form.
3) Indicate a 'standard' consent on the Pre-Enrollment form.
4) On the Consent form, select 'no' for approached for consent. On the drop-down menu, select the reason why consent was not sought:
   "expected to die < 48 hours."



Change in Frequency of IQCODE Administration

Since we first implemented the study, we have removed the baseline IQCODE administration. Therefore moving forward all patients will have one IQCODE administered at the 6-month follow-up. *(Please note that v. 11-Jun-2013 of the SOP does NOT include this update. The next version of the SOP will be updated accordingly.)*

Now that we have some practical experience with a few sites engaging in recruitment activities we have had some excellent questions posed. We will often include FAQs in future newsletters. Please note that in addition, you may access our FAQ log, which is updated regularly, on our study website (http://ovation.ccctg.ca/).

Question	Answer
For patients that go to surgery, do we need to maintain the study assigned MAP target?	Yes. Randomized patients, who go to for surgery, should have their MAP maintained within the study assigned MAP target during surgery.
I have a situation where I have 2 difference concentrations of vasopressor administered to the patient within 1 hour. How do I record this in REDCap?	The rule of thumb to be followed in these instances is to record the last concentration of vasopressor recorded in the hour and the total volume administered to the patient for the entire hour.

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OVATION
OPTIMAL VASOPRESSOR TITRATION