



LESSONS LEARNED AT HCMC AFTER 2 ENROLLMENTS

Before enrollment:

1. Identify best forms of communication. Who is responsible for reporting to whom? What form? (text, page, phone)
2. Coordinators should have a hand-off plan at shift change.
3. Coordinators staying for the dive should anticipate spending dive time (1-2 hours) + an additional 1-1.5 hours.
4. The first few dives provide an opportunity to train other coordinators on the team.
5. Be clear about who is collecting what data during the dives.
6. A good simulation is very important and helps to identify areas that need to be addressed such as any needed equipment, drug availability and staffing shortages.
7. If using a multiplace chamber the location of Licox monitor may require an additional person to be available to provide readings.
8. Communicate with team (RTs in particular) the level of charting required
9. Have a plan for what you will do if you have a peds case (age 16 or 17 years). Staff licensure (for pediatrics) may need to be considered.

At enrollment:

1. As a team, plot out 5-6 days of activities – coverage for Study Coordinators and HBO staff will each require ~40 hours of staffing for dives. From the coordinator's perspective, the enrollments and dives can be demanding and time-consuming. Plan out all the future dives from day 1, so you can schedule staffing accordingly.
2. It is very useful for coordinators to stay around for the duration of the dive. They can ensure that study procedures are performed according to protocol, and provide real-time training to clinical staff regarding documentation of important data points. The presence of the study coordinator also demonstrates to the clinical team that the study team is invested in the study's success.
3. The first few dives provide an opportunity to train other coordinators on the team.
4. LAR may need time to think about study and whether they want their loved one to participate. Be prepared to excuse yourself, give them time to process what's happening and think about the study, and then come back to finish up the consent process.
5. Have the protocol page 24 and the emergency PI hotline number readily available.

After enrollment:

1. Debriefing with entire team is essential and provides an opportunity to identify problem areas and address issues before the next subject is enrolled



Other hints:

1. An iSTAT BG analyzer is very helpful to have.
2. Sometimes families find it helpful to see the HBO chamber and to see their loved one treated. Try to plan a family dive time. After things have settled down and a schedule is established, offer the family an opportunity to witness what happens when their loved one is receiving HBO treatment. This can be very reassuring and gives them sense that they are participating in something very important.
3. Study Coordinators are the 'Protocol Police' and responsible for making sure everyone on the team is prepared and communicating.
4. Compare your site's HBO safety checklist to the one provided by HOBIT leadership. Combining these lists into one, may save some time.