HCMC

CQIP Discussion

11.13.2023

HOBIT

HCMC Secret Sauce

- Clinical Workflow Integration for HOBIT

- Pooled Staffing Model: Acute Care Research Coordinator (ACRC) Group

HOBIT

HCMC Secret Sauce

- Clinical Workflow Integration
  - Research team to understand “typical workflow” (example: NSG is initial consult, SICU is the primary team, HBO has a daily schedule of patients)
  - Establish key “asks” within that workflow (example: need GCS off sedation and study intro from NSG team)
  - Establish what the clinical team can accommodate; what is the *minimum* effort required to accomplish the task (example: RT to transport but not to stay for dives)
  - Closed Loop Communication (example: enrollment debriefs,periodic general updates, problem-solving sessions with key staff)

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- Clinical Workflow Integration
  - Neurosurgery:
    - Strategic involvement of NSG residents and APP:
      - Identify and notify research team
      - Assist in obtaining key inclusion criteria - GCS off sedation, ABG, etc
      - Give clinical update to family and provide study introduction
  - HBO
    - HBO HOBIT coverage plan
    - iSTAT for ABG/PF calculation in HBO
    - Strategic involvement of RT for transport and safety check in HBO

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HCMC Secret Sauce

- Clinical Integration Workflow
  - SICU RN
    - SICU RN staff is a 1:1 assignment for a HOBIT dives
    - SICU RN staff can volunteer to be are HBO trained
      - this is a “skill” benefit for SICU RN recruitment
    - Early in screening, the research Team reaches out to SICU Charge (and Manager if needed) to confirm SICU staff availability for all HOBIT dives
  - RT
    - RT to assist with transport and vent transfer
    - “Heads-up” page upon resurfacing

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HCMC: Example Coordinator Notes

Discuss with NSG team:

- MRN of patient
- Current plan for major surgery (Can include neurosurgery, ortho surgery, abdominal ect.)
- Is there a plan to place an EVD? If not, what is the reason?
- Has family been located? **If yes, have they been updated clinically?**
- **Inform them (clinical team-NSG) that we will need family to be clinically updated prior to contacting them.**
- Ask to order an ABG, ethanol, and pregnancy(if female pt)
- Inform NSG we will need GCS off sedation and paralytics prior to randomization.**Get preferred contact info for future communication**

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Example Introduction “talking points” from the clinical team:
“(After a clinical update) HCMC is part of a national emergency research network that is conducting a clinical trial looking at potential treatment for patients with severe traumatic brain injuries, like the the one (patient name) has now. The choice to participate will be yours to make but we think (patient name) would be a good candidate for the study and we would like our research coordinator team to call you with more details about the trial, if you’d like. Beginning the treatment is time-sensitive, so they’ll be calling you shortly after we hang up. ”

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“Mock Consent” training
Example agenda:

- Navigation of the eConsent platform (and other resources)
- Demonstration of a study introduction by a seasoned attending PI/coordinator
- Trainee conducts a “mock” remote consent on camera (with PM or coordinator as the LAR)
- Trainee received feedback about the mock consent session from the group

HOBIT

Example talking points for the clinical team to introduce the study:
"Hello, my name is (research team member's name). I work with Dr. X from the NSG/SICU/NCC team from HCMC. I'm one of the research nurses (or coordinators) from the HOBIT study that Dr. X told you about just a bit ago. I'm so sorry that this has happened to your (family/spouse/child). I believe Dr. X gave you an update on the clinical situation/plan for care, is that correct? As Dr. X said, we believe (patient's name) would be a good candidate for the HOBIT study. I know this is a difficult time, but as Dr. X mentioned, the treatment is very time sensitive. This study is testing treatment for severe brain injuries, like the one (patient's name) has using oxygen given to patients in a special hyperbaric oxygen chamber. I'll get you a copy of the consent form with more of the details for us to discuss together (send the eConsent or hand them the ipad).

HOBIT

HCMC Secret Sauce

- Pooled Research Coverage Model
  - Mix of Lead Research Coordinators (example: Research Nurses) AND temp/casual support (IMGs, paramedics, RNs)
  - Mix of acute studies (example: stroke, EVT, sepsis, CC, cards)
  - All are cross-trained in enrollment & intervention oversight as required by the protocol
  - Remote and on-site support is utilized in tandem as needed.
- Co-Lead Coordinators
  - Divide the workload for HOBIT and provide balanced support for enrollments

Cost Analysis of a Pooled Coordinator Model versus Traditional Staffing for Acute Stroke Trials

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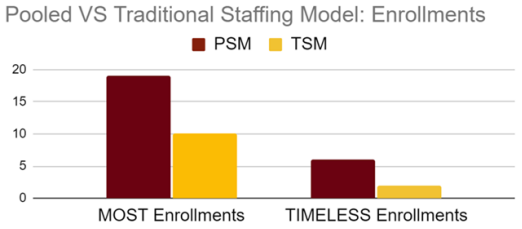
Background

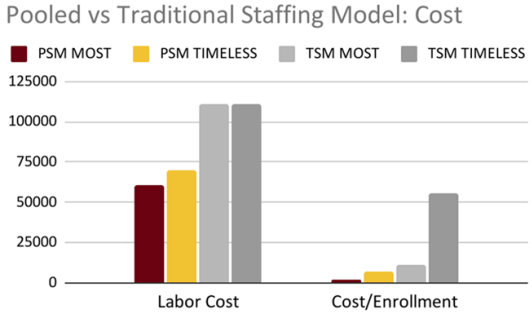
- Traditional staffing models (TSMs) assign a research coordinator to cover specific clinical trials.
- Pooled staffing models (PSMs) utilize research coordinators in enrollment and other tasks to cross-cover multiple clinical trials often enabling expanded coverage beyond daytime/weekday.
- We compared the PSM and TSM model to determine impact on overall cost to the study and trial enrollment.

Methods

- PSM costs were obtained from existing billing records for 1 year (1/1/21-12/31/21) for two Phase III acute trials (NCT03735979, NCT03785678).
- Actual cost for the PSM included the hourly rate: $78/hr and an on call retainer fee: $690/month.
- RN FTE rate was calculated based on the PSM model aggregate salary and institutional comparable RN salaries.
- Coordinator work included: enrollment, subject visits, data entry, query resolution, monitor visits, regulatory management, meetings, training/retraining.



Enrollments with 24/7 PSM VS Enrollments with M-F TSM



Results

- The calculated one-year cost (salary + fringe) of a 1.0 FTE RN research coordinator was $109,755.36.
- During the study period, there were 19 enrollments in MOST; 10 occurred outside daytime working hours.
- The MOST PSM cost was $60,813, equivalent to 0.55 FTE coordinator coverage in a TSM with 90.0% more enrolled subjects.
- There were 6 enrollments in TIMELESS; 4 occurred outside daytime working hours.
- The TIMELESS PSM cost was $70,134, equivalent to the cost of 0.64 FTE of standardized research coordinator in a TSM with 200% more enrolled subjects.

Conclusions

- PSMs may offer a solution to the staffing and coverage challenges faced by many institutions seeking to participate in emergent clinical trials.
- PSM for acute care clinical trials, like stroke, can be cost-effective for individual studies while increasing enrollment opportunities by supporting 24-7 coordinator coverage.

Panel Q & A