Smooth Sailing . . . Cellular Immunotherapy Trials Collaboration and Integration Process

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BACKGROUND

Cellular Immunotherapy Trials* involve new and complex scientific concepts and procedures. The rapid expansion of these trial types at our institution presented logistical and operational challenges. Care for participants involved in a cell therapy trial spans across multiple disciplines and specialty care areas where staff and providers frequently rotate shifts. Responsibilities and effective routes of communication between the Clinical Trials Office, clinical care teams and the cell therapy group needed to be more clearly defined. Additionally, there was a need for improved training and education for all key personnel involved in the treatment of participants receiving care on a cell therapy trial to ensure patient safety and clinical trial compliance.

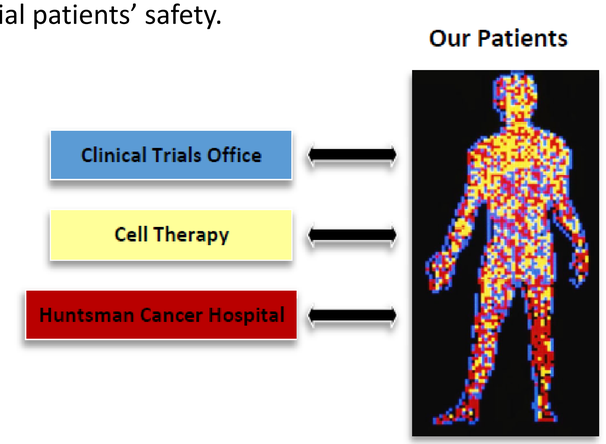
** CAR-T (Chimeric Antigen Receptor T-Cell)*
TIL (Tumor Infiltrating Lymphocytes)
TCR (T-Cell Receptor)
NK (Natural Killer) Cells

GOALS

- Provide education and training on departmental logistics for cellular immunotherapy trials.
- Define and integrate current workflows between the Clinical Trials Office, clinical care teams and cell therapy group to enable seamless patient care while adhering to the protocol requirements.
- Expand oversight of clinical research nurse liaison to include emphasis and involvement in cell therapy trials.

SOLUTIONS AND METHODS

- Establish monthly Cellular Immunotherapy focused meetings with Clinical Trials Office and clinical management to discuss updates on upcoming/active trials, enrollments, issues, positive outcomes, and trends.
- Development of a shared, trial specific cellular immunotherapy tracking spreadsheet used by all committee members was especially useful during the COVID pandemic for communication between groups.
- Implemented clinical logistics meetings prior to a Site Initiation Visit and at the time of first patient enrollment; attended by investigators, clinical care teams, clinical research and cell therapy groups.
- Provided trial specific nursing instructions, Fast Fact Sheets and contact information at the pre-Site Initiation Visit.
- Implemented training of Clinical Trials Office clinical research coordinators and clinic nurses on the new process.
- Inpatient management identified a skilled and focused nursing team to treat and care for the clinical research immunotherapy trial patients with ongoing training provided.
- Promote a consistent theme across groups for our clinical trial patients' safety.



OUTCOMES

- Increased cohesive, collaborative and unified environment between all areas that care for patients enrolled to complex treatment trials.
- Meeting regularly alleviates potential exacerbation of issues due to the consistent communication between meeting members.
- Implementation of an operational system which solidified new staff's knowledge of their role and responsibilities.
- Clinical Trials Office has appointed a solid tumor physician liaison to ensure consistent collaboration and education between the BMT/inpatient teams and principal investigators.

FUTURE PLANS

- Analyze deviation trends pre/post process implementation.
- Develop a survey to measure process improvement.
- Evaluate Report and Learn** trends since implementation.

*** Report and Learn = EMR (Epic) application to report issues contemporaneously for resolution, corrective action and improvements.*

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