

Operationalizing Protocols Through Treatment Plan Guidelines

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1. Background

In December of 2017 City of Hope (COH) implemented the electronic medical record (EMR), EPIC with Beacon treatment plans for drug protocols. At COH, research operations use Beacon treatment plans to build, standard of care and investigational product (IP) administration treatments plans for all patients on treatment trials. To support this endeavor, COH established positions, Protocol Content Administrators (PCA), to be filled with personnel with clinical background. The PCAs create each Beacon treatment plan according to the trial protocol, get study team (PI, nurses, coordinator and pharmacist) validation and send to the Beacon team for EPIC build. The research treatment nurses, due to time and resource constraints cannot always participate in validation meetings. To ensure uniformity and treatment nurse input, COH assigned lead infusion nurses from the Briskin Center for Cancer Research (BCCR) to review treatment plans after validation.

Upon review, differences between treatment plan structure and consistent plans were identified. Additionally, gaps existed regarding standard oncology nursing processes, such as dual nurse dosage verification, as drug dose calculations were not included in treatment plans. Resolution of these issues required repetitive communication between treatment nurses, research nurses and PCAs, resulting in staff frustration and IP administration delays. Additionally, the creation and validation of treatment plans required numerous team members; however, this costly process did not yield the highest quality product. COH needed an improved process and product, reduce staff concerns and resources while ensuring research patient safety.

2. Goals

We needed an improved process that resulted in:

- A treatment plan with instructions for standard, quality and safe patient care;
- Consistent and understandable treatment plans;
- Less utilization of staff time and resources; and
- A rapid study activation timeline.

3. Solutions and Methods

The lead BCCR treatment nurses, with the clinical research team, developed treatment plan guidelines. The development of guidelines also included clinical investigational drug pharmacists. The guidelines contained standard language for procedures and instructions to meet nursing needs, as well as protocol requirements. For example, under “research labs” the guidelines required the use of minutes for all collection windows (instead of hours or percentages) and inclusion of restrictions, such as peripheral draw only.

4. Outcomes

Category: Clinical Trial Operations – Work in Progress

The four-page guidelines offer consistent instructions for inclusion of study tasks and a training tool for new PCAs, research team members and BCCR treatment nurses. The tool will be implemented April 1 evaluating the above metrics.

5. Lessons Learned

Many institutions implemented Beacon treatment plans for research in different ways. With the best of intentions, COH focused on implementing treatment plans for all trials prior to activation, regardless of phase or disease type. While concentrating on ensuring consistency with the protocol, clinical information was omitted causing delays and potential patient safety concerns. The proposed guidelines, collaboratively developed, provide focused research and clinical standards, allowing for reliable, standardized and consistent research treatment plans.