Category: Cross-Cutting Innovation and Collaboration – Completed Project

Coordination of Care - Developing a Framework for Successful Admission and Treatment of Inpatient Clinical Trial Patients - Oncology Setting

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1. Background

The Simmons Comprehensive Cancer Center coordinates care for patients enrolled in clinical trials, including investigational agents that require inpatient admission. Safe and protocol-compliant administration depends on seamless coordination across multidisciplinary teams.

In Spring 2025, an event report identified delayed review of a research electrocardiogram (EKG) showing possible ST-segment elevation myocardial infarction (STEMI), resulting in infusion initiation prior to recognition of the abnormality. Review of the case revealed multiple process gaps with potential safety and protocol compliance implications.

Approximately 57 patients per year are admitted for clinical trial treatment, primarily within the hematologic malignancies and phase I DOTs.

Delivering cutting-edge clinical trials safely requires reliable, standardized inpatient and outpatient processes.

2. Goal

By six months post-implementation, we aim to reduce inpatient care coordination–related safety events for patients admitted to Clements University Hospital for clinical trial treatment to zero by implementing a standardized admissions framework, structured communication pathway, and targeted staff training program.

3. Methods

Following an initial event report in April 2025, a multidisciplinary working group was formed to address identified care coordination gaps. The group met monthly from May to October 2025 and included representatives from inpatient and outpatient pharmacy, clinical research, advanced practice providers, inpatient nursing leadership (bed control and unit leaders), and a physician champion.

4. Outcomes

A fishbone diagram demonstrates the variety of opportunities identified for improved coordination (Figure 1).

Intervention:

The following interventions were planned and implemented:

1. Access updated for all research personnel to scan EKGs to the electronic medical record (EMR) enabling real time review by provider regardless of location

2. Naming convention established for uploads in Epic, and workflow created to facilitate documentation of review
3. Established standardized email template, schedule and recipient list with a daily operating procedure to ensuring consistency moving forward
4. Nurse will obtain appropriate approvals prior to order of emergency medications
5. Eliminated duplicate verification by pharmacy
6. Inpatient advanced practice providers (APPs) included in in-service communications
7. Established scope document incorporated into new inpatient APP onboarding
8. Site Initiation Visit (SIV) invitation extended to additional inpatient staff and materials are shared with outpatient and inpatient teams
9. Inpatient investigational drug service (IDS) pharmacy will perform a prohibited medication review prior to cycle one day one (C1D1)

In addition, follow up meetings occurred post intervention to ensure effectiveness, and effective interventions were established into written Daily Operating Procedure to ensure they are long-lasting.

Results: The group met following all interventions and reported appropriate and consistent communication. No further coordination of care events have been reported for patients being admitted for inpatient treatment on clinical trials.

5. Lessons Learned and Future Directions

A single safety event prompted multidisciplinary collaboration that identified system gaps and led to effective, sustainable solutions. Strengthened care coordination between clinical and research teams improves patient safety and supports SCCC's role as a leading destination for complex clinical trials.

Figure 1