

Developing a Coordinated Care Framework for the Admission and Management of Inpatient Oncology Clinical Trial Participants



Erin Williams, MBA, Ellen Siglinsky, Silviya Meletath, MBS, Shannon Garcia, MS, Zhixin Jiang, MPH, MPAS, PA-C, Sonia Gonzales, PharmD, BCOP, Stefanie Conley, RPh, PharmD, BCOP, Colleen Riley, BSN, RN, OCN, Sarah Tatlock, BSN, RN, TCTCN, Neely Helton, BSN, RN, Teresa Bear, Christine Hong, PharmD, MBA, BCOP, Sawsan Rashdan, MD

Background

Simmons Comprehensive Cancer Center (SCCC) coordinates care for patients enrolled in clinical trials, including investigational therapies that require inpatient admission. Safe, protocol-compliant treatment relies on effective coordination among multidisciplinary teams across inpatient and outpatient settings.

In Spring 2025, an event report identified a delayed review of a research EKG showing a possible ST-elevation myocardial infarction, resulting in initiation of an investigational infusion prior to recognition of the EKG finding. Case review revealed multiple process gaps with potential risks to patient safety and protocol compliance.

Approximately 57 patients annually are admitted for clinical trial treatment, primarily within Hematologic Malignancies and Phase I clinical programs.

As participation in complex clinical trials continues to grow, standardized and reliable processes are essential to ensure safe, coordinated delivery of investigational therapies.

Analysis

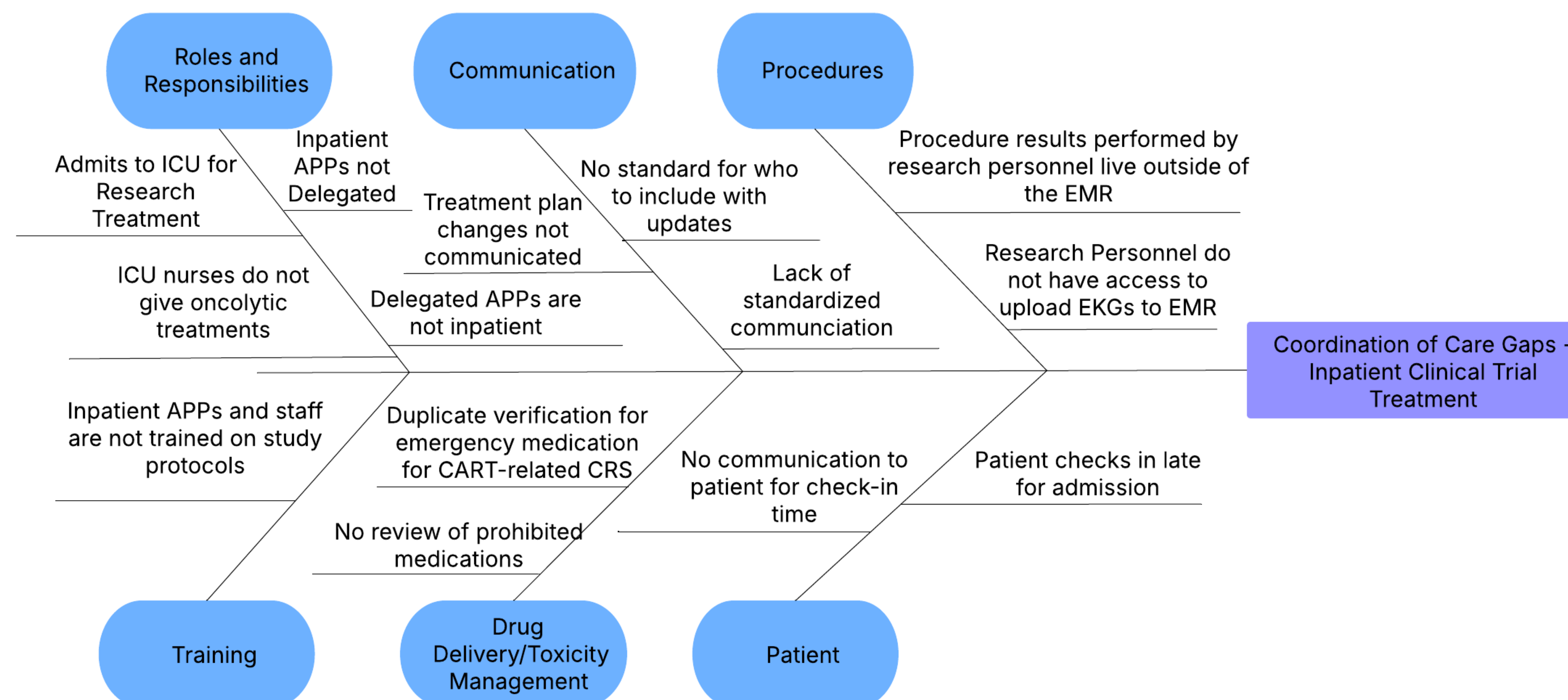
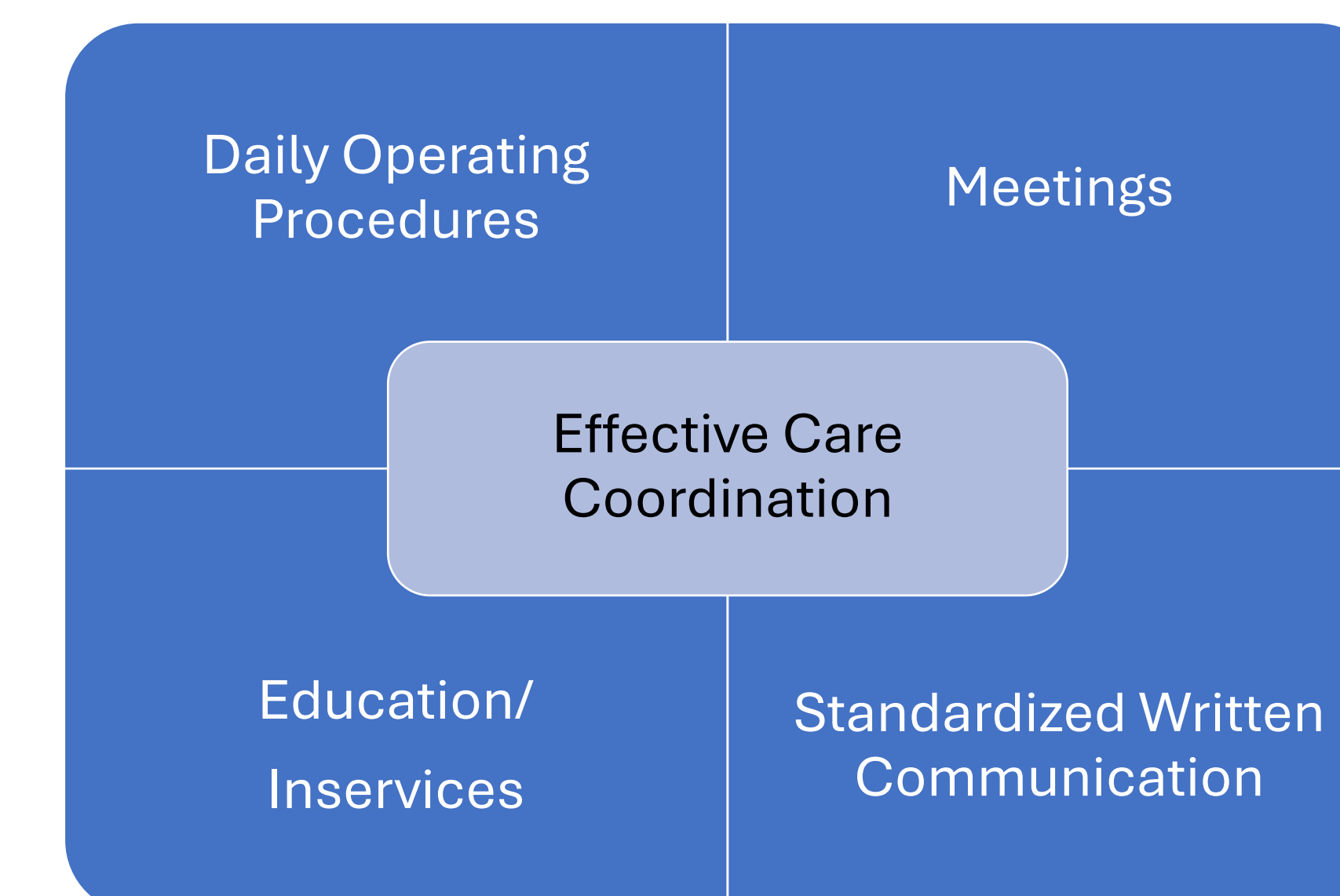


Figure 1. Fishbone diagram of factors contributing to coordination of care gaps for inpatient clinical trial therapies

Interventions

Several interventions were planned and implemented (see **table 2**). In addition, follow up meetings occurred post intervention to ensure effectiveness.

Figure 2 reflects the key components to sustainability including established written procedures, regular meetings, standardized training, ongoing and standardized written communication.



Goal

By December 2025, the SCCC inpatient care units will achieve zero inpatient coordination-related safety events for oncology clinical trial patients admitted to Clements University Hospital for treatment.

Methods

Following a safety event in April 2025, a multidisciplinary quality improvement workgroup was convened to evaluate inpatient clinical trial care coordination processes. From May–October 2025, the team conducted workflow analysis and identified gaps in communication, role clarity, and protocol verification.

Using a Plan–Do–Study–Act framework, the group implemented targeted interventions including a standardized admission framework, structured communication pathway, and focused staff education to improve safe and protocol-compliant care delivery.

The workgroup included representatives from inpatient and outpatient pharmacy, clinical research, advanced practice providers (APPs), inpatient nursing leadership (bed control and unit leaders), and a physician champion.

Table 1: Interventions

- Expanded Electronic Medical Record (EMR) access for research personnel to allow direct scanning and upload of ECGs, enabling real-time provider review regardless of location
- Established a standardized EMR naming convention for ECG uploads and implemented a workflow to support consistent documentation of provider review
- Developed a standardized email template, distribution list, and scheduled communication process, supported by a daily operational procedure to ensure consistent reporting and follow-up
- Eliminated duplicate verification by pharmacy for emergency medications when nurses are following established process to obtain appropriate approvals prior to order.
- Established a standard to include inpatient APPs in in-service communications.
- Incorporated APP research scope document into new inpatient APP onboarding.
- Established a standard to extend invitations to the study Site Initiation Visit (SIV) to additional inpatient staff and share materials with outpatient and inpatient teams.
- Established a process for inpatient IDS pharmacy to perform a prohibited medication review prior to C1D1.

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.

Conclusion

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.