



Enhanced Interdisciplinary Communication Between Inpatient Clinical Staff and the Research Team

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Background

Clinical trials have grown in complexity over the years with an increased number requiring inpatient hospitalization due to central lab demands and toxicity monitoring for side effects such as cytokine release syndrome or tumor lysis syndrome. Given this increased complexity seen at our institution, we anticipated a high potential for communication breakdown that could lead to protocol deviations. It became clear that there was a need for a standardized workflow and an interdisciplinary workgroup to foster a partnership between the Clinical Trial Office (CTO) and the inpatient clinical team to ultimately improve treatment delivery and mitigate potential deviations.

Goals

- To improve interdisciplinary communication for clinical trials that require inpatient hospitalization.
- To provide clear guidance and training for the CTO staff to standardize communications to the Inpatient clinical team.
- Reduce protocol deviations on inpatient clinical trials.

Figure 1. Email Template for Inpatient Notification

Inpatient Clinical Trial Participant	
Clinical Trial Name	
Patient name and MRN	
Admission Date	
Treatment date	
Protocol defined admission length/anticipated discharge date	Also include admission reason Ex: 48 hr post dose admission to monitor for CRS
Enrollment	Do we have it already? Note and attach/plan for enrollment needs
ICE assessments/plan for completion	Attach protocol specific form if needed or delete row if not applicable
Treatment plan name:	
Subject Number:	
Dose Level:	
Primary CRC/CRN	
Back up CRC/CRN	
Treating Physician (primary contact for patient concerns):	
PI (Secondary or escalation contact):	
Travel Distance:	*If known* Helpful to include if far from Froedtert, or if patient staying close at Kathy's House etc.
Tip Sheet/Protocol Guidance document name in SharePoint:	*Copy SharePoint link to specific tip sheet here*
Additional Notes:	

Solutions and Methods

An Inpatient Translational Research Unit (IP TRU) workgroup comprised of CTO staff, IP TRU nurse coordinator, clinical nurse educator, clinical nurse specialist, and inpatient advanced practice providers was created to improve interdisciplinary communication. The IP TRU workgroup started monthly meetings to discuss logistics, process improvement, and review inpatient protocol deviations. If physician feedback or approval is deemed necessary, the IP TRU Physician Liaison attends meetings. Additionally, the IP TRU was created and opened in October 2022 to improve consistency of the inpatient team and an IP TRU nurse coordinator was hired as a liaison between the CTO and the IP TRU.

To standardize CTO workflow an inpatient guideline was created detailing the inpatient study conduct and admission process for the CTO staff. Email templates (**Figure 1**) and contact groups were created to ensure adequate and uniform communications regarding inpatient study participants. The inpatient guideline and email templates were reviewed by the IP TRU workgroup to verify that accurate and relevant information was included. Training on these materials was provided and recorded for the CTO staff and edits to the inpatient process, quick part templates, or guideline are disseminated via email as needed. Training was provided and recorded again in October of 2023 as part of a CTO refresher series.

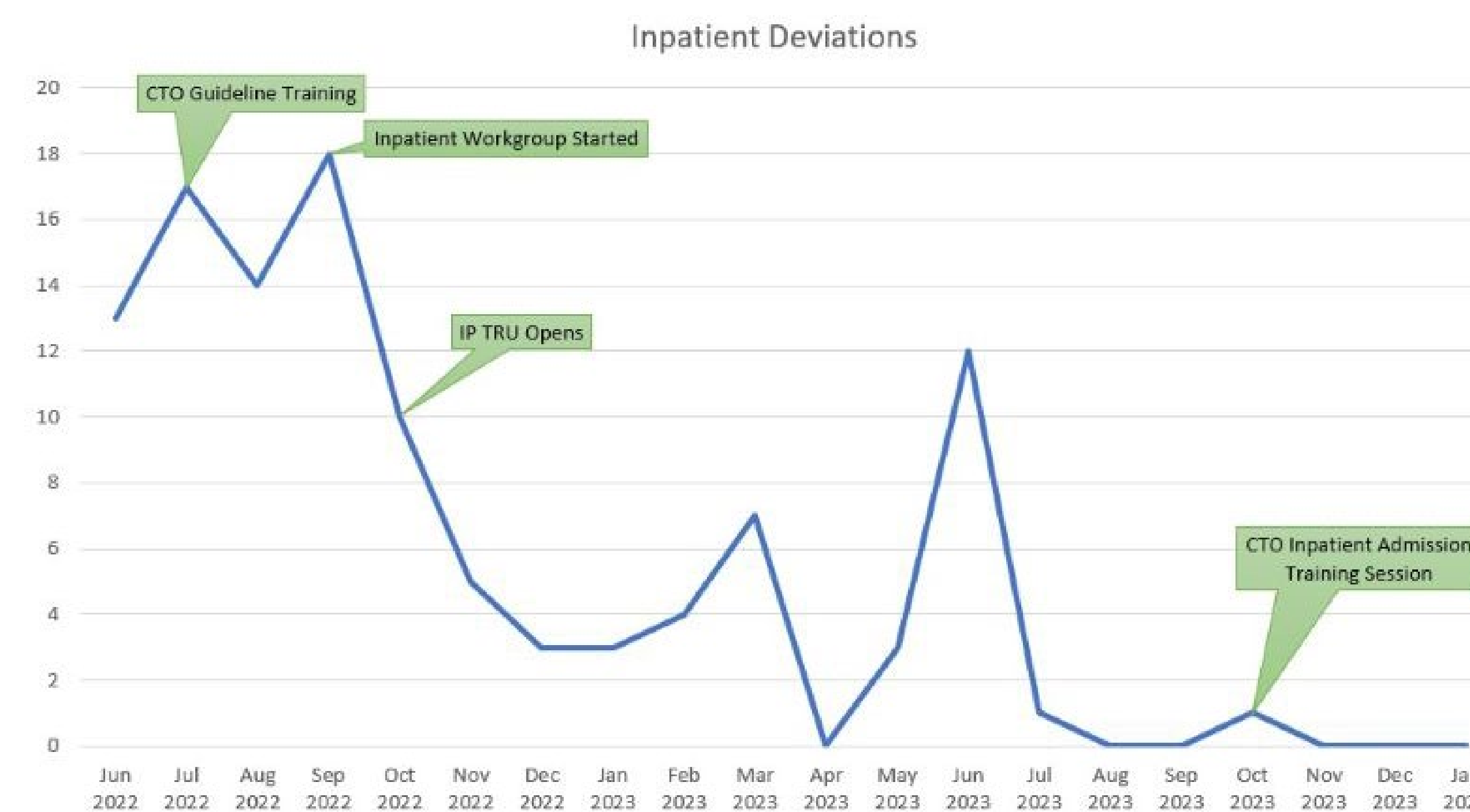
To monitor the impact of the IP TRU and communication interventions, we began tracking protocol deviations (**Figure 2**) and retroactively compared them to deviation logs prior to implementation.

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Outcomes

- Consistency in communication from the CTO to the inpatient team was achieved.
- Interdisciplinary communication has improved through the inpatient workgroup.
- Protocol deviations for inpatient research have decreased since implementation of the IP TRU, CTO guideline, and IP TRU workgroup. Prior to the IP TRU workgroup there were 18 deviations in September 2022, and since October 2023, we have not seen any deviations. Further, in the past 6 months there has only been 1 deviation (average: 0.17 deviations/month).

Figure 2. Protocol deviations related to inpatient care



Lessons Learned and Future Directions

- Over time, the need for IP TRU meetings has decreased from monthly to quarterly.
- We will continue to monitor deviations to ensure the current trend is maintained.
- Given CTO staffing turnover it will be important to monitor deviations and communication errors during the IP TRU workgroup to assess when a retraining is needed.