

Flushing Out Deviations: An Interdisciplinary Approach to Investigational Treatment Compliance

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1. Background

Yale New Haven Hospital (YNHH) treats clinical trial participants on multiple infusion units in New Haven, CT, as well as across fifteen Network Sites throughout Connecticut and Rhode Island. Yale Cancer Center's Clinical Trials Office (YCC CTO) noted recurring deviations in infusion stop times across infusion units for participants on oncology clinical trials through Spring 2022. A root cause assessment revealed variability in flushing practice and End of Infusion (EOI) time documentation across YNHH infusion units. The variability resulted in study drug not being completely flushed through the line, or not within the required time of the applicable protocol.

2. Goals

The goal of the multidisciplinary working group was to implement standard flushing guidelines and infusion time documentation for investigational study drugs across all infusion units, thereby minimizing the risk of infusion time-related deviations and increasing protocol compliance.

3. Solutions and Methods

A multidisciplinary approach was utilized to develop a standard practice for infusion flushing. Representation included members from YNHH nursing, Investigational Pharmacy, and the YCC CTO. YNHH Nursing reviewed current infusion flushing practices to identify gaps and opportunities for standardization and the application of "Small Volume Infusion Flushing Guidelines" was utilized as follows:

1. Verify investigational drug per policy
2. Set pump rate as specified on the drug bag label
3. Set volume to be infused (VTBI) to 20 mL less than stated on the bag
4. Upon completion of the infusion (pump alert):
 - a. Attach secondary Normal Saline/D5 (drug-specific) line to the top side port of the intravenous (IV) tubing
 - b. Set the VTBI for 20 mL
5. Pump alarms at the completion of the infusion
6. Flush line per policy/protocol OR as otherwise specified per study sponsor guidelines.
7. Document in the Medication Administration Record (MAR) the end time of the infusion (time of completion of the 20 ml flush) in real time.

The change in practice ensured all drug remaining in the line was infused and consistently documented at EOI. An updated practice was written, disseminated, and staff trained across all infusion units within the YNHH network. The new practice went live on May 31st, 2022. As part of normal practice, YNHH hosted daily cross-network safety meetings with CTO representation, where any new infusion-related deviations were discussed, and re-training opportunities identified post-roll out.

4. Outcomes

Collaboration between departments improved knowledge and practice regarding infusion deviations and infusion stop time documentation. The application of the new practice improved protocol

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compliance and ensured that all of the investigational product was infused per protocol. A 72 percent decrease in EOI stop time deviations was noted and practice standardization was achieved. Now nearly two years later, this practice is still in use with sustainably low levels of EOI stop time deviations.

5. Lessons Learned and Future Directions

Standardization, implementation, and education of the investigational study drug flushing required an innovative, interdisciplinary approach. Collaboration of hospital and research staff ensured better compliance, patient safety, and trial integrity with notable success. It is recommended that safety-related deviations be discussed with hospital partners and a collaborative approach be taken to correct and prevent future occurrences.