YaleNewHavenHealth
Smilow Cancer Hospital

Flushing Out Deviations: An Interdisciplinary Approach to Investigational Treatment Compliance

Kira Pavlik, Mario Lupone, Kelli-Ann Mancini, Thomas Ferencz, Prashant Patel

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Background

- Yale New Haven Hospital (YNHH) treats clinical trial participants on multiple infusion units throughout the states of Connecticut and Rhode Island.
- Recurring deviations were noted in infusion stop times across infusion units for participants on oncology clinical trials through Spring 2022.
- Root cause assessment revealed variability in flushing practice and End of Infusion (EOI) time documentation across YNHH infusion units.
- Variability resulted in study drug not being completely flushed through the line, or not within the required time of the applicable protocol.

Goals

- A multidisciplinary working group was established to implement standard flushing guidelines and infusion time documentation for investigational study drugs across all infusion units.
- Goal to minimize infusion time-related deviations and increase protocol compliance.

Solutions and Methods

- Multidisciplinary working group included representation from YNHH nursing, Investigational Pharmacy, and the YCC CTO.
- Review of current infusion flushing practices revealed gaps and opportunities for standardization and the application of “Small Volume Infusion Flushing Guidelines” was utilized as shown in Figure 1.
- 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.

Figure 1. Small Volume Infusion Flushing Guidelines

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

Figure 2. Infusion-Related Deviations

Outcomes

- The change in practice ensured all drug remaining in the line was infused and consistently documented at EOI.
- Collaboration between departments improved knowledge and practice regarding infusion deviations and infusion stop time documentation.
- The application of the new practice improved protocol compliance and ensured that all of the investigational product was infused per protocol.
- A **72% decrease in EOI stop time deviations** was noted and practice standardization was achieved.
- Nearly two years later, this practice is still in use with sustainably low levels of EOI stop time deviations (Figure 2.).

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.

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