Priming and Administering Intravenous (IV) Investigational (INV) agents Guideline

Departments: Cancer Center Translational Research Unit (TRU), Day Hospital, Inpatient Medical Oncology units: 7, 8, and 9 CFAC
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Purpose: To provide guidance to clinical staff administering investigational cancer agents and achieve documentation of accurate start and end of infusion time points. Priming INV tubing with drug will lead to accurate samples collected based on these time points, patients to get small volumes of drug timely, and/or to titrate drug at safe increments intended per protocol. This guideline also provides guidance regarding accepted variation in infusion times.

Guideline:

1. Any drug with "INV" or "investigational" in its name will be primed with drug in pharmacy following institutional standards on 3 port primary Polyethylene (PE) lined or non PE lined tubing as applicable per institutional standards with attached Close System Transfer Device (CSTD).
    a. INV agents administered via syringe pump will be primed on compatible syringe pump tubing and will be administered following syringe pump administration workflows
    b. In event of product shortage attempts will be made to replace 1:1 as close as available by manufacturer.
2. Pharmacy will apply "line primed with drug" sticker just proximal to where tubing attaches to patient.
3. Nurse will set up INV infusion as follows:
    a. INV agent will be on 3 port primary tubing administered through Alaris CareFusion pump and will attach to closest connection to patient.
    b. Nurse will spike compatible mini bag solution with short primary tubing to prime the short primary line (this will clear the line after INV agent bag dry).
    c. Clamp short primary tubing.
    d. Place short primary tubing in separate channel.
    e. Connect short primary tubing to the smart site on 3 port primary tubing under the pump.
    f. As applicable, set up TKO line on a third channel, if not already set up.

g. Set up as above and start infusion of INV agent

h. Let INV agent on 3 port primary line run dry to pump.

i. Unclamp compatible solution on short primary line. Program channel at the same rate as the infusion for a volume of 20 mL to clear investigational agent from the line.

4. Factors contributing to an acceptable variance in infusion time

   a. Infusion bags contain an accepted variance of +/- 5-10% overfill
   b. Infusion pumps used to infuse bags have an accepted variance from the programmed rate of +/- 5%
   c. Syringe pumps have an accepted variance from the programmed rate of +/- 2%
   d. To ensure all Investigational Product (IP) reaches the patient all infusion lines are flushed with 20 mL of compatible IV fluid to clear the line of IP
      i. There is a small amount of time required to transition to infusion of a flush
      ii. The end of infusion is documented upon completion of compatible flush

5. **Definition of start time:** When the pump is started with the programmed drug rate regardless of if line is primed with drug or not (also known as Start of Infusion (SOI)).

6. **Definition of stop time:** After the drug in infusion bag is completely infused and the line is clear of drug (also known as End of Infusion (EOI))

7. **Definition of clearing the line of the drug:** Administering the entire volume of active drug, including what is remaining in the infusion line.

    a. Some sponsors may refer to this as the "flush" or "flushing the line"

    b. Clearing all active drug from the line using compatible fluid at the rate the active drug was running at to ensure total dose is administered.

Available Equipment:

c. BD Alaris Pump Infusion Set (3 port primary tubing)

    i. Non DEHP

    ii. Volume of 26 ml, from bag to patient without additional extensions

    iii. Ref# 2426-0007

d. BD Alaris Pump Infusion Set, Low Sorbing (PE Lined) (3 port primary tubing)

    i. Non DEHP

    ii. Volume of 25ml, from bag to patient without additional extensions

    iii. Ref# 24600-0007

e. BD Alaris Pump Infusion Set (Long primary tubing)

    i. Non DEHP

    ii. Volume of 25ml from bag to patient without additional extensions

    iii. Ref# 2420-0007

f. BD Alaris Pump Infusion set, low sorbing tubing, (PE lined) (Short primary tubing)
    i. Non DEHP
    ii. Volume of 15 ml from bag to end of tubing
    iii. Ref # 11426864

g. Baxter clearlink system, Extension set, 0.2micron downstream filter
    i. Non DEHP
    ii. Volume of filter: 5.1 ml
    iii. Ref # 2H8671

h. BD Secondary set
    i. Non DEHP
    ii. Volume 13 ml from bag to end of tubing
    iii. Ref # MS3500-15

i. In cases of institutional practice change or product shortage, volumes listed above and flushing volumes are subject to change and will be adapted to meet program operational needs.

Refer to institutional policy, Elsevier, and specific clinical trial provided equipment for additional information on administration.

References:
Elsevier Clinical Skills:
ONS
Policy Hazardous drug administration
Discussions with other academic institutions
BD rep

Scope: ✓RN ☐Tech/MA ☐Scheduler
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