Radiopharmaceutical Infusion Methods

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THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
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Disclosures

- No financial disclosures
- NMTCB – Board of Directors

Purpose

- To provide a general overview of the benefits and limitations of each infusion technique while adhering to the infusion criteria.

- Overview is based on previous experience with intravenous infusions for investigational and FDA-approved therapeutic radiopharmaceuticals.

Agenda

- Compare three intravenous infusion methods for therapeutic radiopharmaceuticals:
  - Syringe Pump
  - Gravity Method
  - Peristaltic Pump

- Focusing on patient ready to use doses in a vial

Infusion Criteria

1. Safely administer intravenous therapeutic radiopharmaceuticals to patients.

2. Adhere to the ALARA principle when handling and infusing radiopharmaceuticals.

3. Easily identify the start and end of a continuous intravenous infusion.

Syringe Pump Dose Considerations

- Assay: was the radiopharmaceutical measurement verified in a vial or syringe?
  - Need to account for the effects of geometry
- Therapeutic dose transfer from vial to syringe
- Residual Activity: materials used for the vial-to-syringe transfer
- ALARA: multi-cycle therapeutics require manipulation per treatment cycle per patient
- Increased risk of spillage or equipment contamination

Syringe Pump Considerations – USP 825 Section 3

- Therapeutic dose transfer from vial to syringe
- Effective as of Nov 1st, 2023
- Immediate use criteria, sterile radiopharmaceuticals must be administered within 1 hour of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub, or needle) to ambient air, whichever is first.
- Need to consider infusion duration for immediate use criteria

Syringe Pump Considerations – USP 825 Section 3

- Alternative
- Drawn dose in an Isoclass 5 environment, using appropriate PPE whereby staff is annually trained in aseptic dose drawing, and media-fill testing
- BUD is specified at 12 hours under ISO Class 5 and SPRA conditions, per USP 825 Table 7
  - Unless the radiopharmaceutical expires before the 12-hour BUD

Syringe Pump

- Graseby 3100 syringe pump
- Mechanical syringe push
- Programmable Infusion rate for large-volume syringes
- Common setup: radio pharm syringe, three-way-stop cock, saline flush connected to an extension tubing out to the patient
- Syringe clamp identifies the size of the syringe used for the infusion

Syringe Pump

- Observe the start of infusion from a distance
- Dose remains in extension tubing
- Requires staff to push remaining radiopharmaceutical manually
- Saline flush with total syringe shield

Syringe Pump Shielding

- Total Syringe shield, designed for the Graseby 3100 pump
- Lid with lead/tungsten glass for syringe observation
- Heavy! 91lbs
- Maneuverability is difficult

Infusion Criteria – Syringe Pump

1. Safely administer intravenous therapeutic radiopharmaceuticals to patients
   - Conforms

2. Adhere to the ALARA principle when handling and infusing radiopharmaceuticals
   - Additional exposure due to dose draw into a syringe and manual saline flushing post infusion
   - Proximity to the patient

3. Easily identify the start and end of a continuous intravenous infusion
   - Can identify the start of infusion (knowing the extension tubing volume)
   - Infusion is not continuous, requiring manual saline flush to ensure all the therapeutic radiopharmaceutical was administered

Does the syringe pump adhere to the infusion criteria?

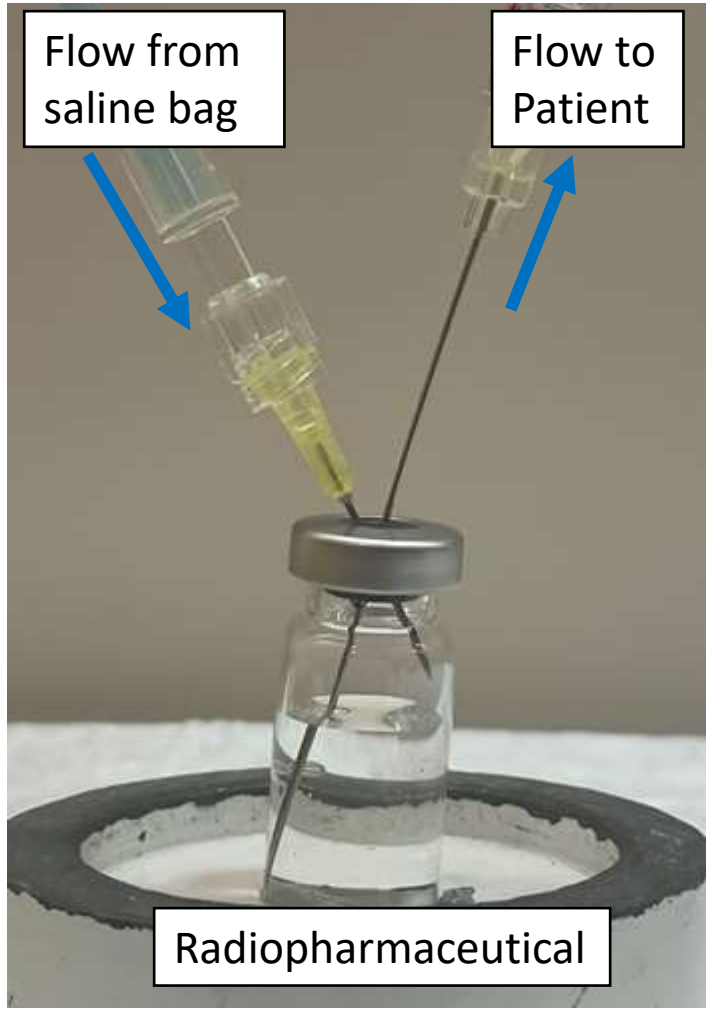
1. Safely administer intravenous therapeutic radiopharmaceuticals to patients
   - Conforms

2. Adhere to the ALARA principle when handling and infusing radiopharmaceuticals
   - Additional exposure due to dose draw into a syringe and manual saline flushing post infusion
   - Proximity to the patient

3. Easily identify the start and end of a continuous intravenous infusion
   - Can identify the start of infusion (knowing the extension tubing volume)
   - Infusion is not continuous, requiring manual saline flush to ensure all the therapeutic radiopharmaceutical was administered

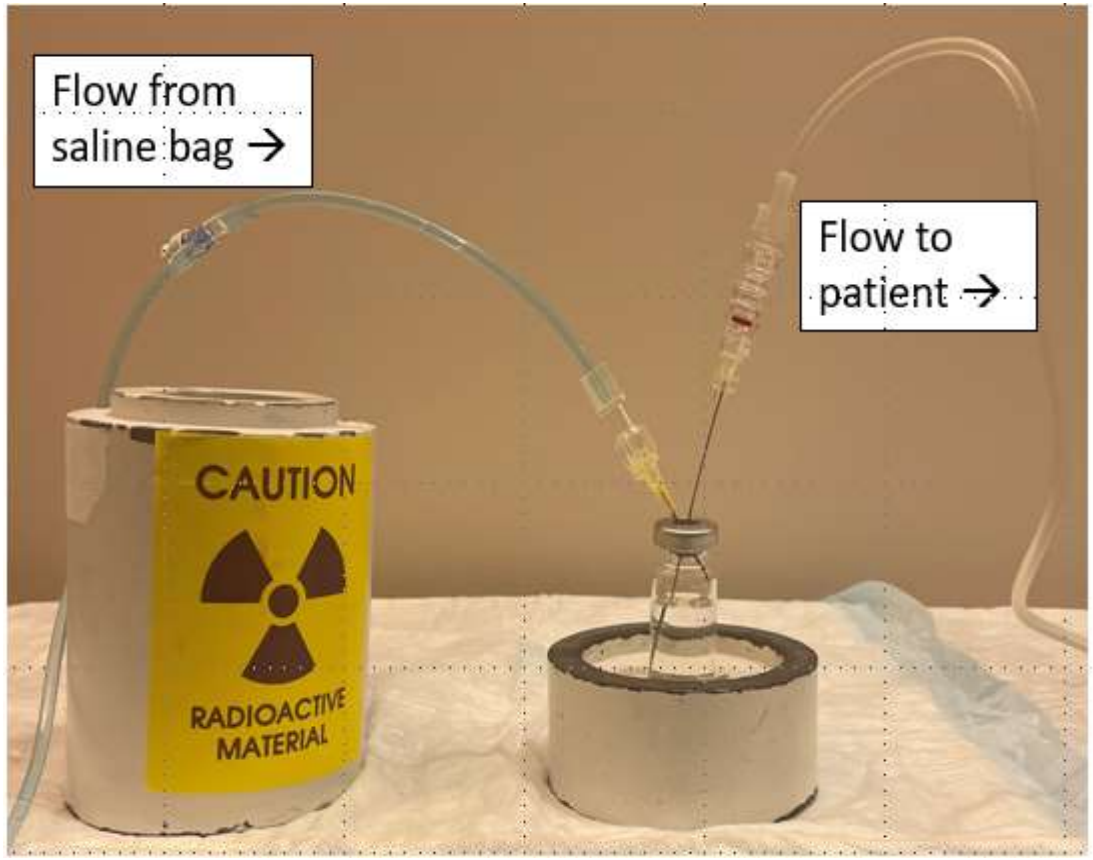
Gravity Method

- Common setup, saline bag with extension tubing connected to a short needle, not touching the radiopharmaceutical
- Long needle in the radiopharmaceutical out to the patient
- Use a clamp to regulate the saline flow into the vial
- Positive vial pressure created from saline pushes the therapeutic dose to the patient



Gravity Method

- Infusion method dilutes the radiopharmaceutical over time with saline
- Potential areas of spillage where needles are inserted into vial septum
- Observe infusion from a distance
- Start and End of Infusion:
  - Digital ion chamber can aid with identifying dose exposure fluctuations to stability



Infusion Criteria – Gravity Method

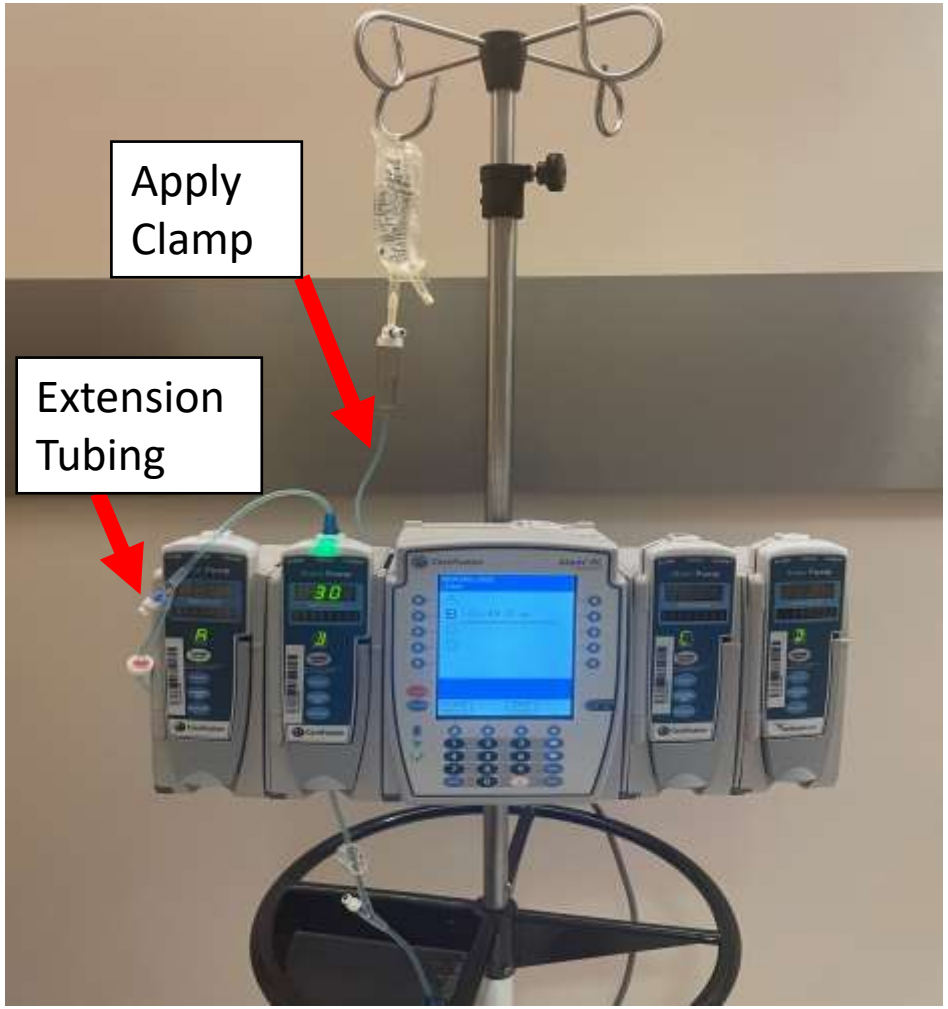
1. Safely administer intravenous therapeutic radiopharmaceuticals to patients
   - Conforms

2. Adhere to the ALARA principle when handling and infusing radiopharmaceuticals
   - Allows for staff to keep their distance during the infusion

1. Easily identify the start and end of a continuous intravenous infusion
   - Continuous saline dilution adds difficulty in identifying the start and end of the infusion
   - Single vial applicable

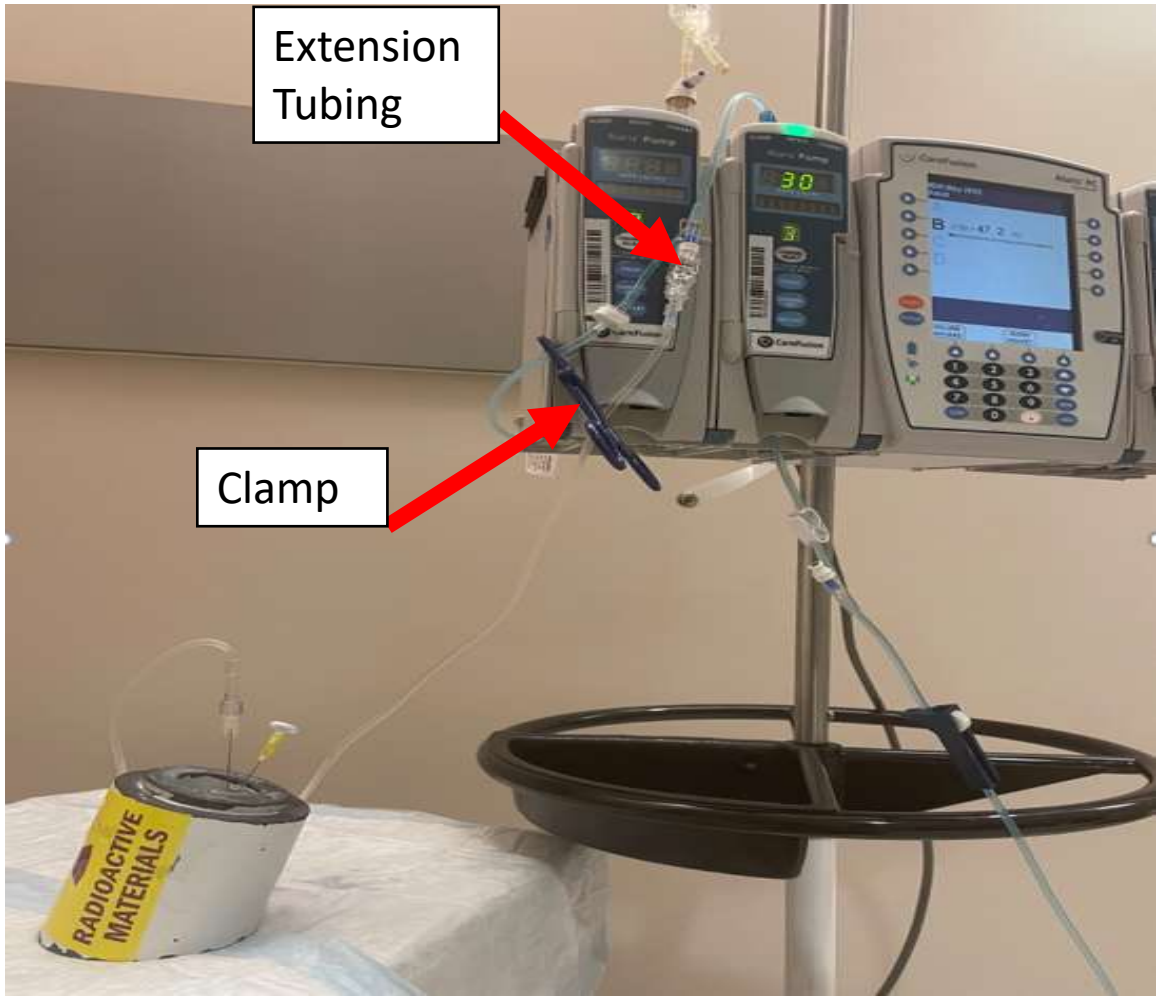
Peristaltic Pump

- Peristaltic pump uses a series of small motor rotations to deliver intravenous medications in a closed tubing system
- Add extra clamp and tubing to infuse from a vial
- Operation
  - Volume to be administered (VBTI)
  - Infusion rate (mL/hr)
- Negative pressure in the vial
- Notification Alarms

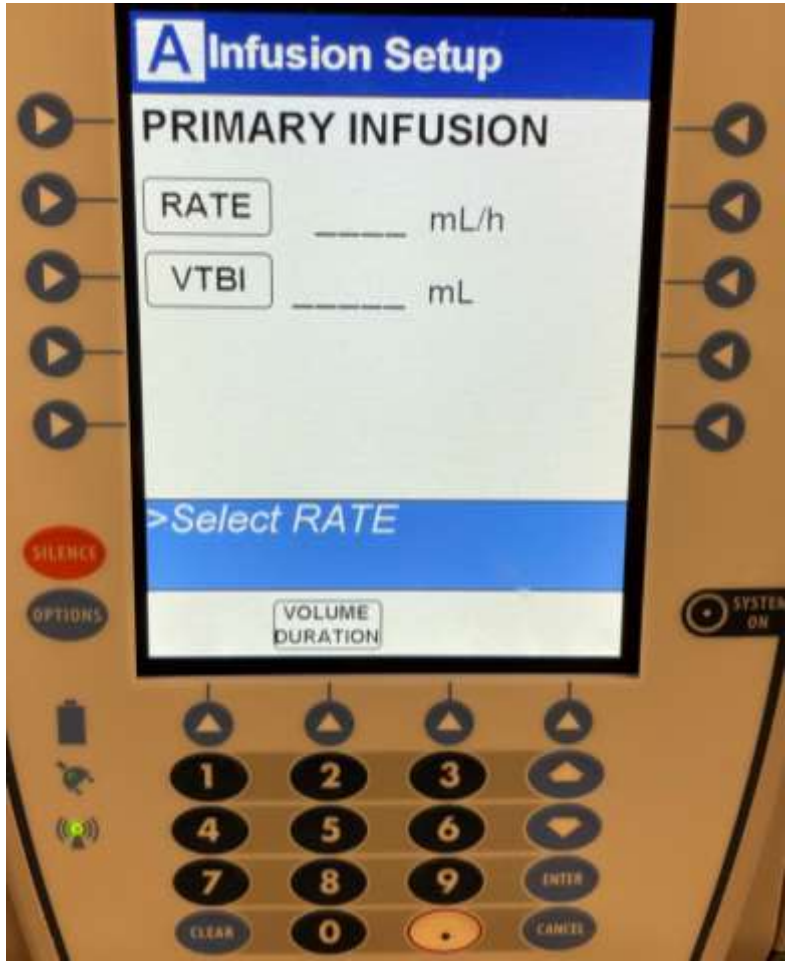


Peristaltic Pump – Single vial

- Clamp and additional extension tubing for infusion
- Accurate and precise infusion of a therapeutic radiopharmaceutical based on volume and duration of infusion
- Observe infusion and patient from a distance



Peristaltic Pump – Infusion Calculator



Dose volume to be Infused (mL)	10	Enter the radiopharm volume to be infused (mL)
Volume of Alaris extension tubing (mL)	20	Enter the volume of the extension tubing (mL)
Duration of Infusion (min)	20	Enter the duration of radiopharm infusion in minutes
Infusion Rate (mL/Hr)	30	Calculated infusion rate to be entered in the Alaris pump (mL/Hr)
Volume to be Administered VTBI (mL)	30	Calculated volume to be entered in the Alaris pump (mL)

Peristaltic Pump – Infusion SOI + EOI

- Identifying the start and end of the radiopharmaceutical infusion
- Using dosage volume, staff can easily identify the start and end of infusion

Alaris Pump Volume Monitoring		
Alaris pump volume indicating start of infusion (mL)	10	Indicates start of infusion based on dosage volume (mL)
Alaris pump volume indicating end of infusion (mL)	0	Indicated end of infusion based on dosage volume (mL)

Peristaltic Pump – Experience

- ^{177}Lu-Biotin + AvidinOX
- ^{177}Lu – OPS201
- ^{177}Lu-Dotatate (Netter 1 & Netter 2)
- ^{177}Lu-Dotatoc
- ^{177}Lu-PSMA - 617 (PSMAfore + PSMAddition)
- ^{131}I - PSMA
- ^{131}I - Azedra
- ^{177}Lu- FAP - Fibroblast Activation Protein
- ^{225}Ac-Dotatate

Infusion Criteria – Peristaltic Pump

1. Safely administer intravenous therapeutic radiopharmaceuticals to patients
   - Conforms

2. Adhere to the ALARA principle when handling and infusing radiopharmaceuticals
   - Allows for staff to stay 6 feet away from patient and dose

3. Easily identify the start and end of a continuous intravenous infusion
   - Continuous infusion
   - Can easily identify the start and end of infusion
   - Ability to sequentially administer single or multiple vials*

Overview

- **Syringe Pump** – considerations, dose geometry, USP 825, heavy pump shielding
- **Gravity Method** – infusing from a vial, USP 825, saline dilution makes identifying the start of infusion and end of infusion difficult
- **Peristaltic Pump** – programable pump infusion from a vial, USP 825, has infusion safety features, can observe continuous infusion from a distance, and has a precise and accurate infusion method

Conclusion and Next Steps

- Consult with your Authorized User, Radiation Safety Officer, and department leadership to identify the best infusion method for your facility
- Advance guidelines for intravenous radiopharmaceutical infusions
- Partner with manufacturers to make infusion kits for FDA-approved therapies Pluvicto, Lutathera, and Azedra
- Develop multi-vial sequential infusion method for high-volume radiopharmaceuticals*

Questions?

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