Radiotherapeutics: Best Practices and Updates

AKRAM HUSSEIN, PHARMD, MBA, BCNP

Speaker Disclosure

There are no disclosures related to this presentation

Speaker Disclosure

iCARE Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider for continuing pharmacy education.

This activity offers 1.5 contact hours (0.15 CEU).

- Target Audience:
- ACPE #:
- Activity Type:

  Knowledge based

  Application based

Learning Objectives

- Evaluate the current nuclear medicine radiotherapy practice and outline opportunities for advancement
- Discuss tools and infrastructure for a successful theranostics center.
- Understand roles within the multidisciplinary team.
- Identify strategies to reduce medical errors in radiotherapy.
- Explore how nuclear pharmacy can support a theranostics center.
- Present updates on current radiotherapies.

Question 1

Which of the following drugs is no longer available on the market?

A. Iodine-131 sodium iodide

B. Iodine-131 iobenguane

C. Radium-223 dichloride

D. Gallium-68 dotatate

Question 2

What is the purpose of the NRC Information Notice?

A. To notify licensees of new safety requirements

B. Requiring all licensees to report medical events to the FDA

C. Expect recipients to take actions as appropriate to avoid similar medical events

D. Guide recipients on how to manage Lu-177m contaminant

Question 3

According to the NRC Notice, which one of the following factors caused infusion failures that resulted in underdosing of patients?

A. Lack of adherence to standard operating procedures

B. Administering the dose without a shield

C. Drug shipment delays

D. Patients receiving the infusion on a recliner

Question 4

One solution to decrease radiopharmaceutical-related medical events is to have all radiotherapeutic preparations managed by which of the following?

A. Radiation oncologist

B. Medical oncologist

C. Medical physicist

D. Nuclear pharmacist

E. Health physicist

Question 5

Which of the following is a potential reason for administering the wrong radiotherapeutic drug or prescribed dose amount?

A. Pharmacist is dispensing and administering the dose

B. Nuclear medicine physician or radiation oncologist administering the dose

C. Same healthcare provider is preparing, dispensing, and administering the radiotherapy

D. AU physician prescribing, AU pharmacist dispensing, and Nuclear Medicine Technologist administering (under supervision of AU)

Question 6

Which item is not one of the responsibilities of the Pharmacy and Therapeutics Committee?

A. Implementing policies and procedures related to institution drug use

B. Overseeing the institution's benefits and prior authorization team

C. Developing and implementing an SOP for off-label drug use

Question 7

Adding all radiopharmaceuticals used at the institution to the formulary is considered a best practice.

A. True

B. False

Question 8

Which of the following is one of the responsibilities of a medical physicist in the multidisciplinary team?

A. Prescribe radiotherapies

B. Support quantitative imaging analysis

C. Administer radiotherapies under the supervision of an AU physician

Question 9

An advanced practice provider (e.g., nurse practitioner or physician assistant) can prescribe radiopharmaceutical therapies?

A. True

B. False

Radiotherapeutics (RPT)?

A special class of radiopharmaceuticals used for the targeted treatment of cancer

Unlike conventional forms of radiation therapy, radiotherapeutics are delivered systemically or locoregionally and target cancerous tissue at the cellular level

Alpha (α)-or beta (β)-particles are typically used to deliver cytotoxic radiation to tumor cells or tumor targets

- Radionuclide+ vector → target cancer cells
  - PRRT
- Natural physiological mechanisms
  - I-131→ accumulate in thyroid cancer

Drug name	FDA Clinical indication	Clinical use status
[^{153}Sm]Samarium-Lexidronam	Palliative care of bone metastasis	FDA approved in 1997; Production stopped in 2021 due to decline in demand
[^{131}I]I-Tositumomab	Non-Hodgkin's Lymphoma	FDA approval withdrawn in 2013 because the post-marketing study intended to verify clinical benefit was not completed
Sodium [^{32}P]P-Orthophosphate	Palliative care of bone metastasis; Polycythemia vera	No commercially available FDA-approved product since 2009
[^{89}Sr]Strontium Chloride	Palliative care of bone metastasis	FDA approved in 1993; Limited utilization
[^{90}Y]Y-Ibritumomab Tiuxetan	Non-Hodgkin's Lymphoma	FDA approved in 2002; Limited utilization (unknown status)
[^{131}I]I-Sodium Iodide	Hyperthyroidism and thyroid cancer	FDA approved in 1976; High utilization
[^{223}Ra]Radium dichloride	Castrate-resistant prostrate cancer with bone metastasis	FDA approved in 2013; High utilization
[^{131}I]Iobenguane	Pheochromocytoma and paraganglioma	FDA approved in 2018; Discontinued early 2024
[^{177}Lu]Lu-DOTA-TATE	Neuroendocrine tumors	FDA approved in 2018; Growing in utilization
[^{177}Lu]Lu-vipivotide tetraxetan	Castrate-resistant prostrate cancer	FDA approved in 2022;

Medical Events Involving Radiotherapeutics

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

August 9, 2024

NRC INFORMATION NOTICE 2024-04: RECENT MEDICAL EVENTS INVOLVING ADMINISTRATION OF THERAPEUTIC RADIOPHARMACEUTICALS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and master materials licensees that are authorized for medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300, "Unsealed Byproduct Material—Written Directive Required." All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to inform licensees of recent reported medical events that involved the administration of therapeutic radiopharmaceuticals. The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar medical events. INs may not impose new requirements, and nothing in this IN should be interpreted to require specific action. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees, as appropriate.

Question 1

Which of the following drugs is no longer available on the market?

A. Iodine-131 sodium iodide

B. Iodine-131 iobenguane

C. Radium-223 dichloride

D. Gallium-68 dotatate

Medical Events Involving Radiotherapeutics

The NRC identified an increase in reports of medical events involving therapeutic radiopharmaceuticals

- 29 events occurred between 2021-2023
- Most of the events are on Lu-177 PSMA -617 and Lu-177 Dotatate

What caused these medical events?

Medical Events Involving Radiotherapeutics

The NRC identified an increase in reports of medical events involving therapeutic radiopharmaceuticals

- 29 events occurred between 2021-2023
- Most of the events are on Lu-177 PSMA -617 and Lu-177 Dotatate

What caused these medical events?

1. Failure to confirm the written directive or prescribed amount prior to administering the dose
2. Incorrect setup or administration procedures
3. Failure to train staff involved in the handling and administration of the radiopharmaceuticals before first usage

Question 2

What is the purpose of the NRC Information Notice?

A. To notify licensees of new safety requirements

B. Requiring all licensees to report medical events to the FDA

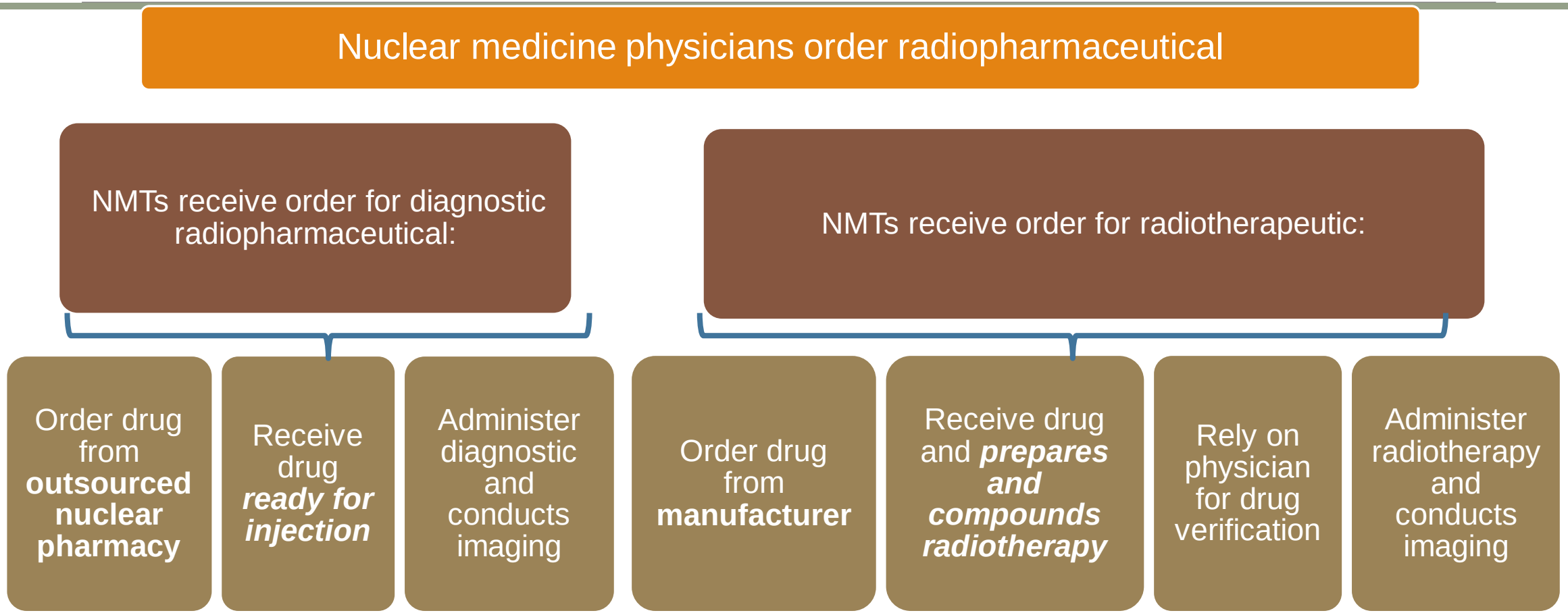
C. Expect recipients to take actions as appropriate to avoid similar medical events

D. Guide recipients on how to manage Lu-177m contaminant

Medical Events Involving Radiotherapeutics

- Administered full dose of 200 mCi instead of the prescribed reduced dose (based on patient's lab results)
- Patient received an expired Ra-223 dichloride
- Switched radiopharmaceuticals for patients receiving treatment on the same day
  - Lu-177 dotatate given to prostate cancer patient and Lu-177 PSMA given to neuroendocrine cancer patient
- Other infusion failures which resulted in under dosing patients
  - Involved leakage
  - Equipment malfunction
  - Lack of adherence o procedures

Current Practice for Handling of Radiopharmaceuticals



Question 3

According to the NRC Notice, which one of the following factors caused infusion failures that resulted in underdosing of patients?

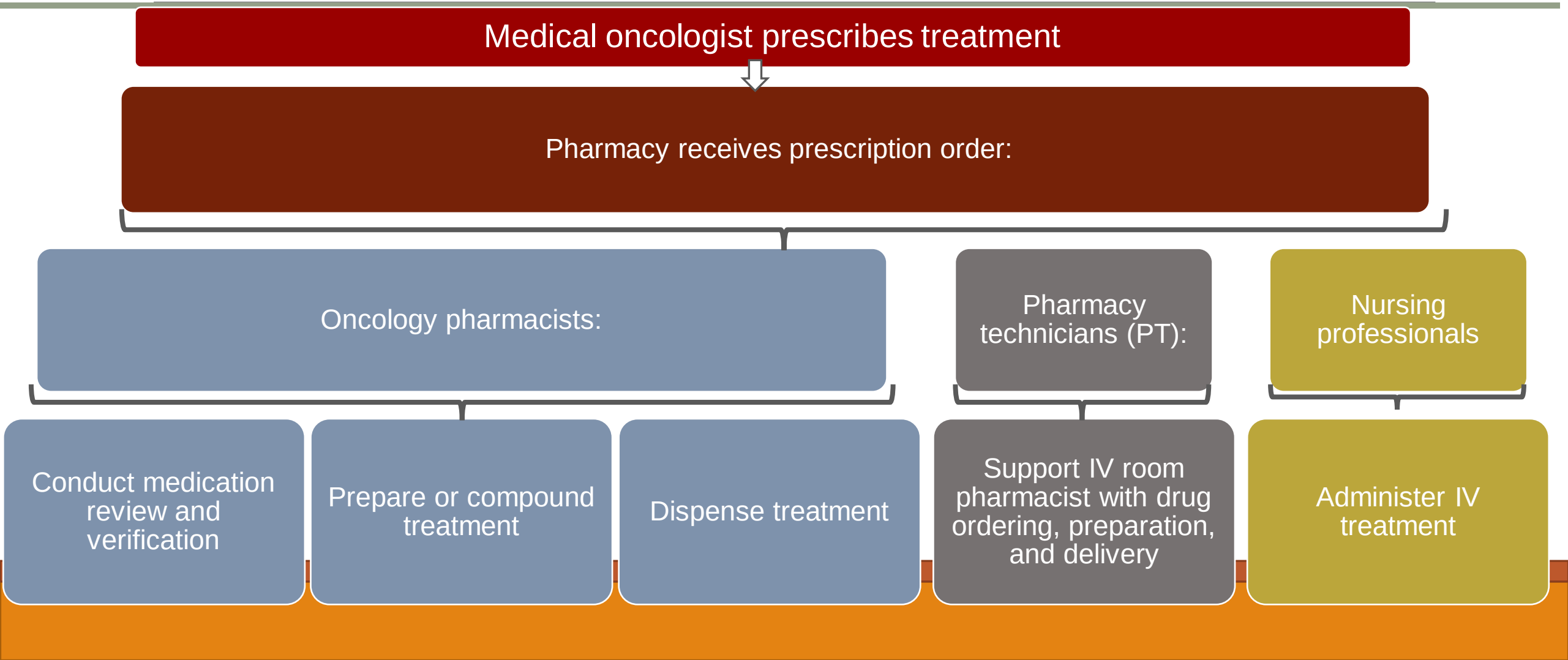
A. Lack of adherence to standard operating procedures

B. Administering the dose without a shield

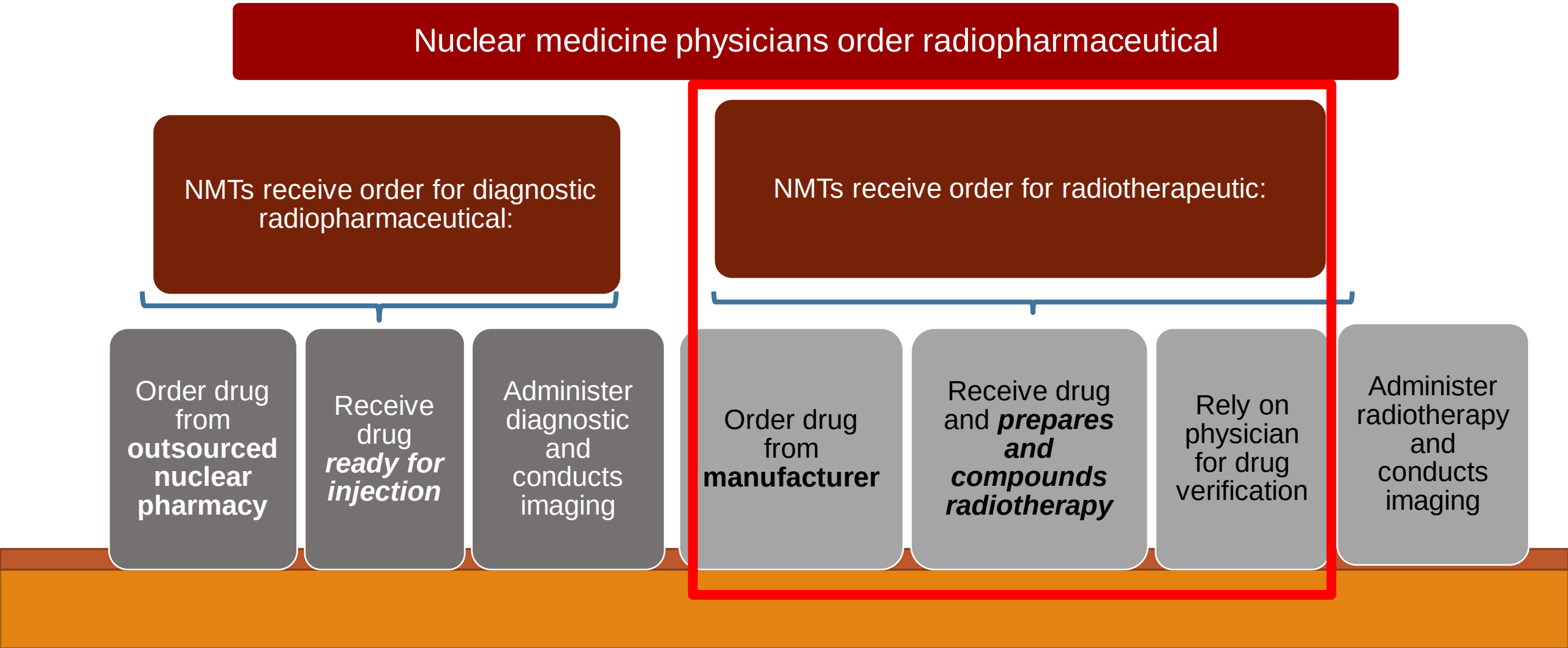
C. Drug shipment delays

D. Patients receiving the infusion on a recliner

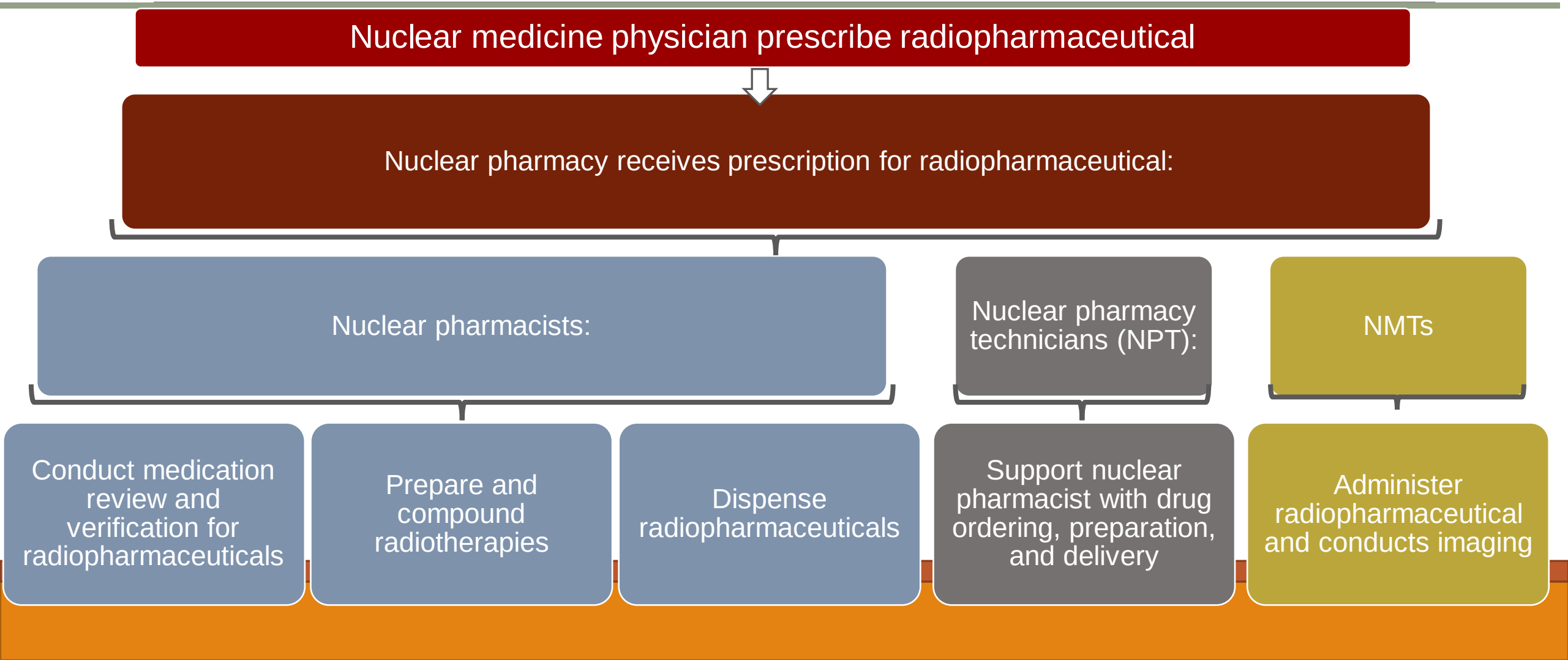
Standard Oncology Practice



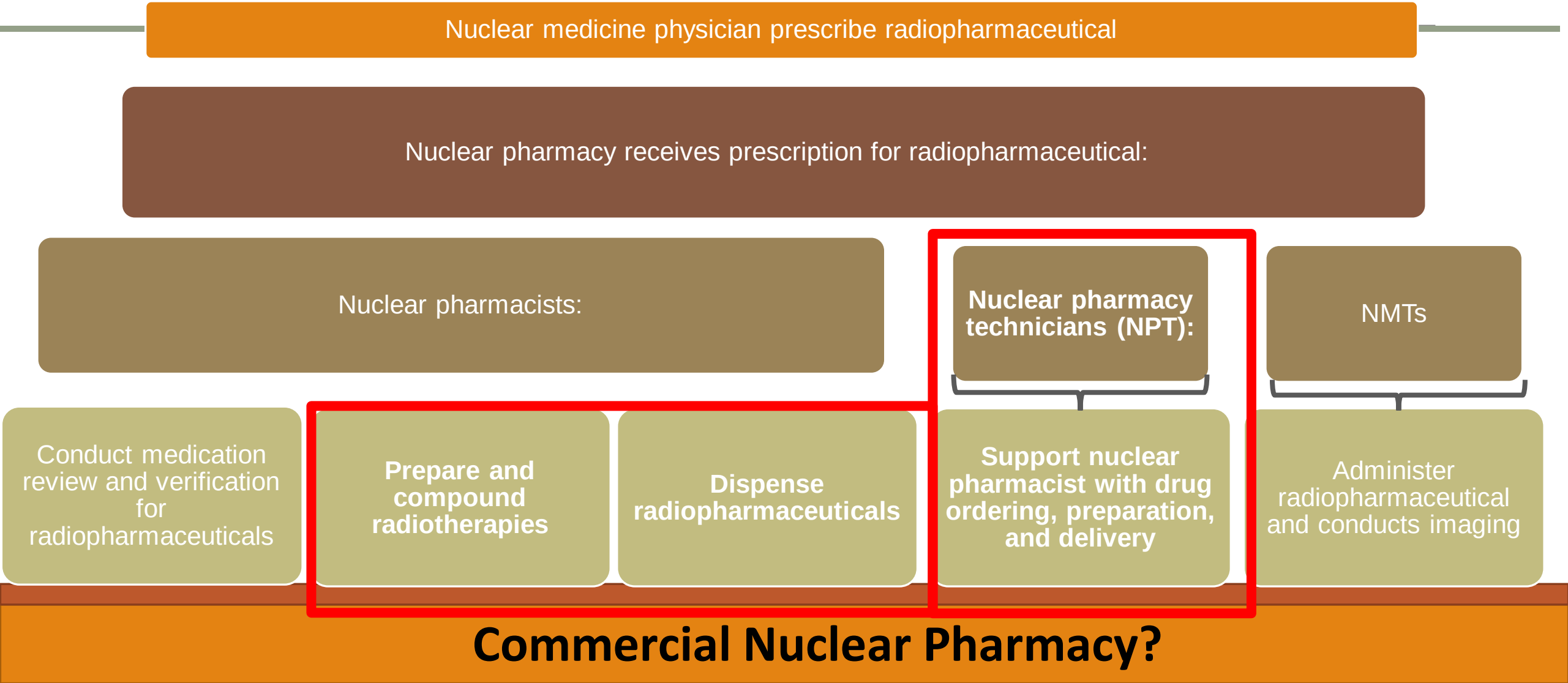
Current practice for handling of radiopharmaceuticals



Best Practice for handling of radiopharmaceuticals Therapy (RPT)



Best Practice for handling of radiopharmaceuticals Therapy (RPT)



Question 4

One solution to decrease radiopharmaceutical-related medical events is to have all radiotherapeutic preparations managed by which of the following?

A. Radiation oncologist

B. Medical oncologist

C. Medical physicist

D. Nuclear pharmacist

E. Health physicist

Best Practice for handling of radiopharmaceuticals Therapy (RPT)

The nuclear pharmacy model adopts best practice for the handling of radiopharmaceuticals, and radiotherapies specifically, ensuring:

- Nuclear pharmacist medication dual review and verification
- Preparation and compounding of radiotherapies in compliance with state and federal regulations
- Pharmacy dispensing with label appropriateness to prevent medical errors
- Designated space designed for the preparation and dispensing of radiopharmaceuticals
- Personnel specifically and uniquely trained and qualified in all aspects of radiopharmaceutical handling and quality control

Pharmacy & Therapeutics(P&T)Committee

Composed of diverse group of healthcare professionals

Manage the Formulary System

- Medication evaluation
  - Evidence based medicine
  - Pharmacoeconomics evaluation
  - Formulary exceptions
- Manage Medication Use
  - Generics, biosimilars, Therapeutic interchange
  - Standard Practice Guidelines

Question 5

Which of the following is a potential reason for administering the wrong radiotherapeutic drug or prescribed dose amount?

A. Pharmacist is dispensing and administering the dose

B. Nuclear medicine physician or radiation oncologist administering the dose

C. Same healthcare provider is preparing, dispensing, and administering the radiotherapy

D. AU physician prescribing, AU pharmacist dispensing, and Nuclear Medicine Technologist administering (under supervision of AU)

Pharmacy & Therapeutics(P&T)Committee

- Responsible for policies & procedures related to drug use
- Reimbursement
- Practice guidelines
- Patient safety considerations
- Drug shortages

Pharmacy & Therapeutics Committee

Should radiopharmaceutical drugs go through the formulary process?

Pharmacy & Therapeutics Committee

Should radiopharmaceutical drugs go through the Formulary process?

YES

Question 6

Which item is not one of the responsibilities of the Pharmacy and Therapeutics Committee?

A. Implementing policies and procedures related to institution drug use

B. Overseeing the institution's benefits and prior authorization team

C. Developing and implementing an SOP for off-label drug use

Benefits-Radiopharmaceuticals on Formulary

Comprehensive Patient Care

- Timely access to the best and most appropriate treatments without delay

Streamlined Workflow and Efficiency

- Avoiding delays in obtaining necessary approvals for off-formulary medications

Enhanced Treatment Flexibility

- More flexibility in selecting the right agent based on the patient's condition, disease stage, or other individual factors

Standardization of Care

- Formulary promotes consistency and standardization of care across the institution

Cost Control and Negotiation

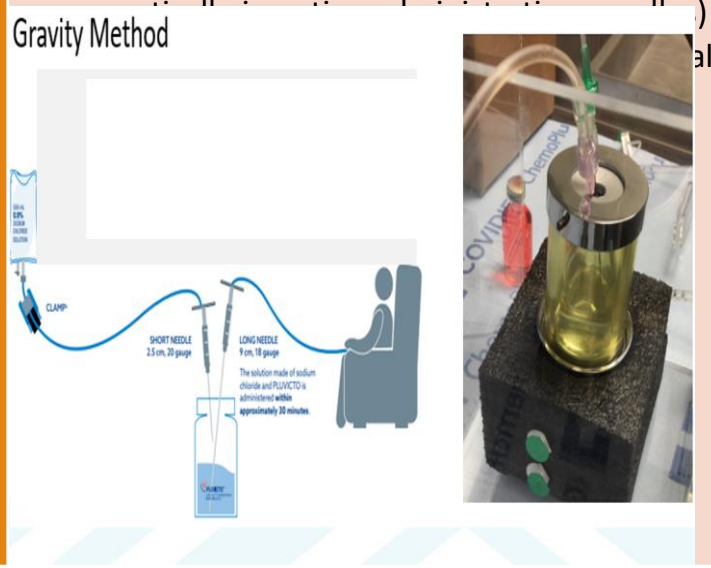
- Price negotiation and bulk purchasing, which can lead to cost savings for the hospital

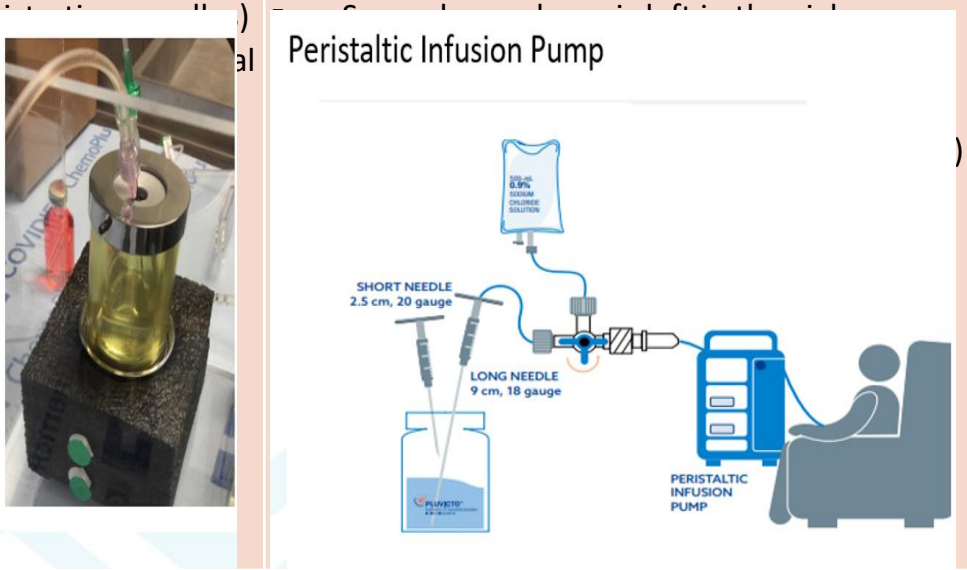
Radiotherapeutics- Infusion Methods

	Gravity with or without IV pump	Peristaltic pump infusion	Syringe pump infusion
Considerations	**Advantages** ▪ The vial remains shielded during the entire administration ▪ No dose manipulation needed for a normal dose **Challenges** ▪ Requires significant preparation time from staff at the patient's bedside (i.e. requires aseptically inserting administration needles) ▪ Increased risk of radioactive spills due to vial pressure failures during needle insertions and the 0.9% NaCl flushing after infusion completion ▪ Increased risk of the misadministration of the prescribed dose ▪ Requires calibrated equipment (e.g. an ion chamber) to determine when the administration is complete ▪ A large drug volume is left in the vial, resulting in a higher amount of radioactive waste	**Advantages** ▪ The vial remains shielded during the entire administration time ▪ No dose manipulation needed for a normal dose ▪ Decreased risk of radioactive contamination from drug leaks **Challenges** ▪ Need for a peristaltic pump ▪ Some drug volume is left in the vial ▪ Requires significant preparation time from staff at the patient's bedside (i.e. requires aseptically inserting administration needles)	**Advantages** ▪ Decreased risk of radioactive contamination from drug leaks ▪ No drug volume is left in the syringe ▪ Minimal preparation time from staff is needed at patient's bed side ▪ Short dose infusion time can increase the number of patients that can be treated **Challenges** ▪ Additional shielding is needed for the syringe pump to prevent radiation exposure ▪ Need for a syringe infusion pump ▪ Dispensing the dose in a syringe may require an ISO 5 class-compliant biological safety cabinet (i.e. must follow regulations regarding sterile drug preparation techniques) ▪ Increased exposure to personnel involved in dose preparation

Radiotherapeutics- Infusion Methods

	Gravity with or without IV pump	Peristaltic pump infusion	Syringe pump infusion
Considerations	**Advantages** ▪ The vial remains shielded during the entire administration ▪ No dose manipulation needed for a normal dose **Challenges** ▪ Requires significant preparation time from staff at the patient's bedside (i.e. requires	**Advantages** ▪ The vial remains shielded during the entire administration time ▪ No dose manipulation needed for a normal dose ▪ Decreased risk of radioactive contamination from drug leaks **Challenges** ▪ Need for a peristaltic pump	**Advantages** ▪ Decreased risk of radioactive contamination from drug leaks ▪ No drug volume is left in the syringe ▪ Minimal preparation time from staff is needed at patient's bed side ▪ Short dose infusion time can increase the number of patients that can be treated





Radiotherapeutics- Extravasation Policy

- A method to identify high risk patients and factors that increase the risk of extravasation
  - Poor vein access
- How to prevent extravasation
  - Assess patient veinous access
- What are the signs/symptoms of extravasation and what action to take?
  - Pain, swelling and redness
- Guideline for management extravasation upon discovery
  - Management may vary depends on type of drug
- Quality assurance program
  - Investigate reported incidents and implement corrective actions

Question 7

Adding all radiopharmaceuticals used at the institution to the formulary is considered a best practice.

A. True

B. False

Radiotherapy- Patient Qualification

Lu-177 PSMA-617	
Patient Name:	Iron Man
MRN:	9999999
Age:	79
Indication	mCRPC
PSMA PET ≤ 3 months	Yes- PSMA-PYL 09/13/2023, 06/27/2024
Androgen receptor pathway	Yes- abiraterone, darolutamide, enzalutamide
Taxane-based therapy	Yes- docetaxel
Prostatectomy	No
Referring oncologist	Dr. Doom

- **Develop and implement a guideline or an SOP for all radiopharmaceutical therapies**
  - Is the patient a good candidate for radiotherapy?
  - Does the patient meet the treatment criteria?

Pluvicto							
Patient Name:	Iron Man						
MRN:	9999999						
Age:	79						
Indication	mCRPC						
PSMA PET ≤ 3 months	Yes- PSMA-PYL 09/13/2023, 06/27/2024						
Androgen receptor pathway	Yes- abiraterone, darolutamide, enzalutamide						
Taxane-based therapy	Yes- docetaxel						
Prostatectomy	No						
Referring oncologist	Dr. Doom						
	Cycle#	1	2	3	4	5	6
	Treatment Date:	01/12/2024	02/23/2024	04/16/2024	06/06/2024	08/05/2024	09/20/2024
	Labs from (One Week?):	01/05/2024	02/16/2024	04/09/2024	05/30/2024	07/24/2024	09/15/2024
Criteria	Range						
WBC	≥ 3 k/µL	12.9	12.6	9.7	10.2	12.4	9.9
Hgb	≥ 9 g/dL	14.8	14.5	10.4	10.2	9.2	9.9
Platelets	≥75 k/µL	224	161	169	154	156	134
ANC	≥ 1.5 K/µL	4.39	4.66	3.72	3.55	3.99	4.53
Sodium	129-155 mEq/L	139	137	139	140	138	137
Potassium	3-6 mEq/L	4.4	4.5	4.9	4.4	4.4	4.3
Serum Creatinine	≤ 1.5 mg/dL ULN (<1.75 mg/dL)	1.07	1.24	1.12	1.15	1.21	1.13
eGFR	≥ 30 mL/min	71	60	67	65	61	66
Calcium	7-12.5 mg/dL	9.5	9.4	9.8	9.6	9.6	9.6
ALT	< 5x ULN in the absence of liver mets *(5X41U/L = 205)*	8	8	12	15	11	11
AST	< 5x ULN in the absence of liver mets *(5X40U/L = 200)*	12	14	16	21	15	16
Albumin	≥ 3 g/dL	4.1	4.1	4.2	4.4	4.3	4.2
PSA		41	40.7	22.3	9.9	9.2	9.2
Testosterone	< 50 ng/dL	6	10	7	11	10	6
Prescribed dose	Normal: 200 mCi Reduced: 160 mCi	200	200	200	200	160	160
AU Physician		Dr. Smith	Dr. Chin	Dr.Smith	Dr.Rock	Dr.Rock	Dr.Chin

Radiotherapy- Patient Qualification

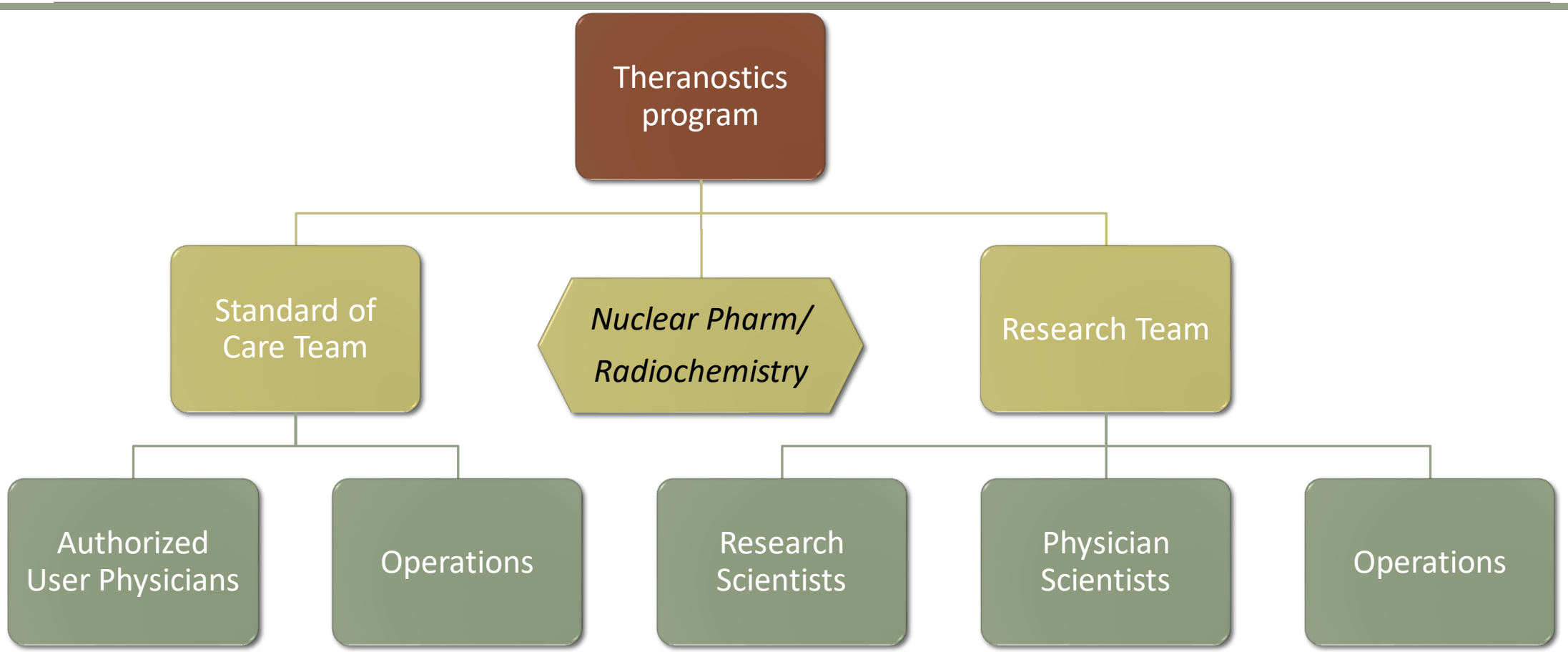
	Cycle#
	Treatment Date:
	Labs from (One Week?):
Criteria	**Range**
WBC	≥ 3 k/µL
Hgb	≥ 9 g/dL
Platelets	≥75 k/µL
ANC	≥ 1.5 K/µL
Sodium	129-155 mEq/L
Potassium	3-6 mEq/L
Serum Creatinine	≤ 1.5 mg/dL ULN (<1.75 mg/dL)
eGFR	≥ 30 mL/min
Calcium	7-12.5 mg/dL
ALT	< 5x ULN in the absence of liver mets ***(5X41U/L = 205)***
AST	< 5x ULN in the absence of liver mets ***(5X40U/L = 200)***
Albumin	≥ 3 g/dL
PSA	
Testosterone	≤ 50 ng/dL
Prescribed dose	**Normal: 200 mCi** **Reduced: 160 mCi**
AU Physician	

- **Develop and implement a guideline or an SOP for all radiopharmaceutical therapies**
  - Is the patient tolerating the radiotherapy
  - Can the patient continue the radiotherapy?

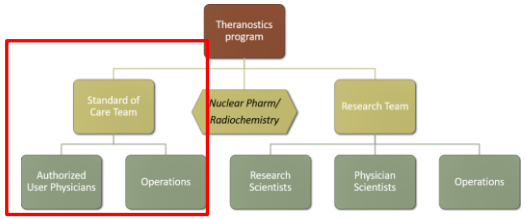
Pluvicto

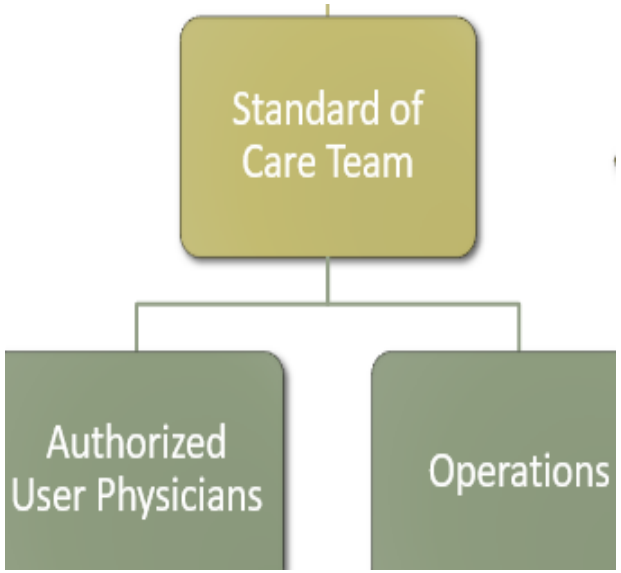
Patient Name:	**Iron Man**						
MRN:	**9999999**						
Age:	79						
Indication	mCRPC						
PSMA PET ≤ 3 months	Yes- PSMA-PYL 09/13/2023, 06/27/2024						
Androgen receptor pathway	Yes- abiraterone, darolutamide, enzalutamide						
Taxane-based therapy	Yes- docetaxel						
Prostatectomy	No						
Referring oncologist	Dr. Doom						
	Cycle#	**1**	**2**	**3**	**4**	**5**	**6**
	Treatment Date:	01/12/2024	02/23/2024	04/16/2024	06/06/2024	08/05/2024	09/20/2024
	Labs from (One Week?):	01/05/2024	02/16/2024	04/09/2024	05/30/2024	07/24/2024	09/15/2024
Criteria	**Range**						
WBC	≥ 3 k/µL	12.9	12.6	9.7	10.2	12.4	9.9
Hgb	≥ 9 g/dL	14.8	14.5	10.4	10.2	9.2	9.9
Platelets	≥75 k/µL	224	161	169	154	156	134
ANC	≥ 1.5 K/µL	4.39	4.66	3.72	3.55	3.99	4.53
Sodium	129-155 mEq/L	139	137	139	140	138	137
Potassium	3-6 mEq/L	4.4	4.5	4.9	4.4	4.4	4.3
Serum Creatinine	≤ 1.5 mg/dL ULN (<1.75 mg/dL)	1.07	1.24	1.12	1.15	1.21	1.13
eGFR	≥ 30 mL/min	71	60	67	65	61	66
Calcium	7-12.5 mg/dL	9.5	9.4	9.8	9.6	9.6	9.6
ALT	< 5x ULN in the absence of liver mets ***(5X41U/L = 205)***	8	8	12	15	11	11
AST	< 5x ULN in the absence of liver mets ***(5X40U/L = 200)***	12	14	16	21	15	16
Albumin	≥ 3 g/dL	4.1	4.1	4.2	4.4	4.3	4.2
PSA		**41**	**40.7**	**22.3**	**9.9**	**9.2**	**9.2**
Testosterone	≤ 50 ng/dL	6	10	7	11	10	6
Prescribed dose	**Normal: 200 mCi** **Reduced: 160 mCi**	**200**	**200**	**200**	**200**	**160**	**160**
AU Physician		Dr. Smith	Dr. Chin	Dr.Smith	Dr.Rock	Dr.Rock	Dr.Chin

Theranostics?



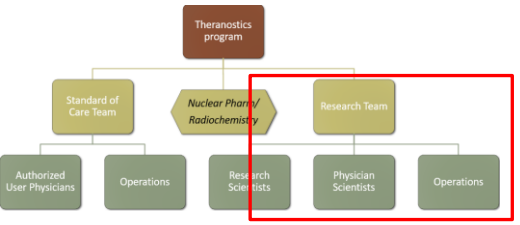
Theranostics?

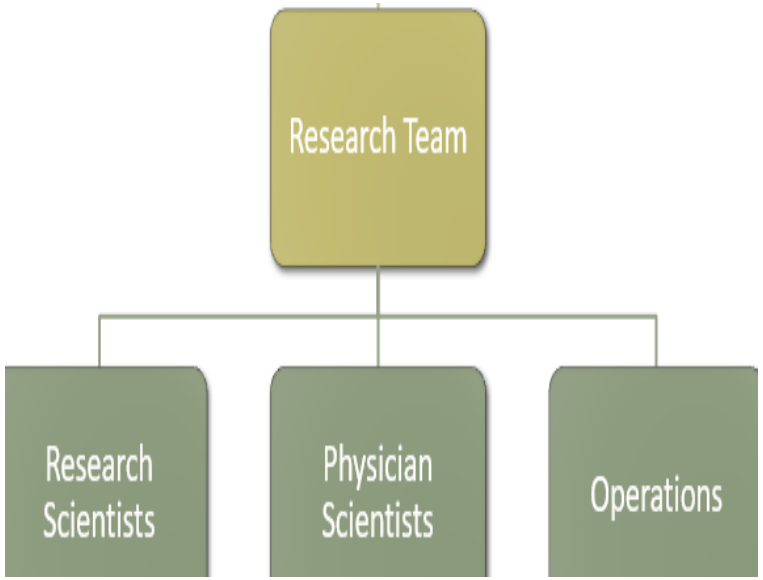




- Authorized User Physicians
- Business Unit Administrator
- Nuclear Medicine Techs
- Schedulers
- Coordinators
- Registered Nurses
- Advance Practice Nurses
- Imaging Physics/Radiation Safety
- Prior Authorization Support

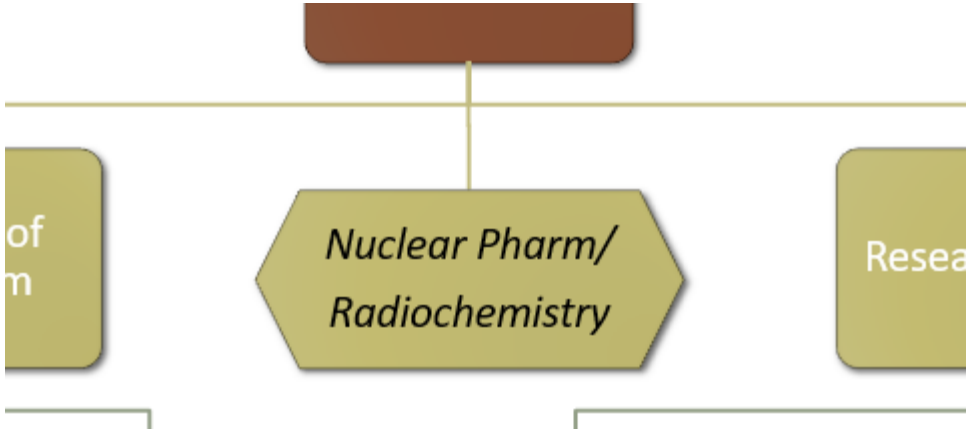
Theranostics?

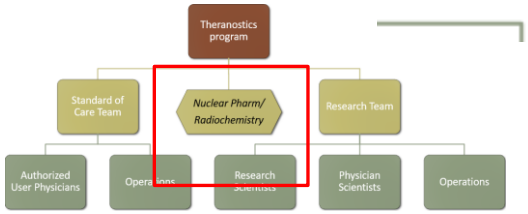




- Authorized User Physicians
- Physician Scientists
- Research Scientists
- Research Nuclear Medicine Techs
- Research Coordinators
- Research Registered Nurses
- Research Advance Practice Nurses
- Imaging physics/Radiation Safety
- Business Unit Administrator
- Scheduler
- Budget and Finance Manager

Theranostics?

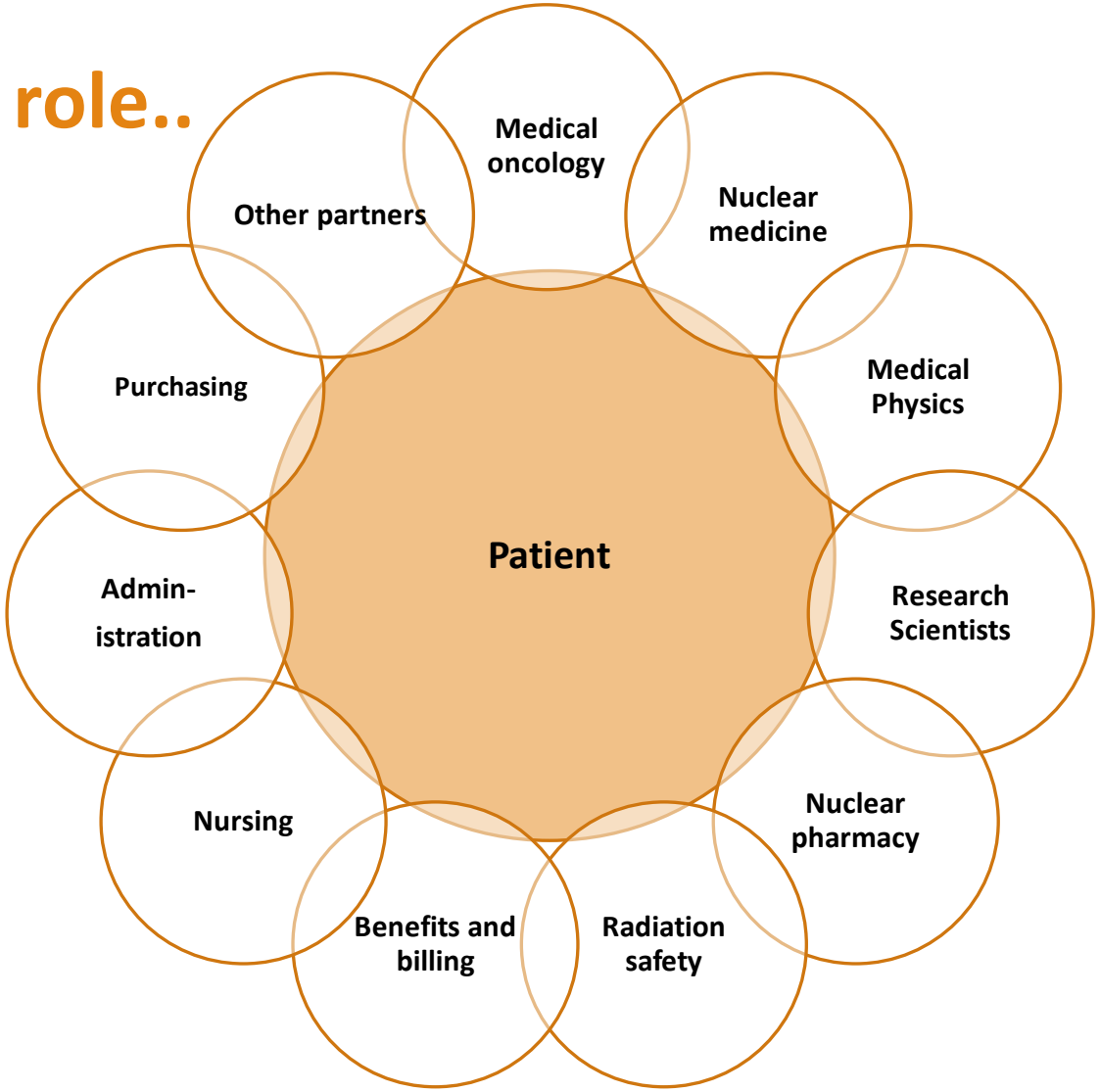




- Nuclear Pharmacy Administrator
- Research Nuclear Pharmacists
- Clinical Nuclear Pharmacists
- Radiochemists
- Nuclear Pharmacy Techs
- Research Pharmacy Techs
- Purchasing/Administrative Support Staff
- Budget and Finance associate
- Couriers/Runners

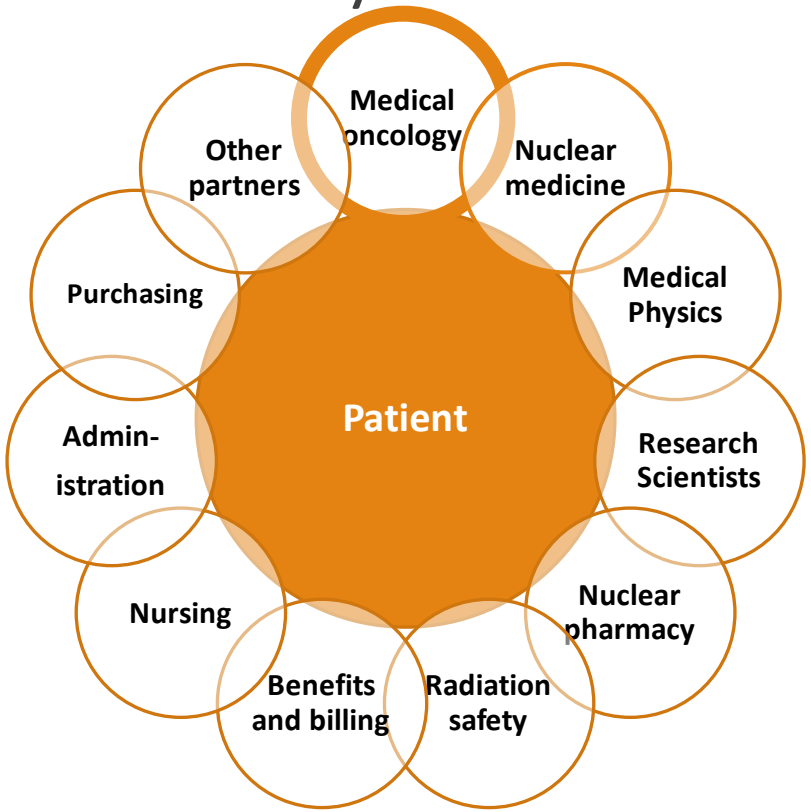
Theranostics-Multidisciplinary Approach

Understand your role..



Theranostics-Multidisciplinary Approach

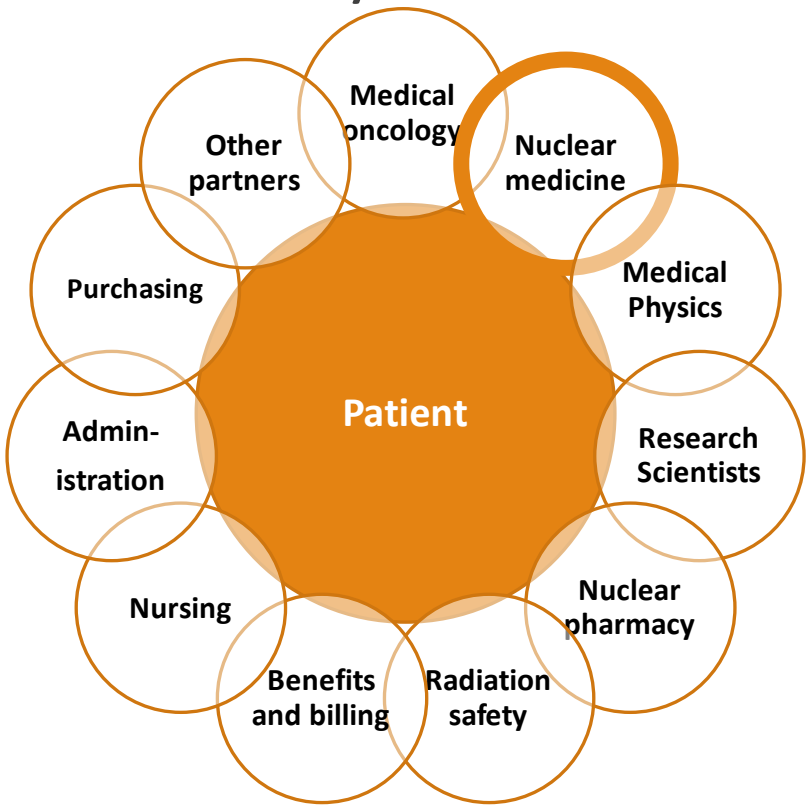
Understand your role?



- Identify candidates for radiotherapy
- Treatment planning
- Monitor treatment response
- Manage side effects
- Patient counseling/education
- Clinical trials

Theranostics-Multidisciplinary Approach

Understand your role?



Nuclear Med Physician

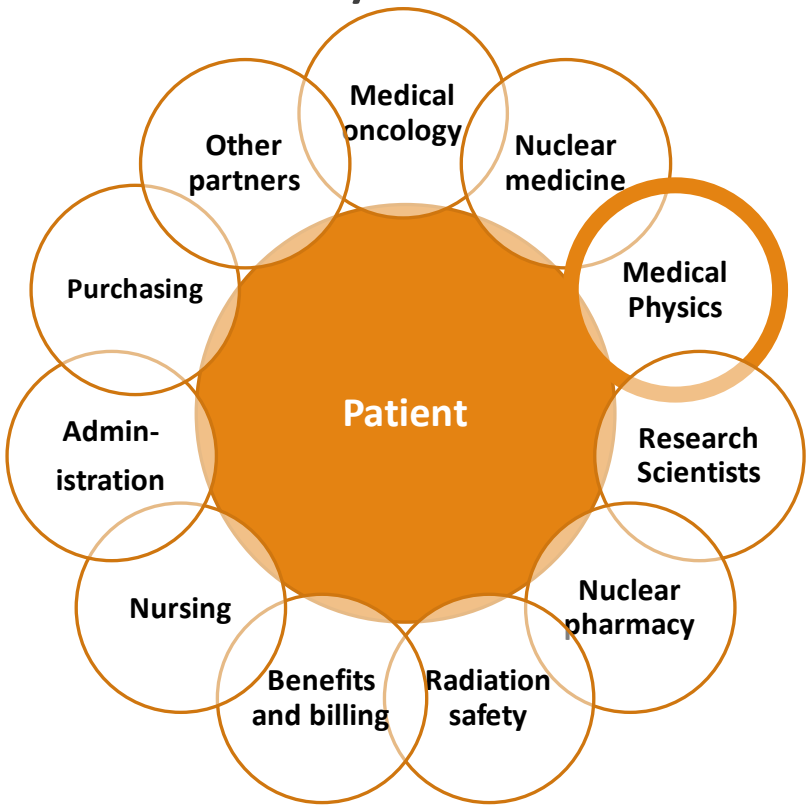
- Evaluates patient eligibility; prescribes radiopharmaceuticals; interprets diagnostic images; monitors treatment responses; manages side effects

Nuclear Medicine Technologist

- Administers radiopharmaceuticals; operates imaging equipment; acquires diagnostic images; educates patients; and ensures adherence to safety protocols during imaging and therapy

Theranostics-Multidisciplinary Approach

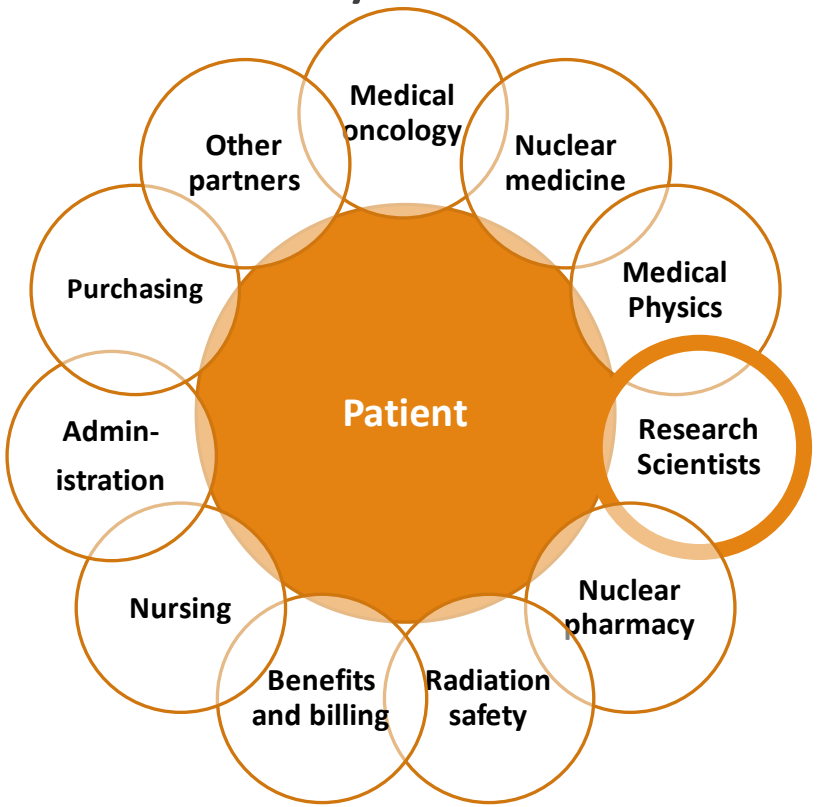
Understand your role?



- Calibrates and maintains imaging equipment and optimizes imaging protocols
- Supports quantitative imaging analysis to ensure high-quality diagnostics and accurate dosimetry for therapy planning

Theranostics-Multidisciplinary Approach

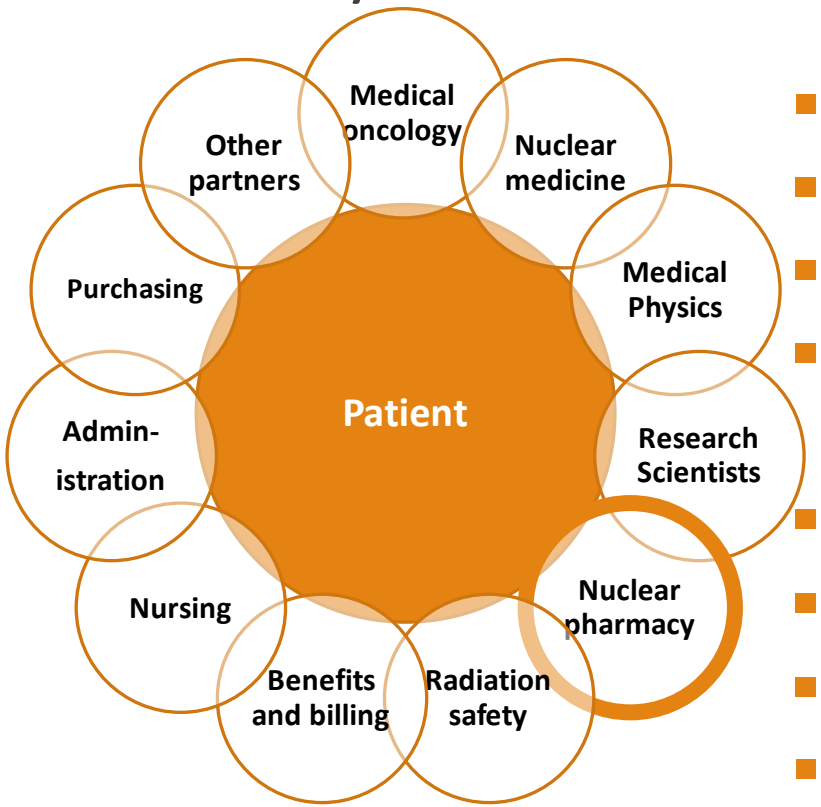
Understand your role?



- Design and develop new radiopharmaceuticals
- Preclinical testing and clinical trial support
- Improving radiochemistry methods

Theranostics-Multidisciplinary Approach

Understand your role?



- Manage addition of radiopharmaceuticals to hospital formulary/ EMR
- Critical resource for Tumor Board
- Oversee RP ordering/purchasing
- Dual drug review/verification
- Prepare, compound and dispense radiopharmaceuticals
- Manage drug shortages
- Manage all investigational radiopharmaceutical agents
- Clinical trial collaboration with research scientists
- Ensure radiopharmaceutical regulatory compliance

Question 8

Which of the following is one of the responsibilities of a medical physicist in the multidisciplinary team?

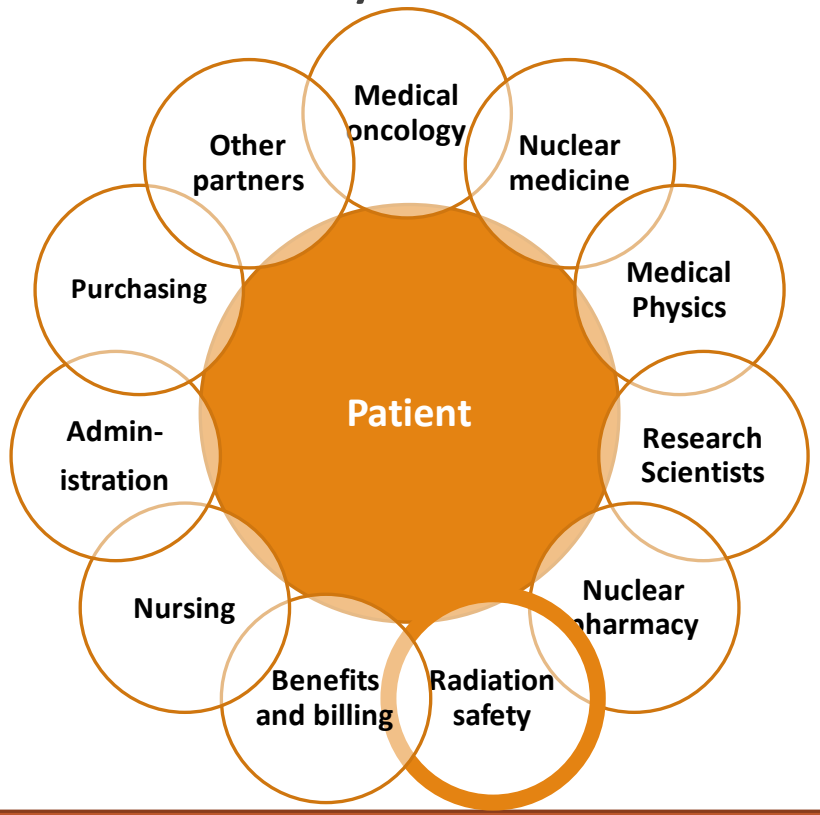
A. Prescribe radiotherapies

B. Support quantitative imaging analysis

C. Administer radiotherapies under the supervision of an AU physician

Theranostics-Multidisciplinary Approach

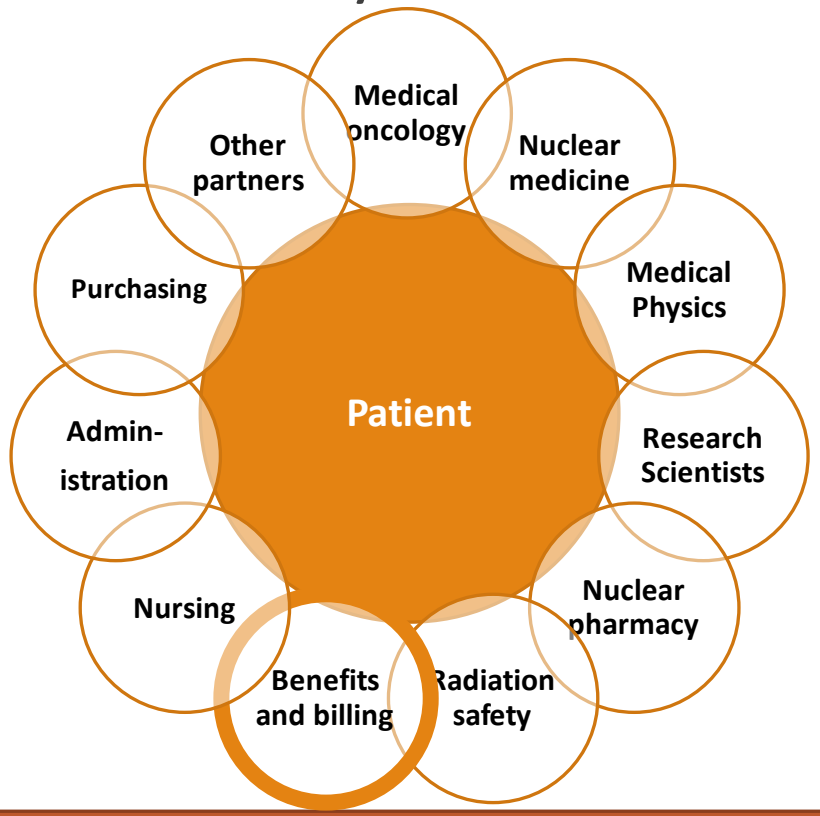
Understand your role?



- Ensures radiation safety protocols are adhered to, monitors radiation exposure for staff and patients
- Manages the safe disposal of radioactive materials to minimize risk

Theranostics-Multidisciplinary Approach

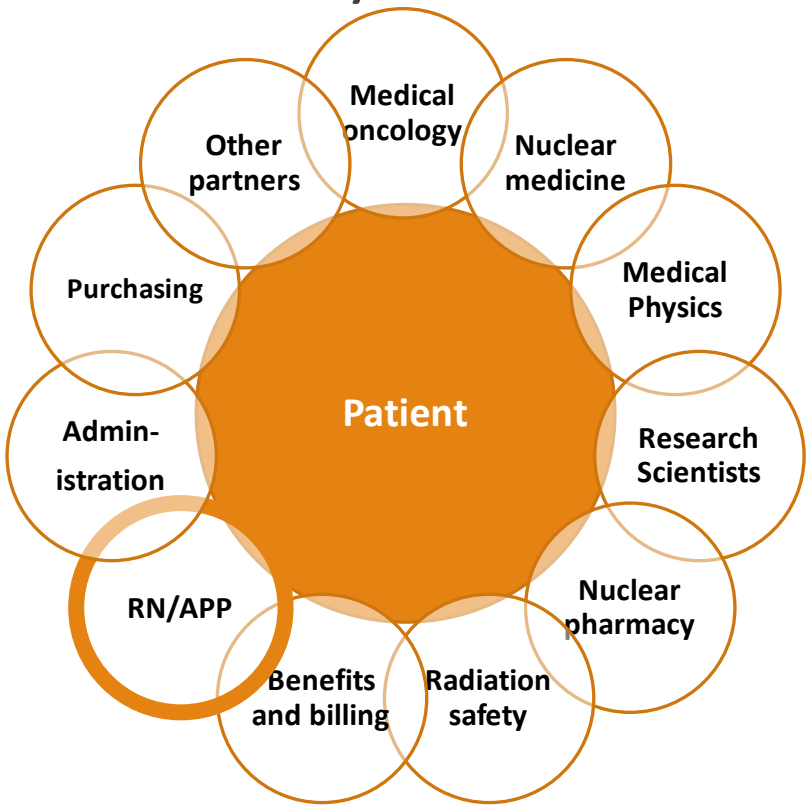
Understand your role?



- Obtains insurance approval for theranostics procedures
- Provides documentation and communicates with insurance providers to secure pre-treatment authorization

Theranostics-Multidisciplinary Approach

Understand your role?



Advanced Practice Provider

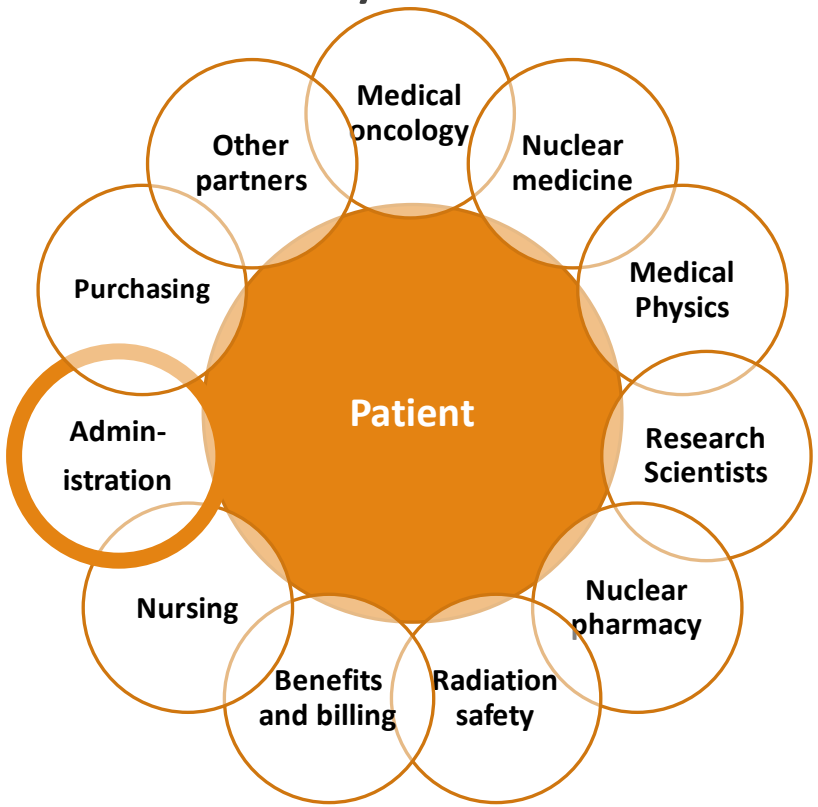
- Performs initial evaluations, assists in treatment planning, educates patients, prescribes supportive medications, and monitors for adverse effects. Acts as a liaison between the physician and the patient, providing continuity of care

Nurse

- Provides patient support throughout the procedure, assists with preparation, monitors vitals, administers non-radioactive medications
- Ensures patient comfort before, during, and after radioactive treatments

Theranostics-Multidisciplinary Approach

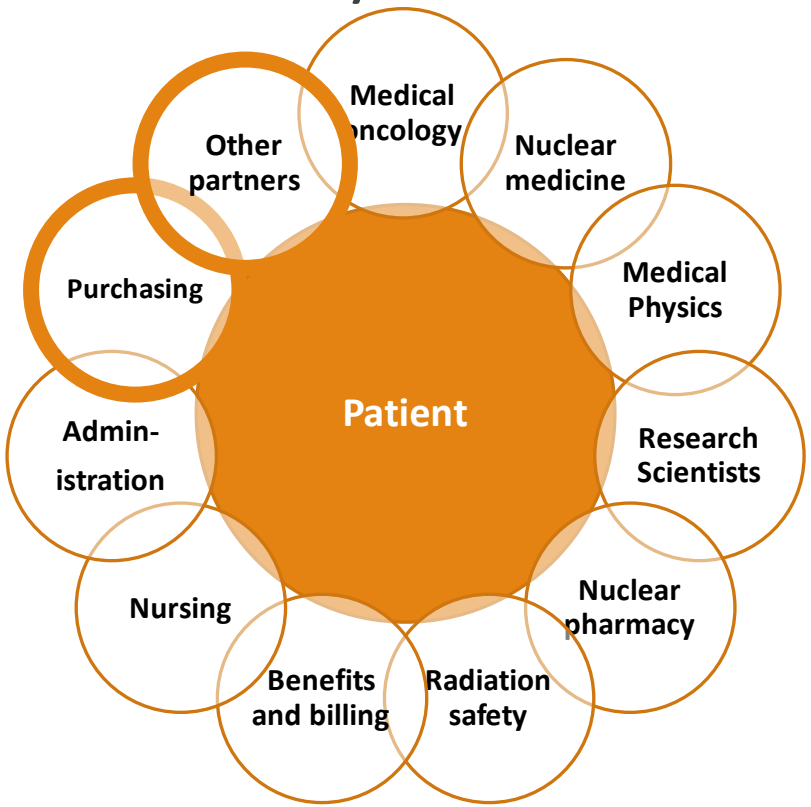
Understand your role?



- Oversees the theranostics program
- Manages staff, coordinates interdepartmental activities and ensures regulatory compliance
- Handles budgeting and leads quality improvement initiatives

Theranostics-Multidisciplinary Approach

Understand your role?



Purchasing

- Manage contracts and purchase orders

Scheduler

- Coordinates appointments for diagnostic imaging, therapies, and follow-up visits

Coordinators

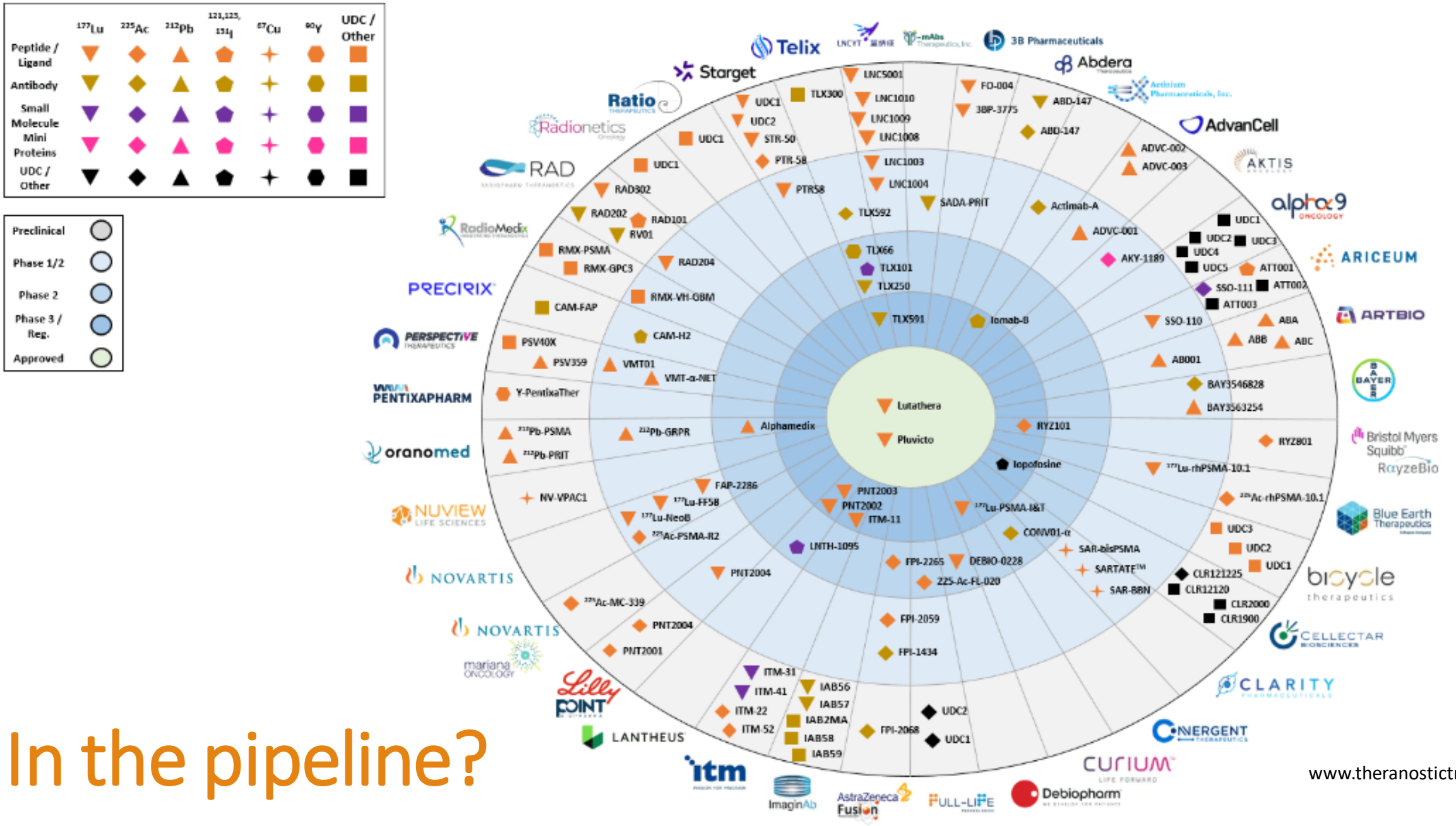
- Manages clinical trial logistical and administrative tasks
- Coordinates between departments, ensures patient education and consent, and tracks patient progress throughout treatment

Question 9

An advanced practice provider (e.g., nurse practitioner or physician assistant) can prescribe radiopharmaceutical therapies?

A. True

B. False



In the pipeline?

www.theranostictrials.org

Future?

Lu-177 dotatate ➔ off label use

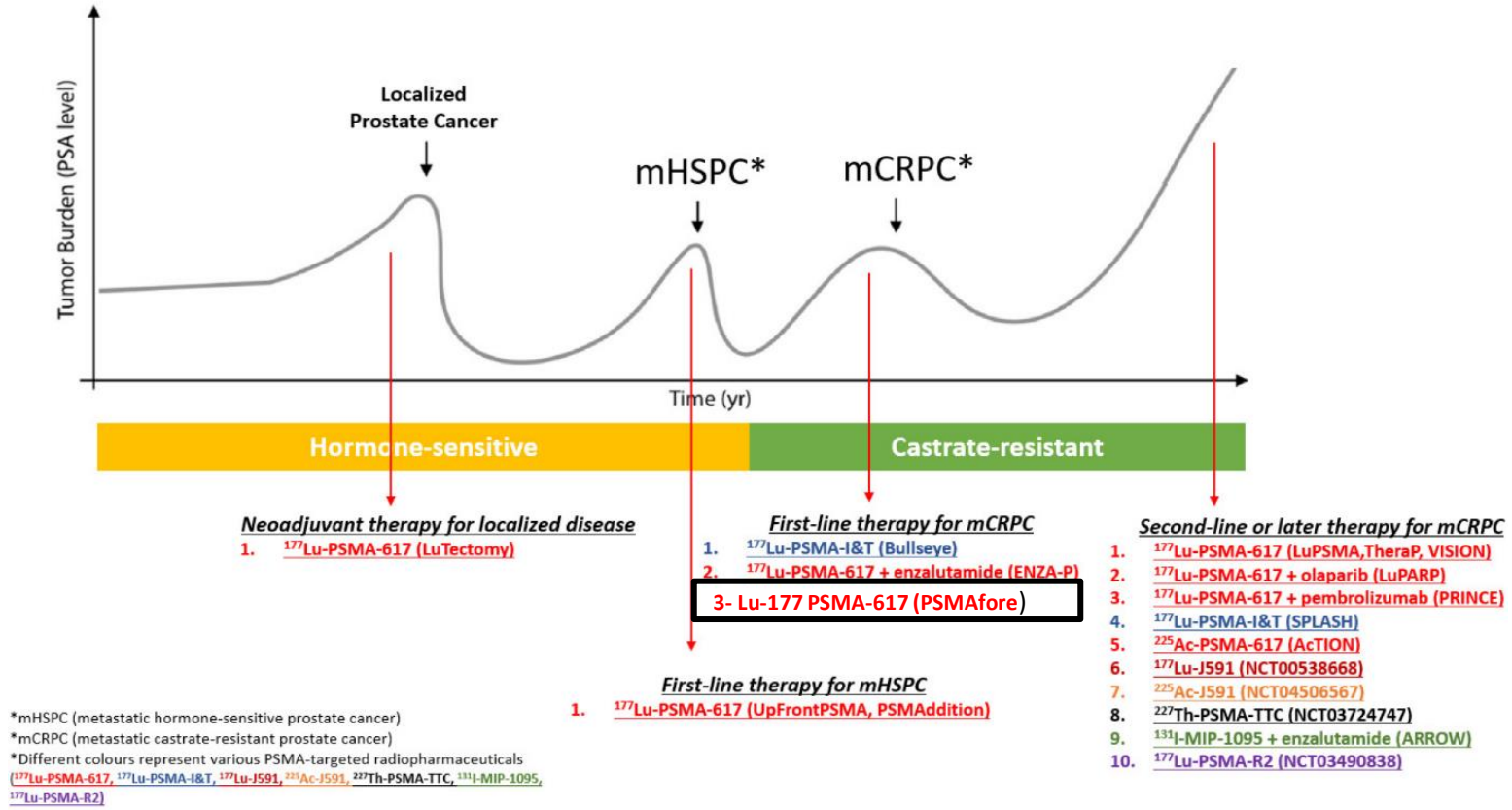
- FDA approved for somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors
- New off label use:
  - Pheochromocytoma/Paraganglioma (PPGL)
  - Radiation- refectory meningioma

Future?

Lu-177 PSMA-617 (PSMAfore Trial)

- Lu-177 PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomized, controlled trial
- Trial met its primary endpoint of radiographic progression free survival (11.6 Lu-177 PSMA months vs 5.56 ARPI)
- Manufacturer plans to file for Lu-177 PSMA-617 pre-taxane label expansion
- Expecting up to 30% increase in Lu-177PSMA-617 demand in 2025 (assuming label expansion approval)

PSMA Research



Zhang H, Koumna S, Pouliot F, Beauregard JM, Kolinsky M. PSMA Theranostics: Current Landscape and Future Outlook. Cancers

Future?

I-131 Iomab-B

- A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic Hematopoietic Cell Transplant Versus Conventional Care in Older Subjects With Active, Relapsed or Refractory Acute Myeloid Leukemia
- Primary end point meet➔ 6 months durable Complete Remission
- FDA did not approve the agent➔ Trial not adequate to support BLA filling
  - Requested an addition head-to-head randomized trial demonstrating an improvement in the overall survival benefit with I-131 Iomab-B

Future?

I-131 iopofosine

- Positive results from its CLOVER WaM pivotal study evaluating iopofosine I 131, targeted radiotherapeutic candidate for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia patients that received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitors

- 80% Overall Response Rate

Next year?

Future?

^{89}Zr-DFO-girentuximab

- Met primary and secondary endpoints, demonstrating a sensitivity of 86%, specificity of 87% and a positive predictive value (PPV) of 93% for clear cell renal carcinoma, including in small, difficult to detect lesions

- Submitted for FDA approval and requested priority review - June/2024

Next year?

Questions?