Disclosures

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Objectives

- Identify key regulatory and accreditation standards related to radiopharmaceuticals
- State the five most commonly ordered radiopharmaceuticals used in a hospital
- Identify medications commonly prepared and administered in a nuclear medicine department
- State requirements for access to medications for a nuclear medicine department

Agenda

- Overview
- Nuclear Pharmacy 101
- Regulatory and accreditation issues
- Q&A

Nuclear Pharmacy Development

- Developed in 1972
- Over 95% of radiopharmaceuticals originate from a centralized nuclear pharmacy
- Most hospitals use an outsourced service managed by the Nuclear Medicine Department

Traditional Roles

- Joint Commission added definition of medication to Medication Management standards
  - Diagnostic / contrast agents
  - Radiopharmaceuticals
- Imaging Department
  - Contrast media
  - Radiopharmaceuticals
  - Other medications used in procedures
Oversight of Medication Management

- Changed from pharmacy standards to organization-wide scope
- Director of Pharmacy expected to oversee all areas of the medication use system

Diagnostic Radiopharmaceuticals

- Short lived “tracers” have no pharmacologic effect
  - 85% are radiolabeled with nuclide Tc-99m (6 hour $T_{1/2}$)
  - Not IV admixture – compounding where chemistry occurs: chelation or precipitation

Nuclear Pharmacy 101

- What is the most commonly prescribed diagnostic radiopharmaceutical?
- Which radiopharmaceuticals should be included on the hospital’s drug formulary?
- What is a Hot Lab?

Most Commonly Used Radiopharmaceuticals

- Tc-99m sestamibi
- Tc-99m tetrofosmin
- Tc-99m medronate
- F-18 fludeoxyglucose
- Tc-99m mebrofenin

Myocardial Perfusion

- Tc-99m sestamibi
- Tc-99m tetrofosmin
Skeletal Imaging

- Tc-99m medronate

Metabolic Imaging of Cancer

- F-18 fludeoxyglucose

Hepatobiliary Imaging

- Tc-99m mebrofenin

Key Radiopharmaceutical Concerns

- Formulary and FDA-approved radiopharmaceuticals
- Sourcing – vendor review
- Protocol review
- Storage and security
- USP <797> compliance
- Adjunct pharmaceutical use

Non-FDA approved Radiopharmaceuticals

- Your nuclear medicine department may unknowingly use non-FDA approved radiopharmaceuticals
- Some licensed radiopharmacies may sell non-FDA approved compounded products instead of commercially available FDA-approved radiopharmaceuticals
- When FDA-approved radiopharmaceuticals are commercially available, such compounded product sales are in contravention of FDA Compliance Policy Guide (CPG), Section 460.200

Non-FDA approved Radiopharmaceuticals

- Some examples include:
  - $^{131}$I NaI therapy capsules
  - $^{123}$I iobenguane (mIBG) injection
  - $^{201}$Tl thallous chloride injection
Licensing of Nuclear Medicine Department

- Nuclear Regulatory Commission or State agency
- Radioactive Materials (RAM) license details
- What can be received and stored
- Where RAM can be handled and stored
- Who may handle the materials

Controlled Substances

- Ioflupane I-123
  - DEA 222 controlled by hospital pharmacy
  - Receipt by nuclear medicine
  - Proper documentation
  - Decay of partial doses
  - Disposition as a controlled substance
- Other controlled substances

Sourcing – Vendor Review

- Arrange a site visit or vendor qualification trip
- All contract nuclear pharmacies must comply with USP<795> and <797>
  - Statement of USP compliance
  - Internal audit process
- All nuclear pharmacies should provide a statement of compliance on request

USP <797> and Nuclear Medicine

- Full USP <797> issues apply if on-site radiopharmaceutical compounding is performed
  - $^{99}$Mo generator used on site
  - $^{99m}$Tc sodium pertechnetate used to compound CSPs

Drug Storage and Security

- Be familiar with the nuclear medicine “hot lab” area
- Radiopharmaceuticals are short-lived
  - Hours / days / minutes
- Permission for early morning deliveries requires a written SOP that identifies authorized personnel
- Handling controlled substance radiopharmaceuticals
- Disposal – decayed on site or returned to the vendor
- All radioactive materials must be secured

USP <797> and Nuclear Medicine

- Contracted unit dose service helps simplify USP <797> compliance
  - Patient dosage administration is not part of USP <797>
- Immediate Use exemption may be used:
  - Fewer than 2 punctures into a septum outside ISO 5 air
  - Only 1 patient within 1 hour and discard the remainder
Regulatory and Accreditation

- Where is the requirement for oversight of in-house preparation of radiopharmaceuticals?
- What elements are required for nuclear medicine technologists to administer radiopharmaceuticals in a health system?
- What elements are required if the nuclear pharmacy delivery occurs prior to opening of the department?

Components of Imaging Department
- Radiology
- CT
- MRI
- Nuclear Medicine
- Interventional Radiology

Nuclear Pharmacy v. Nuclear Medicine
- Nuclear pharmacy
  - Licensed pharmacy
  - Pharmacist in charge
- Nuclear medicine department
  - Usually part of Imaging
  - Oversight by medical Director of Radiology
  - Part of hospital’s regulatory and accreditation surveys

Role of the Radiology Director
- Department direction
  - Medical director / administrative director
- Old days
  - Physician controlled all policies for the department
- What changed

What Changed
- Protocols must be approved by a medical staff committee with pharmacy involvement
  - Joint Commission 2013 MM Element of Performance
- Storage must meet federal, state, and accreditation standards
- Compounded Sterile Preparations must meet USP <797>
- Administration of medication must comply with scope of practice and hospital policy
### Medications Used

- Radiopharmaceuticals
- Non-radiopharmaceuticals used as part of radiology and nuclear medicine procedures
  - Adenosine
  - Dipyridamole
  - Regadenoson
  - Sincalide
  - Others

### Med Use System: Selection

- Formulary
  - Listing
  - FDA approved products
  - Non-sterile compounds
  - Sterile compounds
  - Approval of indications
- Leadership knowledge of and approval of use of contracted services

### Med Use System: Storage

- Who can access medications?
  - Nuclear medicine technologists
  - Physicians
  - Nurses
  - Nuclear pharmacy driver
- What medications are in and out of scope?

### FDA-Approved Radiopharmaceuticals

- Include radiopharmaceuticals on the hospital formulary
  - Obtain a list of all FDA-approved radiopharmaceuticals:
    - Generic and brand names
    - Manufacturers and indications
  - Access to package inserts and MSDS sheets available

### Med Use System: Ordering

- Pharmacy Director should review protocols for:
  - Drug, dosage, and route
  - Indications
  - Formulary agent
  - Source of the drug (FDA approval; compounded)
- Radiology Director should review protocols for:
  - Imaging or therapeutic procedure
  - Delay interval between administration and imaging
  - Images to be obtained
  - Image processing and display parameters

### Med Use System: Selection

- State board of pharmacy regulations
- Hospital policy
Med Use System: Dispensing

- Pharmacist review of orders
  - When required
  - When not required
- In-house preparation of radiopharmaceuticals
  - CMS Hospital Conditions of Participation
- Compounding non-radiopharmaceuticals
  - Cannot be compounded in department for convenience

Med Use System: Administration

- Licensing of nuclear medicine technologists
- Scope of practice
- Competence documentation
- LIP oversight

Med Use System: Monitoring

- CMS regulations and accreditation organization standards
- Medication errors
- Adverse drug reactions
- Incompatibilities

Summary

- Medications used in nuclear imaging
  - Radiopharmaceuticals
  - Adjunct medications
- Medication management also applies to radiopharmaceutical use
  - Formulary
  - FDA-approved radiopharmaceuticals
  - USP<797>
- Collaboration between pharmacy and nuclear medicine to help maintain accreditation compliance

Med Use System: Administration

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Med Use System: Monitoring

- CMS regulations and accreditation organization standards
- Medication errors
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What is the most commonly prescribed diagnostic radiopharmaceutical?
A. Tc-99m medronate
B. Tc-99m mebrofenin
C. Tc-99m sestamibi
D. Tc-99m tilmanocept
E. Tc-99m sodium pertechnetate
• Which radiopharmaceuticals should be included on the hospital’s drug formulary?
  A. Diagnostic radiopharmaceuticals
  B. Therapeutic radiopharmaceuticals
  C. All radiopharmaceuticals used in the institution

• Nuclear medicine technologists may administer radiopharmaceuticals within their scope of practice, as long as what additional criteria is met?
  A. Approval by the Chief of Radiology
  B. Approval by the Director of Pharmacy
  C. Approval in the hospital’s “who may administer medications” policy
  D. No additional approval is necessary, since it is within scope of practice

• A “hot lab” is a...
  A. Facility where drugs may be heated during preparation
  B. Facility where drugs are disposed
  C. Facility where drugs are stored
  D. Facility where drugs are prepared for patient administration
  E. All of the above

• If the nuclear pharmacy delivery occurs prior to opening of the department, which of the following statements is true?
  A. The driver may access the hot lab since he/she is certified by the Department of Transportation to handle radiopharmaceuticals
  B. The driver may access the hot lab if the hospital policy concerning access to medications allows it
  C. The driver may not access the hot lab since he/she is not a hospital employee
  D. The driver may not access the hot lab and should leave the radiopharmaceuticals in a designated area such as pharmacy or materials management

• Requirements for oversight of in-house preparation of radiopharmaceuticals is included in the CMS Hospital Conditions of Participation
  A. True
  B. False