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A Collaborative Approach to Radiopharmaceutical Management

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Given the longstanding autonomy of nuclear medicine departments coupled with an historical hands-off strategy from pharmacy leaders, integrating radiopharmaceuticals into the organization's overall medication management processes can be a challenge. Nonetheless, standards set forth by the Centers for Medicare and Medicaid Services (CMS) and various accrediting organizations apply to radiopharmaceuticals just as they do to any other medication, making it necessary to deploy a single integrated medication management system in order to ensure a safe and quality process for all patients. Through frank, open discussions and well-planned process change, this integration can be accomplished without adversely impacting workflow efficiencies in nuclear medicine or pharmacy.

A Single Medication Management Process

In many organizations, the practice of nuclear medicine (NM) has evolved over decades with these departments making management decisions for radiopharmaceutical (RP) use without any oversight from pharmacy. Generally, RP products were considered supplies for imaging and treated as such. To their credit, many of our colleagues in nuclear medicine have compiled a strong safety record with RP use and built efficient medication management systems. These parallel but separate systems prioritized safe use and handling, patient flow, and ensured quality images to facilitate appropriate diagnosis or treatment. Many decisions are impacted by these priorities, including what products are used, where they are purchased, where and how RPs are received and stored, how they are used, who administers them, who monitors them, and what is discussed with the patient.

Contrary to the common misconception that radiopharmaceuticals are simply dyes, these products are medications whose primary components are radioisotopes and are used largely to aid diagnosis, and in some cases as treatment. It can be valuable to share this definition with colleagues in both pharmacy and nuclear medicine for the purposes of accreditation. Accrediting organizations consider medications to be products carrying the prescription legend and designated as drugs by the Food & Drug Administration (FDA); thus, all medication management standards apply to radiopharmaceuticals. As a result, these standards hold the pharmacy director as well as the pharmacy and therapeutics (P&T) committee responsible for overseeing RPs as part of the organization's medication management system.

Medication management involves a series of processes addressing selection and procurement, storage, ordering and transcribing, preparation and dispensing, administration, and monitoring of all medications. The medication management system (MMS), when appropriately deployed, can help ensure ongoing quality and safety for patients. While separate RP management microsystems may individually lead to effective and safe outcomes, additional safeguards and quality checks are ensured when all medication management is approached as a single system with pharmacy oversight. These safeguards and quality checks impact each component of the system from integration into the P&T process to pharmacist review of protocols and orders to ensuring training and competency of technologists. A comprehensive set of radiopharmaceutical policies and procedures addressing all components of the medication management process that is aligned with quality standards, and is designed to meet the needs of the nuclear medicine department, is essential.

Process changes necessary to integrate RP management within the overall MMS may appear overwhelming for many pharmacy leaders whose departments have had minimal interaction with NM. Initially, pharmacists may be uncomfortable with these products given the separate processes that have evolved. Similarly, many nuclear medicine departments that have long operated independently may face challenges in accepting and making changes, especially for fear that workflow will be adversely impacted. Nevertheless, integration can be accomplished through collaboration; as such, a successful integration requires leadership expertise from both pharmacy and nuclear medicine disciplines.

Integrating Separate Processes

A gap analysis is an excellent first step to determine the degree to which current processes are in compliance with CMS conditions of participation and standards such as those established by TJC. This analysis may uncover issues such as the absence of a comprehensive approach to medication management; the lack of systematic and reproducible learning strategies that can drive improvement and innovation; or a general lack of integration between some medication use practices and the organization's overall MMS. A gap analysis ideally begins with an understanding of the standards in each component of the medication management process. Only then is it possible to review the process to determine areas of partial or no compliance. When a separate microsystem exists for RPs, it is essential to create alignment to remedy this deficiency.

An essential step to integrating separate medication management approaches and achieving regulatory compliance is to establish oversight by the pharmacy director and actively involve the P&T committee in decision-making. One way this can be accomplished is the collaborative development of a unifying set of policies and procedures that merges the separate systems for RPs into the organization-wide MMS. Oversight by the pharmacy director is required by standards; therefore this set of policies and procedures should install the pharmacy director in this role allowing the creation of new process paths in each component portion of the MMS that ensure safety, quality, and value.

A Successful Model

To establish oversight, the pharmacy director may need to address a number of specific issues with RPs, as identified in the gap analysis or

subsequent assessments and inspections. Through open discussion with colleagues in nuclear medicine, these may be resolved in a variety of manners consistent with the standards. At Christiana Care Health System, headquartered in Wilmington, Delaware, while working through such a process change, a steep learning curve was encountered leading to the compilation of a lengthy list of key lessons (see Table 1). The degree of success for solutions that work well at one organization may vary when implemented at another organization. Outcomes can be impacted by organizational design differences, divergent MMS processes, and frankly, the politics involved. That being said, the solutions implemented at Christiana Care were successful in ensuring ongoing compliance and may serve as a model for other organizations.

Lessons Learned

Many pharmacy leaders will quickly discover that their relationship with the leadership in nuclear medicine is under-developed. This may simply be the result of minimal interaction over time. Keep in mind that sudden efforts at relationship building, prompted by the need to comply with these standards, may be held suspect. This is especially true when the NM leadership is reluctant to embrace change and relinquish long-held autonomous decision-making. Efforts to achieve compliance may even be perceived as intrusive by some. Nevertheless, relationship building and collaboration is necessary to build trust and instill confidence that the needs of NM will be met even as they relinquish a level of control.

Procurement

With NM departments often choosing their own RPs and procuring these medications without pharmacy involvement, it is not unusual for a gap analysis to discover issues in the selection and procurement processes. Noncompliance can be due to the P&T committee not being involved in the evidence-based review and approval of RPs to the formulary as is done with all other medications. The P&T committee takes a broad approach to reviewing medications and through this comprehensive and thoughtful assessment, recommendations are made not only as to whether the product should be used, but also what safeguards should be implemented to optimize safety and what usage guidelines should be deployed to optimize value.

When medication sourcing is performed directly by the NM department and no mechanism is in place for communication with the pharmacy director, the oversight function cannot be fulfilled. An approach needs to be deployed that ensures a comprehensive, evidence-based formulary review, FDA-approval of the medication, availability of a quality product, and sourcing from appropriately licensed suppliers. Oversight of selection and procurement need not be onerous; it simply needs to be sufficient to ensure safety and quality. A pharmacy director may satisfy this procurement oversight by establishing mechanisms to periodically review supplier license status, quarterly quality control reports, invoices, and other appropriate reports and logs. Some RP vendors provide software to NM departments to track orders and deliveries for their use in meeting their regulatory and audit needs. Access to this resource can be a rich source of information for the pharmacy director.

Storage and Handling

The storage and handling of radiopharmaceuticals is not only governed by pharmacy regulations, but also by Nuclear Regulatory Commission (NRC) regulations. This adds an additional level of complexity and perhaps requires developing a new area of knowledge. A gap analysis may uncover regulatory issues associated with security of legend medications, occupational handling/shielding, disposal, appropriate storage conditions, or even with the pharmacy director's awareness of locations associated with delivery, transport, and storage of these medications. Security is of paramount importance and should be specifically addressed in policy and procedures (P&Ps). The security state should be inspected at least monthly by pharmacy staff to ensure adherence to federal and state regulations.

Special handling is required with RPs to ensure safety. Low levels of radiation can pose a risk to personnel involved in the medication use process, therefore organizations using RPs must be licensed and adhere to regulations governing both pharmaceutical preparation and radioactive materials. Shielding with lead or tungsten containers and the use of shielding barriers during dosage preparation are necessary. The pharmacy director, in collaboration with NM leadership, must ensure the use of appropriate shielding barriers during dose preparation and institute a process of routine quality checks. Preparation of cold kits using a Mo-99 generator will need specific oversight and P&Ps as well for onsite medication preparation.

These storage and preparation conditions need not be established in the pharmacy, and often are not. However, the pharmacy director must ensure the storage and handling conditions meet all applicable regulations. Equally important to the safeguards and conditions of storage and preparation are P&Ps outlining proper use, and competency assessments confirming staff understanding and ability to adhere. Where appropriate, measures to assure compliance to USP <797> requirements on training, environmental controls, cleaning, garbing, personal validation, and other requirements should also be in place. Inspection and quality assurance methods should be developed and deployed to monitor handling procedures, storage conditions, and competency assessments, as well as ensuring ongoing security of the products.

Procedures should be deployed to routinely identify and remove medications that have exceeded their expiration dates. Most RPs, because of their radioisotopes, decay very quickly (often in less than 24 hours). For this reason, beyond-use dating issues are a constant consideration for technologists working with these medications. Nonetheless, a periodic, systematic review process for expired RPs is important to minimize the risk of inappropriate use. Keep in mind, some medications require decay-in-storage handling procedures to allow decay to background radiation levels before disposal. In these cases, segregation should still occur from those products that are ready to use.

Pharmacist Order Review

Because of the nature of RP use in imaging procedures, standards allow medications to be ordered through ordering plans, provided the protocol ensures appropriate, safe use through a collaborative review process with approval from pharmacy and the P&T committee. Ideally, a pharmacist reviews all medication orders prior to preparation and administration, however, in cases where the licensed independent prescriber (LIP) is in direct control of the case, and assumes this responsibility, review by a pharmacist can be exempted. In a growing number of organizations, this exemption is being phased out and orders are being routed to pharmacy prior to the procedure creating an optimal medication safety approach. In cases where the LIPs perform their own review, it is especially important to establish a performance monitor in which the performance of the protocol is assessed and this information is used for key learning and innovation. The procedural ordering plan should be periodically updated (annually, at minimum) to reflect new evidence affecting safety and/or efficacy as well as evolving evidence-based practice.

Conclusion

Managing radiopharmaceuticals as part of an organization's overall MMS need not be a daunting challenge and can be accomplished with a

collaborative approach. Compliance with CMS conditions of participation and with accreditation standards in medication management is of paramount importance. Above all, oversight of all medications by the pharmacy director is required within a comprehensive MMS aimed at optimizing quality and safety. The initial steps may necessitate a focus on building trust; trust that pharmacy will provide value to the process rather than detract from it. While the unique properties of these agents require additional considerations, leaders with well-deployed medication management systems should have no problems incorporating these agents into their processes.

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Table 1. Principle Issues in Compliant Radiopharmaceutical Management

Following a comprehensive review of Christiana Care Health System's radiopharmaceutical management, we gained some key lessons on building processes to improve the quality and safety of our radiopharmaceuticals. These select issues do not represent an exhaustive list of elements necessary for meeting the CMS conditions of participation or accreditation by TJC or other accrediting bodies.

Key Issues	Lessons Learned
Selection & Procurement	
The formulary system should perform a comprehensive, evidence-based review of radiopharmaceuticals to ensure safety, quality, FDA approval, reasonable cost (including special handling), and availability of quality NM compounds from a licensed supplier.	Gaining agreement from NM to adopt P&T processes and infrastructure was the most critical change in the undertaking and led to compliance with multiple standards, not just medication selection.
The safety and effectiveness of new radiopharmaceuticals should be monitored after inclusion on formulary.	Merging RP event reports into the existing medication event reporting system infrastructure provided a process for follow-up review, trending, and organizational learning.
As with any medication, the formulary should include all RPs and this information should be available to all involved in medication use.	A significant undertaking was required to identify all RPs in use and to review them thoroughly for P&T consideration. Because our formulary information vendor did not have monographs for a majority of the RPs, we worked with them to get these written and uploaded to the formulary, which is available through our intranet.
Storage	
Manufacturer-recommended storage requirements should be assured and pharmacy personnel should inspect the hot lab and all storage areas.	Because these medications are compounded and delivered to NM by an outside vendor, pharmacy's first challenge was learning where they were housed. We also needed to learn about NRC regulations and storage requirements, including appropriate shielding and other special handling issues. Hot lab facilities must meet a variety of requirements including occupational safeguards, and both aseptic (USP <797>) and non-aseptic conditions (USP<795>). We added the NM hot lab to our regular monthly unit inspection list with additional instructions addressing the unique radioactive properties and storage requirements.
Radiopharmaceutical security should be assured to meet both federal and state prescription medication regulations and only authorized personnel should have access to locked areas.	Establishing a chain of custody for received orders and locations for storage was important. Previously, there was no communication mechanism (or requirement) to notify pharmacy of any issues. For purposes of access and handling, we defined authorized personnel as certified nuclear medicine technologists, nuclear medicine nurses, pharmacists, pharmacy technicians, and nuclear medicine physicians privileged at our facility. This was incorporated into the respective job descriptions as appropriate.
Food and medications should be stored separately.	In some cases, RPs are mixed with food or milk and then are stored in the same refrigerator as other food. A policy requiring separation of mixed food/drug from food was key to avoid accidental ingestions, as well as contamination of other RPs. This policy addresses labeling requirements and separate refrigerated storage when preparation is done ahead of administration or in the case of a delay in administration.
Radiopharmaceuticals that are no longer appropriate for administration to patients should be identified and segregated.	Because of the very short half-lives of most RPs, technologists were acutely aware of beyond-use dates and vigilant in recording activity. Nevertheless, a systematic and routine process for separating contaminated, damaged, and expired RPs was deployed. These separated medications have special handling procedures, which in some cases employ a decay-in-storage approach until they meet background levels of radiation before disposal.

Key Issues	Lessons Learned
Ordering & Transcribing	
A licensed independent prescriber (LIP) should directly control the ordering, preparation, and administration of radiopharmaceuticals unless reviewed by a pharmacist for appropriateness.	Standards require that all medication orders be reviewed by a pharmacist unless an LIP controls the process or a delay would harm the patient. When bypassing the pharmacist review of individual orders, the LIP must directly supervise dosage, compounding, packaging, labeling, administration, and monitoring of the patient. Whereas there are differing references for the meaning of "directly control" or "directly supervise," we agreed on physical location of the physician supervising the certified NM technologists (CNMTs) and acknowledgement that the case was underway under his/her responsibility. Because of the procedural nature of RP use, these agents may be incorporated into pre-approved order plans allowing pharmacist input and P&T oversight and approval. These also allow measurement and trending of outcomes as a result of use, which are key to process improvement.
RP dosing guidelines typically recommend ranges, not absolute doses. When the available product cannot meet the P&T pre-approved dosing range, the CNMT should communicate with the physician.	Because of the rapid decay nature of RPs, dosing guidelines describe ranges of activity that will produce the level of imaging needed. When a procedure is ordered, the CNMT is tasked with matching the available product and its current activity with the activity range indicated. On rare occasions, such as using a freshly received compound or a compound near its beyond-use date, the activity will not allow the dose to be within the approved range. Per our process, an event that does not allow the CNMT to carry out the P&T approved plan requires the CNMT to communicate this with the LIP. If the LIP decides to proceed, he/she is then required to perform the dose preparation and administration.
For each procedure, the order, patient history, details of radiopharmaceutical dose administration, patient counseling, and other important elements of the case should be recorded.	All documentation is maintained in our health system's picture archiving and communication system, along with the images from the study. This information is kept indefinitely and is available for review by nuclear medicine or pharmacy staff as needed.
Preparation & Dispensing	
Preparing RP doses for administration or eluting the Mo-99 generator should be performed under the direct supervision of an appropriately trained pharmacist or doctor of medicine or osteopathy.	Radiopharmaceutical use, including preparation, dispensing, administration, and patient monitoring is supervised by an assigned physician. This assignment is posted daily for all shifts in NM. Prior to dose preparation, the CNMT communicates with the LIP, allowing them to meet the direct supervision requirement for dose preparation, administration, and subsequent patient monitoring.
The pharmacy director is responsible for ensuring that sterile product preparation meets USP <797> standards and that staff competency is assessed in accordance.	Competency assessment in sterile product preparation should be conducted as routinely in the NM hot lab areas as it is in pharmacy. Pharmacy provided a template for NM to base their processes on. The new employee and annual competency reports, as well as the monthly hot lab inspection reports are provided to the pharmacy director for oversight.
Administration & Monitoring	
A CNMT should meet the training and competency requirements for medication administration within the scope of their practice, and under the direct supervision of an LIP, be able to administer the prepared dose.	Once the nuclear medicine physician (as the authorized user under the institution's NRC license) approves a particular study or procedure for a patient, a CNMT may administer radiopharmaceuticals under the authorized user's supervision pursuant to the P&T approved protocol.
Patients should receive information on the risks and benefits of the imaging procedure including information regarding the RP to be used. The physician directly supervising administration of the RP bears responsibility for monitoring the patient throughout the procedure and subsequent care.	Because each procedural protocol continually undergoes collaborative review including pharmacist input, it is feasible to have the technologist, under the LIP's supervision, screen for potential drug interactions and contraindications specific to the selected agent. A process was required to ensure patients are informed of the RP used, any potential risks and benefits, and post-procedure instructions. Following administration, monitoring is also built into the procedural protocols as a responsibility of the CNMT, under supervision of the LIP.
To ensure the RP is appropriate, the administering individual should review the patient-specific information including age, sex, diagnoses, allergies, sensitivities, current medications, height, weight, pregnancy/lactation status, and pertinent lab results prior to administration, and ideally prior to preparation.	Because RPs at our organization are ordered through a procedural ordering plan and the process is directly controlled by an LIP, the appropriateness review is performed by the individual administering the RP under the LIP's direct supervision. At a growing number of organizations, a pharmacist conducts this review prior to the procedure. In this case, an order is generated beforehand and routed to the pharmacist for review and approval; however, there are still a significant number of organizations whose procedure remains under the direct control of the LIP.