U.S. Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee on Development of a Generic Process Checklist to Help Reduce Medical Events

Final Report

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Subcommittee Members
Richard Green, BS Pharm (chair)
Rebecca Allen, MS
Richard Harvey, DrPH
Hossein Jadvar, MD, PhD
Melissa Martin, MS
Zoubir Ouhib, MS
NRC Staff Resource: Daniel Dimarco

Charge

On Dec 6, 2022, Dr. Darlene Metter, the ACMUI Chair, created a subcommittee on the development of a generic process checklist to help reduce medical events.

Background

Due to the increased number of medical events in 2021, a suggestion was made for the ACMUI to develop generic process checklists for all user procedures. It was noted that it may be appropriate to have the professional licensing boards take the lead on developing, communicating, and standardizing the checklists.

Development Process:

On 6 January 2025 the subcommittee met and discussed what items should be on a generic process checklist utilized to help avoid medical events in the clinical use of radioactive materials / radiation. It is understood that this generic process checklist would be focused on radiopharmaceutical but could be easily adapted by users to focus on other modalities of the use of radiation in medical care such as brachytherapy or external beam radiation therapy.

Generic Process Checklist Elements (using radiopharmaceuticals as an example)

- Establish patient identity (2 methods utilized)
    - Determine pregnancy status if applicable
- Verify elements of the prescription
    - Is it the correct radiopharmaceutical?
    - Is it the correct dose?
        - Do laboratory results support the dose?
        - Do imaging results support therapy, if being performed?
    - Is it the correct route of administration?
- Are all professionals working within their scope of practice?
- Conduct patient / family support education prior to administration (consultation) and is understood
- Verify that the dose matches the written directive if applicable
    - If written directive, comply with requirements of 10 CFR 35.41
- Is the route of administration patent?
- Measure or calculate the radiopharmaceutical activity
- Administer the dosage
- Check for possible extravasation of injection
- Record keeping is conducted (residual activity?)
- Patient release – dose to the public (Reg guide 8.39) – verbal, with interpreter if required and in writing, documentation
- Contact information of Nuclear Medicine (or other applicable) department

Local Customization is Required

Each licensee / department shall develop a process (checklist) that is specific to their practice and processes. This development should often start by reviewing approved procedure documents and accrediting organization requirements and any national patient safety goals that have been established. All process checklists / processes should work together to assure the "Five Rights of Medication Administration"

- the right patient
- the right drug
- the right route
- the right dose
- the right site and segment
- the right applicator and access device
- at the right time
- with the right team

A "Checklist" does not mean it must be paper based

While a paper checklist could be utilized, it is understood that modern means utilizing software platforms and barcodes could be extremely beneficial in preventing medication errors / medical events. These could include the following.

- CPOE - computerized prescription order entry
- IVWMS- IV Workflow Management Systems
- eMAR - electronic medication administration records
- BCMA - barcode medication administration

E-prescribing "has been shown to reduce medication errors in the ambulatory setting by as much as sevenfold."[1]

It was found that after implementation of BCMA, "nontiming errors had a relative risk reduction (RRR) of 41.4%, …wrong medication errors had a RRR of 57.4%, … wrong dose errors had a RRR of 41.9%, … wrong route of administration errors had a RRR of 68%, … and administration documentation errors had a RRR of 80.3%."[2]

1. Porterfield, A., Engelbert, K., & Coustasse, A. (2014). Electronic prescribing: Improving the efficiency and accuracy of prescribing in the ambulatory care setting. Perspectives in Health Information Management, 11(Spring), 1-13.
2. Shah, K., et al (2016), Bar Code Medication Administration Technology: A Systematic Review of Impact on Patient Safety When Used with Computerized Prescriber Order Entry and Automated Dispensing Devices. Canadian Journal of Hospital Pharmacy, 69 (No 5), 394-402.

Summary

The subcommittee developed a generic process checklist that could be adapted by licensees to help avoid medical events in the clinical use of radioactive materials / radiation. Each licensee / department should develop a process (checklist) that is specific to their practice and processes. Checklists to help prevent medical events would be most effective if they incorporated software platforms and barcoding.

Recommendations

The subcommittee recommends the following.
Each licensee / department should develop a process (checklist) that is specific to their practice and processes.

NRC staff should consider the best means to communicate this process (checklist) recommendation to licensees, either by information notice or guidance document.

Respectfully submitted on February 12, 2025,
Subcommittee on Development of a Generic Process Checklist to Help Reduce Medical Events
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The ACMUI unanimously approved this report as presented during its public meeting on April 7, 2025.