Root Cause Analysis Report

I131 Therapy Given, I123 RAIU intended

Date 12/28/2020

Date of Analysis Conclusion

Prepared by: Michelle White RSO

Reviewed by: Rhonda Roesler
Webex
Traci Nord
Christopher Gregory
Ashley Hanson
Michelle White
Brad Paulson
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Purpose and Scope of the Root Cause Analysis Report

Purpose

Determine the root and contributing causes for the order of I131 Low Dose instead of I123 Scan and Uptake.

Scope

Patient was given a low dose I131 ablation therapy. The provider's intention was for an I123 Scan and Uptake to be performed.

Problem Statement

A written directive was issued and executed while an I123 Scan and Uptake was intended. This originated due to miscommunication between Centralized Scheduling and Nuclear Medicine Scheduling.

Consequences of Event Investigated

A medical event was reported to the Nuclear Regulatory Commission on 12/23/2020 in violation of CFR 35. 3045, Subitem A. ii. A. The patient's thyroid organ was ablated.

Immediate Actions Taken

The Medical Event was reported to Avera Medical Director, Dr. Michael Elliott on December 22, 2020 by the Medical Director, Dr. Mary Carpenter, of the facility of the patient involved.

Dr. Elliott reported the event to the Chairman of the Avera Medical Group, Dr. Brad Paulson, who happened to be the Authorized User who wrote the written directive.

Dr. Paulson suggested that Dr. Ellliott contact the Radiation Safety Officer, Michelle White.

Ms. White and Associate Radiation Safety Officer, Ashley Hanson, researched the Physician Assistant and the Endocrinologist Physician notes. At this time, the intended order for an I123 Scan and Uptake was located.

Phone calls were placed to Dr. Carpenter, PA Stacey Scott, and Dr. Longo for information.

A visit occurred between Nuclear Medicine Medical Director, Christopher Gregory, Ashley Hanson, and Michelle White to discuss reporting the event. Dr. Gregory agreed on the need to report the event to the Nuclear Regulatory Commission.

Event Narrative

1. Stacey Scott, PA's office contacted Avera Centralized Scheduling to order an RAIU (Radioactive Iodine Uptake). See Exhibit A. Order provided to Centralized Scheduling.
2. Avera Centralized Scheduling, Rebecca Matthiesen, called Nuclear Medicine Scheduling asking which Radioactive Iodine Uptake to order.
3. Conversation occurred between Centralized Scheduling and Nuclear Medicine, Kelley Schroeder. Listen to Exhibit B.
4. It was ordered as NM I131 Therapy Thyr Ablation. See Exhibit C.
5. The Requisition order printed out and given to Dr. Paulson.
6. Dr. Paulson wrote the written directive. See Exhibit D.
7. Nuclear Medicine performed the therapy according to Written Directive. See Exhibit E.

Individual Dr. Mary Carpenter.

Event Narrative: The discussion between Dr. Carpenter and Michelle White: Dr. Carpenter's main concern was if their office had ordered incorrectly. Michelle stated that she felt the correct order was

verbalized. Michelle questioned whether the patient had been notified as this was a requirement of the reporting regulation. Dr. Carpenter referred her to Stacey Scott, the immediate provider.

Individual Dr. Charles Longo.

Event Narrative: Dr. Longo expressed that he had a consult virtually. He had been told that an I123 Scan and Uptake and labs were pending. This is in his clinic notes. Michelle asked if he had told the patient and he said that he understood the provider, Stacey Scott, was going to provide the information to the patient. He also stated that I131 ablation was one route that would potentially be pursued but that there were others that would have been considered.

Individual Dr. Christopher Gregory.

Michelle, Ashley, and Dr. Gregory, Nuclear Medicine Director discussed the case. Michelle explained her stance on reporting the event to the NRC. Dr. Gregory was in agreement. He stated he felt the responsibility lies to the Authorized User to review the case prior to writing the written directive. This was the practice for a long time. Just recently he had added that to the procedure because of accreditation needs to be in written form. He had not had a chance to implement the changes yet. See Exhibit F.

Red is new verbage added

Individual Stacey Scott, PA 12/28/2020

Event Narrative: Michelle explained the situation to Stacey and that she had reported this to the Nuclear Regulatory Commission as a medical event. Michelle asked if the patient had been notified. Stacey said that she had talked with the patient this morning. Stacey will send her notes of the patient discussion by fax to Michelle. The two also discussed language to use when ordering an I123 scan and uptake. Stacey also relayed that the patient said that he had no idea that he was receiving a therapy. Michelle assured her that a physician had counseled the patient and that was on record. See Exhibit G.

Group Management discussion, 12/29/2020

Event Narrative: Michelle opened with a synopsis of the Root Cause Analysis performed to date. She and Ashley broke down the timeline of events to the best reconstruction possible. This solicited discussion among meeting participants(Michael Elliott, Rhonda Roesler, Traci Nord, John Mathison, Ashley Hanson, Michelle White, Christopher Gregory, Brad Paulson) Dr. Gregory voiced that the I131 Therapy procedures was in the process of being worked on due to the need to include Authorized User role in the procedure for ICANL. It had not been presented to the physicians to date. He felt this would prevent this event from happening in the future. It was also discussed to have Nuclear Medicine assemble lab, order, and test results and place in the patient's folder prior to requesting a written directive. Dr. Elliott closed the meeting by saying that this was an opportunity for Process Improvement for Avera.

Root Cause Determination

Probable Root Cause

The probable root cause is failure to review the patient's clinical situation prior to writing the written directive.

Contributing Causes

Miscommunication between Centralized scheduling and Nuclear Medicine.

Recommended Corrective Action

Probable Root Cause Corrective Action

Review the new Therapy Procedures with Authorized Users. This includes the first line stating that after obtaining a request from the clinical service, the Authorized User physician must first review the patient's clinical situation and determine if this particular treatment option is appropriate for this patient's situation.

Contributing Cause Corrective Action

Obtain the order from Centralized Scheduling for thyroid studies originating from outside the Avera blueprint. Place this in patient's folder.

Patient history of I123 Scan and Uptake and Thyroid labs are to be gathered and placed in the patient's folder prior to asking for a written directive.