

Root Cause Analysis of Na¹³¹I Contamination

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Establishing a cause-and-effect relationship for an adverse event is one of the key steps in preventing them and involves multiple people, resources, and steps, thus requiring a root cause analysis. Here, we describe a root cause analysis performed in the nuclear medicine department for an event involving Na¹³¹I contamination. Oral administration of Na¹³¹I in a capsule minimizes the risk of contamination and spills. However, the patient must be able to swallow a capsule. Na¹³¹I in capsule form is currently in widespread use for treatment of hyperthyroidism and thyroid cancer. Na¹³¹I in liquid form is rarely available immediately on demand and must be ordered at least 24–48 h in advance of the planned administration. The events leading to the incident, immediate remedial steps taken, and subsequent root cause analysis are described. The corrective actions taken after the root cause analysis, as well as the subsequent effectiveness of these actions, are mentioned. There may be one or multiple causes for an adverse event. It is important to identify the root cause. Corrective actions derived from the root cause can help prevent similar adverse events in the future. Therapeutic procedures in nuclear medicine involve unsealed radioactive sources, further adding a separate layer of immediate steps and reporting to the root cause analysis itself.

Key Words: root cause analysis; Na¹³¹I contamination; radioiodine therapy; hyperthyroidism

J Nucl Med Technol 2021; 49:350–353
DOI: 10.2967/jnmt.121.262492

Saul Hertz first administered radioiodine (Na¹³¹I) to a patient in 1941 at Massachusetts General Hospital as a treatment for hyperthyroidism (1). For a long period, Na¹³¹I was available only in liquid form, but by the 1970s, Na¹³¹I was available in capsule form (2). Oral administration of Na¹³¹I in a capsule minimizes the risk of contamination and spills. However, the patient must be able to swallow a capsule. Na¹³¹I in capsule form is currently in widespread use for treatment of hyperthyroidism and thyroid cancer. Na¹³¹I in liquid form is rarely available immediately on demand and must be ordered at least 24–48 h in advance of the planned administration.

Here, we describe an adverse event in which a hot lab and radioisotope dosing room were contaminated with Na¹³¹I because of an attempt to break open the capsule to dissolve the contents in a cup of water. We also describe the events leading to the incident, the immediate remedial steps taken, the subsequent root cause analysis, corrective actions developed after the root cause analysis, and the subsequent effectiveness of the corrective actions. There may be one or multiple causes for an adverse event, and unless a root cause is determined, a comprehensive corrective action to prevent a similar adverse event in the future is not possible (3,4).

Quality Event. The Na¹³¹I contamination event occurred on October 15, 2019, in the radioisotope dosing room and hot lab of a large community hospital where around 30 patients per year are treated for hyperthyroidism. The facility performs around 6,000 nuclear medicine (NM) procedures per year and has 5 NM technologists and a supervisor. Three NM physicians cover different days of the week. The policy of the hospital regarding patients who are to undergo a radioactive iodine scan and subsequent therapy is to perform a consultation using a checklist (5). Figure 1 shows the policy and protocol for radioiodine therapy for hyperthyroidism.

A 48-y-old woman presented to the NM department for Na¹³¹I therapy for hyperthyroidism. When the authorized user (AU) physician and a resident physician were about to administer the 1.11-GBq (30 mCi) Na¹³¹I capsule in the dosing room, the patient told them that she was unable to swallow the capsule as she had oropharyngeal thrush due to an underlying immunodeficiency.

The AU called the radiopharmacy to obtain Na¹³¹I in liquid form, but it would not be available for another 3 d because the request was being made on a weekend. Since the patient was not willing to return after 3 d, the AU decided to open the Na¹³¹I capsule in the dosing room and empty the contents into a cup of water for the patient to drink. The AU and resident first tried to open the capsule with gloved hands over a cup of water placed on a counter in the treatment room. The Na¹³¹I capsules supplied by the vendor have Na¹³¹I solution injected directly into a small capsule, which is enclosed within a larger capsule. Figure 2 demonstrates the preparation and configuration of these Na¹³¹I capsules.

Received Aug. 6, 2021; revision accepted Sep. 30, 2021.
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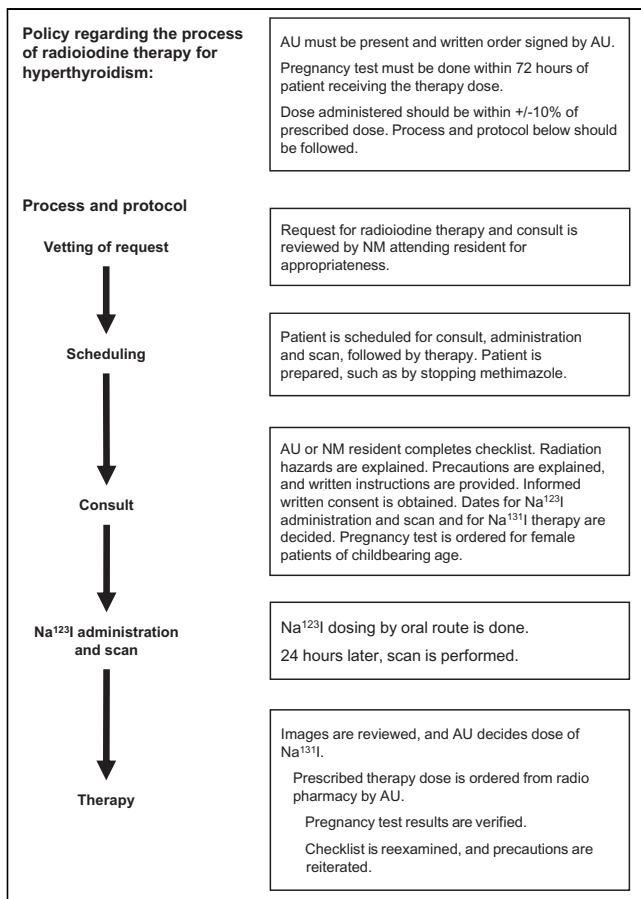


FIGURE 1. Policy and protocol for radioiodine therapy for hyperthyroidism.

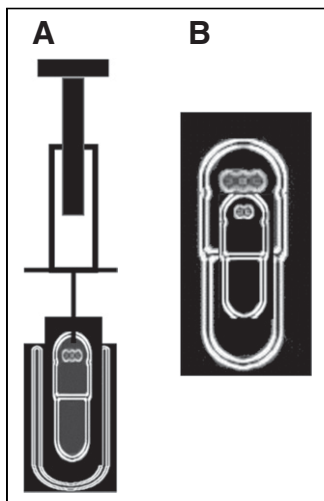


FIGURE 2. (A) Injecting Na¹³¹I into center of inner small capsule. (B) Slipping upper half of large capsule over bottom half to completely cover small capsule, which is then gently pushed down until locked.

Unaware that the capsule had this configuration, the resident and AU opened the outer capsule but could not open the inner capsule. They transported both into the hot lab and, placing them behind a lead glass shield, tried to puncture the inner capsule with a needle. A technologist passing through the area overheard the physicians talking about the attempt to puncture the capsule. She raised concern about contamination and contacted the radiation safety team. The radiation safety officer and an assistant radiation safety officer surveyed the hot lab and dosing room and found

that Na¹³¹I contamination was present on the floor, as well as on the countertop in the dosing room. The radiation levels from the floor contamination were quite high (over 20 mR/h at a distance of 1 m), whereas the levels on the countertop were lower (5 mR/h at 5 cm). An attempt to clean the floor contamination was not successful. The patient did not receive Na¹³¹I therapy, was surveyed for contamination, and was sent home with a plan to reschedule her treatment with liquid Na¹³¹I.

The radiation safety officer surveyed the AU, resident, and technologist and found that the shoes and white coats of all three were contaminated. The shoes and white coats were stored in the radioactive waste room, and the hot lab and dosing room were posted with warning signs for a total of 80 d, the equivalent of 10 half-lives of Na¹³¹I. The facility had a second dosing room and another hot lab that could be used in the interim, and operation of the department was resumed with little interruption. On the next day, the AU, resident, and technologist underwent bioassays to measure radioactivity in the thyroid, and none was found. The radiation safety officer contacted the state nuclear materials regulator within 24 h and provided a detailed report within 30 d. An unbiased team consisting of a NM physician, a technologist supervisor, and another technologist (none of whom were involved in the incident) performed a root cause analysis.

The contamination event and immediate actions are summarized in Figure 3.

QUALITY ANALYSIS

The team asked “why” until the answers guided them toward corrective actions.

Why Did AU and Resident Try to Open Capsule?

The patient could not swallow the capsule, and the radio-pharmacy could not provide Na¹³¹I in liquid form on that day. The policy folder did not specifically mention “do not tamper with the radioiodine capsule.”

Suggested corrective action: The policy will specifically forbid tampering with Na¹³¹I capsules.

Why Was Treating Team Not Aware That Patient Could Not Swallow Capsule?

The patient was in the department on the previous day to undergo a Na¹²³I scan. Another technologist had opened the Na¹²³I capsule, dissolved the contents in a cup of water, and given it to the patient. He also informed the AU about taking these measures. The Na¹²³I capsule contained granules and could be twisted open to release the contents. Even though the contents can be emptied into a glass of water, this method of administration is not correct because it is not possible to assay the dose and there is a possibility of contamination.

Suggested corrective action: All AUs and technologists are to be provided with additional training.

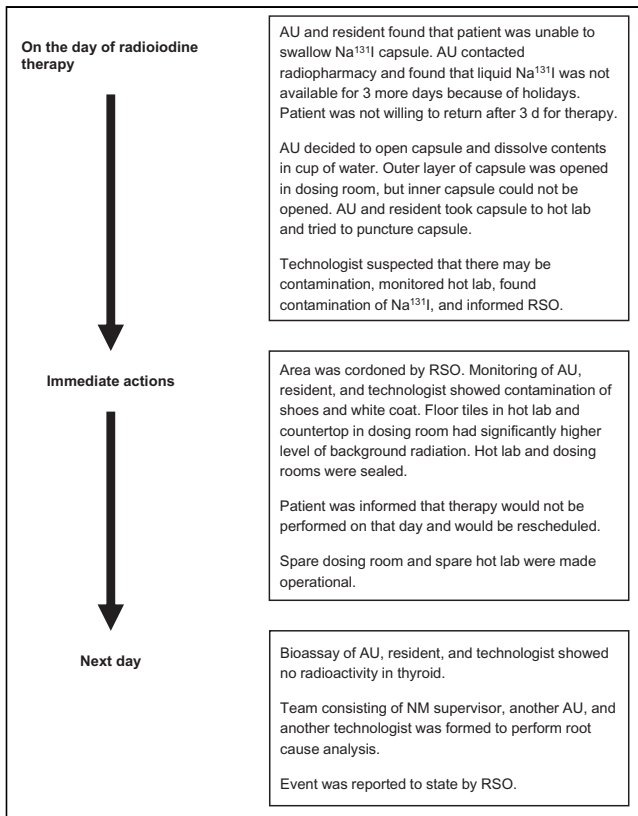


FIGURE 3. Sequence of events on day of radioiodine therapy contamination.

Why Was Inability to Swallow Capsule Not Identified Before Na¹²³I or Na¹³¹I Capsules Were Ordered?

The checklist used for patient consultations before Na¹²³I scanning and Na¹³¹I therapy did not include a check of whether the patient can swallow the capsule.

Suggested corrective action: A question about capacity to swallow the capsule is to be added to the checklist.

Why Was Floor Contamination Not Removable?

The floor of the hot lab and dosing room had 30-cm square tiles. The Na¹³¹I had seeped into the gaps between the tiles. The hot lab was designed almost 2 decades before the incident.

Suggested corrective action: The flooring of the hot lab, dosing areas, and bathrooms in the NM department is to be replaced with continuous linoleum.

CORRECTIVE ACTION

The NM staff, consisting of all technologists, NM physicians, and NM residents, comprehensively reviewed the incident and were retrained within a week afterward. The training was done by a team of experienced AUs, including the directors of the NM departments of 2 major hospitals.

The corrective actions suggested in the root cause analysis were added to the policy and checklist. The consultation form was updated with a line specifically directing that the capsule should not be tampered with under any circumstances.

Continuous linoleum flooring was installed in the renovated hot lab, dosing room, and bathrooms.

The corrective actions for each cause and effect are summarized in Figure 4.

VERIFICATION OF EFFECTIVENESS

Between May 1, 2020, and April 31, 2021, more than 50 hyperthyroid patients have been treated with Na¹³¹I. During that time, no adverse events have been recorded.

Cause-and-effect analysis is needed to prevent errors. Finding a cause is easy and straightforward in a procedure that involves a single step and a single person. Providing health care has become a team effort involving multiple people and steps. When an adverse event takes place during or because of a procedure that involves multiple steps and people, it is necessary to perform a root cause analysis to prevent such events in the future.

In our case, if we had looked at the apparent cause we would have ended up retraining only the AU, resident, and technologist involved. The root cause analysis revealed that multiple additional team members were also misinformed and had—contrary to recommendations—opened Na¹²³I capsules. The root cause analysis exposed deficiencies in the policy and in the checklist used in the protocol. Thus, the root cause analysis resulted in a comprehensive corrective-action plan.

Reporting the exact sequence of events honestly is the critical factor in root cause analysis. Honest reporting is possible when there is no fear of reprisal if unintended human error or deficiency is found in the policy or protocol. Analysis of the event and finding the causes that led to it also depend on having an unbiased team perform the analysis and make the

Event	Why	Corrective action
Radioiodine contamination on day of therapy.	Why was there Na ¹³¹ I contamination? Patient was not able to swallow capsule, liquid Na ¹³¹ I was not available, and AU decided to open capsule so as to dissolve contents in water. Policy did not specifically mention that capsule should not be opened.	Add to policy: "do not tamper with radioiodine capsule," and train the AU involved.
Na ¹²³ I dosing for administration and scan	Why was patient able to swallow Na ¹²³ I capsule on previous day? Patient was not able to swallow Na ¹²³ I capsule. It was opened, and content was dissolved in water by another technologist and another AU.	Retrain whole team, since other technologist and AU opened Na ¹²³ I capsule.
Consult	Why was inability to swallow capsule not known before scan or therapy? Consult checklist did not check for ability to swallow a capsule.	Add to checklist: "determine whether patient can swallow a capsule; if not, order liquid radioiodine."
Radioiodine contamination	Why could contamination not be removed? Tiles were used for flooring in hot lab and dosing room. Iodine powder was in cracks between tiles.	Change flooring of hot lab, dosing room, and bathroom to continuous linoleum sheet.

FIGURE 4. Sequential corrective actions taken for each cause and effect identified while performing root cause analysis.

corrective recommendations. Continuous monitoring after the recommendations are implemented is the way to measure continuous quality improvement. The reported event and subsequent root cause analysis in our case resulted in comprehensive corrective actions, achieving desired outcomes in procedures for over a year of subsequent follow-up.

DISCLOSURE

No potential conflict of interest relevant to this article was reported.

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