Mann & Robert H. Lurie Children's Hospital of Chicago

#### Pediatric lodine 131 Therapy: A root cause analysis

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M Northwestern Medicine

#### AAPM 2017 Conference Theme

## Connecting our Pathways. Unifying our Profession.



Theranostic Radioiodine!

### Radioactive lodine-131 Therapy





- Hyperthyroidism (Grave's Disease):
  - Administered dose is in the range ~10 mCi.
    I-131 is used to partially deactivate an overactive thyroid
- Thyroid Cancer:

  - Administered dose is in the range of ~100 mCi
     I-131 is used to kill remaining thyroid cells or metastases after thyroidectomy
     Generally administered as an inpatient at our institution

## Environmental Protection for Inpatient I-131 Therapy



Radioactive Half Life and Decay	Times
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Isotop e	Producti on Method	Decay Mode	Principal Photon Emissions (keV)	Half-life	Primary Use
11C	Cyclotron	β+, EC	511	20.4 min	Diagnostic
<sup>13</sup> N	Cyclotron	β+	511	9.97 min	Diagnostic
15O	Cyclotron	β+	511	2.03 min	Diagnostic
18F	Cyclotron	β+, EC	511	110 min	Diagnostic
32 <b>P</b>	Reactor	β-		14.3 d	Therapy
67Ga	Cyclotron	(EC, γ)	93, 185, 300	3.26 d	Diagnostic
82Rb	Generator	β+, EC	511	1.25 min	Diagnostic
99mTc	Generator	IT	140	6.02 hr	Diagnostic
111In	Cyclotron	(EC, γ)	172, 247	2.83 d	Diagnostic
123 <b>I</b>	Cyclotron	(EC, γ)	159	13.2 hr	Diagnostic
125I	Reactor	(EC, γ)	27-30	60.1 d	In vitro assays
<sup>131</sup> I	Reactor	(β-, γ)	364	8.04 d	Theragnostic
<sup>201</sup> TI	Cyclotron	(EC, γ)	68-80	3.04 d	Diagnostic

- In January of 2017 we attempted to administer 27 mCi by mouth in gel capsule form to a 7 year old child with metastatic thyroid cancer.
- Most cancer patients are administered larger doses but it was determined that this
  child's metastatic lung diseases was too extensive to risk a large administration
  since this might compromise lung function.
- It was determined that the patient could be safety administered this dose as an outpatient.
- The patient had sever dysphagia (trouble swallowing) post-thyroidectomy and was
  temporary on a liquid diet.
- Following the resumption of a solid diet, the patient still had a fear of swallowing pills and was prescribed pill swallowing therapy.
- Patient was observed by four people (radiologist, nuclear medicine technologist, endocrine nurse, child life specialist) and "swallowed" the dose.

- Attempted administration of 27 mCi of I-131 by mouth in capsule form.
- Staff present in treatment room included the technologist, radiologist, endocrinology nurse, child life specialist, patient.
- After child "successfully"
   After child "successfully"
   swallowed pill, RSO and parents entered treatment

room.

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#### **Root Cause Analysis**

- Staff prepared family for discharge, child needed to use the bathroom.
   Radiologist and nurse leave
- the area.
  After child left the room, staff noticed that radiation was still present.
- still present. Presence of radioactive patient generally limits the ability to detect contamination due to very high background from the administered dose.

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- Staff suspected that child hid the pill instead of swallowing
- Technologist begin sorting through objects in treatment room (toys, personal items, patient ray) the room.
- RSO performed a radiation measurement of child at 1m in hallway. Dose appeared to correspond with administered dose.



- In order to fully establish if pill was in the child's stomach a second technologist decided to make an image of the patient on the gamma
- We needed the child to remove her clothes so we could be certain she did not hide the pill in her pocket.

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#### **Root Cause Analysis**

- RSO inspected the clothing for the pill and did not find anything resembling the gel
- capsule. In order the separate objects in the treatment room and better search for the pill, another staff member removed items to the hot lab in order to take advantage of the shielding.



- Technologist and RSO were unsuccessful in locating the pill and suspected that the background from the patient was interfering with Geiger counter measurements.
- Suspicion shifted to the child's outerwear and the decision was made to move the jacket behind the PET/CT shield in order to shield it from background and search for the pill.



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- Once behind the shield RSO and technologist identified that they themselves were contaminated on their skin and clothing.
- At this point staff moved into PET/CT to access sink and wash isotope from the skin.
   Only at this time did the staff
- become aware that pill was dissolved and spread throughout the environment.

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- Planar anterior and posterior gamma camera images show activity primarily in the right hand.
- Patient was rescanned with arms above head and only small amounts of activity were found in the body (probably from previous treatment).







- Contaminated items from patient and parent were identified and confiscated.
   Family was discharged.
- Senior Director arrived and called for Visqueen barriers to be installed to limit access to hot zone.





- Chief Safety Officer, Environmental Health and Safety, Facilities, Engineering, and Employee Health were contacted by the director and responded to the scene.
- Chief safety officer established demarcation of cold, warm and hot zones.

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Initial decontamination was performed by nuclear medicine staff or two days.

Decontamination efforts were largely unsuccessful and contamination was still spreading despite the zone demarcation.





- RSO's office and conference room were being used for huddles to discuss decontamination plan.
- Both locations became contaminated despite our best efforts follow good decontamination practices.





 A professional radiological material decontamination company was employed

 After 3 days of effort the decontamination company did not find it worthwhile to continue, largely due to the difficulty in decontaminating the wax-free floors.



#### **Root Cause Analysis**

- Ultimately we were able to decontaminate and reopen part of the contaminated areas.
- The hallway was critical to give access to the one gamma camera that was decontaminated so we devised a system approved by our State Inspectors to cover the floor with Visqueen (beta blocker) and rented carpets.

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#### Illinois Title 32 Part 340.1220 "Notification of Incidents"

- c) Additional 24 Hour Notifications for Licensees. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving radioactive material:
  - 1) An unplanned contamination event that:
    - A) Requires access to the contaminated area by workers or the public to be restricted for more than 24 hours by imposing radiological controls in addition to those established by the licensee prior to the event or by prohibiting entry into the area;
    - B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in 10 CFR 20, appendix B, published at 72 Fed. Reg. 55922, October 1, 2007, for the material; and
    - C) Results in access to the area being restricted for a reason other than to either comply with operating procedures established by the licensee, or to allow radionuclides with half-life of less than 24 hours to decay prior to decontamination.

#### **Summary of Consequences of Radioiodine Spill**

- Contaminated over 2,000 square feet of space
- Lost the use of the hot lab and clean room forcing us to use unit doses for 90 days
- Forced us to operate with one gamma camera for 90 days
- Forced us to refer patients to other imaging centers
- Exposed 8 staff members who required daily bioassay for several weeks
- Bioassay had to be contracted to Northwestern because we had contaminated the gamma camera that is used for I-131 thyroid uptake (high resolution collimator camera)
- Damages and decontamination charges exceeding \$50,000
- Required self-reporting to the State of Illinois Emergency Management Agency
   and lead to three on site inspections

#### ILLINOIS EMERGENCY MANAGEMENT AGENCY Governor James K. Joseph Director March 27, 2017 Radioactive Material License IL-01165-01 Laura Gruber, Administrator, Medical Imaging Children's Hoopital of Chicago Medical Center 225 East Chicago Avenue 89 Chicago, Illinois 60611-2991 SUBJECT: Notice of Violation Dear Ms. Gruber: On Junnary 26 and February R, 2017. Mn. Rohin G. Marzadago and Mr. John D. Paponder, representatives of the Agrency, combained an investigation in represents to an information of the Agrency combained and the Agrency by the Agrency by your Radiation Safet Officer. The investigation included a reverse of the event and charded independent radiations surveys of the facilitation and the a follow up visite by me on March R, 2017.

Investigation findings indicate that the following regulation was not met: 32 Ill. Adm. Code 340.510(a)(2).

This regulation requires each licenses to make, or cause to be ende, surveys that evaluate the extent of radiation levels and promiting individual hazands that could be present. Insertion finding indiation that following the administration and an I-131 copies to a patient, adequate anywys by the Notice Modeline staff ware not performed to drate, discover and limit b 111 constantiation presson in the appriment which code have prevented the spread of communitation.

#### **Medical Event?**

A "medical event" involving radioactive materials occurs if BOTH 1. The dose given is not what was prescribed, and the difference meets the  $\ensuremath{\mathsf{NRC}}\xspace's$  reporting requirements, AND

- 2. One or more of the following incidents occur:

   the dose given is off by at least 20 percent from the prescribed dose, either too high or too low,

   the wrong drug is used,

   the drug is given by the wrong route,

   the wrong individual receives the dose,

   a dose is administered to the wrong part of the body and exceeds by 50 percent or more the dose that are as should have received, or

   a aseled source used in the treatment leaks.



State Inspector determined that this did not constitute a Medical Event because the patient interfered with their own treatment!

	Cont	tents of	Reports
	1)	descr the m malf radic expo	report required by subsection (a) of this Section shall include a ription of the event, including the date, time and location of the event, sumfaturer and model number of any equipment that field or inactioned and the identity, quantities and chemical forms of any mulcides involved. Each report shall also describe the extent of sure of individuals to radiation and radioactive material, including, as opriate:
		A)	Estimates of each individual's dose;
		B)	The levels of radiation and concentrations of radioactive material involved;
		C)	The cause of the elevated exposures, dose rates or concentrations; and
		D)	Corrective steps taken or planned to ensure against a recurrence,

#### 1. Assessment of Pill Swallowing Capability

- Carefully assess pill swallowing capability at the time of I-123 diagnostic uptake study
- When interviewing the child it is important to ask if they routinely chew or bite pills when they swallow them.
- In cases where the child struggles at all to swallow the diagnostic pill, they are referred to Child Life for pill swallowing therapy.



#### **Root Cause Analysis: 5 Corrective Actions**

#### 2. Administration of Placebos

- We require the administration multiple placebos for all children.
- There is large amount of time and effort by staff and the patient's family before I-131 therapy so we prefer to perform a placebo at least one time before the therapy date has been assigned. For example
  - Low-iodine diet may be prescribed usually in place for several days or several weeks before therapy.
  - Deprivation from thyroid medication or thyroid prep may be prescribed.
  - Room assignment and preparation for in house iodine patient.

#### 2. Administration of Placebos



- First assessment is made on the day of I-123 thyroid uptake study
- Second assessment is made by placebo administered by service (endocrine) concurrent with a routine appointment before the therapy day is assigned
- Third assessment is made by placebo administered on the day of treatment immediately prior to I-131 dose.
- We now require the patient to swallow the placebo in less than 20 seconds which is what we have determined is the time it takes for the gel capsule to begin to dissolve.

#### **Root Cause Analysis: 5 Corrective Actions**

#### 3. Environment Precautions for Outpatient Therapy

- Most hospitals make little or no measures to protect the environment from contamination in outpatient iodine therapy.
- Due to the unpredictability that is introduced by administering the radioactive isotope to children, we have implemented new controls for outpatient therapy.
- We perform a modified iodine therapy room preparation and incorporate good practices of "scan in – scan out" to limit environmental contamination and ensure that we will detect contamination if it should unexpectedly occur.



Preferred room features for outpatient iodine therapy:

- Sink Glass Doors Located in an area that can be closed off with out a huge disturbance to other work flows or life safety issue (fine ovirt, etc.).
- Large enough to create warm and hot zone Phone to call for help
- Few non-removable objects Shielding, if possible



#### **Root Cause Analysis: 5 Corrective Actions**

#### 3. Environment Precautions for Outpatient Therapy

- All non-essential items are removed from the outpatient treatment room before the dose administration

- Calf length Tyvek booties, thick nitrile gloves, and a garbage can are placed in the warm zone.

#### **Root Cause Analysis: 5 Corrective Actions**

#### 3. Environment Precautions for Outpatient Therapy

- A buddy system is used with one person in the warm zone and the "watcher" in the cold zone.
  - Staff are trained to never leave the warm zone with out scanning and if contamination is detected and to call for help from outside
  - The patient will be asked to change into a paper gown
  - Patient's belongings and outerwear are removed from room and a surgical gown is tied over their street clothes.
  - The parents are asked to wait in a separate location. Only one parent or legal guardian will be allowed in the treatment room if necessary.

  - Staff who enter the treatment room are limited to the administering radiologist
     and the nuclear medicine technologist

# 4. Alternative Method of Administration in Noncompliant Patients

- In consult with gastroenterology at our institution, we have explored the possibility of administering radioactive iodine pills under anesthesia.
- It was determined to be infeasible to use this method of administration because it poses unknown risk to the patient and significant risk to our equipment and personnel.
- To date we refer to other hospitals that are equipped for liquid iodine therapy administration and are developing capabilities to administer liquid iodine in the future.

#### Our Initial Estimated Costs to Develop a Liquid Iodine Therapy Program

- Selection of the appropriate hood for liquid I-131 preparation
- Establish a procedure for preventative maintenance and certification of the hoods
- Establish a procedure for the appropriate handling of liquid iodine (venting times, transport, etc.)
- selection of an appropriate bloassay instrument and procedure for routine bit
- Establish a spill procedure for liquid logine
- Development of procedure for Emergency Response Teams (inpatient code teams, outpatient code teams, ICU teams)
- ~ So far \$2000 in consulting fees

	Qty	Model #	Description	Unit Price	Price
Our Initial Estimated	1		RADIOIODINE FUME HOOD, 115V	\$3,750.00	\$3,750.00
Costs to Develop a Liquid	1		FILTER, CHARCOAL (TEDA) 12" x 12" x 1" Metal Frame	\$200.00	\$200,00
Iodine Therapy Program	1		THYROID UPTAKE SYSTEM,	\$14,595.00	\$14,595.00
				2	
Total \$20-25k range					
Spill \$50k range					
Spill 550k range					
			ROD SOURCE, Co-137, 0,1 uCi	\$365.00	\$365.00
			CHECK SOURCE, Cs-137, 10 uCi	\$185.00	\$185.00
	13		THYROID UPTAKE NECK PHANTOM (Complete with Bottle Carrier, Capsule Holder and 12 Polyethylene Bottles)	\$495.00	\$496.00



#### 5. Modification of Radioactive Spill Procedures

- Our spill procedure planned only for KNOWN spills, it must be modified to detect and prevent the spread of UNKNOWN spills.
   The Radioactive Spill procedure has be modified to reflect the incident command methodology.
- The policy has be rewritten to parallel our existing policy for chemical spills including the following work flow:

Mann & Robert H. Lurie Children's Hospital of Chicago

#### Thank you!

Acknowledgements go to:

Laura Gruber, MBA, RDMS, RT (R) Jacqueline S. Bellm, MBA, CNMT, RT(R) Robert Baron, BSCE, CNMT Stephanie McHugh, CNMT Nicholas Rubert, Ph.D.



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