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Pediatric Iodine 131 Therapy: A root cause analysis

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AAPM 2017 Conference Theme

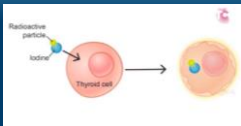
Connecting our Pathways.
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Theranostic Radioiodine!

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Radioactive Iodine-131 Therapy



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

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Environmental Protection for Inpatient I-131 Therapy



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Radioactive Half Life and Decay Times

Isotope	Production Method	Decay Mode	Principal Photon Emissions (keV)	Half-life	Primary Use
^{11}C	Cyclotron	β^+ , EC	511	20.4 min	Diagnostic
^{13}N	Cyclotron	β^+	511	9.97 min	Diagnostic
^{15}O	Cyclotron	β^+	511	2.03 min	Diagnostic
^{18}F	Cyclotron	β^+ , EC	511	110 min	Diagnostic
^{32}P	Reactor	β^-	--	14.3 d	Therapy
^{67}Ga	Cyclotron	(EC, γ)	93, 185, 300	3.26 d	Diagnostic
^{82}Rb	Generator	β^+ , EC	511	1.25 min	Diagnostic
$^{99\text{m}}\text{Tc}$	Generator	IT	140	6.02 hr	Diagnostic
^{111}In	Cyclotron	(EC, γ)	172, 247	2.83 d	Diagnostic
^{123}I	Cyclotron	(EC, γ)	159	13.2 hr	Diagnostic
^{125}I	Reactor	(EC, γ)	27-30	60.1 d	In vitro assays
^{131}I	Reactor	(β^- , γ)	364	8.04 d	Therapeutic
^{201}Tl	Cyclotron	(EC, γ)	68-80	3.04 d	Diagnostic

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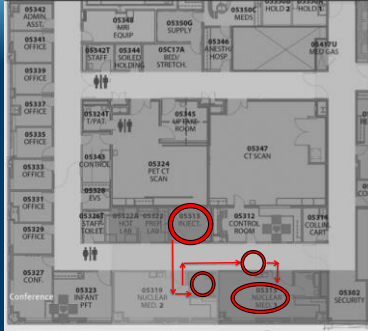
The Event

- 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 safely administered this dose as an outpatient.
- The patient had severe 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.

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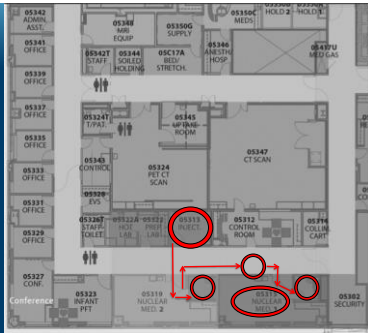
Root Cause Analysis

- 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 camera.
- We needed the child to remove her clothes so we could be certain she did not hide the pill in her pocket.



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.



Root Cause Analysis

- 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.



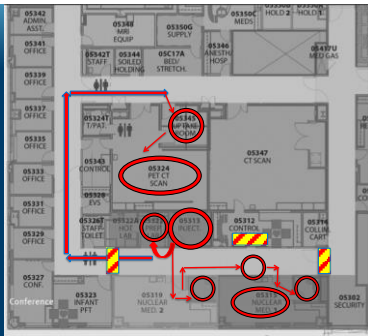
Our standard hospital gloves were completely ineffective at protecting from I-131.....

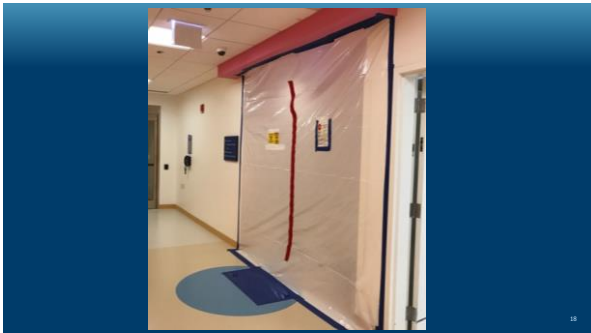


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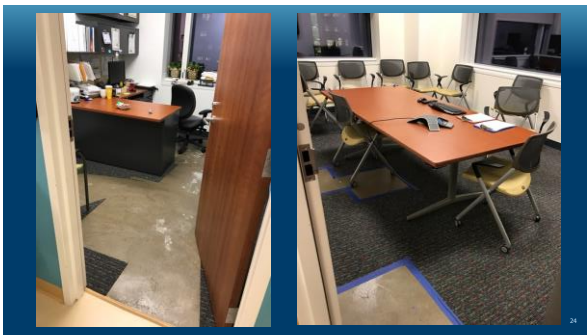
Root Cause Analysis

- 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.



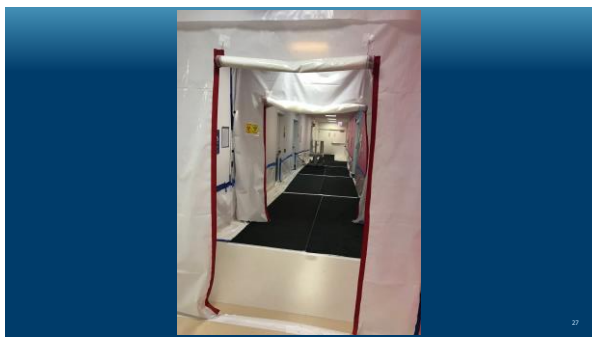


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[illegible]

[illegible]

- 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.

[illegible][illegible]

Root Cause Analysis: 5 Corrective Actions

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.

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1. Pre-swallowing assessment

2. Pill swallowing practice


3. Pill swallowing practice

4. Pill swallowing practice

5. Pill swallowing practice

Practice Swallowing Pills

- Start by practicing with candy
 - Start with a tiny piece and after swallowing two times, move on to bigger ones.
 - If a child has difficulty swallowing a candy go back to the size they were successful on and give plenty of praise.
- Candy
 - Sprinkles
 - Like the kind that are put on cupcakes
 - Nerds
 - Mini M & M's
 - Tic Tacs
 - Regular size M & M's or Skittles
 - Jelly Belly brand jelly beans
 - Good and Plenty
 - Mike and Ike's



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.

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Root Cause Analysis: 5 Corrective Actions

2. Administration of Placebos



Our radiopharmacy supplies us with empty capsules to use as 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.

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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.

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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 (fire exits, etc.)
- Large enough to create warm and hot zone
- Phone to call for help
- Few non-removable objects
- Shielding, if possible



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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
- The floor is papered
- A "hot", "warm" and "cold" is defined and demarcated
- Calf length Tyvek booties, thick nitrile gloves, and a garbage can are placed in the warm zone.
- Staff will wear scrubs tucked inside the Tyvek booties
- A sniffer Geiger counter is available outside the outpatient treatment room with a foot and hand sensor so staff can survey in and out of the warm zone
- A phone is permanently installed so any staff member can call for help if they discover contamination while surveying in and out of the warm zone
- The radioactive spill cart is placed in the cold zone with in reach of the warm zone.

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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 without 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
- A outpatient iodine checklist is used to verify all protective measures are in place

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Root Cause Analysis: 5 Corrective Actions

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.

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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 bioassay instrument and procedure for routine bioassay
- Establish a policy on staff education and training for handling liquid I-131
- Establish a spill procedure for liquid iodine
- Development of procedure for Emergency Response Teams (inpatient code teams, outpatient code teams, ICU teams)
- ~ So far \$2000 in consulting fees

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Our Initial Estimated Costs to Develop a Liquid Iodine Therapy Program

Total \$20-25k range

Spill \$50k range

Qty	Model #	Description	Unit Price	Price
1		RADIOIODINE FUME HOOD, 110V	\$3,750.00	\$3,750.00
1		FILTER, CHARCOAL (TEDA) 12" x 12" x 1" Metal Frame	\$200.00	\$200.00
1		THYROID UPTAKE SYSTEM	\$14,095.00	\$14,095.00
1		ROD SOURCE, Cs-137, 0.1 uCi	\$365.00	\$365.00
1		CHECK SOURCE, Cs-137, 10 uCi	\$185.00	\$185.00
1		THYROID UPTAKE NECK PHANTOM (Complete with Bottle Carrier, Capsule Holder and 12 Polyethylene Bottles)	\$495.00	\$495.00

Root Cause Analysis: 5 Corrective Actions

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.
- A communication call tree has be established for radioactive spills.
- The policy has be rewritten to parallel our existing policy for chemical spills including the following work flow:
 - ✓ Contain
 - ✓ Isolate
 - ✓ Demarcate
 - ✓ Evacuate
 - ✓ Notification/Activation
 - ✓ Call for Outside Help / Decontamination.

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