I-131 MIBG Medical Event

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Tom Wolf, Governor

Patrick McDonnell, Secretary
Outline

• What is MIBG?
• What happened?
• Cause of the event
• Corrective actions
• Things to consider
What is MIBG Therapy?

- I-131 Metaiodobenzylguanidine
- IV therapy
- Used for relapsed or refractory neuroblastoma
Standard Treatment:

• 18 mCi/kg I-131 MIBG
• 30 ml of MIBG is infused over 90 minutes
• Pump is stopped at 45 minutes and reset
• Infusion is followed by 30 ml saline flush for 20 minutes
Infusion Setup

- Port Line
- Pressure Tubing
- Spiros Tube

Infusion Pump
Hi Jenny:

Niki and I have been racking our brains out trying to think of anything interesting on which we’ve been working that would make a good OAS presentation. We’ve not come up with anything fun and/or sexy enough to present. Sorry! But I should also add that I hope nothing comes up real soon.

Have a great Memorial Day weekend!

Thanks,

Terry W. Derstine

Radiation Protection Program Manager
Department of Environmental Protection | Southeast
May 25th, 2018 (Friday)

• The Department was notified at 4:15 pm that a medical event had occurred.
• Children’s Hospital of Philadelphia (CHOP)
• 17 year old male with neuroblastoma
• Prescribed 817 mCi; administered 834 mCi $^{131}$I MIBG
• 7th and final treatment
• ~50% administered
June 7 and 13, 2018

• Investigated both the under-dose and skin contamination

• Interviewed referring physician, Radiation Safety staff, Nuclear Medicine team leader, nuclear medicine technologist, nurse who cared for the patient immediately post-infusion, lead nurse for I-131-MIBG therapies
Friday May 25\textsuperscript{th}, 2018

- **12:30** – MIBG infusion was started
- **13:00**
  - Patient expressed the need to urinate
  - Nuclear Medicine consulted with Radiation Safety and agreed that the toilet was the best option
- **13:15**
  - First half of infusion was completed
  - Patient was disconnected at Spiros tube to use the toilet
  - Patient was reconnected, pump was reset and infusion was resumed
Timeline

• 14:00 - Infusion completed and began saline flush

• 14:30
  – After the flush, nuclear medicine technologist noted blood in the port line and a pinkish fluid on the bed sheets.
  – Nuclear medicine technologist stripped bedding and asked patient if he felt wetness anywhere. Patient indicated his pants were wet at the hip; pants were not removed at this time.
• **14:45 – 16:00**
  – Health physics tech arrived and nuclear medicine tech left area
  – Readings of the patient were taken
    • 48 mR/hour at 1 meter
    • Expected 75 mR/hour
• **16:00**
  – Patient’s pants were removed and all waste and contaminated items were removed from the room
  – Another reading of patient was taken
    • 38 mR/hour at 1 meter
  – 50% of the dose was received by patient

• **16:15**
  – Notification of medical event
  – Friday after normal business hours before Memorial day weekend
  – Notification went through Department stand-by duty officer
Friday after notification:

- Readings of waste, contaminated linens, and clothing indicated 210 mCi (26%) I-131 in waste
- Determined 74% of prescribed dose was administered
- Contamination surveys:
  - Inside room
  - Hallway
What about patient decontamination?
• The patient was given standard hygiene care over the weekend
  – Chlorohexidine wipes
• The patient was never purposefully decontaminated
May 27, 2018 (Sunday)

• Patient reported reddening and discomfort on right hip
• Patient showered twice, but they were unable to remove the contamination
• Readings were taken using a Ludlum 44-9 probe to determine activity
  - 6.5mCi over 2x3cm area
• Estimated skin dose: 500-1,200Gy
Following week:

• Calculations were verified by REAC/TS and Michael Stabin, Ph.D. CHP
• Four days later patient developed moist desquamation, diagnosed with Grade 3 radiation burn
• Patient was referred to Plastics and was monitored by Authorized User
**Effect on Patient**

- Final report to the Department indicated an estimated skin dose of at least 550 Gy
- The patient developed moist desquamation, but no further ulceration. This is consistent with a Grade 3 radiation burn.
- Patient fully recovered from his injury
Causes

• Leak in the system
  – After extensive testing and inspection, no defects in the Spiros tube or line were found
• Policies and procedures are lacking coordination between departments
• Lack of patient decontamination procedures
Corrective Actions

• Absorbent chux under line
• Patient will wear a fluid impermeable gown and gloves
• Infusion is not to be stopped unless medically necessary
• Continuous monitoring of patient during infusion
• Development of fluid management procedure
• Review of infusion system and additional training on the use of the Spiros tube
Corrective Actions

• Two nuclear medicine techs inspect the setup
  – Prior to infusion, during reset, and after flush.

• Nuclear medicine tech checks on patient every 15 minutes

• Proactively looking for contamination on linens, gowns, chux, cart wheels, and floor

• A multidisciplinary MIBG committee has been established to review and update policies
Corrective Actions

- Patient specific decontamination procedures for each case will be developed
- Looking into beta measurement devices to have better ability to detect skin contamination
  - Patients are reading ~1R/hour at 1cm
- Development of a “time-out” procedure when an event occurs
- Conducting drills on responding to a patient contamination incident
Things to Consider
Similar Incidents

• Stage 4A thyroid carcinoma patient undergoing liquid I-131 therapy was contaminated after feeding tube leaked during administration

• I-131 MIBG pediatric patient had minor skin injury to inner thighs and buttocks after urinary catheter leaks

• Y-90 TheraSphere® treatment – catheter leaked causing contamination to the thigh and groin of the patient
Similar Incidents

• Sm-153 – IV tubing damaged and leaked
• Tc-99m – leakage at connection
• I-124 – leakage at connection
• Sm-153 – leakage at connection
• I-131 – IV leaked
• F-18 – IV infiltrated
• And these are just a few...
Final Thoughts

• Increase in liquid therapeutic modalities
  – MIBG
  – IOMAB
  – Lutathera
  – And many more...

• How do we detect and manage contamination in these treatments?

• Is there a complacency in the industry for unsealed medical isotopes?

• Are we aiding in this complacency?
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