

# Patient Deaths After a Radiotherapeutic Treatment

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# AGENDA

- ▶ Theranostics Introduction
- ▶ Patient releasing discussion
- ▶ University of Virginia (UVA) incident
- ▶ Cleveland Clinic (Main Campus) incident
- ▶ Lessons learned
- ▶ Questions

# AND NOW A MESSAGE FROM THE "REBELS"





HOW MANY OF YOU HAVE DEALT  
WITH AN INDIVIDUAL DYING AFTER  
RECEIVING A  
RADIOPHARMACEUTICAL?

# Theranostics Introduction

The term *theranostics* refers to the use of diagnostic and therapeutic agents that share the same molecular target; a major step toward precision medicine, especially for oncologic applications.

Andy Miller said, “We are treating more and more patients with higher amounts of activity, more morbidities, and newer isotopes than ever before.”

And more are coming....

# Theranostic Introduction (continued)

Q1 2024 – CCF (as an example just at our Main Campus)

- ▶ 36 Lu-177 Lutathera (1 of 4 doses)
- ▶ 93 Lu-177 Pluvicto (1 of 6 doses)
- ▶ 28 Y-90 Theraspheres
- ▶ 2 Y-90 SIR-spheres

Q1 2024 – UVA

- ▶ 17 Lu-177 Lutathera
- ▶ 23 Lu-177 Pluvicto
- ▶ 8 Y-90 Theraspheres



Actinium-225 - Wikipedia

Actinium-225 ( $\text{Ac}$ ,  $\text{Ac-225}$ ) is **an isotope of actinium**. It undergoes alpha decay to francium-221 with a half-life of 10 days, and is an intermediate decay product in the neptunium series (the decay chain starting at  $\text{Np}$ ). Except for minuscule quantities arising from this decay chain in nature,  $\text{Ac}$  is entirely synthetic. ... [See more](#)

## Decay and occurrence

Actinium-225 has a half-life of 10 days and decays by **alpha** emission. It is part of the **neptunium series**, for it arises as a **decay product** of neptunium-237 and its **daughters** such ... [See more](#)



# Patient Release

- ▶ 10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material
  - A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the **total effective dose equivalent** to any other individual from exposure to the released individual is **not likely to exceed 5 mSv (0.5 rem)**

# Patient Release (cont)

- ▶ Regulatory Guide 8.39, Revision 1 Release of Patients Administered Radioactive Material

| RADIONUCLIDE | COLUMN 1 ACTIVITY AT OR BELOW WHICH PATIENTS MAY BE RELEASED |       | COLUMN 2 DOSE RATE AT 1 METER, AT OR BELOW WHICH PATIENTS MAY BE RELEASED |          |
|--------------|--|-------|---|----------|
|              | (GBq)  | (mCi) | (mSv/h)   | (mrem/h) |
| I-131        | 1.2  | 33    | 0.07  | 7        |

- ▶ Y-90 was not listed as it was deemed “minimal exposure of the public” (IAEA Release of Patients After Radionuclide Therapy, Report Series No. 63, 2009)
- ▶ Lu-177 was not used yet



# Patient Release (cont)

The activities at which patients can be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," dated October 1, 1970 (Ref. 4). NCRP Report No. 37 uses the following equation to calculate the exposure until time 't' at a distance 'r' from the patient:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-\frac{0.693t}{T_p}})}{r^2} \quad \text{(Equation 1)}$$

|            |   |
|------------|---|
| Where D(t) | = Accumulated exposure at time t, in roentgens                                    |
| 34.6       | = Conversion factor of 24 hrs/day times the total integration of decay (1.44)     |
| $\Gamma$   | = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm                |
| $Q_0$      | = Initial activity of the point source in millicuries, at the time of the release |
| $T_p$      | = Physical half-life in days  |
| r          | = Distance from the point source to the point of interest in centimeters          |
| t          | = Exposure time in days   |

# Patient Release (cont)

- ▶ 2019 HPS Article “Radiation Safety Observations Associated with <sup>177</sup>Lu Dotatate Patients (Kevin Nelson, CHP, Ph.D) stated:
  - Approximately 50% of <sup>177</sup>Lu dotatate is eliminated via the urine 50% in the first 6 h; 70% in 24 h (Kwekkeboom et al. 2001).
  - Since the outpatient procedure takes 4 to 5 hours to complete, the patient excretes approximately 50% of the <sup>177</sup>Lu before leaving the facility.
- ▶ 2021 HPS Article “Patient Release and Instructions for Lutetium Dotatate Radiopharmaceutical Therapy (James Underwood, M.S., CHP) stated:
  - Using Equation 1, NUREG Equation U.1, and the remaining activity at each time interval, the radiation dose to the highest exposed individual during the first 6 hours, 6 to 24 hours, 24 hours to 14 days, and infinite dose after 14 days were 0.05 mSv, 0.08 mSv, 0.42 mSv, and 0.005 mSv respectively.
  - **These result in a total dose of 0.56 mSv for each administration, and a maximum total treatment dose of 2.24 mSv, supporting patient release immediately following treatment,** regardless of the interpretation of the rule. This dose estimate is a reduction of 6.08 mSv from the model including only physical decay.
  - The activity and travel restriction were calculated using Equations 4 and 5 and are summarized in Table 2.

**Table 2. Activity and travel restriction instructions for an administration of 7.4 GBq of Lutathera.**

| Group/activity                | Occupancy factor <sup>a</sup> | Index distance <sup>b</sup> (m) | Restriction time in day(s) |
|-------------------------------|-------------------------------|---------------------------------|----------------------------|
| Member of patient's family    |                               |                                 |                            |
| Non-sleeping partner/adult    | 0.25                          | 1                               | 0                          |
| Non-pregnant sleeping partner | 0.33                          | 0.3                             | 2                          |
| Pregnant sleeping partner     | 0.33                          | 0.3                             | 7                          |
| Pregnant women/children       | 0.25                          | 1                               | 0                          |
| Child held by patient         | 0.2                           | 0.3                             | 5                          |
| Breastfeeding <sup>b</sup>    | 0.17                          | 0.15                            | 7                          |
| Public: Co-worker             | 0.33                          | 1                               | 0                          |
| Travel                        |                               |                                 |                            |
| Non-stop flight (≤16 h)       | N/A                           | 0.6                             | 0                          |
| Non-stop flight (>16 h)       | N/A                           | 0.6                             | 1                          |
| Car ride (24 h)               | N/A                           | 1                               | 0                          |

<sup>a</sup>NCRP (2006).

<sup>b</sup>Gulec and Siegel (2007).

# Patient Release (cont)

- ▶ Proposed Regulatory Guide 8.39, Revision 2 Release of Patients Administered Radioactive Material

| RADIONUCLIDE | COLUMN 1 ACTIVITY AT OR BELOW WHICH PATIENTS MAY BE RELEASED |       | COLUMN 2 DOSE RATE AT 1 METER, AT OR BELOW WHICH PATIENTS MAY BE RELEASED |          |
|--------------|--|-------|---|----------|
|              | (GBq)  | (mCi) | (mSv/h)   | (mrem/h) |
| I-131        | 0.32   | 8.6   | 0.018   | 1.8      |
| Lu-177       | 4.1  | 110   | 0.022   | 2.2      |
| Y-90         | 34   | 920   | 0.054   | 5.4      |
|              |  |       |   |          |

- ▶ All Y-90 and Lu-177 patients will be below these dose rates

# Reality Check

- ▶ Not all patients who are released stay healthy after treatment
- ▶ Some don't hydrate as directed or have poor excretion due to renal issues
- ▶ Some patients will have readmissions for reasons that are not related to this treatment, i.e.; heart attacks or accidents
- ▶ Not all health factors are discussed before treating the cancer
- ▶ Readmission is usually not a huge problem
- ▶ Timely notification to radiation safety is key
- ▶ When a patient passes away, things change significantly

# UVA Patient Death

- ▶ Pluvicto patient on his second treatment treated on a Friday. He says he feels fine and is released.
- ▶ Patient dies at home on Sunday.
- ▶ RSO receives a message stating patient died at a hospital in Richmond.
- ▶ Takes two days to ascertain that patient died at home and was taken to the funeral home on Sunday.
- ▶ Contact the funeral home who states the body is at the crematorium.
- ▶ Crematorium states body has been cremated and is currently in the furnace.

# UVA Patient Death (cont)

- ▶ RSO performed surveys of family home.
- ▶ RSO had multiple conversations with the family regarding arrangements. Family wanted to place ashes in ground at church and take some to Florida.
- ▶ Wife decided to wait the 10 half lives before having a ceremony and taking some ashes to Florida.
- ▶ Funeral home agreed to hold ashes in their crematorium facility in an isolated locker away from any staff.

# CCF Patient Death

- ▶ Patient undergoes Y-90 liver treatment with Theraspheres on 7/2/2014
- ▶ Lives 3 hours away from our facility
- ▶ Health deteriorates rapidly – admitted to his local hospital shortly after treatment – informs staff of Y90 treatment – no issues or concerns
- ▶ Passes on 7/5/2014 (3 days post treatment)
- ▶ Partner calls our liver coordinator nurse and informs them of passing
- ▶ Cremation is desired
- ▶ After consulting with the State and the manufacturer, we recommended no cremation until 30 days post treatment
- ▶ Mortuary had cold storage facility and was able to accommodate this with the cooperation of the family
- ▶ Cremation was completed 8/11/2014 with no issues reported
- ▶ Delayed grieving closure for family

# Lessons Learned

- ▶ Families forget what they've been told upon patient release
- ▶ Funeral home staff and crematorium staff have no radiation knowledge
- ▶ Funeral homes procedures do not require asking about radioactive material
- ▶ Crematorium staff routinely do not wear respiratory equipment or PPE when handling contaminated ashes



# Questions to Think About

- ▶ When is a patient no longer the responsibility of the licensee ?
  - ▶ At release (with or without instructions) ?
  - ▶ Never (i.e., are they always our responsibility) ?
- ▶ Is it the expectation of regulators that a RSO will be able to leave their listed locations of use to provide radiation safety support to the funeral industry ?
- ▶ Does hospital management support such an activity and associated liabilities?
- ▶ What about novel death care issues ?



QUESTIONS?