U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Assumptions Used in Research on Patient Release Following Iodine-131 Therapy

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Research Assumption

Patients are receiving and following good instructions to minimize radiation exposure to others.

Two Practical issues that impact the reliability of the assumption

- **Timing**
- **Quality**

Issue 1: Timing

Timing of discharge instruction for patients determines how thoroughly clinicians can discuss and answer questions, how well instructions are understood, and how well they can be followed. Unfortunately, often instructions are provided at the time of ^{131}I administration.

Timing of Instructions

"I am due to have my RAI the first week in August … I have a million and one questions on it and all I get told by my nuclear medicine dr is I will get instructions the day I get the RAI…I will be coming home right after receiving it. Asked to be admitted to the hospital ~ was told it was not necessary (I have 4 children, married and live in an apartment)."[1]

Timing of Instructions

RAI patients who are given instructions at the time of treatment have similarities to emergency department patients (frightened, feeling ill) whose rate of understanding/following of instructions is reported to be in the 22-25% range. [2,3]

Issue 2: Quality

Lack of standardized guidelines for instructions clinicians must provide for patients, leads to lack of consistency and potential for questionable quality of instruction.

Quality of Instructions

In 2011, MC Greenlee and others, on behalf of the American Thyroid Association, surveyed 311 endocrinologists, nuclear medicine physicians, surgeons, radiation safety officers and other health professionals.

Quality of Instructions

- **Patients often receive radiation safety recommendations from multiple sources.[4,5]**
- **The recommendations disagree with each other.[4,5]**

Quality of Instructions

- **Greenlee reported a gap across the various disciplines regarding which care provider was ultimately responsible for providing the patient with radiation safety instructions.[4,5]**

Quality of Instructions

- **5%–11% of respondents had no threshold to advise patients regarding certain recommendations for the first 24 hours after treatment: avoiding children ages 2–10 years of age, maintaining a specific time and/or distance from other people, and avoiding public transportation.[4,5]**
- **Some did not recommend to patients that they sleep alone or avoid sexual contact.[4,5]**

Quality of Instructions

- **7% recommended avoiding breast-feeding only when the therapeutic activity was >30 mCi, and half did not see a need to avoid breast-feeding beyond the first 48 hours after radioiodine treatment.[4,5]**

Breastfeeding

- **This last statement clearly represents a danger both to the nursing infant from exposure to ^{131}I, as well as to the lactating mother whose breasts are exposed to increased ^{131}I uptake.**
- **ATA guidelines state breastfeeding must stop 6 weeks prior to treatment and not be resumed (safe after subsequent pregnancies) for the protection of both mother and child.**

Quality of Instructions

“My dose was 50 mCi and I was told multiple things. My Endo said a week. The written guidelines from the Nuc Med dept. say 5 days. I have a friend that works in the Nuc Med dept. at another hospital so I asked him,

‘if this was your child, what would you do?’ ”1

“I've noticed is that patients are often given vague or inadequate instructions. Radiation safety is a difficult subject to boil down to a page or two of instructions. This seems to lead to much patient confusion and stress… Add some emotion, stress, fear, hypo[thyroid] symptoms and you are asking for problems. Luckily I have a background in radiation safety or I would have been totally blindsided by the precautions that were expected. There has to be a better way of conveying the message!”[1]

10 year old was treated at a university hospital. Mother was given virtually no instructions for post-treatment period, other than to stay far away from patient in the car on the long drive home. With another young child at home, mother was given no instructions: to isolate the patient from sibling, about solitary sleeping or bathroom use, eating utensils, and laundry. Suspicious re lack of precautions, mom accessed ThyCa for information. She sent her younger child to relatives for 3 days.[6]

Assumption: Release is safe

As reported to the ACMUI on April, 2013, NRC research is making the assumption that the literature shows conclusively that discharge to home immediately following ^{131}I treatment is safe, and is concentrating on discharge to hotels.

Can we assume these conditions?

Venencia et al. treated 14 patients with 30–221mCi of ^{131}I and monitored them with dosimeters placed on the pectoral muscle. Reporting in Journal of Nuclear Medicine, he states using this dosimetry and assuming that another person was always 1m from the treated patient (100% occupancy factor), their exposure did not approach 5.0mSv until the treatment activity was greater than 187mCi.[7]

Can we assume these conditions?

- **What about patients who are not instructed/do not understand to stay 1 meter away?**
- **Treatment activity greater than 187mCi?**
- **Or who work or live with women who are pregnant? Or with children?**
- **Determination of safety clearly assumes that patients have received and understood good instructions.**

Conclusion

- **Research design is flawed, based on the assumption that radiation exposure to the public is minimal based on good post discharge practices.**
- **This assumption relies on the supposition that all patients treated with ^{131}I are being provided with and follow adequate instruction on measures to reduce radiation exposure to the public, at home, in hotels, and in public transportation.**

Conclusion

- **One cannot make the assumption that the public health is protected by assuming that the best case scenario is what is generally happening in the real world.**
- **The research assumption must be verified.**

References

1. www.Inspire.com
2. K. Engel et al. (2009) "Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Don't Understand?" *Annals of Emergency Medicine*. Vol. 53, Issue 4
3. [no authors listed] (2008) "Majority of emergency patients don't understand discharge instructions" *Emergency Department Management* .Vol. 20 No. 9

References

4. Richard T. Kloos, M.D. (2011) Survey of Radioiodine Therapy Safety Practices Highlights the Need for User-Friendly Recommendations. Thyroid 21:2 97-99.
5. Greenlee MC, et al. (2011) Current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners. Thyroid 21:2 151–160.
6. Weil notes. Interview at ThyCa conf. 2012

References

7. Venencia CD, et al. (2002) Hospital discharge of patients with thyroid carcinoma treated with 131I. J Nucl Med 43:61–65.

Abbreviations and Acronyms

- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **Nuc Med: nuclear medicine**
- **ATA: American Thyroid Association**
- **^{131}I: Iodine-131**
- **mCi: millicurie**
- **mSv: millisievert**
- **RAI: Radioactive Iodine**
- **ThyCa: Thyroid Cancer Survivors Association**