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ARTICLE

Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine ^{131}I: Practice Recommendations of the American Thyroid Association

The American Thyroid Association Taskforce on Radioiodine Safety

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Background: Radiation safety is an essential component in the treatment of patients with thyroid diseases by ^{131}I. The American Thyroid Association created a task force to develop recommendations that would inform medical professionals about attainment of radiation safety for patients, family members, and the public. The task force was constituted so as to obtain advice, experience, and methods from relevant medical specialties and disciplines.
Methods: Reviews of Nuclear Regulatory Commission regulations **and International Commission on Radiological Protection recommendations** formed the basic structure of recommendations. Members of the task force contributed both ideas and methods that are used at their respective institutions to aid groups responsible for treatments and that instruct patients and caregivers in the attainment of radiation safety. There are insufficient data on long-term outcomes to create evidence-based guidelines.
Results: The information was used to compile delineations of radiation safety. Factors and situations that govern implementation of safety practices are cited and discussed. Examples of the development of tables to ascertain the number of hours or days (24-hour cycles) of radiation precaution appropriate for individual patients treated with ^{131}I for hyperthyroidism and thyroid cancer have been provided. Reminders in the form of a checklist are presented to assist in assessing patients while taking into account individual circumstances that would bear on radiation safety. Information is presented to supplement the treating physician's advice to patients and caregivers on precautions to be adopted within and outside the home.
Conclusion: Recommendations, complying with Nuclear Regulatory Commission regulations and consistent with guidelines promulgated by the National Council on Radiation Protection and Measurement (NCRP-155), can help physicians and patients maintain radiation safety after treatment with ^{131}I of patients with thyroid diseases. Both treating physicians and patients must be informed if radiation safety, an integral part of therapy with ^{131}I, is to be attained. Based on current regulations and understanding of radiation exposures, recommendations have been made to guide physicians and patients in safe practices after treatment with radioactive iodine.

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Overview

This document presents recommendations to provide health providers with reasoned instructions on radiation safety for patients, their families, caregivers, and the public after radioiodine (^{131}I) therapy. The recommendations should help to ensure compliance with federal regulations of the Nuclear Regulatory Commission (NRC) and reduce the potential for harmful radiation exposure to others, and also to recognize that required actions may differ when attaining compliance with existing local regulations of other jurisdictions, for example, in Canada. Although harm from radiation exposure to personal contacts of ^{131}I-treated patients has not been shown, these recommendations follow the principle of reducing radiation exposure to levels that are as low as reasonably achievable (ALARA). Inherent within ALARA is an acknowledgement that even unapparent radiation injuries are cumulative, and that, over time, small effects contribute to definitive risks.

These recommendations are derived from a review of current practices, expert opinions, and the literature. They are not meant to be evidence-based guidelines since there are insufficient data on long-term outcomes on which to base use or lack of use of any radiation exposure precautions. The recommendations are based on data derived from relevant measurements of radiation exposure, ^{131}I clearance and excretion, and reports of the impact of precautions in limiting radiation exposure. They are meant to clarify safety precautions necessary and helpful in complying with NRC regulations and reducing doses to ALARA. They emphasize the roles of the treating physician and the radiation safety officer (RSO) in individualizing the precautions for each patient while allowing the referring physician to assist in preparing appropriate and adequate pre- and post-therapy actions. The hierarchy of authority and responsibility for radiation safety is delineated in Table 1. Untoward short- and long-term effects of radiation on the treated patient, such as sialadenitis, lacrimal duct obstruction, red marrow suppression, radiation pneumonitis, and secondary neoplasms, are not addressed. However, breast radiation is discussed as an extension of restrictions on breastfeeding.

Background

In 2008, the American Thyroid Association (ATA) assembled a multidisciplinary task force to formulate recommendations for ^{131}I safety precautions. The ATA Board of Directors desired that these recommendations reflect all specialties involved with radioiodine treatments and safety for thyroid patients, their families, caregivers (a term that includes roommates and friends), and the public. They appointed representatives from the relevant disciplines, including Nuclear Medicine, Radiation Safety, Medical Physics, Endocrinology, and Endocrine Surgery. Liaisons from the Clinical Affairs and Public Health committees also assisted the process. Funding was derived solely from the general funds of the ATA. The final document has been approved by the ATA Board of Directors and officially endorsed by the: Academy of Molecular Imaging (AMI), American Association of Endocrine Surgeons (AAES),

Table 1. Hierarchy of Authority and Responsibility for Radiation Safety in Treatment of Patients with Radioiodine (^{131}I)

Nuclear Regulatory Commission (NRC)[a]
- Established by U.S. Congress
- Authority
  - Establishes policies and regulations.
  - Grants licenses to institutions and physicians to treat patients with radioiodine-131.
- Responsibility
  - Ensures radiation safety for patients, families, caregivers, and the public.
  - Issues instructions regarding new policies and regulations.
  - Receives reports of medical events, that is, breaches in radiation safety.
- The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. www.nrc.gov/about-nrc/regulatory/advisory/acmui.html

In "Agreement States," agencies are established by state governments to monitor radiation safety and report to NRC. In other states, the NRC directly oversees observances of radiation safety.

Radioiodine Treatment Teams (for licensure and reports: www.nrc.gov/10CFR 35.190)
- Radiation Safety Officer (RSO)
  - Develops and oversees treatment protocols for patients with usual radiation safety risks.
  - Provides specific advice for patients with unusual safety risks.
  - Reports medical events to State Agency or to NRC.
- A Radiation Health Physicist may bridge the responsibilities between RSOs and Treatment Prescription and Implementation Group.
- **Duties of** Treatment Prescription and Implementation Group (consists of physicians and clinical support staff)
  - With RSO, create treatment protocols for patients with usual radiation safety risks.
  - With RSO, plan specific treatments for patients who may require additional safety precautions.
  - Deliver oral and written advice specific to each patient.
  - Obtain written consent for therapy by patient or guardian.
  - Prescribe therapies.
  - Respond to medical events observed or reported.
  - Report to, discuss with, RSO all medical events in radiation safety.

[a]NRC also regulates radiation safety through specific guidance programs for other organizations such as industrial radiography, commercial radiopharmaceuticals, and nuclear reactors.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), American College of Nuclear Medicine (ACNM), American Head and Neck Society (AHNS), Endocrine Society (ENDO), European Society of Endocrinology (ESE), **International Radiation Protection Agency (IRPA)**, Latin American Thyroid Society (LATS), and Ukrainian Association of Endocrine Surgeons (UAES). The **American College of Surgeons (ACS)** and the American Congress of Obstetricians and Gynecologists (ACOG) acknowledge support of the document.

The overall goal of these recommendations was to limit radiation exposure from patients treated with ^{131}I to family members, caregivers, and the general public, consistent with ALARA and NRC regulations. The task force recognized that several of the precautions traditionally thought to be necessary offered little benefit or protection from radiation exposure, whereas others that were often overlooked served to reduce exposure. They also recognized the critical need of individualization in providing instructions so as to ensure reductions to ALARA for those involved. Individuals differ not only in their social situations but also in the activities of ^{131}I received and rates of clearance from the body. The task force acknowledged that the RSO at each treating facility is critical in treatment planning and execution and should be the final arbiter of precautions for any given patient. However, clinical evaluation and preparation of the patient for the ^{131}I treatment often precedes the encounter with the RSO. A discussion of patient-specific radiation safety precautions should also be part of the shared decision-making with the patient and the referring and/or treating physicians and should allow the patient to select the best timing for ^{131}I treatment and to make appropriate preparations at home and at work.

In the United States, the NRC replaced the Atomic Energy Commission in regulating unsealed sources of radioactivity (Energy Reorganization Act 1974). In 1997 and in 2009 updates (1), the NRC changed its pre-1997 release requirements for patients treated with ^{131}I from an "activity-based limit," the amount administered expressed in millicuries (mCi) or megabecquerels (MBq) to a "dose-based limit," the absorbed dose expressed in roentgen equivalent man (rem) or sieverts (Sv). The resultant "Patient Release Criteria Rule" allows release of treated patients from control of the treating facility with higher levels of radioactivity than previously permissible. This removed the restrictions that mandated a hospital stay in isolation for patients treated with $\geq$33 mCi (1221 MBq) of ^{131}I. Others deemed this change in release criteria unwarranted, and submitted a petition (2) to the NRC requesting that the "Patient Release Criteria Rule" be reversed. The NRC invited public comment regarding this petition, and the ATA submitted a response supporting the established Release Criteria Rule. The Rule was upheld and remains in effect.

The current regulations are less restrictive than those imposed upon ^{131}I therapy practices in some other nations; despite this, there is no evidence that safety has been compromised, even as the care of the patient was made more efficient and economical. On the other hand, patients and the public remain concerned about radiation exposure from the current practices (3).

Significant variability in the instructions for ^{131}I therapy precautions provided to patients by ATA members and health-care providers, in general, became apparent when the ATA began to gather this information. A subsequent survey of ATA members about their institutions' ^{131}I safety precautions confirmed the existence of substantial differences in patient instructions (4). Further, even within some institutions, there was disparity in radiation safety instructions provided by the referring physician, the Nuclear Medicine Department, and/or RSO. As part of this survey, actual patient instruction handouts were solicited from respondents; these were reviewed, evaluated in detail, and found to range from quite proscriptive to relatively lax. Additionally, there were examples of direct contradiction between sets of instructions: for example, one advised "use disposable utensils" and another "to not use disposable utensils." Thus, there was a need to clarify which safety precaution instructions best attain ALARA, comply with the NRC regulations, and achieve patient instruction uniformity so that adherence could be maximized and stress and confusion minimized. The results of the Survey were reviewed in an accompanying editorial (5).

Methods

Review of regulations

Recommendations by the International Commission on Radiological Protection (ICRP)* sanction licensed facilities to release a patient treated with ^{131}I from their control as long as the radiation exposure to any other individual (generally, a family member) encountering the patient will likely not exceed 5 mSv (500 mrem) per annum, and the radiation dose to a child, a pregnant woman, or an individual not involved in the care of the patient will not exceed 1 mSv (100 mrem) per annum **(25)**.

According to NRC regulation 10 CFR 35.75, if any individual is likely to receive more than 1 mSv (100 mrem), then the released patient must be provided with verbal and written instructions that will maintain doses to other individuals as low as reasonably achievable. Patients may not be released if, despite precautionary measures, exposure will exceed 5 mSv (500 mrem) (15). NRC Regulatory Guide 8.39 (6) and updated guidance in NUREG 1556 v.9 (7) provide licensed facilities with information on how to implement the "Patient Release Criteria Rule."

The current NRC Patient Release Criteria allow most patients to be treated with ^{131}I as outpatients (1). The regulations apply to all patients who are treated with unsealed radioactivity, including ^{131}I for thyroid cancer, hyperthyroidism, and goiter. When outpatients who were treated for thyroid cancer and hyperthyroidism and their families were instructed in radiation safety, measurements demonstrated that radiation exposures within the homes did not exceed regulations in comparable studies performed in the United States (8), Canada (9), and Brazil (10).

Radiation health physics

Most of the radiation exposure from patients treated with ^{131}I arises from high-energy gamma rays (photons). Three variables determine the amount of radiation a person receives from a treated patient: the retained radioactivity in the patient, the distance from the patient (radiation levels decrease with square of the distance from the source), and the duration of exposure (see Occupancy Factor (OF) under Definitions

***ICRP (www.icrp.org) is an independent, international organization comprised of leading scientists and policy makers in the field of radiological protection. ICRP provides recommendations and guidance on all aspects of protection against ionizing radiation, but has no regulatory authority in the United States.**

below). The retained radiation activity in the patient is a function of several factors, including, but not limited to, (i) the administered activity, (ii) the mass and function of thyroid tissue as reflected in the concentrations of serum free T4 and thyrotropin (TSH), (iii) the radiopharmaceutical, and (iv) the patient's hydration status and renal function. Therefore, the cumulative external exposure from a patient who has received a given activity of ^{131}I will vary substantially among thyroid cancer patients who are hypothyroid or euthyroid at the time of treatment (11) and among hyperthyroid patients (12). Compared to those with hyperthyroidism, thyroid cancer patients usually receive larger initial ^{131}I activities, but, lacking a thyroid gland, retention declines more rapidly through urinary excretion, and especially when euthyroid patients are prepared for treatment with recombinant human TSH rather than by hormone withdrawal (11). Hyperthyroid patients retain a greater percentage of radioactivity (more is sequestered in the thyroid gland) and also manifest higher levels of circulating radioiodinated thyroid hormones. The effective half-life of ^{131}I in a hyperthyroid gland is usually about 5 days (12).

Another potential radiation exposure pathway is ingestion of ^{131}I excreted/secreted by the treated patient. The majority of the excretion of radioiodine occurs via the urine; small amounts are present in stool, saliva, and other body fluids. Contact with areas contaminated with excreted or secreted ^{131}I from a treated patient could be a source of ingested ^{131}I. This is a special concern for young children, whose thyroid glands (13) and other tissues such as breast (14) are more sensitive to radiation. **Therefore, ICRP recommends following stricter precautions to further reduce radiation exposure to fetuses, children, and the general public (25).**

Definitions in regulatory documents and calculations of radiation exposure

Default administered radioactivity. According to the 1997 report (6), patients may be released when ^{131}I retained activity is at or below 33 mCi.

Equivalents of administered activity are as follows:
1 mCi = 37 MBq and 1 MBq = 0.027 mCi.

Default measured dose rate values. A licensee may release patients, regardless of administered activity, using dose rate measurements and TEDE (total dose effective equivalent in mrem or mSv) to meet NRC criteria for release. TEDE tables should be developed (usually with the aid of an RSO) when exposure rates are likely to be high and especially for the first 8 hours after the patient is released and during which time safe distances from the patient may be difficult to sustain.

Patients may be released when the ^{131}I measured dose rate is $\leq$7 mrem per hour (h) at 1 m as measured by a dose rate meter (6). **As noted above, patients also may be released when the TEDE of ^{131}I is unlikely to exceed 500 mrem (5 mSv). If 100 mrem (1 mSv) may be exceeded in any person, pertinent written and verbal precaution instructions are required (1,15).**

Patient-specific calculations. A patient-specific calculation takes into account the administered ^{131}I activity, its physical half-life and exposure rate constant, OFs (see below), effective half-lives, and thyroid uptake fractions. The resultant dose equation yields 0.17 mrem h^{-1} mCi^{-1} at 1 m (16,17), where 33 mCi gives a dose rate of 5.6 mrem/h at 1 m from a patient. The required information may be found in a TEDE table, a supplement, that provides mrem (mSv) as a function of administered activity and contact hours at 1 m. In examples with assumed values for the variables, calculations demonstrated that patients could be released without exceeding applicable dose limits after treatment with 57 mCi (3177 MBq) for hyperthyroidism and 150 mCi (5550 MBq) for thyroid cancer (7).

Distance and time estimations. Dose rates have been established for a distance of 1 m from a radiation source. To facilitate understanding by the patient and family members, 1 m is approximated to ">3 feet," and to help ensure safety, family members and caregivers of a treated patient are advised to remain well beyond 6 feet as much as possible. The days (24 hours cycles) when a patient may expose others to doses exceeding the foregoing limits noted above is the "restricted time or period."

Occupancy factor. For an ^{131}I-treated patient who arrives home, the OF is usually 0.25, which means that an individual will be exposed to a patient treated with ^{131}I at 1 m 25% of the time, here termed "daytime restriction." The assumed OF for a person sleeping with a patient is 0.33, and, because sleeping is assumed to be at a distance of 0.3 m, exposure is thereby increased and the days (24 hour cycles) containing "nighttime restriction" will generally exceed the limits of daytime restriction (Table 2A-1, A-2).

Annotated references, including additional citations, can be found in the Supplementary Data (available online at www.liebertonline.com/thy).

Results and Discussion

Role of the RSO

All ^{131}I treatments must be prescribed by a provider licensed as an authorized user and thus trained in administration of radiopharmaceuticals. Radiation safety precautions for radionuclide therapy protocols will be created and overseen by the RSO. Additional or individualized patient-specific precautions will also be developed by the RSO as needed (Table 1). A Radiation Health Physicist may be included in the Radioiodine Treatment Team as liaison between the RSO and the Treatment Prescription and Implementation Group. Individualization is stressed in predicting, calculating, and measuring the retained activity in each patient.

It is essential that radiation safety recommendations be discussed with each patient as soon as treatment with ^{131}I is considered. A checklist (Table 3) provides a tool to systematically evaluate the patient, identify potential exposure risks, and determine the suitable treatment setting. The required precautions will often influence the choice and timing of ^{131}I therapy. Preparing the patient, caregivers, and employers ensures familiarity with the recommendations and reduces concerns associated with radiation treatments. Table 4 includes a spectrum of advice to patients. By editing through cross-outs and additions, advice can be made specific for a patient; it must be given verbally as well as in writing so as to enable the patient to ask questions and clarify any misunderstandings.

Reproduction considerations

Recommendation. Patients should be advised in advance that pregnancy is a contraindication to ^{131}I therapy, and they

Table 2. Examples of Precaution Requirements and Recommendations After Treatments with ^{131}I

2A. Restricted Periods

2A-1. Hyperthyroidism [Assumes 50% uptake by thyroid, with effective $T_{1/2}$ of about 5 days (12)]

	mCi (MBq) administered			
	10 (370)	*15 (555)*	*20 (740)*	*30 (1110)*
Nighttime restrictions	Days/24-h cycles			
Sleep in a separate (6-feet separation) bed from adults for days shown.	3	6	8	11
Sleep in a separate bed from pregnant partners, infant, or child for days shown.	15	18	20	23
Daytime restrictions				
You may return to work after days shown.	1	1	2	5
Maximize your distance (6 feet) from children and pregnant women for days shown.	1	1	2	5
Avoid extended time in public places for days shown.	1	1	1	3

2A-2. Thyroid carcinoma/remnant ablation [Assumes that disappearance of ^{131}I is biexponential with early effective $T_{1/2}$ of about 0.76 days, and 2% uptake in remnant with effective $T_{1/2}$ of about 7.3 days (7). Consider formal dosimetry (18) for larger administered doses given to patients with functioning carcinoma. ^{131}I kinetics in euthyroid patients stimulated by recombinant human thyrotropin may differ from those used here (11)]

	mCi (MBq) administered			
	50 (1850)	*100 (3700)*	*150 (5550)*	*200 (7400)*
Nighttime restrictions	Days/24-h cycles			
Sleep in a separate (6-feet separation) bed from adults for days shown.	1	1	2	4
Sleep in a separate bed from pregnant partners, infant, or child for days shown.	6	13	18	21
Daytime restrictions				
You may return to work after days shown.	1	1	1	1
Maximize your distance (6 feet) from children and pregnant women for days shown.	1	1	1	1
Avoid extended time in public places for days shown.	1	1	1	1

2B. Duration of Safe Travel by Public Transportation (Bus, Air, etc.) [Assumes 100 mrem limit and 0.3 m distance. Other assumptions are as in Table **2A-1** *and* **2A-2***]*

2B-1. Hyperthyroidism

	mCi (MBq) administered			
	10 (370)	*15 (555)*	*20 (740)*	*30 (1110)*
Travel time (hours) without exceeding regulatory dose limit				
Day (24-h cycles) 0 (beginning with treatment)	5.9	3.9	2.9	2.0
Day (24-h cycles) 1	9.2	6.1	4.6	3.1
Day (24-h cycles) 2	13.0	8.7	6.5	4.3
Day (24-h cycles) 3	–	10.6	8.0	5.3

2B-2. Thyroid carcinoma/remnant ablation

	mCi (MBq) administered			
	50 (1850)	*100 (3700)*	*150 (5550)*	*200 (7400)*
Travel time (hours) without exceeding regulatory dose limit				
Day (24-h cycles) 0 (beginning with treatment)	1.2	0.6	0.4	0.3
Day (24-h cycles) 1	3.0	1.5	1.0	0.8
Day (24-h cycles) 2	7.2	3.8	2.5	1.9
Day (24-h cycles) 3	15.0	7.5	5.0	3.8
Day (24-h cycles) 4	–	15.0	10.0	7.5

Examples should be modified to meet local and specific patient needs. These examples are based on dose rate of 0.17 mrem h^{-1} mCi^{-1} at 1 m (16,17), 500 mrem per year for family member and caregiver, 100 mrem for pregnant women, children, and the public, and Occupancy Factors for adults of 0.25 except for sleeping 0.33. Resumption of sleeping with a partner assumes a distance of 0.3 m (7).

Table 3. Eligibility Assessment Checklist

It is incumbent upon the Radioiodine Treatment Team and the patient to agree upon a plan that, by environmental and population assessments and by calculations, will not put others at risk of radiation exposure as identified in NRC regulations **and ICRP recommendations**.

Absolute contraindications to ^{131}I therapy (pregnancy and breastfeeding)

1. Determine absence of pregnancy by:
   ___Pregnancy test within 72 hours prior to treatment, or
   ___Historical evidence of hysterectomy, or
   ___No menses for ≥2 years and >48 years old, or
   ___Other incontrovertible evidence for absence of pregnancy.
2. Determine absence of lactation and/or breastfeeding:
   ___By interview and/or clinical examination, or
   ___If uncertain and treatment is needed urgently, recommend ^{123}I scan to assess breast concentration of radioiodine.
   REMEMBER, Breastfeeding or pumping must not be resumed after ^{131}I therapy.

Consider inpatient ^{131}I therapy and consult RSO when

1. Proposed ^{131}I dose is
   ___≥200 mCi (7400 MBq) or
   ___TEDE, despite written instructions, is likely to exceed, 0.5 rem (5 mSv) to an adult family member or caregiver, or to exceed 0.1 rem (1 mSv) to a pregnant woman, child or a member of the general public.
2. The patient is unable to comply with oral and written instructions and therefore will require special planning because of:
   ___Incontinence issues;
   ___Requires help with devices such as Foley catheters, peritoneal dialysis equipment, feeding tubes, etc.;
   ___Cognitive/psychiatric limitations;
   ___Travel/housing limitations;
   ___Other limitations (name).

Information gathering for radiation safety precaution planning

Travel: To home on the day of treatment or subsequently*:*
   ___Patient will drive alone and is competent to do so.
   ___Patient plans to use private car with a driver, or taxi, or car service. The patient must sit alone in a back seat >3 feet from the driver. If travel requires taxi or duration is over 2 hours, consult RSO.
   ___Patient is limited to travel by bus, train, subway, ferry, or other public conveyance. This option requires a calculation of TEDE for other individuals and approval by the RSO (see Tables 2B-1 and 2B-2).

Home: Living arrangements (relationship, age and gender of each household member)
   For all household members, patient must be able to stay >6 feet away most of time (care givers may approach 3 feet up to 25% of the time.)
   Special Household Situations. Check all that apply; provide appropriate information and make an alternate arrangement:
   ___Household member is pregnant, and the patient cannot stay at least 6 feet away all of the time.
   ___Household member(s) are under the age of 16, and the patient can't stay at least 6 feet away all of the time.
   ___Patient is responsible for the care of an infant or young child.
   ___There is not sufficient space to maintain >6 feet distance from others.
   ___Patient unable to sleep alone during nighttime restricted period.
   (Consult RSO and/or consider admission.)
   ___Patient must share a bathroom with others. (Special home arrangements: Emphasize instructions in Table 4, Step 4, General Recommendations).

Work/School: Employment or school status, including required activities, environment, contacts with co-workers or fellow students, and arrangements to commute to work/school. From all co-workers or classmates patient must be able to maintain at least 6 feet distance at all times except for momentary encounters.
   Special Work/School Situations:
   ___Associated with children <16 years of age. If patient cannot stay >6 feet away, delay return to work
   ___Associated with pregnant women. If patient cannot stay >6 feet away, delay return to work.
   ___Food preparation for others. Get special instructions from RSO/Radioiodine Treatment Team.
   Commuting to work or school
   ___Car pooling or public transportation for periods of daytime restriction: make alternate arrangement or obtain special instructions from RSO.

should take measures to prevent pregnancy once treatment with ^{131}I is planned. Pregnant women should never be treated with ^{131}I, and a pregnancy test must be performed before the time (usually within 72 hours) of treatment in all women, from menarche to 2 years after menopause, who could become pregnant. Pregnancy should be delayed for at least 6 months after radioiodine therapy, a delay based on the need to normalize thyroid levels for a successful pregnancy and healthy infant development, and to ensure that additional radiation treatment is not imminent.

There are exceptions to the requirement for a pregnancy test, but there must be incontrovertible evidence that pregnancy is impossible, for example, surgical hysterectomy.

Discussion. There is a delay between conception and the sensitivity of tests to detect pregnancy. Blood and urine

Table 4. Safety Instructions for Patients Receiving Radioiodine Treatment

To be given verbally and in writing and edited as appropriate for the patient.

Dear Patient, (name)_____ *Date:*_____

With regard to your radioiodine therapy, please consider the following.

Step 1: Talk with your doctor or a member of the Radioiodine Treatment Team about

Why treated women must
- ◦ Avoid pregnancy for a period of time and
- ◦ Not breastfeed.

When treated men can consider fathering a child.

Who will give you the radioiodine therapy, and where and when this will happen.

Step 2: Make preparations before treatment and talk with your doctor or a member of the Radioiodine Treatment Team about the following specific items;

Obtaining
- ◦ Wipes and/or toilet paper that can be flushed down the toilet;
- ◦ Disposable gloves if others will be helping to take care of you;
- ◦ Heavy duty (doubled if possible), leak proof, specified plastic trash bags for tissues, paper towels and other things that may be contaminated and trashed;

For your travel:
- ◦ If you are well enough, it is best to drive yourself;
- ◦ If you ride with someone else, confirm she is not pregnant, and maintain a distance of >3 feet (use the back seat on opposite side of the driver);
- ◦ When and where you can take necessary trips;
- ◦ When it is safe to use public transportation;

For home:
- ◦ Living or working with a pregnant woman;
- ◦ Associations with children;
- ◦ Inability to control your urine or bowels;
- ◦ Using special medical equipment, such as catheters, ostomy bags, or anything that could be contaminated by your body fluids;
- ◦ Getting sick easily (throw up or get woozy);
- ◦ Not being able to go directly home; arrangements must be made through your treatment team; hotel and motel stays are not recommended.

Step 3. Your doctor or member of the Radioiodine Treatment Team will discuss with you the following items and fill in the number of days related to each.
- _____ Days that you need to stay >3 feet away from your adult family members and caregivers for at least 18 hours a day, and at least 6 feet away as much as possible.
- _____ Days that you need to stay >6 feet away from babies, children younger than 16 years old and pregnant women.
- _____ Days that you need to stay away from work and close contact with others in public places (movies, shopping, etc).
- _____ Days that you need to stay away from school or day-care (includes both teachers and students).

Step 4. Recommendations for after therapy

At home

Specific recommendations. Ask your doctor for the number of days to:
- ◦ Sleep alone in a bed that is >6 feet away from another person, and, if possible, use a separate bedroom or sleeping room all by yourself;
- ◦ Not kiss anyone;
- ◦ Not have sexual activity;
- ◦ Move your bowels every day and use a laxative if you need help;
- ◦ Empty your bladder (urinate) every hour or so during the day of, and day after your radioiodine treatment; follow your doctor's advice on how much to drink;
- ◦ Use wipes (preferably flushable) to clean the toilet seat after use; men should sit down to urinate and use wipes to remove splatter of urine; wipe yourself dry after urinating so that you do not drip;
- ◦ For a phone you share with others, after use, wipe off the mouthpiece, or, while using, cover the phone with a plastic bag that, after use, is placed in specified plastic trash bag.

General Recommendations especially for patients sharing a bathroom
- ◦ Flush the toilet after each time you use it; flush toilet paper and wipes;
- ◦ Always wash your hands well after using the toilet;
- ◦ Rinse the sink and wash your hands after brushing your teeth to wash away the saliva (spit);
- ◦ Do not share your toothbrush, razor, face cloth, towel, food or drinks, spoons, forks, glasses and dishes;
- ◦ Shower every day for at least the first 2 days after your treatment;
- ◦ Do not cook for other people. If cooking is necessary, use plastic gloves and dispose of in the specified plastic trash bag;
- ◦ Wash your dishes in a dishwasher or by hand; it is better not to use disposable (throw away) dishes which must be put into a specified plastic trash bag;

(continued)

Table 4. (Continued)

- ◦ Try to flush any tissues or any other items that contain anything from your body, such as blood, down the toilet; items that cannot be flushed, such as menstrual pads, bandages, paper/plastic dishes, spoons and forks and paper towels should be put in the specified plastic trash bag;
- ◦ Wash your underwear, pajamas, sheets and any clothes that contain sweat, blood or urine by themselves; use a standard washing machine; you do not need to use bleach and do not need extra rinses;
- ◦ Have any one who helps you clean up vomit, blood, urine, or stool wear plastic gloves; the gloves should then be put in the specified trash plastic bag.

Trash Recommendations

- ◦ Keep the specified plastic trash bags separate from other trash; keep the bags away from children and animals;
- ◦ A member of your Radioiodine Treatment Team will tell you how and when to get rid of the specified plastic trash bag; you may be asked to bring the bag back to your treatment facility, or, after 80 days, the bag may be removed as other trash bags.

Pets

- ◦ Usually pets will not receive enough radiation to harm them. But do not sleep with pets (ask your doctor for how long) since your saliva, perspiration or other secretions may be carried away by the pet.

Outside the Home. Ask Your Doctor or a member of the Radioiodine Treatment Team when:

- ◦ It will be safe to eat out, go shopping and attend events such as religious services, parties and movies;
- ◦ You will be able to return to work and to care for or teach others;
- ◦ It would be safe to donate blood;
- ◦ Special or longer distance travel is possible (Note: For up to 3 months or more following radioiodine treatment you may set off radiation detectors at: national borders, airports, bus and train stations, tunnels, bridges, trash collection sites and even your place of employment); a member of your Radioiodine Treatment Team will issue you a letter or card describing the therapy and the phone number of a person knowledgeable about your treatment (usually at the treating facility) in case local law enforcement agents need to check on this information; you should keep the letter or card containing the information with you whenever you are traveling for at least 3 months.

Emergency Care

- ◦ You will get an information card or letter at the time of your treatment that will show the date, type and amount of radioiodine that you were treated with; carry this card with you at all times for at least 3 months following your treatment;
- ◦ If you are in a traffic accident or any other medical emergency during the first week after your treatment, you should show this card to the medical people to let them know about the date and dose of your radioiodine treatment.

IMPORTANT INFORMATION FOR PATIENTS ON RISKS OF RADIATION

Radiation exposure to others should always be As Low As Reasonably Achievable, a goal often abbreviated as ALARA. If you follow the above advice, the radiation from you to others is likely to be less than what they receive from radiation in nature over a year's time.

Please phone us if:

- you have any questions, and particularly if
- any of the above instructions cannot be followed and/or if
- you see anything that may have accidentally or unavoidably increased exposure of others to radiation.

We welcome your input on how we can improve our methods and advice to patients.

Phone: _____

Sincerely yours,

_____

pregnancy tests are usually positive at about 1 week of gestation or as stated in the package insert. Current urine and serum tests are of nearly equal sensitivity. There may be some treated patients who later discover that they were pregnant at or near the time of the ^{131}I dosing. In these situations, the pregnancy will be in a very early stage, and before the ability of the fetal thyroid gland to concentrate iodide, which commences about 10 to 12 weeks of gestation (19,20). However, there is still a concern for fetal whole-body radiation exposure. Such cases should be handled on a case-by-case basis, and a qualified medical physicist should estimate the absorbed radiation dose to the fetus. In a literature review of patients treated with ^{131}I during pregnancy, each of 13 patients who received as little as 15 mCi after the 10th week of gestation gave birth to babies with hypothyroidism or cretinism; 4 patients who were treated before the 10th week delivered normal infants (20). If a pregnant woman is treated, data must be provided to her obstetrician, and, in an expedited fashion, the patient must be counseled on possible pregnancy outcomes and treatment options.

In a meta-analysis, no evidence was found that ^{131}I treatments impaired fertility (21). In another meta-analysis, radioiodine therapy for thyroid cancer in young men has been associated with transient testicular dysfunction expressed as elevated serum FSH levels for up to 18 months after treatments, and some articles reported low sperm counts exceeding 1-year duration (22). Limited data indicate that fathering a child within 3 months of radiation exposure is not associated with an increase in congenital anomalies or fetal loss, and there is no evidence of long-term reduced fertility. However, men should be advised that full fertility may not occur until after 1 year, and attempts to produce pregnancy should best await a time when they are fully recovered from ^{131}I therapy, a period of at least 3 months.

Breastfeeding

Recommendation. Women who are lactating or have recently stopped breastfeeding should not be treated with ^{131}I since the lactating breast concentrates a substantial amount of iodide. Breastfeeding must be stopped at least 6 weeks before administration of ^{131}I therapy, and a delay of 3 months will more reliably ensure that lactation-associated increase in breast sodium iodide symporter activity (23) has returned to normal. If the ^{131}I treatment is urgent or there is concern regarding residual breast uptake, an ^{123}I scan will detect whether breast concentrations of radioactivity greater than normal (substantially above background) should impose a delay in therapy. Involution of lactating breasts is variable as demonstrated in ^{123}I scans; in a small series, there was evidence that bromocriptine accelerates involution (24); however, this agent must be prescribed in the "off label" mode. Breastfeeding should not be resumed after administration of ^{131}I. Breastfeeding can be safely undertaken after future pregnancies.

Discussion. Breastfeeding should be discontinued for two reasons. The first and most critical is to prevent ^{131}I in the milk from reaching the infant and particularly the infant's thyroid gland. The second reason is to limit radiation of the breast tissue, which, via the increased expression of sodium iodide symporter during lactation, promotes ^{131}I concentration. If a woman is intermittently breastfeeding or if there is obvious milk still present despite cessation of nursing, then ^{131}I treatment should be delayed.

Time and distance

Recommendations. Dose rate calculations from predicted body retentions of ^{131}I determine when the dose at 1 m will be less than the regulatory limit for patient release. During the period in which exposure at 1 m will exceed this limit (i.e., daytime restriction), adult family members and caregivers should remain >6 feet away except during the 25% OF time at 1 m. Invoking the ALARA principle, all individuals should stay at least 6 feet away from each treated patient as much as possible throughout the restricted period. Adult family members or caregivers may be closer than 1 m for brief periods, preferably for only minutes. The duration of these distance restrictions depends largely on the amount of thyroid tissue and the rate of clearance of retained activity that will be assessed by a licensed practitioner in consultation with the RSO.

Table 2A-1 and 2A-2 give examples of days (24-hour cycles) required for compliance with 1-m distance restrictions. These data are based on NRC guidelines, published rates of radiation exposure at 1 m, and published rates of ^{131}I clearance in hyperthyroid and in hypothyroid cancer patients. Similar tables may be constructed for patients who will receive different activities of ^{131}I and/or who are euthyroid on replacement or suppressive therapy with thyroid hormone (and are stimulated by recombinant human TSH).

Constraints on time and distance apply to travel, home, work, school, and social activities.

Post-therapy travel

Recommendations. Optimally, when there is no physical or other impairment, the patient should drive alone in a private car. For this situation, there is no time or distance limit except that the patient should drink sufficient fluids to ensure frequent urination and thereby reduce radioiodine in the bladder. Advance planning should include safety in the use of restrooms during the travel home.

If the patient must ride or drive with another person, then time and distance constraints apply. If the person in the vehicle is also a member of the patient's household, the allowable exposure during the car trip may limit subsequent exposure within the home. TEDE tables should be constructed to determine how radiation safety limits the duration of the trip with another occupant; the minimum separation distance should be >3 feet, for example, one sitting in the driver's seat and the other in the passenger-side back seat. Use of a larger vehicle, such as a van, would permit further separation and consequently a longer period of safe travel. Again, frequent emptying of the patient's bladder should be emphasized but with afore thought to safety in the use of restrooms.

Public transportation or mass transit should be avoided throughout restricted periods as recorded in Table 2B-1 and 2B-2. Special circumstances are in the purview of the RSO and will be based on treatment characteristics and also patient reliability. In a different analysis, International Commission on Radiological Protection has published recommendations (25) that allow use of public transportation by some patients treated for hyperthyroidism: the patient may use this transportation for 0.5 hour after 22 mCi (800 MBq) with progression to 3.5 hours after 5.4 mCi (200 MBq).

Radiation detectors at ports of entry. The International Atomic Energy Agency notes that when releasing patients containing radionuclides with measurable gamma ray emissions, unanticipated detection of radiation from such people is possible, or even likely, by radiation-detection systems at places of employment, international borders, airports, train stations, bridges, tunnels, and other areas. With current technology, it is possible to detect ^{131}I activity as little as 0.01 MBq of ^{131}I at 2 to 3 m (26). It is possible that patients treated with ^{131}I could trigger alarms at such detection sites for 95 days or longer after treatment (26,27). Although the amount of ^{131}I does not endanger the public, if detected, it likely will lead to time-consuming explanations and documentations.

If, within 4 months of receiving ^{131}I therapy, travel is planned, particularly across international borders or via airports, tunnels, and/or over bridges and wherever inspection is likely, a form should be provided to the patient. The form should specify the date of treatment, the radionuclide and activity administered, the treating facility, and the name and telephone number of a contact individual knowledgeable about the case.

Post-therapy living situations

Hotel/motel accommodations. A stay in a hotel or motel is not recommended after treatment with ^{131}I. Without specific environment assessments and dose-rate calculations, hotels and motels should be avoided for the periods of daytime restrictions in Table 2A-1 and 2A-2. The RSO should be consulted if a patient must travel a substantial distance after treatment, requires additional follow-up imaging, or cannot travel home without an overnight stay.

Home accommodations. The occupational factor for 8 hours of sleep is 0.33 and the anticipated distance between sleeping partners is 0.3 m. Patients should sleep alone and at least 6 feet away from any other individual throughout the nighttime restricted period. Use of a separate bedroom or sleeping area would be best. Table 2A-1 and 2A-2 give examples of restriction periods and demonstrate the more extended nighttime restricted periods for sleeping with another. If there are pregnant women, infants, and children under 16 years of age in the home, arrangements should ensure that a distance >6 feet can be maintained between the patient and these occupants for the entire restricted time. Input from the RSO should be sought early in the planning process to adapt post release radiation precautions to the patient's home configuration. Having a treated parent staying in the home with children is often problematic due to children's needs and desires to be near the treated parent. Special arrangements should be made for children to stay with relatives or friends; alternatively, the treated parent may stay with relatives or friends where children and pregnant women are absent.

Work/school accommodations. Upon return to work or school, constraints in time and distance are similar to those in the home environment, with special emphasis on preventing exposure to pregnant women and children.

Personal hygiene

Hygiene precautions are meant to reduce not only external exposure but also ingestion of ^{131}I from secretions and excretions of the patient.

Urine. Urine is the primary excretion route for ^{131}I and is maximal during the first 48 hours after treatment. Sufficient fluid (3–4 L/day) should be consumed to enable frequent urination but care should be taken for hypothyroid patients, and particularly those who are elderly, because there is reduced free-water clearance that may lead to hyponatremia. Diuretics should be discontinued if possible. Patients should adjust their fluid intake to enable voiding every hour while awake for the first day after treatment and continue to void often for the next few days to reduce radiation exposure to the urinary bladder and adjacent internal organs.

The following recommendations are for all restricted periods. Both men and women should sit for urination to avoid splatter of radioactive urine. Patients should wipe themselves dry to avoid dripping and contamination of clothing. Flushing the toilet twice after each use is often recommended, but, unless small children or animals gain access to the toilet, there is little additional benefit from this. However, wiping the rim of the toilet with damp toilet paper (or a flushable wipe) that is subsequently flushed may remove a source of radiation that can reach others. This is especially important when a bathroom is being shared with household members or a public restroom is used. Handwashing after using the toilet should be emphasized.

If urinary incontinence is anticipated, then discussion with the RSO during the planning stages is important, and the duration of the recommendations should be determined on an individual basis. Incontinence pads must be disposed of in a heavy duty (preferably double) plastic trash bag (hereafter referred to as specified trash bag) devoted to radiation waste (see below and Table 4). Flushable clean-up items should be flushed down the toilet. Nonflushable items such as paper towels should be disposed of in the specified trash bag. If a caregiver assists with the clean-up, disposable plastic gloves should be worn during the clean-up process and then disposed of in the specified trash bag.

Stool. During the all restricted periods, patients should follow these recommendations. Emptying of the bowel moderately reduces radiation to the patient and also to individuals nearby. To ensure a daily bowel movement, a laxative may be used. Wiping and flushing should follow the same directions as for urination. Also, defecation accidents require the same precautions for clean-up as described under urinary incontinence.

Saliva. Since ^{131}I concentrations are present in the saliva for as long as 7 days, patients should avoid kissing, especially of children, for the period in which sleeping with others is restricted. Radioactive saliva can contaminate food utensils, beverages, toothbrushes, sinks, pillowcases, and telephone mouthpieces, so precautions apply to all of these items. However, disposable food utensils require special waste considerations; washable utensils are preferable. After eating, washing food utensils, glassware, and dishes in a dishwasher or by hand will suffice; the dishes may be washed with those of the family. If telephone mouthpieces are shared, they should be wiped carefully after use by the patient or covered with an easily removed plastic bag. Personal cell phones are preferred.

Blood, wound drainage, and mucus. The following recommendations apply to the daytime periods of restrictions. Blood from wounds, epistaxis, menstruation, and other sources typically contains low levels of radioactivity, but, nevertheless, requires precautionary clean up; again, anyone providing assistance should use plastic gloves. Bandages, clean-up materials, menstrual pads, and gloves should be disposed of in the specified trash bag. Nasal mucus can also contain ^{131}I and tissues, unless flushable, should be disposed of in the specified trash bag.

Perspiration. A small amount of ^{131}I will appear in sweat, but this could be transferred by hands to the mouths of family members. Bedding and bed clothes should be handled with care during the periods that restrict sleeping with another. Patients should wear disposable plastic gloves if they must prepare meals for others during the same restricted periods. Wiping exercise equipment and similar instruments used by others during the first 48 hours after treatment with flushable wipes should be sufficient to remove any hazard; the paper towels and nonflushable clean-up materials should be disposed of in the specified trash bag. Work and/or exercise clothing that are heavily soiled with perspiration should be washed immediately or kept away from household members until laundered. Likewise, bed clothes soiled with perspiration and/or other secretions and should be laundered before exposure to others.

Vomitus. Nausea occurs frequently and vomiting occasionally, especially in children, after administered activities of 300 mCi (11,100 MBq) or more (28). The gastric mucosa secretes iodide by the same mechanism as chloride so that vomitus contains substantial amounts of ^{131}I for days after the

administered activity has been absorbed. Prophylactic antiemetics may lessen the gastrointestinal symptoms. For all periods of restriction, vomitus should be collected using disposable gloves and preferably, flushed down the toilet; gloves and nonflushable material, such as paper towels, should be placed in the specified trash bag.

Specified bag for waste disposal. The specified trash bags must be leak proof. These bags containing waste can be returned to the Nuclear Medicine facility after 1 to 2 weeks, as determined by the respective treatment personnel. Otherwise the bags should be tightly closed and stored in a secure place at least 6 feet away from people and animals. The bags can be taken to the usual household trash disposal sites after 80 days (10 half lives of ^{131}I) at which time radiation detectors should not produce alarms.

Summary

Two major principles guide radiation safety: sound medical practice and adherence to regulations. Therapies with ^{131}I for thyroid diseases can be performed within NRC regulations by evaluating the requirements for individual patients and giving advice on reducing radiation exposures through appropriate and patient-specific precautions. Periodic re-evaluations of programs and protocols should take into account the observations on adherence to precautions reported by patients. An Annotated Summary of the Literature Review is in the Supplementary Data.

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