

# Patient Misconceptions and Ethical Challenges in Radioactive Iodine Scanning and Therapy\*

M. Sara Rosenthal

*Program for Bioethics and Patients' Rights, University of Kentucky College of Medicine, Lexington, Kentucky*

The use and nature of radioactive iodine (RAI) are complex topics for patients with thyroid conditions to understand. Fear and anxiety over its use, misinformation in patient advocacy books and on the Internet, medical jargon, confusion regarding postscanning and posttreatment procedures, patient literacy, thyroid health status, and several other socioeconomic factors can create serious barriers to genuine informed consent in RAI scanning and treatment. The following discussion will review the origins of patient misconceptions and misinterpretations, including international differences in physician attitudes regarding RAI usage. Next, this article will present the core ethical duties, problems, and moral dilemmas that can arise in the RAI setting. Upon completion of this article, the reader should be able to describe the core ethical principles of respect for persons (patient autonomy), beneficence, nonmaleficence, and justice; describe the 3 components of informed consent; identify common barriers to informed consent and describe how such barriers can lead to misconceptions, misinformation, and refusal of treatment with RAI; and summarize where RAI candidates and patients first look for information and identify the common ways in which misinformation surfaces.

**Key Words:** radioactive iodine; thyroid; patient misconceptions; ethical challenges; bioethics; informed consent

**J Nucl Med Technol 2006; 34:143-150**

**R**adioactive iodine (RAI) is used for diagnostic scanning and therapy in 2 groups of patients with thyroid conditions. Diagnostic scanning with RAI is the standard of care for thyroid cancer patients, who need to be routinely scanned for evidence of recurring disease (1). Scanning to evaluate thyroid nodules for uptake also is common in patients with goiters and low levels of thyrotropin (or thyroid-stimulating hormone; TSH) or in patients with nodular goiters (2).

Patients who have thyroid conditions and who are offered RAI as a treatment comprise patients with Graves'

disease (GD), those exhibiting symptoms of hyperthyroidism, those with toxic nodular goiters (3), and those with thyroid cancers that take up iodine and therefore respond to RAI therapy. Special populations of thyroid cancer patients who have aggressive metastases may be offered extremely high doses of RAI through a technique known as dosimetry. Additionally, some thyroid cancer patients will need more than one RAI treatment dose (1,4).

Patients with GD represent the most common candidates for RAI, because this condition is far more prevalent in the population than thyroid cancer. The majority of patients are women, are computer literate, and express dissatisfaction with their physicians (5-8), particularly because there is community disagreement regarding the goals of therapy in GD: total ablation and hypothyroidism or an attempt to restore the patient to a euthyroid state. Patients who have GD and who compared their therapies often discovered inconsistencies in approaches that raised questions for them. This process led to an increase in support groups for patients with thyroid conditions and patient advocacy literature on hypothyroidism (9) as well as unique support groups for patients with GD, including the National Graves' Disease Foundation (6), GD listserves (10), and patient-authored texts on GD, written by patients who were not provided with adequate information regarding RAI treatment approaches or alternatives to RAI (6,10,11).

Thyroid cancer patients also are more commonly women and are diagnosed at any point during childhood and adult life (1). Again, because of the orphan nature of the disease, thyroid cancer patients are inclined to self-educate about their disease and will specifically use search terms such as "radioactive iodine" to learn more about RAI scans and therapies. In the late 1990s, thyroid cancer patients organized as a group and formed the Thyroid Cancer Survivor's Association ([www.thyca.org](http://www.thyca.org)). Similar groups can be found in Canada and internationally through chat lines and support.

## CULTURAL FEARS OF RAI AND EDUCATION CHALLENGES

There are inherent culturally embedded fears of RAI, based on numerous events in recent history. These include Hiroshima and Nagasaki, the Cold War and ensuing nuclear arms race, nuclear power plant accidents (such as Three Mile Island and Chernobyl), and reports of health effects

Received Dec. 20, 2005; revision accepted May 15, 2006.

For correspondence or reprints contact: M. Sara Rosenthal, PhD, Program for Bioethics and Patients' Rights, University of Kentucky College of Medicine, 131 College of Medicine Office Bldg., Lexington, KY 40536-0086. E-mail: [msrose2@uky.edu](mailto:msrose2@uky.edu)

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in the popular press. In the 1980s, in response to the U.S. proliferation of nuclear arms, a developing “No Nukes” movement began to grow, and prominent antinuclear medical experts, such as Dr. Helen Caldicott, author of *If You Love This Planet* (1982), warned of radiation sickness and global health chaos in the event of global thermonuclear war, spawning a series of high-profile films in the 1980s, such as *The Day After* (1983). There are fears in the general population regarding the words “nuclear” and “radioactivity,” which conjure up images of hair loss and birth defects. It is clear that for patients with low levels of literacy and education, grasping concepts such as “isotope” and “half-life” and some understanding of thyroid function are critical for there to be genuine informed consent (12). Many people also confuse RAI with external-beam radiation, because Internet search terms such as “radiation therapy” on established cancer information sites, such as the American Cancer Society ([www.acs.org](http://www.acs.org)), commonly lead to information on external-beam radiation.

### ORIGINS OF PATIENT EDUCATION MISINFORMATION

Much patient misinformation regarding RAI originates in the GD community. Patients who have GD and who self-educate about their disease can now freely access information on the Internet or in patient advocacy books written by fellow patients with thyroid conditions (6,9–11). Such literature reports the following about RAI:

- Unexpected hypothyroidism can occur. According to GD listserves (10), hypothyroidism is not entirely expected and is seen as proof that RAI is risky or improperly dosed. This misinformation originates with inadequate patient counseling regarding the goals of therapy and informed consent. The term “iatrogenic hypothyroidism” is now used among patients with GD (spelled on one Web site as “yatrogenic” [sic] and suggests victimization. According to one Web site (13), “By having RAI, the thyroid gland is destroyed or seriously damaged with radiation, when the thyroid itself is not the problem, is the victim. GD is a disease of immunity, not of the thyroid. This destruction causes an acute condition, which is curable, into a chronic disease: hypothyroidism, with no way back once the gland has been destroyed.” Although there appears to be an understanding that ablation of the gland palliates hyperthyroidism, there is a collective misinterpretation that with the ablation approach, hypothyroidism is a complication of RAI rather than a therapeutic goal to be further managed with levothyroxine replacement therapy (3).
- RAI causes other cancers. There is much information in the patient advocacy literature on GD regarding the risks of cancer after RAI, based on misconstrued interpretations of the literature on ionizing radiation (14). Although certainly patients receiving high doses

of RAI will need to weigh the risk of dying from metastatic thyroid cancer against the small increased risk of developing other cancers (1), these risk–benefit analyses are entirely misplaced for patients who have GD and are receiving less than 1,221 MBq (33 mCi) at any one time. Full disclosure of genuine risks of other cancers, compared with ordinary risks of daily life and weighed against the risks of alternative treatments, should correct such misconceptions. Another Web site quote reads as follows (15): “RAI was first used to treat hyperthyroidism in the 1950’s. Recent long-term studies show that RAI causes an increased risk of thyroid and small bowel cancers.” This information is repeated on the Web site of the International League of Atomic Women (13), whose target audience is women with GD. The source cited for this information (16) actually concludes with the following statements: “Radioactive iodine was not linked to total cancer deaths or to any specific cancer with the exception of thyroid cancer. Neither hyperthyroidism nor  $^{131}\text{I}$  treatment resulted in a significantly increased risk of total cancer mortality. Although there was an elevated risk of thyroid cancer mortality following  $^{131}\text{I}$  treatment, in absolute terms the excess number of deaths was small, and the underlying thyroid disease appeared to play a role [in the thyroid cancer increase]. Overall,  $^{131}\text{I}$  appears to be a safe therapy for hyperthyroidism.”

- RAI causes Graves’ ophthalmopathy (GO) or makes it worse. Patients must be appropriately counseled about the risk of aggravating existing GO, which can be remedied with steroids before RAI therapy, and quitting smoking (17). In many patients with GO, particularly those who cannot tolerate steroids, it is the standard of care to offer alternatives to RAI, such as surgery or antithyroid medications (3). Increasingly, thyroidology literature reports that patients with only minor signs of GO will not experience worsening of GO (17,18). However, a full disclosure of alternatives is critical, and such patients must give genuine informed consent to RAI.
- Antithyroid medications are safer and more effective than RAI. The international differences in antithyroid medication usage (19–22) raise questions in patients’ minds about the safety of RAI. Many patients who have GD and who are inadequately counseled about RAI only first discover that antithyroid drugs are even available after having RAI and self-educating after treatment. Again, the origins of this misinformation can be corrected by adequate counseling and obtaining genuine informed consent from patients (12).
- Goitrogenic diets can “cure” GD and ought to be offered as a natural alternative to RAI. This misinformation stems from some probable misreading of articles on goitrogens in the medical literature (23) and a reliance on non–peer-reviewed literature in the alternative health press (10).

- Malaise and ill health follow RAI. On the Web site [www.notovertillthefatladysings.com](http://www.notovertillthefatladysings.com) (24), a patient with GD shares her story of ill health and post-RAI “nightmares” in personal blogs, listing a wide array of unrelated symptoms caused by RAI. These symptoms appear under the heading “Post Graves’/RAI Symptom List.” A more critical reading of these symptoms reveals that much of the malaise described by this patient with GD is a sign of hypothyroidism. Indeed, many patients with GD are not properly counseled about the health effects of hypothyroidism and the importance of being appropriately treated with thyroid hormone. Quality-of-life survey instruments for patients with hypothyroidism also are of questionable validity (25).
- Hypothyroidism is mismanaged by conventional physicians, so patients wind up “worse off” after RAI. There is also a large body of patient advocacy literature claiming that hypothyroidism is completely mismanaged by conventional thyroidologists. One popular book (9) asserts that the TSH test is “inappropriate” for detecting hypothyroidism and encourages readers to abandon modern thyroidology in search of nonallopathic treatment of hypothyroidism, including the use of basal body temperature tests (26). Additionally, misinformation regarding appropriate hormone therapy is now rampant. Patients who have hypothyroidism and self-educate may come to believe that levothyroxine sodium is harmful therapy (9,10), that desiccated thyroid hormone confers greater benefit (9), that triiodothyronine is appropriate therapy for the long-term management of hypothyroidism (9,27), and that the TSH test is inappropriate for detecting thyroid function and a sign that a physician is not open-minded or knowledgeable (9,10).

#### International Differences in RAI Usage for GD

In 1991 and 1997, articles published in the journal *Thyroid* reported vast international differences in the treatment of GD (19,20); the data were based on standardized questionnaires and hypothetical GD cases. When polled, 69% of the members of the American Thyroid Association reported that “RAI was the treatment of choice”; 30.5% used antithyroid medications (19,20). Only 22% of the members of both the European Thyroid Association and the Chinese Thyroid Association reported RAI as the treatment of choice; 77% used antithyroid medications. The most notable difference came from Japan and Korea, where only 11% of members of the corresponding associations reported that RAI was the treatment of choice, and 88% used antithyroid medications. These differences were related to cultural attitudes and phobias regarding RAI, discussed earlier, particularly in Japan. The same questionnaire was distributed in Latin America, where only 15.3% of members of the Latin American Thyroid Society chose RAI as the treatment of choice, with 83% selecting antithyroid

medications (21). In Australia, a modified questionnaire was sent to members of the Endocrine Society of Australia; 81% of respondents reported that they opted to treat with antithyroid medications, and only 19% reported that they chose RAI (22). The cost and availability of RAI are the most apparent contributing factors in making RAI the treatment of choice in the United States (19,20), as RAI is viewed as providing a cost savings to the patient because of a more rapid cure. Cultural and attitudinal barriers are cited as the common reasons why RAI is not the treatment of choice outside the United States, particularly because universal health insurance outside the United States makes cost less of a factor for patients. In Japan, there is a reluctance to use RAI because of safety restrictions applied to RAI pharmaceuticals (20).

#### “Radioactive Fallout”

GD patients and patient authors who searched the medical literature with PubMed or Google came across the articles just cited and misconstrued the international differences as safety concerns. Fear and anxiety over the long-term consequences of RAI are apparent on the popular patient advocacy Web site of The International League of Atomic Women (13), which opens its site with the following statements: “We are women with GD who have been treated with Radioactive Iodine—RAI—<sup>131</sup>I—the ATOMIC COCKTAIL! Our motto is: ‘We may as well go forward, because we can’t go back!’” Another popular link reads as follows: “Top 20 Reasons Why I’ll Never Have RAI.” The site is filled with misconstrued facts regarding the dangers of RAI and the consequences of treatment with RAI. The site is careful to provide referencing for its statements; however, some of the citations are confused and misdirect readers to the wrong articles, and others are just misinterpreted articles, with alarming statements taken out of context. In addition, patients reading the literature on this Web site likely would not have the scientific background to accurately interpret the medical literature, would rely on the site to translate the medical literature into plain language, and would trust that the citations are accurate. For example, statements in the medical literature about RAI facilitating “rapid improvement of hyperthyroidism,” convenience, and medical cost benefits (20) are not interpreted as a medical cost benefit to patients, who otherwise are burdened with the financial and emotional costs associated with antithyroid medications, relapses, prolonged hyperthyroidism, and poorer quality of life. Nor does the advocacy literature for patients with GD weigh the risks of surgery, which is associated with greater risks than RAI treatment because thyroid surgery demands experienced surgeons, who may still cause damage to parathyroid glands or vocal cords (28). Instead, advocates for patients with GD conclude from the questionnaire data that because such differences exist, the American Thyroid Association members’ choice of RAI is driven by greed and managed care, overriding patient safety concerns (10,13). Such perceptions

are reinforced by the absence of sufficient counseling about the alternatives or informed consent in the RAI setting.

### **Specific Misconceptions About RAI in Thyroid Cancer Community**

There is information in the medical literature that has been promulgated by some physicians regarding the lifetime limits of RAI (29), constituting an example of physician misconceptions that are communicated to patients (1).

Physicians continue to argue regarding the appropriate extent of surgical resection of malignant thyroid glands and which of their patients need adjuvant RAI therapy. Such conflicts in basic approaches to thyroid cancer magnify the confusion of patients and their advocacy groups. In addition, although statistically higher incidences of breast cancer have been noted for female thyroid cancer patients (30), there is no evidence linking this finding with RAI therapy. This information remains in cyberspace, leading thyroid cancer patients to fear higher doses of RAI or repeated doses of RAI when clinically indicated. Although there are reported statistical cancer risks associated with higher doses of RAI, it is difficult for patients to genuinely weigh those risks against the risk of dying from thyroid cancer. Most patients lack the medical background to understand concepts of proportion and relative risk (31).

Patient misconceptions persist regarding the low-iodine diet (LID); in part, these misconceptions are fueled by the medical community. Some physicians managing thyroid cancer patients refuse to counsel patients about the LID or are themselves misinformed about the utility of the LID (32). Moreover, there is false information regarding dietary restrictions on the LID; this information makes the diet unnecessarily more difficult. Patients who download LID information from the Thyroid Cancer Survivor's Association Web site ([www.thyca.org](http://www.thyca.org)) discover that they cannot have many types of beans, potato skins, or rhubarb and can have only limited quantities of meat, grains, and rice, despite the fact that there is no documented evidence to support these dietary restrictions (32). Patients continue to confuse the LID with a low-sodium diet, and confusion in Canada regarding sources of noniodized salt persists (32).

Finally, misinformation regarding recombinant TSH (rTSH) as an alternative preparation method for scanning persists. Patients in some areas are not counseled about the availability of rTSH as an alternative preparation method, and there is still some disagreement in the medical community regarding appropriate rTSH candidates. Patients do not appreciate that disagreement in the medical community regarding the use of rTSH for RAI is a norm in scientific discourse. Patients interpret different approaches as either "right" or "wrong."

### **Ethical Principles Involved in RAI Scanning and Treatment**

It is clear that the deficiencies in care and counseling in the GD and thyroid cancer communities led to the education movements for patients with thyroid conditions. Health

care providers ought to be aware that in caring for and counseling patients with thyroid conditions, 4 core ethical principles commonly outlined in foundational bioethics works ought to be upheld (33). Although there may be competing tensions in upholding such principles, patient counseling and education and genuine informed consent would be vastly improved by doing so.

### **Respect for Persons (Also Known as Patient Autonomy)**

A health care provider has a duty to respect the wishes, bodily integrity, and health care preferences of patients with thyroid conditions. Thus, information, counseling, and informed consent are all crucial aspects of care supporting this principle (12). When patients with thyroid conditions refuse RAI therapy, issues regarding autonomy are particularly difficult, but reasonable alternative therapies must be offered without coercing patients into selecting RAI instead. For thyroid cancer scanning, the use of rTSH as an alternative preparation method ought to be discussed, even if insurance coverage of its substantial cost is a problem. Issues regarding confidentiality and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) also are related to this principle.

### **Beneficence**

The principle of beneficence means that the health care provider must promote the well-being of patients and avoid harming them. The health care provider also has an obligation to weigh the alternatives to RAI therapy for GD, when reasonable alternatives are available, for patients who may not be optimal RAI candidates because of pregnancy, anxiety over RAI, or moderate to severe GO. When patients refuse RAI therapy, the harm associated with no treatment (as in thyroid cancer) also must be weighed and communicated to the patients. In many cases of GD, for example, the use of antithyroid medications or surgical subtotal thyroidectomy may provide appropriate therapy without the use of RAI. On the other hand, in cases of aggressive metastatic thyroid cancer, there may not be effective alternative treatment options. The absence of informed consent can, of course, lead to harm because patients may be exposed to risks (if refusing therapy, for example) that they could have avoided had they been provided with accurate, (more) complete, or understandable information. For example, steroid use with RAI for patients with GD and with severe GO may prevent the possible worsening of GO (17). Patients with GD also must understand that hypothyroidism after ablation therapy for GD is a stated goal of therapy rather than a risk or complication. The frequent absence of counseling regarding these 2 common issues for patients with GD (6,10) seriously interferes with obtaining informed consent and seriously contributes to misinformation regarding the safety of RAI.

### **Nonmaleficence**

The principle of nonmaleficence is an extension of that of beneficence. Under this principle, the health care provider

ought to strive not to inflict harm to a patient, a requirement also seen as a duty not to refrain from aiding a patient. In short, not to come to a patient's aid and prevent harm, when the patient is, in fact, in harm's way, is maleficence. It is also this principle under which the legal "duty to warn" third parties is invoked (34). The duty to warn is a critical ethical and legal concept in the RAI setting and is discussed further later in this article.

### Justice

Under the principle of justice, it is distributive justice that guides access to RAI therapies and scans, resource allocation, and access to information about RAI. Issues of justice, however, become entangled with literacy and education. Misinformation about RAI as a result of wide gaps in knowledge and noncritical reading of patient advocacy literature can pose tremendous ethical challenges. Indeed, the ability to make an informed decision is directly related to a person's literacy skills and education levels. Literacy and privilege have become entangled with informed consent (31). Additionally, economic barriers can interfere with access to appropriate therapies and medications. A good example is rTSH, which may not be affordable to uninsured patients or patients who need to pay for it out-of-pocket.

### Informed Consent and RAI Therapy

There are inherent ethical and legal requirements for informed consent. A useful model that has the similar demographic challenge of a large number of female patients can be culled from McCullough and Chervenak's "Nine Steps of the Informed Consent Process" (35) and adapted to consent for RAI therapy:

1. The health care provider initiates the process by eliciting from the patient what he or she believes about his or her thyroid condition, diagnosis, alternatives available to manage it, and prognosis under each alternative.
2. The health care provider corrects factual errors and incompleteness in the patient's fund of knowledge. This does not require that the patient receive a complete medical education.
3. The health care provider explains his or her clinical judgment about the patient's condition and all available management strategies (e.g.,  $\beta$ -blockers or antithyroid medications for milder GD), including doing nothing.
4. The health care provider works with the patient as needed or requested to help him or her develop as complete as possible an understanding of his or her condition and alternatives available to manage it.
5. The health care provider works with the patient as needed or requested to help identify relevant values or beliefs influencing decision making. For example, a Japanese or European patient may have certain beliefs about radioactivity based on deep collective historical fears.

6. The health care provider helps the patient as needed or requested to evaluate alternatives in terms of those values and beliefs.
7. The patient undertakes to understand his or her condition, the available management strategies (including doing nothing), and the prognosis under each alternative and expresses his or her subjective interest-based or deliberative interest-based preferences.
8. The health care provider makes a recommendation based on the clinical judgment already explained in step 3.
9. A mutual decision is reached and is implemented.

The architects of this list of 9 steps (35) add that the law requires a health care provider to provide an adequate amount of information to the RAI candidate without interfering with his or her exercise of autonomy in choosing or refusing RAI. Thus, information about RAI needs to be supplied only to fulfill the "reasonable person" standard. This means that the health care provider is required by this precept to "disclose what the hypothetical reasonable person—an individual capable of thinking things through in a rational manner—would want to know in the patient's situation" (35). However, the law does not require that the patient understand well or completely what is disclosed, only that the information be disclosed in a manner and at a level that the patient can reliably be expected to grasp. This obligation is satisfied in the law even if the patient only "roughly" comprehends the information that has been disclosed. However, the law does not fully account for the physician's ethical obligations, because it does not concern itself with what the patient needs to do in this process, or with possible obligations that the patient may have to his or her physician in this process. The law, in other words, ignores what is involved in the patient's understanding of the information provided by his or her physician (35).

Ethicists agree that informed consent is a "transition concept" (12) laden with problems ranging from determining what is good or in the best interests of a particular patient to the question of whose will is being suppressed or enabled through this process (12).

Informed consent, when defined as "the autonomous authorization of a medical intervention by individual patients" (36), implies acceptance of treatment as well as refusal of treatment. Treating someone without his or her consent constitutes battery, and treating someone without adequate informed consent constitutes negligence (36). There are also 3 components of consent: disclosure, capacity and competency, and voluntariness.

### Disclosure

Has a patient been provided with relevant and comprehensive information by his or her clinician? Disclosure means that "a description of the treatment; its expected effects (e.g., duration of hospital stay, expected time to recovery, restrictions on daily activities, scars); information about relevant alternative options and their expected

benefits and relevant risks; and an explanation of the consequences of declining or delaying treatment must be provided. A patient should also be given an opportunity to ask questions, while his/her healthcare providers should be available to answer them" (37).

### Capacity and Competency

Does the patient understand information relevant to a treatment decision and appreciate the reasonably foreseeable consequences of a decision or lack of decision? Does he or she "understand information and appreciate its implications" (36)? Does he or she understand what is being disclosed, and can he or she decide on treatment based on this information? What is problematic about this aspect of informed consent is that the level of information disseminated to the patient with a thyroid condition need not be tailored specifically to him or her but to what a "reasonable person" would want to know, even though many bioethicists agree that disclosure must include facts relevant to the particular person. For example, reasonable patients could make decisions about risk if it were framed within the context of "relative risk" rather than in statistical data that could be difficult to understand (31).

The bioethics literature is rich with critical articles on informed consent regarding what authentically represents a person's capacity to consent (36). When people do not understand the information relevant to a decision, do not appreciate the reasonably foreseeable consequences of a decision or lack of decision, or are not able to decide about a procedure because not enough information has been disclosed, they are considered to lack a genuine capacity to consent. For patients with thyroid conditions, fear of RAI, hypothyroidism, or thyrotoxicosis clearly can become a barrier to capacity. Depression, unclear thinking, and fatigue are common features of hypothyroidism (8), and extreme anxiety is a common feature of patients with thyrotoxicosis (38). Depression and anxiety also are common in patients with thyroid cancer (39). Even more mild hypothyroidism is claimed by patients to be a barrier to decision making and optimum functioning, as evidenced by studies examining effective thyroid hormone therapies through the use of patient questionnaires (40), although their validity has been questioned (25).

### Voluntariness

Is the patient with a thyroid condition being allowed to make his or her health care choice free of any undue influences? To answer this question, one needs to take into consideration internal factors, such as thyrotoxicosis or hypothyroidism, as well as external factors, such as manipulation (41), which involves "the deliberate distortion or omission of information" in an attempt to induce a patient to accept a therapy (41). For example, the Internet is filled with resentful tales from patients who have GD (13) and who were apparently given false reassurances regarding the worsening of GO and the resumption of normal thyroid functioning. Some patient advocacy literature asserts that

hypothyroidism after RAI therapy is evidence of harm (10). Patients who are surprised over aggravated GO or hypothyroidism after RAI therapy clearly were not adequately informed, raising the question of whether the omission of information was a form of coercion (41). Alternatively, distorted negative information presented in patient-generated materials may equally coerce patients into refusing RAI when it is the best option.

### Socioeconomic Barriers to Informed Consent

Barriers to capacity also include wide gaps in knowledge that may be attributable to income, education, literacy, not speaking the same language as the practitioner, and health care provider bias, meaning that assumptions about a patient's intelligence or character affect the level of information disclosed by the practitioner. When language barriers exist in the RAI setting, there are also problems inherent in interpreter ethics. Language intermediaries may not play a neutral role and can influence decision making (42). Many hospitals rely on untrained hospital personnel or staff for interpretation, a practice that fails to take into account the distortion of technical information as well as problems related to confidentiality.

An interpreter has the power to elicit, clarify, translate, omit, or distort messages (42). In the clinical setting, the interpreter may have far more influence on patients than do physicians. There are ethical problems inherent in interpretation, such as confidentiality and accuracy. Interpreter bias can affect the accuracy of information presented to patients.

### Confidentiality and HIPAA

Thyroid cancer patients who have been prepared for an RAI scan by being made hypothyroid (i.e., the withdrawal method) must be warned about the dangers of driving a car or operating machinery. Health care providers have a clear duty to warn RAI recipients about contact with third parties after treatment and about following posttreatment precautions. If a patient receiving RAI does not heed warnings with respect to driving or posttreatment precautions, the health care provider may have an ethical duty to breach HIPAA and warn (34) local authorities responsible for driver's license suspensions, employers, family members, coworkers, or other identifiable third parties who may be at risk as a result of the patient's driving or failure to follow posttreatment precautions. For example, hypothyroid bus drivers, truck drivers, pilots, air traffic controllers, and other such professionals would pose risks to third parties if they continued to work during the posttherapy period.

HIPAA created new requirements for health care providers to protect the privacy and security of certain health information that could be used to identify an individual. Regulations to implement these privacy provisions were published by the Department of Health and Human Services in December 2000. These became known as the HIPAA Privacy Rules, which came into effect April 14, 2003. These privacy rules, which pertain to insurance companies,

hospitals, clinics, medical providers, and pharmacies, make it illegal for health care providers to disclose patient information to any other party, including a patient's family members, without the patient's consent. HIPAA privacy regulations make it illegal for any protected health information to be disclosed to another party without the patient's express consent. Protected health information includes name, address, telephone numbers, fax numbers, e-mail addresses, URLs or IP addresses, birth and death dates, dates relating to admissions or discharges, social security numbers, numbers that identify health records or beneficiary plans, motor vehicle information, and a host of other identifiers (34).

The courts have ruled that the duty to protect confidentiality is not absolute. The duty-to-warn precedent was first introduced by the courts in *Tarasoff v Regents of the University of California*, which held that confidentiality is not absolute when a third party is in danger. The Tarasoff case and its duty-to-warn health law precedent directly challenge confidentiality, one of the core ethical duties in health care provider-patient relationships. There are criteria for evaluating when a duty to warn overrides confidentiality (34). They include gravity of harm, probability of harm, identifiability of at-risk individuals, imminence of harm, probability that intervention can mitigate harm, the degree to which maintaining confidentiality has been exhausted, and whether the patient is the agent of harm (34).

## CONCLUSION

Patients who are inadequately counseled about RAI by either their managing physicians or nuclear medicine practitioners and who may not be offered appropriate alternatives will self-educate about RAI, relying on patient-generated books and Web sites to "translate" the medical literature for them as well as anecdotal accounts by patients about the health effects of RAI. As a result, the complexity of RAI as a health topic for patients with no medical background is wide open for misinterpretation. Additionally, patients who are appropriately counseled may still be vulnerable to misinformation that they read in patient advocacy literature. Correcting misconceptions, misinterpreted facts, and even false information and appropriately warning patients about certain risks need to be raised as critical patient education issues for nuclear medicine practitioners. Patient education materials on RAI that specifically identify myths and facts could become an organized public education mandate of the nuclear medicine community. It should be appreciated, too, that a substantial number of patients who could benefit from RAI therapy never receive it. In addition to large numbers of patients who have GD and who refuse RAI therapy, some thyroid cancer patients are offered only surgery or do not undergo RAI scanning because of poor physician education, bias, or incompetence. Finally, nuclear medicine technologists must appreciate that thyroid cancer patients may not be suffi-

ciently counseled about the LID. Their colleague physicians may be similarly unaware that stable iodine from radiologic studies carried out with intravenous contrast material can significantly interfere with RAI scans and therapy. It may be prudent to offer counseling with appropriate education materials and, in some cases, reschedule scans or therapy when dietary iodine could seriously interfere with uptake.

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*JNMT* 2006;34:143-150.

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*Journal of Nuclear Medicine Technology* is published quarterly.  
SNMMI | Society of Nuclear Medicine and Molecular Imaging  
1850 Samuel Morse Drive, Reston, VA 20190.  
(Print ISSN: 0091-4916, Online ISSN: 1535-5675)

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