Survey of Patient Release Information on Radiation and Security Checkpoints

Patients who receive radiopharmaceuticals in the course of diagnosis or treatment are often released when their bodies still contain elevated amounts of radioactive material. These amounts are sufficiently high to be detected by sensitive radiation monitors for days or even weeks after administration. Several studies have estimated the duration of time in which patients can trigger radiation alarms: for bone and thyroid scans, up to 3 days; for cardiac scans with thallium, up to 51 days; and for iodine therapy, up to 95 days (*1–4*). A number of cases in which patients have activated radiation alarms and then been questioned and even strip-searched by law enforcement personnel have been documented in the scientific literature and by the news media (*5–10*). With millions of radiopharmaceutical procedures offered annually and with the increasing use of radiation detection equipment in public places, these occurrences are likely to continue.

Federal regulations and guidelines describe when and how licensed health care facilities can release patients who have been treated with unsealed byproduct material or with implants containing byproduct material (*11–12*). These guidelines also address the safety instructions that facilities must provide to patients (or to their parents or guardians) to ensure that doses to other individuals remain "as low as reasonably achievable" (ALARA). In December 2003, the U.S. Nuclear Regulatory Commission (NRC) supplemented these guidelines with an Information Notice reminding its licensees that released patients should know the importance of following such instructions so that: (1) doses to other individuals can be maintained ALARA; and (2) the likelihood that the patients will trigger radiation alarms is reduced (*13*).

The NRC has suggested voluntary actions that licensees could take with every released patient who contains detectable amounts of radiation after receiving diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants. These actions include explaining to patients the potential to trigger radiation monitoring alarms and providing them with written information for law enforcement use. In November 2006, the SNM issued a statement that included a number of recommendations and travel tips for patients (*14*). SNM recommended that patients and health care providers discuss how long after treatment patients might emit detectable radiation. Like the NRC, SNM also recommended that patients obtain a letter from their health care providers explaining that they have undergone a nuclear medicine procedure. SNM also outlined the information it believed such documentation should contain.

Despite such efforts by governmental and professional entities, casual conversations with patients who received radiopharmaceuticals suggested to us that many received neither documentation nor counseling. This suggested that many released patients might remain unaware that they emit detectable levels of radiation. Moreover, licensees are likely to adopt a widely varying range of practices as they attempt to comply with the regulatory guidelines about patient release from health care facilities. Some of these practices might adequately inform the patients about this subject, but others might not. The NRC recommendations in the 2003 Information Notice are voluntary, and it is unclear whether and how NRC-licensed health care facilities have responded in routine practice.

This study of how health care facilities informed patients of the radiation alarm issue was conducted in collaboration with the NRC. The study goal was to examine the range of patient release procedures and practices among NRC-licensed health care facilities—*not* to evaluate the adequacy of the existing regulation or the degree of compliance. Through interviews with staff at health care facilities in a number of hospitals and clinics across several states, we documented patient education practices and release procedures. We identified some good practices and also identified areas that could be improved to increase the safety of patients' families and the public and to increase awareness among patients who could potentially trigger radiation detection alarms.

Materials and Methods

On October 13, 2006, the NRC issued Temporary Instruction 2800/039, "Information Collection: Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." These instructions contained our survey interview protocol and directives for NRC regional inspectors on how to gather information during routine, unannounced inspections of NRC-licensed facilities. The temporary instruction was in effect for 3 months.

The interview protocol included several modules designed to obtain the following information: (1) general facility characteristics (e.g., number of beds, number of in- and outpatient diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material); (2) respondent's work experience, involvement in patient release and patient communication,

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and familiarity with the NRC Information Notice; (3) the process of making a decision on patient release; and (4) the process of patient education related to radiopharmaceutical administration, including consent procedures, pre- and postadministration counseling, and any other relevant verbal and written communications. Inspectors were also asked to gather any hard copies of patient instruction and informational material each facility could provide. Before finalizing the interview protocol and providing it as an attachment to the Temporary Instruction, the NRC headquarters circulated it to the regional offices for review and comment.

Data received from the NRC inspectors were of high quality, and inspectors ensured that no relevant questions remained unanswered. In large facilities, several individuals—radiation safety officers (RSO), nuclear medicine technologists, radiation therapy technologists, medical physicists, or authorized users (physicians)—appeared to be involved in the decision processes related to patient release. In a number of such facilities inspectors interviewed more than 1 health care professional. All completed questionnaires were considered in their entirety, even if respondents were based in the same facility. On some occasions, inspectors spoke simultaneously with more than 1 respondent at a facility and combined their input in a single questionnaire. In these cases, if the answers differed between respondents, each reply was considered separately.

This study benefited from collaboration, early engagement, and valuable input from NRC staff. There was no selection bias for the facilities, because the data were collected over a 3-month period following the NRC regions' routine schedule for health care facility inspections. The inspectors had access to relevant health care professionals within each facility. This access ensured a 100% response rate, which would have been quite difficult to achieve without NRC participation. The study did, however, have some limitations. First, the scope was limited to Non-Agreement states. Second, because all interviews were conducted by NRC inspectors, we could not ask follow-up questions for clarification or additional information. Finally, respondents may have been inclined to present their facilities in the best possible light, with concerns that a "wrong" answer might adversely affect the inspection results.

Results and Discussion

Inspectors interviewed 89 health care professionals at 66 facilities in 12 states. The majority of facilities are located in Pennsylvania (18), New Jersey (15), Michigan (11), and Indiana (10). The facilities include a range of large and small hospitals, as well as outpatient-only clinics (Table 1). Surveyed facilities offer various nuclear medicine procedures: diagnostic (55), therapeutic (35), and brachytherapy (20). Table 2 contains the list of procedures and percentages of persons treated as outpatients. We found that smaller hospitals (<200 beds) and outpatient clinics generally offer only diagnostic procedures, whereas larger hospitals perform therapeutic procedures—with unsealed material and implants—and diagnostic procedures. Because of the small sample size in this study, we cannot extrapolate the results to all facilities in the country, but the list of surveyed facilities is sufficiently large and diverse to represent a range of practices in a variety of clinical settings.

The interview protocol included questions on respondent position/title and years of experience. Many respondents had a decade or more of experience, although some joined their facilities recently (Fig. 1). The sample included 11 RSOs, 9 authorized users (physicians), 12 physicists, 43 nuclear medicine technologists, and 14 managerial staff (e.g., diagnostic imaging manager, team leader, or chief operating officer). Inspectors asked respondents to indicate in which of the 3 steps of radiopharmaceutical administration they were involved. Did they (1) inform patients that they would receive radioactive material; (2) make patient-release decisions based on radiological criteria; or (3) communicate risk and safety information to patients? The majority of respondents (84%) participated in at least 2 of these activities. Many (41%) participated in all 3 steps of patient care. In sum, these data suggest that within their facilities, respondents in our sample were familiar with patient release procedures.

We examined whether health care professionals in the surveyed facilities were familiar with the December 9, 2003, NRC Information Notice (*13*). Of the 78 respondents, 66 (85%) said that they were familiar with the notice and 12 respondents (15%) said that they were not. Of the 12 respondents unfamiliar with the notice, 4 began their careers after the notice was issued in 2003, but 8 had many years of professional experience. We found that 11 of these 12 respondents were based in outpatient facilities and that 10 of the 12 were in facilities that offered only diagnostic procedures. We cannot be definitive as to why personnel in outpatient facilities tend to be less familiar with the 2003 NRC Information Notice. It is possible that because many outpatient facilities offer only diagnostic procedures that involve lower amounts of byproduct material, the notice was not considered to be applicable to their activities. In fact, the Information Notice explicitly referred to an incident involving ^{131}I, an isotope not often used for diagnostic procedures. This may also explain why diagnostic patients were found to be less likely than therapy patients to be informed that they might activate radiation detection equipment in public places (Fig. 2).

The interview protocol included a series of questions to ascertain what documentation (if any) facilities provided for their patients to present to security personnel and how security personnel might verify such information. Of 66 facilities, 43 (65%) provided some form of documentation to patients and 21 (32%) were prepared to provide it on request. Two respondents reported that their facilities could not provide such documentation, even on request (1 of these facilities offers cardiac stress tests and another

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TABLE 1
Characteristics of Surveyed Facilities

Facility number	State	Number of beds	Number of procedures performed annually		
			Diagnostic	Therapeutic	Brachytherapy
1	CT	0	1,500	0	0
2	ID	0	800	8	0
3	IN	0	750	0	0
4	IN	0	1,500	0	0
5	IN	0	1,000	15	0
6	KY	0	1,200	0	0
7	MI	0	1,800	0	0
8	MI	0	0	0	50
9	MI	0	2,500	0	0
10	NJ	0	500	0	0
11	NJ	0	4,000	0	0
12	NJ	0	1,250	0	0
13	NJ	0	1,200	0	0
14	NJ	0	750	0	0
15	NJ	0	1,000	0	0
16	NJ	0	2,400	0	0
17	NJ	0	1,000	0	0
18	NJ	0	1,000	21	0
19	OH	0	600	0	0
20	PA	0	4,400	1000	0
21	PA	0	500	0	0
22	PA	0	4,000	0	0
23	PA	0	7,200	0	0
24	PA	0	300	0	0
25	VA	0	750	0	0
26	VA	0	1,500	0	0
27	PA	64	2,700	0	0
28	PA	70	600	0	0
29	PA	74	4,200	3	0
30	PA	90	600	0	0
31	PA	99	1,500	0	0
32	IN	140	10,500	15	0
33	PA	150	3,600	0	0
34	MI	153	5,000	0	3
35	IL	200	7,000	14	0
36	PA	200	1,500	20	0
37	NJ	204	4,200	60	12
38	PA	214	6,000	0	50
39	PA	239	10,900	63	0
40	NJ	240	1,700	9	0
41	IN	250	2,100	15	0
42	MT	250	4,000	47	13
43	MT	250	2,000	29	29
44	PA	250	3,100	10	0
45	MI	263	5,800	0	0
46	IN	275	2,600	45	0
47	WV	277	4,900	45	0
48	IN	280	2,500	41	0
49	PA	285	3,500	11	0
50	NJ	300	4,700	0	0
51	IN	330	3,700	78	0
52	MI	376	11,200	67	80
53	IN	400	6,500	10	30
54	MI	400	7,700	30	6
55	PA	410	8,000	61	20
56	NJ	520	5,000	75	17
57	NJ	550	10,000	133	17
58	NJ	619	6,400	30	30
59	MI	632	10,600	106	0
60	PA	650	7,300	281	60
61	VA	760	6,400	138	40
62	VA	800	21,400	165	17
63	MI	865	17,500	226	15
64	MI	1315	63,700	442	14
65	MI	1700	20,000	205	0
66	IN	Unknown	0	10	70

brachytherapy). The reason for this inability to provide documentation was not further explored by the inspectors. One of these 2 respondents was unfamiliar with the 2003 NRC Information Notice.

We analyzed examples of documentation that 35 facilities provided to the inspectors. Most of these items (74%) were letters or cards on facility stationery specifying the procedure, the amount, and the type of compound administered, as well as its half-life (or card expiration date). The documents also included a telephone number. Figure 3 is among the best examples of such documentation. A few inspectors were given handwritten notes on prescription pads or even on blank pieces of paper, presumably generated during the interview. We doubt that such notes are routinely provided to patients and, more important, that law enforcement personnel would consider such notes to be legitimate. In its notice, the NRC recommended that documentation for security personnel include a statement that "radiation received by the patient presents no danger to the public and is allowed by the NRC medical use regulations." Of the 35 documents we reviewed, 12 included an assertion of this type, in some cases a verbatim quote from the notice. We observed that in a few instances the documentation contained text that someone without technical training might not readily understand. For example, 1 document stated that "this isotope gives off very low-energy X-rays (about 12 kV), most of which are absorbed by his [patient's] body tissue."

Respondents indicated that telephone numbers provided on letters/cards directed the caller to the facility contact, typically a technologist, RSO, or physician, with access to the patient's electronic medical records. According to 58 respondents (79%), their facilities' contacts were available at all times; 2 of these respondents, however, noted that the contact was available "with difficulty." Of those respondents who said that the contact was not available at all times, 2 were based in clinics and 7 in hospitals.

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TABLE 2
Procedures Offered by Surveyed Facilities

Type of procedure*	Annual average for all facilities offering the procedure	Percent as outpatient
Cardiac stress test	2,192	81%
PET scan	1,847	82%
Bone scan	1,187	81%
Hepatobiliary scan	451	68%
Thyroid uptake	410	95%
Multiple gated acquisition	357	90%
Lung scan	335	57%
Whole body scan	109	100%
^{131}I, hyperthyroid	98	95%
Renal scan	93	91%
^{131}I, unspecified	49	99%
^{131}I, thyroid ablation	46	88%
^{131}I-Bexxar	40	100%
Lung implant	33	24%
^{125}I prostate implant	19	100%
^{137}Cs gynecologic implant	15	0

*The table does not include rare procedures with estimated annual number <15.

It should be noted that persons engaged in unlawful conduct could potentially falsify patient documents or even set up false telephone confirmation procedures. Thus, law enforcement officers should have the necessary training and equipment to identify radionuclides used in routine medical applications. Moreover, because disclosure of patient information could violate the provisions of the Health Insurance Portability and Accountability Act, facilities might refuse to share information about a patient when contacted by law enforcement. This could be addressed if, at the same time information cards are provided to patients, facilities obtain patient consent to release relevant information to law enforcement personnel.

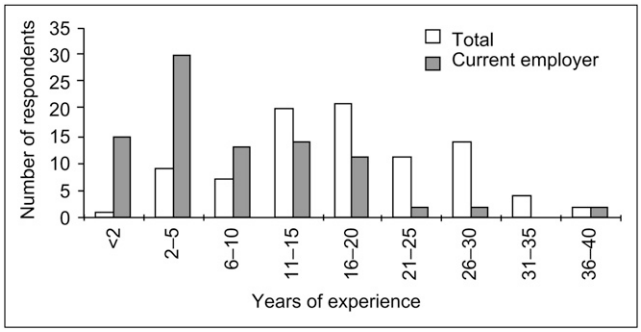


FIGURE 1. Respondents were asked the total number of years of professional experience and the number of years in the surveyed facility.

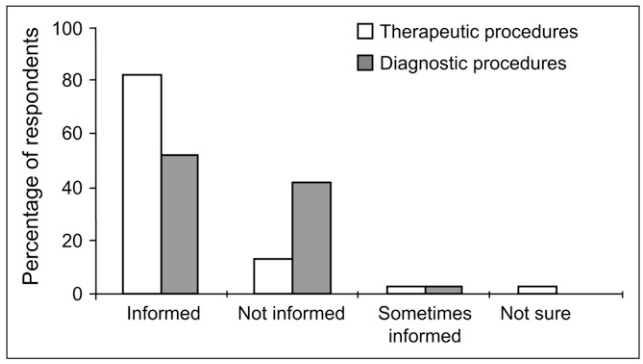
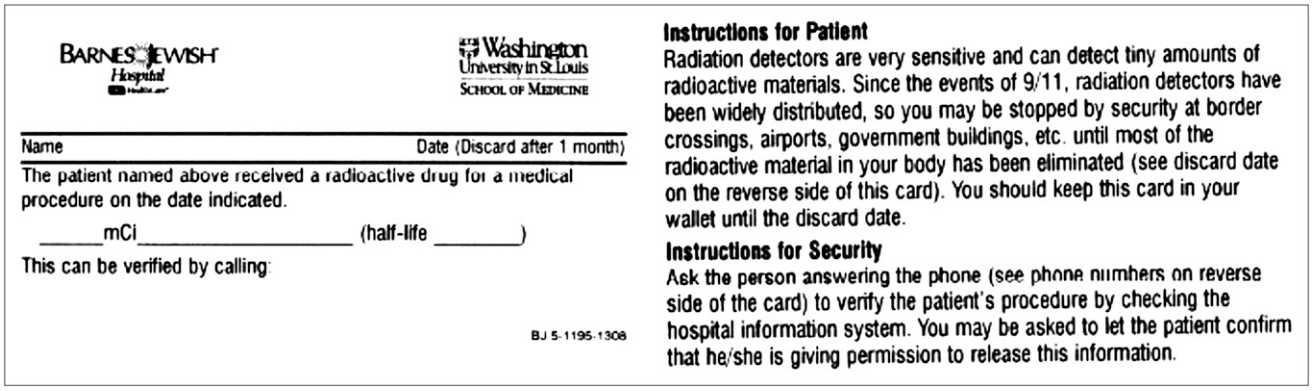


FIGURE 2. Responses of participants who were asked whether patients were informed that their treatments might subsequently activate radiation alarms.

Inspectors asked respondents to recall whether security personnel have ever contacted their facilities about patients triggering alarms. Of 78 respondents, 12 (15%) recalled queries from law enforcement personnel at some point in the past (we had no opportunity to obtain more exact dates for these events). Some respondents briefly described the circumstances, which included patients activating radiation alarms at the U.S.–Canadian border, nuclear power plants, a landfill, and an unspecified location. We do not know how many of these patients carried explanatory documentation with them. We did find, however, that at the time of our survey, 3 of the 12 facilities that had received queries from security personnel about such incidents still did not provide documentation for patients.

Many health care providers may believe that activation of alarms by patients is not a cause for significant concern and are unaware that security detectors are sensitive to low levels of radiation emitted by patients. Indeed, of 27 respondents who work at facilities that do not provide documentation to patients, 18 (67%) considered existing procedures to be adequate. On the other hand, 4 respondents at facilities that do provide such documentation told inspectors that the procedures could be improved through better access to patient information during off hours and by offering documentation to all patients indiscriminately (rather than on request to individuals who are planning to travel). One respondent noted that this issue should be "discussed at the regulatory level," and another said that the government should install better equipment to identify isotopes and "not harass patients."

Section 35.75 in 10 *Code of Federal Regulations* Part 35, "Unsealed Byproduct Material or Implants Containing Byproduct Material," stipulates that patients can be released if the total effective dose equivalent (TEDE) to any other individual from exposure to the released patient is not likely to exceed 5 mSv (*11*). If TEDE to any other individual is likely to exceed 1 mSv, the facility is required to provide released patients (or their parents or guardians) with "instructions, including written instructions, on actions recommended to maintain doses to other individuals as low


BARNES-JEWISH Hospital

Washington University in St. Louis SCHOOL OF MEDICINE

Name Date (Discard after 1 month)

The patient named above received a radioactive drug for a medical procedure on the date indicated.

_____mCi_____ (half-life _____)

This can be verified by calling:

BJ 5-1195-1308

Instructions for Patient

Radiation detectors are very sensitive and can detect tiny amounts of radioactive materials. Since the events of 9/11, radiation detectors have been widely distributed, so you may be stopped by security at border crossings, airports, government buildings, etc. until most of the radioactive material in your body has been eliminated (see discard date on the reverse side of this card). You should keep this card in your wallet until the discard date.

Instructions for Security

Ask the person answering the phone (see phone numbers on reverse side of the card) to verify the patient's procedure by checking the hospital information system. You may be asked to let the patient confirm that he/she is giving permission to release this information.

FIGURE 3. Front /back panels of sample card provided to patients by Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, MO. Courtesy of Henry Royal, MD; used with permission; phone numbers deleted by authors.

as reasonably achievable." Another stipulation includes instructions to be given to breastfeeding women, if necessary. To ascertain how the surveyed facilities implement these guidelines, inspectors posed a series of questions related to patient education at the time of release. We found that all but 5 facilities provided some instructions to patients when TEDE to other individuals was likely to exceed 1 mSv. In fact, 74% of facilities exceeded the regulatory requirement by offering verbal or written instructions (or both) to patients when TEDE to other individuals was likely to be even *less* than 1 mSv. Special instructions were offered to nursing mothers (100% of respondents) and to persons who care for young children (59%). For a patient in the custody of a caregiver (e.g., at a nursing home), information was communicated to the caregiver (76%). Such instructions were usually (63%) given before the procedure was administered.

We examined all written safety materials the surveyed facilities shared with inspectors. The content of safety instructions for ^{131}I treatments and for brachytherapy matched closely the NRC recommendations (*12*). Several facilities used the SNM informational pamphlet for iodine treatment (*15*). A few facilities that administer a variety of procedures provided us with separate instructions for each radiopharmaceutical, or, depending on the dose administered, with other separate instructions. Material for diagnostic procedures included commercial brochures for stress tests. These brochures typically contain preparation instructions, a description of the test, and risk factors for heart disease. While examining these materials, we noticed that they did not always explicitly state that the compound injected during a stress test is radioactive, referring, for example, to "a drug called thallium." In at least 1 facility, the respondent appeared reluctant to talk to patients about radiation, ostensibly to avoid "unduly alarming" them.

Patient Concerns

Inspectors asked respondents how often, in their experience, patients express concerns or request additional information about treatment involving radioactive materials. Although the most frequent response (39 facilities) was that 10%–30% of patients ask such questions, responses varied widely (Fig. 4). In 8 facilities, respondents reported that patients never ask questions or have concerns, and in 4 facilities respondents estimated that between 70% and 80% of patients ask questions and have concerns. Although we examined these outlier facilities more closely, we were unable to identify any elements of patient communication or characteristics of respondents and facilities that could account for such large differences. In the absence of any obvious explanation, we are inclined to attribute the likelihood of patients asking questions to the personality and communication style of the health care professionals with whom they interact (*16–17*); that is, patients will probably ask more questions of health care professionals who appear approachable than of those who appear impatient or brusque.

Respondents were also asked whether patients express any concerns about their ability to comply with instructions given upon release. Most respondents said patients rarely, if at all, express such concerns. When they do, the most common concern is whether they need to minimize time with children and pregnant women or whether to maintain separate sleeping arrangements in the home. Only in a single instance was minimizing time in public mentioned as a compliance criterion that patients found difficult to meet. This does not necessarily mean that patients comply

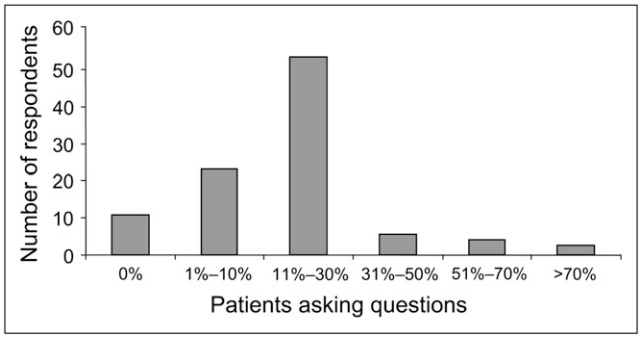


FIGURE 4. Respondents were asked to estimate what percentage of their patients express concerns related to radiation or radioactivity or request additional information.

with instructions to minimize time in public; instead, it indicates that this particular safety requirement is of limited concern to them.

Training in Patient Communication

Respondents were asked whether they had received any training in patient education or patient counseling and, if they had not, whether they would consider such training beneficial. We found that slightly more than half of the respondents had no such training. Among those without training, the majority (67%) indicated that it would be beneficial (Fig. 5A). However, a sizable fraction of respondents (28%) who had no training in patient communication saw no need for such education (Fig. 5B). We could not explore the reasons for this viewpoint. Of respondents who said they had such training, about half received it on the job, during residency, from hospital in-services, or from a colleague (RSO or physician). Others took a class or attended a conference at which such training was offered (an SNM conference in 1 case). We did not have an opportunity to explore further the nature and scope of the training. We found that in 51% of surveyed facilities, patient communication procedures had not changed in the past 5 years, despite the 2003 NRC Information Notice. Of 20 respondents who indicated that some revisions had taken place, 8 said explicitly that the change involved providing more information to travelers. The remainder did not elaborate on the nature of the revisions. Thus, in 20 cases at most, procedural changes included warning patients about the possibility of activating radiation alarms, and these changes were likely the result of the 2003 NRC Information Notice.

In concluding the interview, respondents were asked whether, in their view, it was possible for a patient to leave the facility without the knowledge that their treatments had caused them to emit detectable levels of radiation. The answer varied for therapy and diagnostic patients. None of the 19 respondents who answered this question for therapy patients believed that this could happen with their patients (Fig. 6). By contrast, 11 of 54 respondents (20%) said that a diagnostic patient could leave the facility without the knowledge that he or she emits detectable levels of radiation (Fig. 6). When asked to elaborate on how this might happen, respondents tended to fault the patient: "the patient may not completely understand," "not all patients have the same level of knowledge and not all retain the information," "patient failed to understand instructions," etc. In only 3 cases were respondents prepared to suggest that their facilities might not be providing adequate information: "issue of detectable levels is only reviewed with ^{201}Tl patients," "[we] do not warn patients that they may activate detectors," and "in-depth details are not given to diagnostic patients." Most striking, of the 11 respondents who believed that a patient could leave the facility without understanding that they emit radiation, all but 2 found the existing procedures of patient education adequate. This reluctance on the part of respondents to describe procedures as less than adequate may be related to the fact that NRC inspectors conducted the interviews.

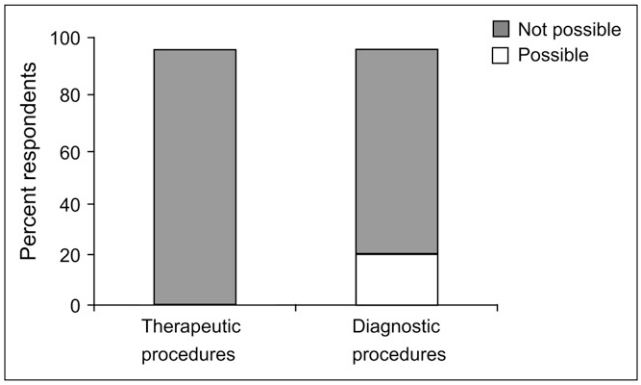


FIGURE 6. Respondents were asked whether it was possible for patients to leave their facilities without knowing that their treatments caused them to emit detectable levels of radiation.

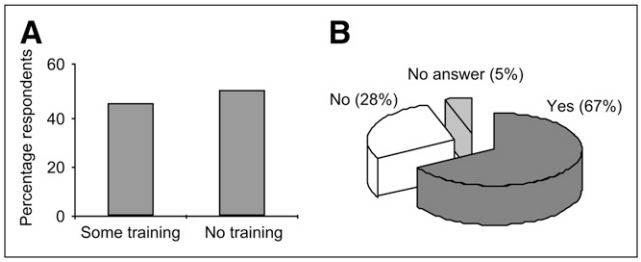


FIGURE 5. (A) Percentages of respondents with and without training in patient education/counseling. (B) Responses from those without training in patient education/communication on whether they would find such training useful.

Conclusion

Our results suggest that many facilities provide patients with adequate safety documentation, educational materials, and verifiable letters or cards for presentation to law enforcement personnel. Nevertheless, in many facilities the educational emphasis appears to be on patients receiving therapeutic treatments. We found that health care professionals in outpatient facilities and at facilities that offer only diagnostic procedures are less likely to be familiar with the 2003 NRC Information Notice. Consistent with this observation, health care providers are less likely to inform patients undergoing diagnostic procedures about the possibility that, for a period of time after their procedure, they may trigger radiation alarms. Thus, facilities that offer only diagnostic radiopharmaceutical procedures could benefit from an outreach program reiterating the information contained in the 2003 Information Notice. This outreach program should emphasize that recommendations contained in the notice apply to *all* released patients with detectable levels of radiation, including patients undergoing diagnostic procedures such as myocardial perfusion imaging or stress tests. Raising awareness in these patients that they emit detectable levels of radiation for a specified time after their procedure may not only prevent lengthy delays and

unpleasant interactions for patients who may trigger radiation alarms, it will have an added benefit. Informed and aware patients will tend to keep radiation doses to others ALARA, which is particularly important for patients living with or caring for small children.

We observed that the quality and utility of the documents provided to patients varied among the facilities. Some were written in excessively technical language, and some appeared unprofessional or lacked key information. Thus, some standardization of basic instructions and documentation given to all released patients would be helpful. Communicating information with patients—especially on a subject like radiation—requires skill and patience. We found that many health care professionals who administer radiopharmaceuticals to patients or who communicate with those patients about the radiation safety aspects of their procedures have had no formal or systematic training in this area. Many respondents reported that such training would be beneficial to their work. We believe that training in effective communication for health care providers at nuclear medicine facilities will enhance patient awareness and satisfaction. An added benefit might surface in the event of a radiation emergency. Even those large numbers of individuals who receive little or no exposure to radiation are likely to need information or counseling. At such a time, a cadre of nuclear medicine or radiation safety professionals who are trained in communication with members of the public would be a valuable community resource.

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Luba Katz, PhD
Abt Associates, Inc.
Cambridge, MA

Armin Ansari, PhD, CHP
Radiation Studies Branch
Centers for Disease Control and Prevention
Atlanta, GA