

Gallagher, Carol

From: Peter Crane <kinderhook46@yahoo.com>
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To: Gallagher, Carol
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Comments of Peter Crane, NRC Counsel for Special Projects (ret.)

After reviewing the archived videorecording of the meeting held on January 31, 2016, it is a pleasure to be able to commend the NRC for a job extremely well done. Credit goes both to the Commissioners whose 2014 Staff Requirements Memorandum started the ball rolling and to the NRC staff members, notably Dr. Donna-Beth Howe, for implementing their directives so thoughtfully and conscientiously.

High praise is also in order for the participants, in person and by telephone, including Dr. Munir Ghesani of the Society for Nuclear Medicine and Molecular Imaging (SNMMI), Gary Bloom of the Thyroid Cancer Survivors' Association (ThyCa); and Tim Lau, a ThyCa facilitator in Wisconsin. Gary and Tim are stalwarts of old, who can be counted on to play a positive role on these subjects, but it is an unexpected pleasure to be able to mention a representative of the SNMMI in the same breath. Dr. Ghesani's open-mindedness, receptivity to what he was hearing, concern for the real-world problems faced by patients, and interest in working collaboratively with patient groups and the NRC mark a new day. Let us hope that this is the start of an era of fruitful cooperation between physicians' groups, the NRC, and patients, based on a shared interest in doing what is right and responsible for everyone affected.

I. Comments on January 21, 2016 meeting.

I would like first to offer comments on what was said in the course of the meeting.

1. Early on, at about 2 hours 13 minutes into the session, a caller brought up the problem of persons with a dangerous occupation – in this case, an arborist who cut himself with a chain saw, severing an artery, on the day after treatment. The commenter, a medical professional, was thinking of the radiological safety aspects, but the perhaps even more important point is the diminished mental and physical capacity of those who have been prepared for treatment by being taken off their medications. This is the unusual case where impairment comes not from taking drugs but from NOT taking them. The patient made hypothyroid in preparation for scanning and treatment has slowed reflexes, making it dangerous to drive, use power tools, etc. Tim Lau once described at a ThyCa conference how, driving while hypothyroid, he failed to brake his truck in time and hit the vehicle ahead.

2. At about 2 hours 15 minutes, a caller named Zubir Ouhib made several excellent suggestions

about guidance:

to separate the guidance into three phases – namely before treatment, during treatment, and after treatment (this is consistent with Dr. Howe’s suggestion);

to keep it simple;

to offer patients a video that they can go back and refer to; and

to ensure that the same guidance is read and viewed by authorized users, nurses, and patients, so that everyone is on the same page.

I would add to this that we need guidance that is available

in the patients’ own languages. “Google Translate” is just one of a number of websites that provide instantaneous translations at no cost. There is every reason for professionals to use it to inform prospective patients whose English is non-existent or poor. Just as a trial, I wrote a sample sentence (“We need to have the capability of providing patients of all nations and all educational levels with information that is readily understandable to them and their loved

ones.") and within
five minutes had
produced translations
of it in four
languages:

Tenemos que tener la capacidad de proporcionar a los pacientes de todas las naciones y todos los niveles educativos con información que es fácilmente comprensible para ellos y sus seres queridos. (Spanish)

Nous devons avoir la capacité de fournir aux patients de toutes les nations et tous les niveaux d'enseignement de l'information qui est facilement compréhensible pour eux et leurs proches. (French)

Tunahitaji kuwa na uwezo wa kutoa wagonjwa wa mataifa yote na ngazi zote za elimu na taarifa kwamba ni urahisi kueleweka kwao na wapendwa wao.
(Swahili)

Peb yuav tsum muaj tus muaj peev xwm ntawm muab cov neeg mob ntawm tag nrho cov haiv neeg thiab tag nrho cov kev kawm them nrog cov ntaub ntawv uas yog npaj meej to taub mus rau lawv thiab lawv hlub. (Hmong)

To be sure, many printers will not support some foreign fonts – Hindi, for example – but it is possible to pull up a Hindi, Mandarin, Russian, etc. text on the computer screen and let the patient read it there.

3. It may have come as a surprise to some participants in the NRC meeting (though not to longtime patients) to hear the phoned-in comments of patients who although scheduled to receive radioactive iodine in coming days had so far been given no guidance whatever by the treating institutions. For example, the patient who called at around 4 hours and 32 minutes into the video was about to be dosed at the University of Cincinnati Medical Center. She has four children and three pets and would not be given guidance until the actual day of treatment.

This is deeply troubling from several standpoints. As a threshold matter, licensees are not supposed to release patients unless they have made a determination, based on an evaluation of

the patient's living situation, that the regulatory limit of 500 millirem to others will not be exceeded. Plainly, this institution is ignoring the need for a case-by-case analysis of the patient's home situation, evidently confident that the regulatory authorities in Ohio, an NRC Agreement State, do not enforce the rule.

How is someone in that patient's situation supposed to ensure that her children and pets remain safe? Waiting until the day of treatment to advise her about radiation safety makes a mockery of the licensee's obligations. Suppose that when she arrives for her dose, quite possibly hypothyroid and therefore with a diminished capacity to take in and act on what she hears, she is told that she should arrange to send her family away for a few days. Even if she can afford this, has someone to look after her children during that time, and is mentally clear enough to process this advice, all this takes preparation. In the real world, it isn't going to happen. This is not responsible public protection, it is merely the pretense of it. It reflects badly not only on the University of Cincinnati Medical Center and the Ohio Department of Health, but also on the NRC. Not only should it be riding herd on the Agreement States, making sure that they are giving more than lip service to the rules, it was also the NRC rule change of 1997 that opened the way to this sort of abuse. I suggest that the NRC should contact the state's Department of Health to make sure that it understands what is involved in living up to its obligations as an Agreement State.

4. Among the callers was Ralph Lieto, a health physicist with long experience in the field. He made the valid point that nuclear medicine departments often know very little about the precautions to be taken. He posed the question: what are the expectations FROM the patient? He suggested that if a patient goes to an institution and does not get proper information, he or she should look elsewhere. That is all very well if you already know the subject, but if you the patient have no prior involvement with radiation, you may have no reason to suspect that what you are being told is incorrect or inadequate. Often, patients only figure out that something is amiss when different medical professionals give them conflicting advice.

5. Tim Lau, at about 2 hours 19 minutes, made several important and highly valid points, including:

the problem of patient non-compliance, which happens all the time (he gave the example of the receptionist at his endocrinologist's office, eight months pregnant, who was approached and greeted cheerfully in a restaurant by a patient who had received a

therapy dose of I-131 the day before);
the fact that patients are being asked to understand complicated information; and
the fact that guidance on avoiding contamination is inadequate.

The last of these needs emphasis. The current NRC Patient Release Rule was premised on the comparative unimportance of contamination as a hazard – a serious mistake, which the NRC rectified only partially in its RIS of 2008 that cited ICRP 94 on the risks to children of contamination, and asked doctors to “consider” hospitalizing patients with small children at home. Perhaps because the release criteria are geared to external dose, from proximity, guidance on contamination has not received the weight it deserves.

6. Dr. Donna-Beth Howe made the point, at about 4 hours 42 minutes, that the institution also needs to prepare so that if the patient cannot be released, it is ready to cope with the situation. This is certainly what should happen, but realistically, if an institution has a blanket policy of releasing everyone, regardless of living situation, they will not have made those preparations. Moreover, if the I-131 is not being administered by a hospital, as is often the case, there is no place to put such a patient.

This points to a central problem, alluded to earlier. The Patient Release Rule envisioned a two-step analysis: first, can we release this patient, and only if the answer is yes, then what precautionary advice do we have to give to him or her. The “we whisk them all out the doors as fast as possible” approach, eloquently stated in 2007 by then ACMUI Chairman Leon Malmud, means that too many licensees skip the first step altogether and go directly to the second. The NRC has so far not done enough to make clear to licensees and to state regulators that there are two hoops, not one, to go through. What is needed is a clear statement from the NRC that says something like this: “If releasing the patient cannot be calculated to result in a maximum radiation dose to others that is below 500 millirems, the patient MUST be hospitalized for treatment. If the particular facility does not offer inpatient treatment, then transfer to a different institution is necessary. The fact that insurance companies may be unwilling to reimburse inpatient treatment does not relieve licensees of their obligation to comply with the regulations, or regulators of the obligation to enforce them.”

II. Relevant websites.

As far as guidance is concerned, I strongly believe that videos, pitched at a reasonably

elementary level, are the best way to get the message across. The British do this very well, as will be seen in the following sites:

<http://www.cancerresearchuk.org/about-cancer/type/thyroid-cancer/treatment/radiotherapy/radioactive-iodine-treatment-for-thyroid-cancer>

<http://www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/radiotherapy/internal/types/radioactive-iodine-therapy#safety>

<http://www.cancerresearchuk.org/about-cancer/type/thyroid-cancer/living/life-after-radioactive-iodine-treatment-for-thyroid-cancer>

[http://www.butterfly.org.uk/Downloads/Radioiodine%20\(I131\)%20Treatment%20\(2011\).pdf](http://www.butterfly.org.uk/Downloads/Radioiodine%20(I131)%20Treatment%20(2011).pdf)

https://www.stgeorges.nhs.uk/wp-content/uploads/2013/10/215_Radiology_Information+for+patients+receiving+radioiodine+treatment.pdf

<https://www.youtube.com/watch?v=Sp67MxN6lbU>

In addition, here is a YouTube video from a Filipino hospital. In the Philippines, incidentally, no one is released from the hospital with more than 15 millicuries of I-131 in his or her system, consistent with First World practice in Europe and Japan. Regrettably, the United States has sub-Third World regulations, thanks to the NRC's surrender to the nuclear medicine lobby in the 1990's, with the result that patients are released in this country with 200 millicuries and sometimes even 400 millicuries in their systems. While there may be scant hope that the United States will ever rise to Filipino standards – the clout of the insurance companies is too great – at least we can learn from that country's guidance. See:

https://www.youtube.com/watch?v=l6FIh69DqQ0&ebc=ANyPxKov1HHKgqfUqMr43yP6blqQgSTaPiUweeYu1rpX1FfrvUQXoUZZCb0Tj1rUahVyErQ0Ozp-xCRzFHCZq_YL4ALPQhl6Qg

The following Australian website is also a good model for presenting basic information in an understandable way:

http://www.insideradiology.com.au/pages/view.php?T_id=44#.VsZzJfkrLIU

A written website that is excellent is that of ThyCa, the Thyroid Cancer Survivors Association.

In addition, some years ago a Canadian website published first-rate draft guidelines, prepared by a team headed by a distinguished American thyroidologist, Dr. Carol Greenlee, of Grand Junction, Colorado. They focused, quite rightly, on safety. See:

http://www.thyroidcancercanada.org/userfiles/files/I-131_Patient_Release_ATA.pdf

But for reasons not immediately obvious, the final version, which appeared in the American Thyroid Association journal *Thyroid* in April 2011, was missing much of what made those guidelines valuable, and Dr. Greenlee had been moved from first on the list of authors to last; Dr. James Sisson was now the lead author. The final article, to put it bluntly, was a mess, replete with mistakes, and was followed two months later in the journal by an extensive list of errata, along with a note expressing appreciation to Dr. Avenel Joseph (of Congressman Markey's office) and me for having brought the errors to the publication's attention. Among other things, Dr. Sisson was unaware of the existence of 10 CFR 35.75. He was under the impression that patient release was governed by 10 CFR Part 20.

Dr. Richard Wendt and Ms. Anne Marie Fisher of M. D. Anderson, the celebrated cancer center in Texas, made a presentation several years ago that contains much valuable information.

Among other things, they make the point, too often neglected, that the default option is inpatient treatment. See: M.D. Anderson, Drs. Wendt and Fisher:

[FisherWendt_Fri_1400_ExhB_Presentation.pdf](#)

I have reviewed a number of websites dealing with patient release and have the following comments on them:

St. Joseph's Hospital, a Canadian website, provides good guidance for patients.

The American Thyroid Association website says nothing whatever about contamination, an inexplicable omission.

The American Association of Physicists in Medicine is generally good, though it says nothing about inhalation as a source of contamination.

The Mayo Clinic guidance is generally good, but when it says "do not hold children on your lap for long periods of time," what are patients to make of that? Does that mean someone just back from the hospital with 200 millicuries of I-131 in her system, much of it in her bladder, can safely hold an infant on her lap for 20 minutes, since that is not a long period of time? Guidance needs to be more explicit than that, and not make patients guess.

The Canadian Cancer Society website offers generally good guidance.

Sloan-Kettering (MSKCC) says that patients should stay in the hospital for two hours after dosing, and not take public transportation. This is very positive, a contrast with the “whisk them out the doors” approach of far too many institutions.

Georgia Regents Medical Center – good.

The Health Physics Society – seriously deficient. The HPS should not be publishing statements such as this: “The total radiation dose to anyone else, even with close, continuous contact, will not cause harmful effects. ... In the United States, patients are released from confinement without restriction on interacting with the public when it is determined that doses received by individuals are at a safe level. There are a number of assumptions about the patient's interactions with the public, but the belief is that the patient really does not present a significant radiation source. In your situation, the patient does not represent a significant risk to your patients or staff. Otherwise, the patient would not have been released from the other hospital.” Compare this to Dr. Malmud’s realistic comments in the October 2007 ACMUI meeting and it is apparent that the HPS is describing a fantasy world, and it should know this. See:

<http://hps.org/publicinformation/ate/faqs/nuclearmedicinetherapy.html>

University of Washington – good, says (appropriately), no breast-feeding after treatment.

Stony Brook University – generally good, though it says not to resume breast-feeding until the doctors approve, and it is hard to imagine that they would ever advise a recently treated patient that it was safe to go back to breast-feeding.

Virginia Mason Hospital, Seattle – makes a good point, which is to stop breast-feeding two weeks before treatment, to minimize radiation exposure to the breasts.

In addition, the guidance in NCRP 105, although not a website, gives valuable guidance to a hypothetical patient receiving 175 millicuries of I-131.

Conclusion

The Commission directive that led to this request for information was certainly well-intentioned, and the NRC staff has been conscientious in fulfilling it. Nevertheless, the more one learns about the present state of affairs, the more it becomes apparent that more fundamental reform is needed, of the sort that only a change in the rules can achieve. If licensees have been ignoring the regulatory requirements until now, as many of them plainly have, what reason is there to think that they will not also ignore the improvements that result

from this exercise? The issue at this point is not to assign blame for the present situation but rather to face up to the reality that the system is broken and needs not just improvement but an overhaul.

Respectfully submitted,

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