AAPM Responds to Follow-up Questions from Congress after Hearing on Radiation in Medicine

Table of Contents

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

March 15, 2010

Dr. Michael G. Herman
President
American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740

Dear Dr. Herman:

Thank you for appearing before the Subcommittee on Health on February 26, 2010, at the hearing entitled "Medical Radiation: An Overview of the Issues."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by March 31, 2010 to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Edward J. Markey

Last summer an article in the New York Times[1] detailed a series of major medical mistakes that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes. In one particular case, the doctor incorrectly implanted radioactive iodine seeds into the patient's health healthy bladder, instead of into the patient's prostate gland where it was intended to treat his prostate cancer. These incidents raised many questions about the adequacy of the Nuclear Regulatory Commission, which has jurisdiction over these types of medical errors, to oversee and investigate these sorts of procedures.

1. Do you think that if a physician accidently irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?

2. There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?

3. Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?

4. What kind of information about the circumstances of a medical error should be reported and collected?

5. Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?

Currently, reporting of medical errors or mis-administrations involving radiation-producing machines is regulated differently by individual States, with variability in both the reporting requirements and how a mis-administration or medical event is defined.

6. How should medical error and mis-administrations be defined?

7. Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

[1] See http://www.nytimes.com/2009/06/21/health/21radiation.html?_r=2

8. Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (ie. for both machine-based and non-machine-based radiation)?

In 1997, NRC changed its regulations (10 CFR 35.75) to allow the immediate release of most cancer patients being treated with medical radioisotopes. In some cases this allows patients who could be emitting unsafe levels of radiation to be released, potentially harming people who might come into contact with them. According to a letter sent from the Nuclear Regulatory Commission to Congressman Edward Markey, it changed these rules because it assumed that the treating physician would be able to perform an individualized analysis of a patient's living situation to ensure that they would not pose harm to their family or the public.

9. Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

10. In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
Fax (301) 209-0862
http://www.aapm.org

Office of the President
Michael G. Herman, PhD
Professor and Chair, Medical Physics
Department of Radiation Oncology
Mayo Clinic
200 First St SW
Rochester , MN 55905
Phone: 507-284-7763 Fax: 507-284-0079
E-mail: herman.michael@mayo.edu

March 31, 2010

Rep. Edward Markey
House of Representatives
c/o Earley Green, Chief Clerk
2108 Rayburn House Office Building
Washington, DC 20515

Re: March 15, 2010 Letter from Chairman Waxman – "Medical Radiation – An Overview of the Issues"

Dear Representative Markey:

On behalf of the American Association of Physicists in Medicine (AAPM) attached are our responses to your follow-up questions from the Subcommittee on Health's February 26th hearing titled "Medication Radiation: an Overview of the Issues." AAPM represents more than 7,000 medical physicists and is committed to ensuring that all patients receive safe, high quality medical care.

If you have additional questions or require further information, please contact Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at lynne@aapm.org or 301-209-3364 or me.

Sincerely,

Michael G. Herman, Ph.D., FAAPM, FACMP

Cc: Committee on Energy and Commerce

1 Attachment

The American Association of Physicists in Medicine's Response to Questions from the Honorable Edward J. Markey (Text in italics quoted from Rep. Markey's letter)

Last summer an article in the New York Times1 detailed a series of major medical mistakes that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes. In one particular case, the doctor incorrectly implanted radioactive iodine seeds into the patient's health healthy bladder, instead of into the patient's prostate gland where it was intended to treat his prostate cancer. These incidents raised many questions about the adequacy of the Nuclear Regulatory Commission, which has jurisdiction over these types of medical errors, to oversee and investigate these sorts of procedures.

1. ***Do you think that if a physician accidently irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?***

   Yes. It is the responsibility of the physician to inform the patient, the hospital authority and the regulatory agency.

2. ***There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?***

   Yes. If the wrong part of the body is irradiated, the rules for how the error is recorded and reported should be uniform despite the source of radiation. From the impact of the radiation exposure, the risks and effects are the same for a similar dose of radiation, no matter what the source of the radiation was.

3. ***Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?***

   Yes, data on medical errors is essential to conduct a trend analysis, make assessments, inform the community, and make improvements. We agree that there should be a centralized data repository of medical errors. Exactly how this is achieved should be discussed further. An independent source for the data collection such as the Conference

of Radiation Control Program Directors (CRCPD), that represents all state regulators could provide such a solution. A partnership between agencies, the medical community and organizations such as CRCPD could also effectively cooperate to develop this repository. The important requirements are that the system allows all of us to learn from actual and potential adverse events in the medical use of radiation by:

- allowing central reporting by medical staff (including radiation therapy physicians, medical physicists, radiation therapists, dosimetrists, others), manufacturers and others in a complete and consistent manner,
- providing search capability to identify patterns, risks and corrective actions and to inform the community, and
- require a partnership between all involved (federal and state government, manufacturers, users, patient advocates).

The national system must be set up in such a way as to be independent of any reporting entity to prevent bias in the data reported. The database should be established such that no patient identification is included in the reports submitted to the reporting entity. The AAPM has been in conversation with FDA to organize a national roundtable for exactly this discussion.

4. ***What kind of information about the circumstances of a medical error should be reported and collected?***

The essential components of any database should include description of the event, the specific equipment, protocol, and procedure type, all in a HIPAA compliant manner. This is similar to the essential components required in the Nuclear Regulatory Commission's Nuclear Materials Event Database (NMED). The reporter should also include at least a preliminary analysis of the root causes of the event. Provisions should be made for anonymous reporting of events, which has been demonstrated to increase the frequency of reports.

5. ***Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?***

Yes, except in rare cases where notification would cause more patient harm than help. Patients should be notified and the rules should be uniform across all states.

6. ***How should medical error and mis-administrations be defined?***

AAPM believes that the definition of medical error should be uniform across radiation treatments. We also believe that the stakeholder community should have an opportunity to work with the regulatory authorities to establish the definition of a medical event that would be uniformly applied. It is possible that the definition of medical error may be

procedure specific, but should remain consistent across the country. There are various models (NRC, some states, FDA– and internationally IAEA) that exist, are different, but could serve as a beginning for developing a uniform system. Such definitions should be expanded to include events that do not cause harm to the patient, but have the potential to do so.

7. ***Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?***

   Yes, and this should follow our answers to items 3, 4, 5 and 6 above. There are several states (e.g., PA, NY, FL) that currently have definitions and mandatory reporting systems in place, but many that do not. A central and national system as described above should include these events.

8. ***Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (i.e., for both machine-based and non-machine-based radiation)?***

   Yes. The impact of the radiation exposure, the risks and effects are the same for a similar dose, no matter what the source of the radiation was – whether radioactive materials or resulting from the operation of radiation-producing equipment.

   In 1997, NRC changed its regulations (10 CFR 35.75) to allow the immediate release of most cancer patients being treated with medical radioisotopes. In some cases this allows patients who could be emitting unsafe levels of radiation to be released, potentially harming people who might come into contact with them. According to a letter sent from the Nuclear Regulatory Commission to Congressman Edward Markey, it changed these rules because it assumed that the treating physician would be able to perform an individualized analysis of a patient's living situation to ensure that they would not pose harm to their family or the public.

9. ***Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?***

   The current regulation does not mandate but allows patient release after a determination is made that the patient can comply with appropriate restrictions. It is the responsibility of the licensee to determine if a patient can be released in accordance with 10 CFR § 35.75. Licensees who are authorized to release patients containing more than 33 mCi of radioactive iodine-131 are required to perform an analysis of the potential radiation exposure to others to assure regulatory limits are not exceeded. NUREG-1556, Volume 9 Section 8.36, *Release of Patients or Human Research Subjects* specifies the guidelines

that must be followed by a licensee prior to releasing a patient in accordance with 10 CFR § 35.75.

The assumptions that the licensee is required to make are conservative. We believe that the existing regulation provides adequate protection of the public. There are patients who may not be candidates for release but that determination should continue to be based on an assessment by the authorized medical professionals involved, and not solely dictated by a simplistic regulation based on a defined quantity of administered radioactivity.

It is imperative, however, that the patient answers questions truthfully and follows the written instructions. Licensees should not be held accountable for patients who choose to ignore the instructions and directions given prior to their release. This is no different than a patient who disregards the instructions on a prescription drug label or over the counter drug.

AAPM discourages the release of patients to hotels following treatment with radioactive iodine-131. While the actual risk to hotel staff might be very small, the public perception of such activity is quite negative and the practice may not reflect an adequate safety culture."

10. In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

NUREG 1556, Volume 9, Appendix U: *Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials* lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR § 35.75. The activity at which patients could be released is calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides*.

Appendix U also discusses the instructions that must be given to the patient prior to the release. Many facilities require the patient to sign these instructions sheets acknowledging the conditions under which they are being released. As stated in response to Question 9 above, licensees should not be held accountable for patients that do not follow the instructions provided to them.

We note that the current dose limit of 5 mSv per treatment to others post-release of the patient assumes that they will be family members, caregivers or others with an interest in the patient, and who will have rare exposure in such situations. Hotel workers do not fall in this category and thus should be limited to 1 mSv per year. Such a prediction is generally beyond the ability of the licensee to make, thus the general process of release to a hotel should be prohibited.