Patients' Needs, Concerns, and Rights in Radiation Medicine

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October 27, 2008

Patient concerns

- Patients want the best possible medical care when faced with illness and disease
  - access to latest scientific advances
- Patients want protection from poor health care practices
- Patients want to understand their options for treatment; they want good information
- Patients want to be treated with dignity and respect
- Patients are concerned about long-term consequences of disease, including quality of life and financial impacts

Role of the Patients' Rights Advocate

- Provide technical advice that helps the NRC develop useful and practical medical regulations (not overly burdensome)
- Provide technical assistance in licensing, inspection, and enforcement cases, if needed
- Provide consulting services when requested
- Bring key issues to the attention of NRC staff for appropriate action
- Be cognizant of the impacts of NRC actions on patient access to health care, and represent the concerns of patients' rights stakeholders

Regulation and Patient Access to Best Health Care

Factors that may impact on patients' rights:

- Trade-offs between regulations that restrict or limit availability or patient access to new treatments
- Slow process for new drug or device regulatory approval
- Regulations that restrict hospitals' and physicians' ability to provide most effective treatments

- The history of the NRC Advisory Committee on the Medical Uses of Isotopes dates back to the Manhattan Project.
- The next few slides show the evolution of federal regulations concerning patients' rights in the context of radioisotope research and the practice of medicine

1946: Announcement of Radioisotopes Availability

- Memo: "Specific Proposals for the National Distribution of Radioisotopes Produced by the Manhattan Engineer District"
  (January 3, 1946 from the Radioisotope Committee of Clinton Laboratories, Oak Ridge, to Colonel S. L. Warren, Medical Director of the Manhattan Project)
- Journal article: "Availability of Radioactive Isotopes: Announcement from Headquarters, Manhattan Project, Washington, D.C."
  (published in *Science* 103:697-705, June 14, 1946)

Historical Context

- 1946: Manhattan Engineering District, Interim Advisory Committee on Isotope Distribution Policy
- Atomic Energy Act of 1946
- 1947: Atomic Energy Commission (AEC), Committee on Isotope Distribution Policy
  - Subcommittee on Allocation and Distribution
  - Subcommittee on Human Applications
- 1950: AEC Advisory Committee on Isotope Distribution

Historical Context (continued)

- 1953: Pres. Eisenhower's "Atoms for Peace" address to the United Nations
- Atomic Energy Act of 1954, with focus on nuclear power and peaceful applications
- Energy Reorganization Act of 1974: split the AEC into the U.S. Nuclear Regulatory Commission and the Energy Research and Development Administration
- Today: The NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides advice on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy

1946: Local Isotope Committees

- Two-tiered system: a) local review, and b) federal government oversight
- Experimental protocols reviewed at the local level before being approved by the federal authority to distribute radioisotopes
- Patient safety of "paramount importance"
- Risk-benefit analysis an integral component of policy on use of isotopes in humans
- *"It is not wise in any way to inhibit investigators with ideas--and yet the safety of the patient must come first."*

1949: Patient Informed Consent

1. Responsibility assumed by a special committee of at least three competent physicians belonging to the institution where the work is to be done
2. A subject must consent to the procedure
3. No reasonable likelihood of producing manifest injury by the radioisotope to be employed

(Paul Aebersold, Subcommittee on Human Applications, March 13, 1949)

1951: Federal Codification

- The first federal regulations on isotope use in human subjects were published in 10 CFR 30.50, 1951 supplement to the 1949 edition, and contained
  - administrative, facility, and personnel requirements for receiving and using radioisotopes
  - but did not include dose limits or patient-consent requirements

1956: AEC Guidelines for Use of Isotopes in Terminally Ill Patients

- Use of radioisotopes with half-lives greater than thirty days not permitted without prior animal studies to establish metabolic properties, unless patients have a short life expectancy
- Limited to patients suffering from diseased conditions and life expectancy of one year or less, with no reasonable probability of the radioactivity employed producing manifest injury

(U.S. Atomic Energy Commission, "The Medical Use of Radioisotopes: Recommendations and Requirements by the At Energy Commission," RC-12, February 1956, Isotopes Extensi

1956: Guidelines for Informed Consent

- Required for all use of radioisotopes in normal (healthy) subjects
- The amount of radioactive tracer must not exceed the "permissible body burden" (an ICRP-2 concept)
- Experiments shall not normally be conducted on infants or pregnant women
- Subjects limited to "volunteers to whom the intent of the study and the effects of radiation have been outlined"
- Required that both the purpose and effects of radiation be explained to the volunteer subjects

1956: Medical Isotope Committee

Three or more physicians plus a qualified radiation physicist

- Review and permit the use of radioisotopes within the institution from the standpoint of radiological health and safety
- Prescribe special conditions such as physical examinations, additional training, designation of limited area or location of use, disposal methods, etc.
- Review records and receive reports from its radiological safety officer
- Recommend remedial action when a person fails to observe safety recommendations and rules
- Maintain committee records

1965: AEC Guide for Medical Use of Radioisotopes

- Described the application process and specific policies for the "Non-Routine Medical Uses of Byproduct Material"
- Reiterated the exclusion of pregnant women
- Required that subject selection criteria be clearly delineated
- Required consent of human subjects or their representatives, except where this is not feasible or where consent is contrary to the best interests of the subjects

1960s: Emerging Role of the FDA

- The Food and Drug Administration developed a more active role in supervising the development of radiopharmaceuticals
- The oversight of radioisotopes research began to change
- The regulatory history of this shift in authority is complex

1997: Patients' Bill of Rights in Medicare and Medicaid

- Pres. Clinton created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and charged it with recommending such measures as may be necessary to promote and assure health care quality and value and protect consumers and workers in the health care system
- The President asked the Commission to develop a "Patients' Bill of Rights" in health care

Patients' Bill of Rights: Goals

- Strengthen consumer confidence that the health care system is fair and responsive to consumer needs
- Reaffirm the importance of a strong relationship between patients and their health care providers
- Reaffirm the critical role consumers play in safeguarding their own health

Federal Statement on Patients' Rights

1. **The Right to Information...** to receive accurate, easily understood information needed to make informed decisions about their health plans, facilities and professionals.
2. **The Right to Choose...** to a choice of health care providers; access to appropriate high-quality health care, including access for women to qualified obstetrician-gynecologists and giving patients with serious medical conditions and chronic illnesses access to specialists.
3. **Access to Emergency Services...** the right to emergency health services when needed.
4. **Being a Full Partner in Health Care Decisions...** the right to participate in all decisions related to their health care.

Patients' Rights (continued)

5. **Care Without Discrimination...** the right to considerate, respectful care, without discrimination based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.
6. **The Right to Privacy...** to communicate with health-care providers in confidence, with confidentiality of their individually-identifiable health care information protected.
7. **The Right to Speedy Complaint Resolution...** to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them.

Patients' Responsibilities

1. **Maintain Good Health.** In a health care system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

Health and Safety Code Section 1288.4; 42 CFR 482.13, *Medicare Conditions of Participation* (64 Fed. Reg. 36070-36089, July 2,1999)

Summary and Conclusions

- The patients' rights advocate is an integral part of this NRC Advisory Committee
- Concerns for protection of patients' rights are based on historical developments that parallel the evolutionary history of this Committee
- The most important elements of patient's rights are established in federal law