U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Patients' Rights Advocacy Perspectives

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Training and Experience (T&E)

- Ethical Tensions

  Patient safety ⟷ Unnecessary regulatory control

  Allow professional associations to determine T&E requirements for alternate pathways?

  Potential for financial conflict of interest, bias

Training and Experience (T&E)

Arguments for alternate pathway:

"Turf" issues are potentially driven by financial considerations

Possibility of unnecessarily limited patient access to treatment

Chilling Pharma interest in research and development of new drugs with limited and decreasing number of physicians to administer

Training and Experience (T&E)

Argument for status quo:

Safety, uniformity, comprehensiveness

To consider:

How well has alternate pathway worked for I-131? Are the release instruction issues related to a lack of awareness and respect for the potential dangers of radionuclide therapy?

Patient Release SECY Paper

"The data indicates the spread of contamination from the patient to other persons can be minimized by following instructions"

Patient Release SECY Paper

"…family members of patients receiving the highest activity I-131 administrations often received some of the lowest doses. This points to the importance of behavior patterns and following ALARA (as low as reasonably achievable) guidance and instructions provided by the licensee."

Patient Release SECY Paper

"For cancer patients…all [transportation] exposure scenarios indicate that transportation situations pose a radiation concern for members of the public."

"licensee's assessment of the patient's likely behavior after release."

Patient Release SECY Paper

"The decision to release the patient should be reviewed before starting treatment to determine the conditions under which the patient is expected to be released, and whether the living arrangements, modes of transportation, and staying at a hotel are such that releasing the patient is unlikely to result in doses above 5 mSv (500 mrem)."

Patient Release SECY Paper

"dominant factor in determining both internal and external doses to members of the public from exposure to a patient that has been administered I-131, is the behavior of the patient after release."

ACMUI Subcommittee Recommendations

"Written and oral instructions must be provided to the patient far enough in advance of treatment, without compromising patient care, to ensure that the patient has sufficient time to determine whether or not he/she can actually comply with the instructions and to make whatever arrangements may be necessary for compliance."

Financial Issues

- 1997 Patient Release rule created environment where health insurers can deny coverage for hospitalizations
- Difficult/impossible to get insurance coverage for hospitalization
- Patients or healthcare facilities on the hook for cost when patient requires hospital isolation

What's Needed

In addition to dose or activity limits that must be considered for patient release, clear and formal regulatory language for assessing behavioral or logistical parameters should be required to justify patient release, or to justify insurance covered hospitalization, in order keep radiation exposures to caregivers and the public ALARA.

Public Health

It has been argued that when to provide release instructions, when and how to assess the likelihood of patient adherence, and when to require hospitalization or delayed release is a "clinical" and "practice of medicine" issue."

It needs to be seen as a public health issue, and well within the purview of NRC regulation.

Safety Culture

Two paradigms

1. Identified/required regulatory reporting

2. De-identified/voluntary, self-reporting

Safety Culture

Identified/Regulatory required reporting fosters a culture of hiding errors and hinders proactive use of experiences for education and enhanced patient safety

De-Identified/voluntary reporting fosters a cooperative culture of shared information re near misses and events with the goal of increasing safety on a global scale

Safety Culture

ACMUI Subcommittee suggests limited trial of required but de-identified reporting to PSO in lieu of existing regulatory process.

Acronyms

- ACMUI: Advisory Committee on Medical Uses of Isotopes
- ALARA: as low as reasonably achievable
- I-131: iodine 131
- mSv: milliseivert
- mrem: millirem
- PSO: patient safety organization
- RAI: radioactive iodine
- SECY: Commission Paper
- T&E: training and experience