SNM
Advancing Molecular Imaging and Therapy

Medical Isotope Shortage, Patient Release & Occupational Exposure Criteria

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Society of Nuclear Medicine

SNM
Advancing Molecular Imaging and Therapy

SNM Overview

- Founded in 1954
- The largest international scientific organization dedicated to molecular imaging and therapy
- A multi-disciplinary organization
  - over 16,000 physicians, scientists, pharmacists, and technologists
  - industry and other partners interested in the diagnostic, therapeutic, and investigational uses of molecular imaging and therapy agents, instrumentation and techniques

SNM
Advancing Molecular Imaging and Therapy

Richard Wahl, MD, FACR

- Director of Nuclear Medicine/PET
  Vice-Chair of New Technology and Business Development
  Henry N Wagner, Jr Professor of Nuclear Medicine
  Professor of Radiology and Oncology
  Russell H Morgan Department of Radiology and Radiological Sciences
  John Hopkins University
- MD, Washington University, St Louis MO
  Board-Certified: Diagnostic Radiology and Nuclear Medicine
- Pioneered use of FDG-PET imaging in cancer and PET/CT fusion
- Inventor, 12 patents including 2 for FDA-approved radioimmunotherapy drugs for lymphoma.
- Over 320 journal articles, 30 book chapters, 4 books, Over 400 invited lectures

Medical Isotope Shortage

- With shortage of Tc99m patients had studies cancelled, lower quality studies substituted, some received higher (or lower) radiation dose study, clinical and economic implications.
  - Next shut down may be the last
  - No clear path towards domestic production for the 16 million Tc-99m clinical procedures in the US annually
- 2 non US reactors on which the US depends for the Mo-99 parent of Tc99m have recently re-started but are “ancient “by reactor standards.
- NRC should expedite applications for construction of Mo-99 production reactors.
- NRC should develop a plan for expediting such applications before applications are submitted.
- Infrastructure should be in place to implement the expedited review process.
- An urgent public heath issue at the national level.

Patient Release Criteria

- Current regulations: *Allow* patient release after determination that the patient can comply with safety instructions, restrictions etc given by medical professionals.
- Extensive peer-reviewed data show it quite straightforward to calculate and control the radiation risk to bystanders or that this risk is excessive.
- In addition to undermining public heath by basing release on activity rather than dose, the proposed rules drive up health care costs without any evidence-based rationale.
  - Some hospitals cannot accommodate radioactive patients so radioisotope therapy may be made unavailable or may be performed less effectively - as multiple low-activity administrations - simply to avoid hospitalization.
  - Patients without access to isotope therapy will need less effective, higher-risk treatments such as deforming surgery or potentially toxic drugs.
  - Hospitalizing otherwise healthy patients unnecessarily exposes them to hospital-based infections and risks including antibiotic-resistant bacteria.
  - Data, including from EANM 2010, show exposure to public as well as to caregivers from patients is already LOW.

Radiation Worker Exposure

- Current guidelines: *Allow* radiation workers in medicine to safely and cost-effectively deliver valuable and medically essential procedures to patients with cancer, thyroid disease, heart disease etc
- ALARA for occupational workers universally applied
- Exposure is sometimes unavoidably greater with very ill patients whose procedures take longer than expected
- Reducing occupational exposure potentially jeopardizes care to patients
- Proposed reduction of 50 mSv/year to 20 mSv/year is not based on firm scientific evidence (ie no *demonstrated* excess cancer risk at 50 mSv/year)
- Every effort should be made to minimize radiation worker exposure, and current regulations accomplish this and appropriately balance patient benefit and provider safety as well as cost
- Recommendation: Keep current safe exposure limit of 50 mSv/year

Summary:

- Reliable domestic supply of Tc-99m is essential for 16 million patient studies/year in the US. NRC requested to provide prompt yet safe facilitation of new facility licensure.
- Patients must have access to radiopharmaceutical therapies. Current guidelines for patient release are safe and allow the treatments to be given throughout the US. NRC should keep current guidelines for release.
- Radiation exposure of radiation workers is essential for health care delivery. NRC should keep current safe exposure limit of 50 mSv/year.

For further information

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