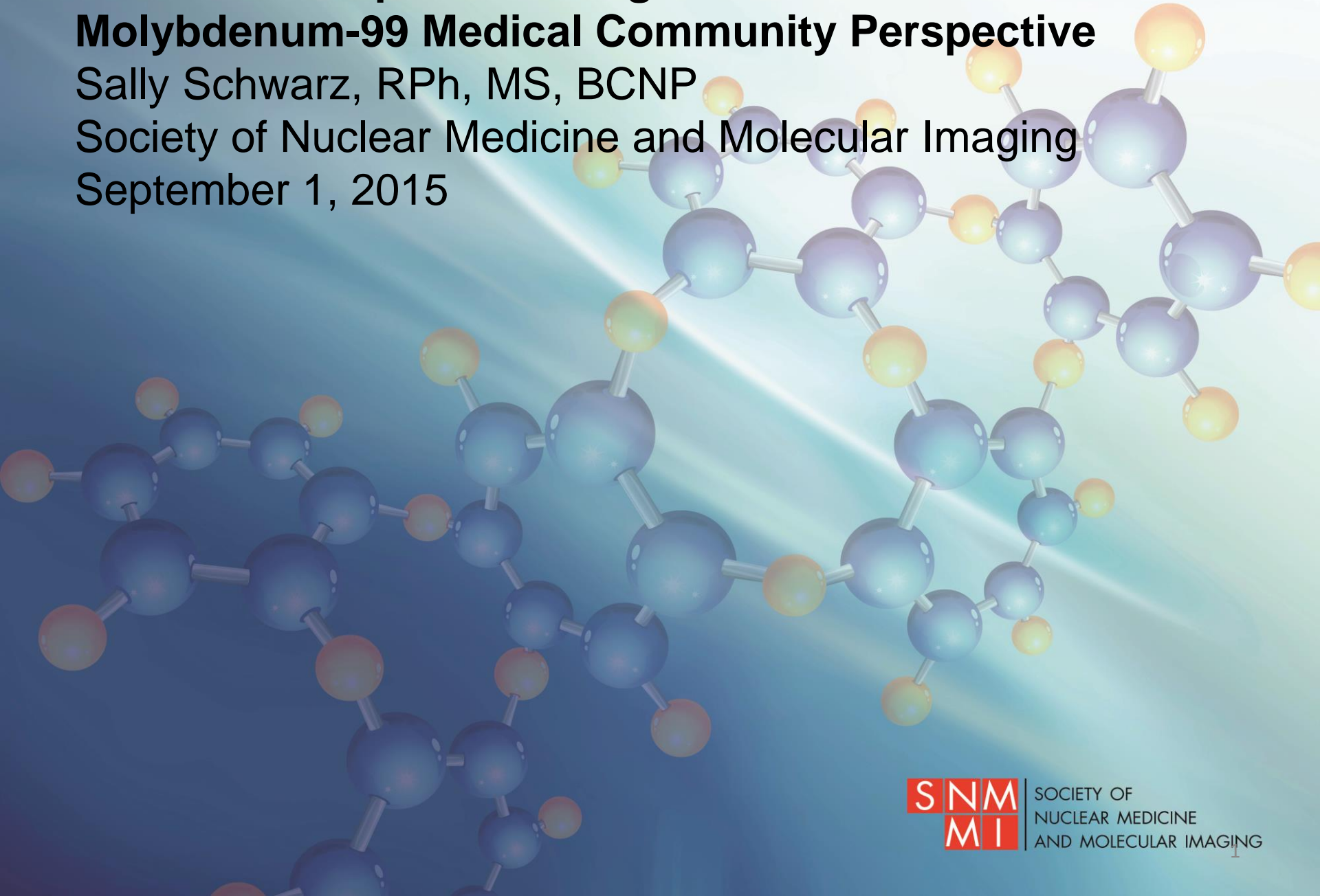


2015 Mo-99 Topical Meeting
Molybdenum-99 Medical Community Perspective
Sally Schwarz, RPh, MS, BCNP
Society of Nuclear Medicine and Molecular Imaging
September 1, 2015



Overview

- About SNMMI
- Climate for Clinicians and Patients
- State of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$
- Recommendations

SNMMI

- Improve health care by promoting nuclear medicine, molecular imaging and radionuclide therapy
- Advocate for patients and the profession
- Provide education for members and the community

SNMMI

- SNMMI Membership
 - 70 Countries
 - Physicians
 - Technologists
 - Radiopharmacists
 - Researchers
 - Physicists
 - Laboratory professionals
 - Patient Advocates

Diagnostic Imaging

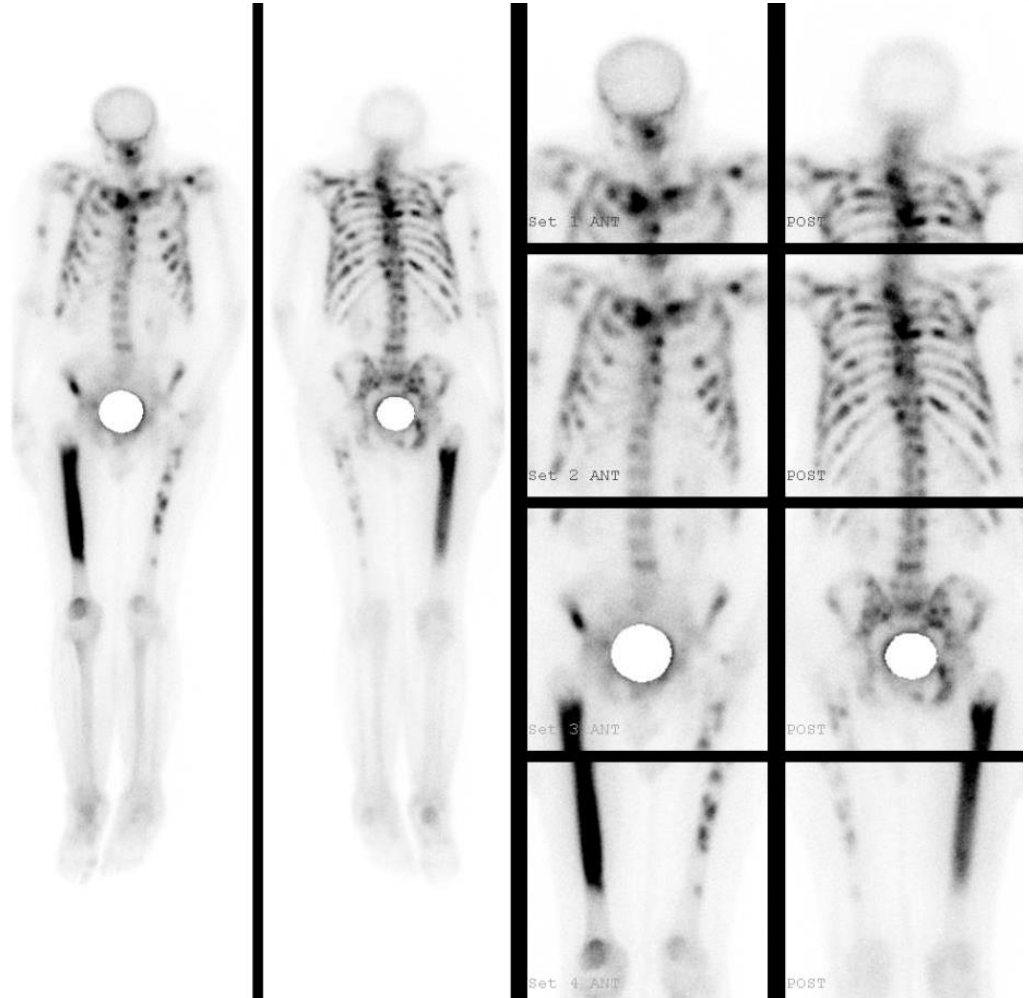
- 40,000 cases performed daily
- Tc-99m ideal due to low dose to patients
- Short half-life must be produced Just In Time
- Mo-99 is produced by aging reactors
- US needs sustainable supply of Mo-99
- US uses 50% of world supply of Mo-99
- Requires diversity in the supply chain and domestic production of Mo-99
- Adequate funding and reimbursement required

Nuclear Medicine in the United States

- Vital part of diagnostic and therapeutic management of patients
- We conduct 18 million imaging studies per year
 - ^{99m}Tc is used in 80% of these studies
 - Nuclear cardiology represents 50%
 - Nuclear oncology represents 25%
 - Other imaging of brain, endocrine system, lungs, GI & GU tract, bones, infection...and the list goes on
- ^{99m}Tc radiopharmaceuticals are also used in *100 clinical trials*

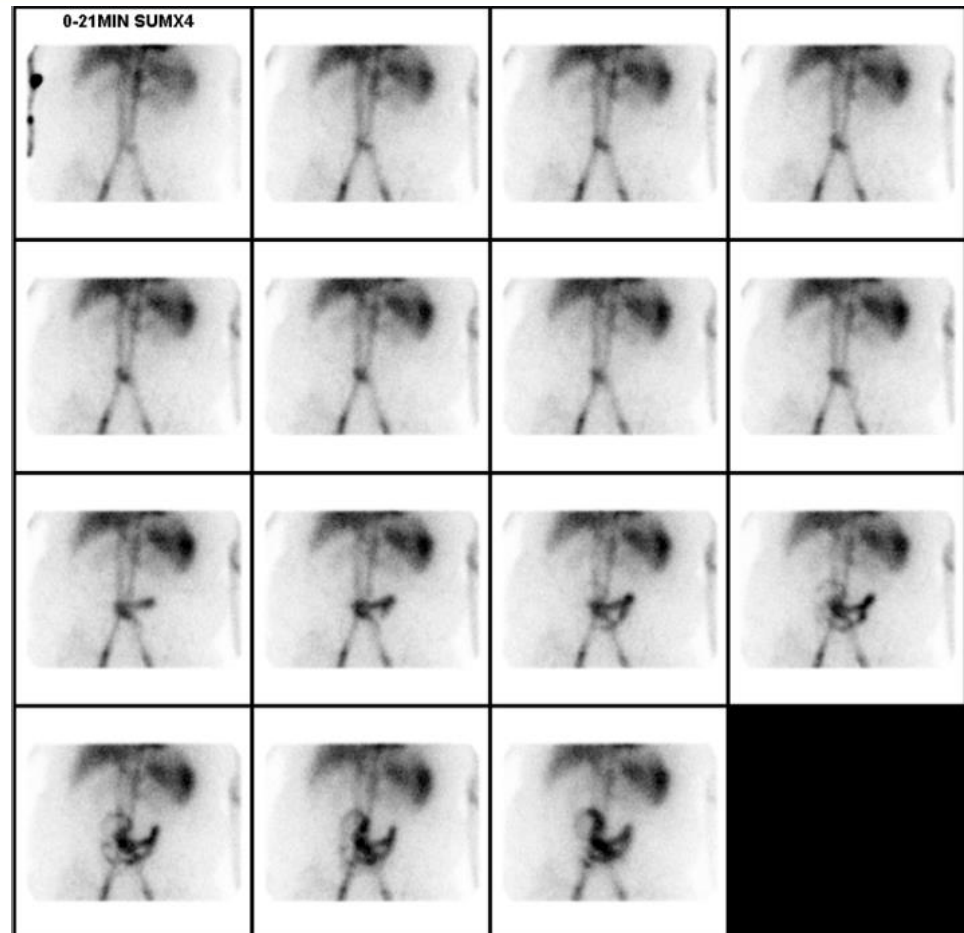
Nuclear Medicine Makes a Difference

- Bone Scan
- 67 year-old male patient with prostate cancer and multifocal pain
- Increased uptake in bones indicates metastatic disease



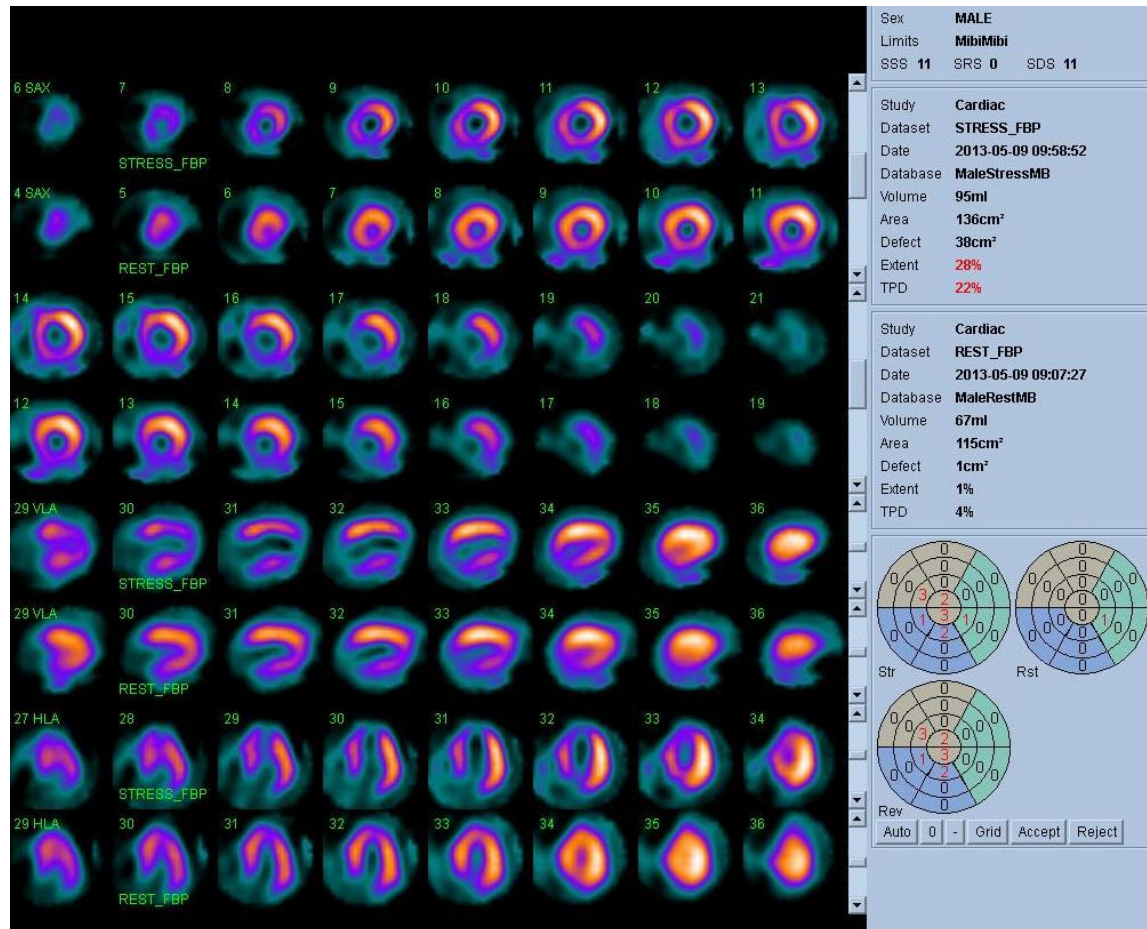
Nuclear Medicine Makes a Difference

- GI bleeding study
- 45 year-old female patient with low blood counts and uncertain site of bleeding
- Bleeding site determined



Nuclear Medicine Makes a Difference

- Stress-rest study
- 59 year-old male patient with atypical chest pain




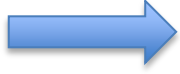
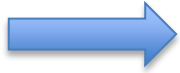

Alternate Studies

CT scans and other technologies used in place of ^{99m}Tc during a shortage could result in:

- Poorer medical care
- Higher radiation exposure
- Lower quality information
- Much higher cost

Other modalities provide anatomical information rather than nuclear medicine's unique functional information

Alternatives to ^{99m}Tc Myocardial Perfusion Imaging

^{82}Rb chloride		Experienced major shortages
^{13}N ammonia		Logistically more difficult
^{201}Tl chloride		Higher Radiation
Coronary CTA		Higher Radiation

State of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ Today – Strengths and Weaknesses

- Strengths
 - Available from a $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ generator
 - ^{99}Mo has a 66 hour half-life, allowing for delivery of radiopharmaceutical doses to rural areas
 - The six hour half-life of $^{99\text{m}}\text{Tc}$ allows for wide distribution of doses from central radiopharmacies
 - Excellent photon energy
 - Low radiation dose to patient
- Weaknesses
 - After the NRU reactor shuts down in 2016, no ^{99}Mo produced in North America
 - After 2016, the U.S. is completely dependent on foreign producers for ^{99}Mo
 - High barrier to market entry--Pricing--although conceptually in agreement with full cost recovery, not all parties participating thus appears unequal

Medical Communities Response

- More efficient use of Tc-99m
- Optimized dosing resulting in reduction in use and demand
- Physicians and Pharmacists have reduced utilization
- Companies have stepped up and increased producers and outage reserve capacity
- Meeting with CMS to discuss reimbursement

Medical Communities Needs

- Reliable, sustainable Mo-99 supply
- Quality - meets the regulations regarding use in humans and the current specifications of approved drugs
- Cost effective

Reimbursement in the US

- Current lag of 2-3 years (hospitals are at a loss)
- Reimbursement upgrade currently tied to non-HEU production
- Non-HEU production is limited and not produced consistently
- In the US, the complexities of the additional CMS payment have proven to be difficult to overcome
- Approximately 25 out of 30,000 Tc-99m doses per day are receiving the additional \$10 payment. Hence there is minimal demand from the US market at this time to promote the use of LEU Mo-99

Molybdenum-99 Subcommittee - Report to the NSAC

- **On June 30 2015**, NSAC's ^{99}Mo Subcommittee submitted an assessment of the ^{99}Mo Program & made four recommendations:
 1. DOE should increase funds available to individual Cooperative Agreement (CA) projects to significantly accelerate establishing domestic ^{99}Mo production.
 2. DOE must support establishment of the Uranium Lease and Take Back (ULTB) Program.
 3. NNSA should document a contingency plan to ensure a supply of ^{99}Mo from Canada within a few months if a shortage appears imminent during 2016-2018.
 4. NNSA should develop a contingency plan to adapt the program should OECD-NEA continue to determine that the global community is not making adequate progress toward full cost recovery in order for domestic production to be economically feasible.

Recommendations

- Full cost recovery should be implemented **before** the conversion from HEU to other production technologies or NNSA should develop a contingency plan to assure domestic development
- There must be a reliable, affordable domestic supply of non-HEU material **before** cutting off HEU exports
- NNSA must work toward greater certainty of costs yet to be determined, including creation of a waste take back program (ULTB) and conversion costs not borne by NNSA.

Recommendations

- NNSA must not look to reduce government spending until a domestic source is established and reliable
- NNSA needs to convey to all stakeholders the process (trigger) by which additional shipments will be made to Canada if a shortage is determined
- NNSA must continue working with CMS, FDA, NRC and others on reducing the complexity of the regulatory and reimbursement structure, particularly the two year time lag for updating the data necessary for proper reimbursement

SNMMI Ongoing Efforts

- Educate and inform customers, payers, societies and governments of FCR and challenges to LEU conversion
- Continue to communicate and educate — patients, nuclear medicine physicians and referring physicians
- Reaching out to CMS regarding reimbursement, hospitals and insurance groups outside our societies may prove beneficial



SOCIETY OF
NUCLEAR MEDICINE
AND MOLECULAR IMAGING

Thank you!



Missouri University Research Reactor (MURR)