THE SUPPLY OF MEDICAL ISOTOPES

AN ASSESSMENT OF THE MARKET ECONOMICS, ALTERNATIVE TECHNOLOGIES AND PROPOSED POLICY APPROACH TO ACHIEVING SUSTAINABILITY

R. CAMERON, A. Y. LOKHOV, C. WESTMACOTT

Nuclear Development Division

OECD Nuclear Energy Agency

HLG-MR Formation and Role

Established by NEA in April 2009

- 22 experts: 13 countries, EC, IAEA
- 2 year mandate: June 2009-2011
- Oversees and assists international efforts – not duplicative

- Significant progress achieved already: communication; co-ordination of reactor schedules; better understanding within supply chain
- Three reports published under *The Supply of Medical Radioisotopes* series:
  - *An Economic Study of the Molybdenum-99 Supply Chain*
  - *Interim Report of the OECD/NEA High-level Group on Security of Supply of Medical Radioisotopes*
  - *Review of Potential Molybdenum-99/Technetium-99m Production Technologies*

Historical Market Development

- Historically - developed unsustainable economic model
  - Started with low prices; structure perpetuated low prices
- Resulted in supply reliability concerns:
  - Not enough financial incentives for new (LEU) infrastructure
  - New reactors struggling to cover ^{99}Mo production investments
  - Supply from ageing reactors not reliable
  - Reserve capacity required but not supported
- Industry survived through government financial support
  - Also supported foreign health care systems/foreign companies
- Social contracts moving towards more commercial funding
- Actions are needed to correct market, policy and technology failures
- Step one: Ensuring full-cost recovery in prices

Current and Sustainable Pricing: Impact on End User

- Illustrative approximate prices

Levelised Unit Cost of ^{99}Mo (LUCM) in €/6-day curie EOP

	From Reactor	From Processor	From Generator	From Radiopharmacy
Current Situation (pre-shortage)	45 €	315 €	375 €	1 810 €

- Reactor ^{99}Mo-related operating costs HIGHER than selling price
- Understand value of supply chain stages in end-user prices

	Irradiation value within final radiopharmaceutical price	Irradiation value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Current Situation (pre-shortage)	0.26 €	0.11%	4.42%

- ^{99m}Tc 11 €; radiopharmaceutical 39 €; reimbursement 245 €
- Indicates price increases likely = small change at patient level

Current and Sustainable Pricing: Impact on End User

- Illustrative approximate prices

Levelised Unit Cost of ^{99}Mo (LUCM) in €/6-day curie EOP

	From Reactor	From Processor	From Generator	From Radiopharmacy
Current Situation (pre-shortage)	45 €	315 €	375 €	1 810 €
Required Prices	55 – 400 €	415 – 855 €	475 – 915 €	1 910 - 2 350 €

- Reactor ^{99}Mo-related operating costs HIGHER than selling price
- Understand value of supply chain stages in end-user prices
- Sustainable pricing requires significant increases upstream...

	Irradiation value within final radiopharmaceutical price	Irradiation value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Current Situation (pre-shortage)	0.26 €	0.11%	4.42%

- ^{99m}Tc 11 €; radiopharmaceutical 39 €; reimbursement 245 €
- Indicates price increases likely = small change at patient level

Current and Sustainable Pricing: Impact on End User

- Illustrative approximate prices

Levelised Unit Cost of ^{99}Mo (LUCM) in €/6-day curie EOP

	From Reactor	From Processor	From Generator	From Radiopharmacy
Current Situation (pre-shortage)	45 €	315 €	375 €	1 810 €
Required Prices	55 – 400 €	415 – 855 €	475 – 915 €	1 910 - 2 350 €

- Reactor ^{99}Mo-related operating costs HIGHER than selling price
- Understand value of supply chain stages in end-user prices
- Sustainable pricing requires significant increases upstream...

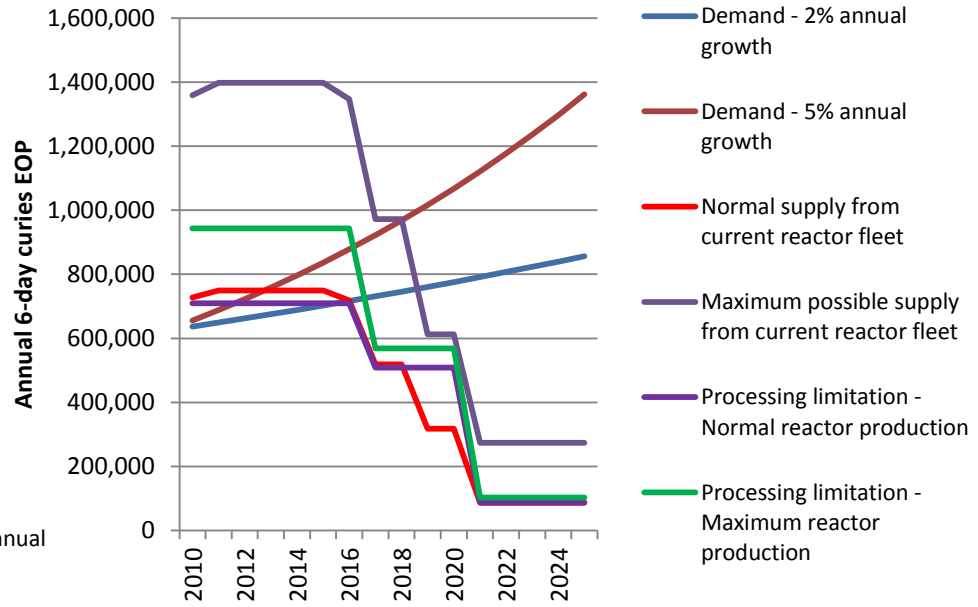
	Irradiation value within final radiopharmaceutical price	Irradiation value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Current Situation (pre-shortage)	0.26 €	0.11%	4.42%
Required Prices	0.33 - 2.39 €	0.14 - 0.97%	5.06 – 5.69%

- ^{99m}Tc 11 €; radiopharmaceutical 39 €; reimbursement 245 €
- ...remains small portion of patient price

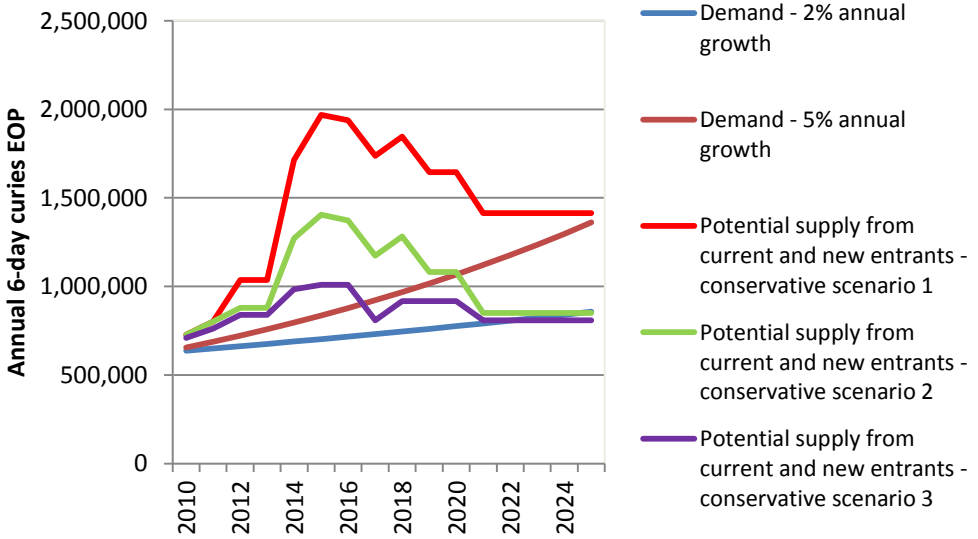
Short-term shortage solved; Long-term concerns remain

- NRU and HFR back on line
- Shortages were symptom of longer-term problems, including insufficient capital investment and processing constraints
- Current reactors scheduled to go offline over next decade

Current Supply vs. Demand



Conservative Potential Supply vs. Demand

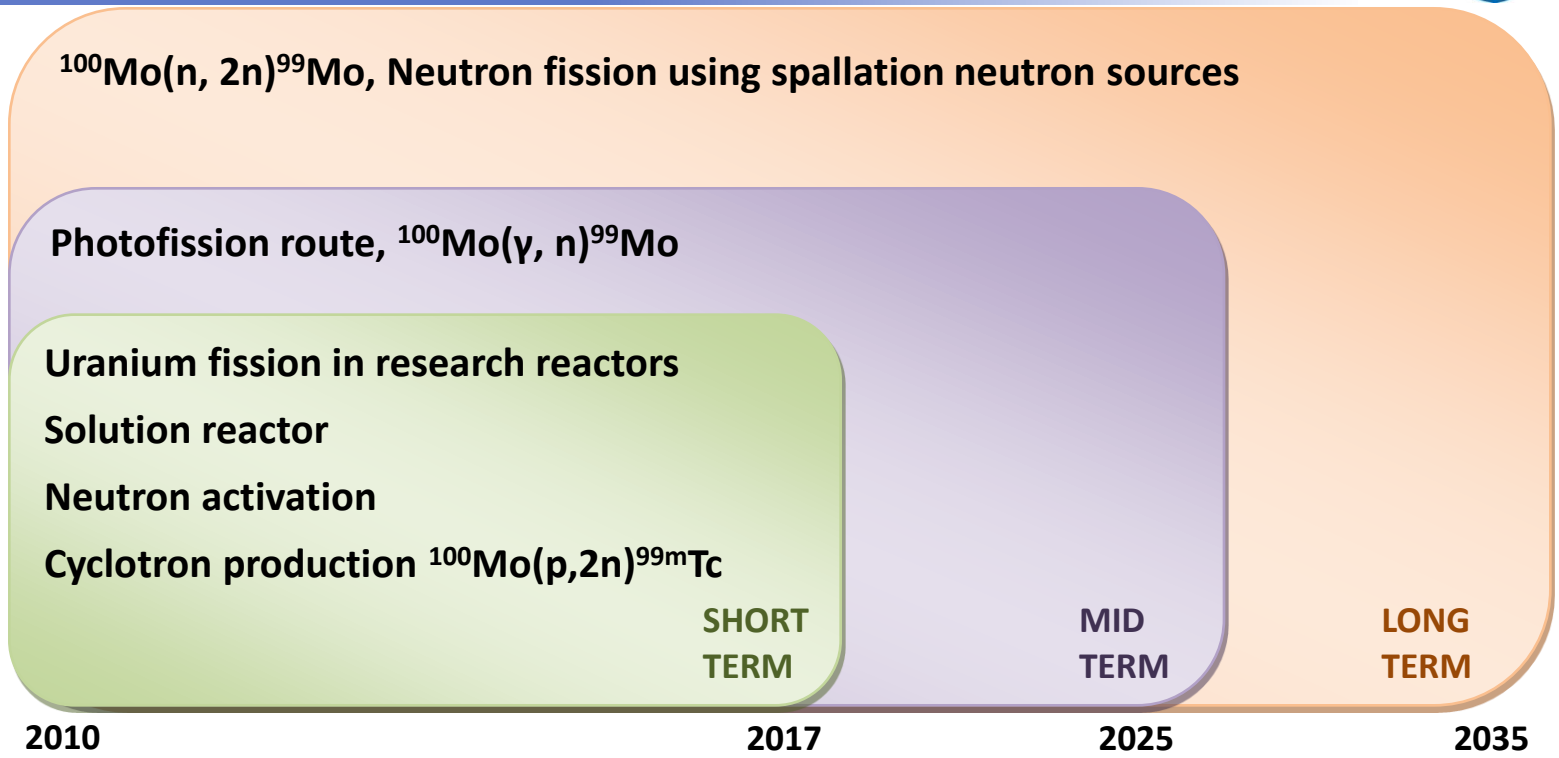


- New projects being discussed and some being developed
- Need to keep working to ensure will happen
- Cannot be lulled into complacency

Processing and Transportation Issues

- Global processing capacity seems sufficient
- However regional capacity limitations affect ability to supply global market, especially if reactor shutdowns
- Processors need to be reasonably close to reactors
- Some regions where processing capacity not sufficient for:
  - Supporting increased production
  - Meeting increased demand
  - Dealing with possible reactor outages globally, or
  - Adapting to changing supply structure as older reactor retired
- Possible barrier to new irradiation capacity
- Transportation regulatory processes and denials of shipment are impediments to reliable supply
  - Streamline and consistency in approvals, and education necessary
  - IAEA working on this matter

Alternative Production Technologies



- Short term is defined as potentially available in the time frame 2010-2017
  - 7 years - order of magnitude for a time needed to build a new research reactor
  - Physical details and the economic data are available from industry
- Mid-term technologies are expected to be available in 2017-2025
  - Preliminary feasibility tests have been performed
  - Construction of experimental facilities is planned
- Long-term technologies are expected to be available after 2025
  - No economic assessment is currently possible

Conclusions for Short-term Technologies

- The use of LEU targets has advantages over HEU
  - Proliferation resistance
  - Easier availability of the target material
  - Easier compliance for target transportation and processing
- However, LEU currently has lower production yield than HEU
  - May require more targets to be irradiated, increased volumes of waste
  - Need to increase the uranium content to counteract
  - No technological or economic reasons not to deploy LEU target based production
- Neutron activation in a research reactor
  - Advantages in terms of safety, waste management and proliferation resistance
  - But low specific activity
  - Current technologies require recycling of the highly enriched molybdenum to be cost-effective; currently not done
  - More development and experience needed in (gel) generator technology for larger deployment
- Direct technetium-99m production using cyclotrons
  - Potential advantages in terms of cost, waste management, proliferation resistance and ease of approval
  - But can only provide local needs; large number of cyclotrons needed to meet world demand
  - Requires significant amounts of highly enriched molybdenum (^{100}Mo)

Policy Approach: Central Pillars

- HLG-MR is developing a cohesive policy approach to:
  - address issues being faced by supply chain
  - move to a long-term secure supply of ^{99}Mo and ^{99m}Tc

Central Pillars of Reform: Issues to be addressed

- Market economics need to be improved
- Structural changes are necessary
  - Multisourcing
  - Contracts need to be adapted
- Government role has to be clearly defined
- An effective co-ordinated international approach is necessary

High-level Policy Approach

- HLG-MR agreed on the approach most likely to achieve necessary reforms in a coherent and comprehensive manner

- Markets should do what they can, but may be limits
- Governments have essential role
  - Supporting market operations by:
    - Ensuring proper environment for investment
    - Addressing market failures
  - While recognising commercial nature of supply chain
- International collaboration is necessary
  - Particularly to avoid policy approaches at the domestic and regional levels that could negatively affect global $^{99}Mo/^{99m}Tc$ supply security
- Transparency is important
  - Ensure market continues evolution to economic sustainability

Policy Approach: Principles

- To ensure consistent fulfilment of responsibilities, HLG-MR formulating detailed policy approach:
  - Principles and supporting recommendations
- Once finalised, will suggest addressing main issues by:

- Implementing full-cost recovery
- Sourcing, valuing and paying for reserve capacity
- Fulfilling essential government role
  - Setting the proper environment for safe and efficient market operations
- Encouraging conversion to using LEU targets
- Collaborating internationally to ensure globally consistency
- Periodical reviews of progress to implementing an economically sustainable supply chain

Conclusions

- HLG-MR and stakeholders have identified issues affecting security of supply
- Significant actions already undertaken
- However, underlying problem – unsustainable economic structure – has not yet been adequately addressed
- Supply shortage could become commonplace over next decade unless longer-terms actions are taken
- Without government financial support, commercial pricing required
- Policy approach to provide consistent and comprehensive steps forward to ensuring long-term security of supply
  - Finalise by June 2011
- More detail available on: www.oecd-nea.org/med-radio