Emergency protocols and the BNMS
Workshop on the Security of Supply of Medical Radioisotopes

29-30 January 2009
Clinical Engagement

Canada | EANM
France | SNM
Korea | IAEA
Spain
UK
• Workshop 4
  “Supply Reliability From Supply Chain To Medical Community”
• Workshop 5
  “Demand Management In The Medical Community”
“Regulators may be asked to balance difficult health and nuclear safety concerns”

- Contingency planning – timely, clear communication to manage limited supply
- Involving representatives nuclear medicine establishments

(M Weightman, UK)
Safety and availability radiopharmaceutical production facilities
ASN/AFSSAPS Paris Jan 2009

“Urgent need to reinforce complete production chain leading to essential service to society”

• Involvement stakeholders
• Importance safety
• Anticipation
  – governments and health authorities should share information on contingency planning
  – Exchange of information about production capacity at different facilities promoted
Health Canada

• Demand challenges
  – Manage demand during inevitable shortages
    • Inform medical community
    • Manage limited supplies
    • Use existing alternative procedures
  – Maximise efficiency distribution chain
  – Address regulatory impediments to supply and distribution
  – Develop, deepen and share contingency plans
  – Review patient scheduling, potential for enhanced sharing of generators/Tc 99m
  – Sustain dialogue meeting March 2009
• US
  – Radiopharmacies
  – SNM survey radiopharmacists delays
• Canada
  – Mixed service
• Australasia
  – Contingency committee with ASNM and ASNMT
• Japan
  – Central distribution, 65% radiopharmacy central
• EANM
  – Severe shortages many member states, Spain best
Supply system of $^{99}\text{Mo}/^{99}\text{mTc}$ Radiopharmaceuticals in Japan

- NTP
- Nordion
- Covidien

- NMP
- FFRI

$\text{Na}_2^{99}\text{MoO}_4$

$^{99}\text{Mo}/^{99}\text{mTc}$

JRIA

- Hospital
- Hospital
- Hospital
- Hospital
- Hospital

$65\%$

About 1300 Hospitals

$35\%$

$^{99}\text{mTc}$ Products

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Emergency Supplying $^{99m}$Tc Radiopharmaceuticals in Japan

$^{99m}$Mo raw material suppliers
- NTP
- Nordion
- Covidien

Pharmaceutical Manufacturer
- NMP
- FFRI

Coordinate

Relevant Authorities

Emergency Information by E-mail, Fax

$^{99m}$Tc-Radiopharmaceuticals

Information by E-mail

Products Route

Emergency Contact

About 1300 Hospitals

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### Breakout 5: Demand Management Effectiveness in the Medical Community

#### Recommended actions – GLOBAL

<table>
<thead>
<tr>
<th>Issues</th>
<th>Recommended actions</th>
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<tbody>
<tr>
<td><strong>1. Management of price increases</strong></td>
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<tr>
<td>A. Support a portion of the changing cost through a global initiative</td>
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<td>B. Create an equivalent of the OPEC (OMEC) for price transparency</td>
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<td>C. Increase the level of reimbursement according to the price increase</td>
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<tr>
<td>D. Increase the efficiency of the generators’ use</td>
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<tr>
<td>E. Communicate on the magnitude and the drivers of the price increase</td>
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<td><strong>2. Pharmaceutical regulation</strong></td>
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<tr>
<td>A. Start an international effort to align the regulations between countries</td>
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<tr>
<td>B. Minimize barriers to supply during crises</td>
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<tr>
<td>C. Harmonize regulations between countries relative to the Mo generator</td>
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<tr>
<td>D. Facilitate authorization issuing for alternatives during shortages</td>
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### Breakout 5: Demand Management Effectiveness in the Medical Community (cont’d)

<table>
<thead>
<tr>
<th>Issues</th>
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</thead>
<tbody>
<tr>
<td><strong>3. Supply versus demand</strong></td>
<td>A. Increase the efficiency of the generators’ use</td>
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<tr>
<td>driven market</td>
<td>B. Centralize the demand (central radio pharmacies)</td>
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<td></td>
<td>C. Optimize patient management (scheduling)</td>
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<td></td>
<td>D. Implement contingency planning during shortages</td>
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<td><strong>4. Lack of transparency</strong></td>
<td>A. Improve/intensify communication between medical community and supply chain</td>
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<td></td>
<td>B. Inform the regulator and the medical community (make it a duty to inform)</td>
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<td></td>
<td>C. Share reactor schedule in real time</td>
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Short term actions

- Reactor owners and operators should continue to share information and to enhance co-ordination of reactor maintenance schedules, with a view to ensuring an uninterrupted global supply of isotopes;
- Options for increasing production from existing reactors in times of global shortage should be further explored and encouraged;
- Current economic conditions for irradiation services should be reviewed to provide better incentives to reactors operators, including where the main mission is research in support of national nuclear energy or scientific programmes;
- Unnecessary impediments to the distribution of medical isotopes, such as restrictions in transport capabilities and denial of shipment by airline companies, should be removed;
- Anticipative actions to avoid the dilemma between meeting nuclear safety requirements or meeting health care needs should be encouraged; in this regard, participants were pleased to be informed of the outcome of the nuclear regulators meeting held in Paris three weeks earlier;
- Radio-pharmacies, hospitals, health product regulators and the medical community should explore options for more efficient patient scheduling and utilisation of Mo-99/Tc-99m generators to make best use of currently available supplies of Mo-99 and/or other potential alternatives.
Longer term actions

Participants underscored the need to develop, deepen and share, as appropriate, contingency plans for future supply disruptions. They urged industry actions to improve the flexibility and efficiency of the distribution chain, as these could make a significant contribution towards increasing the supply of To-99m ultimately delivered to patients.

There was broad agreement that increased transparency among reactor operators, transport operators and distributors, government regulators, and health care professionals would facilitate all efforts. In particular, it is important that the health care community shares early information from all participants in the supply chain concerning potential and real disruptions, including estimates of the timing, duration and severity.
Outcome WG 4 and 5

• Manage better existing capacity at national level
• Demand led distribution networks
• Training

• Communication
  – WG 4 and 5 to Meet
    • SNM Toronto 2009
    • EANM Barcelona 2009
    • WFNMB cape Town 2010

• OECD to consider radioisotope user forum ?IAEA
UK response to challenge
Current position

• Moly supply variable depending on supplier and week
• Short notice of generator capacity limits planning clinical activity
• Data collection SHA on behalf DH
  – Nov 2008  35-75% expected moly delivery
• Many hospitals independent radiopharmacy
Contingency planning required

• Short term
  – Feb Nordian only supplier
    • 30 % global supply

• Medium term
  – Anticipated reduction capacity autumn

• Long term
  – Current practice anticipates full contingency supply.
  – Estimates global capacity 200-250% global demand
  – Currently max 135% demand
BNMS role

• Ensure flow of information
• Ensure best use supplies
• Actions from this meeting?
  – Industry
  – Regulators
  – Radiopharmacy
  – Clinical Service
BNMS role
Ensure flow of information

• Education of users
• Engage with clinical departments
  – Working groups
  – Share solutions to short term shortages
  – Include relevant information in 2009 survey
  – Establish accurate communication with departments
  – RSS feed from website
BNMS role
Ensure flow of information

- Engage with regulators
  - MHRA to understand market and flexibility
  - DH radiation division and HPA
  - ARSAC dose reduction and image optimisation
  - HSE risk assessments fluctuation supply
  - National Imaging Board
    - contingency planning
BNMS role
Ensure best use supplies

• Develop protocols for alternative radiopharmaceuticals
  – Website for better information

• Radiopharmacy option appraisal service delivery models
  – Map current position
  – Consider short and medium term joint working
BNMS role

Ensure best use supplies

• With manufacturers optimise distribution moly
  – New models for generator ordering
  – Demand led draw down and sharing

• Service and staff review with forward planning
Clinical service redesign

- Optimise
  - Clinical demand
  - Moly delivery schedules
  - Staff and service capacity
- Scheduling
- Dose reduction
  - ALARA/ARSAC
- Use new imaging technology to reduce administered activity and maintain quality

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Long term

• Reduce reliance on reactor isotopes
  – Cyclotron capacity

• Refresh imaging capital to optimise diagnostic yield

• 7 day service for best utilisation activity?

• Invest in Science
This is a long term position

• Moly is a scarce resource

• Costs are increasing for producers, manufacturers and users

• This will be an unpredictable variable in service continuity unless we have National and local sustainable service plans
There should be a national contingency plan to ensure safe and consistently available clinical service

BNMS view