

IMPACT OF ISOTOPE SHORTAGES ON MEDICAL COMMUNITY

BACKGROUND

In response to the recent shortage of Mo-99, Dr. Max Lonneux, General Secretary of the Belgian Nuclear Medicine Society provided the following discussion on the impact of isotope shortages in European medical imaging. [Article taken from Global Nuclear Open Source Information Service (GNOSIS) September 9, 2008: Interview with Dr. Max Lonneux by "R.G." in Brussels; date not given: "There is No Vital Risk to Patients"]

Dr. Lonneux is a nuclear medicine physician employed at the Nuclear Medicine Department at the St. Luc University Hospital in Brussels.

Is the shortage of radioisotopes a cause for concern?

[Lonneux] The problem is certainly serious. The type of tracer affected by the shortage, produced by special reactors with a high neutron flow, is used in about 80% of activities in the nuclear medicine sector. The remaining 20% require the use of tracers that are continuing to be produced in sufficient quantities, in the cyclotrons.

At the time of the previous shortage, in Canada, your colleagues said that about 10% of the patients affected were facing life or death decisions and that in between 30% and 40% of other cases the doctors were in danger of making an insufficient diagnosis and of taking inappropriate decisions in the field of treatment.

[Lonneux] We must not be alarmist. The shortage does not generate a vital risk for patients. It is not as if you were immediately cutting off the electricity supply to an operating theater! We were warned as far back as 29 August. Provisions were made to postpone routine check-ups and reserve the stocks of available radioisotopes for the most urgent cases.

For example?

[Lonneux] This morning, at St. Luc, we received just 15% of the usual radioisotope volume. Appointments for patients who were only to undergo a check-up were postponed. On the other hand, we are carrying out the most urgent examinations, such as the scintigraphy of sentinel ganglions in the case of breast cancer, which makes it possible to determine whether or not a surgical intervention is necessary. In this case the diagnosis is an inherent part of the surgical act. And for this we have no replacement solution.

In other cases, alternatives are envisageable however...

[Lonneux] Some scintigrams carried out normally using a technetium-99 can be carried out using other radioisotopes, less indicated but nevertheless effective, such as thallium. Naturally, to examine the condition of the heart... We can also use a PET scan, for example, to detect certain bone diseases or neurological complaints. With a risk of saturation: The planning for PET scanning is full for the coming week.

How do you explain the shortage?

[Lonneux] It is unbelievable. Europe is in a beneficial situation with three production units out of the six that exist worldwide. How is it possible to shut down for maintenance at the same time two of the three units operating in Europe? The sector suffers from a lack of coordination, between the private and public operators, but also from an evident lack of reinvestment. Investing in nuclear technology, even medical, is no longer politically correct!

Did the temporary shutdown of the IRE aggravate the situation?

[Lonneux] The IRE [Institute of Radioelements] intervenes downstream of the production reactors but its role is vital in the production chain. Ideally the Fleurus processing center, which is continuing to be marked by less than transparent communication, should start up for the latter half of September. If not, the shortage will continue until the Petten unit starts up again and that is not expected until the end of October. But at least they communicate there.

DISCUSSION

The above article discusses the effects of isotope shortages on the medical community in Europe. NRC is seeking advice from the ACMUI on the impact of shortages of isotopes on the practice of medicine in the United States. The following questions may guide the ACMUI in responding:

1. Approximately how many procedures using radioactive drugs are performed in a day? Can you categorize the procedures using these drugs by relative percentages (cardiac, bone, thyroid, lung, etc.)? Can you put this into perspective of the procedures that use Tc-99m? I-131? Xe-133?
2. How many procedures using the fission product radioactive drugs must be performed immediately? How many procedures can be postponed a few days? A week? A few weeks? Note: These estimates can be in percentages for a given procedure, e.g. X% of cardiac studies must be performed immediately. Y% of cardiac studies can be postponed Z number of days.
3. How many patients requiring a procedure using fission product radioactive drugs can receive a different test to achieve the same results? Note: This could include procedures that use accelerator produced byproduct materials. These estimates can be given in percentages for a given procedure, e.g., X% of patients having cardiac studies could have a different examination in lieu of the cardiac study involving fission products and still achieve the same diagnostic objective.
4. Are there other uses of fission radionuclides affecting medicine in short supply that NRC is not focused on?



Advancing Molecular Imaging and Therapy

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Nuclear Regulatory Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

To whom it may concern:

The Society of Nuclear Medicine (SNM)—an international professional organization representing more than 16,000 members dedicated to promoting the science, technology, and practical application of molecular imaging and therapy—appreciates the opportunity to assist the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the Nuclear Regulatory Commission (NRC) staff with questions regarding the impact of isotope shortages on the medical community.

1. **Approximately how many procedures using radioactive drugs are performed in a day? Can you categorize the procedures using these drugs by relative percentages (cardiac, bone, thyroid, lung, etc.)? Can you put this into perspective of the procedures that use Tc-99m? I-131? Xe-133?**

There are approximately 20 million procedures performed each year using radioactive drugs. Ninety percent of those are single photon (Tc, Tl, I, Xe). Of those, 90% are Tc, therefore, approximately 16 million procedures are done each year with Tc. This calculates to approximately 70,000 Tc scans per day in the United States.

2. **How many procedures using the fission product radioactive drugs must be performed immediately? How many procedures can be postponed a few days? A week? A few weeks? Note: These estimates can be in percentages for a given procedure, e.g. X% of cardiac studies must be performed immediately. Y% of cardiac studies can be postponed Z number of days.**

On the average, about one third of the studies need to be done promptly and cannot be postponed. These include hepatobiliary, renal, lung scans, and various pre-operative studies such as bone scans, sentinel node mapping, and myocardial perfusion studies. It is possible to postpone some of the surgeries, but this cannot go on for more than 2-3 days.

Regarding nuclear cardiology studies, some outpatients could have their procedures delayed one week, whereas in-patient and emergency department patients need to have their procedures performed the same day. At Vanderbilt Hospital, for example, 90% of patients are either in-patient or emergency department patients. At the Vanderbilt Heart Institute, about 90% are outpatients.

Regarding bone scans, 90% of patients can wait one week. Breast-sentinel nodes are scheduled for surgery the same day, so they can not be rescheduled but the dose is small (0.5 mCi/patient).

3. **How many patients requiring a procedure using fission product radioactive drugs can receive a different test to achieve the same results? Note: This could include procedures that use accelerator produced byproduct materials. These estimates can be given in percentages for a given procedure, e.g., X% of patients having cardiac studies could have a different examination in lieu of the cardiac study involving fission products and still achieve the same diagnostic objective.**

About half the cardiology patients might be evaluated with echocardiography or cardiac catheterization. Most of the renal patients might be evaluated with excretory urograms, which are less quantitative and have higher radiation dose. Sentinel node mapping could be done with dye but is less accurate. There is no good replacement for bone scans, although whole body CT could be used with much higher cost and radiation exposure, and the accuracy would be lower. There is no good substitute for hepatobiliary scans. Lung scans are done with CT angiography, but nuclear studies are done in patients with contrast allergy or renal failure, where no substitute is available.

Nuclear cardiology studies can be switched to dual isotope (Tl/Tc) or rest/stress thallium or potentially rest/stress Rb PET if available

4. **Are there other uses of fission radionuclides affecting medicine in short supply that NRC is not focused on?**

At this time, SNM is unaware of any fission radionuclides that may be in short supply.

SNM has recently surveyed its members in an effort to gain a better understanding as to how the isotope shortage has impacted the nuclear medicine community. A summary of the preliminary results from 419 respondents is as follows:

- Q. Has or is your practice/facility impacted by the molybdenum-99 shortage?
Yes: 298
No: 115
- Q. Do you have access to an alternate technetium generator source?
Yes: 128
No: 241
N/A: 58
- Q. If you answered "yes" to question 4, what is your alternate technetium generator source?
Another hospital: 3
Another commercial pharmacy: 77
Another manufacturer: 49
Other: 15 (includes: "another country", "waiting for delivery from current supplier")
- Q. What percentage of your normal full capacity are you currently able to operate?
0-25%: 11
26-50%: 30
52-75%: 64
76-100%: 309

- Q. When, if ever, do you think you will be down to zero percent capacity during this shortage?
Within a week: 20
Within two weeks: 21
Within three weeks: 4
Within a month: 25
Longer than one month: 30
Never: 307
- Q. If you answered "longer than one month" in the last question, please indicate how much longer you anticipate being down to zero capacity?
2-4 months: 8
4-6 months: 2
Unknown/Don't have an idea: 14
Don't really feel it is a problem yet: 8
- Q. Approximately how many patients per week receive nuclear medicine scans/procedures before August 2008 at your facility?
0-49: 132
50-100: 113
101-300: 70
More than 300: 27
- Q. Approximately how many patients are now receiving nuclear medicine scans/procedures at your facility?
0-50: 186
51-150: 114
150-350: 20
More than 350: 15
- Q. Please indicate any and all changes that were made regarding patient care in response to this shortage?
Postponement of procedure: 198
Cancellation of procedure: 79
Change in procedure: 103
Change in isotope used: 79
Transfer of patient to another facility: 17
Other: 96 (includes: "decrease dosage", "rescheduling of staff and/or patients" and "grouping procedures")
- Q. If you answered "postponement of procedure" to the last question, please indicate how long the procedure was postponed.
Less than one week: 84
1-2 weeks: 82
2-8 weeks: 14
- Q. If you answered "change in procedure" to Question 11, please indicate the procedures that were substituted.
Tl-201 for Tc: 89
F-18 fluoride for bone scans: 2
Rb-82 for Tc: 7
Other non-nuclear procedure: 42
Other: 36 (includes: "reduced doses", "In-111 or I-123 for Tc" and CT instead of V/Q")

Q. If you answered "other non-nuclear procedure" in Question 13, please explain.

CT/CTA: 27

MRI: 5

Stress Echo for MUGA: 17

Catheterization: 2

Ultrasound: 2

Q. If you answered "change in isotope used" in Question 11, please indicate what isotopes were substituted.

Tl-201/Thallium used instead of Tc99: 63

Rb-82: 2

I-123: 2

In-111: 2

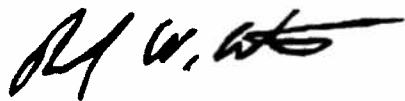
F-18: 1

Co-57: 1

SNM will be happy to share the final survey results with the NRC and ACMUI, once they have been compiled.

The SNM appreciates the opportunity to assist the ACMUI and NRC on this issue. Should you have any further questions or comments, please contact Hugh Cannon, Director of Health Policy and Regulatory Affairs at hcannon@snm.org, or 703.708.9000, ext. 1322.

Sincerely,



Robert Atcher, Ph.D., MBA
SNM President

Cc: Advisory Committee on the Medical Uses of Isotopes