Questions and Answers

Technetium-99m Radiopharmaceutical Product Shortage

What are radiopharmaceutical products?

Radiopharmaceutical products are drugs that contain a component called a radioactive isotope and are used by health care providers in nuclear medicine to image parts of the body and to help diagnose disease. Radiopharmaceuticals may contain one of several types of radioactive isotopes but the isotope technetium-99m (Tc-99m) is in approximately 80% of radiopharmaceuticals. Imaging tests that rely on Tc-99m are the most commonly used tests in nuclear medicine.

What are these products used for?

Radiopharmaceutical products are used to diagnose and treat a variety of conditions and diseases. Radiopharmaceuticals play an important role in performing imaging studies of the heart, blood, brain, thyroid, lungs, liver, kidneys and skeleton, as well as in the imaging of certain tumors.

What is FDA communicating about radiopharmaceuticals?

FDA has recently been notified that there was an unplanned shutdown of a Canadian nuclear reactor that supplies the material used to produce (generate)Tc-99m. This shutdown has caused a world-wide shortage of Tc-99m.

Which radiopharmaceutical products are affected by the shortage?

All radiopharmaceutical products that contain the radioactive isotope Tc-99m are affected. There are other facilities that produce the material needed to make (generate) Tc-99m, and they will continue to produce the material, but these other facilities do not have the capacity to make up for the shortage. We do not know how long the facility in Canada will remain closed, but we expect the shutdown to last at least several months.

How is FDA responding to the shortage?

- FDA is working closely with firms involved in the production of Tc-99m generators to help increase production
- FDA is actively working with nuclear medicine professional organizations to help health care providers stay informed of this situation as it evolves.
- FDA will continue to provide updates on the Tc-99m generator shortage situation on the FDA/CDER Drug Shortage webpage.

What should health care providers do during this shortage?

During the Tc-99m radiopharmaceutical shortage, FDA recommends that nuclear medicine health care providers try to maximize use of available Tc-99m, consider prioritizing clinical diagnostic tests that use Tc-99m, and also consider alternative diagnostic procedures. These recommendations include:

- Prioritize the use of the available Tc-99m to support the most clinically important tests. The importance of a diagnostic test depends on the individual patient and facility needs, the required urgency of the test, and the availability of acceptable alternative tests.

- When scheduling tests, take into consideration the radioactive decay properties of the material used to generate Tc-99m in order to optimize Tc-99m yield. For example, schedule tests throughout the week (to include weekends) to most efficiently use available Tc-99m supplies.

- Consider alternative diagnostic studies when feasible and available. For example, approximately 60% of studies that rely on Tc-99m are used in heart-related procedures, which is a situation where several alternatives may exist.

  Possible alternative diagnostic tests to consider include the following:

  - For coronary artery disease: Thallium-201 gamma scintigraphy, Rubidium-82 positron emission tomography (PET)/computed tomography (CT), Ammonia N-13 PET/CT, echocardiographic stress, or electrocardiographic stress tests.

  - For suspected bone lesions: 18F-Fluorodeoxyglucose PET/CT, Sodium fluoride-18 PET/CT, computerized tomography, or magnetic resonance imaging.

  - For pulmonary emboli: computerized tomographic angiography.

Additional information, including procedure guidelines and potential radiopharmaceutical alternatives for consideration, are available at the following internet addresses:

- Society of Nuclear Medicine: http://interactive.snm.org/
- American Society of Nuclear Cardiology http://www.asnc.org/index.cfm

What do patients need to know during this shortage?

Patients who are scheduled for a nuclear medicine test should be aware that health care providers may need to change appointment times. Health care providers may also change the type of test to be conducted. Patients should talk to their health care provider about their options.

Patients should be aware that the shortage of Tc-99m will not affect the quality of the nuclear medicine tests that are performed using the Tc-99m that is available during the shortage.