Adverse Reactions to Radiopharmaceuticals: The SNM/RSNA USP Drug Product Problem Reporting Program


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To obtain accurate and descriptive data on adverse reactions, biodistribution alterations and other radiopharmaceutical problems, the Radiological Society of North America (RSNA) has joined with the Society of Nuclear Medicine (SNM) and the United States Pharmacopeial Convention (USP), to co-sponsor the USP Drug Product Problem Reporting Program for Radiopharmaceuticals. The USP is a not-for-profit, volunteer organization that is responsible for establishing legally enforceable standards of strength, quality, purity, packaging, labeling and storage for drugs and excipients, and for developing authoritative information on drugs and therapeutics. USP is a partner in MedWatch, the Food and Drug Administration's (FDA) medical products reporting program.

In a study of 3000 randomly selected physicians in many specialties, only 57% were aware of any adverse reaction reporting system (*1*), although the FDA initiated such a system more than two decades ago (*2*). While 14% of the 3000 physicians surveyed had observed an adverse drug reaction in the previous year, only 5% of the total had reported the occurrence. Underreporting may occur because physicians feel they are too busy or believe the reaction is common knowledge. Lack of availability of the USP reporting form also is a reason for failure to report a reaction. This is a problem that we seek to remedy by providing you with the form.

Significant adverse reactions to be reported include:

1. Any adverse effects, whether previously reported frequently or rarely;
2. Adverse effects never before seen or reported following administration of the radiopharmaceutical;
3. Only life-threatening (i.e., requiring hospitalization) or fatal reactions from nonradioactive drug used for pharmacologic intervention, such as dipyridamole, adenosine, furosemide;
4. Anaphylactoid or allergic reactions, proven or suspected;
5. Misadministration.

Reactions not to be reported include:

1. Vasovagal responses, in other words hypotension with bradycardia;
2. Injury from poor injection technique;
3. Deterministic effects from therapy with unsealed sources, such as cytopenia from a beta-emitting therapeutic radiopharmaceutical or neck pain following ^{131}I.

The USP Drug Product Problem Reporting Program for Radiopharmaceuticals form is to be used both for cases where an altered distribution of the radiopharmaceutical is observed and for reporting adverse reactions. As the reporting physician, you have the option to remain anonymous, although it is hoped that you will provide your name, address and phone number. With your help, a member of the Pharmacopeia Committee of the SNM can gather further details that will assist in assigning a level of probability of causation of the adverse reaction to the radiopharmaceutical. This algorithm to categorize probabilities of causation has recently been published (*3*).

Unlike any other reporting program, the USP Drug Product Problem Reporting Program for Radiopharmaceuticals can directly affect the development and revision of USP Standards and Information Monographs. Reported information is shared with the FDA, the product manufacturer, the SNM and the USP Divisions of Standards and Information Development. The reports submitted become part of a database that serves to provide insight into adverse reactions and product problems that can affect the quality of nuclear medicine. This database captures all fields of reported information to allow tracking, analyzing and comparing product problems occurring nationwide.

At the bottom of the second page of the USP reporting form are the address, fax and toll-free number for reporting the radiopharmaceutical problem (see this issue's mailing bag for USP reporting form). E-mail access is www.usp.org/prn. The imaging community should benefit greatly from the information collected in this ongoing collaboration.

REFERENCES

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2. Ford L, Shroff A, Benson W, et al. Society of Nuclear Medicine drug problem reporting system. *J Nucl Med* 1978;19:116-117.
3. Silberstein EB, Ryan J, Pharmacopeia Committee of the Society of Nuclear Medicine. Prevalence of adverse reactions in nuclear medicine. *J Nucl Med* 1996;37:185-192,1064-1067.

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