GUIDELINES FOR THE ADMINISTRATION OF DIAGNOSTIC AND THERAPEUTIC RADIOPHARMACEUTICALS

The following document was prepared by a joint Working Party from the NSW Branch of the ANZSNM and from HURSOG in response to an enquiry from the NSW Radiation Advisory Council (RAC). These guidelines were developed from an analysis of reported incidents and can be used to help departments and practices optimise their own policies and procedures. These Guidelines were adopted by the NSW RAC in 2000.

Definitions

Maladministration "Mistaken administration of a radiopharmaceutical to a patient ... the radiopharmaceutical or its amount or route of administration was inappropriate".....

e.g.
(i) incorrect radiopharmaceutical is administered
(ii) radiopharmaceutical administered to wrong patient
(iii) misinterpretation of request form
(iv) dispensing/reconstituting incorrect radiopharmaceutical or dose

Misadministration "Radiopharmaceutical is correct but performance of its administration is incorrect...."

e.g. (i) extravasation of IV injection
(ii) IV injection into artery

E.D. Williams Editorial
Nuclear Medicine Communications 1995 16, pg 721

Incidents of maladministration arise from a number of sources including labels misread or not read, two patients with the same or similar names, patients where English is a second language or incorrect labelling/measurement of vials or doses.

Appropriate steps should be "….. taken to ensure that the intended agent, in the intended dose, in the intended dosage form is received by the intended patient at the intended time via the intended route of administration..". The Australian Code of Good Radiopharmaceutical Practice 1996 , 835 -836, page 29

Recommended Policies for the Administration of Radiopharmaceuticals

To facilitate accurate and safe administration of radiopharmceuticals, the following policies for administration of radiopharmaceuticals should be in place.

1. Policy: Request form validation

Statement (i) : No test is to be performed without a request form from the referring Medical Practitioner or authorisation from a licensed Nuclear Medicine Physician or Radiologist or Registrar.
All request forms must be checked carefully to ensure that the most appropriate test has been requested and that sufficient information is provided for patient identification. The signature of the referring Medical Officer should be clearly identified.

Statement (ii): For therapies, no treatment dose is to be dispensed without a request form which has been endorsed by a licensed Nuclear Medicine Physician or Radiologist or Registrar. The prescribed activity must be stipulated by a licensed Nuclear Medicine Physician or Radiologist or Registrar of more than 6 months' training.

2. Policy Patient identification

Statement : No patient is to receive a radiopharmaceutical unless two forms of patient identification are verified. The patient's full name, medical record number, DOB and address are valid forms of identification. The patient should tell the person administering the radiopharmaceutical their name. All in-patient identification bands must be checked carefully. This information must be checked against the relevant request form.

3. Policy Female patients of Reproductive Age

Statement (i): All women of reproductive age must be asked whether they could be pregnant before the administration of the radiopharmaceutical. If their status is unclear, consideration must be given to postponing the procedure until after the next menstral period, or to confirming the pregnancy status by a beta-HCG test. It should be noted that pregnancy is not an absolute contraindication to a diagnostic nuclear medicine scan and these could be warranted in certain circumstances (eg, lung scans in pregnancy).

Statement (ii): For therapies, the department or practice must verify the pregnancy status of all women of reproductive age with a beta-HCG result. One should be acquired on the day of treatment; it is preferable to have also determined the beta-HCG result on a separate occasion in the week prior to treatment, however, a careful clinical history is necessary at all times to facilitate accurate interpretation of these laboratory investigations.

Statement (iii): The department or practice should determine whether the patient is breast feeding prior to the administration of the radiopharmaceutical. If the patient is breast feeding, appropriate advice must be given regarding the time necessary to

suspend breast feeding or of the necessity to wean the infant.

4. Policy Radiopharmaceutical reconstitution

Statement: All pharmaceutical and isotope vials must be checked for product identification, content and expiry date. Consult appropriate literature prior to reconstitution of any unfamiliar product. A PDY (Professional Development Year) nuclear medicine technologist with less than 6 months' experience may reconstitute pharmaceuticals only in the presence of a qualified nuclear medicine technologist. Identifying labels with date, expiry time , activity, calibration time, volume and radiopharmaceutical product name should be affixed to the reagent vial and shielding containers. The radiopharmacy records should contain details of all reconstituted radiopharmaceuticals.

5. Policy Radiopharmaceutical patient doses

Statement: All patient doses are to be dispensed within a maximum 10 % variation of the departmental protocol or prescribed activity.
".. Dosage levels are determined based on patient history , age , weight , sex and surface area.." The Australian Code of Good Radiopharmaceutical Practice 1996 , 829 page 28

6. Policy Radiopharmaceutical dispensing

Statement (i): During or after dispensing a patient dose, the radiopharmaceutical and the dispensed activity must be checked against its prescribed activity by the persons dispensing and administering the radiopharmaceutical. A PDY technologist with less than 6 months' experience may dispense patient doses only in the presence of a licensed and accredited nuclear medicine technologist.

All dose labels are to be transferred to the patient's request form, file or work sheet and signed by the person administering the dose.
It is desirable for a second person to check both the patient's identification and the radiopharmaceutical to be administered where possible.
All doses dispensed are to be recorded in the radiopharmacy log.

Statement (ii): Therapeutic doses must be dispensed by, or in the presence of a licensed Nuclear Medicine Physician or Radiologist or Nuclear Medicine Registrar of more than 6 months' training.

7. Policy Aseptic techniques

Statement: Asepsis is to be maintained throughout reconstitution, dispensing , cell labelling and administration procedures.

8. Policy Intravenous injection (diagnostic)

Statement: All Nuclear Medicine Technologists may perform intravenous injections under normal circumstances after appropriate training and/or assessment by a departmental Physician.
Exceptions might include fistula, central lines, QP/QS and stress cardiac studies. Patients with poor venous access may be referred to the Physician, Radiologist or Registrar. The prescribed activity & radiopharmaceutical should be checked by the person undertaking the injection.

In normal circumstances, it is inappropriate for a first year Registrar in Nuclear Medicine or PDY Nuclear Medicine Technologist to administer radiopharmaceuticals unsupervised in the first 6 months of their training.

9. Policy Therapeutic administration

Statement: Therapy doses must be administered by, or in the presence of a licensed Nuclear Medicine physician or Radiologist or Nuclear Medicine Registrar of more than 6 months' training. It is recommended that therapies be preceded by informed consent and patients should be provided with written advice on radiation safety procedures.

Note: More detailed descriptions of Radiopharmaceutical Practice may be referenced in the Australian Code of Good Radiopharmaceutical Practice 1996 , Chapter 8 'Hot Lab Procedures'

Investigation and Reporting of Errors in Radiopharmaceutical Administrations

The NSW Radiation Control Regulation 1993 defines certain events as radiation accidents:

"For the purposes of this Regulation, a radiation accident is to be treated as having occurred if there is an occurrence that involves the misuse of radiation apparatus or maladministration of a radioactive substance used for medical purposes, including:

a)the administration of a radioactive substance for diagnostic purposes in a quantity of more than 50% more than that prescribed;
b)the administration of a radioactive substance for therapeutic purposes at an activity differing by more than 15% from that prescribed;
c)administration of a therapeutic dose of radiation from radiation apparatus or a sealed radioactive source which differs from the total prescribed treatment dose by more than 10%.
d)the unintended administration of radiation as a result of a malfunction of radiation apparatus;
e)administration of a radiopharmaceutical otherwise than as prescribed...."

Once a radiopharmaceutical maladministration has occurred the following procedures must be performed:

1. The person who administered the radiopharmaceutical must immediately inform the Physician on duty and the Chief Nuclear Medicine Technologist (CNMT).

2. The Physician on duty will assess the situation and inform the patient and the referring doctor.

3. The person who administered the radiopharmaceutical must complete the department/practice Incident Form and submit the completed form to the CNMT.

4. For hospital patients, the hospital Medication Incident Form must also be completed. Submit the form to the appropriate staff members according to the hospital's procedures. A copy must be submitted to the CNMT.

5. Departmental investigation and prompt action should follow as soon as possible.

6. Notify the Radiation Safety Officer who will investigate the incident and prepare the required report for the Department's Director and, where appropriate, for the hospital's Radiation Safety Committee and for the Environment Protection Authority.

The report must contain the following particulars:

a) particulars of the incident including the time and the place where it occurred, the persons involved and indicating, as far as is possible, any contributing factors;
b) particulars of any steps taken to mitigate the effects of the maladministration (for example, the administration of stable iodine);
c) particulars of the assessment of the radiation dose to which the patient may have been exposed as a result of the incident, and the potential risks, if any, arising from this exposure.
d) particulars of procedural changes which have been introduced to minimise the risk of a similar incident occuring in the future.

Note: "Contingency plans for dealing with any foreseeable emergency situation involving radioactivity should be written down, displayed and known by personnel."
The Australian Code of Good Radiopharmaceutical Practice 1996 , 804, page 27