Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register

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Abstract

Objective: To describe the incidence, type, causes and consequences of nuclear medicine maladministrations.

Setting and participants: Review of prospectively acquired maladministration reports within the Australian Radiation Incident Register (ARIR), a mandatory incident register managed by the Australian Radiation Protection and Nuclear Safety Agency.

Main outcome measures: Individual reports from 2007 to 2011 were evaluated for dose of radiation exposure and type, cause and consequence of maladministrations. Incidence was estimated using data from Medicare Australia.

Results: There were 149 maladministrations and the estimated incidence was 5.8 per 100 000 nuclear medicine procedures (95% CI, 5.0–6.9). About half of all maladministrations (48%) arose from an incorrect radiopharmaceutical being prepared and/or dispensed. Other causes included mistakenly injecting the wrong radiopharmaceutical because of inattention (n = 27; 18.1%); extravasations, failures in equipment or procedure leading to a non-diagnostic study (n = 25; 16.8%); misinterpreting a request form and performing an incorrect procedure (n = 13; 8.7%); or injecting an incorrect patient (n = 13; 8.7%). ARIR reports focused on active rather than latent causes. Most (n = 147) maladministrations occurred following diagnostic procedures, and the mean effective radiation dose was 7.9 mSv (range, 0.015–45 mSv). Two therapeutic maladministrations likely caused unintended organ injury.

Conclusions: The ARIR provides unique insight into the type, causes and complications of maladministrations in Australia. Nearly all maladministrations occur in a diagnostic context, and the risk of patient harm appears low. Among active causes, radiopharmaceutical preparation and dispensation, and medical supervision before injection merit attention. The ARIR could be refined by attending to latent errors, addressing possible underreporting and securing more complete Medicare data.

In nuclear medicine, a maladministration refers to the wrong patient being injected or the administration of an incorrect radiopharmaceutical type or dosage.[1,2] Although debated, the unintended exposure to ionising radiation from a maladministration may increase the long-term risk of cancer.[3,4] Further, irreversible organ damage has been reported.[5] Hence, nuclear medicine can be hazardous. Australian data suggest that not only is the demand for nuclear medicine increasing but also that it attracts a significant amount of government expenditure,[6] thus highlighting its importance to the community.

Despite the widespread use of nuclear medicine and the potential for harm resulting from maladministrations, there are few publications about the incidence, causes and consequences of maladministrations. Research from other countries[7,8] suggests that maladministrations occur infrequently. However, dissimilar notification criteria and regulatory environments limit their applicability to Australia. A solitary Australian study reported an incidence of 8–9 maladministrations per 100 000 procedures, as well as describing one case in which unintended organ damage occurred.[5] However, data from this study are now 9–13 years old and were sourced only from one state.[5] Alternative statutory and non-statutory data sources are constrained by ambiguous notification criteria,[9] are not truly national in scope,[10] or lack a nuclear medicine focus.[11,12] Thus, there is a paucity of contemporary information about maladministrations, which undermines risk management in nuclear medicine.

In contrast, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has been operating the Australian Radiation Incident Register (ARIR) for several decades as a national repository of data on maladministrations in nuclear medicine.[13] The national scope, explicit notification criteria and mandatory obligation on regulatory bodies to report are unique features and suggest that the ARIR could be the best source of information about maladministrations in Australia. Despite this, an analysis of the ARIR has never been conducted. A review is fundamental to managing risk in nuclear medicine, and the aim of our research is to describe maladministrations reported in the ARIR between 2007 and 2011.

Methods

Australian state and territory radiation protection authorities notify ARPANSA according to certain criteria, including situations when the administered radioactivity exceeds the prescribed dose by more than 50% for diagnostic procedures and by more than 15% for therapies. Further, any procedure administered to an incorrect patient or tissue, involving an incorrect radiopharmaceutical type, or delivered in a manner other than prescribed must also be notified. Other maladministrations that meet the general definition[1,2,8] are notified according to the discretion of the relevant radiation protection authority.[14]

We obtained permission from ARPANSA to study anonymised summaries of individual maladministration cases from 2007 to 2011. These describe the nature and type of individual maladministrations, the years in which they occurred, possible causes and consequences, and the excess radiation dose. Incidents such as radioactive spills were excluded from further analysis.[1,2,8] One of us (G L) categorised maladministrations into five types using previous publications (Box 1).[2,5] Where the narrative permitted, causes of maladministrations were classified as active and/or latent[15,16] according to error classification guides[17] and professional codes

1 Examples of types of nuclear medicine maladministrations

Maladministration type and description	Example
Type 1: Several radiopharmaceuticals are simultaneously prepared for a number of patients, but the incorrect syringe is used for a patient, either because it has not been labelled or its label is misread or not read.	A patient scheduled for a bone scan was due to receive 1000 MBq of Tc-99m HDP. However, the technologist collected a nearby syringe appropriately labelled with the name and activity of a different radiopharmaceutical (1000 MBq of Tc-99m sestamibi) and injected the patient. The ARIR report indicated that the patient was "uncooperative" and that the staff were concerned about the possibility of losing venous access if there had been a delay in injection. The effective dose was 8.5 mSv.
Type 2: A radiopharmaceutical administered to an incorrect patient because two or more patients have the same or similar names, or a procedure is inadvertently requested for an incorrect patient.	A bone scan was requested for a patient. However, the referring doctor inadvertently attached another patient's label to the request form and this patient attended the department. Clerical and technologist staff confirmed the identity of the presenting individual, but there was no pre-procedure medical review and thus no serious attempt to reconcile the individual's clinical details with the information on the request form. The effective dose was 4.5 mSv.
Type 3: A wrong type or dose of radiopharmaceutical is dispensed.	Two patients were referred for biliary scans; however, 125 MBq of thallium-201 chloride (a myocardial perfusion agent) was inadvertently prepared at a commercial radiopharmacy laboratory. The effective dose was 45 mSv.
Type 4: An incorrect procedure is performed because the request form is misinterpreted.	A patient referred for a bone mineral densitometry test incorrectly received 763 MBq of Tc-99m HDP because the referral was misinterpreted. The effective dose was 4.35 mSv.
Type 5: The correct radiopharmaceutical is administered either to the wrong organ, extravasated or the procedure cannot be undertaken as intended because of a fault in equipment.	Two patients received 330 MBq of fluorine-18 fluorodeoxyglucose in preparation for a positron emission tomography scan; however, subsequent to injection, the bed gantry system failed and the patients could not be imaged. The effective dose was 6 mSv.

ARIR = Australian Radiation Incident Register. HDP = hydroxydiphosphonate. MBq = megabequerels. mSv = millisieverts. Tc = technetium. ◆

2 Annual number and estimated incidence of nuclear medicine maladministrations, 2007–2011

Year	Maladministrations reported	Nuclear medicine procedures*	Incidence (95% CI)†
2007	16	468 693	3.4 (2.1–5.6)
2008	40	508 648	7.9 (5.8–10.7)
2009	23	518 991	4.4 (2.9–6.7)
2010	33	502 541	6.6 (4.7–9.2)
2011	37	553 640	6.7 (4.8–9.2)

* Medicare Benefits Schedule data. † Per 100 000 procedures. ◆

of practice.[18] Individual effective (whole-body) radiation exposure in millisieverts (mSv) was estimated using International Commission on Radiological Protection reports.[19-22] Our research was approved by the University of New South Wales Human Research Ethics Committee.

Maladministration numbers, contributing to the numerator in the ARIR, reflect what has been reported to ARPANSA and are derived from all nuclear medicine procedures, including those from Medicare Benefits Schedule (MBS) data,[6] as well as those for which there is no MBS benefit, such as studies on uninsured hospital inpatients and positron emission tomography. While all facilities are required to report maladministrations, it is possible that reports catalogued in the ARIR do not represent all the maladministration incidents that occur.[7,23] The only available denominator, derived from MBS data, thus comprises a subset of all nuclear medicine procedures in Australia. Therefore, the maladministration incidence rate should be regarded only as an estimate. Pearson χ^2 and logistic regression tests (SPSS, version 18 [IBM]) were undertaken to compare incidence rates between years and over the 5 years. A P value of < 0.05 was considered significant. A log linear model was used to calculate 95% confidence intervals.

Results

In total, 149 maladministrations were reported: 16 in 2007, 40 in 2008, 23 in 2009, 33 in 2010 and 37 in 2011. All but two were diagnostic in nature. There were 2 552 513 nuclear medicine procedures recorded by Medicare over this period: 337 999 diagnostic non-imaging, 2 194 063 diagnostic imaging and 20 451 therapeutic nuclear medicine procedures. The incidence of maladministrations for the 5 years was 5.8 per 100 000 procedures (95% CI, 5.0–6.9 per 100 000). In 2007, the incidence of reported maladministrations was lower than in 2008–2011 ($\chi^2 = 11.2$; 4 degrees of freedom [df]; $P = 0.02$) (Box 2), but there was no linear trend in the maladministration reporting rate from 2007 to 2011 ($P = 0.14$). There was no difference in the rate of diagnostic and therapeutic maladministrations ($\chi^2 = 0.08$; 1 df; $P = 0.78$).

About half of all maladministrations arose from an incorrectly prepared and/or dispensed radiopharmaceutical (Box 3). Of these, a little over half originated from a commercial laboratory. In descending order, other maladministrations derived from an incorrect syringe, an inability to obtain diagnostic images because of technical failures and extravasations, and either an incorrect patient or incorrect test (Box 3). In 10 of 13 cases in which an incorrect patient was examined, as well as in all maladministrations involving the wrong procedure, we inferred from the ARIR narratives that, with two exceptions, there had been no review of the patient by a nuclear medicine specialist before radiopharmaceutical administration.

Only 58 reports (39%) identified possible latent causes. These included a facility culture in which patients did not have specialist review before radiopharmaceutical administration to verify the appropriateness of the requested procedure or to confirm that the presenting individual's history matched the clinical details on the request form ($n = 21$; 14%); deficient departmental policies or lack of communication on radiopharmaceutical quality control measures or labelling of syringes ($n = 14$; 9%); faulty internal communication about a failed radiopharmaceutical being inadvertently used ($n = 7$; 5%); deficient induction, training and supervision of new staff ($n = 5$; 3%); extreme workloads and staff shortages ($n = 4$; 3%); equipment failure ($n = 3$; 2%); and other factors relating to training, uncooperative or non-English-speaking patients, and ambiguous or illegible requests ($n = 4$; 3%).

The effective radiation dose was calculated in 147 patients. The mean effective dose was 7.9 mSv (range, 0.015–45 mSv). Fifty-one patients received a dose > 10 mSv, and three received a dose of > 20 mSv. Most maladministrations involved technetium-99m (Box 4).

Two therapeutic maladministrations were recorded. In the first case, a patient with a malignancy received improperly constituted radiolabelled tin-117. Although an effective dose could not be calculated, we suspect that there was a significant absorbed dose to bone marrow and likely adverse haematopoietic consequences. The ARIR report indicated that the patient had a limited life expectancy due to an existing illness, but the effect of the maladministration on short-term clinical status was not recorded. In the second case, a patient with hyperthyroidism received a dose of potassium iodide (iodine-131) that exceeded the requested dose by 50%, which probably increased the long-term risk of developing hypothyroidism.

3 Frequency of active causes of nuclear medicine maladministrations ($n = 149$)

Type	Description	No. (%)
1	Correct label affixed to syringe, but this was either misread or not read	25 (17%)
	No label attached to syringe	2 (1%)
2	Request for procedure inadvertently made by referring doctor for an incorrect patient	10 (7%)
	Incorrect procedure for confirming patient identity	3 (2%)
3	Incorrect radiopharmaceutical prepared	45 (30%)
	Unexpected failure in radiochemical labelling leading to a non-diagnostic scan	9 (6%)
	Incorrect quality control undertaken	9 (6%)
	Administered radioactivity did not conform with what was prescribed	6 (4%)
	Radiopharmaceutical that had previously failed quality control inadvertently used	2 (1%)
4	Incorrect test undertaken	13 (9%)
5	Diagnostic images not obtained	11 (7%)
	Extravasated radiopharmaceutical	7 (5%)
	Equipment failure after radiopharmaceutical injection	3 (2%)
	Failed or incomplete stress test	3 (2%)
	Incorrect organ injected	1 (1%)

Discussion

The ARIR offers unique information about the types, causes and consequences of nuclear medicine maladministrations in Australia. We estimated the incidence of maladministrations to be 5.8 per 100 000 procedures (95% CI, 5.0–6.9). The mean effective radiation dose was 7.9 mSv and, in two cases, unintended organ damage is likely to have occurred. The pattern of reported errors highlighted that certain tasks, such as the preparation and/or dispensation of radiopharmaceuticals and medical supervision of procedures, are vulnerable and merit greater attention.

Our study suggests that maladministrations occur infrequently, and there was no trend for an increase in incidence over the study period. The variation in incidence between years probably reflects the fact that in some years a solitary dispensation error affected multiple patients. Reports from other countries have indicated a maladministration incidence of 0.6^{8} to 30^{7} per 100 000 nuclear medicine procedures but, as with our report, these figures should be considered estimates. A particular challenge in Australia is that there is a two-step reporting process in which notifications are made first to jurisdictional radiation protection authorities and second to ARPANSA. Australian states and territories have a mandatory requirement to report maladministrations to ARPANSA using the same criteria.[14] In contrast, individual facilities face different reporting requirements and non-uniform notification criteria at the state and territory level, thus indicating potential for underreporting at the first step. In other disciplines, underreporting of adverse events can be as high as 50%.[23] In nuclear medicine, one report has suggested that as few as 13% of maladministrations are eventually notified.[7] Therefore, research is warranted to determine the extent of underreporting and to identify barriers to notification in Australia.

The mean effective radiation dose was low, reflecting that nearly all maladministrations occurred within a diagnostic context. Although few patients were exposed to significantly more radiation, from a public health perspective, the risk of carcinogenesis is minuscule when compared with the number of correctly performed nuclear medicine and radiology procedures.

4 Type and frequency of radioisotopes involved in maladministrations ($n = 149$)

Type	No. (%)
Technetium-99m	124 (83%)
Molybdenum-99	7 (5%)
Fluorine-18 fluorodeoxyglucose	4 (3%)
Gallium-67 citrate	2 (1%)
Carbon-14 urea	2 (1%)
Other	10 (7%)

For example, it has been suggested that over 400 cancers per year in Australia can be attributed to correctly performed radiology procedures,[24] whereas the estimated risk from maladministrations is about one excess cancer per 10 000 incidents.[10] In contrast, therapeutic maladministrations, while less numerous in our series, represent a more tangible threat to patient safety. Although the ARIR narratives lack a complete clinical context, the radioactive dose and radiopharmaceutical types (tin-117 and iodine-131) suggest that two patients probably experienced organ damage. In one case, a higher radioactive dose of iodine-131 was administered, which could have increased the risk of eventual hypothyroidism (although hypothyroidism occurs often after treatment with iodine-131, it is not invariable).[25] In the second case, a patient with an underlying malignancy and limited life expectancy received a therapeutic maladministration of tin-117. Due to the high administered radioactive dose, it is likely that there was an effect on bone marrow function, although further details about the clinical impact were unavailable. Nevertheless, outcomes such as these emphasise the importance of seeking additional improvements in underlying individual and systemic causes of maladministrations.

Nearly half of all maladministrations arose from faults in radiopharmaceutical preparation and dispensation. This is similar to previous observations.[5,8] In the ARIR, we identified about half of this maladministration type as originating from commercial suppliers, which is similar to a report from Texas in the United States.[8] In part, this reflects the increasing role that commercial entities have assumed in the manufacture and supply of radiopharmaceuticals. In addition, a small but recognisable latent cause of maladministrations related to tests on incorrect patients or arising from misinterpreted request forms. We infer from the ARIR narratives that these maladministrations may have been prevented by a nuclear medicine specialist reviewing the patient before the radiopharmaceutical was administered. Reconciling the patient's clinical history with the information on the request form requires specialist medical review and conforms with professional codes of practice.[18]

Refinements to the ARIR may be necessary. First, understanding latent rather than active causes is fundamental to rectifying medical errors.[15,16] However, the ARIR summaries identified latent causes in only 39% of cases. This suggests that revisions to the type of information mandated in reports should be considered. Second, calculation of maladministration incidence is problematic. One solution may be for the Australian Government Department of Health and Ageing and specialist nuclear medicine organisations to collaborate with ARPANSA in the supply of aggregate data on the number of positron emission tomography and non-billed procedures, respectively. However, care to uphold confidentiality and avoid double counting would be needed.

In summary, the ARIR offers unique insight about nuclear medicine maladministrations. We estimate that there are around 6 maladministrations per 100 000 procedures and believe that the risk of harm is low. Our findings highlight certain vulnerabilities relating to radiopharmaceutical preparation and/or dispensation and pre-administration checking procedures. More attention to latent causes, consideration of possible underreporting, and securing more comprehensive MBS data may refine the ARIR.

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