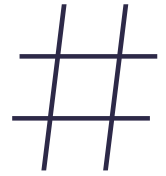
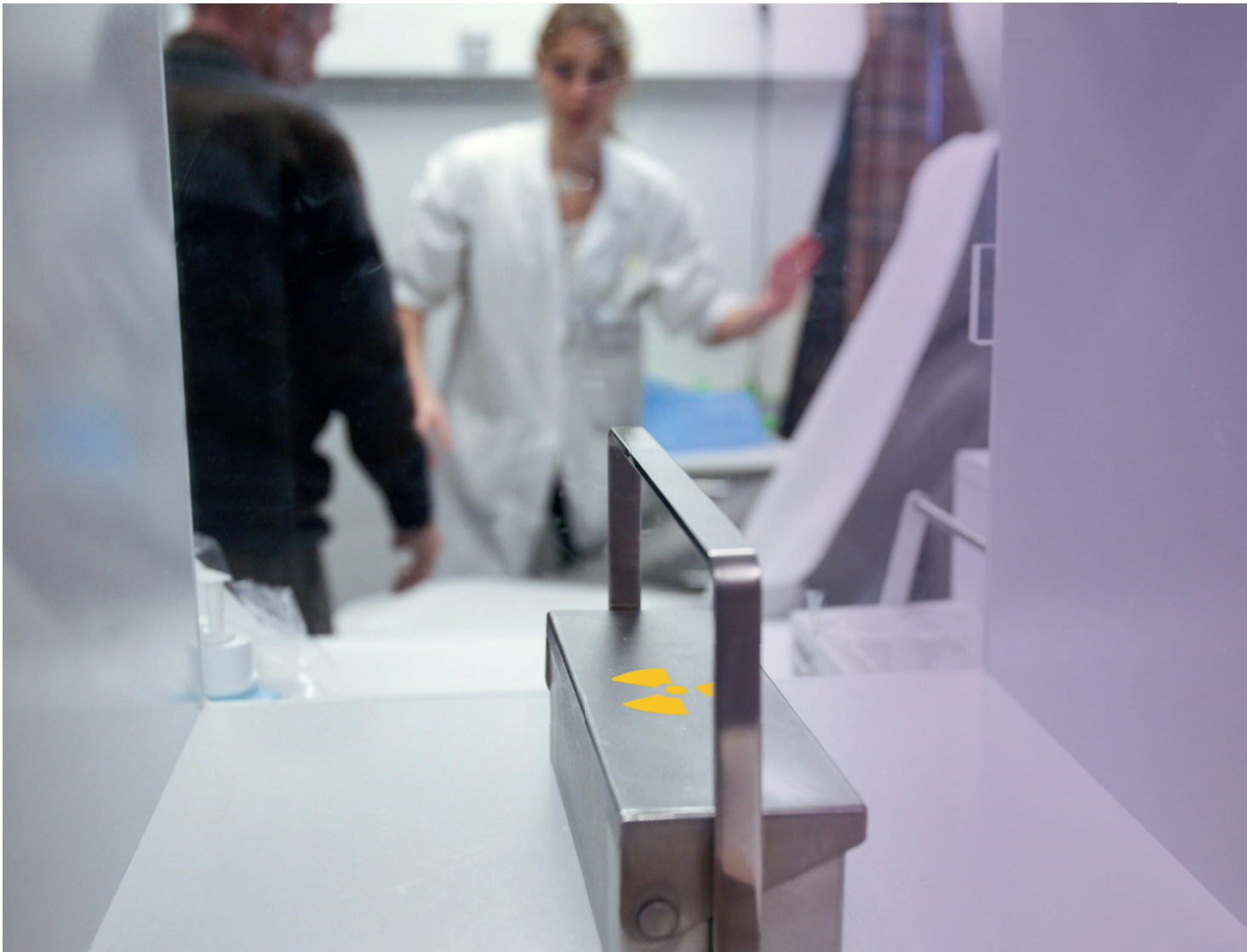


PATIENT SAFETY

PAVING THE WAY FOR PROGRESS



March 2020



SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE

Newsletter for nuclear medicine professionals



EDITORIAL

In July 2016, ASN published recommendations on the handling and administration of radiopharmaceuticals, further to a study carried out by IRSN on the basis of direct observations of work situations.

Today, errors in the activity or type of administered radiopharmaceuticals still represent three-quarters of the significant radiation exposure events reported to ASN in diagnostic nuclear medicine. This is why a multi-professional working group bringing together the professional societies of nuclear medicine decided to examine the question of the medication circuit in-depth.

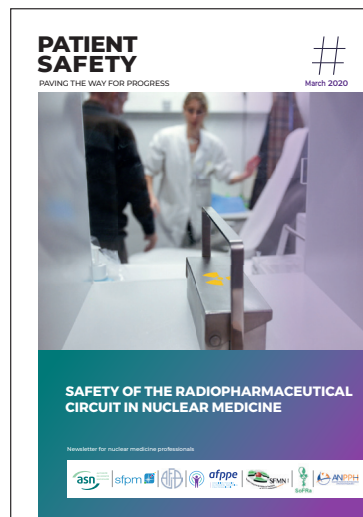
Administration of the right radiopharmaceutical with the right activity dose to the right patient requires the fostering of training, communication between professionals and continuity in tasks. This “Patient safety” issue tells you about the organisational changes adopted by the Albi Hospital Centre further to a radiopharmaceutical administration error, and the actions to secure the radiopharmaceutical circuit in the University Hospital Centres (CHU) of Martinique and Bordeaux.

Experience feedback can provide useful inputs to review the risk analyses in your services, as required by the recent quality assurance obligations in medical imaging¹.

We wish you enjoyable reading!

The Editorial Team

1 - ASN resolution 2019-DC-0660 of 15 January 2019



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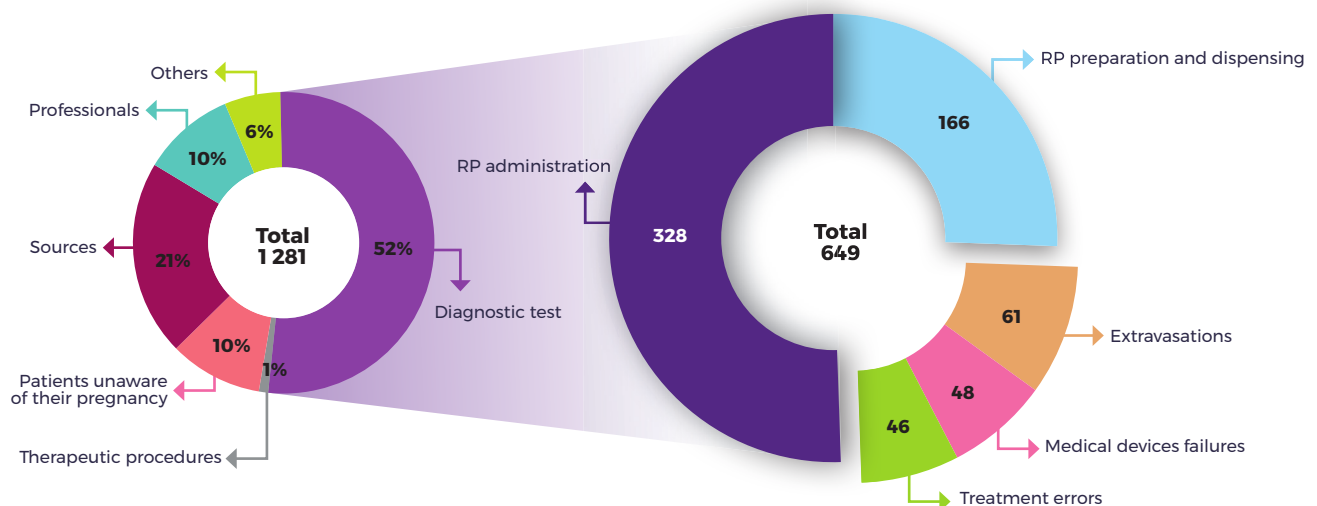
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Key figures

With some 1.5 million procedures per year, nuclear medicine sees a steady increase in its activity. ASN receives about 150 significant radiation exposure event notifications per year in nuclear medicine, which represents 1 event notification for 10,000 examinations.

BREAKDOWN OF ESRS IN NUCLEAR MEDICINE (2007 TO 2019)



More than half of the events concern patients undergoing a diagnostic test, and among these, three-quarters are related to radiopharmaceutical errors.

These events are most often linked to radiopharmaceutical administration and identity vigilance errors, or to deficiencies in the preparation and dispensing of the radiopharmaceutical. They can concern several patients (in the case of an error in multi-dose vials).

Although in the majority of cases these events had no clinical consequences on the patient due to the

low injected activities, they have an impact on the management of each patient and the organisation of the services. In practice, the services give a new appointment. The error leads to a new injection of radiopharmaceutical drugs and as a result to additional exposure, especially if the scintigraphic examination is coupled with a computed tomography scan.



Decoding the events

DIFFERENT TYPES OF ERRORS FOUND AT ALL THE STAGES OF THE RADIOPHARMACEUTICAL CIRCUIT AND THE PATIENT CARE PATHWAY

■ RADIOPHARMACEUTICAL CIRCUIT

- 1. Preparation errors:** choosing the wrong kit, error in the radiolabelling procedure (associated with incorrect heating for example) not detected before administration.
- 2. Dispensation errors:** use of the wrong vial in the shielded enclosure, incorrect sampled activity, syringe labelling error, syringes prepared too soon, resulting in decreased activity dose which no longer corresponds to the prescription.
- 3. Administration (injection) errors:** lack of an identity monitoring check before injection, due to no active questioning of the patient and/or no check of the matching name on the syringe label and the name of the patient.

■ PATIENT CARE PATHWAY

- 1. When taking the appointment:** homonym names resulting in the wrong examination being scheduled for a patient, error in the indicated weight of the patient resulting in the preparation of the wrong dose.
- 2. When the nuclear physician prescribes:** inadequate checking of the clinical justification for the examination request, of the radiopharmaceutical or of the activity dose prescribed.
- 3. When administering the injection:** see “radiopharmaceutical administration (injection) errors” opposite.



Steps for progress

1. Good practices

Put in place an organisation that improves continuity in the tasks and check the interoperability of the medical devices.

■ PHARMACEUTICAL VALIDATION

- Analyse and validate the prescribed activity dose and radiopharmaceutical before the beginning of any radiopharmaceutical syringe preparation.

■ RADIOPHARMACEUTICAL PREPARATION

- Limit the number of different preparations in a given shielded enclosure:
 - Plan the appointments by type of examination over a given day or half-day;
 - Promote dedicated daily work programmes to limit the diversity of tasks.
- Clearly label the radiopharmaceutical vials and the syringes as soon as their preparation is completed;
- Only keep vial(s) that are currently being used in the shielded enclosure;
- Prepare the syringes as shortly as possible before their administration to the patients;
- Limit the number of syringes in the air lock compartment between the preparation room and the injection room;

- Perform a release verification of the radiopharmaceutical syringes.

■ COMMUNICATION BETWEEN THE TEAM PROFESSIONALS

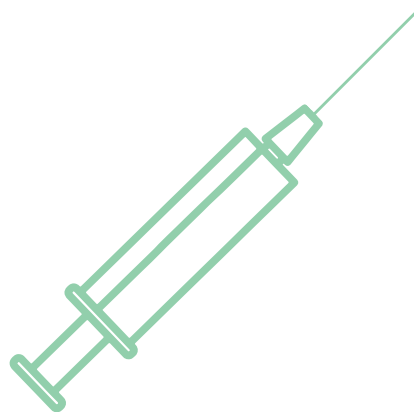
- Ensure the team members are aware of each person's individual constraints;
- Ensure coordination between the professionals to be sure that the prepared syringe is available when the patient is ready for his injection;
- Promote the use of a shared professional language;
- Ensure that the procedures are written and followed by all.

■ HEALTHCARE TEAM TRAINING

- Introduce a workstation empowerment procedure, including the specifics of the medical devices used, with periodic reassessment;
- Plan for a mentoring period for newcomers;
- Carry out a risk assessment prior to any organisational or technical change in order to accompany its introduction.

■ RADIOPHARMACEUTICAL ADMINISTRATION

- Always actively question the patients or relatives in the case of paediatric patients, before any radiopharmaceutical injection;
- Carry out random identity monitoring audits.



Methodological benchmarks

THE ANALYSIS OF AN EVENT IS BASED ON 4 KEY POINTS:
(see Further reading section)

- 1. Exhaustive tracing back of the event sequences / full description**
- 2. Analysis of the root causes by a multidisciplinary team**
- 3. Use of an approved methodology**
- 4. Set out a precise corrective action plan (coordinator, schedule, assessment)**

2. Innovative initiative

In May 2018, the Martinique CHU put in place a barcode system to secure the radiopharmaceutical circuit.

Containers that look alike, leads to take one kit for another: a succession of significant radiation exposure events since 2016 led the team to change local organisation change.

The barcode system was chosen to secure the medication circuit from reception of the radiopharmaceutical products to administration of the radiopharmaceutical to the patient.

An interface has been set up between the barcode readers and the radiopharmacy software Venus®.



“A simple technical solution to prevent the recurrent errors in the radiopharmaceutical circuit”

*Nathalie RIZZO-PADOIN
Laurent MORET
Radiopharmacists
at the Martinique CHU*



In practice

HOW DO YOU USE THE BARCODE SYSTEM ?

As soon as the kits are received, a label is produced and assigned affixed to each vial, indicating the name of the speciality and the batch number. To avoid an error at this stage, the radiopharmacist makes a second check. The barcode is then scanned at the start of each preparation step by the hospital pharmacy technicians, then it is scanned on each syringe by the radiographers before being administered to the patient. The software triggers an alert if there is a mismatch between the scanned barcodes and the data recorded in the Venus® software.

WHAT ARE THE COSTS AND CONSTRAINTS OF THIS SYSTEM?

The main constraint is the large space needed in the shielded enclosure, which is already limited. The system costs about €2,000 for two barcode readers, a label printer and the setting of the Venus® software parameters. This is a small expense compared with mobilising an extra person for systematic double checking. Training of the hospital pharmacy technicians and radiographers for using the barcode readers is ensured in-house by the radiopharmacist and then their ability is checked.

AFTER USING THIS SYSTEM FOR A YEAR-AND-A-HALF, WHAT ARE YOUR CONCLUSIONS ABOUT IT?

The barcode system is not time-consuming and it has proved its effectiveness: according to the pharmacy technicians, some ten errors have been avoided since it was put in place. It can however be overridden in the Venus® software to avoid being blocked in the event of a hardware or computer failure. Furthermore, it is important not to rely entirely on computing aids and to continue to read the labels. We are now considering a second step to enhance identity monitoring by coupling the system with a patient's badge.



The experience of the centres

“Our entire organisation has been revisited to avoid the tasks disruption in the hot lab”

Nuclear medicine service of the Albi Hospital Centre



From left to right: Sabine COUTANT, radiographer and nuclear medicine service RPE-O; Fabrice REZUNGLES, head of the nuclear medicine service; Lillian WHITFIELD, hospital RPE-O; Claire MAHEU, medical officer of health and risk management coordinator, Elisabeth VAXELAIRE, senior healthcare manager.

■ In March 2019, a patient who came for a renal scintigraphy examination was injected by error with a syringe containing NephroMAG® instead of Renocis®. Which organisational factors were deficient?

On that particular day, one of the scheduled patients arrived early. The radiographer who received this patient called the hot lab to ask for the corresponding preparation to be prepared ahead of schedule.

The telephone call disrupted the organisation of the radiographer in the hot lab. He did not place the vial from the preceding preparation in the enclosure access air lock. Consequently, contrary to normal practice, several vials were located in the shielded enclosure. The radiographer made up the new preparation using the vial that was

in front of him, as an automatic reflex, without checking that it was the right one.

■ What emerged from the analysis of the root causes of the event?

The analysis was carried out by the entire nuclear medicine team, assisted by the risk management coordinator. We had a big discussion on the tasks disruptions, which can be particularly problematic in the hot lab. Avoiding breaks in tasks was already our priority in 2017 when we reviewed the organisation of the service. We opted for dedicated daily work programmes to limit the risk of errors. This organisation concerns the radiographers (preparation or injection) and the nuclear physicians (one expert per gamma camera and for the PET scanner).

■ What corrective actions have you implemented?

Our reflection focused above all on the management of exceptional situations. In first-line treatment, the schedule of the day must be maintained. If taking a patient ahead of schedule is envisaged, it is now the hot lab radiographer who gives their consent to take on the patient and not the person at the reception desk.

The telephone has been replaced by an interphone which is more practical because there is no need to withdraw the hands from the glove box to answer: task disruption is limited. Furthermore, the radiographer does not answer the interphone during the activity peak between 8 a.m. and 10 a.m.; it is the radiopharmacist who takes any calls.

The organisation within the hot lab has been revisited to limit



Further reading

RADIOPHARMACEUTICAL DRUGS

- ASN recommendations regarding the handling and administration of radiopharmaceutical drugs (RPD), circular letter of 26 July 2016.
<https://www.asn.fr/Professionnels/Activites-medicales/Medecine-nucleaire/Lettres-circulaires-en-medecine-nucleaire/Manipulation-et-administration-des-medicaments-radiopharmaceutiques>
- Interruptions in tasks when administering medication, aid for improving professional practices, French National Authority for Health (HAS), January 2016.
https://www.has-sante.fr/jcms/c_2618396/fr/interruptions-de-tache-lors-de-l-administration-des-medicaments

- Radiopharmaceutical drug preparation and administration equipment for nuclear medicine. Technical comparisons of the Joint SFPM-SoFra Working Group, November 2019
<http://www.sfpmp.asso.fr/download/index.php?act=download&id=209>
- Diagnostic exploration dosimetry in Nuclear Medicine SFPM Report No. 33, June 2017.
http://documents.sfpmp.fr/docs_sfpmp/sfpmp_2017-33_rapport_dosi_diag_mn.pdf
- Radiation Dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances. ICRP Report No. 128, June 2015.
www.icrp.org/publication.asp?id=ICRP%20Publication%20128

task diversity: the radiographer prepares the radiopharmaceutical medicines for patients scheduled for the two gamma cameras and the radiopharmacist prepares them for the PET scanner. A systematic double-check by the radiopharmacist of the renal scintigraphy preparations has been put in place.

■ What advice would you give our readers to avoid radiopharmaceutical preparation errors?

We have identified three fundamental principles:

- put in place an organisation that fosters task continuity with dedicated work programmes for the day;

- have clear instructions for the occasional treatment of patients ahead of schedule;
- promote qualification of the personnel in the hot lab and in the use of the various medical devices.

“The right dose to the right patient at the right time”

Dr Frédéric DEBORDEAUX
Radiopharmacist
South Hospital Group, Bordeaux CHU



■ What are the impacts of this organisation?

The double validation implies the availability of the nuclear physician and the radiopharmacist in case of emergency, or a change in the dose or the prescribed examination. The medical and pharmaceutical on-call duty system already in place in the service is vital to allow a prompt response.

We have had to adapt our computing tools to interface the appointments software with the radiopharmacy software (Vénus®) and to deploy a simple and ergonomic prescription module to facilitate computerised medical validation.

■ How would you sum up the results of this organisation?

The organisation is reassuring because it limits situations that can result in accidents. Furthermore, it is the physicians and radiopharmacists who assume the responsibility. We must nevertheless remain vigilant, particularly by actively verifying the patient's identity.

■ You have decided to enforce medical justification and a systematic pharmaceutical check before administering any radiopharmaceuticals. Why?

Our centre has the particularity of combining diagnostic, therapeutic and cellular labelling activities in a university environment. We moreover attach particular importance to quality management. The safety of the medication circuit has been gradually enhanced on the initiative of the radiopharmacists, further in particular to a significant event in paediatrics.

■ How is this reflected in practice?

The examination requests for the next day are transferred to the software in the evening.

Each line of the program must indicate a medical prescription with the appropriate activity dose according to the weight, size and profile of the patient, and a pharmaceutical validation. These criteria are mandatory in order to secure the system.

Each morning, the on-call radiopharmacist checks the organisation of the preparation station within the shielded enclosure, particularly to avoid mix-ups vials. The radiopharmacist almost always performs a release check of the preparations (pH, appearance, energy peak, radiochemical purity). The radiographer then performs a visual check when preparing the syringes (absence of particles of septum, etc.).

RISK MANAGEMENT

■ Newsletter “Patient safety – Paving the way for progress” produced by multidisciplinary working groups coordinated by ASN:

- Patient identification, March 2011

- “How do you analyse your significant radiation protection events?” July 2012

<http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals>

■ ASN resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance obligations for medical imaging involving ionising radiation and in diagnostic nuclear medicine

<https://www.asn.fr/Reglementer/Bulletin-officiel-de-l-ASN/Activites-medicales/Decisions-reglementaires/Decision-n-2019-DC-0660-de-l-ASN-du-15-janvier-2019>

PATIENT SAFETY

MARCH 2011 - PATIENT IDENTIFICATION

NOVEMBER 2011 - THE FIRST VERIFICATION SESSION

JULY 2012 - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

APRIL 2013 - WHAT EVENTS MUST BE NOTIFIED TO ASN?

DÉCEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MARCH 2015 - RECORD AND VERIFY: RECORDING ERRORS!

JUNE 2015 - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

MAY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

DECEMBER 2016 - PROTRACTION / FRACTIONATION

SEPTEMBER - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

JUNE 2018 - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION

MARCH 2019 - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

JULY 2019 - IMPROVING THE USE OF CT SCANNER FUNCTIONS

MARCH 2020 - SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE