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Patient safety in nuclear medicine: identification of key strategic areas for vigilance and improvement

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Objective **To determine the types of patient safety incidents and associated harm in nuclear medicine practice.**

Methods **This study included 147 patient safety incidents related to nuclear medicine practice and submitted to the incident reporting system of a tertiary care nuclear medicine department between 2014 and 2019.**

Results **The top-three incident types according to the International Classification for Patient Safety (ICPS) were medication/IV fluids (36/147, 24.5%), clinical administration (28/147, 19.0%), and clinical process/procedure (27/147, 18.4%), altogether comprising 61.9% of incidents. Within the medication/IV fluids domain, half of incident subtypes were attributable to supply/ordering, omitted medicine or dose, and wrong dose/strength of frequency. Within the clinical administration domain, appointment and wrong patient represented the majority of incident subtypes. Within the clinical process/procedure domain, the majority of incident subtypes fell in the categories: specimens/results and incomplete/inadequate. There was no patient harm in 145 (98.6%) of cases, mild patient harm in 1 (0.7%) case, and in 1 (0.7%) case, it remained unclear if there was patient harm. In 4 (2.7%) cases, a Prevention Recovery Information System for Monitoring and Analysis evaluation was performed because of the high risk of reoccurrence and patient harm.**

Conclusions **The majority of patient safety incidents in nuclear medicine occur in three main ICPS categories (medication/IV fluids, clinical administration, and clinical process/procedure, in order of decreasing frequency). These can be considered as key strategic areas for incident prevention and patient safety improvement. Nevertheless, the rate of actual patient harm was very low in our series.** *Nucl Med Commun* **41: 1111–1116**

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Introduction

Patient safety is a crucial element of high-quality healthcare. It has been defined as the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum [1]. However, errors are very common in healthcare. In the United States, the number of deaths attributable to errors has been reported to be as high as 251 454 per year, ranking third behind cancer and heart disease [2]. These data underline the necessity to prioritize efforts to reduce errors and improve patient safety. Research on patient safety has considerably increased after publication of the seminal work "To Err is Human" by the Institute of Medicine in 1999 [3]. Patient safety has been put in the spotlights by several medical disciplines, including radiology [4–6], but the topic has remained relatively underreported in the field of nuclear medicine.

A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient [1]. The Institute of Medicine recommends the development and use of incident reporting systems (IRSs) in healthcare. An IRS may provide frontline caregivers a mechanism to raise concerns, providing voice to these clinicians that management can work to mitigate [7]. As such, IRSs have an important influence on improving patient safety [7]. Previous studies have analyzed IRS data in the settings of primary care [8], general hospital care [9], and medical specialty care including radiology [10,11]. However, there is currently a lack of literature on the yield of an IRS for patient safety incidents in clinical nuclear medicine. Such data can provide valuable insights into how and why patients can be harmed in nuclear medicine practice. Evaluation of the most frequent types of patient incidents and those that actually caused harm may identify key strategic areas for patient safety improvement.

The purpose of this study was therefore to determine the types of patient safety incidents and associated harm which occur in nuclear medicine practice, using the IRS of a tertiary care nuclear medicine department.

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Materials and methods

Study design and incident reporting system

This study was approved by the local institutional review board (number: 2020/016), and the requirement for informed consent was waived. The University Medical Center Groningen is a tertiary care and teaching hospital that provides healthcare services to more than 2 million people in the north-east of the Netherlands. It is the only referral center for tertiary care in this region, and its key priorities are acute care, pediatrics, chronic patients, oncology, psychiatry, the elderly, and transplantations. The far majority of imaging requests for nuclear medicine procedures involve oncologic, infectious/inflammatory, and neurological indications, predominantly in adults, and they are requested by medical specialists, residents, and nonspecialist medical doctors who work in our hospital. In line with the Dutch Healthcare Quality, Complaints and Disputes Act [12], the department of nuclear medicine has an IRS in place. This IRS is managed by an expert team that consists of two quality officers, a safety officer, a medical physicist, a nuclear medicine physician, a logistic planning specialist, a radiation safety expert, a hospital pharmacist, and a nuclear medicine technologist. Both intramural and extramural healthcare professionals can submit patient safety incidents related to nuclear medicine practice in the University Medical Center Groningen to this IRS on a voluntary basis. Submission, handling, and archiving of all patient safety incidents are completely on a digital, paperless basis. All submitted cases are handled by the expert team that gathers information from all parties involved, assesses if any patient harm occurred, determines the need for additional analysis according to the Prevention Recovery Information System for Monitoring and Analysis (PRISMA) method (deemed necessary in the case of high risk of reoccurrence and potential patient harm) [13], gives an advice for patient safety improvement to all relevant parties involved, and documents each case in an anonymized database. All cases that were stored in the most recent 5-year IRS database (October 2015–November 2019) were potentially eligible for inclusion in this study. Cases were excluded if they were not considered a patient safety incident by the expert team. Duplicate cases were also excluded.

Evaluation of patient safety incidents

Patient safety incidents were reviewed by consensus of two radiologists (Ö.K. and T.C.K.). and categorized according to the WHO's International Classification for Patient Safety (ICPS) [1,14–16]. According to the ICPS, there are 13 incident types: clinical administration, clinical process/procedure, documentation, healthcare-associated infection, medication/IV fluids, blood/blood products, nutrition, oxygen/gas/vapor, medical device/equipment, behavior, patient accidents, infrastructure/building/fixtures, and resources/organizational management [1,14–16]. Each incident type can be divided into different subcategories that are described in more details elsewhere [1,14–16]. Subsequently, patient harm severity of each incident was classified according to the definitions of the WHO as none (i.e., outcome was not symptomatic or no symptoms were detected and no treatment was required), mild (i.e., patient outcome was symptomatic, symptoms were mild, loss of function or harm was either minimal or intermediate but short-term and no intervention or only a minimal intervention was required), moderate (i.e., patient outcome was symptomatic, required more than a minimal intervention, and/or an increased length of stay and/or caused permanent or long-term harm or loss of function), severe (i.e., patient outcome was symptomatic, required a life-saving or other major medical/surgical intervention, shortened life expectancy and/or caused major permanent or long-term harm or loss of function), or death (i.e., on balance of probabilities, death was caused or brought forward in the short-term by the incident) [17].

Data analysis

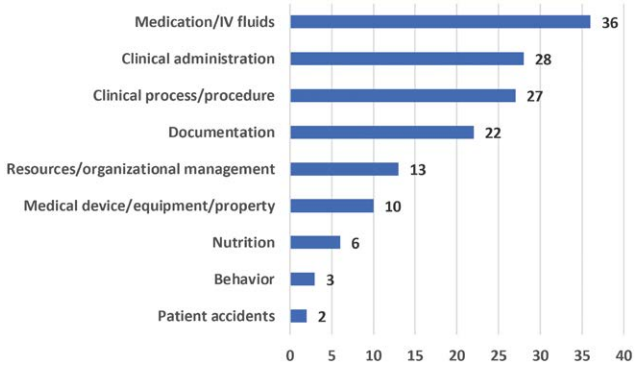
Departments submitting the patient safety incidents, patients' hospital status (i.e., inpatient or outpatient), nuclear medicine procedures involved [i.e., diagnostic single-photon emission imaging, diagnostic PET imaging with low-dose computed tomography (CT) only or with concomitant full-dose contrast-enhanced CT, or therapeutic nuclear medicine procedure], patient harm severities, and decisions to perform a subsequent analysis according to the PRISMA method were descriptively summarized with frequency distributions and graphical representations. All patient safety incidents that actually caused patient harm or that underwent PRISMA evaluation were comprehensively described on an individual basis.

Results

Patient safety incidents: included cases

Between October 2014 and November 2019, 149 cases related to nuclear medicine practice were submitted to the IRS. One case was excluded because it was not considered a patient safety incident by the expert team and one case was excluded because it concerned a duplicate. Eventually, 147 incidents remained for inclusion. These 147 cases were submitted by the departments of nuclear medicine itself (n = 113), internal medicine (n = 11), radiation therapy (n = 6), radiology (n = 5), oncology (n = 4), anesthesia (n = 1), neurology (n = 1), pulmonary medicine (n = 1), surgery (n = 1), and unknown departments (n = 4). Submitted incidents involved inpatients (n = 24), outpatients (n = 22), multiple patients who were either in- or outpatients (n = 8), and patients whose hospital status was unknown (n = 93). Nuclear medicine procedures involved included diagnostic PET/CT imaging [with concomitant full-dose contrast-enhanced CT (n = 34),

Fig. 1



Incident types according to the ICPS [1,14–16] of the 147 included nuclear medicine-related patient safety incidents with corresponding numbers. ICPS, International Classification for Patient Safety.

low-dose CT only (n = 3), and unclear if a concomitant full-dose contrast-enhanced CT was performed (n = 45)], diagnostic single-photon emission imaging (n = 32), diagnostic nuclear imaging but unclear if it involved PET or single-photon emission imaging (n = 1), therapeutic nuclear medicine (n = 10), and unknown nuclear medicine procedure (n = 22).

Patient safety incidents: International Classification for Patient Safety types and subtypes

The top-three incident types were medication/IV fluids (36/147, 24.5%), clinical administration (28/147, 19.0%), and clinical process/procedure (27/147, 18.4%) (Fig. 1), altogether comprising 61.9% of incidents. Within the medication/IV fluids domain, half of incident subtypes were attributable to supply/ordering, omitted medicine or dose, and wrong dose/strength of frequency (Fig. 2). Within the clinical administration domain, appointment and wrong patient represented the majority of incident subtypes (Fig. 2). Within the clinical process/procedure domain, the majority of incident subtypes fell in the categories: specimens/results and incomplete/inadequate (Fig. 2).

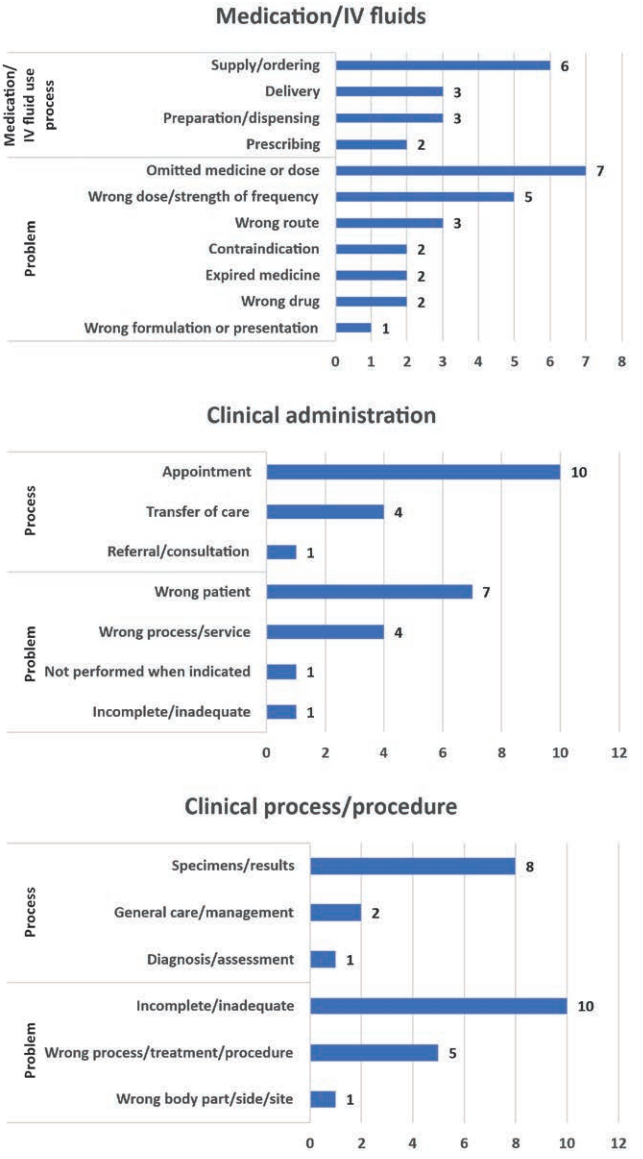
Patient safety incidents: harm severities and PRISMA evaluation

There was no patient harm in 145 (98.6%) of cases, mild patient harm in 1 (0.7%) case, and in 1 (0.7%) case, it remained unclear if the individual was harmed due to the incident. In 4 (2.7%) cases, a subsequent analysis according to the PRISMA method was performed. Table 1 summarizes the single case with actual patient harm and the four cases that underwent PRISMA evaluation.

Discussion

The results of this study show three ICPS categories to be responsible for the majority of all patient safety incidents in nuclear medicine practice: medication/IV fluids,

Fig. 2



Subcategorization according to the ICPS for the top-three incident types that were found in this study (medication/IV fluids, clinical administration, and clinical process/procedure). ICPS, International Classification for Patient Safety.

clinical administration, and clinical process/procedure. Medication/IV fluids comprised most incidents (24.5%), which seems plausible given the central role of radiotracers in nuclear medicine practice. Our results indicate that a particular emphasis should be paid on quality and safety management of the medication/IV fluids subcategories of supply/ordering, omitted medicine or dose, and wrong dose/strength of frequency. Clinical administration ranked second as an area of patient safety concern (19.0%), specifically when it comes to appointment and wrong patient issues. This finding emphasizes the need for a nuclear medicine department to have sufficient and

Table 1 Comprehensive overview of all individual patient safety incidents that actually caused harm and/or that underwent PRISMA analysis because of their seriousness in terms of risk of reoccurrence and potential patient harm

Case no.	Submitting department	Hospital status	Nuclear medicine procedure	Description incident	Incident type	Harm	Advice/action for patient care improvement[a]	PRISMA[b]
1	Nuclear medicine	Unknown	Diagnostic PET/CT[c]	Extravasation of almost all of the FDG and CT contrast agent that was administered (despite check with a saline flush), which caused a painful and swollen arm and required rescheduling of the FDG-PET/CT scan	Medication/IV fluids	Mild	No specific advice given or action taken	No
2	Nuclear medicine	Outpatient	Diagnostic PET/CT[d]	Incomplete patient verification check by the clinical administration staff, as a result of which FDG-PET/CT was performed in a patient who should not have undergone this procedure	Clinical administration	None	Feedback to administrative staff involved	Yes
3	Nuclear medicine	Unknown	Single-photon imaging	^{123}I instead of ^{123}I-mIBG administered	Medication/IV fluids	None	Update of digital administrative planning system, perform double administrative check in a suitable location and time without any distractions, discussion of radiotracer approval procedure and how to deal with errors indicated by the quality control software in staff meeting	Yes
4	Nuclear medicine	Unknown	Diagnostic PET/CT[c]	A patient experienced an allergic reaction to the CT contrast agent that was administered, but there was no nuclear medicine physician available at that time at the end of the day to approve the administration of anti-allergic drugs by the nuclear medicine technician	Resources/ organizational management	None	Feedback to nuclear medicine physician involved and discussion of issue in staff meeting	Yes
5	Nuclear medicine	Not applicable[e]	Diagnostic PET/CT[d]	Two ^{13}N-ammonia PET/CT scans and one ^{18}F-FES PET/CT scan were not adequately archived and therefore lost	Clinical process / procedure	None	Writing of an updated protocol with attention on adequate data archiving and removal, introduction of a double check system for archiving data, and securing all data with a protection tag that prevents unconscious, unintended removal	Yes

CT, computed tomography; IRS, incident reporting system; PRISMA, Prevention Recovery Information System for Monitoring and Analysis.
[a]Initiated by the expert team that manages the IRS.
[b]This column denotes if a subsequent analysis according to the PRISMA method was performed, as decided by the expert team that manages the IRS.
[c]With concomitant full-dose contrast-enhanced CT.
[d]Unclear if a concomitant full-dose contrast-enhanced CT was performed.
[e]Involved multiple patients who were either in- or outpatients.

adequately trained administration staff. Clinical process/procedure emerged as the third most common incident (18.4%), with most errors as a result of delayed availability of results (particularly when a PET/CT examination required interpretation by both a nuclear medicine physician and a radiologist) and incomplete/inadequate examinations (particularly body parts that were not included in the image acquisition field of view). These issues may be overcome by increasing the number of imaging physicians with dual certification in nuclear medicine/PET and diagnostic radiology/CT, and by improving communication between the requesting physician and the nuclear medicine physician who is responsible for assigning procedure protocols.

Besides a few studies that focused on radiopharmaceutical maladministrations [18,19] and radiation incidents [20,21], there are no other studies that performed a comprehensive analysis on the types of patient safety incidents that can be encountered in nuclear medicine practice. Literature on this topic in radiology is also limited. One previous study analyzed 209 patient safety incidents in radiology using the ICPS [11]. Interestingly, just under half (94/209, 45%) of incidents were classified as resources/organizational management (27% of total) and behavior (18% of total) in that study [11]. Most of these incidents (76/94, 81%) were directly related to hospital personnel, including staff failing to follow established protocols, staff being rude, inconsiderate or hostile to other staff or patients, and staff uncontactable for significant periods of time [11]. These findings are completely different from those in the present study, and may reflect differences in patient populations, staff, and hospital culture. They may also be due to inherent differences between nuclear medicine and radiology practice, such as more emergency and out-of-office hours procedures in radiology which can pose more pressure on available staff.

In the present study that comprised a time span of 5 years, 147 patient safety incidents related to nuclear medicine practice were submitted to the departmental IRS. Because our department performs around 12 000 nuclear medicine procedures on an annual basis, the estimated incident rate is 245 per 100 000 procedures. Interestingly, there was no patient harm in 98.6% of submitted cases in this study, and only 2.7% underwent subsequent PRISMA evaluation due to the perceived high risk of reoccurrence and potential patient harm. These findings indicate that incidents in nuclear medicine practice are not uncommon, but usually without a direct negative effect or imminent threat on a patient's wellbeing. Nevertheless, they should be taken seriously to maintain and improve the quality of healthcare.

So far, incident rates for nuclear medicine practice have been lacking in the literature. Previous studies in the field of radiology that also employed an IRS reported varying incident rates of 236.4 [22], 170.2 [23], and 12 [10] per 100 000 procedures. Because the present study is the first of its kind in the field of nuclear medicine, it remains unclear if nuclear medicine incident rates in other institutions are similar. Importantly, the number of incidents (as a proportion of the total amount of procedures performed) that are submitted to an IRS can be regarded as a reflection of a hospital's culture of openness and willingness to learn from errors, the threshold for caregivers to report incidents, and the existing safety of healthcare. Incident rates, along with patient harm rates and proportions of PRISMA evaluations, can be considered as useful metrics of healthcare quality. The findings of the present study may therefore be useful for benchmarking purposes.

This study had some limitations. First, although our hospital and department stimulate a culture of openness to report and learn from errors, and the IRS is a well established mechanism to submit incidents in our hospital, it cannot be excluded that there were incidents that have not been submitted to the IRS. Reporting bias is a well recognized disadvantage of an IRS [24], and it remains unclear whether the relatively small sample size of 147 patients incidents that were analyzed in this study approached the total amount of patient safety incidents that actually occurred in the study time span that comprised 5 years. Because of this limitation and the fact that comparative data were lacking, we cannot conclude that there is indeed a thriving culture of openness thanks to the IRS in our institution. Second, because of the transition to a new hospital-wide electronic patient file system in December 2017, and the fact that reports of many patient safety incidents in the IRS were not detailed enough to determine to which patient category each case belonged, it was not possible to determine the number of patient safety incidents per scan type, referral origin, and patient category. Third, the results of this study are applicable to a tertiary care center that has its own cyclotron facility to produce over 30 radiotracers for clinical use, and that performs approximately 12 000 nuclear medicine procedures on an annual basis. The results may be different for a nontertiary care center without its own radiotracer production facility and with a lower volume of nuclear medicine procedures. Fourth, follow-up studies are necessary to determine if the IRS indeed improves patient safety.

In conclusion, the majority of patient safety incidents in nuclear medicine occur in three main ICPS categories (medication/IV fluids, clinical administration, and clinical process/procedure, in order of decreasing frequency). These can be considered as key strategic areas for incident prevention and patient safety improvement. Nevertheless, the rate of actual patient harm was very low in our series.

Conflicts of interest

There are no conflicts of interest.

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