ENHANCING SAFETY IN NUCLEAR MEDICINE IN AUSTRALIA: a multi-method investigation of risks, incidents and work-processes

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DECLARATION

I certify that the work in this thesis entitled "***Enhancing safety in nuclear medicine in Australia: a multi-method investigation of risks, incidents and work-processes***" has not been previously submitted for a degree to any university or institution other than Macquarie University. I also certify that the thesis is an original piece of research and it has been written by me. Any help and assistance that I received in my research work and the preparation of the thesis itself have been appropriately acknowledged.

In addition, I certify that all information sources and literature used are indicated in the thesis.

The research presented in this thesis was approved by the: Australian Radiation Protection and Nuclear Safety Agency and University of New South Wales Human Research Ethics Committee (reference numbers: HC12219 and HC13288 for chapters 2 and 3, respectively) and Western Sydney Local Health Network (reference number: [4287] AU RED HREC/15/WMEAD/147 and SSA reference number: AU RED SSN15/WMEAD/177) and Macquarie University (reference number 5201500754; for chapter 4).

George Larcos (student number: 43906133)

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ABSTRACT

Nuclear medicine is an important part of modern healthcare in which radiopharmaceuticals are administered to patients for the purpose of diagnosis or treatment. Different types of errors can compromise patient safety in nuclear medicine, however maladministrations are of greatest concern because patients are exposed to unintended ionising radiation with the subsequent potential for organ damage. Although Australia has a statutory incident reporting system, there is no contemporary national perspective on the incidence, causes or complications of maladministrations. As well, there is a paucity of applicable maladministration data from other countries. Therefore, an analysis of contemporary Australian incident data, allied with an approach which defines and measures safety in nuclear medicine in broader ways is warranted.

Since maladministrations are rare incidents, it is unsurprising that existing studies have been descriptive in nature. However, alternative statistical methods may be more suited to study maladministrations. One such method, known as control charts, has been employed for decades in industry and medicine as a quality process tool to graphically display and monitor temporal variations in key incident data. Control charts have advantages over descriptive studies in analysing rare incidents and by identifying 'unnatural' variations in data can lead to novel quality improvement strategies in nuclear medicine.

Understanding how safety is maintained in dynamic, busy and interruption-laden clinical environments requires research beyond incident reports. Work observation studies provide insights into how care is delivered as well as contextual factors, such as interruptions and disruptions to workflow, which may jeopardise safety. Such

investigations can also illustrate the way in which staff adapt to these dynamic environments and could complement existing quality and safety initiatives in nuclear medicine which emphasise technical training and procedural compliance as means to avoid maladministrations. No observation studies of workflows in nuclear medicine have been previously conducted.

This thesis addressed each of these three challenges in order to understand safety in nuclear medicine, address existing gaps in knowledge and stimulate a more comprehensive suite of quality improvement strategies in the future. The program of research commenced with a detailed analysis of the causes, consequences and incidence of maladministrations from 2007-2011 using the Australian Radiation Incident Register (ARIR), as well as an evaluation of the strengths and weaknesses associated with incident reports and the incident reporting system in Australia. There were 149 maladministrations, with an incidence of 5.8 per 100,000 procedures. Nearly half (48%) were caused by failures in radiopharmaceutical preparation and 67% occurred in the work domain of nuclear medicine technologists. Ninety-eight percent of maladministrations occurred in a diagnostic context and led to a mean effective whole body radiation dose of 7.9mSv. There was significant heterogeneity of maladministration notification rates across Australian States and Territories (0-12.2 per 100,000 procedures; $p<0.05$), as well as evidence of incident underreporting (odds ratio=5.9). The ARIR could be improved by attention to latent causes of maladministrations, identifying barriers to notification, implementing uniform prescriptive notification criteria in all Australian States and Territories and better integrating with Medicare data.

Second, application of control charts from 2007-2012 investigated factors associated with 'special cause variation' (signifying greater than expected) in monthly maladministration rates. Special cause variation occurred in only three of 72 months, but accounted for a disproportionately large number of maladministrations (21%; 42 of 197 patients). Most of these incidents (*n*=27) were due to maladministration 'clusters' in which multiple patients were affected either by errors in the bulk manufacture and preparation of radiopharmaceuticals or equipment failure. Control charts reinforce the idea that radiopharmaceutical preparatory processes are vulnerable, especially when occurring on a commercial or bulk manufacturing basis. The ability to actively monitor safety data in nuclear medicine is appealing and could foster engagement with key stakeholders.

Third, an 100-hour work observation study of 11 nuclear medicine technologists at a major Sydney public hospital was undertaken from October to December 2015. The proportions of time spent in eight categories of work tasks, location of task, interruption rate and type and multitasking (tasks conducted in parallel) were recorded and specific safety-oriented strategies used by technologists were catalogued. Technologists completed 5227 tasks and experienced 569 interruptions (mean=4.5 times per hour). Interruptions during radiopharmaceutical preparation occurred at a mean rate of 4.4 times per hour. Some interruptions were initiated by other technologists to convey important information and/or to render assistance. Technologists employed a variety of verbal and non-verbal strategies in all work areas (notably in the hot-lab) to minimise the impact of interruptions and optimise the safe conduct of procedures. Although most were due to individual choices, some strategies reflected overt or subliminal departmental policy. These type of strategies

may highlight process or organisational deficiencies not readily apparent from ARIR incident reports.

The thesis findings show that the ARIR has a central role in characterising maladministrations, but refinements are needed. Control charts can broaden how safety in nuclear medicine is measured, provide new insights on vulnerable work processes and permit more active monitoring of incident data and stakeholder engagement. By illustrating how work is conducted rather than imagined, work observation studies in nuclear medicine offer an understanding of 'real-world' safety and vulnerabilities in nuclear medicine, thus informing quality improvement in complementary ways to incident reports. The research findings are not only pertinent to nuclear medicine in other countries, but can act as a template for promoting safety and refining quality more broadly in medicine.

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Glossary of Abbreviations

α alpha (radiation)

ACT Australian Capital Territory

ANZSNM Australian and New Zealand Society of Nuclear Medicine

ARIR Australian Radiation Incident Register

ARPANSA Australian Radiation Protection and Nuclear Safety Agency

β beta (radiation)

CI confidence interval

CQC Care Quality Commission (United Kingdom)

CT Computed tomography scans

EPA Environment Protection Authority

ESR European Society of Radiology

γ gamma (radiation)

HURSOG Hospital and University Radiation Safety Officers Group

IAEA International Atomic Energy Agency

^{131}I Iodine 131, a commonly used radioisotope for therapeutic procedures

JCAHO Joint Commission on Accreditation of Healthcare Organizations

MBS Medicare Benefits Schedule

mSv millisieverts, the SI unit for measurement of the dose of ionising radiation that is received by the patient

NCRP National Council on Radiation Protection

NDRP National Directory for Radiation Protection (ARPANSA) which contains regulatory requirements that each Australian jurisdiction must adopt

NRC National Radiation Commission (United States of America)

NSW New South Wales

OR odds ratio

^{99m}Tc Technetium 99-metastable, a commonly used diagnostic radioisotope

NT Northern Territory

p P value or probability

PET Positron emission tomography

RAC Radiation or Radiological Advisory Council

RACP Royal Australasian College of Physicians

RaER Radiology Events Register

RANZCR Royal Australian and New Zealand College of Radiologists

RCA Root cause analysis

SA South Australia

UK United Kingdom

US United States of America

WA Western Australia

WHO World Health Organisation

WOMBAT Work Observation Method By Activity Timing

Glossary of Key Terms

Active causes of errors Events or factors that can be clearly identified because of proximity in time or space to an error.

Diagnostic Imaging Disciplines such as nuclear medicine and radiology which use imaging techniques for diagnosis.

Error An avoidable act, such as a failure of a procedure to be completed as intended or the use of an incorrect procedure to achieve an objective.

Latent causes of errors Events or factors that contribute to errors occurring but which lack visibility because they are subliminal or long-standing in nature.

Maladministration The mistaken administration of a radiopharmaceutical to a patient. It includes the administration of the wrong radiopharmaceutical or the wrong radioactivity to the correct patient or the administration of the correct radiopharmaceutical to the wrong patient.

Misadministration The radiopharmaceutical is correct, but the performance of its administration is incorrect, for example extravasation or injecting into an incorrect vessel or anatomic region.

Safety-I The traditional patient safety framework based on specialist education, vocational training, licensing, accreditation and incident reporting of adverse events

Safety-II A newly described model which seeks to promote what individuals and systems do right, thereby avoiding errors from occurring

System This refers to the equipment, protocols, physical environment, individual health professionals and policies of the organisation, professional societies and regulatory authorities that in concert influence the conduct of nuclear medicine examinations.

Acknowledgements

The genesis of this PhD was in 1998 when I started a six year stint as the nuclear medicine expert on the New South Wales Radiation Advisory Council (RAC). It was during that period that I first came across the issue of maladministrations in nuclear medicine (since notification of these type of incidents was a regulatory matter and required review by the RAC). I found it intriguing that there was a repetitive pattern to the type of incidents that occurred, notwithstanding guides on procedures and technical training, as well as broader attention to practice accreditation and licensing of professionals. I was concerned that patients were getting exposed to unnecessary radiation and there were even instances of organ damage. Correcting the problem appeared a Sisyphean task and I was neither convinced that we had sufficient information about what was going wrong nor that a regulatory based approach was the right domain for generating solutions. After I completed two three-year terms on the RAC in 2003, a busy family life and other professional distractions kept me occupied, but the seed had been sown.

By the time I was able to commit to doing a PhD I was in my fifties. Being older than most PhD candidates had both advantages and disadvantages. For starters, I didn't have to worry about getting a job at the end of the process (I already had a pretty good one!) and I could take my time and savour the journey. On the other hand, I had to learn to eat a certain amount of humble pie. Having authored quite a few medical papers I thought I knew a lot about doing research & publishing papers. I soon discovered that I was wrong. More on that later.

There are a few people who helped made this PhD possible and who I specifically want to acknowledge. My parents, Savvas & Alexandra (my mother now deceased),

instilled inquisitiveness and a desire to excel. I am who I am in no small measure because of them. To these two I must add my beautiful wife of thirty years, Helen. She had considerably more challenges in her academic journey and professional career than I, but by her example she inspired me to persevere. Helen's experience with Microsoft excel and pivot tables also proved invaluable when I came to analyse and portray data depicted within chapter 4. Everyone needs someone like her.

I was lucky to have four supervisors, Professors Johanna Westbrook and Andrew Georgiou were my main supervisors and they walked the entire journey with me. Their academic background, high standards and deep insight into patient safety were the exact attributes that I needed and their advice was "A-grade" throughout. I had occasional doubts about what I was doing, but over time I learned to trust them implicitly. Doctors Mirela Prgomet and Lee Collins helped me through specific parts of the program. Mirela guided me through the latter part of the research; her familiarity with the Work Observation Method By Activity Timing (WOMBAT) software program was invaluable for the conduct and analysis of a work observation study of nuclear medicine technologists; for this reason I gave her the nickname, the "WOMBAT queen". Lee helped considerably at the start of the thesis with his intimate knowledge of the Australian Radiation Protection and Nuclear Safety Agency and incident reporting mechanisms in Australia. These four took my rough and clumsy ideas and helped polish them. They were the perfect quartet for this project.

My two sons, Alexander and Eric, also deserve some credit. Their regular banter and jocular 'put-downs' acted as reminders that a PhD isn't a Nobel prize and that sitting at a computer for too long may be less than ideal. At the end of the day, I was still "dad", someone who (allegedly) wore his pants way too high, took the garbage out,

and didn't know which way the toilet roll should face when being replaced! My four-legged friend, Bertie is another family 'member' that I cannot neglect to mention: he was a good emotional outlet, but unfortunately an untimely death in August 2017 meant that he wasn't around at the end.

Keeping perspective during the PhD journey is important. I read many novels for recreation during the time I took to finish the PhD and came across quite a few inspiring quotes for this thesis. For me the pinnacle is in Revelation 5:5 ("*…Do not weep! See, the Lion of the tribe of Judah, the Root of David, has triumphed.…*"); it encapsulates the joy that springs from a seemingly unlikely victory. This thesis feels a little like that, although I accept that the metaphor only goes so far.

List of contributors

Contributions in co-authored articles as tabulated below.

KB=Karen Byth; LC=Lee Collins; AG=Andrew Georgiou; GL=George Larcos;

HL=Helen Larcos; SL=Sharyn Lymer; MP=Mirela Prgomet;, SW=Scott Walter;

JW=Johanna Westbrook.

	Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register	Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement in nuclear medicine	A work observation study of nuclear medicine technologists: interruptions, resilience and implications for patient safety
Concept & design	GL, LC, AG, JW	GL, LC, AG, JW	GL, AG, JW
Planning & implementation	GL	GL, SL	GL, MP
Data Collection	GL	GL	GL
Analysis & interpretation	GL, LC, KB	GL, LC	GL, MP, AG, JW, SW, HL
Writing the article	GL, LC, AG, JW	GL, LC, AG, JW	GL, MP, AG, JW
Overall responsibility	GL	GL	GL

CHAPTER 1

INTRODUCTION

"The only true wisdom is knowing that you know nothing." Socrates (circa 470-399 BC).

1.1 Background: nuclear medicine in healthcare

Nuclear medicine is a discipline within internal medicine that uses injected, inhaled or orally administered agents for diagnosis. These agents, known as 'radiopharmaceuticals', contain a substrate that targets a specific molecule or receptor, located either within or on the surface of cells. The substrate is prepared with a radioisotope that emits ionising radiation capable of being detected by imaging equipment, such as gamma (γ) or positron emission tomography (PET) cameras. The emitted beta (β) or γ radiation permits images and/or measurements to be made of *in-vivo* physiologic, biochemical and metabolic processes, and can complement information acquired from anatomic tests, such as x-rays and computed tomography (CT) scans. As well as diagnosis, nuclear medicine can also be used with a therapeutic intent, mainly for malignancies. In this scenario, radiopharmaceuticals can be administered through various routes, usually orally, intravenously or intra-arterially. The emitted alpha (α) and β radiation can selectively target and/or non-selectively irradiate tumour cells, thus contributing to disease control or cure.

Radiopharmaceuticals can be prepared on-site within the nuclear medicine facility itself or be delivered to the facility by an external (commercial or public hospital) manufacturer. The preparation of radiopharmaceuticals involves either receipt of a

prepared radiopharmaceutical within a single vial for use in a patient or elution[1] of an 'in-house' generator containing the radioactivity, with subsequent compounding, dispensing and quality control to prepare the required radiopharmaceutical (Heller 1996). Mostly, the elution of radioactivity is from a ^{99}Molybdenum/^{99m}Technetium (Tc) generator, since the radioisotope product, ^{99m}Tc, is the most commonly used in nuclear medicine.

In Australia, nuclear medicine procedures are undertaken in public and private hospitals and clinics. Nuclear medicine technologists, working closely with nuclear medicine specialists, radiochemists, medical physicists and nurses, usually prepare, dispense and administer radiopharmaceuticals, as well as preparing patients for procedures, undertaking their scans and developing imaging or therapy data for subsequent reporting. Nuclear medicine technologists therefore play a pivotal role in the provision of nuclear medicine services. Part of the empirical research undertaken in this thesis is devoted to a study of this group of health professionals.

1.2 Ionising radiation in healthcare and nuclear medicine

Energy emitted for nuclear medicine scans are part of the electromagnetic spectrum. The latter includes non-ionising radiation, such as radio waves, microwaves and visible light, and ionising radiation such as x-rays and gamma rays. Ionising radiation is widely used in healthcare for diagnosis and treatment. X-rays and CT use an external source to scan the patient and produce imaging data. On the other hand, in nuclear medicine, radiopharmaceuticals are administered *into* the patient, with the detection of emitted radiation subsequently providing imaging data. Ionising radiation

[1] Elution refers to the process in which ^{99m}Tc is obtained from a generator containing a ceramic column of ^{99}Molybdenum. In this case, the passage of a saline solution over the column results in a soluble solution containing ^{99m}Tc, which can be subsequently used in patients.

has more energy than non-ionising radiation and can cause damage to chemical bonds (Australian Radiation Protection and Nuclear Safety Agency [ARPANSA] n.d., a). Accordingly, medical applications employing ionising radiation are potentially hazardous.

1.3 Patient safety and quality

Patient safety has garnered widespread interest since the United States of America (US) Institute of Medicine's landmark report, "*To Err is Human: Building a Safer Health System*" which suggested that 44,000 to 98,000 patients die every year in US hospitals from medical errors (Kohn et al. 1999). Revised data from the Quality in Australian Health Care Study indicate that 10% of patients in Australian hospitals also suffer an adverse event, a figure which is comparable to other countries such as Canada, Denmark, New Zealand and the United Kingdom (UK) (Smallwood 2006).

Due to the risk of patient harm, efforts to uphold patient safety are widely endorsed and, in Australia, also include political support from health ministers in all Australian jurisdictions (Smallwood 2006). Typically, patient safety strategies draw on perspectives that may involve risk management, clinical governance and quality improvement (Runciman 2002). However, fundamental to the development of these strategies is the need to define what constitutes safety and develop appropriate measurement tools as a foundation to informing quality improvement (Rubin & Leeder 2005; Vincent & Amalberti 2016). This key point underpins both the aims and direction of this thesis and its application in nuclear medicine.

1.4 Why study safety and quality in nuclear medicine?

Research into safety and quality in nuclear medicine in Australia is warranted for several reasons. First, recent estimates indicate that global demand for nuclear medicine scans has tripled from 1984 to 2008 (Adelstein 2014), with about 32.7 million nuclear medicine procedures performed annually (Vano 2011). In Australia, recent data from Medicare suggest that demand for nuclear medicine procedures is growing by about 10% per annum (Department of Human Services, Australian Government 2016). In the financial year ending in June 2016, nuclear medicine scans (excluding PET and non-imaging services) accounted for 2.77% of all diagnostic imaging procedures, which equated to 9.3% of annual Commonwealth government expenditure on diagnostic imaging items and over $265 million in patient fee for services (Department of Human Services, Australian Government 2016). According to recent figures, services for diagnostic imaging (that is, including radiology and nuclear medicine) typically rank as the second or third highest area for Commonwealth government expenditure through Medicare, easily exceeding, for example, outlays for pathology and laboratory tests (Department of Human Services, Australian Government 2016).

Second, the safety agenda in diagnostic imaging has typically centered on errors in the interpretation of diagnostic studies, but the potential for harm from unnecessary tests (Moynihan et al. 2012) and exposure to ionising radiation in contemporary healthcare (Fazel et al. 2009; Dickie & Fitchew 2004) is being increasingly emphasised. This is unsurprising given that there has been a steady rise in the number of persons undergoing medical procedures involving ionising radiation (Dickie & Fitchew 2004), and consequently an increase in the total radiation burden at a community level (Fazel et al. 2009; Schauer & Linton 2009; Adelstein 2014).

Although nuclear medicine represents only about 6% of the total effective radiation dose at a community level, its proportion has risen in the last two decades (Vano 2011; Song 2016). Globally in 2006, CT and nuclear medicine scans constituted nearly 25% of all medical imaging procedures and contributed about 75% of the total effective dose to patients (Schubauer-Berigan & Sigurdson 2011). Radiation exposure per person has more than doubled in the last 25 years, mainly because of growth in CT and nuclear medicine scans (Schauer & Linton 2009). Understandably, these trends have fuelled a debate about the judicious use of these imaging modalities (Lauer 2009). In particular, there are concerns that exposure to low level ionising radiation is carcinogenic (Cardis et al. 2005; Brenner & Hall 2012). However, there are conflicting results concerning the risk of carcinogenesis in patients receiving a dose of less than 100 milliSievert (mSv)[2] (Hendee & O'Connor 2012; Leuraud et al. 2015; McCollough 2016). Nevertheless, the debate highlights the topical nature of ionising radiation in medicine. This thesis explores maladministrations as a safety and quality issue in nuclear medicine because these involve patients mistakenly receiving an incorrect radiopharmaceutical or radioactivity, or an incorrect patient receiving radiopharmaceutical (Keeling & Maltby 1994; Smart 2002; Williams & Harding 1995), thus causing *unintended* radiation exposure. One group has estimated that one excess fatal cancer may be expected per 10,000 maladministrations (Sinclair et al. 1991). Although establishing a clear relationship between low levels of ionising radiation and carcinogenesis may be challenging (McCollough 2016), quantifying how often maladministrations occur and the radiation exposure received during these incidents remain important prerequisites for risk communication and management in nuclear medicine.

[2] A Sievert is a derived unit of ionising radiation and a measure of its effect on health in the human body.

Third, as well as an increasing demand for certain diagnostic procedures, including lymphoscintigraphy studies and positron emission tomography (PET) (Van Dyke et al. 2016), the wider use of β-emitting radioisotopes, such as ^{90}Yttrium and ^{177}Lutetium (Larson & Krenning 2005; Kwekkeboom et al. 2003), in conjunction with an increasing application of therapeutic nuclear medicine (International Atomic Energy Agency [IAEA] n.d.), underscores the potential for maladministrations to cause organ damage (Smart 2002; Sinclair et al. 1991) (in contrast to γ emitters for diagnosis, photons from β-emitting radioisotopes traverse only a small distance; the generally higher administered radioactivity and concentration of radio energy in a small volume thus increase the potential for organ damage).

Fourth, there is limited information about the incidence, causes and complications of maladministrations. In Australia there have only been three publications in peer-reviewed medical journals specifically on maladministrations, only one of which is recent (Smart 2002; Yenson et al. 2005; Kearney & Denham 2016). In the first Australian study, an informal observational review conducted by the New South Wales (NSW) hospital and university radiation safety officers group (HURSOG) revealed 14 maladministrations occurring over a three year period from 1997 to 1999 (Smart 2002). These maladministrations were:

> "*discussed informally at the meetings of the NSW HURSOG*"

(Smart 2002, p. 14) which were conducted every two months. Smart (2002) neither elaborated on how the cases were identified nor did he calculate an incidence. The second Australian study was a systematic analysis of maladministrations reported to the NSW Radiation Advisory Council (RAC) over a five year period from 1999 to 2003. This study revealed 57 maladministrations and the authors calculated an incidence of 8-9 maladministrations per 100,000 nuclear medicine procedures, using

concurrent data from Medicare Australia (Yenson et al. 2005). However, these data were derived from a single Australian State (NSW) and are now over a decade old. Third, a recent review of publicly available summaries from national and Australian State radiation regulatory authorities reported on 198 maladministrations, but the focus of the study was on compliance with 'time-out' protocols for confirming patient identity and type of procedure and radiopharmaceutical, not on incidence, complications or other causes (Kearney & Denham 2016). Moreover, Livingstone (2016) has cautioned that reviews of aggregated data, such as in annual reports, could overlook fundamental information available from individual reports, such as failures in communication and other causes of errors.

Information about the incidence, causes and complications of maladministrations from other countries is also limited. There have been only two such publications in peer reviewed medical journals, one each from Texas and Scotland (Charlton & Emery 2001; Martin 2005). Two additional publications examined radiation incidents more broadly in diagnostic imaging and industry and included data on several maladministrations. One of these was from the UK, which reported one nuclear medicine maladministration amongst 38 radiation incidents involving radiotherapy and diagnostic x-rays, but no other details were provided (Gill 1992). A study from China on industrial and medical radiation related incidents between 1988 and 1998 reported 332 incidents, of which only two were maladministrations (Li et al. 2007). The US National Commission on Radiation Protection (NCRP) issued a commentary on typical causes and consequences of maladministrations, but this report is over two decades old and there is no reference to maladministration numbers or incidence (Sinclair et al. 1991).

Collectively, the five publications from Texas, Scotland and Australia reflect 813 maladministrations (table 1.4.1, below).

Table 1.4.1 Publications with reported maladministration numbers

Authors	Jurisdiction	Period	Numbers
Charlton & Emery (2001)	Texas, US	1988-1997	355
Martin (2005)	west of Scotland	1995-2004	189
Smart (2002)	NSW	1997-1999	14
Yenson et al (2005)	NSW	1999-2003	57
Kearney & Denham (2016)	Australia	2003-2014	198 (11 incidents from radioactive spills & other incidents not counted)

Reports issued by radiation regulatory authorities from other countries represent another potential source of information about maladministrations, however at present annual reports are issued only by the US Nuclear Regulatory Commission (NRC) and UK Care Quality Commission (CQC). Recent reports show that databases within organisations such as the World Health Organisation (WHO) and the European Atomic Energy Community lack a nuclear medicine focus (Vano 2011) or are used to generate reports on technical standards (Rehani et al. 2011), rather than for broader quality improvement initiatives. There is a system for maladministration incident reporting in New Zealand, but no annual reports are published (Office of Radiation Safety, New Zealand Ministry of Health, n.d.). There are no statutory European Union incident registers, although certain countries such as Belgium are reported to be considering the introduction of incident reporting systems (Clarijs 2011).

In the US, the NRC reports to Congress on 'abnormal occurrences,'[3] however, there has been no evaluation of the data on which these annual reports are based and it is not clear whether or how the NRC reports are used to inform quality improvement strategies in nuclear medicine. Further, not all states in the US supply data to the NRC (Sinclair et al. 1991; Miller 1994) which might limit the generalisability of its data. In the UK, the CQC has been issuing annual reports since 2006-2007. In 2014 there were 55 maladministrations (CQC 2015). Further detail on incidents involving medical exposure to ionising radiation have not been made publicly available, although the most recent CQC annual report (2016) described 1277 notifications in which radiation exposure was much greater than prescribed; these were from an estimated total of 45 million procedures, including incidents across all disciplines, not just nuclear medicine.

Data from the above sources permit preliminary observations about how maladministrations might arise. For example, Yenson and colleagues (2005) described five different types and the above studies suggest that the most common (47-81%) appears to involve the preparation and dispensation of radiopharmaceuticals (Kearney & Denham 2016; Charlton & Emery 2001; Martin 2005; Yenson et al. 2005), thus falling within the work domain of nuclear medicine technologists. Other types of maladministrations are due to incorrect patient identification, performing an incorrect procedure because of a misinterpreted request and mistakenly using a syringe prepared for another patient. However, the relative proportions of other types are well defined in only two studies (Yenson et al. 2005; Kearney & Denham 2016). Therefore, additional research is needed to characterise

[3]Abnormal recurrences are defined as maladministrations in which the administered radioactive dose is at least 50% greater than what is prescribed.

vulnerabilities in nuclear medicine processes as a prelude to informing quality improvement.

It is also possible to make prefatory remarks about the incidence and consequences of maladministrations (including radiation received) (table 1.4.2, below).

Table 1.4.2 Maladministration incidence, consequences, and proportion due to incorrect radiopharmaceutical preparation and dispensation

Authors	Incidence	Incorrect radiopharmaceutical preparation & dispensation (%)	Radiation dose	Organ damage
Smart (2002)	Not reported	57	Not reported	Not reported
Yenson et al. (2005)	8-9/100,000	61	Median=6.8 mSv	Hypothyroidism occurred in 3.5% of cases (post ^{131}
Charlton & Emery (2001)	0.6-3.7/100,000	65	Not reported	Not reported
Martin (2005)	30/100,000	47	Most <10mSv	Not reported
Sinclair et al. (1991)	Not reported	81	4.4mSv	Described potential for hypothyroidism post
CQC (2011)	0.6/100,000	Not reported	Not reported	Not reported
van der Pol et al. (2017)	Not assessed	Not reported (this report focused on extravasated radioactivity)	1.78-1000 Sv (tissue dose)	Erythema, skin ulcer & limb swelling

It can be seen that there is a substantial variation in reported maladministration incidence and there is no contemporary national Australian perspective. Whole body

effective radiation received from maladministrations appears low, although Yenson and colleagues (2005) have cautioned that some incidents can involve exposure up to 39mSv. Maladministrations occurring in a therapeutic context are more concerning because of the potential for organ damage, however, of the published data, only two have examined their relative proportions: therapeutic maladministrations represented only one of 381 incidents (Sinclair et al. 1991) and three of 57 incidents (Yenson et al. 2005). The NCRP has estimated that about 5% of all maladministrations occurring in the US are therapeutic in nature (Sinclair et al. 1991), although others have suggested that it could be as low as 0.01% (Miller 1994). Therapeutic maladministrations therefore appear to be uncommon, but a contemporary assessment of their proportion relative to diagnostic maladministrations would be useful. Other limitations about data on maladministrations specifically, and safety more generally in nuclear medicine are discussed below (section 1.5).

Section 1.5 Limitations of existing evidence base on maladministrations in nuclear medicine

The existing evidence base for maladministrations in Australia has limited numbers and is based on data which are either aggregated, old or derived from a single state. Further, some reports include incidents such as radioactive spills or contamination and therefore, are not a direct patient safety issue (Kearney & Denham 2016). A second problem is that applying lessons learned from data from other countries is challenging because regulatory notification criteria may vary between jurisdictions or, in the case of the US, because of concerns about the data collection process (Sinclair et al. 1991; Miller 1994). Although nuclear medicine procedures on incorrect patients or using an incorrect radiopharmaceutical are universally recognised as maladministrations, there are different approaches regarding discrepancy between

the *prescribed* and *administered* radioactivity (see table 1.5.1, below) and incidents involving contamination of external surfaces. As illustrations, Charlton & Emery (2001) included some cases (such as radioactive spills) that neither affected patients nor met generally accepted definitions for maladministrations (Williams & Harding 1995; Smart 2002). As well, the authors acknowledged that the:

> "*incidence of self-reported diagnostic maladministrations in all medical settings may be underestimated using only TDH-BRC[4] misadministration criteria*" (Charlton & Emery 2001, p. 589).

In the study from the west of Scotland, data were obtained from over 20 hospitals serving a population of 2.8 million (Martin 2005) . A centralised reporting system was in place with hospital departments in the region, and staff were invited to report on maladministrations if there had been an unintended:

> "*excess radiation dose*" (Martin 2005, p. 913);

however, there was no explicit guidance on:

> "*a lower level to be exempt from reporting*" (Martin 2005, p. 913).

Table 1.5.1 Criteria used in various jurisdictions for notifying about excess radioactive dose in maladministrations

Jurisdiction	Criterion for notification
European	Unintended exposure: a medical exposure that is significantly different from the medical exposure intended for a given purpose (European Society of Radiology [ESR], 2015)
UK	"..*at least 2.5 times greater than the intended dose*" for examinations in which the patient exposure is expected to exceed 5 mSv (Department of Health, UK, n.d., & 2017)

[4] TDH BRC=Texas Department of Health Bureau of Radiation Control

Jurisdiction	Criterion for notification
US	The dose or dosage is "...*at least 50% greater"* than that prescribed (US NRC 2011, p. A5)
Australia	During a diagnostic procedure, the "*activity of the substance administered exceeds the activity prescribed in the hospital or practice standard protocol for that test by 50% or more"*. For a therapy, the *activity administered differs from that prescribed by 15% or more* (ARPANSA 2017, p.37)

Therefore, the applicability of maladministration data from other countries to Australia is challenging. A third problem is that previous research has concentrated on maladministration numbers and/or incidence to measure safety, but these appear to be rare events and it is possible that descriptive studies may contain unintended biases (Grimes & Schulz 2002).

Another limitation is that existing radiation protection and patient safety practices in nuclear medicine are focused on rectifying perceived deficits in technical training and/or achieving procedural compliance as means to avoid maladministrations (RACP 2016; Smart 2007; Kearney & Denham 2016) (see table 1.5.2, below). Whilst understandable, the safety and quality focus in nuclear medicine is narrow as a consequence. In regards to patient safety, Scobie and colleagues (2006, p. S51) have emphasised that:

> "*a variety of measures are needed to fully understand the system; quantitative and qualitative measures are both useful in different ways"*.

This thesis explores how other types of measures might be useful for characterising safety and informing quality improvement in nuclear medicine.

Table 1.5.2 Existing recommendations on preventing maladministrations

Country or jurisdiction (authors)	Recommendations
UK (Williams & Harding 1995)	• All request forms should be checked carefully to ensure that the procedure required is clear and has been properly requested and sufficient information is given to identify the patient • The hospital's patient identification procedures must be followed rigorously by anyone who administers radiopharmaceuticals • During or after the dispensing of radiopharmaceuticals, critical details should be checked by a second person not involved in their preparation • It seems to help comprehension if labels are read out aloud when checking them. For diagnostic procedures, it is good practice for a second person to check that the patient and the radiopharmaceutical have been properly identified • For therapeutic doses, all aspects of identification and checking or obtaining other information (for example, concerning pregnancy or breastfeeding) should be witnessed by a second person, and dispensing and measurement of the radioactivity must also be checked independently.
NSW (Yenson et al. 2005)	• Encourage open, blame-free reporting of incidents • Promote double-checking of radiopharmaceutical preparation and dispensing • Use colour coding of lyophilised vials for clearer identification and promote coordination amongst manufacturers at a national level • Use information technology to help with radiopharmaceutical labelling and dispensing

Australia, NSW, Victoria, South Australia & Tasmania (Kearney & Denham 2016)	• Provide extensive radiopharmacy training for new staff members • Implement integrated software packages for managing radiopharmaceutical supply and dispensing • Encourage coordination amongst nuclear medicine personnel to ensure the administration of correct radiopharmaceutical type and activity • Use correct formulae and calculators for paediatric nuclear medicine procedures • Regularly update department protocols and ensure accessibility • Improve supervision and encourage “time-out” compliance • Remove disincentives for error reporting • Create a culture of safety
Texas (Charlton & Emery 2001)	• Inform design of initial technologist and radiopharmacist training programs • Enhance patient identification and product labelling, storage and ordering techniques

NSW (Smart 2002)	• Request form validation: no test is to be performed without the request being reviewed by a nuclear medicine specialist or registrar • Patient identification: verify two forms of identification and the patient should tell the person administering the radiopharmaceutical their name • All women of reproductive age must be asked whether they could be pregnant and if unclear, consider either deferring the procedure or performing a pregnancy test • For therapeutic procedures, the pregnancy status must be verified • The identity, content and expiry date of all pharmaceutical and isotope vials must be checked • Identifying labels (with date, activity, radiopharmaceutical type and expiry time) should be affixed to reagent vial and shielding containers • Radiopharmacy records should contain relevant details of reconstituted radiopharmaceuticals • All doses are to be dispensed with a maximum 10% variation of the departmental protocol for prescribed activity • The dispensed activity should be determined according to the patient's history, age, weight, gender or surface area • During or after dispensing, the radiopharmaceutical and dispensed activity must checked against the prescribed activity by the person dispensing and administering the radiopharmaceutical • A second person should check the patient's identification and radiopharmaceutical to be administered • All dispensed doses should be recorded in the radiopharmacy log • The prescribed activity and radiopharmaceutical type should be checked by the person undertaking the injection

West of Scotland, Martin (2005)	• All procedures to be authorised by the nuclear medicine practitioner or operator • Radiology information systems to alert for duplicate requests or requests for the wrong patient • Patient identity check to confirm the correct identity of the patient to be studied • Quality control system to avoid errors in the preparation of radiopharmaceuticals • Use of radionuclide dose calibrator to avoid the wrong activity being administered
Australia, Denham & Page (2017)	• Use clearly defined protocols with as few abbreviations as possible and clear distinction between similar sounding protocols • Automatically save raw images to picture archiving and communication systems • Have a system in place in which paperwork for procedures to be undertaken and those already performed are not mixed up with each other

To consider additional ways to characterise safety and inform quality improvement in nuclear medicine it is necessary to first review what existing mechanisms are in place (sections 1.6 and 1.7, below).

1.6 Patient safety and quality improvement strategies in nuclear medicine in Australia: the current state of play

Currently, patient safety and quality initiatives in nuclear medicine in Australia are based on a traditional system of vocational training, registration and licensing of health personnel (specialist doctors, nuclear medicine technologists, medical physicists and radiochemists), accreditation of facilities in which nuclear medicine is practised, the promulgation of policy and procedure guidelines for the conduct of nuclear medicine procedures, preparation and quality control of

radiopharmaceuticals, and guides on equipment maintenance. Collectively, their purpose is to promote accountability and professional competence, and these provide the basis for minimising patient harm and informing quality improvement strategies (Board & Watson 2010; Runciman 2002). Incident reporting forms part of the tapestry for upholding safety and informing quality improvement and is widely used in medicine (Singer & Vogus 2013; Runciman 2002). The specific strategies that are currently used to promote safety and quality in nuclear medicine in Australia are described in section 1.7 (below).

1.7 Training, licensing and accreditation in nuclear medicine in Australia

Healthcare personnel in nuclear medicine receive discipline-specific university and workplace 'on-the-job' training. For nuclear medicine specialists there is a formal two or three-year program administered by the Joint Specialist Advisory Committee which is open to candidates who have satisfactorily completed the part 1 and part 2 examinations of the Royal Australasian College of Physicians (RACP) and Royal Australian and New Zealand College of Radiologists (RANZCR), respectively (Royal Australasian College of Physicians 2016). Curriculum based training is undertaken at accredited nuclear medicine facilities in teaching hospitals and supplemented with specific training courses in cross-sectional anatomy, medical physics, radiation protection and radiochemistry. However, there are no courses specifically devoted to safety in nuclear medicine. For nuclear medicine technologists, there is a three-year program of university education, combined with practical training in nuclear medicine facilities in hospitals and private practices (Australian and New Zealand Society of Nuclear Medicine [ANZSNM], n.d., a). Both programs lead to vocational qualifications through acquisition of specialist knowledge and procedural skills, and are consistent with contemporary educational practices (Cooke et al. 2006; Watson & Jolly 2013).

Continuing professional development is an essential element of ongoing registration with the Australian Health Practitioner Regulation Agency (Australian Health Practitioner Regulation Agency, n.d.).

In addition, there is a statutory requirement for individual and facility radiation licensing, designed to authorise and promote consistency in the type of radiopharmaceuticals that nuclear medicine personnel may use for medical purposes. There is also statutory guidance on radiation protection of patients (including justification of procedures, management of radioactive waste and occupational exposure to radiation) (ARPANSA 2014). These statutory requirements are consistent with international standards (IAEA 2005; Chen 2014).

Finally, there is a system of accreditation of individual nuclear medicine facilities, which informs technical standards for equipment, reference levels for administered radioactivity to adult and paediatric patients, guidelines on the responsibilities of nuclear medicine specialists for the quality and safety of procedures, information provided to patients, and research and advocacy in nuclear medicine (ANZSNM, n.d., b.; Australasian Association of Nuclear Medicine Specialists 2014).

Although it is feasible to measure health professional attributes and competency using domains such as clinical expertise and decision-making, teaching and learning, communication and professionalism, leadership, health advocacy, collaboration and teamwork, this line of research is outside the scope of this thesis. Further, there is a:

> "*a dearth of robust, fit for purpose tools for assessing clinical performance in routine clinical practice*"

in Australia (Scott et al. 2011, p. 151). As a consequence, measuring safety and developing quality improvement strategies for nuclear medicine in Australia through an evaluation of training, education, licensing and accreditation systems could also be problematic.

Section 1.8 Moving the research agenda in nuclear medicine safety and quality forward

In contrast, a more appealing alternative for research into safety and quality may be in the evaluation of nuclear medicine incident reports. In other medical disciplines, incident reports have:

> "*become an entrenched and critical component of safety management"* (Thomas et al. 2011, p. 635).

As well as describing adverse events, they can shed light on deficiencies in training, licensing and curricula (Mahajan 2010).

Incident reporting has been the most widely researched method for quality improvement and various disciplines within Australia have established voluntary incident reporting systems (Barraclough & Birch 2006; Board & Watson 2010). For example, the Radiology Events Register (RaER), is devoted to incidents in diagnostic imaging (Jones et al. 2010a) and has been employed to highlight vulnerabilities across a broad spectrum of activities in radiology (Jones at al. 2010b). The RaER is a good template for foreshadowing how incident registers can portray and measure safety in nuclear medicine in broad ways.

Section 1.9 The Australian Radiation Incident Register (ARIR): a role in refining safety and quality in nuclear medicine?

The RaER is a voluntary program administered under the auspices of the RANZCR. In contrast, nuclear medicine is one of a few medical disciplines for which a statutory incident reporting framework exists at both national (ARPANSA 2017) and Australian State and Territory levels (Smart 2002). The ARIR is a product of the existing incident reporting system and acts as a catalogue of individual maladministration reports received from each Australian State and Territory radiation protection authority since 1971 (Topfer n.d.). Summaries on the causes and consequences of maladministrations are issued on an annual basis as part of ARPANSA's regulatory obligations. The contemporary nature of the Australian reporting system and mandatory requirement for States and Territories to submit data to ARPANSA according to an agreed national framework (National Directory for Radiation Protection [NDRP]) are distinct attributes.

Thus, a detailed study of individual maladministration reports archived within the ARIR might be useful in broadening the portrayal of key safety indices in nuclear medicine and developing commensurate quality improvement strategies. Despite this, there has been no research into what individual reports within the ARIR reveal about the type, causes and consequences of maladministrations. Further, an assessment of the quality of its data, as well as any caveats inherent within a statutory based incident reporting system are lacking. Therefore, research into the ARIR and the statutory incident reporting system would be needed before alternative safety measurement parameters and quality improvement recommendations could be developed.

Section 1.10 Studying the ARIR: potential challenges

There are several potential barriers in studying maladministrations that are archived within the ARIR. The first of these reflects discrepancies in notification criteria used by regulatory authorities in Australian States and Territories. Clause 1 of schedule 13 in the NDRP (ARPANSA 2017, p. 37) describes a maladministration as:

> "*any unintended or ill-advised event when using....radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person....outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems....*".

However, there is variability regarding the magnitude of the *discrepancy* between the activity that is *prescribed* and what is *administered* constitutes a maladministration. For example, Western Australia (WA), Victoria and New South Wales (NSW) are consistent with the national criteria and regard an incident as a maladministration when:

> "*an abnormal or unplanned radiation exposure occurs either during the administration of a radioactive substance for diagnostic or therapeutic purposes and exceeds what is prescribed by 50% and 15%, respectively*"

(NSW Department of Environment and Heritage 2003; Department of the Premier and Cabinet, WA Government 1983; Victoria Department of Health 2005). Although using a different threshold, South Australia (SA) can also be considered to be consistent with the NDRP because maladministrations are defined as occurring when:

> "*the effective dose or an intake of any radioactive substance is more than twice that which is likely to occur during any operation normally carried out with that source of ionising radiation*"

(SA Government 2000, p. 13). In contrast, regulatory authorities in Tasmania and Queensland stipulate that the administered dose of radioactivity merely "complies" with the request (Tasmania Government 2005, part 2, section 9; Queensland Government 1999, p. 56). In the Australian Capital Territory (ACT), the relevant Parliamentary Act states that staff:

> "*must ensure that the treated person does not receive a dose of radiation from the procedure that is not in accordance with the request*"

(ACT Government 2012, p. 9). In the Northern Territory (NT), a maladministration is defined as:

> "*an incident adversely affecting, or likely to adversely affect, the health or safety of any person because of the emission of radiation*"

(NT Government 2016, p. 10). Thus, despite uniformity at the federal level, there is a spectrum of definitions used by the various Australian state and territory radiation protection authorities. Consequently, it is possible that certain types of maladministrations are under- or overrepresented in the ARIR, which could in turn distort information about maladministration causes and therefore, potentially the type of suggested quality improvement initiatives in nuclear medicine. Assessing the impact of these factors on the ARIR is explored in this thesis.

Another potential limitation in studying the ARIR is that maladministrations are not only rare events, but can fluctuate over time (Yenson et al. 2005; Charlton & Emery 2001). In this setting, distinguishing random variation in data from that which is genuine and indicative of an important safety issue may be difficult. Therefore, alternative statistical methods are necessary in this context. One such statistical method, known as control charts, permits the portrayal of temporal trends in key data, and has been a powerful tool for identifying problems and informing quality

improvement in diverse areas in medicine (Thor et al. 2007). A vast spectrum of variables, covering eight broad categories can be evaluated, as illustrated in table 1.10 (below). Typically, data are graphically displayed over time and abnormal fluctuations (known as 'unnatural variability') are analysed to highlight potential causes. Control charts have not hitherto been applied in nuclear medicine, but could permit nuclear medicine incident report data to be portrayed and analysed in novel ways.

Table 1.10 Examples of how control charts have been applied in other fields of medicine (adapted from Thor et al. 2007)

Variable category	Examples from literature
Biomedical laboratory results	Blood glucose results
Clinical measurements	Blood pressure readings
Patient health indices	Number of patient falls
Clinical management	Rate or number of events
Financial resources	Cost per procedure
Experience of healthcare	Patient satisfaction indices
Staff supervision or training	Proportion of employees that have completed mandatory training
Other	Patient waiting times

Third, a recent report has suggested that incident registers used by Australian healthcare organisations are limited by an inadequate amount of information within incident reports, thus restricting a refined analysis of aetiology and the ability to obtain quality improvement. As well, they are confounded by underreporting (Mahajan 2010) and are prone to a "non-random" sample of events, with disproportionately more severe incidents and a lack of focus on resilience (Thomas

et al. 2011). Runciman (2002, p. 250) has outlined several appealing characteristics for national incident registers, including mechanisms for:

> "*rapid feedback and evidence of action*", "*involving and informing all stakeholders*", "*agreed standards for reporting*" and "*disseminating successful strategies*".

Further, Roger (2015, p. 329) has emphasised that:

> "*quality control of registries is critical to their value for outcomes research and clinical care*"

and so, recommended regular audits to assure accuracy and completeness of data.

Thus, assessment of the nature and impact of ARIR data, and any inconsistencies in the data collection process is warranted before any additional indices and quality improvement in nuclear medicine could be suggested. Another method by which safety and quality in nuclear medicine may be more broadly promoted is discussed below (section 1.11).

Section 1.11 Nuclear medicine technologists and maladministrations: opportunity for research

The majority of maladministrations appear to arise from errors during radiopharmaceutical preparation and dispensation (Yenson et al. 2005; Martin 2005; Charlton & Emery 2001; Sinclair et al. 1991; Kearney & Denham 2016). Nuclear medicine technologists are the personnel who usually prepare and administer radiopharmaceuticals and there is evidence that interruptions experienced by them can contribute to maladministrations (Yenson et al. 2005), in keeping with concerns about interruptions in other fields of medicine (Westbrook et al. 2010). However, the rate and nature of interruptions experienced by nuclear medicine technologists have

not hitherto been evaluated. It is possible that an understanding of how nuclear medicine technologists uphold safety during busy, dynamic and interruption-laden working conditions could not only highlight additional ways in which safety can be measured, but might help develop additional quality improvement strategies.

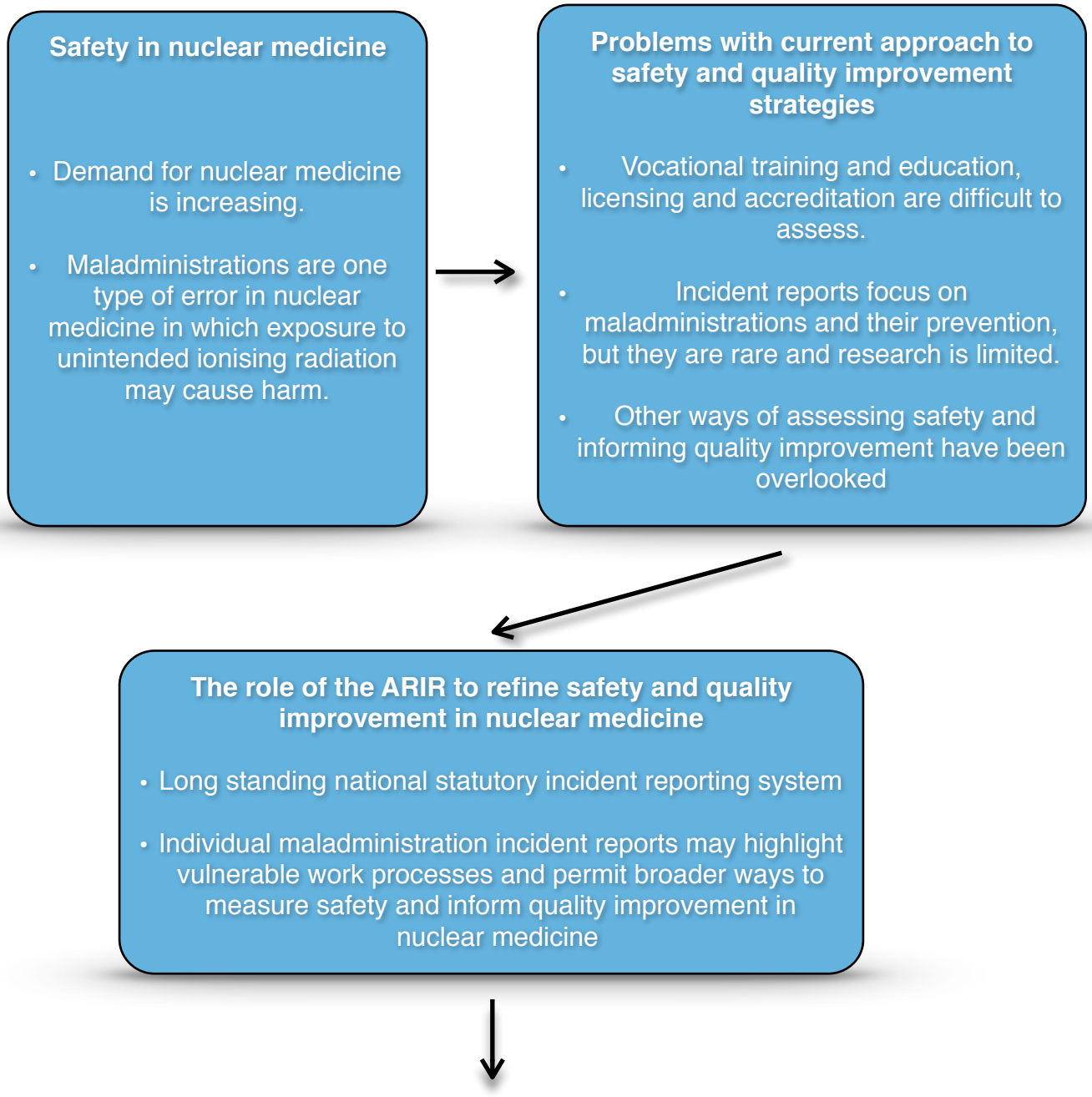
Section 1.12 Gaps in the literature and rationale for research

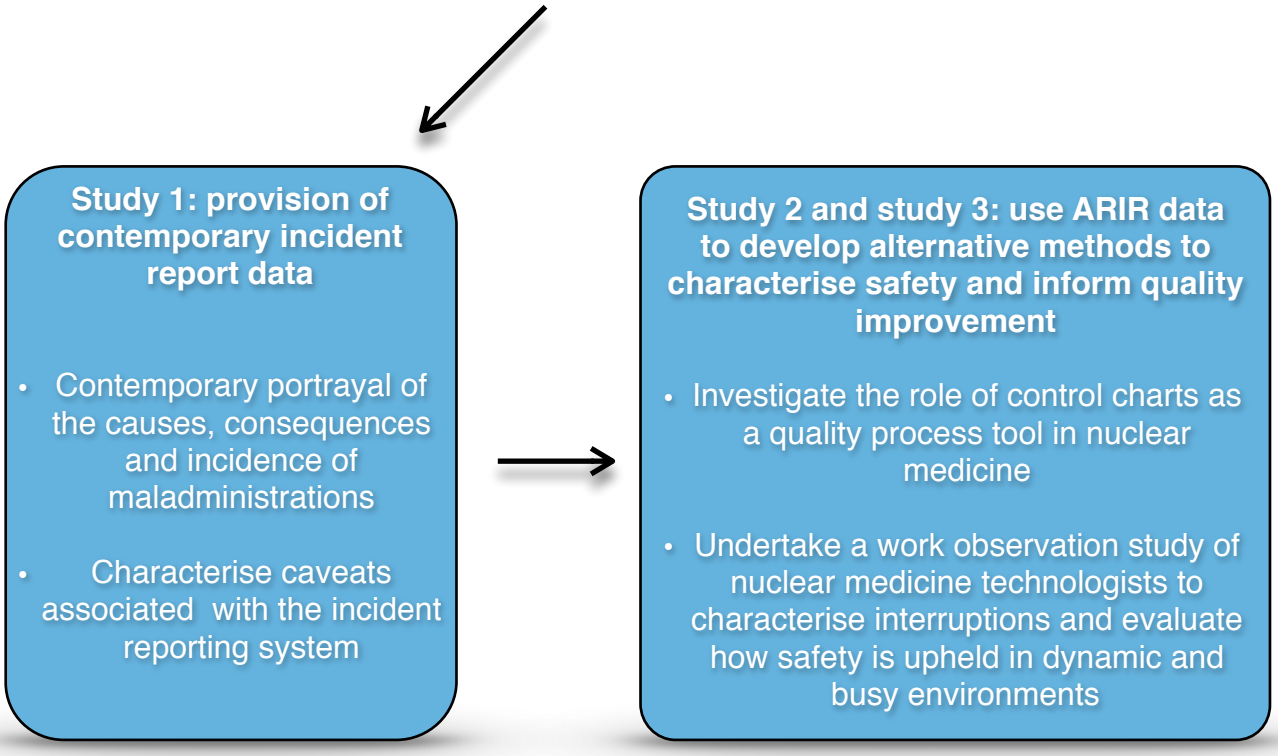
The preceding analysis in this chapter has identified the following gaps. First, there is virtually no contemporary information about the causes, incidence and complications of maladministrations in Australia or elsewhere. Since existing radiation protection initiatives in nuclear medicine (Smart 2007) are drawn from an old and limited evidence base, it is possible that at least some of these are deficient or misdirected (Shojania et al. 2007). Second, despite an established national incident reporting system, potential lessons from incident reports are scarcely used to inform quality improvement in nuclear medicine (Smart 2007); further, the only contemporary analysis of the ARIR has been limited to a review of publicly available summaries (Kearney & Denham 2016) and consequently may have neglected fundamental information contained in individual reports. Third, the ARIR is managed within a statutory framework, but the quality of its data and limitations arising from the incident reporting process or disparate notification criteria are unknown. Any potential limitations, such as underreporting, should be evaluated before any quality improvement strategies can be suggested. Fourth, alternative quality process tools, such as control charts, could add to information obtained from previous cross-sectional reports on maladministrations, but have never been applied in nuclear medicine. Finally, interruptions experienced by nuclear medicine technologists have been implicated in some maladministrations (Yenson et al. 2005). Despite this, the rate and nature of interruptions that technologists experience are unexplored. A work

observation study of nuclear medicine technologists could not only characterise interruptions, but illustrate how they manage competing priorities and uphold safety, thus leveraging a broader patient safety perspective and potentially introducing a complementary tool for quality improvement.

The rationale for this thesis is schematically illustrated below (Figure 1.12).

Figure 1.12 Rationale for the research

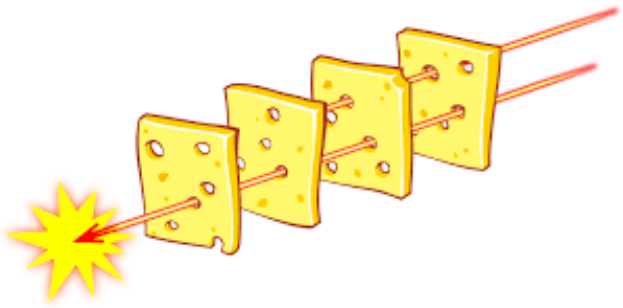




Section 1.13 Theoretical foundations for the research program

The theoretical ideas underpinning the research to be undertaken fall in two main parts. The first encompasses error theory and is based on the popularly called *Swiss cheese* model (Reason 2000). In brief, several defensive barriers or layers exist, which in concert normally prevent medical errors from being realised. The type and nature of the barriers vary according to the discipline, but encompass factors related to patients, individual or groups of healthcare personnel, physical features of the workplace, the characteristics of the broader organisation and external environments, as well as the nature of individual tasks being undertaken. When mistakes in one or more of these barriers (that is, holes in individual slices of cheese) align, it is possible for patient harm to occur (see figure 1.13, below).

Figure 1.13 The Swiss cheese model analogy for errors in healthcare



Although it is likely that defences are not as linear or hierarchical as conceptualised in the Swiss cheese model or indeed that any single model can adequately capture the complexity of some accidents (van Beuzekom et al. 2010; Li & Thimbleby 2014; Reason et al. 2006), the logic inherent in the model's linear causal relationship is intuitively appealing and an important reason for the widespread use of incident registers.

Error theory has contributed to a shift in emphasis from deficiencies in individual acts to the role played by underlying system factors in the genesis of errors (Nolan 2000; Vincent et al. 1998). These underlying system factors are described as *latent* because they are often long standing and overlooked. In contrast, *active* factors are easily recognisable by their temporal and/or geographic proximity to the incident in question and often include an individual human element. Despite their immediacy and apparent prominence, active factors are now considered less important in causing errors in medicine (Nolan 2000; Vincent et al. 1998). Indeed, it has been suggested that without correction of the underlying latent factors, errors are inevitable

whoever is involved, thus spawning the phrase "*the second victim*" to refer to individual health care workers who are inappropriately blamed for incidents (Wu 2000). The extent to which ARIR reports permit identification of active and latent factors is explored in chapter 2.

Section 1.14 An alternative patient safety theoretical model: when things go right

The second theoretical consideration in this thesis stems from growing acknowledgement that, despite concerted efforts to learn from when things have gone wrong, adverse incidents in healthcare have not declined since the Institute of Medicine's "*To err is human*" report (Shojania & Thomas 2013; Vincent et al. 2008; Buist & Middleton 2013). Consequently, the spotlight has transitioned from an emphasis on learning from mistakes (as depicted in incident reports) and consequent adherence to appropriate standards and procedure guidelines, to understanding:

"*what enabled us to maintain the integrity of the system*"

(Thomas et al. 2011, p. 638). This paradigm shift reflects the emergence of a new theoretical concept for patient safety, known as "safety-II" or "resilience".

Safety-I (which incorporates discipline specific training, attainment of qualifications, licensing and accreditation, continuing professional development, adherence to procedures and guidelines, and learning from mistakes identified in incident reports) and safety-II differ as summarised in Table 1.14 (below):

Table 1.14 A comparison of key differences between resilience and incident reporting (adapted from Hollnagel 2012)

Safety-I (adherence to standards and guidelines and learning from incident reporting)	Safety-II (resilience)
Uses theory of error	Uses theory of action
Relies on avoiding things that go “wrong”	Promotes things that go “right”
Reactive	Proactive
Samples and assesses failures and incidents	Samples normal working practices
Limited to a fraction of available data	Uses nearly all available health system data
Minimises potentially harmful variations in practice by ensuring compliance with guidelines, rules and audits	Refines safety and sustains success by promoting flexibility in the face of varying and potentially disruptive circumstances at work
Useful in technical systems in which linear causality can be applied	May be better suited to complex variable systems, such as health care organisations
There is competition between safety and “core” business	Safety and “core” business are complementary

The concept of safety-II has been reasonably well articulated, but methods to assess it are in their infancy (Anderson et al. 2016). One suggestion has centered on auditing the extent to which health care organisations and individuals conform with principles that are recommended and/or considered ideal (Costella et al. 2009). Although it would be feasible to adapt this to nuclear medicine, the auditing process imposes additional training and administrative requirements. Further, the validity of measurements obtained for audits is uncertain (Modak et al. 2007) and there is concern that checklist based audits are reductionist in that they may oversimplify inherently complex processes (Catchpole & Russ 2015).

In contrast to auditing, a more pragmatic area of research may lie in understanding the nature of tasks undertaken by key healthcare personnel and how they maintain safety whilst managing competing priorities and potentially disruptive events, such as interruptions. As previously mentioned (section 1.11), there may be a link between interruptions and distractions experienced by nuclear medicine technologists and maladministrations (Yenson et al. 2005). Although interruptions in healthcare organisations are considered inevitable and likely contribute to errors, the nature of the link is not well-defined (Raban & Westbrook 2014; Grundgeiger & Sanderson 2009). Thus, a direct observation study of nuclear medicine technologists could characterise the rate and nature of interruptions that they experience, as well as portray how they maintain or create safe working situations, and sustain performance under a range of conditions, both expected and unexpected (Vanderhaegen 2015). This could lead to new ways of characterising and measuring safety in nuclear medicine. It is possible that more thoughtful workplace interventions around interruption management and design of new technologies (Raban & Westbrook 2014; Walter et al. 2015; Grundgeiger & Sanderson 2009) could be devised in nuclear medicine. Measurements by direct observation of nuclear medicine technologists using simple hand-held computer tablets and validated work-observation software are now feasible, having been employed in other medical disciplines (Westbrook & Ampt 2009). This research is reported in chapter 4.

Section 1.15 Scope of this research

The empirical work in this thesis has three main parts, covering ARIR incident reports, Australian incident reporting systems and nuclear medicine technologists. First, I describe the status of maladministrations in Australia through an exploration of the ARIR. The ARIR data are derived from reports of individual maladministrations

and offer a description of individual incidents, their causes, complications including radiation exposure and organ damage, and any remedial action undertaken. These data permit the type of maladministration to be defined according to previous guides (Williams & Harding 1995; Yenson et al. 2005). It is also possible to estimate the maladministration incidence by comparison to publicly available data on total numbers of nuclear medicine procedures from Medicare Australia (Department of Human Services, Australian Government 2017).

Second, I evaluate the extent to which individual ARIR reports permit identification of active and latent causes of maladministrations and assess the magnitude of underreporting and impact of differences in maladministration notification criteria at State and Territory level. As well, I employ control charts to study temporal changes in maladministration data. Control charts can be used to highlight factors associated with 'significant cause variation' in maladministration notification rates (that is, variation which is greater than expected based on historic patterns of the data) (Thor et al. 2007). This type of approach might uncover complementary information about vulnerable nuclear medicine processes and illustrate other ways by which fluctuations in maladministration data can be interpreted.

Third, a work observation study of nuclear medicine technologists permits an assessment of the rate and nature of interruptions that they experience, notably during radiopharmaceutical preparation and dispensation, as well as providing insight into how nuclear medicine technologists adapt to potentially disruptive events and maintain safety under varying conditions. This type of research may help identify additional ways to measure safety and inform quality improvement in nuclear medicine.

Section 1.16 Objectives and research questions

In the context of widespread interest in promoting patient safety and limited information about maladministrations, there is an opportunity to broaden the approach for measuring safety and developing novel quality improvement strategies in nuclear medicine. Accordingly, my thesis question is as follows:

"Safety and quality improvement in nuclear medicine in Australia: what can control charts and work observation studies add to incident reports?"

The research aims were to:

• Use the ARIR to describe the contemporary incidence and consequences of maladministrations in Australian nuclear medicine,

• Identify causes of maladministrations and vulnerable work processes using incident reports,

• Identify potential limitations in the current incident reporting system,

• Apply control charts to maladministration data to identify vulnerable processes and factors associated with 'unnatural variability',

• Use a work observation study of nuclear medicine technologists to measure the rate and nature of interruptions that they experience, and identify and characterise safety oriented strategies and,

• Articulate novel quality improvement strategies that can complement information obtained from incident reports.

These aims are addressed by the following three main research questions which frame the thesis and drive the specific work. At each point, there are several supplementary questions:

Question 1: How can an assessment of the ARIR and the incident reporting system be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?

• What is the incidence of maladministrations?

• What is the relative proportion of the different maladministration types?

• Can active and latent causes be identified from incident reports?

• Can vulnerable work processes in nuclear medicine be characterised?

• What is the mean and range of effective whole body radiation doses imparted by maladministrations?

• What is the risk of organ damage?

• What improvements to the ARIR incident reports could be suggested?

• Can the degree of underreporting of maladministrations be estimated?

• Do dissimilarities in jurisdictional maladministration criteria influence the rate of notifications?

• Are any revisions to the statutory incident reporting system needed and if so, what?

Question 2: How can control charts be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?

• How can control charts portray maladministration data?

• What factors are associated with 'unnatural variability' in maladministration rates and types?

• Can control charts identify vulnerabilities in nuclear medicine not apparent from incident reports?

• What quality improvement strategies could be developed?

Question 3: How can a direct observation study of nuclear medicine technologists be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?

• What is the rate and nature of interruptions experienced by nuclear medicine technologists?

• Is there a role for interruptions management during radiopharmaceutical preparation and dispensation in nuclear medicine facilities?

• What examples of safety oriented strategies can be identified through direct observation of nuclear medicine technologists and can these be classified?

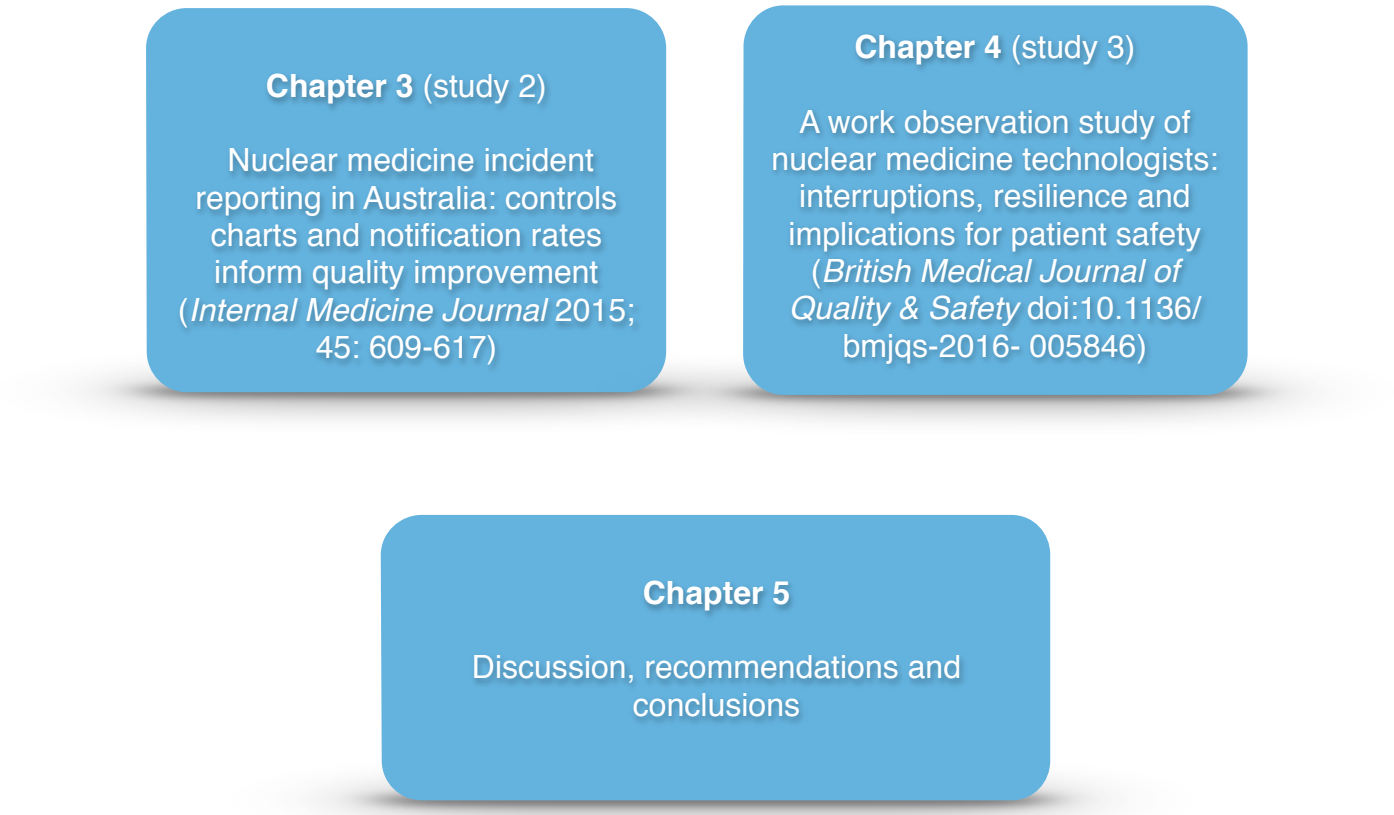
• To what extent can work observation data be used to inform quality improvement in nuclear medicine?

The literature review and theoretical framework reinforce the knowledge gaps and the importance of addressing these questions. Three research studies organised into three chapters provide evidence to answer the above questions.

Section 1.17 Research outline

A schematic summary of my thesis' outline is provided in Figure 1.17 (see below). The thesis is organised into five chapters.

Figure 1.17 Structure of the thesis



Chapter 1 provides the introduction and context for the thesis. The empirical work is in chapters 2, 3 and 4, each with their own focus. Chapter 2 describes the status of maladministrations in Australia from the ARIR perspective. The report describes the incidence and types of maladministrations, as well as highlighting the potential for organ damage and the extent to which both active and latent causes can be inferred from ARIR reports. Chapter 3 shows the role of control charts in exploring ARIR data, as well as providing an estimation of underreporting and assessment of impact of dissimilarities in jurisdictional notification criteria on regional notification rates. Chapter 4 is a direct observation study of technologists in the nuclear medicine department of a large public teaching hospital in Sydney, Australia. The study

describes the rate and nature of interruptions that technologists experience and identifies and classifies examples of resilient strategies used by nuclear medicine technologists.

Chapter 5 features the discussion, outlines the contribution of the empirical work on the literature gaps and considers the implications of this research for quality improvement in nuclear medicine

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CHAPTER 2

Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register (published in Medical Journal of Australia 2014; 200: 37-40)

"The successful man will profit from his mistakes and try again in a different way."

Dale Carnegie (1888-1955).

Section 2.1 Introduction

To orient the reader, I clarify how the term 'maladministration' is used in this thesis and distinguish it from '*misadministrations*' and '*notifiable incidents*' (section 2.2). In sections 2.3 and 2.4 I provide background information about the purpose of the ARIR, as well as the source, content and management of maladministration notifications, respectively. Section 2.5 presents the empirical research performed in response to thesis question 1 (see table 2.1, below) and reproduced with permission of the Medical Journal of Australia (see appendix, p. 134). In section 2.6 I summarise the key findings and discuss implications for informing quality improvement in nuclear medicine.

Table 2.1 Research question 1 revisited

Question 1: How can an assessment of the ARIR and the incident reporting system be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
What is the relative proportion of the different maladministration types?
Can active and latent causes be identified from incident reports?
Can vulnerable work processes in nuclear medicine be characterised?

What improvements to the ARIR incident reports could be suggested?

Section 2.2 Defining maladministrations

Regarding the incorrect administration of a radiopharmaceutical to a patient, two terms have been used, namely *misadministrations* and *maladministrations* (Smart 2002; Williams & Harding 1995). Although the terms have been used interchangeably, they describe distinct events. Misadministrations occur when the patient, radiopharmaceutical type and administered activity are correct, but the administration is performed incorrectly, typically when an intravenously administered agent is accidentally extravasated during injection. In this situation, the quality of images are often poor or non-diagnostic. In contrast, a maladministration describes a situation in which the radiopharmaceutical type and/or administered activity is incorrect or the radiopharmaceutical is administered to an incorrect patient (Smart 2002; Williams & Harding 1995). For this thesis I consider both as 'maladministrations' because they each fulfil the definition used by ARPANSA (ARPANSA 2017) and both expose the patient to unintended ionising radiation (Keeling & Maltby 1994; Yenson et al. 2005). Further, a *repeat* nuclear medicine procedure is usually required in both scenarios, thus adding to a patient's overall radiation exposure for that procedure.

As well, the definition of a maladministration is distinguished from the notification criteria that are used by Australian State and Territory regulatory authorities. The distinction means that some maladministrations may not be considered as notifiable incidents, which may influence the type of information archived within the ARIR (addressed specifically in chapter 3).

Section 2.3 The purpose of the ARIR

The National Heath and Medical Research Council originally established incident reporting for nuclear medicine in 1971. Until the passage of the Australian Radiation Protection and Nuclear Safety (ARPANS) Act and its supporting regulations, reports of maladministrations were made on a voluntary basis to the Commonwealth (subsequently Australian) Radiation Laboratory (Topfer, n.d.). From 2004 annual reports summarising maladministrations and radiation incidents in other fields became publicly available through the ARPANSA online portal (ARPANSA, n.d., a)

According to ARPANSA, the ARIR has four main objectives. First, to highlight specific procedures which may cause a potential hazard to patients or the environment; second, to act as a national focus for information on ionising radiation incidents and accidents; third, to guide users of radiation on preventing or limiting the consequences of radiation accidents through various publications and; fourth, to help ARPANSA generate reports and provide advice to regulatory and other bodies as required (ARPANSA, n.d., b). Although these objectives are framed according to statutory obligations, the ARIR, like the RaER, could be used not only to understand incidents, but to broaden how safety in nuclear medicine is conceived. Part of the research undertaken in this chapter, as well as within chapter 3, illustrates how this can be accomplished.

Section 2.4 The source, content and management of maladministration data in the ARIR

The ARIR includes incidents in 31 categories covering both medical and non-medical (industrial) applications. Amongst medical applications, the register covers incidents

in nuclear medicine, radiology, radiotherapy, cardiology and dental uses. For the reasons mentioned in section 1.2, this thesis focuses on nuclear medicine.

Maladministrations that appear in the ARIR have been submitted to ARPANSA by one of eight Australian State or Territory radiation protection authorities. As indicated in section 1.6.2, the NDRP has been endorsed by all Australian governments with one aim being uniformity in radiation protection practices, including incident reporting (ARPANSA 2017). This means that State and Territory radiation protection authorities receive must report maladministrations to ARPANSA for inclusion in the ARIR, assuming that they fulfil the notification criteria (see table 2.4 below).

Table 2.4 The language of the National Directory for Radiation Protection for the National Incident reporting framework (ARPNSA 2017, pp. 37-38)[5]

Section heading	Description
Definition of a radiation incident (section 13, preamble)	Any unintended or ill-advised event when using ionizing apparatus, specified types of non-ionizing radiation apparatus or radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.
Types of incidents to be reported to the ARIR (section 13, preamble)	Radiation incidents of the following types must be reported to ARPANSA for inclusion in the Register. In some cases judgements will need to be made by the Authority in regard to whether an incident is too minor for reporting to the Register.

[5] For this table, I have copied the spelling used by ARPANSA, specifically the American "ionizing" rather than "ionising".

Schedule 13.1 Medical exposure of patients	When during the administration of a radioactive substance for diagnostic purposes, the activity of the substance administered exceeds the activity prescribed in the hospital/ practice standard protocol for that test by 50% or more; when during the administration of a radioactive substance for therapeutic purposes, the activity administered differs from that prescribed by 15% or more; when during administration of a therapeutic dose of radiation from a radiation apparatus or a sealed radioactive source, the dose delivered differs from the total prescribed treatment dose by more than 10%; any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong radiopharmaceutical; any diagnostic procedure other than as prescribed by the medical practitioner; any diagnostic procedure resulting in an observable acute radiation effect.
Schedule 13.2 Incidents that cause or may lead to radiation injuries or radiation doses exceeding the annual dose limits to workers or members of the public	Note that situations where radiation injuries or high doses [exceeding 0.25 Sv whole body, 0.75 Gy organ dose, 6 Gy skin dose] occur must be reported to the ARIR as soon as possible, and within 24 hours. ARPANSA will report incidents exceeding these doses to the IAEA for inclusion on their severe incidents database.
Schedule 13.3 Lost or stolen radioactive sources or radiation apparatus	Self explanatory
Schedule 13.4 Transport of radioactive material	Where packaging is damaged during freight handling or transport; or where a package is transported without the required documentation, placarding or labelling.
Schedule 13.5 Unintentional or unauthorised discharges of radioactive materials into the environment	Reporting is required when the unintentional or unauthorised activity discharged exceeds 100 times the exempt activity for that radionuclide specified in Schedule 4 of this Directory.
Schedule 13.6 Damage to, or malfunctioning of, a radiation apparatus or sealed source apparatus	Reporting is required where the damage or malfunction could in any way affect the radiation safety of the apparatus, including issues such as the shielding integrity or causing increased radiation levels.

Schedule 13.7 Contamination with, or dispersal of, a radioactive material	Reporting is required where a surface or material is contaminated by a radioactive substance resulting from the spillage of more than 100 times the exempt activity of that substance specified in Schedule 4 of this Directory.
Schedule 13.8 Out of control source of radiation	Reporting is required for situations where a radiation source is out of control. Out of control means, for example, that the source is not safely secured or shielded, or contamination is not confined.
Schedule 13.9 Non-ionizing radiation	Reporting is required for occurrences where there is actual injury, or the potential for injury, as a result of operator error, damage or malfunction of the equipment, or failure of management systems, for the types of non-ionizing radiation equipment specified below: (i) lasers; (ii) radiofrequency generating equipment; (iii) man-made sources of ultraviolet radiation; (iv) magnetic resonance imaging machines.
Schedule 13.10 Nuclear incidents	Reporting is required for events such as criticality incidents or events related to the safety of a nuclear reactor
Schedule 13.11 Other incidents that the authority considers warrant reporting	This could include near-miss situations that should serve as a warning to other users. It could also include situations where radiation monitors at the entrance of scrap metal processing factories and landfill sites are triggered.

The sources of reported maladministrations in the ARIR are jurisdictional (that is, Australian State and Territory) radiation protection authorities, which in turn receive reports from public hospital and private hospital or clinic nuclear medicine or diagnostic imaging facilities.

Once notified to ARPANSA, maladministrations become part of the ARIR and are managed by ARPANSA staff (ARPANSA, n.d., c.). Annual reports are made available through the ARPANSA website (ARPANSA, n.d., a.) and these include details about numbers and categories of maladministrations, estimated effective radiation exposure and causes. More detailed information about individual incidents is not available publicly, but for the purpose of this thesis was obtained in correspondence with ARPANSA (see appendix p. 137).

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 (GL) 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 4.35mSv.
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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Section 2.6 Chapter conclusions and recommendations

The major findings and conclusions of the research into the ARIR are tabulated below (table 2.6.1).

Table 2.6.1 Thesis question 1, findings and implications for safety and quality improvement in nuclear medicine

Question 1: How can an assessment of the ARIR and the incident reporting system be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
Findings • Incidence=5.8 per 100,000 nuclear medicine procedures (95% confidence interval [CI]=5.0-6.9) • Most (98.7%) maladministrations occur in a diagnostic context and the mean effective whole body radiation dose from maladministrations is 7.9mSv (range, 0.015-45mSv); however, 34% of maladministrations are associated with a dose exceeding 10mSv and in three of 149 cases the dose exceeded 20mSv • 1.3% of maladministrations are from therapeutic procedures and these can cause organ damage • The major maladministration type (48%) arises from errors in the preparation of the radiopharmaceutical to be administered or in the administered radioactivity deviating significantly from what has been prescribed • ARIR reports permit identification of active factors contributing to maladministrations in 100% of cases; in contrast, ARIR reports permit identification of latent factors in only 39% of cases

Question 1: How can an assessment of the ARIR and the incident reporting system be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?

Implications for safety and quality improvement

- The ARIR is a useful repository of information about maladministrations in nuclear medicine and can aid the development of additional safety parameters in nuclear medicine
- Radiopharmaceutical preparation and dispensation tasks are most vulnerable
- Most maladministrations fall within the work domain of nuclear medicine technologists
- The content of individual reports can be refined by using a standardised error template
- Latent causes of maladministrations should not be neglected in individual incident reports and specific training in root cause analysis (RCA) may be helpful

This is the first time that the incidence of maladministrations in Australia has been calculated. The figure of 5.8 per 100,000 nuclear medicine procedures is a critical step toward risk communication in nuclear medicine, however it remains imprecise for various reasons, including caveats associated with access to data on numbers of PET and non-billed procedures performed on public hospital inpatients, as well as underreporting. Perhaps of greater importance than the incidence *per se*, however is that annual incident reports issued by ARPANSA are scarcely used for quality improvement and then only to reinforce adherence to procedural guidelines and technical training for individuals (Kearney & Denham 2016). However, corrective strategies which focus on human activity or adherence to checklists are now thought to be relatively ineffective and compliance does not necessarily guarantee that:

> "*tasks are well executed or that patient safety culture is high*" (Clay-Williams & Colligan 2015, p. 428) .

Trbovich and Shojania (2017, p.350) have gone further and likened these type of strategies to the:

"*swatting away of mosquitoes*" rather than "*draining the swamp*".

An additional limitation may be that the incident reporting system in Australia is rooted in a statutory framework, and it can be argued that ARPANSA effectively fulfils its obligations once annual reports are generated. Therefore, a strategy to help shift the focus from a regulatory to patient safety domain may be useful. Using ARIR data to initiate regular dialogue with key stakeholders in nuclear medicine, radiation protection and patient safety may be helpful in this regard.

Whereas ARIR reports permitted identification of active factors in all 149 maladministrations, latent factors were identified in only 39% of reports. This is perhaps unsurprising because assigning causes to maladministrations may not be straightforward for several reasons. Despite RCA being a mandatory element of the statutory reporting process in nuclear medicine, it requires individuals to have appropriate expertise in incident investigation within healthcare organisations. However, these skills are difficult to attain and thus, some authors have expressed doubt about the ability of RCAs to consistently deliver improvements in healthcare quality (Peerally et al. 2017; Nicolini et al. 2011). As well, incident report authors need to have a grasp of the underlying theoretical ideas. For example, incident reports can be subject to hindsight bias, namely the tendency to identify a cause when an adverse outcome is already known (Harrington 2005), notwithstanding "poor to moderate" inter-observer agreement as to the causes (Thomas et al. 2002). As well, 'linear causality' (that is, that a maladministration can be attributed to a particular cause) or variations such as 'domino causality' (in which one event triggers several anticipated and unanticipated secondary incidents) (Vincent 1999; Dovey & Phillips

2004), is often assumed, but these concepts may not necessarily apply in healthcare (Vincent 1999; Harrington 2005). Thus, Harrington (2005, p. 339) states that:

> "*In many complex cases the cause of an event is not observable and requires the exercise of clinical judgment…*"

Vincent (1999, p. 405) has added that we should learn to:

> "*look beyond the immediate failures to their deeper causes"*.

The implementation of standardised error templates in RCA in nuclear medicine may facilitate the identification of latent causes of maladministrations. The language used to define key terms and convey information about errors in medicine can be as important as questions about the quality of the data itself (Scobie et al. 2006; Williams & Osborn 2006; Harrington 2005). A WHO report, commissioned on behalf of the WHO Alliance for Patient Safety, has emphasised the importance of a *standardised* patient safety event classification that can yield information about the epidemiology of adverse events (Sherman & Loeb 2005), thus not only permitting active and latent factors to be explicitly defined, but to be applicable across different facilities and jurisdictions.

Most classification schemes in medicine have been developed for incidents in intensive care, general practice, nursing or hospital pharmacies (Sherman & Loeb 2005; Loeb & Chang 2003) and are either not suited for nuclear medicine and/or only permit a superficial analysis of incidents (Loeb & Chang 2003; Rodrigues et al. 2011). In contrast, the *Generic Occurrence Classification for Incidents and Accidents in the Health Care System*, *Eindhoven Classification Model for Medical Domain* and *Joint*

Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Taxonomy all appear appropriate because they implicitly uphold contemporary error theories (Reason 2000; Vincent 1999), can be customised to nuclear medicine and permit a level of complexity that reflects the different types of maladministrations and their respective causes (Loeb & Chang 2003; Battles & Shea 2001).

The feasibility of using one or these three classification schemes has been illustrated in several studies which assessed errors in radiology, radiation oncology and nuclear medicine (Brook et al. 2010; Hamilton et al. 2003; Rodrigues et al. 2011; Kearney & Denham 2016; Denham & Page 2017). These reports show that it is possible to express the causes of maladministrations using a combination of active and latent factors, as well as considering the role played by individuals and systems. An illustration of how these factors could be incorporated in an error classification scheme is shown below (table 2.6.2).

Table 2.6.2 An example of how an error classification scheme could be used for maladministrations

Error type	Description	Example in nuclear medicine
Human skill	Procedure that is appropriately planned but poorly executed because of a 'slip' or 'lapse' in attention	Neglecting to check or misreading the label on a syringe that has been prepared for another patient

Error type	Description	Example in nuclear medicine
Human knowledge	An individual is unfamiliar with the requested procedure	Performing a lung ventilation perfusion scan instead of the less frequently requested lung clearance scan
Human rule based	A previously sound procedure is found to be deficient in a specific circumstance	A failure to update quality control procedure can contribute to improperly prepared radiopharmaceuticals and consequent maladministrations
Human performance	Deficient technical skills	Extravasation of radiopharmaceutical due to an improperly inserted cannula
Violation	Failure to perform a task as specified according to the facility's policies and protocols	Neglecting to undertake quality control assessment of a prepared radiopharmaceutical
Equipment failure	Failure in a scanner or other device	The gantry on a PET camera fails after the patient has been injected
Patient factors	Refusal, uncooperative, or clinical status affects the scan	A patient becomes unwell after being injected and the scan cannot be obtained
Deficient culture	Organisational attitudes and policies subliminally or overtly undermine patient safety	Failure of nuclear medicine specialist and/or registrar to routinely interview patients before injection
Deficient facility rule	Non-existent or out-dated procedures	Procedures for an uncommonly performed procedure may be unavailable

Error type	Description	Example in nuclear medicine
Deficient communication	Guidance or advice from senior staff or discussion among staff leads to an information vacuum	An external manufacturer advises the chief technologist of revisions in the process required for quality control of a certain radiopharmaceutical, but this information is not communicated to the technologists performing the quality control.
Deficient supervision and training	Inadequate induction training and/or supervision of new members of staff	Incorrect preparation of a radiopharmaceutical by an inadequately supervised student
Management planning	Staff shortages due to planned and unplanned leave affect the workload of individual team members	Individual team members are pressured to care for an unusually high number of patients.
Workplace environment	Poor design or layout	The design of lighting, room layout or ergonomics of workstation placement within a room may be unsuitable for quality care

This type of table shows that the causes of maladministrations can not only be classified using a standardised template, but can incorporate Reason's error theory (Reason 2000). Thus, a more refined assessment of factors contributing to individual incidents can be obtained.

Data in this publication highlight processes in nuclear medicine which are most likely to contribute to maladministrations. Most maladministrations (65%; types 1 and 3) reflect errors in radiopharmaceutical preparation and combined with at least some type 5 errors suggest that work processes related to nuclear medicine technologists

as they prepare, dispense and administer radiopharmaceuticals remain inherently vulnerable. This finding has two implications, one theoretic and the other practical.

From a theoretic perspective, it is possible that the Swiss cheese model may be imperfect for nuclear medicine. It has been argued that in normal circumstances, the presence of a vulnerability in one defensive layer is insufficient to cause an adverse patient event and that incidents occur when vulnerabilities in two or more defensive layers align (Reason 2000). However, my research suggests that at least some maladministration types might occur because one particular defensive barrier is more critical than others. Nolan has reinforced this idea by emphasising that within any system:

> "*a few of the steps will be more hazardous or have error rates that are substantially worse than the rest…"* (Nolan 2000, p. 773).

From a practical perspective, existing recommendations and guides on radiopharmaceutical preparation, storage and ordering, double-checking, colour coding of lyophilised vials, training, time-out protocols and use of information technology reflect the ease with which active factors have been identified (Yenson et al. 2005; Charlton & Emery 2001; Smart 2002; Martin 2005; Kearney & Denham 2016; Williams & Harding 1995). The use of barcode technology (Matanza et al. 2014) for verifying patient identity and radiopharmaceutical type and radioactivity is a more recent promising innovation. However, these recommendations have largely emphasised the same points for over a decade, which highlights the narrow domain in which nuclear medicine quality improvement strategies have operated. Research undertaken in chapter 4 offers an opportunity to broaden the scope of quality improvement strategies.

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CHAPTER 3

Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement (published in Internal Medicine Journal 2015; 45; 609-617).

"*If you do not know how to ask the right question, you discover nothing*." *W. Edwards Deming* (1900-1993).

Section 3.1 Introduction

In the preceding chapters, I suggested that data within the ARIR could be affected by underreporting and, notwithstanding commitment to national uniformity principles within the NDRP, dissimilarities in statutory notification criteria used by jurisdictional regulatory authorities. One of the objectives of this chapter is to characterise the effect of these factors. Chapter 2 confirmed that maladministrations in Australia are rare events (Larcos et al. 2014) and in this context, control charts may be better suited than descriptive studies to highlight vulnerabilities and portray alternative safety measurements in nuclear medicine. This chapter addresses thesis question 2 (see table 3.1, below). In section 3.2 I briefly review the design and plotting of control charts. Section 3.3 presents the empirical research conducted in response to the thesis questions and is reproduced with permission of John Wiley and sons (see appendix, p. 135). Section 3.4 summarises my conclusions and recommendations for quality improvement in nuclear medicine.

Table 3.1 Thesis question 2 revisited

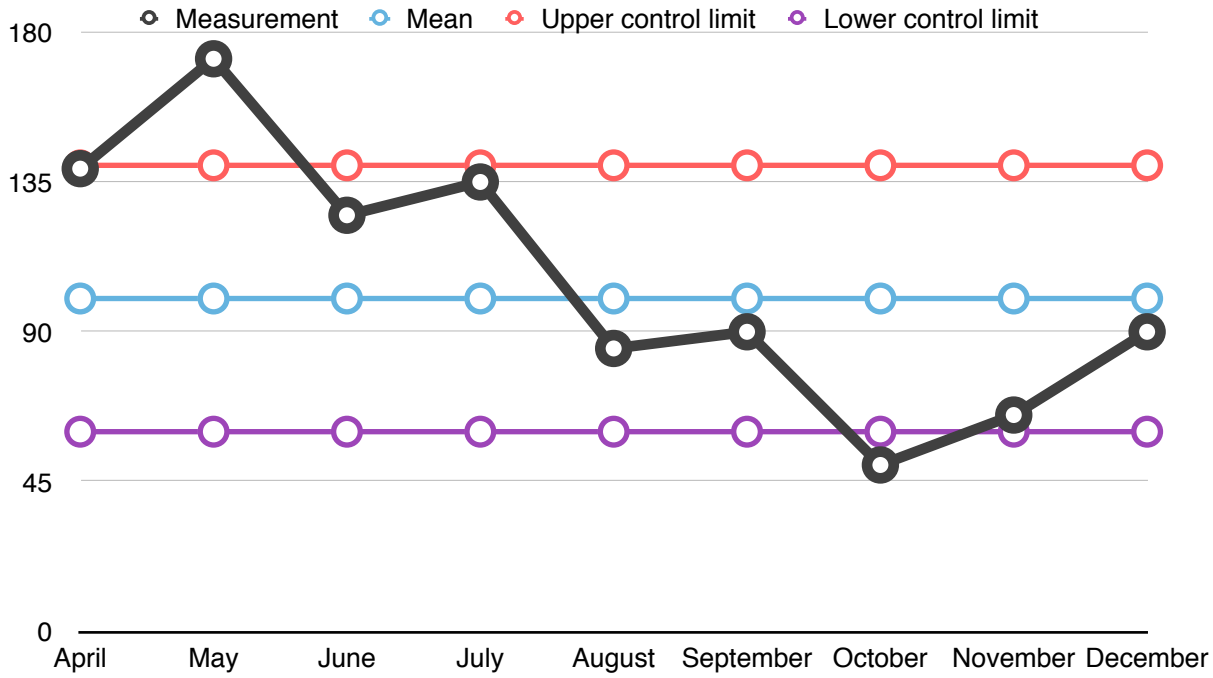
Question 2: How can control charts be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
How can control charts portray maladministration data?
What factors are associated with 'unnatural variability' in maladministration rates and types?
Can control charts identify vulnerabilities in nuclear medicine not apparent from incident reports?
What quality improvement strategies could be developed?

Section 3.2 Control charts: an overview

Control charts are graphs of data presented chronologically, with the purposes of understanding and improving processes (Benneyan 1998). Originally developed for industrial manufacturing, control charts have been widely applied in medicine (Thor et al. 2007). Control charts typically include a plot of data over time, plus three additional lines (indicating the centre line derived from the mean and the upper and lower control limits, usually set at three standard deviations above and below the mean, respectively) (Mohammed et al. 2008). In figure 3.2 below, data points that appear between control limits indicate that the process is stable, with data varying according to chance, thus signifying 'common cause variation'. In contrast, data points at May and October are outside control limits and therefore indicate 'special cause variation'. The probability of these occurring by chance is about one in 370 (Mohammed et al. 2008), thus highlighting the need to explore factors which may be contributing to this 'unnatural variability'. Special cause variation can also be considered present if data exhibit certain trends, such as eight data points trending up or down, or two out of three consecutive values on the same side of the centre line and beyond two standard deviations (Mohammed et al. 2008).

Control charts not only portray a spectrum of variables, but have been used to monitor processes and assess the effectiveness of quality interventions in various health care settings (Thor et al. 2007; Benneyan 1998). In nuclear medicine, they have potential for expanding how safety can be measured, beyond raw numbers of maladministrations per annum.

Figure 3.2 Depiction of a control chart



Various types of control charts can be constructed, depending on whether the data being analysed are discrete or continuous in nature (Benneyan 1998; Mohammed et al. 2013). For the measurements undertaken in section 3.3, I employed the *x-mr* chart which has been described as:

> "*a robust, versatile chart that has been used with a variety of processes*" (Mohammed et al. 2013, p. 139)

Section 3.3 Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement (reprinted from Internal Medicine Journal, 2015; 45: 609-617)

INTERNAL MEDICINE JOURNAL

Internal Medicine Journal **45** (2015)

ORIGINAL ARTICLES

Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement

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Key words
hospital incident reporting, healthcare, quality assurance, radiation protection, nuclear medicine, risk management.

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Abstract

Background: Australia has a statutory incident reporting system for radiopharmaceutical maladministrations, but additional research into registry data is required for the purpose of quality improvement in nuclear medicine.
Aims: We (i) used control charts to identify factors contributing to special cause variation (indicating higher than expected rates) in maladministrations and (ii) evaluated the impact of heterogeneous notification criteria and extent of underreporting among jurisdictions and individual facilities, respectively.
Methods: Anonymised summaries of Australian Radiation Incident Register reports permitted calculation of national monthly maladministration notification rates for 2007–2012 and preparation of control charts. Multivariate logistic regression assessed the association of population, insurance and regulatory characteristics with maladministration notifications in each Australian State and Territory. Maladministration notification rates from two facilities with familiarity of notification processes and commitment to radiation protection were compared with those elsewhere.
Results: Special cause variation occurred in only 3 months, but contributed to 21% of all incidents (42 of 197 patients), mainly because of 'clusters' of maladministrations ($n = 24$) arising from errors in bulk radiopharmaceutical dispensing. Maladministration notification rates varied significantly between jurisdictions (0 to 12.2 maladministrations per 100 000 procedures ($P < 0.05$)) and individual facilities (31.7 vs 5.8 per 100 000; $\chi^2 = 40$; 1 degree of freedom, $P < 0.001$).
Conclusions: Unexpected increases in maladministration notifications predominantly relate to incident 'clusters' affecting multiple patients. The bulk preparation of radiopharmaceuticals is a vulnerable process and merits additional safeguards. Maladministration notification rates in Australia are heterogeneous. Adopting uniform maladministration notification criteria among States and Territories and methods to overcome underreporting are warranted.

Introduction

In nuclear medicine, maladministrations are a particular complication in which there is exposure to unintended ionising radiation. These can arise from the study of an incorrect patient, use of an incorrect radiopharmaceutical or activity, or procedure failure necessitating a repeat test.[1,2] Australia has statutory incident reporting for maladministrations at both State and Federal levels. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) catalogues maladministration reports in the Australian Radiation Incident Register (ARIR). As the national repository of data, information in the ARIR could be pivotal in promoting patient safety and refining radiation protection procedures in nuclear medicine.

Although causes of maladministrations have been reported,[1–4] additional research is required before any quality improvements can be contemplated. Despite its national scope, reported maladministrations in the ARIR are not only rare, but vary over time.[2] The ability to distinguish variation that occurs by chance from that

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which is genuine[5] and potentially indicative of an important safety issue is critical to the development of quality improvement strategies in nuclear medicine.

Interpreting incident registry data presents at least two other challenges. One is unique to the Australian regulatory system and reflects dissimilarities in maladministration notification criteria employed by the various jurisdictions.[6,7] The second arises from underreporting, which is prevalent in other medical incident registers[8] and likely to apply in nuclear medicine.[2,9] Both these factors are likely to distort the type of incidents that are reported and should also be properly characterised.

One solution to the problem of naturally fluctuating data is statistical process control or 'control charts'. These are quality process tools that have been used in diverse medical settings to understand historical patterns in the variation and stability of data and to evaluate the effectiveness of quality interventions.[5,10] Control charts graphically display key measurements, such as the number of maladministrations per month. 'Special cause variation' describes data that lie beyond control limits or exhibit specified trends within control limits that signify 'unnatural' variability.[5,11] The identification of factors associated with special cause variation could be instrumental in identifying key vulnerabilities in nuclear medicine processes.

Potential limitations in the Australian incident reporting system can be addressed in alternative ways. First, using multivariate regression analysis,[12] the association between reported maladministrations and variables such as type of notification criteria can be evaluated. Second, rather than estimating underreporting,[2,9] notification rates from selected individual nuclear medicine facilities with verifiable familiarity of regulatory notification processes and interest in radiation protection could arguably serve as a more robust standard for determining underreporting.

Accordingly, to inform quality improvement in nuclear medicine, we (i) used control charts to identify factors contributing to special cause variation in reported maladministrations and (ii) evaluated notification rates for Australian States and Territories and selected individual facilities to estimate the impact of heterogeneous notification criteria and extent of underreporting, respectively.

Methods

Calculation of monthly national maladministration notification rates

To prepare control charts, we obtained permission from ARPANSA to study anonymised reports of maladministrations in the ARIR from January 2007 to December 2012. The ARIR summaries allowed calculation of the number of maladministrations per month. We classified maladministrations into five types using previous guides (Table 1)[1,2] and estimated the monthly maladministration notification rate by dividing the number of maladministrations for a given month by the corresponding number of nuclear medicine procedures recorded in the Australian Medicare Benefits Schedule (MBS).[13] We considered instances such as radiopharmaceutical extravasation to represent maladministrations in keeping with other studies[1,2] and in recognition that exposure to unintended ionising radiation occurred.

Table 1 Maladministration types

Maladministration type	Description
1	Several radiopharmaceuticals are simultaneously prepared for several 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.
2	A radiopharmaceutical administered to an incorrect patient because two or more have the same or similar names, or a procedure is inadvertently requested for an incorrect patient.
3	A wrong type or dose of radiopharmaceutical is dispensed.
4	An incorrect procedure is performed because the request form is misinterpreted.
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.

Construction of control charts for maladministrations reported to ARPANSA

We used a widely used and robust form of control charts, known as the *Xmr* chart.[5,11] In the *X* chart, maladministration notification rates were plotted for each month from January 2007 to December 2012 and we then depicted the central line (*X bar*) by calculating the mean. The mean moving range is the sum of the difference in successive monthly notification rates divided by the number of measurements minus one.[5,11] The upper control limit, representing three standard deviations, was derived from the mean moving range, according to a previous guide.[11] Using monthly maladministration notification rates as an exemplar, we defined common and special cause variation as follows:

Table 2 Australian jurisdictional notification criteria

Criterion type	Wording in parliamentary act or regulation	Jurisdiction
Prescriptive	An abnormal or unplanned radiation exposure occurs whether during the administration of a radioactive substance for diagnostic or therapeutic purposes and exceeds what is prescribed by 50% and 15% respectively.[16–18]	NSW, WA, Victoria*
Prescriptive	The effective dose or an intake of any radioactive substance is more than twice that which is likely to occur during any operation normally carried out with that source of ionising radiation.[19]	SA
Discretionary	Nuclear medicine users must ensure that the administered radioactivity 'complies' with the requested procedure.[20,21]	Tasmania and Queensland
Discretionary	Nuclear medicine users 'must ensure that the treated person does not receive a dose of radiation from the procedure that is not in accordance with the request'.[22]	ACT
Discretionary	'Nuclear medicine users must ensure that the treated person does not receive a dose of radiation from the carrying out of the procedure in an amount or a way that does not comply with the request for the diagnostic procedure or prescription for the therapeutic procedure'.[23]	NT

*In Victoria, there is an additional requirement to report any incident in which 'any human diagnostic procedure other than that prescribed that could lead to an effective dose exceeding 1 mSv'.[18] ACT, Australian Capital Territory; NSW, New South Wales; NT, Northern Territory; SA, South Australia; WA, Western Australia.

the former describes a monthly notification rate that is 'stable', lies within control limits and varies according to chance, whereas the latter describes a notification rate that exceeds control limits or exhibits certain trends between control limits that suggest a process that is 'out of control'.[5,11] After studying the monthly maladministration notification rates for special cause variation, we also constructed monthly control charts for the number of: type 3 maladministrations; maladministration 'clusters' in which two or more patients were affected in the same incident; and maladministrations arising from commercial radiopharmacies. For ease of viewing, we integrated the *X* and *mr* charts into a single panel.

State and territory maladministration notification rates

We corresponded with and/or reviewed respective Radiation Advisory Council (RAC) annual reports in which summaries of maladministrations are recorded. Maladministration numbers were compiled for each Australian State and Territory for a 5-year period starting either June 2006 or January 2007 (in four jurisdictions (New South Wales (NSW), South Australia (SA), Tasmania and Queensland) annual reports are published on a financial year basis).

We also considered factors that could influence the denominator in notification rate calculation, namely access to services and number of nuclear medicine procedures recorded in the MBS. Accordingly, we documented population size, proportion of persons residing in remote or very remote communities[14] and health insurance rates[15] for each Australian State and Territory for the same 5-year period. Regulatory requirements for maladministration notifications were also examined.[16–23] These are similar across Australian States and Territories, except for the following: first, a radiation safety officer (RSO) is not mandatory in all jurisdictions. A RSO within a nuclear medicine facility may be associated with more maladministration notifications because of their familiarity with regulatory requirements. Second, there is a divergent approach concerning the threshold for notification when the administered activity differs from what is prescribed. In particular, some jurisdictions (NSW, Victoria, SA and Western Australia (WA)) specify the limit above which a deviation in activity becomes notifiable, whereas others use discretionary language and the judgement for notification resides with individual specialists (Table 2).

Estimation of maladministration underreporting

We determined maladministration notification rates from two nuclear medicine facilities in Sydney whose medical physicist and physician staff have served on the NSW RAC and have published articles on radiation protection and/or maladministrations.[1,2,7,24] We reasoned that because of their familiarity with regulatory processes and interest in radiation protection, there would be a high likelihood that maladministrations would be notified to the radiation regulatory authority.

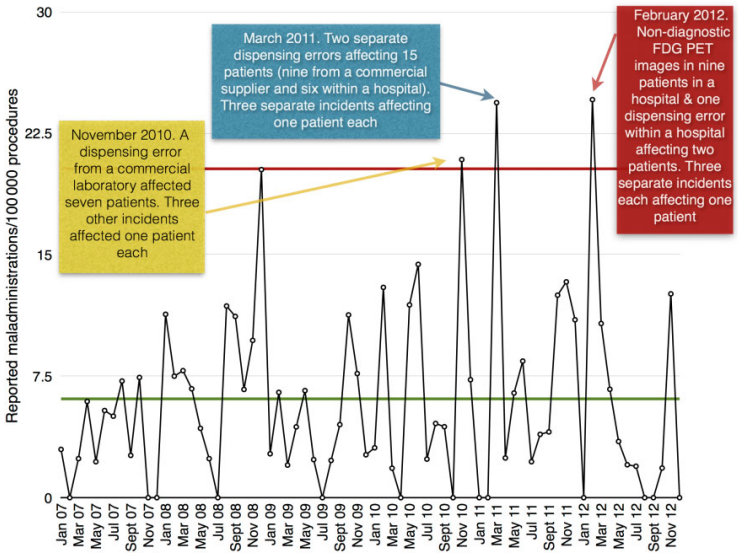

Figure 1 Xmr chart: National monthly maladministration notification rate. (○), X; (—), central line; (—), upper limit (mr).

Since both facilities are accredited for specialist training and are located within teaching hospitals, it is possible that the type and complexity of nuclear medicine procedures (and therefore inherent risk of maladministrations) could be different from facilities elsewhere. Accordingly, we recorded the number of accredited training facilities and nuclear medicine practices within Australia and compared the type of procedures performed in these two facilities with those recorded in the MBS.[25–27] The number of maladministration notifications from the two Sydney facilities between 2009 and 2011 was obtained by direct correspondence. The sum of maladministrations in the ARIR for the same period minus those from the two selected facilities represented notifications from all other nuclear medicine facilities.

Statistical analysis

For control charts, we conducted a narrative of events in months associated with special cause variation. For comparison of maladministration notification rates among Australian States and Territories and between the two selected facilities and elsewhere, we used Fisher's exact and Pearson Chi-squared tests and 95% confidence intervals (CI). To determine independent variables associated with maladministration notifications backward stepwise variable selection multivariate logistic regression (SPSS, version 21, IBM, Chicago, IL, USA) was employed. Logistic regression was used because the dependent variable in our study, namely maladministrations, can be regarded as being a dichotomous outcome (i.e. as either occurring or not). A P value of <0.05 was considered statistically significant. The University of NSW Human Research Ethics Committee approved our research.

Results

Depiction of special cause variation for monthly maladministration notification rate

Control charts for 2007–2012 monthly maladministration notification rates are depicted in Figure 1. The central and upper limits were 6.1 and 20.3 maladministrations per 100 000 procedures respectively. There was special cause variation in 3 months (November 2010, March 2011 and February 2012), with a notification rate exceeding the upper control limit (20.87, 24.38 and 24.6 respectively). Forty-two maladministrations occurred in these 3 months, representing about 21% of the total ($n = 197$) for the entire 6 years; the predominant event in these months were four incidents in which errors during bulk radiopharmaceutical preparation caused maladministration 'clusters' in 24 patients. These maladministrations were attributed to commercial and hospital laboratories in 16 and 8 patients respectively. Non-diagnostic images requiring repeat studies contributed to nine maladministrations. Maladministrations from separate unrelated incidents were noted in the remaining nine cases.

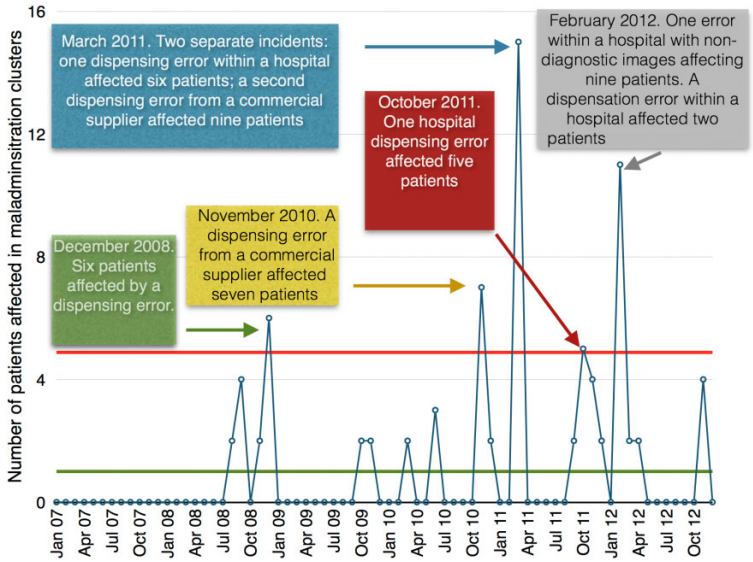

Figure 2 Xmr chart: monthly maladministration clusters.

Maladministrations 'clusters' occurred in 19 of the 72 months and affected 75 patients (Fig. 2). However, special cause variation was identified in only five of these 19 months (December 2008 (n = 6), November 2010 (n = 7), March 2011 (n = 15), October 2011 (n = 5), February 2012 (n = 11); central line = 1, upper control limit = 4.86). These 44 maladministrations related to six incidents from bulk radiopharmaceutical dispensation errors (n = 35 patients) or a single incident involving equipment malfunction (n = 9 patients).

Special cause variation in type 3 maladministrations and maladministrations arising from commercial laboratories occurred in the same 4 months (December 2008, November 2010, March 2011 and November 2012; Figs 3,4).

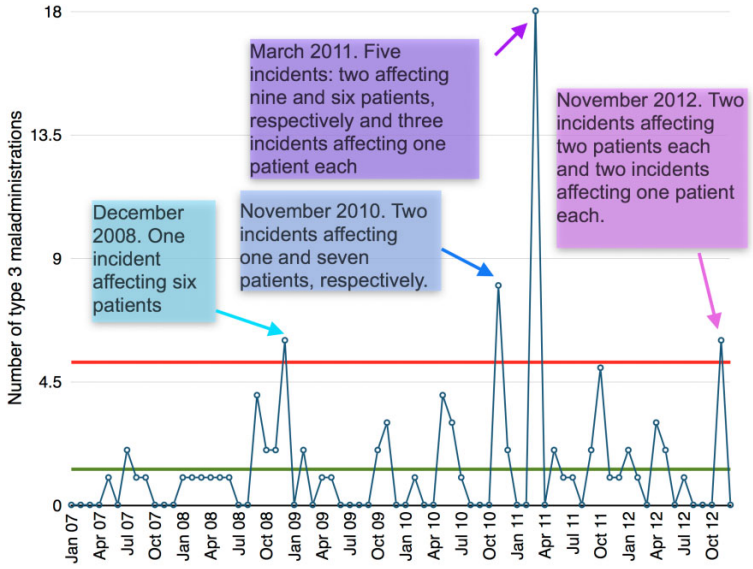

Figure 3 Xmr chart for type 3 maladministrations. (), Measurement; (), central line; (), upper control limit.

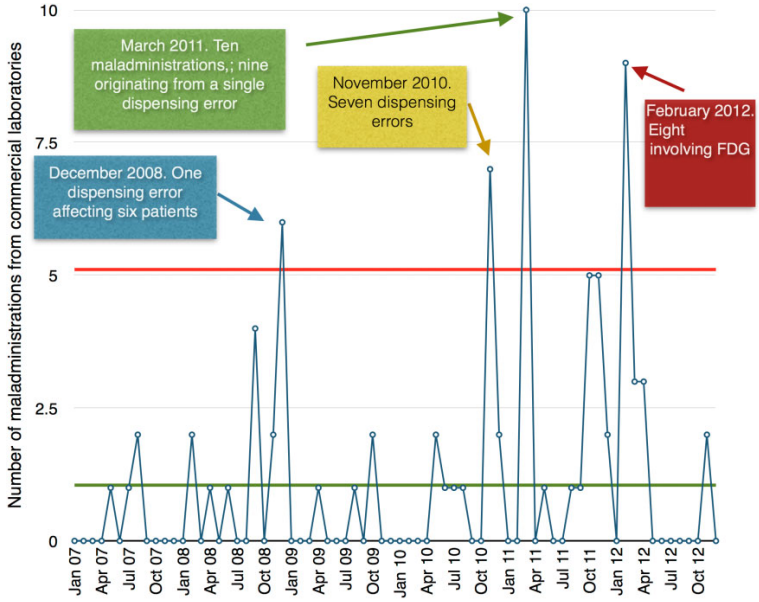

Figure 4 Maladministrations from commercial laboratories. (○), Measurement; (—), central line; (—), upper control limit.

Assessment of notification rates in Australian States and Territories, 2007–2011

Population, insurance and regulatory characteristics, maladministration numbers and notification rates for all States and the two Territories are provided in Table 3. There were no reported maladministrations in the Australian Capital Territory (ACT) or the Northern Territory (NT). For Tasmania, six maladministrations relating to a single incident occurred in 1 year, but there was none in the other 4 years. In WA, there were two maladministrations in each of 2007, 2009 and 2010 with three maladministrations in each of 2008 and 2011. In SA, there were two maladministrations in 2007–2008, 2008–2009 and 2010–2011, with one each in 2006–2007 and 2009–2010. In Queensland, there were no maladministrations in 2007, one in 2008 and 2011, and three in 2010. In Victoria, there were 5 maladministrations in 2007, 7 in 2008, 17 in 2009, 11 in 2010 and 6 in 2011. In NSW, there were 78 reported maladministrations (nine in 2006–2007, 10 in 2007–2008, 21 in 2008–2009, 10 in 2009–2010 and 28 in 2010–2011). Among States and Territories, the maladministration notification rate varied from 0 to 12.2 per 100 000 ($P < 0.001$).

Using backward stepwise variable selection logistic regression, the only factor independently associated with

Table 3 Australian State and Territory maladministration notification rate, 2007–2012

	ACT	NT	Tas	WA	SA	Qld	Vic	NSW
Incidents	0	0	6	12	8	5	46	78
MBS procedures	39 220	9472	49 061	163 228	134 798	374 397	571 611	1 115 993
Notification rate per 100 000 (95% CI)	0 (0–9.8)	0 (0–40.5)	12.2 (5.6–26.7)	7.4 (4.2–12.9)	5.9 (3.0–11.7)	1.3 (0.6–3.1)	8 (6–10.7)	6.7 (5.4–8.4)
Criterion type	D	D	D	P	P	D	P	P
RSO	D	D	M	M	M	M	D	D
Population ('000)	351.2	224.8	502.6	2387.2	1645	4406.8	5427.7	7099.7
Remote (%)	0	44.3	2.1	6.5	3.7	3.1	0.085	0.52
Private health insurance (%)	54.9	34.8	43.2	50.5	44.7	42.3	43	45.2

ACT, Australian Capital Territory; D, discretionary; M, mandatory; MBS, Medicare Benefits Schedule; NSW, New South Wales; NT, Northern Territory; P, prescriptive; Qld, Queensland; RSO, radiation safety officer; SA, South Australia; T, Tasmania; Vic, Victoria; WA, Western Australia.

Table 4 Selected Sydney hospitals' maladministration notification rate, 2009–2011

Facility	Maladministration number	Nuclear Medicine procedures	Notification rate per 100 000 procedures (95% CI)
Facility A	6	24 459	24.5 (11.2–53.5)
Facility B	5	10 268	48.7 (20.8–113.9)
Facility A and B	11	34 727	31.7 (17.7–56.7)
All Australian facilities	93	1 575 172	5.9 (4.8–7.2)

CI, confidence interval.

Table 5 Comparison of nuclear medicine procedures at selected Sydney facilities and within the MBS

	MBS	Facility A	Facility B
Low dose CT (with SPECT)	19%	12.4%	18.2%
Stress/rest myocardial perfusion	15.4%	10.6%	14.6%
Whole bone scan +SPECT	12.7%	14.8%	9%
Whole body bone scan	9.8%	4%	4.6%
Regional bone scan + SPECT	6%	4.1%	1.7%
Thyroid	4.9%	5%	2%
Regional bone scan	4.7%	4.4%	1.9%
Lung ventilation/perfusion	3.4%	7%	8.9%
Lymphoscintigraphy	2%	1.3%	7.3%
Gated heart pool scan	2%	1.9%	13.6%
Total	79.9%	65.5%	81.8%

CT, computed tomography; MBS, Medicare Benefits Schedule; SPECT, single photon emission computed tomography.

maladministration notifications was the presence of prescriptive reporting criteria ($P < 0.001$; 1 degree of freedom (df)). The odds ratio (OR) for maladministration notification was 3.05 (95% CI = 1.65–5.64) for jurisdictions with prescriptive versus discretionary criteria. This finding persisted on exclusion of data from the ACT and NT ($P < 0.001$; 1 df; OR = 2.74; 95% CI = 1.48–5.05).

Determination of underreporting, 2009–2011

The two Sydney facilities with verifiable familiarity of notification criteria and interest in radiation protection issues notified of five and six maladministrations respectively. Nine of these maladministrations involved separate patients; two patients were affected in one incident. The maladministration notification rates for these two facilities were similar to each other ($P = 0.32$), but both were individually and collectively significantly higher when compared with rates for all other Australian facilities combined ($\chi^2 = 40$, 1 df, $P < 0.001$) (Table 4). The OR for maladministration notifications from these two facilities was 5.9 (95% CI = 3.2–11.2) compared with other Australian facilities and 6.4 (95% CI = 3.2–12.5) compared with other NSW facilities.

Including these two facilities, Australia has 36 nuclear medicine departments that are accredited for specialist training in nuclear medicine.[26] In turn, these 36 facilities form part of the approximately 200 facilities across Australia in which nuclear medicine services are performed.[27] Nine imaging types accounted for nearly 80% of all nuclear medicine procedures in the MBS.[25] The same nine procedures also accounted for the majority of studies at the two Sydney facilities (65.5% and 81.8% respectively) (Table 5).

Discussion

Maladministrations are rare but represent an important patient safety issue in nuclear medicine, because of potential complications related to unintended ionising radiation.[1,2] Although failures contributing to maladministrations can occur at any time from a procedure being requested to a patient being scanned or treated, the most common type reflects errors in the preparation of radiopharmaceuticals.[1,2,4] Maladministrations occur infrequently, with an estimated incidence of less than one per 10 000 nuclear medicine procedures.[2] This low incidence, coupled with natural variability in the rate of reported maladministrations, means that appropriate statistical methodology should be used to inform quality improvement.

To this end, control charts have been employed widely as quality improvement tools in medicine[5,10,11] and our study is an example of their application in nuclear medicine. We found that control charts could highlight factors associated with significant variations in the maladministration notification rate. In particular, special cause variation in the monthly maladministration notification rate reflects maladministration 'clusters' in which multiple patients are affected as part of the same underlying event. These types of incidents contrast with the usual pattern of maladministrations in which a single patient is affected per event.[1–4] Further, we identified the bulk preparation of radiopharmaceuticals (mainly from commercial laboratories) and equipment failure as contributing factors. In many cases, there can be an interval of several hours between radiopharmaceutical administration and patient scanning and so it is possible for multiple patients to be injected before an error with an incorrect radiopharmaceutical or equipment failure is appreciated. Regarding the former cause, we suggest that research into vulnerabilities during the radiopharmaceutical preparation and dispensation process is warranted. This could include the role of interruptions during radiopharmaceutical

preparation,[3] organisational weaknesses[28] and the implementation of bar-coding technology during radiopharmaceutical preparation.[29]

There is significant variation in notification rates among Australian States and Territories and our analysis implies that discrepancies in jurisdictional notification criteria are at least partly responsible. Jurisdictions with prescriptive maladministration notification criteria have an approximately threefold higher notification rate, probably because there is more clarity about whether a particular incident should be reported. Based on our data, we recommend that the same prescriptive notification criteria be adopted in all eight Australian jurisdictions. Our suggestion would mean regulatory changes in at least four jurisdictions but would be consistent with national uniformity principles. [6] Our findings have implications for the type of notification criteria used in conjunction with other national nuclear medicine incident registers, such as in the United Kingdom.[30]

Previously, the extent of underreporting to nuclear medicine incident registers was based on opinion.[1,2,9] We illustrated an alternative method by which underreporting of maladministrations could be derived. However, we caution that the observed difference in notification rates at facility level could have several causes. We showed that there are dissimilarities in the type of procedures undertaken, likely reflecting the fact that the two selected facilities are located within tertiary referral public hospitals, whereas data in the MBS represent diverse settings. It is possible that a finite number of procedures at these two facilities are more complex and consequently more maladministrations ensue. However, a previous study of 57 maladministrations in NSW indicated that public and private nuclear medicine facilities experienced the same type of maladministrations,[1] suggesting that procedure complexity does not necessarily increase the risk of any particular type of maladministration. Further, in the context of 36 accredited training facilities within Australia, we would have expected to see significantly more maladministrations than were actually recorded within the ARIR. Another reason for the difference in notification rates may be related to deficiencies in supervision and/or staff expertise at the two Sydney facilities, thus rendering them more vulnerable to maladministrations. However, this would seem counterintuitive given their commitment to radiation protection and patient safety.[1,2,7,24] Finally, there may be significant underreporting of maladministrations from other facilities, both in NSW and other jurisdictions. Although speculative, we suspect that this is the most likely cause because there is strong evidence for underreporting in other disciplines.[31] Assuming that our estimate of the extent of underreporting is correct, then the national maladministration notification rate could be five to six times higher than suggested in a recent report on the ARIR.[2] More importantly, the likelihood of underreporting denies ARPANSA and radiation protection experts the opportunity to understand fully the causes, types and consequences of maladministrations. Consequently, contemporary communication and management of risk in nuclear medicine may be compromised.

Our study has several implications for attaining quality improvement in Australian nuclear medicine. Control charts have potential for use as a monitoring tool, but certain refinements would be required. Currently, ARPANSA provides publicly available aggregated summaries about maladministrations on an annual basis, meaning that identification of emerging trends can lag significantly. We suggest that more frequent 'real-time' evaluation of ARIR data would be useful, although this could also be time consuming.[10,11] As well, collaboration with other stakeholders, including the Australasian Association of Nuclear Medicine Specialists, in the review of data and dissemination of relevant lessons about maladministrations may overcome the current lack of engagement[32] and reinforce the promotion of patient safety. Finally, implementing nationally uniform prescriptive notification criteria and research into identifying the type of barriers to incident reporting in nuclear medicine would be worthwhile.

Conclusion

To summarise, the use of control charts and maladministration notification rates can inform quality improvement by identifying deficiencies in nuclear medicine processes and incident reporting. The bulk manufacture of radiopharmaceuticals is associated with maladministration 'clusters' and higher than expected notification rates and therefore merits additional safeguards. Significant variations in maladministration notification rates exist across the country and we recommend the adoption of prescriptive notification criteria by all jurisdictions, as well as the promotion of incident reporting.

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Section 3.4 Chapter conclusions and recommendations

The major findings from this research are tabulated below (tables 3.4.1 and 3.4.2), reflecting an assessment of caveats associated with Australia's statutory reporting system and insight obtained from the use of control charts.

Table 3.4.1 Australia's statutory incident reporting system: findings and suggestions for quality improvement

Parts of thesis question 1: Identify potential limitations in the current incident reporting system. • **Can the degree of underreporting of maladministrations be estimated?** • **Do dissimilarities in jurisdictional maladministration criteria influence the rate of notifications?** • **Are any revisions to the statutory incident reporting system needed and if so, what?**
Findings • There is significant variation in notification rates across Australian States and Territories (0-12.2 per 100,000 nuclear medicine procedures; $p<0.001$) • Jurisdictions with prescriptive notification criteria are more likely to report maladministrations to ARPANSA than jurisdictions with discretionary criteria (odds ratio [OR]=3.05; 95% CI=1.65-5.64) • Two Sydney based nuclear medicine facilities with verifiable knowledge of nuclear medicine regulatory processes and interest in patient safety have an OR of maladministration notification of 5.9 (95% CI=3.2-11.2) compared to all other Australian nuclear medicine facilities
Implications for safety and quality improvement • Australian State and Territory jurisdictions should adopt uniform prescriptive notification criteria for maladministrations • Underreporting of maladministrations is likely and the national maladministration incidence could be five to six times higher than estimated. Research on identifying causes of underreporting may be needed

Table 3.4.2 Control charts in maladministrations: findings and suggestions for quality improvement

Thesis question 2: How can control charts be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
Findings • Various indices, reflecting safety in nuclear medicine, can be graphically displayed on a monthly basis • Unnatural variation in maladministration rates occurred in 3 of 72 months, but contributed to 21% (42 of 197) of all incidents • Maladministration clusters cause 'unnatural variability' in monthly notification rates and relate to errors in the bulk manufacture of radiopharmaceuticals or equipment failure, thus affecting multiple patients as part of the same incident
Implications for safety and quality improvement • Control charts permit safety in nuclear medicine to be illustrated and measured in an expanded way and can complement information from the ARIR • Control charts can be configured to display parameters of interest related to maladministrations on a monthly basis • Control charts permit monitoring on a 'real-time' basis and can facilitate engagement with stakeholders in nuclear medicine, radiation protection and patient safety • Assessment of work practices and safety culture in commercial manufacturers of radiopharmaceuticals is indicated

A novel finding in chapter 3 regards underreporting of maladministrations. Although it is unsurprising that underreporting occurs, its extent in nuclear medicine has never been researched. In other medical disciplines Mahajan (2010, p. 72) has suggested that only:

> "*a small percentage*"

of incidents are ever reported. Westbrook and colleagues (2015) quantified that only 1.3% of clinically important prescribing errors were reported to hospital incident reporting systems, and the remainder were unreported probably because they were

undetected by hospital staff. Whilst most maladministrations would be clinically detectable, data in this chapter show that the incidence of maladministrations could nevertheless be up to six times higher than estimated from chapter 2 (Larcos et al. 2014). Further, while the barriers to incident reporting are generally known (table 3.4.3, below), I highlighted a unique cause for nuclear medicine incident underreporting in Australia, that is, the nature of notification criteria themselves exert an influence. In nuclear medicine, jurisdictions with prescriptive criteria (NSW, Victoria, SA and WA) have a notification rate which is approximately three times higher (odds ratio=3.05; 95% CI=1.65-5.54) than in jurisdictions with discretionary criteria (Queensland, Tasmania, ACT & NT). Eliminating this barrier would require changes to regulations and/or statutes in Queensland, Tasmania and the two Territories, but would be consistent with national uniformity principles (ARPANSA 2017).

Table 3.4.3 Barriers to incident reporting

Authors (year of publication)	Barrier type
Waring (2005)	Concern about adverse consequences on the reporting individual, such as litigation and blame
Kaldjian et al. (2008)	Unfamiliarity with what & how to report
Braithwaite et al. (2005); Noble & Pronovost (2010)	Reporting systems and forms are too complex
Kaldjian et al. (2008); Noble & Pronovost (2010)	An absence of a reporting culture or uncertainty about whose responsibility it is to report
Lawton & Parker (2002); Noble & Pronovost (2010)	The event may not be considered to have severe consequences or to represent a serious deviation from protocol
Noble & Pronovost (2010)	Concern about breach of confidentiality
Kaldjian et al. (2008)	Completing the report is time consuming and likelihood that nothing positive will ensue

Authors (year of publication)	Barrier type
Evans et al. (2006)	A lack of feedback
Kaldjian et al. (2008)	Uncertainty about the true causes of the incident
Waring (2005)	A perception that errors are inevitable
Waring (2005)	A rejection of bureaucratic oversight and 'intrusion' of management into medical matters
Waring (2005)	A feeling that it is not the responsibility of doctors to notify
Westbrook et al. (2015)	Difficulty in detecting that an error had occurred

In chapter 2 I suggested the need to move the focus of ARIR incident reports from a regulatory domain to one in which patient safety and quality are emphasised. Research from section 3.3 shows the potential of using control charts *both* as a quality process tool *and* as a mechanism to achieve this transition. Control charts permit 'real-time' monitoring of temporal trends in maladministration data; this compares to the current situation (in which annual reports become publicly available many months after data have been compiled), and offers the opportunity for ARPANSA to better engage professional groups in nuclear medicine and radiation protection. Control charts are suited for rare events such as maladministrations and can be configured to analyse a broad spectrum of safety measures in nuclear medicine; for example, instead of maladministration notifications per annum, effective whole body radiation dose per incident, type of maladministration or origin of incident (private or hospital clinic) could be assessed on a monthly basis.

The empirical research in section 3.3 indicates that maladministration clusters contribute to special cause variation in notification rates. Although maladministration clusters have been previously reported (Martin 2005), findings in this thesis emphasise the link to errors in the bulk manufacture of radiopharmaceuticals and

failures in equipment, and reinforce the ability of control charts to provide unique insight about vulnerabilities in nuclear medicine processes. Work processes in commercial manufacturers of radiopharmaceuticals are likely dissimilar to clinical nuclear medicine departments and control charts could be used to explore processes and assess quality interventions in these particular environments. Research in chapter 4 offers an opportunity to reinforce safeguards and identify new ways to mitigate risk.

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CHAPTER 4

A work observation study of nuclear medicine technologists: interruptions, resilience and implications for patient safety (published in British Medical Journal Quality and Safety online first 5 October 2016; doi:10.1136/ bmjqs-2016-005846)

"*Measure what is measurable, and make measurable what is not so*". *Galileo Galilei (1564-1642).*

Section 4.1 Introduction

This chapter centres on thesis question 3 (see table 4.1, below). Previous research has suggested that interruptions may increase the risk of errors in the dispensation of medications in hospitals (Westbrook et al. 2010). Data in chapters 2 and 3 confirm the vulnerability of certain tasks undertaken by nuclear medicine technologists, notably radiopharmaceutical preparation and dispensation (Larcos et al. 2014; Larcos et al. 2015). Despite long standing guides on technical training and procedural compliance (Smart 2002; Charlton & Emery 2001), research in chapter 2 shows that neither the rate nor numbers of maladministrations per annum has declined in recent years (Larcos et al. 2014). Thus, there is a need to consider alternative ways of measuring safety and informing quality improvement strategies in nuclear medicine. In section 4.2 I provide background information about interruptions in healthcare and different approaches to their assessment. Section 4.3 presents the empirical research published in the British Medical Journal of Quality and Safety and reprinted with permission of the British Medical Journal publishing group (see appendix, p. 136). In section 4.4 I summarise the key findings and provide recommendations for quality improvement in nuclear medicine.

Table 4.1 Thesis question 3 revisited

Thesis question 3: How can a direct observation study of nuclear medicine technologists be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
What is the rate and nature of interruptions experienced by nuclear medicine technologists?
Is there a role for interruptions management during radiopharmaceutical preparation and dispensation in nuclear medicine facilities?
What examples of safety oriented strategies can be identified through direct observation of nuclear medicine technologists and can these be classified?
To what extent can work observation data be used to inform quality improvement in nuclear medicine?

Section 4.2 A review of interruptions, interruptions management and tools for work observation studies in healthcare

Typically, environments in healthcare organisations are busy and many staff experience interruptions that often necessitate task discontinuation. Depending on local contextual factors, interruptions have been reported to occur at a variable rate (from 0.5 to more than 40 per hour) (Grundgeiger & Sanderson 2009), with potential for lapses in memory, tasks remaining uncompleted or time devoted to various clinical tasks being reduced (Westbrook et al. 2010). Higher rates of interruptions reflect additional expected or unexpected work requirements and could indicate inefficient work practices or environments (Weigl et al. 2013). It has been suggested that interruptions contribute to about 10-15% of medication errors (Grundgeiger & Sanderson 2009). Although there have been no direct studies of nuclear medicine technologists, studies of nurses on medication rounds or pharmacists in both hospital

and community settings show that interruptions average 1.8-5.98 per hour (Westbrook et al. 2011; Flynn et al. 1999), with the suggestion that there is a linear relationship between errors in dispensation of medications and interruptions (Flynn et al. 1999). In some cases, staff may "multitask", meaning that they conduct tasks in parallel. Although multitasking may therefore preserve efficiency and performance, there remains a cognitive burden which may go unrecognised by the individual (Weigl et al. 2013). On the other hand, interruptions in the workplace can also be positive, since they may refocus attention on patients and important tasks (Rivera-Rodriguez & Karsh 2010; Westbrook et al. 2017).

This body of research has implications for this thesis, because the most commonly reported type of maladministration is one which arises from an error in the preparation and/or dispensation of a radiopharmaceutical (Yenson et al. 2005; Charlton and Emery 2001; Martin 2005). Despite this, 'cause and effect' is difficult to establish for various reasons, including the fact that intrusions, distractions and breaks can all be characterised as interruptions even though their impact on memory and task processing may be quite dissimilar (Jett & George 2003), making comparison between studies difficult (Grundgeiger & Sanderson 2009). As well, the rate and nature of the interruption, and the social network patterns in which these occur are probably of greater importance than the interruption *per se* (Gillie & Broadbent 1989; Westbrook 2014; Westbrook et al. 2017). 'Quiet' zones and other interruption management strategies have been trialled on some general medical wards, but the evidence of benefit is weak (Raban & Westbrook 2014) and the

intervention itself may impose unwanted costs and consequences (Westbrook et al. 2017).

As a consequence, assessment of interruptions in healthcare organisations have evolved from the 'who, what, where and when' of errors to a more nuanced characterisation of how activities are coordinated, how staff interact with one another and the problem solving skills they invoke in the face of interruptions (Laxmisan et al. 2007). Studies of work processes can be conducted in various ways, but computer simulation and controlled experiments lack generalisability to clinical settings. In contrast, Walter et al. (2015, p. 118) have stated that:

> "*qualitative observational studies can provide insights about relationships, social dynamics, individual motivations and thought processes in a way that quantitative studies cannot…*"

Observation data can be recorded on handheld tablets using the Work Observation Method By Activity Timing (WOMBAT) software program (Westbrook & Ampt 2009). The WOMBAT program has been shown to have high inter-rater reliability (Westbrook & Ampt 2009) and has been employed in critical care settings (Ballermann et al. 2011; Li et al. 2015), general medical wards (Westbrook & Ampt 2009; Walter et al. 2014) and the emergency department (Westbrook et al. 2010). Various health professionals including nurses (Westbrook et al. 2011; Westbrook et al. 2017), junior doctors (Richardson et al. 2016; Westbrook et al. 2010), registrars and specialists (Westbrook et al. 2010) have been studied using WOMBAT. Although WOMBAT has not been used in nuclear medicine, there are eight broad categories of

mutually exclusive work tasks that can be adapted to the nuclear medicine context.

Research using WOMBAT in nuclear medicine is presented below (section 4.3).

Section 4.3 A work observation study of nuclear medicine technologists: interruptions, resilience and implications for patient safety

ORIGINAL RESEARCH

OPEN ACCESS

A work observation study of nuclear medicine technologists: interruptions, resilience and implications for patient safety

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ABSTRACT

Background Errors by nuclear medicine technologists during the preparation of radiopharmaceuticals or at other times can cause patient harm and may reflect the impact of interruptions, busy work environments and deficient systems or processes. We aimed to: (a) characterise the rate and nature of interruptions technologists experience and (b) identify strategies that support safety.

Methods We performed 100 hours of observation of 11 technologists at a major public hospital and measured the proportions of time spent in eight categories of work tasks, location of task, interruption rate and type and multitasking (tasks conducted in parallel). We catalogued specific safety-oriented strategies used by technologists.

Results Technologists completed 5227 tasks and experienced 569 interruptions (mean, 4.5 times per hour; 95% CI 4.1 to 4.9). The highest interruption rate occurred when technologists were in transit between rooms (10.3 per hour (95% CI 8.3 to 12.5)). Interruptions during radiopharmaceutical preparation occurred a mean of 4.4 times per hour (95% CI 3.3 to 5.6). Most (n=426) tasks were interrupted once only and all tasks were resumed after interruption. Multitasking occurred 16.6% of the time. At least some interruptions were initiated by other technologists to convey important information and/or to render assistance. Technologists employed a variety of verbal and non-verbal strategies in all work areas (notably in the hot-lab) to minimise the impact of interruptions and optimise the safe conduct of procedures. Although most were due to individual choices, some strategies reflected overt or subliminal departmental policy.

Conclusions Some interruptions appear beneficial. Technologists' self-initiated strategies to support safe work practices appear to be an important element in supporting a resilient work environment in nuclear medicine.

BACKGROUND

Healthcare personnel operate in dynamic and busy environments in which urgent and non-urgent tasks vie for attention and prioritisation.[1] Multitasking and interruptions such as overhead pages, telephone calls and distractions from other staff and patients are widespread and may contribute to errors.[2–4] Further, deficiencies in work systems and processes can cause unexpected delays and magnify the challenges.[5] Therefore, understanding the rate and nature of interruptions that personnel experience, how everyday clinical work is delivered and the systems in which personnel operate merit additional study and research in these topics could identify other ways to improve safety.

In nuclear medicine, the maladministration of radiopharmaceuticals is an important patient safety issue because the unintended exposure to ionising radiation may be harmful.[6] Research indicates that technologists are directly involved in about 70% of maladministrations,[6] but there has been little evaluation regarding their work patterns, the interruptions that they experience and the environment in which tasks are undertaken. Typically, technologists prepare radiopharmaceuticals in a designated 'hot-lab' area featuring appropriately shielded workbenches, sinks, refrigeration for lyophilised products, radioactivity counters, disposal bins and other material. Procedures are mostly routine in nature and there is usually adequate notice of the type of

study required at the start of each working day. Consequently, radiopharmaceuticals are often prepared in batches for patients having similar procedures and then dispensed into separate syringes for later use. Urgent procedures are occasionally requested, which necessitates the preparation of some radiopharmaceuticals for an individual patient at short notice. Once prepared, the same or other technologists deliver radiopharmaceuticals to injection or scanning rooms for administration to patients. Since most procedures are routine and can take several hours to complete the various components of the scan, the majority of studies commence in the morning. Usually, technologists work in teams to undertake procedures, with specific tasks allocated to different individuals; in some cases, however, a single technologist is responsible for the conduct of all tasks related to a patient's procedure. As well, two different cameras are used to study patients as part of the same procedure, necessitating coordination of staff and resources. Images are subsequently analysed, archived and presented to doctors for interpretation. Technologists have responsibility for scheduling and coordination of procedures, liaison with other health professionals, quality assurance and administrative tasks. Thus, technologists are comprehensively involved in the complete cycle of nuclear medicine procedures, working in dynamic ways with one other, as well as other clinical staff, in multiple locations within the department.

Patient safety in nuclear medicine may be enhanced by managing interruptions, since it is possible that these contribute to maladministrations, especially during vulnerable tasks such as the preparation of radiopharmaceuticals.[7] 'Quiet zones' and other interruption management strategies during medication preparation and administration have been trialled on some general medical wards, but the evidence of benefit is weak.[8] Further, there may be undesirable consequences because some alerts or interruptions from equipment or other staff may bolster safety in certain circumstances.[2 9] Thus, more empirical evidence is needed to inform the development of quality interventions in nuclear medicine.

Incident reporting is widely used to inform quality improvement, but provides limited insights into how healthcare personnel create and maintain safety at work (as occurs the vast majority of the time). In nuclear medicine, for example, Australian Incident Registry data identify circumstances directly related to maladministrations and it is unsurprising that ensuing quality improvement strategies have sought to remedy perceived deficits in procedural compliance or training.[6 10 11] Concern about the narrow focus inherent in identifying what has gone wrong (as reflected in incident report data) has stimulated calls for an additional approach in patient safety to explore aspects of 'resilience' in the workplace.[12] In contrast to incident reporting, assessment of resilience in the workplace proactively samples a much larger source of data and refines safety by promoting flexibility rather than compliance with protocols, guides and training.[12 13] That is, understanding how nuclear medicine technologists adapt to unpredictable workloads and disruptive events and the strategies they invoke to maintain safety in dynamic environments with inherent deficiencies in equipment, systems and processes[5] could lead to a better understanding of what happens when things go right.[12 13] An approach incorporating resilience could lead to novel quality improvement strategies in nuclear medicine, but this requires careful research because resilient behaviours are often implicit.[14]

Accordingly, the primary objectives of this work observation study of nuclear medicine technologists were to: (a) characterise their work patterns, including the rate and nature of interruptions they experience and (b) identify strategies that support safety in the workplace. A secondary objective was to use these results to suggest quality improvement strategies in nuclear medicine that may complement those derived from incident reporting.[6 11]

MATERIALS AND METHODS

Study design and sample

We conducted a direct observational time and motion study in the nuclear medicine department of a major public teaching hospital (975 beds) in Sydney, which performs about 5600 general nuclear medicine and positron emission tomography (PET) studies annually. The department has 11 technologists (six full-time and five part-time), three of whom are designated as 'seniors' (ie, responsible for specific administrative and supervisory roles, in addition to the tasks undertaken by the junior staff). The 11 technologists have between 1 and 23 years of experience (mean=6.6 years) post-professional development year (in Australia, technologists typically receive 3 years of university training and become registered after a further year of 'on-the-job' training). All 11 technologists were invited to participate and received information about the purpose of the study and the nature of the proposed observations. A total of 100 hours of observation were conducted between 07:00 and 16:30 on weekdays from October to December 2015. We allocated 50% of the observation sessions to periods in which radiopharmaceutical preparatory activities were most intense (typically, early and midmorning times). To evaluate whether there was an association between seniority and rate of interruptions, we devoted 50% of observation sessions to the three senior technologists. To satisfy these two parameters, we determined on a weekly basis which periods to monitor. If there was more than one eligible technologist for a given period, we used a random draw to determine the individual to be observed. There was no departmental

policy on interruptions, although the use of smartphones was discouraged except during personal times.

Data collection

One member of our team, with intimate knowledge of nuclear medicine processes, unobtrusively observed a participating technologist from several metres and collected information for periods of 30–120 min while they carried out their usual work tasks. Observational data were recorded on a handheld tablet, using the Work Observation Method By Activity Timing (WOMBAT) software program,[15] adapted to a nuclear medicine environment. Eight broad categories of mutually exclusive work tasks (some with subcategories) were developed after extensive observation and pilot testing (table 1). A researcher who had extensive experience of the WOMBAT observational approach trained the observer. During pilot testing, the observer and researcher iteratively reviewed and adjusted preliminary findings to ensure that the full range of technologists' tasks was captured and appropriately categorised. The WOMBAT program has previously been shown to have high (>85%) inter-rater reliability.[15] Although we did not specifically assess reliability in this context, we used the same template and principles to assign nuclear medicine-specific tasks into the various categories for this study. Despite its potentially vulnerable nature,[6 11] we did not create a separate work category for radiopharmaceutical preparation because this task is an important element of indirect care. Nevertheless, its inclusion as a subcategory rendered sufficient transparency for us to separately determine the rate of interruptions associated with these tasks.

Recorded tasks were automatically time-stamped on data entry and the observer recorded whom the subject was with and the location where the task was performed. Interruptions and multitasking were recorded using buttons in WOMBAT and were defined as follows: an interruption occurred when a technologist ceased a current task to respond to an external stimulus; multitasking occurred when the technologist continued their current task while responding to an external stimulus, for example, preparing radiopharmaceutical while talking to a colleague. Tasks which were suspended due to interruption remain visible in WOMBAT to permit recording if the original task was resumed. This feature allows recording of the length and nature of each interruption and multitask.

Table 1 Nuclear medicine technologist task classification

Task category	Definition	Included activities
Direct care	Tasks directly related to patient care	Preparing a camera or room for a scan Assisting a patient before or after a procedure Scanning a patient Interacting with patient and/or relative
Indirect care	Tasks indirectly related to patient care	Review of request forms, bookings, preparation requirements for tests Washing hands Cleaning or preparing workbenches, scan equipment and beds Changing bed linen Radiopharmaceutical preparation Quality control Analysing scan Disposal and/or return of radioactive waste, paperwork
Documentation	Data entry into computer or paperwork	Recording doses administered, quality control results and patient demographics
Professional communication	Any work-related discussion with another staff member	Communication on scheduling, transfers, preparation for procedures, protocol to be used and handover of care Includes the use of fixed or mobile phones or pages
Social	Any social or personal activity or discussion	Personal phone calls and discussions Tea, lunch and personal breaks Private reading Private email or social media Bathroom breaks
Supervision and education	Any activity focused on teaching or education	Supervision of other staff members or students Mandatory health training Research Participating in departmental education sessions
Administrative	Any administrative activity not directly related to direct or indirect care or documentation	Preparing rosters Purchase of supplies Maintenance of equipment Employment issues
In transit	Work-related movement between rooms or tasks	Includes movement between scanning rooms, movement outside the department to visit patients on wards

In addition to the structured WOMBAT data collection, we employed an iterative process to develop a list of strategies that technologists used to uphold safety.[12 13] The observer used his knowledge of nuclear medicine processes to identify potentially eligible strategies across the spectrum of tasks and in all departmental areas. For this part of the study, we did not specifically focus on the level of the seniority of the participant. Rather, the observer documented any behaviour, for example, placing sticky notes on a radiopharmaceutical phial or choosing not to interrupt a colleague, which prima facie contributed to maintaining or creating safe working situations. Strategies could pertain to an individual's behaviour or reflect the use of a tool or an agreed strategy used by the entire cohort. Following observation sessions, the observer then conferred with the participating technologist to ask about the observed strategies and only those behaviours that had a confirmed safety intent were retained. Subsequent periods of unstructured observation and discussion at other times with the same or other participants were used to expand the list.

Once the list of strategies with a confirmed safety intent had been compiled, the project team then discussed and reached agreement about the classification of these strategies. For this purpose, we used a previous report[16] to classify each recorded strategy according to four categories. The categories, with descriptions in parentheses, are as follows: 'responsiveness' (reacting effectively when a situation changes); 'attentiveness (taking appropriate action considering the situation at hand); 'anticipation' (proactively making a decision or taking a course of action that has an expected consequence in a given situation) and 'past experience' (drawing on existing knowledge to influence the sequence and nature of work activities).

The research was approved by the hospital and university research ethics committees and written informed consent was obtained from all 11 technologists, all of whom participated in the study.

Data analysis

Descriptive analyses were performed for: the total number of tasks; the total time that tasks were 'active' in each category (ie, only tasks that were being actively performed, rather than paused by interruptions); the proportion of time spent on various tasks at different times during the day and rates of interruptions and multitasking. In addition, we used linear regression to assess the relationship between the interruption rate and the number of tasks, hours of observation and number of nuclear medicine and PET procedures for that day. We also determined whether any interrupted tasks were not resumed.

Data were analysed in Microsoft Excel (2016) with pivot tables and 95% CIs were calculated using a Poisson distribution. Student's t-test was used to compare the rate of interruptions experienced by senior and junior technologists.

RESULTS

Task times, interruptions and multitasking

During the 100 hours of observation, 5227 tasks were observed. The task-specific distribution of technologists' time is shown in table 2. Direct care tasks consumed the highest proportion of technologists' time (34.6%), although there was a variation during the day. For example, direct care tasks represented about 40% of all tasks at 09:00, increasing slightly in proportion at 14:00, from which time their proportion tapered to about 20% by the end of the working day. Indirect care tasks were the next most frequent in number (28.8%), but these were most predominant between 07:30 and 09:00, when technologists were preparing for the various procedures scheduled for the day. Supervision, social and administrative tasks also displayed distinct variations according to the time of day. The mean time allocated to each of the eight work categories from 07:00 to 16:30 is shown in figure 1.

There were 116.6 task hours during the 100 hours of observation, demonstrating that technologists multitasked 16.6% of their time. The highest rate of

Table 2 Distribution of task times, multitasking and interruption rates

Task category	Number of tasks (%)	Task time (hours)	Mean task time (s)	% task time spent multitasking (95% CI)	Interruption rate per hour, (95% CI)
Direct care	1102 (21.1)	34.6	112	42.8 (26.3 to 59.3)	4.4 (3.8 to 5.1)
Indirect care	1221 (23.4)	28.8	85	20.0 (5.4 to 34.6)	6.0 (5.2 to 6.9)
Documentation	224 (4.3)	3.8	61	12.6 (0 to 46)	8.4 (6.1 to 11.5)
In transit	814 (15.6)	7.3	32	9.9 (0 to 31.6)	10.3 (8.3 to 12.5)
Professional communication	1478 (28.3)	17.7	43	42.2 (19.2 to 65.2)	3.5 (2.7 to 4.4)
Social	196 (3.7)	12.0	220	7.2 (0 to 21.8)	1.4 (0.9 to 2.2)
Supervision or education	162 (3.1)	9.2	204	41.6 (9.8 to 73.5)	4.6 (3.4 to 6.0)
Administrative	30 (0.6)	3.2	384	7.8 (0 to 37.2)	4.7 (2.9 to 7.5)

Task times do not add to 100 hours because some tasks were undertaken simultaneously (ie, when multitasking).

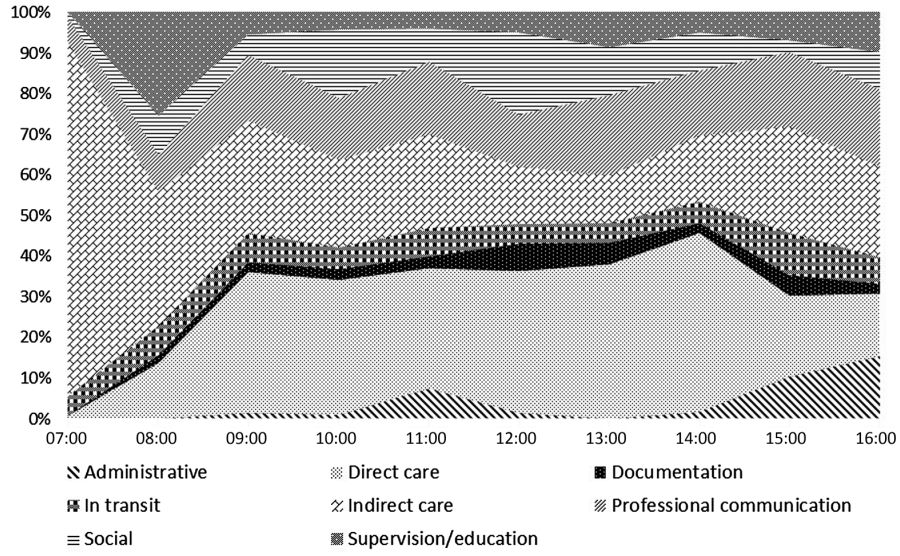

Figure 1 Time allocated to different tasks by nuclear medicine technologists from 07:00 to 16:00.

multitasking occurred during direct care or when the technologist was supervising or educating another technologist (42.8% and 42.2%, respectively). The multitasking rate during indirect care was 20% (95% CI 5.4% to 30.6%). A common example was professional communication occurring while preparing a radiopharmaceutical. Multitasking mostly occurred at one point in time only; however, some individual tasks of longer duration featured several instances of multitasking (up to 13 separate times). Multitasking never involved more than two tasks simultaneously. The mean duration of multitasking was 60 s (range, 1–647 s).

Five hundred and sixty-nine tasks (10.9% of the total) were interrupted, with the highest rate occurring when a technologist was in transit (10.3 interruptions/hour). The overall interruption rate was 4.5/hour (95% CI 4.1 to 4.9) across all tasks (table 2).

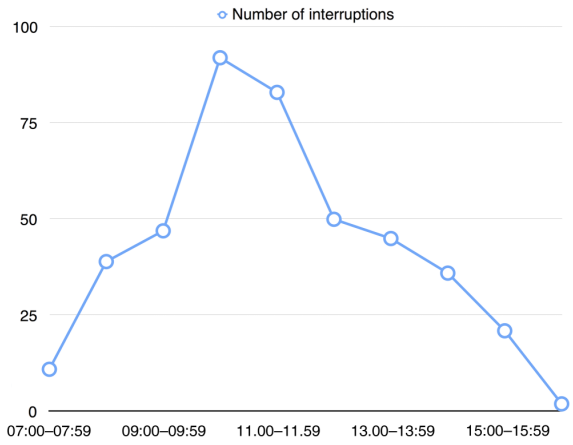

Figure 2 Number of interruptions over a working day.

When tasks were interrupted, most (n=426; 74.9%) were only interrupted once, but 143 tasks (25.1%) were interrupted on two or more occasions, including one that was interrupted 10 times. Most interruptions (n=331; 58.2%) were experienced in scan rooms. The mean time to return to the primary task was 75 s (range: 3–1289 s). All tasks were resumed after being interrupted. Interruptions were most common during mid to late mornings (figure 2). Indirect care tasks were interrupted 6 times/hour (95% CI 5.2 to 6.9), but the subcategory of radiopharmaceutical preparatory tasks had a mean interruption rate of 4.4 interruptions/hour (95% CI 3.3 to 5.6). Senior and junior nuclear medicine technologists experienced 5.5 and 4.3 interruptions/hour, respectively (p=0.91). The interruption rate per hour was not related to the number of procedures, observed tasks or hours of observation for that day (r^2=0.11, p=0.67, degrees of freedom=3).

Strategies used by technologists to support safe work

The majority of safe work behaviours were noted in the hot-lab area, with some consistent examples including: (a) the use of bar-coding technology to label all syringes with the correct patient name, radiopharmaceutical type and radioactivity, (b) manual colour coding of the daily patient schedule according to the radiopharmaceutical type, (c) quality assurance summaries that were prominently displayed as visual aids in the hot-lab and (d) the early arrival of hot-lab staff for duty. Behaviours involving communication and/or handover between staff were most common and included both verbal and non-verbal modes. The latter comprised sticky notes, syringe labels and whiteboards and again mainly featured in the hot-lab area. Some visual aids, such as the manual colour coding of patient

lists for batch radiopharmaceutical preparation, acted as an *aide-memoire* for individuals, rather than a communication mechanism between technologists. Further, some strategies reflected decisions made by individual technologists at a particular time (eg, not interrupting a colleague or deferring taking a break), although others (such as the implementation of bar-coding for syringes, the use of a whiteboard and rostering a single technologist to therapeutic nuclear medicine) reflected a deliberate decision by the cohort and its managers to uphold safe work practices. We noted that some interruptions among technologists were designed to facilitate technical information about patients or procedures or to render assistance in the completion of certain tasks. Among resilient behaviours, responsiveness, attentiveness, anticipation and past experience were identified in approximately equal numbers, although some could be classified using more than one characteristic (table 3).

DISCUSSION

Our study demonstrated that nuclear technologists experienced an interruption on average every 13.3 min that divert their attention for around 75 s before returning to their primary task. Technologists experienced an interruption every 13.6 min while preparing radiopharmaceuticals, which is the most safety critical element of their work. Some interruptions were initiated by other technologists in order to convey important information to one another, facilitate the optimum conduct of procedures and render assistance in the completion of tasks. Technologists employed various strategies, which were mostly self-initiated, to safeguard tasks that are perceived as vulnerable.

The average interruption rate in nuclear medicine is similar to that reported for doctors working in general community hospital settings[3] and slightly less than reported for Australian doctors in intensive care units and emergency departments.[17 18] In a previous review, interruption management strategies, including the wearing of manual vests, the use of prominently displayed signs or lanyards discouraging interruptions, checklists and diversion techniques, showed that the evidence for benefit was limited.[8] Interruption management strategies may have implications in nuclear medicine because errors during radiopharmaceutical preparation and administration contribute to the majority of maladministrations.[6 11] Our data show that technologists preparing radiopharmaceuticals were interrupted on average 4.4 times/hour; this is slightly less than the overall average for the department and much less than in other areas, such as in scanning rooms or while technologists are in transit. Thus, the formal institution of quiet zones in the hot-lab area, even for busier times of the day, may provide limited benefit. Further, this type of interruption management strategy could be counterproductive because we witnessed examples of other technologists occasionally interrupting the observed individual to convey key technical details about specific patients or procedures or to render assistance for tasks.

Multitasking was evident with all task categories, with the highest rates noted during direct care, professional communication and while supervising other colleagues. The discrepancy in multitasking rates between task categories probably reflects differences in the nature of the primary task, its perceived vulnerability to failure if paused, interruption rate, proximity of other health personnel and patients and the configuration of the room in which the task is being conducted. While multitasking is thought to impose a cognitive load and may be deleterious to the primary task,[2 19] the nature and timing of the interaction, the type of primary task being conducted and characteristics of the persons involved are important contextual factors.[20] As an example, multitasking in the hot-lab commonly involved the participating technologist actively mixing compounds or measuring radioactivity while conferring with a colleague about a specific patient or procedure. This type of multitask permits the transfer of important information, without the technologist having to pause at critical times during radiopharmaceutical preparation. Therefore, multitasking may foster efficiency in certain circumstances. This is consistent with a previous report[21] and suggests that restrictions on multitasking, even during potentially vulnerable tasks such as radiopharmaceutical preparation may have unwanted consequences.

Our results showed that technologists often employed various strategies to buttress the safe conduct of procedures in specific circumstances and across all work areas. Some strategies (such as arriving early to commence radiopharmaceutical preparatory tasks before peak interruptions were likely to occur or avoiding interrupting colleagues at inopportune times) were explicitly focused on avoiding interruptions, whereas others (such as prominently displayed summaries of quality assurance procedures in the hot-lab, appointment of specific technologists to undertake therapeutic procedures from start to finish and the use of sticky notes on request forms and prepared radiopharmaceutical syringes to help with information transfer) were not. Although many strategies reflected individual choices in relation to a particular task, these tended to be observed in most or all of the technologist cohorts, despite the lack of a formal policy. We suggest that this indicates the existence of an informal communication network in which potential 'process failures' are recognised and solutions implemented by the technologists themselves. This type of approach is consistent with 'second-order' problem solving as reported by Tucker and Edmondson.[22] However, one important difference from their problem-solving model is that, with a few exceptions, most strategies in our study were implemented without specific managerial input.

Table 3 Case examples of resilience in nuclear medicine

Description	Location	Individual choice or formal policy	Resilience characteristic(s)
Staff arrive at work ~10–15 min earlier than officially scheduled to commence radiopharmaceutical preparation and avoid interruptions	Hot-lab	Individual choice, but consistently observed in all individuals rostered to this role	Anticipatory
At key times, technologists preparing or administering radiopharmaceuticals would not respond to telephone calls, overhead pages or attempts by other staff to initiate communication	Hot-lab, scan room, injection room	Individual choice, observed on some occasions	Responsive, past experience
During radiopharmaceutical preparation, staff keep their eyes on the material being prepared and sometimes elect not to respond to professional or social communication or choose to 'multitask' by keeping their focus on the material being prepared while responding to others	Hot-lab	Individual choice, observed on some occasions	Responsive, past experience
Use of bar-coding technology for individual radiopharmaceuticals	Hot-lab	Formal departmental policy, used consistently by all technologists rostered to this role	Attentive, past experience
Use of sticky notes on patient request forms or phials to convey key information, especially if a technologist is expecting to be absent for a while	Hot-lab, scan room, clerical area	Individual choice, but consistently observed in all individuals rostered to this role	Anticipatory
Printout of requested procedures for the day are colour-coded for tests requiring different radiopharmaceuticals	Hot-lab	Individual choice, but consistently observed in all individuals rostered to this role	Attentive, anticipatory
Printouts conveying important elements of quality assurance procedures are displayed at eye level in the hot-lab radiopharmaceutical work area	Hot-lab	Formal departmental policy, used consistently by all technologists rostered to this role	Attentive, past experience
Technologists defer initiating conversation with a colleague if he/she appears busy	All work areas	Individual choice, observed on some occasions	Anticipatory, past experience
The use of whiteboard to convey weekly information about the delivery of external supplies	Hot-lab	Formal departmental policy, implemented by senior technologists	Attentive, anticipatory
Some interruptions, usually in the form of professional communication between technologists, are used to alert one another to potential pitfalls about procedures or patients; for example, a request for a thyroid scan may be converted to a parathyroid scan after medical review, thus necessitating the preparation of a different radiopharmaceutical	Patient waiting room, scan room, hot-lab, in transit	Individual choice, but consistently observed in all individuals in the direct care of a patient	Attentive, responsive, anticipatory
Multitasking is frequently employed by all technologists, sometimes to avoid external stimuli from interrupting the primary task	All work areas	Individual choice, but consistently observed in all individuals	Responsive
Certain high-risk procedures, particularly therapeutic nuclear medicine, are rostered to an individual technologist who becomes responsible for all aspects of its conduct	Hot-lab, scan room, patient waiting room	Formal departmental policy adopted by all technologists rostered to this role	Anticipatory, past experience
Some technologists defer their lunch or break in order to stay in the control room (adjacent to scanners) so as to troubleshoot any potential complications during a procedure	Scan rooms	Individual choice, observed in a few technologists	Responsive, anticipatory
Some interrupted tasks may be resumed by a second technologist to help continue a procedure and/or ensure quality is maintained	Scan rooms, hot-lab	Individual choice, observed on some occasions	Responsive
Although most staff carry mobile telephones, these are switched to vibrate and are not looked at, except during personal time	All work areas	Directive from the chief technologist	Past experience
If a senior technologist does not respond to an overhead page or telephone call, the clerical staff redirect the call to another senior technologist	Clerical work area	Individual choice, observed on some occasions	Responsive
Scan protocols and patient information sheets are stored on all computers for easy access	Scan rooms, clerical areas	Departmental policy used by all nuclear medicine technologists	Attentive, anticipatory
Technologists proactively contact patients and external health professionals before the procedure is scheduled to facilitate smooth conduct of procedures	Clerical areas, scan rooms	Individual choice, but observed in all individuals rostered to this role	Anticipatory

The identification of resilient strategies among technologists has several implications for patient safety in nuclear medicine. The technologists were found to implicitly uphold safety in broad ways and the type of resilient strategies that are identified may provide important clues about underlying organisational deficiencies, including inadequate staffing, faulty equipment, poor workplace design and miscommunication among staff.[5 22] Promotion of resilience among technologists should be accompanied by thoughtful analysis and correction of any operational vulnerabilities. For example, changes in quality control requirements from time to time, as well as the exacting nature of radiochemistry and limited shelf-life of various products have been shown to contribute to certain types of maladministrations.[6] Thus, coordination and collaboration among technologists are critical towards the timely delivery and safe preparation of various radiopharmaceuticals. The use of a whiteboard in the hot-lab is an obvious strategy in our department, but in other facilities could signal the need to modify technologist rostering or how tasks are allocated. Radiation protection and patient safety initiatives in nuclear medicine in Australia have been developed almost exclusively from the narrow domain of a statutory incident reporting system.[6 7 10 11] Our findings suggest that looking at interventions which support and enable resilient behaviours could provide additional value in improving safety in nuclear medicine.

Our research has several potential limitations. First, errors in the preparation of radiopharmaceuticals represent the main type of maladministrations and can occur in various settings, including from commercial manufacturers.[6 7 11] Work practices in commercial entities are likely significantly different from those in clinical nuclear medicine facilities. We do not exclude the possibility of benefit from interruption management in commercial entities. Second, we highlighted certain strategies among technologists that have characteristics of resilience.[16] However, refining the approach would require assessing not just whether a particular strategy can be identified in any individual technologist, but how consistently these are applied from day to day. As well, the interobserver reproducibility of the classification system we used is undefined and is worthy of testing in future studies. Third, our data derive from a single institution, but it is one of the largest in the country. Nuclear medicine practices likely vary, at least subtly, between facilities. The rate of interruptions experienced by nuclear medicine technologists at other facilities may differ. Finally, it is possible that participating technologists may have subtly altered or improved their work habits because they knew that they were being observed. We tried to limit this effect by spending many hours in pilot testing, thus allowing technologists to become familiar with the nature of the study. Further, we conducted the research over 3 months and recorded technologists' behaviour on multiple occasions at different times of the day, which minimised the likelihood for significant persistent changes in behaviours.

In summary, nuclear medicine technologists experience about 4.5 interruptions/hour, mainly in work areas and on tasks not directly related to radiopharmaceutical preparation and administration. Further, some interruptions are beneficial and thus, controlling interruptions per se may be counterproductive. Technologists employ various strategies that uphold safety, some of which are not specifically related to interruptions. It is possible to identify resilient behaviours among technologists and this information might aid the assessment of individual incidents, as well as contribute to the identification of new interventions which promote patient safety in nuclear medicine.

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Data sharing statement Original data are stored at the Australian Institute of Health Innovation (Macquarie University, Sydney, Australia) and can only be accessed by the research team members.

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Section 4.4 Chapter conclusions and recommendations

The major findings and implications for quality improvement are tabulated below (table 4.4.1).

Table 4.4.1 Thesis question 3, findings and implications for quality improvement

Question 3: How can a direct observation study of nuclear medicine technologists be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?
Findings • Average interruption rate=4.5 per hour (95% CI=4.1-4.9) • Interruption rate during radiopharmaceutical preparation=4.4 per hour (95% CI=3.3-5.6) • Multitasking occurs 16.6% of the time • Some interruptions are used to convey important technical information about procedures or patients • Technologists uphold safety in broad ways, not necessarily in relation to interruptions • Both verbal and non-verbal techniques are used, including electing not to interrupt colleagues at critical moments and use of radiopharmaceutical preparation summaries displayed at eye level in the hot-lab. • Most safety oriented strategies are self-initiated

Question 3: How can a direct observation study of nuclear medicine technologists be used to characterise safety in nuclear medicine and what quality improvement strategies can be developed?

Implications for quality improvement

- Strategies focused on reducing interruptions in nuclear medicine may have unintended adverse consequences
- Traditional incident reports can overlook strategies used by staff to uphold safety
- It is possible to identify and classify resilience amongst technologists using previously reported guides
- Safety oriented strategies used by technologists can highlight vulnerabilities in work processes as well as within the department and organisation
- This type of research highlights an additional way by which safety in nuclear medicine can be evaluated and complementary safety strategies developed
- Theoretical models integrating error theory with resilience can be developed

I have shown that that direct observation studies of nuclear medicine technologists are fundamental in understanding not only the rate and nature of interruptions that they experience, but can also provide insight into workplace vulnerabilities some of which may not be apparent from incident reports (Tucker & Edmondson 2003; Tucker et al. 2008). For example, the manual labelling of syringes was previously shown to be vulnerable, with instances of non-labelling, incorrect labelling or misreading of hand-written information, contributing to a significant number of maladministrations (Yenson et al. 2005). This vulnerable work process was addressed by the purchase and use of bar-coding technology, as illustrated by research in section 4.3 and supported by other authors (Matanza et al. 2014) as a quality initiative in nuclear medicine. Martin (2005, p. 919) has agreed that maladministrations provide an opportunity to consider:

"*operating conditions….staffing levels…equipment maintenance…*"

Therefore, quality improvement strategies in nuclear medicine should not only consider lessons from incident reports, but harness solutions engineered by the technologists themselves or their managers to rectify flaws in equipment, workplace design or work processes.

Another key finding is that some interruptions can be beneficial. Thus, interruption management strategies in nuclear medicine and other medical disciplines should not be implemented without consideration of what:

> "*aspects of performance are affected by the interruption*"

(Grundgeiger & Sanderson 2009, p. 303). Rivera-Rodriguez & Karsh (2010) emphasised that interruptions may reflect the need for regular dialogue and collaboration amongst healthcare personnel and agreed that the elimination of all interruptions may be deleterious.

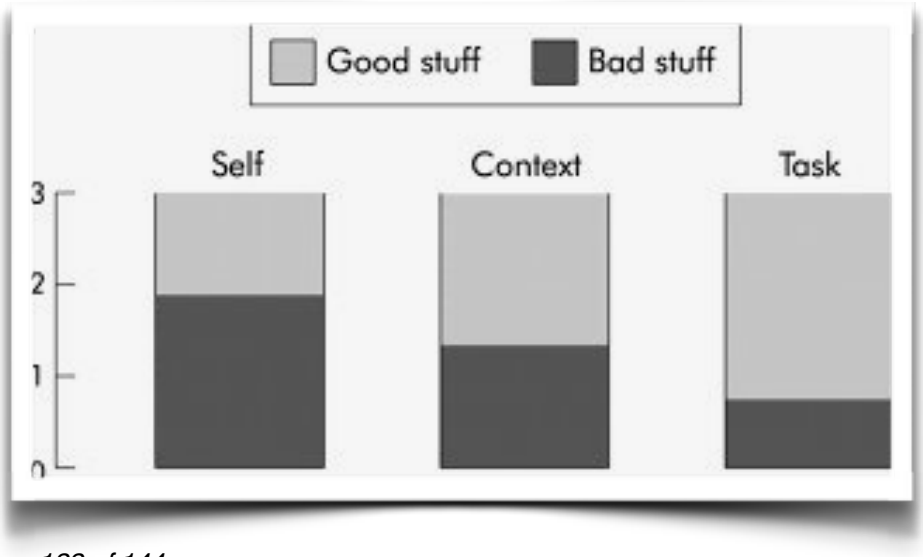
The concept of resilience not only provides a complementary model through which errors in medicine can be understood, but provides insight into organisational weaknesses and hitherto unsuspected work process vulnerabilities. More specifically, the emergence of the concept of resilience means that variations in how healthcare personnel complete their tasks should not necessarily be viewed as deleterious, but rather may reflect cognitively demanding situations in which there is a trade-off between efficiency and thoroughness (Grundgeiger & Sanderson 2009). Recognition that this type of trade-off is implicit in modern healthcare environments (Weigl et al. 2013) has implications beyond nuclear medicine.

Another implication of research in section 4.3 is that it affords an opportunity to refine the theoretical concepts underpinning how maladministrations are viewed. Reason revisited the Swiss cheese model in 2004 when it became apparent that safety systems in healthcare organisations was not necessarily analogous to those in nuclear power plants or the aviation industry (from which the Swiss cheese model was developed); in particular, he argued that defences in healthcare organisations centre primarily on the "mental" skills of healthcare personnel whereas those in non-health sectors are based mainly on technology for their defences (Reason 2004). In his "three bucket model", the individual healthcare worker, the context in which he or she is operating and the task being undertaken contain elements of safety and threats, or:

"*good*" and "*bad stuff*",

respectively (Reason 2004, p. ii32; see figure 4.4, below). The likelihood of an adverse event relates to the proportion of good and bad stuff in each bucket. The three bucket model does not necessarily replace the Swiss cheese model, rather it emphasises the importance of "error wisdom" of healthcare personnel at the "sharp" end of healthcare (Reason 2004).

Figure 4.4 Three bucket model



Research in section 4.3 illustrates that resilient strategies represent a subliminal type of error wisdom and could therefore be incorporated into the three bucket model. For example, different aspects of radiopharmaceutical preparation can be safeguarded through decisions on commencement time of individual shifts, not interrupting a colleague and use of information technology (reflecting 'self', 'context' and 'task', respectively). Resilient strategies used by nuclear medicine technologists can not only be promoted as a mechanism to increase the 'good stuff' within each of the three buckets, but can be categorised based on research from Lundberg and colleagues (2009) as tabulated below (table 4.4.2):

Table 4.4.2 Identifying and measuring resilience exhibited by nuclear medicine technologists

Purpose	Strategy characteristic	Extent
Buttressing communication	Anticipation	Individual
Coordination	Responsiveness	Small teams
Offsetting cognitive burden	Attentiveness	Entire cohort
Assisting in the conduct or monitoring of work processes	Past experience	Entire cohort

To summarise, this work observation study of nuclear medicine technologists at a large teaching hospital in Sydney provides an opportunity to analyse work as conducted, rather than imagined. The distinction is important because it highlights a research approach into safety and quality improvement in nuclear medicine which is broader than has hitherto been the case. Work observation studies can characterise

the impact of interruptions on vulnerable work processes and identify subliminal strategies that could be promoted as a complementary way to buttress safety in nuclear medicine. The work can not only be readily undertaken in other hospitals, but extended to consider commercial manufacturers of radiopharmaceuticals

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CHAPTER 5

Thesis conclusions and recommendations.

"All of science is nothing more than the refinement of everyday thinking." Albert Einstein (1879-1955).

Section 5.1 Summary

Nuclear medicine has both diagnostic and therapeutic applications and plays an important role in contemporary Australian healthcare. Growing demand for nuclear medicine services, allied with potential for harm from instances in which procedures are undertaken incorrectly, underscore the need for safe working systems and a disposition toward quality improvement. Current safety management strategies are based on a system of vocational training and adherence to guidelines and checklists. Although there is an existing statutory incident reporting system for nuclear medicine in Australia, lessons from the ARIR are seldom analysed and this information deficit is compounded by a paucity of research in safety in nuclear medicine globally. Further, many nuclear medicine technologists operate in interruption-laden environments and it is possible that the existing safety approach derived from linear 'cause and effect' thinking and rule based solutions may be unsuitable for complex healthcare organisations (Pederson 2016). This thesis seeks to rectify the knowledge gap about maladministrations and to broaden how safety in nuclear medicine might be measured and promoted. The original findings in this thesis provide clarity on the contemporary status of maladministrations in nuclear medicine and broaden the foundation for measuring safety and informing quality improvement, not only in nuclear medicine, but in all medical disciplines.

Section 5.2 Original thesis contributions

The literature review in chapter 1 was an important starting point for the thesis and provided justification for all three objectives. For decades the global patient safety agenda has been strongly influenced by the US Institute of Medicine's "*To Err is Human"* report (Kohn et. al 2000) and incident reporting systems, as well as standardisation of practice through training, licensing, accreditation and guidelines have become the dominant manifestations of efforts to promote safety (McDonald et al. 2006; Pederson 2016). However, nuclear medicine presents somewhat of a contrast. Despite relatively little analysis of incident reports, either from Australia or elsewhere, or on the methodological constraints inherent in analysing rare events, the safety agenda in nuclear medicine has repeatedly invoked rule based solutions and standardisation of work as a panacea for risk management. Although consistent with the dominant:

> "*measure and manage orthodoxy*" (Waring 2009),

the effect of unpredictable working conditions (Martin 2005) and interruptions (Yenson et al. 2005) on vulnerable work processes have remained unexplored. The expansion of nuclear medicine as a therapeutic modality and potential for organ damage further underscores the need for research in this field.

The article in chapter 2 shows both the advantages and disadvantages of the ARIR (Larcos et al. 2014). On the one hand, the provision of detail about the types and complications of maladministrations at a national level is an important prerequisite for risk communication in nuclear medicine. On the other hand, there are valid concerns about the statutory data collection process and report content, and the suitability of linear causality in healthcare as an explanation for why incidents occur. Recognition that incident reports in nuclear medicine have fundamental limitations has been

largely overlooked in previous research in this field (Yenson et al. 2005; Martin 2005; Charlton & Emery 2001; Sinclair et al. 1991; Smart 2002). Nevertheless, this paper not only highlights the need for, but reframes how the safety and quality agenda in nuclear medicine may be advanced.

One way by which this may occur is shown in the article in chapter 3, which characterises for the first time constraints that are inherent within the ARPANSA statutory incident reporting system, particularly with respect to impact of underreporting and dissimilarities in notification criteria employed at a jurisdictional level (Larcos et al. 2015). Whilst the former requires additional research to understand barriers to maladministration notifications, the latter is amenable to correction through the application of national uniformity principles (ARPANSA 2017). The article also illustrates how safety in nuclear medicine can be measured beyond raw numbers of maladministrations per annum. Further, the ability to portray the upper and lower limits of the temporal variation in nuclear medicine safety data can facilitate assessment of specific quality interventions and foster interaction with stakeholders in radiation protection and patient safety, neither of which has hitherto been part of the quality and safety agenda in nuclear medicine.

Research in chapters 2 and 3 has reinforced the idea that radiopharmaceutical preparation and dispensation tasks are vulnerable. Whilst not novel *per se*, the finding nevertheless permits the research agenda in nuclear medicine to canvas new ideas about safety and quality improvement. Martin (2005) and Yenson and colleagues (2005) suggested that interruptions experienced by nuclear medicine technologists could be a contributing factor to the most common type of maladministration. It is known that environments in healthcare organisations are

busy, interruption-laden and unpredictable (Grundgeiger & Sanderson 2009) and thus, evaluating the rate and nature of interruptions experienced by nuclear medicine technologists represents a logical extension of research conducted in chapters 2 and 3. The article presented in chapter 4 characterised the rate and nature of interruptions experienced by nuclear medicine technologists across various work categories. While the results suggest that 'interruption free zones' in the hot-lab or during safety critical tasks may have undesirable consequences, the ability to conduct a work observation study helped realise another objective, namely depicting the strategies used by technologists to maintain safety in nuclear medicine for the bulk of their working hours. These safety oriented strategies can provide important clues about vulnerable work processes or equipment (Tucker et al. 2008) that would not necessarily be identified in incident reports. This type of research could be readily applied in other contexts, for example commercial radiopharmaceutical laboratories.

Section 5.3 Thesis conclusions

There are several key themes that emerge from the body of research undertaken in this thesis. The ARIR represents an important corpus of data about maladministrations in nuclear medicine in Australia. Although imperfect, I have suggested several ways by which the ARIR might better portray safety in nuclear medicine and thereby stimulate additional quality interventions. The leveraging of information from work observation studies introduces another dimension by which safety in nuclear medicine can be understood and more enduring solutions for quality improvement engendered. Many of the thesis findings not only apply to nuclear medicine in other countries, but can be used more broadly in other medical disciplines.

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Appendix (p.134-144) of this thesis has been removed as it may contain sensitive/confidential content