RADIATION INDUCED LENS CHANGES AND DEVELOPMENT OF A RADIATION SAFETY FRAMEWORK FOR INTERVENTIONALISTS

by

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DEDICATION

Dot, thank you for…
taking me down rabbit holes
and up secret staircases
for unplanned late-night movies
and scampers along Bloubergstrand
that our hearts and souls resonated.
Thank you for teaching me to see colour.
Thank you for seeing the extraordinary in me.
I will always hide you in the echoes of my being.

Dot Vermeulen (13 September 1985- 29 April 2015)

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LIST OF ACRONYMS

ALARA	**As low as reasonably achievable**
CAS	**Complex adaptive systems**
cath. lab	**Catheterisation laboratory**
CT scan	**Computed tomography scan**
CME	**Continued medical education**
CRP	**Culture of radiation protection**
CRS	**Culture of radiation safety**
DAP	**Dose area product**
DED	**Dry eye disease**
Gy	**Gray**
HCW	**Healthcare worker**
ICRP	**International Commission on Radiological Protection**
ILO	**International Labour Organization**
IR	**Ionising radiation**
mSv	**Millisievert**
OHSA	**Occupational Health and Safety Act**
PCC	**Patient Centred Care**
PPE	**Personal protective equipment**
PSC	**Posterior sub-capsular**
TBUT	**Tear breakup time**
TLD	**Thermoluminescent dosimeter**
UHC	**Universal Healthcare Coverage**
QC	**Quality of Care**

SUMMARY

Background: Ionising radiation (IR) is a modality that is increasingly being used in diagnostic, prognostic, therapeutic and interventional procedures. The health effects due to IR exposure can be deterministic or stochastic. Deterministic effects refer to effects that are seen at a minimal threshold level. These effects include skin burns and cytopaenia. Stochastic effects refer to effects where a minimum threshold is not evident. These include carcinomas and recently cataracts are thought to fall into this group. Interventionalists are at increased risk of developing cataracts due to IR exposure.

The use of personal protective equipment (PPE) is essential to mitigate against the effects of IR on the eyes. Lead glasses, lead visors and ceiling suspended screens are essential for protecting the eyes of radiation healthcare workers (HCWs) in the catheterisation laboratory. PPE is often not readily available and interventionalists are notoriously non-compliant with donning PPE, especially lead glasses. They do not consistently wear their dosimeters either.

Essential to reducing the risk of cataracts associated with IR is to ensure that education and training on radiation safety is formalised in the training of interventionalists and that there is ongoing reinforcement of this training.

Creating and sustaining a culture of radiation protection (CRP) is essential to changing attitudes and behaviour towards radiation safety practices. A CRP ensures better patient safety and improves quality of care.

Methods: This was a cross sectional prospective study that used multiple methods to address the research question. There was a qualitative and quantitative component. The qualitative component used individual interviews and group interviews to understand interventionalists' perceptions about radiation and its effects on their health; to garner insight to their training in radiation safety; and to make meaning of how they understood what a CRP was. The quantitative components included a slit lamp examination and the completion of a survey. We compared a group of doctors not routinely occupationally exposed to IR to a group of interventionalists that are occupationally exposed to IR. There was no randomisation. Participation was voluntary and participants granted informed consent. The study was approved by an ethics committee.

Results: The prevalence of cataracts possibly associated with IR exposure was 18.8% in the exposed group and the prevalence of posterior sub-capsular (PSC) cataracts in this group was 5.9%. PSC cataracts were 2.2 times more likely to occur in the exposed compared to the unexposed group.

Lead glasses were consistently used by 10.2% of the interventionalists. Females were 4.3 times more likely to report that PPE was not available. Qualitative data showed that interventionalists had a culture where PPE such as lead aprons were consistently used but lead glasses were not a priority. Participants had poor knowledge of the dose limits and they did not consistently use dosimeters.

There was a dearth of radiation protection training for interventionalists in South Africa. Radiologists received dedicated teaching on radiation safety while cardiologists did not always receive teaching on the topic. This was especially true for cardiologists. Participants generally agreed that there was a gap in their education and training in radiation safety training. Only 44.1% of participants thought their training was adequate. The majority of participants (95.4%) indicated that they wanted radiation safety training as part of their curriculum.

A CRP was a strong theme that emerged as a conduit to creating a culture of radiation safety and participants supported the notion of developing a better CRP to promote radiation safety.

Conclusion: IR exposure remains a high risk in the cath. lab exposing interventionalists to the risk of developing cataracts. This can be mitigated by improving training radiation safety and encouraging utilisation of PPE. Developing and sustaining a CRP is essential to improving radiation safety in the cath. lab.

PREAMBLE

I started the journey on this PhD in January 2015. It was a serendipitous encounter with William Rae on the stairs of the medical school of the University of the Free State. I had reached a critical life moment and had decided to quit my job and travel to India to "find myself." William and I exchanged views on my reasons for wanting to leave. He invited me to a meeting to give input on the study design of a project he wanted to initiate. And as they say the rest is history. I didn't quit my job- well not then anyway. I didn't go to India- well not then anyway. But I did begin an amazing adventurous journey.

I have written and presented the findings of the PhD on four continents: Africa, Asia, Australia and Europe. It was shaped and formed in thirteen countries: South Africa, Lesotho, The U.K., France, Hungary, Italy, Poland, Slovakia, The Netherlands, Spain, India, Nepal, Australia and Qatar. It was nurtured and fed in many more villages, towns and cities and transitioned through several airports, train stations and ports. The journey has brought many people along my path who have inspired me and contributed to the success of this project.

The journey was about the process. This process is embodied in the work of the artist (and my friend) Dot Vermeulen entitled, *Accept and Reject.* In this work, the artist illustrates how in the research process as in life we collect things and reject them. I have collected incredible amounts of data and paper for this PhD and distilled them into the pages of this thesis. These pages can never fully capture the impression this journey has etched into my life. I have come to love and embrace the voyage I embarked upon. It created moments for introspection and reflection. It has taught me about myself and about people. I have come to understand that the love of knowledge and understanding things is rooted in curiosity and persistence. It allowed the magic of research to unfold for me. It fuelled the passion I have for wanting to know and understand phenomena. It allowed me to glean from scholars far greater than I. It took me by the hand and led me into the caverns of my inner self and left me more confident about my capabilities as a researcher; more enthused about the pursuit of knowledge; and more excited about this beautiful pilgrimage called Life.

It presented me with an opportunity to learn and explore a topic that I started off knowing very little about. And it has left me knowing something about radiation safety and radiation epidemiology, but also left me with more questions than answers.

This PhD was never an arduous drudgery for me. I had moments that were very difficult and frustrating. There were times when the midnight oil had long burnt out and I welcomed the dawn. There were moments when despair threatened to overwhelm me especially when participants refused to participate. But it was the vision of why I was on this journey that sustained me. From the start, I made the journey my own. I listened to the stories of PhD graduates that had preceded me and took courage from their successes but refused to internalise their views that this was a difficult road to walk. I refused to read self-help PhD books. I purposed from the start that this would be my journey and that I would fill every moment of it with enthusiasm, passion and sheer enjoyment. I have not been disappointed.

I draw this journey to a close knowing that it is not "Checkmate." It is the conduit to the start of another phase. I exit the game triumphantly.

"Daring ideas are like chessman moved forward. They may be beaten, but they may start a winning game."

Johann Wolfgang van Goethe

COLLECT AND REJECT

by

André Rose

Order/chaos/chaos/order/chaos/cha…/order.

Stacked in paper piles that reach like towers to the sky
Hoarded in the caverns of cyber space
Secured on sticks and hard drives
Copies and copies of copies
And versions named and renamed
Till you are left unsure which gave birth to which

Snippets incessantly added to the pile
Till the hoard becomes a mountain
And the mountain will not move
Every byte seemingly as important as the byte before
Backups and backups of backups
Outdated. Undated till the chronology muddles

Delving.
Gathering.
Investigating.
Reverting.
Rejecting.
Accepting.

Data flowing. Data static.
Eureka moments snapped up by frustration.
Numbers adding up to nothing.
Criteria met. Assumptions violated.
Backed against the wall. Rabbit holes open.
Numbers adding up to meaning. Meaning snaps.

Distilled to the covers of a book.
Trapped in PDF.
The journey paints itself
Culminating in red with a tap,
As the Sages pretend.

"Collect and Reject"
Dot Vermeulen 2013
Digital print 2/10
480 x 490mm

RADIATION INDUCED LENS CHANGES AND DEVELOPMENT OF A RADIATION SAFETY FRAMEWORK FOR INTERVENTIONALISTS

CHAPTER 1

CREATING THE CONTEXT

"The saddest aspect of life right now is that science gathers knowledge faster than society gathers wisdom"

(Isaac Asimov)

1.1 INTRODUCTION

Ionising radiation has revolutionised modern medicine. It has made it possible to visualise a disease, to grapple with its anatomy and physiology and in recent years has taken us to a level where we can disrupt the progression and spread and in some cases even cure the disease. Having an X-ray or CT scan or even an angiogram has become part of our *lingua franca.* We all have an uncle, an aunt, a parent, a child or even ourselves who have had a radiological procedure. And we spare no thought for the potential health effects it may have on us. Doctors occupationally exposed to ionising radiation exposure hardly ever consider it as an occupational hazard and radiation protection is largely neglected. The rapid advances in the science of fluoroscopy has far outstripped the wisdom this fraternity has applied to controlling it. Too little has been done to build and nurture the culture of radiation protection in South Africa but, it is not too late to disrupt the status quo. This research set out to understand where these fault lines were and how to offer insights that would influence the creation of a culture of radiation protection to protect radiation healthcare workers and patients.

This chapter provides the structure for the thesis. The Background section roots the study in the current literature. It discusses what ionising radiation is and how it affects human tissues.

It describes the effects it can have on human organs particularly on the eyes and the crystalline lens of the eye. The chapter discusses radiation dose estimation to the eye. It presents how operators can protect themselves from ionising radiation in the catheterisation laboratory (cath. lab). It explores what a culture of radiation (CRP) is and what training in radiation protection safety means.

Furthermore, the chapter deliberates on why the research was necessary and presents the justification for the study. It describes the conceptual framework and the epistemological position of the study. It reflects on the rationale for the methodology employed to conduct the study. The aims and objectives are mentioned. It discusses the ethical considerations. The chapter concludes by giving an overview of the structure of the thesis.

1.2 BACKGROUND

Radiation may be ionising or non-ionising. In this thesis “radiation” refers to ionising radiation unless stated otherwise. Ionising radiation is used in the food industry, industrial processes, the mining sector and in medical science. Radiation is a double-edged sword with beneficial and detrimental effects. Radiation can be beneficial for the therapeutic management of cancers and other diseases and for diagnostic imaging and image guided treatments as performed by interventional radiologists and cardiologists, but it may also cause potential harm (Nikjoo *et al*. 2012).

1.3 WHAT IS IONISING RADIATION?

Radiation consists of elementary particles with sufficient energy to pass through matter and cause ionisation of atoms. Radiation can be divided into electromagnetic waves, charged and un-charged particles. The former includes the ionising photons found in diagnostic imaging departments and this is the type of radiation considered here (Nikjoo *et al*. 2012). Ionising radiation exists as either a particulate or electromagnetic nature. (Desouky *et al*. 2015).

1.4 EFFECTS OF RADIATION ON HUMAN TISSUE

Ionising radiation causes damage to tissues in different ways. The mechanical kinetic model postulates that the ionising beam passes through the cell and may collide with different parts of the cell nucleus and damage results because (a) there is injury to various cell structures and/or (b) there is a flaw in the repair process of the double stranded DNA molecule (Zhao *et al*. 2017). The damage may be due to direct structural damage, or because of the formation of radical oxygen or nitrogen species in the cytosol. These free radical species can disrupt the cell homeostasis (Desouky *et al*. 2015).

The damage to the nuclear material may either be a double stranded break (DSB) or replication stress on the single stranded DNA (ssDNA) (Nickolo 2017). Interference with the repair pathway of the DSB may result in cell cycle arrest, collapse or destabilisation of repair at the DNA fork, or a graded response at different points of the cell cycle which may result in survival or death of the cell (Nickolo 2017).

The damage from the ionisation may place stress on the repair process which results in apoptosis, autophagy, necrosis or a mitotic catastrophe which causes genome instability or cell death (Nickolo 2017). Genomic instability can be immediate or delayed. Minor genomic changes can be tolerated, but extreme changes may result in mutations and chromosomal aberrations and subsequent cell death (Nickolo 2017).

The effects of radiation on the eye have mainly been described for high dose radiation exposure in atomic bomb survivors, nuclear radiation fallout survivors and patients receiving high dose radiation treatment. According to Ober *et al.* (2005), radiation may affect all the different anatomical structures of the eye as follows:

- Iris: acute iritis, atrophy and glaucoma;
- Conjunctiva: acute conjunctivitis, keratinisation, necrosis and haemorrhaging;
- Cornea: keratitis, neovascularisation, drying, perforation, keratinisation;

- Lacrimal gland: atrophy, decreased tear production;
- Eye lids: erythema, dermatitis, ulceration, necrosis;
- Sclera: acute injection, thinning, perforation;
- Orbital bone: retarded bone growth, atrophy;
- Retina: transient oedema, retinopathy, neovascularisation, exudates, detachment (Ober *et al*. 2005; Kaushik *et al*. 2012); and
- Optic nerve: swelling, neuropathy, atrophy infarcts.

The lens of the eye is an avascular structure and the surrounding aqueous and vitreous fluids supply the lens with nutrients (Kleiman 2012). The lens of the eye is unique in that there is no cell damage or degradation of cells, but rather that injury is incurred because of an accumulation of DNA damage (Barnard *et al*. 2016). The injury does not occur because of a dose response rate, but rather because of a dose and dose-rate effectiveness factor (DDREF) (Dauer *et al*. 2010). The DDREF is the factor that is applied to a risk model to estimate the dose to the tissue. The dose to tissues like the eye was based on a single high dose that atomic bomb survivors received but this linear relationship cannot be applied in the occupational setting where the exposure is not just once off. To account for this the DDREF can be used to estimate the dose to tissue in an occupational setting. The primary way in which the lens of the eye is affected by ionising radiation is that it develops opacifications that can mature into cataracts (Little 2013). The latency period between exposure and developing cataracts is uncertain and seems to be dose dependent (Hammer *et al*. 2013).

The effects of radiation may be deterministic or stochastic (Stewart *et al*. 2012). Deterministic effects refer to effects that are only seen if the tissues or organs are exposed to more than some minimum radiation dose threshold (Stewart *et al*. 2012). Deterministic effects include e.g. skin burns and cytopaenia (Brown & Rzucidlo 2011). Stochastic effects refer to effects that are seen even if there is not a minimum dose exposed to and includes, e.g., carcinomas (Stewart *et al*. 2012; Brown & Rzucidlo 2011). Previously opacifications in the lens of the eye were thought to be a deterministic effect (Brown & Rzucidlo 2011). Evidence is mounting that the effects may be related to a reduced threshold exposure or may even be stochastic in nature (Hammer *et al*. 2013).

1.5 OCCUPATIONAL RADIATION INDUCED CATARACTS

The lenses of the eye are of the most radiosensitive organs (Ober *et al*. 2005). Ionising radiation exposure increases the risk of developing cataracts (Kleiman 2012). Radiation Health Care Workers (HCWs) are at increased risk of developing occupationally induced cataracts when compared to occupations where there is no occupational radiation exposure (Seals *et al*. 2016). The cath. lab is a high-risk area for radiation exposure. Interventional radiologists and cardiologists performing fluoroscopy procedures are radiation HCWs that have of the highest risk for developing cataracts (Ciraj-Bjelac *et al*. 2010). The cataracts related to radiation exposure typically occur in the posterior capsule of the lens (Kleiman 2012). There is, however, mounting evidence that it may also occur in the cortical and posterior sub-capsular region (Stahl *et al*. 2016).

1.6 RADIATION EXPOSURE

A linear no threshold model (LNT model) is used to explain the probability of developing detrimental health effects due to low dose radiation exposure. According to this model exposure at high doses of radiation (e.g. atomic bomb survivors) are extrapolated linearly to zero effect at zero dose (i.e. without a threshold considered) to see what the effects would be like at low dose radiation exposure. The LNT model was used to establish the radiation dose limits established by the International Commission on Radiological Protection (ICRP) (Desouky *et al*. 2015). Assumptions were also made about what an acceptable occupational risk is and how much increased risk would be tolerable for radiation workers. The thresholds or limits set were then set at a (arbitrary) fraction of what would be considered acceptable risk levels.

The International Labour Organization (ILO) has set the following dose limits for occupational exposure for ionising radiation:

(a) An effective dose of 20 mSv per year averaged over five consecutive years;

(b) An effective dose of 50 mSV in any single year;

(c) An equivalent dose to the lens of the eye of 150 mSV in a year. (Niu 2011)

1.7 RECOMMENDATIONS OF RADIATION DOSE TO THE EYE

The ICRP's latest recommendations (2011) for the occupational dose to the eye is that it does not exceed 20 mSv annually averaged over five years and no single year may exceed 50 mSv. This is a reduction as previously recommended by the ILO. (Niu 2011) The threshold for radiation cataractogenesis was set at 0.5 Gy (ICRP 2011). There is, however, increasing evidence that there is no threshold and cataractogenesis may be stochastic in nature (Ainsbury *et al*. 2009).

1.8 UNCERTAINTIES IN LENS DOSIMETRY

The dose to the eye is based on assumptions about the wearer's protective clothing and the scatter from the patient and for safety reasons a safety margin is included so that the actual effective dose is overestimated (Miller *et al*. 2010). There are many uncertainties in how this dose is estimated and there are many formulae to calculate it with little consensus on how the dose can or should be estimated.

1.9 RADIATION PROTECTION LEGISLATIVE AND REGULATORY FRAMEWORK IN SOUTH AFRICA

The Hazardous Substance Act (Act of 1973) governs the procurement and utilisation of radiation equipment in South Africa (SA Government 1973). This Act explains how radiation equipment should be properly used, the maintenance regulations and the disposal of such equipment. The Act makes adequate provision for the regulatory component of radiation control, but falls short with respect to the policing of the Act (Herbst & Fick 2012).

The Code of Practice for Users of Medical X-ray Equipment was developed by the Radiation Control Unit in the Department of Health to govern the requirements and recommendations for radiation safety associated with the use of medical x-ray equipment. (Directorate Radiation Control 2015) The Code governs who can apply for a licence to use X-ray equipment. It stipulates the acquisition and disposal of equipment and the building of new X-ray suites and their modification. It importantly also stipulates how patients and radiation healthcare workers should be protected from the effects of ionising radiation. The Code is provides guidance in what should be happing with respect to radiation protection in the cath. lab but it is not comprehensive or prescriptive in the totality of how this protection should be implemented. Furthermore, the enforcing and monitoring of such radiation practices are prescribed.

The Occupational Health and Safety Act (OHSA) (1993) stipulates that the employer has to provide a workplace that is safe for the employee (SA Government 1993). This Act (OHSA) makes provision by extension that personal protective equipment (PPE) would be provided in the workplace as part of the provision of a safe work place. Thus, by extension it would regulate that the employee should ensure that the cath. lab should be a safe workplace and that the regulation for its design would be in place and that PPE is provided.

1.10 PRINCIPLES OF RADIATION PROTECTION IN THE CATHETERISATION LABORATORY

Radiation safety in the cath. lab is underpinned by three principles: justification, optimisation and shielding. Protection should be geared towards protecting the patient and the radiation HCW (Spruce 2017). Radiation HCWs should always apply the "as low as reasonably achievable" (ALARA) principle to enhance radiation safety in the cath. lab. The ALARA principle stresses that use of ionising radiation should consider time, distance and shielding.

The health risk to patients and operators associated with using ionising radiation has necessitated that careful consideration be given to its usage. The clinician referring the patient for an investigation or procedure or the operator should carefully weigh all available options to decide if exposure to ionising radiation is the best option. The justification for choosing ionising radiation must be informed by the cost-benefit gained against other modalities such as ultrasonography or magnetic resonance imaging (Cousins & Sharp 2004).

Optimal imaging practices include for example collimation and using short bursts of radiation exposure as opposed to continuous operation. Fluoroscopy loop recording can be used to review dynamic flow processes. The number of fluoroscopy images can be reduced and digital subtraction can be employed. A more radio-opaque catheter tip can aid visualisation. The patient should be positioned correctly so that the patient is as far from the X-ray tube as possible. The interventionalists should be in a low-scatter area (Miller *et al*. 2010). In a study in Norway it was found that there was lack of optimisation of procedures which increased non-compliance with regulations aimed at improving radiation safety (Silkoset *et al*. 2015).
The quantity of procedures being done using ionising radiation has increased making the control of this hazard in the medical workplace imperative in order to protect radiation HCWs (Bhargavan 2008). Radiation exposure in the cath. lab can be optimised in different ways, e.g., raising an awareness of the dangers of radiation exposure and applying safety principles are critical to establishing a safer radiation workplace (Seals *et al*. 2016). The occupational hierarchy of control can be applied to mitigate this occupational hazard. The hierarchy consists of elimination of the hazard, substitution of it, engineering controls, administrative controls and use of personal protective equipment (PPE). Elimination is the most effective control measure and the use of PPE the least effective control measure, but still remains an important control measure in radiation safety control (National Institute for Occupational Safety and Health (NIOSH) 2016).

The increasing utilisation of ionising radiation in modern medicine precludes elimination as a likely control measure (Bhargavan 2008). Substitution of ionising radiation with non-ionising radiation or hybrid technologies is gaining traction, but there are still some procedures like fluoroscopy that require the use of ionising radiation. Engineering controls have resulted in improvements in the imaging equipment and resulted in reduction in the dose these machines emit (Miller 2013). Reduction in dose competes with the quality of the image that can be produced. The quality of the image often reduces as the dose used is reduced. Engineering controls include how the cath. lab is designed (or re-designed) and the design of the imagining equipment (Klein *et al*. 2009). The costs, risks and benefits of securing a safer workplace should guide hospital managers when making decisions securing the safety in the cath. lab (Klein *et al*. 2009). These first three control measures are mentioned for completeness sake, but were not explored in the study. This study focused on the administrative controls and the use of PPE as part of the radiation safety practice of participants.

The administrative controls include measures such as rotating staff through ionising and non-ionising work areas and the monitoring of radiation exposure. The monitoring of dosimeters is an important measure for monitoring radiation exposure and for quality assurance in the cath. lab. It ensures that staff are not exposed to radiation levels beyond regulatory stipulations (Badawy *et al*. 2016). This protects radiation HCWs and improves patient safety and hence quality of care.

Monitoring of radiation exposure is an important control measure and is done through monitoring of dosimeter badges. Interventionalists are often poorly compliant with wearing radiation monitoring badges (dosimeters) (Sánchez *et al*. 2012). A robust monitoring system is thus essential for the control of dosimeters in the cath. lab. The challenge with the thermoluminescent dosimeter (TLD) badges is that there is a delay between the execution of a procedure and the reporting of the dose received. Operators may have difficulty in correlating high readings to specific procedures and this makes it a challenge to change specific clinical practices (Aerts *et al*. 2014). The utilisation of real time dosimeters can help address this problem. These monitors are, however, costly which limits their availability (Badawy *et al*. 2016).

The range of PPE available for protection in the cath. lab incudes lead gloves, lead aprons, thyroid shields, lead caps and lead glasses or visors (Spruce 2017). Operators are generally more likely to consistently use lead aprons compared to any of the other PPE devices. In a study conducted in the United Kingdom it was reported that lead glasses were not used consistently (Ainsbury *et al*. 2014). The shielding available includes lead drapes, ceiling suspended screens, mobile screens and a suspended radiation protection system (Marichal *et al*. 2011). There is a range of newer non-lead based materials that have been developed which shields against radiation as effectively as lead based devices (Scuderi *et al*. 2006). They are lighter than lead based garments and may be ergonomically better, but are more expensive (Scuderi *et al*. 2006). The non-lead materials offer similar protection as the lead based devices and they are non-toxic (Zuguchi *et al*. 2008).

PPE utilisation is determined by availability of the protective devices, how the device fits the operator and the dexterity of performing procedures with the device (Honda & Iwata 2016). Accessibility to PPE increases its adherence (Snipes *et al*. 2015). Availability of devices may be facilitated by hospital management prioritising radiation safety and making funds available to timeously procure PPE. Administrators of health facilities should not underestimate the role they play in securing a safe workplace (Engel-Hills 2005). If all members of the cath. lab team have access to personal devices it could aid compliance (Cremen & McNulty 2014).

The ergonomic design of devices is a key factor in encouraging compliance. Operators are more likely to use PPE if it is not heavy and if it fits them well (Cremen & McNulty 2014). PPE that fits correctly would also confer maximum protection to the user and therefore, it is important that employers provide PPE based on the morphology of the users (Rivett *et al*. 2016). The design of PPE that hampers effective use and execution of procedures should be addressed (Broughton *et al*. 2013). The PPE should not hamper interventionalists performing (complex) procedures. The utilisation by HCWs is generally poor and better ways to incentivise compliance with PPE needs to be developed (Kang *et al*. 2017).

1.11 TRAINING IN RADIATION SAFETY

Education and training lay the foundations for radiation safety for radiation HCWs. The training in radiation safety is generally suboptimal for cardiologists (Kuon *et al*. 2015; Rose & Rae 2017). Interventionalists need to be trained on how to use imaging equipment properly to reduce the dose to patients and operators (Azpiri-lópez *et al*. 2013). Radiation training should be part of the formalised training program and the continuous medical education programs of interventionalists to be maximally effective (Rehani 2007; Kim *et al*. 2010). A Polish study showed a dearth of knowledge on radiation safety awareness among medical staff and recommended that systematic education programs were required to address this shortfall (Szarmch *et al*. 2015). In two independent studies the researchers demonstrated that doctors being trained as specialists have inadequate knowledge about radiation safety (Sadigh *et al*. 2014; Friedman *et al*. 2013). In one of these studies the researchers reported that radiologists in training generally had a better knowledge on radiation safety than other specialists in training (Sadigh *et al*. 2014).

The introduction of radiation physics and radiobiology may add a burden to an already packed training program for interventionalists, but it is crucial that radiation safety is addressed in their curriculum (Rehani 2007). The training should be the responsibility of the training and regulatory bodies of the disciplines (Cousins & Sharp 2004). Radiation HCWs need to keep up to date with the developments in radiation protection to ensure that they create and maintain a safe environment in the cath. lab (Engel-Hills 2005).

Specialists in training (registrars) demonstrated poor knowledge about radiation safety. Training is essential, however, it cannot be a once off activity and there needs to be continued reinforcement of training and safety principles for it to be effective. One study reported that the effects of training started to dissipate after three months and required continuous reiteration (Georges *et al*. 2009).

It is essential that interventionalists (and all radiation HCWs) should demonstrate that they have acquired adequate knowledge to mitigate the risk of radiation exposure in the cath. lab (Fazel *et al*. 2014). Medical and radiation protection societies should be proactive in improving radiation safety knowledge and training. They should be supported in providing a safer radiation workplace by medical physics and radiation protection experts (Vano 2015). There is also a role for occupational medicine departments to facilitate the monitoring and control of the radiation workplace and to ensure radiation HCWs receive regular routine medical examinations (Killewich *et al*. 2011).

1.12 CULTURE OF RADIATION PROTECTION

The safety of patients undergirds the notion that all HCWs hold as a common value. Safety culture is a dynamic system of the individual's actions and the structure of an organisation where constraining and enabling factors are produced to create an environment in which patients are kept safe (Groves *et al*. 2011). Physicians are largely unaware of the radiation they expose patients to (Correia *et al*. 2005). This poses a risk to patients and compromises quality of care.

There is a growing need internationally to improve healthcare delivery. This will require that local systems are adaptive to respond to this need (Elshaug *et al*. 2017). The care delivered should be optimised so that it is "needed, wanted, clinically effective, affordable, equitable and responsible" and in so doing it ensures that there is not an over provision of services (Elshaug *et al*. 2017). The growing demand on radiation services for diagnostic, prognostic and interventional reasons places a demand on these services that may result in over utilisation (Bhargavan 2008). The risk is that a culture that fails to prioritise radiation safety may evolve. It is essential that interventionalists change their working patterns to ensure that they create a safe work environment (Roberts & Peet 2016).

The work culture in an organisation may have four main expressions or a combination of these four structures. These include a clan culture (cohesive, participatory leadership), a developmental culture (creative, adaptive leadership), a hierarchical culture (leadership bound by rules and policies) and a rational culture (competitive and goal orientated) (Wagner *et al*. 2014). A teamwork structure promotes patient safety and facilitates quality improvement (Speroff *et al*. 2010). The role of the heads of department and managerial structures of radiation facilities are crucial to ensure that a CRP is forged and promoted. A

CRP encourages and promotes radiation safety in the workplace and is everyone in the cath. lab's responsibility (Groves *et al*. 2011).

1.13 CONCLUDING REMARKS

Ionising radiation utilisation in modern medicine has been highly beneficial in promoting the health and well-being of patients. The potential health risks to patients and radiation HCWs can be mitigated by educating patients and radiation HCWs about how radiation can affect them. Educating and continued training in radiation safety helps to create and sustain a CRP which protects patients and radiation HCWs. Creating this CRP is a proactive endeavour that requires regular and persistent promotion.

1.14 PROBLEM STATEMENT

The application of radiation as a treatment, diagnostic and interventional modality and its utilisation in developing countries has and continues to increase globally. There is an important balance between beneficiation from radiation utilisation and its potential health impact. This study considered these two aspects to determine the prevalence of cataracts and the CRP in South African interventionalists which have not been investigated previously.

1.15 JUSTIFICATION OF THE RESEARCH

Radiation associated cataracts in cath. lab operators is an established relationship. This relationship has however never been described before in South African interventionalists. The use of ionising radiation continues to increase for diagnostic, prognostic and interventional procedures globally and in South Africa. South Africa has a two-tiered health system and radiation safety control measures are often not consistent across these two systems. Determining the prevalence of radiation associated cataracts in South African interventionalists and understanding the CRP they operate under would assist us to understand the extent of the situation in South Africa. This in turn would help to develop a radiation safety framework that can improve radiation safety by influencing the CRP in the country. This is important because we invest a large amount of financial and human resources in training interventionalists and we should protect this scarce resource. All workers including radiation health care workers deserve to work in a workplace that is safe. Ultimately though it is about protecting the patient. They are often vulnerable, uninformed about the factors that can affect their health detrimentally and for this reason all efforts must be made to protect them.

1.16 CONCEPTUAL FRAMEWORK

The research question was complex and as such it was necessary to integrate different theoretical frameworks to make meaning of the research question. Organisational theory was used to understand the complexity of the CRP (Laegaard & Bindslev 2006; Batras *et al*. 2016). Organisational theory helps explain the complex relationship between organisations and their environment (Birken *et al*. 2017). The occupational hierarchy of control was used to understand utilisation of personal protective equipment (PPE) (National Institute for Occupational Safety and Health (NIOSH) 2016).

CRP is a complex construct which is influenced by a myriad of factors. The nonlinear interrelationship of physiological processes, individual behaviour, workplace and organisation culture and clinical practice necessitated a theoretical paradigm that allowed the interactions of the individual components affecting the phenomenon to be investigated and therefore, complex adaptive systems (CAS) theory was used (Beurden *et al*. 2016). CAS theory offers a framework to understand and interrogate the research question because it offers a synthesis of the overarching paradigms and allowed us to construct meaning of the research phenomenon. It further allowed us freedom to move away from a reductionist approach and allowed the multiplicity of the research phenomenon to unfold (Beurden *et al*. 2016).

In CAS theory, the following aspects are characteristic of the system:

- There are many elements that interact with each other and exchange information (Holden 2005);

- The interactions are non-linear (Holden 2005);
- The system is open with feedback loops that can either enhance or distract the interaction, but both are required (Holden 2005);
- In CAS there is a constant state of flux resulting in constant change (Holden 2005);
- Complex systems have a peculiar character and no single element or agent can predict outcomes (Holden 2005; Rowe & Hogarth 2005); and
- The complexity is consequent to the patterns of interaction between the elements (Holden 2005).

Antecedents and consequences are two other important consequences to consider when understanding a phenomenon through the lens of CAS theory (Holden 2005). In a complex system the main antecedents are the individual agents (Holden 2005). In this study these agents would be, e.g., the interventionalists, nurses, radiographers, the radiation protection officer and the facility manager and the patients. A complex system requires that the antecedents should be able to interact. Adaptation or emergence results when the agents interact with each other and mutually affect each other (Holden 2005). The emergence is richer and more meaningful the greater the diversity of the agents (Rowe & Hogarth 2005).

CAS theory is a theoretic framework that recognises that healthcare organisations are dynamic and fluid. The systems and the actors within this system are not predictable and have multiple complex interactions. This allowed us to move away from a reductionist understanding of how the healthcare system operates. It offered an overarching theory to integrate the different theoretical frameworks used to understand the research question.

1.17 EPISTEMOLOGICAL POSITION

A pluralistic pragmatic approach was used to conduct this research (Goldkuhl 2012). Pragmatism is concerned with action and change and how knowledge and action interact with each other (Goldkuhl 2012). In the case of this research we wanted to understand how organisational design and behaviour interacts with each other to produce the responses offered by the participants and their attitudes towards radiation safety. A pragmatic approach allowed the researcher to grapple with and understand the multiple layers that the research question raised. These layers included, but were not limited to, the culture of care that exists among doctors; their socialisation as custodians of health within a community and the privilege their occupation affords them to make decisions about their occupational safety; and the safety of the colleagues they work with and that of their patients.

The complexity of the research phenomenon required a multiple-methods approach to be used and this required an epistemological approach that accommodated this paradigm (Feilzer 2010). Pragmatism offers a paradigm that permits the phenomenon to be positioned within a philosophical structure that allowed us to better understand the social phenomena and social and organisational constructs (Feilzer 2010). Pragmatism relies on abductive reasoning which allowed the researcher to vacillate to and fro between inductive and deductive reasoning (Morgan 2007). This meant that we could make meaning based on what has already been said about the phenomenon and integrate it into understandings that emerged.

1.18 RATIONALE FOR THE METHODOLOGY USED

The intricacy of the research question required the research design to be malleable to allow for the research process not to be a rigid prescriptive plan that is followed, but rather that it formed a guide for the actions needed to delve into the problem. It was necessary to apply different research methods to achieve this objective. Qualitative and quantitative techniques using multiple methods were employed to collect data. This facilitated exploration of the multifaceted nature of the research question. Using qualitative and quantitative methods in a pragmatic integrated and supportive way allowed the researcher to draw on the strengths of these two methods (Onwuegbuzie & Leech 2005).

The use of multiple methods allowed the researcher to produce detailed and contextualised data that quantitative or qualitative methods would not have been able to produce on their own (Shneerson & Gale 2015). The use of both methods offers better insight into the research question (Shneerson & Gale 2015).

In addition, an interdisciplinary approach was embarked upon at the conceptualisation of the study, the analysis and integration of the data, and the writing of the peer reviewed articles (O'Cathain *et al*. 2008). Interdisciplinary research allowed the researcher to understand a complex health challenge because the different disciplines were used synergistically as required to aid in creating meaning to understand this complex healthcare construct (Malterud 2001). Interdisciplinary research is process orientated and allows for non-linear thinking. It requires that the research team work in an integrated manner (Hesse-Biber 2016). This manner of thinking was essential to allow the researcher to address the research question. It will thus be noted by the reader that the author list for each of the papers differs as appropriate for each article presented.

The research strategy was a synthesis of the quantitative studies (survey and ophthalmological screening) and the qualitative study (interviews). The studies were linked at a methodological and data analysis level and created a synthesis that helped understand this complex health problem.

1.19 DELIMITATIONS OF THE STUDY

The study had a quantitative and qualitative component. The quantitative component included a survey and screening of cataracts in participants. The quantitative part of the study included doctors who performed fluoroscopic procedures and were thus occupationally exposed to ionising radiation and other doctors who were not routinely occupationally exposed to ionising radiation. The interventionalists included interventional radiologists, adult interventional cardiologists and paediatric interventional cardiologists. The doctors not occupationally exposed to ionising radiation included general practitioners, family physicians, surgeons, paediatricians, specialist physicians and pathologists. The qualitative study included only interventionalists working with ionising radiation. The study excluded other radiation HCWs because we were interested in understanding the perspectives of doctors who work with ionising radiation.

1.20 AIMS AND OBJECTIVES

1.20.1 Aims

The aims of this study were to:

i. Determine the prevalence of occupational related cataracts among South African interventionalists.
ii. Explore the culture of radiation protection among South African interventionalists.

1.20.2 Objectives

The objectives of this study were:

i. To describe the prevalence of radiation associated cataracts in South African interventionalists.
ii. To compare a group of interventionalists occupationally exposed to ionising radiation to a group of doctors occupationally unexposed to ionising radiation.
iii. To determine the relationship between cataracts and occupation in the study population.
iv. To determine the use and attitude towards personal protective equipment (PPE) among the interventionalists.
v. To determine the training in radiation safety among South African interventionists.
vi. To explore the culture of radiation protection among South African interventionalists.
vii. To develop a framework for radiation protection in the catheterisation laboratory in South Africa.

1.21 ETHICAL CONSIDERATIONS

The study was approved by the Human Ethics Committee of the University of the Free State (ECUFS 44/2015) (cf. Appendix A). Permission was obtained from conference organisers to conduct the research at various conferences throughout South Africa. The participants gave individual informed consent for participation in the survey and the ophthalmological screening. They also signed individual informed consent for participation in the discussion groups and the in-depth interviews. Not all participants that were screened participated in the survey and vice versa. They were asked not to divulge the content of the discussion beyond the discussion groups.

The names of the participants were presented on the survey and ophthalmological data collection sheets so that they could be linked, but the final database was de-identified. All data were kept in a safe place and electronic databases were password protected.

1.22 STRUCTURE OF THE THESIS

This thesis was completed as a composite of an introductory chapter, six articles and two supporting articles. The articles form the chapters in the thesis and are linked via a narrative synthesis. Four articles were published and two are in the process awaiting publication.

Chapter 1 provides the background to the study, the theoretical framework, the epistemological framework and the methodological rationale. The researcher explains the aims and objectives of the study and consider the ethical aspects of conducting the study.

Chapter 2 describes the methodology used. This chapter consists of a prologue in which the overall approach and methods are described. The research methods are described in an article. The researcher describes how the study was done and the rationale for choosing the methodology used.

Chapter 3 describes the main ophthalmological findings in the study. This chapter addresses Objectives 1, 2 and 3. The chapter presents the prevalence of radiation induced cataracts and compares it to doctors not occupationally exposed to ionising radiation. It emphasises the clinically importance of the radiation induced cataracts in this group of doctors. This chapter also appended (cf. Appendix B) with the ophthalmological findings described other than cataracts.

Chapter 4 explores the use of personal protective equipment. Chapter 3 delineated the consequences of occupational radiation exposure to the eyes. There are, however, protective measures available for mitigating this. In this chapter, the researcher explore what the qualitative and quantitative rationale is for these interventionalists to not use the PPE resources available at their disposal.

Chapter 5 consists of two articles through which the researcher describes the status quo of training of interventionalists in South Africa. The qualitative article takes a pragmatic approach to understanding what the shortfalls are in radiation safety training in South Africa and offers insights to addressing these gaps. The quantitative article documents what the interventionalists stated their training needs were.

Chapter 6 explores what a culture of radiation protection is in the South African context. This chapter is the crux of what is essential to re-shaping the existing culture in the catheterisation laboratory into one that is inclusive of embracing every member in the catheterisation laboratory as responsible for establishing and nurturing a CRP. This chapter urges the reader to consider that to truly avert the detrimental effects of ionising radiation on the eye as reported in Chapter 3 a deliberate effort has to be made.

Chapter 7 is a synthesis that amalgamates the multifaceted concepts that emerged from the research. In this chapter, the researcher offers to draw conclusions of the research process, the methodologies employed, the ramifications for radiation healthcare workers and their patients and the researcher suggests a framework for radiation protection is South Africa.

In the ensuing chapters, the researcher invites the reader to journey with him and discover the understanding of the research that was conducted, how it unearthed more than he anticipated and raised more questions than could ever be answered.

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CHAPTER 2

METHODOLOGY

"Good, sound research projects begin with straightforward, uncomplicated thoughts that are easy to read and understand"

(John W. Creswell)

2.1 INTRODUCTION

The research question at first appeared straightforward. We wanted to determine the prevalence of cataracts in interventionalists and what their training in radiation safety was. Exploring the concept, however, revealed a complex multifaceted dimension that required us to design the study in a way that allowed us to investigate the various exciting facets the research posed. The result was a mixed methods study that cut across at least four disciplines (public health, occupational health, medical physics and ophthalmology). This made for a thrilling exploration of the research question. The endeavour raised challenges of interdisciplinary collaboration and the difficulty of engaging a study population group that are best described as "hard to reach". The methods were published as, *A multiple methods approach: radiation associated cataracts and occupational radiation safety practices in interventionalists in South Africa,* in the Journal of Radiological Protection (Rose *et al*. 2017). The methodologies for the different articles, which constitutes this thesis, are also described in each separate article as well (cf. Chapters 3-6).

For the ease of description, the quantitative and qualitative components of the study are described separately. However, it must be considered that the findings are interrelated and have to be understood holistically.

2.2 STUDY 1: QUANTITATIVE COMPONENT

The quantitative study consisted of a survey and a slit lamp examination. Participants completed an online survey or a paper based version (cf. Appendix C). They also had a slit lamp examination and the findings were recorded on a clinical examination sheet (cf. Appendix D).

2.2.1 Study design

This was a prospective cross-sectional study.

2.2.2 Study population

The participants consisted of doctors occupationally exposed to ionising radiation namely interventional radiologists, adult interventional cardiologists and interventional paediatric cardiologists. A group of doctors not occupationally exposed to ionising radiation were used as a comparative group. These included general practitioners, specialist family physicians, specialist physicians, paediatricians, surgeons, pathologists and a range of other doctors (cf. Figure 2.1).

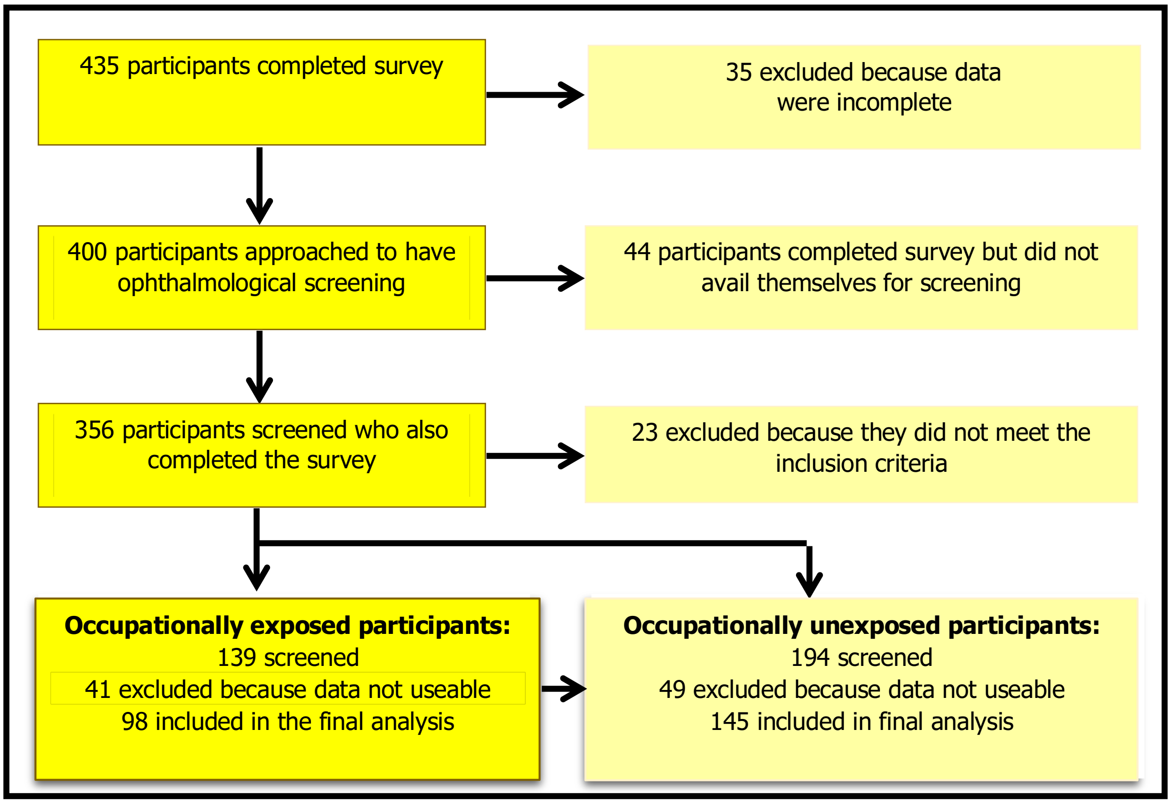

Figure 2.1: Illustration of the study population for the quantitative component

2.2.3 Sampling strategy

There was no randomisation. All eligible, willing participants were included in the study (Willingness to participate in the study was not always forthcoming though!)

2.2.4 Study site

The data were collected at several conferences across South Africa. The target population (interventionalists) are generally very busy and not readily available for participating in research. For this reason, it was decided to target specialised conferences that they would likely be attending. Over a period of about two years we traversed South Africa to "look into the eyes" of this hard to reach community. The Table 2.1 below illustrates where participants were recruited.

Table 2.1 Conferences at which data were collected

DATA COLLECTION	DATE	PARTICIPANTS RECRUITED
Interventional radiology workshop (Bloemfontein)	May 2015	Radiologists
Paediatric cardiology workshop (Cape Town)	July 2015	Paediatric cardiologists
SA Heart Annual Cardiology Congress (Sun City)	September 2015	Cardiologists General physicians
South African Annual Radiology Congress (Johannesburg)	March 2016	Radiologists General physicians
Africa Health and Public Health Association of South Africa Congress (Johannesburg)	March 2016	Radiologists General physicians
SA Heart Annual Cardiology Congress (Cape Town)	September 2016	Cardiologists General physicians
General practitioner update course (Bloemfontein)	March 2017	General practitioners
Forensic pathology conference (Bloemfontein)	March 2017	Forensic pathologists

2.2.5 Data collection tool

The data were collected using a survey (cf. Appendix C). The ophthalmological screening data were captured on the form as illustrated in Appendix D.

2.2.6 Data collection

The data were collected at conferences as stated in Table 2.1 above. Individuals were also approached at the University of the Free State clinical departments to collect data for the unexposed group.

2.2.7 Data management

The data were captured directly into an Excel spreadsheet when the electronic survey was completed or transferred to this database from the paper-based survey. The survey data were linked to the slit lamp examination data using the participant's name and surname. The final composite database was de-identified and a unique study number assigned and this was used in the analysis. The data were kept in a locked cupboard and the electronic data were password protected.

2.2.8 Data analysis

The analysis for each article is described in the relevant article. The data were analysed descriptively and analytically. We calculated means and standard deviations (SD) for parametric data. Medians and interquartile ranges (IQR) were computed for the nonparametric data. Frequency tables were constructed for categorical data. Linear regression models were developed where appropriate. We calculated odd ratios (OR) as appropriate. Comparative statistics were done for comparing left and right eyes for the cataract findings. The data were analysed in STATA®. A detailed description of the analysis for each article is presented in the subsequent chapters.

2.2.9 Limitations and strengths

A major limitation of the quantitative component of this project was that there was no randomisation of participants into the study. The sample size was small which may have affected the statistical power of the study. The strength of this study is that it is the first study of its type in South Africa looking at occupationally induced cataracts among interventionalists. It was a bold and ambitious project, which required extensive financial and human resources.

2.3 STUDY 2: QUALITATIVE COMPONENT

The qualitative component of this study consisted of six in-depth interviews and 30 individual in-depth interviews.

2.3.1 Study design

This was a cross sectional design.

2.3.2 Study population

The study population consisted of interventionalists consisting of radiologists, adult cardiologists and paediatric cardiologists. The participants ranged from doctors who were still training as interventionalists to those who were heads of department. It included doctors from the public and private sectors. This provided a broad spectrum of participants that adequately represents the landscape of interventionalists in the South African context. The study population for the qualitative research is described in depth in Chapter 5.

2.3.3 Sampling

Purposive sampling was done. The recruiting strategies included snowballing, targeted sampling and person-place-time sampling.
The participants were selected on the basis that they could contribute to better fulfilling the objectives of the study.

The recruitment of participants was not easy. The interventionalists often cited that they were busy and could not participate in the study. They were a difficult and hard to reach study population.

2.3.4 Study site

The participants were recruited from across South Africa. They were conveniently recruited at the conferences where data were collected for the quantitative data. Participants were also contacted and appointments made to interview them.

2.3.5 Data collection tool

The demographic data of the participants were collected using a data collection sheet (cf. Appendix E). The interviews were conducted using the interview schedule (cf. Appendix F).

2.3.6 Data collection

The data were audio recorded and transcribed verbatim. The researcher also kept field notes.

2.3.7 Data management

The audio recordings were downloaded and kept on a computer that was password protected. The transcribed data were also kept on a password-protected computer.

2.3.8 Data analysis

The data were analysed thematically. The data were transcribed and coded. The codes were grouped and arranged into themes. Two researchers analysed the data independently. The two researchers then met to discuss the codes and themes that emerged. The researchers reached consensus on the themes. This is described in detail in Chapter 6.

2.3.9 Limitations and strengths

A limitation of the qualitative component is that it did not include a full spectrum of all members of the cath. lab. The study, however, had a wide spectrum of participants representing a wide range of interventionalists and the findings may be transferable to the general South African interventionalists' population and similar settings elsewhere.

2.4 PILOT STUDY

A questionnaire (cf. Appendix C) was developed from the literature and from the inputs of a panel of experts. The questionnaire developed was piloted with one cardiology resident, one paediatric cardiology resident, three radiology residents and five urology residents and two urology consultants at the University of the Free State. The pilot study was a valuable insight to understand how the interventionalists understood the questions and to ensure that we were getting responses that addressed the questions we were trying to elucidate.

They were asked to comment on the content of the questionnaires, their readability and ease of comprehension. Suggested changes were incorporated into the final draft. The panel of experts reviewed the final draft questionnaire and a final questionnaire was composed. The electronic version of the questionnaire was refined until the filters functioned properly.

The qualitative interview schedule was refined based on feedback from participants and during interviews and was adjusted accordingly.

2.5 ETHICAL CONSIDERATIONS

The study was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of the Free State (ECUFS 44/2015). The ethics certificate is presented in Appendix A. Written informed consent was obtained from participants for the qualitative and quantitative components. Informed consent was assumed when participants agree to proceed with the online questionnaire.

2.6 CONCLUSION

The design of this study is in itself the strength of the study. The process of anticipating and mitigating the factors that would ensure the success of the project required innovative thinking that challenged the paradigms of the entire research team. The unique study population never ceased to provide endless awe, amusement and tongue biting moments. Designing a study where the participants are normally the researchers requires non-linear approaches to exploring the research question.

2.7 REFERENCES: CHAPTER 2

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A multiple methods approach: radiation associated cataracts and occupational radiation safety practices in interventionalists in South Africa

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Abstract

Ionising radiation is a modality used in diagnostic and therapeutic medicine. The technology has improved and resulted in lower dose exposure but there has been an escalation in the quantity of procedures, their duration and complexity. These factors have meant increased occupational radiation exposure for interventionalists. Ionising radiation exposure can have detrimental health effects and includes radiation skin burns, various carcinomas, genetic and chromosomal aberrations and cataractogenesis of the lenses of the eye. The lenses of the eye are of the most radiosensitive organs and the risk of cataracts is high despite low radiation dose exposures. The use of personal protective equipment (PPE) is a method that can be used to mitigate the risk for developing lens opacifications. The consistent and effective utilisation of PPE is marred by availability, proper fit and ease of use when performing procedures. Radiation safety training is imperative to enforce a culture of radiation safety among interventionalists. The aim of this study was to quantify and describe cataracts among South African interventionalists and to understand their radiation safety practices. For this purpose, a cross sectional study was designed using multiple methods. A survey was conducted to determine the demographics and the risk factors of doctors exposed to radiation to doctors not exposed. The radiation workload and radiation safety practices of interventionalists were explored. Both groups had slit lamp examinations. The data were analysed analytically and a regression model developed looking at the outcomes and the risk factors. Qualitative in-depth interviews and group interviews were conducted to explore the perceptions of interventionalists regarding radiation safety. Deductive and inductive thematic analysis was done. Interdisciplinary research is challenging but offers tremendous opportunity for exploring and tackling complex issues related to securing a safe radiation work environment.

Keywords: radiation cataracts, radiation safety, occupational radiation dose, interventionalistsonal radiation dose, interdisciplinary research

1. Introduction

Ionising radiation, although potentially harmful, is used in many modalities in diagnostic and therapeutic medicine. There have been substantive advancements in the technology resulting in reduced doses for performing procedures [1]. In the last 2–3 decades the number of procedures being carried out by interventionalists has however increased together with their complexity [1]. Despite the technological advances resulting in a reduced dose, the cumulative dose may potentially increase because interventionalists spend more time doing more complex procedures. This results in increased occupational radiation exposure for interventionalists.

The effects of radiation on the body are manifold. They include skin damage, haemopoietic carcinomas, thyroid cancer, brain tumours and ophthalmic changes [2, 3]. The eyes are extremely radiosensitive and can be affected in the following ways: radiation retinopathy, neuropathy, papilopathy and lens changes. The most common changes to the eye are the development of cataracts in the lens [4, 5].

Interventional cardiologists and interventional radiologists are the two categories of medical radiation workers that have the highest radiation dose exposure [6]. This places them at increased risk of developing occupational radiation-associated cataracts [7, 8].

Radiation-associated cataracts may develop due to low dose exposure and until recently were thought to be a deterministic effect [9, 10]. The prevalence of cataracts is higher in radiation healthcare workers compared to the average population [11]. The most common site for radiation-associated cataracts to develop is in the posterior sub-capsular area of the lens [5].

The occupational hazard hierarchy of control is a framework that can be applied to the control of occupational radiation exposure in the interventional catheterisation theatre [12]. The least effective control measure in this framework is the utilisation of personal protective equipment (PPE), but it is an important control measure for radiation safety. PPE has to be used properly and consistently for it to be effective. There is inconsistent and improper use of PPE in many occupational settings. The reasons for this include poor availability, ill-fitting PPE, low or no choice in selecting the PPE and hampering the performance of procedures [13].

Effective radiation control measures in the catheterisation theatre require that a culture of radiation safety be developed. The establishment of this culture hinges on the participation of the entire team that works in the catheterisation theatre and this depends on the norms and attitudes within the workplace [7, 13].

Critical to developing this radiation safety culture is ensuring that radiation safety training is core to the training of the end users [14, 15]. In South Africa radiation physics and radiobiology are part of the core curriculum of radiologists, but this is not the case for the training of electro-physiologists, adult cardiologists and paediatric cardiologists. Changes in the training curriculum of the interventionalists will thus be critical to fostering this culture [5, 16].

There is a need to investigate the occurrence of radiation-associated cataracts and radiation safety practices among interventionalists in South Africa. Literature searches of several databases including PubMed and Medline did not yield similar studies for South Africa (and Africa) and this necessitates further investigation to identify and address these shortfalls.

The aim of this study was to compare the occurrence of cataracts in South African interventionalists occupationally exposed to radiation to a group of non-occupationally exposed doctors, to evaluate the risk factors for cataracts and to look at utilisation of PPE. The study qualitatively explored the knowledge, attitudes and practices of interventionalists to radiation safety. The aim of this article is to describe the methodology for this study.

2. Methods, materials and study design

2.1. Study design

This was a cross sectional study with exposed and non-exposed participants using multiple methods (quantitative and qualitative). A nested case control study compared cases to a control group.

2.2. Population and setting

The exposed participants were interventionalists who regularly perform fluoroscopic work and included adult and paediatric interventional cardiologists, and interventional radiologists. The comparison group comprised unexposed doctors who do not do fluoroscopic work and included general practitioners, family physicians, specialist physicians, surgeons and paediatricians. The exposed and unexposed groups were comparable to each other socially and differed chiefly in their occupational exposure to radiation.

The exposed group was recruited at several specialised national conferences and workshops in South Africa and this ensured representativeness of South Africa because they were from across the country. There are approximately 229 adult cardiologists, 41 paediatric cardiologists and 50 interventional radiologists in South Africa and they work in either the public or private sectors or both. The Health Professions Council of South Africa and the Cardiology and Radiology Societies of South Africa supplied these statistics (February 2016). These highly specialised interventionalists are concentrated in the major cities in South Africa viz. Johannesburg, Cape Town, Pretoria, Durban and Bloemfontein.

The unexposed participants were recruited in Bloemfontein, and incidentally at the conferences where the exposed group were recruited. The researchers approached various clinical departments at the public and private hospitals and practices in the city to recruit the unexposed participants.

In the case control analysis, the cases and controls were matched on age and sex. The cases were all participants diagnosed with lens opacities (exposed and unexposed groups). The controls were frequency matched from the cohort.

2.3. Participant enrolment

Participant recruitment began in May 2015. Qualitative data collection was completed July 2016. Ophthalmological screening will continue until February 2017. There was no

Table 1. Particiants enrolled into the study thus far.

	Completed questionnaire	Had ophthalmological screening
Adult cardiologists	37	35
Paediatric cardiologists	41	23
Radiologists	48	13
Not exposed comparative group	94	32
Participants excluded because they were not doctors e.g. radiographers and scrub nurses	19	3

randomisation and all participants eligible for enrolment were included. Participants with a history of radiotherapy and penetrating eye trauma were excluded from the study. Participants had to be doctors to be included in the study. The participants enrolled to date are tabulated in table 1.

2.4. Quantitative component of the study

2.4.1. Quantitative data collection tools

2.4.1.1. Questionnaire. The self-administered questionnaire (table 2) developed collected information on demographics, medical history, occupational history, and radiation workload exposure and radiation safety practices and training. The questionnaire was developed based on literature and existing questionnaires. An expert panel of radiologists, cardiologists (adult and paediatric), a medical physicist, an ophthalmologist, an occupational medicine specialist and a public health medicine specialist assisted with the development of the questionnaire. Experts assisted with developing the section relevant to their discipline. The questionnaire was reviewed several times by this expert panel and once finalised it was piloted and a final version was developed based on the pilot study. The expert panel approved the final version. A biostatistician reviewed the final questionnaire to ensure all the necessary data would be collected in alignment with the aim of the study and an analysis plan was developed. The final questionnaire was developed in electronic survey format using Evasys® (www.evasys.co.uk) and in hard copy format.

2.4.1.2. Cataract grading and ophthalmological screening tool. There are several tools available for grading cataracts for this purpose and these include the World Health Organisation Simplified Cataract Grading System (WHOSCGS), the Lens Opacities Classification System, the Wisconsin Cataract Grading System (Wisconsin system) and the Oxford Clinical Cataract Classification System [17–19]. A challenge with various grading systems is that they have different cut off points making comparison difficult [19].

The bases of all these grading systems however is that they describe the anatomy of the cataract, the morphology of it, the colouration and the degree of opacification. The WHOSCGS was developed as a simplified classification system to allow for screening of cataracts by observers with minimal ophthalmological training making it user friendly with good user agreement [17]. The grading is comparable to the other systems as it collects similar information. The grading tool is available on open access, which influenced our decision to use this grading system. The WHOSCGS is also the standard grading system used in the Department of Ophthalmology at the University of the Free State (UFS) and the ophthalmic examiner was au fait with it [17].

Table 2. Information collected in self-administered questionnaire.

Demographics
Sex Age and date of birth City working in
Medical history
Weight Height Chronic diseases: diabetes, hypertension, cancer, myopia, glaucoma, congenital cataracts, obesity, rheumatoid arthritis, autoimmune diseases Eye conditions: cataracts, previous surgery, previous trauma, chronic infections Ionising radiation exposure: CT brain, radiotherapy Non-ionising radiation exposure: outdoor activities, hobbies, use of dark glasses Drug history: oral contraception, steroids Smoking history Alcohol usage
Occupational history
Capacity worked in Location worked and duration worked Fluoroscopic work? Biplane work? Right or left handed? Vascular access?
Radiation workload
List of procedures, the mean number of procedures per week, the duration of the procedures, the average number of cine runs and frames per procedure?
Radiation safety
Use of PPE: suspended screen, lead apron, thyroid shield, and lead glasses/goggles? Barriers to utilisation of PPE: availability of PPE, years utilised, fit of PPE, ease of utilisation? Personal radiation dosimetry: utilisation, dosimetry readings, and knowledge of radiation limits? Radiation safety training: trained in radiation safety as a doctor, trained in the use of x-ray equipment, and trained how to protect self and patients from radiation exposure?

The ophthalmological screening tool (table 3) is routinely used in the Department of Ophthalmology at the UFS. This tool collected information on external examination of the eye, the pupil colour, tear break up time, visual acuity, examination of the lens of the eye and the macular. The anatomical position (cortical, nuclear and posterior subcapsular) of all opacities was recorded.

2.4.2. Quantitative data collection. The scientific meetings where data were collected included an interventional radiology workshop, a paediatric cardiology interventional workshop, and the annual radiology and cardiology societies of South Africa conferences. The organisers of the conferences and workshops were approached beforehand to obtain permission to conduct research at these scientific meetings. We requested that a hyperlink to

Table 3. Ophthalmological screening tool.

Name		
Date of birth		
Medical history	*Y/N*	*Treatment*
Diabetes		
Hypertension		
Tuberculosis		
Epilepsy		
Asthma		
Other		
Allergies		
Left eye	*Examination*	*Right eye*
	Visual acuity:	
	Without glasses	
	With glasses	
	Lids and tarsus	
	Conjunctiva	
	Pupil	
	Cornea	
	Lens:	
	Anterior chamber	
	Posterior chamber	
	Vitreous	
	Disc	
	Disc: cup ratio	
	Macular	
	Vessels	
	Periphery	
	Muscle movements	
	Tear break up time	
	Pressure	

our online questionnaire be sent to prospective conference and workshop delegates. A letter explaining the study was sent with the hyperlink. Reminders were sent prior to the upcoming scientific meetings. At the scientific meetings the delegates were invited to voluntarily complete the questionnaire online or the hard copy version.

An incentive was provided at the scientific meetings to increase participation in the study. All participants at these meetings were included into a lucky draw for a pair of lead glasses. Appropriate banners were placed at the scientific meetings to increase awareness of the study. An informed research assistant was tasked to lobby delegates to participate in the study.

The screening was done by a senior ophthalmology resident trained by the head of department of the Department of Ophthalmology (UFS). All the screening was done by the same clinician/examiner using the same slit lamp. This improved reliability and repeatability of the findings. All delegates were invited to have a free ophthalmological slit lamp examination to screen for cataracts. They were explained that the examination comprises dilatation of their pupils that could cause minor discomfort and that their pupils could remain dilated for up to 2–3 h. A short acting mydriatic drug was used. Participants were asked about drug allergies prior to administration of the mydriatic medication. Ten minutes after the participants' pupils were dilated they had the ophthalmological examination. Participants were advised to avoid direct sunlight and not to drive for at least 2–3 h post dilatation. The eye findings were linked to the questionnaire completed.

2.4.3. Quantitative sampling strategy. Targeted convenience sampling was used for the quantitative component.

2.4.4. Quantitative data analysis. The data were analysed descriptively and analytically using STATA® 14 (http://stata.com). The demographic data were described. The exposed and unexposed groups were compared. We estimated the odds ratios for various risks between the exposed and unexposed groups. We controlled for age and confounders such as diabetes, myopia, and penetrating trauma to the eye, steroid use and radiation exposure.

We estimated the work related radiation workload using information reported by the participants in the questionnaire and scatter radiation dose estimates. The scatter radiation dose estimates were based on work done by Vano [20]. We estimated the workload adapting the methodology used by Ciraj-Bjelact [11]. We estimated workload exposure (WL) per procedure using the following function:

$$\mathrm{WL(procedure)} = (Y \times P \times D) \times M,$$

where

Y is the number of years a procedure was done, P is the number of that procedure/year, D is the dose/procedure and M is the protection modification factor.

The dose per procedure was based on work previously done in South Africa. We used dose reference levels and dose area products estimated in these studies [21, 22]. The modification factor (M) was calculated taking into consideration the use of the ceiling suspended screen and the protective eyewear and radial access and angulation. A protection modification factor of 0.1 for the use of screens and protective eyewear and 2.0 for radial access were applied [23]. We applied a correction factor of 1.8 for angulation [11, 23]. The total workload estimates were the sum of the workloads of all the different procedures over time.

There are many factors that influence workload radiation exposure and affect the estimates [23]. We recognise that we cannot control for all of these factors, but believe that this estimation will provide us with a good estimate of the relative workloads, which we assume to be approximately proportional to the radiation exposure to the eye.

In the nested case control analysis we frequency matched for age and sex to increase precision of the estimates.

2.5. Qualitative component of the study

2.5.1. Qualitative data collection tools. An interview schedule (table 4) was developed to ensure the researcher collected thick data. The interview schedule was designed to ensure uniformity of the questions asked. The schedule was discussed with several qualitative researchers and suggestions were incorporated and the adaptations included accordingly.

2.5.2. Qualitative data collection. Qualitative research allows the researcher to explore the depth of a subject and to hear the unique voice of the targeted participants [24]. The participants for the qualitative data collection could also be included as participants for the quantitative component.

Table 4. Interview schedule.

1. How do you think radiation exposure can affect your health? How can it affect your eyes?
2. What do you understand by having a 'culture of radiation safety' in the workplace? Is there such a culture in your workplace? (Probe)
3. Whose responsibility is radiation safety in the workplace?
4. How do you protect yourself from the effects of radiation in your workplace? What personal protective equipment (PPE) do you use? Is this PPE readily available? (Probe) Do you always use the prescribed PPE? (Probe)
5. How do you think radiation safety training can be improved for interventionalists?
6. Is there anything else about radiation safety that we have not covered that you would like to add?

The researcher conducted 6 group interviews and 30 in-depth individual interviews. An interview schedule (table 4) was used to guide the discussions. The researcher has experience with qualitative research and conducted the interviews. Data collection was continued until data saturation was reached. We decided that we had reached data saturation when we started getting recurring responses and were finding that no new information was emerging. The interviews were audio recorded and transcribed verbatim. All interviews were conducted only in English, which is the *lingua franca* for the medical fraternity in South Africa.

2.5.3. Qualitative sampling strategy. The researchers aimed to understand how the participants perceived radiation safety in the workplace and the stakeholders responsible for this safety [25]. Purposive sampling (snowball) was used to recruit participants and key informants were contacted directly [26, 27].

2.5.4. Qualitative data analysis. Data were analysed as we received it. We used Braun and Clarke's steps in the analysis process [28, 29]. The researchers independently read the transcripts and coded the data. The codes were organised into categories and the categories grouped into themes. We used a deductive and inductive approach. We discussed the interpretations that emerged. We debated the themes and then reached consensus on the findings, which will be presented elsewhere. The qualitative software package MAXQDA® 12 (http://maxqda.com) was used to analyse the qualitative data.

3. Ethical considerations

The study was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the UFS (ECUFS 44/2015). (The certificate is obtainable from ethicsFHS@ufs.ac.za.) Written informed consent was obtained from participants for the qualitative and quantitative components. Informed consent was assumed when participants agreed to proceed with the online questionnaire.

4. Strengths and limitations of this study

This is the first study of its type in South Africa. Similar studies have been done elsewhere in the world [30, 31]. We believe we will make a contribution to the epidemiology of occupational radiation-associated cataracts in the African context. Low participation may however introduce uncertainty and bias [32]. Participation was voluntary in the exposed and unexposed groups, which may have introduced selection bias. The self-administered questionnaire may have introduced bias. The ophthalmic examiner was aware of the exposure status of the participants because the delegates at the conferences came for the specified conference e.g. a cardiologist at the cardiology conference. The workload exposure will be estimated and will not be a direct dose measurement.

5. Discussion

This study was conducted in South Africa, which has a different occupational context to other settings where similar studies were completed. Several similar studies looking at radiation induced occupational cataracts were done in the USA, Europe and South America [31]. The social context of these countries and the ethos that underpins their health sectors are often more homogeneous compared to South Africa which has a two-tiered public and private sector. The equity divide between the public and private health care sectors in South Africa is tremendous [33].

The private sector is well developed while the public health sector is ailing. The private healthcare sector is comparable to any developed country, and characterised by profit driven costs. High patient loads, shortages of medical equipment and poor human resource establishments, burden a failing public health system in South Africa. It is not uncommon that South African doctors work in both systems [33, 34]. The working hours in the public sector are long due to low staff complements while the private sector is market driven. The movement of skilled healthcare professionals from the public to private sectors exacerbates the inequity within the health system.

Radiation safety practices differ between South Africa and other settings, which may affect the prevalence of occupational radiation associated cataracts. In South Africa, especially the public sector where the technology may not be as advanced, there may be a resultant increased workload exposure. This study may help us understand the workloads, doses, and safety practices in the private and public sectors.

Interventionalists' training is long and intensive. In an article on cardiology training in South Africa, Sliwa *et al* (2016) deliberated that there has been an increase in the burden of cardiac diseases in South Africa without a reciprocal increase in trained cardiologists [35]. This contributes to perpetuating the shortage of highly skilled doctors such as interventionalists, which strengthens the need to ensure a safe work environment. This study will assist us to understand the prevalence of radiation-associated cataracts and radiation safety practices in South Africa. This will assist with developing recommendations for improving this workplace environment in South Africa.

6. Conclusion

The occurrence of radiation-associated cataracts and the radiation safety practices among South African interventionalists are poorly understood. To make sense of the complexity of these issues it was necessary to take an interdisciplinary approach. The skills and knowledge of several disciplines are crucial to define the problem and propose plausible solutions for it. We believe that this study offers a novel way of combining the paradigm of several disciplines and a blend of methodologies to address the research problem and offers solutions relevant to the research environment in which the study was conducted.

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Authors' contribution

WR and AR conceptualized the study. AR wrote the protocol with input from WR. PC and WM provided technical input for the study protocol. AR wrote the first draft of this paper. All authors gave input to the article. All authors read and approved the final manuscript. We thank Margaret Ann Sweetlove for assisting with the workload exposure calculation.

Conflict of interest

All authors declare that there are no conflicts of interest.

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CHAPTER 3

CATARACT AND OTHER OPHTHALMOLOGICAL FINDINGS IN INTERVENTIONALISTS

"But, I nearly forgot, you must close your eyes otherwise you won't see anything"
(Alice in Wonderland, Lewis Carroll)

3.1 INTRODUCTION

I can vividly visualise the day I first read the classic novel Alice in Wonderland. I must have been around 12 years old. It was a warm winter's day in the June school holidays. I was sitting on the low boundary wall of our neighbour eating oranges under the warm Northern Cape sun and desperately trying to avoid getting squirts of orange juice over the library book. Years later I think about the interventionalists in this study and reflect that unless they open their eyes and change their radiation safety practices to ensure that their eyes are protected they run the risk of closing them. And while cataracts are largely curable through surgery it is an unnecessary burden that affects the work productivity and impacts on the health system.

In this chapter, the researcher will present the cataract findings in interventionalists. The findings are presented as a manuscript in publishable format which was submitted for publication at the time of writing this thesis. One of the primary aims of this study was to determine the prevalence of cataracts in South African interventionalists occupationally exposed to ionising radiation (IR). This group of occupationally exposed interventionalists are compared to a group of doctors that are not routinely occupationally exposed to ionising radiation. The findings reflect that the interventionalists are at greater risk than the unexposed doctors and this warrants them taking precautions to reduce their risk of cataracts.

This chapter also presents the ophthalmological findings other than cataracts. This data was collected as part of the larger study project but formed part of a Masters in Medicine (Ophthalmology) project and the findings are presented as a manuscript which was submitted for publication at the time of writing the thesis (cf. Appendix B).

3.2 BACKGROUND

Interventionalists are doctors that use ionising radiation to perform fluoroscopic procedures for diagnostic and therapeutic reasons. They include interventional radiologists, interventional adult and paediatric cardiologists, urologists, anaesthetists and orthopaedic and vascular surgeons. This study confined itself to interventional radiologists and adult and paediatric cardiologists because they utilise techniques that expose patients to some of the highest doses in diagnostic radiology.

The eyes are highly radiosensitive organs and are at risk of a plethora of pathologies consequent to ionising radiation (IR) exposure (Donnenfeld *et al*. 1993). The effects of IR on the eyes include skin erythema, mydriasis, punctual occlusion, corneal epithelia damage, dry eye disease, cataracts and retinopathy (Donnenfeld *et al*. 1993; Zamber & Kinyoun 1992).

Cataracts associated with ionising radiation exposure commonly occur in the posterior sub-capsular region, but have been reported to occur in the cortical region as well (Stahl *et al*. 2016). In some studies, the prevalence is reported to be between 17-54% in interventionalists occupationally exposed to IR (Jacob *et al*. 2013; Seals *et al*. 2016). In contrast, there are reports showing a much lower prevalence (Auvinen *et al*. 2015; Thrapsanioti *et al*. 2017).

Dry eye disease (DED) is a debilitating condition due to lacrimal gland dysfunction resulting in reduced tear production and interrupts the tear film function of the eye (Craig *et al*. 2017). IR may disrupt lacrimal gland function and thus attenuate the prevalence of DED in interventionalists. It has important ramifications on the quality of life of those it affects

(Uchino & Schaumberg 2014). It thus has important public health consequences warranting protection of the radiation healthcare worker in the workplace.

3.3 KEY FINDINGS

There were 356 initial participants in the study. The table below describes how the final number of participants were derived (cf. Table 3.1).

Table 3.1 Final number of participants

	TOTAL SCREENED	EXCLUDED FROM ANALYSIS	INCLUDED IN ANALYSIS
Radiologists	53	28	25
Adult cardiologists	45	3	42
Paediatric cardiologists	41	10	31
Unexposed	194	49	145
Failed to meet inclusion criteria	23	23	
Total	**356**	**113**	**243**

The following were the key findings:

- The average age of the entire cohort was 46.4 years (SD±11.7); of the exposed participants was 45.7 years (SD±10.0) and of the unexposed was 46.8 years (SD±12.8); p=0.769.
- Males were more than females in all categories.
- The average number of years worked was 15.9 (SD±11.8) overall and 12.9 (SD±9.6) in the exposed and 17.9 (SD±12.7) in the unexposed group; p=0.004.
- The risk factors for cataracts were similar in the exposed and unexposed categories.
- There was no statistical difference between the groups meaning that they were comparable to each other.
- There were 5 (5.9%) posterior sub-capsular cataracts in the exposed group and 4 (2.8%) in the unexposed group.

- The number of cataracts (posterior sub-capsular and cortical) in the exposed group was 16 (18.8%) and in the unexposed group it was 20 (14.0%).
- The number of nuclear cataracts in the exposed group was 21 (24.7%) and in the unexposed group was 48 (32.9%).
- Interventionalists were 2.2 times more likely (OR 2.2; 95% CI [0.578-8.611]; p=0.244) to develop posterior sub-capsular cataracts.
- The tear breakup time (TBUT) was used as an indication of dry eye disease. The TBUT was reduced in approximately 46.3% of the exposed group.

3.4 REFLECTIONS AND CONCLUSION

The prevalence of cataracts in the exposed group potentially due to ionising radiation exposure was 18.8% and in the unexposed group it was 13.9%. Cataracts was estimated to be responsible for 34% (29-39.8%) of blindness and 24.2% (19.3-29.6%) of moderate to severe blindness in southern Africa between 1990-2010 (Naidoo *et al*. 2014). The weighted prevalence of self-reported cataracts in South Africa in people > 50 years was 4.4%, which was lower than reported in other low to middle income countries (Phaswana-mafuya *et al*. 2017). This may, however, be an underestimate because participants were from a poor socioeconomic background and may have had access to poorer health services (Phaswana-mafuya *et al*. 2017). Despite these limitations though the prevalence of cataracts due to radiation exposure remains high in our cohort.

There was not a statistical difference between the exposed and unexposed groups, but posterior sub-capsular cataracts were a factor of 2.2 more likely in the exposed cohort and this is clinically significant. Cataract is the world's leading cause of blindness and visual impairment. These sequelae have important long-term ramifications as they can affect occupational performance, days lost from work, they could impact on quality of care and they thus can add to the burden of the health system.

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RADIATION INDUCED CATARACTS IN SOUTH AFRICAN INTERVENTIONALISTS OCCUPATIONALLY EXPOSED TO IONISING RADIATION

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1. INTRODUCTION

Ionising radiation (IR) is integral and essential in modern medical diagnostic, prognostic and interventional procedures. [1] The number of procedures has dramatically increased globally over the past few decades. [1] The technology has improved and lower radiation doses are delivered to patients. Interventionalists are however performing more complex procedures which take longer and they are thus occupationally exposure to IR for longer and their eyes are at particular risk of developing cataracts in the long term. [2] Interventional clinicians such as interventional radiologists and interventional cardiologists are radiation healthcare workers (HCWs) most at risk for radiation exposure in the catheterisation laboratory. [3] Cardiac catheterisation procedures expose operators to radiation doses 2-3 orders of magnitude greater when compared to other interventional procedures. [4] Interventional radiologists receive similar radiation doses as interventional cardiologists in the catheterisation laboratory. [2]

The effects of IR on interventionalists include stochastic effects such as cancer, and genetic aberrations. [5] The stochastic effects include radiation induced cataracts. [6] It was previously thought that the relationship between ionising radiation exposure and cataractogenesis was deterministic, but increasingly there is uncertainty about a threshold level and evidence is mounting that the effects may be evident even at low doses. [7–9] There are also pending answers about the additive effect of low dose radiation on other cataract risk factors. [8] Doses to the lens of the eye tends to be considerably higher than dose to the whole body and hence the greatest concern is cataracts. Low dose exposure to ionising radiation places radiation health care workers (HCWs) at increased risk of developing cataracts if they are not adequately protected. [10] The lenses of the eyes are highly radiosensitive and there is a strong correlation between occupational radiation exposure and cataracts. [9]

Cataracts related to occupational radiation exposure are frequently reported to occur in the posterior sub-capsular (PSC) region of the lens of the eye but recent data suggests that it may also occur in the cortical region. [11] Radiation induced cataracts also occur more commonly in the left eye compared to the right eye, related to the position in which the interventional cardiologist is working with respect to the beam. [11] In a French study, it was shown that cardiologists had a prevalence of PSC cataracts of 17% (N= 109; CI:10-24%; odds ratio of 3.8 (1.3-11.4)). [12] In another study the prevalence of PSC cataracts was reported as 54% (N=56; CI: 35-73; relative risk of 5.7 (CI: 1.5-22)). [13] In contrast, separate Greek and Finnish studies showed there was no statistically significant difference between cataract findings in interventionalists occupational exposed to IR and a group of doctors not occupationally exposed to IR. [14,15] It is however difficult to compare studies on the prevalence of occupational radiation induced cataracts to each other because these studies used different grading systems, different assessments of risk factors and there are concerns about dosimetry because of dose uncertainties. [7] These discrepancies therefore do not negate the clinical significance of these studies and the importance of protecting the eyes of doctors (and other radiation HCWs) in this occupational setting.

This is particularly important given the mounting evidence of the detrimental biological effects of low dose radiation to the eyes, which has resulted in the International Commission on Radiological Protection (ICRP) revising its exposure limit recommendations: from 150mSv per year to 20mSv per year, averaged over five years, with no one year exceeding 50mSv. This has potentially major implications for resource constrained environments such as South Africa. In such settings the implementation, control and monitoring of regulatory structures would be a challenge making it difficult to comply with ICRP recommendations to reduce the dose as mentioned above. [16]

South Africa has a paucity of highly trained doctors such as interventionalists which is compounded by an escalating burden of disease that requires these skills for its management. [17] It is thus important that this human resource is protected and that safety in the workplace is optimised. This can be achieved through several initiatives such as measuring and monitoring ionising radiation exposure in the workplace, enforcing personal dosimetry utilisation and feedback, promoting informed decision making when using imaging in clinical practice, appropriate use of imaging equipment, encouraging consistent and appropriate use of personal protective equipment, formalised training and continued medical education on radiation safety and engaging hospital management structures to support all aspects of promoting radiation safety in the workplace. [18–20] Underpinning these initiatives is the creation of a culture of radiation protection (CRP). [21] This CRP is the cornerstone of the norms, values and standards within an organisation. [22]

The aim of the study was to determine the prevalence of occupational related cataracts and the risk profile of interventionalists compared to an occupationally unexposed group of doctors in South Africa.

2. METHODS

2.1 Study design

This was a prospective cross sectional study which formed part of a larger multiple methods study which is described elsewhere. [23]

2.2 *Study population*

Our initial sample included 356 participants of which 139 were occupationally exposed to ionising radiation. This included 53 radiologists, 45 adult cardiologists, 41 paediatric cardiologists, 194 doctors not exposed to IR and 23 participants who were not doctors. We excluded 28 radiologists, 3 adult cardiologists, 10 paediatric cardiologists, 49 doctors who were not occupationally exposed to IR and the 23 participants who were not doctors. The final cohort thus included 25 radiologists, 42 adult cardiologists, 31 paediatric cardiologists and 145 doctors not occupationally exposed to IR. The exposed participants were from all the major centres in South Africa where interventional procedures are done.

2.3 *Data collection*

Data collection was done between May 2015 and March 2017. Data were collected at conferences and workshops across South Africa. The survey was conducted using a paper based system as well as an electronic format. The questionnaire collected demographic data, medical risk factors, non-occupational exposure, occupational workload, personal protective equipment utilisation, dosimetry practice and radiation safety training. [23]

2.4 *Ophthalmological examination*

All participants had a bio-microscopy slit lamp examination by the same trained ophthalmologist using the same slit lamp. The clinician was not blinded to the participants because we screened at specific conferences such as radiology or cardiology conferences. Their eyes were dilated and a bio-microscopy slit lamp examination was conducted. [23] Cataracts were classified according to the World Health Organisation Simplified Cataracts Grading Score (WHOSCGS). [24] The cataracts were graded as cortical, nuclear or posterior sub-capsular (PSC). [24] Visual acuity was measured using a modified Snellen Chart.

2.5 Workload estimation

Workload was calculated from self-administered questionnaires completed by interventionalists (total 95) who indicated type of procedure, the number of procedures per week and the number of years worked with fluoroscopy guided interventional procedures. Average Dose Area Product (DAP) values per procedure were obtained from previous work done in SA. [25,26] As DAP reflects not only the dose within the radiation field, but also the area of tissue irradiated it is a better indication of scattered radiation which is the source of radiation to the eye. Three categories of modifiers were considered: (1) a reducing modifier accounting for attenuation afforded by the use of ceiling suspended screens and the frequency of use of these screens; (2) a similar modifier for the use of lead glasses and the frequency of use of these glasses; and (3) an escalating modifier for radial (as opposed to femoral) approach and its frequency of use. The maximum modifying factors were taken from published data. [3]

2.6 Statistical Analysis

Statistical analyses were performed using R software version 9.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria, URL http://www.R-project.org.).

The comparison of demographics between the participants occupationally exposed to ionising radiation and those not occupationally exposed was conducted using the Mann-Whitney U-test and Chi-squared test according to the nature of the covariates (continuous and categorical respectively).

Ordinary logistic regression, adjusted on age, was conducted to analyse and compare the cataracts in the left and/or right eyes in the two population groups. In order to identify the risk factors associated to Cortical and PSC cataracts using the left and right eye scoring within each participant, a mixed effect logistic regression was performed generating odds ratios and 95% confidence intervals (R-package lme4).

3. ETHICAL CONSIDERATIONS

The study was approved by the Health Sciences Ethics Committee of the University of the Free State (ECUFS44/2015). The ethics certificate is obtainable from the Ethics Committee (ethics@ufs.ac.za). All participants consented to completing the survey and to having a bio-microscopy slit lamp examination.

4. RESULTS

Table 1 represents the basic demographic data and the risks factors for cataracts of the participants. There were 243 participants in total and 98 were routinely occupationally exposed to IR. We included only participants who both completed the survey and had the bio-microscopy slit lamp examination. The exposed interventionalists included 25 radiologists, 42 adult cardiologists and 31 paediatric cardiologists.

There was no statistical difference between the exposed and unexposed groups (except for hypertension) which meant that the two groups were comparable in all respects including age, sex and risk factors. In the analysis, years worked for the exposed group refers to how many years they worked performing fluoroscopy procedures and thus is a measure of their duration of occupational exposure to IR. Years worked in the unexposed group refers to how long they have worked as doctors.

The use of PPE is not present in the article and will be reported elsewhere. However, we do want to report that 11 (10.2%) of participants reported using lead glasses consistently and 66 (61.1%) reported never using lead glasses.

Table 1 Demographics and risk factors with percentages for categorical variables and mean ±SE (standard error) for continuous variables. p-values are for comparison of exposed and unexposed groups

	ALL PARTICIPANTS	EXPOSED	UNEXPOSED	P-VALUE
Covariate	N=243	n=98	n=145	
Age	46.4 (±11.7)	45.7 (±10.0)	46.8 (±12.8)	0.769
Sex				
Male	160 (65.8)	68 (69.4)	92 (63.4)	0.338
Female	83 (34.2)	30 (30.6)	53 (36.6)	
Years worked	15.9 (±11.8)	12.9 (±9.6)	17.9 (±12.7)	0.004
Risk Factors				
Smokers	16 (6.6)	7 (7.1)	9 (6.2)	0.773
Years smoking	1.21 (±5.3)	1.23 (±4.8)	1.2 (±5.6)	0.780
Uses alcohol	132 (54.3)	60 (61.2)	72 (49.7)	0.076
Years using alcohol	12.2 (±14.6)	14.5 (±15.3)	10.6 (±13.8)	0.036
Myopia	39 (16.0)	17 (17.3)	22 (15.2)	0.651
Hypertension	29 (11.9)	3 (3.1)	26 (17.9)	**0.000**
Diabetes	11 (4.5)	2 (2.0)	9 (6.2)	0.125
Obesity	14 (5.8)	3 (3.1)	11 (7.6)	0.138
Steroid use	1 (0.4)	0	1 (0.7)	0.410

Table 2 showed there was no risk factors that were statistically significantly associated with any risk factor for cortical or PSC cataracts.

Table 2 The univariate analysis for cortical and Psc cataracts risk factors

	CORTICAL		PSC	
COVARIATE	OR [CI]	P-VALUE	OR [CI]	P-VALUE
Sex	1.4 [0.87; 2.33]	0.151	0.3 [0.04; 2.15]	0.224
Year worked	1.0 [0.98; 1.02]	0.964	1.0 [0.96; 1.04]	0.970
Smoking	0.7 [0.35; 1.50]	0.378	0.4 [0.14; 1.07]	0.061
Alcohol	1.0 [0.62; 1.55]	0.931	1.3 [0.49; 3.28]	0.615
Myopia	1.3 [0.78; 2.20]	0.308	0.6 [0.12; 2.77]	0.479
Hypertension*	1.1 [0.61; 1.85]	0.820	-	-
Diabetes	2.1 [1.00; 4.21]	0.044	1.3 [0.25; 6.31]	0.783
Obesity‡	1.6 [0.70; 3.49]	0.270	-	-

* There were no participants who had PSC and had hypertension and therefore a univariate analysis could not be run.

‡ There were not sufficient observations to run the model and the analysis predicted perfect failure for PSC.

In Table 3 the combined prevalence of PSC and cortical cataracts was 18.8% in the exposed and 13.9% in the unexposed group. The prevalence of PSC cataracts in the exposed group was 5.9% and 2.8% in the unexposed group, giving an OR of 2.2 [95%CI 0.58; 8.61]. Although the difference between the exposed and unexposed groups for PSC was not statistically significant, it was based on very small numbers of cases and the increase was restricted to the left (and most exposed) eye. The 2.2 fold increase in the exposed group may therefore be of clinical significance.

Table 3 Description of cataracts after exclusion of participants less than 35 years and less than 5 years' experience

	All participants	Exposed group	Unexposed group		
	N=229	N=85	N=144		
Posterior sub capsular	**n (%)**	**n (%)**	**n (%)**	**OR* [CI]**	**p-value**
PSC uni or bilateral	9 (3.9)	5 (5.9)	4 (2.8)	2.2 [0.578; 8.611]	0.244
PSC left eye	9 (3.9)	5 (5.9)	4 (2.8)	2.2 [0.578; 8.611]	0.244
PSC right eye	3 (1.3)	1 (1.1)	2 (1.4)	1.3 [0.101; 16,988]	0.836
PSC bilateral	3 (1.3)	1 (1.1)	2 (1.4)	1.3 [0.101; 16.988]	0.836
Cortical					
Cortical uni or bilateral	27 (11.8)	11 (12.9)	16 (11.1)	1.4 [0.590; 3.408]	0.435
Cortical left eye	26 (11,4)	11 (12.9)	15 (10.4)	1.6 [0.653; 3.975]	0.300
Cortical right eye	21 (9.2)	7 (8.2)	14 (9.7)	1.1 [0.379; 2,963]	0.911
Cortical bilateral	20 (8.7)	7 (8.2)	13 (9.0)	1.3 [0.432; 3.647]	0.676
Nuclear					
Nuclear uni or bilateral	69 (30.1)	21 (24.7)	48 (33.3)	0.6 [0.330; 1,260]	0.200
Nuclear left eye	63 (27.5)	17 (20.0)	46 (31.9)	0.5 [0.252; 1.035]	0.062
Nuclear right eye	65 (28.4)	20 (23.5)	45 (31.3)	0.7 [0.346; 1.337]	0.263
Nuclear bilateral	59 (25.8)	16 (18.8)	43 (29.9)	0.5 [0.262; 1.094]	0.087

* OR, odds ratio adjusted on age

In Table 4 we would have expected a pattern showing an increase in risk with age and occupational exposure to ionising radiation. Even if significant risk of PSC and Cortical cataracts was found among the exposed practitioners with career duration less than 5 years and between 11-20 years respectively, a global risk trend was not demonstrated. The correlation between years exposed to IR and cataract was not demonstrated. On the other hand, the age was confirmed as a major risk factor in both types of cataracts increasing the odds by 6-7% for each additional age year.

Table 4 PSC and Cortical cataracts according to career after excluding participants >35 years of age and < 5 years' experience

	Estimated parameter	SE	OR [CI]	p-value
PSC				
Unexposed (n=144)	1	-	1 [1; 1]	Ref
0-5 years (n=27)	1.56	0.74	4.77 [1.12; 20.42]	**0.04***
6-10 years (n=25)	0.55	0.99	1.73 [0.25; 12.10]	0.58
11-20 years (n=28)	1.08	0.78	2.95 [0.64; 13.66]	0.17
>20 years (n=17)	-3.8	0.92	0.69 [0.11; 4.17]	0.68
Age	0.06	0.03	1.06 [1.00; 1.12]	0.04
Cortical cataracts				
Unexposed (n=144)	1	-	1 [1; 1]	Ref
0-5 years (n=27)	0.90	0.54	2.46 [0.85; 7.16]	0.10
6-10 years (n=25)	-0.33	0.78	0.72 [0.16; 3.36]	0.68
11-20 years(n=28)	0.92	0.39	2.52 [1.18; 5.36]	**0.02***
>20 years (n=17)	-0.18	0.36	0.83 [0.41; 1.67]	0.61
Age	0.07	0.02	1.07 [1.04; 1.10]	0.00

Table 5 demonstrates the years worked with fluoroscopy and the lifetime workload exposure when lead suspended ceiling screens, lead glasses and radial access are considered.

Table 5 Estimated radiation workload exposure in Gy.cm^2

Years worked with fluoroscopy	
Median years	10
Interquartile range	5-20
Minimum	1
Maximum	42
Estimated lifetime radiation workload (Gy.cm$^{2)}$	
Modified for lead glasses & screens used	76 636
Interquartile range	35 033.6- 212 409.6
Minimum	336.3
Maximum	3 600 420
Modified for lead glasses & screens used & radial access	77 418
Interquartile range	35 033.6- 280 336.4
Minimum	336.3
Maximum	4 320 504

5. DISCUSSION

The exposed and unexposed groups were both doctors and thus comparable to each other occupationally and socio-economically. In previous studies the control groups were often support staff such as nurses. The comparability of the two groups was further reaffirmed when adjusting for confounders and it did not change the results (not shown?).

The bio-microscopy slit lamp examination was done by the same ophthalmologist. The advantage of using a single ophthalmologist is that it does not introduce inter-observer bias. The grading was done according to the WHOSCGS grading system. [24] This is a standardised system cataract grading system which is freely available. This however does make it difficult to compare the findings to studies that used a different scoring system.

There was no statistically significant difference between the prevalence of cortical and PSC cataracts in the interventionalists occupationally exposed to ionising radiation compared to the occupationally unexposed group although 2.2 and 1.4 fold increases were observed, based on small numbers of cases. This is in contrast to previous studies which showed a prevalence of between 3- to 5-fold increases compared to an unexposed group. [12,13,27] Our findings however corroborate that of two other studies that showed a lower prevalence of radiation associated cataracts compared to the preceding studies cited. [14,15] The combined cataracts for PSC and cortical was 18.8%. There is evidence to suggest that cortical cataracts may also be associated with radiation. [11] Although there was no statistical difference in the prevalence of PSC cataracts between the occupationally exposed group compared to the unexposed group, PSC cataracts were 2.2 times more likely than in the unexposed group (OR 2.2; CI [0.578; 8.611]; p-value = 0.244). This is clinically significant.

Our findings further, showed an increase in cataracts in the left eye compared to the right eye but this finding was consistent between the exposed and the unexposed groups. This finding is in contrast to current literature which reports that radiation induced cataracts are more common in the sub-capsular region in the left eye of interventionalists occupationally exposed to ionising radiation. [12]

South African interventionalists spend 2-3 days per week in the catheterisation laboratory and thus may have less accumulated occupational exposure to ionising radiation than interventionalists in other countries. We postulate that this may be a reason that the prevalence of PSC cataracts is less. Another possible reason would have been that the interventionalists were using consistently using lead glasses. However, our study should that only 10.2% of participants consistently lead glasses and therefore, there must be other factors that could explain the difference between our findings and studies which showed a higher prevalence.

We did not directly measure the radiation dose to the eye and this is a limitation of this study. Future studies should measure radiation dose to the eye in the South African context. The workload estimates calculated are limited by the many confounders that could affect the radiation workload estimate. The calculations however consider those main factors that could have influenced the workload dose estimates. The workload exposures were a life time dose exposure estimate which were extrapolated from a self-completed questionnaire and may have been affected by recall bias. We could not show a dose response relationship to the prevalence of cataracts.

The strength of this study is that it is the first to determine the prevalence of cataracts in interventionalists occupationally exposed to ionising radiation in a low resource African setting. Africa is rapidly acquiring advanced radiological technologies and it is crucial to protect the health workforce that will be operating these machines.

The findings do not negate previous findings of a higher prevalence of radiation induced cataracts. It however does support the need for greater vigilance in radiation protection measures for the eye and the need to develop a CRP in the catheterisation laboratory in order to prevent radiation damage to the eyes. A South African study showed an underdeveloped

CRP within the South African context especially among South African cardiologists. [21] The use of personal protective eyewear is imperative to protecting the eyes of interventionalists and should be part of a radiation safety culture. [28] Education and training is key to developing a CRP. [29] The training programme for interventionalists and especially cardiologists in South Africa requires urgent and decisive intervention to aid developing an entrenched CRP. [19,30]

6. CONCLUSION

Although there was no statistical difference between exposed and unexposed groups, possibly due to the relatively small numbers of subjects included in the study, posterior sub-capsular cataracts were more likely to occur in interventionalists occupationally exposed to ionising radiation. Radiation safety measures should be implemented, encouraged and enforced in interventionalists occupationally exposed to ionising radiation to mitigate for ionising radiation damage to the eyes. Although this study was conducted in South Africa the recommendations are transferable to other resource constrained settings in Africa.

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CHAPTER 4

PERSONAL PROTECTIVE EQUIPMENT AND DOSIMETRY

W

E A R

Y O U R

L E A D G

L A S S E S

(Adapted Snellen chart)

4.1 INTRODUCTION

Primum non nocere meaning "first do no harm" is a fundamental medical injunction engrained into doctors. We are sworn to protect our patients and not to intentionally harm them. This oath should, however, be inclusive of ourselves and our colleagues. Crucial to protecting the patient is ensuring that the doctor takes care of himself or herself. Radiation protection hinges on basic fundamental principles such as the use of personal protective equipment (PPE) and monitoring of radiation exposure.

In this chapter, the researcher will describe the types of PPE available; the use of different PPE in the catheterisation laboratory (cath. lab) by interventionalists; and their use of personal dosimeters. The PPE use is presented as a publishable manuscript which was submitted to the *Journal of Occupational Safety and Ergonomics (JOSE)* and was still under review at the time of writing this thesis. The dosimeter utilisation was presented at the *55th Annual Congress of the South African Association of Physicists in Medicine and Biology (SAAPMB)* and published as conference proceedings in the journal *Physica Medica* (Rose & Rae 2017).

4.2 BACKGROUND

The regulation of occupational hazards is governed by the occupational hierarchy of control as illustrated in Figure 4.1 below (National Institute for Occupational Safety and Health (NIOSH) 2016). This system employs a tiered approach to dealing with occupational hazards to reduce their potential risk to cause harm. The primary strategy in the control process is to eliminate a hazard and lastly to make use of PPE. The total elimination of ionising radiation (IR) is not possible in the cath. lab which strengthens the necessity to engage and enforce the use of PPE to mitigate the effects of IR on the health of all radiation workers in the cath. lab.

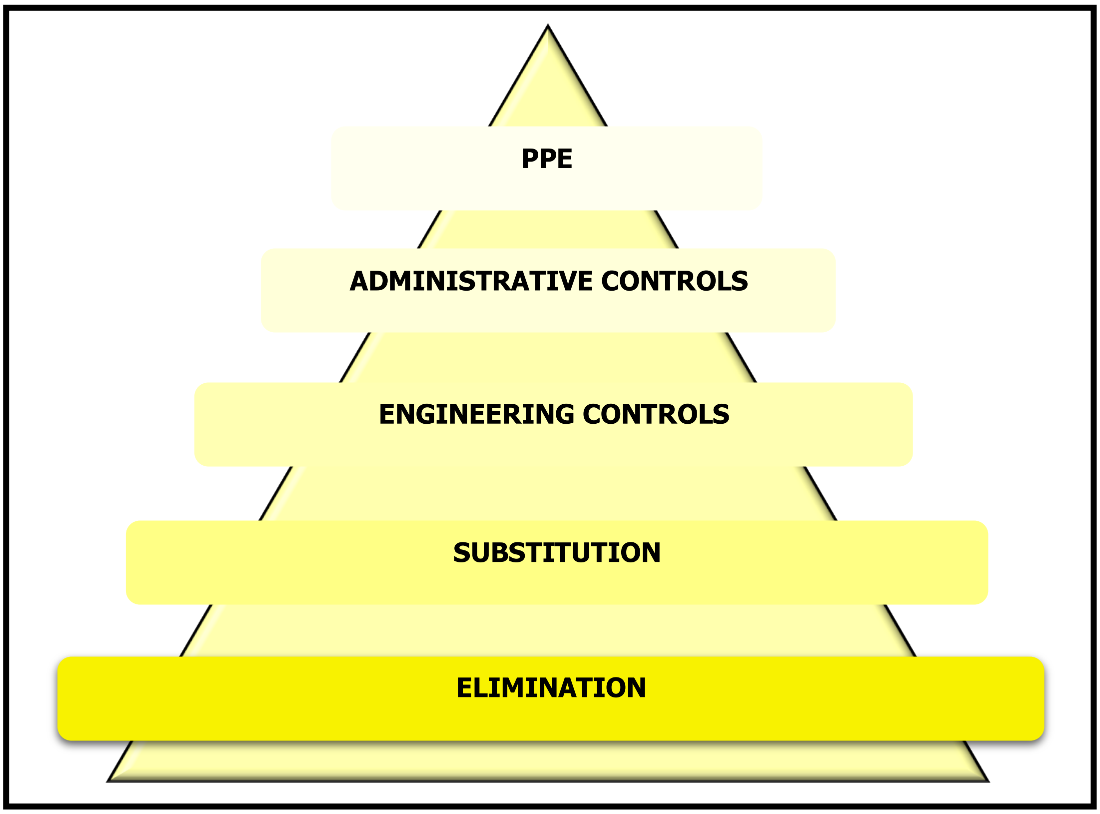

Figure 4.1 The occupational hierarchy of control

The most basic PPE available in the cath. lab includes the ceiling suspended screen, mobile screens, lead drapes, lead aprons, thyroid shields and lead glasses or visors (Chida *et al*. 2010). This is illustrated in Figure 4.2 below. Availability of PPE facilitates its utilisation (Snipes *et al*. 2015). The PPE should, however, also fit well and be comfortable and acceptable to the user (Honda & Iwata 2016). The dexterity with which interventionalists can perform procedures influences their compliance with consistently using the PPE (Badawy *et al*. 2016). Improvements in ergonomic design of PPE have resulted in lighter, better fitting PPE (Miller *et al*. 2010). These improvements have particularly benefitted women who have previously struggled finding PPE that is light weight and is designed for their particular body habitus (Cremen & McNulty 2014). The cost of the improved PPE, however, may still be costly which limits access to acquisition especially in the public sector. This requires concerted effort from health facility managers to balance already strained budgets to acquire appropriate PPE with ensuring workplace safety and thus patient safety (Bartal *et al*. 2016).

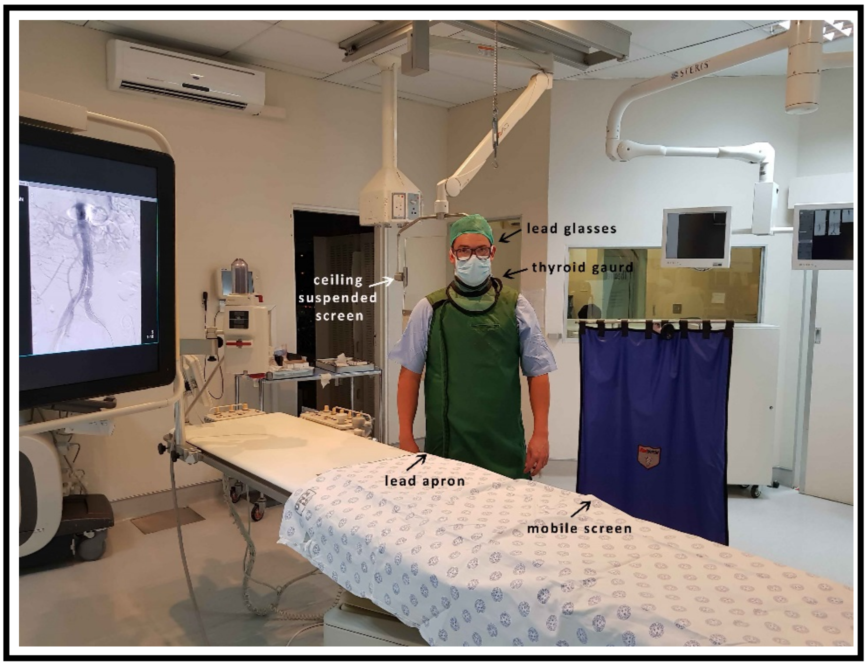

Figure 4.2 PPE in the catheterisation laboratory

The personal monitoring of radiation exposure is an important aspect of radiation control in the workplace. This monitoring can be passive or active. (Badawy *et al*. 2016) The challenge of passive monitoring is that radiation HCWs are often poorly compliant with wearing the dosimeters, but they also report that they do not receive timely feedback on their dose exposure. The delay in getting feedback makes it difficult for the interventionalist to recall which procedure may have resulted in increased exposure and thus opportunities to improve practice and reduce dose are missed (Aerts *et al*. 2014). Real time or active monitoring negates this shortfall and can improve clinical practice, reduce dose to the cath. lab staff and patient (Badawy *et al*. 2016).

4.3 KEY FINDINGS

In the quantitative component 108 interventionalists completed the survey. Participants who completed the survey but did not have the bio-microscopy ophthalmological screening were retained in the analysis. The findings showed:

- The majority of participants (68.5%) were male.
- The median age was 45.8 years (SD±9.9).
- There were 35 (32.4%) radiologists, 41 (38.0%) adult cardiologists and 32 (29.6%) paediatric cardiologists.
- The median number of years worked with ionising radiation was 10 (IQR 5-17).
- Lead aprons were consistently used 98.1% of the time.
- Lead glasses were only used consistently 10.2% of the time.
- Consistent use of the ceiling suspended screen, the lead apron, the thyroid shield and the lead glasses was 7.4%.
- Females were 4.3 times more likely to report that PPE was not available.
- Dosimeters were consistently worn by 58.3% of participants and 12.9% never wore a dosimeter.
- The majority of participants (95.4%) could not recall their dosimeter readings in the past year.
- Only **one** person knew the correct annual exposure limits.
- Availability and proper fitting PPE emerged as an important theme in the qualitative data.
- Hospital managers are critical stakeholders in facilitating availability of PPE in the cath. lab and in so doing ensuring that a safe work environment is created.

- Creating and nurturing a culture of radiation safety where PPE utilisation is a normative and prioritised component is essential to creating a culture of radiation protection (CRP).

4.4 REFLECTIONS AND CONCLUSION

The compliance of wearing PPE depends on the culture of radiation safety in the cath. lab., the availability of PPE and the comfort of using it and being able to perform interventional procedures with it. Likewise, consistent use of dosimeters feeds off the culture of radiation safety. Monitoring of radiation dose exposure is import for the interventionalists, their fellow cath. lab colleagues and importantly the patient. Creating a culture of safety depends on the education and training interventionalists receive and this will foster a CRP. In Chapter 3, the researcher demonstrated that ionising radiation associated cataracts are of occupational concern and in this chapter, the researcher illustrated that the protection mechanisms that should be in place to mitigate these effects are underutilised. In chapters 5 and 6, the researcher will show how we can disrupt this status quo and create a culture that fosters better radiation safety in the cath. lab.

4.5 REFERENCES: CHAPTER 4

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PERSONAL PROTECTIVE EQUIPMENT (PPE) AVAILABILITY AND UTILISATION AMONG INTERVENTIONALISTS

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ABSTRACT

OBJECTIVE

This study explored PPE availability and PPE utilisation among interventionalists in the catheterisation laboratory which is a highly contextualised workplace.

METHODS

A cross sectional study using mixed methods. Participants (108) completed a survey. A hyperlink was sent to participants or they were asked to complete a paper based survey. Purposively selected participants (54) were selected for individual (30) or group (6) interviews. The interviews were conducted at conferences or appointments were made to see the participants. Logistic regression was done. The qualitative data were analysed thematically.

RESULTS

Lead glasses were consistently used 10.2% and never used 61.1% of the time. All forms of PPE were inconsistently used by 92.6% of participants. Females were 4.3 times more likely to report that PPE was not available. PPE compliance was related to fit and availability.

CONCLUSIONS

PPE use was inconsistent and not always available. Improving PPE compliance protects patients and operators.

Keywords: PPE availability, PPE utilisation, gender parity in the workplace, quality of care

1. INTRODUCTION

Ionising radiation is increasingly being used for diagnostic, therapeutic and interventional procedures in medicine. The technology has advanced, resulting in equipment emitting lower radiation doses but procedures have however become more complex and longer in duration and this poses an increased occupational health risk to radiation healthcare workers (HCWs). [1,2] The increase in fluoroscopic procedures necessitates the implementation of a culture of radiation protection (CRP) to produce a safer workplace. [3]

The effects of radiation exposure may be stochastic or deterministic. These effects may include skin changes, carcinomas and cataracts. [4] Skin changes may include burns and hair loss. Radiation-induced occupational malignancies are of the most dreaded consequences of ionising radiation exposure. [5] This may be consequent of DNA damage or chromosomal aberrations. [5] The common malignancies include leukaemia, thyroid, breast and brain cancers. The crystalline lenses of the eyes are of the most radiosensitive tissues in the body. [6] Data suggests that cataractogenesis may be stochastic rather than deterministic in effect and that changes may occur even at very low radiation dose exposure. [7] The pathogenesis of radiation-induced cataracts may be due to oxidation processes or damage to proteins. [8]

A radiation protection programme (RPP) in the workplace is an important approach to mitigate for the effects of ionising radiation on health. Such a programme would include management structures, policies, operating procedures and organizational structures. [1] These organizational arrangements would include aspects such as the provision and maintenance of personal protective clothing, monitoring and evaluation of dosimeter readings and training and education. [1] A well formulated RPP will assist in establishing and sustaining a CRP. A CRP is a complex concept and is influenced by the core values, norms and attitudes of those working in the catheterisation laboratory (cath. lab). (9) The findings of a CRP in the South African context are extensively explored elsewhere. (S. Afr. J. Rad., ahead of print).

The use of PPE is an important mitigating factor for preventing the stochastic and deterministic health effects of ionising radiation. [10] Lighter and more robust PPE will offer better protection and increased compliance. [5] PPE includes ceiling suspended screens, thyroid guards, lead aprons and lead glasses. [11] PPE should be used properly and regularly for it to be beneficial. The consistent utilisation of PPE is underpinned by availability, fit, and dexterity when performing procedures. [12] In a survey conducted in the USA, urology residents reported lack of availability of PPE as a key reason for poor utilisation. [13]

Ceiling suspended shields can reduce scatter radiation to the head, neck and lens by 50-90% depending on the positioning of the screen but they are often not available in the catheterisation laboratory. [14] The screens may however hamper performing procedures with dexterity. [14] The screens are often used irregularly. [15] Thyroid guards and lead aprons are of the most consistently used PPE with up to 96% utilisation reported. [13] Lead aprons are often reported as heavy and cumbersome to work with. Appropriate sizes especially for smaller users and women are sometimes not readily available. In a study done in Irish hospitals, Cremen and McNulty (2014) found that there were not sufficient and appropriately sized lead aprons at the sites surveyed in their study. [16] Lead glasses if worn consistently and fits properly can reduce the dose to the eye by a factor of 3-5. [17] The use of lead glasses is affected by their availability, the weight, the fit and ease with which the interventionalists can perform a procedure. A common complaint is that the glasses steam up during procedures and are heavy. [17] Lead glasses are frequently used inconsistently. [13]

The aim of this article is to report on PPE utilisation practices and availability of PPE among South African interventionalists.

2. MATERIALS AND METHODS

This study forms part of a larger study the methods of which are described elsewhere. [18] We had a quantitative component where were conducted a survey and collected data on demographics of the participants, risk factors for cataracts, occupational exposure to ionising radiation, use and availability of PPE and training in radiation safety. This article only presents the data on their use and availability of PPE. The participants who completed the survey were also invited to have their eyes screened for cataracts. We also had a qualitative component were we conducted interviews and gathered data on the perceptions of interventionalist to radiation safety and PPE availability and use. This article only reports on PPE availability and use. The participants who participated in the survey were not necessarily the same participants in the interviews and vice versa but there were participants who participated in both parts of the study.

2.1 Study description

This was a cross sectional mixed methods study. The data were collected at seven national conferences across South Africa in different South African cities including Johannesburg, Cape Town and Bloemfontein. The participants were interventionalists (radiologists and adult and paediatric cardiologists). We included radiologists and cardiologists because there are differences in their training which may explain differences in their use of PPE. Interventionalists are defined as doctors who perform interventional procedures using fluoroscopy guided ionising radiation.

Data were collected using an electronic survey questionnaire, Evasys ® (www.evasys.co.uk) or a paper based questionnaire and 108 interventionalists participated and they were not randomly selected. Participants (54) were purposively selected for in-depth interviews (30) and group interviews (6) until data saturation was reached. The participants were selected to include a diversity of interventionalists representing doctors who had just started working with ionising radiation, mid-career professionals, senior professionals and heads of department across the three categories of interventionalists.

2.2 Study definition of PPE utilisation and fit and registrars

Consistent PPE utilisation was defined as PPE use more than 70% of the time in the last month. We calculated consistent PPE use of all four PPE used viz. using the ceiling suspended shield, the lead apron, the thyroid shield and the lead glasses all the time. Lead glasses were poorly used and we also looked at PPE if they were excluded. Fit of the PPE was a subjective recall of how the PPE generally fitted.

Registrars refer to doctors in the process of specializing and may also be known as residents.

2.3 Data analysis

The quantitative data were analysed descriptively and analytically. Associations between PPE utilisation and PPE availability were done. Regression models predicting for PPE utilisation and PPE availability were constructed.

We analysed the qualitative data using Braun and Clarke's steps. [19,20] The transcripts were transcribed verbatim. A thematic analysis was done. The data were coded and arranged into categories and then grouped into themes using a deductive and inductive approach. The researchers initially independently analysed the data and then debated themes and reached consensus on the final findings.

3. ETHICAL CONSIDERATIONS

The study was approved by the University of the Free State (ECUFS 44/2015). All participants provided written informed consent. Informed consent was implied when participants agreed to participate in the online questionnaire.

4. RESULTS

Quantitative findings

Table 1 Demographic characteristics of 108 interventionalists

Variable	
Gender n(%)	
Male	74 (68.5)
Female	34 (31.5)
Age (years)	
Mean (SD)	45.8 (9.9)
Range	30-69
Weight (kg)	
Mean (SD)	75 (13.8)
Range	45-110
Height (cm)	
Mean (SD)	172.5 (8.8)
Range	150-194
BMI	
Mean (SD)	25.1 (3.7)
Range	16.5-35.5
Occupational category n(%)	
Radiologists	35 (32.4)
Adult cardiologists	41 (38.0)
Pediatric cardiologists	32 (29.6)
Years worked with ionizing radiation	
Median	10
IQR	5-17
Range	1-40
Sector worked n(%)	
Public	47 (43.6)
Private	40 (37.0)
Both	21 (19.4)

Table 2 The use of different types of PPE amongst participants and reasons why they would not consistently use this PPE

	CEILING SUSPENDED SCREEN	LEAD APRON	THYROID SHIELD	LEAD GLASSES
Utilization of PPE				
	N=108 (%)	**N=108 (%)**	**N=108 (%)**	**N=108 (%)**
Uses PPE >70%	75 (69.4)	106 (98.1)	79 (73.1)	**11 (10.2)**
Never uses PPE	21 (19.4)	2 (1.9)	8 (7.4)	**66 (61.1)**
	n=46 (%)	**n=106 (%)**	**n=100 (%)**	**n=42 (%)**
Reported that the PPE fitted well	n/a	95 (89.6)	87 (87)	32 (76.2)
Years using PPE				
Median	5	10	9	3
IQR	3-10	5-19	4-15	2-6
Range	1-20	1-40	1-35	1 -30
Reasons why they would not consistently use PPE (multiple responses possible)				
	N=108 (%)	**N=108 (%)**	**N=108 (%)**	**N=108 (%)**
Not available	44 (40.7)	1 (0.9)	1 (0.9)	41 (38.0)
Difficulty performing procedures	16 (14.8)	0	4 (3.7)	16 (14.8)
PPE does not fit well	n/a	0	9 (8.3)	6 (5.6)

100 (92.6%) of participants (N=108) did not consistently use all PPE simultaneously. If use of lead glasses was excluded from assessing consistent use then 34 (31.5%) of the participants inconsistently used their PPE.

Table 3 Biavariate analysis for lack of PPE availability and PPE utilisation as the dependent variables

	N (%)	χ^2	OR (CI)	p-value
Lack of PPE availability				
Sex		13.2	5.4 (2.07; 13.8)	**<0.000**
Male	43 (41.9)			
Female	27 (79.4)			
Occupation		18.1		**<0.000**
Pediatric cardiologists	25 (78.1)	10.9	4.7 (1.79; 12.07)	**<0.001**
Radiologists and adult cardiologists	33 (43.4)			
Training received	20 (52.6)	0.03	1.1 (0.49; 2.36)	0.869
	t-test	**Mean difference**	**CI**	**p-value**
Height	2.8	4.67	1.39; 7.95	**0.006**
BMI	1.5	1.11	-0.31; 2.53	0.124
Ranked level of exposure	1.5	0.20	-0.61; 0.45	0.134
PPE utilization				
Age	2.6	5.72	0.85; 10.59	**0.05**
Height	-0.3	-1.05	-7.50; 5.41	0.749
BMI	-0.2	-0.22	-2.95; 2.50	0.871
Ranked level of exposure	-0.8	-0.21	-0.70; 0.29	0.410

Bi-variate analysis could not be done for PPE utilisation as the independent variable and sex, occupation, PPE availability and training in radiation safety as the dependent variable because in all cases there were expected cells with less than five counts and the assumptions were violated.

Table 4 Logistic regression models for PPE utilization and PPE availability as the dependent variables

MODEL 1: LOGISTIC REGRESSION: DEPENDENT VARIABLE PPE UTILIZATION				
Variable	**Adjusted OR**	**CI**	**p-value**	**Degrees of freedom**
Age	0.9	0.83; 1.01	0.068	1
Sex	1.6	0.21; 13.01	0.640	1
BMI	1.0	0.81; 1.25	0.940	1
Ranked exposure	1.7	0.47; 6.41	0.412	1
Occupation			0.948	2
Adult cardiologists	1.3	0.12; 14.84	0.808	1
Pediatric cardiologists	1.4	0.19; 9.77	0.757	1
PPE availability	2.2	0.37; 13.16	0.386	1
Training received	0.6	0.10; 3.91	0.606	1
Model 2: Logistic regression: Dependent variable PPE availability				
Sex	4.3	1.47; 12.82	**0.08**	1
PPE utilization	0.5	0.10; 3.13	0.430	1
Training received	0.9	0.31; 2.50	0.809	1
Occupation			**0.003**	2
Adult cardiologists	0.1	0.05; 0.45	**0.001**	1
Radiologists	0.3	0.08; 1.08	0.065	1

Model 1 did not significantly predict PPE utilisation, $\chi 2 = 6.1$ (p=0.642) and the model only predicted 13.3% of the variance in PPE utilisation.

Model 2 significantly predicted PPE availability, $\chi 2 = 27.3$ ($p < 0.000$) and the model predicted 29.9% of variance in PPE availability. In the post-hoc analysis sex and occupation were significant predictors of PPE utilisation. Females were 4.3 times more likely than males to report lack of PPE availability. Paediatric cardiologists were 6.8 times more likely to report lack PPE availability.

Qualitative findings

Participants reported greater readiness to use lead aprons and thyroid shields than for using lead glasses. PPE compliance was related to availability and fit. They were unlikely to use the PPE if it was cumbersome to wear, if it was difficult to perform procedures with or if it was not easily accessible. Women reported that they had challenges with getting PPE that fitted them well and was not too heavy. The participants reported that if hospital mangers ensured availability of PPE it would facilitate their utilisation of it.

5. LIMITATIONS

The qualitative component had a low statistical power because interventionalists were a hard to reach study population and challenging to recruit. The participants who completed the survey were not randomly selected and this may have introduced selection bias. There may also have been recall bias as PPE utilisation and PPE fit were self-reported. The participants selected for the qualitative component were purposively selected to include a diversity of interventionalists but the findings are not generalizable but may be transferable to similar settings.

6. DISCUSSION

The use of radiation protection PPE in the catheterisation laboratory is a complex matter. It is influenced by factors such as the availability of PPE, the fit of the PPE and the ease of doing procedures with it. [21] In our study participants indicated that they consistently used ceiling suspended screens, lead aprons and thyroid shields more than 70% of the time. One participant remarked that wearing the lead apron was like "wearing a uniform and you didn't perform a procedure without it." The use of lead glasses was very low with a high number of people indicating that they never used it. This finding is consistent with that of interventionalists in a UK study where lead glasses were underutilised compared to other PPE. [22] The use of lead glasses reduces the radiation dose to the eye by 70-98% based on various studies. [7,23] It is thus imperative that employers provides appropriately fitting lead glasses for the interventionalists to reduce cataracts. [24]

The provision of PPE increases the uptake for using it. [25] In our study, a low number of participants cited lack of availability of PPE as a reason for not using it. Females were 4.3 times more likely to report that PPE was not available. In a study in the USA they found that barriers to PPE utilisation included that it was time consuming to don, it was burdensome to use, they did not receive training on using it and availability was an issue. [26] Our qualitative findings similarly indicated that poor compliance for using the PPE was related to the weight of the lead aprons and lead glasses, the cumbersomeness of performing procedures with the lead aprons and not readily having access to appropriately fitting PPE. This contrasts with the quantitative findings where participants who consistently wore PPE indicated that the fit of the PPE was generally not an issue. It may however be for this reason that they were consistent in using the PPE. Those participants who did not consistently wear PPE may well have cited reasons as illustrated in the literature for not using it consistently.

I don't like wearing the lead gowns because they are heavy and they don't always have the right sizes. (Female, Paediatric cardiologist)

The problem is the size, 'cause we have one pair or two pairs. There's […] one size for everyone, we not all the same sizes so for some of us it may not fit. (Female, Radiologist).

The lead apron is ok but if you use it and the lead glasses and thyroid shield and lead gloves and skull caps it can be cumbersome. (Cardiologist).

Females have a different body habitus to men and this has to be cogitated in the design and procurement of radiation PPE. PPE currently available on the market for women is ergonomically designed to suit their build and this should be considered when PPE is purchased. Health managers are crucial to facilitating creation of a CRP by ensuring that PPE is readily available. Improving PPE utilisation at an individual level has limitations and it is important that this agenda is driven at a managerial level as well. [21] Participants regarded the role of health managers of paramount importance to facilitating compliance with wearing their PPE.

So, I would imagine it's the hospital's responsibility to provide it [PPE]. I mean we're employed by the hospital. The hospital has a responsibility to all its employees to maintain [their] safety. (Paediatric cardiologist).

It's the hospitals responsibility to provide that [PPE]. It's my responsibility to use it. (Radiologist).

I don’t think the CEOs of the hospital take radiation safety seriously and [they] don’t listen if there are problems with PPE or equipment. (Cardiologist).

Poor availability of PPE is an important reason for poor compliance of utilisation. [27] Our survey data indicated that PPE availability was not ranked highly by participants which contrasted strongly with the qualitative findings where many participants reported lack of availability as a determining factor for poor utilisation. This disjunction suggests that if PPE is available but not being used that there may be other factors that fuel the perception that it is not available. Woman may have this perception because although the PPE might be available the appropriate sizes and ergonomic fit might not be available.

Ja and it becomes such a hassle to try and get a thyroid shield and to try and get goggles that you just don’t. You don't have enough time in a day to try and look for it cause you never goanna find it in any case. So, then you just ignore it and you go with the lead apron only. That's what most of us do. (Radiology registrar).

We don't have the caps. Even the screen that you put in front, that's become difficult for us to use because we feel like it's interfering [with the procedure] and we want to push it out of the way. But we just need to get into the habit that it must be there and you've got to learn to work around it. That it becomes so engrained that you just do it. Because the lead apron we wear without even thinking. (Radiology registrar).

The appropriate procurement of PPE for women is important because failing to do so nurtures gender disparity in the workplace. The catheterisation laboratory is a highly contextualised work space where gender disparities and inequalities may still be present. Deliberately ensuring provision for appropriate PPE for women in the cath.lab aids to create a more equitable workplace. Creating this milieu requires deliberate concerted effort from managerial structures. One participant reflected on making suitable PPE available for women as follows:

It’s untrue that there isn't suitable alternatives PPE for women. It is available but your hospital has to buy this equipment. The PPE is available in your size that is light weight, from goggles to shields, to the actual lead itself and it's available in different styles. You know if you don't like a single suit you can get your split skirt and top, or whatever. It's available but if nobody [management] thinks that you are that important that you shouldn't get it then you must wear something that's too large and just doesn't protect you. But I think lastly when you know you are the Registrar we also think ag, this will be over in four years [so you don’t make a fuss]. (Female, Radiology Registrar).

The universal and consistent use of lead aprons is starkly contrasted with the poor uptake of the lead glasses.

Interventionalists are a highly skilled medical workforce and take a long time to train. It is a costly endeavour that is human resource and financially intensive. The demand for more interventionalists has increased as the burden of diseases they can treat has escalated. [28] It is thus important that these HCWs are protected in the workplace. [29] The use of radiation equipment and interventional procedures has increased dramatically and it is important that appropriately skilled radiation workers are available to operate these machines and perform the complex procedures. [30] Developing and promoting a culture that practices good PPE utilisation is thus crucial. The ramifications of not promoting radiation safety may well have dire consequences years later due to increased radiation induced health effects in patients and radiation HCWs.

This study has important implications for radiation safety policies and practical implementation of PPE control in the radiation workplace especially in emerging economies. The findings should urge radiation regulatory bodies to evaluate and possibly review policies about PPE utilisation. It should motivate departments using radiation to revise their PPE guidelines. It should galvanize radiation protection officers to re-think how to improve compliance of PPE utilisation. It should encourage hospital managers to be proactive in ensuring PPE is available and developing a CRP in the catheterisation laboratory. Future studies could include other members of the catheterisation laboratory to get a holistic understanding of the qualitative and quantitative utilisation of PPE. A larger randomised survey sample size would improve the statistical power of the study.

7. CONCLUSION

Availability and proper fitting PPE remains important considerations in the utilisation of PPE among radiation healthcare workers. The responsibility of the individual is important to facilitate this practice but the role of hospital management is vital to entrench compliance. Creating and nurturing a culture of radiation safety where PPE utilisation is a normative and prioritised component is essential to improving compliance. The consistent use of PPE is an essential quality assurance activity to protect radiation HCWs from radiation exposure and promotes patient safety.

Conflict of interest

All authors declare there are no conflicts of interest.

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CHAPTER 5

TRAINING OF INTERVENTIONALISTS IN RADIATION SAFETY

"It is impossible for a man to learn what he thinks he already knows"

(Epictetus)

5.1 INTRODUCTION

Epictetus was a Greek philosopher in the Stoic tradition who purported the view that individuals were personally responsible for their actions which can be controlled through rigorous self-discipline. The preceding chapters delineated the problem of cataracts due to ionising radiation exposure and proposed an understanding of why the problem existed. These chapters built an argument for the need for changing outcomes by training and educating interventionalists in radiation safety. This Chapter explores what the perceptions of interventionalists are on the education they received and their ongoing training in the field of radiation safety. It explores how the interventionalists considered that this dearth in their training could be addressed. The Chapter peels through a myriad of layers to explore how to address the issue of radiation education and training taking into consideration the views of a diversity of interventionalists at different career levels.

This chapter presents the qualitative and quantitative findings on radiation safety training in the study population. It consists of two articles that were published on the topic. The first of these articles, *Perceptions of radiation safety training among interventionalists in South Africa*, was published in the Cardiovascular Journal of Africa (2017) (Rose & Rae 2017). This article captures the perceptions of interventionalists on radiation safety in South Africa. The second article, *A survey on radiation safety training among South African interventionalists,* are data from the survey conducted and was accepted for publication in the African Journal of Health Professions Education (AJHPE) (Ahead of print, 2018). Although the two articles were published separately they present coherent corroborative evidence on radiation safety training among South African interventionalists. The two articles investigate radiation safety training from a qualitative and quantitative perspective. The quantitative analysis offers reasons around what interventionalists understood the shortfalls in their training are. The qualitative synthesis delves into making meaning of the gaps in training. The articles together would have been too long for publication and for this reason was published separately. Please note the formatting required by the AJHPE is retained and therefore differs from the formatting and referencing style used in this chapter.

5.2 BACKGROUND

Training in radiation safety is a critical element for providing radiation healthcare workers (HCWs) with the necessary knowledge they need to understand the sequelae of radiation exposure for themselves, their co-workers and their patients (Sadigh *et al*. 2014). Knowledge and training will aid to shape their radiation safety practices and foster a culture of radiation safety training (Vano 2015). Evidence suggests that even small changes in practice will profoundly reduce radiation exposure (Azpiri-lópez *et al*. 2013).

South African radiologists have dedicated training in radiation physics and radiation biology. It forms part of their Part I examination (CMSA n.d.). Radiation physics and radiobiology is mentioned in the cardiology syllabus, but they do not have dedicated training on the topic (CMSA n.d.). The literature consistently reports that radiation safety should be part of the formal training curriculum of radiation HCWs as it improves the understanding of radiation safety and adherence to safety programmes (Georges *et al*. 2009; Szarmch *et al*. 2015; Miller *et al*. 2010). One study showed that the impact of training started to wane after three months necessitating regular updates (Georges *et al*. 2009). Cardiologists are generally inadequately trained in radiation safety (Kim *et al*. 2010). There is a need to improve the training in radiation safety of all interventionalists.

5.3 KEY FINDINGS

There were 54 participants in the in-depth interviews (30) and the group interviews (six groups). The survey was completed by 108 interventionalists. The qualitative and quantitative findings from this study support each other:

- Occupational radiation exposure was ranked as important by 97.2% of participants.
- In the interviews participants recognised the importance of radiation safety in the workplace and that radiation safety was necessary to achieve this.
- Most participants (35.2%) reported receiving training in radiation safety. The paediatric cardiologists reported the lowest level (15.6%) of training received in radiation safety.
- Radiologists generally reported they received adequate training in radiobiology and radiation physics. Cardiologists received little or no training and their knowledge of the subject was scant.
- Only 44.1% of the participants indicated that they considered their training adequate.
- In the qualitative interviews radiologists however consistently reported that they considered their training adequate.
- Participants (95.4%) indicated they wanted radiation safety to be part of their training curriculum.
- There was consensus that training was essential with only a few cardiologists not deeming it necessary to have such training.

5.4 REFLECTIONS AND CONCLUSION

The qualitative and quantitative studies presented reflect that interventionalists regard radiation safety as an important consideration in their daily work. There is a discrepancy between the knowledge and training between cardiologists and radiologists. The former has gaps in their training and it is necessary that their training institutions and regulatory bodies address this. Radiologists are adequately trained, but need better continued medical education (CME) programs to remain up to date in this field. In an editorial (cf. Appendix G) on, *Perceptions of radiation safety training among interventionalists in South Africa,* the author describes the findings of this study as “sobering” and that there is “a complacency and lack of knowledge regarding radiation safety” among cardiologists (Brown 2017).

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A survey of radiation safety training among South African interventionalists

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Background. Ionising radiation is increasingly being used in modern medicine for diagnostic, interventional and therapeutic purposes. There has been an improvement in technology, resulting in lower doses being emitted. However, an increase in the number of procedures has led to a greater cumulative dose for patients and operators, which places them at increased risk of the effects of ionising radiation. Radiation safety training is key to optimising medical practice.
Objective. To present the perceptions of South African interventionalists on the radiation safety training they received and to offer insights into the importance of developing and promoting such training programmes for all interventionalists.
Methods. In this cross-sectional study, we collected data from interventionalists (N=108) using a structured questionnaire.
Results. All groups indicated that radiation exposure in the workplace is important (97.2%). Of the participants, the radiologists received the most training (65.7%). Some participants (44.1%) thought that their radiation safety training was adequate. Most participants (95.4%) indicated that radiation safety should be part of their training curriculum. Few (34.3%) had received instruction on radiation safety when they commenced work. Only 62% had been trained on how to protect patients from ionising radiation exposure.
Conclusion. Radiation safety training should be formalised in the curriculum of interventionalists' training programmes, as this will assist in stimulating a culture of radiation protection, which in turn will improve patient safety and improve quality of care.

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Interventionalists are highly specialised doctors who undergo rigorous training. The use of ionising radiation is an integral part of their medical practice and potentially poses major occupational health risks, such as skin damage, genetic and chromosomal aberrations, carcinomas and cataract formation.[1] The use of this modality for diagnostic, treatment and interventional procedures has increased substantially, posing greater occupational risks.[2] In medicine, occupational radiation protection is challenging and increased vigilance is required to protect radiation healthcare workers (HCWs).[1]

Ionising radiation places patients at risk of developing skin reactions and alopecia, malaise, gastrointestinal problems, damage to heart and lungs, and primary and secondary carcinomas.[3] Patients may receive an increased radiation dose owing to over-investigation, because of the complexity and duration of procedures or poor radiation safety practices by operators.[3] Improved knowledge of radiation safety for patients may assist in reducing these complications and thus improve the quality of care.[4]

Specialists require dedicated training in radiation safety, as it effectively reduces radiation risk and optimises radiation safety practices.[5] There is a need to elevate the level of training received by interventional cardiologists to that of interventional radiologists.[6] This may be challenging, as the cardiologists' curriculum already comprises an enormous volume of work, but it is important that professional and regulatory bodies find a way to implement and foster these changes in the interest of interventionalists and their patients.[6]

Developing a culture of learning will assist in developing a culture of radiation protection (CRP), which is essential to lessen radiation exposure. A CRP is a combination of the knowledge, beliefs and practices in an organisation that promotes radiation safety in the workplace.[7] Creating and sustaining a CRP is the responsibility of the catheterisation laboratory team (doctors, nurses and radiographers) and managers.[8] The latter are responsible for ensuring that the equipment is functional and maintained and for providing sufficient and correct personal protective equipment (PPE).[8] A CRP creates awareness of the risks of radiation injury to patients and operators and facilitates improved compliance with PPE use.[7] This culture can be stimulated by including radiation safety training in the formal curriculum of all interventionalists.[9]

The objective of this article is to present the findings of the perceptions of South African (SA) interventionalists on the radiation safety training they received and to offer insights into the importance of developing and promoting such training programmes for all interventionalists in SA.

Methods

In this cross-sectional study, we collected data by means of a structured survey. The study forms part of a larger multiple-methods study, which is described elsewhere.[10]

The study population consisted of SA radiologists, adult cardiologists and paediatric cardiologists. Data were collected at cardiology and radiology conferences between May 2015 and September 2016 by an electronic survey system (EvaSys, UK) (www.evasys.co.uk) and hard copy. The hyperlink to the survey was emailed to delegates at the conferences and workshops and to academic departments in SA. Hard copies of the survey were handed out at the scientific meetings. There was no randomisation and all eligible interventionalists willing to participate were included in the study. The data were captured electronically, exported to Stata version 14 (StataCorp., USA), and a descriptive analysis was done.

Ethical approval

Ethical approval was granted by the Human Research Ethics Committee of the Faculty of Health Sciences, University of the Free State, Bloemfontein, SA (ref. no. ECUFS 44/2015). Participants provided written informed consent, and consent was assumed if participants proceeded with the online survey.

Results

A total of 108 interventionalists completed the survey. Table 1 presents a descriptive analysis of this group, which illustrates their demographic characteristics and the radiation safety training they received.

Discussion

Interventional procedures place patients and operating staff in the catheterisation laboratory at increased risk of adverse health effects owing to radiation exposure.[1,3] Most participants (97.2%) ranked occupational radiation exposure as an important consideration (Table 1), which suggests that they were aware that ionising radiation is an occupational risk. It is, however, important to explore their understanding of the risk and its sequelae. Despite technological improvements, resulting in equipment emitting lower doses, low-dose radiation may still have detrimental effects on health.[3] Therefore, training in radiation safety is imperative and essential for protecting staff in the radiation workplace.[11]

Overall, participants reported receiving low levels (35.2%) of training in radiation safety. Radiologists reported higher levels (65.7%) of training than cardiologists. These results are similar to those of other studies, where radiologists demonstrated higher levels of knowledge of radiation safety.[9] The median duration of time worked for all participants was 10 (interquartile range 5 - 20) years; participants might therefore have had difficulty recalling their training, which might have introduced bias.

Even though radiobiology and radiation physics are included in the Part I examination for the Fellowship of the College of Diagnostic Radiologists of South Africa, not all the radiologists reported having received training in radiation safety.[12] It is unclear why, despite their training for the Part I examination, radiologists did not report having received training in radiation safety.

It is concerning that there is a difference in training between radiologists and cardiologists, as the interventional procedures performed by these two groups result in similar radiation exposure – placing them at similar

Table 1. Radiation-safety training among South African interventionalists

Demographic characteristics	Radiologists, n=35	Adult cardiologists, n=41	Paediatric cardiologists, n=32	Total, N=108
Age, years				
Median	43	48	43	44
IQR	36 - 49	41 - 59	39 - 53	39 - 53
Range	30 - 60	31 - 69	32 - 59	31 - 69
Sex, n (%)				
Male	17 (48.6)	37 (90.2)	20 (62.5)	74 (68.5)
Female	18 (51.4)	4 (9.8)	12 (37.5)	34 (31.5)
Worked, years				
Median	11	11	9	10
IQR	5 - 16	5 - 21	5 - 14	5 - 20
Range	2 - 32	1 - 40	1 - 28	1 - 40
Sector, n (%)				
Public	14 (40.0)	11 (26.8)	22 (68.7)	47 (43.5)
Private	15 (42.9)	23 (56.1)	2 (6.3)	40 (37.1)
Both	6 (17.1)	7 (17.1)	8 (25.0)	21 (19.4)
Perception of occupational radiation exposure, n (%)				
Important	35 (100)	39 (95.1)	31 (96.9)	105 (97.2)
Somewhat important	0	2 (4.9)	1 (3.1)	3 (2.8)
Received radiation safety training, n (%)	23 (65.7)	10 (24.4)	5 (15.6)	38 (35.2)
Training should be part of the curriculum, n (%)	34 (97.1)	39 (95.1)	30 (93.8)	103 (95.4)
Received radiation safety induction on commencing work, n (%)	19 (54.3)	14 (34.2)	4 (12.5)	37 (34.3)
Received at least one talk on radiation safety, n (%)	21 (60.0)	25 (60.9)	7 (21.9)	53 (49.1)
Trained on how to protect patients from radiation, n (%)	28 (80.0)	25 (60.9)	14 (43.8)	67 (62.0)
Trained on how to use X-ray equipment, n (%)	24 (68.6)	20 (48.8)	8 (25.0)	52 (48.2)
	n=31	n=24	n=13	N=68
Considered training adequate, n (%)	19 (61.3)	8 (33.3)	3 (23.1)	30 (44.1)

IQR = interquartile range.

risk.[6] It is important that different specialties employing radiation receive dedicated instruction and training in radiation safety to optimise their medical practice.[13]

Most participants (95.4%) indicated that it was necessary to include radiation safety in the curriculum. Overall, participants indicated low levels of satisfaction (44.1%) with the level of radiation safety training they had received. The combination of these two factors should encourage the curriculum developers for these two groups to investigate and address this omission, especially for cardiology training.[13]

One study indicated that implementation of a training programme resulted in a significant short- and long-term reduction in radiation dose to patients and radiation HCWs.[14] Advocating small behavioural changes among interventionalists reduces radiation during procedures, but requires educating them, especially cardiologists.[15] Encouraging more optimal radiation practices is very difficult and necessitates proactive training strategies.[16] Training in radiation safety greatly improves reduction in radiation dose to patients and operators.[16] Training programmes, however, cannot be a once-off event. In a study by Georges *et al.*[16] it was found that the duration of the impact of training was up to a maximum of 3 months and then tended to decrease.[16] This suggests that there needs to be continuing reinforcement and training in this field. We suggest that the topic should be part of continuing medical education programmes and incorporated into radiology and cardiology conferences.

Training of interventionalists in radiation safety may have two very important consequences. Firstly, it may increase awareness of ionising radiation as an unseen occupational hazard and facilitate utilisation of PPE to mitigate the effects of radiation. This protects an already scarce and highly skilled healthcare workforce. Secondly, radiation HCWs may become more vigilant when considering the dose administered, thus protecting the patient. Patient safety is the keystone of quality care.[4]

Study limitations

This study did not explore participants' understanding of specific health risks related to ionising radiation. It also did not investigate the participants' thoughts with regard to the content and depth of a radiation safety curriculum. There may be recall bias from participants in reporting the training they received. It should be investigated why all the radiologists did not report having received training in radiation safety. A culture of radiation protection is discussed in an article linked to this study.[17]

Conclusion

Establishing and maintaining an adequate radiation safety training programme is crucial to instilling and sustaining a culture of radiation protection, which can protect radiation workers and patients and improve the quality of care. Radiation safety training should be part of formal training programmes and its importance emphasised for it to be effective. Further research is necessary to determine the areas of deficit in radiation safety among interventionalists and how these can be addressed.

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Conflicts of interest. None.

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Cardiovascular Topics

Perceptions of radiation safety training among interventionalists in South Africa

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Abstract

Exposure to ionising radiation may have deterministic and stochastic health effects, which include skin changes, chromosomal aberrations, cataracts and carcinomas. Formalised training in radiation safety and protection improves knowledge on the subject and facilitates greater compliance in safety practices. This qualitative study included 54 interventionalists (adult and paediatric cardiologists, and interventional radiologists). The participants were purposively selected and interviewed to explore their perceptions about radiation safety. A thematic analysis of the transcripts was done using a deductive and inductive approach. Findings showed participating cardiologists had less knowledge about radiation safety than participating radiologists. Cardiologists reported little or no formal training on radiation safety and did not display a culture of radiation safety. There was no consensus on how the training gap should be addressed. There is a perceived need to change and enhance the radiation safety culture among interventionists, and the participants proffered some ideas. These included the need for re-curricularisation of cardiologists' training to create awareness of radiation safety practices.

Keywords: radiation safety training, interventionalists' training, radiation awareness, occupational radiation safety, cardiology training

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Continuous improvements are taking place in radiological imaging technology, with an accompaning reduction in radiation exposures required for imaging.[1] There has however also been an increase in patient load, and fluoroscopic procedures are becoming more complex and taking longer to perform.[2,3] This consequently increases radiation exposure to operators.

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Evidence is mounting that even at low-dose exposure, there are important biological consequences.[4] Ionising radiation can produce detrimental biological effects, which include acute and chronic skin effects, chromosomal abnormalities, various carcinomas and cataracts.[5-7] The effects of radiation exposure may be deterministic or stochastic.[8] It is therefore imperative that health professionals working with ionising radiation are adequately informed and trained on the dangers associated with using this modality, so they can protect themselves better.[9]

Adequate understanding of the effects of occupational radiation exposure and vigilant radiation safety practices among interventionists are essential to protect the health of this group of healthcare professionals. It is concerning that interventional cardiologists need to make decisions about radiation use for their patients and protection for themselves with the level of training they receive in radiobiology and radiation physics.[9] The required knowledge level may be effectively achieved by incorporating changes in their training curriculum and in on-going continued medical education (CME) programmes, as is evidenced by radiology training programmes.[1]

Training and formal lectures targeted at developing a culture of radiation safety are crucial to developing a culture of radiation safety.[10] Radiation physics and radiobiology is part of the curriculum for radiology registrars in South Africa. They are examined on these topics in their Part I examination, but have no subsequent examination on these topics.[11]

Rehani argues that the intensity of radiation used by interventional cardiologists is no less than that used by interventional radiologists and for this reason, the two disciplines should have similar training in radiobiology and radiation physics.[12] This is however not practical at present in South Africa and requires an alternative approach to improving radiation safety knowledge, awareness and practice in non-radiologist clinicians.[12]

Interventionalists are highly skilled doctors. In South Africa, there is a dearth of skilled medical personnel and an even greater shortage of highly skilled interventionalists. The demand for this skill is not being met by the output of subspecialists qualifying.[13] It is therefore crucial to protect the health of those already in service and those who will enter the field. Adequate training is not just about developing skills acumen, but also instilling vigilant radiation safety practices, and this can be entrenched through the formal training curriculum. Influencing changes in a curriculum is challenged by various factors, such as prevailing perceptions from the fraternity.

The aim of this article was to report on the perception of South African interventionalists on radiation education and safety training.

Methods

This was a qualitative study in which we conducted group and in-depth interviews. Qualitative research aims to capture the specific voice of the participants on this topic by producing rich insights into the experiences, values and understanding of participants on the matter.[14]

Thirty individual interviews were conducted and six group interviews with between two and six participants were facilitated. Table 1 provides a detailed description of the participants, who were predominantly male (61%). The study population consisted of adult interventional cardiologists, paediatric interventional cardiologists and interventional radiologists, and are referred to collectively as interventionalists. Adult and paediatric cardiologists are collectively referred to as cardiologists, unless otherwise specified.

The participants were purposively selected because they could contribute to an understanding of the perception of South African interventionalists on radiation education and safety training.[15,16] We used targeted sampling in this study,[17,18] and approached specific informants, such as the heads of departments, to participate in the study.

The purposive selection also ensured that participants represented the opinions of people with a wide range of demographic characteristics, including those from different regions, levels of training, professions, and sectors where they worked, as shown in Table 1. We therefore attempted to include the full range of people involved, to get a clear impression of the overall feeling within South Africa.

We commenced the qualitative data collection in May 2015 and ended in July 2016 when we determined that data saturation had been reached and there was a representative spread of all categories of professionals. Data were collected at several conferences and workshops using an interview schedule. Participants were asked what they thought the radiation safety training requirements for their respective disciplines were, whether the requirements matched their expectations, and if there was room for improvement, how a change could be executed.

The study was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of the Free State (ECUFS 44/2015). Written informed consent was obtained from all participants. In the discussion groups, the participants were asked not to divulge their responses outside the group.

Table 1. Demographic characteristics of the participants ($n = 54$)

Parameters	*Number (%)*
Gender	
Male	33 (61.1)
Female	21 (38.9)
Median age (years)	41 (IQR 35–55)
Median years worked	6.5 (IQR 2–20)
Categories of professionals	
All interventionalists	54
Radiologists	16 (29.6)
Radiology registrars	13 (24.1)
Adult cardiologists	10 (18.5)
Adult cardiology fellows	6 (11.1)
Paediatric cardiologists	7 (13.0)
Paediatric cardiology fellows	2 (3.7)
Sector worked	
Public only	29 (53.7)
Private only	9 (13.0)
Public and private	18 (33.3)
Levels of training	
In training[1]	21 (38.9)
Junior professionals[2]	4 (7.4)
Mid-level professionals[3]	12 (22.2)
Senior professionals[4]	11 (20.4)
Heads of departments	6 (11.1)
City worked in	
Johannesburg	17 (31.5)
Bloemfontein	13 (24.1)
Cape Town	9 (16.7)
Pretoria	5 (9.3)
Other[5]	7 (12.9)
Outside of South Africa[6]	3 (5.5)

IQR, interquartile range; [1]cardiology fellows and radiology registrars; [2]less than five years post qualifying; [3]five to 15 years post qualifying; [4]more than 15 years post qualifying; [5]Durban, Kimberley, Mthatha, Pietermaritzburg; [6]Australia, New Zealand, United Kingdom.

Statistical analysis

Thematic analysis using a deductive and inductive approach was used.[19,20] The interviews were audio-recorded and transcribed verbatim. We then checked the transcripts against the audio recordings for accuracy. Data included the researcher's field notes.

Data were analysed as we received it. We used Braun and Clarke's steps in the analysis process.[21] The researchers independently read the transcripts and coded the data. The codes were organised into categories and the categories were grouped into themes. We discussed the interpretations that emerged. We debated the themes and then reached consensus on the findings. This article explores only the theme of radiation safety, training and education.

Results

The main themes that were formed included: 'knowledge and awareness of radiation effects', 'education and training in radiation safety', and 'the role of senior professionals in fostering a culture of education and training'. In the quotes below (AC) refers to adult cardiologists, (PC) to paediatric cardiologists and (R) to radiologists. There was no difference between men and women in how they responded to the training they received.

Knowledge and awareness of radiation effects

Radiologists generally had a well-informed opinion about how ionising radiation worked and the effects it could have on their health and the health of their patients. As one radiologist reported:

> 'I don't think there is any theory that we're missing out on [in training] if you do the proper course work for your primary exams. I think that covers everything that's necessary' (R).

Radiologists often spoke confidently about how radiation affected health and consistently described the consequences as 'stochastic and deterministic effects' (R). They displayed a familiarity with the literature on the topic.

This contrasted with the cardiologists whose understanding resonated with what you would expect from a non-radiologist doctor. A paediatric cardiology fellow reflected on the effects of ionising radiation on her health as follows:

> 'I haven't thought about it [laughs] to be completely honest. We go there [the cath lab] each week and we have our little [dosimeter] badges. We don't really think about what's happening' (PC).

A radiologist from New Zealand corroborated this view stating:

> 'It is assumed that the doctors understand about radiation, but this isn't the case' (R).

Education and training in radiation safety

There was a distinct difference between cardiologists and radiologists in their training in radiobiology and radiation physics. The cardiologists receive very little or no formal training in these subjects while radiologists have it as part of their core-training curriculum.

> 'I think as postgraduates they [radiology registrars] get enough training on radiation safety. I would like to see it [radiation safety] as part of every imaging congress for the staff because it is often neglected. But if you have an imaging congress, that must be part of it; to remind all the people at the congress about radiation protection. I think that will go a far way already in reminding them about safety measures and radiation protection. And then in our normal academic programme to just make sure that it receives enough attention' (R).
>
> 'Perhaps [there should be] a short course on the amount of exposure that there is you get in relation to how much work you do. You know, a couple of lectures or a lecture on that. Uhmm and to ... implement that into the [cath] lab. But that's what I think should be done; I had no training about radiation whatsoever, not … in any way' (AC).
>
> 'Cause they [cardiologists] didn't do physics, they haven't done like physics, like part of our training is physics and [it is in] the exam, it is not part of their training. I don't know if they actually are aware of it [the effects of radiation]' (R) reflecting on cardiology training in radiation safety.
>
> 'I think it [radiation physics] should be highlighted as something [that should] at least be done at the first year' (R), in response to training in radiation safety for doctors using ionising radiation as a modality.
>
> Junior and recently qualified cardiologists expressed concern that they were using a modality that could have dire consequences to their long-term health, but were not being trained in how to safely use radiation.
>
> 'We don't really have training, it is just like we do self-study for physics' (AC) fellow.

The paediatric cardiology heads of departments that participated in the study unanimously expressed the opinion that it was an important but neglected aspect of the content of their training programmes. They generally held the view that more could and should be done to improve the training and awareness on the topic. They however expressed the concern that their departments were not necessarily equipped to do such training and that other departments such as medical physics should assist with this training. (After the interview with the PC quoted below, a question on radiation safety was asked in the CMSA examinations for paediatric cardiology in April 2016.)

> 'I've been an examiner in paediatric cardiology for a while. For over 10 years I haven't seen a question about it [radiation safety]. So, it's not of importance and nobody discusses it. So, there should be training and it should be in the curriculum…' (PC).
>
> 'It [radiation safety] is something that we've never discussed or ever brought up in a meeting until you came along actually. How do we incorporate that when we train our fellows? I don't remember ever been told anything by my consultants with regards to radiation safety for myself when I was being trained. Maybe we can add some training because at the moment there isn't any. There's no training!' (PC).

Adult cardiology heads of department (HOD) were divergent on their views. They recognised that radiation safety was important and lacking in their programmes, but did not think that the current training programme needed re-evaluation. They were concerned that the volume of work was already too much for the cardiology fellows.

> 'Ja, it's hard to uhhh, cardiology is vast on its own. Adding a section on radiation is asking a bit much. But I think uhhmm, in the syllabus, that we give, you know there is a syllabus, a cardiologist syllabus for the trainees. Somewhere in that syllabus it should emphasise the fact or some knowledge should be given around radiation and the issues about radiation' (C) HOD.

Participants reflected that education and training was however not a once-off exercise and that frequent and constant reinforcing was needed.

> 'I do think education does have a very important role if one is making people aware. I would hope that you would then gradually improve their performance in the lab but it is something I think needs reinforcing regularly because I've seen very experienced operators still behaving badly in the cath lab. I've seen it a huge amount. And so, I think we just have to keep reinforcing good practice and keep educating them' (R) UK.

The role of senior professionals in fostering a culture of education and training

At one training institution, the head of adult cardiology was very dismissive of the topic. This HOD was reluctant to participate in the study, stating that a more junior cardiologist should be interviewed. Despite explaining the nature of the study and stating that we were interested in hearing his/her voice as HOD on training in radiation safety, the HOD was still not interested in participating in the study. This created the impression that the HODs of some training units were not interested in the topic. This dismissive attitude towards radiation safety was also recognised by other participants in the study:

> 'Yes, yes they [heads of departments] are shocking yes. No, no, no that's exactly true and that's certainly true and I can promise you that is not just in South Africa. That will be all over ja' (R) UK.

Discussion

The increasing utilisation of ionising radiation for diagnostic, therapeutic and interventional procedures necessitates great vigilance in using the modality. This strengthens the case for interventionalists to be adequately trained in the use of radiation. Improving knowledge on the effects of ionising radiation on the health of patients and operators requires improved access to training and education on the topic. The literature consistently cites that formalising radiation safety and training in the curriculum is essential for improving and maintaining radiation safety practices for interventionalists.[1,22]

In a study by Sadighm *et al*., they found an increased awareness about radiation among radiology residents compared to non-radiology residents.[9] Even though we had not quantified our findings, we interpreted that radiologists were generally more knowledgeable on the effects of radiation and safety precautions compared to cardiologists. We postulate that this is because of the formalisation of radiobiology and radiation physics in their training curriculum. It is concerning that this discrepancy exists, as cardiologists are exposed to similar radiation workloads to radiologists and the dose exposure is likely to increase as the complexity of cardiology procedures increases.[12]

An effective way to improve the knowledge of radiation safety is to provide opportunities for education and training in the subject during specialisation. Limacher *et al.* argues that the best way to ensure adequate training in radiation safety is to formalise it in the curriculum.[5] Radiobiology and radiation physics is mandatory for radiologists in South Africa and is a formal part of their training programme.[11] This is not the case for cardiologists in South Africa (personal communication). Szarmach *et al*. state that radiation safety can only be addressed by educating all healthcare professionals, irrespective of their position, and that they need to be trained 'thoroughly and systematically'.[23] Reinforcing radiation safety messages and training optimises radiation safety.[24]

The Colleges of Medicine curriculum prescribes radiation physics and radiobiology as learning outcomes for both radiologists and cardiologists.[11] From the interviews and from personal discussions with interventionalists involved with training specialists, it emerged that there was no standardised teaching of radiation safety at the various training institutions. Instruction in the topic ranged from in-house teaching, registrars or clinical fellows attending short courses, or self-learning on the topic. Uniformity in content and instruction will facilitate that interventionalists are adequately trained in this area and that radiation safety is reinforced across South Africa.[1,23,24]

It is inconsistent, and hence ineffective, if the leadership of a clinical unit does not actively promote radiation safety and training but expects junior staff to adhere to these principles.[25] The attitude of the HOD of a unit is key to developing a culture of radiation education and training. Radiation safety as a priority will not permeate the department if those at the helm are not recognising it as a priority and championing the cause.

The views expressed by South African interventionalists were corroborated by at least three international interventionalists. The views of these international doctors are included to illustrate that the experience and challenges of training cardiologists and radiologists in radiation safety are not unique to South Africa.

Developing, strengthening and sustaining a radiation education and training culture in South Africa among interventionalists will require changes in their formal training and deliberate inclusion in their CME programmes. Education is crucial to establishing a radiation safety culture and will require buy-in at all levels.

Limitations of the study

The participants were purposively sampled and the findings are not generalisable to the whole population of South African interventionists. The participants however reflect the population of interest and the findings may be transferable in similar settings. The findings highlight that radiation safety is an important aspect of training and that it is imperative to adequately train interventionalists in this field. Further research is needed to better understand this issue and how to incorporate it into interventionalists' training programmes.

Conclusion

Radiobiology and radiation physics is formalised in the training curriculum for radiologists, resulting in greater awareness about radiation dangers and greater vigilance in radiation safety practice. There is a paucity of knowledge about radiation safety practices among cardiologists in South Africa, and cardiologists need to be empowered to make more informed decisions about using ionising radiation, in order to protect themselves and their patients. This can be achieved by including it in their formal training curriculum and raising the expected outcomes to that of radiologists.

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CHAPTER 6

CREATING A CULTURE OF RADIATION PROTECTION

"We are the Borg. Lower your shields and surrender your ships. We will add your biological and technological distinctiveness to our own. Your culture will adapt to service us. Resistance is futile"

(The Borg, Star Trek)

6.1 INTRODUCTION

In the classic science fiction television series, Star Trek, The Borg is a transhumanist species that swarms through the universe destroying civilizations and their cultures. They rob species of the element that uniquely identifies them and characterises their being. Their objective is to mould the culture of the species they assimilate to serve a perverse objective of achieving perfection. They offer a perfect antagonist identity to the values that shapes, underpins and motivates the Federation. The Federation is the icon of freedom and the protection of the individual.

We, however, do not live in a matrix of assimilated homogenous beings. We are part of a society that is shaped and coloured by a plethora of different cultures. We allow these cultural differences to rub against each other and bring them into our workspaces. Our diversity, while a strength, does lend itself to conflict and may adversely affect how we engage in the workplace. The workplace offers a unique environment to allow our individual cultural identities to merge and co-create the culture of the spaces we work in. Each workplace culture is in a state of flux as it establishes its unique cultural identity while allowing itself to be influenced by the multiplicity of cultures that integrate themselves into the collective organisational culture. And it is this malleable strength that has to be implored to create a culture of radiation protection in the catheterisation laboratory.

In Chapter 3, the researcher reported the prevalence of radiation associated cataracts in South African interventionalists. Chapter 4 explored the reasons for them not using existing protection measures. Chapter 5 describes the dearth in education and training in radiation safety and builds the argument that this is the conduit to facilitate improved radiation safety in the cath. lab. In Chapter 6, the researcher argues that it is imperative to create and sustain a culture of radiation protection (CRP) to ensure a culture of radiation safety in the workplace and in so doing build a culture that protects the radiation healthcare worker and the patient. This will ensure that quality care is provided. This chapter is a synthesis of the qualitative findings of the study. The chapter consists of an article entitled, *Interventionalists' perception of a culture of radiation protection,* which was published in the South African Journal of Radiology (2018) (Rose *et al*. 2018). This chapter describes what a culture of radiation protection (CRP) is and how this culture expresses itself in the South African context.

6.2 BACKGROUND

Ionising radiation is increasingly being used in the catheterisation laboratory and poses potential health risks to patients and operators (Bhargavan 2008). This risk can be mitigated by promoting radiation safety practices. These safety practices include developing, implementing and enforcing policies and guidelines; justification for procedures; optimisation and dose reduction when performing procedures; applying the as low as reasonably achievable (ALARA) principle; provision and obligatory use of personal protective equipment (PPE) and regulation of dosimetry (Klein *et al*. 2009; Cousins & Sharp 2004; Engel-Hills 2005; Durán *et al*. 2013; Malone *et al*. 2012; Badawy *et al*. 2016).

Safety practices become entrenched when they are inculcated as part of a CRP. Creation of a CRP is the collective responsibility of the entire cath. lab team. The values, attitudes and norms within a workplace help shape the organisational culture within it. (Fridell & Ekberg 2016) These attributes should be taken into consideration when endeavouring to create a CRP. A CRP enforces safety practices and benefits patients and the radiation healthcare worker. (Fencl 2015) Education is essential to creating awareness about ionising radiation as an occupational hazard and for creating continued awareness about it (Georges *et al*. 2009).

6.3 KEY FINDINGS

The key themes that emerged from the qualitative data were:

- Culture of radiation protection: this was a complex theme that intersected with the other themes and this interrelation is illustrated in Figure 6.1 below.
- Knowledge and awareness of radiation: there was a difference between cardiologists and radiologists with respect to the knowledge about radiation and its effects on health. Radiologists generally appeared more informed than cardiologists.
- Radiation safety practice: cardiologists appeared to be less vigilant about radiation safety practices. This may be related to their knowledge and training.
- PPE utilisation: participants were aware of personal protective equipment (PPE) that was available, but not consistently using it.
- Education and training: cardiologists were generally undertrained in radiation safety. There is a need to re-evaluate the curricula on radiation safety training for interventionalists in South Africa.

The qualitative findings suggest that there is a need to better understand how a culture of radiation protection can be developed and sustained in South Africa.

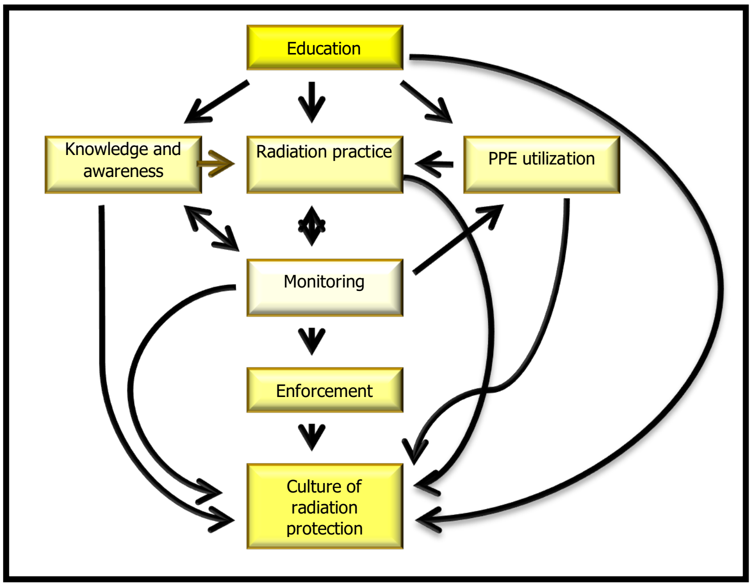

Figure 6.1 Culture of radiation protection is a complex construct intersecting with several other themes

6.4 REFLECTIONS AND CONCLUSION

The drive needed to transform the CRP among South African interventionalists requires systemic changes. It requires a paradigm shift in how interventionalists understand their role in the cath. lab team. This requires changes in policies and standard operating procedures. It demands regulatory bodies to examine existing regulations and legislation and adapt them where necessary but more importantly to enforce them where appropriate. This transformation is dependent on all actors in the team to co-create and sustain a CRP.

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Interventionalists' perceptions on a culture of radiation protection

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Background: Occupational exposure to ionising radiation poses potential health risks to radiation workers unless adequate protection is in place. The catheterisation laboratory is a highly contextualised workplace with a distinctive organisational and workplace culture.

Objective: This study was conducted to understand the culture of radiation protection (CRP).

Methods: This study was a qualitative study and data were collected through 30 in-depth and 6 group interviews with 54 purposively selected South African interventionalists (interventional radiologists and cardiologists). The participants included a diversity of interventionalists who varied in sex, geographic location and years of experience with fluoroscopy. The transcribed data were analysed thematically using a deductive and inductive approach.

Results: 'Culture of radiation protection' emerged as a complex theme that intersected with other themes: 'knowledge and awareness of radiation', 'radiation safety practice', 'personal protective equipment (PPE) utilisation' and 'education and training'.

Conclusion: Establishing and sustaining a CRP provides an opportunity to mitigate the potentially detrimental health effects of occupational radiation exposure. Education and training are pivotal to establishing a CRP. The time to establish a culture of radiation in the catheterisation laboratory is now.

Introduction

Ionising radiation is a modality that is neither seen nor heard and is intangible. It is a health hazard for patients and radiation healthcare workers (HCWs). Interventionalists are doctors who perform fluoroscopically guided procedures for diagnosing or treating patients. They include interventional cardiologists and interventional radiologists. Vascular surgeons, urologists, orthopaedic surgeons and anaesthesiologists may also perform fluoroscopic procedures as part of their practice. Interventionalists are not always aware of the detrimental long-term effects that radiation exposure may have on their health and may be negligent in implementing and consistently applying radiation safety practices.

The increasing use of fluoroscopy for diagnostic, therapeutic and interventional procedures necessitates greater vigilance in the use of this modality within the workplace. The increasing trend in ionising radiation utilisation in medical procedures has increased diagnostic exposure from X-rays, computed tomography (CT) scans, mammography and nuclear medicine scans.[1] Therapeutic use includes angioplasty, radiation therapy for tumours and therapeutic use of radioisotopes. Interventional practices include fluoroscopic procedures like radio-ablation, pacemaker insertion and embolisation.[1] There has been an increase in the duration and complexity of these procedures, resulting in greater cumulative occupational exposure to operators.[2]

The most at risk professions include interventional radiologists and cardiologists.[3] Operators performing fluoroscopic work have an increased occupational risk of developing ionising radiation-induced health detriments.[4] The effects of ionising radiation exposure may be stochastic or deterministic.[5] Stochastic effects have no threshold limit and occur randomly; for example, genetic aberrations and cancers. Deterministic effects occur when an exposure threshold is exceeded and the outcomes include skin changes; they may also occur in patients who are overexposed.[6] Protection of radiation HCWs in the workplace is essential because they may experience effects such as cataracts.[7]

Protection from ionising radiation in the workplace hinges on providing an enabling environment for radiation safety, application of the as low as reasonably achievable (ALARA) principle, monitoring of the radiation dose received (dosimetry), complying with international occupational dose limits and regular and consistent use of personal protective equipment (PPE). All of these aid in creating a culture of radiation protection (CRP) in the workplace.[8,9] This culture is underpinned by a set of norms and values that shape how it is developed, implemented and maintained.[10] It is thus vital that a CRP should be developed, implemented and sustained to protect radiation healthcare professionals.[11]

A CRP is imperative for protecting HCWs from the effects of radiation. Such a culture includes compliance with the radiation regulations, use of PPE, compliance by all of the radiation team and adequate monitoring and evaluation.[2] The genesis of such a culture is sparked and sustained by adequate education and training.[12]

Personal protective equipment is used to reduce the exposure to radiation for HCWs, thereby minimising the risk of radiation health effects.[13] The range of PPE includes ceiling suspended screens, lead aprons, lead caps, thyroid guards and lead glasses or visors.[14] The effectiveness of PPE depends on its consistent use. Consistency of use depends on availability, fit of the PPE and the comfort when performing procedures.[15] A recent study has shown that when workers have access to PPE, it is more likely to increase their utilisation of it.[16] In a survey on attitudes of PPE usage, it was found that certain devices such as lead aprons and thyroid shields were widely used and considered 'standard practice', while other devices that protected more radiosensitive organs such as the lenses of the eyes were used inconsistently.[17]

The behaviour in an environment like the catheterisation laboratory depends on the interplay between the attitude of individuals, the comportment of professionals and the engagement between administrative and managerial staff.[18] Organisational culture in a health facility is shaped by four key factors: responsiveness, team hierarchy, care philosophy and communication.[19] These dynamic interactions are a conduit to the barriers and facilitators which shape a CRP.

Formal training in radiation safety reduces the dose to patients and HCWs in the catheterisation laboratory.[12] Formalised training and continued education on radiation safety help establish and sustain a CRP in the workplace. Radiation safety training and education needs to form part of the formalised curriculum of radiation HCWs in order for it to be taken seriously.[20] Continued medical education (CME) can help consolidate and sustain the training and preservation of a CRP to ensure a safer workplace.[21] This CME programme should be consistent and reinforced regularly to maintain its effectiveness.[12]

The aim of this article is to present the perceptions of interventionalists on what constitutes a CRP. The findings reflect on the challenges for developing a CRP in the workplace, how to establish such a culture and how to continue to foster it. We reflect on how these principles can be universally applied.

Methods

Study design

This study had a qualitative design which formed part of a larger multiple methods study which is described elsewhere.[22]

Participant selection

The participants were all interventionalists and included adult cardiologists, paediatric cardiologists and interventional radiologists with different levels of expertise. They included specialists in training, junior and senior specialists and heads of departments. We purposefully included a diversity of participants to reflect the gender, number of years worked, different professional categories, sectors worked in, levels of training and cities worked in South Africa – a total of 54 participants (see Table 1).

The participants were purposively selected because they worked in the catheterisation laboratory and offered insights into radiation protection issues in this workplace. They were interviewed at conferences or at a suitable location, usually their workplaces, based on appointments scheduled. Snowball sampling was employed and participants were asked to recommend interventionalists they thought would be willing to participate in the study and these were followed up.[23] We also targeted specific informants, such as the heads of departments, to participate in the study.[24]

Data collection

We conducted six group interviews of between two and six people and 30 in-depth interviews with individuals. Data collection started in May 2015 and ceased in July 2016 when we determined that data saturation had been reached. Data were collected at four conferences and three workshops in South Africa. These included one Paediatric Interventional Cardiology workshop and two Interventional Radiology workshops. The conferences included two annual conferences for the Cardiology Society of South Africa, one annual

TABLE 1: The characteristics of 54 participants in six group interviews and 30 in-depth interviews.

Variable	In training	Junior†	Mid career‡	Senior§	HOD
Sex					
Male	12	1	6	10	4
Female	9	3	6	1	2
Occupation					
Radiologist	-	1	7	5	2
Adult cardiologist	-	1	2	5	2
Paediatric cardiologist	-	2	3	1	2
Paediatric fellow	2	-	-	-	-
Cardiology fellow	6	-	-	-	-
Radiology resident	13	-	-	-	-
Sector					
Public	21	3	3	2	1
Private	-	0	1	6	-
Both	-	1	8	3	5

HOD, head of department.

†, Less than 5 years of experience post-qualifying; ‡, 5–15 years of experience post-qualification; §, more than 15 years of experience post-qualification. Dash indicates this category is not applicable.

conference for the Radiological Society of South Africa and two additional radiology conferences aimed at special interest groups for radiologists. Individuals at radiology, cardiology and paediatric cardiology departments at the university training centres were contacted directly. Selected interventionalists in the private sector were also contacted directly.

A semi-structured interview schedule was used. The questions were open-ended which prompted participants to express their perceptions on the effects of radiation on health, what a culture of radiation safety meant and whether it existed in their workplace, their utilisation of PPE and their thoughts on radiation safety and training and how this could be improved for their respective specialties. Probing questions were asked to get a deeper understanding of participants' responses.

Analysis

Thematic analysis using a deductive and inductive approach was used.[25,26] This analysis was chosen because we wanted to describe and interpret the depth of the experiences of the participants.[27] We decided on some themes based on the literature (deductive approach) and allowed other codes and themes to emerge from the content of the data (inductive approach). The interviews were audio-recorded and transcribed verbatim. The transcripts were checked against audio recordings for accuracy. Data included the researcher's field notes.

The data were analysed on an ongoing basis, which included the following steps[27]: Two researchers (André Rose and Kerry E. Uebel) independently read the transcripts and coded the data. We developed a code book as we analysed the data. The codes were organised into categories and the categories were grouped into themes. The interpretations were discussed as they emerged, and the researchers reflected on the disparities and relationships and debated the themes that arose and then reached consensus on the findings. This was an iterative process and the researchers met several times to discuss codes and categories as they emerged.

Context of the study

Radiologists receive 4 years of training which includes radiobiology and medical physics and it is prescribed in their formal curriculum. They are examined on it as part of their first qualifying examination (usually within their first 18 months of study). It is usually not re-examined in their exit examination.[28] There is inconsistent coverage of radiation safety in their CME seminars.

Cardiologists have a 3-year training programme to subspecialise in the discipline following qualification as physicians or paediatricians. Radiation safety is mentioned in the syllabus of cardiologists as a learning objective, but it is not formally taught and there is usually poor coverage of it in CME seminars.[28]

South Africa has a two-tiered health system, with an ailing public health system and a thriving and well-established private health system. Interventional radiology and cardiology services are offered in both sectors. It is not uncommon that doctors work in both sectors. Both sectors have challenges, but shortage of equipment such as PPE is common in the public sector. The public sector often has a high patient load with a poor staff complement which does not match the workload.

Trustworthiness

Our findings are congruent with what is truly happening in practice, based on the researcher's observations, the data obtained and what is reported in the literature.[29] The researcher is a (medical) doctor, has worked in a catheterisation laboratory previously and has insight into this work environment. He also spent time observing interventionalists in their workplace.[29]

We conducted in-depth interviews and group interviews which are acceptable and well-described techniques widely reported in the literature.[30] We achieved site triangulation by including a variety of different interventionalists from different hospitals, cities and from both public and private sectors.[29] The participants were also at different levels of expertise and included specialists in training to senior specialists and heads of departments. This allowed us to get a better understanding of how the different views converge on an understanding of radiation safety culture in the workplace.[31]

This study has good representation of different categories of interventionalists from across South Africa and offers important qualitative insights into how interventionalists understand what a CRP is. The findings, although not generalisable, can be transferred to the broader South African interventionalist community and similar contexts elsewhere.[29,32]

Limitations

The qualitative design of the study allowed us to generate hypotheses but not to test them. The study did not investigate the reasons of differences between the cardiologists' and radiologists' knowledge of radiation. It also did not fully explore the complexity of what constitutes a CRP and the factors facilitating the creation and establishment of a successful CRP. The sampling strategy restricted the participants in the study and as such offers only the perspectives of the interventionalists and not that of all members of the catheterisation laboratory team. Future studies would add value by exploring these areas and including other members of the catheterisation laboratory team, such as nurses and medical radiation technologists (radiographers).

Ethical consideration

The study was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of the Free State (ECUFS 44/2015). Written informed consent was obtained from all participants. In the group interviews, the participants were asked not to divulge the responses outside the group. The recordings and transcribed data were stored in a secure place.

Findings

In this section, we report on the following themes that were identified in the data: 'culture of radiation protection', 'knowledge and awareness of radiation', 'radiation safety practice', 'PPE utilisation', 'monitoring of safety practices' and 'education and training'. CRP emerged as an overall theme that intersects with the other themes.

The following notations are used in the article to denote the participants:

- HOD for head of department
- R for radiologists,
- AC for adult cardiologists and
- PC for paediatric cardiologists.
- Cardiologists may refer to either adult or paediatric cardiologists.
- We use the term 'resident' to refer to a doctor who is in the process of specialising. In South Africa, residents are referred to as registrars.

Culture of radiation protection

Culture of radiation protection is a complex overarching theme. It has many facets that intersect with several of the other themes. Participants offered a plethora of perspectives on what constituted a CRP, on how to establish it and how to sustain it. Participants mentioned that it depended on the education and training they received, the role of various stakeholders, monitoring structures, policies and how they were enforced and the dynamics between team members in the catheterisation laboratory.

Radiologists generally expressed the view that they were well informed about radiation safety and felt that they had a well-established CRP within their work environments:

> 'But in Radiology Departments it [CRP] is engrained in us. The problem is the rest [other disciplines using ionizing radiation]; it's not engrained in them.' [R, HOD]

> 'I think we're more aware than many others. When you take an orthopaedic surgeon or urologist who is using ionising radiation they certainly are not nearly as aware as we are. So, the culture of radiation safety would, I think, depend on all workers, everyone involved in the procedure, everyone in the room all working together to reduce radiation exposure.' [R]

Cardiologists expressed heterogeneous opinions on the CRP in their workplaces. Some cardiologists stated there was very little attention given to the issue, while others stated they recognised the importance of it, but it was not diligently enforced in the workplace:

> 'Radiation control is strictly controlled by guidelines and the problem is we ignore [these] guidelines.' [R]

The consensus amongst most interventionalists was that the responsibility of creating a CRP lies with several stakeholders. These stakeholders included scrub nurses, radiographers and doctors working in the catheterisation laboratory. There was a general opinion that a top down approach was necessary and that the head interventionalist had to take the lead to establish, maintain and enforce a CRP within the work environment. This view is reflected in the understanding of a radiology resident as follows:

> 'It's about enforcing, and it needs to be top down though, I do agree about that. Your HOD needs to drive it, your consultants need to set good examples and then your registrars who join the program will automatically follow it. No exceptions.' [R]

Knowledge and awareness of radiation

There was generally a distinct difference between the knowledge and awareness of cardiologists and that of radiologists pertaining to the effects of radiation. Cardiologists were not unaware that ionising radiation was a hazard, whereas radiologists seemed to engage more easily on how radiation could affect their health and that of their patients. Although the knowledge of these two groups was not quantified, the radiologists appeared to be more knowledgeable:

> 'There are two labs, the catheterisation laboratory and the electrophysiology lab and I don't know the difference in radiation exposure between the two. It would be nice to know the difference. It is a gap in my education.' [AC]

Many participants commented that because radiation was invisible and the health effects were often long term, proper vigilance was lacking. This resulted in poor radiation safety practices, which potentially compromised their health and that of their patients. The knowledge and awareness about the effects of radiation appeared to be linked with formal training. One cardiologist reflected on awareness of the dangers of radiation only after having had bilateral cataracts removed. There were participants who reflected that they knew colleagues who had experienced negative effects possibly attributed to radiation such as brain tumours:

> 'No, I am much more aware after I got the cataracts, I actually had to look at [the situation]. Because I thought why am I getting cataracts and then I thought and said whoa, it must be radiation you know. So, I actually look at radiation now with different eyes.' [AC]

Radiation safety practice

Participants were generally not familiar with the policies and legislation that regulate radiation safety. It was of particular concern that heads of department (especially cardiologists) were not well acquainted with the necessary policies, legislation and regulatory bodies:

> 'I am not even aware of that [radiation regulations]. So, I don't know who draws up these guidelines. I don't know where they've been published. Uhm, so if there are any guidelines then it needs to be distributed to the user. It's pointless drawing up guidelines without uhm, you know informing people, making people aware that these guidelines exist. I am a professor of cardiology and I am not sure where these guidelines are.' [AC, HOD]

> 'So there probably are some policies and regulations [but] we don't know what they are.' [PC, Senior]

Participants reflected that radiation safety practice hinged on applying basic principles such as justification for a procedure, the distance maintained from the patient during operation and the X-ray beam, and utilisation of PPE.

Strong opinions were expressed that the practice of radiation safety in the catheterisation laboratory was the responsibility of the individual as well as the entire team. They noted that while individuals were responsible to ensure they had applied principles such as the inverse square law, the ALARA rule and the use of PPE, there also needed to be senior team leaders responsible to check that all staff members complied with standard practice. They generally agreed that the team should have the freedom to challenge other members within the team about radiation safety practices, but recognised that this was complicated by the power dynamic that existed between differently ranked professionals within the team. This power disparity was particularly evident in the private sector where participants reported that the rest of the team was unlikely to challenge the doctor. It appeared that the public sector doctors were willing to abide by structures put in place to ensure their safety and were more willing to be instructed by, for example, a scrub nurse or radiographer. The attitudes of some doctors and an unwillingness to listen to others in the team were noted as barriers to good radiation safety practice:

> 'And part of their bad habits is their egos because they don't want to be told by the radiographer take your foot off the pedal. "I'm in charge, I am the big doctor here."' [R, HOD]

Participants expressed the view that radiation safety practice was also the responsibility of stakeholders that did not ordinarily form part of the catheterisation laboratory team. These actors included the radiation safety officers, the medical physics department and the hospital management. Participants also mentioned the critical role of hospital management in ensuring adequate quality control, maintenance and timely replacement of machines and PPE:

> 'The HOD and CEO need to be responsible for ensuring equipment works and is fixed.' [R]

> 'Hospital management needs to ensure equipment is kept up to date and maintained properly.' [AC]

There was poor awareness about the existence, role and function of radiation safety officers. Participants were not always sure what role the medical physics department played or should play. In some instances, they were not even aware of the existence and function of such a department within their facilities:

> 'I don't know the name of the radiation control board.' [AC]

> 'There is no communication between us and the radiation control board.' [AC]

A dominant view that emerged from the study was that the participants felt a strong sense of responsibility to their patients, even if performing a procedure without adequate radiation protection would jeopardise their own safety and health. This attitude underpins the culture of care that exists with some doctors. Procedures were sometimes performed self-sacrificially in the interest of the patient, but at the cost of compliance with standardised radiation safety practices:

> '[Be]cause our job is about the patient and that's why we do what we do. And that's actually how the whole of medicine generally works. [...] So, it's simply not in our makeup [to think about ourselves]. [...], but you know ninety-nine percent of our focus is for the patient and then the other one percent is for maybe a few other things.' [PC]

Personal protective equipment utilisation

Participants noted both barriers and facilitators to PPE utilisation. Barriers included poor availability and quality control, poor fit, inadequate size ranges and equipment being cumbersome to use. Factors that facilitated the use of PPE included the hospital management accepting responsibility to supply PPE and individual interventionalists also taking responsibility to use PPE and to purchase their own PPE in cases where it is not readily available in their facility.

Personal protective equipment utilisation was not quantified in this study, but the most commonly reported PPE used were lead aprons. Thyroid guards were less commonly used. Lead glasses were either used very infrequently or not at all. Ceiling suspended shields were hardly ever used, but were frequently reported not to be available. There was generally very poor awareness of ceiling suspended shields and mobile shields. Only one participant indicated that he used lead gloves and a lead cap.

Participants reported that PPE was not always available. They usually had sufficient lead aprons, but other PPE was frequently unavailable in the public sector, with a notable shortage or absence of lead glasses and thyroid shields. Lead glasses were particularly in short supply and were often not replaced when damaged or lost:

> 'It becomes such a hassle to try and get a thyroid shield and to try and get goggles that you just don't. You don't have enough time in a day to try and look for it [be]cause you never gonna find it in any case. So, then you just ignore it and you go with the lead apron only. That's what most of us do.' [R, resident]

Participants who worked mainly in the public sector also noted the lack of availability of different sizes and designs of PPE as a problem. They noted that they did not have access to newer more ergonomically designed PPE and were often forced to settle for equipment that was too heavy or ill-fitting. The participants generally held the opinion that they wanted a range of choices for PPE. Women participants stated that some equipment was inappropriate for their physique. A female radiologist made the following remark:

> 'The problem is the size, [be]cause we have one pair or two pairs. There's [...] one size for everyone, we [are] not all the same sizes so for some of us it may not fit. [R]

The ability to perform procedures dexterously strongly influenced PPE utilisation. Many participants described that lead glasses were awkward to use during procedures and cannot be used over prescription glasses. One participant stated:

> 'They [lead glasses] are bulky, they mist up and they cause pressure on the nose.' [AC]

> '[…] the challenges are if you using prescription glasses. Because then you have to make yourself a set of lead prescription glasses. It's a bit expensive, but if you realise the environment that you [are] working in uhm, [then] you could invest bit of money towards your own safety. […]. Cardiologists are making a lot of money, but a blind cardiologist doesn't mean anything.' [R]

There was consensus amongst participants that hospital management was responsible for supplying adequate PPE for their staff and for ensuring adequate and continuous quality control of PPE:

> 'So, I would imagine it's the hospital's responsibility [to provide PPE]. I mean we're employed by the hospital. The hospital has a responsibility to all its employees to maintain [their] safety.' [PC]

> 'It's the hospital's responsibility to provide that [PPE]. It's my responsibility to use it.' [R]

Many participants also reflected that individuals had a responsibility to use PPE regularly and that owning their own personal PPE could act as a stimulus for consistent utilisation:

> 'Hmm, it becomes second nature, I mean it comes with the turf, hmm, it's almost like my uniform I mean you don't even think about having to put on your lead apron when you [are] going to do a procedure, to put on your thyroid shield, your collar. I mean those things come almost automatic to you now.' [AC]

Monitoring of safety practices

Participants raised the issue of monitoring of radiation safety and stated there was inconsistent use of dosimeters, lack of feedback on the radiation they were exposed to and there was a need for more regular occupational medical examinations.

Many participants reported inconsistent utilisation of personal dosimetry badges either because they forgot to wear their dosimeters, they were not held accountable to wear them, they received no feedback about previous readings, or worryingly because high readings might limit the work they could do in the catheterisation laboratory:

> 'No, I must tell you honestly sometimes I am working so hard that's [radiation safety] really the last thing on my mind. You always wear protective gear, but I can honestly tell you I don't wear my radiation badge at all, never. It's in my bag and that's it. I don't wear it when I'm doing screening, I don't wear it when I'm doing angiography and I don't wear it, no.' [R, resident]

> 'We don't get regular reports of our radiation doses.' [PC]

Most participants commented that they did not receive sufficient regular feedback on doses they were exposed to. Many were unaware of the medical physics departments at their facilities or what role these departments should be playing in monitoring their dose exposure. This lack of feedback on their dosimetry readings not only influenced their inconsistent use of dosimeters but also denied them of the opportunity to improve their radiation safety practices by being able to check monthly doses received:

> 'You wear dosimeters and it seems as if nobody checks them or does anything.' [AC]

Participants commented that real-time monitoring would improve their radiation safety practice, as it would give an immediate indication of their own and the patients' radiation exposure and aid to plan future procedures.

Some participants reflected that they almost never received regular periodic occupational health examinations. This was especially true for the private sector.

Education and training

We identified two broad categories with respect to education and training. Firstly, formal education and CME, which interventionalists receive as part of their training. Radiologists received formal instruction in radiobiology and radiation physics, which was part of their core curriculum, while cardiologists received little or no formal instruction in it. Radiologists were generally satisfied with the level of formal education they received in the discipline but noted that they thought that other medical disciplines using ionising radiation such as cardiology, orthopaedics and urology were undertrained in the subject. A head of the department (HOD) in radiology reflected on the discrepancy in training between different medical disciplines using radiation as follows:

> 'The interventional group and people that I work with, there are no bad habits in that group. The bad habits are with our friends the cardiology group, orthopods and vascular surgeons. Because the vascular surgeons that are doing interventional work are not being trained as a radiation worker so they've got bad habits.' [R, HOD]

> 'Many other disciplines do not have the training in radiation that radiologists have.' [R]

The cardiologists expressed differing views on their formal training ranging from not deeming it necessary to receive formal instruction to expressing a definite need to have such instruction. A senior paediatric cardiologist stated, 'We can add some training [on radiation safety] because at the moment there isn't any'. In contrast, an HOD in cardiology expressed the view that there was no need to formally train cardiologists in radiation safety.

Many of the cardiologists and radiologists described the need for proper induction and that radiation safety should be comprehensively covered in CME activities and at conferences. A radiologist from New Zealand reflected that work induction in the radiation workplace was lacking and is needed:

> 'Ah, I think it [induction] often gets forgotten, I think the nurses are orientated, ah, I think it is probably needed; we need a more formal process. And I think in particular the doctors, they go into the lab and it is assumed that the doctors understand about radiation [but] that isn't the case.' [R]

Secondly, the issue of mentorship by more senior specialists was a way for fostering a culture of education and radiation safety training. Junior participants expressed the view that it was the responsibility of senior specialists to provide guidance on education and training in radiation safety:

> 'Well, it's not senior people's responsibility [to get junior doctors to wear PPE], but junior doctors often will take the lead if the more senior doctors do so, if you are a junior interventionalist and your mentor doesn't wear that [PPE] you're less likely to wear them.' [AC]

We have included the views of three international interventionalists who were interviewed at the conferences because they corroborate the views of the South African interventionalists. The experiences of the international interventionalists and their South African counterparts were similar.

Discussion

In this section, we offer a synthesis of what constitutes a CRP based on the themes that emerged. We explore organisational and workplace culture, safety culture and how training and education fosters development of a CRP.

Organisational and workplace culture

Organisational culture in a health facility is a complicated construct that is built on the values, attitudes and norms within an organisation.[10] It is these beliefs, norms, attitudes and values that create the governance framework that prescribes acceptable and expected behaviour within an organisation.[33] The behaviour evolves because of the social constructs of the employees, their professional background and its underpinning ethos, the rules and regulations that govern their workplace and the influence of managerial and administrative structures.[18,19] Organisational behaviour shapes the culture within an organisation and determines the success of the health facility.[34]

The behaviour in the organisation is moulded at an individual and group level.[35] The catheterisation laboratory is a highly contextualised work environment. In this workplace, doctors often leverage a power dynamic over other members of the team. There may also be a gender disparity between team members as the interventionalists are still mainly males and the nurses and radiographers (radiology technicians) are predominately females. This may hinder members of the team such as nurses and radiographers from challenging the non-compliant safety practices of interventionalists. This interdisciplinary power dynamic and gender disparity are characteristics of many workplaces (catheterisation laboratories) in South Africa.

In our findings, participants highlighted this difference, illustrating that other members of the catheterisation laboratory team like nurses and radiographers may feel like they could not challenge doctors. Interventionalists stated that this power imbalance may be a barrier to fostering a CRP in the workplace. Changing this behaviour is difficult and poses a hurdle to establishing a healthy and inclusive responsibility in developing a CRP. However, culture is a dynamic construct and malleable to change.[19] It is this strength that should be leveraged to challenge and change the prevailing culture within the catheterisation laboratory.

Change management principles can help disrupt this hierarchal behaviour. There are several change management strategies that can be used to bring about this change. The steps in the change process proposed by Kotter's model underpin several of these change strategies, making it an ideal change management strategy.[36,37] These steps include: (1) creating urgency for the change process, (2) forming the partnerships needed for the change, (3) formulating a vision and strategy, (4) communicating the change vision, (5) empowering the key stakeholders for the change and action required, (6) establishing short-term goals, (7) consolidating the change and facilitating further change and (8) cementing these attitudes within the culture.[36,37]

Negotiating this change involves communicating the message that every member of the catheterisation laboratory team has a responsibility to their personal safety, the team's safety and the patient's safety. Radiation safety is a collective effort. The change needed to create a CRP depends on everyone's participation and not solely on an individual.[35]

A CRP hinges on a symbiotic relationship between the catheterisation laboratory team and the facility's managerial team. How this relationship forges itself is indicative of the resulting CRP. The relationship between healthcare managers and clinical staff is often contentious because of competing priorities. Healthcare managers often prioritise cost-saving measures, which may compete with safety measures.[38] Health budgets, profit margins and cost-saving measures are an important consideration for health managers, which may shape decisions about procurement of new equipment, maintenance of existing machines and the acquisition of PPE. These objectives can be a barrier to a culture of safety. It is thus important that the head of the catheterisation laboratory must be astute in negotiating resources for safety. This is especially pertinent in resource-constrained environments. The South African regulations stipulate what type of PPE must be worn and this can also be leveraged when negotiating for resources.

Different values compete to create one of the following four organisational cultures (or a combination of them): clan culture (cohesive, participatory leadership), developmental culture (creative, adaptive leadership), hierarchical culture (leadership bound by rules and policies) and rational culture (competitive and goal orientated).[33] Participants suggested that a hierarchical structure should be fostered. This may, however, hinder rather than facilitate a CRP. A hierarchal structure favours tension between doctors and other professionals and between managerial structures and clinicians.[19] A participatory and inclusive approach would be an enabling approach in the co-creation of a CRP between the various team members.[39]

Safety culture

A culture of safety is imperative in any workplace. The attitude towards safety is part of the underpinning values of an organisation and the cornerstone for developing good radiation safety practices. A safety culture is cultivated by the response of HCWs to PPE utilisation and the monitoring structures that keep these practices in check.

Safety and care should interact synergistically with each other. A culture of care is a balance between the science and humanity of medicine.[40] Doctors (and other HCWs) wrestle with the challenge of balancing patient-centred care (PCC) with sophisticated technologies and the necessary safety precautions that accompany it. Participants indicated that they would rather perform interventional procedures without PPE than compromise the care of patients. This action, though seemingly noble, is a breach of safety practices and places the HCW and the patient at risk and in so doing compromises the safety and quality of care. PCC has to be holistic, placing the patients' safety and the quality of care at its centre and drawing on collaboration of all members of the health team.[41]

The occupational health risks associated with ionising radiation may be offset with consistent and appropriate PPE utilisation.[42] Consistent use depends on the availability and fit of the PPE, education in using it correctly and the dexterity to perform procedures with it in place.[15,43] Interventionalists reported attitudes and behaviour to PPE use congruent with findings in the literature and compliance depended on availability and proper fit.

There are personal and systemic factors that influence the use of PPE. The individual primarily makes the decision to use the PPE, but this behaviour may be influenced by the prevailing safety culture within the organisation. A strong safety culture will positively affect the use of PPE.[44] It is thus crucial that the culture within the catheterisation laboratory embraces and encourages such a culture as a norm.

Participants expressed the view that managerial structures were responsible for ensuring provision of PPE. Managerial structures are an important enabler to ensure availability of PPE and to foster a CRP.[8] Together with the person designated to oversee radiation safety in the catheterisation laboratory and the radiation officer, they can ensure that appropriately fitting PPE is procured timely for the catheterisation laboratory team. Provision of PPE facilitates increased uptake of utilisation of PPE.[16]

Dosimeter monitoring is an important component of regulating radiation exposure in the workplace.[7] The monitoring offers the users an opportunity to know the radiation exposure they are receiving and to adjust operating procedures' exposure time to reduce the dose exposure to themselves and the patients.[8] Interventionalists are notorious for poor compliance and inconsistently using their dosimeter badges.[45] Developments in individual dosimetry monitoring such as real-time and wireless monitoring systems will promote better compliance.[2] A CRP would help encourage a different attitude towards using dosimeters and facilitate radiation monitoring in the workplace.

Incorporation of an occupational health surveillance system would be integral to radiation safety monitoring. The unique nature of occupational radiation exposure would require a bespoke medical system for this category of work.[46]

Education and training

Interventionalists need to be educated and trained so that they can understand the risks and benefits of using ionising radiation.[47] Education and training helps stimulate and sustain a CRP. However, training should be regular and consistent to ensure reinforcement and continued adherence.[12] Training aids in instilling autonomy towards radiation safety in radiation operators.[48] The training curriculum on radiation safety is inadequate for South African cardiologists and the gap in this training requires urgent attention.[49,50] The training needs to be included in the formal training curriculum and in the CME programme to ensure consistency in practice.[12] Training provokes improvement in the radiation management skills of operators, which improves the safety of all team members and patients in the catheterisation laboratory.[51] The theme of education and training related to this study is extensively explored elsewhere.[49]

The results from this study are significant because they provide insights into the work and organisational culture in this highly contextualised work environment. They highlight risky occupational practices that can be mitigated with change management strategies. Africa is acquiring high-tech imaging equipment at an accelerated rate, but the workplace culture that should match this change is lagging and poses a potential health risk to a highly skilled workforce and the patients they serve. Furthermore, the study is significant because it offers insights for establishing policies and practice guidelines for developing a CRP in this work environment. These insights are universally applicable.

Conclusion and implications for practice

The increased utilisation of ionising radiation in modern medicine is likely to remain unabated, but the escalation in the number of procedures performed and the increase in the complexity of the procedures will result in operators being exposed to larger cumulative radiation doses. Mitigating this occupational risk will require greater vigilance in promoting a CRP. Developing and strengthening this culture requires a change in organisational and workplace culture towards radiation safety. A well-developed and continuous education programme is imperative to initiating and sustaining a CRP. A well-developed CRP promotes patient safety and improves quality of care. It requires commitment from both the radiology and cardiology fraternities to embrace a paradigm shift towards garnering support for radiation safety in the workplace.

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Competing interests

The authors declare that they have no financial or personal relationship(s) which may have inappropriately influenced them in writing this article.

Authors' contributions

W.I.R. and A.R. conceptualised the study. A.R., W.I.R. and K.E.U. analysed the data. A.R. wrote the first draft of this article. All authors provided input for the article and read and approved the final version. They thank Dr Asta Rau from the Centre for Health Systems Research and Development (University of the Free State), who read the manuscript and offered technical insights into the qualitative methodology. They also thank Rothea Pelser and Annamarie Du Preez for library assistance.

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CHAPTER 7

SYNTHESIS AND CONCLUSION

“27 Tekel: You have been weighed on the scales and found wanting”

Daniel 5:27

7.1 INTRODUCTION

Belshazzar the Babylonian king is hosting a lavish party. The crème de la crème of Babylonian society is revelling at the auspicious occasion. The jovial atmosphere is violently disrupted when a hand appears and inscribes strange text on the wall. The king’s wise men fail to ascribe meaning to the text and Daniel is summonsed to interpret it. He explains that due to the arrogance and unrepentant nature of the Babylonian king he will lose his kingdom. Similarly, in South Africa with regard to a culture of radiation safety in the catheterisation laboratory, the writing is on the wall, and we have been found wanting. This study has highlighted the detrimental effects of unshielded ionising radiation exposure for interventionalists’ eye health; it has drawn attention to the lack of compliance with utilisation of personal protective measures; it has underscored the gaps in interventionalists (particularly cardiologists’) radiation safety training; and explored the deprivation in the culture of radiation protection. The study has also offered insights to regenerating and repairing this cultural paucity.

Complex Adaptive Systems Theory (CAS) was used as a conceptual framework to create a structure to understand the research question. The findings illustrated that there are multiple layers that interact with each other to create meaning and understanding of the phenomenon. It has not been possible to reduce the understanding to a linear model and for this reason CAS has proven an appropriate model that allowed us to explore the inter-relationships between individual behaviour and organisational behaviour. The epistemological position of the research was a pluralistic pragmatic approach. This approached meant that we could peal the various layers within the findings and so try and

understand how they interact with each other and create meaning for each other. How this played itself off in the research outcomes is that we are able to appreciate the convoluted relationships between individual behaviour and the culture of the fraternity and the culture of the organisation (or health facility). The power dynamics between different stakeholders, while not fully explored, are eluded to. Thus, for example, gender tensions are highlighted as well has tension between doctors vs. other staff in the cath. team.
This Chapter is a synthesis of the findings and insights to cataracts in interventionalists in South Africa, their training in radiation safety and perspectives on a CRP. This Chapter brings together a cohesive understanding of how the layers interrelate and feed into and off each other. It proposes a framework for improving radiation safety by interventionalists in the cath. lab and how to develop and sustain a culture of radiation protection.

7.2 PUBLIC HEALTH IMPLICATIONS

7.2.1 Policy implications

The key to strengthening any healthcare system is to develop, implement, regulate and monitor sound policies and guidelines. The policies can be implemented at a macro and micro level and need to be strategic and operational. Strategic policies at a macro level need to, for example, direct what the national regulations need to be in terms of radiation control. The South African national policy framework on radiation safety defines the regulatory framework for the use of IR for medical reasons (Directorate Radiation Control 2015). It stipulates how facilities should be designed and the radiation protection measures that operators have to take (Directorate Radiation Control 2015). There is, however, poor monitoring and enforcement of these regulations (Herbst & Fick 2012). This is largely due to resource constraints.

At a micro and operational level, there needs to be facility policies and guidelines that translate how the macro policies are interpreted and implemented. Developing standard operating procedures (SOPs) for the control of radiation exposure is essential for health facilities where IR is used. It is at this level that the facility management has to be proactive and engage the operators of the catheterisation laboratory. The development of SOPs is the responsibility of the radiation protection officer (medical physics departments), the head of the cath. lab (radiology and cardiology departments) and auxiliary staff such as the radiographers and nursing staff.

7.2.2 Quality of care

The National Core Standards (NCS) for health facilities developed by the South African National Department of Health (NDoH) are a set of standards developed to benchmark healthcare in South African health facilities (Department of Health South Africa 2011). The NCS were developed to improve the quality of care (QC) as we move towards Universal Healthcare Coverage (UHC). There are seven domains in the NCS. The scope of the domains that relate to radiation safety are patient safety, clinical governance and clinical care; leadership and governance; operational management and facilities and infrastructure (Department of Health South Africa 2011).

These three domains speak to how the patient has a right to healthcare that is not harmful to them. Risk from radiological procedures should thus be minimised. It covers how the strategic management provided by hospital management should ensure that leadership is proactive in providing the support structures necessary to plan and mitigate for risks and to improve the quality of care. This means that facility managers are responsible for ensuring that the cath. lab is a safe workplace. They are responsible for the timely maintenance of radiological imaging equipment and for ensuring that PPE is available and in working order.

7.2.3 CRP improves patient safety and quality of care

A CRP becomes a mouthpiece for the patient. Patients are often disempowered in the medical consultation. They may not have the knowledge and insight to negotiate for their management during the consultation and often unquestioningly accept recommendations made by doctors. This power disjunction means that patients may sometimes be subjected to unnecessary radiological procedures which may place them at an increased risk of unwarranted radiation exposure. A CRP places the responsibility on the interventionalists to require rigorous justification for the procedure from the referring doctor (Vano *et al.* 2016). This engagement between the referring doctor and the interventionalist could avert unnecessary radiation exposure to the patient and thus improves patient safety (Meisinger *et al.* 2016). Improving the safety of the patient also improves quality of care and hence quality assurance.

7.2.4 Cost saving measures

In a resource constrained healthcare system cost saving measures are essential to build and strengthen the health care system. Fluoroscopic procedures are expensive and major cost drivers in a facility's budget. New technologies etch their way into the package of services in these resource constrained environments and there has to be a balance between providing cost effective care and technologically advanced care. This makes it even more crucial that these modalities of treatment are provided by skilled personnel in strictly controlled work environments. A CRP will help ensure that such a work environment is created (Rose *et al.* 2018).

7.2.5 Educational considerations

Education and training has been a central theme in the findings of this study and a gap in radiation safety training of South African interventionalists is reported (Rose & Rae 2017). This gap in the training of interventionalists, especially that of cardiologists, is recognised by the fraternity (Brown 2017). Formalised incorporation of radiation safety training is critical to developing an awareness about the effects of radiation exposure in the workplace and how to mitigate for it (Sheyn *et al.* 2008; Kim *et al*. 2010). On-going education is essential to ensure that behaviour is re-enforced (Georges *et al*. 2009).

7.2.6 Bioethical considerations

The principles of bioethics are autonomy, beneficence, non-maleficence and justice (Beauchamp 2003). The principle of autonomy dictates that the patient should be adequately informed of the procedure and the risk it holds (Malone & Zolzer 2016). Patients are often not adequately informed of their risks having a fluoroscopic procedure. In a CRP, this can be averted. Overriding this autonomy is tantamount to medical paternalism which should be avoided at all cost. The principles of beneficence and non-maleficence require that we act in the interest of the patient (Malone & Zolzer 2016). Beneficence dictates that we act in the interest of the patient; and non-maleficence that we avoid harm to the patient. It also raises ethical considerations of the responsibility of the interventionalist to secure the safety of the rest of the cath. lab team by being compliant with using PPE and taking adequate precautions to minimise radiation exposure. Justice speaks to the fairness of distributing the risks and benefits (Malone & Zolzer 2016).

In summary, the public health implications call for policies that aid in providing a framework to guide how radiation protection should be implemented. It considers that in a workplace where a CRP is healthy and thriving, QC is a natural and consequential outflow and promotes better awareness of patient safety. It refocuses attention on the patient and it guards against the commodification of health. Education helps to pull together and cement a CRP. The ethical considerations act as a moral compass to protect the patient and the rest of the cath. lab team.

7.3 OCCUPATIONAL HEALTH IMPLICATIONS

7.3.1 Radiation protection measures

The old occupational health adage, a safe workplace is a happy workplace, holds true once again for workplace safety in the catheterisation laboratory (cath. lab). This highly contextualised workplace is an archetype of the modern medical work environment. It is characterised by modern highly technologically advanced medical equipment that offers promises of longevity and healing. These gains, however, do not come without cost. Ionising radiation (IR) is a physical hazard in the workplace that can have tremendous detrimental health impacts if not used properly. It is thus imperative that the necessary measures are employed to abate the risk attributable to this hazard. The control measures include a change in attitude and practice in the cath. lab; implementation and enforcement of basic control measures such as ALARA; techniques to reduced scatter radiation and overexposure of the patient; and changes in how radiation exposure is monitored and controlled (Durán *et al*. 2013; Meisinger *et al*. 2016). The reinforcement of these principles secures a culture of radiation safety which fuels a CRP (Rose *et al.* 2018).

7.3.2 Dosimetry

There also need to be great vigilance in personal monitoring of radiation exposure (Aerts *et al.* 2014). A culture of wearing personal dosimeters, knowing exposure limits and knowing the dose of radiation they receive need to be inculcated into interventionalists (and other radiation HCWs) (Malone *et al*. 2012). Real-time dosimeter monitoring can improve radiation safety awareness and practices. Coupled with this the radiation protection officers and the departments of medical physics within institutions have to improve their visibility and involvement within institutions to promote and ensure better radiation safety awareness (Rose & Rae 2017; Vano 2015). This will add to the regeneration of a CRP (Rose *et al.* 2018).

7.3.3 Monitoring and surveillance

A monitoring and surveillance programme for radiation workers should be part of the occupational health services in a health facility to mitigate the risk for this hazard (Nasterlack 2011). This service should be part of routine occupational services where facilities render occupational health services. In cases where occupational health services are outsourced it should be included in the bouquet of services purchased. There is a legal and ethical responsibility that the employer ensures that all workers in the variety of work places within the health facility are cared for and protected.

7.3.4 Creating a CRP

Implementing radiation protection measures like using PPE; improving dosimetry; and implementing monitoring and surveillance systems are crucial to securing a safe workplace (Rose *et al.* 2018). The importance of a safe radiation workplace is coupled to macro reasons linked to protecting a health workforce that is scarce and highly skilled (Meisinger *et al.* 2016). This is especially relevant in the context of a resource constrained environment which faces a shortage of skilled healthcare workers (HCWs) (George *et al.* 2009). The workforce is one of the most important components of the health system and ensures that the health system thrives and provides essential services (Hongoro & McPake 2004). Enforcing radiation safety protection measures will help contribute to ensuring that radiation healthcare workers remain highly protected.

There is also downstream beneficiation to securing a safe workplace such as reducing occupational compensation claims and medical litigation by patients harmed within the system. It potentially reduces days lost at work. This may have repercussions for the economy. Averting sequelae such as cataracts reduces the burden on the health systems as well (cf. Chapter 3).

In summary, the occupational health implications call for greater awareness of how to protect interventionalists; it urges greater vigilance in dosimetry; strengthening occupational monitoring and evaluation systems; and fostering a CRP.

7.4 FRAMEWORK FOR RADIATION SAFETY FOR INTERVENTIONALISTS

The following framework is proposed for radiation safety for interventionalists and as a way of generating a culture of radiation protection.

Figure 7.1 Framework for radiation safety in South Africa

In the proposed framework radiation safety hinges on policies at different levels being developed and implemented; it depends on stakeholder engagement at all levels; and is enabled by factors such as availability of appropriate PPE and maintenance of equipment. The safety culture creates a feedback loop with a CRP. A CRP results in better quality of care, a safer workplace, changes in behaviour towards radiation safety, changes in how an organisation responds to the culture of safety and in how occupational health services respond to managing and monitoring radiation HCWs. The system for monitoring and evaluation feeds back into iterating and sustaining the CRP. Education and training forms the cornerstone to keep the complex system functional.

7.5 THE IMPACT OF THE RESEARCH

I had the opportunity to present on the topic of radiation safety in the cath. lab at a paediatric cardiology workshop (Cape Town 2015). The delegates at this workshop indicated that they had previously not given much consideration to radiation safety in the cath. lab and that the talk and the explanation of the study raised an awareness on the topic.

The data were collected at radiology and cardiology conferences in South Africa. Often, I had the opportunity to explain the nature of the study to the delegates which further raised an awareness on the topic. The findings were presented in various scientific journals which are included in the Chapters of this thesis. An editorial (cf. Appendix G) on the article on training highlighted the importance of radiation safety training for interventionalists. (Brown 2017) The findings were further disseminated through presentations at eight different scientific conferences (cf. Appendices H1-H8).

The impact of the research process in itself can have an influence in creating an awareness of the topic being investigated. Anecdotally we found that activities such as setting up the slit lamp to screen eyes, or handing out pamphlets or putting up posters to recruit participants created an interest which raised an awareness on the topic. The impact that the research process itself had, was presented at the International Atomic Energy Association

(IAEA) International Conference on Radiation Protection in Medicine in Vienna, Austria, 11-15 December 2017 (cf. Appendix I).

We hosted a colloquium, *Radiation Safety in South Africa: Too Little but Not Too Late*, from 5 to 6 December 2017. The colloquium brought together experts from different stakeholders in radiation safety, including three international speakers (cf. Appendix J). The meeting was well attended with about 30 to 40 attendees on each day. The audience brought together key stakeholders such as the South African Medical Association (SAMA), the South African Registrars Association (SARA), representatives from the private sector, the National Institute for Occupational Health (NIOH), a representative from the Gauteng Department of Health (Public Health directorate), representatives from the Central University of Technology, the University of the Free State, the University of Pretoria and the University of the Witwatersrand.

A notable absence was the Colleges of Medicine (CMSA) for the Colleges of Radiology, Cardiology and Paediatric Cardiology. They were invited, but declined to attend. The Departments of Cardiology and Radiology at the University of the Free State were also invited, but were not represented. Only one paediatric cardiology interventionalist attended, but only for the session at which he was a speaker. The notable absence of these departments speaks volumes as to the significance these departments consider the importance of radiation safety. It is a situation that bears itself out in the findings of this study. The colloquium highlighted key concepts in radiation protection. It also offered a platform for me to present the key findings of the research in its entirety in one setting. The colloquium's success was also contributed to by the fact that it offered an opportunity for many different departments and disciplines, which attend to different aspects of radiation safety, to meet simultaneously and exchange ideas and network.

The project allowed for building research capacity as well. An ophthalmology registrar assisted with the screening of the eyes and data collection. He used the data to describe the ophthalmological findings in interventionalists (Appendix B) for his research project. I co-supervised his Masters' project.

7.6 STRENGTHS, LIMITATIONS AND AREAS FOR FURTHER RESEARCH

7.6.1 Strengths

A strength of this study is that it used a rigorous methodology to address a complex health systems issue (Rose *et al.* 2017). Qualitative and quantitative methods combined to give a richer and more meaningful understanding of the research question (Shneerson & Gale 2015). The triangulation of the methods and findings allowed us to create the depth needed to better understand the challenges of radiation safety in the cath. lab in South Africa. The novel nature of this research in the South African context further exposed a research area in the South African context which has raised many research questions such as understanding the nature of a CRP in South Africa and the challenges in measuring doses to the eye. The qualitative sample included a diversity of participants which covers the spectrum of categories of interventionalists at different levels of experience. This allows for transferability at different levels in similar contexts *(Rose et al.* 2018).

7.6.2 Limitations

The limitations of this study include the scope of the study and flaws in the methodology (Rose *et al.* 2017). The study included only the interventionalists in the cath. lab. The qualitative and quantitative aspects was delimited to this group. This was because of resource and time constraints and because we were interested in understanding this group as they are most at risk to develop radiation associated cataracts. The perceptions offered are also limited to those of the interventionalists, but we recognise that the entire cath. lab team creates the CRP and therefore, their perspectives are important, but lacking in the qualitative aspect of this study.

The study design was cross sectional and as such has inherent fault lines. It is difficult to draw causal relationships based on this study design. The quantitative sample was not randomly selected which limits drawing conclusions of generalisability. Furthermore, the participants were self-selected into the quantitative component, which introduces a selection bias.

The dose estimates have too many confounders that can be considered for this to be an accurate estimate of the workload exposure. However, we used the best estimates based on work that was done in the South African context.

7.6.3 Areas for future research

This study raised the following questions which can be, and are being, explored in future studies in radiation safety in the South African context:

i. The dose to the eyes should be measured in the South African context to get a more objective estimate of the dose to the eye (a medical physics master's student has already embarked on this project).
ii. The training of interventionalists in radiation safety has been found lacking, but this study did not analyse the curriculum content of the interventionalists and cannot recommend how the content has to be redressed or if there merely needs to be a reinforcing of the existing curriculum. A future study could explore the strengths and weakness of the formalised curriculum for interventionalists (and compare the cardiologists' curriculum to that of radiologists' curriculum).
iii. A future study should explore the policy implications for developing and implementing a CRP.
iv. An interesting and informative study would be to better understand how the organisational structures within health structures respond to and support the establishment and maintenance of a CRP.
v. In light of the advent of the introduction of a policy of UHC in South Africa it will be important to investigate if radiation safety is prioritised to ensure patient and staff safety and thus to improve quality of care.

7.7 CLOSING REMARKS

Delivering quality healthcare in a resource constrained environment like South Africa presents numerous challenges. South Africa, like many low to middle income countries, is seen as a market that is opening up to the influx of the latest technologies. The increase in the availability and utilisation of radiological imaging equipment poses potential health risks to the operators and the patients. Ensuring that operators are adequately skilled to use these technologies is only one aspect of ensuring a safe work environment.

Resource constraints may preclude that the necessary protective gear is readily available. However, there are many precautionary measures that can be implemented that require little layout of capital. These measures call on a change in attitude. They call for a paradigm shift in how interventionalists (and other radiation healthcare workers) think about radiation safety and the collective responsibility they have towards themselves, their colleagues and their patients. In this study, I have demonstrated a high risk for developing cataracts in interventionalists and that the prevailing radiation safety culture has been found wanting. I hope this research will open the eyes of interventionalists and their fraternity to the possibility of change, change that will ensure that the vision for quality healthcare for all South Africans remains crystal clear.

7.8 REFERENCES: CHAPTER 7

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CONFERENCES AND MEETINGS PRESENTED

---

1. Radiation induced lens changes and development of a radiation safety framework for interventionalists. Paediatric Cardiology Workshop, Cape Town (South Africa). 27-21 July 2015.
2. Lens changes and radiation safety practices amongst paediatric cardiologists in South Africa: Preliminary findings. SA Heart Congress. Sun City (South Africa). 10-12 September 2015 (cf. Appendix H1).
3. Radiation associated cataracts and occupational radiation safety practices in interventionalists in South Africa: A multiple methods approach. (Poster presentation). Public Health Association of South Africa (PHASA) Conference East London (South Africa). September 2016 (cf. Appendix H2).
4. 3rd Regional Workshop on Radiation Safety Culture in Health Care: a focus on paediatric radiology. Stellenbosch (South Africa). 3rd November 2016. Facilitated a workshop.
5. Perceptions of Radiation Safety and Training among interventionalists in South Africa. 54th Annual South African Association of Physicists in Medicine and Biology (SAAPMB). 6th -10th September 2016 (cf. Appendix H3).
6. Radiation safety training and education in South Africa: an unseen calamity. Human Resources for the South African Health System Conference. Pretoria (South Africa). 28-29 November 2016 (cf. Appendix H4).
7. Radiation safety practices among South African interventionalists: Reflections on accessing a "hard-to-reach" population. 15th World Congress on Public Health. Melbourne (Australia). 3-7 April 2017 (cf. Appendix H5).
8. Radiation induced lens changes and development of a radiation safety framework for interventionalists. ISGlobal, Barcelona (Spain). 12 May 2017. Departmental presentation.
9. Using multiple methods to understand radiation safety practices in South African interventionalists. Mixed Methods International Research Association (MMIRA) Conference. Pretoria (South Africa) 30 August- 1 September 2017 (cf. Appendix H6).

10. Dosimetry utilisation and practices among South African interventionalists. 55th Annual South African Association of Physicists in Medicine and Biology (SAAPMB). 25-27 September 2017 (cf. Appendix H7).
11. Cataract findings among South African interventionalists. 17th Asia Oceania Congress of Medical Physics (AOCMP) and 38th Annual Conference of Association of Medical Physicists of India (AMPICON) 2017 Congress. Jaipur (India). 4-7 November 2017 (cf. Appendix H8).
12. How research can impact radiation safety culture in South African catheterisation laboratories. IAEA International Conference on Radiation Protection in Medicine. Achieving Changes in Practice. Vienna (Austria). 11-15 December 2017. Presented by Modise Mongane (Appendix I).

COURSES ATTENDED

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1. European Educational Programme in Epidemiology (EEPE). Advanced Epidemiology and Statistical Models. Florence, Italy. 20th June- 8th July 2016.

2. Interviewing and Qualitative Data Analysis. African Doctoral Academy. Stellenbosch, South Africa. January 2017.

3. CONCERT: European Joint Programme for the Integration of Radiation Protection Research. Barcelona, Spain. 3-7 July 2017.

APPENDIX A

ETHICAL APPROVAL FROM THE UFS

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

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Ms M Marais

2015-05-25

REC Reference nr 230408-011
IRB nr 00006240

DR A ROSE
DEPT OF COMMUNITY HEALTH
UFS
BLOEMFONTEIN

Dear Dr A Rose

ECUFS NR 44/2015 **DEPARTMENT OF COMMUNITY HEALTH**
PROJECT TITLE: RADIATION INDUCED LENS CHANGES AND DEVELOPMENT OF A RADIATION SAFETY FRAMEWORK FOR INTERVENTIONALISTS.

1. You are hereby kindly informed that, at the meeting held on 19 May 2015, the Ethics Committee approved the above project.

2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

4. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

5. Kindly use the ECUFS NR as reference in correspondence to the Ethics Committee Secretariat.

Yours faithfully

....
DR SM LE GRANGE
CHAIR: ETHICS COMMITTEE

cc: Prof Rae

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MANUSCRIPT SUBMITTED FOR PUBLICATION

OPHTHALMOLOGICAL FINDINGS IN SOUTH AFRICAN INTERVENTIONALISTS OCCUPATIONALLY EXPOSED TO IONISING RADIATION

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OPHTHALMOLOGICAL FINDINGS IN SOUTH AFRICAN INTERVENTIONALISTS OCCUPATIONALLY EXPOSED TO IONISING RADIATION

ABSTRACT

Background

Ionising radiation (IR) is an occupational hazard for interventionalists working in the catheterisation laboratory. Damage may be as a result of direct or indirect damage to the DNA molecules. The radiation effects can be stochastic or deterministic. Exposure to IR can affect the eye lids by causing skin erythema, mydriasis and punctal occlusion. There may be damage to the corneal epithelium causing irritation and damage. Cataracts commonly develop in the posterior sub-capsular region. Radiation retinopathy is similar to diabetic retinopathy. Dry eye syndrome may develop.

Objectives

This study describes the ophthalmological findings in a group of South African interventionalists occupationally exposed to ionising radiation.

Methods

A prospective cross-sectional study was done. Interventional radiologists (25), adult cardiologists (42) and paediatric cardiologists (31) from across South Africa were recruited at conferences and included in the study. Convenience sampling was done. Participants' eyes were dilated and they had a slit lamp examination. They completed a survey which collected data on the risk factors and co-morbid diseases. Descriptive analysis was done. Ethics clearance was obtained.

Results

The median age of the 98 interventionalists screened was 43.5 years. They worked with radiation for a median of 7.5 years. Cataracts occurred in 10.2% of participants in the left eye and 5.1% occurred in the posterior sub-capsular region. The vitreous was abnormal in about 19.4% of participants. The tear break-up time was abnormal in approximately 48% of participants.

Conclusion

IR is an occupational hazard posing a risk to the eyes of interventionalists. They are at increased risk of cataracts and dry eye syndrome which can affect their occupational performance and quality of life. Education can have a positive influence on the radiation safety practices of interventionalists which could reduce the detrimental effects of IR on their eyes.

Keywords: ophthalmological changes radiation; occupational radiation exposure; eye changes radiation; dry eye disease; radiation cataracts; interventionalists

BACKGROUND

Ionising radiation (IR) is an occupational health risk for radiation healthcare workers. [1] Doctors who routinely use IR to perform fluoroscopic procedures are at increased risks for the health effects due to ionising radiation if they are not properly shielded and protected. [1] These doctors include interventional radiologists, interventional adult and paediatric cardiologists, urologists, orthopaedic surgeons and vascular surgeons.

Radiation induced injury may be acute where changes are observed immediately post radiation exposure; consequential effects appear days to weeks later; and late effects emerge months to years after exposure. [2] IR causes damage by several mechanisms. There may be direct damage to DNA molecules resulting in cell damage and subsequent cell death.[3]

Indirectly water or other molecules may be energised to form free radicles which then cause cell destruction and necrosis. [3] Ionising radiation-induced bystander effects (RIBE) occur when the effects of radiation are seen in adjacent nearby cells which were not directly radiated and this results in DNA molecular damage. [4] The effects of the IR may be stochastic or deterministic. [5] Stochastic effects do not have a threshold limit and include carcinomas, genetic aberrations and cataract formation. [5] Deterministic effects have a threshold limit and include skin changes. [5] The eyes are highly radiosensitive organs and every anatomical structure of the eye may be affected if exposed enough IR.

The initial changes to the lids of the eyes include inflammatory changes, loss of hair around the lids and skin erythema. [6] Persistent eyelid changes include mal-pigmentation, persistent mydriasis and punctal occlusion. [6] Acutely post-radiation exposure to high levels of radiation conjunctival inflammation may occur which may complicate and result in ulceration and infection. [6] Conjunctival injection is a late feature and may result in sub-conjunctival haemorrhages. [6] Loss of conjunctival goblet cells may result in dry eyes. [6]

Radiation can damage the eye film resulting in damage to the corneal epithelial cells. This causes reduced corneal sensation causing discomfort and irritation. Damage may result in ocular surface keratinization, corneal degenerative pannus formation, and eventual corneal perforation. [6]

The lens of the eye is highly radiosensitive and damage to it may result in cataract formation. Evidence suggest that cataracts are formed due to stochastic rather than deterministic radiation effects. [7] The cataracts may be cortical, nuclear or posterior sub-capsular (PSC). Ionising radiation induced cataracts are commonly associated with the PSC region. [8]

The uvea is highly vascular and radiation damage may result in protein leaking from the vessels causing inflammation. [6] Iris neovascularisation causes iris synechia which causes obstruction and subsequent glaucoma. [6] Scleritis is a result of thinning of the sclera. [6]

Radiation retinopathy consequent to high dose radiation exposure may cause changes similar to diabetic retinopathy. [9] Radiation damages the vascular endothelium and causes a retinal vasculopathy and includes retinal hard exudates, haemorrhages, microaneuryms, cotton-wool spots and telangiectasia. [10]

IR is an occupational hazard that poses a threat to the health of the radiation Health Care Worker. The effects on the eye are varied and it is thus important that the eye is shielded to protect it from the potentially disabling effects of IR. The poor use of protective eyewear among interventionalists may be due to insufficient understanding of the health risks but encouraging radiation safety practices may have a positive effect on the eye health of interventionalists. [11]

The aim of this study was to describe the ophthalmological changes in a group of doctors occupationally exposed to ionising radiation.

METHODS

The study was nested in a larger study the methods of which are described elsewhere. [12]

Design: This was a cross sectional prospective study.

Setting: Data were collected at seven conferences across South Africa held in the cities of Bloemfontein, Cape Town, Stellenbosch and Johannesburg.

Population: Interventionalists were defined as doctors who use ionising radiation to perform fluoroscopic procedures. We included 98 of the following interventionalists: interventional radiologists (25), adult cardiologists (42) and paediatric cardiologists (31). There was no randomisation and all eligible willing participants were included in the study.

Data collection: Participants were asked to complete a survey to collect data on their demographics, risk factor profile, occupational profile and training profile. Participants were invited to have an ophthalmological examination. Their eyes were dilated and examined with a slit lamp. Visual acuity was measured with a Snellen Chart. The eye findings were linked to the survey data. Data were collected from June 2015 till September 2017.

Analysis: A descriptive analysis was done using STATA 15®. Averages were estimated for parametric data. Medians and interquartile ranges (IQR) were calculated for nonparametric data. Frequencies were computed for categorical data.

RESULTS

We screened 121 interventionalists and excluded 23 because they had not completed the survey. There are approximately 50 interventional radiologists (IR), 229 adult cardiologists (AC) and 41 paediatric cardiologists (PC) in South Africa according to statistics from the Radiology and Cardiology Societies of South Africa (February 2016). Our cohort thus represented 50% of IR, 18% of AC and 76% of PC. The median age (43.5 years) of interventionalists included in the study was young. The majority of interventionalist were male.

Table 1 Demographic details of 98 interventionalists

	Radiologist n (%)	Adult Cardiologist n (%)	Paediatric Cardiologist n (%)	Total interventionalists N (%)
Number	25 (25.5)	42 (42.9)	31 (31.6)	98 (100)
Age				
Median	43	47.5	41	43.5
IQR	39-49	39-57	37-52	38-52
Minimum	30	31	32	30
Maximum	60	69	69	69
Sex				
Male	13 (52)	37 (88.1)	18 (58.1)	68 (69.4)
Female	12 (48)	4 (11.9)	13 (42.9)	30 (30.6)
Years worked with ionising radiation				
Median	5	9	7	7.5
IQR	<1-15	3-20	1-13	3-15
Min	<1	<1	<1	<1
Max	32	40	27	40

The risk factors were self-reported and as such have some limitation on their interpretation. The weight and height used to calculate body mass index (BMI) was self-reported. There were no risk factors in any of the groups that were greater than is expected for the general population. Myopia was slightly higher in the PCS.

Table 2 Self-reported risk factors and comorbid diseases in 98 interventionalists. Multiple Reponses possible.

	Radiologist n (%)	Adult Cardiologist n (%)	Paediatric Cardiologist n (%)	Total interventionalists N (%)
Number	25 (25.5)	42 (42.9)	31 (31.6)	98 (100)
Smokers	3 (12)	2 (4.8)	2 (6.5)	7 (7.1)

Median years	25	12.5	18	15
IQR	10-25	10-15	15-21	10-25
Median number cigarettes per day	12	6	5	8
IQR	4-15	2-10	2-8	2-12
Consumes alcohol	9 (36)	33 (78.6)	18 (58.1)	60 (61.2)
Median years	20	25	20	20
IQR	15-25	18-30	11-30	15-30
Units per day	2	2	2	2
IQR	1-2	1-3	1-2	2-3
Steroids	0	0	0	0
Diabetes	1 (4)	1 (2.4)	0	2 (2.04)
Self-reported hypertension	2 (8)	1 (2.4)	0	3 (3.1)
BMI				
Median	23.9	25.8	25.4	25.1
IQR	21.2-27.2	23.3-29.0	24.4-26.6	19.4-31.7
Myopia	4 (16)	6 (14.3)	7 (22.6)	17 (17.4)
Glaucoma	0	1 (2.4)	0	1 (1.0)
Uveitis	1 (4)	0	0	1 (1.0)
Trauma	0	0	2 (6.5)	2 (2.04)
Previous eye symptoms	2 (8)	2 (4.8)	2 (6.5)	6 (6.1)

The majority of participants had normal vision and brown eyes. There were no pathologies observed in the iris. The prevalence of cortical and PSC cataracts together was 18.8%. The vitreous was abnormal in 19.3% of participants. The optic nerve was abnormal in 15.3% of participants. The tear breakup time was reduced in approximately 48% of participants suggestive of dry eye disease.

Table 3 Ophthalmological findings in 98 interventionalists. More than one finding possible in a participant.

	Right eye n (%)	**Left eye n (%)**
Visual acuity		
Normal vision (≥ 0.5)	91 (92.9)	90 (93.9)
Abnormal (< 0.5)	7 (7.1)	8 (8.1)
Lid		
Normal	78 (79.6)	78 (79.6)
Meibomian gland dysfunction	16 (16.3)	16 (16.3)
Allergic eye disease	3 (3.1)	3 (3.1)
Anatomical defect	1 (1.0)	1 (1.0)
Conjunctiva		
Normal	90 (91.8)	91 (92.8)
Pingueclae	3 (3.1)	3 (3.1)
Pterygium	2 (2.0)	0
Reactive conjunctiva	2 (2.0)	3 (3.1)
Other	1 (1.1)	1 (1.0)
Iris		
Brown	73 (74.5)	73 (74.5)
Blue	19 (19.4)	18 (18.4)
Green	6 (6.1)	7 (7.1)
Lens (cataract)[1]		
Posterior sub-capsular (PSC)	1 (1.0)	**5 (5.1)**
Cortical	8 (8.2)	**12 (12.2)**
Nuclear	21 (21.4)	18 (18.4)

Vitreous		
Normal	79 (80.6)	79 (80.6)
Signs of syneresis	**16 (16.3)**	**16 (16.3)**
Posterior vitreous detachment	**3 (3.1)**	**2 (2.0)**
Degeneration	0	**1 (1.0)**
Ocular nerve		
Normal	83 (84.7)	83 (84.7)
Features of myopia	9 (9.2)	9 (9.2)
Crowded disc	6 (6.1)	6 (6.1)
Fundus		
Normal	97 (98.9)	98 (100)
Abnormal	1 (1.1)	0
Tear breakup time		
Normal (> 10 sec)	49 (52.1)	52 (55.3)
Reduced (≤10 sec)	**37 (39.4)**	**34 (36.2)**
Severe (<6 sec)	**8 (8.5)**	**8 (8.5)**

[1] Not controlled for age.

DISCUSSION

Interventionalists are at increased risk of developing radiation induced cataracts. [7] Radiation induced cataracts are commonly described to occur in the PSC. [1] In a French study the prevalence of PSC cataracts was estimated at 17%. [13] In similar studies the prevalence of PSC cataracts are noted to be as high as 38% and 52%. [7] The prevalence of PSC cataracts in our cohort was lower than reported in other studies. [13] This may be because of a lower median age and lower median number of years exposed to occupational ionising radiation. The findings are clinically significant as it suggests that even at a lower median age and years of IR exposure participants are at risk of developing cataracts early and this may be occupationally related. Cataracts associated with occupational exposure to IR are typically described to occur more commonly in the left eye and in the PSC region but recent evidence suggests that cortical cataracts may also be associated with IR exposure. [14] The prevalence for cataracts (cortical and PSC) was 17.3% which further adds weight to our argument that the presence of these cataracts is of clinical significance.

The Tear Film and Ocular Surface Society (TFOS) defines dry eye disease (DED) as a multifactorial disease of the ocular surface due to loss of homeostasis of the tear film with accompanying eye symptoms. [15] The prevalence varies between 5-50% and varies between regions. [15] In an Australian study the prevalence of DED varied between 5.5-16.3% depending on the test used to make the diagnosis. [16] In a Japanese study the prevalence was higher in women (21.6%) compared to men (12.5%). [17] The diagnosis of DED is made on the basis of symptomatology and one or more homeostatic marker results. [15] A clinical diagnosis of DED was made in this study but we did corroborate our findings by asking participants to report on their symptomatology. The tear break time (TBUT) was measured and used as a proxy suggestive of DED. We used a cut-off of ≤ 10 seconds to indicate a reduced TBUT with moderate impairment and ≤ 6 seconds for severely reduced TBUT. [18] DED is a debilitating socio-medical condition that affects the quality of life of those affected. [19] This has serious implications for the quality of life of interventionalists as the TBUT was approximately 48% and may be related to occupational IR exposure.

Cataracts, dry eye syndrome and other ophthalmological changes that may be related to occupational IR exposure are not life threatening and are generally surgically or medically treatable and even curable but they may detrimentally affect quality of life and occupational

performance. [19]They have public health and economic implications as they may affect work performance and they are costly to treat. [15] This necessitates implementing measures to prevent these outcomes.
There is a need to improve awareness of the health risk to the eye among interventionalists so as to reduce the complications associated with occupational IR exposure. [11] General practitioners, ophthalmologists and occupational health physicians should also be vigilant in considering this risk as part of routine screening and examination of interventionalists.
Implementation of these preventative measures requires developing and sustaining a culture of radiation protection. [20] This can be achieved by formally including radiation physics and radiobiology in the training curriculum of interventionalist. A South African study showed that there was a gap in the training on radiation safety in South African cardiologists. [21] Radiation safety training however also needs to be ongoing for it to be effective. [22] Adequate education on radiation safety mitigates the occupational risk of IR exposure to interventionalists working in the catheterisation laboratory. [1]

CONCLUSION

Interventionalists are at increased risk of developing ophthalmological complications due to occupational exposure of ionising radiation. They are at increased risk to develop dry eye disease and cataracts especially in the posterior sub-capsular region. They need to be screened regular for these ophthalmological changes. Mitigating factors should be implemented and enforced to protect them from this occupational hazard. Formalising radiation safety training in their training curriculum is a necessary mitigating preventative strategy.

ABBREVIATIONS

BMI: Body Mass Index
CRP: Culture of Radiation Protection
DED: Dry Eye Disease
IR: Ionising radiation
IQR: Interquartile Range
PSC: Posterior Sub-capsular
TBUT: Tear Break-up Time
TFOS: Tear Film and Ocular Surface Society

ETHICS APPROVAL

All participants voluntarily participated in the study and gave informed consent for the survey and the ophthalmological screening. Participants were free to withdraw from any part of the study at any time. The study was approved by the Health Sciences Research Ethics Committee of the University of XXX (XXX- removed to de-identify will be added later).

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

COMPETING INTERESTS
The authors declare they have no competing interests.

FUNDING
Removed to de-identify will be added later.

AUTHOR CONTRIBUTIONS
Removed to de-identify will be added later

ACKNOWLEDGEMENTS
Not applicable

CONFLICT OF INTEREST
All authors declare that there are no conflicts of interest.

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ONLINE SURVEY OR A PAPER BASED VERSION

EvaSys	Radiation Effects and Radiation Safety Training amongst Interventionalists	Electric Paper
University of the Free State EVASYS External and Internal Users	EvaSys 2015 Radiation Effects and Radiation Safety Training amongst Interventionalists (andre_hardekopie)	

Mark as shown: ☐ ☒ ☐ ☐ ☐ Please use a ball-point pen or a thin felt tip. This form will be processed automatically.
Correction: ☐ ■ ☐ ☒ ☐ Please follow the examples shown on the left hand side to help optimize the reading results.

1. Radiation Effects and Radiation Safety Training amongst Interventionalists: André Rose

You have been asked to participate in a research study. Please note that by completing this questionnaire you are voluntarily agreeing to participate in this research study. Ethics clearance was obtained from the Faculty of Health Sciences Committee and the clearance number is 44/2015. Your information and your data will be treated confidentially at all times. We are asking that you provide contact details as we would like to contact you later and offer you a free cataract screening test. Your name will not be published. The results of the study may be published.

Thank you for your willingness to participate.

André Rose

2. Demographics

2.1 **Sex** ☐ Male ☐ Female

2.2 **Age in numbers (ex. 24)**

☐☐

2.3 **Date of birth** (dd/mm/yyyy)

☐☐/☐☐/☐☐☐☐

2.4 **Which city/town do you work in?**

☐ Bloemfontein ☐ Cape Town ☐ Durban
☐ Johannesburg ☐ Port Elizabeth ☐ Pretoria
☐ Stellenbosch ☐ Pietermaritzburg ☐ Other

2.5 **Specify which city**

[ ]

3. Medical history

3.1 **Weight in kilograms e.g. 70kg**

☐☐☐

3.2 **Height in centimeters e.g. 178cm**

☐☐☐

3.3 **Do you suffer from any of the following medical conditions (mark all that are applicable):**

☐ Diabetes ☐ Hypertension ☐ Myopia
☐ Cancer ☐ Glaucoma ☐ Arthritis
☐ Obesity ☐ Cataracts ☐ Congenital opacities of the lens
☐ Rheumatoid arthritis ☐ Auto immune disease ☐ chronic diarrhea
☐ none

3. Medical history [Continue]

3.4 **Have you received treatment from any of the following treatment modalities (mark all that are applicable):**
- ☐ Chemotherapy
- ☐ Radiotherapy
- ☐ Nuclear medicine procedures
- ☐ Phototherapy e.g. for skin conditions
- ☐ none

3.5 **Do you have a history of any eye conditions (mark all that are applicable)**
- ☐ Uveitis
- ☐ Eye infection
- ☐ Trauma to the eye
- ☐ Cataracts
- ☐ Family history of eye conditions
- ☐ no

3.6 **Are you taking any of the following medication on a chronic bases (mark all that are applicable):**
- ☐ Oral Steroids
- ☐ Oral oestrogen contraception
- ☐ none

3.7 **Have you had any of the following procedures to the eye (mark all that are applicable):**
- ☐ Removal of cataracts
- ☐ Any surgery to the eye
- ☐ No

3.8 **Have you ever had screening for cataracts?** ☐ Yes ☐ No

3.9 **If yes what were the findings** ☐ Lens changes ☐ No lens changes ☐ Other

3.10 **Please specify what the findings were**

4. Habits

4.1 **Do you currently smoke?** ☐ Yes ☐ No

4.2 **If you currently smoke or have smoked in the past; how many years have you smoked for?**

4.3 **How many cigarettes do you smoke on average per day**

4.4 **Do you drink alcohol on a regular basis?** ☐ Yes ☐ No

4.5 **How much alcohol do you drink on average in a week?**
- ☐ Less than or one glass/unit per week
- ☐ 2-4 glasses/ units per week
- ☐ 5-7 glasses/ units per week
- ☐ 8-10 glasses/ units per week
- ☐ More than 10 glasses/units per week

4.6 **Approximately how many years have you been drinking alcohol?**

5. Non occupational radiation exposure

5.1 **Are you exposed to any sources of radiation?**
- ☐ No
- ☐ Not sure
- ☐ Regular outdoor sun exposure e. g. sport, surfing
- ☐ Previous radiation procedure to the head e.g. CT scan or X-ray
- ☐ Hobbies
- ☐ Other

5.2 **Please specify which sources of radiation you are exposed to**

5. Non occupational radiation exposure [Continue]

5.3 **Do you consistently wear dark glasses or shaded prescription glasses when outdoors?**
☐ Yes ☐ No

6. Occupation

6.1 **What is your occupation?**
☐ 1. Interventionalist radiologist/ fellow
☐ 2. Interventionalist adult cardiologist/ fellow
☐ 3. Electrophysiologist /fellow
☐ 4. Interventionalist paediatric cardiologist/ fellow
☐ 5. Specialist physician
☐ 6. Family medicine physician
☐ 7. General paediatrician
☐ 8. Other

6.2 **Please specify your occupation**

6.3 **How many years have you been working in this capacity? (Including time while training).**

6.4 **Do you work in the:** ☐ Public sector ☐ Private sector ☐ Both

6.5 **On a scale of 1-10 (where 1 = no exposure and 10 = maximum workload) how would you rank your occupational radiation exposure (interventional workload)?**

6.6 **Do you work with fluoroscopy guided interventional procedures?** ☐ Yes ☐ No

6.7 **How many years have you worked with fluoroscopy guided interventional procedures?**

6.8 **Are you left handed or right handed?** ☐ Left ☐ Right

Regarding arterial access when performing fluroscopy please consider the following:

		Used less than 50% of the	Used more than 50% of the	Never used
6.9	**Radial artery access**	☐	☐	☐
6.10	**Femoral artery access**	☐	☐	☐

6.11 **Do you use bi-plane equipment?** ☐ Yes ☐ No

6. **Occupation** [Continue]

6.12 **If yes for how many years have you been using it?**

7. **Occupation[Continue]**

Typical fluoroscopy work load in an average week for a radiologist. Answer those that apply to you.

Renal arteriogram

7.1 **Average no. of procedures/ week e.g. 10**

7.2 **Average time for the procedure e.g. 120 min**

7.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

7.4 **Av. Number of frames per series e.g. 100**

Transferal outflow

7.5 **Average no. of procedures/ week e.g. 10**

7.6 **Average time for the procedure e.g. 120 min**

7.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

7.8 **Av. Number of frames per series e.g. 100**

Percutaneous renal stone removal

7.9 **Average no. of procedures/ week e.g. 10**

7.10 **Average time for the procedure e.g. 120 min**

7.11 **Av. Number of series or cine runs per procedure e.g. 10-20**

7. Occupation[Continue] [Continue]

7.12 **Av. Number of frames per series e.g. 100**

PTA leg/arm/renal

7.13 **Average no. of procedures/ week e.g. 10**

7.14 **Average time for the procedure e.g. 120 min**

7.15 **Av. Number of series or cine runs per procedure e.g. 10-20**

7.16 **Av. Number of frames per series e.g. 100**

ERCP (Endoscopic retrograde cholangiopancreatography)

7.17 **Average no. of procedures/ week e.g. 10**

7.18 **Average time for the procedure e.g. 120 min**

7.19 **Av. Number of series or cine runs per procedure e.g. 10-20**

7.20 **Av. Number of frames per series e.g. 100**

8. Occupation [continue]

Hickman line

8.1 **Average no. of procedures/ week e.g. 10**

8.2 **Average time for the procedure e.g. 120 min**

8.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

8. Occupation [continue] [Continue]

8.4 **Av. Number of frames per series e.g. 100**

Four vessel angiogram

8.5 **Average no. of procedures/ week e.g. 10**

8.6 **Average time for the procedure e.g. 120 min**

8.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

8.8 **Av. Number of frames per series e.g. 100**

Nephrostogram/my

8.9 **Average no. of procedures/ week e.g. 10**

8.10 **Average time for the procedure e.g. 120 min**

8.11 **Av. Number of series or cine runs per procedure e.g. 10-20**

8.12 **Av. Number of frames per series e.g. 100**

Aneurysm embolization

8.13 **Average no. of procedures/ week e.g. 10**

8.14 **Average time for the procedure e.g. 120 min**

8.15 **Av. Number of series or cine runs per procedure e.g. 10-20**

8.16 **Av. Number of frames per series e.g. 100**

9. Occupation [continue]

PTC (Percutaneous trans-hepatic cholangiography

9.1 **Average no. of procedures/ week e.g. 10**

9.2 **Average time for the procedure e.g. 120 min**

9.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

9.4 **Av. Number of frames per series e.g. 100**

Six vessel angiogram

9.5 **Average no. of procedures/ week e.g. 10**

9.6 **Average time for the procedure e.g. 120 min**

9.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

9.8 **Av. Number of frames per series e.g. 100**

Oesophageal dilatation

9.9 **Average no. of procedures/ week e.g. 10**

9.10 **Average time for the procedure e.g. 120 min**

9.11 **Av. Number of series or cine runs per procedure e.g. 10-20**

9.12 **Av. Number of frames per series e.g. 100**

Permanent catheter revision

9.13 **Average no. of procedures/ week e.g. 10**

9. **Occupation [continue]** [Continue]

9.14 **Average time for the procedure e.g. 120 min**

9.15 **Av. Number of series or cine runs per procedure e.g. 10-20**

9.16 **Av. Number of frames per series e.g. 100**

10. Occupation [continune]

Arch of aorta

10.1 **Average no. of procedures/ week e.g. 10**

10.2 **Average time for the procedure e.g. 120 min**

10.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

10.4 **Av. Number of frames per series e.g. 100**

Transbachial outflow

10.5 **Average no. of procedures/ week e.g. 10**

10.6 **Average time for the procedure e.g. 120 min**

10.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

10.8 **Av. Number of frames per series e.g. 100**

10.9 **Other: specify**

10. Occupation [continue]   [Continue]

10.10 **Average no. of procedures/ week e.g. 10**

10.11 **Average time for the procedure e.g. 120 min**

10.12 **Av. Number of series or cine runs per procedure e.g. 10-20**

10.13 **Av. Number of frames per series e.g. 100**

10.14 **Other: specify**

10.15 **Average no. of procedures/ week e.g. 10**

10.16 **Average time for the procedure e.g. 120 min**

10.17 **Av. Number of series or cine runs per procedure e.g. 10-20**

10.18 **Av. Number of frames per series e.g. 100**

11. Occupation [continue]

Typical fluoroscopy work load in an average week for a cardiologist/electrophysiologist.
Diagnostic angiography

11.1 **Average no. of procedures/ week e.g. 10**

11.2 **Average time for the procedure e.g. 120 min**

11.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

11. Occupation [continue]   [Continue]

11.4 **Av. Number of frames per series e.g. 100**

Ablation

11.5 **Average no. of procedures/ week e.g. 10**

11.6 **Average time for the procedure e.g. 120 min**

11.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

11.8 **Av. Number of frames per series e.g. 100**

Complex PCI involving rotablation

11.9 **Average no. of procedures/ week e.g. 10**

11.10 **Average time for the procedure e.g. 120 min**

11.11 **Av. Number of series or cine runs per procedure e.g. 10-20**

11.12 **Av. Number of frames per series e.g. 100**

CTO

11.13 **Average no. of procedures/ week e.g. 10**

11.14 **Average time for the procedure e.g. 120 min**

11.15 **Av. Number of series or cine runs per procedure e.g. 10-20**

11.16 **Av. Number of frames per series e.g. 100**

12. Occupation [continue]

Percutanteous prothetic valve implantation

12.1 **Average no. of procedures/ week e.g. 10**

12.2 **Average time for the procedure e.g. 120 min**

12.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

12.4 **Av. Number of frames per series e.g. 100**

Percutaneous coronary intervention

12.5 **Average no. of procedures/ week e.g. 10**

12.6 **Average time for the procedure e.g. 120 min**

12.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

12.8 **Av. Number of frames per series e.g. 100**

Congentital heart defect repair

12.9 **Average no. of procedures/ week e.g. 10**

12.10 **Average time for the procedure e.g. 120 min**

12.11 **Av. Number of series or cine runs per procedure e.g. 10-20**

12. **Occupation [continue]** [Continue]

12.12 **Av. Number of frames per series e.g. 100**

13. Occupation [Continue]

13.1 **Other: specify**

13.2 **Average no. of procedures/ week e.g. 10**

13.3 **Average time for the procedure e.g. 120 min**

13.4 **Av. Number of series or cine runs per procedure e.g. 10-20**

13.5 **Av. Number of frames per series e.g. 100**

14. Occupation [Continue]

Typical fluoroscopy work load in an average week for a paediatric cardiologist.

Diagnostic angiography

14.1 **Average no. of procedures/ week e.g. 10**

14.2 **Average time for the procedure e.g. 120 min**

14.3 **Av. Number of series or cine runs per procedure e.g. 10-20**

14.4 **Av. Number of frames per series e.g. 100**

Interventional procedure

14. Occupation [Continue] [Continue]

14.5 **Average no. of procedures/ week e.g. 10**

14.6 **Average time for the procedure e.g. 120 min**

14.7 **Av. Number of series or cine runs per procedure e.g. 10-20**

14.8 **Av. Number of frames per series e.g. 100**

14.9 **Other: specify**

14.10 **Average no. of procedures/ week e.g. 10**

14.11 **Average time for the procedure e.g. 120 min**

14.12 **Av. Number of series or cine runs per procedure e.g. 10-20**

14.13 **Av. Number of frames per series e.g. 100**

15. Use of personal protective equipment (PPE)

Consider your use of the following PPE and tick the most appropriate block

	Never	<30% of the time	31-50% of the time	51-70% of the time	71-100% of the time
15.1 **Ceiling suspended screen**	☐	☐	☐	☐	☐

15.2 **How many years have you used a ceiling suspended screen?**

15. Use of personal protective equipment (PPE) [Continue]

	Never	<30% of the time	31-50% of the time	51-70% of the time	71-100% of the time
15.3 **Lead apron**	☐	☐	☐	☐	☐

15.4 **How many years have you used the lead apron?**

15.5 **Does the lead apron fit well?** ☐ Yes ☐ No

	Never	<30% of the time	31-50% of the time	51-70% of the time	71-100% of the time
15.6 **Thyroid shield**	☐	☐	☐	☐	☐

15.7 **How many years have you used a thyroid shield?**

15.8 **Does the thyroid shield fit well?** ☐ Yes ☐ No

	Never	<30% of the time	31-50% of the time	51-70% of the time	71-100% of the time
15.9 **Lead glasses/ lead visor**	☐	☐	☐	☐	☐

15.10 **How many years have you used lead glasses?**

15.11 **Do the lead glasses/ visor fit well?** ☐ Yes ☐ No

16. Use of personal protective equipment (PPE) [continue]

If you do not always use PPE tick all the options that apply to you:

16.1 **Ceiling suspended screen availability**

☐ **It is never available**
☐ **It is difficult to do procedures with**
☐ **It offers no protection**
☐ **I have never been taught how to use it**
☐ n/a

16. Use of personal protective equipment (PPE) [continue] [Continue]

16.2 **Lead apron availability**
- ☐ **It is never available**
- ☐ **It is difficult to do procedures with**
- ☐ **It offers no protection**
- ☐ **It never fits me properly**
- ☐ **I have never been taught how to use**
- ☐ n/a

16.3 **Thyroid shield availability**
- ☐ **It is never available**
- ☐ **It is difficult to do procedures with**
- ☐ **It offers no protection**
- ☐ **It never fits me properly**
- ☐ **I have never been taught how to use it**
- ☐ n/a

16.4 **Lead glasses/visor availability**
- ☐ **It is never available**
- ☐ **It is difficult to do procedures with**
- ☐ **It offers no protection**
- ☐ **It never fits me properly**
- ☐ **I have never been taught how to use it**
- ☐ n/a

17. Personal radiation dosimetry

17.1 **Do you use a personal radiation dosimeter?**
- ☐ 1. Never
- ☐ 2. Less than 30% of the time
- ☐ 3. Between 31-50% of the time
- ☐ 4. Between 51-70% of the time
- ☐ 5. Between 71-100% of the time

17.2 **Do you use more than one personal radiation dosimeter?**
- ☐ Yes
- ☐ No

17.3 **Where do you place the personal radiation dosimeter?**
- ☐ Over the lead apron
- ☐ Under the lead apron

17.4 **If you use a second personal radiation dosimeter where do you place it?**
- ☐ Over the lead apron
- ☐ Under the lead apron

17.5 **What was your typical personal radiation dosimetry levels in the past year?**
- ☐ I do not know

17.6 _______ mSv/year

17.7 **What do you think is the maximum radiation dose that you should be exposed to in one year?**
- ☐ I do not know

17.8 _______ mSv/year

18. Radiation safety training

18.1 **Do you think that radiation exposure is an important consideration for you in your work?**
- ☐ Not important
- ☐ Somewhat important
- ☐ Important
- ☐ Very important

18.2 **Did you receive specific training in radiation safety during your training as a doctor/ interventionist?**
- ☐ Yes
- ☐ No
- ☐ I cannot remember
- ☐ Not applicable

18.3 **Do you think this training was adequate?**
- ☐ Yes
- ☐ No
- ☐ Not applicable

18.4 **Should radiation safety be part of the formal training of interventionalists/doctors training?**
- ☐ Yes
- ☐ No
- ☐ It does not matter, one learns about it from experience

18. Radiation safety training [Continue]

18.5 **Did you receive an induction about radiation protection when you started working?**
- ☐ Yes
- ☐ No
- ☐ Not sure
- ☐ Not applicable

18.6 **Have you ever had a talk about how you can protect yourself from radiation exposure in the workplace?**
- ☐ Yes
- ☐ No
- ☐ Not sure
- ☐ Not applicable

18.7 **Have you ever been informed about how you can protect your patients from radiation exposure?**
- ☐ Yes
- ☐ No
- ☐ Not sure
- ☐ Not applicable

18.8 **Have you been shown how to use X-ray equipment?**
- ☐ Yes
- ☐ No
- ☐ Not sure
- ☐ Not applicable

19. Contact information: so we can contact you later for a free slit lamp cataract screening test.

19.1 If you are interested in a free slit lamp cataract screening test, then select YES and complete the questions that follow. If not, select NO and submit
- ☐ Yes
- ☐ No

19.2 **Name:**

19.3 **Email address:**

19.4 **Telephone:**

This is the end of the questionnaire. Thank you for participating in the survey.

APPENDIX D

OPHTHALMOLOGICAL SCREENING DATA FORM

OPHTHALMOLOGY REFERRAL CLINIC   OFTALMOLOGIE VERWYSINGS KLINIEK

Name/Naam: ______________________ Dat: ______________

DOB / Geboorte datum: ______________________ UM nr: ______________

Complaint/Klagte: ______________________________________

1. Alg Toestand__________ 2. Voedingstat__________ 3. Psig stat__________

Medical history/Mediese geskiedenis: ______________________

Diabetes		Rx
Hipertensie		Rx
TB		Rx
Epilepsie		Rx
Asma		Rx
Ander		Rx

Allergies/Allergieë: ______________________

Examination/Ondersoek:

__________ VA without / sonder __________

__________ VA with / met __________

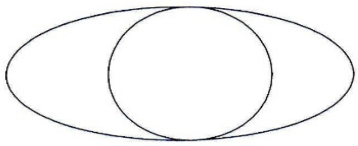
__________ Lids + tarsus / Lede + tarsus __________

__________ Conjunctiva / Konjunktiva __________

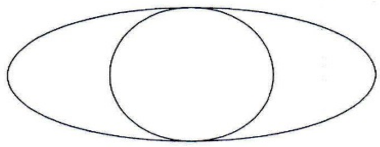
__________ Pupil __________

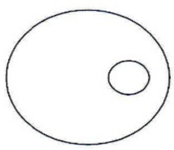
__________ Cornea / Kornea __________

__________ AC / VK __________

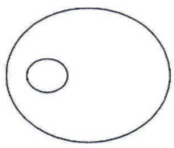


Lens:
Vitreous:

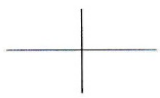




Disc
C:D
Macula
Vessels
Periphery



Gonio:
Movements/Bewegings:



__________ Tear break up time / Traanopbreektyd: __________

__________ Pressures/Drukke: __________

__________ Autorefr: __________

__________ Diagnosis/Diagnose: __________

Dilatasie: ______________________

Doctor's notes and prescriptions / Dokters notas en voorskrifte:

Review/Opvolg: ______________________

APPENDIX E

DATA COLLECTION SHEET

Radiation Induced Lens Changes and Development of a Radiation Safety Framework for Interventionalists.

	Question	**Code**
1	Age _______________	
2	Sex: Male Female	
3	Occupation: Radiologist Cardiologist	
4	Number of years worked as cardiologist or radiologist:	
5	City you work in:	
6	Where do you work: Public sector Private sector Both	

APPENDIX F

INTERVIEW SCHEDULE

Focus group discussion guide

The participants will be asked the three basic questions below. Depending on the responses from the participants the researcher will probe with certain questions if these questions do not emerge from the discussion.

1. How do you think that radiation exposure can affect your health?
    a. Probe questions:
        i. How can radiation affect your eyes?
2. What do you understand by having a culture of radiation safety in the workplace?
    a. Probe questions:
        i. Is there such a culture in your workplace?
        ii. Do you have such a culture?
3. How do you protect yourself from the effects of radiation exposure?
    a. Probe questions:
        i. What personal protective equipment do you use?
        ii. Is this PPE readily available?
        iii. Why is the PPE not readily available?
        iv. Do you always use the PPE? If, not why?
4. How do you think the training on radiation safety can be improved for interventionalists?

CVJAFRICA CARDIOVASCULAR JOURNAL OF AFRICA • Volume 28, No 3, May/June 2017 139

Editorial

Radiation safety: time to act

SC Brown

It is an acknowledged fact that interventional cardiologists have the highest occupational radiation exposure of all medical professionals. As a matter of fact, interventional cardiac procedures represent the largest contribution of ionising radiation source after computerised tomography and nuclear medicine. Modern therapies and the need for quality radiological imaging have dramatically increased the use of ionising radiological imaging in cardiology.

Radiation safety is rapidly becoming an important issue. The first major drive towards this goal gave rise to the establishment of the international radiation protection association (IRPA) in late 2002, leading to the publication of guiding principles for establishing a radiation-protection culture.[1] The aim of such a culture is to substantially reduce radiation dose to both patients and staff.

Biological effects of radiation

It should be taken into account that patients, technicians, nurses and cardiologists are at risk of these effects. There are two categories of unwanted effects when exposed to ionising radiation:

- Deterministic effects: here an identifiable threshold level exists and the severity of effect intensifies with increasing dosage of exposure. Biological effects occur as a result of cell damage and death. Symptoms are related to the extent of cell death. Dermatological effects and cataracts are typical examples of deterministic effects.
- Stochastic effects: these follow a linear non-threshold theory, which essentially means these effects occur by chance. There is no minimum exposure, and risk increases linearly with radiation dose received. Cancer in an exposed individual occurs due to the mutation of cells as a result of chromosomal translocations.

Health hazards

- Cataracts: posterior sub-capsular cataracts have been reported in 50% of cardiologists and 41% of nurses working in interventional catheterisation laboratories.[2] The authors observed that lens changes were associated with several years of work without eye protection and cumulative doses were in the range of 0.1 to 18.9 Sv.
- Brain tumours: several case reports of brain tumours have emerged in the literature and have occurred in more than 31 physicians working in catheterisation laboratories, mostly interventional cardiologists.[3-5] Of particular interest is the fact that up to 85% of brain tumours were left sided – the area of the head closest to the X-ray tubes. The physicians in this report were exposed to ionising radiation over a period of 12 to 30 years.
- Other: thyroid changes and neoplasms, hypertension, hyperlipidaemia, reproductive and even psychological effects have been described.[6-8] Hair loss and skin damage may follow prolonged exposure during fluoroscopic procedures. These vary from temporary erythema to necrosis of the skin and subcutaneous tissues. A single dose of 6–8 Gy on a 5-cm^2 field may trigger tissue damage.[9] It should be noted that the hands of operators receive the highest exposure during cardiac interventions.

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Food for thought

The article by Rose *et al*. (page 196) in this edition of the journal gives a sobering perspective on radiation protection in South Africa.[10] The study included public- and private-sector radiologists and cardiologists. It is obvious from the results that a complacency and lack of knowledge regarding radiation safety is prevalent among cardiologists.

In essence, the results show that little or no formal education for cardiology fellows regarding radiation protection is offered during training. Even more disconcerting is the fact that even though heads of units (both adult and paediatric cardiology) acknowledged the need for radiation safety measures and training, precious little appears to be done to address the issue. This is compounded by the fact that junior fellows expressed concerns regarding the effects of radiation exposure on their long-term health, and that only one question regarding radiation safety appeared in the national exit examinations for cardiologists.

What should be done?

It is mandatory to establish a radiation safety culture for cardiologists. Basic training should be available for all healthcare workers in the catheterisation laboratory, and ongoing radiation safety courses should be obligatory. Unless training units actively promote and examine fellows on radiation safety, little will change.

Simple precautions to minimise exposure to patients, staff and operators should be instituted as enshrined in the ALARA (as low as reasonably achievable) principles. The American Heart Association statement on enhancing radiation safety in cardiovascular imaging may be followed as a guideline – clear strategies and action plans to reduce exposure to patients and staff should be followed.[11] Institutional insensitivity should also be addressed and the proper fundamental principles of radiation protection should be rigidly applied.

The profession should be concerned about how interventionists and young cardiologists with long careers ahead of them can avoid the ravages of exposure to ionising radiation. Over a lifetime, how much radiation exposure is acceptable and how much are we at risk of the complications of prolonged and recurrent exposure? The time to act is now.

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PRESENTATION AT SA HEART CONGRESS

Spring 2015 Volume 12 • Number 4
SA heart

66 (8%); p=0.02, respectively]. Multivariable analysis using logistic regression showed that cardiogenic shock [OR 5.92 {95% CI 2.86 - 12.28}; p<0.001], cardiac failure [OR 4.80 {95% CI 2.61 - 8.82}; p<0.001], cerebrovascular accident [OR 3.95 {95% CI 1.48 - 10.58}; p=0.01], complete heart block [OR 3.50 {95% CI 1.22 - 10.09}; p=0.02], increasing age [OR 1.04 {95% CI 1.02 - 1.01}; p<0.001] and a greater discharge cTnT value [OR 1.61 (95% CI 1.01 - 2.56); p=0.04] conferred a significantly higher odds of mortality.

Conclusions: This study shows that, in addition to cardiogenic shock, cardiac failure, cerebrovascular accident, complete heart block and increasing age, higher cTnT level at discharge is an important independent predictor of mortality in patients with AMI, and could further improve the prognostic accuracy of admission values of cTnT, based on relevant patents.

Lens changes and radiation safety practices amongst paediatric cardiologists in South Africa: Preliminary results

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Introduction: The eyes are one of the most radiosensitive organs. The effects of radiation on the eyes ranges from burns, keratinisation, macula changes and cataracts. The posterior sub-capsular lens is the most common site for cataracts and are 3.9 times more likely in interventional cardiologists. Radiation occupational workers are exposed to increased radiation risk in the absence of adequate radiation safety practices and with inadequate utilisation of personal protective equipment. Cardiologists are of the most at risk occupational categories for radiation exposure. This study was done to assess the understanding of paediatric cardiologists and their ability to mitigate these risks, and to determine if lens changes are seen in this occupational group.

Methods: This was a cross sectional study. Data were collected at a Paediatric Cardiology workshop (Red Cross Children's Hospital). Participants completed a survey and screened their eyes for lens changes. Data were analysed descriptively. Ethics clearance (ECUFS 44/2015) was obtained from the UFS.

Results: The response rate was 60% (24). Three participants were excluded because they did not meet the inclusion criteria, 38% (8) were female. The average age was 43, 19% (4) had myopia whilst 24% (5) reported chronic eye infections. Of the participants 33% (7) reported having previously been screened for cataracts with no eye changes. The average number of years worked was 9.6. The average number of diagnostic procedures per week were 4 and the interventional procedures were 2.5 per week. Everyone used a lead apron all the time and 80% (17) used a thyroid shield all the time whilst 95% (20) never used lead glasses. Of the participants 33% (7) had cataract changes and 14% (3) had other eye changes.

Conclusion: Preliminary results showed eye changes in 33% of participants. There was low compliance with the PPE utilisation. There needs to be greater vigilance and increased radiation safety compliance to mitigate for the risks.

Children admitted to a paediatric intensive care unit (PICU) with Fulminant Dilated Cardiomyopathy (DCMO) or Myocarditis in a tertiary academic hospital

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Introduction: In South Africa curative treatment for children with DCMO/myocarditis is limited. During exacerbation these children need frequent readmission for supportive treatment.

Method: A retrospective folder review describing patient characteristics, PICU treatment and outcome of children with fulminant DCMO/myocarditis admitted to Red Cross PICU between January 2010 and July 2015.

Results: Ninety-five children (36 males, 59 female), median age of 27.8 months were identified. All presented in Ross stage 4 cardiac failure (77% in cardiogenic shock), with an overall median lactate of 6.5mmol/l on admission. On presentation the left ventricular ejection fraction was <30% in 79% and 9 developed intra-cardiac clots. Aetiology was presumed viral myocarditis in 87% and 13% idiopathic. Adenovirus PCR was positive in 28, Parvovirus in 19 with multiple positive viral studies in 32.

The median number of ICU admissions per patient was 1.5 (range 1 - 5) and length of ICU stay was 14.9 days (1 - 69). Fifty-five percent required ventilation for median of 8.1 days. Hundred percent required inotropic support for a median of 8.2 days. Eighty-two present were treated with Milrinone, 78% on Dobutamine and 33% on Adrenaline infusions. The median maximum inotrope score was 21.9.

Complications during ICU stay included: kidney injury in 68% with two patients needing dialysis, liver derangement in 43%, neurological events in 25% and 34% suffering a cardiac arrest episode. Thirty-three percent had arrhythmias of which 27% needed electrical cardioversion and 57% drug treatment during PICU stay.

Sixty-three (66%) children survived to ICU discharge. The overall survival was 47%. Of the survivors, the median number of ward readmissions was 3.7 (range 1 - 19). Total median length of ward stay was 23.2 days (1 - 138).

Of the survivors, only 22 were seen at cardiac outpatients during 2015, the rest are presumed lost to follow up.

Conclusion: In our setting DCMO/myocarditis is associated with significant duration of hospital stay, morbidity and mortality.

APPENDIX H2

PRESENTATION AT PUBLIC HEALTH ASSOCIATION OF SOUTH AFRICA CONFERENCE

Radiation Associated Cataracts and Occupational Radiation Safety Practices in Interventionalists in South Africa: A Multiple Methods Approach.

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BACKGROUND

- Ionising radiation is widely used in diagnostic and therapeutic medicine.
- The associated technology has improved and this has resulted in lower patient doses, but there has been a marked escalation in the quantity of procedures, their duration and complexity, and these factors have meant increased occupational radiation exposure for interventionalists.
- The aim of this study was to describe cataracts among South African interventionalists and to understand their radiation safety practices.
- The aim of this paper is to reflect on the methodology of the study and the challenges of interdisciplinary research.

METHODS

- This was a cross sectional study using multiple methods.
- Qualitative and quantitative techniques were used.
- A self-administered questionnaire was conducted.
- Participants were screened for cataracts.
- A group of occupational exposed doctors will be compared to a group of unexposed doctors.
- The quantitative data will be analysed analytically and a regression model developed relating the outcomes and the risk factors. Qualitative interviews and focus groups were conducted to explore the perceptions of interventionalists regarding radiation safety.
- This data will be analysed thematically.

DISCUSSION

- The researchers encountered challenges from the conceptualisation of the study, the development of the methodology and the execution of the study.
- The struggles were rooted in the normal research process but the interdisciplinary nature of the study highlighted the challenge of interdisciplinary collaboration.
- The challenges included overcoming bureaucratic university structures, finding meaning in the different jargons and reaching consensus of conceptualization of ideas.

CONCLUSION

Interdisciplinary research is challenging, but offers tremendous opportunity for tackling complex issues in occupational medicine

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Introduction. The objective of this study is to validate Monte Carlo (MC) based calculations for small irregularly shaped intra-operative radiotherapy (IORT) electron beams. Treatment is delivered using an electron beam passing through an IORT cone with custom built irregularly-shaped alloy cut-outs.

Materials and methods. All measurements were performed on the Siemens Primus LINAC utilising the PTW MP3 therapy beam analyser and PTW pinpoint chamber.

Percentage depth dose and profiles at various depths were obtained for the 6 MeV, 12 MeV and 18 MeV electron beams with the standard $10 \times 10\ cm^2$ and 5 cm circle applicators for MC commissioning purposes.

Identical measurements were done with the IORT cones of diameters 19 mm, 45 mm and 64 mm with and without irregularly-shaped alloy cut-outs. Output factors for all energy/applicator, energy/cone and energy/cut-out combinations were measured. DOSXYZnrc was used to calculate 3D dose distributions in a voxel-based phantom using the individual phase space files (obtained from BEAMnrc simulations) as the source. The data-extraction tools BEAMDP, MCSHOW, Grace, Verisoft and STATDOSE were used to extract and analyse the simulation results.

Results. For all the energies investigated, direct comparison between measurement and simulation of R_{max}, R_{90}, R_{80}, and R_{50} yielded differences of less than 1 mm for the standard $10 \times 10\ cm^2$ and 5 cm circle applicators used for MC commissioning.

For the IORT cones and cut-outs, maximum differences of 1.5 mm and 1.0 mm respectively were observed for these points.

All points that failed the Gamma Index (GI) criteria of 3 mm/3% for profile comparisons were in the high dose gradient regions and/or at the extreme lateral extent of the beam.

A maximum difference of 4.04% and 7.82% in cone factor and cut-out factor respectively was observed for the smallest cone and cut-out for 6 MeV.

The statistical variance of all MC calculations was below 1%.

Conclusion. The MC based dose calculation system evaluated in this study has been successfully validated and is acceptable for clinical implementation.

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O23. Perceptions of radiation safety and training among interventionalists in South Africa

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Introduction. Ionising radiation is an unseen, yet potentially harmful, modality widely used in diagnostic and therapeutic medical procedures. There have been ongoing improvements in imaging technology with an associated reduction in radiation exposures required for imaging. There has however also been an increase in patient load and procedures have become more complex and of longer duration. This consequently increases radiation exposure to operators. It is thus imperative to improve training of interventionalists on the safe utilisation of radiation. The aim of this study was to understand the current perceptions of radiation safety training of interventionalists and to make recommendations for future training.

Materials and methods. This study is part of a larger mixed methods study. Data were collected qualitatively. Adult cardiologists, paediatric cardiologists and radiologists were interviewed individually or as part of a focus group. Focus groups consisted of 2–6 participants. The data were transcribed verbatim and coded and analysed thematically. Ethics clearance was obtained from the Health Sciences Research Ethics Committee of the Faculty of Health Sciences, UFS (ECUFS 44/2014).

Results. There were 54 participants in total. Six focus groups were constituted. Thirty individuals were interviewed. Cardiologists generally had less knowledge of the effects of radiation on their health compared to radiologists. The cardiologists had little or no dedicated teaching during their fellowship training in contrast to radiologists who have formal training requirements.

Conclusion. There is a dearth of knowledge on radiation safety practices among cardiologists in South Africa. Radiation physics and radiobiology is formalized in the training curriculum for radiologists resulting in appropriate awareness about radiation dangers and informed vigilance in radiation safety practice. The training of cardiologists with respect to radiation safety needs to be improved to ensure better safety practices; although there is no consensus on training standards within the professional groups.

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O24. Calibration of radiation monitoring instruments at the NMISA

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Introduction. Radiation monitoring instruments are calibrated to ensure measurements of the instrument are reliable and accurate in all ranges and for energy spectrum in which the instrument is expected to function. The Dosimetry Section (Radiation Protection) of NMISA provides the calibration service for all types of radiation monitoring instruments. This paper will focus on the calibration of surface contamination monitor in terms of 2π efficiency and surface activity response (SAR), survey meter in terms of ambient dose equivalent (ADE) rate and electronic personal dosimeter (EPD) in terms of personal dose equivalent (PDE). Measurements are traceable to the national standards calibrated at NPL, PTB and BIPM.

Materials and methods. Measurements for determining the 2π efficiency and surface activity response of the surface contamination monitor were performed using the wide area reference sources and linearity measurements were performed using Cs-137 source. Survey meter and electronic personal dosimeter were calibrated using Cs-137 and Am-241 sources. Calibrations were performed in accordance with ISO 4037-3, ISO 8769 and SANAS TR 18-02. IAEA report series no. 16 is also used as a guideline.

Results. The uncertainties in the 2π efficiency and surface activity response were estimated not to exceed $\pm 11\%$ and ±4,0% respectively. For the survey meter and electronic personal dosimeter, the average error for all calibrated ranges did not exceed ±15% and the average percentage error per point for all ranges did not exceed ±25%.

Conclusion. The results obtained from calibrations were conforming to the SANAS TR 18-02 requirements and certificates issued in accordance with the ISO/IEC 17025:2005.

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O25. Measurement of radon level from selected houses in Ibadan, Nigeria

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Introduction. Radon is a naturally occurring colourless, odourless, tasteless radioactive gas. The World Health Organization (WHO)

APPENDIX H4

PRESENTATION AT HUMAN RESOURCES FOR THE SOUTH AFRICAN HEALTH SYSTEM CONFERENCE

Radiation safety training and education in South Africa: an unseen calamity.

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Background

Clinicians are increasingly demanding more ionising radiation based investigations to assist with making diagnostic decisions and as a treatment modality. This potentially places a greater burden on the human and financial resources of the health system. An added demand to perform procedures equates to an increased demand in finances for more personal and better equipment. The escalation in complex procedures further stresses the health system, because more highly skilled health professionals will be required. Radiation healthcare workers include radiologists, cardiologists, nuclear medicine physicians, radiographers, nurses, pharmacists and medical physicists. The increased duration of the procedures exposes patients and radiation healthcare professionals to larger cumulative doses of ionising radiation. It is thus imperative that these highly skilled professionals are adequately trained and educated in radiation physics and radiobiology. This necessitates their training to address this.

Methods

This was a qualitative study looking at the perceptions and attitudes of radiation healthcare workers as relates to their training in radiation safety. The study population included only interventionalists. In-depth interviews and group interviews were conducted and audio recorded. The data were transcribed verbatim and analysed deductively. The ethics clearance for this study is ECUFS 44/2015.

Results

Participants reported that there was a dearth of training with respect to radiation safety education and training in their curricula. They reported that post training continued medical education courses often provided little opportunity to address the paucity of training in this area. There was however no consensus on the structure that restructuring of their curriculum should take.

Conclusion

The findings may be applicable and extrapolated to all categories of healthcare radiation professionals in South Africa. Restructuring of the curriculum and the continued medical education of these workers is essential to protect the health of these highly skilled health professionals.

APPENDIX H5

PRESENTATION AT HUMAN RESOURCES FOR THE SOUTH AFRICAN HEALTH SYSTEM CONFERENCE

Radiation Safety Practices Among South African Interventionalists: Reflections on Accessing a 'Hard-to-Reach' Population.

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BACKGROUND

Ionizing radiation is used in various modalities in diagnostic and therapeutic medicine. The associated technology has improved resulting in lower patient doses, but there has been a marked escalation in the quantity of procedures, their duration and complexity, resulting in increased occupational radiation exposure for interventionalists. Social position, vulnerability and hiddenness characterise hard-to-reach populations. An atypical perspective of these definitions allowed us to consider the participants through this lens. In this presentation, we reflect on accessing this "hard-to-reach" population.

METHODS

This was a cross sectional study using multiple methods. Qualitative and quantitative techniques were used. A survey was conducted using electronic and paper based systems to collect quantitative data. Ophthalmological screening was done. Qualitative interviews and focus groups were conducted.

FINDINGS AND DISCUSSION

There was lower than expected uptake of the electronic survey despite access to infrastructure and active recruitment. Participants were more comfortable with a paper-based system. They stated they were too busy to participate and exhibited what was interpreted as an elevated sense of importance. They were reluctant to have their eyes dilated citing it interfered with their ability to work or drive afterwards. We used creative advertising to attract participants. Recruiting strategies were adapted and included snowball, targeted, time-location-space and respondent driven sampling. The interviewer had developed rapport because of his occupation and previously having worked with some participants. This was important, as the participants seemed to more readily accept an "insider".

CONCLUSION

Interventionalists are difficult to access and require vigilance and creativity in recruiting their participation.

Keywords: Epidemiology, Research methodologies and methods, Occupational health, Public health workforce

Key Messages:

1. Conducting research among highly skilled health professionals requires tremendous stealth and perseverance.
2. Accessing 'hard-to-reach' communities as participants can require creativity and willingness to conduct the research outside of the norms defined by traditional research methods.
3. Reaching 'hard-to-reach' populations is challenging but offers immense reward in capturing the voice of these communities.

PRESENTATION AT MIXED METHODS INTERNATIONAL RESEARCH ASSOCIATION CONFERENCE

USING MULTIPLE METHODS TO UNDERSTAND RADIATION SAFETY PRACTICES IN SOUTH AFRICAN INTERVENTIONALISTS

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BACKGROUND

Ionising radiation is increasingly being used in medicine for diagnostic, therapeutic and interventional procedures. [1] Occupational radiation exposure carries health risks for patients and radiation healthcare workers. The detrimental health effects may be stochastic or deterministic in effect. The deterministic effects have a threshold limit and includes effects such skin burns and cytopaenia. [2] Stochastic effects can occur even if there is no there is no minimum dose exposure and includes effects such as carcinomas. [2,3] Radiation induced cataracts were previously thought to be deterministic in nature but evidence is mounting that it is stochastic in nature. [4] These aspects are typically measured using a quantitative approach. The effects of radiation on health can be mitigated by applying the principles of limitation, justification and optimisation. [5] Education and continuous training underpins creating a culture of radiation safety. [6]

The research question was what was the prevalence of radiation induced cataracts and the radiation safety culture in South African interventionalists?

The multiplicity of the research question necessitated that a research design be employed that was not rigid or prescriptive and which allowed for malleability in addressing the research question. Qualitative and quantitative techniques were engaged in a pragmatic integrated and supportive manner and allowed the researcher to draw on the strengths of both techniques. [7] Quantitative techniques are traditionally used in medical science and to determine the prevalence of cataracts it was necessary to use this method; but our interest in understanding the organisational work behaviour nuances of the participants to radiation safety required a qualitative approach. The use of multiple methods allowed the researcher to produce detailed and contextualised data that qualitative or quantitative data could not produce on its own. [8] This offered better insights to the understanding of the research phenomenon. [8] In addition we used an interdisciplinary approach and engaged with occupational medicine, public health, medical physics and ophthalmology. This offered challenges on pushing the comfort boundaries of the disciplines. [9]

The aim of this article is to describe the rationale for using mixed methods to investigate cataracts in interventionalists and to understand their radiation safety practices.

METHODS

A comprehensive detail of the methodology is described elsewhere. [10]

We administered a structured survey to collect quantitative data on risk factors, occupational history and safety practices. We screened interventionalists and a group of unexposed doctors. We conducted six group interviews and 36 in-depth interviews and collected qualitative data on attitudes and behaviour in radiation safety; the training culture and expectations; and the culture of radiation protection. Quantitative analysis included descriptive and analytical analysis. Qualitative data were analysed thematically using a deductive approach where were related the findings to what was in the literature and the remaining themes that emerged from the data were analysed using an inductive approach. Ethics clearance (ref. no. ECUFS 44/2015) was received from the University of the Free State.

FINDINGS AND REFLECTIONS

We found cataracts potentially associated with radiation occupational exposure in 18.8% of interventionalists. The themes that emerged included CRP, knowledge and awareness of radiation, radiation safety practice, PPE utilisation, monitoring of safety practices, education and training. Data collection was challenging because this was a difficult to reach population who are normal the researchers and not the research participants. Interventionalists were reluctant to participant in the study citing reasons such as that they were too busy to participate in research or that they had nothing to contribute by participating. The qualitative data helped make meaning of the complex layers that constitutes the culture of radiation protection in this group.

CONCLUSION

Interdisciplinary research allowed us to understand this multifactorial health issue. Mixed methodologies offered a means of approaching this complex health issue.

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APPENDIX H7

PRESENTATION AT ANNUAL SOUTH AFRICAN ASSOCIATION OF PHYSICISTS IN MEDICINE AND BIOLOGY

The steep dose falloff in the depth dose puts a constraint on the allowed energy variation that could lead to ±2 mm shifts in beam quality parameters e.g. R50 or R80. It is desirable that these shifts be measured to determine their variation around the commissioned values for R80.

Beam quality measurements previously were measured using ionization chambers or film. The aim of this study is to report on the possibility to measure R80 using EPID images taken from electron beams initially collimated by an electron applicator, as currently investigated. The Elekta EPID is an amorphous Si diode type and is thus a matrix of small dose meters. Therefore the amount of electrons interacting with it should determine its signal.

Measurements were performed on an Elekta SL25 MLC and Elekta Precise linear accelerators. A Perspex wedge is used to absorb in falling electron beam, leaving increasing energy electrons to reach the EPID surface. An image is then formed from which the information is used to correlate its data with water bath data.

Preliminary results indicate that, in principle, this technique can be used to verify electron beam quality data.

O15. Risk analysis based on the occurrence and severity of incidents from an institutional incident learning system

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Background and Purpose: The aim of this study was to develop an institutional Incident Learning System (ILS), estimate the occurrence and severity of radiotherapy incidents that were reported over a period of 6 years, and then rank the major radiotherapy processes based on their vulnerability for errors at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

Material and Methods: A total of 129 radiotherapy incidents were reported from January 2010 to December 2015 at CMJAH. Data was collected from the Departmental Incident Report files and the radiotherapy errors were classified into five levels (where levels 1 and 2 were considered clinically significant, reportable errors and levels 3 to 5 as errors without clinical significance [1]). In addition to this, the AAPM TG-100 [2] severity scoring table (1 to 10) was used to evaluate the risk.

Results: 97% of incidents were related to External Beam Radiotherapy (EBRT). About 93% of incidents were process-related. 33% (42 reports) of incidents arose at the treatment planning stage, and incidents during the treatment delivery and patient treatment data transfer processes were 27% (35 incidents) and 21% (27 incidents), respectively. About 27% (35 out of 129) were clinically significant (Level 1 and 2) with high severity values (≥ 7).

Conclusions: Due to the severity and occurrence of incidents, pre-treatment processes (treatment planning and data transfer processes) were found to have the highest risk for treatment errors. By strengthening pre-treatment quality control measures in the department, a significant number of treatment errors could be prevented.

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O16. Dosimetry utilisation and practices among South African interventionalists

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Background: Ionising radiation is increasingly being used in diagnostic and therapeutic procedures posing an increased occupational risk to operators. It is imperative to mitigate this risk. Dosimetry is an important consideration to monitor and control ionising radiation in radiation healthcare workers. There is often inconsistent dosimetry utilisation in these workers.

Methods: We used multiple methods to evaluate dosimetry practices in South African interventionalits. We conducted a survey and did in-depth and group interviews. We used STATA 12 to do a descriptive analysis of the quantitative data. A thematic analysis of the qualitative data was done using a deductive and inductive approach. Ethics clearance was obtained (ECUFS 44/2015).

Results: The survey was completed by 108 participants and 74 were male. Mean age was 45.8 (SD 9.9). There were 35 radiologists, 41 cardiologists and 32 paediatric cardiologists included. The mean years worked was 12.7 (SD 9.7). Fourteen (12.9%) never wore their dosimeters, 63(58.3%) consistently wore it. Eight (7.4%) wore a second dosimeter. 77 (81.9%) placed the dosimeter under the lead apron. 103 (95.4%) participants were not sure what their dosimetry measurements were in the past year. Of the five that indicated they knew the maximum dose expose to the eye only one reported it correctly. In the qualitative findings participants reported they did not know the role of medical physics departments, they received poor feedback about dosimetry readings and there was low vigilance in using dosimeters.

Conclusion: There was poor dosimeter utilisation in this study. Participants were not aware of the role of medical physics departments. Dosimetry as a means of monitoring and improving radiation safety practices in the catheterisation laboratory must be improved to create an improved culture of radiation protection.

O17. High resolution dose verification – Do we really gain anything?

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Introduction: 2D array devices, utilizing multiple measurement points, are widely used for quick Intensity Modulated Radiotherapy (IMRT) verification. Their limitations include low resolution measurements as the detectors are spaced magnitudes of millimetres from each other. Generally, this can be improved by repetition measurements, manually stepping the device in-between the detector-less spaces. This process is however time consuming, requiring justification for the perceived gain in measurement accuracy.

Material and Methods: Multileaf Collimator (MLC) positional verification was performed with a 2D diode array (SunNuclear Mapcheck2) with 1-mm stepping increments using: a picket-fence pattern, composite IMRT dose planes. Measurements were converted into IBA OmniPro™ format with in-house developed software. Measurements were performed on 3 beam-matched Siemens Artiste linear accelerators (LINACS). IMRT measurements were repeated with an ionization chamber array (PTW1500). Gamma

APPENDIX H8

PRESENTATION AT 38TH ANNUAL CONFERENCE OF ASSOCIATION OF MEDICAL PHYSICISTS OF INDIA CONGRESS

CATARACT FINDINGS AMONG SOUTH AFRICAN INTERVENTIONALISTS

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Introduction. Ionising radiation is indispensable as a diagnostic, prognostic and therapeutic modality in modern western medicine. Ionising radiation is an established occupational health hazard in the catheterisation laboratory. Exposure may result in health effects such as skin changes, carcinomas, chromosomal aberrations and cataracts. The lenses of the eyes are higher radiosensitive and cataracts in radiation health workers commonly occurs in the posterior capsular (PC) region of the lens. The left eye is often affect up to three times more commonly than the right eye. The dose per procedure varies from 10 to more than 1 000 micro Sievert and depends on the type and duration of the procedure, the skill of the operator and the dose reduction strategies employed (such as personal protective equipment (PPE) used and policies and guidelines followed). **Objectives.** The aim of this study was to describe the prevalence of occupational related radiation induced cataracts in South African interventionalists. **Materials and methods.** This study was a cross sectional observational study. The participants were from several different cities in South Africa and were recruited at various conferences. The participants included exposed doctors (interventional radiologists, cardiologists and paediatric cardiologists) and a comparative group of unexposed doctors. All participants completed a survey which collected data on their risk for cataracts, their occupational history, their utilisation of PPE and their training in radiation safety. They had their eyes dilated and had a slit-lamp examination. The data were analysed using STATA 12®. Descriptive and analytical analysis was done. The study received ethical approval from the University of the Free State (UFS44/2014). **Results.** There were 351 participants (144 exposed) and 267 (119 exposed) had their eyes screened. The median age was 46.1(exposed) and 45.5 years (unexposed). There were 89 (72.4%) men and 34 (27.6%) women (exposed). The median years worked was 10 (exposed) and 14 (unexposed). The median years doing fluoroscopic procedures was 9.5 years. The risk factors for cataract included diabetes 5 (4.1%) in exposed and 12 (5.9%) in the unexposed ($p=0.473$); BMI 25.5 ±3.5 (exposed), 26.2 ±4.7 (unexposed); there were two participants that used steroids (unexposed). There were 53 radiologists, 54 adult cardiologists and 37 paediatric cardiologists. In the left eye, there were 34 cataracts (16 in exposed group). In the right eye, there were 25 cataracts (exposed). In the left nucleus, there were 16 opacities (5 in the exposed) and in the right nucleus there were 15 opacities (4 in the exposed). In the left cortex, there were 31 opacities (15 in the exposed). In the right cortex, there were 25 opacities (10 in the exposed group). In the left posterior capsule, there were 11 cataracts, 6 (5.0%) in exposed and 5 (3.4%) in unexposed ($p=0.195$). In the right posterior capsule, there were 5 cataracts 2 (1.7%) in exposed and 3 (2.0%) in the unexposed ($p=0.831$). Nuclear and cortical cataracts were the most common which is expected. Cataracts were more common on the left in the exposed. **Discussion.** Interventionalists are at increased risk to develop radiation related cataracts. Cortical and nuclear cataract was more common which may be associated with age related changes. The increased prevalence in left side in exposed participants' cataracts suggest an occupational cause. There was a significant difference between exposed and unexposed participants in the posterior capsular category. In conclusion, there should be increased vigilance in radiation protection measures to protect interventionalists from developing cataracts due to ionising radiation exposure.

APPENDIX I

PRESENTATION AT IAEA INTERNATIONAL CONFERENCE ON RADIATION PROTECTION IN MEDICINE

HOW RESEARCH CAN IMPACT RADIATION SAFETY CULTURE IN SOUTH AFRICAN CATHETERISATION LABORATORIES

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ABSTRACT

Ionizing radiation is an integral part of modern medicine. The modality offers tremendous benefits for diagnosis, treatment and prognosis of patients. But radiation increases risk of harm for patients and staff. Occupationally related radiation induced cataracts occur in some interventionalists, and this risk should be mitigated. This can be achieved by cultivating a culture of radiation protection (CRP). Several activities can enhance a CRP amongst interventionalists including: formalising radiation safety education and training curricula for radiation workers, implementation of radiation protection policies, encouraging support for such policies and implementation of national regulations. Currently an active research project studying the prevalence of cataracts among South African (SA) interventionalists, and investigating their radiation safety practices, demonstrates how research may, in itself, modify the CRP. The article considers the impact that the research process itself may have on a CRP. Such projects having inclusive involvement of members of the relevant professions are seldom carried out in SA. Opportunities were created to influence debate on radiation safety and to encourage a positive CRP in SA. It is proposed that an effective and potentially long-lasting intervention for enhancement of a CRP may be to do research which involves active participation of the radiation worker community.

INTRODUCTION

Imaging modalities using ionising radiation form the basis of many diagnostic, prognostic and therapeutic procedures in modern medicine. [1] These modalities offer great benefit, but are accompanied by potential health risks for patients and operators. These risks may include, amongst others: skin effects, carcinomas, and cataracts. The lenses have been shown to be prone to developing opacifications which may develop into complete cataracts. [2] This has important health implications for radiation healthcare workers (HCWs).

Safety in catheterisation laboratories can be secured in the following ways: engagement of clinicians to consider alternate modalities in imaging patients, application of the ALARA principle when imaging, vigilance in monitoring patient doses during patient procedures, and consistent use of personal protective equipment (PPE). [3] Management of medical radiation facilities should be engaging and proactive in facilitating a safe radiation work environment. [3] The can be expedited by ensuring that procurement processes are in place to ensure that equipment is purchased, serviced, and that appropriate and adequate PPE is available.

These measures are what determine and shape the culture of radiation protection (CRP) in an organisation. [4,5] The heads of department of radiation units are crucial to fostering a CRP. It is however also the responsibility of everyone in a department to be aware of radiation safety issues and to promote and sustain this culture. Imperative to developing and maintaining a CRP is to include it in the formal training and continued medical educational activities of interventionalists and other radiation HCWs. [4,6]

The aim of the study is to describe key findings and how the research activities of the project contributed to raising awareness about radiation safety in catheterisation laboratories in SA, and therefore how the research process itself impacts radiation safety culture.

METHODS

This is an observational case study (hereafter called the study) describing the activities related to a national interdisciplinary project using multiple methods to describe the prevalence of cataracts in South African (SA) interventionalists and to understand their radiation safety practices, being carried out in interventional radiology and cardiac catheterisation laboratories country wide, details of which are described elsewhere. [7]

Details of the contacts made, the events organized, and the outputs delivered and planned, are described. The number of contacts is given in context of the total numbers of professionals within the disciplines involved during the activities of the PhD. Multiple methods were used to determine the prevalence of cataracts in SA as it had not been described before (quantitative). The researchers also wanted to understand the current radiation safety culture in SA (qualitative). Professionals from the following disciplines were invited to participate in the project to help understand the multiple layers of the research question: public health, occupational health, medical physics and ophthalmology.

The project population included adult cardiologists, paediatric cardiologists and radiologists that perform interventional fluoroscopy see Table 1. A control group of doctors unexposed to radiation was also included.

TABLE 1: Show the population used in the study from different disciplines as well as their respective numbers

	Interventional Radiologists	Adult cardiologists	Paediatric cardiologists	Unexposed group
Approximate number in SA	50	229	41	N/A
Completed survey	47	45	40	194
Had ophthalmological screening	25	42	31	145
Participated in interviews	28	16	10	N/A

The quantitative component comprised a survey and ophthalmological screening for cataracts. The qualitative component consisted of in-depth interviews and group interviews using a semi-structured interview schedule.

The data were mainly collected at conferences, scientific workshops and CME meetings see Table 2. At some of these meetings the opportunity arose to introduce the reason for the project and mention about the concerns of radiation safety in the cath. lab. While it cannot be quantified, the impact the researchers' presence had at these meetings is anecdotally believed to have raised awareness about radiation safety in the radiation workplace environment.

TABLE 2: Shows the conferences attended and the approximate number of people that attended

Conference/ meeting	Approximate number of attendees
Interventional radiology workshop (2015)	40 interventional radiologists
Paediatric interventional cardiology workshop (2015)	30 paediatric cardiologists
SA Heart (Nat. cardiology congress) (2015)	200 cardiologists
SA Radiological Society Conference (2015)	400 radiologists
Family Medicine workshop (2015)	30 family medicine doctors
SA Heart (Nat. cardiology congress) (2016)	200 cardiologists
Radiology congress (2016)	100 radiologists
Family medicine workshop (2017)	30 family medicine doctors
Forensic medicine congress (2017)	60 doctors

RESULTS AND DISCUSSION

The personal contact and involvement of the groups being studied included professionals who were asked various focused questions on their attitudes, training and practices with regards radiation protection. Although this group reached a smaller more limited segment of the target population, the involved and deliberate participation of these participants was more focused and interactive than those filling in the survey or having their eyes examined. All Heads of Department were approached and made aware of the project and invited to participate. The Colleges of Medicine of South Africa (CMSA) and the Medical Research Council of SA (SAMRC) are aware of the project and the SAMRC is acknowledged as the funder of the bursary.

There were 243 participants completed the questionnaire and had an eye screen. There were 25 (10.3%) radiologists, 42 (17.3%) cardiologists, 31 (12.8%) paediatric cardiologists and 145 (59.6%) unexposed doctors. Cataracts were present in 23 (13%) of participants. 13 (56%) of the cataracts found were in interventionalists.

The qualitative findings showed that radiologists tended to be better trained in radiation safety than cardiologists. [6] Radiologists tended to be more aware than cardiologists of what constituted a CRP. Both radiologists and cardiologist agreed that building and sustaining a culture of radiation protection was needed. Formalised training was an important consideration in establishing a CRP.

Participants reflected during the interviews that they felt that the research had made a difference to their attitudes and behaviour in the radiation working environment. One cardiologist reported, “It [radiation safety] is something we’ve never discussed or even brought up in a meeting until you can along actually.” While another cardiologist said: “I am actually worried now. It made me realise how and ...we didn't think about these things” implying the research process had sensitised them to issues on radiation safety.

There was poor compliance in using dosimeters. Only 59 (58.3%) of participants indicated they consistently used dosimeters. The qualitative data reflected that participants were not vigilant in using dosimeters because they did not receive consistent and regular feedback on their exposure, they were not held accountable for wearing it and they frequently forgot to take it into the cath. lab.

TRANSLATION AND DISSEMINATION OF RESEARCH FINDINGS

The findings from this project were presented at several forums and it is believed that this may have had an impact in raising awareness about ionising radiation safety in the catheterisation laboratory. These presentations are summarised in Table 3. The work emanating from this project has been published in two peer review journals [6,7] and three other publications are either awaiting submission, or have been submitted for review.

TABLE 3: National and international congresses where the findings of the project was presented

Scientific meeting or Conference	Work presented
Paediatric interventional workshop (Cape Town, 2015)	Talk on radiation safety
SA Heart (2016)	Preliminary findings on paediatric cardiologists
Human Resources for the South African Health System (Pretoria, 2016)	Radiation safety training and education in South Africa: an unseen calamity.
Mixed Methods International Research Association Conference (Pretoria, 2017)	Using multiple methods to understand radiation safety practices in South African interventionalists.
South African Association of Physicists in Medicine and Biology (Durban,2017)	Dosimetry utilisation and practices among South African internationalists.
World Federation of Public Health Associations (Melbourne, 2017)	Radiation Safety Practices Among South African Interventionalists: Reflections on Accessing a 'Hard-to-Reach' Population.

LIMITATIONS

The observed research activities probably made an impact, but it cannot be assumed that all research in the field will have similar effects. Secondly, it is biased in that the observer of the research project is involved and has a conflict of interest and thus influences interpretation of what was observed.

The observed project also had limitations as it did not measure actual doses and estimates are based on self-reported workload which may under- or over-estimate the workload dose. Future studies looking at empirical dose measurements to the eye are needed. The project did not explore how a culture of radiation protection could be initiated and established in SA and future studies may wish to explore this aspect. The project did not investigate the role management plays in establishing a CRP and future studies could look at this aspect. Future studies could explore issues around patient safety.

DISCUSSION

Radiation safety in the catheterisation laboratory in South Africa is not well described. The project has helped to bridge this gap. It has created awareness about radiation safety by engaging with the Radiological Society of South Africa, The Cardiology Society of South Africa (SA Heart), the Paediatric Cardiology Society of South Africa and the Medical Research Council of South Africa. Participants expressed the opinion that they were more informed and aware of radiation risk and effects following their participation. This is seen as evidence that the process of doing the research project in itself made an impact on the culture of radiation protection amongst interventional radiologists.

CONCLUSION AND RECOMMENDATIONS

Observational case studies involve studying an individual or small group. There have been very few studies considering how the research process itself brings about change and education of the studied group. [8] These may assist in understanding activities or special cases, but they cannot be used to establish causality and cannot make predictions. A single research project is described here where the overarching aim was to positively influence the culture of radiation protection in SA. The findings around attitudes toward aspects of radiation protection, lens changes and risks in the studied population, and current training and education of interventionalists all contributed to increasing awareness in the studied group. The impact of this research on cultural behaviour is difficult to quantify, but a follow up project could be carried out in two years or more from now to determine if attitudes and perceptions of the target populations have changed. Researchers and some participants felt that although influencing the culture of radiation protection in SA was not the stated aim of this project, it has, as a result of its many and diverse activities and high level of exposure, contributed to raising awareness about radiation protection amongst interventionalists and thus hopefully contributed to an improved radiation safety culture in SA. A stated aim was to motivate changes in the curriculum of interventionalists in training as this will greatly encourage a change in behaviour and facilitate a CRP. Our appeal is that more research of this nature should be encouraged and carried out as an instrument of change in our discipline.

The project described in this study addresses several areas relevant to the IAEA International Conference on Radiation Protection in Medicine (11-15 December 2017): the

Bonn Call to Action (2012) by identifying gaps in radiation protection in South Africa and implemented measures to address these gaps (section C.1), radiation safety issues surrounding interventionalists performing fluoroscopic procedures (section C.3 and C.5), understanding the culture of radiation protection in the SA context and facilitated debate on the topic by medical professionals using ionising radiation (section C.10 and C.11). Talks were presented on radiation safety in the cath. lab to paediatric interventional cardiologists (About 75% of SA paediatric interventional cardiologists were present at this talk). As a final attempt to disseminate the findings of this project, a national colloquium on radiation safety is planned for 5-6 December 2017, targeting the Presidents of the Cardiology, Radiology, Orthopaedic and Urology South African Colleges of Medicine (section C.14), and the research project has stimulated ideas for future projects, such as eye dosimetry of SA interventionalists (section C.15). All this is evidence that this research project has made an impact on radiation protection culture and others like it may also achieve this goal. It is thus recommended that research itself can make an impact and researchers should bear this in mind when developing their protocols to make the most of this aspect of research project implementation.

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APPENDIX J

PRESENTATION AT RADIATION SAFETY IN SA: TOO LITTLE BUT NOT TOO LATE

TUESDAY - 5 DECEMBER 2017		
Time	**Topic**	**Speaker**
08h30-09h00	**Registration**	
09h00-09h10	Welcome	André Rose (UFS)
09h10-09h20	Opening address	Wayne Marais (UFS)
09h20-10h20	Strengthening radiation safety culture in health care	Maria Perez (WHO)
10h20-10h30	**COFFEE BREAK**	
10h30-11h00	Key PhD findings	André Rose (UFS)
11h00-11h30	Basic radiation physics and radiobiology	Elisabeth Cardis (ISGlobal)
11h30-12h00	Radiation and the eye	Lumko Ngetu (UFS)
12h00-12h45	Ethics talk: Would you brush your teeth in a burning house? Risk communication and consent in radiation exposure	Dirk Hagermeister
12h45-13h15	**LUNCH**	
13h15-14h00	Legal consideration in the workplace	Gerda Du Toit (UFS)
14h00-15h00	What occupational health and safety interventions will be welcomed by practitioners?	David Rees (NIOH)
15h00-15h10	**TEA**	
15h10-15h45	Protecting the patient from radiation	Elisa Pasqual (ISGlobal,Spain)
15h45-16h00	Questions, recap and closure	Andre Rose (UFS)
18h30 for 19h00	Gala dinner at Pimentos	
WEDNESDAY - 6 DECEMBER 2017		
Time	**Topic**	**Speaker**
08h30-09h00	**Registration**	
09h00-10h00	Plenary talk	Elisabeth Cardis (ISGlobal, Spain)
10h00-10h45	The role of the medical physics department in radiation safety	William Rae (UFS)
10h45-11h00	**TEA**	
11h00-11h45	The cardiologists and radiation	Prof Stephen Brown (UFS)
11h45-12h30	Radiation safety training	Belinda v/d Merwe and Henra Muller
12h30-13h15	**LUNCH**	
13h15-14h15	Organisational change	Nosa
14h15-14h45	Panel discussion	William Rae, Elisabeth Cardis, André Rose
14h45-14h50	**GRAB A CUP**	
14h50-15h15	Radiation safety: Too little but not too late	André Rose (UFS)
15h15-15h30	Closure and vote of thanks	André Rose (UFS)