

**THE RISKS OF MEDICAL IMAGING: A SURVEY OF DOCTORS' KNOWLEDGE AND  
CONSENTING PRACTICE**

Dr Tamiya Nair

Student number: NRXTAM001

Supervisor: Professor Savvas Andronikou

University of Cape Town

Submitted to the University of Cape Town in partial fulfilment of the requirements for the  
degree

**Master of Medicine in Diagnostic Radiology**

**Faculty of Health Sciences**

**UNIVERSITY OF CAPE TOWN**

**Cape Town, 2017**

The copyright of this thesis vests in the author. No quotation from it or information derived from it is to be published without full acknowledgement of the source. The thesis is to be used for private study or non-commercial research purposes only.

Published by the University of Cape Town (UCT) in terms of the non-exclusive license granted to UCT by the author.

## Declaration

I, Tamiya Nair, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signed by candidate

Tamiya Nair

On this 19<sup>th</sup> day of December 2017

## **Publications and presentations**

This work has never been published.

## **Abstract**

### **Background:**

Diagnostic imaging forms an integral part of patient evaluation and its use has increased dramatically. Not only is medical imaging a source of increased radiation dose, but also poses other risks such as those related to the procedure performed, the contrast and drugs administered, acoustic and heat deposition and para-magnetic risks. While many studies have assessed doctors' knowledge of radiation risk, data regarding doctors' knowledge of the remaining risks of medical imaging and doctors' attitudes toward consenting practice for imaging is lacking.

### **Aim:**

To survey and compare the levels of knowledge between referring clinicians and radiologists regarding the risks to patients undergoing medical imaging and to explore doctors' attitudes toward consenting practice.

### **Method:**

A cross sectional, observational, descriptive study design was employed. The study was conducted using a non-validated, piloted, self-administered three-page questionnaire. The questionnaire was distributed to doctors in various stages of their medical careers at a tertiary level hospital. The questionnaire was constructed in sections including demographics, risks of medical imaging and consent practice. The maximum score potentially attainable was 79, with a point given for each correct answer. No points were given for incorrect, unsure or blank responses.

### **Results:**

A total of 431 questionnaires were distributed but only 85 doctors (19 radiologists and 66 clinicians) returned a completed survey, yielding a response rate of 19,7%. Older respondents with more years of experience had greater levels of knowledge regarding the risks of medical imaging. There were no significant differences according to gender or university. Although the levels of knowledge of risk was poor overall, radiologists had greater levels of knowledge (mean knowledge score expressed as a percentage =79%

compared to that of clinicians= 71%). The largest proportion of doctors' (49%) were of the opinion that clinicians should be responsible for obtaining consent for medical imaging. Only 18% of doctors (radiologists and clinicians) and 5% of clinicians admitted to feeling adequately prepared to obtain consent for medical imaging.

**Conclusion:**

We successfully surveyed and compared the levels of knowledge of medical imaging risks amongst doctors and determined their attitudes toward responsibility for consent. The levels of knowledge of the risks of medical imaging is inadequate among radiologists and poor amongst non-radiologists. While statutory body guidelines recommend that the performing health care provider obtain consent, there remains varying opinion as to who should obtain consent. The largest proportion of doctors' were of the opinion that clinicians should obtain consent for medical imaging - this despite clinicians' feelings of inadequacy when consenting patients to the risks of imaging. It is therefore important to take into consideration the levels of knowledge and comfort when making decisions as to who is best suited to obtain consent for medical imaging. With the increased dependence on medical imaging as part of the diagnostic work up, awareness of the risks of medical imaging is of tantamount importance. It is essential to review educational curricula and local policies in order to improve the levels of knowledge of risks of medical imaging amongst healthcare providers, thereby ensuring improved patient safety.

## Acknowledgements

I would like to express my sincere gratitude to all those who have supported me on this journey:

- To my supervisor, Professor Savvas Andronikou, thank you for your time, patience and encouragement. You continue to be an inspiration.
- To Professor S.J. Beningfield, thank you for all your support over the years.
- To Professor M. Kidd, thank you for your assistance with the statistical analysis.
- To Dr T. Crede, Dr G. Parolis, Dr P. Raubenheimer and Dr D. Thomson, thank you for the kind assistance with recruitment of participants for this survey.
- To my "Dear Boys": Christiaan, Trevor and Vittorio. I am truly lucky to have you all in my life.
- Lastly to my parents Ronnie and Kay Nair, without whom none of this would be possible. Thank you for your love, support and encouragement.

## Table of contents

Declaration .....	2
Publications and presentations .....	3
Abstract .....	4
Acknowledgements .....	6
Table of contents .....	7
List of Figures .....	10
List of Tables .....	11
1. Rationale .....	12
2. Literature review .....	14
2.1. Risks of medical imaging .....	14
2.1.1. Ionizing radiation/ Dose .....	14
2.1.2. Iodinated contrast media used in CT .....	16
2.1.3. Risks of MRI .....	17
2.1.4. Contrast media used in MRI .....	17
2.1.5. Sedation and drug related risks .....	19
2.1.6. Procedural risks .....	20
2.2. Consent .....	22
2.3. Knowledge of risk and need for undergraduate radiological education .....	23
2.4. Existing surveys of knowledge with regard to risk .....	24
3. Aim .....	27
4. Study Objectives .....	27
5. Methods .....	28

5.1. Study Design .....	28
5.2. Study population and sampling .....	28
5.3. Sample size calculation .....	28
5.4. Materials and methods .....	29
5.5. Data collection .....	30
6. Statistical analysis .....	30
7. Ethics .....	31
7.1. Informed consent process .....	31
7.2. Data safety .....	32
8. Results: .....	33
8.1. Sample population: .....	33
8.2. Demographics: .....	34
8.2.1 Age: .....	34
8.2.2. Year of graduation: .....	35
8.2.3. Gender: .....	37
8.2.4. University: .....	39
8.2.5. Department: .....	40
8.2.6. Professional level: .....	42
8.3. Knowledge of the risks of imaging: .....	43
8.3.1. Knowledge of the risks of radiation: .....	43
8.3.2. Knowledge of the risks of contrast nephropathy: .....	45
8.3.3. Knowledge of procedural risks: .....	47
8.3.4. Knowledge on the use of procedural sedation: .....	55

8.4. Consenting practice: .....	56
8.5. Referral patterns: .....	59
9. Discussion: .....	61
10. Study limitations:.....	70
11. Conclusion: .....	71
12. Recommendations:.....	72
13. Appendices: .....	74
13.1. Appendix A: Ethics clearance certificate .....	74
13.2. Appendix B: Annual progress report/ renewal: 2016-2017 .....	75
13.3. Appendix C: Annual progress report/ renewal: 2017-2018 .....	76
13.4. Appendix D: Hospital permission to conduct research .....	77
13.5. Appendix E: Questionnaire consent .....	78
13.6. Appendix F: Questionnaire .....	79
14. References .....	82

## List of Figures

**Figure 1:** Schematic representation of study sample and response rate

**Figure 2:** Scatter plot of age versus total knowledge scores

**Figure 3:** Scatter plot comparing year of graduation against total knowledge scores

**Figure 4:** Pie chart illustrating gender distribution of sample population

**Figure 5:** Graph comparing gender against total knowledge scores

**Figure 6:** Pie chart demonstrating distribution of respondents by department

**Figure 7:** Graph stratifying total knowledge scores by department

**Figure 8:** Comparison of scores achieved by clinicians and radiologists regarding the risks of radiation

**Figure 9:** Comparison of doctors' knowledge of the risks of contrast nephropathy across various modalities

**Figure 10:** Comparison of doctors' knowledge of CT related procedural risks

**Figure 11:** Comparison of doctors' knowledge of fluoroscopy related procedural risks

**Figure 12:** Comparison of doctors' knowledge of intervention related procedural risks

**Figure 13:** Comparison of doctors' knowledge of when consenting on the risks of a conventional peripheral angiogram

**Figure 14:** Comparison of doctors' knowledge of MRI related procedural risks

**Figure 15:** Comparison of doctors' knowledge of when consenting on the risks of MRI

**Figure 16:** Schematic representation of the number of incorrect responses regarding the procedural risks of ultrasound

**Figure 17:** Graphic representation of the percentage of correct responses regarding the use of procedural sedation

**Figure 18:** Graph representing doctors' perceptions as to the health care provider responsible for consenting patients to the risks of medical imaging

**Figure 19:** Pie chart illustrating doctors' level of comfort when consenting patients to the risks of medical imaging

**Figure 20:** Pie chart demonstrating clinicians' responses to the question: "Have you ever referred a patient for medical imaging knowing that the results would not affect the outcome?"

**Figure 21:** Graph listing clinicians' reasons for imaging referral knowing that patient outcome would be unaffected

## **List of Tables**

**Table 1:** Summary of age range

**Table 2:** Distribution of respondents according to year of clinical experience

**Table 3:** Frequency distribution of respondents according to university

**Table 4:** Frequency distribution of respondents according to professional level

**Table 5:** Differences in scores for the category doctors' knowledge of the procedural risks of medical imaging

## 1. Rationale

Diagnostic imaging forms an integral part of patient evaluation and its use has increased dramatically.<sup>1</sup> Not only is medical imaging a source of increased radiation dose, but also poses other risks such as those related to the procedure performed, adverse effects of contrast, the risks of sedation and medication administered, para-magnetic risks, acoustic risks and heat deposition.<sup>2-8</sup>

Clinicians currently refer for imaging with increasing frequency for a myriad of reasons ranging from defensive practice against medicolegal litigation, a rise in entrepreneurial activity by physicians, shorter hospital stays, patient demand, improved speed and accuracy of diagnosis and to supply a larger population.<sup>9</sup>

In the South African context, being faced with a quadruple burden of disease and with access to improved technology, it stands to reason that there would be a greater reliance on radiological imaging in the investigative workup of patients.<sup>10</sup>

Despite the rules governing radiation equipment and practice, there are no absolute regulations guiding referral practice, which is instead left to the discretion of the referring practitioner.

The increased availability of medical imaging does make it prone to overutilization and together with rapidly advancing technology and novel applications, the cost of health care has steadily inflated.<sup>11,12</sup> Many authors caution against the excessive use of imaging arguing that in up to 20 – 50% of cases, imaging does not significantly alter patient outcome and translates instead to exposure to unnecessary risk.<sup>1,2,5,6</sup>

The literature reveals that consenting patients to the risks of medical imaging is often lacking, with uncertainty regarding issues such as who should consent the patient, what risks should be covered, when and how consent should be obtained.<sup>13-18</sup> Many patients are often not aware of and have not been consented to the risks of the investigations that they are about to undergo.<sup>3,14,15,17,18</sup> This may be explained, in part, by the lack of

knowledge amongst health care workers themselves regarding the risks of medical imaging.<sup>14,19–21</sup>

Radiology remains an elusive field to the medical student and despite it being one of the fastest growing medical specialties, to date there are neither local nor international standardized, structured undergraduate training programs aimed at guiding medical trainees on appropriate referral of patients and educating them on the associated risks of each imaging modality.<sup>22–24</sup>

Local data regarding the awareness of the risks of medical imaging and consent practices is necessary to advocate for the use of best practice guidelines such that both the patient and the clinician are protected.

This planned survey aims to establish the level of awareness amongst doctors on the risks associated with medical imaging, to understand the perceptions around responsibility for consent and to gauge the levels of confidence amongst doctors with regards to consent for medical imaging. Doctors at varying stages of their medical careers at Groote Schuur Hospital, one of three tertiary level institutions in Cape Town, were sampled.

The imaging modalities currently available at Groote Schuur Hospital (GSH) include radiography, mammography, ultrasonography (US), computed tomography (CT), fluoroscopy, interventional radiography, magnetic resonance imaging (MRI), positron emission tomography (PET), scintigraphy and single-photon emission computed tomography (SPECT). Each modality carries potential risks to the patient and the staff operating the equipment and as such cautious consideration should be given to each investigation requested.

## **2. Literature review**

### **2.1. Risks of medical imaging**

The risks of diagnostic imaging are multi-factorial and include the ever-controversial risk of radiation as well as procedure related risks, risks relating to sedation and medication administered (including intravenous contrast), para-magnetic risks, acoustic risks and heat deposition.

#### **2.1.1. Ionizing radiation/ Dose**

World-wide populations are exposed to both naturally occurring "background" radiation consisting of exposures arising from cosmic, terrestrial, inhalational (radon) and ingested (K-40, C-14) sources. Artificial sources include medical, atmospheric nuclear testing, occupational exposures and consumer items (including cigarettes, air travel and building materials). When added together, these sources form an estimated dose of 3mSv per annum.<sup>25</sup>

Most of the epidemiological data regarding the adverse effects of ionizing radiation have been extrapolated from information gathered from atomic bomb survivors at Hiroshima and Nagasaki or populations living near nuclear disasters such as Chernobyl.<sup>3,26</sup> Even though research suggests that all radiation exposures may be detrimental, whether such estimations assess the ramifications on people exposed to lower clinical doses of ionizing radiation has been extensively debated.<sup>3</sup>

International committees such as NCRP and ICRP (National Council on Radiation Protection and International Commission on Radiation Protection) state that "the most widely accepted risk models estimate the lifetime attributable risk of radiation-induced cancer with a linear no-threshold dose–response curve".<sup>27</sup> It is clear that high doses of ionizing radiation, such as those received from nuclear disasters, are directly associated with an increase in radiation poisoning and actual cancers.<sup>28</sup> For lower doses of radiation, such as those used in diagnostic imaging, the linear no-threshold dose concept has been the most widely accepted theory. This assumes that the risk of malignancy is a linear

correlation with the biological effect of the absorbed radiation dose i.e. any exposure to radiation above zero-dose linearly increases the risk of carcinogenesis and death.<sup>28</sup>

Radiation side effects can thus be divided into deterministic and stochastic, each having detrimental effects on the patient. Deterministic effects, such as cataract formation, skin erythema, burns and hematopoietic damage amongst others, have a threshold dose at which they occur and the severity tends to increase with an increase in dose.<sup>3,29</sup> With regard to stochastic effects, there is no threshold dose for an effect to occur and examples include radiation induced cancers and genetic effects. The probability of a stochastic effect occurring increases with dose however the severity of the effect remains unrelated to dose.<sup>29</sup>

A recent landmark observational retrospective cohort study in the United Kingdom reported a positive association between ionizing radiation dose from computed tomography scans and the excess relative risk of haematological and brain tumours in children.<sup>30</sup> A similar, larger study in Australia, compared children exposed to CT with unexposed controls.<sup>31</sup> Both studies have provided concordant results to those extrapolated from the Life Span Study of Japanese atomic bomb survivors, however Mathew et al demonstrated not only an increase in haematological and brain tumours, but a 24% increased incidence of all cancers in those participants who were exposed to CT in childhood.<sup>26,31</sup> These studies bolster support for the popular linear no threshold dose-response theory.<sup>32</sup>

There are many modalities in a diagnostic imaging department that utilize ionizing radiation in image production. Examples include plain film, fluoroscopy and CT. CT has the highest associated dose risk and its increasing usage is of some concern.<sup>33,34</sup> Surveys of United States medical facilities show that the annual number of CT examinations have increased from approximately 3.6 million in 1980, to 13.3 million in 1990, and to 33 million in 1998.<sup>33</sup> The technical capabilities of CT are rapidly improving providing multi-slice hardware and new applications, such as CT fluoroscopy, that have the potential to increase radiation exposures to patients.<sup>33</sup>

Average surface radiation doses in adults have been estimated by various investigators using phantoms and these range between 30–70 mGy (3.0–7.0 rad) per head scan series and 20–50 mGy (2.0–5.0 rad) for abdominal series.<sup>33,35,36</sup> This means that a typical abdominal CT is 200–300 times more than that of a typical chest radiograph, 20–30 times more than a single view craniocaudal mammogram, and approximately 10–20 times more than a typical abdominal radiograph.<sup>33</sup> It was estimated that in 2001, about 13% of all United States radiology procedures were CT examinations which contributed approximately 30% of the collective dose in the United States.<sup>33</sup> It is important that radiologists remain responsible users of the modality and be viewed as guardians of public health by being involved in the promotion of public awareness of the radiation risks related to CT.<sup>33</sup>

### **2.1.2. Iodinated contrast media used in CT**

The use of contrast media in radiology has increased alongside the increasing use of diagnostic imaging.<sup>37</sup> Adverse events after injection of iodinated contrast media fall into three categories: toxic reactions, immediate hypersensitivity reactions, and events unrelated to the exposure of contrast material itself e.g. vasovagal reactions.<sup>38,39</sup>

Clinical symptoms of immediate hypersensitivity reactions include pruritis and urticaria (most common), flushing, nausea, cramping, diarrhoea and rhinitis.<sup>38</sup> More severe presentations including cardiovascular shock and cardio-respiratory arrest. The most significant risk factor for an immediate hypersensitivity reaction was a previous immediate reaction. Other risk factors included severe allergy, asthma, cardiac disease and treatment with beta-blockers.<sup>38</sup>

Contrast media have evolved from the creation of non-ionic, low-osmolar contrast media to minimize the incidence of immediate hypersensitivity reactions, to the development of iso-osmolar contrast media which has further decreased these reactions.<sup>37</sup> Despite these advances acute renal failure, or contrast media-induced nephropathy (CIN), remains a major complication of diagnostic imaging examinations.<sup>37</sup>

Contrast media-induced nephropathy is defined as "an increase in serum creatinine level of  $\geq 0.5$  mg/dL (44  $\mu$ mol/L) or  $\geq 25\%$  above the baseline occurring within 3 days after intravascular administration of contrast media, without an alternative cause".<sup>37</sup> Contrast media-induced nephropathy has become the third leading cause of acute renal failure necessitating hospitalization. The overall reported incidence ranging from 2% in the general population to approximately 11% in hospitalized patients.<sup>40</sup> In patients with underlying hypertension, cardiovascular disease, diabetes mellitus, or pre-existing renal insufficiency, the incidence is even higher (20%–50%).<sup>40</sup> Other risk factors reported by Ledneva et al. include large volumes of contrast media, intra-arterial route of administration of contrast media, repeated use of contrast media (within 72 hours), dehydration, advanced age, use of concomitant nephrotoxic drugs, multiple myeloma and liver diseases.<sup>37</sup>

Many physicians who refer patients for imaging procedures necessitating contrast media are not fully aware of the risk for contrast media-induced nephropathy.<sup>41</sup> A survey by Konen et al. of 203 physicians who commonly referred patients for CT scans, showed that more than half were not aware of the potential risks associated with contrast media and less than half considered type 2 diabetes mellitus to be a risk factor for complications.<sup>41</sup>

### **2.1.3. Risks of MRI**

MRI has been regarded as the safer alternative to modalities that make use of ionizing radiation, for example CT.<sup>42</sup> This is not to say that MRI is completely risk free. The risks result from the pulsed radiofrequency field resulting in heat deposition, pulsed gradient fields that can result in electromagnetic induction and strong static magnetic fields that result in ferromagnetic interactions and implanted-device dysfunction.<sup>42</sup>

### **2.1.4. Contrast media used in MRI**

Intravenous Gadolinium-based contrast media are widely used in magnetic resonance imaging (MRI) for a number of reasons: improved sensitivity of lesion detection, better diagnostic specificity and more accurate delineation of extent of the disease.<sup>43</sup>

MRI contrast media were believed to have superb safety profiles with almost no side effects, which resulted in them being used routinely as the safe alternative modality to CT in patients with hypersensitivity to CT contrast media.<sup>39</sup> In separate studies both Murphy et al. and Li et al. reported a similar incidence (approximately 0,01%) of severe life-threatening anaphylactoid reactions with Gadolinium-based contrast agents.<sup>43,44</sup> In a similar study Caro et al. investigated the risk of life-threatening events with iodinated contrast agents, reporting an incidence of 0.031% for low-osmolarity iodinated radiographic contrast and 0.157% for conventional ionic contrast media, thus confirming that gadolinium-based MR contrast media are safer.<sup>45</sup>

Immediate hypersensitivity reactions occur within 1 hour of MR contrast media and range from mild pruritis and urticaria, to more severe reactions such as angioedema, bronchospasm, and anaphylaxis.<sup>39</sup>

Risk factors for immediate hypersensitivity reactions are female gender, allergies and asthma.<sup>39</sup> The type of contrast media also determined risk, with Gadodiamide having the lowest rate (0.013%) of immediate hypersensitivity reactions and Gadobenate dimeglumine the highest (0.22%).<sup>39</sup> The incidence of immediate hypersensitivity reactions increased depending on the number of exposures to MR contrast.<sup>39</sup> Nausea, vomiting, sweating, warmth, anxiety and reactions involving the site of injection such as pain and burning sensations were not considered when making these calculations of risk.<sup>39</sup>

In addition to a lower incidence of hypersensitivity reactions when compared to iodinated contrast media, gadolinium also has a lower incidence of contrast induced nephropathy. Risk factors for contrast induced nephropathy include renal insufficiency, advanced age, diabetes, liver and heart disease, intra-arterial injection and high volumes of contrast administration, amongst others.<sup>46</sup>

Nephrogenic systemic fibrosis (NSF) is a fibrosing disorder of insidious onset, exclusively affecting patients with renal impairment, with most cases reported having been exposed to Gadolinium.<sup>47</sup> Systemic involvement includes fibrosis of organs such as the lung, myocardium, and striated muscle, resulting in significant disability and morbidity.<sup>47</sup>

Patients with higher cumulative doses of Gadopentetate dimeglumine had a higher risk of developing NSF than those receiving lower cumulative doses.<sup>47</sup>

In the paediatric population there are only ten biopsy-confirmed cases of NSF held in record at the Yale NSF registry, and as such there is insufficient evidence to determine risk accurately in this population.<sup>48</sup> Based on the theory that immature renal function places the paediatric population at risk, administration of high risk Gadolinium agents is not advisable in the neonate, is cautioned in the infant population and should be delayed further in the premature and very low birth weight infants.<sup>49</sup>

### **2.1.5. Sedation and drug related risks**

Diagnostic imaging sometimes requires the administration of medications, for example peri-procedural sedation for intervention or antispasmodics during fluoroscopic barium enemas. It is reported that the greatest proportion of adverse events occurring during the delivery of health care relates to the ordering and administration of medications.<sup>6</sup> Incorrect dosage calculation is one of the leading causes of prescribing error, with an incidence reportedly as high as 15%.<sup>6</sup>

Sedation during diagnostic imaging utilizes drugs aimed at safeguarding spontaneous respiration and protective reflexes while diminishing awareness, memory, and discomfort during unpleasant procedures.<sup>7</sup> The incidence of complications relates to the drug or drug combinations used, the dose and rate at which administered and patient sensitivity.<sup>50</sup>

Hypoxia, apnoea, cardiovascular instability, paradoxical reactions, emesis and aspiration are some of the complications of procedural sedation reported by Miller et al.<sup>6</sup> Major complications such as respiratory compromise, hypotension and dysrhythmia are reported to be below 1%.<sup>6</sup>

Arepally et al. investigated the rate of adverse events associated with conscious sedation during interventional procedures.<sup>51</sup> The reported incidence of respiratory complications resulting from excessive sedation occurred most often, with an incidence approximately

5%. This increased depending on the procedure being performed, for example respiratory complications were greatest (9%) with biliary drainages.<sup>51</sup> No cardiac arrests occurred during this study. Hypotension was considered a major adverse event, with an incidence of approximately 2%.<sup>51</sup>

Drugs such as Hyoscine Butylbromide (Buscopan) are commonly used in the radiology department as a gastroparetic and antispasmodic agent. Common side effects described include dry mouth, postural hypotension, blurred vision, confusion, cognitive impairment and less commonly hypersensitivity reactions. Toxic doses may result in neuromuscular blockade and cardio-respiratory arrest.<sup>52</sup>

Metoclopramide may be used for promotion of peristalsis or as an anti-emetic in the radiology department. At usual therapeutic doses it is generally well tolerated. The more common side effects are usually mild and transient, consisting of drowsiness, restlessness, bowel disturbances, dizziness and faintness. Serious extra-pyramidal side effects may occur at higher doses.<sup>53</sup>

Beta-blockers may be utilized for the acquisition of CT coronary angiograms, amongst other procedures. Common side effects include bradycardia, arteriolar and bronchial constriction.<sup>54</sup>

#### **2.1.6. Procedural risks**

The scope of interventional radiology is vast, utilizing image guidance in the diagnosis and treatment of pathologies of the various systems, including vascular, hepatobiliary, thoracic, genitourinary and central nervous systems. The incidence of complications is increasing, and this may be in part due an overall increase in the number of medical interventions.<sup>55</sup> Procedures include the percutaneous placements of stents, balloon dilatation or embolization amongst others. Although relatively safe, these procedures are not without risk and include not only the hazards of radiation exposure and contrast

administration but also those occurring locally at the site of intervention as well as remote and systemic complications.<sup>56</sup>

Local complications include haemorrhage, formation of a false aneurysm, arteriovenous fistula, thrombosis, or nerve damage. Intervention site complications include arterial dissection, vascular occlusion or rupture, injury to biliary ducts or neighbouring structures and failed deployment of devices. Remote complications include distant micro and macroembolisation, migration of deployed devices and in extreme cases death.<sup>8</sup>

Rudstrom investigated the nature of iatrogenic vascular injuries associated with postoperative death within 30 days in a population of Swedish patients that underwent interventional procedures.<sup>8</sup> The approximate reported incidences of death following iatrogenic vascular injuries were 88%, 83% and 78% in the hands of interventional cardiologists, interventional radiologists and general surgeons respectively.<sup>8</sup> Of these injuries 42% were considered avoidable and were the result of either inferior standard of care or deviation from accepted standards of practice.<sup>8</sup> Recommendations made by the investigating team included careful consideration of non-invasive alternatives as well as the need for clear procedural indications in vulnerable patient populations and careful risk-benefit assessment.<sup>8</sup>

## 2.2. Consent

Medical professionals are governed by various statutes including the South African Constitution, the National Health Act, the Health Professions Council of South African (HPCSA) guidelines and common law. Specifically, the National Health Act dictates that patients be provided with the necessary information regarding their health status, the diagnostic and treatment options available and the benefits and risks of each option.<sup>57</sup> It is advocated that the health care provider clearly delineates the scope of consent being sought, particularly if multiple practitioners provide care or multiple different investigations and treatments are offered, as is often the case.

The HPCSA, a national professional board governing health care practitioners, provides guidelines as to who should obtain consent in these circumstances. In the HPCSA booklet "Seeking patients' informed consent: the ethical considerations", it states that the responsibility for consent lies with the health care practitioner "providing care or undertaking an investigation", as this practitioner is presumed to have a comprehensive understanding of the procedure or treatment proposed.<sup>58</sup> This should ideally be the practitioner performing the investigation or providing the treatment, however the task may be delegated to an alternative health care provider who complies with the HPCSA's consent guidelines, is adequately qualified and knowledgeable about the proposed examination or therapy.<sup>58</sup> It is important to note that the definition of a health care provider according to the National Health Act of 2003 incorporates not only doctors, but all practitioners regulated by the HPCSA including radiographers, who are responsible for performing the imaging examination.<sup>57</sup>

A group of radiologists, Semelkar et al. proposed that the provision of information about the risks of medical imaging be performed by radiological technologists or radiologic physician assistants.<sup>16</sup> They propose that radiologists could instead be reserved for more complex scenarios, thus saving time and avoiding a reduction in patient throughput. In contrast, a group of radiographers, Friedrich-Nel et al. found in a recent online survey

that 67% of radiographers polled were of the opinion that the referring doctors should obtain informed consent for patients undergoing medical imaging.<sup>59</sup>

Review of the available literature and the statutory body guidelines reveal that there remains varying opinions as to who should obtain consent. The available guidelines are open to misinterpretation stemming from the absence of explicit delegation of responsibility and a failure to provide clear guidance as to what constitutes sufficient knowledge and appropriate qualification.

### **2.3. Knowledge of risk and need for undergraduate radiological education**

There is increased reliance on diagnostic imaging for information necessary to ensure patient wellbeing.<sup>9,60</sup> Often the information from diagnostic imaging investigations is obtained at a risk to the patient, that few doctors have a clear understanding of.<sup>9</sup> According to Blackmore, radiologists who have training in imaging physics and imaging techniques, are ideally suited to influence decision making as to patient selection and how best to image patients but are often not consulted adequately.<sup>61</sup> Increased awareness among referring doctors and patients themselves would help reduce the number of inappropriate examinations and decrease the radiation risk.<sup>9</sup>

In 2007 it was reported that there were no standardized undergraduate radiology teaching programs at an international level.<sup>23</sup> It was also documented that the amount of teaching given to medical students in radiology and nuclear medicine was often inadequate.<sup>23</sup> An introduction to radiological techniques should provide a basic knowledge for clinicians to make use of radiology appropriately in caring for patients.<sup>22</sup> Key objectives of such an introductory course should include gaining appropriate information on radiological examinations for various clinical scenarios, understanding the relative risks of each modality and learning how referring practitioners can be responsible to lower patient radiation exposure.<sup>22</sup>

An argument can be made that such in depth knowledge falls within the realm of the radiologist and Blackmore describes two models for the role of a radiologist with regard

to facilitating the management of requests for patient imaging. In the radiologist 'production model', radiologists are part of a process where images are produced, interpreted and results are communicated.<sup>61</sup> Under the radiologist 'professional model', radiologists are physician experts in diagnostic imaging, specialists in imaging acquisition, interpretation and consultation with an active role in determining how best to apply the imaging information to clinical care.<sup>61</sup>

The concept of 'prima non nocere' (first do no harm) and best practice guidelines require doctors to have an understanding of the potential risks of imaging investigations and allow for appropriate risk/benefit evaluations.<sup>62</sup> Where this knowledge is lacking, appropriate consultation with radiologists becomes necessary in their capacity as experts described by the professional model. The emergence of medico-legal proceedings both internationally and in South Africa concerning radiation exposure from CT scans, as well as escalating health care costs, make this an important issue for all doctors.<sup>62</sup>

#### **2.4. Existing surveys of knowledge with regard to risk**

Lee et al. administered a survey in 2002, the first of its kind, in a US academic medical centre emergency department to assess the level of awareness of patients, referring physicians and radiologists concerning the radiation dosage and the associated risks.<sup>18</sup> The survey demonstrated that most physicians did not counsel patients with regard to the radiation dose or the possible long terms risks associated with CT prior to their being investigated.<sup>18</sup> Perhaps this may be in part due to their own lack of knowledge, as the study went on to prove that most physicians were not aware of accurate dose estimates and did not perceive any increased cancer risks from CT, regardless of their level of experience.<sup>18</sup> Many radiologists were also unable to accurately characterize the dose estimate but nearly half perceived a possible increased cancer risk.<sup>18</sup> The recommendations of the study were that radiology departments be proactive in disseminating information relating to radiation dose and possible long term consequences to referring doctors, patients and the general public in order to foster trust in the radiology community.<sup>18</sup>

The systematic review by Krille et al. assessed physicians' knowledge of radiation dose, finding that only a minority of physicians were well informed regardless of type of education, level of expertise or speciality.<sup>20</sup> Attending radiation protection courses had a positive influence on knowledge in 40% of physicians.<sup>20</sup> The review also demonstrated that improved knowledge of radiation dose did not necessarily lead to reduced CT use in the diagnostic process.<sup>20</sup>

Borgen et al. explored clinicians' knowledge and consideration of radiation dose in relation to referral practice and further explored the differences between physicians and non-physicians. Once again it was demonstrated that most clinicians underestimated the radiation dose from high dose imaging such as barium enemas and CT.<sup>63</sup> Approximately 1 in 10 clinicians incorrectly associated MRI with ionizing radiation while 5% did so with sonography.<sup>63</sup> In terms of risk-benefit consideration, most clinicians weighed the impact of imaging on a patient's clinical outcome higher than the risk of radiation while the patient's request for medical imaging was of lesser concern to practitioners.<sup>63</sup> With regards to use of referral guidelines, close to 60% acknowledged the existence of guidelines but only a third actually made use of such practice.<sup>63</sup> Regarding referral patterns that were known not to affect treatment outcome, most clinicians reported that patient reassurance and conferring to the patient a sense of being taken seriously were rated more important than a perceived lack of time or compensation for insufficient clinical examination.<sup>63</sup> The differences highlighted by Borgen between physicians and non-physicians (general practitioners, chiropractors and physiotherapists), included that non-physicians reported fewer referrals that were unlikely to affect treatment outcome, were more concerned about radiation risk and made use of referral guidelines to a greater extent.<sup>63</sup>

Borgen's recommendations concluded that aside from improving clinician knowledge, attitudes should also be targeted i.e. if the referring practitioners are concerned more about radiation risk, then they would be less likely to request imaging that would not affect treatment outcome.<sup>63</sup> A novel suggestion for improving referring clinicians' knowledge was to incorporate guidelines into the hospital's computerized referral system so that real time access to decision support was available. This may prove helpful in our

local setting as PACS/RIS has recently been implemented at Groote Schuur Hospital with plans for future roll out in all state hospitals in South Africa.

It is evident from international literature that there is widespread underestimation of radiation risk of CT and high dose exams. In a German cross sectional survey it was estimated that 41% of prescribers indicated that they seek radiologist consultation prior to requesting paediatric CT scans.<sup>64</sup> In the same study almost 20% of practitioners expressed interest in being provided with content regarding radiobiology.<sup>64</sup>

An investigator from Ireland, Reddan et al. conducted a telephonic survey polling European radiologists as to their knowledge of the risks of contrast associated nephropathy.<sup>65</sup> The study demonstrated a variable, but often poor understanding of the definition, risk and impact of contrast induced nephropathy.<sup>65</sup>

In a local study, published by Andronikou et al, South African radiologists were found to have limited knowledge of paediatric computed tomography scanning and methods of dose reduction.<sup>66</sup> This was found despite the majority of respondents (90%) acknowledging that the radiologist is ultimately accountable for dose reduction during computed tomography scanning.<sup>66</sup>

There is paucity of data in the literature documenting the awareness of radiologists and clinicians regarding the remaining risks of medical imaging, such as sedation and paramagnetic risks. Local data pertaining to doctors' knowledge of the risks of medical imaging and their perception of responsibility for consent is also deficient. This study aims to address the gap in the literature and establish the local status quo for the Western Cape. In so doing, it may be possible to extrapolate these insights to the broader South African context, allowing for the institution of appropriate teaching programmes and interventions that inform future policy and improve practice.

### **3. Aim**

To survey and compare the levels of knowledge between radiologists and referring clinicians regarding the risks to patients undergoing medical imaging, to assess the perceptions regarding responsibility for consenting patients about these risks and to identify the levels of confidence amongst doctors when consenting patients to the risks of medical imaging.

### **4. Study Objectives**

1. To determine the demographics of clinicians referring for medical imaging with respect to qualification, years of practice, experience and speciality
2. To determine radiologists' and referring clinicians' knowledge of the risks of radiation, procedural risks, side effects of contrast agents, sedation, drugs, and paramagnetic risks.
3. To determine the perceptions of radiologists' and clinicians' with respect to responsibility for consenting patients on the risks of medical imaging as well as levels of confidence in consenting patients to these risks.
4. To develop a set of recommendations for improving clinical knowledge, practice of referral and dose reduction to patients for the purposes of protecting them from adverse effects of radiation, contrast media, drugs and sedation.

Null hypothesis: There are no difference in the knowledge, attitude and practices of clinicians and radiologists.

Alternative hypothesis: There are differences in the knowledge, attitude and practices of clinicians and radiologists.

## **5. Methods**

### **5.1. Study Design**

A cross-sectional, observational, descriptive study design was employed and the study was conducted using a non-validated, pre-tested, self-administered, structured questionnaire.

### **5.2. Study population and sampling**

The target population comprised all radiologists and all doctors referring patients for imaging to the Department of Radiology at Groote Schuur Hospital, a tertiary academic institution. Medical students, elective exchange doctors and non-physician referrers were excluded.

### **5.3. Sample size calculation**

The sample size calculation was based on a similar study by Lee et al. that found an effect size of 24% difference in accuracy of knowledge of radiation risk between radiologists and clinicians.<sup>21</sup> In order to achieve the same effect size in our study, with 80% power at 95% confidence levels, the two sided Fisher's exact test was used to calculate a required sample size of 32 radiologists and 256 clinicians. The calculated sample size was also fitting, as it was comparable to the approximate population of doctors at GSH at the time of the study (estimated to be around 30 radiologists and 500 non-radiologist clinicians).

#### **5.4. Materials and methods**

Hard copies of the self-administered questionnaire (see section 13.6, Appendix F) were distributed at the beginning of the clinico-radiological meetings by the primary investigator. As all doctors at Groote Schuur Hospital are required to communicate primarily in English, an English questionnaire was employed. Meetings were attended by both radiologists and clinicians in varying stages of their careers, from internship to consultant level. The questionnaires were completed in an anonymous fashion and placed in a sealed box at the meeting room exit. Survey cards were made available for six months to incorporate all weekly, fortnightly and monthly meetings. To prevent the duplication of data, all doctors who had answered the questionnaires at a previous meeting were asked to refrain from filling out a second survey questionnaire.

To reduce sample bias, the primary investigator supplemented the distribution of questionnaires at meetings with visits to various clinical departments. In so doing, doctors who did not attend clinico-radiological meetings, such as staff from outpatients, casualty and radiology departments and night shift workers, were also sampled.

The questionnaire was adapted from previous surveys for use in our local setting and to include aspects that have not previously been investigated, such as risk of medications used during procedures and procedural risks. The questionnaire was piloted amongst a target group to ensure that all questions were easy to understand and un-ambiguous. A focus group discussion was held, following the pilot survey, to discuss the relevancy of questions and ensure that no pertinent topics were excluded and that any sensitive topics were dealt with appropriately. The questionnaire was then adapted and improved to accommodate for this.

## **5.5. Data collection**

The completed surveys were placed into a sealed box. The primary investigator entered responses manually into an electronic database created with the programme Microsoft Excel, using a double entry technique. The following broad categories were created:

1. Demographic information of doctors, qualification level, years of experience, professional level and field of expertise.
2. Doctors' knowledge of risk: In this section of the questionnaire, the various risks were divided into sub-categories, such as radiation, contrast, procedural and drug risks. Respondents' were give a point for each correct answer. The points were summated to give sub-scores as well as a total knowledge score. No negative marking was applied for incorrect answers.
3. Doctors' perceptions regarding responsibility for consent of patients for medical imaging as well as their confidence levels when consenting patients.

## **6. Statistical analysis**

The data analysis was performed using STATA. All respondents were stratified into sub-groups (such as medical speciality, institution and years of experience), which were then correlated to the levels of knowledge, in the form of accuracy scores. This was then transposed against perceptions of responsibility for and confidence levels in consenting patients to the risks of medical imaging.

Categorical data was analysed using cross tabulation to create contingency tables. The  $X^2$  test was used to assess the relationships between categorical variables. Fisher's exact test was used where the requirements for the  $X^2$  test could not be met.

The measure of association was assessed using the odds ratio and corresponding 95% confidence interval.

The 5% significance level was used throughout, unless specified otherwise. Pearson's correlation coefficients were used to determine the association/relationship between knowledge score and demographics such as age, years of experience and job levels:

0.50 and above	high/strong association
0.30 to 0.49	moderate association
0.10 to 0.29	weak association
below 0.10	little if any association

The results are presented as tabulated or illustrated frequencies or percentages for categorical variables.

## **7. Ethics**

Ethical approval for the study was obtained through the UCT ethics committee (please see section 13.1, Appendix A). Permission to conduct the survey at the hospital was obtained from hospital management (please see section 13.4, Appendix D). Permission was also obtained from the relevant heads of each department surveyed. All surveys were voluntary and were conducted and collected anonymously.

### **7.1. Informed consent process**

Informed consent was inferred after participants read the introductory letter and then completed the survey (please see section 13.5, Appendix E). It was emphasized that participation was voluntary. Data was collected anonymously and securely. Participants were encouraged to complete the survey but were informed that the questionnaire could be terminated at any point. No vulnerable or minor populations were surveyed.

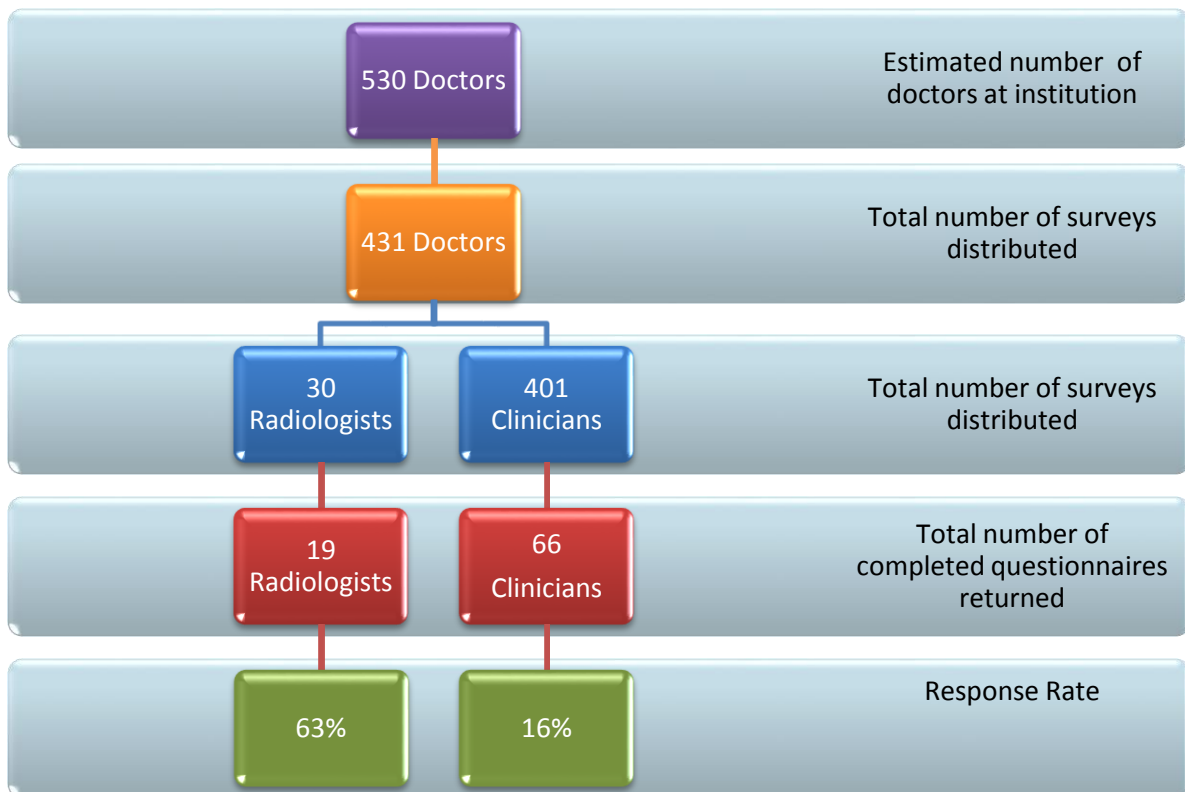
## **7.2. Data safety**

Data was collected anonymously by allocating a random number code to each participant. The key to this code was only be available to the primary investigator and supervisors. Hard copies of the questionnaires were stored within a sealed box in the department of Radiology. Digital data was stored on the personal laptop of the primary investigator with backup copies on two separate hard drives, all password protected and only available only to the researchers.

## 8. Results:

### 8.1. Sample population:

As summarised in Figure 1, a total of 431 questionnaires were distributed amongst 30 radiologists and 401 non-radiologists, out of a total estimated population of 530 doctors in varying stages of their career at one of the foremost tertiary training and research institutions in South Africa. Of those invited to participate, only 85 doctors completed the survey, resulting in an overall response rate of 19,7%. The response rate for radiologists was higher 63,3% (19/30) compared to 16,5% (66/401) for clinicians.



**Figure 1: Schematic representation of the study sample and response rate**

## 8.2. Demographics:

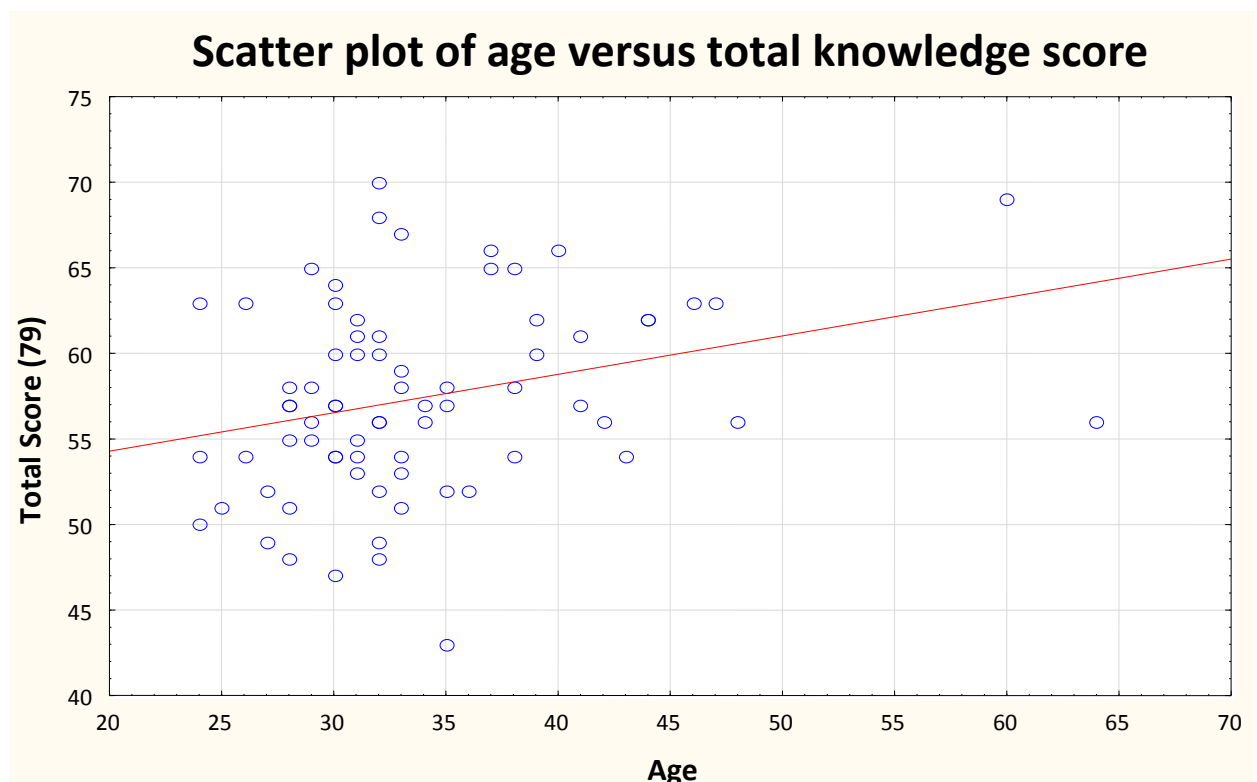
### 8.2.1 Age:

There was a total of 85 respondents with 12 respondents choosing not to disclose their age. The findings are summarised in table 1 below.

Age (years)	Total (n)	Minimum	Maximum	Mean	Standard deviation	Median	25th percentile	75th Percentile
	73	24	64	33.8	7.2	32	30	37

**Table 1. Summary of age range in years**

Figure 2 below demonstrates a statistically significant positive linear relationship between age and total knowledge score (p-value = 0.01), such that higher knowledge scores correlated to older respondents.



**Figure 2: Scatter plot of age versus total knowledge scores (n=73)**

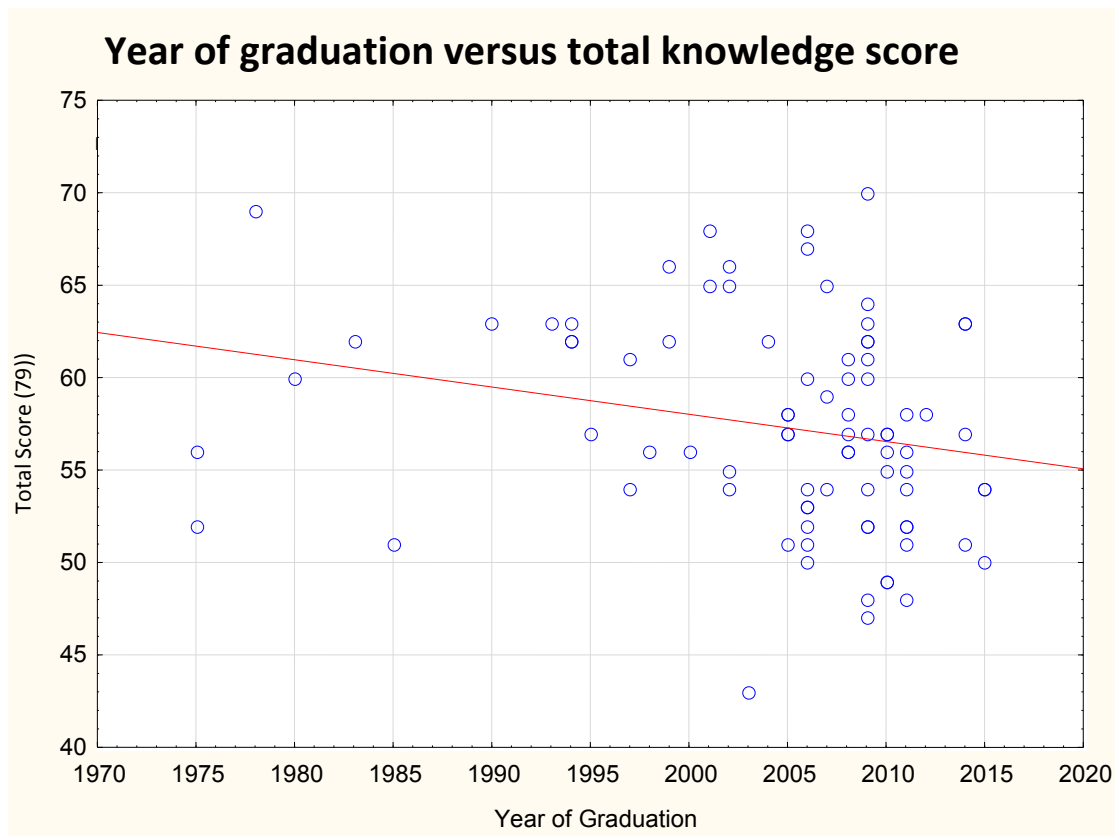
### 8.2.2. Year of graduation:

The largest proportion of respondents (75%) had obtained their undergraduate medical degrees after 2001. Table 2 below summarises the distribution of respondents' years since graduating from medical school.

Range in years since graduation:	Number =85 (%):
Did not disclose	1 (1%)
1975-1985	6 (7%)
1986-1995	6 (7%)
1996-2005	19 (22,5%)
2001-2015	53 (63,5%)

**Table 2: Distribution of respondents according to years of clinical experience**

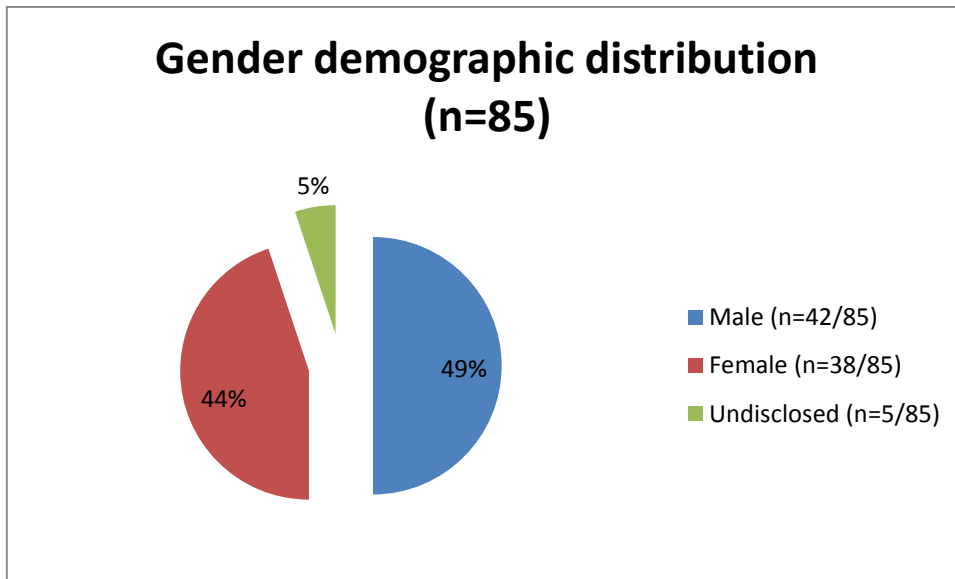
The scatter plot below (figure 3) charts the year of graduation against the total knowledge score and demonstrates a statistically significant, negative linear relationship (p-value =0.00), such that earlier graduation, and therefore greater years of experience, correspond to a higher knowledge score. One participant chose not to disclose their year of graduation.



**Figure 3: Scatter plot comparing year of graduation against total knowledge scores (n=84)**

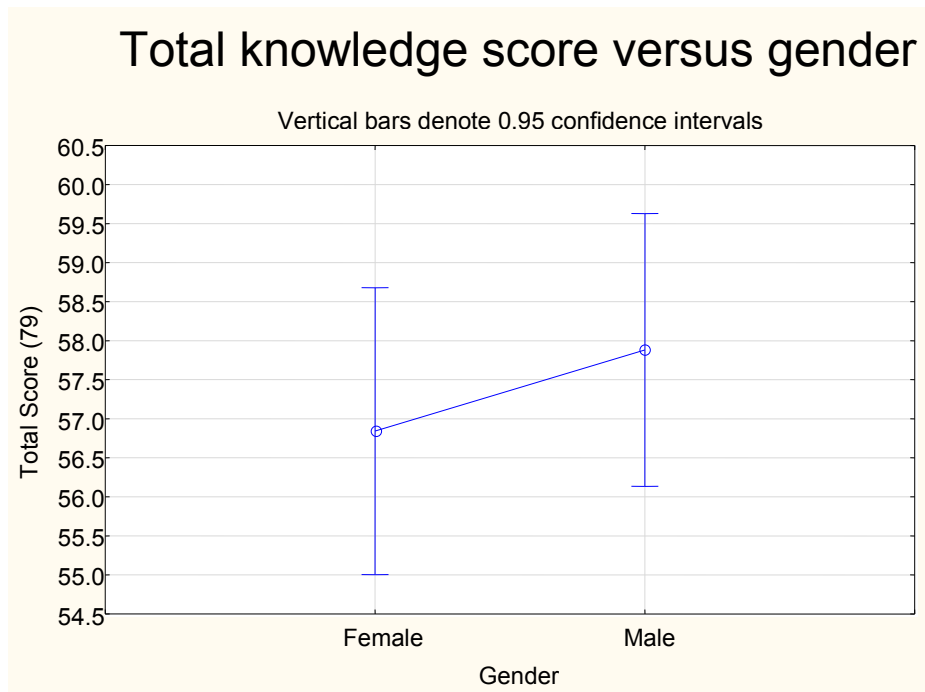
### 8.2.3. Gender:

The gender distribution of participants is summarised in figure 4 below.



**Figure 4: Pie chart illustrating gender distribution of sample population (n=85)**

Figure 5 below demonstrates no statistically significant difference in the overall knowledge scores according to gender with males scoring an average of 73% and females 72% (p-value = 0.38).



**Figure 5: Graph comparing gender against total knowledge scores (n=85)**

#### 8.2.4. University:

The distribution of responses included not only participants from all 8 medical schools within South Africa, but also 17 respondents from international universities, 9 of these respondents being trained in neighbouring African countries. The findings are summarised in table 3 below.

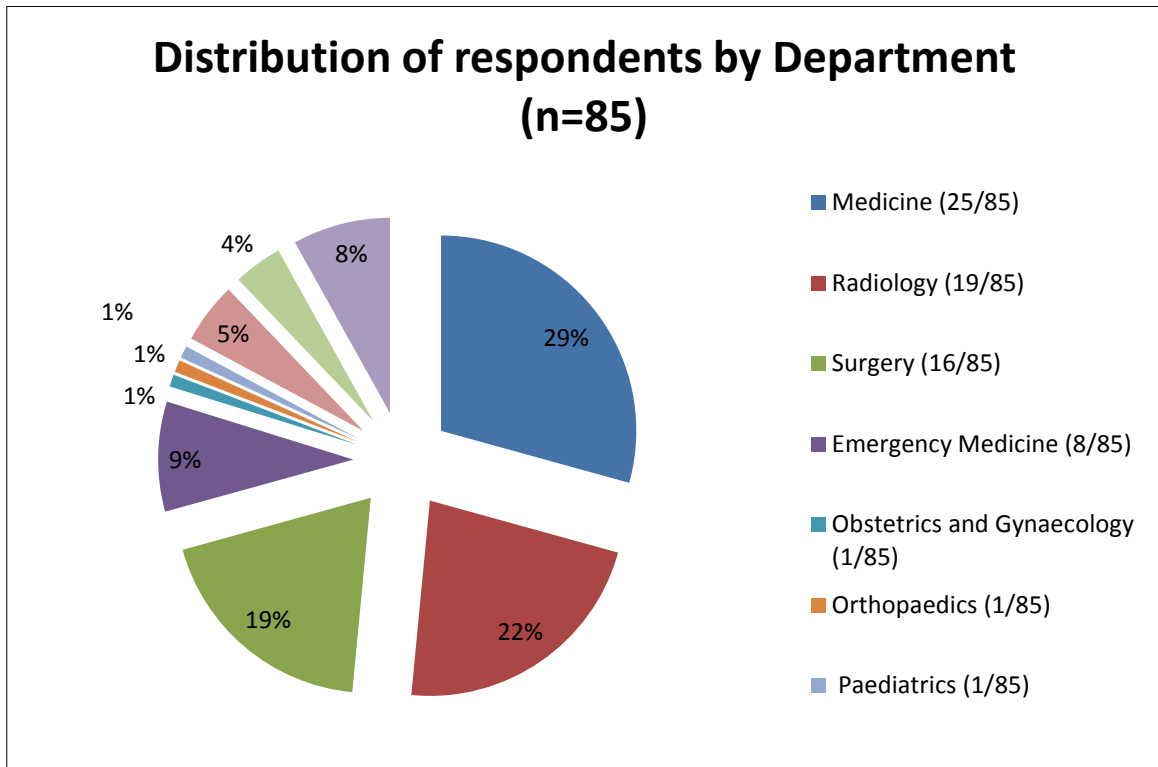
<u>University</u>	<u>N=85 (%)</u>
Sefako Makgatho Health Sciences University (Medunsa)	2 (2%)
University of Cape Town	36 (42%)
University of the Free State	2 (2%)
University of Kwa Zulu Natal	6 (7%)
University of Pretoria	6 (7%)
University of Stellenbosch	5 (6%)
University of Witwatersrand	8 (9%)
Walter Sisulu University	3 (4%)
International	17 (20%)

**Table 3: Frequency distribution of respondents according to University**

There was no significant statistical difference in the total knowledge scores between the local universities, nor when comparing local (mean total knowledge score of 57/ 79 [72%]) to international universities (mean total knowledge score of 56/ 79 [71%]); p-value= 0.75.

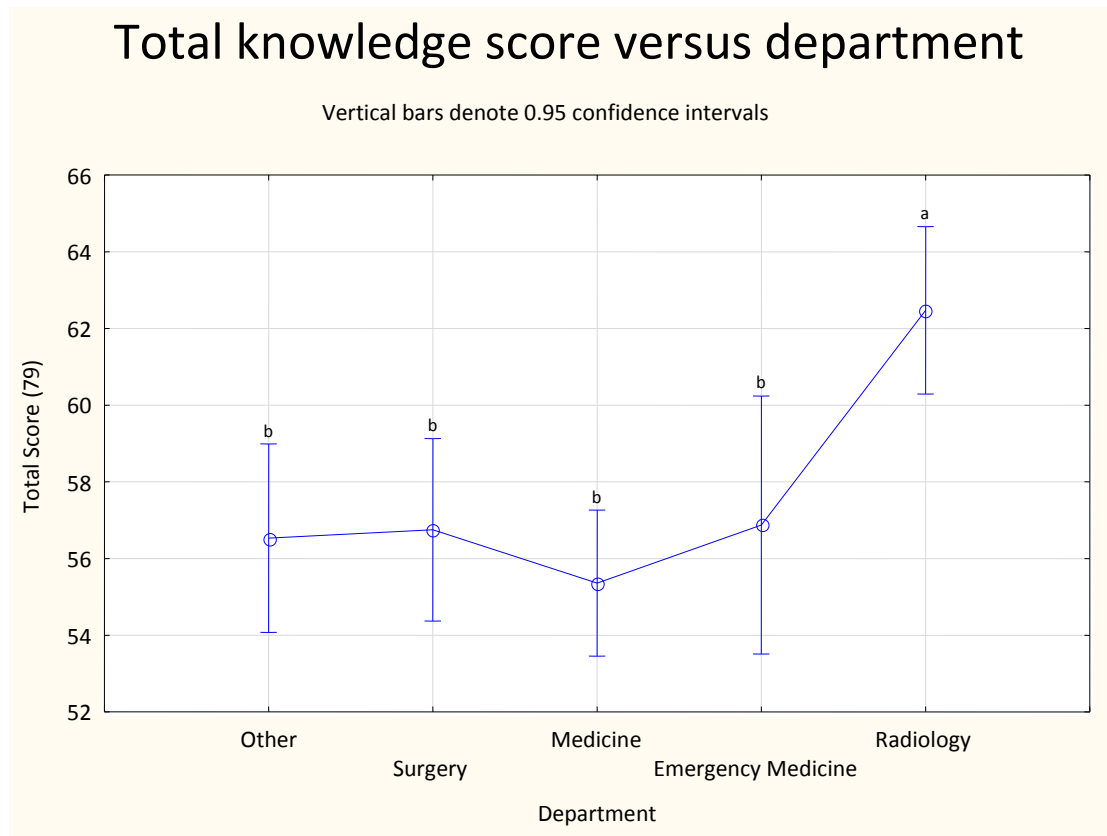
### 8.2.5. Department:

The distribution of respondents according to clinical department is illustrated by figure 6 below, with the largest proportion of respondents from Internal Medicine 25/85 (29%).



**Figure 6: Pie chart demonstrating distribution of respondents by department (n=85)**

There was a statistically significant difference ( $p < 0.01$ ) in total knowledge score between radiologists and clinicians as illustrated in figure 7 below. The group labelled "other" included departments such as anaesthetics, nuclear medicine, orthopaedics and obstetrics and gynaecology. There was no significant difference in the total knowledge scores amongst the various clinical departments, when radiology (group a) was excluded.



**Figure 7: Graph stratifying total knowledge scores by clinical department, where *a* represents radiology and *b* the various clinical departments (n=85)**

### 8.2.6. Professional level:

Table 4 below stratifies participants by professional level. The group "other" was constituted by 1 sessional consultant and 2 sub-specialist fellows. The consultant group included two heads of department.

<b><u>Job title:</u></b>	<b><u>N=85 (%)</u></b>
Consultant	19 (22%)
Registrar	46 (54%)
Medical officer	10 (12%)
Intern	7 (8%)
Other	3 (4%)

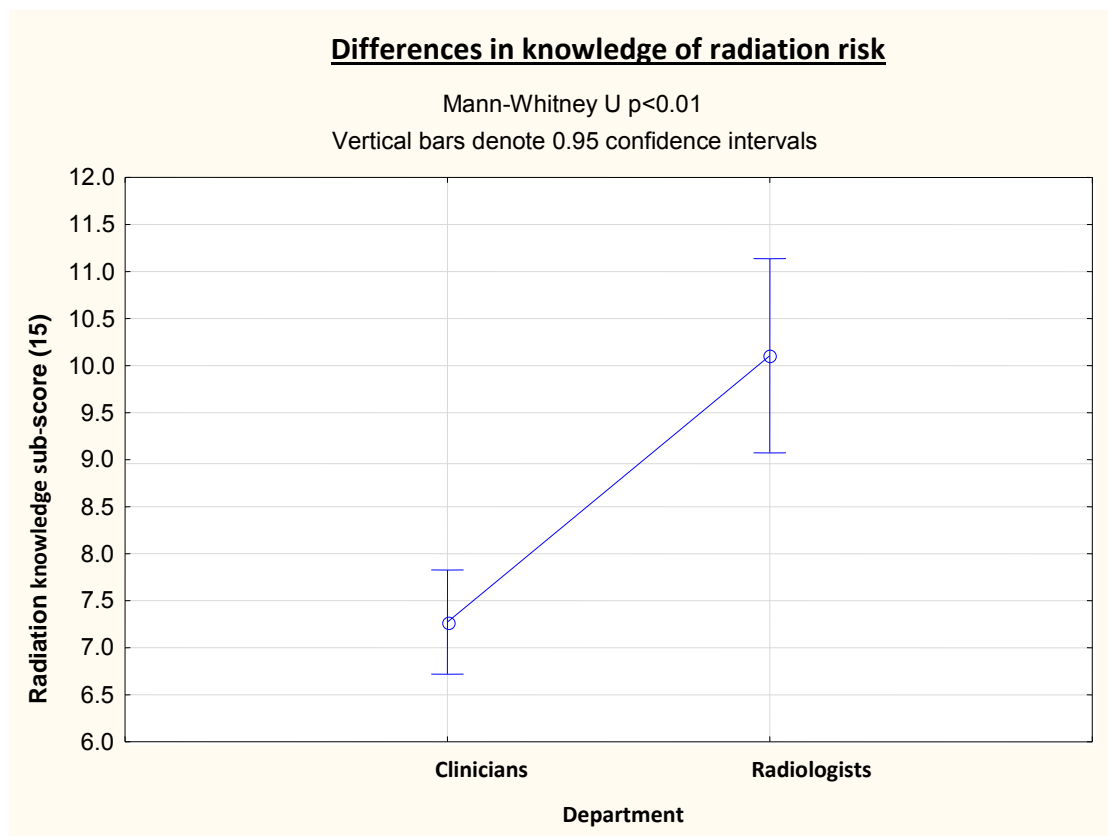
**Table 4. Frequency distribution of respondents according to professional level.**

### 8.3. Knowledge of the risks of imaging:

Doctors' knowledge of the risks of imaging were categorised into the following groups: knowledge of radiation, contrast, procedural and drug related risks.

#### 8.3.1. Knowledge of the risks of radiation:

In this sub-category, there was a statistically significant difference (p-value <0.01) in the mean radiation knowledge sub-scores between radiologists who scored 10/ 15 (67%) and non-radiologists who scored 7/15 (47%), as illustrated in the graph below (figure 8).



**Figure 8: Comparison of scores achieved by clinicians and radiologists regarding the risks of radiation (n=85)**

Radiologists were also more likely to correctly associate procedures such as a barium enema (18/19 [95%] radiologists compared to 36/66 [55%] clinicians; p value= 0.001), conventional vascular angiography (19/19 [100%] radiologists compared to 39/66 [59%] clinicians; p value=0.00021) and SPECT (16/19 [84%] radiologists compared to 37/66

[56%] clinicians; p value=0.037) with the risk of exposure to ionising radiation and MRI to the lack thereof (19/19 [100%] radiologists compared to 53/66 [80%] clinicians; p value=0.026).

Both groups were similarly aware that while radiography (50/66 [76%] clinicians and 17/19 [89%] radiologists; p value=0.1) and CT (54/66 [82%] clinicians and 18/19 [95%] radiologists; p value=0.1) exposed patients to the risk of radiation, sonography did not (61/66 [92%] clinicians and 19/19 [100%] radiologists; p value=0.5).

When asked to determine the radiation dose of a single chest radiograph, 3/66 (5%) of clinicians and 9/19 (47%) of radiologists answered correctly (p-value = 0.000). When asked to estimate the lifetime risk of fatal cancers following an abdominal CT, 6/66 (9%) of clinicians and 5/19 (26%) of radiologists answered correctly (p value= 0.0049). Similarly, 5/66 (8%) of clinicians and 4/19 (21%) of radiologists answered correctly when estimating the risk of developing a cancer following childhood CT (p-value=0.1).

More clinicians could correctly answer that a single chest radiograph exposed one to more radiation than a 5-hour flight (19/66 [29%] clinicians compared to 3/19 [16%] radiologists; p value= 0.0054). When asked to compare the radiation dose of a CT Chest to that of an hour spent at Chernobyl in 2010, more than half of the clinicians (36/66, 55%) were unsure. Only 3/19 (16%) of radiologists and 10/66 (15%) of clinicians answered correctly that a CT chest exposed one to a greater dose of radiation than an hour at Chernobyl in 2010.

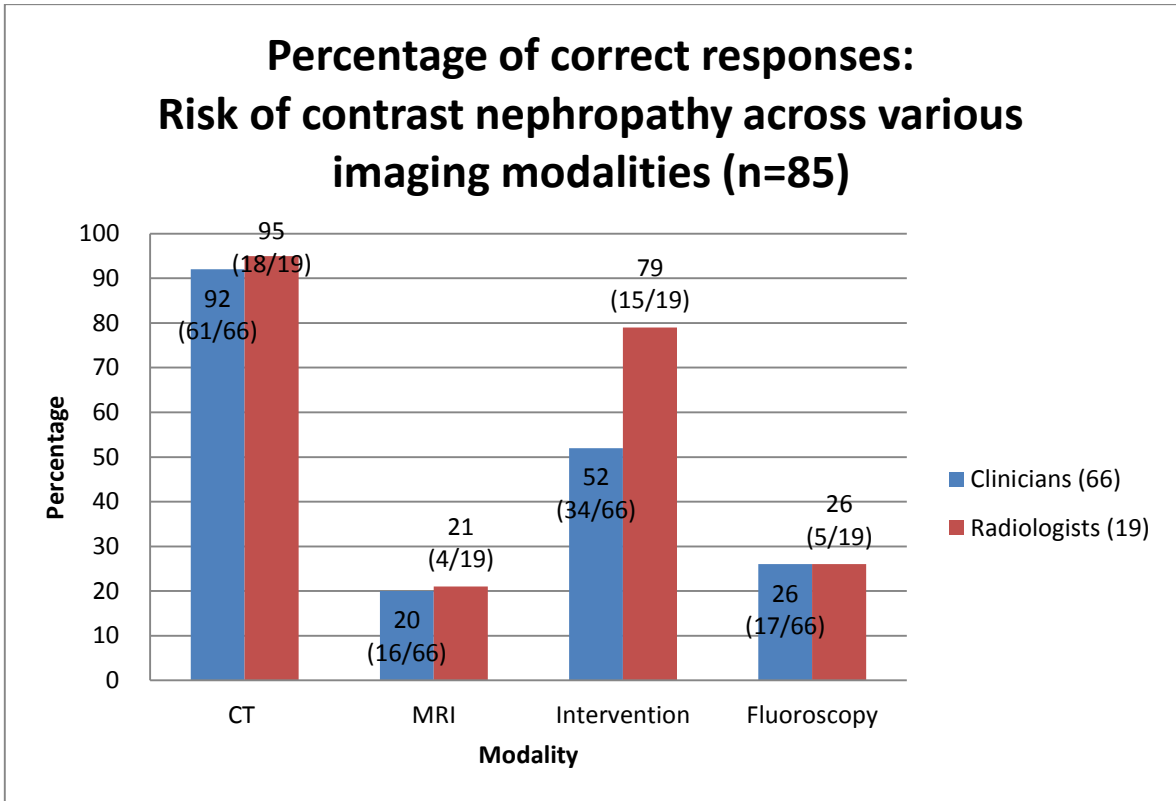
The radiation dose received from a CT chest is less than that received from smoking 1,5 packs of cigarettes per day over a period of a year. Radiologists were more likely than clinicians to answer this question correctly, (9/19 [47%] radiologists compared to 19/66 [29%] clinicians; p value=0.012). A large proportion of doctors (59/66 [89%] clinicians and 18/19 [95%] radiologists; p value=0.14) correctly responded that the negative effects of exposure to radiation was greater for a child than for an adult.

Deterministic effects of radiation exposure include cataract induction and skin erythema, a question that more radiologists answered correctly when compared to clinicians (29/66 [44%] clinicians, 15/19 [79%] radiologists; p value =0.008).

### **8.3.2. Knowledge of the risks of contrast nephropathy:**

Most doctors accurately answered that intravenous iodinated contrast media placed patients at risk for contrast nephropathy during CT with no significant difference in accuracy between the two groups (61/66 [92%] clinicians and 18/19 [95%] radiologists; p-value= 0.7). Only a small proportion (17/66 [26%] clinicians and 5/19 [26%] radiologists) acknowledged the possibility of this risk occurring during fluoroscopic procedures (refer to figure 9 below).

Regarding contrast usage during interventional procedures, radiologists (15/19, 79%) were more aware of the risk of contrast nephropathy than clinicians (34/66, 52%); p-value= 0.038. However, both groups were equally unaware of the risk of contrast nephropathy following intravenous gadolinium contrast administration, with only 13/66 (20%) of clinicians and 4/19 (21%) of radiologists accurately answering this question, as illustrated in the figure below (figure 9).



**Figure 9: Comparison of doctors' knowledge of the risk of contrast nephropathy across various modalities (n=85)**

### 8.3.3. Knowledge of procedural risks:

Doctors' knowledge of procedural risks was categorised according to modality namely CT, MRI, ultrasound, intervention and fluoroscopy. Table 5 below summarises the various procedural risks and compares the average scores obtained by radiologists and clinicians.

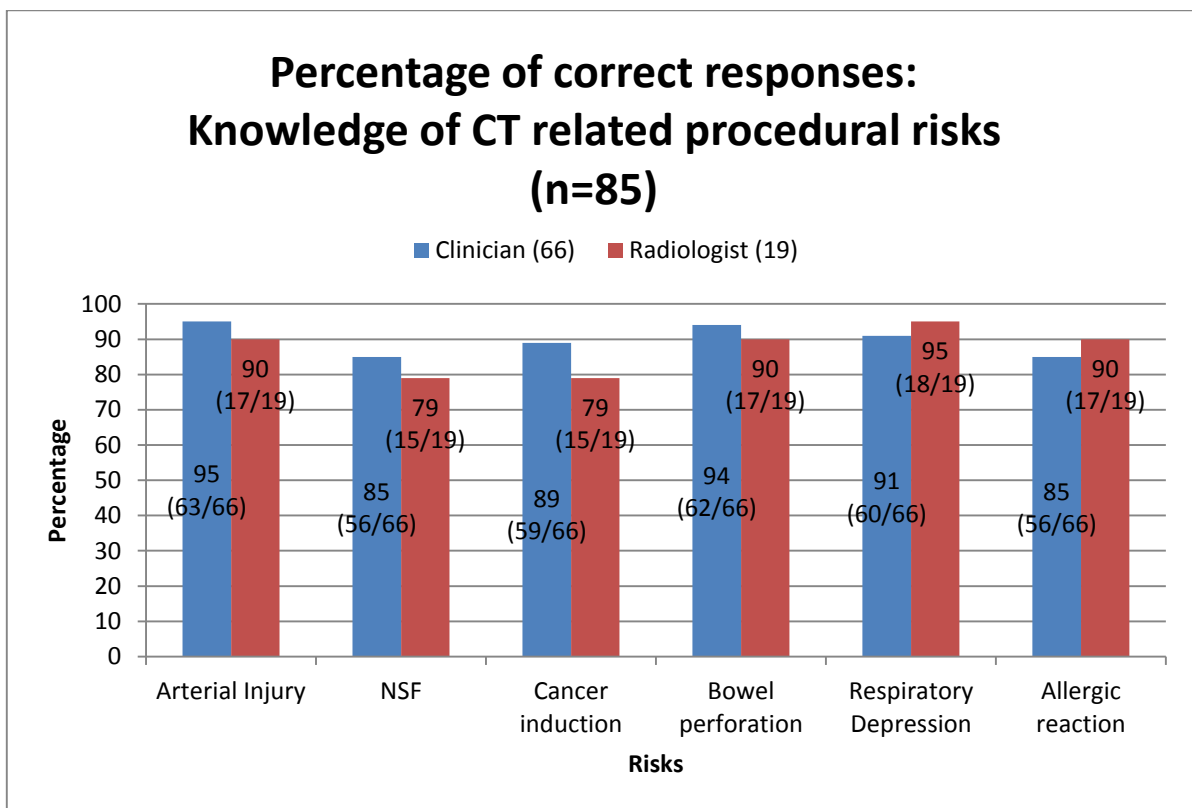
<b><u>Modality</u></b> <b><u>(maximum score)</u></b>	<b><u>Radiologists' mean score</u></b> <b><u>(standard deviation)</u></b> <b><u>{n=19}</u></b>	<b><u>Clinicians' mean score</u></b> <b><u>(standard deviation) {n=66}</u></b>	<b><u>p-value</u></b>
<b>CT (8)</b>	7.15 (0.89)	7.27 (0.95)	0.99
<b>MRI (13)</b>	10.2 (1.32)	9.16 (1.58)	0.99
<b>Ultrasound (8)</b>	7.89 (0.31)	7.96 (0.17)	0.99
<b>Intervention (14)</b>	11.21 (1.61)	9.36 (1.88)	0.99
<b>Fluoroscopy (8)</b>	5.74 (0.9)	5.15 (1.04)	0.99

**Table 5 Differences in scores for the category doctors' knowledge of the procedural risks of medical imaging (n=85)**

There were no statistically significant differences in the mean sub-scores for the various categories of procedural risks. The results are explained in further detail in the individual sub-categories below.

### 8.3.3.1. Knowledge of computed tomography (CT) related procedural risks:

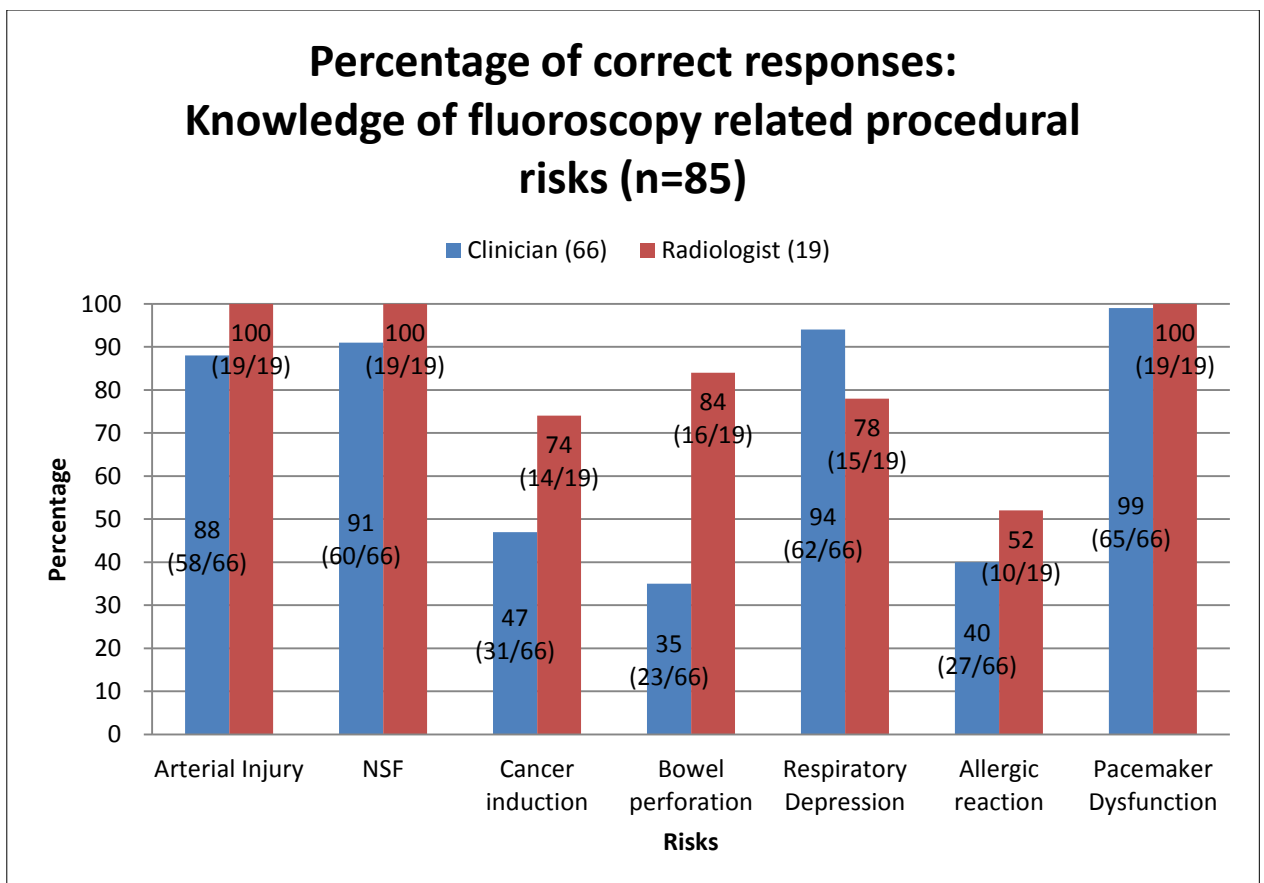
Overall doctors' knowledge regarding the procedural risks of CT was high. Most doctors were able to correctly answer that nephrogenic systemic fibrosis (NSF) was not associated with CT. They also correctly estimated that the risks of arterial injury, bowel perforation and respiratory depression were low and that notable risks included allergic reactions to contrast media and cancer induction. Clinicians were more likely to answer correctly that CT was linked to cancer induction (59/66 [89%] clinicians compared to 15/19 [79%] radiologists; p-value=0.2). These findings are graphically represented in figure 10 below.



**Figure 10: Comparison of doctors' knowledge of CT related procedural risks (n=85)**

### 8.3.3.2. Knowledge of fluoroscopy related procedural risks:

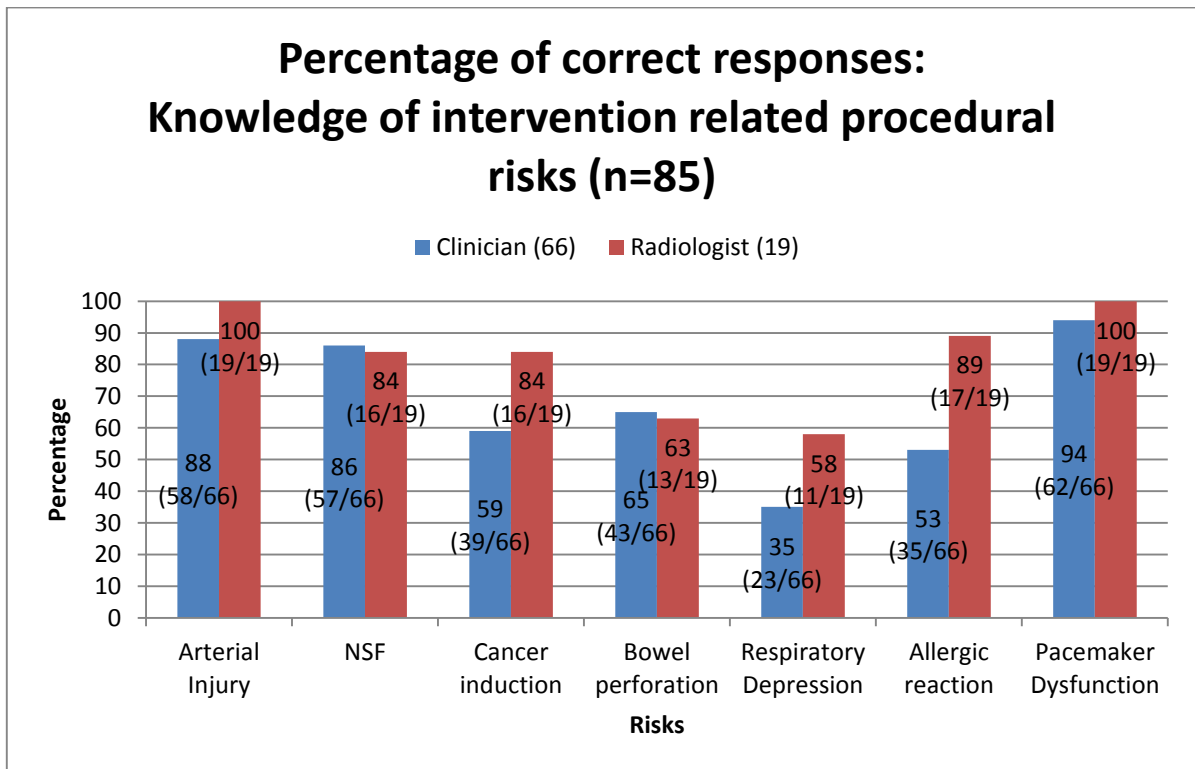
Regarding fluoroscopic risks, most respondents correctly answered that arterial injury, respiratory depression and pacemaker dysfunction were negligible risks and that nephrogenic systemic fibrosis was not a consideration. Of significance, a large proportion of clinicians (43/66, 65%) were unaware of the potential risk of bowel perforation during fluoroscopic procedures such as a barium enema. In comparison, 16/19 (84%) radiologists answered this question correctly (p-value =0.00017). Regarding awareness of the carcinogenic risks of fluoroscopy, radiologists were more likely to answer correctly (14/19, [74%] radiologists compared to 31/66 [47%] clinicians; p-value= 0.03). Figure 11 below summarises these findings.



**Figure 11: Comparisons of doctors' knowledge of fluoroscopy related procedural risks (n=85)**

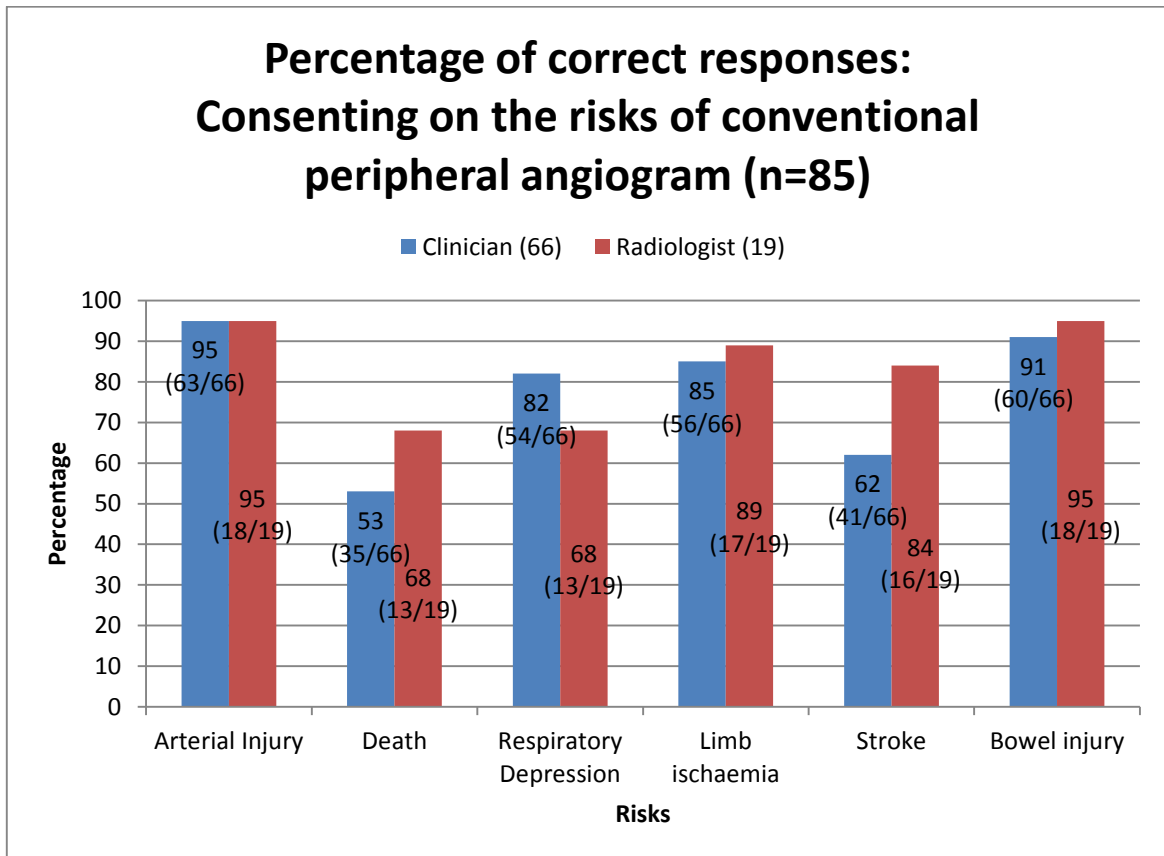
### 8.3.3.3. Knowledge of intervention related procedural risks:

Statistically significant findings included a greater number of correct responses for radiologists regarding the risks of cancer induction (16/19 [84%] radiologists compared to clinicians 39/66 [59%], p-value=0.05), respiratory depression (11/19 [58%] radiologists compared to clinicians 23/66 [35%], p-value=0.07) and allergic reactions (17/19 [89%] radiologists compared to clinicians 35/66 [53%], p-value=0.003) during interventional procedures (refer to figure 12 below). Most doctors were equally aware that nephrogenic systemic fibrosis (NSF) and pacemaker dysfunction were not associated with interventional procedures, while arterial injury and bowel perforation were potential risks during interventional procedures.



**Figure 12: Comparison of doctors' knowledge of intervention related procedural risks (n=85)**

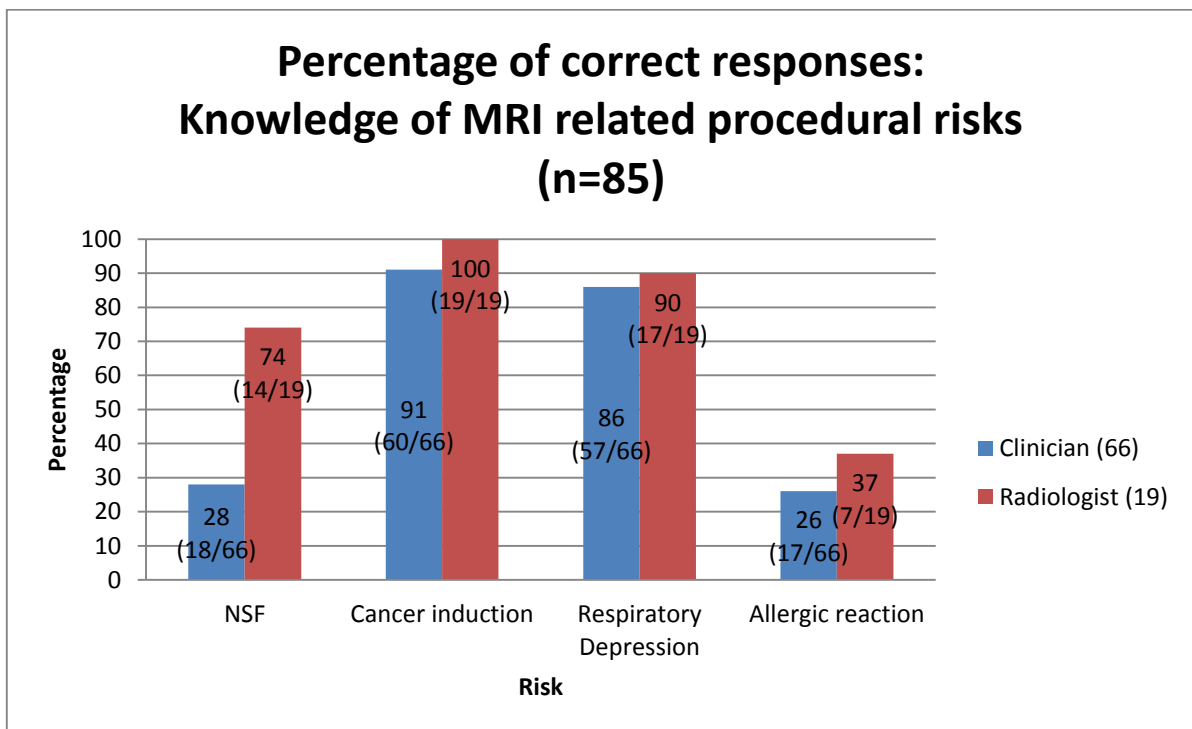
On consenting patients to the risks of a conventional peripheral angiogram, both groups included the most important risks such as arterial injury, limb ischaemia and stroke and excluded risks such as respiratory depression, bowel injury and death, as summarised in figure 13 below.



**Figure 13: Comparison of doctors' knowledge when consenting on the risks of a conventional peripheral angiogram (n=85)**

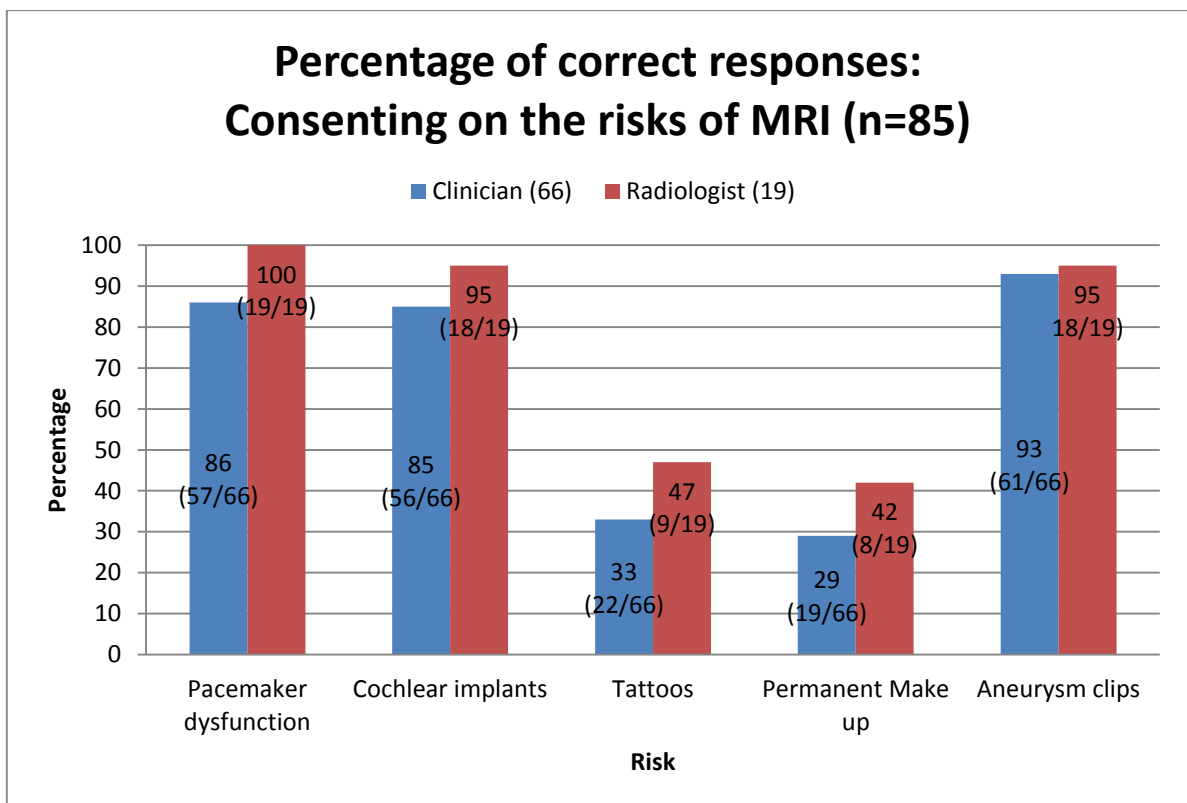
#### 8.3.3.4. Knowledge of magnetic resonance imaging (MRI) related procedural risks:

There was a statistically significant difference in knowledge scores between the two groups regarding the risk of nephrogenic systemic fibrosis, with 18/66 (27%) clinicians and 14/19 (74%) radiologists providing the correct answer ( $p$ -value=0.00039). Both groups were similarly aware that allergic reactions from contrast media, respiratory depression and cancer induction were negligible risks. The percentage of correct responses within each grouping are summarised in figure 14 below.



**Figure 14: Comparison of doctors' knowledge of MRI related procedural risks (n=85)**

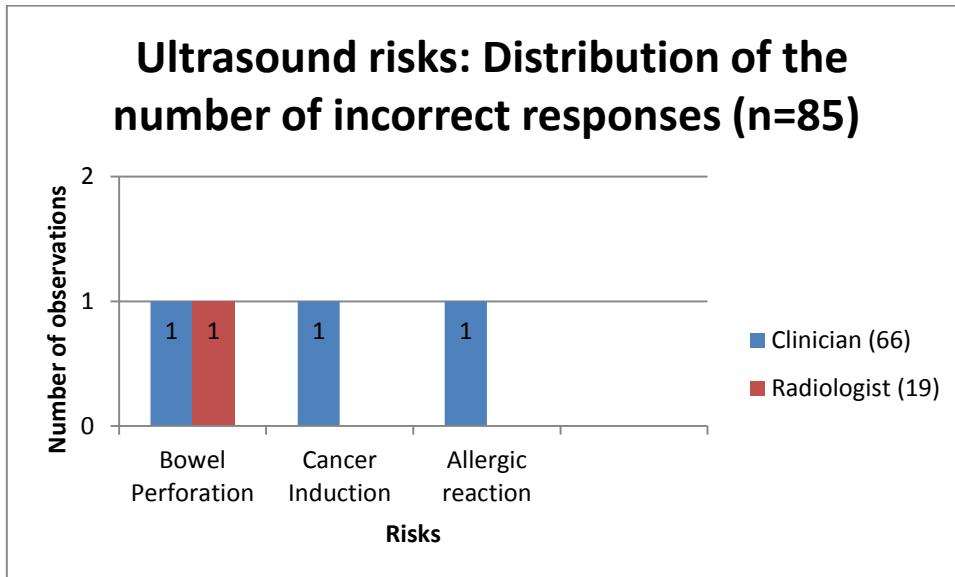
On testing doctors' knowledge of the paramagnetic risks of MRI, there was a trend of radiologists having a greater percentage of correct responses, as illustrated in figure 15 below, with a statistically significant difference when asked about pacemaker dysfunction during an MRI (correct responses amongst radiologists 19/19 [100%] versus 57/66 [86%] clinicians; p-value=0.02). Both groups were similarly aware of the risks of cochlear implants and aneurysm clips but unaware of the potential dangers presented by tattoos and permanent makeup.



**Figure 15: Comparison of doctors' knowledge when consenting on the risks of MRI (n=85)**

### 8.3.3.5. Knowledge of Ultrasound (US) related procedural risks:

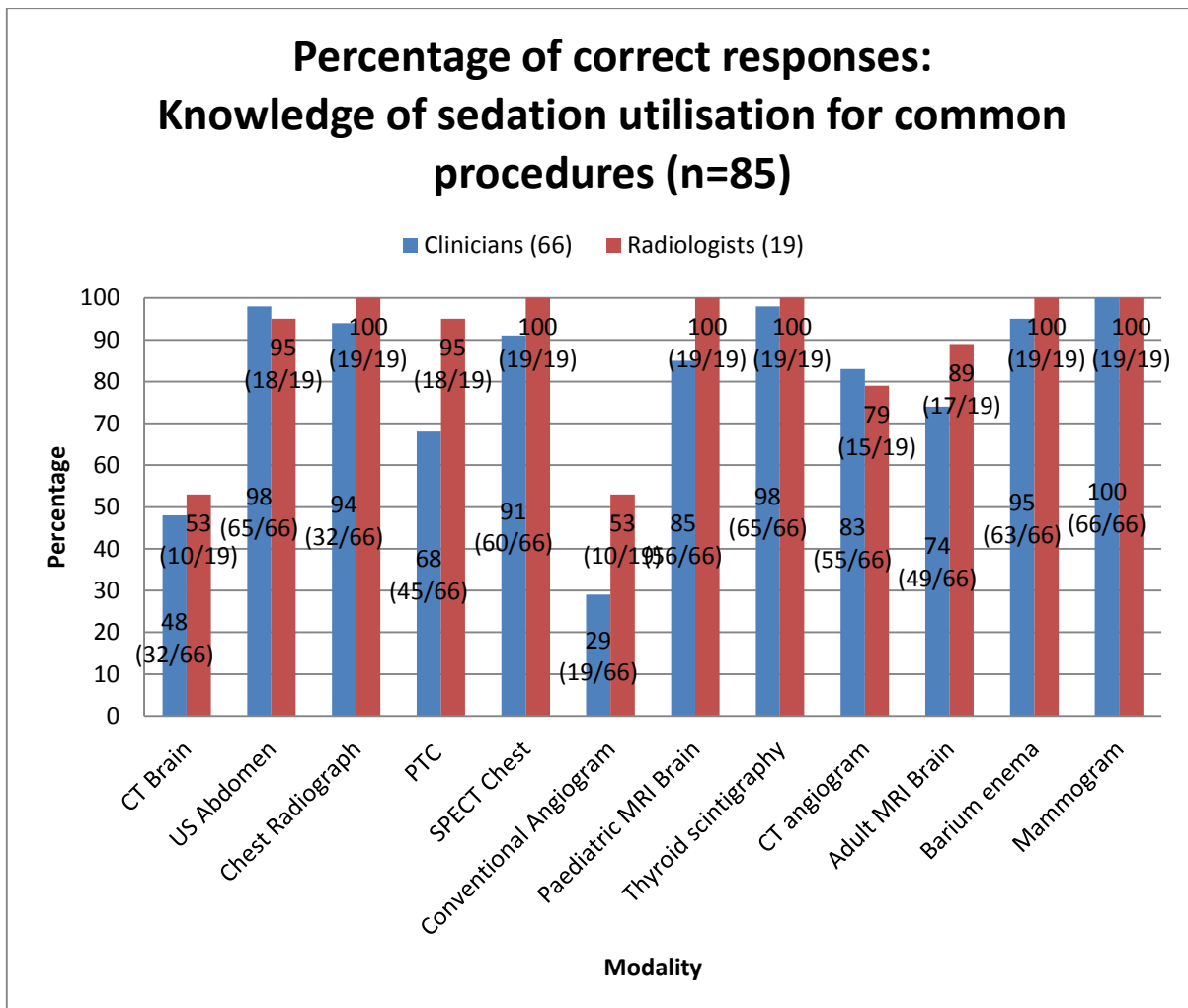
Ultrasound was perceived as the modality with the least potential for risk. Out of 85 respondents, 4 doctors (1 radiologist, 3 clinicians) supplied incorrect answers regarding the risks of ultrasound, as summarised in figure 16.



**Figure 16: Schematic representation of the number of incorrect responses regarding the procedural risks of ultrasound (n=85)**

### 8.3.4. Knowledge on the use of procedural sedation:

There were differences in doctors' knowledge when it came to the usage of sedation during interventional procedures such as transhepatic percutaneous cholangiograms (45/66 [68%] clinicians versus 18/19 [95%] radiologists; p-value =0.019) and conventional peripheral angiograms (19/66 [29%] clinicians versus 10/19 [53%] radiologists; p-value=0.05), with radiologists having a greater percentage of correct responses, as summarised in figure 17 below.



**Figure 17: Graphic representation of the percentage of correct responses regarding the use of procedural sedation for various modalities(n=85)**

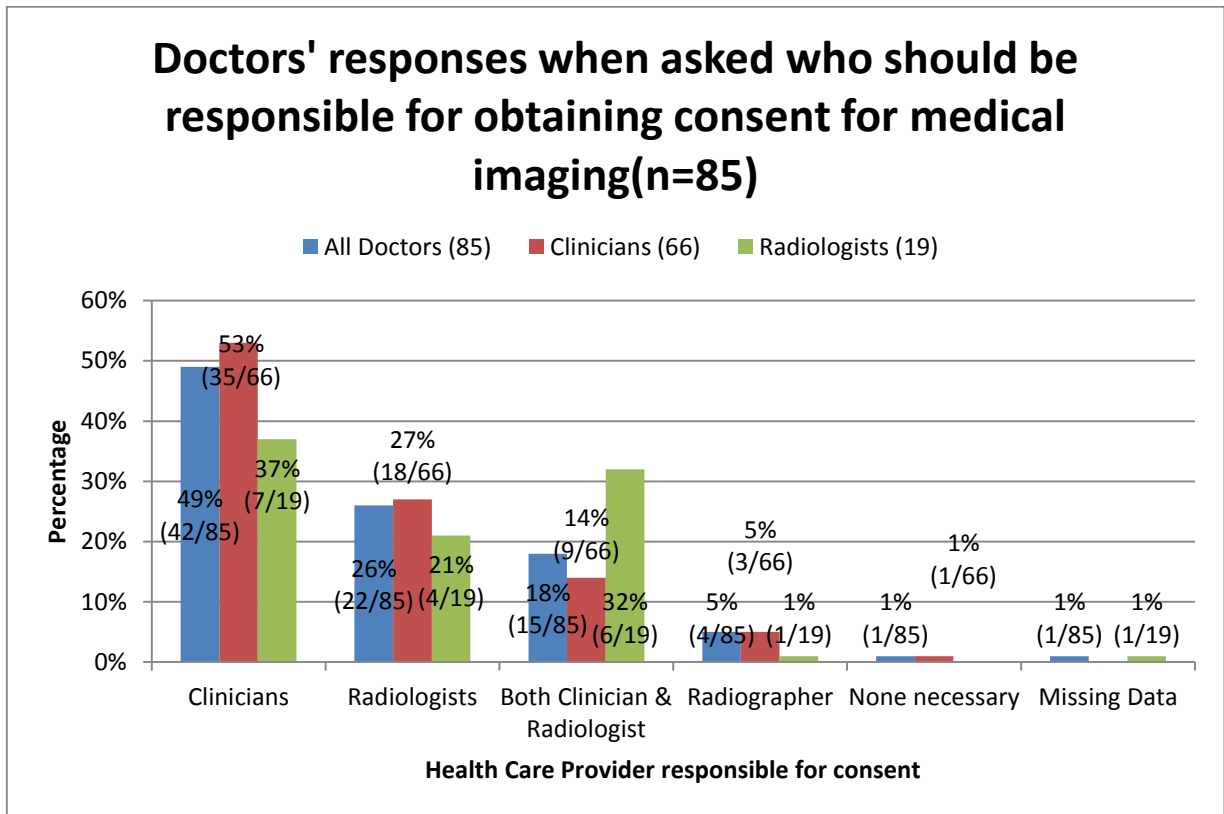
#### **8.4. Consenting practice:**

The largest proportion of doctors (42/85 doctors; 49%) felt that the clinician should consent patients on the risks of imaging, while 22/85 (26%) doctors felt that it was the radiologist's responsibility, 15/85 (18%) doctors believed it to be a joint responsibility between radiologists and clinicians, 4/85 (5%) doctors the responsibility of the radiographer and 1/85 (1%) felt that consent was not necessary at all. A sole respondent chose not to answer the question.

Of the 19 radiologists who participated, 4/19 (21 %) believed that the responsibility fell to the radiologist to consent the patient, 7/19 (37%) believed it was the responsibility of the clinician, 6/19 (32%) a joint responsibility of both the radiologist and the clinician and 1/19 (5%) the responsibility of the radiographer. One radiologist (5%) chose not to answer this question.

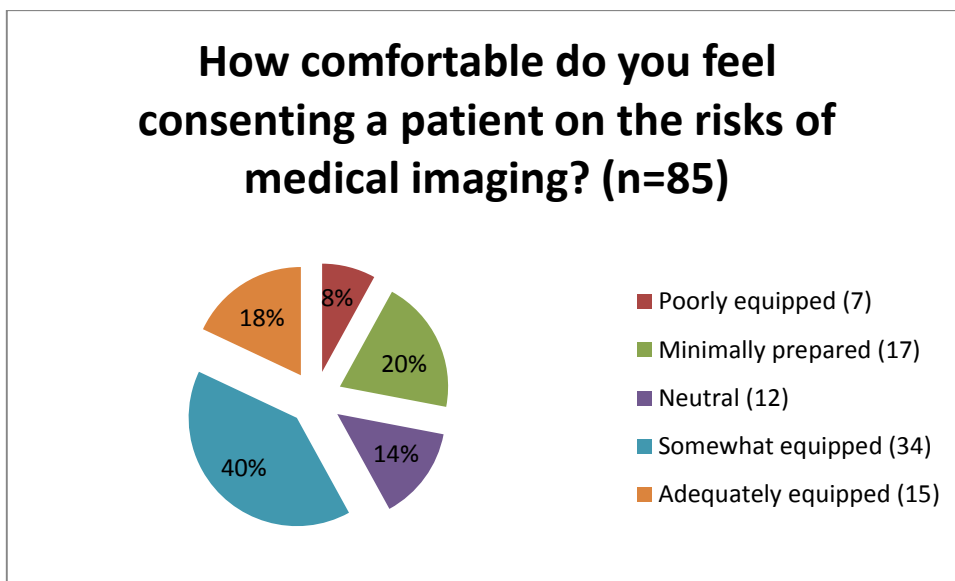
Of the non-radiologist grouping, 35/66 (53%) believed consenting a patient to be the responsibility of the clinician, 18/66 (27%) the responsibility of the radiologist, 9/66 (14%) a joint responsibility, 3/66 (5%) the radiographer's duty and 1/66 (1%) believed consent was not necessary.

Figure 18 below summarises doctors' responses when posed the question of who they believe to be responsible for obtaining consent for medical imaging. The data was stratified into three groups: an overall response by the total number of doctors (n=85) which was then divided into two separate groups of clinicians (n=66) and radiologists (n=19).



**Figure 18: Graph demonstrating doctors' perceptions as to the health care provider responsible for consenting patients to the risks of medical imaging (n=85)**

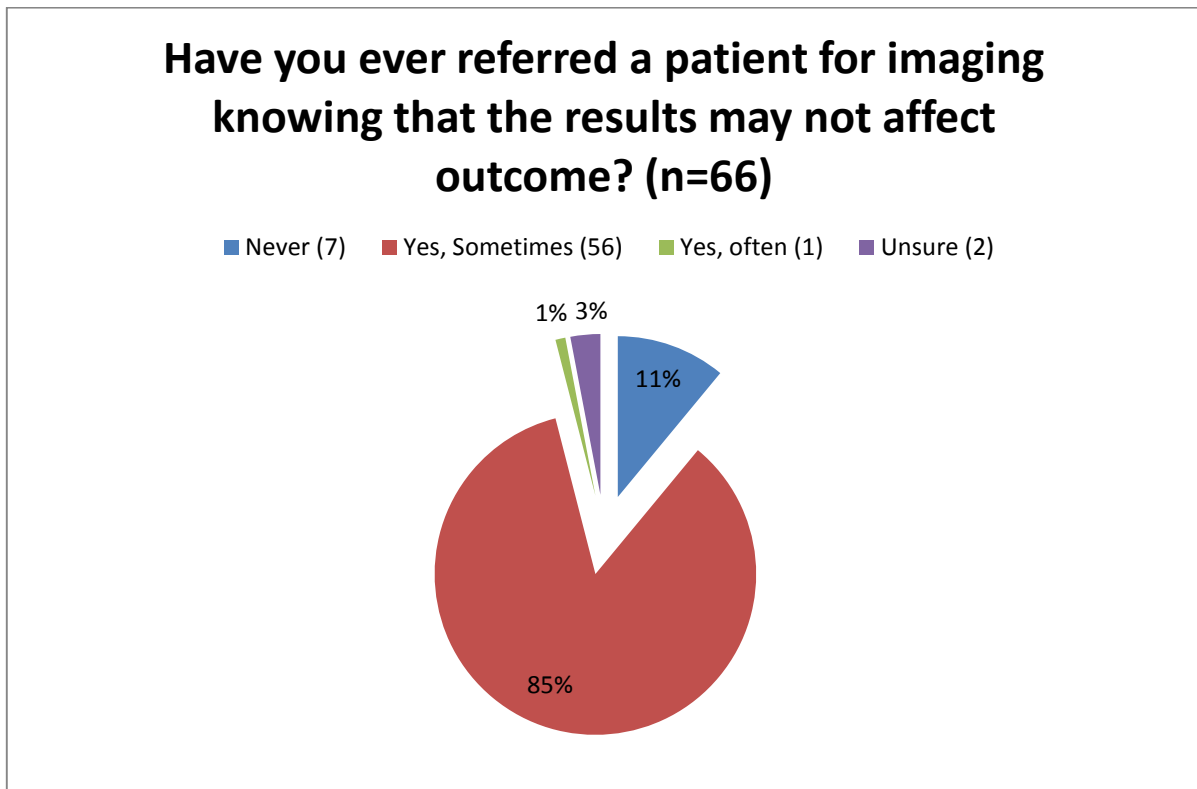
When questioned on how comfortable doctors felt consenting patients to the risks of medical imaging, only 15/85 (18%) of participants felt adequately prepared, a group consisting of 10 radiologists and 5 clinicians. The largest group of doctors (34/85; 40%), comprising 9 radiologists and 25 clinicians, felt only somewhat equipped when it came to consenting patients. The remaining 36 participants, all clinicians, felt either neutral (12/85, 14%), minimally prepared (17/85, 20%) or poorly prepared (7/85; 8%) when it came to consenting patients, as illustrated in the pie graph (figure 19) below.



**Figure 19: Pie chart illustrating doctors' levels of comfort when consenting patients to the risks of medical imaging (n=85)**

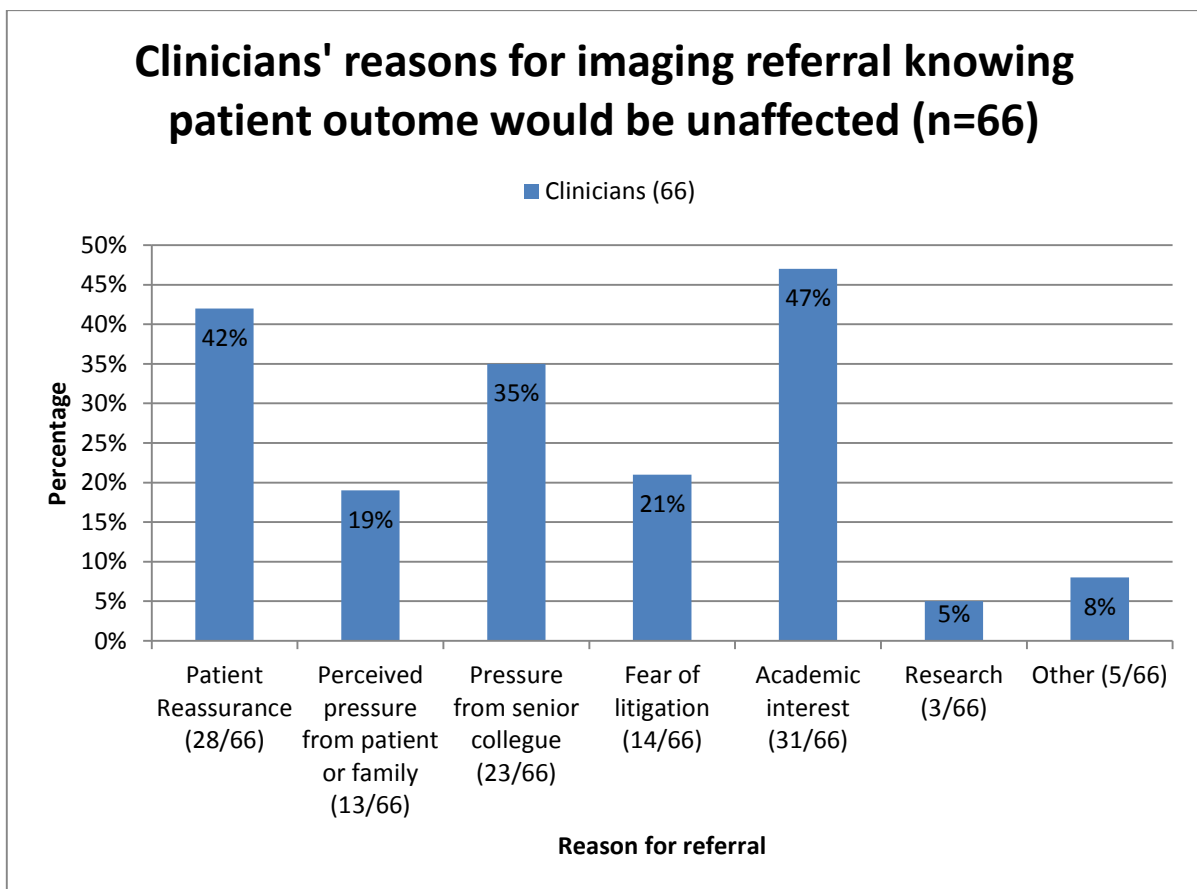
### 8.5. Referral patterns:

Clinicians were asked if they had ever referred patients for imaging knowing that the outcome would not be affected. Radiologists were excluded from this question, being non-referrers. The largest proportion 56/66 (85%) admitted to sometimes referring patients for imaging, despite knowing that the results would have no impact on patient outcome. The remaining responses are summarised in figure 20 below.



**Figure 20: Pie chart demonstrating clinicians' responses to the following question: "Have you ever referred a patient for imaging knowing that the results may not affect the outcome?" (n=66)**

Clinicians most commonly reported academic interest (31/66, 47%), patient reassurance (28/66, 42%) and pressure from a senior colleague (23/66, 35%) as their main reasons for referring patients for imaging while aware that the outcome would be unaffected. These findings are summarised in figure 21 below. A small proportion (5/66, 8%) of clinicians selected the option "other" stating that radiology was often utilised without alteration of the final treatment outcome as a screening or prognostication tool, as well as to document the patient's baseline e.g. a baseline chest radiograph in an ICU patient.



**Figure 21: Graph listing clinicians' reasons for imaging referral knowing that patient outcome would be unaffected (n=66)**

## 9. Discussion:

With increased utilisation of medical imaging as part of the diagnostic process, there has been a concomitant increase in the related risks to which patients are exposed. For health care practitioners, awareness of these potential dangers is essential in order to counsel, protect and empower patients. Both doctors' and patients' need to understand the risks of medical imaging in order to make informed decisions. This is vital when considered in the context of proposed strategies such as the National Department of Health Ten Point Plan that aims to improve the quality of health services, the National Department of Health Human Resource Strategy for the Health Sector that promotes the up scaling and revitalisation of education and training of the health workforce and the Western Cape Department of Health Healthcare 2030 document that envisions a person-centred approach to wellness.<sup>67</sup> It is therefore crucial to assess the local factors driving increased referrals for medical imaging, the current levels of existing knowledge amongst doctors of the risks of medical imaging, as well as doctors' perceptions regarding the responsibility for consenting patients.

With this in mind and with the aid of a purposefully developed, self-administered questionnaire, it was decided to explore doctors' knowledge of the risks of medical imaging as well as the perceptions of responsibility for consent for medical imaging amongst both radiologists and clinicians at our local institution.

Numerous prior studies have focussed predominantly on assessing the awareness of radiation dose and radiation related risks, such as cancer induction amongst various groups ranging from medical students to specialist doctors.<sup>19,20,74-77,21,62,68-73</sup> Furthermore research has also been performed internationally to assess doctors' knowledge of contrast nephropathy due to both iodinated and gadolinium containing contrast media.<sup>65,78-80</sup> Our study is unique in extending the assessment of knowledge to include radiation, contrast and procedure related risks across a range of diagnostic imaging modalities, as well as comparing doctors' knowledge of risk with doctors' levels of comfort when consenting patients to the risks of medical imaging.

Of the two groupings, a better response rate was received from radiologists (63%), four times that of clinicians (refer to figure 1). Factors which may have influenced this include fewer radiologists across a smaller geographic location within the hospital allowing for easier distribution of questionnaires, as well as a closer working relationship with the investigators.

Advanced age, earlier year of graduation and therefore additional years of experience correlated to better knowledge scores. This may not be as intuitive as it sounds, as there have been numerous technological advances in diagnostic imaging in the recent years. Doctors' having qualified prior to the introduction of equipment such as MRI may not be as familiar with the modality or its associated risks. Furthermore, research on the risks of medical imaging, especially regarding radiation risks, has grown considerably in the last 15 years. Doctors' who have graduated earlier may not be aware of this, as found in a 2012 study by Brown et al, who demonstrated an inverse relationship between knowledge of radiation dose and years of experience.<sup>62</sup>

There was no significant difference in knowledge between the different genders or amongst the various universities, both local and international.

Overall radiologists had significantly better total knowledge scores than clinicians - this may be expected considering their post-graduate training received. A small proportion of the radiologists' sampled, which included both registrars and consultants, was found to only have equivalent knowledge to that of the clinicians sampled, despite the additional post-graduate training received. When radiologists were excluded from the sample, there was no significant difference in knowledge scores amongst the various clinical departments.

The risks of medical imaging were then sub-divided into main categories, including the risks of radiation, contrast nephropathy, procedural risks (including CT, fluoroscopy, intervention, MRI and ultrasound) and drugs, specifically focussing on the use of peri-procedural sedation.

Despite radiologists performing statistically better in the sub-category of knowledge of radiation risk (radiologists mean sub-score = 10/15 [67%] versus clinicians = 7/15 [47%]), there remained significant gaps in their knowledge with a percentage of radiologists who erroneously believed that the following modalities were radiation free: SPECT (3/19; 16%), radiography (2/19; 11%), fluoroscopy (1/19; 5%) and CT (1/19; 5%).

Radiologists performed better than clinicians when it came to knowledge of dose exposures arising from SPECT, conventional vascular angiography and fluoroscopic barium enema. Similar results were reported by Lumbreras et al, who found that clinicians had poorer knowledge of radiation exposure associated with diagnostic imaging tests such as barium enemas and urography.<sup>68</sup>

According to the NHS England, imaging requests utilising modalities such as fluoroscopy, angiography and SPECT are less commonly requested compared to modalities such as radiography and CT and as such the knowledge of the attributable risks may be less well known.<sup>81</sup> These tests may also be requested when specific conditions need to be excluded during the diagnostic work up and as such access may be limited to a smaller group of specialist or sub-specialist doctors. Furthermore, studies utilising fluoroscopy and conventional angiography may have decreased in recent years as the scope of CT has increased.

Only 3/66 (5%) clinicians and 9/19 (47%) radiologists knew the estimated dose of a single chest radiograph, low figures considering that radiography is the most commonly requested investigation.<sup>81</sup>

A CT examination with an effective dose of 10 mSv (equivalent to the approximate dose received from an abdominal CT) is estimated to have a 1 in 2000 increase in the possibility of a fatal cancer.<sup>82</sup> While a large proportion of clinicians (39/66; 59%) were unsure of the correct answer, 10/19 (52%) of radiologists selected options that underestimated the occurrence of fatal cancers resulting from CT.

Although our study showed that most doctors were aware that radiation posed a greater risk to children when compared to adults (resulting from the longer post-exposure life expectancy as well as the relative radio-sensitivity of developing tissues), only a small proportion of doctors (21% of radiologists and 8% of clinicians) correctly answered that the risk of cancer following a childhood CT was increased by 24% compared to those who were unexposed.<sup>31,83</sup> A large percentage of doctors had either underestimated this particular risk (47% radiologists and 68% clinicians), or believed there to be no additional risk altogether (16% radiologists and 11% clinicians).

An important factor to take into consideration is that only one of the doctors sampled worked in the field of Paediatrics, Groote Schuur hospital being predominantly an adult hospital with only a small, specialised paediatric endocrine unit. Paediatric patients are instead referred directly to the Red Cross War Memorial Children's hospital. We would expect that the responses would be different in a paediatric hospital setting, with a greater awareness of the risks of radiation amongst paediatricians, paediatric surgeons and paediatric radiologists.

In an attempt to overcome the obvious advantage given to radiologists by postgraduate training in medical physics, a few questions were developed that relied on respondents' general knowledge such that doses from common radiological investigations were compared to various activities, including flight travel, smoking or a visit to a radioactive site such as Chernobyl. Clinicians had a greater accuracy in estimating that a chest radiograph exposed one to more radiation than a five-hour aeroplane flight, equivalent accuracy in estimating that a CT chest exposed one to more radiation than an hour at Chernobyl and a decreased accuracy in estimating that a CT chest exposed one to less radiation than that received by smoking 1,5 packets of cigarettes per annum (the result of radioactive polonium and lead contained in cigarettes).

The second subcategory focussed on doctors' knowledge of contrast induced nephropathy (CIN) across the various modalities. In an in-depth survey of radiologists' knowledge and perceptions of CIN and its risk factors when performing CT examinations, Reddan et al discovered that while radiologists understood that CIN in CT was important,

their knowledge of the definition and risk factors was sometimes poor.<sup>65</sup> Unlike the Reddan study, knowledge of the definition of CIN and its risk factors did not fall within the scope of our study. We did find that both radiologists and clinicians were similarly aware of the potential risk of CIN during CT, whereas a greater proportion of clinicians were unaware of renal failure arising as a result of contrast usage during interventional procedures.

Both groups of doctors had poor knowledge of the risk of CIN arising from intravenous iodinated contrast injection during fluoroscopic procedures, as well as the less common, but as significant risk of contrast nephropathy following intravenous gadolinium administration, particularly in at-risk populations such as diabetics, renal failure and the elderly.<sup>65</sup>

Regarding the procedural risks of medical imaging, the overall knowledge scores were high for those risks associated with CT and ultrasound, with variable accuracy for risks associated with fluoroscopy, intervention and MRI. This may again be partially attributed to ultrasound and CT being more commonly requested, often substituting fluoroscopic and interventional studies, with doctors therefore being more aware of the associated risks.<sup>81</sup>

Most discrepancies in the levels of knowledge of procedural risks between the two groups were associated with the specific risk of cancer induction. Recent studies in both the UK and Australia point to a possible link between increased cancer risk and exposure to radiation doses from diagnostic medical imaging, cautioning against indiscriminate use.<sup>30,31</sup> In our study, radiologists had a greater awareness of the increased risk of cancers associated with fluoroscopy and intervention compared to clinicians. Although not statistically significant, clinicians were unexpectedly more aware of the carcinogenic risks linked to CT (89% correct responses from clinicians compared to 79% from radiologists;  $p$ -value = 0.2). These results were similar to that of Brown et al, who found that although qualified radiologists had a greater knowledge of CT dose estimates, interns and residents from all specialties had higher recognition of the increased lifetime risk of cancer attributable to CT.<sup>62</sup>

Regarding other procedural risks, both groups were not cognizant of the potential for local organ damage, such as bowel perforation during interventional procedures. Clinicians were additionally unaware of the potential risk of bowel perforation during fluoroscopic procedures such as barium enemas.

Overall radiologists were more accurate in identifying contrast allergies as a potential risk of CT and intervention and to a lesser degree MRI and fluoroscopic procedures. As contrast media may be used for each of the above modalities, allergic reactions remain a clinical concern irrespective of the administered volume or route of administration, although higher volumes and intravascular route of administration more commonly result in allergic reactions.<sup>84</sup>

There was a significant difference in knowledge of the risk of nephrogenic systemic fibrosis (NSF) as a complication of gadolinium usage during MRI (28% correct responses from clinicians compared to 74% from radiologists,  $p$ -value= 0.00039). No comparative data could be found on review of the literature. To our knowledge, the surveys available have assessed either nephrologists knowledge of NSF or gadolinium utilisation by radiographers in the UK and Ghana with no surveys having compared the levels of knowledge amongst clinicians and radiologists.<sup>78-80</sup>

Exposure to a pulsed radiofrequency field, such as that of an MRI scan, may result in heat and energy deposition as well as dysfunction of implantable devices such as a cardiac pacemaker. These risks, although uncommon, may lead not only to significant injury such as burns but also can be potentially life threatening.<sup>42</sup> Regarding the risks of MRI, overall radiologists had superior knowledge, and more specifically there was a significant difference in knowledge of the risk of pacemaker dysfunction, (radiologists 100% correct responses compared to clinicians with 86%,  $p$ -value = 0.02). Both groups had poor knowledge of the potential harm that may result from iron oxide found in tattoos and permanent make up, such as burns and local irritation.

Doctors' believed ultrasound to be the safest diagnostic imaging modality, with no significant difference between the two groups with regard to the levels of knowledge of ultrasound related risks.

Radiologists were more cognizant of the risks of sedation usage during interventional procedures (such as percutaneous transhepatic cholangiograms and conventional peripheral angiograms) when compared to clinicians, with similar numbers of correct responses for the remaining modalities.

A large percentage of clinicians (86%; 57/66) admitted to requesting imaging knowing that the results would not affect patient outcome. This is a practice that not only increases unnecessary referrals for imaging, but also exposes patients to increased risks. Clinicians were driven by academic interest, patient reassurance and pressure from senior colleagues.

While the local guidelines (HPCSA and the National Health Act) state that either the practitioner performing the study or the most knowledgeable practitioner should obtain consent, the largest proportion of respondents in our study believed that the responsibility for consenting patients on the risks of medical imaging resided with referring clinicians.<sup>57,58</sup> This would prove a challenging task considering that not only did clinicians have lower knowledge scores overall but out of all respondents in our study, only 5 clinicians (6%) felt adequately equipped to consent patients.

With the current overhaul of health care systems and a move toward people centred health care, there is a requirement for doctors not only to be technically skilled and knowledgeable, but also to be able to communicate risk-benefit assessments effectively to patients' and their families. It is essential for health care practitioners to empower patients to take charge of their well being and the informed consent process may be an effective tool that can be employed to do this. However, this may not be possible if, as our study has demonstrated, doctors are not fully aware of the risks of imaging and do not feel adequately prepared to communicate these risks to patients. Practitioners are

nonetheless expected to consent patients despite their limitations or may instead chose to do so despite their shortcomings.

There are many policies governing current medical practice with a renewed focus on skilled professionals providing safe, quality health care to all. Training institutions have a duty to impart knowledge to all health care providers, while statutory bodies have a responsibility to implement clear guidelines. We assert that in order for this to happen, professional bodies and policy makers need to enter into constructive debate and formulate answers to the questions that our research has generated.

Should radiologists be expected to consent patients, it is evident that they will require additional ongoing training and support. How and by whom should this training be provided?

Radiologists may be reluctant to take on this responsibility for a variety of reasons. Reasons may include not being the primary health care provider, not having access to adequate clinical information on the clinical request card or access to complete patient records. Radiologists may also be unaware of the extent to which a patient has been counselled on their illness and may wish to avoid causing further undue patient anxiety by providing superfluous information. Skill scarcity, effective time management and decreased patient throughput are further reasons for the reluctance on the part of radiologists to fully engage with patients on the consent process.

Should we look internationally to strategies such as the Eurotom law that requires a radiological examination to be justified prior to the patient being referred for medical imaging?<sup>16,85</sup> While this may limit interruption of the radiologists' work flow, it creates a requirement for ongoing clinician education that aims to improve knowledge of the risk-benefit analysis applied to medical imaging. Radiologists may be looked towards to provide educational support. In so doing, they may also allay doctors' feelings of inadequacy and ill-preparedness when consenting patients' on the risks of medical imaging.

No matter the scenario, it is evident that ongoing professional development is required. Improving knowledge amongst clinicians would assist in making informed decisions regarding the choice of imaging and how best to mitigate patient risk. Improved knowledge amongst radiologists would facilitate safer imaging practices as well as enable them to better communicate with and empower patients with the necessary knowledge required to take charge of their health choices.

Our study has highlighted issues surrounding consent of patients for imaging that require further clarification. While various guidelines recommend that the performing doctor, in this case the radiologist, should obtain consent, a large proportion of doctors sampled believed this to be the responsibility of the clinician. Institutional policies dealing with consent issues may need to be developed in order to circumvent conflict between health care providers and to avoid instances in which patients are not adequately counselled but instead are provided with sufficient information required to make informed decisions regarding their health.

## **10. Study limitations:**

The completion of this questionnaire based survey required time, both on the part of the researchers who were required to administer the questionnaire, as well as the participants who required time to complete the document. As such, access to the target population and obtaining a representative sample was limited by the availability of time.

As no pre-existing validated questionnaire existed, a tool was developed using similar non-validated questionnaires. Despite pre-test piloting amongst peers the reliability and sensitivity of the questionnaire remain unvalidated.

There is a paucity of previous research assessing the levels of knowledge of risk amongst radiologists and clinicians, the perceived responsibility for these risks and the confidence of doctors in their ability to adequately consent patients to the risks of medical imaging. Our study serves as an initial exploration into this identified gap in the literature and encourages further investigation.

The assessment of medical practice via a questionnaire-based survey relies on reported behaviour rather than routine practice. Our study, assessed opinions on who should obtain consent for the risks of medical imaging and perhaps future research could review doctors' actual consenting practice.

## **11. Conclusion:**

We successfully surveyed doctors' knowledge of the risks of medical imaging, compared the levels of knowledge between radiologists and clinicians and explored the attitudes towards responsibility for consent.

Our study revealed that overall radiologists had superior knowledge of the risks of medical imaging (total knowledge score expressed as a percentage =79%) compared to that of clinicians (71%). While there was no significant difference in the knowledge scores according to gender or university, older respondents with more years of experience had higher knowledge scores. We found doctors' knowledge to be deficient particularly when it came to radiation risks, the risks of drug and contrast usage, allergies, paramagnetic risks of MRI and procedural risks for the less commonly encountered modalities such as fluoroscopy and intervention.

There were conflicting opinions regarding who should obtain consent for medical imaging, with 49% of doctors' being of the opinion that clinicians should be responsible. Furthermore, only 18% of doctors (radiologists and clinicians) and 5% of clinicians admitted to feeling adequately prepared to obtain consent for medical imaging. It is therefore important to consider not only the levels of doctors' knowledge but also their comfort levels and confidence in their ability to consent patients prior to making decisions on who is best suited to obtaining consent.

## **12. Recommendations:**

It is evident that educational reform is required amongst all health care providers with regard to the risks of medical imaging. Health care providers have a duty to align with the goals of people centred health care systems, improved technical skills and provision of quality care.

Training curricula should be reviewed in order to accommodate for the increased dependence upon diagnostic imaging in health care. Modification of training programmes is suggested, with a view to include structured teaching in the field of diagnostic radiology, with a particular focus on risk-benefit analyses and risk reduction strategies. Training should be on an ongoing basis to ensure that knowledge is current. Continuing professional development programmes may also be employed to ensure that the levels of knowledge are maintained.

Information in various formats such as posters, booklets and dose cards, should be made available to doctors. Novel ways of conveying the risks to doctors' could include pop-up overlays that appear on the electronic request pro-forma. These boxes could contain not only information on the risks of the modality requested, but may also provide clinicians with decision support by including algorithms and alternative choices for safe imaging

Pre-existing campaigns, such as "Image Wisely" and "Image Gently", empower doctors with the knowledge and confidence required to engage with patients, specifically regarding the risks of radiation<sup>86</sup>. Following on the success of these above campaigns, expansion of programmes to include the remaining risks of diagnostic imaging, such as contrast and paramagnetic risks, may serve to further improve the levels of knowledge.

Policy makers and health care providers should review the available regulations to ensure clarity, while statutory bodies should ensure that these policies are propagated amongst its' members.

Our survey was exploratory and as such future research may look to include other health care providers, such as radiographers and nursing staff. The review of actual consent practice as opposed to reported practice may be a further focus for investigation.

## 13. Appendices:

### 13.1. Appendix A: Ethics clearance certificate



UNIVERSITY OF CAPE TOWN  
Faculty of Health Sciences  
Human Research Ethics Committee



Room E52-24 Old Main Building  
Groote Schuur Hospital  
Observatory 7925  
Telephone [021] 406 6338 • Facsimile [021] 406 6411  
Email: [ros.tsama@uct.ac.za](mailto:ros.tsama@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

08 June 2015

**HREC REF: 247/2015**

**Prof S Andronikou**  
Division of Radiology  
C16, NGSB

Dear Prof Andronikou

**PROJECT TITLE: THE RISKS OF MEDICAL IMAGING: A SURVEY OF DOCTORS' KNOWLEDGE AND PERCEPTIONS (MMed candidate: Dr Tamiya Nair)**

Thank you for your response to the Faculty of Health Sciences Human Research Ethics Committee dated 29 May 2015.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**Approval is granted for one year until the 30<sup>th</sup> June 2016.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

**Please quote the HREC REF in all your correspondence.**

**We acknowledge that the student, Dr T Nair will also be involved in this study.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**


Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH

HREC 247/2015

13.2. Appendix B: Annual progress report/ renewal: 2016-2017


**UNIVERSITY OF CAPE TOWN**  
 IYUNIBESITHI YASEKAPA - UNIVERSITEIT VAN KAAPSTAD

**HUMAN RESEARCH ETHICS COMMITTEE**  
 FACULTY OF HEALTH SCIENCES  
 Human Research Ethics Committee

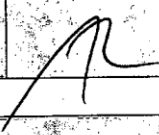
**FHS016: Annual Progress Report / Renewal**  
 20 JUN 2016

HEALTH SCIENCES FACULTY  
 UNIVERSITY OF CAPE TOWN

HREC office use only (FWA00001637; IRB00001938)

This serves as notification of annual approval, including any documentation described below.

<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30.6.2017
<input type="checkbox"/> Not approved	See attached comments		

Signature Chairperson of the HREC		Date Signed	21/6/2016
-----------------------------------	---	-------------	-----------

Comments to PI from the HREC

**Principal Investigator to complete the following:**

**1. Protocol information**

Date (when submitting this form)	03/06/16		
HREC REF Number	247/2015	Current Ethics Approval was granted until	30 June 2016
Protocol title	The Risks of Medical Imaging: A survey of Doctor's knowledge and perceptions		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	n/a		
Principal Investigator	Prof S. Andronikou		
Department / Office Internal Mail Address	doctor.andronikou@gmail.com		

1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

13.3. Appendix C: Annual progress report/ renewal: 2017-2018



**FHS016: Annual Progress Report / Renewal**

HREC office use only (FHS0001837; IRB0001938)  
 This serves as notification of annual approval, including any documentation described below.

<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30 June 2018
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	25/6/17

Comments to be completed by HREC

**Principal Investigator to complete the following:**

**1. Protocol Information**

Date (when submitting this form)	20/06/17		
HREC REF Number	247/2016	Current Ethics Approval was granted until	30 June 2017
Protocol title	The Risks of Medical Imaging: A survey of Doctor's knowledge and perceptions		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	No		
If yes, could you please provide the HREC Ref's for all sub-studies? <small>(note: A separate FHS016 must be submitted for each sub-study)</small>	n/a		
Principal Investigator	Prof S. Andronikou		
Department / Office Internal Mail Address	doctor.andronikou@gmail.com		

1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.3 Has sponsorship of this study changed? if yes, please attach a revised summary of the budget.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No



## 13.4. Appendix D: Hospital permission to conduct research



### GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bernadette Eick  
E-mail : [Bernadette.Eick@westerncape.gov.za](mailto:Bernadette.Eick@westerncape.gov.za)

Professor S. Andronikou  
Division of Radiology  
C16 – New Main Building

E-mail: [tamiyanair@hotmail.com](mailto:tamiyanair@hotmail.com)

Dear Professor Andronikou

**RESEARCH PROJECT: The Risks of Medical Imaging: A Survey of Doctors' Knowledge and Perceptions (Mmed Candidate: Dr Tamiya Nair)**

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research subject to the approval of the respective Heads of Department.

Please note the following:

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please introduce yourself to the person in charge of an area before commencing.
- f) Please discuss the study with the respective HOD before commencing.
- g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- h) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'B Eick'.

**DR BERNADETTE EICK**  
**CHIEF OPERATIONAL OFFICER**  
Date: 8<sup>th</sup> July 2015

C.C. Mr. L. Naidoo  
Professor E. Weimann  
Professor S. Beningfield

G46 Management Suite, Old Main Building,  
Observatory 7925

Tel: +27 21 404 6288 fax: +27 21 404 6125

Private Bag X,  
Observatory, 7935

[www.capegateway.gov.za](http://www.capegateway.gov.za)

## 13.5. Appendix E: Questionnaire consent

**Dear Colleague**

You are invited to take part in the following study that is being undertaken for a Masters of Medicine dissertation in Diagnostic Radiology by Dr Tamiya Nair and Prof. Savvas Andronikou at the University of Cape Town. By means of a questionnaire, we aim to assess doctors' knowledge and perceptions of the risks of medical imaging at Groote Schuur hospital. In identifying these factors, it is hoped that effective policy change may be made to improve practices and facilitate improvement in future academic training programmes.

Participation in this study is **voluntary** and should you choose to answer the questionnaire, you may terminate it at any point. Termination of the questionnaire or non – participation in this study will not adversely affect you in any way. Your employment prospects at Groote Schuur Hospital will not be affected.

Feedback will be provided in the form of a short power point presentation or handouts in order build upon any gaps in knowledge. The benefits of participation include fostering research that may further improve patient safety and outcomes. Data may be used by the relevant policy makers to improve upon limitations in the current medical training programmes (both undergraduate and postgraduate training).

The questionnaire will take approximately 10 - 15 minutes to complete and consist predominantly of multiple-choice answers and true or false options. Kindly tick or circle the appropriate option(s). Please note that for specified questions, more than one answer is acceptable. You may answer any or all questions that are applicable. No identifying data is attached to the questionnaire; therefore your responses are **anonymous**. Your input will be blinded to the researcher and will be treated with the strictest of confidentiality.

The results of the study may be published, and/or presented at a congress. All information presented will be anonymous. Informed consent is assumed if you answer the questionnaire. Kindly complete the following questionnaire if you are a medical doctor practising at Groote Schuur Hospital and have not completed this questionnaire previously.

Should you have any further queries or require more information regarding this study please feel free to contact us:

**Chief Researcher:** Dr Tamiya Nair  
Department of Radiology  
University of Cape Town  
tamiyanair@hotmail.com  
021 404 4122

**Supervisor:** Professor Savvas Andronikou  
doctor.andronikou@gmail.com

Should you have any ethical concerns regarding the study or the rights and welfare of participants please feel free to contact:

**University of Cape Town Faculty of Health Sciences Human Research Ethics Committee**

Address: E52, Room 24 Old Main Building, Groote Schuur Hospital, Observatory

Telephone: 021-4066492 Fax: 021-4066411

Thank you for your time.

### 13.6. Appendix F: Questionnaire

#### THE RISKS OF MEDICAL IMAGING:

Please indicate your selection with a tick or cross where applicable

Age:	Gender:	Male	Female	Prefer not to disclose	
From which university did you obtain your undergraduate degree?					
In which year did you complete your undergraduate medical degree?					
Current position:	Intern		Medical Officer	Consultant	
	Community Service		Registrar	Other(please specify):	
Which department do you work in?	Medicine	Surgery	Paediatrics	Radiology	Trauma
	Emergency Medicine		Obstetrics and Gynaecology		
	Other:				

Who do you believe is responsible for consenting patients regarding the risks of medical imaging?							
Consent is not necessary	The Radiographer	The Radiologist	The requesting Doctor	Other			
On a scale of 1-5 (1=poorly equipped and 5= adequately equipped) how comfortable do you feel advising patients on the risks of medical imaging?							
Unsure	1 (Poorly equipped)	2 (Minimally Prepared)	3 (Neutral)	4 (Somewhat equipped)	5 (Adequately equipped)		
Which of the following investigations are associated with the risk of ionising radiation? <i>You may select more than one option.</i>							
Chest X-ray	Doppler Ultrasound Lower limb	Barium enema	SPECT Chest	Aortic digital subtraction angiogram	CT Brain	MRI Spine	Unsure
What is the lifetime risk of a fatal cancer induction associated with abdominal CT?							
Nil	1 / 50	1 / 1000-10000	1/ 20 000 -50 000	1/ 200 000 -500 000	1/ 1000 000 -5000 000	Unsure	
Have you ever requested imaging for a patient, knowing that the results of the investigation would be unlikely to affect further management/ patient outcome? Please skip this question if you work in the Radiology department.							
Never	Yes Sometimes	Yes Often	Unsure	Other :			

If you have answered yes to the previous question, please select from the list below a reason why. You may select more than one option if applicable. Skip this question if you have answered "Never" or "Unsure".						
Patient reassurance		Perceived pressure from patient or patient's family		I was told to by a senior colleague but I don't feel it was justified		
Fear of litigation	Academic interest		Research		Unsure	
Other- Please specify:						
Please indicate by ticking the boxes, which risks are commonly associated with each modality. You may tick more than one answer for each modality.						
Modality →	CT	MRI	US	Interventional Radiology	Fluoroscopy	
Risk ↓						
Arterial Injury						
Contrast nephropathy						
Nephrogenic systemic fibrosis						
Cancer induction						
Bowel Perforation						
Respiratory depression						
Allergic reaction						
Pacemaker dysfunction						
What is the approximate dose of a standard PA chest X-ray ?						
0,02mSv	2mSv	0,2Gy	200mSv	200Sv	2000 radons	Unsure
The estimated risk of developing a cancer from childhood exposure to CT is:						
No risk	0,2 percent that of unexposed	10 percent that of unexposed	24 percent that of unexposed	50 percent that of unexposed		

Procedural sedation is commonly used during which of the following procedures (you may circle more than one option):						
CT Brain	Ultrasound Abdomen	Chest Radiograph	Percutaneous transhepatic cholangiography	SPECT chest	Conventional peripheral angiogram	
Paediatric MRI brain	Thyroid Scintigraphy	CT Angiogram	Adult MRI brain	Barium Enema	Mammogram	
Your patient is about to undergo a peripheral angiogram. Please circle which of the following risks are important to mention during the consent process? Selecting more than one answer is acceptable.						
Arterial injury	Death	Respiratory depression	Limb ischaemia	Stroke	Bowel injury	
Prior to MRI examination it is important to let the radiologist know about the presence of which of the following items:						
Cochlear implants	Metallic heart valves	Tattoos	Permanent Make up	Aneurysm clips	All of the above	
Are the following statements true or false:				True	False	Unsure
• The radiation received from a single chest radiograph is less than the radiation received during a 5 hour flight from Cape Town to Mauritius and back.						
• The average CT Chest scan exposes one to more radiation than spending one hour at Chernobyl in 2010						
• The average CT Chest scan exposes one to more radiation risk than smoking 1,5 packs of cigarettes per day for a year						
• Children are at a greater risk for radiation induced cancer than adults.						
• Transient erythema and cataract induction are both deterministic (threshold related) risks of ionising radiation						

## 14. References

1. Elliott A. Issues in medical exposures. *J Radiol Prot.* 2009 June;29(2A):A107–A121.
2. Hernanz-Schulman M. Potential risks in radiology departments. *Pediatr Radiol* 2008;38(4):720–727
3. Davies HE, Wathen CG, Gleeson F V. Risks of exposure to radiological imaging and how to minimise them. *BMJ* 2011;342(d947):589–593.
4. Cousins C, Sharp C. Medical interventional procedures — reducing the radiation risks. *Clin Radiol.* 2004;59(6):468–473.
5. Marshall J, Martin T, Downie J, Maliszka K. A comprehensive analysis of MRI research risks: in support of full disclosure. *Can J Neurol Sci.* 2006;34(1):11–17.
6. Miller M, Levy P, Patel MM. Procedural sedation and analgesia in the emergency department: what are the risks? *Emerg Med Clin N Am.* 2005;23(2):551–572.
7. Hall JM. Procedural sedation by registered nurses in the interventional radiology setting: incorporating evidence-based practice regarding medication selection, fasting, and mitigating cardiorespiratory complications. *J Radiol Nurs.* 2005;24(4):63–68.
8. Rudström H, Bergqvist D, Björck M. Iatrogenic vascular injuries with lethal outcome. *World J Surg.* 2013;37(8):1981–1987.
9. Picano E. Sustainability of medical imaging. Vol. 328, *BMJ.* 2004;328(7439):578-580
10. Mayosi BM, Lawn JE, van Niekerk A, Bradshaw D, Abdool Karim SS, Coovadia HM. Health in South Africa: changes and challenges since 2009. *Lancet.* 2012;380(9858):2029–2043.
11. Hendee WR, O'Connor MK. Radiation risks of medical imaging: separating fact from fantasy. *Radiology.* 2012;264(2):312–321.
12. Hendee WR, Becker GJ, Borgstede JP, Bosma J, Erickson BA, Maynard CD, et al. Addressing overutilization in medical imaging. *Radiology.* 2010;257(1):240–245.
13. Reuter R. An overview of informed consent for radiologists. *AJR Am J Roentgenol.* 1987;148(1):219–227.
14. Picano E. Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno. *BMJ.* 2004;329(7470):849–851.
15. Recchia V, Dodaro A, Braga L. Event-based versus process-based informed consent to address scientific evidence and uncertainties in ionising medical imaging. *Insights Imaging.* 2013;4(5):647–653.
16. Semelka RC, Armao DM, Elias J, Picano E. The information imperative: is it time for an informed consent process explaining the risks of medical radiation? *Radiology.* 2012;262(1):15–18.
17. Bush WH. Informed consent for contrast media. *AJR Am J Roentgenol.* 1989;152(4):867–869.
18. Lee CI, Haims AH, Monico EP, Brink JA, Forman HP. Diagnostic CT scans: assessment of patient, physician, and radiologist awareness of radiation dose and possible risks. *Radiology.* 2004;231(2):393–398.
19. Shiralkar S, Rennie A, Snow M, Galland RB, Lewis MH, Lloyd-Williams M, et al. Doctors' knowledge of radiation exposure: questionnaire study. *BMJ.* 2002;119(92):371–372.
20. Krille L, Hammer GP, Merzenich H, Zeeb H. Systematic review on physician's

- knowledge about radiation doses and radiation risks of computed tomography. *Eur J Radiol.* 2010;76(1):36–41.
21. Lee RKL, Chu WCW, Graham CA, Rainer TH, Ahuja AT. Knowledge of radiation exposure in common radiological investigations: a comparison between radiologists and non-radiologists. *Emerg Med J.* 2012;29(4):306–308.
  22. Gunderman RB, Stephens CD. Teaching medical students about imaging techniques. *AJR Am J Roentgenol.* 2009;192(4):859–861.
  23. Ell PJ. Undergraduate teaching of radiology and nuclear medicine. *Eur J Nucl Med.* 1997;24(9):1081–1082.
  24. Lass P, Scheffler J. Undergraduate teaching of nuclear medicine in European universities. *Eur J Nucl Med Mol Imaging.* 2003;30(7):1018–1023.
  25. United Nations Scientific Committee on the Sources and Effects of Atomic Radiation. Sources and Effects of ionizing radiation: Report of the United Nations Scientific Committee on the effects of atomic radiation to the General Assembly with scientific annexes. New York:UN 2008.
  26. Preston DL, Kusumi S, Tomonaga M, Izumi S, Ron E, Kuramoto A, et al. Cancer incidence in atomic bomb survivors. Part 3: Leukemia, lymphoma and multiple myeloma, 1950 – 1987. *Radiat Res.* 1994;137(2 suppl):S68–S97.
  27. Griffey RT, Sodickson A. Cumulative radiation exposure and cancer risk estimates in emergency department patients undergoing repeat or multiple CT. *AJR Am J Roentgenol.* 2009;192(4):887–892.
  28. Kepros JP, Opreanu RC, Samaraweera R, Briningstool A, Morrison C, Mosher BD, et al. Whole body imaging in the diagnosis of blunt trauma, ionizing radiation hazards and residual risk. *Eur J Trauma Emerg Surg.* 2012;39(1):15–24.
  29. Fushiki S. Radiation hazards in children - lessons from Chernobyl, Three Mile Island and Fukushima. *Brain Dev.* 2013;35(3):220–227.
  30. Pearce MS, Salotti J, Little MP, McHugh K, Lee C, Kim KP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet.* 2012;380(9840):499–505.
  31. Mathews JD, Forsythe AV, Brady Z, Butler MW, Goergen SK, Bymes GB, et al. Cancer risk in 680 000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ.* 2013;346(f2360):1–18.
  32. Sodickson A. CT radiation risks coming into clearer focus. *BMJ.* 2013;346(f3102):1–2.
  33. Nickoloff EL, Alderson PO. Radiation exposures to patients from CT: Reality, public perception, and policy. *AJR Am J Roentgenol.* 2001;177(2):285–287.
  34. Parry RA, Glaze SM, Archer BR. The AAPM/ RSNA physics tutorial for residents: Typical patient radiation doses in diagnostic radiology. *Radiographics.* 1999;19(5):1289–1302.
  35. Rothenberg LN, Pentlow KS. Radiation dose in CT. *Radiographics.* 1991;12(6):1225–1243.
  36. Conway BJ, Slayton RJ, Suleiman OH, Antonsen RG, Rueter FG. Average radiation dose in standard CT examinations of the head: Results of the 1990 NEXT study. *Radiology.* 1992;184(1):135–140.
  37. Ledneva E, Karie S, Launay-Vacher V, Janus N, Deray G. Renal safety of Gadolinium-based contrast media in patients with chronic renal insufficiency. *Radiology.*

- 2009;250(3):618–628.
38. Brockow K, Christiansen C, Kanny G, Clément O, Barbaud A, Bircher A, et al. Management of hypersensitivity reactions to iodinated contrast media. *Allergy*. 2005;60(2):150–158.
  39. Jung J, Kang H, Kim M, Lee W, Min K, Han M, et al. Immediate hypersensitivity reaction to Gadolinium-based MR contrast media. *Radiology*. 2012;264(2):414–422.
  40. Finn WF. The clinical and renal consequences of contrast-induced nephropathy. *Nephrol Dial Transplant*. 2006;21(1):2–10.
  41. Konen E, Konen O, Katz M, Levy Y, Rozenman J, Hertz M. Are referring clinicians aware of patients at risk from intravenous injection of iodinated contrast media? *Clin Radiol*. 2002;57(2):132–135.
  42. Dill T. Contraindications to magnetic resonance imaging: non-invasive imaging. *Heart*. 2008;94(7):943–948.
  43. Li A, Wong CS, Wong MK, Lee C, Au Yeung MC. Acute adverse reactions to magnetic resonance contrast media – Gadolinium chelates. *BJR*. 2006;79(941):368–371.
  44. Murphy KJ, Brunberg JA, Cohan RH. Adverse Reactions to Gadolinium Contrast Media: A Review of 36 Cases. *AJR Am J Roentgenol*. 1996;167(4):847–849.
  45. Caro JJ, Al CET. The cost-effectiveness of replacing high osmolality with low-osmolality contrast media. *AJR Am J Roentgenol*. 1992;159(4):869–874.
  46. Thomsen HS. Gadolinium-based contrast media may be nephrotoxic even at approved doses. *Eur Radiol*. 2004;14(9):1654–1656.
  47. Abujudeh H, Kaewlai R, Kagan A, Chibnik LB, Nazarian RM, High WA, et al. Nephrogenic Systemic Fibrosis after Gadopentetate Dimeglumine Exposure: Case Series of 36 Patients. *Radiology*. 2009;253(1):81–89.
  48. Weller A, Barber JL, Olsen OE. Gadolinium and nephrogenic systemic fibrosis: An update. *Pediatr Nephrol*. 2014;29(10):1927–1937
  49. Reiter, Theresa, Ritter O, Prince MR, Nordbeck P, Wanner C, Nage E, et al. Minimizing risk of nephrogenic systemic fibrosis in cardiovascular magnetic resonance. *J Cardiovasc Magn Reson*. 2012;14(31):1–11.
  50. Jagoda AS, Godwin S, Burton JH, Gerardo CJ, Hatten BW, Mace SE, et al. Clinical policy: procedural sedation and analgesia in the emergency department. *Ann Emerg Med*. 1998;31(5):663–677.
  51. Arepally A, Oechsle D, Kirkwood S, Savader SJ. Safety of conscious sedation in interventional radiology. *Cardiovasc Interv Radiol*. 2001;24(3):185–190.
  52. Milner A. Near-fatal outcome after administration of Hyoscine-N-butylbromide (Buscopan). *S Afr J Anaesthesiol Analg*. 2010;16(4):38–41.
  53. Desta Z, Wu GM, Morocho AM, Flockhart DA. The gastroprokinetic and antiemetic drug metoclopramide is a substrate and inhibitor of cytochrome P450 2D6. *Drug Metab Dispos*. 2002;30(3):336–343.
  54. Maffei E, Palumbo A a, Martini C, Tedeschi C, Tarantini G, Seitun S, et al. “In-house” pharmacological management for computed tomography coronary angiography: heart rate reduction, timing and safety of different drugs used during patient preparation. *Eur Radiol*. 2009;19(12):2931–2940.
  55. Faulkner K. Radiation protection in interventional radiology. *BJR*. 1997;70(832):325–326.
  56. Ozoilo K, Stein M. Paraplegia complicating embolization for bleeding intercostal artery in penetrating trauma. *Injury Extra*. 2013;44(8):70–73.

57. South African Government. The National Health Act No 61 of 2003. Government Gazette. 2004;469(26595):1–94.
58. The Health Professions Council of South Africa. Seeking patients' informed consent: The ethical considerations. HPCSA. 2016(4):2-15
59. Friedrich-Nel H. Radiographers' opinion on patients' rights to informed consent: results of an online survey. *The South African Radiographer*. 53(1):27-32
60. Bunge E, Herman L. Usage of diagnostic imaging procedures: A nationwide hospital study. *Radiology*. 1987;163(2):569–573.
61. Blackmore CC. Defining quality in radiology. *J Am Coll Radiol*. 2007;4(4):217–223.
62. Brown N, Jones L. Knowledge of medical imaging radiation dose and risk among doctors. *J Med Imaging Radiat Oncol*. 2013;57(1):8–14.
63. Borgen L, Stranden E, Espeland A. Clinicians' justification of imaging: Do radiation issues play a role? *Insights Imaging*. 2010;1(3):193–200.
64. Merzenich H, Krille L, Hammer G, Kaiser M, Yamashita S, Zeeb H. Paediatric CT scan usage and referrals of children to computed tomography in Germany: A cross-sectional survey of medical practice and awareness of radiation related health risks among physicians. *BMC Health Serv Res*. 2012;12(1):1-7.
65. Reddan D, Fishman EK. Radiologists' knowledge and perceptions of the impact of contrast-induced nephropathy and its risk factors when performing computed tomography examinations: a survey of European radiologists. *Eur J Radiol*. 2008;66(2):235–245.
66. Andronikou S, van Wyk M, Pillay T, Segwe A, Odwe O, Dlangamandla S, et al. Imaging children gently: A survey of South African radiologists regarding safe computed tomography practice in children. *Transactions*. 2012;56(1):38–44.
67. Western Cape Government Health. Healthcare 2030: The road to wellness. Cape Town: Department of Health. 2014.
68. Lumbreras B, Vilar J, González-Álvarez I, Guilabert M, Parker LA, Pastor-Valero M, et al. Evaluation of clinicians' knowledge and practices regarding medical radiological exposure: findings from a mixed-methods investigation (survey and qualitative study). *BMJ Open*. 2016;6(10):1-11
69. Willoughby H, Ahmed H, Jenkinson R, Edwards A. GP speciality trainees' knowledge, attitude and practice regarding risks associated with common radiological investigations. *Educ Prim Care*. 2013;24(5):355–362.
70. Salaam AJ, Danjem SM, Salaam AA. Knowledge, attitude and practice of radiology among final year medical students. *Int J Sci Res Publ*. 2016;6(1):161-168.
71. Zewdneh D, Dellie ST, Ayele T. A study of knowledge & awareness of medical doctors towards radiation exposure risk at Tikur Anbessa specialized referral and teaching hospital, Addis Ababa, Ethiopia. *IOSR J Pharm Biol Sci*. 2012;2(4):2278–3008.
72. Mubeen SM, Abbas Q, Nisar N. Knowledge about ionising and non-ionising radiation among medical students. *J Ayub Med Coll Abbottabad*. 2008;20(1):118-121.
73. Bosanquet DC, Green G, Bosanquet AJ, Galland RB, Gower-Thomas K, Lewis MH. Doctors' knowledge of radiation - a two-centre study and historical comparison. *Clin Radiol*. 2011;66(8):748–751.
74. Uri IF. Lack of radiation awareness among referrers: implications and possible solutions. *Int J Clin Pract*. 2012;66(6):574–581.

75. Arslanoğlu A, Bilgin S, Kubalı Z, Ceyhan, MN, İlhan MN, Maral I. Doctors' and intern doctors' knowledge about patients' ionizing radiation exposure doses during common radiological examinations. *Diagn Interv Radiol*. 2007;13(2):53–55.
76. Soye JA, Paterson A. A survey of awareness of radiation dose among health professionals in Northern Ireland. *Br J Radiol*. 2008;81(969):725–729.
77. Puri S, Hu R, Quazi RR, Voci S, Veazi P, Block R. Physicians' and midlevel providers' awareness of lifetime radiation-attributable cancer risk associated with commonly performed CT studies: relationship to practice behavior. *AJR Am J Roentgenol*. 2012;199(6):1328–1336.
78. Rees O, Agarwal SK. Nephrogenic systemic fibrosis: UK survey of the use of gadolinium-based contrast media. *Clin Radiol*. 2010;65(8):636-641
79. Piersson AD, Gorleku PN. Nephrogenic systemic fibrosis: A survey of the use of gadolinium-based contrast agents in Ghana. *Radiography*. 2017;23(4):e108-e113
80. Abdel-Kader K, Patel PR, Kallen AJ, Sinkowitz-Cochran RL, Bolton WK, Unruh ML. Nephrogenic systemic fibrosis: A survey of nephrologists' perceptions and practices. *Clin J Am Soc Nephrol*. 2010;5(6):964-971
81. Dixon S. Official Diagnostic Imaging Dataset Statistical Release. NHS England. 2017;1(1):2-18
82. U.S. Food and Drug Administration. Medical X-ray Imaging - What are the Radiation Risks from CT?[Internet]. Center for Devices and Radiological Health; 2009 [cited 2017 Nov 26]. Available from: <https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm>
83. Kutanzi KR, Lumen A, Koturbash I, Miousse IR. Pediatric exposures to ionizing radiation: Carcinogenic considerations. *Int J Environ Res Public Health*. 2016;13(11):1-14.
84. Beckett KR, Moriarity AK, Langer JM. Safe Use of Contrast Media: What the Radiologist Needs to Know. *Radiographics*. 2015;35(6):1738-1750.
85. Akata D, Adam EJ, Damilakis J, Ducou le Pointe H, Loose R, et al. Summary of the European directive 2013/59/Euratom: Essentials for health professionals in radiology. *Insights Imaging*. 2015;6(4):411–417.
86. Brink JA, Amis ES. Image Wisely: A campaign to increase awareness about adult radiation protection. *Radiology*. 2010;257(3):601–602.